UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 September 30, 2019

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: 001-38112

ATHENEX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**43-1985966**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1001 Main Street, Suite 600 **Buffalo, NY**	**14203**
(Address of principal executive offices)	**(Zip Code)**

(716) 427-2950
(Registrant's telephone number, including area code)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an 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	☐	Small 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 October 31, 2019, the registrant had 77,505,885 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 61,481	$ 49,794
Restricted cash	25,424	—
Short-term investments	42,273	57,629
Accounts receivable, net of chargebacks and other deductions of $19,909 and $13,101, respectively, and allowance for doubtful accounts of $133 and $9, respectively	17,168	12,951
Inventories	28,451	28,787
Prepaid expenses and other current assets	38,744	21,658
Total current assets	213,541	170,819
Property and equipment, net	19,272	11,447
Goodwill	37,293	37,495
Intangible assets, net	8,972	10,848
Operating lease right-of-use assets, net	8,517	—
Deferred income tax assets	—	486
Total assets	$ 287,595	$ 231,095
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,206	$ 12,997
Accrued expenses	69,994	37,718
Current portion of operating lease liabilities	2,810	—
Current portion of long-term debt	958	961
Total current liabilities	89,968	51,676
Long-term liabilities:		
Deferred compensation	2,541	2,825
Deferred rent	—	2,022
Long-term operating lease liabilities	7,579	—
Long-term debt and finance lease obligations	52,681	45,803
Total liabilities	152,769	102,326
Commitments and contingencies (See Note 16)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 250,000,000 shares authorized at September 30, 2019 and December 31, 2018; 79,142,305 and 68,668,986 shares issued at September 30, 2019 and December 31, 2018, respectively; 77,469,385 and 66,996,066 shares outstanding at September 30, 2019 and December 31, 2018, respectively	79	69
Additional paid-in capital	700,000	591,064
Accumulated other comprehensive loss	(423)	(656)
Accumulated deficit	(545,738)	(443,716)
Less: treasury stock, at cost; 1,672,920 shares at September 30, 2019 and December 31, 2018	(7,406)	(7,406)
Total Athenex, Inc. stockholders' equity	146,512	139,355
Non-controlling interests	(11,686)	(10,586)
Total stockholders' equity	134,826	128,769
Total liabilities and stockholders' equity	$ 287,595	$ 231,095

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

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
Product sales, net	$ 19,237	$ 13,309	$ 66,433	$ 37,385
License fees and consulting revenue	115	5,096	325	30,278
Grant revenue	12	23	110	166
Total revenue	19,364	18,428	66,868	67,829
Costs and operating expenses:				
Cost of sales	17,071	11,965	53,915	32,734
Research and development expenses	19,588	51,202	62,570	99,077
Selling, general, and administrative expenses	16,283	11,493	48,640	37,390
Total costs and operating expenses	52,942	74,660	165,125	169,201
Operating loss	(33,578)	(56,232)	(98,257)	(101,372)
Interest income	(650)	(654)	(1,408)	(1,314)
Interest expense	1,745	1,712	5,254	1,777
Loss before income tax expense (benefit)	(34,673)	(57,290)	(102,103)	(101,835)
Income tax expense (benefit)	114	(30)	1,019	(286)
Net loss	(34,787)	(57,260)	(103,122)	(101,549)
Less: net loss attributable to non-controlling interests	(29)	(11,090)	(1,100)	(11,222)
Net loss attributable to Athenex, Inc.	$ (34,758)	$ (46,170)	$ (102,022)	$ (90,327)
Unrealized gain (loss) on investment, net of income taxes	1	(37)	(79)	3
Foreign currency translation adjustment, net of income taxes	(310)	(554)	312	(477)
Comprehensive loss	$ (35,067)	$ (46,761)	$ (101,789)	$ (90,801)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 13)	$ (0.45)	$ (0.70)	$ (1.41)	$ (1.42)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 13)	77,297,555	66,399,091	72,552,248	63,806,787

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

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ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(In thousands, except share data)

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non-controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at January 1, 2018	59,894,362	$ 60	$ 423,805	$ (326,276)	$ (146)	(1,672,920)	$ (7,406)	$ 90,037	$ 685	$ 90,722
Sale of common stock, net of costs and discounts of $4,611	4,765,000	4	68,051	—	—	—	—	68,055	—	68,055
Stock-based compensation cost	—	—	2,161	—	—	—	—	2,161	—	2,161
Restricted stock expense	—	—	540	—	—	—	—	540	—	540
Stock options and warrants exercised	289,487	1	1,262	—	—	—	—	1,263	—	1,263
Net loss	—	—	—	(7,298)	—	—	—	(7,298)	(41)	(7,339)
Other comprehensive income, net of tax	—	—	—	—	683	—	—	683	—	683
Balance at March 31, 2018 (unaudited)	64,948,849	$ 65	$ 495,819	$ (333,574)	$ 537	(1,672,920)	$ (7,406)	$ 155,441	$ 644	$ 156,085
Stock-based compensation cost	—	—	3,081	—	—	—	—	3,081	—	3,081
Vesting of restricted stock	210,000	—	462	—	—	—	—	462	—	462
Stock options and warrants exercised	27,630	—	296	—	—	—	—	296	—	296
Research and development licensing fee satisfied with stock	107,181	—	2,000	—	—	—	—	2,000	—	2,000
Net loss	—	—	—	(36,859)	—	—	—	(36,859)	(91)	(36,950)
Other comprehensive loss, net of tax	—	—	—	—	(566)	—	—	(566)	—	(566)
Balance at June 30, 2018 (unaudited)	65,293,660	$ 65	$ 501,658	$ (370,433)	$ (29)	(1,672,920)	$ (7,406)	$ 123,855	$ 553	$ 124,408
Sale of common stock, net of costs and discounts of $907	2,679,528	3	49,090	—	—	—	—	49,093	—	49,093
Issuance of warrants	—	—	3,140	—	—	—	—	3,140	—	3,140
Stock-based compensation cost	—	—	2,316	—	—	—	—	2,316	—	2,316
Vesting of restricted stock	30,000	—	5	—	—	—	—	5	—	5
Stock options and warrants exercised	290,538	—	1,401	—	—	—	—	1,401	—	1,401
Research and development licensing fee satisfied with stock	267,952	—	29,545	—	—	—	—	29,545	—	29,545
Net loss	—	—	—	(46,170)	—	—	—	(46,170)	(11,090)	(57,260)
Other comprehensive loss, net of tax	—	—	—	—	(591)	—	—	(591)	—	(591)
Balance at September 30, 2018 (unaudited)	68,561,678	$ 68	$ 587,155	$ (416,603)	$ (620)	(1,672,920)	$ (7,406)	$ 162,594	$ (10,537)	$ 152,057

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non-controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at January 1, 2019	68,668,986	$ 69	$ 591,064	$ (443,716)	$ (656)	(1,672,920)	$ (7,406)	$ 139,355	$ (10,586)	$ 128,769
Stock-based compensation cost	—	—	1,693	—	—	—	—	1,693	—	1,693
Stock options exercised	49,632	—	278	—	—	—	—	278	—	278
Net loss	—	—	—	(35,233)	—	—	—	(35,233)	(997)	(36,230)
Other comprehensive income, net of tax	—	—	—	—	1,071	—	—	1,071	—	1,071
Balance at March 31, 2019 (unaudited)	68,718,618	69	593,035	(478,949)	415	(1,672,920)	(7,406)	107,164	(11,583)	95,581
Sale of common stock, net of costs of $54	10,033,362	10	100,309	—	—	—	—	100,319	—	100,319
Stock-based compensation cost	92,723	—	3,382	—	—	—	—	3,382	—	3,382
Stock options exercised	92,442	—	559	—	—	—	—	559	—	559
Net loss	—	—	—	(32,031)	—	—	—	(32,031)	(74)	(32,105)
Other comprehensive loss, net of tax	—	—	—	—	(529)	—	—	(529)	—	(529)
Balance at June 30, 2019 (unaudited)	78,937,145	$ 79	$ 697,285	$ (510,980)	$ (114)	(1,672,920)	$ (7,406)	$ 178,864	$ (11,657)	$ 167,207
Stock-based compensation cost	130,000	—	2,148	—	—	—	—	2,148	—	2,148
Stock options exercised	75,160	—	567	—	—	—	—	567	—	567
Net loss	—	—	—	(34,758)	—	—	—	(34,758)	(29)	(34,787)
Other comprehensive loss, net of tax	—	—	—	—	(309)	—	—	(309)	—	(309)
Balance at September 30, 2019 (unaudited)	79,142,305	$ 79	$ 700,000	$ (545,738)	$ (423)	(1,672,920)	$ (7,406)	$ 146,512	$ (11,686)	$ 134,826

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

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (103,122)	$ (101,549)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,808	2,424
Stock-based compensation expense	7,223	8,659
Amortization of debt discount	770	256
Deferred rent expense	—	329
Loss (gain) on disposal of assets and impairment charges	224	(62)
Research and development license fees settled with convertible bond and stock	—	31,545
Deferred income taxes	486	(316)
Changes in operating assets and liabilities:		
Receivables, net	(4,217)	1,397
Prepaid expenses and other assets	(17,086)	(6,290)
Inventories	336	(8,670)
Accounts payable and accrued expenses	38,458	(3,038)
Net cash used in operating activities	(74,120)	(75,315)
Cash flows from investing activities:		
Purchase of property and equipment	(8,513)	(2,501)
Payments for licenses	(4,175)	—
Purchases of short-term investments	(57,014)	(110,605)
Sales and maturities of short-term investments	72,290	31,981
Net cash provided by (used in) investing activities	2,588	(81,125)
Cash flows from financing activities:		
Proceeds from sale of stock	100,373	122,666
Proceeds from issuance of debt	6,464	50,000
Costs incurred related to the sale of stock	(54)	(5,118)
Costs incurred related to the issuance of debt	—	(1,593)
Proceeds from exercise of stock options	1,404	2,960
Repayment of finance lease obligations and long-term debt	(136)	(551)
Net cash provided by financing activities	108,051	168,364
Net increase in cash, cash equivalents, and restricted cash	36,519	11,924
Cash, cash equivalents, and restricted cash, beginning of period	49,794	39,284
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	592	(100)
Cash, cash equivalents, and restricted cash, end of period (See Note 3)	$ 86,905	$ 51,108
Supplemental cash flow disclosures		
Interest paid	$ 4,415	952
Non-cash investing and financing activities:		
Accrued purchases of property and equipment	$ 1,106	$ 445
Cost of equity raise in accounts payable and accrued expenses	$ —	$ 400
Common stock issued in lieu of licensing cash payment	$ —	$ 31,545
Right-of-use assets recognized in exchange for new operating lease obligations	$ 583	$ —

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

1. Company and Nature of Business

Organization and Description of Business

Athenex, Inc. and subsidiaries (the "Company" or "Athenex"), originally under the name Kinex Pharmaceuticals LLC ("Kinex"), formed in November 2003, commenced operations on February 5, 2004, and operated as a limited liability company until it was incorporated in the State of Delaware under the name Kinex Pharmaceuticals, Inc. on December 31, 2012. The Company changed its name to Athenex, Inc. on August 26, 2015.

Athenex is a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer. The Company's mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. The Company's current clinical pipeline is derived from Orascovery, Src Kinase Inhibition, T-cell receptor-engineered T-cells ("TCR-T"), and Arginine Deprivation Therapy research platforms. The Company has assembled a leadership team and has established global operations across the pharmaceutical value chain to execute its mission to become a global leader in bringing innovative cancer treatments to the market and improve health outcomes. The Company is primarily engaged in conducting research and development activities through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, conducting preclinical and clinical testing, recruiting personnel, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development and commercialization activities. The Company also conducts commercial sales of specialty products through its wholly owned subsidiary, Athenex Pharmaceutical Division ("APD"), and 503B products through its wholly-owned subsidiary, Athenex Pharma Solutions ("APS").

Follow-On Offering

In January 2018, the Company completed an underwritten public offering of 4,300,000 shares of its common stock. The Company granted the underwriters a 30-day option to purchase up to an additional 645,000 shares of common stock. In February 2018, the underwriters partially exercised their option, purchasing an additional 465,000 shares of common stock. All shares were offered by the Company at a price of $15.25 per share. The aggregate net proceeds were $68.1 million, net of underwriting discounts and commissions and offering expenses of $4.6 million.

Debt and Equity Offering

On July 3, 2018, the Company closed a privately placed debt and equity financing deal with Perceptive Advisors LLC and its affiliates ("Perceptive") for gross proceeds of $100.0 million and received aggregate net proceeds of $97.1 million, net of fees and offering expenses. The Company entered into a 5-year senior secured loan for $50.0 million of this financing and issued 2,679,528 shares of its common stock at a purchase price of $18.66 per share for the remaining $50.0 million. The loan matures on the fifth anniversary from the closing date and bears interest at a floating per annum rate equal to London Interbank Offering Rates ("LIBOR") (with a floor of 2.0%) plus 9.0%. The Company is required to make monthly interest-only payments with a bullet payment of the principal at maturity. The loan agreement contains specified financial maintenance covenants. In connection with the loan agreement, the Company granted Perceptive a warrant for the purchase of 425,000 shares of common stock at a purchase price of $18.66 per share. This was accounted for as a detachable warrant at its fair value and is recorded as an increase to additional paid-in-capital on the condensed consolidated statement of stockholders' equity.

Private Placement

On May 7, 2019, the Company closed a private placement with Perceptive Life Sciences Master Fund, Ltd., Avoro Capital Advisors (formerly known as venBio Select Fund LLC), OrbiMed Partners Master Fund Limited and the Biotech Growth Trust PLC (combined known as OrbiMed), (collectively, the "Investors"), pursuant to which the Company sold an aggregate of 10 million shares of its common stock to the Investors at a purchase price of $10.00 per share for aggregate net proceeds of $99.9 million, net of offering expenses of approximately $0.1 million. These shares were subsequently registered with the Securities and Exchange Commission ("SEC") on July 23, 2019.

Significant Risks and Uncertainties

The Company has incurred operating losses since its inception and, as a result, as of September 30, 2019 and December 31, 2018 had an accumulated deficit of $545.7 million and $443.7 million, respectively. As of September 30, 2019, the Company had $129.2 million of cash, cash equivalents, restricted cash, and short-term investments. Operations have been funded primarily through the sale of common stock and, to a lesser extent, from convertible bond financing, a senior secured loan, revenue, and grant funding. The Company will require significant additional funds to conduct clinical trials and to fund its operations, including commercialization activities if its drug candidates are ever approved by the U.S. Food and Drug Administration ("FDA"). There can be no assurances, however, that additional funding will be available on favorable terms, or at all. If adequate funds are not available, the Company may be required to delay, modify, or terminate its research and development programs or reduce its planned commercialization efforts. The Company believes that it will be able to obtain additional working capital through equity financings or other arrangements to fund operations, including additional public offerings; however, there can be no assurance that such additional financing, if available, can be obtained on terms acceptable to the Company. If the Company is unable to obtain such additional financing, the Company will need to reevaluate future operating plans and might delay, modify, or terminate its research and development programs or reduce its planned commercialization efforts. Accordingly, there is substantial doubt regarding the Company's ability to continue as a going concern.

These condensed consolidated financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of the business. The Company's recurring losses from operations and negative cash flows from operations have raised substantial doubt regarding its ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company has a senior secured loan agreement with Perceptive which contains various covenants. A breach of any of these covenants could result in a default. If a default under this loan agreement is not cured or waived, the default could result in the acceleration of debt, which could require the Company to repurchase or repay the debt in full prior to the date it is otherwise due. If the Company defaults, the lender may seek repayment through the Company's subsidiary guarantors or by executing on the security interest granted pursuant to the loan agreement.

The Company is subject to a number of risks similar to other biopharmaceutical companies, including, but not limited to, the lack of available capital, possible failure of preclinical testing or clinical trials, inability to obtain marketing approval of product candidates, competitors developing new technological innovations, unsuccessful commercialization strategy and launch plans for its proprietary drug candidates, market acceptance of the Company's products, and protection of proprietary technology. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate sufficient product revenue and might not, if ever, achieve profitability and positive cash flow.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles in the United States of America ("GAAP") for interim financial information (Accounting Standards Codification ("ASC") 270, *Interim Reporting*) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity with GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. These condensed consolidated financial statements reflect the accounts and operations of the Company and those of its subsidiaries in which the Company has a controlling financial interest. Intercompany transactions and balances have been fully eliminated in consolidation.

Results of the Company's operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results expected for the year ending December 31, 2019, or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 11, 2019.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amount of revenue and expenses during the reporting period. Such management estimates include those relating to assumptions used in clinical research accruals, chargebacks, allowance for doubtful accounts, inventory reserves, income taxes, the estimated useful life and recoverability of long-lived assets, and the valuation of stock-based awards. Actual results could differ from those estimates.

Leases

On January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2016-02,*Leases (Topic 842)* on a modified retrospective basis and did not restate comparative periods as permitted under the transition guidance. The Company elected the package of practical expedients as permitted, which carries forward the Company's assessments prior to the date of initial application with respect to lease classifications, initial direct costs as well as whether an existing contract contains a lease. The Company recognizes operating leases with terms greater than one year as right-of-use ("ROU") assets and lease liabilities on its condensed consolidated balance sheet. The Company's finance leases are included in property and equipment, net and long-term debt and finance lease obligations on the condensed consolidated balance sheet. A majority of the Company's operating leases are for real estate properties used in operations located in the U.S. and Asia. The Company's finance leases are for manufacturing equipment in the U.S.

ROU assets and lease liabilities are recognized based on the present value of the future lease payments over the contractual terms of the operating leases. The Company uses its incremental borrowing rate based on the information available at the date of initial adoption in determining the present value of the future lease payments. The Company uses the stated rate per each lease agreement in determining the finance lease liabilities. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. The lease liabilities and ROU asset are amortized over the term of the lease with operating lease expenses being recognized on a straight-line basis over the lease terms.

The Company elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for short-term leases.

Concentration of Credit Risk, Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, restricted cash, and short-term investments. The Company deposits its cash equivalents in interest-bearing money market accounts and certificates of deposit and invests in highly liquid U.S. treasury notes, commercial paper, and corporate bonds. The Company deposits its cash with multiple financial institutions. Cash balances exceed federally insured limits. The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer and establishing a minimum allowable credit rating. The Company also has significant assets and liabilities held in its overseas manufacturing facility, and research and development facility in China, and therefore is subject to foreign currency fluctuation.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, "*Leases (Topic 842),*" which requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. The new standard establishes a ROU model that requires a lessee to recognize a ROU asset representing the right to use the underlying asset over the lease term and lease liability on the balance sheet for all leases with a term longer than 12 months. Lease obligations are to be measured at the present value of lease payments and accounted for using the effective interest method. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. For finance leases, the leased asset is depreciated on a straight-line basis and recorded separately from the interest expense in the income statement resulting in higher expense in the earlier part of the lease term. For operating leases, the depreciation and interest expense components are combined, recognized evenly over the term of the lease, and presented as a reduction to operating income. The ASU requires that assets and liabilities be presented or disclosed separately and classified appropriately as current and noncurrent. The ASU further requires additional disclosure of certain qualitative and quantitative information related to lease agreements. In July 2018, the FASB issued new guidance that provided for a new optional transition method that allows entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to opening retained earnings. Under this approach, comparative periods are not restated.

The Company adopted the new lease standard on January 1, 2019 and used the effective date asthe date of initial application. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which allowed the Company (1) to not reassess whether any expired or existing contracts are or contain leases, (2) to not reassess the lease classification for any expired or existing leases, and (3) to not reassess initial direct costs for any existing leases. The Company also elected the single component practical expedient, which requires the Company, by class of underlying asset, not to allocate the total consideration to the lease and nonlease components based on their relative stand-alone selling prices. This single component practical expedient requires the Company to account for the lease component and nonlease component(s) associated with that lease as a single component if (i) the timing and pattern of transfer of the lease component and the nonlease component(s) associated with it are the same and (ii) the lease component would be classified as an operating lease if it were accounted for separately. In preparation for adoption of the standard, the Company implemented internal controls to enable the preparation of financial information. The standard had a material impact on the consolidated balance sheet, with no material impact on its consolidated statement of operations and comprehensive loss. On the adoption date, the Company recognized $9.8 million of operating lease ROU assets, $11.9 million of operating lease liabilities, and derecognized its existing deferred rent balance of $2.1 million.

In June 2018, the FASB issued ASU No. 2018-07, "*Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*," which expands the scope of Topic 718, "*Compensation – Stock Compensation*," which only included share-based payments to employees, to include share-based payments issued to nonemployees for goods and services. The ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will only need to remeasure liability-classified awards that have not yet been settled as of the date of adoption, and equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The Company adopted this standard on January 1, 2019 and the adoption of this ASU did not impact the Company's condensed consolidated financial statements.

Recently Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, "*Measurement of Credit Losses on Financial Instruments"* to improve reporting requirements specific to loans, receivables, and other financial instruments. The new standard requires that credit losses on financial assets measured at amortized cost be determined using an expected loss model, instead of the current incurred loss model, and requires that credit losses related to available-for-sale debt securities be recorded through an allowance for credit losses and limited to the amount by which carrying value exceeds fair value. The new standard also requires enhanced disclosure of credit risk associated with financial assets. The standard is effective for interim and annual periods beginning after December 15, 2019 with early adoption permitted. Based on the composition of the Company's investment portfolio and other financial assets, current market conditions and historical credit loss activity, the adoption of this standard is not expected to have a material impact on the Company's condensed consolidated financial statements.

3. Restricted Cash

The Company's restricted cash balance of $25.4 million as of September 30, 2019 consisted of $25.0 million of secured deposits held in a designated bank account for the issuance of an irrevocable standby letter of credit with an expiration date of December 15, 2019 related to a milestone payment arrangement pursuant to the license agreement between the Company and Almirall S.A. ("Almirall"), and $0.4 million of restricted cash deposits as security.

4. Inventories

Inventories consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Raw materials and purchased parts	$ 3,597	$ 4,092
Work in progress	2,012	3,166
Finished goods	22,842	21,529
Total inventories	$ 28,451	$ 28,787

5. Intangible Assets, net

The Company's identifiable intangible assets, net, consist of the following (in thousands):

	September 30, 2019			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	$ 8,935	$ 3,184	$ —	$ 5,751
Polymed customer list	1,593	1,101	—	492
Polymed technology	3,712	1,194	—	2,518
Product rights	525	360	165	—
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	715	—	—	715
Effect of currency translation adjustment	(504)	—	—	(504)
Total intangible assets, net	$ 14,976	$ 5,839	$ 165	$ 8,972

	December 31, 2018			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets				
Licenses	$ 8,935	$ 2,060	$ —	$ 6,875
Polymed customer list	1,593	938	—	655
Polymed technology	3,712	999	—	2,713
Product rights	530	263	—	267
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	1,026	—	298	728
Effect of currency translation adjustment	(390)	—	—	(390)
Total intangibles, net	$ 15,406	$ 4,260	$ 298	$ 10,848

As of September 30, 2019, licenses at cost include an Orascovery license of $0.4 million, licenses purchased from Gland Pharma Limited ("Gland") of $4.3 million, and a license purchased from MAIA Pharmaceuticals, Inc. ("MAIA") for $4.0 million. The Orascovery license with Hanmi Pharmaceuticals Co. Ltd. ("Hanmi") was purchased directly from Hanmi and is being amortized on a straight-line basis over a period of 12.75 years, the remaining life of the license agreement at the time of purchase. The licenses purchased from Gland are being amortized on a straight-line basis over a period of 5 years, the remaining life of the license agreement at the time of purchase. The license purchased from MAIA is being amortized over a period of 7 years, the remaining life of the license agreement at the time of purchase.

The remaining intangible assets were acquired in connection with the acquisitions of APS (formerly known as QuaDPharma), Polymed Therapeutics, Inc. ("Polymed"), and Comprehensive Drug Enterprises ("CDE"). Intangible assets are amortized using an economic consumption model over their useful lives. The APS customer list is being amortized on a straight-line basis over 7 years. The Polymed customer list and technology are amortized on a straight-line basis over 6 and 12 years, respectively. The CDE in-process research and development, ("IPR&D"), will not be amortized until the related projects are completed. IPR&D will be tested annually for impairment, unless conditions exist causing an earlier impairment test (e.g., abandonment of project). During the three months ended September 30, 2019, the Company determined that its product rights, initially acquired as IPR&D in connection with the acquisition of CDE, was impaired due to a lack of historical and forecasted sales and therefore, the related balance of $0.2 million was written-off as impaired and is included within research and development expenses in the condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 2019. The weighted-average useful life for all intangible assets was 7.7 years as of September 30, 2019.

The Company recorded $0.5 million and $0.4 million of amortization expense for the three-month periods ended September 30, 2019 and 2018, respectively, and $1.4 million and $1.2 million of amortization expense for the nine-month periods ended September 30, 2019 and 2018, respectively.

6. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, restricted cash, short-term investments, an equity investment, accounts receivable, accounts payable, accrued liabilities, and debt. Short-term investments and the equity investment are stated at fair value. Cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities, and debt, are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date of such amounts.

ASC 820, *Fair Value Measurements*, establishes a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy under the ASC 820 are described as follows:

Level 1—Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2—Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means; and
- If the asset or liability has a specified (contractual) term, the Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3—Inputs to the valuation methodology are unobservable, supported by little or no market activity, and are significant to the fair value measurement.

Transfers between levels, if any, are recorded as of the beginning of the reporting period in which the transfer occurs. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

The following tables represent the fair value hierarchy for those assets and liabilities that the Company measures at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2019 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 32	$ 32	$ —	$ —
Short-term investments - commercial paper	21,164	—	21,164	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	10,000	—	10,000	—
Short-term investments - commercial paper	32,022	—	32,022	—
Available-for-sale investment	251	251	—	—
Total assets	$ 63,469	$ 283	$ 63,186	$ —

	Fair Value Measurements at December 31, 2018 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 25	$ 25	$ —	$ —
Short-term investments - commercial paper	5,396	—	5,396	—
Financial assets included within short-term investments				
Short-term investments - commercial paper	36,544	—	36,544	—
Short-term investments - corporate notes	16,699	—	16,699	—
Short-term investments - U.S. government bonds	3,998	—	3,998	—
Available-for-sale investment	388	388	—	—
Total assets	$ 63,050	$ 413	$ 62,637	$ —

The Company classifies its money market funds within Level 1 because it uses quoted market prices to determine their fair value. The Company classifies its commercial paper, corporate notes, certificates of deposit, and U.S. government bonds within Level 2 because it uses quoted prices for similar assets or liabilities in active markets and each has a specified term and all Level 2 inputs are observable for substantially the full term of each instrument.

The Company owns 68,000 shares of PharmaEssentia, a company publicly traded on the Taiwan OTC Exchange. As of September 30, 2019 and December 31, 2018, the Company's investment in PharmaEssentia was valued at the reported closing price on such dates. This investment is classified as a Level 1 investment and is recorded as an available-for-sale investment within short-term investments on the Company's condensed consolidated balance sheet.

7. Acquisitions

CIDAL

On June 27, 2019, the Company entered into a definitive asset purchase agreement ("the APA") with CIDAL Limited, a British Virgin Islands company limited by shares, and several of its affiliates ("CIDAL"). CIDAL operates as a contract research organization with headquarters in Guatemala and operations in various countries in Latin America. Pursuant to the terms of the APA, the Company acquired certain assets of CIDAL in exchange for agreeing to assume certain liabilities of CIDAL, and subject to certain contingencies and post-closing purchase price adjustments, issuing shares of the Company's common stock to CIDAL. Under the terms of the APA, the Company also agreed to milestone payments of up to an aggregate of 67,796 shares of the Company's common stock upon the achievement of certain developmental and regulatory milestones through the third quarter of 2021. The transactions contemplated by the asset purchase agreement closed on October 31, 2019. We believe the acquisition strategically strengthens the Company's clinical research and operations capabilities and further supports its clinical development worldwide. The Company accounted for the asset purchase using the acquisition method of accounting and accordingly, the identifiable assets acquired, and liabilities assumed were recorded based upon management's estimates of current fair values as of the acquisition date. The purchase price amounted to approximately $2.2 million, consisting of approximately $1.1 million of liabilities assumed and approximately $1.1 million of contingent consideration. The Company received net cash of $0.8 million, acquired fixed assets of less than $0.1 million, and recorded goodwill of approximately $1.4 million.

AXIS

On June 29, 2018, the Company entered into a Share Subscription Agreement ("SSA") for Axis Therapeutics Limited ("Axis"), a subsidiary of the Company jointly owned by the Company and Xiangxue Life Sciences Limited ("XLifeSc"). Under the SSA, the Company contributed $30.0 million cash for a 55% ownership interest in Axis and XLifeSc contributed a license for IPR&D of certain immunotherapy technology for a 45% ownership interest in Axis. Also, on June 29, 2018, through a license agreement entered into between XLifeSc and Axis, XLifeSc granted Axis an exclusive, sublicensable worldwide (excluding mainland China) right and license to use its proprietary TCR-engineered T Cell therapy to develop and commercialize products for oncology indications ("TCR-T License"). Upon effectiveness of the TCR-T License and satisfaction of certain conditions of the license agreement, the Company issued 267,952 shares of its common stock equal to $5.0 million to XLifeSc as an upfront payment by Axis. On September 14, 2018, the Company completed the $30.0 million cash injection to Axis and all the closing conditions under the SSA were fulfilled.

The Company has consolidated the financial statements of Axis into itscondensed consolidated financial statements as of and for the nine months ended September 30, 2019 and as of and for the year ended December 31, 2018using the voting interest model. The nonmonetary exchange of 45% of the shares of Axis for the IPR&D from XLifeSc has been accounted for as an asset acquisition that does not constitutea business under ASC 805. Therefore, the acquisition of IPR&D was expensed as a research and development expense at its fair value. The Company determined that the fair value of the equity issued to XLifeSc was $24.5 million, considering the $30.0 million contribution made by the Company for its 55% ownership interest and the arms-length nature of the transaction. Accordingly, the Company recorded an expense of $24.5 million within research and development expenses on its consolidated statements of operations and comprehensive loss for the year ended December 31, 2018

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued wages and benefits	$ 6,277	$ 5,061
Accrued clinical expenses	2,848	2,653
Accrued operating expenses	5,994	8,128
Deferred revenue	20,071	190
Accrued R&D licensing fees	382	4,827
Accrued tax withholdings	256	—
Accrued selling fees and rebates	1,436	423
Accrued construction costs	32,730	16,436
Total accrued expenses	$ 69,994	$ 37,718

The accrued construction costs relate to the building of the manufacturing facility in Dunkirk, NY. Of this amount, the Company expects $32.1 million to be reimbursed by New York State. This amount is recorded within prepaid expenses and other current assets on the Company's condensed consolidated balance sheet as of September 30, 2019. $20.0 million of the deferred revenue relates to a milestone payment received in connection with an out-license agreement; see Note 15 – *Revenue Recognition* for additional details.

9. Income Taxes

The Company did not record a provision for federal income taxes for the nine months ended September 30, 2019 because it expects to generate a loss for the year ending December 31, 2019 and the Company's net deferred tax assets continue to be fully offset by a valuation allowance. Tax expense to date is the result of recording a valuation allowance against the deferred tax asset related to foreign tax benefits on losses in the People's Republic of China ("PRC") and tax withheld in Spain from a milestone payment received in connection with an out-license agreement with Almirall.

10. Debt and Lease Obligations

Debt

The Company's debt as of September 30, 2019 and December 31, 2018, consists of the following (in thousands):

	September 30, 2019	December 31, 2018
Current portion of mortgage	$ 70	$ 779
Current portion of bank loan	697	—
Current portion of finance and capital lease obligations	191	182
Current portion of operating lease obligations	2,810	—
Long-term portion of finance and capital lease obligations	277	422
Long-term portion of operating lease obligations	7,579	—
Long-term portion of mortgage	670	—
Chongqing Maliu Credit Agreement	5,583	—
Senior secured loan, net of debt discount and financing fees of $3,849 and $4,619, respectively	46,151	45,381
Total	$ 64,028	$ 46,764

The mortgage payments, assumed in connection with the acquisition of CDE, extend through December 31, 2020.

During 2018, Perceptive issued a senior secured loan to the Company with a principal value of $50.0 million and a maturity date of June 30, 2023. The loan bears interest at a floating per annum rate equal to LIBOR (with a floor of 2.0%) plus 9.0%. The Company is required to make monthly interest-only payments with a bullet payment of the principal at maturity.

During the first quarter of 2019, the Company was issued an unsecured, subordinated bank loan from China Merchants Bank to fund operations in China. This loan has a principal value of $0.7 million, a maturity date of December 11, 2019, and bears interest at a fixed rate of 5.7% annually.

During the second quarter of 2019, the Company entered into a credit agreement which amended the existing partnership agreement with Chongqing Maliu Riverside Development and Investment Co., LTD ("CQ"), for a Renminbi ¥50.0 million line of credit to be used for the construction of the new active pharmaceutical ingredient ("API") plant in China. The Company is required to repay the principal amount with accrued interest within three years after the plant receives the U.S. Current Good Manufacturing Practices ("cGMP") certification, with 20% of the total loan with accrued interest is due within the first twelve months following receiving the certification, 30% of the total loan with accrued interest due within twenty-four months, and the remaining balance with accrued interest due within thirty-six months. Interest accrues at the three-year loan interest rate by the People's Bank of China for the same period on the date of the deposit of the full loan amount. As of September 30, 2019, the balance due to CQ was $5.6 million.

Lease Obligations

The Company has operating leases for office and manufacturing facilities in several locations in the U.S. and Asia and has three finance leases for manufacturing equipment used in its facilities near Buffalo, NY. The components of lease expense are as follows (in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating lease cost	$ 793	$ 2,365
Finance lease cost:		
Amortization of assets	21	46
Interest on lease liabilities	7	24
Total net lease cost	$ 821	$ 2,435

The Company has elected to exclude short-term leases from its operating lease ROU assets and lease liabilities. Lease costs for short-term leases were not material to the financial statements for the three months ended September 30, 2019. Variable lease costs for the three and nine months ended September 30, 2019 were not material to the financial statements.

Supplemental balance sheet information related to leasesis as follows (in thousands, except lease term and discount rate):

	September 30, 2019
Operating leases:	
Operating lease ROU assets, net	$ 8,517
Current operating lease liabilities	$ 2,810
Long-term operating lease liabilities	7,579
Total operating lease liabilities	$ 10,389
Finance leases:	
Property and equipment, at cost	$ 660
Accumulated amortization, net	(46)
Property and equipment, net	$ 614
Current obligations of finance leases	$ 191
Long-term portion of finance leases	277
Total finance lease obligations	$ 468
Weighted average remaining lease term (in years):	
Operating leases	5.54
Finance leases	2.36
Weighted average discount rate:	
Operating leases	13.0%
Finance leases	5.9%

Supplemental cash flow information related to leases is as follows (in thousands):

	Nine Months Ended September 30, 2019
Cash paid for amount included in the measurements of lease liabilities:	
Operating cash flows from operating leases	$ 2,515
Operating cash flows from finance leases	24
Financing cash flows from finance leases	136
ROU assets recognized in exchange for new operating lease obligations	$ 583

Future minimum payments and maturities of leases is as follows (in thousands):

Year ending December 31:	Operating Leases	Finance Leases
2019 (remaining three months)	$ 823	$ 54
2020	2,941	214
2021	2,534	214
2022	2,354	21
2023	2,095	—
Thereafter	3,952	—
Total lease payments	14,699	503
Less: Imputed interest	(4,310)	(35)
Total lease obligations	10,389	468
Less: Current obligations	(2,810)	(191)
Long-term lease obligations	$ 7,579	$ 277

11. Related Party Transactions

During the nine months ended September 30, 2019 and 2018, the Company entered into transactions with individuals and companies that have financial interests in the Company. Related party transactions included the following:

a. In 2015, CDE signed an agreement with Avalon BioMedical (Management) Limited and its subsidiaries ("Avalon") under which Avalon would receive certain administrative services and would occupy space at CDE's research location. Avalon would reimburse CDE for these administrative services as incurred and pay CDE a percentage of the total rent payment based on its staff headcount occupying the Hong Kong research and development facility (See Note 16—*Commitments and Contingencies*). Certain members of the Company's board and management collectively have a controlling interest in Avalon. The Company does not hold any interest in Avalon and does not have any obligations to absorb losses or any rights to receive benefits from Avalon. As of September 30, 2019 and December 31, 2018, Avalon held 786,061 shares of the Company's common stock, which represented approximately 1% of the Company's total issued shares for both periods. Balances due from Avalon recorded on the condensed consolidated balance sheets were not significant.

In June 2018, the Company entered into two in-licensing agreements with Avalon wherein the Company obtained certain intellectual property ("IP") from Avalon to develop and commercialize the underlying products. Under these agreements the Company is required to pay upfront fees and future milestone payments and sales-based royalties. During the nine months ended September 30, 2018, the Company recorded $5.5 million of upfront fees, consisting of $3.5 million in cash and $2.0 million in equity, as research and development expenses on its condensed consolidated statement of operations and comprehensive loss. There were no fees paid during the three months ended September 30, 2018. During the three and nine months ended September 30, 2019, the Company recorded a $1.0 million milestone fee paid to Avalon, as research and development expenses on its condensed consolidated statement of operations and comprehensive loss.

In June 2019, the Company entered into an agreement whereby Avalon will hold a 90% ownership interest and the Company will hold a 10% ownership interest of the newly formed entity under the name Nuwagen Limited ("Nuwagen"), incorporated under the laws of Hong Kong. Nuwagen is principally engaged in the development and commercialization of herbal medicine products for metabolic, endocrine, and other related indications. The Company will contribute nonmonetary assets in exchange for the 10% ownership interest. The Company will not consolidate Nuwagen under the voting model but will record its interest as an investment under the cost method. As of September 30, 2019, the Company had not yet recorded the investment since the transaction has not closed.

b. The Company earns licensing revenue from PharmaEssentia, an entity in which the Company has an investment classified as available-for-sale (see Note 6—*Fair Value Measurements*). No revenue was received from PharmaEssentia during the three and nine months ended 2019 and 2018. Funds paid to PharmaEssentia under cost-sharing agreements amounted to $0.2 million for each of the three and nine months ended September 30, 2019 and net funds received from PharmaEssentia pursuant to these agreements amounted to $0 and $0.3 million for the three and nine months ended September 30, 2018, respectively.

c. The Company receives certain clinical development services from ZenRx Limited and its affiliate ("ZenRx"), a company for which one of the Company's executive officers serves on the board of directors. In connection with such services, the Company made payments to ZenRx of $1.8 million and $0.1 million for the three months ended September 30, 2019 and 2018, respectively, and $2.4 million and $0.3 million for the nine months ended September 30, 2019 and 2018, respectively. In April 2013, the Company entered into a license agreement with ZenRx pursuant to which the Company granted an exclusive, sublicensable license to use certain of the Company's IP to develop and commercialize oral irinotecan and encequidar, and oral paclitaxel and encequidar in Australia and New Zealand, and a non-exclusive license to manufacture a certain compound, but

only for use in oral irinotecan and encequidar and oral paclitaxel and encequidar. ZenRx is responsible for all development, manufacturing and commercialization, and the related costs and expenses, of any product candidates resulting from the agreement. No revenue was earned from this license agreement in the periods presented in these consolidated financial statements.

d. Certain family members of executives perform consulting services for the Company. Such services were not significant to the condensed consolidated financial statements.

12. Stock-Based Compensation

Common Stock Option Plans

The Company has four equity compensation plans, adopted in 2017, 2013, 2007 and 2004 (the "Plans") which, taken together, authorize the grant of up to 16,000,000 shares of common stock to employees, directors, and consultants. On May 23, 2019, the board of directors approved the amendment and restatement of the 2017 Omnibus Incentive Plan, which increases the number of shares available for issuance under the 2017 plan by up to 500,000 shares, subject to the approval of the Company's stockholders at the Company's 2020 annual meeting of stockholders. Additionally, on June 14, 2017, the Company adopted its 2017 Employee Stock Purchase Plan (the "ESPP"), which authorizes the issuance of up to 1,000,000 shares of common stock for future issuances to eligible employees.

Stock Options

The total fair value of stock options vested and recorded as compensation expense during the three months ended September 30, 2019 and 2018, and nine months ended September 30, 2019 and 2018 was $2.0 million, $2.3 million, $5.8 million, and $7.6 million, respectively. As of September 30, 2019, $17.0 million of unrecognized cost related to non-vested stock options was expected to be recognized over a weighted-average period of approximately 1.8 years. The total intrinsic value of options exercised was approximately $1.8million and $6.5 million for the nine months ended September 30, 2019 and 2018, respectively.

The following table summarizes the status of the Company's stock option activity granted under the Plans to employees, directors, and consultants (aggregate intrinsic value in thousands):

	Stock Options	Weighted-Average Exercise price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	10,687,650	$ 8.51	6.87	$ 44,688
Granted	867,000	13.13	—	—
Exercised	(217,234)	6.26	—	—
Forfeited and expired	(159,473)	13.82	—	—
Outstanding at September 30, 2019	11,177,943	$ 8.83	5.91	$ 37,195
Vested and exercisable at September 30, 2019	8,497,160	$ 7.16	5.12	$ 42,506

The Company determines the fair value of stock-based awards on the grant date using the Black-Scholes option pricing model, which is impacted by assumptions regarding several highly subjective variables. The following table summarizes the weighted-average assumptions used as inputs to the Black-Scholes model during the periods indicated:

	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Weighted average grant date fair value	$ 8.04	$ 9.87
Expected dividend yield	—%	—%
Expected stock price volatility	64%	59%
Risk-free interest rate	2.61%	2.60%
Expected life of options (in years)	6.3	6.1

Employee Stock Purchase Plan

The ESPP is available to eligible employees (as defined in the plan document). Under the ESPP, shares of the Company's common stock may be purchased at a discount (15%) of the lesser of the closing price of the Company's common stock on the first trading or the last trading day of the offering period. The current offering period extends from July 1, 2019 to November 30, 2019. The Company expects to offer six-month offering periods after the current period. The 2017 Plans reserved 1,000,000 shares of common stock for issuance under the ESPP. Stock-based compensation related to the ESPP amounted to $0.1 million for each of the three months ended September 30, 2019 and 2018, and $0.2 million and $0.1 million for the nine months ended September 30, 2019 and 2018, respectively.

Restricted Stock Awards

During the nine months ended September 30, 2019, the Company granted 92,723 restricted stock awards to employees in lieu of a cash bonus. Stock-based compensation related to this stock award amounted to $1.1 million for the nine months ended September 30, 2019.

The Company granted 130,000 restricted stock awards to employees during the nine months ended September 30, 2019. Stock-based compensation related to the restricted stock awards amounted to $0.1 million for the three and nine months ended September 30, 2019. As of September 30, 2019, $1.9 million of unrecognized cost related to non-vested restricted stock awards were expected to be recognized over a weighted-average period of approximately 1.2 years.

Stock-Based Compensation Cost

The components of stock-based compensation and the amounts recorded within research and development expenses and selling, general, and administrative expenses in the Company's consolidated statements of operations and comprehensive loss consisted of the following for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock options	$ 2,008	$ 2,316	$ 5,808	$ 7,558
Restricted stock expense	140	6	140	1,007
Stock grants to officers and employees	—	—	1,105	—
Employee stock purchase plan	82	94	250	94
Total stock-based compensation expense	$ 2,230	$ 2,416	$ 7,303	$ 8,659
Cost of sales	$ 62	$ 64	$ 189	$ 164
Research and development expenses	746	688	2,251	1,915
Selling, general, and administrative expenses	1,422	1,664	4,863	6,580
Total stock-based compensation expense	$ 2,230	$ 2,416	$ 7,303	$ 8,659

13. Net Loss per Share Attributable to Athenex, Inc. Common Stockholders

Basic net loss per share is calculated by dividing net loss attributable to Athenex, Inc. common stockholders by the weighted-average number of common shares issued, outstanding, and vested during the period. Diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common stock and common stock equivalents for the period using the treasury-stock method. For the purposes of this calculation, warrants to purchase common stock and stock options are considered common stock equivalents but are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Stock options and other common stock equivalents	11,634,810	11,119,444	11,004,831	10,397,140
Unvested restricted shares	49,457	4,891	16,667	152,808
Total potential dilutive shares	11,684,267	11,124,335	11,021,498	10,549,948

14. Business Segment, Geographic, and Concentration Risk Information

The Company has three operating segments, which are organized based mainly on the nature of the business activities performed and regulatory environments in which they operate. The Company also considers the types of products from which the reportable segments derive their revenue (only applicable to two reportable segments). Each operating segment has a segment manager who is held accountable for operations and has discrete financial information that is regularly reviewed by the Company's chief operating decision-maker. Consequently, the Company has concluded each operating segment to be a reportable segment. The Company's operating segments are as follows:

Oncology Innovation Platform—This operating segment performs research and development on certain of the Company's proprietary drugs, from the preclinical development of its chemical compounds, to the execution and analysis of its several clinical trials. It focuses specifically on Orascovery and Src Kinase Inhibition research platforms, and TCR-T Immunotherapy and Arginine Deprivation Therapy. This segment operates in the United States, Taiwan, Hong Kong, mainland China, and the United Kingdom.

Global Supply Chain Platform—This operating segment includes APS and Polymed. APS is a contract manufacturing company that provides small to mid-scale cGMP manufacturing of clinical and commercial products for pharmaceutical and biotech companies and for use as internal supplies to the clinical studies and commercial development of the Company's proprietary drugs. APS also performs microbiological and analytical testing for raw material and formulated products and has expanded to manufacture and sell pharmaceutical products under Section 503B of the Compounding Quality Act within the Federal Food, Drug & Cosmetic Act ("FDCA"). Polymed markets and sells API in North America, Europe, and Asia from its locations in Texas and China. Polymed also develops new compounds and processing techniques, and recently completed construction of a new API manufacturing facility in Chongqing, China. The 440,000-square-foot facility will produce validation batches in the fourth quarter of 2019 and is expected to commence commercial operations in the first half of 2020. The Company has an existing API manufacturing facility in Chongqing, China, where operations are currently suspended.

Commercial Platform—This operating segment includes APD, which focuses on the manufacturing, distribution, and sales of specialty pharmaceuticals. This segment provides services and products to external customers based mainly in the United States.

The Company's Oncology Innovation Platform segment operates and holds long-lived assets located in the United States, Taiwan, Hong Kong, mainland China, and the United Kingdom. The Global Supply Chain Platform segment operates and holds long-lived assets located in the United States and China. The Commercial Platform segment operates and holds long-lived assets located in the United States. For geographic segment reporting, product sales have been attributed to countries based on the location of the customer.

Segment information is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total revenue:				
Oncology Innovation Platform	$ 115	$ 5,117	$ 421	$ 30,532
Global Supply Chain Platform	7,969	7,092	30,714	17,991
Commercial Platform	12,006	7,315	38,279	23,006
Total revenue for reportable segments	20,090	19,524	69,414	71,529
Intersegment revenue	(726)	(1,096)	(2,546)	(3,700)
Total consolidated revenue	$ 19,364	$ 18,428	$ 66,868	$ 67,829

Intersegment revenue eliminated in the above table reflects sales from the Global Supply Chain Platform to the Oncology Innovation Platform.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total revenue by product group:				
API sales	$ 3,647	$ 3,690	$ 12,308	$ 9,538
Medical device sales	—	1,322	—	2,342
Contract manufacturing revenue	93	17	382	412
Commercial product sales	15,497	8,280	53,743	25,092
License fees	—	5,000	—	30,000
Other revenue	127	119	435	445
Total consolidated revenue	$ 19,364	$ 18,428	$ 66,868	$ 67,829

Intersegment revenue is recorded by the selling segment when it is realized or realizable and all revenue recognition criteria are met. Upon consolidation, all intersegment revenue and related cost of sales are eliminated from the selling segment's ledger.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss attributable to Athenex, Inc.:				
Oncology Innovation Platform	$ (29,732)	$ (37,638)	$ (87,127)	$ (65,985)
Global Supply Chain Platform	(3,376)	(6,089)	(3,829)	(16,780)
Commercial Platform	(1,650)	(2,443)	(11,066)	(7,562)
Total consolidated net loss attributable to Athenex, Inc.	$ (34,758)	$ (46,170)	$ (102,022)	$ (90,327)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total depreciation and amortization:				
Oncology Innovation Platform	$ 227	$ 174	$ 626	$ 505
Global Supply Chain Platform	376	490	1,012	1,185
Commercial Platform	398	245	1,170	734
Total consolidated depreciation and amortization	$ 1,001	$ 909	$ 2,808	$ 2,424

	September 30, 2019	December 31, 2018
Total assets:		
Oncology Innovation Platform	$ 174,938	$ 135,878
Global Supply Chain Platform	65,833	58,816
Commercial Platform	46,824	36,401
Total consolidated assets	$ 287,595	$ 231,095

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total revenue:				
United States	$ 15,624	$ 9,559	$ 54,119	$ 27,405
India	1,684	259	3,066	1,701
China	563	306	1,837	1,917
South Korea	513	—	513	—
Austria	476	2,227	4,423	5,102
Germany	398	—	602	—
United Kingdom	—	—	1,023	—
Spain	—	5,000	—	30,000
Other foreign countries	106	1,077	1,285	1,704
Total consolidated revenue	$ 19,364	$ 18,428	$ 66,868	$ 67,829

	September 30, 2019	December 31, 2018
Total property and equipment, net:		
United States	$ 10,791	$ 6,549
China	8,481	4,898
Total consolidated property and equipment, net	$ 19,272	$ 11,447

Customer revenue and accounts receivable concentration amounted to the following for the identified periods. These customers relate to the Commercial Platform segment and the Global Supply Chain Platform segment.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Percentage of total revenue by customer:				
Customer A	17%	12%	20%	13%
Customer B	22%	11%	17%	8%
Customer C	17%	13%	16%	9%
Customer D	—	27%	—	44%
Customer E	2%	10%	6%	6%

	September 30, 2019	December 31, 2018
Percentage of total accounts receivable by customer:		
Customer A	40%	16%
Customer B	35%	18%
Customer C	10%	12%

15. Revenue Recognition

The Company records revenue in accordance with ASC, Topic 606 '*Revenue from Contracts with Customers*." Under Topic 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the entity performs the following five steps: (i) identifies the contract(s) with a customer; (ii) identifies the performance obligations in the contract; (iii) determines the transaction price; (iv) allocates the transaction price to the performance obligations in the contract; and (v) recognizes revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts 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. Below is a description of the principal activities – separated by reportable segments – from which the Company generates its revenue (See Note 14 – *Business Segment, Geographic, and Concentration Risk Information*).

1. Oncology Innovation Platform

License fees and consulting revenue

The Company out-licenses certain of its IP and provides related consulting services to pharmaceutical companies in specific territories that allow the customer to use, develop, commercialize, or otherwise exploit the licensed IP. In accordance with Topic 606, the Company analyzes each of its out-licensing contracts with customers to identify each of the Company's performance obligations within the contract. Each out-license contains multiple performance obligations. The Company has determined that each of its out-license agreements with customers are classified as functional licenses and are capable of being distinct, because the IP that is licensed carries standalone value and is not expected to be altered through the life of the agreement. Therefore, for each of its out-licensing agreements, the Company has determined that the execution of the license and delivery of the IP to the licensee is distinct from the other performance obligations identified in the arrangement within the context of the contract. The Company has considered the development services it is required to perform and determined that these services do not modify the license to the IP delivered. Also, the Company does not deem the license and the development services to be interdependent. As such, the Company records revenue at a point-in-time for its out-licensing if any of the transaction price is allocated to the obligation, including up-front licensing fee payments. The Company's classification of each out-license as such requires significant judgment to be used by management. The Company considers the economic and regulatory characteristics of the licensed IP to determine if it has standalone value on the date of the licensing, which would make the licensing distinct and dictate that the Company recognizes any transaction price allocated to the license performance obligation at a point-in-time. Revenue recognized at a point-in-time for the execution of a distinct licensing of IP amounted to $0 and $5.0 million for the three months ended September 30, 2019 and 2018, and $0 and $30.0 million for the nine months ended September 30, 2019 and 2018, respectively.

Other performance obligations in the Company's out-licensing agreements include reaching milestone development and regulatory events by performing research and development activities over the licensed IP. The Company reached a milestone event under an agreement with Almirall during the nine months ended September 30, 2019. The Company considers milestones to be variable consideration, as the entitlement to the consideration is contingent on the occurrence or nonoccurrence of future events. The Company has determined that milestone performance obligations are satisfied at a point-in-time. Certain out-licensing agreements include performance obligations to manufacture and provide drug product in the future for commercial sale when the licensed product is approved. For the commercial development milestones, the consideration in exchange for the license of the Company's IP is contingent on the customer's subsequent sales to another commercial customer. Consequently, the sales- or usage-based royalty exception would apply. Revenue will be recognized for the commercial development milestones as the underlying sales occur. To date, the Company has not satisfied any of these performance obligations as none of its drugs have been approved by the regulatory agencies in any of the licensed territories.

In addition to the multiple performance obligations, the Company's out-licensing agreements include variable pricing. After the performance obligations are identified, the Company determines each portion of the transaction price, which generally includes upfront fees, milestone payments, and royalty payments. The Company begins by allocating the payments set forth in the agreement to the performance obligation to which the consideration is related. Then, the Company considers whether or not that transaction price is fixed, variable, or subject to return. If any portion of the transaction price is constrained by more than one performance obligation, the Company allocated that portion of the transaction price to the performance obligation that will be satisfied later and will not recognize revenue until it is fully satisfied and the constraint on the transaction price no longer exists. There are no other significant methods employed to allocate the transaction price to performance obligations in a contract. The Company exercises significant judgment when allocating the variable transaction prices to the proper performance obligations, considering if any of those payments are refundable or are contingent on any future events. The Company did not use any other significant judgments related to out-licensing revenue during the nine months ended September 30, 2019 and 2018.

Grant revenue

The Company receives grant award funding to support its continuing research and development efforts. The Company considers these grants to be operating revenue as they support the Company's primary operating activities. Revenue is recognized when the underlying performance obligation is satisfied, which is generally when all grant eligibility criteria are met at a point-in-time. Grant revenue is not significant to the condensed consolidated financial statements.

2. Global Supply Chain Platform

The Company's Global Supply Chain Platform manufactures API for use internally in its research and development activities as well as its clinical studies, and for sale to pharmaceutical customers globally. The Company generates additional revenue on this platform, by providing small to mid-scale cGMP manufacturing of clinical and commercial products for pharmaceutical and biotech companies and selling pharmaceutical products under 503B regulations set forth by the FDA.

Revenue earned by the Global Supply Platform is recognized when the Company has satisfied its performance obligation, which is the shipment or delivery of drug products. The underlying contracts for these sales are generally purchase orders and the Company recognizes revenue at a point-in-time. Any remaining performance obligations related to product sales are the result of customer deposits and are reflected in the deferred revenue contract liability balance.

3. Commercial Platform

The Company's Commercial Platform generates revenue by distributing specialty products through independent pharmaceutical wholesalers. The wholesalers then sell to an end-user, normally a hospital, alternative healthcare facility, or an independent pharmacy, at a lower price previously established by the end-user and the Company. Sales are initially recorded at the list price sold to the wholesaler. Because these prices will be reduced for the end-user, the Company records a contra asset in accounts receivable and a reduction to revenue at the time of the sale, using the difference between the list price and the estimated end-user contract price. Upon the sale by the wholesaler to the end-user, the wholesaler will chargeback the difference between the original list price and price at which the product was sold to the end-user and such chargeback is offset against the initial estimated contra asset. The significant estimates inherent in the initial chargeback provision relate to wholesale units pending chargeback and to the ultimate end-user contract selling price. The Company bases the estimate for these factors on product-specific sales and internal chargeback processing experience, as well as estimated wholesaler inventory stocking levels. The Company also offers cash discounts, which approximate 2.3% of the gross sales price, as an incentive for prompt customer payment, and, consistent with industry practice, the Company's return policy permits customers to return products within a window of time before and after the expiration of product dating. The Company expects that its wholesale customers will make prompt payments to take advantage of the cash discounts and expects customers to use their right of return. Therefore, at the time of sale, product revenue and accounts receivable are reduced by the full amount of the discount offered and the return expected. As of September 30, 2019 and December 31, 2018, the Company's total provision for chargebacks and other deductions totaled $19.9 million and $13.1 million, respectively, included as a reduction of accounts receivable. The Company's total expense for chargebacks and other deductions was $20.4 million and $11.4 million for the three months ended September 30, 2019 and 2018, respectively, and $59.8 million and $24.3 million for the nine months ended September 30, 2019 and 2018, respectively.

The Company also offers contractual allowances, generally rebates or administrative fees, to certain wholesale customers, group purchasing organizations ("GPOs"), and end-user customers, consistent with pharmaceutical industry practices. Settlement of rebates and fees may generally occur from one to five months from date of sale. The Company provides a provision for contractual allowances at the time of sale based on the historical relationship between sales and such allowances. Contractual allowances are reflected in the condensed consolidated financial statements as a reduction of revenue and accounts receivable or as accrued expenses.

The Company exercises significant judgment in its estimates of the variable transaction price at the time of the sale and recognizes revenue when the performance obligation is satisfied. Factors that determine the final net transaction price include chargebacks, fees for service, cash discounts, rebates, returns, warranties, and other factors. The Company estimates all of these variables based on historical data obtained from previous sales finalized with the end-user customer on a product-by-product basis. At the time of sale, revenue is recorded net of each of these deductions. Through the normal course of business, the wholesaler will sell the product to the end-user, determining the actual chargeback, return products, and take advantage of cash discounts, charge fees for services, and claim warranties on products. The final transaction price per product is compared to the initial estimated net sale price and reviewed for accuracy. The final prices and other factors are immediately included in the Company's historical data from which it will estimate the transaction price for future sales. The underlying contracts for these sales are generally purchase orders including a single performance obligation, generally the shipment or delivery of products and the Company recognizes this revenue at a point-in-time.

Disaggregation of revenue

The following represents the Company's revenue for its reportable segment by country, based on the locations of the customer.

	For the Three Months Ended September 30, 2019 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 3,618	$ 12,006	$ 15,624
India	—	1,684	—	1,684
China	115	448	—	563
South Korea	—	513	—	513
Austria	—	476	—	476
Germany	—	398	—	398
Other foreign countries	—	106	—	106
Total revenue	$ 115	$ 7,243	$ 12,006	$ 19,364

	For the Three Months Ended September 30, 2018 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 2,244	$ 7,315	$ 9,559
Spain	5,000	—	—	5,000
Austria	—	2,227	—	2,227
China	117	189	—	306
India	—	259	—	259
Other foreign countries	—	1,077	—	1,077
Total revenue	$ 5,117	$ 5,996	$ 7,315	$ 18,428

	For the Nine Months Ended September 30, 2019 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 15,840	$ 38,279	$ 54,119
Austria	—	4,423	—	4,423
India	—	3,066	—	3,066
China	421	1,416	—	1,837
United Kingdom	—	1,023	—	1,023
Germany	—	602	—	602
South Korea	—	513	—	513
Other foreign countries	—	1,285	—	1,285
Total revenue	$ 421	$ 28,168	$ 38,279	$ 66,868

	For the Nine Months Ended September 30, 2018 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Spain	$ 30,000	$ —	$ —	$ 30,000
United States	—	4,399	23,006	27,405
Austria	—	5,102	—	5,102
China	532	1,385	—	1,917
India	—	1,701	—	1,701
Other foreign countries	—	1,704	—	1,704
Total revenue	$ 30,532	$ 14,291	$ 23,006	$ 67,829

The Company also disaggregates its revenue by product group which can be found in Note 14 – *Business Segment, Geographic, and Concentration Risk Information*.

Contract balances

The following table provides information about receivables and contract liabilities from contracts with customers. The Company has not recorded any contract assets from contracts with customers.

	September 30, 2019	December 31, 2018
	(In Thousands)	
Accounts receivable, gross	$ 37,210	$ 26,061
Chargebacks and other deductions	(19,909)	(13,101)
Allowance for doubtful accounts	(133)	(9)
Accounts receivable, net	$ 17,168	$ 12,951
Deferred revenue	20,071	190
Total contract liabilities	$ 20,071	$ 190

The following tables illustrate accounts receivable balances by reportable segments.

	September 30, 2019 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ —	$ 4,888	$ 32,322	$ 37,210
Allowance for doubtful accounts, chargebacks, and other deductions	—	(120)	(19,922)	(20,042)
Accounts receivable, net	$ —	$ 4,768	$ 12,400	$ 17,168

	December 31, 2018 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ —	$ 7,814	$ 18,247	$ 26,061
Allowance for doubtful accounts, chargebacks, and other deductions	—	(9)	(13,101)	(13,110)
Accounts receivable, net	$ —	$ 7,805	$ 5,146	$ 12,951

As of September 30, 2019, $20.0 million of the deferred revenue balance relates to a license milestone payment received pursuant to an agreement held by the Oncology Innovation Platform and $0.1 million relates to customer deposits made by customers of the Global Supply Chain Platform and is included within accrued expenses on the condensed consolidated balance sheet. Upon the delivery and acceptance of certain clinical trial data by the customer, the Company will recognize revenue of $20.0 million and upon the delivery of certain drug product, the Company will recognize revenue of $0.1 million. The performance obligations to which this consideration was allocated was not satisfied as of September 30, 2019 and therefore, no revenue was recognized upon receipt of the milestone payment. The Company will recognize this amount as revenue when the underlying performance obligation is satisfied.

As of December 31, 2018, the $0.2 million contract liability related to customer deposits made by customers of the Global Supply Chain Platform. The Company satisfied its performance obligations allocated to these contract liabilities during the nine months ended September 30, 2019.

Practical expedients used

During the adoption of ASC 606, the Company applied the practical expedient in paragraph 606-10-10-4, the*Portfolio Approach*. This allowed the Company to apply the new revenue standard to a portfolio of contracts with similar characteristics because it reasonably expected that the effects on the financial statements of applying the guidance to the portfolio would not differ materially from applying the guidance to the individual contracts within that portfolio. The Company used this to determine the cumulative catch-up required under the modified retrospective transaction method. The Company used the portfolio approach for product sales under the Global Supply Chain Platform and product sales under the Commercial Platform. The Company did not use this approach for its out-licensing contracts, because each of those contracts have unique economic characteristics.

The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations related to the license of IP. This practical expedient is applied because the out-licensing agreements include sales-based royalties in exchange for the license of IP accounted for in accordance with Topic 606 and there is significant uncertainty surrounding the future variable consideration that could be received.

16. Commitments and Contingencies

Future minimum payments under the non-cancelable operating lease consists of the following as of December 31, 2018 (in thousands):

Year ending December 31:	Minimum payments
2019	$ 2,943
2020	2,466
2021	2,040
2022	1,902
2023	1,675
Thereafter	3,099
	$ 14,125

Legal Proceedings

From time to time, the Company may be subject to claims and litigation arising in the ordinary course of business. These claims could include assertions that the Company's products infringe existing patents or claims that the use of its products has caused personal injuries. The Company intends to vigorously defend any such litigation that may arise under all defenses that would be available. Regardless of the outcome, litigation can have an adverse impact on the Company because of prosecution, defense and settlement costs, unfavorable awards, diversion of management resources and other factors.

Vasopressin (Generic version of Vasostrict®)

On August 13, 2018, APS and APD, our wholly-owned subsidiaries, filed a complaint for declaratory judgment against Par Pharmaceuticals, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (together, "Par") in the United States District Court for the Western District of New York (the "Court"), seeking a declaratory judgment from the Court that our compounded vasopressin drug products in ready-to-use form did not infringe on patents that Par has with respect to its Vasostrict® product and that Par's patents are invalid. On July 9, 2019, the Court ordered dismissal of our complaint for lack of subject matter jurisdiction. We did not appeal this dismissal. While Par has not alleged that our compounded vasopressin infringed any of its patents, Par could do so by commencing an infringement lawsuit against us. If such an infringement lawsuit were brought and a court ruled for Par, Athenex could be enjoined from further production of compounded vasopressin within in the United States and sale of compounded vasopressin in or from the United States and for payment of damages to Par for U.S. manufacture or sale of compounded vasopressin that has already taken place.

In addition, on August 13, 2018, APS and APD filed a motion to intervene and seek the dismissal of Par Sterile Products, LLC's and Endo Par Innovation Company, LLC's complaint against the FDA and certain governmental officials in the United States District Court for the District of Columbia (the "DC Court"). Our motion to intervene was granted. These two Par entities have sought declaratory and injunctive relief, including a preliminary injunction, against FDA and certain governmental officials that: (i) vasopressin be delisted from Category 1 of FDA's list of bulk drug substances under evaluation pursuant to Section 503B of the FDCA, (ii) the expansion of FDA's enforcement discretion to Category 1 substances, be enjoined; and (iii) that FDA be enjoined from authorizing the compounding of vasopressin under Section 503B of the FDCA. We and FDA filed motions for judgment on the pleadings. On February 7, 2019, before resolving the above pending motions, the DC Court stayed the case until the earlier of: (i)

March 15, 2019; (ii) FDA publishes in the Federal Register a final determination about whether to include vasopressin on the clinical need list; or (iii) Par notify the Parties and the Court of a substantial change in circumstances necessitating a decision on Plaintiffs' Motion for Preliminary Injunction. On March 4, 2019, FDA published in the Federal Register its final decision not to include vasopressin on the list of bulk drug substances for which there is a clinical need. On the same day, we (Athenex, Inc., APS, and APD) filed a complaint in the DC Court against FDA seeking to vacate its final decision. Par Sterile Products, LLC and Endo Par Innovation Company, LLC joined this case as intervenors. On March 11, 2019, the DC Court extended the stay of Par's lawsuit against FDA until resolution of the motions for summary judgment in this newer related case.

In our case against the FDA, the FDA represented to the DC Court that "until the Court issues a decision on the merits of this action, the FDA will not initiate enforcement action against Athenex based solely on Athenex's use of the bulk drug substance vasopressin to compound drugs and distribute those drugs" and the DC Court incorporated the FDA's representation into its published order. As such, Athenex produced and distributed compounded vasopressin during the period that the case was pending before the DC District Court and prior to its decision.

On April 30, 2019, the DC Court held a hearing on the parties' cross motions for summary judgment. On August 1, 2019, the DC Court issued a ruling upholding the FDA's vasopressin decision and dismissing Athenex's complaint. On August 2, 2019, Athenex filed a notice of appeal with the U.S. Court of Appeals for the District of Columbia Circuit and a motion for a stay or injunction of the DC Court's order pending appeal. On September 6, 2019, the DC Court denied Athenex's motion for a stay or injunction pending appeal. Athenex then filed a motion for voluntary dismissal of the appeal. On October 1, 2019, the DC Court granted our motion to voluntarily dismiss the appeal and dismissed the case. Par filed a motion to voluntarily dismiss its complaint against the FDA and certain governmental officials in the DC Court. Athenex did not oppose this motion and, on September 27, 2019, the DC Court granted Par's motion to dismiss the action and dismissed the case. Athenex has ceased producing and distributing vasopressin since the DC Court's August 1, 2019 decision.

17. Subsequent Events

On October 31, 2019, the Company consummated the asset acquisition of CIDAL (see Note 7 –*Acquisitions*).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the unaudited condensed consolidated financial statements and the notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2018 included in our Annual Report on Form 10-K for the year ended December 31, 2018. Unless the context indicates otherwise, as used in this Quarterly Report, the terms "Athenex," the "Company," "we," "us," and "our" refer to Athenex, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted. This discussion and other parts of this quarterly report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, filed with the Securities and Exchange Commission on August 7, 2019.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and section 27A of the Securities Act of 1933, as amended (the "Securities Act"). All statements other than statements of historical fact are "forward-looking statements" for purposes of this Quarterly Report. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, business strategy, potential market size, potential growth opportunities, the timing and results of clinical trials, and potential regulatory approval and commercialization of product candidates. In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. These words are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section included in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date hereof to conform these statements to actual results or to changes in our expectations, except as required by law.

Overview and Recent Developments

We are a global biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. We are organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform and a Global Supply Chain Platform. Our current clinical pipeline in the Oncology Innovation Platform is derived from four different platform technologies: (1) Orascovery, based on a non-absorbed P-glycoprotein inhibitor, (2) Src kinase inhibition, (3) T-cell Receptor-engineered T-cells ("TCR-T"), and (4) arginine deprivation therapy. We have assembled a strong and experienced leadership team and have established global operations across the pharmaceutical value chain to execute our mission to become a global leader in bringing innovative cancer treatments to the market and improve health outcomes. Below we describe our current plans to advance the technology in our Oncology Innovation Platform.

Lead Orascovery platform drug candidate: Oral paclitaxel and encequidar

In August 2019, we announced topline data showing that oral paclitaxel and encequidar ("Oral Paclitaxel") met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.

A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the intent-to-treat ("ITT") population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.

Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.

Based on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival ($p = 0.077$) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival ($p = 0.11$) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free.

In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

We will be making an oral presentation at the San Antonio Breast Cancer Symposium in December 2019 where we plan to release further data regarding our Oral Paclitaxel Phase III clinical trial.

In October 2019, we announced that we received Orphan Designations from the European Commission (EC) for paclitaxel and encequidar for the treatment of soft tissue sarcoma, following a positive opinion from the European Medicines Agency (EMA).

We intend to establish Oral Paclitaxel as the chemotherapy of choice for patients receiving chemotherapy for metastatic breast cancer and intend to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in 2020 to secure regulatory approval of Oral Paclitaxel for metastatic breast cancer. If we receive regulatory approval from the FDA, we plan to explore establishing Oral Paclitaxel in other oncology indications where we believe taxanes will continue to be a foundational treatment and continue to explore combination therapies. Our strategy is to develop and, if we receive approval from the FDA, commercialize Oral Paclitaxel in the U.S. through our Commercial Platform. We also plan to evaluate marketing options outside of the U.S., including using our internal resources, partnering with others, or out-licensing the product. In the next few months, we plan to focus on:

- quantitative and qualitative market research, including on health outcomes and qualitative pricing, to understand our customers, patients, and the market;
- examining our competitive landscape;
- developing brand strategy;
- developing key opinion leader relationships;
- attending priority medical conferences to increase awareness of the Company and Oral Paclitaxel;
- creating a market access strategy;
- developing and executing a scientific publication plan;
- developing our patient and patient advocacy strategy;
- completing account, physician and patient segmentation in order to prioritize and target commercial efforts effectively;

- developing our distribution and patient support plans;
- developing our patient adherence to therapy strategy;
- completing our organizational design to determine the overall size of our go-to-market commercial team based on our market opportunity;
- continuing to hire key commercial and medical affairs leadership roles;
- completing a life cycle plan for Oral Paclitaxel; and
- preliminary marketing and launching forecasts.

We can provide no assurance that we will be successful in obtaining the FDA's approval to commercialize Oral Paclitaxel.

Lead Src Kinase Inhibition platform candidate: Tirbanibulin ointment, for Actinic Keratosis (AK)

In the first quarter of 2019, we presented topline results from the two Phase 3 studies of tirbanibulin ointment in the treatment of AK in a late breaker session at the 2019 American Academy of Dermatology ("AAD") Annual Meeting. Results showed that 44% and 54% of patients in studies KX01-AK-003 and KX01-AK-004, respectively, achieved 100% AK lesion clearance at Day 57 (See Table 1). The patient compliance rate in these two studies was greater than 99%. There was a statistically significant greater clearance rate in favor of tirbanibulin ointment 1% versus vehicle in each of the pre-specified patient subgroups. Safety results showed that tirbanibulin ointment was well tolerated. Treatment-related adverse events occurred in 11-20% of patients in the two Phase 3 studies. These events were generally transient mild to moderate application site symptoms, such as pruritus or pain. There were no serious adverse events or early discontinuations that were considered related to the study drug. Local skin reactions were mostly mild to moderate and transient erythema, flaking/scaling and crusting. We believe that this product, if approved by regulatory authorities, could have a major impact in the medical treatment of AK.

As of July 22, 2019, there were no serious adverse events that were considered to be related to the study treatment.

Table 1: Efficacy Results of Tirbanibulin Ointment 1% in the Field Treatment of Actinic Keratosis, as presented at the 2019 AAD Annual Meeting in March 2019

Study	**KX01-AK-003**			**KX01-AK-004**		
% of Subjects in the Intent-To-Treat Population (Number of Subjects)	Tirbanibulin N=175	Vehicle N=176	p-value	Tirbanibulin N=178	Vehicle N=173	p-value
100% AK Clearance on Day 57	**44% (N=77)**	**5% (N=8)**	**<0.0001[a]**	**54% (N=97)**	**13% (N=22)**	**<0.0001[a]**
Face	50%	6%	<0.0001	61%	14%	<0.0001
Scalp	30%	2%	<0.0001	41%	11%	0.0003
≥75% AK Clearance on Day 57	68%	16%	<0.0001[a]	76%	20%	<0.0001[a]

Note:
a = p-value calculated based on Cochran-Mantel-Haenszel (CMH)

In October 2019, we announced a progress update from our partner Almirall, S.A. ("Almirall") on tirbanibulin ointment for the treatment of AK. We also completed pre-NDA consultation with the U.S. FDA. We expect to file an NDA with the FDA for tirbanibulin ointment during the first quarter of 2020.

Lead TCR-T platform candidate: TAEST Therapy

In the first quarter of 2019, we announced that our partner, Xiangxue Life Sciences Limited ("XLifeSc"), received notice of allowance from the China National Medical Product Administration ("NMPA," formerly known as the China Food and Drug Administration) of its Investigational New Drug ("IND") application to initiate registrational related clinical studies in China of TCR

affinity-enhancing specific T-cell ("TAEST") therapy in patients with solid tumors that are HLA-A*02:01 positive and NY-ESO-1 positive. The cancer immunotherapy product, named TAEST16001 injection, is based on TAEST technology generated T-cells, with enhanced binding affinity, against the antigen NY-ESO-1 and is HLA-A*02:01 restricted.

Lead Arginine Deprivation Therapy platform candidate: Pegtomarginase

In the second quarter of 2019, the FDA allowed the IND application for the clinical investigation of Pegtomarginase for the treatment of patients with advanced malignancies.

Also, in the second quarter of 2019, we presented preclinical study results of Pegtomarginase in a poster session at the 2019 American Society of Clinical Oncology Annual Meeting. The biologic agent demonstrated high enzymatic activity, predictable pharmacokinetic-pharmacodynamic profiles, and cytotoxicity in vitro. Mouse xenograft models showed good tumor growth inhibition activity at tolerable doses with only transient weight loss during therapy.

Additional business developments

In September 2019, we announced that our partner, Guangzhou Xiangxue Pharmaceutical Co., Ltd., initiated a Phase I study in China of KX2-361 (formerly known as KX-02) oral treating advanced malignant solid tumors on the strength of encouraging results in preclinical studies. The Phase I clinical study in China is a single-center, open-label dose escalation trial that will enroll 36-72 patients with advanced malignant solid tumors who have no standard treatment or standard treatment failed.

In September 2019, we announced that we had completed construction of the new active pharmaceutical ingredient ("API") facility in Chongqing, China. The 440,000-square-foot facility will produce validation batches in the fourth quarter of 2019 and is expected to commence commercial operations in the first half of 2020. The construction of the facility is part of our strategy for vertical integration in order to capture value across the supply chain. Once operational, the facility is expected to expand our API production capabilities to further support our global clinical development needs and ensure the supply of API for commercial launches. The new API facility was constructed in accordance with an agreement with Chongqing Maliu Riverside Development & Investment Co., Ltd.

In the second quarter of 2019, we chose to suspend our operations at our API plant in Chongqing, based on the concerns raised by the Department of Emergency Management of Chongqing ("DEMC") related to the location of our plant. Due to this suspension, we are currently unable to sell API, which has impacted our revenue. We can provide no assurances of when, if at all, production of API will resume at the plant. We currently have secured additional API suppliers for our ongoing clinical studies, in the event the suspension continues for longer than expected.

We have three operating segments: our Oncology Innovation Platform, Global Supply Chain Platform and Commercial Platform. Since inception, we have devoted a substantial amount of our resources to research and development of our lead product candidates under our Orascovery, Src Kinase Inhibition research platforms, and TCR-T Immunotherapy and Arginine Deprivation Therapy. We have incurred significant net losses since inception. Our net losses were $102.0 million and $90.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of $545.7 million and $443.7 million, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- Continue to advance our lead programs, Orascovery and Src Kinase Inhibition research platforms, through clinical development;
- Continue our current preclinical and clinical research program and development activities;
- Advance the preclinical and clinical research program and development activities of our in-licensed technology platforms, TCR-T Immunotherapy and Arginine Deprivation Therapy;
- Seek to identify additional research programs and product candidates;
- Continue to invest in acquiring or in-licensing other drugs and technologies;
- Continue to invest in our manufacturing facilities;
- Continue to invest in further developing our Commercial Platform ahead of our intended proprietary drug launch;

- Hire additional research, development and business personnel;
- Maintain, expand and protect our intellectual property ("IP") portfolio; and
- Incur additional costs associated with operating as a public company.

We have funded our operations to date primarily from the issuance and sale of our common stock through public offerings, private placements, and convertible bonds, debt and, to a lesser extent, through revenue generated from our Global Supply Chain Platform. As of September 30, 2019, we had cash, cash equivalents, restricted cash, and short-term investments of $129.2 million.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) the sales of generic injectable products by our Commercial Platform; (ii) the sales of 503B and API products by our Global Supply Chain Platform; (iii) licensing and collaboration projects conducted by our Oncology Innovation Platform, which generates revenue in the form of upfront payments, milestone payments and payments received for providing research and development services for our collaboration projects and for other third parties; and (iv) grant awards from government agencies and universities for our continuing research and development efforts.

We do not anticipate revenue being generated from sales of our product candidates under development in our Oncology Innovation Platform until we have obtained regulatory approval. We cannot assure you that we will succeed in achieving regulatory approval for our drug candidates as planned, or at all.

Cost of Sales

Along with sourcing from third-party manufacturers, we manufacture clinical products in our cGMP facility in New York. Cost of sales primarily includes the cost of finished products, raw materials, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as transportation costs. Cost of sales also includes depreciation expense for production equipment, changes to our excess and obsolete inventory reserves, and certain direct costs such as shipping costs, net of costs charged to customers.

Research and Development Expenses

Research and development expenses consist of the costs associated with in-licensing of product candidates, milestone payments, conducting preclinical studies and clinical trials, activities related to regulatory filings and other research and development activities. Our current research and development activities mainly relate to the clinical development of our Oncology Innovation Platform:

Orascovery platform—Comprised of our in-licensed and novel P-gp inhibitor, encequidar (formerly known as HM30181A), that is combined with various chemotherapeutic agents and enables the agents to be absorbed into the blood when given orally:

- Oral paclitaxel and encequidar, combining encequidar with an oral dosage form of paclitaxel;
- Oral irinotecan and encequidar, combining encequidar with an oral dosage form of irinotecan;
- Oral docetaxel and encequidar, combining encequidar with an oral dosage form of docetaxel;
- Oral topotecan and encequidar, combining encequidar with an oral dosage form of topotecan; and
- Oral eribulin and encequidar, combining encequidar with an oral dosage form of eribulin.

The World Health Organization has recommended "encequidar" as the International Nonproprietary Name (INN) for HM30181A.

Src Kinase Inhibition platform—Targets the tyrosine kinase protein in regulating cell growth that leads to blockade of metastasis:

- Tirbanibulin (also known as KX2-391 or KX-01) ointment, Src kinase inhibitor topically administered to treat skin cancers and pre-cancers;
- Tirbanibulin oral, Src kinase inhibitor orally administered to treat certain solid and liquid tumors; and
- KX2-361 (also known as KX-02), Src kinase inhibitor orally administered to treat brain cancer, such as glioblastoma multiforme (GBM).

The World Health Organization has recommended "tirbanibulin" as the INN for KX2-391.

TCR-T Immunotherapy and Arginine Deprivation Therapy platform—licensed in July 2018, and are still in early stage R&D development phase:

- The TCR-T immunotherapy technology harnesses and enhances the patient's own immune cells to target and eliminate cancer. It is a cell-based therapy that takes advantage of unique attributes of TCR mediated target recognition and provides a potent and selective TCR-T directed response against cancer cells.
- The Arginine Deprivation Therapy product, based on pegylated genetically engineered human arginase, targets cancer growth and survival by interrupting the supply of an essential amino acid, arginine, to a proportion of cancers with disrupted urea cycle.

We expense research and development costs as incurred. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or clinical site activations. We do not allocate employee-related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development.

We cannot determine with certainty the duration, costs and timing of the current or future preclinical or clinical studies of our drug candidates. The duration, costs, and timing of clinical studies and development of our drug candidates will depend on a variety of factors, including:

- The scope, rate of progress, and costs of our ongoing, as well as any additional, clinical studies and other research and development activities;
- Future clinical study results;
- Uncertainties in clinical study enrollment rates;
- Significant and changing government regulation; and
- The timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate.

Research and development activities are central to our business model. We expect our research and development expenses to continue to increase for the foreseeable future as we continue to support the clinical trials of Oral Paclitaxel, oral irinotecan and encequidar, oral docetaxel and encequidar, oral topotecan and encequidar, oral eribulin and encequidar, tirbanibulin ointment, tirbanibulin oral and KX2-361, as well as initiate and prepare for additional clinical and preclinical studies, including TCR-T and Arginine deprivation program activities. We also expect spending to increase in the research and development for API, 503B and specialty products. There are numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will likely impact our clinical development programs and plans.

Selling, General and Administrative Expenses

Selling, general and administrative, ("SG&A"), expenses primarily consist of compensation, including salary, employee benefits and stock-based compensation expenses for sales and marketing personnel, and for administrative personnel that support our general operations such as executive management, legal counsel, financial accounting, information technology, and human resources

personnel. SG&A expenses also include professional fees for legal, patent, consulting, auditing and tax services, as well as other direct and allocated expenses for rent and maintenance of facilities, development of the facility in Dunkirk, NY, insurance and other supplies used in the selling, marketing, general and administrative activities. SG&A expenses also include costs associated with our commercialization efforts forour proprietary drugs, such as market research, brand strategy and development work on market access, scientific publication, product distribution and patient support. Our expenses related to operating as a public company may increase when we are no longer able to rely on the "emerging growth company" exemption to certain disclosure and attestation requirements pursuant to the Jumpstart our Business Startups Act of 2012 ("JOBS Act").

Results of Operations

Three Months Ended September 30, 2019 Compared to Three Months Ended September 30, 2018

The following table sets forth a summary of our condensed consolidated results of operations for the three months ended September 30, 2019 and 2018, together with the changes in those items in dollars and as a percentage. This information should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Three Months Ended September 30,			
	2019	2018	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	$ 19,237	$ 13,309	$ 5,928	45%
License fees and consulting revenue	115	5,096	(4,981)	-98%
Grant revenue	12	23	(11)	-48%
Total revenue	19,364	18,428	936	
Cost of sales	(17,071)	(11,965)	(5,106)	43%
Research and development expenses	(19,588)	(51,202)	31,614	-62%
Selling, general, and administrative expenses	(16,283)	(11,493)	(4,790)	42%
Interest income	650	654	(4)	-1%
Interest expense	(1,745)	(1,712)	(33)	2%
Income tax (expense) benefit	(114)	30	(144)	NM
Net loss	(34,787)	(57,260)	22,473	
Less: net loss attributable to non-controlling interests	(29)	(11,090)	11,061	NM
Net loss attributable to Athenex, Inc.	$ (34,758)	$ (46,170)	$ 11,412	

Revenue

Revenue from product sales increased significantly to $19.2 million for the three months ended September 30, 2019, from $13.3 million for the three months ended September 30, 2018, an increase of $5.9 million or 45%. This increase was primarily attributable to an increase of $4.7 million in specialty product revenue resulting from the increasing sales volume of existing products and the launch and sales of two new products, and an increase of $2.5 million in 503B revenue resulting from vasopressin sales, which was discontinued as of August 1, 2019. These increases were offset by a decrease in medical device sales of $1.3 million due to the phase out of such product sales, while API revenue and contract manufacturing revenue varied insignificantly from the prior year. Other revenue decreased by $5.0 million due to a decrease in licensing revenue. As we ceased production of vasopressin and suspended production of API, we expect to see a decline in revenue of these two product lines for the remainder of the year.

Cost of Sales

Cost of sales for the three months ended September 30, 2019 totaled $17.1 million, an increase of $5.1 million, or 43%, as compared to $12.0 million for the three months ended September 30, 2018. This was primarily due to the increase of $4.9 million in cost of sales resulting from the sale of specialty products and $0.2 million from 503B and API products. The increase in cost of sales was in line with the increase in product sales.

Research and Development Expenses

Research and development ("R&D") expenses for the three months ended September 30, 2019 totaled $19.6 million, a significant decrease of $31.6 million, or 62%, as compared to $51.2 million for the three months ended September 30, 2018. This was primarily due to a decrease in licensing fees, product development, clinical operations, and R&D related compensation and included the following:

- $30.3 million decrease as a result of milestone payments for drug in-licensing fees which occurred in 2018 and were related to a $29.5 million non-cash license fee related to the license of TCR-T technology in connection with the establishment of Axis Therapeutics Limited ("Axis"), of which $24.5 million related to the fair value of the IPR&D and $5.0 million related to the Company's common stock issued to XLifeSc;
- $2.1 million decrease of product development costs related to the scale up of 503B operations and the launch of certain specialty products in 2018;
- $1.7 million decrease of clinical studies costs related to the supply of encequidar and tirbanibulin ointment for clinical studies. In addition, patient costs on the two Phase 3 tirbanibulin studies continued to decrease as both Phase 3 studies wound down; and
- $0.4 million decrease in R&D related compensation expense.

The decrease in these R&D expenses was offset by an increase of $2.7 million of preclinical development costs related to the Arginine Deprivation Therapy and TCR-T Immunotherapy platforms and a $0.2 million increase due to an impairment charge of in-process research and development.

Selling, General, and Administrative Expenses

SG&A expenses for the three months ended September 30, 2019 totaled $16.3 million, an increase of $4.8 million, or 42%, as compared to $11.5 million for the three months ended September 30, 2018. This was primarily due to an increase of $3.0 million related to the costs of preparing to commercialize our proprietary drugs, if approved, and, an increase of $1.8 million of general administrative expenses including legal fees and other professional service fees, while administrative related compensation expense remained consistent with the prior year.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments and remained consistent for the three months ended September 30, 2019 and 2018. Interest expense totaled $1.7 million for both the three months ended September 30, 2019 and 2018. The interest expense in the both periods was incurred from our long-term debt with Perceptive Advisors LLC ("Perceptive") entered into during the third quarter of 2018.

Nine Months Ended September 30, 2019 Compared to Nine Months Ended September 30, 2018

The following table sets forth a summary of our condensed consolidated results of operations for the nine months ended September 30, 2019 and 2018, together with the changes in those items in dollars and as a percentage. This information should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Nine Months Ended September 30,			
	2019	2018	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	$ 66,433	$ 37,385	$ 29,048	78%
License fees and consulting revenue	325	30,278	(29,953)	-99%
Grant revenue	110	166	(56)	-34%
Total revenue	66,868	67,829	(961)	
Cost of sales	(53,915)	(32,734)	(21,181)	65%
Research and development expenses	(62,570)	(99,077)	36,507	-37%
Selling, general, and administrative expenses	(48,640)	(37,390)	(11,250)	30%
Interest income	1,408	1,314	94	7%
Interest expense	(5,254)	(1,777)	(3,477)	NM
Income tax (expense) benefit	(1,019)	286	(1,305)	NM
Net loss	(103,122)	(101,549)	(1,573)	
Less: net loss attributable to non-controlling interests	(1,100)	(11,222)	10,122	-90%
Net loss attributable to Athenex, Inc.	$ (102,022)	$ (90,327)	$ (11,695)	

Revenue

Our product sales increased significantly to $66.4 million for the nine months ended September 30, 2019, from $37.4 million for the nine months ended September 30, 2018. However, total revenue for the nine months ended September 30, 2019 decreased by $1.0 million, as compared to $67.8 million for the nine months ended September 30, 2018. The decrease was primarily due to the absence in the 2019 period of $30.0 million in license milestone revenue earned during 2018, and $2.3 million decrease in medical device product sales and contract manufacturing revenue, offset by a $15.2 million increase in specialty product sales resulting from the increasing sales volume of the existing products and the launch and sales of new products, a $13.4 million increase in 503B sales mainly attributable to vasopressin sales in the first half of 2019, and a $2.7 million increase in sales of API in early months of the year. Revenue from 503B and API sales are expected to decline for the remainder of the year as we ceased production of vasopressin in August 2019 and suspended production of API in the second quarter of 2019.

Cost of Sales

Cost of sales for the nine months ended September 30, 2019 totaled $53.9 million, an increase of $21.2 million, or 65%, as compared to $32.7 million for the nine months ended September 30, 2018. This was primarily due to the increase of $16.9 million in cost of sales from the sale of specialty products and $4.3 million in cost of sales from 503B and API products. The increase in cost of sales was lower than that in product sales, primarily as a result of changes in our product portfolio.

Research and development

R&D expenses for the nine months ended September 30, 2019 totaled $62.6 million, a decrease of $36.5 million, or 37%, as compared to $99.1 million for the nine months ended September 30, 2018. This was primarily due to a decrease in licensing fees, product development, and clinical operations and included the following:

- $31.7 million decrease as a result of milestone payments for drug in-licensing fees which occurred in 2018 and were related to a $29.5 million non-cash license fee related to the license of TCR-T technology in connection with the establishment of Axis, of which $24.5 million related to the fair value of the IPR&D and $5.0 million related to the Company’s common stock issued to XLifeSc;
- $7.1 million decrease of product development costs related to the scale up of 503B operations and the launch of certain specialty products in 2018; and
- $4.7 million decrease of clinical development costs related to encequidar and tirbanibulin ointment.

The decrease in these R&D expenses was offset by an increase of $6.6 million of preclinical development costs related to the Arginine Deprivation Therapy and TCR-T Immunotherapy platforms, a $0.2 million increase due to an impairment charge of in-process research and development, and a $0.2 million increase of R&D related compensation expense.

Selling, General, and Administrative Expenses

SG&A expenses for the nine months ended September 30, 2019 totaled $48.6 million, an increase of $11.2 million, or 30%, as compared to $37.4 million for the nine months ended September 30, 2018. This was primarily due to an increase of $9.3 million related to the costs of preparing to commercialize our proprietary drugs, if approved, and an increase of $2.8 million of general administrative expenses including legal fees and other professional service fees, offset by a decrease of $0.9 million in administrative related compensation expense.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments and increased by $0.1 million, or 7%, for the nine months ended September 30, 2019. Interest expense for the nine months ended September 30, 2019 totaled $5.3 million, an increase of $3.5 million as compared to $1.8 million interest expense for the nine months ended September 30, 2018. The interest expense in the current period was incurred from our long-term debt entered into with Perceptive during the third quarter of 2018.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our R&D programs, SG&A costs associated with our operations, and the development of our specialty drug operations in our Commercial Platform and 503B operations and the investment we are making in our pre-launch activities in anticipation of commercializing our proprietary drugs. We incurred net losses of $102.0 million and $90.3 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $545.7 million. Our operating activities used $74.1 million and $75.3 million of cash during the nine months ended September 30, 2019 and 2018, respectively. We intend to continue to advance our various clinical and pre-clinical programs which we expect will lead to increased cash outflow of R&D costs and increase our investments in commercialization activities for our proprietary drugs. In addition, we can provide no assurance that the funding requirements to diversify the product portfolio for specialty drug products in the Commercial Platform and 503B operations will decline in the future. Our principal sources of liquidity as of September 30, 2019 are cash and cash equivalents, restricted cash, and short-term investments totaling $129.2 million.

In July 2018, we closed a privately placed debt and equity financing deal with Perceptive for gross proceeds of $100.0 million and received aggregate net proceeds of $97.1 million, net of fees and offering expenses. We entered into a 5-year senior secured loan for $50.0 million of this financing and issued 2,679,528 shares of our common stock at a purchase price of $18.66 per share for the remaining $50.0 million. The loan matures on the fifth anniversary from the closing date and bears interest at a floating per annum rate equal to LIBOR (with a floor of 2.0%) plus 9.0%. We are required to make monthly interest-only payments with a bullet payment of the principal at maturity. The loan agreement contains specified financial maintenance covenants. In connection with the loan agreement, we granted Perceptive a warrant for the purchase of 425,000 shares of common stock at a purchase price of $18.66 per share.

On May 7, 2019, we completed a private placement equity offering of 10 million shares of our common stock. All shares were offered by us at a price of $10.00 per share to three institutional investors, namely Perceptive, Avoro Capital Advisors (formerly known as venBio Select Advisor), and OrbiMed (the “Investors”). The aggregate net proceeds received by us from the offering were $99.9 million, net of offering expenses of approximately $0.1 million.

Based on the current operating plan, we expect that our cash, cash equivalents, and restricted cash as of September 30, 2019, together with cash to be generated from our operating activities, will enable us to fund our operations into the third quarter of 2020. We expect that our expenses will increase as we continue to fund clinical and preclinical development of our research programs, pre-launch activities of our proprietary drugs, funding of our Commercial Platform and manufacturing facilities, and working capital and other general corporate purposes. We have based our estimates on assumptions that might prove to be wrong, and we might use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to accurately estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

Our future capital requirements will depend on many factors, including:

- Our ability to generate revenue and profits from our Commercial Platform or otherwise;
- The costs, timing and outcome of regulatory reviews and approvals;
- Progress of our drug candidates to progress through clinical development successfully;
- The initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- The costs of preparing our Commercial Platform for the commercialization of our proprietary drugs;
- The costs of construction and fit-out of planned drug at both Dunkirk and API manufacturing facilities;
- The number and characteristics of the drug candidates we pursue;
- The costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our IP rights and defending IP related claims;
- The extent to which we acquire or in-license other products and technologies; and
- Our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

We believe that the existing cash and cash equivalents, restricted cash, and short-term investments will not be sufficient to enable us to complete all necessary development or commercially launch our proprietary drug candidates. 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, collaborations, strategic alliances, licensing arrangements, and government grants. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect rights of holders of common stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and might require the issuance of warrants, which could potentially dilute the ownership interest of holders of common stock. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we might have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that might not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we might be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (74,120)	$ (75,315)
Net cash provided by (used in) investing activities	2,588	(81,125)
Net cash provided by financing activities	108,051	168,364
Net effect of foreign exchange rate changes	592	(100)
Net increase in cash, cash equivalents, and restricted cash	$ 37,111	$ 11,824

Net Cash Used in Operating Activities

The use of cash in our operating activities resulted primarily from our net loss adjusted for non-cash charges and changes in components of working capital. The primary use of our cash in the periods presented was to fund our research and development, regulatory and other clinical trial costs, drug licensing costs, inventory purchases, pre-launch commercialization activities, and other expenditures related to sales, marketing and administration.

Net cash used in operating activities was $74.1 million for the nine months ended September 30, 2019. This resulted primarily from our net loss of $103.1 million, adjusted for non-cash charges of $11.5 million, and by cash provided by our operating assets and liabilities of $17.5 million. Our operating assets increased $4.2 million for accounts receivable mainly related to the increased sales of specialty products in the current period, and less than $0.1 million for inventory of all drug products, while prepaid expenses and other assets increased by $17.1 million primarily related to Dunkirk construction. Our operating liabilities increased by $38.5 million mainly due to an increase of $16.3 million related to Dunkirk construction, and $20.0 million of deferred revenue related to a milestone payment received from Almirall S.A. (“Almirall”). We will recognize the milestone payment revenue upon confirmation from Almirall of their satisfactory review of certain data we submitted pursuant to the license agreement with Almirall. Our net non-cash charges during the nine months ended September 30, 2019 primarily consisted of $7.2 million of stock-based compensation expense, and $2.8 million depreciation and amortization expense.

Net cash used in operating activities was $75.3 million for the nine months ended September 30, 2018. This resulted principally from our net loss of $101.5 million, adjusted for non-cash charges of $42.8 million, and by cash used in our operating assets and liabilities of $16.6 million. Our operating assets decreased $1.4 million for accounts receivable related to API product sales as our API supplies to clinical studies increased and external sales decreased, while inventory increased by $8.7 million primarily related to the specialty drugs, and prepaid and other expenses increased by $6.3 million primarily related to Dunkirk construction which is expected to be reimbursed by New York State. Our operating liabilities increased by $3.0 million, mainly due to an increase in accrued expenses, related to Dunkirk construction. Our net non-cash charges during the nine months ended September 30, 2018 primarily consisted of $8.7 million of stock-based compensation expense, $31.5 million of R&D license fees settled with common stock, and $2.4 million depreciation and amortization expense.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $2.6 million for the nine months ended September 30, 2019, compared to $81.1 million net cash used in the nine months ended September 30, 2018. The difference was primarily due to more cash being used in 2018 to purchase short-term investments, including commercial paper, corporate notes, and U.S. government bonds.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $108.1 million for the nine months ended September 30, 2019, which primarily consisted of net proceeds of $99.9 million from the issuance of our common stock from a private placement with the Investors, net of offering expenses of approximately $0.1 million, and $6.5 million from the issuance of debt to fund our new API plant in China.

Net cash provided by financing activities was $168.4 million for the nine months ended September 30, 2018, which primarily consisted of net proceeds of $117.5 million from our follow-on public offering and privately placed equity raised with Perceptive, net of underwriter discount and offering costs of approximately $5.1 million, net proceeds of $48.4 million from the issuance of debt with a detachable warrant, net of offering costs of $1.6 million, and $3.0 million from the exercise of employee stock options.

Contractual Obligations

A summary of our contractual obligations as of September 30, 2019 is as follows:

	Payments Due by Period				
	Within 1 Year	1 to 3 years	3 to 5 years	More than 5 years	Total Amounts Committed
	(in thousands)				
Operating leases	$ 3,131	$ 4,936	$ 4,181	$ 2,452	$ 14,700
Long-term debt	768	2,345	53,908	—	57,021
Finance lease obligations	214	289	—	—	503
Licensing fees	382	—	—	—	382
	$ 4,495	$ 7,570	$ 58,089	$ 2,452	$ 72,606

The above table includes the Company's operating leases and the amounts committed under those leases by each location: (1) The rental of our global headquarters in the Conventus Center for Collaborative Medicine in Buffalo, NY; (2) the rental of our research and development facility in the IC Development Centre in Hong Kong; (3) the rental of the Commercial Platform headquarters in Chicago, IL; (4) the rental of our clinical research and development facility in Cranford, NJ; (5) the rental of our clinical data management center in Taipei, Taiwan; (6) the rental of our Global Supply Chain distribution office in Houston, TX; (7) the rental of our Global Supply Chain API manufacturing facility in Chongqing, China; and (8) the rental of various other facilities and equipment located mainly in Buffalo, NY.

Off-Balance Sheet Arrangements

We do not maintain any off-balance sheet partnerships, arrangements, or other relationships with unconsolidated entities or others, often referred to as structured finance or special purpose entities, which are established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. These estimates form the basis for judgments we make about the carrying values of our assets and liabilities, which are not readily apparent from other sources. We base our estimates and judgments on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that the assumptions and estimates associated with research and development expenses, chargebacks, stock-based compensation and inventory reserves have the most significant impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

With the exception of the change in accounting for leases under ASC 842 (see Note 10 –*Debt and Lease Obligations),* there have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in our Annual Report on Form 10-K for the year ended December 31, 2018.

Recent Accounting Pronouncements

In the normal course of business, we evaluate all new accounting pronouncements issued by the Financial Accounting Standards Board, the SEC, or other authoritative accounting bodies to determine the potential impact they may have on our condensed consolidated financial statements. See Note 2 of the Notes to Condensed Consolidated Financial Statements contained in Item 1 of this quarterly report on Form 10-Q for additional information about these recently issued accounting standards and their potential impact on our financial condition or results of operations.

JOBS Act

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, (the "JOBS Act,") an "emerging growth company" can delay the adoption of new or revised accounting standards until such time as those standards would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards at the same time as other public companies that are not emerging growth companies. There are other exemptions and reduced reporting requirements provided by the JOBS Act that we currently take advantage of. For example, as an emerging growth company, we are exempt from Sections 14A (a) and (b) of the Exchange Act which would otherwise require us to (1) submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency" and "say-on-golden parachutes;" and (2) disclose certain executive compensation related matters. We also rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and the rule requiring us to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will continue to remain an "emerging growth company" until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering, or December 31, 2022, (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1 billion, (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years, or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Foreign Currency Exchange Risk

A significant portion of our business is located outside the United States and, as a result, we generate revenue and incur expenses denominated in currencies other than the U.S. dollar, a majority of which is denominated in Chinese Renminbi ("RMB"). In the nine months ended September 30, 2019 and 2018, approximately 1% and 2%, respectively, of our sales, excluding intercompany sales, were denominated in foreign currencies. As a result, our revenue can be significantly impacted by fluctuations in foreign currency exchange rates. We expect that foreign currencies will represent a lower percentage of our sales in the future due to the anticipated growth of our U.S. business. Our international selling, marketing, and administrative costs related to these sales are largely denominated in the same foreign currencies, which somewhat mitigates our foreign currency exchange risk rate exposure.

Currency Convertibility Risk

A portion of our revenues and expenses, and a portion of our assets and liabilities are denominated in RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China, ("PBOC"). However, the unification of exchange rates does not imply that RMB is readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in Chinese central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Interest Rate Sensitivity

We had cash, cash equivalents, restricted cash, and short-term investments of $129.2 million as of September 30, 2019. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in U.S. market interest rates is not expected to have a material impact on our condensed consolidated financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

As of September 30, 2019, we had $50 million of debt with Perceptive that bears interest at a floating per annum rate equal to 1-Month LIBOR (with a floor of 2%) plus 9%. If 1-Month LIBOR increased by 1%, we would be required to pay Perceptive an additional $0.5 million in interest annually. If 1-Month LIBOR decreased by 1%, we would be required to pay Perceptive $0.5 million less in interest annually. A material change in the short-term interest rate environment could have a material adverse effect on our condensed consolidated financial condition or results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Board Chairman (Principal Executive Officer) and our Chief Financial Officer (Principal Financial and Accounting Officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2019. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits 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 a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2019, our Chief Executive Officer and Board Chairman (Principal Executive Officer) and our Chief Financial Officer (Principal Financial and Accounting Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On August 13, 2018, APS and APD, our wholly-owned subsidiaries, filed a complaint for declaratory judgment against Par Pharmaceuticals, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (together, "Par") in the United States District Court for the Western District of New York (the "Court"), seeking a declaratory judgment from the Court that our compounded vasopressin drug products in ready-to-use form did not infringe on patents that Par has with respect to its Vasostrict® product and that Par's patents are invalid. On July 9, 2019, the Court ordered dismissal of our complaint for lack of subject matter jurisdiction. We did not appeal this dismissal. While Par has not alleged that our compounded vasopressin infringes any of its patents, Par could do so by commencing an infringement lawsuit against us. If such an infringement lawsuit were brought and a court ruled for Par, Athenex could be enjoined from further production of compounded vasopressin within in the United States and sale of compounded vasopressin in or from the United States and for payment of damages to Par for U.S. manufacture or sale of compounded vasopressin that has already taken place.

In addition, on August 13, 2018, APS and APD filed a motion to intervene and seek the dismissal of Par Sterile Products, LLC's and Endo Par Innovation Company, LLC's complaint against the FDA and certain governmental officials in the United States District Court for the District of Columbia (the "DC Court"). Our motion to intervene was granted. These two Par entities have sought declaratory and injunctive relief, including a preliminary injunction, against FDA and certain governmental officials that: (i) vasopressin be delisted from Category 1 of FDA's list of bulk drug substances under evaluation pursuant to Section 503B of the FDCA, (ii) the expansion of FDA's enforcement discretion to Category 1 substances, be enjoined; and (iii) that FDA be enjoined from authorizing the compounding of vasopressin under Section 503B of the FDCA. We and FDA filed motions for judgment on the pleadings. On February 7, 2019, before resolving the above pending motions, the DC Court stayed the case until the earlier of: (i) March 15, 2019; (ii) FDA publishes in the Federal Register a final determination about whether to include vasopressin on the clinical need list; or (iii) Par notify the Parties and the Court of a substantial change in circumstances necessitating a decision on Plaintiffs' Motion for Preliminary Injunction. On March 4, 2019, FDA published in the Federal Register its final decision not to include vasopressin on the list of bulk drug substances for which there is a clinical need. On the same day, we (Athenex, Inc., APS, and APD) filed a complaint in the DC Court against FDA seeking to vacate its final decision. Par Sterile Products, LLC and Endo Par Innovation Company, LLC joined this case as intervenors. On March 11, 2019, the DC Court extended the stay of Par's lawsuit against FDA until resolution of the motions for summary judgment in this newer related case.

In our case against the FDA, the FDA represented to the DC Court that "until the Court issues a decision on the merits of this action, the FDA will not initiate enforcement action against Athenex based solely on Athenex's use of the bulk drug substance vasopressin to compound drugs and distribute those drugs" and the DC Court incorporated the FDA's representation into its published order. As such, Athenex produced and distributed compounded vasopressin during the period that the case was pending before the DC District Court and prior to its decision.

On April 30, 2019, the DC Court held a hearing on the parties' cross motions for summary judgment. On August 1, 2019, the DC Court issued a ruling upholding the FDA's vasopressin decision and dismissing Athenex's complaint. On August 2, 2019, Athenex filed a notice of appeal with the U.S. Court of Appeals for the District of Columbia Circuit and a motion for a stay or injunction of the DC Court's order pending appeal. On September 6, 2019, the DC Court denied Athenex's motion for a stay or injunction pending appeal. Athenex then filed a motion for voluntary dismissal of the appeal. On October 1, 2019, the DC Court granted our motion to voluntarily dismiss the appeal and dismissed the case. Par filed a motion to voluntarily dismiss its complaint against the FDA and certain governmental officials in the DC Court. Athenex did not oppose this motion and, on September 27, 2019, the DC Court granted Par's motion to dismiss the action and dismissed the case. Athenex has ceased producing and distributing vasopressin since the DC Court's August 1, 2019 decision.

Item 1A. Risk Factors.

See "Risk Factors" in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 for a detailed discussion of the risk factors affecting the Company. There have been no material changes to our previously disclosed risk factors.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth below.

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		Form	File	Exhibit	Filing Date
31.1	Certification of the Chief Executive Officer and Board Chairman (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
31.2	Certification of the Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of the Chief Executive Officer and Board Chairman (Principal Executive Officer) and the Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	XBRL Instance Document.	—	—	—	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith

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.

Athenex, Inc.

Date: November 12, 2019

By: /s/ Johnson Y.N. Lau
Chief Executive Officer and Board Chairman
(Principal Executive Officer)

Date: November 12, 2019

By: /s/ Randoll Sze
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Johnson Y.N. Lau, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athenex, Inc. (the registrant);

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(s) 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(s) 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: November 12, 2019

/s/ Johnson Y.N. Lau

Name: Johnson Y.N. Lau
Title: Chief Executive Officer and Board Chairman
(Principal Executive Officer)

Exhibit 31.2

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

I, Randoll Sze, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athenex, Inc. (the registrant);

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(s) 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(s) 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: November 12, 2019

/s/ Randoll Sze
Name: Randoll Sze
Title: Chief Financial Officer
(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

In accordance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Johnson Y.N. Lau, Chief Executive Officer and Board Chairman (Principal Executive Officer) of Athenex, Inc. (the "registrant"), and Randoll Sze, Chief Financial Officer of the registrant (Principal Financial Officer), each hereby certifies that, to the best of their knowledge:

1. The registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Report and results of operations of the registrant for the period covered by the Report.

Date: November 12, 2019

/s/ Johnson Y.N. Lau
Name: Johnson Y.N. Lau
Title: Chief Executive Officer and Board Chairman
(Principal Executive Officer)

/s/ Randoll Sze
Name: Randoll Sze
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)