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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38112

ATHENEX, INC.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 1, 2021, the registrant had 109,319,039 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 73,594	$ 69,587
Restricted cash	16,500	16,500
Short-term investments	14,918	138,636
Accounts receivable, net of chargebacks and other deductions of $25,855 and $12,552, respectively, and provision for credit losses of $9,247 and $9,637, respectively	33,757	23,603
Inventories	31,577	28,846
Prepaid expenses and other current assets	14,491	14,789
Total current assets	184,837	291,961
Property and equipment, net	51,916	34,388
Goodwill	67,617	38,891
Intangible assets, net	73,887	10,218
Operating lease right-of-use assets, net	6,511	7,921
Other assets	1,126	950
Total assets	$ 385,894	$ 384,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 22,877	$ 18,673
Accrued expenses	40,126	38,273
Current portion of operating lease liabilities	3,044	3,185
Current portion of long-term debt and finance lease obligations	7,487	2,010
Total current liabilities	73,534	62,141
Long-term liabilities:		
Long-term operating lease liabilities	4,753	6,355
Long-term debt and finance lease obligations	143,107	146,577
Deferred tax liabilities	1,817	56
Contingent consideration	23,486	—
Other long-term liabilities	3,318	3,852
Total liabilities	250,015	218,981
Commitments and contingencies (See Note 17)		
Stockholders' equity:		
Common stock, par value $0.001 per share, 250,000,000 shares authorized at September 30, 2021 and December 31, 2020; 110,991,959 and 95,066,195 shares issued at September 30, 2021 and December 31, 2020, respectively; 109,319,039 and 93,393,275 shares outstanding at September 30, 2021 and December 31, 2020, respectively	111	95
Additional paid-in capital	969,315	901,864
Accumulated other comprehensive loss	(1,037)	(1,134)
Accumulated deficit	(809,025)	(713,644)
Less: treasury stock, at cost; 1,672,920 shares at September 30, 2021 and December 31, 2020	(7,485)	(7,406)
Total Athenex, Inc. stockholders' equity	151,879	179,775
Non-controlling interests	(16,000)	(14,427)
Total stockholders' equity	135,879	165,348
Total liabilities and stockholders' equity	$ 385,894	$ 384,329

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product sales, net	$ 27,035	$ 24,780	$ 68,780	$ 83,494
License and other revenue	5,262	10,696	26,465	39,089
Total revenue	32,297	35,476	95,245	122,583
Cost of sales	25,644	24,510	61,712	77,088
Gross Profit	6,653	10,966	33,533	45,495
Operating expenses:				
Research and development expenses	17,731	18,390	61,928	57,597
Selling, general, and administrative expenses	22,794	22,220	66,145	65,454
Total operating expenses	40,525	40,610	128,073	123,051
Operating loss	(33,872)	(29,644)	(94,540)	(77,556)
Interest income	39	112	200	710
Income from government grant	2,459	—	2,459	—
Interest expense	5,100	3,595	15,692	6,833
Loss on extinguishment of debt	—	3,048	—	10,278
Loss before income tax expense (benefit)	(36,474)	(36,175)	(107,573)	(93,957)
Income tax expense (benefit)	262	1,093	(10,619)	4,080
Net loss	(36,736)	(37,268)	(96,954)	(98,037)
Less: net loss attributable to non-controlling interests	(679)	(462)	(1,573)	(1,351)
Net loss attributable to Athenex, Inc.	$ (36,057)	$ (36,806)	$ (95,381)	$ (96,686)
Unrealized gain (loss) on investment, net of income taxes	5	(48)	2	1
Foreign currency translation adjustment, net of income taxes	81	85	95	(396)
Comprehensive loss	$ (35,971)	$ (36,769)	$ (95,284)	$ (97,081)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 14)	$ (0.33)	$ (0.44)	$ (0.93)	$ (1.17)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 14)	109,292,740	83,712,060	102,111,218	82,314,802

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 January 1, 2020	83,231,063	$ 83	$ 763,648	$ (567,465)	$ (635)	(1,672,920)	$ (7,406)	$ 188,225	$ (12,370)	$ 175,855
Stock-based compensation cost	—	—	1,864	—	—	—	—	1,864	—	1,864
Restricted stock expense	(3,000)	—	397	—	—	—	—	397	—	397
Stock options exercised	70,200	—	344	—	—	—	—	344	—	344
Net loss	—	—	—	(19,429)	—	—	—	(19,429)	(289)	(19,718)
Other comprehensive loss, net of tax	—	—	—	—	(506)	—	—	(506)	—	(506)
Balance at March 31, 2020 (unaudited)	83,298,263	83	766,253	(586,894)	(1,141)	(1,672,920)	(7,406)	170,895	(12,659)	158,236
Sale of common stock and issuance of stock in connection with acquisition	51,691	—	269	—	—	—	—	269	—	269
Stock-based compensation cost	—	—	2,640	—	—	—	—	2,640	—	2,640
Restricted stock expense	—	—	413	—	—	—	—	413	—	413
Stock options exercised	12,500	—	125	—	—	—	—	125	—	125
Issuance of warrants, net	—	—	5,342	—	—	—	—	5,342	—	5,342
Non-controlling interests	—	—	—	—	—	—	—	—	198	198
Net loss	—	—	—	(40,451)	—	—	—	(40,451)	(600)	(41,051)
Other comprehensive income, net of tax	—	—	—	—	74	—	—	74	—	74
Balance at June 30, 2020 (unaudited)	83,362,454	83	775,042	(627,345)	(1,067)	(1,672,920)	(7,406)	139,307	(13,061)	126,246
Sale of common stock and issuance of stock in connection with acquisition	11,522,598	11	118,619	—	—	—	—	118,630	—	118,630
Stock-based compensation cost	—	—	2,513	—	—	—	—	2,513	—	2,513
Restricted stock expense	(7,820)	—	178	—	—	—	—	178	—	178
Stock options exercised	82,430	1	696	—	—	—	—	697	—	697
Issuance of warrants, net	—	—	1,202	—	—	—	—	1,202	—	1,202
Net loss	—	—	—	(36,806)	—	—	—	(36,806)	(462)	(37,268)
Other comprehensive income, net of tax	—	—	—	—	37	—	—	37	—	37
Balance at September 30, 2020 (unaudited)	94,959,662	$ 95	$ 898,250	$ (664,151)	$ (1,030)	(1,672,920)	$ (7,406)	$ 225,758	$ (13,523)	$ 212,235

	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 January 1, 2021	95,066,195	$ 95	$ 901,864	$ (713,644)	$ (1,134)	(1,672,920)	$ (7,406)	$ 179,775	$ (14,427)	$ 165,348
Stock-based compensation cost	—	—	2,205	—	—	—	—	2,205	—	2,205
Restricted stock expense	—	—	29	—	—	—	—	29	—	29
Stock options exercised	119,425	—	852	—	—	—	—	852	—	852
Net loss	—	—	—	(25,050)	—	—	—	(25,050)	(553)	(25,603)
Other comprehensive income, net of tax	—	—	—	—	293	—	—	293	—	293
Balance at March 31, 2021 (unaudited)	95,185,620	95	904,950	(738,694)	(841)	(1,672,920)	(7,406)	158,104	(14,980)	143,124
Sale of common stock	33,373	—	133	—	—	—	—	133	—	133
Issuance of common stock in connection with acquisition of Kuur and settlement of transaction incentive liability assumed	15,601,667	16	58,412	—	—	—	—	58,428	—	58,428
Stock-based compensation cost	—	—	2,387	—	—	—	—	2,387	—	2,387
Restricted stock expense	—	—	57	—	—	—	—	57	—	57
Stock options exercised	160,000	—	727	—	—	—	—	727	—	727
Treasury stock repurchase	—	—	—	—	—	—	(79)	(79)	—	(79)
Net loss	—	—	—	(34,274)	—	—	—	(34,274)	(341)	(34,615)
Other comprehensive loss, net of tax	—	—	—	—	(282)	—	—	(282)	—	(282)
Balance at June 30, 2021 (unaudited)	110,980,660	111	966,666	(772,968)	(1,123)	(1,672,920)	(7,485)	185,201	(15,321)	169,880
Issuance of common stock in connection with Cidal acquisition	11,299	—	—	—	—	—	—	—	—	—
Stock-based compensation cost	—	—	2,450	—	—	—	—	2,450	—	2,450
Restricted stock expense	—	—	199	—	—	—	—	199	—	199
Net loss	—	—	—	(36,057)	—	—	—	(36,057)	(679)	(36,736)
Other comprehensive income, net of tax	—	—	—	—	86	—	—	86	—	86
Balance at September 30, 2021 (unaudited)	110,991,959	$ 111	$ 969,315	$ (809,025)	$ (1,037)	(1,672,920)	$ (7,485)	$ 151,879	$ (16,000)	$ 135,879

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,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (96,954)	$ (98,037)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,668	3,207
Stock-based compensation expense	7,328	8,005
Amortization of debt discount	2,253	1,185
Change in fair value of contingent consideration	3,647	—
Write off of deferred debt issuance costs	648	—
Loss on disposal of assets and impairment charges	112	222
Loss on extinguishment of debt	—	10,278
Deferred income taxes	(10,781)	53
Changes in operating assets and liabilities, net of effect of acquisition:		
Receivables, net	(10,154)	(26,304)
Prepaid expenses and other assets	(393)	11,017
Inventories	(2,731)	3,025
Accounts payable and accrued expenses	(609)	(9,739)
Net cash used in operating activities	(103,966)	(97,088)
Cash flows from investing activities:		
Purchase of property and equipment	(17,196)	(6,710)
Payments for licenses	(1,588)	(83)
Cash acquired from Kuur acquisition	1,425	—
Purchases of short-term investments	(68,672)	(97,956)
Sales and maturities of short-term investments	192,393	46,345
Net cash provided by (used in) investing activities	106,362	(58,404)
Cash flows from financing activities:		
Proceeds from sale of stock	133	126,769
Proceeds from issuance of debt	783	119,897
Proceeds from issuance of warrants	—	7,039
Costs incurred related to the sale of stock	—	(7,590)
Costs incurred related to the issuance of debt and warrants	—	(7,187)
Repurchase of treasury stock	(79)	—
Proceeds from exercise of stock options	1,579	1,165
Investment from non-controlling interest	—	198
Deposits for long-term debt	—	(648)
Repayment of finance lease obligations and long-term debt	(1,064)	(54,315)
Net cash provided by financing activities	1,352	185,328
Net increase in cash, cash equivalents, and restricted cash	3,748	29,836
Cash, cash equivalents, and restricted cash, beginning of period	86,087	127,674
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	259	(201)
Cash, cash equivalents, and restricted cash, end of period (See Note 3)	$ 90,094	$ 157,309
Supplemental cash flow disclosures		
Interest paid	$ 7,715	$ 3,081
Non-cash investing and financing activities:		
Accrued purchases of property and equipment	$ 3,100	$ 948
Accrued purchases of licenses	$ 1,600	$ 2,500
Stock issued in connection with the acquisition of Kuur	$ 52,786	$ —
Fair value of acquisition-related contingent consideration	$ 19,839	$ —
Equipment purchased with capital lease obligation	$ —	$ 581
Accrued cost of debt issuance	$ —	$ 1,425
Accrued cost of stock offering	$ —	$ 280
ROU assets derecognized from modification of operating lease obligations	$ (113)	$ (468)
ROU assets recognized in exchange for operating lease obligations	$ 86	$ —

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

1. Company and Nature of Business

Organization and Description of Business

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

Athenex is a biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. The Company's mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. The Company has assembled a strong and experienced leadership team and has established operations across the pharmaceutical value chain to execute our goal of becoming a leader in bringing innovative cancer treatments to the market and improving health outcomes.

The Company is organized around three operating segments: (1) its Oncology Innovation Platform, dedicated to the research and development of our proprietary drugs; (2) its Commercial Platform, focused on the sales and marketing of our specialty drugs and the market development of our proprietary drugs; and (3) its Global Supply Chain Platform, dedicated to providing a stable and efficient supply of APIs for our clinical and commercial efforts. The Company's current clinical pipeline in the Oncology Innovation Platform is derived from four different technologies: (1) Orascovery, based on a P-glycoprotein ("P-gp") pump inhibitor, (2) Src Kinase Inhibition, (3) Cell Therapy, and (4) Arginine Deprivation Therapy.

The Company is primarily engaged in conducting research and development activities through corporate collaborators, in-licensing and out-licensing pharmaceutical compounds and technology, conducting preclinical and clinical testing, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development and commercialization activities. The Company also conducts commercial sales of specialty products through its wholly owned subsidiary, Athenex Pharmaceutical Division ("APD"), and 503B products through its wholly owned subsidiary, Athenex Pharma Solutions ("APS").

Going Concern

These condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred operating losses since its inception and, as a result, as of September 30, 2021 and December 31, 2020 had an accumulated deficit of $809.0 million and $713.6 million, respectively. As of September 30, 2021, the Company had cash and cash equivalents of $73.6 million, restricted cash of $16.5 million, and short-term investments of $14.9 million. The Company projects insufficient liquidity to fund its operations through the next twelve months beyond the date of the issuance of these condensed consolidated financial statements. This condition raises substantial doubt about the Company's ability to continue as a going concern.

In response to the Company's projected insufficient liquidity, management's plans include seeking additional funding through planned product launches, leveraging the existing sales agreement with SVB Leerink (described below), and/or seeking funding through alternative means. There can be no assurances, however, that additional funding will be available on favorable terms, or at all. Because management's plans have not yet been finalized and are not within the Company's control, such plans cannot be considered probable of being achieved. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

These condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Other Significant Risks and Uncertainties

On August 20, 2021, the Company entered into a sales agreement (the "Sales Agreement") with SVB Leerink LLC, in connection with the offer and sale of up to $100,000,000 of shares of the Company's common stock, par value $0.001 per share ("ATM Shares"). The ATM Shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to a registration statement on Form S-3 (File No. 333-258185) that became effective on August 12, 2021. As of September 30, 2021, the Company had not sold any shares under the Sales Agreement.

In February 2021, the Company received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding the Company's New Drug Application ("NDA") for oral paclitaxel and encequidar ("Oral Paclitaxel") for the treatment of metastatic breast cancer ("mBC"). The FDA issues a CRL to indicate that the review cycle for an application is complete and that the application is not ready for approval in its present form. In the CRL, the FDA indicated its concern of safety risk to patients in terms of an increase in neutropenia-related sequelae on the Oral Paclitaxel arm compared with the IV paclitaxel arm in the Phase III study. The FDA also expressed concerns regarding the uncertainty over the results of the primary endpoint of objective response rate (ORR) at week 19 conducted by blinded independent central review ("BICR"). The FDA stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR. The FDA recommended that Athenex conduct a new adequate and well-conducted clinical trial in a patient population with mBC representative of the population in the U.S. The FDA determined that adequate risk mitigation strategies to improve toxicity, which may involve dose optimization as well as, or in addition to, exclusion of patients deemed to be at higher risk of toxicity, would be required in any new clinical trial of Oral Paclitaxel. During the second quarter of 2021, the Company held a Type A meeting with the FDA. At the meeting, the Company provided additional analyses, including overall survival (OS) data on patient subgroups, to provide a more comprehensive summary of the risk/benefit assessment. The Company also proposed to collect additional OS data that could inform the design of a new clinical study. In October 2021, the Company held another Type A meeting with the FDA, and the purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. After careful consideration of the feedback provided by the FDA, the Company decided that it will not currently be pursuing regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. and determined to redeploy its resources to focus on other ongoing studies of Oral Paclitaxel and its cell therapy platform.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

Results of the Company's operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results expected for the year ending December 31, 2021, or for any other future annual or interim period. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the Securities and Exchange Commission ("SEC") on March 1, 2021.

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 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, measurement of acquired assets and assumed liabilities in business combinations, provision for credit losses, inventory reserves, deferred income taxes, the estimated useful life and recoverability of long-lived assets, and the valuation of stock-based awards and other items as appropriate. Actual results could differ from those estimates.

Credit Losses

The Company estimates and records a provision for its expected credit losses related to its financial instruments, including its trade receivables and contract assets recorded under Financial Accounting Standards Board ("FASB") ASC 606, Revenue from Contracts with Customers ("Topic 606"). The Company considers historical collection rates, current financial status of its customers, macroeconomic factors, and other industry-specific factors when evaluating for current expected credit losses. Forward-looking information is also considered in the evaluation of current expected credit losses. However, because of the short time to the expected receipt of accounts receivable and contract assets, the Company believes that the carrying value, net of excepted losses, approximates fair value and therefore, relies more on historical and current analysis of such financial instruments.

Business Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Identifiable amortizing intangible assets are recorded on the consolidated balance sheet at fair value and amortized over their estimated useful lives. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as goodwill.

Contingent Consideration

Contingent consideration arising from a business acquisition is included as part of the purchase price and is recorded at fair value as of the acquisition date. Subsequent to the acquisition date, the Company remeasures contingent consideration arrangements at fair value at each reporting period until the contingency is resolved. The changes in fair value are recognized within selling, general, and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Government Grant Income

In connection with the partnership with the State of New York (the "State") to construct an ISO Class 5 high potency oral and sterile injectable pharmaceutical manufacturing facility in Dunkirk, New York, the Company has received funds from the State as reimbursement for certain operating expenses incurred related to such construction. Grants related to income are presented as part of the condensed consolidated statements of operations and are to be recognized when (1) the Company is eligible to receive the grant, and (2) the Company is able to comply with the relevant conditions of the grant. During the three and nine months ended September 30, 2021, the Company received and recognized $2.5 million of government grant income within income from government grant on its condensed consolidated statements of operations and comprehensive loss related to the arrangement with the State. No such amounts were recognized during the three or nine months ended September 30, 2020.

Concentration of Credit Risk, Other Risks and Uncertainties

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

3. Restricted Cash

The Company had a restricted cash balance of $16.5 million as of September 30, 2021 and December 31, 2020 held in a controlled bank account in connection with the Company's senior secured loan agreement and related security agreements (the "Senior Credit Agreement") with Oaktree Fund Administration, LLC, as administrative agent, and the lenders party thereto (collectively, "Oaktree"). The Senior Credit Agreement requires the Company to maintain, in a debt service reserve account, a minimum cash balance equal to twelve months of interest on the outstanding loans under the Senior Credit Agreement.

4. Inventories

Inventories consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials and purchased parts	$ 3,659	$ 6,498
Work in progress	4,291	776
Finished goods	23,627	21,572
Total inventories	$ 31,577	$ 28,846

5. Business Combination

On May 4, 2021, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Kuur Therapeutics, Inc., a Delaware corporation ("Kuur") whereby it acquired 100% of the outstanding shares of Kuur (the "Merger"). Under the terms of the Merger Agreement, the Company's wholly owned subsidiary, Athenex Pharmaceuticals LLC, a Delaware limited liability company, merged with and into Kuur, with Kuur surviving as a wholly owned subsidiary of the Company. Kuur is a leading developer of off-the-shelf CAR-NKT cell immunotherapies for the treatment of solid and hematological malignancies. The Company believes the acquisition strategically combines its TCR program with the groundbreaking NKT cell platform to provide a solution that may address some of the known limitations associated with the first generation of cell therapy treatments focused on autologous CAR-T.

Pursuant to the Merger Agreement, an upfront fee of $70.0 million was paid to Kuur shareholders and its former employees and directors, comprised primarily of equity in the Company's common stock. Additionally, Kuur shareholders and its former employees and directors are eligible to receive up to $115.0 million of milestone payments, which may be paid, at the Company's sole discretion, in either cash or additional common stock of the Company (or a combination of both).

The Company identified the Merger as a business combination pursuant to ASC 805 and used the acquisition method of accounting to account for the transaction. The purchase price, after adjusted for closing conditions, consisted of 14,228,066 shares of the Company's common stock issued at $3.71 per share with a fair value of $52.8 million, plus the fair value of the future milestone payments amounting to $19.8 million, recorded as contingent consideration. The Company recorded the fair value of this contingent consideration as a liability based on the probabilities of Kuur achieving the milestones and the present value of such payments. These inputs are not observable in the market and therefore are considered Level 3 inputs.

The Company estimated fair values on May 4, 2021 for the preliminary allocation of consideration to the net tangible and intangible assets acquired and liabilities assumed in connection with the Merger. During the measurement period, the Company will continue to obtain information to assist in finalizing the fair value of assets acquired and liabilities assumed, which may differ materially from these preliminary estimates. If any measurement period adjustments are material, those adjustments, including any related impacts to net income, will be applied in the reporting period in which the adjustments are determined. The Company is in the process of conducting a valuation of the assets acquired and liabilities assumed, most notably, the in-process research & development and contingent consideration, and the final allocation will be made when completed, including the result of any identified goodwill. Accordingly, the provisional measurements noted below are preliminary and subject to modification in the future. During the three months ended September 30, 2021, the Company recorded a measurement period adjustment to reflect the estimated fair value of in-process research and development ("IPR&D"), as a result of changes in the underlying assumptions, including projected expenses and the estimated discount rate. This measurement period adjustment resulted in the increase of IPR&D of $1.4 million, a decrease in the deferred tax liability assumed of $0.2 million, and a decrease in goodwill of $1.6 million from the initial measurement reported as of June 30, 2021. To estimate the preliminary fair value of the identifiable intangible assets acquired, the Company used projected discounted cash flow method, which requires assumptions of projected revenues and expenses and an estimated discount rate, among other inputs, each of which is not observable in the market and thus are considered Level 3 inputs. The Company assumed $8.9 million of transaction incentive liability to Kuur's key employees and independent company directors, of which $3.3 million was paid in cash and $5.6 million was paid in 1,373,601 shares of the Company's common stock at $4.11 per share. The following table summarizes the purchase price and the initial estimates of the fair values of assets and liabilities acquired at the date of acquisition (in thousands):

Preliminary Allocation of Consideration:		
Stock issued (14,228,066 shares at $3.71)	$	52,786
Contingent consideration		19,839
Purchase price:	$	72,625
Net assets acquired:		
Cash and cash equivalents	$	1,425
Prepaid expenses and other current assets		133
In-process research & development		64,900
Accounts payable		(39)
Accrued expenses		(1,037)
Deferred income tax liability		(12,543)
Transaction incentive liability		(8,925)
Total identifiable net assets		43,914
Goodwill		28,711
Total purchase price allocation	$	72,625

Goodwill in the amount of $28.7 million was recorded for the excess of the purchase price over the fair value of the assets acquired and liabilities assumed. The goodwill recorded in connection with this acquisition is not deductible for income tax purposes. A deferred tax liability in the amount of $12.5 million was recorded related to the future taxable income as a result of the book to tax basis difference arising from the IPR&D.

The fair value of the acquired IPR&D relates to two products, including (a) an allogenic product in which NKT cells are engineered with a CAR targeting CD19, and (b) an allogenic product in which NKT cells are engineered with a CAR targeting GPC3. These IPR&D projects were valued using an income approach, specifically a projected discounted cash flow method, adjusted for the probability of technical success (PTS). The projected discounted cash flow models used to estimate the Company's IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset including the following:

- Estimates of potential cash flows to be generated by the project and resulting asset, which was developed utilizing estimates of total patient population, market penetration rates, demand risk adjustment factors, and product pricing;
- Estimates regarding the timing of and the expected cost of goods sold, research and development expenses, selling, general, and administrative expenses to advance the clinical programs to commercialization;
- Estimates of profit sharing and cash flow adjustments;

- The projected cash flows were then adjusted using PTS factors that were selected considering both the current state of development and the nature of the proposed indication; and
- Finally, the resulting probability-adjusted cash flows were discounted to present value using a risk-adjusted discount rate, developed considering the market risk present in the forecast and the size of the asset.

This acquisition was made to benefit the Company's R&D efforts, providing synergies with other assets in the Company's pipeline and therefore, is included in the Oncology Innovation Platform. The operating results of Kuur have been included within the Company's Oncology Innovation Platform operating segment from the date of acquisition. Kuur added revenue of $0 for the three and nine months ended September 30, 2021 and contributed a net loss of $2.5 million and $3.0 million for the three and nine months ended September 30, 2021, respectively.

Acquisition-related costs, including legal, regulatory, and consulting costs, amounted to $3.5 million, and are included within selling, general, and administrative expenses in the Company's consolidated statement of operations and comprehensive loss.

Unaudited Pro Forma Financial Results

The following table presents supplemental unaudited pro forma information for the acquisition as if it had occurred on January 1, 2020. The unaudited pro forma financial results for the three and nine months ended September 30, 2021 include the following adjustments: (1) removal of direct acquisition-related costs which would not have been incurred had the businesses been owned on the beginning of the prior reporting period, (2) the deferred tax effect if the intangible assets and purchase accounting were recorded as of the beginning of the prior reporting period, and (3) the removal of the change in fair value of Kuur convertible debt which was converted prior to the consummation of the acquisition. The pro forma results do not include any anticipated synergies or other expected benefits of the acquisitions. The unaudited pro forma financial information is for informational purposes only and is not necessarily indicative of either future results of operations of the combined entity or results that might have been achieved had the acquisitions been consummated as of the beginning of the prior reporting period. The following table presents the unaudited pro forma consolidated financial information for the three and nine months ended September 30, 2021 (in thousands):

Unaudited pro forma financial information (Athenex and Kuur Consolidated)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Consolidated revenue	$ 32,297	$ 35,476	$ 95,245	$ 123,633
Consolidated net loss	$ (36,057)	$ (38,410)	$ (94,254)	$ (93,912)

6. Intangible Assets, net

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

	September 30, 2021			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	$ 13,179	$ 6,610	$ —	$ 6,569
Polymed customer list	1,593	1,579	—	14
Polymed technology	3,712	1,880	—	1,832
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	728	—	—	728
Kuur IPR&D	64,900	—	—	64,900
Effect of currency translation adjustment	(156)	—	—	(156)
Total intangible assets, net	$ 83,956	$ 10,069	$ —	$ 73,887

	December 31, 2020			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets				
Licenses	$ 12,641	$ 5,157	$ —	$ 7,484
Polymed customer list	1,593	1,418	—	175
Polymed technology	3,712	1,685	—	2,027
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	728	—	—	728
Effect of currency translation adjustment	(196)	—	—	(196)
Total intangibles, net	$ 18,478	$ 8,260	$ —	$ 10,218

In connection with the acquisition of Kuur, the Company identified three drug candidate projects and two were classified as IPR&D and recorded at their fair value on the acquisition date. Included in the IPR&D is the historical know-how, cell treatment protocols, and procedures expected to be needed to complete the related phase of testing. The fair value of IPR&D was determined for each project, or unit of account, using unobservable, level 3 inputs (*see Note 5—Business Combination*). IPR&D intangible assets are not amortized, but rather are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed, abandoned, or transferred to a third party.

As of September 30, 2021, licenses at cost include an Orascovery license of $0.4 million, licenses purchased from Gland Pharma Limited (“Gland”) of $4.4 million, a license purchased from MAIA Pharmaceuticals, Inc. (“MAIA”) for $4.0 million, licenses purchased from Ingenus Pharmaceuticals, LLC (“Ingenus”) for $3.0 million, and licenses of other specialty products of $0.9 million. The Orascovery license with Hanmi Pharmaceuticals Co. Ltd. (“Hanmi”) was purchased directly from Hanmi and is being amortized on a straight-line basis over a period of 12.75 years, the remaining life of the license agreement at the time of purchase. The licenses purchased from Gland are being amortized on a straight-line basis over a period of 5 years, the remaining life of the license agreement at the time of purchase. The license purchased from MAIA is being amortized over a period of 7 years, the remaining life of the license agreement at the time of purchase. Of the $3.0 million licenses purchased from Ingenus, a $2.0 million license is being amortized over a period of 5 years, the estimated useful life of the license agreement and a $1.0 million license purchased from Ingenus is being amortized over a period of 3 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 Polymed Therapeutics, Inc. (“Polymed”) and Comprehensive Drug Enterprises (“CDE”). Intangible assets are amortized using an economic consumption model over their useful lives. The Polymed customer list and technology are amortized on a straight-line basis over 6 and 12 years, respectively. The CDE IPR&D will not be amortized until the related projects are completed. IPR&D is tested annually for impairment, unless conditions exist causing an earlier impairment test (e.g., abandonment of project). The Company recorded no impairment of IPR&D during the nine months ended September 30, 2021. The weighted-average useful life for all intangible assets was 6.5 years as of September 30, 2021.

The Company recorded $0.4 million and $0.5 million of amortization expense for the three-month periods ended September 30, 2021 and 2020, respectively, and $1.5 million and $1.4 million of amortization expense for the nine-month periods ended September 30, 2021 and 2020, respectively.

The Company’s goodwill balance is the result of current and prior period acquisitions and is allocated to the Global Supply Chain Platform reporting unit and the Oncology Innovation Platform reporting unit. Changes in goodwill balances reported within the unaudited condensed consolidated balance sheet as of September 30, 2021 are due to acquisition of Kuur on May 4, 2021, contributing goodwill of $30.3 million, and the effect of foreign currency on goodwill from acquisitions of subsidiaries that have a functional currency other than USD.

During the first quarter of 2021, due to the significant decrease in its market capitalization, the Company evaluated the impact on each of its reporting units to assess whether there was a triggering event requiring it to perform a goodwill impairment test (ASC350-20-35). The Company determined a triggering event occurred and, as such, performed an interim goodwill quantitative impairment test for its reporting units. It also considered certain qualitative factors, such as the Company's performance, business forecasts, and expansion plans. It reviewed key assumptions, including revisions of projected cash flows and future revenue for reporting units against the results of the annual quantitative impairment test performed during the last quarter of 2020. Using both the income approach and the market approach for its Global Supply Chain Platform and Oncology Innovation Platform, with the discount rate selected considering and capturing the related risk associated with the forecast, the Company compared the fair value of the two reporting units to carrying value. Based on the results, the fair value of each of our reporting units exceeded their carrying value and the goodwill was not impaired. However, there can be no assurances that goodwill will not be impaired in future periods. Estimating the fair value of goodwill requires the use of estimates and significant judgments that are based on a number of factors. These estimates and judgments may not be within the control of the Company and accordingly it is reasonably possible that the judgments and estimates could change in future periods.

7. Fair Value Measurements

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

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

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

Level 2—Inputs to the valuation methodology include:

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

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

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

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

	Fair Value Measurements at September 30, 2021 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 5,084	$ 5,084	$ —	$ —
Short-term investments - U.S. government bonds	7,800	—	7,800	—
Short-term investments - commercial paper	33,499	—	33,499	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	14,702	—	14,702	—
Available-for-sale investment	216	216	—	—
Total assets	$ 61,301	$ 5,300	$ 56,001	$ —
Liabilities:				
Contingent consideration - Kuur	$ 23,486	$ —	$ —	$ 23,486
Total liabilities	$ 23,486	$ —	$ —	$ 23,486

	Fair Value Measurements at December 31, 2020 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Financial assets included within cash and cash equivalents				
Money market funds	$ 5,615	$ 5,615	$ —	$ —
Short-term investments - certificates of deposit	4,070	—	4,070	—
Short-term investments - U.S. government bonds	5,000	—	5,000	—
Short-term investments - commercial paper	34,860	—	34,860	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	20,696	—	20,696	—
Short-term investments - U.S. government bonds	14,998	—	14,998	—
Short-term investments - commercial paper	102,715	—	102,715	—
Available-for-sale investment	227	227	—	—
Total assets	$ 188,181	$ 5,842	$ 182,339	$ —

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

The Company owns 68,000 shares of PharmaEssentia, a company publicly traded on the Taiwan OTC Exchange. As of September 30, 2021 and December 31, 2020, the Company's investment in PharmaEssentia was valued at the reported closing price on such dates. This investment is classified as a Level 1 investment and is recorded as an available-for-sale investment within short-term investments on the Company's condensed consolidated balance sheets.

The Company accounted for the acquisition of Kuur as business combinations under the acquisition method of accounting. All assets and liabilities were measured at fair value as of the acquisition date. As a result of the purchases, the Company became liable for contingent consideration payable to certain previous owners of Kuur. This contingent consideration is measured at fair value using unobservable level 3 inputs, including (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the regulatory events on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases (decreases) in any of those inputs could result in a lower or higher fair value measurement, and such changes in fair value measurement could have an impact on future earnings. The total undiscounted amount of the milestone payments underlying this liability is $115.0 million. These payments are contingent on the achievement of various regulatory milestones which are expected to occur between 2022 and 2027, and may be paid, at the Company's sole discretion, in either cash or common stock (or a combination of both). The milestone payments have been adjusted based on a probability of occurrence of 31.9%, and the discount rates used to calculate the present value of future payments were based on risk-free rates plus risk-adjusted spreads based on the Company's estimated incremental borrowing rate and was between 13.79% and 15.07% for the valuation of the contingent consideration as of September 30, 2021. The acquisition of Kuur is described in Note 5—*Business Combination* and the fair value of the contingent consideration is discussed further in Note 11 – *Contingent Consideration*.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued selling fees, rebates, and royalties	$ 9,184	$ 9,046
Accrued wages and benefits	7,605	6,720
Accrued clinical expenses	5,530	2,949
Accrued interest	4,374	3,583
Accrued operating expenses	3,944	3,222
Accrued inventory purchases	3,357	3,714
Deferred revenue	3,213	1,147
Accrued tax withholdings	1,653	1,948
Accrued construction costs	1,000	4,104
Accrued R&D licensing fees	266	366
Accrued costs for product launch	—	1,474
Total accrued expenses	$ 40,126	$ 38,273

The accrued construction costs relate to the building of the manufacturing facility in Dunkirk, NY. This amount is expected to be funded by New York State and is recorded within prepaid expenses and other current assets on the Company's condensed consolidated balance sheet as of September 30, 2021.

9. Income Taxes

The Company did not record a provision for U.S. federal income taxes for the nine months ended September 30, 2021 because it expects to generate a loss for the year ending December 31, 2021 and the Company's net deferred tax assets continue to be fully offset by a valuation allowance. Income tax benefit for the nine months ended September 30, 2021 is primarily the result of the taxable temporary difference due to the deferred tax liability recognized for the indefinite lived intangible assets acquired in connection with the acquisition of Kuur's IPR&D. This taxable temporary difference is considered a source of taxable income to support the realization of deferred tax assets from the acquirer which resulted in a reversal of the Company's valuation allowance.

Under the provisions of Section 382 of the Internal Revenue Code ("IRC"), net operating loss and credit carryforwards and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the IRC. During the nine months ended September 30, 2021, the Company experienced such a change in ownership of its common stock. Currently, the limitations imposed by Sections 382 are not expected to impair the Company's ability to fully realize its net operating losses ("NOL"); however, the annual usage of NOLs incurred prior to the change in ownership is limited. In addition, if the Company earns net taxable income in the future, its ability to use the pre-change net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to the Company.

10. Debt and Lease Obligations

Debt

The Company's debt as of September 30, 2021 and December 31, 2020, consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Current portion of mortgage	$ 740	$ 731
Current portion of bank loan	774	764
Current portion of senior secured loan and financing fees	5,660	70
Current portion of finance lease obligations	313	445
Current portion of operating lease obligations	3,044	3,185
Long-term portion of finance lease obligations	379	537
Long-term portion of operating lease obligations	4,753	6,355
Chongqing Maliu credit agreement	7,736	7,641
Senior secured loan, net of debt discount and financing fees of $9,348 and $11,601 respectively	134,992	138,399
Total	$ 158,391	$ 158,127

Senior Credit Agreement

On June 19, 2020 ("Closing Date"), the Company entered into the Senior Credit Agreement with Oaktree to borrow up to $225.0 million in five tranches, with a maturity date of June 19, 2026. Three tranches ("Tranche A", "Tranche B", and "Tranche D") of the term loans with an aggregate principal amount of $150.0 million were drawn by the Company in 2020. One tranche ("Tranche C") of $25.0 million will be available to the Company from 90 days after the Closing Date through June 20, 2022, subject to the Company's satisfaction of a certain regulatory milestone; and the last tranche of $50.0 million ("Tranche E") will be available to the Company from 90 days after the Closing Date through June 19, 2023, also subject to the Company's satisfaction of a certain commercial milestone. Based on the Company's recent decision to not pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S., the Company does not expect to be eligible to borrow under Tranche C or Tranche E of the Senior Credit Agreement. The loan bears interest at a fixed annual rate of 11.0%. The Company allocated the proceeds of the drawn tranches between liability and equity components and the fair value of such equity components, along with the direct costs related to the issuance of the debt were recorded as an offset to long-term debt on the consolidated balance sheets. The debt discount and financing fees are amortized on a straight-line basis, which approximates the effective interest method, over the remaining maturity of the Senior Credit Agreement. The effective interest rate of Tranches A, B and D, including the amortization of debt discount and financing fees amounts to 13.3% annually. The Company is required to make quarterly interest-only payments until June 19, 2022, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity. Beginning on September 17, 2020, the Company was required to pay a commitment fee on any undrawn commitments equal to 0.6% per annum, payable on each subsequent funding date or the commitment termination date. Prepayments of the loan, in whole or in part, will be subject to early prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. Upon the final payment, the Company must also pay an exit fee calculated based on a percentage of the aggregate principal amount of all tranches advanced to the Company, and as of September 30, 2021 and December 31, 2020, the Company has reflected a long-term exit fee liability of $3.0 million within long-term debt and finance lease obligations on the consolidated balance sheet.

The Senior Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants and conditions that were customarily required for similar financings. The Company is subject to certain financial covenants under the Senior Credit Agreement, including (1) a minimum liquidity amount in cash or permitted cash equivalent investments of $20.0 million from the closing date until the date on which the aggregate principal amount of loans outstanding is greater than or equal to $150.0 million (the "First Step-Up Date"), $25.0 million from the First Step-Up Date until the date on which the aggregate principal amount of loans outstanding balance is equal to $225.0 million (the "Second Step-Up Date"), and $30.0 million from the Second Step-up Date until the maturity date; (2) minimum revenue no less than 50% of target revenue beginning with the fiscal quarter ended on December 31, 2020 and with respect to each such subsequent fiscal quarter prior to the revenue covenant termination date; (3) leverage ratio covenant not to exceed 4.50 to 1.00 as of the last day of any fiscal quarter beginning with the first fiscal quarter following the revenue covenant termination date. At September 30, 2021, the Company was in compliance with all applicable debt covenants.

Revenue Interest Financing Agreement

On August 4, 2020, the Company entered into a Revenue Interest Financing Agreement with Sagard Healthcare Royalty Partners, LP ("Sagard"), pursuant to which Sagard agreed to pay the Company $50.0 million to provide funding for the Company's development and commercialization of Oral Paclitaxel upon receipt of marketing authorization for Oral Paclitaxel by the U.S. FDA for the treatment of mBC. In the event the Company is unable to do so before December 31, 2021, Sagard will have a termination right. The Company believes that it is unlikely that it will be able to obtain marketing authorization for Oral Paclitaxel by the U.S. FDA and draw funds from the Revenue Interest Financing, due to the results of the Type A meeting with the FDA. Therefore, the Company wrote off its deferred debt issuance costs related to the Revenue Interest Financing for $0.6 million during the three months ended June 30, 2021, and has included such expense within interest expense on its condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2021. No such expenses were recorded during the three months ended September 30, 2021.

Credit Agreements, Bank Loan and Mortgage

During the second quarter of 2019, the Company entered into a credit agreement which amended the existing partnership agreement with Chongqing Maliu Riverside Development and Investment Co., LTD ("CQ"), for a Renminbi ¥50.0 million (USD $7.7 million at December 31, 2020) line of credit to be used for the construction of the new API plant in China. The Company is required to repay the principal amount with accrued interest within three years after the plant receives the cGMP certification, with 20% of the total loan with accrued interest due within the first twelve months following receiving the certification, 30% of the total loan with accrued interest due within twenty-four months, and the remaining balance with accrued interest due within thirty-six months. Interest accrues at the three-year loan interest rate by the People's Bank of China for the same period on the date of the deposit of the full loan amount, which is expected to approximate 4.75% annually. If the Company fails to obtain the cGMP certification within three years upon the acceptance of the plant, it shall return all renovation costs with the accrued interest to CQ in a single transaction within the first ten business days. As of September 30, 2021, the balance due to CQ was $7.7 million.

On May 15, 2020, the Company entered into a credit agreement with China Merchants Bank, enabling the Company to draw up to Renminbi ¥5.0 million (USD $0.8 million at September 30, 2021) during the period through May 14, 2021. The Company drew the entire available credit in July 2020 and repaid the credit agreement in full on May 14, 2021. On May 28, 2021, the Company entered into a credit agreement on the same terms as that which was repaid, and withdrew the full Renminbi ¥5.0 million (USD $0.8 million at September 30, 2021) on that date. This loan has a maturity date of May 28, 2022 and bears interest at a fixed rate of 4.35% annually. The Company is required to pay the outstanding principal and all accrued interest at maturity.

The mortgage payments, assumed in connection with the acquisition of CDE, extend through December 31, 2021.

Lease Obligations

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 748	$ 774	$ 2,241	$ 2,300
Finance lease cost:				
Amortization of assets	75	66	224	164
Interest on lease liabilities	20	20	66	46
Total net lease cost	$ 843	$ 860	$ 2,531	$ 2,510

The Company has elected to exclude short-term leases from its operating lease right-of-use ("ROU") assets and lease liabilities. Lease costs for short-term leases were not material to the financial statements for the three months ended September 30, 2021 and 2020. Variable lease costs for the three months ended September 30, 2021 were not material to the financial statements.

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

	September 30, 2021	December 31, 2020
Finance leases:		
Property and equipment, at cost	$ 1,535	$ 1,535
Accumulated amortization, net	(509)	(347)
Property and equipment, net	$ 1,026	$ 1,188
Current obligations of finance leases	$ 313	$ 445
Long-term portion of finance leases	379	537
Total finance lease obligations	$ 692	$ 982
Weighted average remaining lease term (in years):		
Operating leases	3.68	4.23
Finance leases	2.38	3.40
Weighted average discount rate:		
Operating leases	12.8%	12.8%
Finance leases	9.7%	10.4%

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

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Cash paid for amount included in the measurements of lease liabilities:		
Operating cash flows from operating leases	$ (2,569)	$ (2,419)
Operating cash flows from finance leases	(66)	(46)
Financing cash flows from finance leases	(285)	(195)
ROU assets derecognized from modification of operating lease obligations	(113)	(468)
ROU assets recognized in exchange for operating lease obligations	$ 86	$ -

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

Year ending December 31:	Operating Leases	Finance Leases
2021 (remaining three months)	$ 849	$ 117
2022	2,895	275
2023	2,088	247
2024	2,002	177
2025	1,472	—
Thereafter	479	—
Total lease payments	9,785	816
Less: Imputed interest	(1,988)	(124)
Total lease obligations	7,797	692
Less: Current obligations	(3,044)	(313)
Long-term lease obligations	$ 4,753	$ 379

Pursuant to the public-private partnership agreements with the State of New York, the Company will rent the manufacturing facilities in Dunkirk, NY. The facility is in the final stage of completion and is not yet operational. No lease costs were incurred related to the manufacturing facility during the three-month period ended September 30, 2021. As of October 1, 2021, the Company entered into a lease for the facilities in Dunkirk, NY (see Note 18—*Subsequent Events*).

On January 5, 2021, Chongqing Sintaho Pharmaceuticals Co., Ltd. ("CQ Sintaho"), a subsidiary of the Company in China, entered into a lease agreement with Chongqing International Biological City Development & Investment Co., Ltd ("CQ D&I"). Under the lease agreement, the provisions of which are consistent with those agreed upon in the 2015 Agreement, CQ Sintaho leased the newly constructed API facility, or Sintaho API Facility, of 34,517 square meters rent-free, for the first 10-year term, with an option to extend the lease for an additional 10-year term, during which, if CQ Sintaho is profitable, it will pay a monthly rent of 5 RMB per square meter of space occupied. The Company determined the lease commenced in the first quarter of 2021, as it was operational and CQ Sintaho could direct the use of the facility. The Company also evaluated the probability of exercising the renewal and purchase options, and determined that it is not reasonably certain whether it will exercise those options. Therefore, the lease term is comprised only of the rent-free period and the recognition of the right-of-use asset and liability did not have a significant effect on the Company's consolidated financial statements.

The Company exercises judgment in determining the discount rate used to measure the lease liabilities. When rates are not implicit within an operating lease, the Company uses its incremental borrowing rate as its discount rate, which is based on yield trends in the biotechnology and healthcare industry and debt instruments held by the Company with stated interest rates. The Company re-assesses its incremental borrowing rate when new leases arise, or existing leases are modified.

11. Contingent Consideration

The fair value measurements of contingent consideration liabilities are determined using unobservable Level 3 inputs. These inputs include (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases (decreases) in any of those inputs could result in a lower or higher fair value measurement. The Company expects that these milestones will be achieved at varying times between 2022 and 2027.

The following table represents a reconciliation of the contingent consideration liability related to the acquisition of Kuur measured on a recurring basis using level 3 inputs as of September 30, 2021 (in thousands):

Balance as of May 4, 2021	$	19,839
Adjustment to fair value		3,647
Balance as of September 30, 2021	$	23,486

The increase of the contingent consideration was due to the time value of money from the initial measurement date (Kuur acquisition date) to September 30, 2021, as well as updated probabilities of future cash flows related to R&D milestones. The adjustment to the contingent consideration liability is included within selling, general, and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive loss.

12. Related Party Transactions

During the nine months ended September 30, 2021 and 2020, the Company entered into transactions with individuals and companies that have financial interests in the Company. Related party transactions included the following:

a. In June 2018, the Company entered into two in-licensing agreements with Avalon BioMedical (Management) Limited and its affiliates ("Avalon") wherein the Company obtained certain IP from Avalon to develop and commercialize the underlying products. Under these agreements the Company is required to pay upfront fees and future milestone payments and sales-based royalties. During the three and nine months ended September 30, 2021 and 2020, no fees were paid to Avalon in connection with the license agreements. Certain members of the Company's board and management collectively have a controlling interest in Avalon. The Company does not hold any interest in Avalon and does not have any obligations to absorb losses or any rights to receive benefits from Avalon. As of September 30, 2021, and December 31, 2020, Avalon held 786,061 shares of the Company's common stock, which represented approximately 1% of the Company's total issued shares for both periods. Balances due from Avalon recorded on the condensed consolidated balance sheets were not significant. In July 2021, the Company made $2.0 million milestone payment to Avalon pursuant to its license agreement.

In June 2019, the Company entered into an agreement whereby Avalon would hold a 90% ownership interest and the Company would hold a 10% ownership interest of the newly formed entity under the name Nuwagen Limited ("Nuwagen"), incorporated under the laws of Hong Kong. Nuwagen is principally engaged in the development and commercialization of herbal medicine products for metabolic, endocrine, and other related indications. The Company contributed nonmonetary assets in exchange for the 10% ownership interest. In July 2020, the transaction closed. The activities of Nuwagen were not material to the financial statements for the three or nine months ended September 30, 2021 or the three months ended September 30, 2020.

b. The Company earns licensing revenue from PharmaEssentia, an entity in which the Company has an investment classified as available-for-sale (see Note 7—*Fair Value Measurements*). During the nine months ended September 30, 2021, the Company recorded $0.5 million milestone fee earned from PharmaEssentia under a license agreement. The Company did not earn any licensing revenue from PharmaEssentia in the three months ended September 30, 2021. The Company recorded $1.0 million milestone fee earned during the three and nine months ended September 30, 2020. There were no funds paid to PharmaEssentia under the cost-sharing agreements for the three and nine months ended September 30, 2021. Funds paid to PharmaEssentia under the license and cost-sharing agreements amounted to $0.1 million and $0.4 million for the three and nine months ended September 30, 2020, respectively.

   In September 2020, Axis Therapeutics Limited ("Axis"), a majority-owned subsidiary of the Company, entered into a collaboration agreement with PharmaEssentia, pursuant to which Axis granted to PharmaEssensia an exclusive, non-transferrable and revocable sublicense of TCR-engineered T-Cell therapy for the development of the technology in Taiwan. Axis received license fees of $1.0 million, net of $0.3 million withholding tax, in each of the fourth quarter of 2020 and the third quarter of 2021. These fees, amounting to $2.0 million, were recorded as deferred revenue as of September 30, 2021.

c. In April 2013, the Company entered into a license agreement with ZenRx Limited ("ZenRx"), a company for which one of the Company's executive officers serves on the board of directors, pursuant to which the Company granted an exclusive, sublicensable license to use certain of the Company's IP to develop and commercialize oral irinotecan and encequidar ("Oral Irinotecan"), and Oral Paclitaxel in Australia and New Zealand, and a non-exclusive license to manufacture a certain compound, but only for use in Oral Irinotecan and Oral Paclitaxel. ZenRx is responsible for all development, manufacturing and commercialization, and the related costs and expenses, of any product candidates resulting from the agreement. No revenue was earned from this license agreement in the periods presented in these consolidated financial statements.

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

13. Stock-Based Compensation

Common Stock Option Plans

The Company has four equity compensation plans, adopted in 2017, 2013, 2007 and 2004 (the "Plans") which, taken together, authorize the grant of up to 16,000,000 shares of common stock to employees, directors, and consultants. On May 23, 2019, the board of directors approved the amendment and restatement of the 2017 Omnibus Incentive Plan (the "2017 Plan"), which increases the number of shares available for issuance under the 2017 Plan by up to 3,500,000 shares, which was approved by the Company's stockholders at the Company's 2020 annual meeting of stockholders. On April 26, 2021, the board of directors approved an amendment to the 2017 Plan, which increases the number of shares available for issuance under the 2017 Plan by 5,000,000 shares, which was approved by the Company's stockholders at the Company's 2021 annual meeting of stockholders. The Company also has an employee stock purchase plan, the 2017 Employee Stock Purchase Plan (the "ESPP"), adopted on June 14, 2017, which authorizes the issuance of up to 1,000,000 shares of common stock for future issuances to eligible employees.

Stock Options

The total fair value of stock options vested and recorded as compensation expense during the three months ended September 30, 2021 and 2020, and nine months ended September 30, 2021 and 2020 was $2.4 million, $2.5 million, $6.9 million, and $7.0 million, respectively. As of September 30, 2021, $14.1 million of unrecognized cost related to non-vested stock options was expected to be recognized over a weighted-average period of approximately 1.7 years. The total intrinsic value of options exercised was approximately $0.2 million and $1.1 million for the nine months ended September 30, 2021 and 2020, respectively.

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

	Stock Options	Weighted-Average Exercise price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	12,496,888	$ 9.26	5.42	$ 22,463
Granted	889,095	3.87	—	—
Exercised	(279,425)	5.64	—	—
Forfeited and expired	(287,674)	8.61	—	—
Outstanding at September 30, 2021	12,818,884	$ 9.00	5.16	$ —
Vested and exercisable at September 30, 2021	9,662,986	$ 8.50	4.09	$ —

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

	Nine Months Ended September 30,	
	2021	2020
Weighted average grant date fair value	$ 3.87	$ 6.93
Expected dividend yield	—%	—%
Expected stock price volatility	68%	67%
Risk-free interest rate	1.27%	0.92%
Expected life of options (in years)	6.2	6.2

Restricted Stock Awards

The Company granted 860,595 restricted stock units with a weighted-average fair value of $3.68 per share during the three months ended September 30, 2021 and 908,595 restricted stock units with a weighted-average fair value of $3.73 per share during the nine months ended September 30, 2021. No restricted stock awards were granted during the three or nine months ended September 30, 2020. Stock-based compensation related to the restricted stock awards amounted to $0.2 million for each of the three months ended September 30, 2021 and 2020, and $0.3 million and $1.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, $3.4 million of unrecognized cost related to non-vested restricted stock awards were expected to be recognized over a weighted-average period of approximately 2.3 years.

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 June 1, 2021 to November 30, 2021. The Company expects to offer six-month offering periods after the current period. The ESPP reserved 1,000,000 shares of common stock for issuance under the ESPP. Stock-based compensation related to the ESPP amounted to less than $0.1 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively, and $0.1 million and $0.3 million for the nine months ended September 30, 2021 and 2020, respectively.

Stock-Based Compensation Cost

The components of stock-based compensation and the amounts recorded within cost of sales, 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, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	$ 2,426	$ 2,513	$ 6,926	$ 7,017
Restricted stock expense	199	178	285	988
Employee stock purchase plan	24	169	116	239
Total stock-based compensation expense	$ 2,649	$ 2,860	$ 7,327	$ 8,244
Cost of sales	$ 47	$ 64	$ 161	$ 173
Research and development expenses	795	934	2,067	2,892
Selling, general, and administrative expenses	1,807	1,862	5,099	5,179
Total stock-based compensation expense	$ 2,649	$ 2,860	$ 7,327	$ 8,244

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

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options and other common stock equivalents	13,839,655	13,039,431	13,609,426	12,400,738
Unvested restricted shares	362,275	50,750	147,025	76,750
Total potential dilutive shares	14,201,930	13,090,181	13,756,451	12,477,488

15. Business Segment, Geographic, and Concentration Risk Information

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

Oncology Innovation Platform— This operating segment performs research and development on certain of the Company's proprietary drugs, from the preclinical development of its chemical compounds, to the execution and analysis of its several clinical trials. It focuses specifically on cell therapy programs, Orascovery and Src Kinase Inhibition research platforms, and arginine deprivation therapy.

Global Supply Chain Platform— This operating segment includes APS and Polymed and the construction of the manufacturing facilities in Chongqing, China, and Dunkirk, NY. APS is a manufacturing company that supplies sterile injectable drugs to hospital pharmacies across the U.S. APS manufactures products under Section 503B of the Compounding Quality Act within the Federal Food, Drug & Cosmetic Act ("FDCA"). Additionally, APS provides products for the development and manufacturing of the Company's proprietary drug candidates as well as providing the Company with a cGMP analytical services function. Polymed is primarily in the business of marketing and selling API in North America, Europe, and Asia from its locations in Texas and China. Polymed also develops new compounds and processing techniques and is in the final phase of completion of the new API manufacturing facility in Chongqing, China.

Commercial Platform— This operating segment includes APD, which focuses on the manufacturing, distribution, and sales of specialty pharmaceuticals, and Athenex Oncology, which focus on the manufacturing, distribution, and sales of specialty pharmaceuticals and the pre-launch commercial activities for the Company's proprietary drugs, respectively. This segment provides services and products to external customers based mainly in the U.S.

The Company's Oncology Innovation Platform segment operates and holds long-lived assets located in the U.S., Taiwan, Hong Kong, mainland China, the United Kingdom, and Latin America. The Global Supply Chain Platform segment operates and holds long-lived assets located in the U.S. and China. The Commercial Platform segment operates and holds long-lived assets located in the U.S. 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,	
	2021	2020	2021	2020
Total revenue:				
Oncology Innovation Platform	$ 5,122	$ 10,440	$ 26,093	$ 38,832
Global Supply Chain Platform	6,484	3,808	20,804	12,505
Commercial Platform	21,030	21,729	50,080	73,484
Total revenue for reportable segments	32,636	35,977	96,977	124,821
Intersegment revenue	(339)	(501)	(1,732)	(2,238)
Total consolidated revenue	$ 32,297	$ 35,476	$ 95,245	$ 122,583

Intersegment revenue eliminated in the above table reflects $0.3 million and $1.1 million in sales from the Global Supply Chain Platform to the Oncology Innovation Platform for the three and nine months ended September 30, 2021, respectively, and $0.5 million and $2.2 million for the three and nine months ended September 30, 2020, respectively. Intersegment revenue eliminated in the above table also reflects $0 and $0.6 million in sales from the Global Supply Chain Platform to the Commercial Platform for the three and nine months ended September 30, 2021, respectively, and $0 for both three- and nine-month periods ended September 30, 2020.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total revenue by product group:				
License fees	$ 5,114	$ 24,484	$ 26,068	$ 80,868
Commercial product sales	25,890	10,434	63,923	38,815
API sales	727	296	3,581	2,547
Contract manufacturing revenue	418	—	1,275	79
Other revenue	148	262	398	274
Total consolidated revenue	$ 32,297	$ 35,476	$ 95,245	$ 122,583

Intersegment revenue is recognized by the selling segment 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. Upon consolidation, all intersegment revenue and related cost of sales are eliminated from the selling segment's ledger (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss attributable to Athenex, Inc.:				
Oncology Innovation Platform	$ (25,524)	$ (21,024)	$ (51,087)	$ (57,006)
Global Supply Chain Platform	(6,101)	(5,249)	(13,727)	(16,980)
Commercial Platform	(4,432)	(10,533)	(30,567)	(22,700)
Total consolidated net loss attributable to Athenex, Inc.	$ (36,057)	$ (36,806)	$ (95,381)	$ (96,686)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total depreciation and amortization:				
Oncology Innovation Platform	$ 221	$ 201	$ 658	$ 565
Global Supply Chain Platform	548	469	1,572	1,391
Commercial Platform	432	416	1,438	1,251
Total consolidated depreciation and amortization	$ 1,201	$ 1,086	$ 3,668	$ 3,207

	September 30, 2021	December 31, 2020
Total assets:		
Oncology Innovation Platform	$ 217,908	$ 234,153
Global Supply Chain Platform	108,290	99,087
Commercial Platform	59,696	51,089
Total consolidated assets	$ 385,894	$ 384,329

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total revenue:				
United States	$ 31,394	$ 18,123	$ 90,717	$ 61,646
China	321	10,963	1,178	39,601
South Korea	445	—	1,556	1,693
India	—	—	906	—
United Kingdom	—	6,357	—	19,289
Other foreign countries	137	33	888	354
Total consolidated revenue	$ 32,297	$ 35,476	$ 95,245	$ 122,583

	September 30, 2021	December 31, 2020
Total property and equipment, net:		
United States	$ 26,924	$ 15,511
China	24,992	18,877
Total consolidated property and equipment, net	$ 51,916	$ 34,388

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,	
	2021	2020	2021	2020
Percentage of total revenue by customer:				
Customer A	22%	8%	16%	5%
Customer B	18%	12%	15%	8%
Customer C	16%	0%	27%	0%
Customer D	15%	15%	15%	9%
Customer E	0%	27%	0%	31%
Customer F	0%	18%	0%	16%

	September 30, 2021	December 31, 2020
Percentage of total accounts receivable by customer:		
Customer A	35%	24%
Customer B	20%	33%
Customer C	15%	16%
Customer D	15%	0%
Customer E	0%	6%

16. Revenue Recognition

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

1. Oncology Innovation Platform

The Company out-licenses certain of its IP to other 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 the contracts to identify its performance obligations within the contract. Most of the Company's out-license arrangements contain multiple performance obligations and variable pricing. After the performance obligations are identified, the Company determines the transaction price, which generally includes upfront fees, milestone payments related to the achievement of developmental, regulatory, or commercial goals, and royalty payments on net sales of licensed products. The Company considers whether the transaction price is fixed or variable, and whether such consideration is subject to return. Variable consideration is only included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. If any portion of the transaction price is constrained, it is excluded from the transaction price until the constraint no longer exists. The Company then allocates the transaction price to the performance obligation to which the consideration is related. Where a portion of the transaction price is received and allocated to continuing performance obligations under the terms of the arrangement, it is recorded as deferred revenue and recognized as revenue when (or as) the underlying performance obligation is satisfied.

The Company's contracts may contain one or multiple promises, including the license of IP and development services. The licensed IP is capable of being distinct from the other performance obligations identified in the contract and is distinct within the context of the contract, as upon transfer of the IP, the customer is able to use and benefit from it, and the customer could obtain the development services from other parties. The Company also considers the economic and regulatory characteristics of the licensed IP and other promises in the contract to determine if it is a distinct performance obligation. The Company considers if the IP is modified or enhanced by other performance obligations through the life of the agreement and whether the customer is contractually or practically required to use updated IP. The IP licensed by the Company has been determined to be functional IP. The IP is not modified during the license period and therefore, the Company recognizes revenues from any portion of the transaction price allocated to the licensed IP when the license is transferred to the customer and they can benefit from the right to use the IP. For the three and nine month period ended September 30, 2021, the Company recognized license revenue of $5.1 million and $26.1 million, respectively, of which $20.0 million was recognized upon the achievement of the first commercial milestone pursuant to the 2017 Almirall out-license arrangement upon the launch of Klisyri® (tirbanibulin) in the U.S., $5.0 million was recognized upon the launch of Klisyri® (tirbanibulin) in Europe pursuant to the 2017 Almirall out-license arrangement, and $0.5 million was recognized for an upfront fee upon transferring IP to the customer upon execution of the second amendment to the 2011 PharmaEssentia license agreement. For the nine-month period ended September 30, 2020, the Company recognized revenue of $37.7 million, net of $2.3 million value added tax ("VAT") collected on behalf of the counterparty, upon transferring certain IP to the customer. The Company recognized $9.4 million in license revenue, net of $0.6 million value added tax ("VAT"), and $1.0 million in license revenue from two of the Company's out-license arrangements for the three-month period ended September 30, 2020.

Other performance obligations included in most of the Company's out-licensing agreements include performing development services to reach clinical and regulatory milestone events. The Company satisfies these performance obligations at a point-in-time, because the customer does not simultaneously receive and consume the benefits as the development occurs, the development does not create or enhance an asset controlled by the customer, and the development does not create an asset with no alternative use. The Company considers milestone payments to be variable consideration measured using the most likely amount method, as the entitlement to the consideration is contingent on the occurrence or nonoccurrence of future events. The Company allocates each variable milestone payment to the associated milestone performance obligation, as the variable payment relates directly to the Company's efforts to satisfy the performance obligation and such allocation depicts the amount of consideration to which the Company expects to be entitled for satisfying the corresponding performance obligation. The Company re-evaluates the probability of achievement of such performance obligations and any related constraint and adjusts its estimate of the transaction price as appropriate. To date, no amounts have been constrained in the initial or subsequent assessments of the transaction price. The Company did not recognize revenue from other performance obligations included in the Company's out-licensing agreements during the three and nine-month periods ended September 30, 2021 and 2020.

Certain out-license agreements include performance obligations to manufacture and provide drug product in the future for commercial sale when the licensed product is approved. For the commercial, sales-based royalties, the consideration is predominantly related to the licensed IP and is contingent on the customer's subsequent sales to another commercial customer. Consequently, the sales- or usage-based royalty exception would apply. Revenue will be recognized for the commercial, sales-based milestones as the underlying sales occur. The Company recorded $0.1 million and $0.3 million of royalty revenue related to sales of Tirbanibulin during the three and nine months ended September 30, 2021, respectively. No royalty revenue was recorded during the nine months ended September 30, 2020.

The Company exercises significant judgment when identifying distinct performance obligations within its out-license arrangements, determining the transaction price, which often includes both fixed and variable considerations, and allocating the transaction price to the proper performance obligation. The Company did not use any other significant judgments related to out-licensing revenue during the three and nine-month periods ended September 30, 2021 and 2020.

2. Global Supply Chain Platform

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

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.

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. Upon the sale by the wholesaler to the end-user, the wholesaler will chargeback the difference, if any, between the original list price and price at which the product was sold to the end-user. The Company also offers cash discounts, which approximate 2.3% of the gross sales price, as an incentive for prompt customer payment, and, consistent with industry practice, the Company's return policy permits customers to return products within a window of time before and after the expiration of product dating. Further, the Company offers contractual allowances, generally in the form of rebates or administrative fees, to certain wholesale customers, group purchasing organizations ("GPOs"), and end-user customers, consistent with pharmaceutical industry practices. Revenues are recorded net of provisions for variable consideration, including discounts, rebates, GPO allowances, price adjustments, returns, chargebacks, promotional programs and other sales allowances. Accruals for these provisions are presented in the consolidated financial statements as reductions in determining net sales and as a contra asset in accounts receivable, net (if settled via credit) and other current liabilities (if paid in cash). As of September 30, 2021, and December 31, 2020, the Company's total provision for chargebacks and other deductions included as a reduction of accounts receivable totaled $25.9 million and $12.6 million, respectively. The Company's total provision for chargebacks and other revenue deductions was $38.8 million, and $21.3 million for the three months ended September 30, 2021, and 2020, respectively, and $91.3 million and $66.4 million for the nine months ended September 30, 2021 and 2020, respectively.

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, 2021 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ 5,091	$ 5,273	$ 21,030	$ 31,394
South Korea	—	445	—	445
China	8	313	—	321
Other foreign countries	23	114	—	137
Total revenue	$ 5,122	$ 6,145	$ 21,030	$ 32,297

	For the Three Months Ended September 30, 2020 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 2,751	$ 15,372	$ 18,123
China	10,440	523	—	10,963
United Kingdom	—	—	6,357	6,357
Other foreign countries	—	33	—	33
Total revenue	$ 10,440	$ 3,307	$ 21,729	$ 35,476

	For the Nine Months Ended September 30, 2021 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ 25,535	$ 15,102	$ 50,080	$ 90,717
South Korea	—	1,556	—	1,556
India	—	906	—	906
China	25	1,153	—	1,178
Other foreign countries	533	355	—	888
Total revenue	$ 26,093	$ 19,072	$ 50,080	$ 95,245

	For the Nine Months Ended September 30, 2020 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	$ —	$ 7,451	$ 54,195	$ 61,646
China	38,753	848	—	39,601
United Kingdom	—	—	19,289	19,289
South Korea	—	1,693	—	1,693
Other foreign countries	79	275	—	354
Total revenue	$ 38,832	$ 10,267	$ 73,484	$ 122,583

The Company also disaggregates its revenue by product group which can be found in Note 15 – *Business Segment, Geographic, and Concentration Risk Information*.

Contract balances

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

	September 30, 2021 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ 14,174	$ 3,246	$ 51,439	$ 68,859
Chargebacks and other deductions	—	—	(25,855)	(25,855)
Provision for credit losses	(8,919)	(191)	(137)	(9,247)
Accounts receivable, net	$ 5,255	$ 3,055	$ 25,447	$ 33,757
Deferred revenue	2,744	469	—	3,213
Total contract liabilities	$ 2,744	$ 469	$ —	$ 3,213

	December 31, 2020 (In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	$ 10,783	$ 4,074	$ 30,935	$ 45,792
Chargebacks and other deductions	—	(1)	(12,551)	(12,552)
Provision for credit losses	(8,919)	(164)	(554)	(9,637)
Accounts receivable, net	$ 1,864	$ 3,909	$ 17,830	$ 23,603
Deferred revenue	1,001	146	—	1,147
Total contract liabilities	$ 1,001	$ 146	$ —	$ 1,147

As of September 30, 2021 and December 31, 2020, the deferred revenue balances relate to customer deposits made by customers of the Oncology Innovation Platform and Global Supply Chain Platform and are included within accrued expenses on the condensed consolidated balance sheets.

There were no other material changes to contract balances during the three and nine months ended September 30, 2021.

17. Commitments and Contingencies

Future minimum payments under the non-cancelable operating leases consists of the following as of September 30, 2021 (in thousands):

Year ending December 31:	Minimum payments
2021 (remaining three months)	$ 849
2022	2,895
2023	2,088
2024	2,002
2025	1,472
Thereafter	479
	$ 9,785

Legal Proceedings

Following our receipt of the CRL in February 2021 and the subsequent decline of the market price of the Company's common stock, two purported securities class action lawsuits were filed in the U.S. District Court for the Western District of New York on March 3, 2021 and March 22, 2021, respectively, against the Company and certain members of its management team seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

The complaints generally allege that between August 7, 2019 and February 26, 2021 (the purported class period), the Company and the individual defendants made materially false and misleading statements regarding the Company's business in connection with the Company's development of Oral Paclitaxel for the treatment of metastatic breast cancer and the likelihood of FDA approval, and that the plaintiffs suffered losses when the Company's stock price dropped after its announcement on February 26, 2021 regarding receipt of the CRL. The complaints seek class certification, damages, fees, costs, and expenses. On August 5, 2021, the Court consolidated the two actions and appointed a lead plaintiff and lead counsel. Pursuant to a stipulated scheduling order, the lead plaintiff will file a consolidated complaint no later than November 19, 2021. Defendants' motion to dismiss is due by January 25, 2022; plaintiffs' opposition to that motion is due by March 28, 2022; and the defendants' reply is due by May 20, 2022. The Company and the individual defendants believe that the claims in the consolidated lawsuits are without merit, and the Company has not recorded a liability related to these shareholder class actions as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims but there can be no assurances as to the outcome.

Shareholder Derivative Lawsuit

On June 3, 2021, a shareholder derivative lawsuit was filed in the United States District Court for the District of Delaware by Timothy J. Wonnell, allegedly on behalf of the Company, that piggy-backs on the securities class actions referenced above. The complaint names Johnson Lau, Rudolf Kwan, Timothy Cook, and members of the Board as defendants, and generally alleges that they caused or failed to prevent the securities law violations asserted in the securities class actions. On September 13, 2021, the Court (i) granted the defendants' motion to stay the derivative action until after resolution of the motion to dismiss the consolidated securities class actions, and (ii) administratively closed the derivative litigation, directing the parties to promptly notify the Court when the related securities class action has been resolved so the derivative action can be reopened. The Company and the individual defendants believe the claims in the shareholder derivative action are without merit, and the Company has not recorded a liability related to this lawsuit as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims should the case be reopened, but there can be no assurances as to the outcome.

18. Subsequent Event

On October 1, 2021, the Company entered into a lease agreement with Fort Schuyler Management Corporation ("FSMC"), a not-for-profit corporation affiliated with the State of New York, to lease the 409,000 square feet, newly constructed cGMP ISO Class 5 high potency pharmaceutical manufacturing facility located in Dunkirk, NY. The lease agreement calls for annual rent payments of $2 for an initial 10-year term, with the option for the Company to renew under the same terms and conditions for an additional 10-year term. The provisions of the lease agreement are consistent with those agreed upon in the 2015 Agreement for Medical Technology Research, Development, and Innovation and Commercial Alliance ("Alliance Agreement"), and subsequent amendments, under which FSMC agreed to fund the construction costs of a new manufacturing facility in Dunkirk, NY, up to $208.0 million. Under the terms of the lease agreement and 2015 Alliance Agreement, the Company has committed to spend $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.5 billion on operational expenses if the Company elects to extend the lease for a second 10-year term. The Company also committed to hiring 450 employees at the Dunkirk facility within the first 5 years of operations, including hiring at least 300 new employees within 2.5 years of the Dunkirk facility becoming operational. The Company has identified this as an operating lease and it impact is not expected to be material to the financial statements.

On October 5, 2021, the Company held a Type A meeting with the FDA regarding the NDA for Oral Paclitaxel in mBC. The purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the Complete Response Letter received in February 2021 and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. After consideration of the feedback provided by the FDA, the Company decided that it will not currently be pursuing regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. and will redeploy its resources to focus on other ongoing studies of Oral Paclitaxel and its cell therapy platform.

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, 2020 included in our Annual Report on Form 10-K for the year ended December 31, 2020. 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 discussed in the section entitled "Risk Factors" included in our Annual Report on Form 10-K for the year ended December 31, 2020 and in Part II—Item 1A—Risk Factors below.

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, the impact of COVID-19 on our business, and potential regulatory approval and commercialization of product candidates. In some cases, forward-looking statements may be identified by terminology such as "believe," "may," "will," "should," "predict," "goal," "strategy," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect," "seek" and similar expressions and variations thereof. These words are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2020 and the additional risk factors described herein. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business. In light of these risks, uncertainties and assumptions, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

Overview and Recent Developments

We are a biopharmaceutical company dedicated to becoming a leader in the discovery, development and commercialization of next generation drugs for the treatment of cancer. Our mission is to improve the lives of cancer patients by creating more effective, safer and tolerable treatments. We have assembled a strong and experienced leadership team and have established operations across the pharmaceutical value chain to execute our goal of becoming a global leader in bringing innovative cancer treatments to the market and improving health outcomes.

We are organized around three operating segments: (1) our Oncology Innovation Platform, dedicated to the research and development of our proprietary drugs; (2) our Commercial Platform, focused on the sales and marketing of our specialty drugs and the market development of our proprietary drugs; and (3) our Global Supply Chain Platform, dedicated to providing a stable and efficient supply of active pharmaceutical ingredients ("API") for our clinical and commercial efforts. Our current clinical pipeline in the Oncology Innovation Platform is derived from four different technologies: (1) Orascovery, based on a P-glycoprotein ("P-gp") pump inhibitor, (2) Src Kinase Inhibition, (3) Cell Therapy, and (4) Arginine Deprivation Therapy.

On September 27, 2021, we announced that our partner, Almirall (Almirall, S.A., BME: ALM), launched Klisyri® (tirbanibulin) in Germany and the UK, after receiving approval from the European Commission in July 2021, for the topical treatment of actinic keratosis (AK) of the face or scalp in adults. Klisyri was also approved for the treatment of AK by the UK Medicines and Healthcare products Regulatory Agency in August 2021. Almirall launched Klisyri in the U.S. in February 2021 after Athenex received approval from the U.S. Food and Drug Administration ("FDA") for the commercialization of Klisyri in the United States for the same drug indication usage in December 2020. The launch in the U.S. resulted in a milestone payment of $20.0 million pursuant to our 2017 out-license agreement with Almirall, recognized as income in the first quarter of 2021, and the launch in Europe resulted in a milestone payment of $5.0 million, recognized as income in the third quarter of 2021.

In early October 2021, we held a Type A meeting with the FDA regarding the New Drug Application ("NDA") for oral paclitaxel and encequidar ("Oral Paclitaxel)" in metastatic breast cancer ("mBC"). The purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the Complete Response Letter ("CRL") received in February 2021 and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. After careful consideration of the feedback provided by the FDA, we decided we will not currently pursue regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. and determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our CAR-NKT and TCR-T cell therapies.

We are also evaluating Oral Paclitaxel in other indications and in combination with other therapies. We completed enrollment in our Phase 2 study of Oral Paclitaxel in the treatment of cutaneous angiosarcoma and intend to discuss a registration pathway with the FDA. Our Phase 1 study of Oral Paclitaxel in combination with pembrolizumab in patients with advanced solid malignancies is ongoing. In September 2021, Athenex presented dose finding results from this study at the European Society of Medical Oncology ("ESMO") Congress 2021, in a poster presentation. We are proceeding into the expansion phase of this study and will enroll additional patients with non-small cell lung cancer to further evaluate the safety and clinical activity of Oral Paclitaxel in combination with pembrolizumab. The I-SPY 2 trial evaluating Oral Paclitaxel in combination with dostarlimab in neoadjuvant breast cancer patients is also ongoing.

Additionally, the development of our other Orascovery product candidates is ongoing. We are planning Phase 2 studies for both oral irinotecan and encequidar ("Oral Irinotecan") and oral docetaxel and encequidar ("Oral Docetaxel"). A Phase 1 study of oral eribulin and encequidar ("Oral Eribulin") in patients with solid tumors is ongoing.

Development of clinical candidates under the NKT (natural killer T) cell therapy platform acquired as part of the Agreement and Plan of Merger (the "Merger Agreement") with Kuur Therapeutics, Inc (formerly known as Cell Medica, "Kuur") in May 2021, is ongoing. KUR-501 is being tested in the phase 1 GINAKIT2 clinical study in patients with relapsed-refractory (R/R) high risk neuroblastoma. The GINAKIT2 study is supported by our Company and conducted by our collaborator, Baylor College of Medicine ("BCM"), and is currently recruiting patients. The ANCHOR clinical study is a phase 1, first-in-human, dose escalation evaluation of KUR-502 in adults with R/R CD19 positive malignancies including B cell lymphomas, acute lymphoblastic leukemia ("ALL"), and chronic lymphocytic leukemia ("CLL"). The ANCHOR study is being sponsored and conducted by BCM and is currently recruiting patients. KUR-503 is a product, in which NKT cells are engineered with a CAR targeting GPC3 (glypican-3). GPC3 is a molecule that is highly expressed on most hepatocellular carcinomas ("HCC"), but not normal liver or other non-neoplastic tissue, making it an ideal target. KUR-503 is currently in preclinical development and the Company is planning to submit an Investigational New Drug ("IND") application to the FDA in 2022.

Pursuant to the terms of the Merger Agreement, we paid $70.0 million upfront to Kuur shareholders and its former employees and directors, comprised primarily of equity in the Company's common stock. Additionally, Kuur shareholders and its former employees and directors are eligible to receive up to $115.0 million of milestone payments, which may be paid, at the Company's sole discretion, in either cash or additional common stock of the Company, or a combination of both. For additional information, please see "Part I, Item 1, Note 5—*Business Combination*."

The other technology in our Cell Therapy platform is our TCR-T immunotherapy technology under which we are advancing TCR affinity-enhancing specific T-cell (TAEST) therapy with our first T cell therapy product, TCRT-ESO-A2. We received IRB approval to conduct the Phase 1 trial of TCRT-ESO-A2, which is ready to enroll patients. TCRT-ESO-A2 is an autologous T cell receptor (TCR)-T cell therapy targeting solid tumors that are NY-ESO-1 positive in HLA-A*02:01 positive patients.

With respect to Arginine Deprivation therapy, the Phase 1 trial of PT01 for the treatment of patients with advanced malignancies is ongoing.

We suspended production activities at our Taihao API facility in Chongqing, China, in May 2019, based on concerns raised by the Department of Emergency Management of Chongqing ("DEMC") related to the location of our plant. We subsequently resumed producing API at the Taihao facility primarily for our ongoing clinical studies and commercial launches of proprietary drugs in accordance with local regulatory guidance, while we started building out Sintaho, a new API facility in Chongqing. In July 2021, we received verbal notice from the DEMC that we will be required to terminate the production activities at its Taihao API facility at the end of 2021. We are continuing to engage in dialogue with the DEMC. While a certain extent of our operations are now being conducted at Sintaho, the new API facility in Chongqing, we are in the process of moving the remainder of the operations and production activities to Sintaho and exploring other sources of API, in the event we are unable to reach an agreement with the DEMC for the continued production activities of the Taihao API facility.

On October 1, 2021, we entered into a lease agreement with Fort Schuyler Management Corporation ("FSMC"), a not-for-profit corporation affiliated with the State of New York, to lease the 409,000 square feet, newly constructed cGMP ISO Class 5 high potency pharmaceutical manufacturing facility located in Dunkirk, NY. While we entered into a lease for this facility, we cannot commence operating the facility until we obtain the appropriate permits. We expect to be able to operate the Dunkirk facility in the fourth quarter of 2022. For additional information, please see "Part I, Item 1, Note 18—*Subsequent Events*."

COVID-19 related measures and recent business updates

Since early 2020, after monitoring developments related to the spread of COVID-19, we have undertaken a number of measures in response to the COVID-19 pandemic, with a goal to prioritize the health and safety of our employees and ensure continuity in our business. These measures included implementing a work-from-home policy at various times and other efforts in accordance with recommendations by local authorities for certain of our personnel across the globe as well as imposing restrictions on travel and in-person meetings to protect the health and safety of our workforce while we continue to advance our clinical programs and operations. We have continued to add additional safety procedures and tools in all our locations. We adhere to all state and federal requirements as the same may be in force from time to time.

We have been deemed an "essential business" by New York State and, as a result, we have experienced minimal disruptions at our New York-based operations in Clarence and Buffalo. Despite these efforts, we may from time to time experience additional disruptions related to the COVID-19 pandemic resulting from employees falling ill with COVID-19. We have supplied our employees with appropriate face coverings and other necessary personal protective equipment and have taken other measures to reduce the risk of the spread of COVID-19 at our work sites. We are actively monitoring our operations and supply chain across the globe and are making adjustments to respond to logistical challenges that arise due to the COVID-19 pandemic where appropriate, particularly due to the emergence and spread of the COVID-19 Delta variant, which has already impacted our operations and supply chain during the first nine months of 2021 as discussed further below. We have continued to produce medicines that are used to treat COVID-19 as part of our commitment to contribute to the COVID-19 relief effort.

With respect to our clinical development program, for our earlier stage product candidates, we have experienced and expect to continue to experience slowed enrollment for our clinical trials as well as suspensions in our clinical trials as healthcare resources are diverted to address the COVID-19 pandemic. We remain committed to advancing our pipeline while ensuring the safety of all participants as well as the integrity of the data. We will continue to monitor developments with respect to the COVID-19 pandemic as well as industry and regulatory best practices for continuing clinical development programs during the pandemic, including, if and where appropriate, the use of virtual communications, interviews, and visits as well as self-administration and remote monitoring techniques to address health and safety concerns while minimizing disruptions and delays to our clinical development timelines.

We also put in place a number of measures intended to adjust or allocate resources towards prioritizing key business operations such as clinical and regulatory activities, and to delay or defray compensation costs in order to preserve our cash on hand and liquidity during a volatile period in the U.S. and global capital markets.

However, a lack of sustained recovery or further deterioration in market conditions related to the general economy and the industries in which we operate, a sustained trend of weaker than anticipated financial performance, further decline in our share price for a sustained period of time, or an increase in the market-based weighted average cost of capital, among other factors, could significantly impact the impairment analysis and may result in future impairment charges that, if incurred, could have a material adverse effect on our financial condition and results of operations.

While the disruptions to our business caused by the pandemic are currently expected to be temporary, there is still uncertainty regarding the pandemic's overall duration and the severity of any future outbreaks. For example, the surge of COVID-19 cases in the first half of 2021 in India, a country where we source supplies and maintain partnerships that are key to our specialty drug business, including API, presented business and supply chain disruption risks for us. We could face similar risks in other regions, or a resurgence in India, to the extent the virus is not able to be contained, there is widespread sickness and disruptions on operations while in the event state actors impose lockdowns, restrictions on the operations of businesses and other containment measures to combat the spread of the virus. The scope and impact of any such measures is not yet known and will depend on a number of factors, including but not limited to the ultimate spread and severity of the outbreaks and the scope, duration and impact of containment measures on

individuals and businesses. If our partners experience significant or extended disruptions to their business due to COVID-19, it could result in substantial supply shortages and harm our special drug business, as well as our overall financial condition and results of operations.

As a result of the significant decrease in our market capitalization since we last performed a goodwill impairment test in the fourth quarter of 2020, we evaluated the impact on each of its reporting units to assess whether there was a triggering event during the first quarter of 2021, requiring it to perform a goodwill impairment test (ASC350-20-35). We determined a triggering event occurred and, as such, performed an interim goodwill quantitative impairment test for our reporting units. We compared the fair value of our Global Supply Chain Platform and Oncology Innovation Platform reporting units to carrying value. Based on the results, the fair value of each of our reporting units exceeded their carrying value, and the goodwill was not impaired (see Part I, Item 1. Note 6—*Intangible Assets, Net*). However, there can be no assurances that goodwill will not be impaired in future periods. Estimating the fair value of goodwill requires the use of estimates and significant judgments that are based on a number of factors. These estimates and judgments may not be within our control and accordingly it is reasonably possible that the judgments and estimates could change in future periods.

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 technology platforms, as well as under the Cell Therapy platform and Arginine Deprivation Therapy technology, while building up our commercial infrastructure. We have incurred significant net losses since inception.

For the nine months ended September 30, 2021, our net loss was $97.0 million, compared to $98.0 million for the same period in 2020. As of September 30, 2021 and December 31, 2020, we had an accumulated deficit of $809.0 million and $713.6 million, respectively. We expect to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will cover the following activities as we:

- Advance the research and clinical development activities of our cell therapy programs, including the development of Kuur's pipeline and our TCR-T immunotherapy product;
- Continue to advance our Orascovery and Src Kinase Inhibition technology platforms, through clinical and regulatory development;
- Continue certain of our current preclinical and clinical research program and development activities;
- Continue to invest in our manufacturing facilities in Dunkirk and Chongqing;
- Continue to advance the preclinical and clinical research program and development activities of our in-licensed technology platforms;
- Seek to identify additional research programs and product candidates within existing platform technologies;
- Attain new drugs and technologies through acquisitions or in-licensing opportunities if complementary to our core business;
- Hire additional research, development and business personnel;
- Maintain, expand and protect our intellectual property ("IP") portfolio; and
- Incur additional costs associated with operating as a public company.

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

We have funded our operations to date primarily from the issuance and sale of our common stock through public offerings, senior secured loans, private placements, and to a lesser extent, from convertible bond financing, revenue, and grant funding. As of September 30, 2021, we had cash and cash equivalents of $73.6 million, restricted cash of $16.5 million, and short-term investments of $14.9 million.

On August 20, 2021, we entered into a sales agreement (the "Sales Agreement") with SVB Leerink LLC, in connection with the offer and sale of up to $100,000,000 of shares of our common stock, par value $0.001 per share ("ATM Shares"). The ATM Shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to a registration statement on Form S-3 (File No. 333-258185) that became effective on August 12, 2021. As of September 30, 2021, we had not sold any shares under the Sales Agreement.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) the sales of generic injectable products by our Commercial Platform; (ii) 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; (iii) the sales of 503B and API 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. 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, certain direct costs such as shipping costs, net of costs charged to customers, and royalty costs related to in-license agreements.

Research and Development Expenses

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

We expense R&D 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 R&D programs because these costs are deployed across multiple product programs under R&D.

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, regulatory activities, and other R&D 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, including without limitation delays caused by the ongoing COVID-19 pandemic, could mean a significant change in the costs and timing associated with the development of that drug candidate.

R&D activities are central to our business model. We expect our R&D expenses to continue to increase for the foreseeable future as we continue to support the clinical and regulatory development activities of our Cell therapy platform product candidates, our Orascovery platform product candidates, our Src Kinase Inhibition platform product candidates, as well as initiate and prepare for additional clinical and preclinical studies, including for our arginine biologics products and other small molecule programs. We also expect spending to increase in the R&D 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,

regulatory and public health, including the ongoing COVID-19 pandemic, factors beyond our control will likely impact our clinical development programs and plans.

Selling, General and Administrative Expenses

Selling, general and administrative, ("SG&A"), expenses primarily consist of compensation, including salary, employee benefits and stock-based compensation expenses for sales and marketing personnel, and for administrative personnel that support our general operations such as executive management, legal counsel, financial accounting, information technology, and human resources personnel. SG&A expenses also include professional fees for legal, patent, consulting, auditing and tax services, as well as other direct and allocated expenses for rent and maintenance of facilities, development of the facility in Dunkirk, NY, insurance and other supplies used in the selling, marketing, general and administrative activities. SG&A expenses also include costs associated with our commercialization efforts for our proprietary drugs, such as market research, brand strategy and development work on market access, scientific publication, product distribution, and patient support.

We anticipate that our SG&A expenses will increase in future periods to support increases in our research and development. We expect these increases will likely result in increased headcount, increased share compensation charges, expanded infrastructure and increased costs for insurance. We also anticipate increases to legal expenses due to the on-going class action lawsuit (*see Note 17 Commitments and Contingencies*), insurance premium, compliance, accounting and investor and public relations expenses associated with being a public company.

Results of Operations

Three Months Ended September 30, 2021 Compared to Three Months Ended September 30, 2020

The following table sets forth a summary of our condensed consolidated results of operations for the three months ended September 30, 2021 and 2020, together with the changes in those items in dollars and as a percentage. This information should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Three Months Ended September 30,			
	2021	2020	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	$ 27,035	$ 24,780	$ 2,255	9%
License fees and other revenue	5,262	10,696	(5,434)	-51%
Total revenue	32,297	35,476	(3,179)	
Cost of sales	(25,644)	(24,510)	(1,134)	5%
Gross profit	6,653	10,966	(4,313)	
Research and development expenses	(17,731)	(18,390)	659	-4%
Selling, general, and administrative expenses	(22,794)	(22,220)	(574)	3%
Interest income	39	112	(73)	-65%
Income from government grant	2,459	—	2,459	100%
Interest expense	(5,100)	(3,595)	(1,505)	42%
Loss on extinguishment of debt	—	(3,048)	3,048	-100%
Income tax expense	(262)	(1,093)	831	-76%
Net loss	(36,736)	(37,268)	532	
Less: net loss attributable to non-controlling interests	(679)	(462)	(217)	47%
Net loss attributable to Athenex, Inc.	$ (36,057)	$ (36,806)	$ 749	

Revenue

Revenue from product sales increased to $27.0 million for the three months ended September 30, 2021, from $24.8 million for the three months ended September 30, 2020, an increase of $2.2 million or 9%. This increase was primarily attributable to an increase in 503B product sales of $2.1 million as the result of the increase in demand for certain drugs used to treat patients hospitalized with COVID-19. API product sales and contract manufacturing sales each experienced an increase of $0.4 million. These increases were offset by a decrease in APD product sales of $0.7 million, resulting primarily from a significant prior year increase in demand for COVID-19 related drugs and for FDA shortage products during 2020, including some significant non-recurring orders. Fluctuations in the infection rate and the spread of the global health pandemic and market demand may continue to significantly affect our product sales in the future.

License fees and other revenue decreased by $5.4 million, for the three months ended September 30, 2021. This decrease was primarily due to the recognition of $5.1 million in license and royalty revenue from Almirall for the launch of Klisyri in the Europe in September 2021, while we recognized $10.4 million in license revenue during the three months ended September 30, 2020, pursuant to license agreements with Xiangxue and PharmaEssentia.

Cost of Sales

Cost of sales for the three months ended September 30, 2021 totaled $25.6 million, an increase of $1.1 million, or 5%, as compared to $24.5 million for the three months ended September 30, 2020. The increase was primarily due to an increase of $2.9 million in cost of 503B product sales as production levels increased. Cost of APD product sales increased by $0.9 million, while the cost of API product sales decreased by $0.1 million. Additionally, cost of sales related to royalties for license income decreased by $2.5 million due to the royalty payment that was incurred in 2020 on the license revenue from Xiangxue.

Research and Development Expenses

R&D expenses for the three months ended September 30, 2021 totaled $17.7 million, a decrease of $0.7 million, or 4%, as compared to $18.4 million for the three months ended September 30, 2020. This was primarily due to a decrease in costs of clinical operations, Oral Paclitaxel product development and medical affairs costs, and costs of preclinical operations and included the following:

- $2.4 million decrease in costs of clinical operations after the completion of the Phase 3 studies for tirbanibulin ointment and Oral Paclitaxel;
- $1.8 million decrease in Oral Paclitaxel product development and medical affairs costs incurred in connection with the potential product launch;
- $1.0 million decrease in costs of preclinical operations, primarily related to docetaxel and paclitaxel; and
- $0.4 million decrease in R&D related compensation expenses.

The decrease in these R&D expenses was partially offset by a $2.6 million increase in cell therapy development costs, a $2.0 million increase in drug licensing costs related to licenses for specialty drug products, and a $0.3 million increase in costs of other product development.

Selling, General, and Administrative Expenses

SG&A expenses for the three months ended September 30, 2021 totaled $22.8 million, an increase of $0.6 million, or 3%, as compared to $22.2 million for the three months ended September 30, 2020. This was primarily due to a $3.2 million increase from the change in fair value of contingent consideration, a $2.1 million increase in operating costs including insurance and IT costs and professional fees, a $1.9 million increase in compensation related costs, and a $1.1 million increase in site preparation costs related to the manufacturing facility in Dunkirk, NY. This was partially offset by a $7.7 million decrease in costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020 and slowed upon receipt of the Complete Response Letter in February 2021.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments and totaled less than $0.1 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense totaled $5.1 million and $3.6 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense in the current period was incurred from the senior secured loan agreement and related security agreements (the "Senior Credit Agreement") with Oaktree Fund Administration, LLC, as administrative agent, and the lenders party thereto (collectively, "Oaktree"), while interest expense in the prior period was primarily incurred from debt under a former credit agreement with Perceptive Advisors LLC and its affiliates.

Income from Government Grant

Income from government grant consisted of a reimbursement of operating expenses received from New York State pursuant to our agreement to construct a cGMP ISA Class 5 high potency pharmaceutical manufacturing facility in Dunkirk, NY. Distributions by New York State under this arrangement in prior years were made for direct construction costs that were capital in nature and were not made to offset our operating expenses incurred in relation to such construction.

Loss on extinguishment of debt

We recognized $3.0 million loss on the extinguishment of debt related to the assignment of a portion of the senior secured loan from Oaktree's co-investors to Sagard Healthcare Royalty Partners, LP ("Sagard") during the three months ended September 30, 2020.

Income Tax Expense

For the three months ended September 30, 2021, income tax expense amounted to $0.3 million, compared to income tax expense of $1.1 million for the same period in 2020. The income tax expense in the prior year was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30, 2020

The following table sets forth a summary of our condensed consolidated results of operations for the nine months ended September 30, 2021 and 2020, together with the changes in those items in dollars and as a percentage. This information should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q. Our operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Nine Months Ended September 30,			
	2021	2020	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	$ 68,780	$ 83,494	$ (14,714)	-18%
License fees and other revenue	26,465	39,089	(12,624)	-32%
Total revenue	95,245	122,583	(27,338)	
Cost of sales	(61,712)	(77,088)	15,376	-20%
Gross profit	33,533	45,495	(11,962)	
Research and development expenses	(61,928)	(57,597)	(4,331)	8%
Selling, general, and administrative expenses	(66,145)	(65,454)	(691)	1%
Interest income	200	710	(510)	-72%
Income from government grant	2,459	—	2,459	100%
Interest expense	(15,692)	(6,833)	(8,859)	130%
Loss on extinguishment of debt	—	(10,278)	10,278	NM
Income tax benefit (expense)	10,619	(4,080)	14,699	NM
Net loss	(96,954)	(98,037)	1,083	
Less: net loss attributable to non-controlling interests	(1,573)	(1,351)	(222)	16%
Net loss attributable to Athenex, Inc.	$ (95,381)	$ (96,686)	$ 1,305	

**NM used to indicate a percentage change that is not meaningful*

Revenue

Revenue from product sales decreased to $68.8 million for the nine months ended September 30, 2021, from $83.5 million for the nine months ended September 30, 2020, a decrease of $14.7 million or 18%. This decrease was primarily attributable to a significant prior year increase in APD product sales of $23.4 million as the result of increased demand for COVID-19 related drugs and for FDA shortage products during 2020, including some significant non-recurring orders. In addition, in the first half of 2021, we experienced significant COVID-related challenges in our Indian supply chain and to a lesser extent in China. As a result, we were not able to receive some inventory from our partners located in these regions for a certain period of time. Fluctuations in the infection rate and the spread of the global health pandemic and market demand may continue to significantly affect our product sales in the future. This decrease was partially offset by an increase in 503B product sales, contract manufacturing revenue, and API product sales of $6.5 million, $1.2 million, and $1.0 million, respectively.

License fees and other revenue decreased to $26.5 for the nine months ended September 30, 2021, from $39.1 million for the nine months ended September 30, 2020, a decrease of $12.6 million, or 32%. For the nine months ended September 30, 2021, we recorded $20.0 million and $5.0 million of license revenue pursuant to the 2017 Almirall License Agreement upon the launch of Klisyri in the U.S. in February 2021 and in Europe in September 2021, respectively, and $0.5 million related to the upfront fee pursuant to the Second Amendment to the 2011 PharmaEssentia License Agreement. For the nine months ended September 30, 2020 we recognized $37.7 million in license revenue, net of $2.3 million value added tax (“VAT”), and $1.0 million in license revenue, pursuant to the 2019 Xiangxue License Agreement and the 2013 PharmaEssentia License Agreement, respectively.

Cost of Sales

Cost of sales for the nine months ended September 30, 2021 totaled $61.7 million, a decrease of $15.4 million, or 20%, as compared to $77.1 million for the nine months ended September 30, 2020. The decrease was primarily due to a decrease of $13.6 million in cost of APD product sales, generally in-line with the decrease in the product sales. Cost of sales related to royalties for license income also decreased by $5.7 million from the royalty payment incurred in 2020 on the license revenue from Xiangxue and cost of API product sales decreased by $0.3 million. Cost of 503B product sales increased by $4.2 million as production levels increased.

Research and Development Expenses

R&D expenses for the nine months ended September 30, 2021 totaled $61.9 million, an increase of $4.3 million, or 8%, as compared to $57.6 million for the nine months ended September 30, 2020. This was primarily due to an increase in costs related to Oral Paclitaxel, drug licensing costs, cell therapy costs, and compensation, and included the following:

- $7.8 million increase in Oral Paclitaxel product development, API, and medical affairs costs associated with the potential product launch in 2021;
- $4.8 million increase in drug licensing costs, due to license payments for specialty pharmaceutical products and a license milestone payment related to Arginine deprivation therapy;
- $2.8 million increase in cell therapy development costs; and
- $0.9 million increase in R&D related compensation expenses.

The increase in these R&D expenses was partially offset by a decrease of $7.8 million in costs of clinical operations after completion of the Phase 3 studies for tirbanibulin ointment and Oral Paclitaxel, a decrease of $4.0 million in regulatory costs in connection with our NDA preparations, and decrease of $0.2 million in costs of other product development.

Selling, General, and Administrative Expenses

SG&A expenses for the nine months ended September 30, 2021 totaled $66.1 million, an increase of $0.7 million, or 1%, as compared to $65.4 million for the nine months ended September 30, 2020. This was primarily due to a $3.8 million increase in compensation related costs, a $3.6 million increase from the change in fair value of contingent consideration, a $3.6 million increase in professional fees and other expenses related to the acquisition of Kuur, and an increase of $3.6 million in operating costs including insurance costs, IT costs, and other professional fees. These were partially offset by a $13.9 million decrease of costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020 and slowed upon receipt of the Complete Response Letter in February 2021.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments and decreased to $0.2 million from $0.7 million for the nine months ended September 30, 2021 and 2020, respectively. Interest expense totaled $15.7 million and $6.8 million for the nine months ended September 30, 2021 and 2020, respectively. Interest expense in the current period was incurred from the Senior Credit Agreement with Oaktree and the write-off of deferred debt issuance costs related to the Revenue Interest Financing Agreement (the “Revenue Interest Financing”) with Sagard, while interest expense in the prior period was primarily incurred from debt under a former credit agreement with Perceptive Advisors LLC and its affiliates.

Income from Government Grant

Income from government grant consisted of a reimbursement of operating expenses received from New York State pursuant to our agreement to construct a cGMP ISA Class 5 high potency pharmaceutical manufacturing facility in Dunkirk, NY. Distributions by New York State under this arrangement in prior years were made for direct construction costs that were capital in nature and were not made to offset our operating expenses incurred in relation to such construction.

Loss on extinguishment of debt

We recognized $7.2 million loss on the extinguishment of debt related to the termination of the senior secured loan agreement with Perceptive and a $3.0 million loss on the partial extinguishment of debt related to the assignment of a portion of the senior secured loan from Oaktree’s co-investors to Sagard during the nine-months ended September 30, 2020.

Income Tax (Benefit) Expense

For the nine months ended September 30, 2021, income tax benefit amounted to $10.6 million, compared to income tax expense of $4.1 million for the same period in 2020. The income tax benefit in the current year is primarily the result of taxable temporary difference due to the deferred tax liability recognized for the indefinite lived intangible assets acquired in connection with the acquisition of Kuur's in-process research and development ("IPR&D"). This taxable temporary difference is considered a source of taxable income to support the realization of deferred tax assets from the acquirer which resulted in a reversal of our valuation allowance. The income tax expense in the prior year was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our R&D programs, SG&A costs associated with our operations, and the development of our specialty drug operations in our Commercial Platform and 503B operations and the investment we made in our pre-launch activities in anticipation of commercializing our proprietary drugs. We incurred net losses of $97.0 million and $98.0 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $809.0 million. Our operating activities used $104.0 million and $97.1 million of cash during the nine months ended September 30, 2021 and 2020, respectively. We intend to continue to advance our various clinical and pre-clinical programs which we expect will lead to continuous cash outflow of R&D costs. We have reduced our planned expenditures in 2021 related to Oral Paclitaxel. In addition, we can provide no assurance that our funding requirements to diversify our product portfolio for specialty drug products in our Commercial Platform and 503B operations will decline in the future. Our principal sources of liquidity as of September 30, 2021 were cash and cash equivalents totaling $73.6 million, restricted cash of $16.5 million, held in a controlled bank account in connection with the Senior Credit Agreement with Oaktree, and short-term investments totaling $14.9 million, which are generally high-quality investment grade corporate debt securities.

Our obligations under the Senior Credit Agreement are guaranteed by us and certain of our existing domestic subsidiaries and subsequently acquired or organized subsidiaries subject to certain exceptions. Our obligations under the Senior Credit Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of our direct subsidiaries, and (ii) a perfected security interest in all of our tangible and intangible assets.

The Senior Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. In addition, the Senior Credit Agreement contains certain financial covenants, including, among other things, maintenance of minimum liquidity and a minimum revenue test, measured quarterly until the last day of the second consecutive fiscal quarter where the consolidated leverage ratio does not exceed 4.5 to 1, provided that thereafter we cannot allow our consolidated leverage ratio to exceed 4.5 to 1, measured quarterly. Failure of the Company to comply with the financial covenants will result in an event of default, subject to certain cure rights of the Company. At September 30, 2021, we were in compliance with all applicable covenants.

Outlook

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth. We may borrow additional funds on terms that may include restrictive covenants, including covenants that further restrict the operation of our business, liens on assets, high effective interest rates, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

On August 20, 2021, we entered into a Sales Agreement with SVB Leerink LLC, pursuant to which we may offer and sell up to $100,000,000 in an at-the-market offering of our ATM Shares. As of September 30, 2021, we had not sold any shares under the Sales Agreement.

As of September 30, 2021, we had cash and cash equivalents of $73.6 million, restricted cash of $16.5 million, and short-term investments of $14.9 million. We believe that the existing cash and cash equivalents, restricted cash, and short-term investments will not be sufficient to fund current operating plans through one year after the date that these unaudited condensed consolidated financial statements are issued. The Company's estimates are based on relevant conditions that are known and reasonably knowable at the date of these consolidated financial statements being available for issuance and are subject to change due to changes in business, industry or macroeconomic conditions. Further, we do not expect to have access to additional capital under the Senior Credit Agreement and the Revenue Interest Financing Agreement, unless we renegotiate these arrangements. We have based these estimates on assumptions that may prove to be wrong, and we could spend the available financial resources much faster than expected and need to raise additional funds sooner than anticipated.

We have made certain changes to our budgeted expenses in light of the CRL for Oral Paclitaxel we received in February 2021 and the Type A meetings with the FDA, including curtailing commercialization expenses and investing in additional products for our specialty pharma business. However, we expect that our expenses will increase as we continue to fund clinical and preclinical development of our research programs by advancing certain product candidates in our pipeline, including product candidates on our Orascovery and Src Kinase Inhibition technology platforms, our cell therapy programs, our specialty drug products, working capital and other general corporate purposes. Capital expenditure at both Dunkirk and Sintaho facilities will continue to grow and be significant as we build out both plants to manufacture drugs including 503B, Tirbanibulin APIs and injectable products. 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, some or all of which may be impacted by the COVID-19 pandemic, including:

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

We 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, 2021 and 2020:

	Nine Months Ended September 30	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (103,966)	$ (97,088)
Net cash provided by (used in) investing activities	106,362	(58,404)
Net cash provided by financing activities	1,352	185,328
Net effect of foreign exchange rate changes	259	(201)
Net increase in cash, cash equivalents, and restricted cash	$ 4,007	$ 29,635

Net Cash Used in Operating Activities

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

Net cash used in operating activities increased $6.9 million, or 7%, for the nine months ended September 30, 2021.

Net cash used in operating activities was $104.0 million for the nine months ended September 30, 2021. This resulted primarily from our net loss of $97.0 million, adjusted for non-cash charges of $17.7 million, non-cash income benefit of $10.8 million related to the reversal of our valuation allowance on our deferred tax assets to offset the deferred tax liability assumed in connection with the acquisition of Kuur's IPR&D, and by cash used by our operating assets and liabilities of $13.9 million. Our operating assets increased $10.2 million for accounts receivable mainly related to the timing of license revenues and increase in 503B sales, increased $0.4 million in prepaid expenses and other assets, and increased $2.7 million for inventory of all drug products. Our operating liabilities decreased by $0.6 million mainly due to a decrease in accrued construction costs for the Dunkirk, NY facility and accrued costs for potential product launch, partially offset by an increase in deferred revenue and accrued clinical expenses. Our net non-cash charges during the nine months ended September 30, 2021 consisted of $7.3 million of stock-based compensation expense, $3.7 million depreciation and amortization expense, $3.6 million change in fair value of contingent consideration, $2.3 million amortization of debt discount, and $0.6 million write-off of deferred debt issuance costs related to the Revenue Interest Financing.

Net cash used in operating activities was $97.1 million for the nine months ended September 30, 2020. This resulted primarily from our net loss of $98.0 million, adjusted for non-cash charges of $22.9 million, and by cash used by our operating assets and liabilities of $22.0 million. Our operating assets increased $26.3 million for accounts receivable mainly related to the contract asset recognized from license revenue in the current period and the increased sales of specialty products during the nine-months ended September 30, 2020, decreased by $11.0 million for prepaids related to the Dunkirk construction and other assets, and $3.0 million for inventory of all drug products. Our operating liabilities decreased by $9.7 million mainly due to a decrease in accrued construction costs and accrued inventory purchases, offset by an increase in accrued selling costs and rebates, and an increase in accrued wages and benefits, and other operating liabilities. Our net non-cash charges during the nine months ended September 30, 2020 primarily consisted of $10.3 million of loss on extinguishment of debt, $8.0 million of stock-based compensation expense, $3.2 million depreciation and amortization expense, and $1.2 million amortization of debt discount.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $106.4 million for the nine months ended September 30, 2021, compared to $58.4 million used in the nine months ended September 30, 2020. The difference was primarily due to more cash being provided by the sales and maturities of short-term investments and cash acquired from the acquisition of Kuur, partially offset by an increase in cash paid for property and equipment at our API and Dunkirk facilities and cash paid for in-licenses fees related to our specialty drugs during the nine months ended September 30, 2021.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1.4 million for the nine months ended September 30, 2021, which consisted of $1.6 million from the exercise of stock options, and $0.8 million proceeds from the issuance of debt, partially offset by $1.1 million repayment of debt and finance lease obligations.

Net cash provided by financing activities was $185.3 million for the nine months ended September 30, 2020, which primarily consisted of $126.8 million from the sale of common stock and $118.0 million from the draw downs of debt from our credit facility with Oaktree and $1.9 million to fund our new API plant in China, $7.0 million from the issuance of warrants to Oaktree and Sagard, and $1.2 million from the exercise of stock options, partially offset by $54.3 million repayment of Perceptive debt, and $7.6 million and $7.2 million issuance costs related to our underwritten follow-on public offering and the new Oaktree debt, respectively.

Contractual Obligations

A summary of our contractual obligations as of September 30, 2021 is as follows:

	Payments Due by Period				
	Within 1 Year	1 to 3 years	3 to 5 years	More than 5 years	Total Amounts Committed
	(in thousands)				
Operating leases	$ 3,176	$ 4,157	$ 2,241	$ 211	$ 9,785
Long-term debt	6,434	25,777	130,401	—	162,612
Finance lease obligations	329	487	—	—	816
Licensing fees	1,066	600	—	—	1,666
	$ 11,005	$ 31,021	$ 132,642	$ 211	$ 174,879

The above table includes the Company's operating leases and the amounts committed under those leases by each location: (1) the rental of our global headquarters in the Conventus Center for Collaborative Medicine in Buffalo, NY; (2) the rental of our R&D facility in the IC Development Centre in Hong Kong; (3) the rental of the Commercial Platform headquarters in Chicago, IL; (4) the rental of our clinical research headquarters in Cranford, NJ; (5) the rental of our clinical data management center in Taipei, Taiwan; (6) the rental of eight facilities for our contract research organization throughout Latin America; (7) the rental of our Global Supply Chain distribution office in Houston, TX; (8) the rental of our Global Supply Chain API manufacturing facility in Chongqing, China; and (9) the rental of other facilities and equipment located mainly in Buffalo, NY.

The long-term debt is comprised of (1) the principal and fees related to the three tranches drawn on our Senior Credit Agreement with Oaktree; (2) our credit arrangement with Chongqing Maliu Riverside Development and Investment Co., LTD; and (3) our mortgage assumed in connection with the acquisition of CDE.

The finance lease obligations represent the lease of various equipment for our facilities in and near Buffalo, NY.

The license fee obligations are due in connection with our in-licensing arrangements for certain of the Commercial Platform's specialty products.

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 R&D 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.

Business Acquisitions

The Company accounts for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Identifiable amortizing intangible assets are recorded on the consolidated balance sheet at fair value and amortized over their estimated useful lives. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as goodwill.

Contingent Consideration

Contingent consideration arising from a business acquisition is included as part of the purchase price and is recorded at fair value as of the acquisition date. Subsequent to the acquisition date, the Company remeasures contingent consideration arrangements at fair value at each reporting period until the contingency is resolved. The changes in fair value are recognized within selling, general, and administrative expenses in the Company's consolidated statement of operations and comprehensive loss. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Recent Accounting Pronouncements

In the normal course of business, we evaluate all new accounting pronouncements issued by the FASB, the SEC, or other authoritative accounting bodies to determine the potential impact they may have on our condensed consolidated financial statements.

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 each of the nine months ended September 30, 2021 and 2020, approximately 1% of our sales, excluding intercompany sales, were denominated in foreign currencies. As a result, our revenue can be impacted by fluctuations in foreign currency exchange rates, however, the impact of fluctuations in foreign currency exchange rates on our revenues is not expected to be significant, as we expect that foreign currencies will continue to represent a low 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. The People's Republic of China ("PRC") government uses a single rate of exchange as quoted daily by the People's Bank of China, ("PBOC"). The PRC imposes a number of procedural requirements that limit the ability to readily convert RMB 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 PRC central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Interest Rate Sensitivity

We had cash, cash equivalents, restricted cash, and short-term investments of $105.0 million as of September 30, 2021. 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.

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 Interim Chief Accounting Officer (Principal Financial and Accounting Officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our Chief Executive Officer and Board Chairman (Principal Executive Officer) and our Interim Chief Accounting Officer (Principal Financial and Accounting Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

On May 4, 2021, the Company entered into the Merger Agreement with Kuur Therapeutics, Inc., a Delaware corporation ("Kuur") whereby it acquired 100% of the outstanding shares of Kuur. Under the terms of the Merger Agreement, the Company's wholly owned subsidiary, Athenex Pharmaceuticals LLC, a Delaware limited liability company, merged with and into Kuur, with Kuur surviving as a wholly owned subsidiary of the Company. We are currently integrating Kuur into our operations and internal control processes and, pursuant to the Securities and Exchange Commission staff interpretative guidance that assessment of a recently acquired business may be omitted from the scope of an assessment for a period not to exceed one year from the date of acquisition, the scope of our assessment of our internal controls over financial reporting at September 30, 2021 does not include Kuur.

Changes in Internal Control over Financial Reporting

Except for internal controls related to integration activities associated with our acquisition of Kuur, there were no changes in the Company's internal controls over financial reporting during the fiscal quarter ended September 30, 2021, that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Securities Litigation

Following our receipt of the CRL in February 2021 and the subsequent decline of the market price of the Company's common stock, two purported securities class action lawsuits were filed in the U.S. District Court for the Western District of New York on March 3, 2021 and March 22, 2021, respectively, against the Company and certain members of its management team seeking to recover damages for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

The complaints generally allege that between August 7, 2019 and February 26, 2021 (the purported class period), the Company and the individual defendants made materially false and misleading statements regarding the Company's business in connection with the Company's development of Oral Paclitaxel for the treatment of metastatic breast cancer and the likelihood of FDA approval, and that the plaintiffs suffered losses when the Company's stock price dropped after its announcement on February 26, 2021 regarding receipt of the CRL. The complaints seek class certification, damages, fees, costs, and expenses. On August 5, 2021, the Court consolidated the two actions and appointed a lead plaintiff and lead counsel. Pursuant to a stipulated scheduling order, the lead plaintiff will file a consolidated complaint no later than November 19, 2021. Defendants' motion to dismiss is due by January 25, 2022; plaintiffs' opposition to that motion is due by March 28, 2022; and the defendants' reply is due by May 20, 2022. The Company and the individual defendants believe that the claims in the consolidated lawsuits are without merit, and the Company has not recorded a liability related to these shareholder class actions as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims but there can be no assurances as to the outcome.

Shareholder Derivative Lawsuit

On June 3, 2021, a shareholder derivative lawsuit was filed in the United States District Court for the District of Delaware by Timothy J. Wonnell, allegedly on behalf of the Company, that piggy-backs on the securities class actions referenced above, seeking to recover damages on behalf of the Company. The complaint names Johnson Lau, Rudolf Kwan, Timothy Cook, and members of the Board as defendants, and generally alleges that they caused or failed to prevent the securities law violations asserted in the securities class actions. On September 13, 2021, the Court (i) granted the defendants' motion to stay the derivative action until after resolution of the motion to dismiss the consolidated securities class actions, and (ii) administratively closed the derivative litigation, directing the parties to promptly notify the Court when the related securities class action has been resolved so the derivative action can be reopened. The Company and the individual defendants believe the claims in the shareholder derivative action are without merit, and the Company has not recorded a liability related to this lawsuit as the risk of loss is remote. The Company and the individual defendants intend to vigorously defend against these claims should the case be reopened, but there can be no assurances as to the outcome.

Item 1A. Risk Factors.

For a discussion of the Company's potential risks or uncertainties, please see: (i) "Part I—Item 1A—Risk Factors" and "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC; (ii) "Part II—Item 1A—Risk Factors" and "Part I—Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Quarterly Report on Form 10-Q for the quarters ended March 31, 2021 and June 30, 2021 filed with the SEC; and (iii) the additional risks described below.

We face litigation and legal proceedings and, while we cannot predict the outcomes of such proceedings and other contingencies with certainty, some of these outcomes could adversely affect our business and financial condition.

Following our receipt of the CRL in February 2021 and the subsequent decline of the market price of the Company's common stock, two purported class action lawsuits were filed in the U.S. District Court for the Western District of New York on March 3, 2021 and March 22, 2021, respectively, against the Company and certain members of its management team, and a related shareholder derivative lawsuit was filed in the U.S. District Court for the District of Delaware on June 3, 2021. Defending against these and any future lawsuits and legal proceedings may involve significant expense, be disruptive to our business operations and divert our management's attention and resources. Negative publicity surrounding such legal proceedings may also harm our reputation, our stock price, and adversely impact our business and financial condition.

Further, we cannot predict with certainty the outcomes of these legal proceedings. The outcome of some of these legal proceeding could require us to take, or refrain from taking, actions which could negatively affect our operations or could require us to pay substantial amounts of money adversely affecting our financial condition and results of operations.

The resurgence of COVID-19 in India and other countries where we source supplies may create supply chain risk and disruption risks.

The recent surge of COVID-19 cases in India during the first half of 2021, a country where we source supplies and maintain partnerships that are key to our generics business, including API, presented business and supply chain disruption risks for the Company. For example, we were unable to receive inventory from our partners in India for a certain period of time. We could face similar risks in other regions, or a resurgence in India, to the extent the virus is not able to be contained, there is widespread sickness and disruptions on operations and also in the event state actors impose lockdowns, restrictions on the operations of businesses and other containment measures to combat the spread of the virus. The scope and impact of any such measures is not yet known and will depend on a number of factors, including the ultimate spread and severity of the outbreaks and the scope, duration and impact of containment measures on individuals and businesses. If our partners experience significant or extended disruptions to their business due to COVID-19, it could result in substantial supply shortages and harm our generics business, as well as our overall financial condition and results of operations.

The Kuur acquisition will increase our capital requirements and failure to successfully integrate Kuur's business and operations may adversely affect the combined Company's future results.

We believe that the acquisition of Kuur will result in certain benefits, including certain cost synergies, drive product innovations, and operational efficiencies. However, to realize these anticipated benefits, the businesses of will depend on the Company's ability to successfully integrate Kuur's business. We may fail to realize the anticipated benefits of the acquisition in our expected time frame, if at all, for a variety of reasons and the acquisition subjects the Company to a number of additional risks, including the following:

- Increased operating expenses and cash requirements;
- The assumption of indebtedness or contingent liabilities;
- The issuance of additional equity securities upon the achievement of milestones in the Merger Agreement which would result in additional dilution;
- Assimilation of operations, intellectual property, products, and product candidates of Kuur, including difficulties associated with integrating new personnel;
- The diversion of financial and managerial resources from our existing product programs and initiatives as we focus efforts on the integration Kuur's business;
- Retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships of the acquired business;
- Risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals;
- Our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- Risk of conducting research and development activities in new therapeutic areas or treatment modalities in which we have little to no experience; and
- Successfully combining and integrating the acquired business into our existing business to fully realize the benefits of such acquisition.

The integration may result in additional and unforeseen expenses or delays. If Athenex is not able to successfully integrate Kuur's business and operations, or if there are delays in combining the businesses, the anticipated benefits of the Merger may not be realized fully or at all or may take longer to realize than expected.

Our access to additional capital under the Senior Credit Agreement, Sagard Revenue Interest Financing Agreement and our out-licensing agreements is dependent on the fulfillment of certain conditions, where applicable, and achievement of certain milestones, some of which may be impossible or difficult to achieve in the near term, if at all.

Under our senior secured loan agreement, dated June 19, 2020 and related securities agreements with Oaktree Fund Administration, LLC, as administrative agent, and the lenders party thereto (the "Senior Credit Agreement"), the Revenue Interest Financing Agreement entered into with Sagard on August 4, 2020 (the "Revenue Interest Financing Agreement") and our out-licensing arrangements, our ability to access additional capital is dependent on our ability to achieve various regulatory and commercial milestones related to our Oral Paclitaxel program. In early October 2021, the Company held a Type A meeting with the FDA, and the purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the CRL and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S. After careful consideration of the FDA feedback, the Company decided that it will not currently be pursuing regulatory approval for Oral Paclitaxel monotherapy for the treatment of mBC in the U.S. Accordingly, we do not expect to be able to achieve the milestones under the Senior Credit Agreement or the Revenue Interest Financing Arrangement. Our Senior Credit Agreement provides that we must meet funding conditions related to the approval and commercialization of Oral Paclitaxel to draw down the remaining $75.0 million of commitments under Senior Credit Agreement. Each of the Senior Credit Agreement and the Revenue Interest Financing Agreement also require bringdowns of various representations and warranties as a condition to funding and our access to funding under the Revenue Interest Financing Agreement is dependent on the approval of Oral Paclitaxel. The Revenue Interest Financing Agreement also provides Sagard with a termination right in the event we do not receive a marketing authorization for Oral Paclitaxel by December 31, 2021. Given the Company's recent decision to not pursue regulatory approval for Oral Pacitaxel for the treatment of mBC in the U.S., the agreement will be subject to Sagard's right of termination and we will generally not be able to access additional funds under our financing arrangements. Further, in the event we do not meet the funding conditions and/or achieve the various commercial and regulatory milestones in our out-licensing agreements, in which case we will need to raise additional capital and can provide no assurances that we will be able to do so when needed or on acceptable terms. In the event we are unable to access additional capital we would be forced to delay, reduce or eliminate our research and drug development programs or commercialization efforts. In addition, the failure to meet these conditions and milestones would have broader implications on the value and prospects of our Company and could impair our ability to raise such additional necessary capital, grow our business, retain key employees and continue our operations.

Manufacturing risks, including our inability to manufacture API used in the clinical trials of our proprietary product candidates could adversely affect our ability to commercialize our products and product candidates.

Our business strategy depends on our ability to manufacture API in sufficient quantities and on a timely basis so as to meet our needs to manufacture our product candidates for our clinical trials and to meet consumer demand for our products, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- Our inability to manufacture API and clinical products in sufficient quantities to meet the needs of our clinical trials or to commercialize our products;
- Our inability to manufacture API at our Taihao API facility after the end of 2021, unless we are able to extend operations at the facility following further dialogue with the DEMC;
- Our inability to manufacture API in the event our manufacturing facilities' operations, including those at our Taihao API facility, are suspended indefinitely or terminated due to events beyond our control;
- Our inability to secure alternative sources of API or product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- Our failure to increase production of products to meet demand;
- Our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- Difficulty identifying and qualifying alternative suppliers for components in a timely manner and
- Potential damage to or destruction of our manufacturing equipment or manufacturing facility.

In addition, we conduct manufacturing operations at our facilities in Chongqing, China to manufacture API. As a result, our business is subject to risks associated with those facilities in particular and doing business in China generally, including:

- The likelihood that we will be required to terminate production activities at our Taihao API facility at the end of 2021 based on verbal notice from the DEMC, and the possibility of our operations at our Taihao API facility being suspended indefinitely or terminated by an order of the local government due to events beyond our control;

- The impact of the ongoing COVID-19 pandemic on our operations in China;
- The possibility that the costs of continuing to build out and maintain the new Sintaho API facility in Chongqing exceed the revenue we are able to generate from manufacturing API at the facility;
- Adverse political and economic conditions, particularly those negatively affecting the trade relationship between the U.S. and China;
- Trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- Potentially negative consequences from changes in tax laws;
- Difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- Potentially lower protection of intellectual property rights;
- Unexpected or unfavorable changes in regulatory requirements;
- Possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the U.S.; and
- Difficulties in managing foreign relationships and operations generally.

We recently received verbal notice from the DEMC in July 2021 that we will be required to terminate the production activities at our Taihao API facility at the end 2021. We are engaging in dialogue with the DEMC but if we are unable to continue production activities, we will need to incur significant capital expenditures to move production lines, including that of our tirbanibulin API, to our Sintaho API facility, and we may experience supply chain issues as a result which could impair our ability to meet our supply obligations to our partners.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. If, as we expect, our need for API increases, or demand for our products increase, we will have to invest additional resources to purchase components, hire and train employees and enhance our manufacturing processes and may have to use alternate suppliers of API to meet our needs. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. Any of these factors may affect our ability to manufacture our product and could reduce our revenues and profitability.

We are dependent on our key personnel, and if we are not successful in attracting and retaining qualified personnel, we may not be able to successfully implement our business strategy. Additionally, certain members of our leadership may engage in other business ventures that may have interests in conflict with ours.

We are highly dependent on Dr. Lau, our Chief Executive Officer, Dr. Kwan, our Chief Medical Officer and the other principal members of our management and scientific teams. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by changes in the price of our common stock that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

The loss of any member of the Company's senior management, either permanently or for an indeterminate period of time, and/or failure to successfully implement our succession plan to enable the effective transfer of knowledge or to facilitate smooth transitions in leadership could significantly disrupt the management of the Company's business and impair the Company's ability to execute its business strategies. We have had significant changes in senior management, including the departure of our Chief Financial Officer, General Counsel and President, China Division, and more changes could occur. Senior management transition periods, including adding new personnel, could be difficult as new employees gain an understanding of our business and strategy. If we are unable to successfully integrate new employees, we may have difficulty maintaining compliance with our internal control over financial reporting, disclosure controls and procedures, and executing our business strategy, which could have an adverse effect on our overall financial condition. Furthermore, replacing executive officers and key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may choose to hire part-time employees or use consultants. As a result, certain of our employees, officers, directors and consultants may not devote all of their time to our business, and may from time to time serve as officers, directors and consultants of other companies. These other companies may have interests in conflict with ours. For instance, Dr. Johnson Lau, who serves as our Chief Executive Officer and Chairman, Dr. Manson Fok, who serves on our board of directors, are also directors of Avalon, a stockholder of ours. Dr. Lau also serves as the Chief Executive Officer of Axis, a joint venture that we majority own.

We also face competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

During the quarter ended September 30, 2021, CIDAL Limited ("CIDAL") achieved the last of its six clinical milestones associated with earning the contingent equity consideration from our acquisition of certain of CIDAL's assets. Accordingly, on September 30, 2021, the Company issued 11,299 shares of common stock to CIDAL. In issuing the shares to CIDAL, the Company relied on an exemption from registration under the Securities Act, as set forth in Section 4(a)(2) of the Securities Act.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

On October 1, 2021, the Company entered into a lease agreement with Fort Schuyler Management Corporation ("FSMC"), a not-for-profit corporation affiliated with the State of New York, to lease the 409,000 square feet, newly constructed cGMP ISO Class 5 high potency pharmaceutical manufacturing facility located in Dunkirk, NY. The lease agreement calls for annual rent payments of $2 for an initial 10-year term, with the option for the Company to renew under the same terms and conditions for an additional 10-year term. The provisions of the lease agreement are consistent with those agreed upon in the 2015 Agreement for Medical Technology Research, Development, and Innovation and Commercial Alliance ("Alliance Agreement"), and subsequent amendments, under which FSMC agreed to fund the construction costs of a new manufacturing facility in Dunkirk, NY, up to $208.0 million. Under the terms of the lease agreement and 2015 Alliance Agreement, the Company has committed to spend $1.52 billion on operational expenses during the initial 10-year term, and an additional $1.5 billion on operational expenses if the Company elects to extend the lease for a second 10-year term. The Company also committed to hiring 450 employees at the Dunkirk facility within the first 5 years of operations, including hiring at least 300 new employees within 2.5 years of the Dunkirk facility becoming operational. The Company has identified this as an operating lease and it impact is not expected to be material to the financial statements.

Effective as of October 12, 2021, Kuur, a wholly owned subsidiary of the Company, and Baylor College of Medicine ("Baylor") entered into a Second Amended and Restated Co-Development Agreement (the "Co-Development Agreement") and a Second Amended and Restated Exclusive License and Option Agreement (the "License Agreement"). Both agreements have been in place since 2016 and were previously amended and restated on February 28, 2020, prior to the Company's acquisition of Kuur, and generally provide for Kuur and Baylor to collaborate on projects relating to NKT cells and cellular immunotherapy products for the treatment of cancer. The Co-Development Agreement was amended to expand the size of the Joint Steering Committee from eight to ten members, with five members each appointed by Kuur and Baylor, and to update administrative provisions describing how the day-to-day collaboration between the parties is conducted. In addition, the Co-Development Agreement extends the term of the agreement to October 12, 2026, unless earlier terminated, and provides that the agreement will automatically renew for additional five-year periods unless either party gives 365 days' prior notice to terminate the agreement. The License Agreement was amended to remain consistent with the Co-Development Agreement and clarifies the royalties payable for any products that are a combination of the products subject to the license and another active agent. Other than this clarification, the amounts payable under the License Agreement were not changed.

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	Sales Agreement, dated August 20, 2021, by and between Athenex, Inc. and SVB Leerink LLC as sales agent.	Form 8-K	001-38112	1.1	August 20, 2021
10.2	Consulting Agreement, dated September 1, 2021, between Athenex, Inc. and Randoll Sze.	Form 8-K	001-38112	10.1	September 3, 2021
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 Interm Chief Accounting 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 Interm Chief Accounting Officer (Principal Financial and Accounting Officer) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	—	—	—	Filed herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	—	—	—	Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Athenex, Inc.

Date: November 4, 2021

By: /s/ Johnson Y.N. Lau

Chief Executive Officer and Board Chairman
(Principal Executive Officer)

Date: November 4, 2021

By: /s/ Steve Adams

Interim Chief Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2021

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

Exhibit 31.2

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

I, Steve Adams, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2021

/s/ Steve Adams
Name: Steve Adams
Title: Interim Chief Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In accordance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Johnson Y.N. Lau, Chief Executive Officer and Board Chairman (Principal Executive Officer) of Athenex, Inc. (the "registrant"), and Steve Adams, Interim Chief Accounting 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, 2021, 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 4, 2021

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

/s/ Steve Adams
Name: Steve Adams
Title: Interim Chief Accounting Officer
(Principal Financial and Accounting Officer)