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 June 30, 2020

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

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 August 1, 2020, the registrant had 49,298,390 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 amounts)

	June 30, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 183,099	$ 82,253
Marketable securities	17,509	54,407
Accounts receivable, net	21,524	37,115
Inventories	19,392	16,529
Prepaid expenses and other current assets	5,043	5,371
Total current assets	$ 246,567	$ 195,675
Property and equipment, net	17,795	13,662
Right-of-use assets	7,414	8,223
Total assets	$ 271,776	$ 217,560
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,886	$ 15,258
Accrued expenses and other current liabilities	15,410	19,610
Deferred revenue	5,000	—
Operating lease liabilities	1,422	1,351
Current portion of long-term debt	7,639	—
Total current liabilities	$ 37,357	$ 36,219
Long-term operating lease liability, net	6,790	7,609
Long-term debt, net	52,829	40,176
2024 convertible notes, net	157,990	153,413
Other long-term liabilities	295	251
Total liabilities	$ 255,261	$ 237,668
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2020 and December 31, 2019 and 0 shares issued and outstanding at June 30, 2020 and December 31, 2019	—	—
Stockholders' equity		
Common stock, $0.001 par value; 100,000,000 shares authorized; 49,270,392 and 38,361,476 shares issued and outstanding, at June 30, 2020 and December 31, 2019, respectively	49	38
Additional paid-in capital	754,483	648,391
Accumulated other comprehensive income	3	62
Accumulated deficit	(738,020)	(668,599)
Total stockholders' equity (deficit)	16,515	(20,108)
Total liabilities and stockholders' equity	$ 271,776	$ 217,560

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues				
Product revenue, net	$ 15,451	$ 16,953	$ 35,578	$ 27,517
Operating expenses				
Cost of sales	5,481	1,398	7,757	3,160
Research and development	12,507	16,125	33,641	31,550
Selling, general and administrative	24,730	33,103	54,029	65,325
Total operating expenses	42,718	50,626	95,427	100,035
Loss from operations	(27,267)	(33,673)	(59,849)	(72,518)
Other (expense) income				
Interest income	95	831	522	1,842
Interest expense	(5,002)	(3,949)	(9,723)	(7,885)
Other (expense) income	(197)	304	(123)	536
Total other (expense) income	(5,104)	(2,814)	(9,324)	(5,507)
Loss before income taxes	(32,371)	(36,487)	(69,173)	(78,025)
Income tax expense	248	—	248	—
Net loss	$ (32,619)	$ (36,487)	(69,421)	(78,025)
Net loss per common share, basic and diluted	$ (0.76)	$ (0.96)	$ (1.71)	$ (2.05)
Weighted average common shares outstanding, basic and diluted	42,776	38,010	40,664	38,001
Other comprehensive (loss) income:				
Unrealized (losses) gains from available-for-sale securities, net of tax of $0	(3)	125	(59)	307
Total other comprehensive (loss) income	(3)	125	(59)	307
Comprehensive loss	$ (32,622)	$ (36,362)	$ (69,480)	$ (77,718)

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

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

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (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)
Issuance of common stock net of issuance costs	10,615	10	96,754			96,764
Issuance of common stock for equity awards, net of shares withheld for taxes	11		1			1
Employee stock purchase plan	82		891			891
Stock-based compensation expense			3,787			3,787
Net loss					(32,619)	(32,619)
Other comprehensive loss				(3)		(3)
Balance at June 30, 2020	49,270	$ 49	$ 754,483	$ 3	$ (738,020)	$ 16,515

	Common Stock		Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2018	37,946	$ 38	$ 628,944	$ (77)	$ (518,826)	$ 110,079
Issuance of common stock for equity awards	47	—	—			—
Stock-based compensation expense			3,853			3,853
Net loss					(41,538)	(41,538)
Other comprehensive income				182		182
Balance at March 31, 2019	37,993	$ 38	$ 632,797	$ 105	$ (560,364)	$ 72,576
Issuance of common stock for equity awards	8	—	—			—
Employee stock purchase plan	106		1,040			1,040
Stock-based compensation expense			4,217			4,217
Net loss					(36,487)	(36,487)
Other comprehensive income				125		125
Balance at June 30, 2019	38,107	$ 38	$ 638,054	$ 230	$ (596,851)	$ 41,471

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)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (69,421)	$ (78,025)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation	751	435
Amortization of right-of-use assets	809	553
Stock-based compensation expense	8,438	8,070
Non cash interest expense	292	—
Accretion of discount on marketable securities	(52)	(836)
Loss on disposal of fixed assets	262	—
Amortization of debt discount and debt issuance costs	4,577	4,184
Premium paid on securities purchased	(17)	(26)
Changes in operating assets and liabilities:		
Accounts receivable	15,591	(9,468)
Inventory	(2,502)	(4,512)
Prepaid expenses and other current assets	328	1,287
Accounts payable	(7,540)	(271)
Accrued expenses and other current liabilities	(4,375)	787
Deferred revenue	5,000	—
Lease liabilities	(748)	(541)
Net cash used in operating activities	(48,607)	(78,363)
Cash flows from investing activities		
Purchases of property and equipment	(5,538)	(1,068)
Purchases of marketable securities	(12,490)	(96,198)
Sale and redemption of marketable securities	49,398	138,061
Net cash provided by investing activities	31,370	40,795
Cash flows from financing activities		
Proceeds from borrowings under term loan	15,000	—
Proceeds from revolving line of credit	20,000	—
Repayments of revolving line of credit	(15,000)	—
Proceeds from the offering of common stock	97,289	—
Payments of public offering costs	(107)	—
Payments on notes payable	—	(5,000)
Proceeds from the exercise of stock options	10	—
Proceeds from employee stock purchase plan	891	1,040
Net cash provided by (used in) financing activities	118,083	(3,960)
Net increase (decrease) in cash and cash equivalents	100,846	(41,528)
Cash and cash equivalents at beginning of period	82,253	87,229
Cash and cash equivalents at end of period	$ 183,099	$ 45,701
Non-cash investing and financing activities		
Right-of-use asset obtained in exchange for operating lease obligation	—	7,046
Purchases of property and equipment in accounts payable and accrued expenses	2,126	—
Public offering costs included in accounts payable or accrued	418	—
Supplemental disclosures of cash flow information		
Cash paid for interest	5,048	3,699

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, a type of degenerative 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, which is an investigational IA gene therapy product candidate in clinical development for the treatment of OA, and FX301, a preclinical product candidate, which is being developed as a locally administered peripheral nerve block for control of post-operative pain.

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 June 30, 2020, the Company had cash, cash equivalents, and marketable securities of approximately $200.6 million.

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 when, if ever, the Company will realize significant revenue from the sales of ZILRETTA or if the development efforts supporting the Company's pipeline, including future clinical trials, will be successful.

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, or the Company's operating results or cash flows.

In the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2020, the Company disclosed that there was substantial doubt about its ability to continue as a going concern as a result of conditions that existed as of March 31, 2020. Specifically, those conditions included an expected material decline in revenue due to COVID-19 as compared to its prior expectations, and as a result, it was deemed probable that the Company would fail to meet the revenue covenant within the Company's amended and restated credit and security agreement described in Note 9. In the three months following March 31, 2020, the Company took certain actions designed to alleviate the substantial doubt, including reducing certain operating expenses through hiring and travel freezes, suspension and/or termination of active clinical trials, reduction of certain marketing expenses, and elimination of non-essential operating expenses, modifying the amended and restated credit and security agreement, and completing an equity offering of 10,615,385 shares of the Company's common stock which resulted in $96.8 million of net proceeds to the Company. The amendment to the amended and restated credit and security agreement resulted in a change in the minimum liquidity threshold that determines whether or not the revenue covenant is applicable. Pursuant to the amendment, the Company's minimum liquidity threshold now includes certain accounts receivable as deemed eligible under the amended and restated credit and security agreement, in addition to cash, cash equivalents, and marketable securities. Additionally, prior to May 2021, the minimum revenue covenant, if it applies in the future, is unmodified 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. As of June 30, 2020, the Company was in compliance with all covenants under the amended and restated credit and security agreement.

Additionally, while purchases of ZILRETTA by physicians, clinics, and certain medical centers or hospitals (i.e., healthcare providers who administer ZILRETTA to patients) dropped precipitously in the latter part of March into early April due to the adverse impact of COVID-19 on the operations of these healthcare providers, as the second quarter progressed, there was an increase in demand for ZILRETTA such that total ZILRETTA purchases by healthcare providers for the second quarter were consistent with the first quarter of this year. The Company currently expects to be able to maintain the $80.0 million liquidity threshold for at least 12 months following the issuance of these financial statements. Taking these factors together, 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. Management believes that current cash, cash equivalents, and marketable securities on hand at June 30, 2020 will be sufficient to fund operations for at least the next 12 months from the issuance date of these financial statements.

The future viability of the Company is dependent on its ability to fund its operations through sales of ZILRETTA, and/or raise 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 period after 12 months from issuance of these financial statements and would need to 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 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. 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 research and development activities, which could adversely affect its prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2020, and for the three and six months ended June 30, 2020 and 2019, 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 12, 2020.

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2020 and December 31, 2019, and for the three and six months ended June 30, 2020 and 2019, is unaudited. The December 31, 2019 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 and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020, or any future period.

Recent Accounting Pronouncements

Accounting Standards Recently Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 is effective for fiscal years, and the interim periods within those years, beginning after December 15, 2019 and early adoption is permitted. The Company adopted this standard as of January 1, 2020. The adoption of ASU 2016-13 did not have a material impact on the Company’s condensed consolidated financial statements.

In July 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). The new standard modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, as part of the FASB’s disclosure framework project. ASU 2018-13 is effective for fiscal years, and the interim periods within those years, beginning after December 15, 2019 and early adoption is permitted. Additionally, the new standard permits an entity to early adopt any removed or modified disclosures upon issuance of the ASU and delay adoption of the additional disclosures until their effective date. ASU 2018-13 removes the requirement to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy. The Company early adopted this portion

of the standard as the quarter ended September 30, 2018. The Company adopted the remainder of the standard as of January 1, 2020. The adoption of the remainder of ASU 2018-13 did not have a material impact 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 and six months ended June 30, 2020 and the year ended December 31, 2019.

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 June 30, 2020, 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 — Beginning in the third quarter of 2019, the Company began offering 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.

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 and six months ended June 30, 2020 and 2019:

(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, 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
Provision related to sales in the current quarter	1,417	133	98	892	2,540
Credits and payments made	(1,172)	(262)	(1)	(528)	(1,963)
Adjustments related to prior period sales	—	90	—	2	92
Balance as of June 30, 2020	$ 1,830	$ 359	$ 603	$ 892	$ 3,684
Balance as of December 31, 2018	$ 601	$ 491	$ 125	$ —	$ 1,217
Provision related to sales in the current quarter	741	24	57	—	822
Credits and payments made	(332)	(36)	(33)	—	(401)
Balance as of March 31, 2019	1,010	479	149	—	1,638
Provision related to sales in the current quarter	1,196	121	92	—	1,409
Credits and payments made	(1,157)	(65)	(6)	—	(1,228)
Balance as of June 30, 2019	$ 1,049	$ 535	$ 235	$ —	$ 1,819

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 of ZILRETTA in Greater China (consisting of mainland China, Hong Kong and Macau, and Taiwan). Under the terms of the agreement, HK Tainuo is obligated to pay the Company an upfront payment of $10.0 million. 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 will be responsible for the clinical development, product registration and commercialization of ZILRETTA in Greater China and Jiangsu Tainuo will serve 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. 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 revenue related to the upfront payment of $10.0 million, of which $5.0 million was received as of June 30, 2020 and the remaining $5.0 million is due in the third quarter of 2020, will be recognized as the Company's supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. The Company concluded that the license and supply performance obligations were not distinct, and therefore the transaction price will be recognized

as revenue over the period that the Company performs its supply obligations. *No* revenue was recognized associated with this contract as of June 30, 2020.

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 costs 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 2024 Convertible Notes and term loan) 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 June 30, 2020 and December 31, 2019 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2020 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 86,241	$ —	$ —	$ 86,241
Marketable securities	7,993	9,516	—	17,509
	$ 94,234	$ 9,516	$ —	$ 103,750

	Fair Value Measurements as of December 31, 2019 Using:			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ —	$ 69,733	$ —	$ 69,733
Marketable securities	—	54,407	—	54,407
	$ —	$ 124,140	$ —	$ 124,140

As of June 30, 2020, the Company's cash equivalents and marketable securities that are invested in money market funds, overnight repurchase contracts, and U.S. Treasury bills are valued using Level 1 inputs based on quoted prices for identical securities in active markets. The Company measures the fair value of certain marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. Amortization and accretion of discounts and premiums are recorded in other income. As of December 31, 2019, the Company's cash equivalents and marketable securities were classified within Level 2 of the fair value hierarchy.

The Company had a term loan outstanding under its 2015 credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank (the "2015 term loan"). On August 2, 2019, the Company entered into an amended and restated credit and security agreement with Silicon Valley Bank as agent, MidCap Financial Trust, and Flexpoint MCLS Holdings, LLC (collectively, the "Lenders"), providing for a term loan of $40.0 million (the "2019 term loan") and a revolving credit facility of up to $20.0 million. 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. In February 2020, the Company drew down the full $20.0 million available under the revolving credit facility. On May 18, 2020, the Company entered into an amendment to the amended and restated credit and security agreement (the "amendment"). Pursuant to the amendment, 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 amount outstanding on the 2019 term loan is reported at its carrying value in the accompanying balance sheet as of June 30, 2020. 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 June 30, 2020. 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 $171.9 million at June 30, 2020.

4. Marketable Securities

As of June 30, 2020 and December 31, 2019 the fair value of available-for-sale marketable securities by type of security was as follows:

	June 30, 2020			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 1,997	$ —	$ —	$ 1,997
U.S. government obligations	$ 7,994	$ —	$ —	$ 7,994
Corporate bonds	$ 7,515	$ 3	$ —	$ 7,518
	$ 17,506	$ 3	$ —	$ 17,509

	December 31, 2019			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$ 6,189	$ —	$ —	$ 6,189
U.S. government obligations	29,950	24	—	29,974
Corporate bonds	18,206	38	—	18,244
	$ 54,345	$ 62	$ —	$ 54,407

As of June 30, 2020 and December 31, 2019, marketable securities consisted of $17.5 million and $54.4 million, respectively, of investments that mature within 12 months. There were no investments with maturities greater than 12 months as of June 30, 2020 and December 31, 2019. 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 and six months ended June 30, 2020.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following as of June 30, 2020 and December 31, 2019:

(In thousands)	June 30, 2020	December 31, 2019
Prepaid expenses	$ 4,700	$ 5,072
Deposits	61	61
Interest receivable on marketable securities	82	238
Other	200	—
Total prepaid expenses and other current assets	$ 5,043	$ 5,371

6. Inventory

Inventory consisted of the following as of June 30, 2020 and December 31, 2019:

(In thousands)	June 30, 2020	December 31, 2019
Raw materials	$ 3,479	$ 2,846
Work in process	10,334	7,575
Finished goods	5,579	6,108
Total inventories	$ 19,392	$ 16,529

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 and six months ended June 30, 2020, the Company expensed $3.4 million to cost of sales for unabsorbed manufacturing and overhead costs related to the operation of the United Kingdom facility at Patheon UK Limited. As of June 30, 2020, the Company determined that no write-downs to finished goods inventory for potentially excess, dated or obsolete inventory were required.

7. Property and Equipment, Net

Property and equipment, net, as of June 30, 2020 and December 31, 2019 consisted of the following:

(In thousands)	June 30, 2020	December 31, 2019
Computer and office equipment	$ 1,203	$ 1,184
Manufacturing equipment	12,297	12,147
Furniture and fixtures	609	609
Software	455	455
Leasehold improvements	1,157	1,157
Construction in progress	11,153	6,077
	26,874	21,629
Less: Accumulated depreciation	(9,079)	(7,967)
Total property and equipment, net	$ 17,795	$ 13,662

Depreciation expense for the three and six months ended June 30, 2020 was approximately $0.6 million and $0.8 million, respectively, compared to $0.2 million and $0.4 million, respectively, for the same periods in the prior year. The Company disposed of one piece of equipment during the six months ended June 30, 2020 and recorded a loss on the disposal of $0.3 million. As of June 30, 2020, 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 June 30, 2020 and December 31, 2019:

(In thousands)	June 30, 2020	December 31, 2019
Research and development	$ 1,597	$ 1,924
Payroll and other employee-related expenses	7,922	8,748
Professional services fees	1,845	4,888
Accrued interest	1,464	1,356
Product revenue reserves	1,854	2,306
Accrual for employee stock purchase plan	166	183
Other	562	205
Total accrued expenses and other current liabilities	$ 15,410	$ 19,610

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. 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 and cash equivalents held with Silicon Valley Bank) 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. The revenue covenant is set annually and is based on the greater of a conservative percentage of the year's approved forecast and modest growth over the trailing twelve months of actual revenues.

On May 18, 2020, the Company entered into an amendment to the amended and restated credit and security agreement. Pursuant to the amendment, 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. Under the credit facility, as amended, the Company remains subject to a minimum liquidity threshold, such that at any time the Company's liquidity is below $80.0 million, the Company will become subject to a minimum revenue covenant. However, pursuant to the amendment, the Company's liquidity now includes certain accounts receivable as deemed eligible under the credit and security agreement, in addition to cash, cash equivalents, and marketable securities. Prior to May 2021, the minimum revenue covenant, if it applies in the future, is unmodified 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. Also pursuant to the amendment, the final payment due upon repayment or maturity of the term loans was changed from 4.75% of the term loan amount to 6.75% of the term loan amount.

The amended and restated credit and security agreement also has a material adverse event clause. If the 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 June 30, 2020, the Company was compliant with all covenants.

Borrowings under the 2019 term loan 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 June 30, 2020, the carrying value of the term loan was approximately $55.4 million, of which $7.6 million is due within 12 months and $47.8 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 June 30, 2020, annual principal and interest payments due under the 2019 term loan were as follows:

Year	Aggregate Minimum Payments *(in thousands)*
2020	2,138
2021	20,090
2022	20,371
2023	19,117
2024	5,249
Thereafter	—
Total	$ 66,965
Less interest	(8,252)
Less unamortized portion of final payment	(3,245)
Total	$ 55,468

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, in connection with the amendment to the amended and restated credit and security agreement, the Company repaid $15.0 million, reducing the outstanding principal balance on the revolver to $5.0 million, 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 June 30, 2020, 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 and six months ended June 30, 2020 was $3.9 million and $7.7 million, respectively, including $2.2 million and $4.3 million, respectively, related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of June 30, 2020:

	(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	25,676
Carrying value 2024 Convertible Notes	$ 157,990

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 and six months ended June 30, 2020 and 2019 were as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Risk-free interest rates	0.51-0.56%	1.89 - 2.41%	0.51 - 1.79%	1.89 - 2.67%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term (in years)	6.0	6.0	6.0	6.0
Expected volatility	70.3 - 72.3%	68.6 - 68.9%	65.4 - 72.3%	68.6 - 69.5%

The following table summarizes stock option activity for the six months ended June 30, 2020:

(In thousands, except per share amounts)	Shares Issuable Under Options	Weighted Average Exercise Price Per Share
Outstanding as of December 31, 2019	4,775	$ 17.99
Granted	420	14.98
Exercised	(5)	12.88
Cancelled	(263)	17.80
Outstanding as of June 30, 2020	4,927	$ 17.75
Options vested and expected to vest at June 30, 2020	4,927	$ 17.75
Options exercisable at June 30, 2020	3,381	$ 18.13

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 4,691 shares of the Company's common stock, with an aggregate intrinsic value of approximately $15,139, were exercised during the six months ended June 30, 2020.

At June 30, 2020 and 2019, there were options for the purchase of approximately 4,926,718 and 4,972,362 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 6.7 years and 7.2 years, respectively, and with a weighted average exercise price of $17.75 and $18.23 per share, respectively.

The weighted average grant date fair value of options granted during the six months ended June 30, 2020 and 2019 was $8.94 and $8.78 per share, respectively.

Restricted Stock Units

During the six months ended June 30, 2020, the Company awarded 953,375 RSUs to employees at an average grant date fair value of $11.61 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 2020 RSU awards is a grant of 175,000 RSUs to the Company's Chief Executive Officer. These RSUs have a performance condition in that they will only vest if the Company reaches a certain revenue threshold at December 31, 2020. If the threshold is reached, the vesting schedule will be the same as RSUs granted to other employees. As of June 30, 2020, the Company concluded that it was not probable that the performance condition would be met. Therefore, no expense has been recognized on these awards during the six months ended June 30, 2020.

The following table summarizes the RSU activity for the six months ended June 30, 2020:

(In thousands, except per share amounts)	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested balance as of December 31, 2019	853	$ 15.84
Granted	953	11.61
Vested/Released	(209)	16.44
Cancelled	(122)	14.86
Nonvested Balance as of June 30, 2020	1,475	$ 13.11

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 and six months ended June 30, 2020 and 2019 as follows:

	For the three months ended June 30,		For the six months ended June 30,	
(In thousands)	2020	2019	2020	2019
Research and development	$ 1,087	$ 1,385	$ 3,289	$ 2,541
Selling, general and administrative	2,700	2,832	5,149	5,529
Total	$ 3,787	$ 4,217	$ 8,438	$ 8,070

As of June 30, 2020, unrecognized stock-based compensation expense for stock options outstanding was approximately $15.5 million which is expected to be recognized over a weighted average period of 2.3 years. As of June 30, 2020, unrecognized stock-based compensation expense for RSUs outstanding was $17.1 million which is expected to be recognized over a period of 2.9 years.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the three and six months ended June 30, 2020 and 2019:

	For the three months ended June 30,		For the six months ended June 30,	
(In thousands, except per share amounts)	2020	2019	2020	2019
Numerator:				
Net loss	$ (32,619)	$ (36,487)	$ (69,421)	$ (78,025)
Net loss:	$ (32,619)	$ (36,487)	$ (69,421)	$ (78,025)
Denominator:				
Weighted average common shares outstanding, basic and diluted	42,776	38,010	40,664	38,001
Net loss per share, basic and diluted	$ (0.76)	$ (0.96)	$ (1.71)	$ (2.05)

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 June 30,		For the six months ended June 30,	
	2020	2019	2020	2019
Shares issuable upon conversion of the 2024 Convertible Notes	7,515	7,515	7,515	7,515
Stock options	4,987	5,104	4,925	4,938
Restricted stock units	1,479	963	1,196	718
Total	13,981	13,582	13,636	13,171

12. Commitments and Contingencies

Operating Leases

Burlington Lease

The Company leases approximately 36,500 square feet of office space in Burlington, Massachusetts under a lease that began in May 2013 and was originally scheduled to expire on October 31, 2023 (the "Lease"). Upon adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 8.9%, the Company's estimated incremental borrowing rate, over the 4.8-year remaining term.

In June 2019, the Company amended the Lease to add approximately 5,330 square feet of additional 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 lease commencement date for the additional space, which represents the date the Company first had access to the space, was July 1, 2019. The Company accounted for the Amended Lease as a lease modification that is a separate contract from the original lease and recorded an incremental right-of-use asset and lease liability of $2.5 million, which represents the present value of the lease payments relating to the new space, as well as the lease payments relating to the 18-month extension of the existing space, as of the modification date, discounted at 6.8%.

The straight-line lease cost for the Amended Lease (including the expense relating to the original Lease) amounted to $0.4 million and $0.9 million, respectively, for the three and six months ended June 30, 2020, and was included in operating expenses. As of June 30, 2020, the remaining lease term on the Amended Lease was 4.8 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.

Upon adoption of ASU 2016-02, the Company recorded a right-of-use asset and corresponding lease liability for the Lease on January 1, 2019, by calculating the present value of lease payments, discounted at 8.4%, the Company's estimated incremental borrowing rate, over the 3.2-year remaining term. The Woburn lease includes an option to extend the term of the lease for two years. Since the Company adopted ASU 2016-02 using the Comparatives under 840 approach, it did not reassess the determination of its operating leases as leases, and therefore no options to extend the lease were included in the calculation of the lease liability as of June 30, 2020. The straight-line lease cost for the Woburn lease amounted to $46,000 and $92,000, respectively, for the three and six months ended June 30, 2020, and was included in operating expenses. As of June 30, 2020, the remaining lease term on the Woburn lease was 1.7 years.

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. In June 2020, the Company informed Patheon of its intent to restart manufacturing in the fourth quarter. 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.

As of June 30, 2020, the remaining lease term on the Patheon lease was 7.3 years. The straight-line lease cost amounted to $55 thousand and $113 thousand, respectively for the three and six months ended June 30, 2020, 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 June 30,		For the six months ended June 30,	
Operating lease cost	**2020**	**2019**	**2020**	**2019**
Operating lease cost included in operating expenses	$ 514	$ 369	$ 1,027	$ 738
Operating lease cost included in inventory	55	48	113	93
Total operating lease cost	569	417	1,140	831
Operating cash flows from operating leases	739	590	1,557	1,094

Maturities of lease liability due under these lease agreements as of June 30, 2020 were as follows:

Year	Operating Lease Obligations (in thousands)
2020	$ 989
2021	2,018
2022	1,865
2023	1,873
2024	1,915
Thereafter	1,180
Present value of imputed interest	(2,418)
Total	$ 7,422

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 is extended. The total term of the agreement is five 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. The Supply Agreement will renew for two successive two year terms upon mutual written consent by both parties.

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. In 2018, the Company paid GeneQuine $750,000 for the milestone of initiating a GLP toxicology study of FX201. In addition, the Company paid GeneQuine a $750,000 payment 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. This milestone was recognized as research and development expense in the first quarter of 2020. 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. The upfront fee was attributed to the intellectual property acquired and recognized as research and development expense in December 2017 as the FX201 product candidate had not been commercially approved and had no alternative future use. The milestone payments for the GLP toxicology study and the acceptance of the IND were also recorded to research and development expense in the fourth quarters of 2018 and 2019, respectively. Future milestone payments earned prior to regulatory approval of FX201 would be 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 June 30, 2020, 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.

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. As of June 30, 2020, the Company concluded that the first milestone relating to the initiation of the first GLP toxicology study was probable of being achieved, as the GLP toxicology study commenced on April 13, 2020. The Company recorded a milestone payment of $500,000 to research and development expense in the first quarter of 2020. The Company may also be required to make additional milestone payments during the development of FX301, including up to $8.0 million through initiation of a Phase 2 proof of concept (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 June 30, 2020, 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.

13. Subsequent Events

On July 16, 2020, the Company's Compensation Committee of the Board of Directors approved the grant of restricted stock units ("RSUs") to substantially all the Company's employees, including executive officers. The number of shares of the Company's common stock subject to each RSU is generally equal to the employee's target annual equity grant, except for the Company's chief executive officer whose RSU grant was half of the target annual equity grant. The RSU's granted to the Company's executive officers

vest in equal annual installments over a 3-year vesting period, while the RSUs granted to the Company's non-executive employees vest 1/3rd on the one-year anniversary of the grant date and 2/3rds on the second-year anniversary of the grant date.

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, 2019 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 12, 2020.

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, a type of degenerative arthritis, referred to as OA.

On October 6, 2017, the U.S. Food and Drug Administration, or 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, a preclinical product candidate, which is being developed as a locally administered peripheral nerve block for control of post-operative pain.

ZILRETTA combines a commonly administered steroid, triamcinolone acetonide, or TA, with poly lactic-co-glycolic acid, referred to as PLGA, delivering a 32 mg dose of TA to provide extended therapeutic concentrations in the joint and persistent analgesic effect. Both the magnitude and duration of pain relief provided by ZILRETTA in clinical trials were clinically meaningful with the magnitude of pain relief amongst the largest seen to date in OA clinical trials. The overall frequency of treatment-related adverse events (AEs) in these trials was similar to those observed with placebo and no drug-related serious AEs were reported.

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 June 30, 2020, we have raised approximately $913 million and 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 May 26, 2020, we completed an equity offering of our common stock, which resulted in the sale of 10,615,385 shares of our common stock at a price to the public of $9.75 per share including shares sold pursuant to the exercise in full of the underwriters' option to purchase additional shares. We received net proceeds from the follow-on financing of $96.8 million after deducting underwriting discounts, commissions, and offering costs.

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 is affecting our employees, patients, communities and business operations, as well as the U.S. economy and

financial markets. COVID-19 continues to rapidly evolve. In mid-March, the U.S. declared a national emergency and states implemented various "social distancing" and "stay at home" measures to mitigate the spread of COVID-19. In turn, we closed our offices in Burlington, MA and instructed all of our employees to work from home, including all of our field-based personnel. We also undertook prudent and disciplined steps to reduce expenses across the organization, including hiring and travel freezes; elimination of live presence at medical and industry conferences, reductions in in-person physician speaker programs, reductions in market research and select marketing programs and materials; and elimination of non-essential operating expenses. In addition, we paused our Phase 1 trial of FX201 (which we subsequently restarted); discontinued our Phase 2 trial investigating ZILRETTA in shoulder OA and adhesive capsulitis (AC) due to the small number of patients enrolled; and, we temporarily paused manufacturing activities for ZILRETTA to avoid excess levels of inventory

Due to the significant impacts of COVID-19 on patient flow at healthcare providers, purchases of ZILRETTA by healthcare providers dropped precipitously in the latter part of March and that decline continued into early April, when weekly purchases of ZILRETTA by healthcare providers reached a nadir of 627 units. Despite this precipitous decline, our Musculoskeletal Business Managers (MBMs) found most accounts were receptive to "e-detailing," and in the second quarter our MBMs were able to gain access to some healthcare providers who had been previously very difficult to reach due to busy office and surgical schedules. Additionally, by the end of the quarter, the vast majority of our MBMs were able to return to the field to do to in-person calls on accessible physician offices. Correspondingly, our Commercial team conducted a series of focus groups with physicians around the country who confirmed that the pandemic had resulted in many patients facing extensive delays for total knee replacement (TKR) surgery, and caused other patients to postpone surgery indefinitely.

We conducted a survey of 30 orthopedists and approximately 60% of the respondents indicated they were using ZILRETTA to help manage patients facing delays to TKR, and those prescribers indicated that almost one third of their current ZILRETTA use was for this purpose. We believe this contributed to the month-over-month growth of ZILRETTA purchases by healthcare providers in the second quarter, which was 4,863 units, 13,547 units and 18,287 units in April, May and June respectively. In total, approximately 36,700 units of ZILRETTA were purchased in the second quarter, which was essentially in line with the first quarter of 2020. We recognize revenue primarily on sales of ZILRETTA to specialty distributors and a specialty pharmacy versus the purchases of ZILRETTA by healthcare providers. Due to the impacts of COVID-19, the level of product inventory held at specialty distributors at the end of the first quarter was higher than prior quarters. As purchases of ZILRETTA by healthcare providers increased throughout the second quarter, the specialty distributors worked through their elevated inventory levels. As a result, the aggregate number of ZILRETTA units that our specialty distributors purchased and that we recognized as revenue in the second quarter was less than the aggregate amount purchased by healthcare providers from specialty distributors during this period.

To help ensure adequate and uninterrupted supply of ZILRETTA to meet anticipated future demand, in June we informed Patheon of our intent to restart manufacturing in the fourth quarter. In addition, we resumed our clinical trial of FX201 in the second quarter, and we aim to initiate a trial investigating ZILRETTA in shoulder OA in 2021.

While we are encouraged by the growth of ZILRETTA purchases by healthcare providers we saw from April to June and the evolving role of ZILRETTA in managing knee pain for patients experiencing TKR delays, the future impact of COVID-19 on our business remains uncertain and unpredictable.

Q2 2020 Commercial Metrics

We closely track and provide quarterly updates on several quantitative uptake metrics to provide perspective on the progress of the ZILRETTA launch. Since the launch in November 2017 through June 30, 2020:

- 3,858 of our approximately 5,000 target accounts had purchased ZILRETTA. This reflects growth of 186 since March 31, 2020 when 3,672 accounts had purchased product.
- 77% of purchasing accounts (2,983) had placed at least one reorder up from 2,832 accounts that had reordered ZILRETTA as of March 31, 2020.
- 1,023 accounts had made ZILRETTA purchases of more than 50 units; 1,102 accounts had purchased 11 to 50 units; and 1,733 accounts had purchased between 1 and 10 units.
- Accounts purchasing more than 50 ZILRETTA units accounted for 213,721 of the 249,024 ZILRETTA units purchased.

Pipeline Updates

FX201 – 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 produce human interleukin-1 receptor antagonist (IL-1Ra) whenever inflammation is present within the joint. Based on the promising preclinical data generated to date, a single injection of FX201 could potentially enable expression of IL-1Ra in an osteoarthritic joint for at least a

year. By controlling chronic inflammation for extended periods of time, we believe FX201 holds the potential to both reduce OA pain and modify OA 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 of 2033.

In March 2020, we successfully dosed the first patients in a Phase 1, multicenter, open-label, dose-escalation trial evaluating the safety and tolerability of FX201 in patients with painful OA of the knee. As discussed above, we voluntarily suspended enrollment in the FX201 Phase 1 clinical trial in April as a result of COVID-19 in consideration of guidance issued by FDA and resumed the trial in late May.

FX301 – 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 new preclinical program, known as FX301, will consist of XEN402 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 XEN402 near target nerves for up to a week. Unlike typical local anesthetics, the selective pharmacology of XEN402 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.

We continue to advance the preclinical program for FX301, and we anticipate initiating FX301 clinical trials in 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 is obligated to pay us an upfront payment of $10.0 million. 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 will be responsible for the clinical development, product registration and commercialization of ZILRETTA in Greater China and Jiangsu Tainuo will serve 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. The revenue related to the upfront payment of $10.0 million, of which $5.0 million was received as of June 30, 2020 and the remaining $5.0 million is due in the third quarter of 2020, will be recognized as our supply obligation is fulfilled over the term of the supply agreement, which has not yet commenced. We concluded that the license and supply performance obligations were not distinct, and therefore the transaction price will be recognized as revenue over the period that we perform our supply obligations. No revenue was recognized associated with this contract as of June 30, 2020.

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. We continue to incur certain fixed overhead costs related to the operation of

the manufacturing facility at Patheon while production activities are temporarily suspended. These fixed overhead costs would typically be capitalized to ZILRETTA inventory but are recorded to cost of sales over the period in which production is suspended.

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 decrease over the remainder of 2020 relative to the prior year. As part of our expense reduction steps taken in response to the COVID-19 pandemic, we terminated the Phase 2 clinical trial investigating ZILRETTA in shoulder OA and AC and temporarily suspended the FX201 single ascending dose trial which resulted in a deferral of spending related to clinical trials, and eliminated other non-essential operating expenses. 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.

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 decrease over the remainder of 2020 as compared to the prior year. As a result of the adverse effect of COVID-19 on our revenues, we have taken steps to reduce our operating expenses, including by reducing certain 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 market research and select marketing programs and materials. 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.

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 net accretion of premiums and 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, 2019 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 six months ended June 30, 2020.

RESULTS OF OPERATIONS

Comparison of the Three and Six Months Ended June 30, 2020 and 2019

The following tables summarize our results of operations for the three and six months ended June 30, 2020:

	Three Months Ended June 30,			
(In thousands)	2020	2019	Change	% Increase/ (Decrease)
Revenues:				
Product revenue, net	$ 15,451	$ 16,953	$ (1,502)	(8.9)%
Operating expenses:				
Cost of sales	5,481	1,398	4,083	292.1%
Research and development	12,507	16,125	(3,618)	(22.4)%
Selling, general and administrative	24,730	33,103	(8,373)	(25.3)%
Total operating expenses	42,718	50,626	(7,908)	(15.6)%
Loss from operations	(27,267)	(33,673)	6,406	(19.0)%
Other (expense) income:				
Interest income	95	831	(736)	(88.6)%
Interest expense	(5,002)	(3,949)	(1,053)	26.7%
Other income	(197)	304	(501)	(164.8)%
Total other (expense) income	(5,104)	(2,814)	(2,290)	81.4%
Loss before income taxes	(32,371)	(36,487)	4,116	(11.3)%
Income tax expense	248	—	248	100.0%
Net loss	$ (32,619)	$ (36,487)	3,868	(10.6)%

	Six Months Ended June 30,			
(In thousands)	2020	2019	Change	% Increase/ (Decrease)
Revenues:				
Product revenue, net	$ 35,578	$ 27,517	$ 8,061	29.3%
Operating expenses:				
Cost of sales	7,757	3,160	4,597	145.5%
Research and development	33,641	31,550	2,091	6.6%
Selling, general and administrative	54,029	65,325	(11,296)	(17.3)%
Total operating expenses	95,427	100,035	(4,608)	(4.6)%
Loss from operations	(59,849)	(72,518)	12,669	(17.5)%
Other (expense) income:				
Interest income	522	1,842	(1,320)	(71.7)%
Interest expense	(9,723)	(7,885)	(1,838)	23.3%
Other income	(123)	536	(659)	(122.9)%
Total other (expense) income	(9,324)	(5,507)	(3,817)	69.3%
Loss before income taxes	(69,173)	(78,025)	8,852	(11.3)%
Income tax expense	248	—	248	100.0%
Net loss	$ (69,421)	$ (78,025)	8,604	(11.0)%

Product Revenue

We began commercially selling ZILRETTA within the United States in October 2017, following FDA approval on October 6, 2017. Net product revenue for the three months ended June 30, 2020 and 2019 was $15.5 million and $17.0 million, respectively. For the six months ended June 30, 2020 and 2019, we recorded net product revenue of $35.6 million and $27.5 million, respectively. The period-over-period changes are primarily due to changes in the number of ZILRETTA units sold. We recognize revenue primarily on sales of ZILRETTA to specialty distributors and a specialty pharmacy versus the purchases of ZILRETTA by healthcare providers. Due to the impacts of COVID-19, the levels of product inventory held at specialty distributors at the end of the first quarter was higher than prior quarters. As purchases of ZILRETTA by healthcare providers increased throughout the second quarter, the specialty distributors worked through their elevated inventory levels. As a result, the aggregate number of ZILRETTA units that our specialty distributors purchased and that we recognized as revenue in the second quarter was less than the aggregate amount purchased by healthcare providers from specialty distributors during this period. As of June 30, 2020, ZILRETTA inventory levels at our specialty distributors were consistent with the levels at the end of prior quarters, other than March 31, 2020. 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 $5.5 million and $1.4 million for the three months ended June 30, 2020 and 2019, respectively. For the three months ended June 30, 2020, cost of sales was comprised of $1.6 million related to the actual cost of units sold, $3.4 million of unabsorbed overhead associated with the voluntary, temporary suspension of manufacturing activities at Patheon due to COVID-19 impacts on sales of ZILRETTA, and $0.5 million of period costs and other adjustments. For the three months ended June 30, 2019, cost of sales were solely comprised of $1.4 million related to the actual cost of units sold.

Cost of sales was $7.8 million and $3.2 million for the six months ended June 30, 2020 and 2019, respectively. For the six months ended June 30, 2020, cost of sales consisted of $3.6 million related to the actual cost of units sold, $3.4 million of unabsorbed manufacturing overhead, and $0.8 million of period costs and adjustments. For the six months ended June 30, 2019, cost of sales consisted of $2.7 million related to the actual cost of units sold and $0.4 million of period costs and adjustments.

Research and Development Expenses

	Three Months Ended June 30,			
(In thousands)	**2020**	**2019**	**Change**	**% Increase/ (Decrease)**
Direct research and development expenses by program:				
ZILRETTA	$ 2,319	$ 5,017	$ (2,698)	(53.8)%
FX201	1,243	1,363	(120)	(8.8)%
Portfolio expansion	1,511	623	888	142.5%
Other	258	911	(653)	(71.7)%
Total direct research and development expenses	5,331	7,914	(2,583)	(32.6)%
Personnel and other costs	7,176	8,211	(1,035)	(12.6)%
Total research and development expenses	$ 12,507	$ 16,125	$ (3,618)	(22.4)%

	Six Months Ended June 30,			
(In thousands)	**2020**	**2019**	**Change**	**% Increase/ (Decrease)**
Direct research and development expenses by program:				
ZILRETTA	$ 7,145	$ 10,307	$ (3,162)	(30.7)%
FX201	4,958	2,341	$ 2,617	111.8%
Portfolio expansion	3,409	1,293	2,116	163.7%
Other	899	1,500	(601)	(40.1)%
Total direct research and development expenses	16,411	15,441	970	6.3%
Personnel and other costs	17,230	16,109	1,121	7.0%
Total research and development expenses	$ 33,641	$ 31,550	$ 2,091	6.6%

Research and development expenses were $12.5 million and $16.1 million for the three months ended June 30, 2020 and 2019, respectively. The decrease in research and development expenses of $3.6 million was primarily due to a decrease of $2.7 million in development expenses for ZILRETTA due to lower ZILRETTA clinical trial activity during the period, as well as a decrease of $1.0 million in salary and other employee-related costs and stock-based compensation expense related to lower headcount.

Research and development expenses were $33.6 million and $31.6 million for the six months ended June 30, 2020 and 2019, respectively. The increase in research and development expenses of $2.1 million was primarily due to an increase of $1.1 million in salary and other employee-related costs, as well as an increase in expenses related to FX201 related to the payment of $2.5 million to GeneQuine for dosing the first human patient in the Phase 1 clinical trial, and an increase in other portfolio expenses of $1.5 million, primarily related to GLP toxicology studies for FX301, offset by a decrease of $3.2 million in development expenses for ZILRETTA due to lower ZILRETTA clinical trial expenses during the period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $24.7 million and $33.1 million for the three months ended June 30, 2020 and 2019, respectively. Selling expenses were $16.8 million and $24.8 million for the three months ended June 30, 2020 and 2019, respectively. The year over year decrease of $8.0 million was primarily due to the expense reduction measures taken in response to COVID-19; in particular, the elimination of live presence at industry conferences, reductions in in-person physician speaker programs and reductions in market research and select marketing programs and materials, as well as a reduction in travel expenses as MBMs were generally unable to visit healthcare practices in person due to various “stay at home” orders. General and administrative expenses were $7.9 million and $8.3 million for the three months ended June 30, 2020 and 2019, respectively, which represents a decrease of $0.4 million.

Selling, general and administrative expenses were $54.0 million and $65.3 million for the six months ended June 30, 2020 and 2019, respectively. Selling expenses were $37.3 million and $48.6 million for the six months ended June 30, 2020 and 2019, respectively. The year-over-year decrease in selling expenses of $11.3 million was primarily due to the expense reduction measures described above taken in response to COVID-19. General and administrative expenses were $16.7 million for each of the six months ended June 30, 2020 and 2019.

Other Income (Expense)

Interest income was $0.1 million and $0.8 million for the three months ended June 30, 2020 and 2019, respectively. Interest income was $0.5 million and $1.8 million for the six months ended June 30, 2020 and 2019, 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 $5.0 million and $3.9 million for the three months ended June 30, 2020 and 2019, respectively. Interest expense was $9.7 million and $7.9 million for the six months ended June 30, 2020 and 2019. The increase in interest expense can be attributed to the interest incurred associated with the term loan that we entered into in August 2019 under the amended credit and security agreement, as well as the revolving credit facility, which we drew down in February 2020.

Foreign Withholding Taxes

The provision for income taxes for the three and six months ended June 30, 2020 was comprised of $0.2 million in foreign withholding taxes related to the HK Tainuo upfront payment.

Liquidity and Capital Resources

For the six months ended June 30, 2020, we generated $35.6 million in net product revenue. We have incurred significant net losses in each year since our inception, including net losses of $149.8 million, $169.7 million, and $137.5 million, for fiscal years 2019, 2018, and 2017, respectively, and $69.4 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $738.0 million. We anticipate that we will continue to incur losses over the next few years.

Since our inception through June 30, 2020, 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. From our inception through June 30, 2020, we had raised approximately $913 million from such transactions, including amounts from our initial and follow-on public offerings during 2014, 2016, 2017, and most recently in May of 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.

In response to the economic and business disruption caused by COVID-19, we recently undertook prudent and disciplined steps to reduce expenses across our organization, including hiring and travel freezes, suspension or termination of active clinical trials and deferral of select preclinical activities, reductions in in-person physician speaker programs, market research and select marketing programs, and elimination of non-essential operating expenses. As a result of these actions, we expect that our research and development and selling, general and administrative expenses will decrease in 2020 as compared to the prior year. However, 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 June 30, 2020, we had cash, cash equivalents, and marketable securities of $200.6 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 these financial statements. 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 will be 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. 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 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; this “minimum interest” payment will take effect on January 1, 2020. 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. Beginning on January 1, 2020, 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.

The following table shows a summary of our cash flows for each of the six months ended June 30, 2020 and 2019:

(In thousands)	Six Months Ended June 30, 2020	2019
Cash flows used in operating activities	$ (48,607)	$ (78,363)
Cash flows provided by investing activities	31,370	40,795
Cash flows provided by (used in) financing activities	118,083	(3,960)
Net increase (decrease) in cash and cash equivalents	$ 100,846	$ (41,528)

Net Cash Used in Operating Activities

Operating activities used $48.6 million of cash in the six months ended June 30, 2020. The cash flow used in operating activities resulted primarily from our net loss for the period of $69.4 million, partially offset by changes in our operating assets and liabilities of $5.8 million and non-cash charges of $15.1 million. Changes in our operating assets and liabilities consisted primarily of a $15.6 million decrease in accounts receivable, a $0.3 million decrease in prepaid expenses and other current assets, and a $5.0 million increase in deferred revenue related to the license agreement with HK Tainuo, partially offset by a $2.5 million increase in inventory, a decrease of $11.9 million in accounts payable and accrued expenses and a $0.7 million decrease in lease liabilities and other long-term liabilities primarily due to principal lease payments. Our non-cash charges consisted primarily of $8.4 million of stock-based compensation expense, $4.6 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, $0.8 million related to the amortization of right-of-use assets, $0.8 million of depreciation, $0.3 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.

Operating activities used $78.4 million of cash in the six months ended June 30, 2019. The cash flow used in operating activities resulted primarily from our net loss for the period of $78.0 million and changes in our operating assets and liabilities of $12.7 million, offset by non-cash charges of $12.4 million. Changes in our operating assets and liabilities consisted primarily of a $9.5 million increase in accounts receivable, a $4.5 million increase in inventory, and $0.5 million decrease in lease liabilities primarily due to principal lease payments, partially offset by a $1.3 million decrease in prepaid expenses and other current assets, and an increase of $0.5 million in accounts payable and accrued expenses. Our non-cash charges consisted primarily of $8.1 million of stock-based compensation expense, $4.2 million related to the amortization of the debt discount and debt issuance costs related to the 2024 Convertible Notes, $0.6 million related to the amortization of right-of-use assets, and $0.4 million of depreciation, partially offset by $0.8 million of net accretion of discounts related to our investments.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $31.4 million in the six months ended June 30, 2020. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $49.4 million, partially offset by cash used to purchase marketable securities of $12.5 million and $5.5 million used for capital expenditures, primarily relating to the purchase of equipment associated with the expansion of our manufacturing facilities at Patheon.

Net cash provided by investing activities was $40.8 million in the six months ended June 30, 2019. Net cash provided by investing activities consisted primarily of cash received from the redemption and sale of marketable securities of $138.1 million, partially offset by cash used to purchase marketable securities of $96.2 million. In addition, $1.1 million of cash was used for capital expenditures, including $0.2 million for lab equipment and $0.9 million for manufacturing equipment associated with the expansion of our manufacturing facilities at Patheon.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $118.1 million for the six months ended June 30, 2020, of which $97.2 million related to the net proceeds received from the offering of our common stock, offset by public offering costs paid during the period of $0.1 million, $0.9 million relating to employee stock purchases through our employee stock purchase plan, as well as $20.0 million borrowed under the revolving credit facility associated with our 2019 term loan.

Net cash used in financing activities was $4.0 million for the six months ended June 30, 2019. Net cash used in financing activities in the six months ended June 30, 2019 consisted primarily of $5.0 million related to the payment of principal on our 2015 term loan, partially offset by $1.0 million received from employee stock purchases through our employee stock purchase plan.

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 2019 Annual Report on Form 10-K. There have not been any material changes to such contractual obligations or potential milestone payments since December 31, 2019, 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 Loan

We have borrowed $55.0 million under the 2019 term loan. Borrowings under the 2019 term loan 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 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 $171.9 million at June 30, 2020.

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 June 30, 2020 we had $4.5 million in

liabilities denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in a $0.4 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 June 30, 2020, we had an immaterial amount of cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in an immaterial 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.

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 June 30, 2020, 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 June 30, 2020 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

You should consider carefully the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below with an asterisk (*) next to the title contain changes to the description of the risk factors associated with our business previously disclosed in our Annual Report on Form 10-K filed on March 12, 2020. The risks and uncertainties below are those identified by us as material, but there are also additional risks and uncertainties that we are unaware of that may become important factors that affect us. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected, and the market price of our common stock would likely decline.

Risks Related to Our Financial Condition and Need for Additional Capital

(*) We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses over the next few years.

We have a limited operating history. To date, we have focused primarily on developing our commercialized product, ZILRETTA. Any additional product candidates we develop will require substantial development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred significant net losses in each year since our inception, including net losses of $149.8 million, $169.7 million, and $137.5 million, for fiscal years 2019, 2018, and 2017, respectively, and $69.4 million for the six months ended June 30, 2020. As of June 30, 2020, we had an accumulated deficit of $738.0 million. We expect to incur net losses over the next few years as we continue to invest in the commercialization of ZILRETTA and advance our development programs.

We have devoted most of our financial resources to product development and commercialization. To date, we have financed our operations exclusively through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. The U.S. Food and Drug Administration, or FDA, granted marketing approval and we launched commercial sales of ZILRETTA in the fourth quarter of 2017. We have a limited history of commercializing ZILRETTA and cannot guarantee that our commercialization efforts will result in product revenues that meet our peak sales expectations or those of analysts and investors.

In December 2019, a novel strain of coronavirus, which causes the COVID-19 disease (“COVID-19”), was first reported in Wuhan, China and has since become a global pandemic, resulting in the U.S. declaring a national emergency. Many states implemented various “social distancing” and “stay at home” measures to mitigate the spread of COVID-19. While some states are seeing cases of COVID-19 decline, other areas of the country are experiencing a surge in cases. As a result, while practices in some regions are beginning to see patients and resume elective procedures, others are having to close due to the surge in cases. ZILRETTA is required to be administered by healthcare professionals and since mid-March, as a result of COVID-19, patient access to physician offices and clinics has been limited, as healthcare practices have implemented varying responses to the pandemic. Although some practices have begun to reopen, other regions of the country have required practices to shut down in-person patient visits altogether, while others are open to only critical or acute cases. In addition, we believe many patients across the country have been reluctant to visit physician offices and clinics due to fear of contracting COVID-19. As a result of these adverse impacts on the operations of healthcare providers that administer ZILRETTA to patients and patients’ willingness to make in-person visits to healthcare facilities, we have experienced and expect to continue experiencing for the remainder of 2020, and possibly longer, a meaningful diminution in revenue as compared to our prior expectations.

We also expect to continue to incur substantial expenses as we invest in the commercialization of ZILRETTA, scale up commercial manufacturing of ZILRETTA, conduct additional clinical trials for this product and continue our development activities with respect to our pipeline product candidates. As a result of the foregoing, we expect to continue to incur significant losses and negative cash flows over the next few years.

(*) Our revenues may not be sufficient to cover our future expenses and we may never be profitable.

Our ability to generate significant revenue and achieve profitability depends primarily on our ability to successfully commercialize ZILRETTA, as well as our ability to obtain regulatory approval for and then successfully commercialize other product candidates. We may never succeed in these activities and may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with new pharmaceutical products and development efforts, we are unable to predict the timing or amount of increased expenses, when, or if, we will begin to generate revenue from product sales sufficient to cover our operating expenses, or when, or if, we will be able to achieve or maintain profitability. In addition, despite recent actions aimed at reducing our operating expenses, our expenses could increase beyond expectations if we determine that additional sales and marketing personnel or other resources are necessary to successfully commercialize ZILRETTA or if we face any legal or regulatory action related to the commercialization of ZILRETTA.

If we are unable to generate sufficient revenues from product sales, particularly from sales of ZILRETTA, or to maintain an acceptable cost structure related to our operations, we may not become profitable and may need to obtain additional funding to continue operations.

(*) Our existing indebtedness contains restrictions that limit our flexibility in operating our business. As a result of these restrictions, there is a risk that we may be required to repay our outstanding indebtedness earlier than we expect.

On August 2, 2019, we entered into the Amended and Restated Credit and Security Agreement with Silicon Valley Bank, MidCap Financial Trust, and Flexpoint MCLS Holdings, LLC which provides for a term loan of $40.0 million and a revolving credit facility up to $20.0 million. We concurrently drew down the $40.0 million term loan and used $7.7 million of the proceeds to repay the remaining amount owed on our prior credit facility. In February 2020, we drew down $20.0 million from the revolving credit facility. 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. The Amended and Restated Credit and Security Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;
- enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- amend, modify or waive any of our organizational documents;
- license, transfer or dispose of certain assets;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends;
- enter into material transactions with affiliates; and
- amend or waive provisions of material agreements in certain manners.

Under the credit facility, as amended, we are subject to a minimum liquidity threshold, such that at any time our liquidity is below $80.0 million, we will become subject to a minimum revenue covenant. Pursuant to the Amendment, the minimum liquidity

threshold includes certain accounts receivable as deemed eligible under the Amended and Restated Credit and Security Agreement, in addition to cash, cash equivalents, and marketable securities. Prior to May 2021, the minimum revenue covenant, if it applies in the future, is unmodified 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.

If the revenue covenant becomes applicable to us and we fail to meet it, the commitments under the Amended and Restated Credit and Security Agreement could be terminated and any outstanding borrowings, together with accrued interest, under the Amended and Restated Credit and Security Agreement could be declared 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. The restrictive covenants in the Amended and Restated Credit and Security Agreement could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the Amended and Restated Credit and Security Agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Amended and Restated Credit and Security Agreement. In the case of a continuing event of default under the Amended and Restated Credit and Security Agreement, the lenders could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the lenders a security interest under the Amended and Restated Credit and Security Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Amended and Restated Credit and Security Agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

In April 2017, we also issued $201.3 million principal amount of our 3.375% Convertible Senior Notes due 2024, or the 2024 Convertible Notes. The 2024 Convertible Notes will mature on May 1, 2024, unless earlier redeemed, repurchased or converted in accordance with the terms of the indenture governing the notes. If specified bankruptcy, insolvency or reorganization-related events of default occur, or if certain other events of default occur, including a default under the Amended and Restated Credit and Security Agreement resulting in an obligation to repay the indebtedness, and the trustee or certain holders of the 2024 Convertible Notes elect, the principal of, and accrued and unpaid interest on, all of the then-outstanding 2024 Convertible Notes will automatically become due and payable. In addition, if we undergo certain fundamental change transactions specified in the indenture governing the 2024 Convertible Notes, the holders of the notes may require us to repurchase their notes at a price equal to 100% of the principal amount of the notes, plus any accrued and unpaid interest.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay or refinance our indebtedness at the time any such repayment or repurchase is required. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

(*) If we fail to obtain additional financing, we may be forced to delay, reduce or eliminate our product development programs and/or commercialization activities.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials, and building and maintaining sales and marketing capabilities, is expensive. While we have recently implemented certain measures to reduce our near-term operating expenses, we cannot guarantee that we will realize the expected reductions in our expenses.

As of June 30, 2020, we had cash, cash equivalents, and marketable securities of approximately $200.6 million and working capital of $209.2 million. Regardless of our expectations as to how long our cash, cash equivalents, and marketable securities will fund our operations, changing circumstances may cause us to consume capital more rapidly than we currently anticipate.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if 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. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly scale back or discontinue commercialization of ZILRETTA or the further development of ZILRETTA or our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- seek corporate partners to assist in the commercialization of ZILRETTA on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to ZILRETTA or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

We may sell additional equity or debt securities to fund our operations, which may result in dilution to our stockholders and impose restrictions on our business.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which could adversely impact our existing stockholders as well as our business. The sale of additional equity or convertible debt securities would result in the issuance of additional shares of our capital stock and dilution to all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Risks Related to Commercialization Activities

(*) Our prospects are highly dependent on the successful commercialization of ZILRETTA. To the extent ZILRETTA is not commercially successful, our business, financial condition and results of operations may be materially adversely affected.

ZILRETTA is our only drug that has been approved for sale and it has only been approved for the management of OA pain of the knee for patients in the United States. We are focusing a significant portion of our activities and resources on ZILRETTA, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize ZILRETTA in the United States.

Successful commercialization of ZILRETTA is subject to many risks. We have never, as an organization, commercialized a product prior to ZILRETTA, and there is no guarantee that we will be able to do so successfully with ZILRETTA for its approved indication. There are numerous examples of failures to meet expectations of market potential, including by pharmaceutical companies with more experience and resources than us.

Market acceptance of ZILRETTA and any other product for which we receive approval, will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the ability to demonstrate the impact of real world evidence;
- the timing and market introduction of competitive products;
- the clinical indications for which the product is approved;
- acceptance by physicians, the medical community and patients of the product as a safe and effective treatment;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies;

- the convenience of prescribing, administrating and initiating patients on the product;
- the potential and perceived advantages and/or value of the product over alternative treatments;
- the cost of treatment in relation to its value compared to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement by third-party payers and government authorities to support ZILRETTA's pricing;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

With respect to ZILRETTA, while we have established a commercial team and sales force, there are many factors that could cause the commercialization of ZILRETTA to be unsuccessful, including a number of factors that are outside our control. The commercial success of ZILRETTA depends on the extent to which patients and physicians accept and adopt ZILRETTA as a treatment for OA pain of the knee, and we do not know whether our or others' revenue estimates in this regard will be accurate. For example, if the patient population suffering from OA pain of the knee is smaller than we estimate or if physicians are unwilling to prescribe or patients are unwilling to use ZILRETTA, the commercial potential of ZILRETTA will be limited. In addition, if ZILRETTA is not convenient for physicians to use, then it may not achieve widespread adoption, regardless of its efficacy and safety. For example, ZILRETTA is a buy-and-bill product and must be administered only by a health care professional in an office, clinic or hospital setting. In addition, ZILRETTA requires a multi-step preparation process, which may discourage some physicians from using ZILRETTA. Moreover, ZILRETTA's product label indicates that the efficacy and safety of repeat administration have not been demonstrated, and we believe this may impact our commercialization efforts. While we successfully completed a Phase 3b repeat dose study of ZILRETTA and our sNDA was approved and the product label was modified, the FDA did not agree to remove the limitation of use with respect to repeat administration. We also do not know how physicians, patients and payers will respond to the pricing of ZILRETTA in the long-term. Beginning in the second half of 2019, we introduced a volume-based rebate program to eligible purchasers and healthcare providers of ZILRETTA that positively impacted sales. We have continued to use rebate and discount programs for customers in the first quarter of 2020 and may continue to do so into the future. We are unable to predict how these rebate programs could potentially affect buying patterns and net sales in future quarters.

If we experience any disruption in the commercial supply of ZILRETTA due to manufacturing or distribution issues, the disruption would impact ZILRETTA sales and may adversely affect physicians', patients' and payers' use of ZILRETTA, negatively impacting uptake and long-term commercialization efforts.

Physicians may not prescribe ZILRETTA and patients may be unwilling to use ZILRETTA if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for ZILRETTA in terms of label updates or clinical development in additional indications, may adversely impact the commercial results and potential of ZILRETTA. Thus, significant uncertainty remains regarding the commercial potential of ZILRETTA.

If the commercialization of ZILRETTA is unsuccessful or perceived as disappointing, our stock price could decline significantly, and the long-term success of the product and our company could be harmed.

(*) COVID-19 has adversely impacted our commercialization of ZILRETTA.

COVID-19 has severely impacted our commercialization of ZILRETTA. For example, the Federal Government, along with State and local governments, have taken preventive and proactive measures to slow the spread of COVID-19. These measures include the issuance of "social distancing" or "stay at home" measures, which vary in scope and duration, but generally require businesses not considered "essential" to close their physical offices or curtail operations. As a result, some practices could experience financial insolvency and never reopen. While some healthcare facilities and physician offices, particularly those in major markets, have begun to reopen and reschedule previously cancelled or postponed non-emergency or elective procedures, certain regions of the U.S. are experiencing an increase in COVID-19 cases which has resulted in additional delays in procedures, such as intra-articular injections for OA pain, or otherwise restricted patient visits. Even in those markets where facilities are operating with fewer restrictions, we believe patients have been reluctant to seek treatment for fear of contracting COVID-19. These impediments and disruptions in patient care have resulted in a decreased volume of ZILRETTA being administered which has translated into decreased sales.

As the COVID-19 pandemic continues to rapidly evolve, with certain regions of the country experiencing increases in COVID-19 cases and others experiencing decreases, we are uncertain as to whether certain states may implement new "stay at home" measures or how healthcare practices will respond. Even in those regions where healthcare operations and patient visits are allowed to fully resume, we expect that it will take some time for activities to return to levels seen before the pandemic. We expect sales of ZILRETTA to continue to be negatively impacted for the foreseeable future until the effects of COVID-19 are fully resolved. It is also possible that a prolonged impact of COVID-19 and the associated reduction of physician office visits could force various

healthcare practices, particularly smaller primary care or orthopedic practices, to permanently close or to consolidate with larger practices or healthcare groups, which could cause us to lose previously-established physician relationships and result in a setback in our efforts to increase adoption of ZILRETTA.

If we are unable to differentiate ZILRETTA from existing generic therapies for the treatment of OA, or if the FDA or other applicable regulatory authorities approve generic products that compete with ZILRETTA, our ability to successfully commercialize ZILRETTA would be adversely affected.

Immediate-release TA and other injectable immediate-release steroids, which are the current intra-articular, or IA, standard of care for OA pain, are available in generic form and are therefore relatively inexpensive compared to the pricing for ZILRETTA. These generic steroids also have well-established market positions and familiarity with physicians, healthcare payers and patients. Although we believe the proven and extended pain relief evidenced in our clinical trials demonstrate that ZILRETTA represents a clinically meaningful and highly efficacious option for patients and physicians, it is possible that we will receive data from additional clinical trials or in a post-marketing setting from physician and patient experiences with the commercial product that does not continue to support such interpretations. It is also possible that the FDA, physicians and healthcare payers will not agree with our interpretation of our existing and future clinical trial data. If we are unable to demonstrate the value of ZILRETTA based on our clinical data, patient experience, as well as real world evidence, our opportunity for ZILRETTA to maintain premium pricing and be commercialized successfully would be adversely affected. For example, although ZILRETTA showed numeric improvements through week 12 in validated, OA specific pain, stiffness, function and quality of life exploratory measures and showed numeric improvements in average daily pain, it did not achieve statistical significance at the week 12 ADP timepoint compared to immediate-release TA. As a result, it is possible that healthcare payers will not agree with our assessment that ZILRETTA's proven pain relief supports premium pricing.

In addition to existing generic steroids, such as immediate-release TA, the FDA or other applicable regulatory authorities may approve other generic products that could compete with ZILRETTA, if we cannot adequately protect it with our patent portfolio. Once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as ZILRETTA. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our products would materially adversely impact our ability to successfully commercialize ZILRETTA.

(*) We face significant competition from other biopharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. In addition, the competition in the pain and OA market is intense. We have competitors both in the United States and internationally, including major multinational pharmaceutical and biotechnology companies. For example, the injectable OA treatment market today includes many injectable immediate-release steroids, including TA, the active ingredient in ZILRETTA, as well as hyaluronic acid, or HA, injections. In addition, we expect that injectable therapies, such as ZILRETTA, will continue to be used primarily after oral medications no longer provide adequate pain relief. To the extent that new or improved oral or other systemically administered pain medications are introduced that demonstrate better long-term efficacy and safety, patients and physicians may further delay the introduction of injectable therapies, such as ZILRETTA in the OA treatment continuum. ZILRETTA could also face competition from other formulations or devices that deliver pain medication on an extended basis, such as transdermal delivery systems or implantable devices.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staffs and experienced commercial and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than ZILRETTA or any other product candidate that we are currently developing or that we may develop.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of ZILRETTA and our other product candidates, including relative to marketed products and product candidates in development by third parties;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- the ability to commercialize and market ZILRETTA and any of our other product candidates that receive regulatory approval;
- the price of ZILRETTA and any of our future products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect our intellectual property rights;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of ZILRETTA and any of our other product candidates that receive regulatory approval; and
- acceptance of ZILRETTA and any of our other product candidates that receive regulatory approval by patients, physicians and other healthcare providers.

If our competitors market products that are more effective, safer, less expensive or offer discounts or rebates that allow physicians to receive more net reimbursement than ZILRETTA, we may not achieve commercial success. Increased financial pressure on physician practices may cause them to favor therapies that are discounted or provide greater net reimbursement than ZILRETTA. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our products or product candidates obsolete, less competitive or not economical.

(*) If we are unable to maintain sales and marketing capabilities or enter into agreements with third parties to market, distribute and sell our product candidates, we may be unable to generate adequate revenue.

Our strategy is to commercialize ZILRETTA in the United States with a targeted sales and marketing organization. While we have established our commercial team and our sales force, we do not have prior experience commercializing pharmaceutical products as an organization. In order to successfully market ZILRETTA, we must continue to build and maintain our sales, marketing, managerial, compliance and related capabilities or make arrangements with third parties to perform these services. These efforts will continue to be expensive and time-consuming, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not generate significant revenue from ZILRETTA.

Additionally, our strategy in the United States includes distributing ZILRETTA through a limited network of third-party specialty distributors, a specialty pharmacy, group purchasing organizations and other third parties. While we have entered into these agreements to purchase and/or distribute ZILRETTA in the United States, the counterparties may not perform as agreed or they may terminate their agreements with us. For example, ZILRETTA sales are concentrated with two specialty distributors, which together represented approximately 68% and 81% of our sales for the years ended December 31, 2019 and 2018, respectively. Loss of either specialty distributor through contract termination or its failure to distribute effectively would adversely affect ZILRETTA's distribution. While we have entered into these agreements on commercially reasonable terms, there is no guarantee that we will be able to continue to do so, if at all.

We and any third parties that we may engage in the future will be competing with many companies that currently have extensive and well-funded marketing and sales operations. If we, alone or with commercialization partners, are unable to compete successfully against these established companies, the commercial success of ZILRETTA or any other approved products will be limited. In addition, if we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our customer base, including specialty distributors, specialty pharmacies, group purchasing organizations and other direct customers, our ability to effectively commercialize ZILRETTA and generate product revenues would be limited.

(*) Customer buying patterns and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our short-term results.

Our results of operations, including, in particular, product revenues, may vary from period to period due to a variety of factors, including the buying patterns of our specialty distributors, specialty pharmacy, group purchasing organizations, and other direct purchasers, which vary from quarter to quarter, and may be impacted by seasonality (such as in the first quarter of the year when patient deductibles tend to be reset). In the event these customers with whom we do business limit their purchases of ZILRETTA, sales of ZILRETTA could be adversely affected. For example, if customers anticipate a reduction in expected rebates or discounts, or possible disruptions in supply chain, they may order ZILRETTA in larger than normal quantities which could cause sales of ZILRETTA to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns, inventory levels, increases in returns of ZILRETTA, delays in purchasing products or delays in payment for products by our customers could also have a negative impact on our revenue and results of operations. For example. due to the impacts of COVID-19, the levels of product inventory held at specialty distributors at the end of the first quarter was higher than prior quarters. As purchases of ZILRETTA by healthcare providers increased throughout the second quarter, the specialty distributors worked through their elevated inventory levels. As a result, the aggregate number of ZILRETTA units that our specialty distributors purchased from us and that we recognized as revenue in the second quarter was less than the aggregate amount purchased by healthcare providers from specialty distributors during this period. 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.

(*) If we are unable to effectively train and equip our sales force, our ability to successfully commercialize ZILRETTA will be harmed.

We are required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing ZILRETTA for the treatment of patients with OA of the knee. In addition, we must train our sales force to ensure that an appropriate and compliant message about ZILRETTA is being delivered. Due to the COVID-19 pandemic, our MBMs have begun using a mix of in-person and virtual interactions with physicians to convey key information about ZILRETTA and/or aid physicians and their staff in prescribing and obtaining reimbursement for ZILRETTA. While we have attempted to maintain the effectiveness of our sales and marketing efforts, it may not be as effective as in the pre-COVID environment, as access to some providers and some states remains limited. If we are unable to maintain an effectively trained sales force and equip them with compliant and effective materials, including medical and sales literature to help them appropriately inform and educate customers regarding the potential benefits and safety of ZILRETTA and its proper administration, our efforts to successfully commercialize ZILRETTA could be put in jeopardy, which would negatively impact our ability to generate product revenues.

(*) If we are unable to achieve and maintain adequate levels of third-party payer coverage and reimbursement for ZILRETTA, or, if approved, any other product candidates, on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of ZILRETTA and any other approved product candidates depend on the availability of coverage and adequate reimbursement from third-party payers, including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payers, among others. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from third-party payers are critical to product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. The resulting reimbursement payment rates for ZILRETTA and, if approved, our other product candidates, might not be adequate or may require co-payments that patients find unacceptably high.

As of January 1, 2019, we received a product-specific J-Code for ZILRETTA (J-3304), which helped reduce reluctance by physicians to prescribe ZILRETTA based on reimbursement concerns. However, some third-party payers nevertheless may still require documented proof that patients meet certain eligibility criteria in order to be reimbursed for ZILRETTA, for example requiring that a patient first try and fail treatment with an injection of generic corticosteroid. Also, third-party payers may require that pre-approval, or prior-authorization, be obtained from the payer for reimbursement of ZILRETTA, or limit coverage to one injection or a limited number of injections over a set time period. Patients are unlikely to use ZILRETTA and, if approved, any other products, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. For example, ZILRETTA is sold to physicians on a “buy and bill” basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third-party payer, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer ZILRETTA because they would have to fund the purchase of the product and then seek reimbursement, because they may consider ZILRETTA

reimbursement rates to be lower as compared to other treatments, or because they do not want the additional administrative burden required to obtain reimbursement for the product.

In addition, the market for ZILRETTA and any of our other product candidates may depend significantly on access to third-party payers' medical policies, drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement, as well as inclusion of ZILRETTA on the reimbursement policies and formularies used by large physician practices and hospitals. The industry competition to be included in such policies or formularies often leads to downward pricing pressures on pharmaceutical companies, and we may be required to offer discounted rates to certain government and other payers to ensure coverage of our drugs. Also, third-party payers, physician practices and hospitals may refuse to include a particular branded drug in their policies or formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payers, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer and one payer's determination to provide coverage for ZILRETTA does not ensure that other payers also will provide coverage. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for ZILRETTA or, if approved, any of our other product candidates, may not be available or adequate in either the United States or international markets, or may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution costs. If coverage and reimbursement are not available or only available at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, including ZILRETTA, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

(*) Guidelines and recommendations published by various organizations can reduce the use of ZILRETTA and any other products we may commercialize.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products and product candidates. In addition, professional societies, such as the American Academy of Orthopedic Surgeons, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities with respect to specific classes of products. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that do not recognize ZILRETTA or our other product candidates, suggest limitations or inadequacies of ZILRETTA or our other product candidates, or suggest the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers, could result in decreased use or adoption of ZILRETTA or any future products.

ZILRETTA is available to a much larger number of patients and in broader populations through our commercialization efforts as compared to the patients in the clinical studies. We do not know whether the results of ZILRETTA's use in such larger number of patients and broader populations will be consistent with the results from our clinical studies.

While the FDA granted approval of ZILRETTA based on the data included in the NDA, including data from our completed pivotal Phase 3 clinical trial, we do not know whether the results that served as the basis for the FDA's approval of ZILRETTA will be consistent with commercial results as a large number of patients and broader populations are exposed to ZILRETTA and are exposed over longer periods of time, including results related to safety and efficacy. New data relating to ZILRETTA, including from adverse event reports or our ongoing studies of ZILRETTA in other indications, may result in additional changes to the product label and may adversely affect sales, or result in withdrawal of ZILRETTA from the market. The FDA and regulatory authorities in other jurisdictions may also consider any new data in connection with further marketing approval applications. If ZILRETTA or any additional approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a Risk Evaluation and Mitigation Strategy;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is promoted or administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from maintaining market acceptance of the affected product and could substantially increase the costs of commercializing ZILRETTA or any additional products.

(*) Recently enacted and future legislation, including health care reform measures, may increase the difficulty and cost for us to commercialize ZILRETTA and any future products and may affect the prices we may obtain.

The United States and some foreign jurisdictions are considering, or have enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell ZILRETTA, and if approved for sale, our other potential products, profitably. Among policy makers and third-party payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been, and may continue to be, significantly affected by major legislative, congressional and enforcement initiatives. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, was enacted, which was intended to, among other items, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the PPACA provisions of importance to the pharmaceutical industry are the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Open Payments program, created under Section 6002 of PPACA, and its implementing regulations that require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to "payments or other transfers of value" made or distributed to physicians, as defined by such law, and teaching hospitals, and that applicable manufacturers and applicable group purchasing organizations report annually to CMS ownership and investment interests held by physicians and their immediate family members;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for non-compliance;
- an FDA-approval framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There remain legal and political challenges to certain aspects of PPACA. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, signed into law on December 22, 2017, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by PPACA on certain individuals that fail to maintain qualifying health coverage for all of part of a year commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans, or QHPs, and health insurance issuers under PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. On December 14, 2018, a Texas U.S. District Court Judge ruled that PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how this litigation and other efforts to repeal and replace PPACA will impact PPACA and our business.

In addition, since the PPACA was enacted, other legislative changes have been proposed and adopted that may impact the extent to which we are able to successfully commercialize any of our product candidates that receive regulatory approval. For example, in

August 2011, then-President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, two percent per fiscal year through 2030 unless Congress takes additional action. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices, including at the federal level several recent U.S. Congressional inquiries and legislation designed to, among other things, increase drug pricing transparency, reduce the cost of drugs under Medicare, review relationships between pricing and manufacturer patient assistance programs, and reform government program drug reimbursement methodologies. Any reduction in reimbursement from Medicare, Medicaid or other government-funded programs may result in a similar reduction in payments from private payers. The Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and implemented others under its existing authority. On July 24, 2020, President Trump announced four executive orders related to prescription drug pricing that attempt to implement several of the Trump administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. The probability of success of these newly announced policies and their impact on the U.S. prescription drug marketplace is unknown Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize ZILRETTA and any future products for which we receive regulatory approval.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, as well as additional downward pressure on the price that we receive for any approved product, including ZILRETTA. It is possible that additional governmental action is taken to address COVID-19. For example, on April 18, 2020, CMS announced that QHP issuers under the PPACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to COVID-19.

Risks Related to Product Development and Regulatory Compliance

We may never obtain regulatory approval of ZILRETTA for repeat administration or additional indications, approval of our other product candidates in the United States, or we may never obtain approval for or commercialize ZILRETTA or our other product candidates outside of the United States, which would limit our ability to realize their full market potential.

While ZILRETTA has been approved for the management of OA pain of the knee, the approved product label originally contained a limitation of use, or LOU, stating that ZILRETTA is not intended for repeat administration. On December 26, 2019, the FDA approved our supplemental new drug application, or sNDA, to revise the product label for ZILRETTA. The sNDA was based on data from an open-label Phase 3b clinical trial, which indicated that repeat administration of ZILRETTA for treatment of OA knee pain was safe and well tolerated with no deleterious impact on cartilage or joint structure observed through X-ray analysis. While the LOU was updated from stating ZILRETTA was not intended for repeat administration to stating that the efficacy and safety of repeat administration of ZILRETTA have not been demonstrated, we were not successful in our efforts to remove the LOU entirely. The

FDA did not find the data submitted in the sNDA sufficient to approve a removal of the LOU. If we are unable to remove the LOU or expand the label for ZILRETTA, our ability to fully market ZILRETTA may be limited.

While ZILRETTA has been approved by the FDA for the treatment of patients with OA of the knee in the United States, it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market ZILRETTA for other indications or in other jurisdictions, or in order to market any of our other product candidates, we must obtain regulatory approval for each indication and in each applicable jurisdiction, and we may never be able to get such approval for ZILRETTA or our other product candidates. In particular our pipeline product candidates, FX201 and FX301, are at early stages of development and if we cannot complete development of these product candidates and obtain regulatory approvals to market them, we may never recover our investment.

Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our potential future products in those countries. Other than ZILRETTA in the United States, we do not have any products approved for sale in any jurisdiction, and we do not have experience in obtaining regulatory approval in international markets. If we do not receive marketing approval for ZILRETTA for any other indication or from any regulatory agency other than the FDA, we will never be able to commercialize ZILRETTA for any other indication in the United States or for any indication in any other jurisdiction. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals for our other product candidates, or if regulatory approval in international markets is delayed, our potential market will be reduced and our ability to realize the full market potential of ZILRETTA or our other product candidates will be harmed. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the results generated in our completed ZILRETTA pivotal Phase 3 clinical trial do not ensure that any future ZILRETTA clinical trial will be successful or consistent with the results generated in the Phase 3 trial.

Product candidates may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, while FX201 has demonstrated successful results in numerous animal models, we have not yet completed our Phase 1 clinical trial and cannot predict if it will behave similarly in our human trials as it has in the animal studies. In addition to the safety and efficacy trials of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. In any event, our future clinical trials may not be successful.

If ZILRETTA or any other product candidate is found to be unsafe or lack efficacy or feasibility in particular indications, we will not be able to obtain regulatory approval for the indication and our business could be materially harmed.

(*) COVID-19 has adversely impacted and will likely continue to adversely impact 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, our investigational intra-articular gene therapy product candidate, in patients with OA of the knee. The decision was made in consideration of the recent 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 around when we will be able to restart the study, and the costs required to maintain it in an inactive status.

As COVID-19 continues to disrupt our ability to conduct clinical trials, we cannot predict with confidence whether, if ever, or when we will restart enrollment in or initiate new clinical trials for our clinical candidates in the United States and other countries. For example, while we subsequently restarted our Phase 1 clinical trial of FX201 in late May 2020, and we anticipate restarting clinical development of ZILRETTA in patient with shoulder OA in 2021, we cannot guarantee that further spread of COVID-19 or additional restrictions implemented by government agencies or healthcare facilities in response to COVID-19 will not force us to delay, suspend or terminate these trials. 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.

(*) Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval for our product candidates.

We may experience delays in clinical trials of our products and product candidates. Our clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; or
- the impact of COVID-19 and actions taken to mitigate its spread.

If initiation or completion of our clinical trials are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business.

The regulatory approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates or for ZILRETTA in additional indications, our business will be harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Although we received regulatory approval of ZILRETTA for the treatment of OA knee pain, it is possible that none of our other product candidates will ever obtain regulatory approval or that we will not be able to obtain regulatory approval for ZILRETTA in additional indications.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market ZILRETTA in additional indications or to market our other product candidates at all, which would harm our business, results of operations and prospects.

In addition, even if we were to obtain approval for other product candidates or for ZILRETTA in other indications, regulatory authorities may approve such product candidates or indications for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

Our product candidates may not receive regulatory approval despite success in clinical trials. Even if we successfully obtain regulatory approval to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

(*) Changes in funding for the FDA and other government agencies or their ability to maintain operations due to the impact of COVID-19 could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The operations of the FDA and other government agencies may also be reduced due to "social distancing" and "stay at home" measures, employee illnesses and other impacts from the COVID-19 pandemic.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or for labeling supplements and other regulatory requests to be acted upon, which would adversely affect our business.

The FDA granted marketing approval of ZILRETTA for the treatment of patients with OA pain of the knee, and we could face liability if a regulatory authority determines that we are promoting ZILRETTA for any off-label uses.

A company may not promote "off-label" uses for its drug products. An off-label use is the use of a product for an indication that is not described in the product's FDA-approved label in the United States or for uses in other jurisdictions that differ from those approved by the applicable regulatory agencies. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from pharmaceutical companies or their employees, including sales representatives, with respect to off-label uses of products for which marketing clearance has not been issued. A company that is found to have promoted off-label use of its product may be subject to significant liability, including civil and criminal sanctions. We intend to comply with the requirements and restrictions of the FDA and other regulatory agencies with respect to our promotion of ZILRETTA and any future products, but we cannot be sure that the FDA or other regulatory agencies will agree that we have not violated these restrictions. For example, as part of our promotion strategy for ZILRETTA we communicate certain results from our Phase 3 clinical trial and other clinical data that are consistent with, but not directly included in, the product label. While we believe our communication of this data is in accordance with FDA guidance and applicable laws, we cannot be certain that the FDA or other regulatory agencies will agree with our use of this data or our sales force may use such data in a way that is inconsistent with our policies. As a result, we may be subject to criminal and civil liability. In addition, our management's attention could be diverted to handle any such alleged violations. A significant number of pharmaceutical companies have been the target of inquiries and investigations by various U.S. federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of HHS, the FDA, the Federal Trade Commission and various state Attorneys General offices. These investigations have alleged violations of various U.S. federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, or the FDCA, the federal False Claims Act, the Prescription Drug Marketing Act, anti-kickback laws, and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a qui tam suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Any relationships with healthcare professionals, principal investigators, consultants, actual and potential customers, and third-party payers in connection with our current and future business activities are and will continue to be subject, directly or indirectly, to federal and state healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, administrative penalties, imprisonment, exclusion, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight, and curtailment or restructuring of our operations.

Our operations are directly or indirectly subject to various federal and state healthcare laws, including without limitation, fraud and abuse laws, false claims laws, marketing expenditure tracking and disclosure (or "sunshine") laws, government price reporting, and health information privacy and security laws. Our potential exposure under such laws increased significantly with the commercialization of ZILRETTA in the United States through our dedicated sales force. Our costs associated with compliance are also likely to increase. These laws may impact, among other things, our current activities with investigators and research subjects, as well as sales, marketing, promotion, manufacturing, distribution, pricing, discounting, customer incentive programs, physician speaker programs, and other business arrangements and activities. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or arranging for the purchase, lease, or order of any good, item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform services involving the use or disclosure of individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the PPACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives;

- analogous state, local, and foreign laws and regulations, such as anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers and entities, or marketing expenditures; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA, thus complicating compliance efforts;

- the Foreign Corrupt Practices Act, or FCPA, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- state and federal government price reporting laws that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement, rebates and/or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts); and

- the European Union's General Data Protection Regulation ((EU) 2016/679), or GDPR, which went into effect in May 2018, and which introduces strict requirements for processing personal data of individuals within the EU.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices, including activities undertaken by third parties on our behalf, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. For example, we participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates

are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations, including as a result from recent changes to our commercial contracting and pricing strategies, to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition. In addition, the HHS Office of Inspector General and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price, or AMP, and best price, or BP, for compliance with reporting requirements under the Medicaid Drug Rebate Program. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations. Moreover, while we do not bill third-party payers directly and our customers make the ultimate decision on how to submit claims, from time-to-time we may provide reimbursement guidance to patients and healthcare providers. If a government authority were to conclude that we provided improper advice and/or encouraged the submission of a false claim for reimbursement, we could face action against us by government authorities. If any of the physicians or other providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside of the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

ZILRETTA is still subject to substantial, ongoing regulatory requirements, and our other product candidates may face future development and regulatory difficulties.

The FDA approved ZILRETTA only for the treatment of OA knee pain. If any other ongoing clinical studies of ZILRETTA are negative, the FDA could decide to withdraw approval, add warnings or narrow the approved indication in the product label.

ZILRETTA is, and, if approved, our other product candidates, will also be, subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, and adherence to commitments made in the NDA. If we or a regulatory agency discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

We rely on third-party collaborators to assist us in meeting our reporting and related obligations. While we work closely with these third parties, we do not control all of their activities. If our third-party collaborators do not meet the relevant commitments, we may fail to meet our applicable regulatory requirements.

If we fail to comply with applicable regulatory requirements for ZILRETTA or for any other approved product candidate, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;

- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

If we fail to develop, acquire or in-license other potential future product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop, acquire or in-license and commercialize a portfolio of potential future product candidates in addition to ZILRETTA. Our primary means of expanding our pipeline of product candidates is to select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current pipeline, or that otherwise fit into our development or strategic plans on terms that are acceptable to us, and/or develop improved formulations and delivery methods for existing FDA-approved products. Developing new formulations or delivery methods of existing or potential future product candidates or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

Risks Related to Our Reliance on Third Parties

We rely completely on third parties to manufacture our commercial supplies of ZILRETTA and our preclinical and clinical drug supplies for our other product candidates.

If we were to experience an unexpected loss of supply of ZILRETTA or our other product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience disruptions in commercial supply of ZILRETTA or delays, suspensions or terminations of clinical trials or regulatory submissions. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third-party manufacturers to manufacture our products and product candidates, including Patheon with respect to finished drug supplies of ZILRETTA, must obtain and maintain approval by the FDA. While we work closely with our third-party manufacturers on the manufacturing process for our products and product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third-party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third-party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

In addition, we have no control over the ability of our contract manufacturers or other third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve, or withdraws approval for, these facilities for the manufacture of our products and product candidates, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercialize, develop, or obtain or maintain regulatory approval for our products and product candidates.

We are particularly reliant on Patheon with respect to maintaining ZILRETTA manufacturing capacity. These Patheon facilities required approval from the FDA as a condition of regulatory approval for ZILRETTA, as we rely exclusively on Patheon for commercial supplies of ZILRETTA. In addition, because Patheon manufactures ZILRETTA in the United Kingdom, or U.K., it needs to maintain and update its facility license with the applicable U.K. regulatory agencies and any delay or inability to do so would delay or prevent Patheon from being able to produce commercial supplies of ZILRETTA. Furthermore, the manufacturing process for ZILRETTA is unique and involves specialized equipment and proprietary processes, which subjects us to heightened risks that Patheon will experience delays in the manufacturing process.

We also rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce ZILRETTA and our other product candidates for our clinical trials and commercial sales. There are a limited number of suppliers for raw materials that we use to manufacture our products and product candidates and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and ZILRETTA for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our

manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials for ZILRETTA or for any other approved products, there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our products, including ZILRETTA.

We expect to continue to depend on contract manufacturers or other third-party manufacturers for the foreseeable future. We have entered into long-term commercial supply agreements with our current contract manufacturers in order to maintain adequate supplies to manufacture finished ZILRETTA drug product. We may, however, be unable to enter into such agreements or do so on commercially reasonable terms for potential future product candidates, which could have a material adverse impact upon our business.

(*) We rely on certain sole sources of supply for our products and product candidates and any disruption in the chain of supply may disrupt commercialization of ZILRETTA or cause delay in developing, obtaining approval for, and commercializing our products and product candidates.

Currently, we use the following sole sources of supply for manufacturing ZILRETTA: Farmabios SpA for TA, Evonik Corporation for PLGA, and Patheon for finished microspheres drug product. Because of the unique equipment and process for loading TA onto PLGA microspheres, transferring finished drug product manufacturing activities for ZILRETTA to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching ZILRETTA finished drug suppliers may involve substantial cost and could result in a failure to maintain adequate supplies of ZILRETTA. We expect that for the foreseeable future Patheon will be the only manufacturer qualified as a commercial supplier of ZILRETTA with the FDA. From time to time, commercial batches of ZILRETTA may fail to meet required specifications and be unavailable for commercial sale. If we experience multiple successive batch failures, or if supply from Patheon is otherwise interrupted, there could be a significant disruption in commercial supply. Any alternative vendor would need to be qualified through an NDA supplement, which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new ZILRETTA supplier is relied upon for commercial production.

As COVID-19 continues to spread globally, we may experience disruptions that could severely impact our supply chain, which would cause disruption to clinical trials and commercialization of ZILRETTA. For example, COVID-19 has resulted in increased travel restrictions and the shutdown or delay of business activities in various regions, including certain activities of one of our suppliers in Italy. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to COVID-19, our ability to continue meeting commercial demand for ZILRETTA in the United States or advancing development of our product candidates may become impaired. We recently modified our agreement with Patheon to suspend our minimum ZILRETTA purchase requirements for the remainder of 2020 as we expect lower demand due to COVID-19. While we have communicated to Patheon our intent to reinitiate manufacturing operations in the fourth quarter of 2020, we cannot be certain that we will be able to maintain sufficient commercial supply if there is a rapid increase in ZILRETTA demand as the impact of COVID-19 abates.

These factors could cause the disruption of the commercialization of ZILRETTA; delay clinical trials, regulatory submissions, required approvals or commercialization of any of our other product or product candidates; cause us to incur higher costs; or prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required clinical or commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue in the event of a product stockout for ZILRETTA or any of our other product candidates that is approved and launched.

Our other product candidates also rely on sole sources of supply for the preclinical and clinical supply of materials. The manufacturing processes for our product candidates are complex, and it may be difficult or impossible to finalize appropriate processes for the scaled manufacture of the product candidates.

Manufacturing issues may arise that could increase product and regulatory approval costs or disrupt or delay commercialization.

As we scale up manufacturing of ZILRETTA and other product candidates, we may encounter product, packaging, equipment and process-related issues that may require refinement or resolution in order to proceed with our planned clinical trials or maintain regulatory approval for commercial marketing. In the future, we may identify impurities or other product related issues, which could result in increased scrutiny by regulatory authorities, suspensions of commercial activities or product recalls, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our products or product candidates.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon and plan to continue to rely upon third-party CROs to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Council for Harmonization guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates may be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

(*) We may not be successful in establishing effective collaborations and/or maintaining development and commercialization collaborations in the United States or territories outside of the United States, and our partners may not devote sufficient resources to the development or commercialization of our products or product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop or commercialize certain of our products or product candidates and our financial condition and operating results.

We may seek third-party collaborators and/or licensees for the development and commercialization of our product candidates. For instance, we have entered into an exclusive license agreement for the development and commercialization of ZILRETTA in China, Hong Kong, Macau and Taiwan with HK Tainuo and Jiangsu Tainuo. We intend to seek to enter into additional collaborations for developing, marketing and commercializing our product candidates in certain territories at the appropriate time in the future. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements and otherwise to comply with their contractual obligations.

Even if we are able to establish effective collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. In addition, the terms of any such collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common stock. In some cases, we may be responsible for continuing development of a product or product candidate or research program under collaboration and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain.

Further, we may become subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the division of development or commercialization responsibilities or expenses, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a partner could act in its own self-interest, which may be adverse to our best interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our products or product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability:

Collaborations involving our product candidates would pose the following risks to us:

- we can expect to relinquish some or all of the control over the future success of that product candidate to the third party;
- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may fail in their development or commercialization efforts with our product candidate, in which event the development and commercialization of such product candidate could be delayed or terminated;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may fail to successfully design or implement clinical trials and may collect and publish clinical trial data that are inconsistent with, or contradictory to, our clinical trial results;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

- collaborators may deviate from established guidelines, instructions and/or best practices for product handling and storage which may compromise the safety, purity, potency, and effectiveness of our products and potentially result in the occurrence of serious adverse events in patients using our product(s);

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaborators could reduce or withhold the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;

- collaborators may take actions inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or

- collaborators could be unwilling to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and other technically qualified personnel in our industry, particularly in the greater Boston, Massachusetts area where our headquarters is located, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous biotechnology and pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in the commercialization of ZILRETTA or clinical studies of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical trials and the sale of ZILRETTA and any other products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, or others coming into contact with our products or product candidates. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and perception of our products in the market;
- withdrawal or suspension of marketing approvals;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- decreased demand for our products approved for commercial sale; and
- reputational harm.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action or mass tort lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If we collaborate with third parties to develop and commercialize products outside of the United States, a variety of risks associated with international operations could materially and adversely affect our business.

If we enter into agreements with third parties to market ZILRETTA, and if approved, our other product candidates, outside of the United States, we expect to be subject to additional risks related to entering into international business relationships. For instance, we have entered into an exclusive license agreement for the development and commercialization of ZILRETTA in China, Hong Kong, Macau and Taiwan with HK Tainuo and Jiangsu Tainuo. Agreements with third parties such as our existing agreement with HK Tainuo and Jiangsu Tainuo subject us to certain risks including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- different government payer systems, multiple payer-reimbursement regimes or patient self-pay systems, and price controls;
- potential noncompliance with the FCPA, the U.K. Bribery Act 2010, or similar antibribery and anticorruption laws in other jurisdictions as well as various regulations pertaining to data privacy, such as the GDPR;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our commercial and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs, and the development of our product candidates could be delayed.

If we fail to comply with applicable U.S. and foreign privacy and data protection laws and regulation, we may be subject to liabilities that adversely affect our business, operations and financial performance.

We are subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA, and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information on covered entities, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of personal health information. In addition to HIPAA, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, and storage of personal information.

We may also be subject to or affected by foreign laws and regulation, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about employees, patients and healthcare providers in connection with clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose

additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the GDPR, which introduced strict requirements for processing personal data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and leverage information about them. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to 20 million euros or up to 4% of the annual global revenue. While companies are afforded some flexibility in determining how to comply with the GDPR's various requirements, it has and will continue to require significant effort and expense to ensure continuing compliance with the GDPR. Moreover, the requirements under the GDPR may change periodically or may be modified by European Union, or EU, national law, and could have an effect on our business operations if compliance becomes substantially costlier than under current requirements. It is possible that each of these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

(*) Business interruptions could delay us in the process of developing or commercializing our products and product candidates.

Our headquarters are located in Burlington, Massachusetts. We are vulnerable to natural disasters such as hurricanes, tornadoes and severe storms, as well as other events that could disrupt our operations. We do not carry insurance for natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations. Further, our operations, and those of our contractors, consultants and collaborators, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. For example, the COVID-19 pandemic has caused disruptions to our clinical development activities as well as the operations of various third parties upon which we rely. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us, our ability to continue meeting commercial demand for ZILRETTA in the United States or advancing development of our product candidates may become impaired.

Exposure to U.K. political developments, including the outcome of the referendum on membership in the European Union, could impact our suppliers and harm our business.

The U.K.'s referendum to leave the EU, or "Brexit," has caused and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the U.K.'s relationship with the EU. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. The tax consequences of the U.K.'s withdrawal from the EU are uncertain as well. Brexit may also have a detrimental effect on our suppliers, which could, in turn, adversely affect our revenues and financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know how, and intend to seek marketing exclusivity for any approved product, including ZILRETTA, in order to protect the intellectual property related to our products and product candidates, and to date we have three issued patents covering ZILRETTA in the United States.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and our current or future licensors' or collaborators' patent rights are highly uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or product candidates in the United States, including through the inter-partes review process, or in other foreign countries. Even for our issued patents and if other patents do successfully issue, third parties may challenge their inventorship, ownership, validity, enforceability or scope in the courts or patent offices in the United States and abroad. This may result in such patents being narrowed or invalidated, which could limit our ability to stop others from using or commercializing similar or identical technologies or products, or limit the duration of the patent protection for our technologies and products. If this were to occur, early generic competition could be expected against ZILRETTA and potentially reduce the value of our product candidates in development. Also, a third party may challenge our rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If our patent applications with respect to ZILRETTA or our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop ZILRETTA or our other product candidates and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will not be found invalid and unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals for additional indications or in additional jurisdictions, the period of time during which we could market ZILRETTA or any product candidate under patent protection could be reduced. See "Business—Patents and Patent Applications" in our Annual Report on Form 10-K for additional information regarding our material patents and patent applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to the TA-formulated PLGA microspheres in ZILRETTA, including those that relate to precise pharmaceutical release. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the U.S. Patent and Trademark Office, or U.S. PTO. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are commercializing or developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of ZILRETTA and/or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any drug substance formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtain a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtain a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable

cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our products or product candidates, which could harm our business significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents, licensed patents or our other intellectual property. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Accordingly, for such undetectable infringement or misappropriation our ability to recover damages will be negligible, and we could be at a market disadvantage because we may lack the resources of some of our competitors to monitor for and detect infringement. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in litigation proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from infringing on our intellectual property rights in all countries outside the United States, and competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former

employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our owned or licensed patents directed to our product candidates may expire or have limited commercial life before the product candidate is approved for marketing in a relevant jurisdiction.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after our product candidates obtain regulatory approval, which may subject us to increased competition and reduce or eliminate our ability to recover our development costs. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Although we may be able to seek extensions of patent terms where available, including in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent, we cannot be certain that an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. The applicable authorities, including the EMA, FDA, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We have in-licensed or acquired a portion of our intellectual property necessary to develop our product candidates, and if we fail to comply with our obligations under any of these arrangements, we could lose such intellectual property rights.

We are a party to and rely on several arrangements with third parties, which give us rights to intellectual property that is necessary for the manufacture of ZILRETTA and the development of FX201 and FX301. Our current arrangements impose various development, royalty and other obligations on us. If we materially breach these obligations or if our counterparts fail to adequately perform their respective obligations, these exclusive arrangements could be terminated, which would result in our inability to develop, manufacture and sell products that are covered by such intellectual property.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize our affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to such third parties.

In many cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex, legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build a name recognition among potential partners or future, potential customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. If we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Ownership of Our Common Stock

(*) 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. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- the success or perceived success of the commercialization of ZILRETTA;
- the impact of COVID-19 and actions taken to mitigate its spread, including changing estimates as to how long such impact will last;
- 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 product 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 in any period, 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 are in the early stages of the ZILRETTA launch, we and the analysts who cover our company have limited ability to accurately predict future sales results, and actual results may differ materially from our expectations or those of such analysts.

In addition, the stock market in general, and the Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies like ours. Broad market and industry factors may continue to negatively affect the market price of our common stock, regardless of our actual operating performance.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved

controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

(*) We will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. For example, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the SEC annually, quarterly and current reports with respect to our business and financial condition. We have incurred and will continue to incur costs associated with the preparation and filing of these reports. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and the Nasdaq Global Market have imposed various other requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

(*) If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others, those associated with revenue recognition and accrued expenses related to preclinical and clinical development costs. We base our estimates on historical experience, known trends and events, contractual milestones, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. Any significant differences between our actual results and our estimates could materially affect our financial position, results of operations and cash flows.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity and/or convertible debt securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We may need significant additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 equity incentive plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. The number of shares available for future grant under the 2013 plan will automatically increase each year by 4% of all shares of our capital stock outstanding as of December 31 of the prior calendar year, subject to the ability of our board of directors to take action to reduce the size of the increase in any given year. Currently, we plan to register the increased number of shares available for issuance under the 2013 plan each year. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

(*) Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our net operating loss ("NOL"), carryforwards could expire unused and be unavailable to offset future tax liabilities because of their limited duration or because of restrictions under U.S. tax law. As of December 31, 2019, we had U.S. federal and state NOLs of $404.3 million and $300.0 million, respectively. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, as modified by the CARES Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs, particularly for tax years beginning after December 31, 2020, may be limited. It is uncertain if and to what extent various states will conform to the Tax Act and the CARES Act.

Section 382 of the Internal Revenue Code of 1986, as amended, or Section 382, contains rules that limit the ability of a company that undergoes an ownership change to utilize its net operating losses, or NOLs, and tax credits existing as of the date of such ownership change. Under the rules, such an ownership change is generally any change in ownership of more than 50% of a company's stock within a rolling three-year period. The rules generally operate by focusing on changes in ownership among stockholders considered by the rules as owning, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company. Future ownership changes as defined by Section 382 may further limit the amount of NOL carryforwards that could be utilized annually to offset future taxable income.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Additionally, our Amended and Restated Credit and Security Agreement with Silicon Valley Bank, MidCap Financial Trust, and Flexpoint MCLS Holdings, LLC contains covenants that restrict our ability to pay dividends. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder of such corporation for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

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).
10.1	Amendment 1 to Amended and Restated Credit and Security Agreement, dated May 18, 2020, by and among Flexion, Silicon Valley Bank as agent, MidCap Financial Trust, Flexpoint MCLS Holdings, LLC and the other lenders from time to time party thereto (Exhibit 99.1, Current Report on Form 8-K, filed with the SEC on May 19, 2020).
10.2	Side Letter to the Patheon Manufacturing and Supply Agreement dated as of April 8, 2020 (Exhibit 10.2, Quarterly Report on Form 10-Q, filed with the SEC on May 7, 2020).
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: August 5, 2020

By: /s/ Michael D. Clayman

Michael D. Clayman
Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2020

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: August 5, 2020

/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: August 5, 2020

/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: August 5, 2020

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

Date: August 5, 2020

/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.