
**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, 2018

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
(State or other jurisdiction of
incorporation or organization)

1001 Main Street, Suite 600
Buffalo, NY
(Address of principal executive offices)

43-1985966
(I.R.S. Employer
Identification No.)

14203
(Zip Code)

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

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
Non-accelerated filer

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 November 2, 2018, the registrant had 66,893,883 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,108	\$ 39,284
Short-term investments	90,309	11,753
Accounts receivable, net of chargebacks and other deductions of \$13,154 and \$3,711, respectively, and allowance for doubtful accounts of \$27 and \$84, respectively	7,071	8,468
Inventories	25,231	16,561
Prepaid expenses and other current assets	13,983	7,692
Total current assets	187,702	83,758
Property and equipment, net	11,174	9,651
Investment	399	328
Goodwill	37,501	37,795
Intangible assets, net	7,254	8,572
Deferred income tax assets	437	121
Other long-term assets	—	188
Total assets	<u>\$ 244,467</u>	<u>\$ 140,413</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 12,694	\$ 16,659
Accrued expenses	28,060	25,776
Deferred revenue	364	1,202
Current portion of long-term debt - related parties	—	491
Current portion of long-term debt	978	1,015
Total current liabilities	42,096	45,143
Long-term liabilities:		
Deferred compensation	2,678	2,313
Deferred rent	2,087	1,760
Capital lease obligations	424	475
Long-term debt	45,125	—
Total liabilities	92,410	49,691
Commitments and contingencies (See Note 13)		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 250,000,000 shares authorized at September 30, 2018 and December 31, 2017; 68,561,678 and 59,894,362 shares issued at September 30, 2018 and December 31, 2017, respectively; 66,888,758 and 58,221,442 shares outstanding at September 30, 2018 and December 31, 2017, respectively		
	68	60
Additional paid-in capital	587,155	423,805
Accumulated other comprehensive (loss)	(620)	(146)
Accumulated deficit	(416,603)	(326,276)
Less: treasury stock, at cost; 1,672,920 shares at September 30, 2018 and December 31, 2017	(7,406)	(7,406)
Total Athenex, Inc. stockholders' equity	162,594	90,037
Non-controlling interests	(10,537)	685
Total stockholders' equity	152,057	90,722
Total liabilities and stockholders' equity	<u>\$ 244,467</u>	<u>\$ 140,413</u>

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)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue:				
Product sales, net	\$ 13,309	\$ 13,662	\$ 37,385	\$ 21,978
License fees and consulting revenue	5,096	60	30,278	756
Grant revenue	23	272	166	436
Total revenue	<u>18,428</u>	<u>13,994</u>	<u>67,829</u>	<u>23,170</u>
Costs and operating expenses:				
Cost of sales	11,965	8,082	32,734	15,058
Research and development expenses (See Note 6)	51,204	11,944	99,077	55,949
Selling, general, and administrative expenses	11,493	10,364	37,390	33,795
Total costs and operating expenses	<u>74,662</u>	<u>30,390</u>	<u>169,201</u>	<u>104,802</u>
Operating loss	<u>(56,234)</u>	<u>(16,396)</u>	<u>(101,372)</u>	<u>(81,632)</u>
Interest expense	1,058	353	463	6,010
Loss on derivative liability	—	6,548	—	15,411
Loss before income tax benefit	<u>(57,292)</u>	<u>(23,297)</u>	<u>(101,835)</u>	<u>(103,053)</u>
Income tax (benefit) expense	(30)	11	(286)	(52)
Net loss	<u>(57,262)</u>	<u>(23,308)</u>	<u>(101,549)</u>	<u>(103,001)</u>
Less: net loss attributable to non-controlling interests	(11,091)	(34)	(11,222)	(114)
Net loss attributable to Athenex, Inc.	<u>\$ (46,171)</u>	<u>\$ (23,274)</u>	<u>\$ (90,327)</u>	<u>\$ (102,887)</u>
Unrealized (loss) gain on investment, net of income taxes	(37)	4	3	(30)
Foreign currency translation adjustment, net of income taxes	(554)	242	(477)	922
Comprehensive loss	<u>\$ (46,762)</u>	<u>\$ (23,028)</u>	<u>\$ (90,801)</u>	<u>\$ (101,995)</u>
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 10)	<u>\$ (0.70)</u>	<u>\$ (0.41)</u>	<u>\$ (1.42)</u>	<u>\$ (2.18)</u>
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 10)	<u>66,399,091</u>	<u>57,134,889</u>	<u>63,806,787</u>	<u>47,238,452</u>

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

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 (loss)	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non-controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at December 31, 2016	42,342,706	\$ 42	\$ 237,581	\$ (195,106)	\$ (1,304)	(1,656,920)	\$ (7,406)	\$ 33,807	\$ 862	\$ 34,669
Sale of common stock, net of costs and discounts of \$11,706	6,900,000	7	64,187	—	—	—	—	64,194	—	64,194
Conversion of bonds	8,522,728	9	98,920	—	—	—	—	98,929	—	98,929
Stock-based compensation cost	400,000	—	10,090	—	—	—	—	10,090	—	10,090
Research and development license purchased with stock	568,182	1	6,249	—	—	—	—	6,250	—	6,250
Vesting of restricted stock	421,982	1	1,619	—	—	—	—	1,620	—	1,620
Stock options and warrants exercised	512,586	—	1,208	—	—	—	—	1,208	—	1,208
Repurchase of common stock	—	—	—	—	—	(16,000)	—	—	—	—
Non-controlling interests	—	—	—	—	—	—	—	—	49	49
Net loss	—	—	—	(102,887)	—	—	—	(102,887)	(114)	(103,001)
Other comprehensive income, net of tax	—	—	—	—	892	—	—	892	—	892
Balance at September 30, 2017 (unaudited)	<u>59,668,184</u>	<u>\$ 60</u>	<u>\$ 419,854</u>	<u>\$ (297,993)</u>	<u>\$ (412)</u>	<u>(1,672,920)</u>	<u>\$ (7,406)</u>	<u>\$ 114,103</u>	<u>\$ 797</u>	<u>\$ 114,900</u>

	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss)	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non-controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at December 31, 2017	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 \$5,518	7,444,528	7	117,141	—	—	—	—	117,148	—	117,148
Issuance of warrants	—	—	3,140	—	—	—	—	3,140	—	3,140
Stock-based compensation cost	—	—	7,558	—	—	—	—	7,558	—	7,558
Vesting of restricted stock	240,000	—	1,007	—	—	—	—	1,007	—	1,007
Stock options and warrants exercised	607,655	1	2,959	—	—	—	—	2,960	—	2,960
Research and development license purchased with stock	375,133	—	31,545	—	—	—	—	31,545	—	31,545
Net loss	—	—	—	(90,327)	—	—	—	(90,327)	(11,222)	(101,549)
Other comprehensive loss, net of tax	—	—	—	—	(474)	—	—	(474)	—	(474)
Balance at September 30, 2018 (unaudited)	<u>68,561,678</u>	<u>\$ 68</u>	<u>\$ 587,155</u>	<u>\$ (416,603)</u>	<u>\$ (620)</u>	<u>(1,672,920)</u>	<u>\$ (7,406)</u>	<u>\$ 162,594</u>	<u>\$ (10,537)</u>	<u>\$ 152,057</u>

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (101,549)	\$ (103,001)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,424	2,585
Stock-based compensation expense	8,659	11,710
Change in fair value of derivative liability	—	15,411
Amortization of debt discount	256	3,349
Deferred rent expense	329	640
(Gain) loss on disposal of assets and impairment charges	(62)	80
Research and development license purchased with convertible bond and stock	31,545	13,250
Interest incurred on converted bonds	—	2,759
Deferred income taxes	(316)	(108)
Changes in operating assets and liabilities:		
Receivables, net	1,397	(3,682)
Prepaid expenses and other assets	(6,290)	(2,722)
Inventories	(8,670)	(7,395)
Accounts payable and accrued expenses	(3,038)	3,480
Net cash used in operating activities	(75,315)	(63,644)
Cash flows from investing activities:		
Purchase of property and equipment	(2,501)	(4,384)
Receipt of deposit	—	80
Payments for licenses	—	(1,550)
Purchases of short-term investments	(110,605)	(55,282)
Sale of short-term investments	31,981	14,114
Net cash used in investing activities	(81,125)	(47,022)
Cash flows from financing activities:		
Proceeds from sale of stock	122,666	75,900
Proceeds from issuance of debt	50,000	30,000
Costs incurred related to the sale of stock	(5,118)	(10,168)
Costs incurred related to the issuance of debt	(1,593)	—
Proceeds from exercise of stock options	2,960	1,208
Investment from non-controlling interest	—	49
Repayment of capital lease obligations and long-term debt	(551)	(896)
Net cash provided by financing activities	168,364	96,093
Net increase (decrease) in cash and cash equivalents	11,924	(14,573)
Cash and cash equivalents, beginning of period	39,284	33,125
Effect of exchange rate changes on cash and cash equivalents	(100)	710
Cash and cash equivalents, end of period	\$ 51,108	\$ 19,262
Non-cash investing and financing activities:		
Accrued purchases of property and equipment	\$ 445	\$ 150
Cost of equity in accounts payable and accrued expenses	\$ 400	\$ -
Convertible bond issued in lieu of licensing cash payment	\$ —	\$ 7,000
Common stock issued for purchase of license (See Note 6)	\$ 31,545	\$ 6,250
Common stock issued upon the conversion of bonds	\$ —	\$ 98,929
Property and equipment financed under capital lease	\$ —	\$ 242

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

Athenex, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Company and Nature of Business

Organization and Description of Business

Athenex, Inc. (the “Company” or “Athenex”) is a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer through its Orascovery and Src Kinase Inhibition research platforms. The Company originally formed under the name Kinex Pharmaceuticals LLC (“Kinex”) 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.

The Company’s primary activities since inception have been conducting research and development activities internally and through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, and conducting preclinical and clinical testing, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development activities. In addition to licensing and consulting revenue, the Company also generates revenue from its commercial and global supply chain platforms. See Note 12 – *Revenue Recognition*.

Initial Public Offering

In June 2017, the Company completed its initial public offering (“IPO”) on the Nasdaq Global Select Market. An aggregate of 6,900,000 shares of its common stock were sold at \$11.00 per share for cash proceeds of \$64.2 million, net of underwriting discounts and commissions of \$6.1 million and offering costs of \$5.6 million.

In connection with the IPO, convertible bonds with an aggregate principal value of \$68.0 million, and a carrying value of \$55.8 million, were converted into 7,727,273 shares of common stock. In September 2017, the remaining convertible bond with a principal value of \$7.0 million was converted into 795,455 shares of common stock, at a 20% discount from the IPO price.

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. Net proceeds were \$68.1 million, after deducting 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. The Company was in compliance with such covenants as of September 30, 2018. 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.

Significant Risks and Uncertainties

The Company has incurred operating losses since its inception and, as a result, as of September 30, 2018 and December 31, 2017 had an accumulated deficit of \$416.6 million and \$326.3 million, respectively. Operations have been funded primarily through the sale of common stock and, to a lesser extent, from convertible bond financing, senior secured loan, revenue, and grant funding. The Company will require significant additional funds to conduct clinical trials and to fund its operations. 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 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 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.

Athenex 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, 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.

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 operations for the three and nine months ended September 30, 2018 are not necessarily indicative of the results expected for the full fiscal year or for any future annual or interim period. These 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, 2017, filed with the Securities and Exchange Commission ("SEC") on March 26, 2018.

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.

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 and short-term investments. The Company deposits its cash equivalents in interest-bearing money market accounts and invests in highly liquid U.S. treasury notes, commercial papers 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 in China, and therefore is subject to foreign currency fluctuation.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, “Leases (Topic 842)” which requires that lessees distinguish between finance and operating leases and recognize the assets and liabilities that arise from the leases on the balance sheet. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and is required to be applied on a modified retrospective basis. The Company will adopt the new standard effective January 1, 2019 and expects its operating leases, as disclosed in Note 13 – *Commitments and Contingencies*, to be subject to the new standard. The Company will recognize right-of-use assets and operating lease liabilities on its consolidated balance sheets upon adoption, which will increase its total assets and liabilities.

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 is evaluating the effect of this standard on its consolidated financial statements.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (“ASU”) No. 2014-09, “*Revenue from Contracts with Customers (Topic 606)*”, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU has replaced most historical revenue recognition guidance in U.S. GAAP when it became effective. The Company adopted this standard on January 1, 2018 using the modified retrospective transition method. The Company did not record a cumulative catch-up adjustment upon adoption, as there was no effect on the timing or amount of revenue recognized for existing contracts that were not completed as of the implementation date. Refer to Note 12 – *Revenue Recognition* for more information on the effect of this ASU.

In November 2016, the FASB issued ASU 2016-18, “*Statement of Cash Flows (Topic 230): Restricted Cash*.” The primary purpose of this ASU is to reduce the diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. This ASU will require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017. This ASU is required to be applied retrospectively. The Company adopted this standard on January 1, 2018 and the adoption of this ASU did not impact the Company’s condensed consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “*Stock Compensation—Scope of Modification Accounting*,” which provides guidance as to when a modification of a share-based award must be accounted for. In general, if a modification of the terms and conditions of an award does not change the fair value of the award (or calculated value or intrinsic value, if used instead of fair value), does not change the vesting conditions of the award, and does not change the classification of the award as an equity instrument or a liability instrument, then an entity need not account for the modification. This guidance is effective in the first quarter of fiscal year 2018. The new rules are applied prospectively to awards modified after the adoption date. The Company adopted this standard on January 1, 2018 and the adoption of this ASU did not impact the Company’s condensed consolidated financial statements.

3. Inventories

Inventories consist of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials and purchased parts	\$ 2,778	\$ 1,471
Work in progress	3,303	1,877
Finished goods	19,150	13,213
Total inventories	<u>\$ 25,231</u>	<u>\$ 16,561</u>

4. Intangible Assets, net

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

	September 30, 2018			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	\$ 4,650	\$ 1,836	\$ —	\$ 2,814
Polymed customer list	1,593	873	—	720
Polymed technology	3,712	930	—	2,782
Product rights	530	231	—	299
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	1,026	—	—	1,026
Effect of currency translation adjustment	(387)	—	—	(387)
Total intangible assets, net	<u>\$ 11,124</u>	<u>\$ 3,870</u>	<u>\$ -</u>	<u>\$ 7,254</u>

	December 31, 2017			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets				
Licenses	\$ 4,650	\$ 1,173	\$ —	\$ 3,477
Polymed customer list	1,593	675	—	918
Polymed technology	3,712	762	—	2,950
Product rights	530	132	—	398
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	1,106	—	80	1,026
Effect of currency translation adjustment	(197)	—	—	(197)
Total intangibles, net	<u>\$ 11,394</u>	<u>\$ 2,742</u>	<u>\$ 80</u>	<u>\$ 8,572</u>

As of September 30, 2018, licenses at cost include an Orascovary license of \$0.4 million and licenses purchased from Gland Pharma Limited ("Gland") of \$4.3 million. The Company purchased the Orascovary license directly from Hanmi Pharmaceuticals Co. Ltd. ("Hanmi") and is amortizing it 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 five 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 Athenex Pharma Solutions ("APS" or "Athenex Pharma Solutions," and 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 was 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). No impairment charges were recorded during the nine months ended September 30, 2018. During the nine months ended September 30, 2017, the Company abandoned a project and thus wrote off the related balance of \$0.1 million as impaired and included it in the research and development expenses in the consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2017. The weighted-average useful life for all intangible assets was 8.77 years as of September 30, 2018.

The Company recorded \$0.4 million of amortization expense for both the three-month periods ended September 30, 2018 and 2017, respectively, and \$1.2 million of amortization expense for both the nine-month periods ended September 30, 2018 and 2017, respectively.

5. Fair Value Measurements

Financial instruments consist of cash and cash equivalents, 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, 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, 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:				
Money market funds	\$ 5,028	\$ 5,028	\$ —	\$ —
Short-term investments - commercial paper	45,064	—	45,064	—
Short-term investments - corporate notes	18,126	—	18,126	—
Short-term investments - U.S. government bonds	32,141	—	32,141	—
Investment	399	399	—	—
Total assets	\$ 100,758	\$ 5,427	\$ 95,331	\$ —

Fair Value Measurements at December 31, 2017 Using:				
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	\$ 13,804	\$ 13,804	\$ —	\$ —
Short-term investments - commercial paper	14,982	—	14,982	—
Short-term investments - corporate notes	2,824	—	2,824	—
Short-term investments - U.S. government bonds	5,006	—	5,006	—
Investment	328	328	—	—
Total assets	\$ 36,944	\$ 14,132	\$ 22,812	\$ —

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, 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 each of September 30, 2018 and December 31, 2017, the Company's investment in PharmaEssentia was valued at the reported closing price. This investment is classified as a Level 1 investment.

6. Asset Acquisition

On June 29, 2018, the Company entered into a Share Subscription Agreement ("SSA") for Axis Therapeutics ("Axis"), a subsidiary of the Company jointly owned by Athenex and Xiangxue Life Sciences Limited ("XLifeSc"). Under the SSA, Athenex 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, Athenex 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 its consolidated financial statements as of and for the nine months ended September 30, 2018 using the voting interest model. The nonmonetary exchange of 45% of the shares of Axis for the IPR&D from XLife has been accounted for as an asset acquisition that does not constitute a business under ASC 805. Therefore, the acquisition of IPR&D was expensed as 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. This is a non-cash expense.

7. Income Taxes

The Company did not record a provision for federal income taxes for the nine months ended September 30, 2018 because it expects to generate a loss for the year ending December 31, 2018 and the Company's net deferred tax assets continue to be nearly fully offset by a valuation allowance. Tax benefit to date relates to foreign tax benefit on losses in the Peoples Republic of China ("PRC") offset by state franchise taxes and amortization of long-lived intangible assets in the U.S. and PRC.

8. Related Party Transactions

During the nine months ended September 30, 2018 and 2017, 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 13—*Commitments and Contingencies*). 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, 2018 and December 31, 2017, Avalon held 786,061 and 678,880 shares of the Company's common stock, respectively, which represented approximately 1% of the Company's total issued shares for both periods. Balances due from Avalon recorded on the 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 from Avalon in an effort 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 expense on its condensed consolidated statement of operations and comprehensive loss. During the nine months ended September 30, 2018, 107,181 shares of common stock were issued to Avalon at a price of \$18.66 per share, the closing price of the stock on the date the agreement was executed, in connection with the license agreements.

- b. The Company receives consulting and licensing revenue from PharmaEssentia, a company in which Athenex has an investment classified as available-for-sale (see Note 5—*Fair Value Measurements*). Revenue recorded and cost-sharing funds received from PharmaEssentia amounted to \$0 for both the three months ended September 30, 2018 and 2017, and \$0.3 and \$0.5 million for the nine months ended September 30, 2018 and 2017, respectively.
- c. The Company receives certain clinical development services from ZenRx Limited and its subsidiaries (“ZenRx”), a company for which one of our executive officers serves on the board of directors. In connection with such services, the Company made payments to ZenRx of \$0.1 million and \$0.2 million for the three months ended September 30, 2018 and 2017, respectively, and \$0.3 million and \$0.5 million for the nine months ended September 30, 2018 and 2017, 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 our intellectual property to develop and commercialize Oratecan and Oraxol in Australia and New Zealand, and a non-exclusive license to manufacture a certain compound, but only for use in Oratecan and Oraxol. 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. The Company received consulting services from RSJ Consulting LLC (“RSJ”), a limited liability company for which one of our executive officers serves as the principal. Services incurred from RSJ amounted to \$0 million and less than \$0.1 million for the three months ended September 30, 2018 and 2017, respectively, and \$0 million and \$0.1 million for the nine months ended September 30, 2018 and 2017, respectively.
- e. During the first quarter of 2017, the Company issued and sold \$4.0 million in convertible bonds to two related parties. One of the holders of more than 5% of our outstanding common stock as of the IPO date and a director of the Company each purchased \$2.0 million in convertible bonds. In June 2017, these bonds were converted into 2,727,273 shares of common stock.
- f. Certain family members of executives perform consulting services to the Company. Such services were not significant to the consolidated financial statements.

9. Stock-Based Compensation

Common Stock Option Plans

The Company has three common stock option plans adopted in 2013, 2007 and 2004 (the “Plans”) which authorize the grant of up to 11,800,000 common stock options to employees, directors, and consultants. Additionally, on June 14, 2017, the Company adopted its 2017 Omnibus Incentive Plan and 2017 Employee Stock Purchase Plan (the “2017 Plans”). Under the 2017 Plans, 5,200,000 shares of common stock were reserved for future issuance to employees, directors, and consultants, including 1,000,000 reserved for the Employee Stock Purchase Plan (“ESPP”), which was established at the time of the IPO but under which no shares have yet been issued.

Stock Options

The total fair value of stock options vested and recorded as compensation expense during the three months ended September 30, 2018 and 2017, and nine months ended September 30, 2018 and 2017 was \$2.3 million, \$2.3 million, \$7.6 million, and \$5.7 million, respectively. As of September 30, 2018, \$20.0 million of unrecognized cost related to non-vested stock options was expected to be recognized over a weighted-average period of approximately 1.9 years. The total intrinsic value of options exercised was approximately \$6.5 million and \$1.6 million for the nine months ended September 30, 2018 and 2017, respectively.

The following table summarizes the status of the Company’s stock option activity granted under the Plans to employees, directors, and consultants (in thousands, except stock option amounts and exercise price):

	Stock Options	Weighted-Average Exercise price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	10,176,643	\$ 7.19	6.83	\$ 88,615
Granted	1,411,650	17.25		
Exercised	(607,655)	5.59		
Forfeited and expired	(194,135)	10.77		
Outstanding at September 30, 2018	<u>10,786,503</u>	\$ 8.53	6.64	\$ 75,562
Vested and exercisable at September 30, 2018	<u>7,808,020</u>	\$ 6.51	5.80	\$ 70,511

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 a number of 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, 2018	September 30, 2017
Weighted average grant date fair value	\$ 9.87	\$ 6.90
Expected dividend yield	—%	—%
Expected stock price volatility	59%	66%
Risk-free interest rate	2.60%	1.74%
Expected life of options (in years)	6.1	6.2

Restricted Stock

Restricted stock grants cliff vest on the anniversaries of their grant dates. During the nine months ended September 30, 2018, 240,000 restricted shares were vested and as of September 30, 2018, no restricted shares remained unvested.

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, 2018 to November 30, 2018. The Company expects to offer 6-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 the three and nine months ended September 30, 2018 and \$0 for all preceding periods.

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, 2018 and 2017 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Stock options	\$ 2,316	\$ 2,349	\$ 7,558	\$ 5,690
Vesting of restricted stock grants	6	540	1,007	1,620
Stock awarded to directors and officers	—	—	—	4,400
Employee stock purchase plan	94	—	94	—
Total stock-based compensation expense	\$ 2,416	\$ 2,889	\$ 8,659	\$ 11,710
Cost of sales	\$ 64	\$ 48	\$ 164	\$ 96
Research and development expenses	688	567	1,915	1,475
Selling, general, and administrative expenses	1,664	2,274	6,580	10,139
Total stock-based compensation expense	\$ 2,416	\$ 2,889	\$ 8,659	\$ 11,710

10. 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 share and common shares equivalents for the period using the treasury-stock method. For the purposes of this calculation, warrants for 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,	
	2018	2017	2018	2017
Stock options and other common stock equivalents	111,119,444	10,736,494	10,397,140	9,989,045
Unvested restricted shares	4,891	265,000	152,808	444,544
Total potential dilutive shares	<u>111,124,335</u>	<u>11,001,494</u>	<u>10,549,948</u>	<u>10,433,589</u>

11. 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. 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. This segment focuses specifically on the Orascovery oral absorption platform, the Src Kinase inhibitors, and the transmucosal drug delivery system. This segment performs research in the United States, Taiwan, Hong Kong, and mainland China.

Global Supply Chain Platform—This operating segment includes Athenex Pharma Solutions and Polymed. Athenex Pharma Solutions is a contract manufacturing company that provides small to mid-scale Current Good Manufacturing Practices ("cGMP") manufacturing of clinical and commercial products for pharmaceutical and biotech companies. Athenex Pharma Solutions also performs microbiological and analytical testing for raw material and formulated products and has expanded and begun to manufacture and sell pharmaceutical products under 503B regulations set forth by the U.S. Food and Drug Administration ("FDA"). Polymed markets and sells active pharmaceutical ingredient ("API") and medical devices in North America, Europe, and Asia from its locations in Texas and China. Polymed also develops new compounds, processing techniques, and manufactures API at Taihao, a cGMP facility in Chongqing, China.

Commercial Platform—This operating segment includes Athenex Pharmaceutical Division, 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, and mainland China. 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,	
	2018	2017	2018	2017
Net (loss) income attributable to Athenex, Inc.:				
Oncology Innovation Platform	\$ (37,639)	\$ (22,558)	\$ (65,985)	\$ (83,836)
Global Supply Chain Platform	(6,089)	(1,564)	(16,780)	(4,693)
Commercial Platform	(2,443)	848	(7,562)	(14,358)
Total consolidated net loss attributable to Athenex, Inc.	\$ (46,171)	\$ (23,274)	\$ (90,327)	\$ (102,887)
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total revenue:				
Oncology Innovation Platform	\$ 5,117	\$ 205	\$ 30,532	\$ 1,208
Global Supply Chain Platform	7,092	8,601	17,991	19,407
Commercial Platform	7,315	7,378	23,006	9,274
Total revenue for reportable segments	19,524	16,184	71,529	29,889
Intersegment revenue	(1,096)	(2,190)	(3,700)	(6,719)
Total consolidated revenue	\$ 18,428	\$ 13,994	\$ 67,829	\$ 23,170

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,	
	2018	2017	2018	2017
Total revenue by product group:				
API sales	\$ 3,690	\$ 5,345	\$ 9,538	\$ 10,369
Medical device sales	1,322	562	2,342	1,128
Contract manufacturing revenue	17	250	412	934
Commercial product sales	8,280	7,505	25,092	9,547
License fees	5,000	—	30,000	500
Consulting revenue	96	60	278	256
Grant revenue	23	272	167	436
Total consolidated revenue	\$ 18,428	\$ 13,994	\$ 67,829	\$ 23,170

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,	
	2018	2017	2018	2017
Total depreciation and amortization:				
Oncology Innovation Platform	\$ 174	\$ 130	\$ 505	\$ 342
Global Supply Chain Platform	490	548	1,185	1,569
Commercial Platform	245	243	734	674
Total consolidated depreciation and amortization	\$ 909	\$ 921	\$ 2,424	\$ 2,585

	September 30, 2018	December 31, 2017
Total assets:		
Oncology Innovation Platform	\$ 164,480	\$ 65,966
Global Supply Chain Platform	51,327	51,128
Commercial Platform	28,660	23,319
Total consolidated assets	<u>\$ 244,467</u>	<u>\$ 140,413</u>

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Total revenue:				
United States	\$ 9,559	\$ 8,114	\$ 27,405	\$ 11,056
Spain	5,000	—	30,000	—
India	259	3,015	1,701	5,275
Austria	2,227	964	5,102	2,682
China	306	1,038	1,917	2,267
Other foreign countries	1,077	863	1,704	1,890
Total consolidated revenue	<u>\$ 18,428</u>	<u>\$ 13,994</u>	<u>\$ 67,829</u>	<u>\$ 23,170</u>

	September 30, 2018	December 31, 2017
Total property and equipment, net:		
United States	\$ 6,458	\$ 5,305
China	4,716	4,346
Total consolidated property and equipment, net	<u>\$ 11,174</u>	<u>\$ 9,651</u>

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,	
	2018	2017	2018	2017
Percentage of total revenue by customer:				
Customer A	27%	—%	44%	—%
Customer B	13%	5%	9%	4%
Customer C	12%	16%	13%	11%
Customer D	11%	5%	8%	3%
Customer E	10%	7%	6%	11%
Customer F	1%	18%	2%	20%

	September 30, 2018	December 31, 2017
Percentage of total accounts receivable by customer:		
Customer A	27%	18%
Customer B	20%	10%
Customer C	13%	6%
Customer D	10%	4%
Customer E	—%	26%
Customer F	—%	13%

12. 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. Following is a description of principal activities – separated by reportable segments – from which the Company generates its revenue (See Note 11 – *Business Segment, Geographic, and Concentration Risk Information*).

1. Oncology Innovation Platform

License fees and consulting revenue

The Company out-licenses certain of its intellectual property (“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 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 a distinct performance obligation. 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-licensing 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 \$5.0 million and \$0 for the three months ended September 30, 2018 and 2017, respectively, and \$30.0 million and \$0 for the nine months ended September 30, 2018 and 2017, respectively.

Other performance obligations included 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 did not reach any milestone events during the nine months ended September 30, 2018 and reached one milestone event during the nine months ended September 30, 2017 resulting in \$0.5 million of revenue recognized. The Company recorded the associated milestone payment as revenue at a point-in-time. Certain out-licensing agreements include performance obligations to manufacture and provide drug product in the future when the licensed product is approved for commercial sale. 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 each 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, 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. Performance obligations in these contracts include various eligibility conditions that the Company must satisfy to maintain the grant agreement. Grant revenue is not significant to the consolidated financial statements. Performance obligations remaining as of September 30, 2018 were not material to the financial statements and do not significantly alter the Company's business operations. Contracts for the grant revenue include a fixed transaction price and a single performance obligation. Therefore, the transaction price is allocated to the single obligation and there are no further allocation methods or assumptions used.

2. Global Supply Chain Platform

The Company's Global Supply Chain Platform manufactures API for use internally in its research and development and clinical studies and for sale to pharmaceutical customers globally. API revenue earned by the Global Supply Platform is recognized when the Company has satisfied its performance obligation, which is the shipment or the 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.

The Company also generates revenue, to a lesser extent, 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.

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. As of September 30, 2018 and December 31, 2017, the Company's total provision for chargebacks and other deductions totaled \$13.2 million and \$3.7 million, respectively, included as a reduction of accounts receivable. The Company's total expense for chargebacks and other deductions was \$10.6 million and \$3.3 million for the three months ended September 30, 2018 and 2017, respectively, and \$22.7 million and \$5.1 million for the nine months ended September 30, 2018 and 2017, respectively.

The Company offers cash discounts, which approximate 2.0% 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. The Company considers payment performance and historical return rates and adjusts the accrual to reflect actual experience. As of September 30, 2018 and December 31, 2017, the Company's accrual for cash discounts and return accrual included as a reduction of accounts receivable were not material to the consolidated financial statements.

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 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, 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
India	—	258	—	258
Austria	—	2,227	—	2,227
China	117	189	—	306
Other foreign countries	—	1,077	—	1,077
Total revenue	\$ 5,117	\$ 5,996	\$ 7,315	\$ 18,428

	For the Three Months Ended September 30, 2017			
	(In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	\$ —	\$ 736	\$ 7,378	\$ 8,114
India	—	3,015	—	3,015
Austria	—	964	—	964
China	205	833	—	1,038
Other foreign countries	—	863	—	863
Total revenue	\$ 205	\$ 6,411	\$ 7,378	\$ 13,994

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

For the Nine Months Ended September 30, 2017				
(In Thousands)				
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	\$ —	\$ 1,781	\$ 9,274	\$ 11,055
India	—	5,275	—	5,275
Austria	—	2,682	—	2,682
China	708	1,058	—	1,766
Other foreign countries	500	1,892	—	2,392
Total revenue	<u>\$ 1,208</u>	<u>\$ 12,688</u>	<u>\$ 9,274</u>	<u>\$ 23,170</u>

The Company also disaggregates its revenue by product group which can be found in Note 11 – *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, 2018	December 31, 2017
(In Thousands)		
Accounts receivable, gross	\$ 20,252	\$ 12,263
Chargebacks and other deductions	(13,154)	(3,711)
Allowance for doubtful accounts	(27)	(84)
Accounts receivable, net	<u>\$ 7,071</u>	<u>\$ 8,468</u>
Deferred revenue	<u>\$ 364</u>	<u>\$ 1,202</u>
Total contract liabilities	<u>\$ 364</u>	<u>\$ 1,202</u>

The following tables illustrate accounts receivable balances by reportable segments.

September 30, 2018				
(In Thousands)				
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	\$ 9	\$ 3,369	\$ 16,874	\$ 20,252
Chargebacks and other deductions	—	—	(13,154)	(13,154)
Allowance for doubtful accounts	—	(27)	—	(27)
Accounts receivable, net	<u>\$ 9</u>	<u>\$ 3,342</u>	<u>\$ 3,720</u>	<u>\$ 7,071</u>

December 31, 2017				
(In Thousands)				
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	\$ 49	\$ 4,553	\$ 7,661	\$ 12,263
Allowance for doubtful accounts, chargebacks, and other deductions	—	(84)	(3,711)	(3,795)
Accounts receivable, net	<u>\$ 49</u>	<u>\$ 4,469</u>	<u>\$ 3,950</u>	<u>\$ 8,468</u>

As of September 30, 2018, \$0.4 million of the deferred revenue balance relates to customer deposits made by customers of the Global Supply Chain Platform.

As of December 31, 2017, the \$1.2 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, 2018.

There were no other material changes to contract balances during the nine months ended September 30, 2018.

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 intellectual property (“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.

13. Commitments and Contingencies

Future minimum payments under the non-cancelable operating leases consisted of the following as of September 30, 2018(in thousands):

Year ending December 31:	Minimum payments
2018 (remaining three months)	\$ 712
2019	2,383
2020	2,247
2021	1,844
2022	1,802
Thereafter	4,672
	<u>\$ 13,660</u>

Legal Proceedings

From time to time, the Company is subject to claims and litigation arising in the ordinary course of business. These claims may include assertions that the Company’s products infringe existing patents and 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.
Vasopressin (Generic version of Vasostriect®)

On August 13, 2018, Athenex Pharma Solutions and Athenex Pharmaceutical Division, LLC, wholly-owned subsidiaries of the Company, 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”). The Company is seeking a declaratory judgment from the Court that the Company’s compounded Vasopressin drug products in ready-to-use form do not infringe on patents that Par has with respect to its Vasostriect® product and that Par’s patents are invalid. On October 22, 2018, Par filed a motion to dismiss the complaint on the basis that the Court does not have subject matter jurisdiction and that motion is currently pending.

In addition, on August 13, 2018, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC filed a motion to intervene and seek the dismissal of Par's complaint against the FDA and certain governmental officials in the United States District Court for the District of Columbia. Par has sought declaratory and injunctive relief against the FDA and certain governmental officials that: (i) Vasopressin be delisted from Category 1 of the FDA's list of bulk drug substances under evaluation pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act ("FDCA"), (ii) the expansion of the FDA's enforcement discretion to Category 1 substances, be enjoined; and (iii) that the FDA be enjoined from authorizing the compounding of Vasopressin under Section 503B of the FDCA. Athenex's motion to intervene was granted. Par filed a preliminary injunction motion and Athenex and the FDA filed motions for judgment on the pleadings. Prior to hearing those motions, the Court issued an order staying the litigation until the earlier of December 31, 2018 or when the FDA issues its final clinical need determination for Vasopressin. On August 14, 2018, the Company began selling compounded Vasopressin Injection in ready-to-use premix IV bags. The Company has sold and will continue to sell these products. Therefore, an adverse final determination that the patent is valid and infringed could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

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, 2017 included in our Annual Report on Form 10-K for the year ended December 31, 2017. 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 this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 this Quarterly Report and in our Annual Report on Form 10-K for the year ended December 31, 2017. 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 of our Annual Report on Form 10-K for the year ended December 31, 2017 to conform these statements to actual results or to changes in our expectations, except as required by law.

Overview

We are a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer. We have two late-stage clinical drug candidates: (1) Oraxol, for metastatic breast cancer, our leading Orascovery drug candidate, combines a novel oral formulation of paclitaxel with HM30181A (a novel, orally non-absorbable, gastrointestinal tract P-glycoprotein pump inhibitor), (2) KX-01 Ointment for actinic keratosis, our leading Src Kinase Inhibition drug candidate, is a novel small molecule therapeutic which has multiple mechanisms of actions including: (a) the inhibition of the activity of Src Kinase and (b) the inhibition of tubulin polymerization.

Our robust clinical pipeline includes small molecule, biologic and cellular therapies for treatment of cancer. We continue to fuel the rapid expansion of this clinical pipeline now comprised of eight total Investigational New Drug applications ("IND"), five of which were allowed in the US alone within the last five years, and more are planned. Our Orascovery oral absorption platform technology, using our novel, highly-selective P-gp inhibitor in combination with widely-used oncology drugs, enables oral administration of currently injectable-only drugs. We have two Src Kinase/tubulin polymerization inhibitors, KX-01 and KX-02, which are being developed orally for cancers such as glioblastoma, as well as topically for the pre-cancerous skin disease actinic keratosis. On the biologics front, recently, we have strategically in-licensed Pegtomarginase, which is an enzyme capable of depleting tumors of a key resource for their growth and survival, the amino acid arginine. Lastly, our newly formed subsidiary, Axis Therapeutics Limited ("Axis") has in-licensed the worldwide (excluding mainland China) rights of all the intellectual properties and know-how of a TCR-engineered T Cell therapy ("TCR-T"), which harnesses and enhances the patient's own immune cells to target

and eliminate cancer. Overall, our clinical pipeline balances a range of therapeutic approaches for the treatment of cancer to enable us to improve the lives of cancer patients.

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 and Src Kinase Inhibition research platforms. Since 2016, we have also devoted a significant amount of our resources to the building of our commercial platform. We have incurred significant net losses since inception. Our net losses were \$90.3 million and \$102.9 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$416.6 million. 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, and advance those of our recently in-licensed technology platforms;
- 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;
- Hire additional research, development and business personnel;
- Maintain, expand and protect our intellectual property 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, including public offerings, and convertible bonds, debt and, to a lesser extent, through revenue generated from our Global Supply Chain Platform and Commercial Platform. As of September 30, 2018, we had cash, cash equivalents and short-term investments of \$141.4 million.

Recent Developments

We have made significant clinical progress on two of our lead drug candidates from our Src Kinase Platform and our Orascovery Platform, KX-01 Ointment and Oraxol. We have also expanded our drug portfolio with the acquisition of TCR-T cell therapy technology and replenished our pipeline filing an additional IND for an oral form of Eribulin.

KX-01 Ointment

Two Phase 3 Pivotal Efficacy Studies of KX2-391 in Actinic Keratosis

In July 2018, our two Phase 3 pivotal efficacy studies had achieved their primary endpoint of 100% clearance of actinic keratosis (AK) lesions at Day 57 within the face or scalp treatment areas, with each study achieving statistical significance ($p < 0.0001$). Statistical significance ($p < 0.001$) was achieved for both face and scalp subgroups as well. These two double-blind, randomized, vehicle-controlled, studies were designed as pivotal Phase 3 efficacy and safety studies to support the registration of KX2-391 (or KX-01) as field therapy for AK of the face and scalp. The studies, each conducted at 31 centers in the U.S., enrolled a total of 702 subjects. KX2-391, or vehicle ointment, was applied once daily for 5 days. In addition to the clinical activity of KX2-391, the local skin reaction profile was within expectations, in line with the Phase 2 study reported in the annual American Academy of Dermatology meeting in February 2018 in San Diego. Both studies are still on-going to complete the one-year follow-up of the patients who had complete responses. We will be submitting a request to the US FDA for a pre-NDA submission meeting to discuss the data and regulatory submission timelines. We plan to submit the topline and other related data from the Phase 3 studies for presentation at an upcoming scientific meeting.

Oraxol

Positive Recommendation by the Data and Safety Monitoring Board upon the Second Interim Analysis of Oraxol

In September 2018, we received a positive recommendation by the Data and Safety Monitoring Board (“DSMB”) of its second interim analysis of the Oraxol 001 Phase 3 Clinical Trial, a randomized controlled clinical trial comparing Oraxol monotherapy against intravenous (IV) paclitaxel monotherapy in patients with metastatic breast cancer. The DSMB reviewed the efficacy and safety data of this clinical trial, noted that more than 320 patients have been recruited, and unanimously recommended that the Company continues this clinical study and recruitment of patients. We are continuing to advance this clinical trial.

Presentation of Encouraging Clinical Trial Efficacy and Safety Results of Oraxol at the European Society for Medical Oncology (“ESMO”)

In October 2018 we presented encouraging efficacy and safety data of Oraxol in the treatment of metastatic breast cancer patients obtained from a Phase 2 clinical trial conducted in Taiwan. The data were presented at the ESMO Congress on October 21, 2018. Results from twenty-four patients with metastatic breast cancer were reported. Eleven patients (45.8%) achieved partial remission (PR), 10 patients (41.7%) had stable disease (SD) (two patients with SD will have their last CT scans conducted in early November and therefore, the overall PR rate may be higher), and 3 patients had progressive disease (PD). Drug-related serious adverse events consisting of Grade 4 neutropenia were observed in 3 patients and all recovered completely. There was no dose-limiting neuropathy observed. The Oraxol pharmacokinetic profiles at week 1 were reproducible at week 4, and the plasma AUC exposure is similar to those reported for intravenous paclitaxel at 80mg/kg weekly.

Immunotherapy

Axis Therapeutics and TCR-T License Agreement

In September 2018, we completed the closing process under the Share Subscription Agreement for Axis Therapeutics. This included a \$30.0 million cash from Athenex (via Athenex HK Innovative, “AHKI”) to Axis and issuance of Axis shares to Athenex (via AHKI) and XLifeSc. Also Axis entered into a license agreement with XLifeSc, pursuant to which 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. Upon effectiveness of the TCR-T License and satisfaction of certain conditions in the license agreement, Axis made an upfront payment of the Company’s common stock equal to \$5.0 million to XLifeSc, and Axis will be required to make payments to XLifeSc worth up to \$110.0 million in aggregate upon the occurrence of certain regulatory and sales milestones to be achieved in the U.S., the EU, China and Japan. In addition, XLifeSc will pay royalty payments to Axis based on aggregate net income generated from sales of any products using the licensed intellectual property in mainland China.

Preliminary Results of Patients Receiving T-Cell Receptor Affinity Enhancing Specific T-Cell Therapy (TAEST) Showed Encouraging Positive Clinical Signals

In October 2018, we, along with XLifeSc, announced the preliminary results of TAEST technology generated T-cell therapy studied in nine end-stage cancer patients who failed all standard treatments. In the first three patients, dose escalation in one patient and full dose in two patients were tested. All three patients showed an acceptable safety profile. Two of the patients showed stable disease with survival of 6 and 10 months, respectively. One patient with lung cancer showed a small tumor reduction, and a reduction in pain and softening of the subcutaneous metastasis following treatment. Lymphodepletion was added to the protocol in patients 4 through 9. Treatment was well tolerated with fever (n=5), chills (n=4), weakness (n=4), and mild skin rash (n=3) observed. Two patients (one breast cancer, one synovial sarcoma) had more than 40% reduction in tumor size, as measured by CT scans. The patient with breast cancer also had healing of two metastatic skin ulcers. Two other patients (one liver cancer patient with retroperitoneal recurrence after resection, one with thyroid cancer) showed stable disease. Both of these patients showed significant tumor necrosis shortly after the treatment, resulting in the formation of cavitation in the middle of the tumors. Clinically, there was also symptomatic relief of local pain reported during the period of radiologic evidence of increased tumor necrosis. The remaining two patients with lung cancer had stable disease for more than 60 days after treatment. This study also observed the expected cytokine response, detection of TCR-expression on T-cells, and persistence of the introduced TCR-gene in all patients during therapy.

Expanded Pipeline

FDA Allowance of Investigational New Drug Application of Eribulin ORA to Begin Clinical Trials

In October 2018, we announced that the FDA has allowed the Investigational New Drug (IND) application for Athenex's oral version of Eribulin currently named Eribulin ORA. This FDA action allows Athenex to commence its clinical trial program, currently planned for first half of 2019. Eribulin, an effective treatment for metastatic breast cancer and liposarcoma, is currently limited to intravenous administration. Utilizing Athenex’s proprietary Orascovery platform with Eribulin, we were able to demonstrate that good oral absorption of Eribulin is possible, based on preclinical studies. In addition, the Eribulin active pharmaceutical ingredient (API) has been developed internally using a novel synthetic approach. We believe these developments demonstrate the broad utility of the Orascovery platform and our commitment to becoming a major global oncology biopharmaceutical company.

Strategic Initiatives

Strategic Realignment with Collaborative Partner, Hanmi Pharmaceutical

In September 2018, the Company and its business partner, Hanmi Pharmaceutical, realigned the strategic development of two collaborative projects. The Company expanded its territory under the Orascovey Program to include the Middle East and North Africa as well as South Africa. Given the progress that has been made in the various clinical programs, the Company and its collaborator believe that expansion of its territories worldwide will result in more rapid advancement of the clinical and regulatory process across the globe. Hanmi Pharmaceutical will continue to oversee the development and regulatory efforts of the Orascovey Program in South Korea.

The Company has received back from Hanmi Pharmaceutical the rights to KX-01 Oral Formulation for South Korea, China, and other Asian territories. KX-01 Ointment (KX2-391) was shown to be effective and safe for actinic keratosis (AK) in two Phase 3 clinical studies conducted in the U.S., with both studies having met their primary endpoint of 100% clearance of AK lesions at Day 57 within the treatment areas, with statistical significance ($p < 0.0001$). The arrangement will allow Athenex to explore the potential of KX-01 Oral Formulation globally.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) 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, (ii) the sales of generic injectable products by our Commercial Platform, (iii) the sales of API, medical devices, and 503B products by our Global Supply Chain Platform, 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 and APIs at our cGMP facility in China. 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, 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 the following programs:

Orascovey platform—Comprised of our in-licensed and novel P-gp inhibitor, HM30181A, that is combined with various chemotherapeutic agents and enables them to be absorbed into the blood when given orally:

- Oraxol, combining HM30181A with an oral dosage form of paclitaxel;
- Oratecan, combining HM30181A with an oral dosage form of irinotecan;
- Oradoxel, combining HM30181A with an oral dosage form of docetaxel;
- Oratopo, combining HM30181A with an oral dosage form of topotecan; and
- Oral eribulin, combining HM30181A with an oral dosage form of eribulin.

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

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

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 Oraxol, Oratecan, Oradoxel, Oratopo, Oral Eribulin, KX-01 ointment, KX-01 oral and KX-02, as well as initiate and prepare for additional clinical and preclinical studies. 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 includes professional fees for legal, patent, consulting, auditing and tax services, as well as other direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in the selling, marketing, general and administrative activities. 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 JOBS Act.

Results of Operations

Three Months Ended September 30, 2018 Compared to Three Months Ended September 30, 2017

The following table sets forth a summary of our condensed consolidated results of operations for the three months ended September 30, 2018 and 2017, together with the changes in those items in dollars and percentage. This information should be read together with our 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,			
	2018	2017	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	\$ 18,428	\$ 13,994	\$ 4,434	32%
Cost of sales	(11,965)	(8,082)	(3,883)	48%
Research and development expenses*	(51,204)	(11,944)	(39,260)	329%
Selling, general, and administrative expenses	(11,493)	(10,364)	(1,129)	11%
Interest expense	(1,058)	(353)	(705)	200%
Unrealized loss on derivative liability	—	(6,548)	6,548	-100%
Income tax benefit (expense)	30	(11)	41	-373%
Net loss	(57,262)	(23,308)	(33,954)	146%
Less: net loss attributable to non-controlling interests	(11,091)	(34)	(11,057)	NM
Net loss attributable to Athenex, Inc.	\$ (46,171)	\$ (23,274)	\$ (22,897)	

*Research and development expenses for the three months ended September 30, 2018 include a non-cash expense of \$24.5 million related to the acquisition of the IPR&D of certain immunotherapy technology from XLifeSc in connection with the establishment of Axis (refer to Note 6 of the Notes to the Condensed Consolidated Financial Statements).

Revenue

Revenue for the three months ended September 30, 2018 was \$18.4 million, an increase of \$4.4 million, or 32%, as compared to \$14.0 million for the three months ended September 30, 2017. The increase was primarily attributable to an increase in licensing revenue of \$5.0 million, a \$1.0 million increase in sales of our 503B products, and a \$0.7 million increase in medical device sales. This was offset by decreases in API sales of \$1.7 million, contract manufacturing revenue of \$0.2 million, grant revenue of \$0.2 million, and other product sales of \$0.2 million.

Cost of Sales

Cost of sales for the three months ended September 30, 2018 totaled \$12.0 million, an increase of \$3.9 million, or 48%, as compared to \$8.1 million for the three months ended September 30, 2017. This was primarily due to the increase of \$1.9 million cost of sales from the specialty products and \$2.0 million cost of sales from 503B and API products. The increase in gross profit was primarily due to the licensing revenue in the current year. Changes in availability of products and market demand could increase or decrease our revenue and gross profit.

Research and Development Expenses

Research and development (“R&D”) expenses for the three months ended September 30, 2018 totaled \$51.2 million, an increase of \$39.3 million, or 329%, as compared to \$11.9 million for the three months ended September 30, 2017. This was primarily due to an increase in licensing fees and clinical operations and included the following:

- \$30.4 million increase in drug licensing fees primarily due to a \$29.5 million non-cash license fee related to the purchase of TCR-T 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;
- \$6.5 million increase of clinical trial costs with the progression of the Phase 3 trials of KX-01 Ointment and Oraxol;
- \$2.0 million increase of employee salary and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and clinical activities, including the expansion of our clinical R&D team in Taiwan;
- \$0.6 million increase of R&D expenses related to the pre-launch activities of our proprietary products and the development of our specialty products; and
- \$0.2 million increase of R&D costs related to product testing of 503B products as they were introduced and production was scaled-up to a commercial level.

These increased costs were offset by a decrease in API and other R&D costs of \$0.5 million.

Selling, General, and Administrative Expenses

SG&A expenses for the three months ended September 30, 2018 totaled \$11.5 million, an increase of \$1.1 million, or 11%, as compared to \$10.4 million for the three months ended September 30, 2017. This was primarily due to an increase in professional fees of \$0.9 million from legal fees incurred in conjunction with the launch of 503B products and an increase in employee compensation of \$0.5 million, offset by a decrease of \$0.3 million in selling and marketing expenses related to the launch of specialty products.

Interest Expense

Interest expense for the three months ended September 30, 2018 totaled \$1.1 million, a change of \$0.7 million as compared to \$0.4 million interest expense for the three months ended September 30, 2017. The interest expense in the current period was incurred from our long-term debt with Perceptive Advisors LLC and its affiliates (“Perceptive”). The interest expense in the prior period was incurred from a convertible bond that was converted into the Company’s common stock in the third quarter of 2017.

Loss on Derivative Liability

Loss on derivative liability for the three months ended September 30, 2018 decreased by \$6.6 million compared to the three months ended September 30, 2017. This decrease was due to the change in the fair value of the derivatives embedded within the convertible bonds we issued to a licensor in the first quarter of 2017 and was converted in the third quarter of 2017. The derivative liability was no longer outstanding as of September 30, 2018.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2017

The following table sets forth a summary of our condensed consolidated results of operations for the nine months ended September 30, 2018 and 2017, together with the changes in those items in dollars and percentage. This information should be read together with our 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,			
	2018	2017	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	\$ 67,829	\$ 23,170	\$ 44,659	193%
Cost of sales	(32,734)	(15,058)	(17,676)	117%
Research and development expenses*	(99,077)	(55,949)	(43,128)	77%
Selling, general, and administrative expenses	(37,390)	(33,795)	(3,595)	11%
Interest expense	(463)	(6,010)	5,547	-92%
Unrealized loss on derivative liability	—	(15,411)	15,411	-100%
Income tax benefit	286	52	234	450%
Net loss	(101,549)	(103,001)	1,452	-1%
Less: net loss attributable to non-controlling interests	(11,222)	(114)	(11,108)	NM
Net loss attributable to Athenex, Inc.	<u>\$ (90,327)</u>	<u>\$ (102,887)</u>	<u>\$ 12,560</u>	

*Research and development expenses for the nine months ended September 30, 2018 include a non-cash expense of \$24.5 million related to the acquisition of the IPR&D of certain immunotherapy technology from XLifeSc in connection with the establishment of Axis (refer to Note 6 of the Notes to the Condensed Consolidated Financial Statements).

Revenue

Revenue for the nine months ended September 30, 2018 was \$67.8 million, an increase of \$44.7 million, or 193%, as compared to \$23.2 million for the nine months ended September 30, 2017. The increase was primarily attributable to \$30.0 million in upfront license fees, a \$13.7 million increase in specialty products sold through our Commercial Platform, a \$2.0 million increase in sales of our 503B products, and a \$0.4 million increase in API and medical device sales. This was offset by decreases in other out-licensing fees of \$0.5 million, contract manufacturing revenue of \$0.5 million, and \$0.4 million in other product sales and grant revenue.

Cost of Sales

Cost of sales for the nine months ended September 30, 2018 totaled \$32.7 million, an increase of \$17.6 million, or 117%, as compared to \$15.1 million for the nine months ended September 30, 2017. This was primarily due to the increase of \$13.2 million cost of sales from the specialty products and \$4.4 million cost of sales from 503B and API products. The gross profit from product sales decreased primarily due to the impact of the costs incurred for the scale-up of production for new products in our 503B outsourcing facility and a greater margin on shortage specialty products in 2017. Changes in availability of products and market demand could increase or decrease our revenue and gross profit.

Research and Development Expenses

R&D expenses for the nine months ended September 30, 2018 totaled \$99.1 million, an increase of \$43.1 million, or 77%, as compared to \$55.9 million for the nine months ended September 30, 2017. This was primarily due to an increase in licensing fees and clinical operations and included the following:

- \$19.9 million increase of clinical trial costs with the progression of the Phase 3 trials of KX-01 Ointment and Oraxol;
- \$14.8 million increase in drug licensing fees primarily due to a \$29.5 million non-cash license fee related to the purchase of T-Cell technology in connection with the establishment of Axis, of which \$24.5 million related to the fair value of the IPR&D and \$5 million related to the Company's common stock issued to XLifeSc. This was offset by a decrease in license fees incurred for specialty products;
- \$5.0 million increase of employee salary and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and clinical activities, including the expansion of our clinical R&D team in Taiwan;
- \$1.6 million increase of R&D costs related to product testing of 503B products as they were introduced and production was scaled-up to a commercial level;
- \$1.3 million increase of R&D expenses related to pre-launch activities and testing of our proprietary products and products for our Commercial Platform;
- \$0.7 million increase of the cost of preclinical studies as research was performed on an oral formulation of Eribulin; and
- \$0.6 million increase in novel and general research and development.

These increased costs were offset by a decrease in API R&D of \$0.8 million.

Selling, General, and Administrative Expenses

SG&A expenses for the nine months ended September 30, 2018 totaled \$37.4 million, an increase of \$3.6 million, or 11%, as compared to \$33.8 million for the nine months ended September 30, 2017. This was primarily due to an increase in professional fees and operating activities and included the following:

- \$2.2 million increase in professional fees including legal fees incurred in conjunction with the launch of 503B products and consulting fees related to the construction of our manufacturing facility in Dunkirk, NY; and
- \$2.1 million increase of other office expenses including insurance expenses, government fees and business permit, rent and utilities, property taxes, and other expenses

These costs were offset by a decrease in employee compensation of \$0.7 million from stock-based compensation incurred in the prior year in connection with our IPO.

Interest Expense

Interest expense for the nine months ended September 30, 2018 totaled \$0.5 million, a decrease of \$5.5 million as compared to \$6.0 million interest expense for the nine months ended September 30, 2017. The interest expense in the current period was incurred from our long-term debt with Perceptive. The interest expense in the prior period was primarily incurred from the convertible bonds we issued between the third quarter of 2016 and the second quarter of 2017, which were converted into the Company's common stock in 2017.

Loss on Derivative Liability

Loss on derivative liability for the nine months ended September 30, 2018 decreased by \$15.4 million compared to the nine months ended September 30, 2017. This decrease was due to the change in the fair value of the derivatives embedded within the convertible bonds we issued between the third quarter of 2016 and the second quarter of 2017. The derivative liability was no longer outstanding as of September 30, 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 and SG&A costs associated with our operations. We incurred net losses of \$90.3 million and \$102.9 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$416.6 million. Our primary use of cash is to fund R&D costs. Our operating activities used \$75.3 million and \$63.6 million of cash during the nine months ended September 30, 2018 and 2017, respectively. Our principal sources of liquidity as of September 30, 2018 are cash and cash equivalents totaling of \$51.1 million and short-term investments totaling \$90.3 million, which are generally U.S. government or high-quality investment grade corporate debt securities.

In June 2017, the Company sold an aggregate of 6,900,000 shares of its common stock at a price of \$11.00 per share in its IPO for cash proceeds of \$64.2 million, net of underwriting discounts and commissions of \$6.1 million and offering costs of \$5.6 million. In January 2018, the Company issued and sold 4,300,000 shares of its common stock at a public offering price of \$15.25 per share. In addition, 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 exercised their option to purchase an additional 465,000 shares of common stock at the offering price of \$15.25 per share. Net proceeds of the 2018 offering were approximately \$68.1 million, after deducting underwriting discounts and commissions and offering expenses of approximately \$4.6 million.

In July 2018, the Company 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. 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.

Based on our current operating plan, we expect that our cash, cash equivalents and short-term investments as of September 30, 2018, together with cash to be generated from our operating activities, will enable us to fund our operating expenses and capital expenditures requirements into the fourth quarter of 2019. We expect that our expenses will increase substantially as we continue to fund clinical development of our Orascovery and Src Kinase Inhibition research programs and fund new and ongoing research and development activities 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 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, timings, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- The number and characteristics of the drug candidate we pursue;
- The costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property 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 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, 2018 and 2017:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash used in operating activities	\$ (75,315)	\$ (63,644)
Net cash used in investing activities	(81,125)	(47,022)
Net cash provided by financing activities	168,364	96,093
Net effect of foreign exchange rate changes	(100)	710
Net increase (decrease) in cash and cash equivalents	<u>\$ 11,824</u>	<u>\$ (13,863)</u>

Net Cash Used in Operating Activities

The use of cash 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 purchase, and other expenditures related to sales, marketing and administration.

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 primarily related to API 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 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 used in operating activities was \$63.6 million for the nine months ended September 30, 2017. This resulted principally from our net loss of \$103.0 million, adjusted for non-cash charges of \$49.7 million, and by cash used in our operating assets and liabilities of \$10.3 million. Our net non-cash charges during the nine months ended September 30, 2017 primarily consisted of \$15.4 million of fair value change in derivative liabilities, \$13.3 million of licensing fees settled by bonds and equity, \$11.7 million of stock-based compensation expense, \$3.7 million of convertible bonds interest, \$3.3 million amortization of debt discount, and \$2.6 million depreciation and amortization expense.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$81.1 million for the nine months ended September 30, 2018, compared to \$47.0 million for the nine months ended September 30, 2017. The increase was primarily due to cash used in purchasing 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 \$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, compared with \$96.1 million for the nine months ended September 30, 2017, which included \$75.9 million from the issuance of common stock, which resulted in net proceeds of \$65.7 million from the IPO due to \$6.1 million of underwriting discounts and commissions and \$4.1 million of certain offering costs, and \$30.0 million from the issuance of convertible bonds.

Contractual Obligations

A summary of our contractual obligations as of September 30, 2018 is as follows:

	Payments Due by Period				Total Amounts Committed
	Within 1 Year	1 to 3 years	3 to 5 years	More than 5 years	
	(in thousands)				
Operating leases	\$ 2,499	\$ 4,225	\$ 5,036	\$ 1,900	\$ 13,660
Long-term debt	795	—	50,000	—	50,795
Capital lease obligations	183	363	61	—	607
Licensing fees	759	—	—	—	759
	<u>\$ 4,236</u>	<u>\$ 4,588</u>	<u>\$ 55,097</u>	<u>\$ 1,900</u>	<u>\$ 65,821</u>

The following 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 with \$8.8 million committed, (2) the rental of our research and development facility in the IC Development Centre in Hong Kong with \$0.1 million committed, (3) the rental of the Commercial Platform headquarters in Chicago, IL with \$2.5 million committed, (4) the rental of our clinical research and development facility in Cranford, NJ with \$0.4 million committed, (5) the rental of our clinical data management center in Taipei, Taiwan with \$0.7 million committed, (6) the rental of our Global Supply Chain distribution office in Houston, TX with \$0.1 million committed, and (7) the rental of our Global Supply Chain API manufacturing facility in Chongqing, China with \$1.1 million committed.

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 revenue recognition as a result of the adoption of ASC 606 (see Note 12 – *Revenue Recognition*), 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, 2017.

Recent Accounting Pronouncements

In the normal course of business, we evaluate all new accounting pronouncements issued by the FASB, 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 are currently evaluating. 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, (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 Securities and Exchange Commission (“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, 2018 and 2017, approximately 3% and 5%, 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 and cash equivalents of \$51.1 million and short-term investments of \$90.3 million as of September 30, 2018, which consisted primarily of U.S. government or high quality investment grade corporate debt securities. 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, 2018, we had \$50 million of debt with Perceptive that bears interest at a floating per annum rate equal to LIBOR (with a floor of 2%) plus 9%. A material change in the short-term interest rate environment could have a material adverse effect on our 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, 2018. The term “disclosure controls and procedures,” as defined in Rule 13a15(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, 2018, 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, 2018 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, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC, wholly-owned subsidiaries of the Company, 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”). The Company is seeking a declaratory judgment from the Court that the Company’s compounded Vasopressin drug products in ready-to-use form do not infringe on patents that Par has with respect to its Vasostrict® product and that Par’s patents are invalid. On October 22, 2018 Par filed a motion to dismiss the complaint on the basis that the Court does not have subject matter jurisdiction and that motion is currently pending.

In addition, on August 13, 2018, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC filed a motion to intervene and seek the dismissal of Par’s complaint against the FDA and certain governmental officials in the United States District Court for the District of Columbia. Par has sought declaratory and injunctive relief against the FDA and certain governmental officials that: (i) Vasopressin be delisted from Category 1 of the FDA’s list of bulk drug substances under evaluation pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act (“FDCA”), (ii) the expansion of the FDA’s enforcement discretion to Category 1 substances, be enjoined; and (iii) that the FDA be enjoined from authorizing the compounding of Vasopressin under Section 503B of the FDCA. Athenex’s motion to intervene was granted. Par filed a preliminary injunction motion and Athenex and the FDA filed motions for judgment on the pleadings. Prior to hearing those motions, the Court issued an order staying the litigation until the earlier of December 31, 2018 or when the FDA issues its final clinical need determination for Vasopressin. On August 14, 2018, the Company began selling compounded Vasopressin Injection in ready-to-use premix IV bags. The Company has sold and will continue to sell these products. Therefore, an adverse final determination that the patent is valid and infringed could have an adverse effect on the Company’s business, results of operations, financial condition and cash flows.

Item 1A. Risk Factors.

In addition to the other information contained in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A “Risk Factors” in our 2017 Form 10-K in evaluating our business, financial position, future results, and prospects. The information presented below updates and supplements those risk factors for events, changes and developments since the filing of the 2017 Form 10-K and should be read in conjunction with the risks and other information contained in the 2017 Form 10-K. The risks described in our 2017 Form 10-K, as updated below, are not the only risks we face. Additional risks that we do not presently know or that we currently believe are not material could also materially adversely affect our business, financial position, future results and prospects.

The Company entered into a \$50.0 million senior secured loan agreement, which subjects the Company to significant interest rate and credit risk.

On June 29, 2018, the Company entered into a 5-year \$50.0 million loan agreement with Perceptive, which closed on July 3, 2018, bearing interest at a floating per annum rate equal to LIBOR (with a floor of 2%) plus 9%. Thus, a change in the short-term interest rate environment (especially a material change) could have a material adverse effect on our business, financial condition, cash flows and results of operations and could cause the market value of our common shares to decline. As of September 30, 2018, we did not have any outstanding interest rate swap contracts.

We may not be able to refinance, extend, or repay our substantial indebtedness owed to our senior secured lender, which would have a material adverse effect on our financial condition and ability to continue as a going concern.

We anticipate that we will need to raise a significant amount of debt or equity capital in the future in order to repay our outstanding debt obligations owed to our senior secured lender when they mature on July 3, 2023 and fund our operations. We will owe our senior secured lender \$50.0 million upon execution of the senior secured loan agreement. We are required to make monthly interest-only payments with a bullet payment of the principal at maturity. If we are unable to raise sufficient capital to repay these obligations at maturity and we are otherwise unable to extend the maturity dates or refinance these obligations, we would be in default. We cannot provide any assurances that we will be able to raise the necessary amount of capital to repay these obligations or that we will be able to extend the maturity dates or otherwise refinance these obligations. Upon a default on the senior debt, our senior secured lender would have the right to exercise its rights and remedies to collect, which would include foreclosing on our assets. Accordingly, a default would have a material adverse effect on our business and, if our senior secured lender exercises its rights and remedies, we would likely be forced to seek bankruptcy protection.

Covenants in the agreements governing our existing debt agreement restrict the manner in which we conduct our business.

The senior secured loan agreement contains various covenants that limit, subject to certain exemptions, our ability and/or our restricted subsidiaries' ability to, among other things:

- Incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- make loans, investments, or acquisitions;
- engage in any other business other than the business engaged in on the date of the loan agreement;
- pay dividends or make distributions on capital stock by any subsidiary;
- make any unscheduled payments on the Company's existing debt prior to the stated maturity thereof;
- sell assets and capital stock of our subsidiaries;
- enter into certain transactions with affiliates; and
- sell, transfer, license, lease, or dispose of our or our subsidiaries' assets.

The restrictions contained in our senior secured loan agreement governing our debt could adversely affect our ability to:

- finance our operations;
- make needed capital expenditures;
- make strategic acquisitions or investments or enter into alliances;
- withstand a future downturn in our business or the economy in general;
- engage in business activities, including future opportunities, that may be in our interest; and
- plan for or react to market conditions or otherwise execute our business strategies.

A breach of any of these covenants could result in a default under the senior secured loan agreement governing our debt. Further, additional indebtedness that we incur in the future may subject us to further covenants. If a default under any such loan agreement is not cured or waived, the default could result in the acceleration of debt, which could require us to repurchase or repay debt prior to the date it is otherwise due and that could adversely affect our financial condition.

Our ability to comply with the covenants contained in our senior secured loan agreement may be affected by events beyond our control, including prevailing economic, financial, and industry conditions. Even if we are able to comply with all of the applicable covenants, the restrictions on our ability to manage our business in our sole discretion could adversely affect our business by, among other things, limiting our ability to take advantage of financings, mergers, acquisitions, and other corporate opportunities that we believe would be beneficial to us. In addition, our obligations under the loan agreement are secured, on a first-priority basis, and such security interests could be enforced in the event of default by the collateral agent for the loan agreement.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities Offerings

On June 13, 2017, our Registration Statement on Form S-1 (File No. 333-217928) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 6,900,000 shares of our common stock at a price of \$11.00 per share for aggregate cash proceeds of approximately \$64.2 million, net of underwriting discounts and commissions and offering costs.

On January 24, 2018, our Registration Statement on Form S-1 (File No. 333-222640) relating to the follow-on public offering of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 4,765,000 shares of our common stock at a price of \$15.25 per share for aggregate cash proceeds of approximately \$68.1 million, net of underwriting discounts and commissions and offering costs.

There has been no material change in the expected use of the net proceeds from our public offerings, as described in our final prospectus filed with the SEC on June 15, 2017 and January 25, 2018, respectively, pursuant to Rule 424(b) of the Securities Act. As of September 30, 2018, both of these offerings have terminated.

Repurchases of Equity Securities by the Issuer

None.

Item 3. Defaults upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None.

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
10.1	Registration Rights Agreement dated as of July 3, 2018 by and between Athenex, Inc. and Perceptive Life Sciences Master Fund, Ltd.	Form 10-Q	001-38112	10.7	August 14, 2018
10.2 ⁺	Employment Agreement by and between the Company and Randall Sze dated as of August 20, 2018.	Form 8-K	001-38112	10.1	August 20, 2018
10.3 [^]	First Amendment to License and Development Agreement by and between Athenex, Inc., Almirall, S.A., and Aqua Pharmaceuticals LLC, dated as of September 26, 2018.	—	—	—	Filed herewith
10.4 [^]	Letter Agreement by and between Athenex, Inc., Almirall, S.A. and Aqua Pharmaceuticals LLC, dated as of September 26, 2018	—	—	—	Filed herewith
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

⁺ Indicates management contract or compensatory plan.

[^] Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 406 under the Securities Act. In accordance with Rule 406, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

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 14, 2018

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

Date: November 14, 2018

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

Portions of this exhibit marked [*] are requested to be treated confidentially.

FIRST AMENDMENT TO LICENSE AND DEVELOPMENT AGREEMENT

This FIRST AMENDMENT TO LICENSE AND DEVELOPMENT AGREEMENT (this “First Amendment”) is made and entered into as of this 26th day of September, 2018 (“Effective Date”) by and between Athenex, Inc., a corporation organized and existing under the laws of the state of Delaware, USA, with a principal place of business at 1001 Main Street, Suite 600, Buffalo, New York 14203 (“Athenex”), Almirall S.A., a corporation organized and existing under the laws of Spain with a principal place of business at Ronda del General Mitre 151, Barcelona 08022 (“Almirall”), and Aqua Pharmaceuticals, LLC, a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 707 Eagleview Blvd., Suite 200, Exton, PA 19341 (“Aqua”).

WITNESSETH:

WHEREAS, Athenex, Almirall and Aqua entered into a License and Development Agreement on December 11, 2017 for the license by Athenex to Almirall and Aqua of certain rights in the topical formulation of Athenex’s compound KX-01/KX2-391 (“License”);

WHEREAS, Athenex, Almirall and Aqua wish to amend the terms of the License to amend Section 4.2(a);

NOW, THEREFORE, based upon the above Recitals, the mutual promises and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. All capitalized terms used in this First Amendment and not defined herein shall have the meaning given to them in the License. Except as amended by this First Amendment, the License shall continue in full force and effect.
2. Section 4.2(a) shall be superseded and replaced with the following:

(a) **Current Product Payment.** Within forty-five (45) days of being provided with the Day 57 Phase 3/Phase 1 Contact Sensitization Data, Almirall shall notify Athenex in writing whether or not such data is, in Almirall’s sole discretion, satisfactory to Almirall and Aqua. If such notice indicates that such data is satisfactory, or no such notice is provided within such forty-five (45) day period, Almirall and Aqua shall pay in total to Athenex \$[*] within thirty (30) days of the earlier of such notice or expiration of such forty-five (45) day period. If such notice indicates that such data is not satisfactory, this Agreement shall terminate upon receipt of such notice. If, within forty-five (45) days after Almirall is provided the 12 Months Phase III Long-Term Recurrence Data, Almirall provides written notice to Athenex that such data is not satisfactory, the Agreement shall terminate upon such notice and Athenex shall reimburse to Almirall and Aqua any payment made under this Section 4.2(a). Athenex’s reimbursement shall be done in accordance with the proportion used by Almirall and Aqua for the payments made in accordance with Section 4.1 and within thirty (30) days of such notice to Athenex.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

3. Athenex has, and hereby agrees that, upon the request of Almirall and Aqua, to continue to refrain from publicly disclosing certain terms of the License which it otherwise would have had the contractual and legal right to disclose under the terms of the License.

IN WITNESS WHEREOF, Athenex, Almirall and Aqua have executed this First Amendment as of the date first set forth above.

ATHENEX, INC.

/s/ Johnson Lau

By: Johnson Lau

Title: Chief Executive Officer &
Board Chairman

ALMIRALL, S.A.

/s/ Peter Guenter

By: Peter Guenter

Title: Chief Executive Officer

AQUA PHARMACEUTICALS, LLC

/s/ Peter Guenter

By: Peter Guenter

Title: Chairman

Portions of this exhibit marked [*] are requested to be treated confidentially.



September 26, 2018

Almirall, S.A.
Ronda del General Mitre 151
Barcelona 08022
Spain
Attn: SVP Corporate Legal

Aqua Pharmaceuticals LLC
707 Eagleview Blvd., Suite 200
Exton, PA 19341
Attn: Chief Executive Officer

Re: License and Development Agreement

Dear Sirs,

Reference is made to the License and Development Agreement, dated as of December 11, 2017, by and among Athenex, Inc. ("Athenex"), Almirall, S.A. ("Almirall") and Aqua Pharmaceuticals LLC ("Aqua"), as amended by a First Amendment to License Agreement dated as of September 26, 2018 (collectively, the "License Agreement").

This letter sets forth the understanding and agreement among Athenex, Almirall and Aqua with respect to the royalty that Athenex would pay to Almirall for certain license rights if the License Agreement is terminated pursuant to Section 4.2(a) of the License Agreement. Specifically, Athenex, Almirall and Aqua agree as follows:

1. If the License Agreement is terminated pursuant to Section 4.2(a), upon Almirall's delivery of written notice that the applicable data that Athenex delivers is not satisfactory, the provisions of Section 8.4(e) including, without limitation, the license rights granted by Almirall to Athenex, shall apply to such termination, subject to the terms of this letter.

2. The royalty that Athenex shall pay to Almirall for the license rights under Section 8.4(e)(ii) shall be the addition of (i) a variable portion being a percentage of the Net Sales of the Licensed Products in the Territory to be negotiated in good faith and mutually agreed upon by the Parties, taking into account the value of the intellectual property subject to such license or determined by an independent certified public accounting firm, as set forth in such Section 8.4(e) and (ii) an agreed lump sum amount of US\$[*], payable by Athenex within 30 days of such notice to Almirall and Aqua in accordance with the proportion used by Almirall and Aqua for the payments made in accordance with Section 4.1 of the License Agreement.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC. [ATHENEX.COM](http://www.ATHENEX.COM)



3. If the Parties are unable to agree on the total amount of the variable portion of such payment due under Section 8.4(e)(ii) within 30 days of Almirall's notice under Section 4.2(a), Athenex shall pay Almirall US\$[*] within such 30 days, and the Parties agree to engage an independent certified public accounting firm to determine such variable portion, in accordance with Section 8.4(e). For the sake of clarity, the Parties agree that no amounts payable by Athenex to Almirall or Aqua upon termination of the License Agreement (including without limitation the foregoing US\$[*] lump sum or the amount to be refunded in accordance with Section 4.2(a), when applicable) shall be considered or deducted when calculating the total value of the relevant intellectual property at the time of determining the variable portion of the royalty payable by Athenex to Almirall under Section 8.4(e).

4. All capitalized terms used in this letter and not defined herein shall have the meaning given to them in the License Agreement. Except as amended by this letter, the License Agreement shall continue in full force and effect.

Please confirm your agreement with the terms set forth in this letter, by signing and returning a copy of this letter to the undersigned.

Athenex, Inc.

By: /s/ Johnson Lau
Name: Johnson Lau
Title: Chief Executive Officer & Board Chairman

Agreed to and Accepted:

Almirall, S.A.

By: /s/ Peter Guenter
Name: Peter Guenter
Title: Chief Executive Officer

Aqua Pharmaceuticals LLC

By: /s/ Peter Guenter
Name: Peter Guenter
Title: Chairman

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

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)) 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) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];
 - (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 14, 2018

/s/ Johnson Y.N. Lau

Name: Johnson Y.N. Lau

Title: Chief Executive Officer and Board Chairman
(Principal Executive Officer)

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)) 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) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];
 - (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 14, 2018

/s/ Randoll Sze

Name: Randoll Sze

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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 and Accounting 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, 2018, 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 14, 2018

/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)