

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38112

ATHENEX, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**1001 Main Street, Suite 600
Buffalo, NY**

(Address of principal executive offices)

43-1985966

(I.R.S. Employer
Identification No.)

14203

(Zip Code)

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Small reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 April 30, 2021, the registrant had 93,512,700 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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 47,980	\$ 69,587
Restricted cash	16,500	16,500
Short-term investments	123,186	138,636
Accounts receivable, net of chargebacks and other deductions of \$17,264 and \$12,552, respectively, and provision for credit losses of \$9,482 and \$9,637, respectively	20,189	23,603
Inventories	26,324	28,846
Prepaid expenses and other current assets	16,968	14,789
Total current assets	251,147	291,961
Property and equipment, net	41,778	34,388
Goodwill	38,840	38,891
Intangible assets, net	9,482	10,218
Operating lease right-of-use assets, net	7,462	7,921
Other assets	947	950
Total assets	\$ 349,656	\$ 384,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 15,858	\$ 18,673
Accrued expenses	28,714	38,273
Current portion of operating lease liabilities	3,161	3,185
Current portion of long-term debt and finance lease obligations	1,970	2,010
Total current liabilities	49,703	62,141
Long-term liabilities:		
Long-term operating lease liabilities	5,832	6,355
Long-term debt and finance lease obligations	147,265	146,577
Deferred tax liabilities	58	56
Other long-term liabilities	3,674	3,852
Total liabilities	206,532	218,981
Commitments and contingencies (See Note 15)		
Stockholders' equity:		
Common stock, par value \$0.001 per share, 250,000,000 shares authorized at March 31, 2021 and December 31, 2020; 95,185,620 and 95,066,195 shares issued at March 31, 2021 and December 31, 2020, respectively; 93,512,700 and 93,393,275 shares outstanding at March 31, 2021 and December 31, 2020, respectively	95	95
Additional paid-in capital	904,950	901,864
Accumulated other comprehensive loss	(841)	(1,134)
Accumulated deficit	(738,694)	(713,644)
Less: treasury stock, at cost; 1,672,920 shares at March 31, 2021 and December 31, 2020	(7,406)	(7,406)
Total Athenex, Inc. stockholders' equity	158,104	179,775
Non-controlling interests	(14,980)	(14,427)
Total stockholders' equity	143,124	165,348
Total liabilities and stockholders' equity	\$ 349,656	\$ 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 March 31,	
	2021	2020
Revenue:		
Product sales, net	\$ 20,360	\$ 18,547
License and other revenue	20,665	28,388
Total revenue	41,025	46,935
Cost of sales	16,405	19,572
Gross Profit	24,620	27,363
Operating expenses:		
Research and development expenses	23,070	17,192
Selling, general, and administrative expenses	22,120	25,748
Total operating expenses	45,190	42,940
Operating loss	(20,570)	(15,577)
Interest income	29	413
Interest expense	4,908	1,673
Loss before income tax expense	(25,449)	(16,837)
Income tax expense	154	2,881
Net loss	(25,603)	(19,718)
Less: net loss attributable to non-controlling interests	(553)	(289)
Net loss attributable to Athenex, Inc.	\$ (25,050)	\$ (19,429)
Unrealized gain (loss) on investment, net of income taxes	16	(68)
Foreign currency translation adjustment, net of income taxes	277	(438)
Comprehensive loss	\$ (24,757)	\$ (19,935)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 12)	\$ (0.27)	\$ (0.24)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted (See Note 12)	93,429,935	81,539,548

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 income, net of tax	—	—	—	—	(506)	—	—	(506)	—	(506)
Balance at March 31, 2020 (unaudited)	<u>83,298,263</u>	<u>\$ 83</u>	<u>\$ 766,253</u>	<u>\$ (586,894)</u>	<u>\$ (1,141)</u>	<u>(1,672,920)</u>	<u>\$ (7,406)</u>	<u>\$ 170,895</u>	<u>\$ (12,659)</u>	<u>\$ 158,236</u>
	Common Stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Treasury Stock		Total Athenex, Inc. stockholders' equity	Non- controlling interests	Total stockholders' equity
	Shares	Amount				Shares	Amount			
Balance at 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 loss, net of tax	—	—	—	—	293	—	—	293	—	293
Balance at March 31, 2021 (unaudited)	<u>95,185,620</u>	<u>\$ 95</u>	<u>\$ 904,950</u>	<u>\$ (738,694)</u>	<u>\$ (841)</u>	<u>(1,672,920)</u>	<u>\$ (7,406)</u>	<u>\$ 158,104</u>	<u>\$ (14,980)</u>	<u>\$ 143,124</u>

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

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

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (25,603)	\$ (19,718)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,274	1,086
Stock-based compensation expense	2,234	2,261
Amortization of debt discount	779	256
Loss on disposal of assets and impairment charges	—	173
Deferred income taxes	2	48
Changes in operating assets and liabilities:		
Receivables, net	3,414	(34,728)
Prepaid expenses and other assets	(2,176)	3,748
Inventories	2,523	(3,101)
Accounts payable and accrued expenses	(12,323)	4,430
Net cash used in operating activities	(29,876)	(45,545)
Cash flows from investing activities:		
Purchase of property and equipment	(7,341)	(1,736)
Payments for licenses	(1,088)	(64)
Purchases of short-term investments	(55,784)	(23,571)
Sales and maturities of short-term investments	71,250	14,920
Net cash provided by (used in) investing activities	7,037	(10,451)
Cash flows from financing activities:		
Proceeds from issuance of debt	—	435
Proceeds from exercise of stock options	852	344
Repayment of finance lease obligations and long-term debt	(98)	(47)
Net cash provided by financing activities	754	732
Net decrease in cash, cash equivalents, and restricted cash	(22,085)	(55,264)
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	478	(427)
Cash, cash equivalents, and restricted cash, end of period (See Note 3)	\$ 64,480	\$ 71,983
Supplemental cash flow disclosures		
Interest paid	\$ 7,708	\$ 1,390
Non-cash investing and financing activities:		
Accrued purchases of property and equipment	\$ 1,215	\$ 1,009
Accrued purchases of licenses	\$ 1,800	\$ 500
ROU assets derecognized from modification of operating lease obligations	\$ —	\$ (468)
ROU assets recognized in exchange for operating lease obligations	\$ —	\$ 353

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 proprietary 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”).

Significant Risks and Uncertainties

The Company has incurred operating losses since its inception and, as a result, as of March 31, 2021 and December 31, 2020 had an accumulated deficit of \$738.7 million and \$713.6 million, respectively. As of March 31, 2021, the Company had cash and cash equivalents of \$48.0 million, restricted cash of \$16.5 million, and short-term investments of \$123.2 million.

The Company believes that the existing cash and cash equivalents, restricted cash, and short-term investments will enable us to meet our current operational liquidity needs and fund operations into the second half of 2022. The Company has based these estimates on assumptions that may prove to be wrong, and it could spend the available financial resources much faster than expected and need to raise additional funds sooner than anticipated. Operations have been funded primarily through the sale of common stock, senior secured loans, and to a lesser extent, from convertible bond financing, revenue, and grant funding. The Company will require significant additional funds to conduct clinical trials and to fund its commercialization and manufacturing operations. There can be no assurance that this funding will be available for our use when needed, or at all. If adequate funds are not available, the Company may be required to delay, modify, or terminate its research and development programs or reduce its planned commercialization efforts. Further, if the Company is unable to obtain additional financing, the Company will need to reevaluate future operating plans. Although the Company plans to raise additional funds, these plans are subject to market conditions which are outside of its control and therefore cannot be deemed to be probable.

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. 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 metastatic breast cancer representative of the population in the U.S. The FDA determined that additional 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, are required to support potential approval of the NDA. We are working to consider the appropriate next steps in the development of Oral Paclitaxel. We have been preparing for and plan to request a meeting

with the FDA and plan to engage in a dialogue on the design and scope of a clinical trial to address the FDA's requirements and align on the next steps required to obtain approval. The Company's ability to potentially commercialize Oral Paclitaxel, and the timing of potential commercialization, is dependent on the discussion with the agency, the Company's resubmission of its NDA, ultimate FDA approval, and potentially additional capital.

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; 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 product revenue and might not, if ever, achieve profitability and positive cash flow.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles in the United States of America ("GAAP") for interim financial information (Accounting Standards Codification ("ASC") 270, *Interim Reporting*) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity with GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. These condensed consolidated financial statements reflect the accounts and operations of 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 months ended March 31, 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 expected losses, approximates fair value and therefore, relies more on historical and current analysis of such financial instruments.

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 March 31, 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):

	March 31, 2021	December 31, 2020
Raw materials and purchased parts	\$ 3,054	\$ 6,498
Work in progress	1,728	776
Finished goods	21,542	21,572
Total inventories	<u>\$ 26,324</u>	<u>\$ 28,846</u>

5. Intangible Assets, net

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

	March 31, 2021			
	Cost/Fair Value	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:				
Licenses	\$ 12,641	\$ 5,745	\$ —	\$ 6,896
Polymed customer list	1,593	1,482	—	111
Polymed technology	3,712	1,754	—	1,958
Indefinite-lived intangible assets:				
CDE in-process research and development (IPR&D)	728	—	—	728
Effect of currency translation adjustment	(211)	—	—	(211)
Total intangible assets, net	<u>\$ 18,463</u>	<u>\$ 8,981</u>	<u>\$ —</u>	<u>\$ 9,482</u>
	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	<u>\$ 18,478</u>	<u>\$ 8,260</u>	<u>\$ —</u>	<u>\$ 10,218</u>

As of March 31, 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 \$0.8 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 in-process research and development, (“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 impairments of IPR&D during the three months ended March 31, 2021. The weighted-average useful life for all intangible assets was 7.1 years as of March 31, 2021.

The Company recorded \$0.6 million and \$0.5 million of amortization expense for the three-month periods ended March 31, 2021 and 2020, respectively.

The Company’s goodwill balance is the result of 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 March 31, 2021 are due to 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.

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

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

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

Level 2—Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;

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

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

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

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

	Fair Value Measurements at March 31, 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	\$ 5,497	\$ 5,497	\$ —	\$ —
Short-term investments - certificates of deposit	1,000	—	1,000	—
Short-term investments - commercial paper	22,548	—	22,548	—
Financial assets included within short-term investments				
Short-term investments - certificates of deposit	22,769	—	22,769	—
Short-term investments - U.S. government bonds	15,000	—	15,000	—
Short-term investments - commercial paper	85,185	—	85,185	—
Available-for-sale investment	232	232	—	—
Total assets	\$ 152,231	\$ 5,729	\$ 146,502	\$ —

	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 March 31, 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 sheet.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Accrued wages and benefits	\$ 7,798	\$ 6,720
Accrued selling fees, rebates, and royalties	4,388	9,046
Accrued operating expenses	3,804	3,222
Accrued construction costs	3,421	4,104
Accrued inventory purchases	2,397	3,714
Accrued clinical expenses	2,073	2,949
Accrued tax withholdings	1,863	1,948
Accrued costs for product launch	1,415	1,474
Deferred revenue	1,289	1,147
Accrued R&D licensing fees	266	366
Accrued interest	—	3,583
Total accrued expenses	<u>\$ 28,714</u>	<u>\$ 38,273</u>

The accrued construction costs relate to the building of the manufacturing facility in Dunkirk, NY. This amount, plus an additional \$0.4 million paid by the Company is expected to be funded by New York State. Therefore, \$3.8 million is recorded within prepaid expenses and other current assets on the Company's condensed consolidated balance sheet as of March 31, 2021.

8. Income Taxes

The Company did not record a provision for U.S. federal income taxes for the three months ended March 31, 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. Tax expense to date is primarily the result of tax withheld in Taiwan, in the amount of \$0.1 million, on milestone payments in connection with an out-license agreement.

9. Debt and Lease Obligations

Debt

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

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Current portion of mortgage	\$ 729	\$ 731
Current portion of bank loan	761	764
Current portion of senior secured loan	70	70
Current portion of finance lease obligations	410	445
Current portion of operating lease obligations	3,161	3,185
Long-term portion of finance lease obligations	474	537
Long-term portion of operating lease obligations	5,832	6,355
Chongqing Maliu credit agreement	7,614	7,641
Senior secured loan, net of debt discount and financing fees of \$10,822 and \$11,601 respectively	139,178	138,399
Total	<u>\$ 158,229</u>	<u>\$ 158,127</u>

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. 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 March 31, 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 March 31, 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, 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 metastatic breast cancer. In the event the Company is unable to do so before December 31, 2021, Sagard will have a termination right. In exchange for the Product Payment, the Company agreed to make payments to Sagard equal to 5.0% of its world-wide net sales of Oral Paclitaxel, subject to a hard cap equal to the lesser of 170% of the Product Payment and the Put/Call Price as discussed below and further set forth in the Revenue Interest Financing Agreement. The Company is required to make certain additional payments to Sagard to the extent Sagard has not received Payments equaling at least \$20.0 million by September 30, 2024 and at least \$50.0 million by August 4, 2026, in the amount of the applicable shortfall, and, subject to the Hard Cap, if Sagard has not received Payments equaling at least \$85.0 million by the tenth anniversary of the date the Product Payment is funded, in an amount such that Sagard will have obtained a 6.0% internal rate of return on the Product Payment.

The Company’s obligations under the Revenue Interest Financing Agreement are secured, subject to customary permitted liens and other agreed upon exceptions and subject to an intercreditor agreement with Oaktree as administrative agent for the lenders under our Senior Credit Agreement, by a perfected security interest in (i) accounts receivable arising from net sales of Oral Paclitaxel and (ii) intellectual property that is claiming or covering Oral Paclitaxel itself or any method of using, making or manufacturing Oral Paclitaxel.

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 is due within the first twelve months following receiving the certification, 30% of the total loan with accrued interest due within twenty-four months, and the remaining balance with accrued interest due within thirty-six months. Interest accrues at the three-year loan interest rate by the People’s Bank of China for the same period on the date of the deposit of the full loan amount, 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 March 31, 2021, the balance due to CQ was \$7.6 million.

On May 15, 2020, the Company entered into a credit agreement with China Merchants Bank, enabling the Company to draw up to a Renminbi ¥5.0 million (USD \$0.8 million at March 31, 2021) during the period through May 14, 2021. The Company drew the entire available credit in July 2020. This loan has a maturity date of May 14, 2021 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 March 31,	
	2021	2020
Operating lease cost	746	\$ 755
Finance lease cost:		
Amortization of assets	75	34
Interest on lease liabilities	24	6
Total net lease cost	\$ 845	\$ 795

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 March 31, 2021 and 2020. Variable lease costs for the three months ended March 31, 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):

	March 31, 2021	December 31, 2020
Finance leases:		
Property and equipment, at cost	\$ 1,535	\$ 1,535
Accumulated amortization, net	(422)	(347)
Property and equipment, net	\$ 1,113	\$ 1,188
Current obligations of finance leases	\$ 410	\$ 445
Long-term portion of finance leases	474	537
Total finance lease obligations	\$ 884	\$ 982
Weighted average remaining lease term (in years):		
Operating leases	3.96	4.23
Finance leases	3.06	3.40
Weighted average discount rate:		
Operating leases	12.8%	12.8%
Finance leases	10.8%	10.4%

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

	Three Months Ended March 31, 2021	Three Months Ended March 31, 2020
Cash paid for amount included in the measurements of lease liabilities:		
Operating cash flows from operating leases	\$ (979)	\$ (820)
Operating cash flows from finance leases	(24)	(6)
Financing cash flows from finance leases	(98)	(47)
ROU assets derecognized from modification of operating lease obligations	—	(468)
ROU assets recognized in exchange for operating lease obligations	\$ —	\$ 353

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

Year ending December 31:	Operating Leases	Finance Leases
2021 (remaining nine months)	\$ 2,577	\$ 351
2022	2,918	275
2023	2,096	248
2024	2,002	157
2025	1,472	—
Thereafter	478	—
Total lease payments	11,543	1,031
Less: Imputed interest	(2,550)	(147)
Total lease obligations	8,993	884
Less: Current obligations	(3,161)	(410)
Long-term lease obligations	<u>\$ 5,832</u>	<u>\$ 474</u>

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. However, no lease term had commenced as of March 31, 2021, as it was not yet operational and the Company could not direct the use of the facility. No lease costs were incurred related to the manufacturing facility during the three-month period ended March 31, 2021.

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 had commenced as of March 31, 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.

10. Related Party Transactions

During the three months ended March 31, 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 (“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 months ended March 31, 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 March 31, 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 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 months ended March 31, 2021.

- b. The Company earns licensing revenue from PharmaEssentia, an entity in which the Company has an investment classified as available-for-sale (see Note 6—*Fair Value Measurements*). During the three months ended March 31, 2021, the Company recorded \$0.5 million milestone fee earned from PharmaEssentia under a license agreement. There were no funds paid to PharmaEssentia under the license and cost-sharing agreements for the three months ended March 31, 2021 and 2020.

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 PharmaEssentia an exclusive, non-transferrable and revocable sublicense of TCR-engineered T Cell therapy for the development of the technology in Taiwan. Axis received license fee of \$1.0 million, net of \$0.3 million withholding tax, in the fourth quarter of 2020. This amount was recorded as deferred revenue as of March 31, 2021.

- c. The Company receives certain clinical development services from ZenRx Limited and its affiliate (collectively, “ZenRx”), a company for which one of the Company’s executive officers serves on the board of directors. In connection with such services, the Company made payments to ZenRx of \$0.3 million and \$0.5 million for the three months ended March 31, 2021 and 2020, respectively. In April 2013, the Company entered into a license agreement with ZenRx pursuant to which the Company granted an exclusive, sublicensable license to use certain of the Company’s IP to develop and commercialize oral irinotecan and encequidar (“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 family members of executives perform consulting services for the Company. Such services were not significant to the condensed consolidated financial statements.

11. 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, subject to the approval of 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 March 31, 2021 and 2020 was \$2.2 million and \$1.9 million, respectively. As of March 31, 2021, \$16.5 million of unrecognized cost related to non-vested stock options was expected to be recognized over a weighted-average period of approximately 1.8 years. The total intrinsic value of options exercised was approximately \$0.2 million and \$0.8 million for the three months ended March 31, 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):

	<u>Stock Options</u>	<u>Weighted- Average Exercise price</u>	<u>Weighted- Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at December 31, 2020	12,496,888	\$ 9.26	5.42	\$ 22,463
Granted	20,000	11.90	—	—
Exercised	(119,425)	7.10	—	—
Forfeited and expired	(32,830)	12.92	—	—
Outstanding at March 31, 2021	<u>12,364,633</u>	\$ 9.28	5.20	\$ —
Vested and exercisable at March 31, 2021	<u>9,504,028</u>	\$ 8.21	4.28	\$ —

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:

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
Weighted average grant date fair value	\$ 7.40	\$ 7.32
Expected dividend yield	—%	—%
Expected stock price volatility	68%	67%
Risk-free interest rate	1.37%	0.75%
Expected life of options (in years)	6.3	5.0

Restricted Stock Awards

No restricted stock awards were granted during the three months ended March 31, 2021 and 2020. Stock-based compensation related to the restricted stock awards amounted to less than \$0.1 million and \$0.4 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, \$0.3 million of unrecognized cost related to non-vested restricted stock awards were expected to be recognized over a weighted-average period of approximately 1.4 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 December 1, 2020 to May 31, 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 \$0.1 million for each of the three months ended March 31, 2021 and 2020.

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 months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Stock options	\$ 2,205	\$ 1,864
Restricted stock expense	29	397
Employee stock purchase plan	46	70
Total stock-based compensation expense	\$ 2,280	\$ 2,331
Cost of sales	\$ 56	\$ 54
Research and development expenses	601	946
Selling, general, and administrative expenses	1,623	1,331
Total stock-based compensation expense	\$ 2,280	\$ 2,331

12. 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 March 31,	
	2021	2020
Stock options and other common stock equivalents	13,899,191	11,347,475
Unvested restricted shares	22,500	105,000
Total potential dilutive shares	13,921,691	11,452,475

13. Business Segment, Geographic, and Concentration Risk Information

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

Oncology Innovation Platform— This operating segment performs research and development on certain of the Company's proprietary drugs, from the preclinical development of its chemical compounds, to the execution and analysis of its several clinical trials. It focuses specifically on Orascovery and Src Kinase Inhibition research platforms, cell therapy programs 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 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 March 31,	
	2021	2020
Total revenue:		
Oncology Innovation Platform	\$ 20,665	\$ 28,387
Global Supply Chain Platform	8,207	3,714
Commercial Platform	13,259	15,542
Total revenue for reportable segments	42,131	47,643
Intersegment revenue	(1,106)	(708)
Total consolidated revenue	\$ 41,025	\$ 46,935

Intersegment revenue eliminated in the above table reflects \$0.6 million in sales from the Global Supply Chain Platform to the Commercial Platform and \$0.5 million in sales from the Global Supply Chain Platform to the Oncology Innovation Platform (in thousands).

	Three Months Ended March 31,	
	2021	2020
Total revenue by product group:		
License fees	\$ 20,500	\$ 28,381
Commercial product sales	18,061	17,502
API sales	1,868	1,022
Contract manufacturing revenue	430	23
Other revenue	166	7
Total consolidated revenue	\$ 41,025	\$ 46,935

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 March 31,	
	2021	2020
Net loss attributable to Athenex, Inc.:		
Oncology Innovation Platform	\$ (5,441)	\$ (958)
Global Supply Chain Platform	(3,682)	(5,986)
Commercial Platform	(15,927)	(12,485)
Total consolidated net loss attributable to Athenex, Inc.	\$ (25,050)	\$ (19,429)

	Three Months Ended March 31,	
	2021	2020
Total depreciation and amortization:		
Oncology Innovation Platform	\$ 207	\$ 175
Global Supply Chain Platform	523	496
Commercial Platform	544	415
Total consolidated depreciation and amortization	<u>\$ 1,274</u>	<u>\$ 1,086</u>

	March 31,	December 31,
	2021	2020
Total assets:		
Oncology Innovation Platform	\$ 199,741	\$ 234,153
Global Supply Chain Platform	101,621	99,087
Commercial Platform	48,294	51,089
Total consolidated assets	<u>\$ 349,656</u>	<u>\$ 384,329</u>

	Three Months Ended March 31,	
	2021	2020
Total revenue:		
United States	\$ 38,645	\$ 17,522
China	205	28,513
Other foreign countries	2,175	900
Total consolidated revenue	<u>\$ 41,025</u>	<u>\$ 46,935</u>

	March 31,	December 31,
	2021	2020
Total property and equipment, net:		
United States	\$ 20,902	\$ 15,511
China	20,876	18,877
Total consolidated property and equipment, net	<u>\$ 41,778</u>	<u>\$ 34,388</u>

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

	Three Months Ended March 31,	
	2021	2020
Percentage of total revenue by customer:		
Customer A	49%	0%
Customer B	11%	9%
Customer C	9%	11%
Customer D	9%	7%
Customer E	0%	60%

	March 31,	December 31,
	2021	2020
Percentage of total accounts receivable by customer:		
Customer A	36%	33%
Customer B	30%	24%
Customer C	10%	16%
Customer D	0%	6%

14. 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-month period ended March 31, 2021, the Company recognized license revenue of \$20.5 million, 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 in the U.S., 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. Under the collaboration agreement between Axis Therapeutics and PharmaEssentia, the Company received \$1.0 million, net of \$0.3 million withholding tax, of upfront fees allocated to its performance obligation to deliver functional IP to the Customer. As of March 31, 2021, the Company had not satisfied this performance obligation by delivering the license with the data necessary for the customer to benefit from the right to use the IP and, therefore, the amount was recorded as deferred revenue.

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 month periods ended March 31, 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 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-month periods ended March 31, 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 March 31, 2021, and December 31, 2020, the Company's total provision for chargebacks and other deductions included as a reduction of accounts receivable totaled \$17.3 million and \$12.6 million, respectively. The Company's total provision for chargebacks and other revenue deductions was \$25.6 million, and \$24.9 million for the three months ended March 31, 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 March 31, 2021			
	(In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
United States	\$ 20,157	\$ 5,229	\$ 13,259	\$ 38,645
China	8	197	—	205
Other foreign countries	500	1,675	—	2,175
Total revenue	\$ 20,665	\$ 7,101	\$ 13,259	\$ 41,025

	For the Three Months Ended March 31, 2020			
	(In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
China	\$ 28,308	\$ 205	\$ —	\$ 28,513
United States	—	1,980	15,542	17,522
Other foreign countries	79	821	—	900
Total revenue	\$ 28,387	\$ 3,006	\$ 15,542	\$ 46,935

The Company also disaggregates its revenue by product group which can be found in Note 13 – *Business Segment, Geographic, and Concentration Risk Information*.

Contract balances

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

	March 31, 2021	December 31, 2020
	(In Thousands)	
Accounts receivable, gross	\$ 46,935	\$ 45,792
Chargebacks and other deductions	(17,264)	(12,552)
Provision for credit losses	(9,482)	(9,637)
Accounts receivable, net	\$ 20,189	\$ 23,603
Deferred revenue	1,289	1,147
Total contract liabilities	\$ 1,289	\$ 1,147

The following tables illustrate accounts receivable and contract asset balances by reportable segments.

	March 31, 2021			
	(In Thousands)			
	Oncology Innovation Platform	Global Supply Chain Platform	Commercial Platform	Consolidated Total
Accounts receivable, gross	\$ 9,167	\$ 3,589	\$ 34,179	\$ 46,935
Chargebacks and other deductions	—	—	(17,264)	(17,264)
Provision for credit losses	(8,919)	(138)	(425)	(9,482)
Accounts receivable, net	248	3,451	16,490	20,189

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	<u>\$ 1,864</u>	<u>\$ 3,909</u>	<u>\$ 17,830</u>	<u>\$ 23,603</u>

As of March 31, 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 months ended March 31, 2021.

15. Commitments and Contingencies

Future minimum payments under the non-cancelable operating leases consists of the following as of March 31, 2021 (in thousands):

Year ending December 31:	Minimum payments
2021 (remaining nine months)	\$ 2,577
2022	2,918
2023	2,096
2024	2,002
2025	1,472
Thereafter	478
	<u>\$ 11,543</u>

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. The defendants expect that these two lawsuits will be consolidated and a lead plaintiff appointed in the coming months. Additional similar lawsuits might be filed. The Company and the individual defendants believe that the claims in these lawsuits are without merit, and the Company has not recorded a liability related to this shareholder class action lawsuit 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.

16. Subsequent Event

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”). Kuur is a leading developer of off-the-shelf CAR-NKT cell immunotherapies for the treatment of solid and hematological malignancies. Pursuant to the terms of the Merger Agreement, the Company will pay \$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). 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. Due to the recency of the Merger Agreement, the Company has not yet completed its assessment of the fair value of the assets acquired, the liabilities assumed and the contingent considerations. The Company will account for this in accordance with ASC 805, Business Combinations, and its evaluation the effect on its consolidated financial statements during the second quarter of 2021.

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.

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 APIs for our clinical and commercial efforts. Our current clinical pipeline in the Oncology Innovation Platform is derived from four different proprietary technologies: (1) Orascopy, based on a P-glycoprotein (“P-gp”) pump inhibitor, (2) Src Kinase Inhibition, (3) Cell Therapy, and (4) Arginine Deprivation Therapy.

On May 4, 2021, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Kuur Therapeutics, Inc., a Delaware corporation (“Kuur”). Kuur is a leading developer of off-the-shelf CAR-NKT cell immunotherapies for the treatment of solid and hematological malignancies. Pursuant to the terms of the Merger Agreement, we will pay \$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). We believe the acquisition strategically combines our 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.

On December 15, 2020, we announced that the FDA has approved Klisyri® (tirbanibulin) for the topical treatment of actinic keratosis (AK) on the face or scalp. Klisyri® is our first FDA approved branded proprietary product, manufactured by us, highlighting the vertically integrated capabilities of the Company ranging from a preclinical lead to a developed product for market launch. The Phase III trials evaluated the efficacy and safety of tirbanibulin ointment 1% (10 mg/g) in adults with actinic keratosis on the face or scalp and included 702 patients across 62 sites in the United States. Enrollment of patients was controlled to achieve a 2:1 ratio of facial: scalp treatment areas. Patients were randomly assigned in a 1:1 ratio to receive tirbanibulin ointment or vehicle ointment, which was self-administered to a contiguous treatment area of 25cm² on the face or scalp containing 4-8 typical AK lesions once daily for five consecutive days. Both Phase III trials, KX01-AK-003 and KX01-AK-004, met the primary endpoint, which was defined as 100% clearance of AK lesions at Day 57 within the face or scalp treatment areas, each trial achieving a highly statistically significant result (p<0.0001). In KX01-AK-003, complete clearance was observed in 44% of the patients treated with tirbanibulin versus 5% for those treated with vehicle, and in KX01-AK-004, complete clearance was observed in 54% of the patients treated with tirbanibulin versus 13% for vehicle. Furthermore, tirbanibulin also achieved the secondary endpoint of partial (≥75%) clearance of lesions in each trial (68% of patients receiving tirbanibulin versus 16% receiving vehicle in KX01-AK-003, and 76% versus 20% respectively in KX01-AK-004). Both results were again highly statistically significant (p<0.0001). In both trials, patient-reported adverse events were mostly transient mild application-site pruritus and application-site pain. No patients experienced a serious adverse event or discontinuation due to tirbanibulin or vehicle in either clinical trial. Signs of local skin reactions assessed by investigators were mostly mild to moderate erythema, flaking or scaling that peaked at day 8 (maximum mean composite local skin reaction score ≤4.3 out of 18 across both trials) and resolved spontaneously in about 2 weeks.

Klisyri® was launched in the U.S., led by our partner Almirall S.A. (“Almirall”) on February 18, 2021, which resulted in a milestone payment of \$20.0 million pursuant to the license agreement. Almirall will employ its expertise to support the development of tirbanibulin in Europe and Almirall will also commercialize the product in European countries, including Russia, if approved in those jurisdictions.

In September 2020, we announced that the U.S. FDA accepted for filing our NDA for Oral Paclitaxel for the treatment of metastatic breast cancer (“MBC”) and has granted the application Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA set a target action date of February 28, 2021. In February 2021, we received a Complete Response Letter (“CRL”) from the FDA regarding its NDA for Oral Paclitaxel for the treatment of metastatic breast cancer. 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 agency stated that the BICR reconciliation and re-read process may have introduced unmeasured bias and influence on the BICR. The agency recommended that we conduct a new adequate and well-conducted clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S. The agency determined that additional risk mitigation strategies to improve toxicity, which may involve dose optimization and / or exclusion of patients deemed to be at higher risk of toxicity, are required to support potential approval of the NDA. We plan to request a meeting with the FDA to discuss the FDA’s response, engage in a dialogue on the design and scope of a clinical trial to address the agency’s requirements, and align on the next steps required to obtain approval. Our ability to potentially commercialize Oral Paclitaxel, and the timing of potential commercialization, is dependent on the discussion with the agency, our resubmission of its NDA, ultimate FDA approval, and potentially additional capital.

We are also evaluating Oral Paclitaxel in combination with other therapies, including anti-VEGF and anti-PD-1 therapies. We are studying Oral Paclitaxel with ramucirumab in a Phase 1b study in patients with advanced gastric cancer who failed previous chemotherapy. Our Phase 1/2 study of Oral Paclitaxel in combination with pembrolizumab, or Keytruda, in patients with advanced solid malignancies is ongoing.

In addition to our lead product candidate, 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.

The other technologies in our Oncology Innovation Platform are 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, and our Arginine deprivation therapy technology under which we are advancing PT01.

In September 2020, we announced that the FDA allowed our Investigational New Drug (IND) application for TCRT-ESO-A2, 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. TCRT-ESO-A2 is being developed by Axis Therapeutics Limited, a joint venture between Athenex and Xiangxue Life Sciences Limited ("XLifeSc"). We plan to initiate a Phase 1 trial in 1H 2021. TCRT-ESO-A2 is similar to TAEST16001, an autologous cell-based therapy being developed simultaneously by XLifeSc for clinical application in China in that both therapies express the same affinity-enhanced TCR.

PT01 targets cancer growth and survival by removing the supply of arginine to cancers that have a disrupted urea cycle. The FDA allowed our IND application for the clinical investigation of PT01 for the treatment of patients with advanced malignancies in 2019. We plan to initiate first human exposure in 2021.

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 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. 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 for later-stage product candidates and pre-launch commercial 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. The recent surge of COVID-19 cases in India, a country where we source supplies and maintain partnerships that are key to our specialty drug business, including API, presents business and supply chain disruption risks for us 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 governments in India impose additional 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 in India and the scope, duration and impact of containment measures on individuals and businesses. If our partners in India 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 Note 5 *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, Src Kinase Inhibition research platforms, and TCR-T Immunotherapy and Arginine Deprivation Therapy, and to buildup of our commercial infrastructure. We have incurred significant net losses since inception.

For the three months ended March 31, 2021, our net loss was \$25.6 million, compared to \$19.7 million for the same period in 2020. As of March 31, 2021 and December 31, 2020, we had an accumulated deficit of \$738.7 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:

- Continue to advance our lead programs, Orascovery and Src Kinase Inhibition technology platforms, through clinical and regulatory development;
- Though we have reduced our planned expenditures in 2021 while there is uncertainty around the best path forward for Oral Paclitaxel, we may need to continue to invest in further developing our Commercial Platform ahead of any intended proprietary drug launch and other drug candidates upon approval;
- Continue certain of our current preclinical and clinical research program and development activities;
- Continue to invest in our manufacturing facilities in Dunkirk and Chongqing;
- Advance the preclinical and clinical research program and development activities of our in-licensed technology platforms, and cell therapy programs;
- 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, including pursuant to our Senior Credit Agreement and Revenue Interest Financing Agreement, or potentially pursuant to new arrangements with different lenders. 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 March 31, 2021, we had cash and cash equivalents of \$48.0 million, restricted cash of \$16.5 million, and short-term investments of \$123.2 million.

Key Components of Results of Operations

Revenue

We derive our consolidated revenue primarily from (i) the sales of generic injectable products by our Commercial Platform; (ii) 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 clinical development 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 trials of our Orascovery platform product candidates, and our Src kinase inhibition platform product candidates, as well as initiate and prepare for additional clinical and preclinical studies, including for the cell therapy 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 15 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 March 31, 2021 Compared to Three Months Ended March 31, 2020

The following table sets forth a summary of our condensed consolidated results of operations for the three months ended March 31, 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 March 31,			
	2021	2020	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue				
Product sales, net	\$ 20,360	\$ 18,547	\$ 1,813	10%
License fees and other revenue	20,665	28,388	(7,723)	-27%
Total revenue	41,025	46,935	(5,910)	
Cost of sales	(16,405)	(19,572)	3,167	-16%
Gross profit	24,620	27,363	(2,743)	
Research and development expenses	(23,070)	(17,192)	(5,878)	34%
Selling, general, and administrative expenses	(22,120)	(25,748)	3,628	-14%
Interest income	29	413	(384)	-93%
Interest expense	(4,908)	(1,673)	(3,235)	193%
Income tax expense	(154)	(2,881)	2,727	-95%
Net loss	(25,603)	(19,718)	(5,885)	
Less: net loss attributable to non-controlling interests	(553)	(289)	(264)	91%
Net loss attributable to Athenex, Inc.	<u>\$ (25,050)</u>	<u>\$ (19,429)</u>	<u>\$ (5,621)</u>	

Revenue

Revenue from product sales increased to \$20.4 million for the three months ended March 31, 2021, from \$18.5 million for the three months ended March 31, 2020, an increase of \$1.8 million or 10%. This increase was primarily attributable to an increase of \$2.8 million in sales of 503B products. Fluctuations in the infection rate and the spread of the global health pandemic and market demand can significantly affect our product sales in the future. API product sales increased by \$0.8 million and contract manufacturing revenue from supply of Klisyri to our partner Almirall increased by \$0.4 million due to the launch of the drug in February 2021. These increases were offset by a decrease of \$2.3 million in APD sales.

License fees and other revenue decreased by \$7.7 million, or 27%. For the three months ended March 31, 2021, we recorded \$20.0 million of license revenue pursuant to the 2017 Almirall License Agreement upon the launch of Klisyri in the U.S., and \$0.5 million related to the upfront fee pursuant to the Second Amendment to the 2011 PharmaEssentia License Agreement. For the three months ended March 31, 2020 we recognized \$28.3 million in license revenue, net of \$1.7 million value added tax (“VAT”), pursuant to the 2019 Xiangxue License Agreement.

Cost of Sales

Cost of sales for the three months ended March 31, 2021 totaled \$16.4 million, a decrease of \$3.2 million, or 16%, as compared to \$19.6 million for the three months ended March 31, 2020. The decrease was primarily due to the \$2.0 million royalty payment incurred in 2020 on the license revenue from Xiangxue. The decrease in cost of specialty product sales was in-line with the decrease in revenue. Cost of 503B and API product sales increased slightly as production levels increased. Changes in the availability of products and market demand could increase or decrease our revenue and gross profit related to these products in the future.

Research and Development Expenses

R&D expenses for the three months ended March 31, 2021 totaled \$23.1 million, an increase of \$5.9 million, or 34%, as compared to \$17.2 million for the three months ended March 31, 2020. This was primarily due to an increase in pre-launch product development costs, preclinical operations, and drug licensing costs and included the following:

- \$6.3 million increase in Oral Paclitaxel and Encequidar product development and API costs and medical affairs costs prior to receipt of the Complete Response Letter in 2021;
- \$2.2 million increase in preclinical operations, related to the development of TCR-T technology and Oral Eribulin;
- \$0.5 million increase in drug licensing costs related to specialty drug product in-licenses; and
- \$0.4 million increase in R&D related compensation expenses.

The increase in these R&D expenses was partially offset by a \$2.9 million decrease in clinical studies and patient costs on Oral Paclitaxel after completion of the Phase 3 studies and a \$0.6 million decrease in regulatory, API development, and 503B development costs.

Selling, General, and Administrative Expenses

SG&A expenses for the three months ended March 31, 2021 totaled \$22.1 million, a decrease of \$3.6 million, or 14%, as compared to \$25.7 million for the three months ended March 31, 2020. This was primarily due to a decrease of \$4.4 million related to the costs of 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. This was partially offset by an increase of \$0.7 million of general and administrative costs related to increased hiring, professional fees, IT costs, and other operational costs.

Interest Income and Interest Expense

Interest income consisted of interest earned on our short-term investments totaled less than \$0.1 million and \$0.4 million for the three months ended March 31, 2021 and 2020, respectively. Interest expense totaled \$4.9 million and \$1.7 million for the three months ended March 31, 2021 and 2020, respectively. Interest expense in the current period was incurred from the Senior Credit Agreement with Oaktree, while interest expense in the prior period was incurred from debt under a former credit agreement with Perceptive Advisors LLC and its affiliates.

Income Tax Expense

For the three months ended March 31, 2021, we incurred income tax expense of \$0.2 million, compared to \$2.9 million for the same period in 2020. The decrease was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements in the prior year.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our R&D programs, SG&A costs associated with our operations, and the development of our specialty drug operations in our Commercial Platform and 503B operations and the investment we are making in our pre-launch activities in anticipation of commercializing our proprietary drugs. We incurred net losses of \$25.6 million and \$19.7 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$738.7 million. Our operating activities used \$29.9 million and \$45.5 million of cash during the three months ended March 31, 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 and though we have reduced our planned expenditures in 2021 while there is uncertainty around the best path forward for Oral Paclitaxel, we expect to increase our investments in commercialization activities for our proprietary drugs, if approved. 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 March 31, 2021 were cash and cash equivalents totaling \$48.0 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 \$123.2 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 March 31, 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, including pursuant to the Senior Credit Agreement, or potentially pursuant to new arrangements with different lenders. 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.

As of March 31, 2021, we had cash and cash equivalents of \$48.0 million, restricted cash of \$16.5 million, and short-term investments of \$123.2 million. We believe that the existing cash and cash equivalents, restricted cash, and short-term investments will enable us to meet our current operational liquidity needs and fund operations into the second half of 2022. 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, and will need to find alternative sources of financing until such time as Oral Paclitaxel is approved or will need to renegotiate these arrangements. We have based these estimates on assumptions that may prove to be wrong, and it 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 pending further discussion with the FDA on the best pathway forward for Oral Paclitaxel, 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 our estimates are also subject to change depending on the outcome of our discussions with the FDA with respect to Oral Paclitaxel, 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 development successfully;
- The initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- The costs of preparing our Commercial Platform for the commercialization of our proprietary drugs;
- The costs of construction and fit-out of planned drug at both Dunkirk and API manufacturing facilities;
- The number and characteristics of the drug candidates we pursue;
- The costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our IP rights and defending IP related claims;
- The extent to which we acquire or in-license other products and technologies; and
- Our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

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

Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	\$ (29,876)	\$ (45,545)
Net cash provided by (used in) investing activities	7,037	(10,451)
Net cash provided by financing activities	754	732
Net effect of foreign exchange rate changes	478	(427)
Net decrease in cash, cash equivalents, and restricted cash	<u>\$ (21,607)</u>	<u>\$ (55,691)</u>

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 decreased \$15.7 million, or 34%, for the three months ended March 31, 2021. The decrease is primarily attributable to the increase in product sales and collection of license fees during the three months ended March 31, 2021.

Net cash used in operating activities was \$29.9 million for the three months ended March 31, 2021. This resulted primarily from our net loss of \$25.6 million, adjusted for non-cash charges of \$4.3 million, and by cash used by our operating assets and liabilities of \$8.6 million. Our operating assets increased \$3.4 million for accounts receivable mainly related to the increased sales of 503B products, increased \$2.5 million for inventory of all drug products, and offset by \$2.2 million decrease in prepaid expenses and other assets. Our operating liabilities decreased by \$12.3 million mainly due to a decrease in accrued selling fees and royalties on our specialty drugs, accrued purchases of specialty drug inventory, and accrued interest paid in the current period on our Senior Credit Agreement with Oaktree, partially offset by an increase in accrued wages and benefits. Our net non-cash charges during the three months ended March 31, 2021 primarily consisted of \$2.2 million of stock-based compensation expense, \$1.3 million depreciation and amortization expense, and \$0.8 million amortization of debt discount.

Net cash used in operating activities was \$45.5 million for the three months ended March 31, 2020. This resulted primarily from our net loss of \$19.7 million, adjusted for non-cash charges of \$3.8 million, and by cash used by our operating assets and liabilities of \$29.7 million, the majority of which was due to the licensing fee receivable. Our operating assets increased \$34.7 million for accounts receivable mainly related to the contract asset recognized from license revenue in the three months ended March 31, 2020 as well as increases sales of specialty products, \$3.1 million for inventory of all drug products, and partially offset by a \$3.7 million decrease in prepaids and other assets. Our operating liabilities increased by \$4.4 million mainly due to an increase related the construction of our Dunkirk facility. Our net non-cash charges during the three months ended March 31, 2020 primarily consisted of \$2.3 million of stock-based compensation expense and \$1.1 million depreciation and amortization expense.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$7.0 million for the three months ended March 31, 2021, compared to \$10.5 million used in investing activities in the three months ended March 31, 2020. The difference was primarily due to more cash being provided by the sales and maturities of short-term investments, 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 three months ended March 31, 2021.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$0.8 million for the three months ended March 31, 2021, which consisted of \$0.9 million from the exercise of stock options, partially offset by \$0.1 million repayment of finance lease obligations.

Net cash provided by financing activities was \$0.7 million for the three months ended March 31, 2020, which primarily consisted of \$0.4 million from the issuance of debt to fund our new API plant in China and \$0.3 million from the exercise of stock options.

Contractual Obligations

A summary of our contractual obligations as of March 31, 2021 is as follows:

	Payments Due by Period				Total Amounts Committed
	Within 1 Year	1 to 3 years	3 to 5 years	More than 5 years	
Operating leases	\$ 3,389	\$ 4,702	\$ 3,085	\$ 367	\$ 11,543
Long-term debt	1,560	25,473	27,900	107,666	162,599
Finance lease obligations	430	502	99	—	1,031
Licensing fees	1,066	1,000	—	—	2,066
	<u>\$ 6,445</u>	<u>\$ 31,677</u>	<u>\$ 31,084</u>	<u>\$ 108,033</u>	<u>\$ 177,239</u>

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 of 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 first and second tranche of our Senior Credit Agreement with Oaktree; (2) our credit arrangement with Chongqing Malu 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.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in our Annual Report on Form 10-K for the year ended December 31, 2020.

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 the three months ended March 31, 2021 and 2020, approximately 0% and 1%, respectively, 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. We expect that foreign currencies will represent a lower percentage of our sales in the future due to the anticipated growth of our U.S. business. Our international selling, marketing, and administrative costs related to these sales are largely denominated in the same foreign currencies, which somewhat mitigates our foreign currency exchange risk rate exposure.

Currency Convertibility Risk

A portion of our revenues and expenses, and a portion of our assets and liabilities are denominated in RMB. 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 \$187.7 million as of March 31, 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 Chief Financial Officer (Principal Financial and Accounting Officer), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 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 March 31, 2021, our Chief Executive Officer and Board Chairman (Principal Executive Officer) and our Chief Financial Officer (Principal Financial and Accounting Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended March 31, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

Item 1. 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. The defendants expect that these two lawsuits will be consolidated and a lead plaintiff appointed in the coming months. Additional similar lawsuits might be filed. The Company and the individual defendants believe that the claims in these lawsuits are without merit, and the Company has not recorded a liability related to the lawsuits 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.

Item 1A. Risk Factors.

For a discussion of the Company's potential risks or uncertainties, please see "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 and 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. 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, a country where we source supplies and maintain partnerships that are key to our generics business, including API, presents business and supply chain disruption risks for the Company 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 governments in India impose additional 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 in India and the scope, duration and impact of containment measures on individuals and businesses. If our partners in India 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.

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

Not applicable

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		Form	File	Exhibit	Filing Date
10.1	Manufacture and Supply Agreement dated as of January 15, 2021 by and between Athenex Pharmaceutical Division, LLC and Ingenus Pharmaceuticals, LLC.	Form 10-K	001-38112	10.52	March 1, 2021
10.2	Second Amendment to License Agreement dated as of February 15, 2021 by and between Athenex, Inc. and PharmaEssentia Corp.	—	—	—	Filed herewith
10.3	Agreement and Plan of Merger, by and among Athenex, Inc., Athenex Pharmaceuticals LLC, Kuur Therapeutics, Inc., the holders of the shares of Series C Preferred Stock or Series C-1 Preferred Stock (the “Merger Stockholders”), Kevin S. Boyle, Sr., Kurt C. Gunter and Melinda K. Lackey (the “Key Employees”), the members of the Company Board (as defined therein), (the “Independent Company Directors”) and Shareholder Representative Services LLC, solely as representative, agent and attorney-in-fact of the Merger Stockholders, Key Employees and Individual Company Directors, dated May 4, 2021.	Form 8-K	001-38112	10.1	May 5, 2021
10.4	Lock-Up Agreement between Athenex, Inc. and Touchstone Innovations Businesses LLP (IP Group), dated May 4, 2021.	Form 8-K	001-38112	10.2	May 5, 2021
10.5	Lock-Up Agreement between Athenex, Inc. and each of the parties named therein, dated as of May 4, 2021.	Form 8-K	001-38112	10.3	May 5, 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 Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
32.1	Certification of the Chief Executive Officer and Board Chairman (Principal Executive Officer) and the Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	—	—	—	Filed herewith
101.INS	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: May 6, 2021

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

Date: May 6, 2021

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

SECOND AMENDMENT TO LICENSE AGREEMENT

This SECOND AMENDMENT TO LICENSE AGREEMENT (this “Amendment”) is made and entered into as of this 15th day of February, 2021 (“Effective Date”) by and between Athenex, Inc., formerly known as Kinex Pharmaceuticals, LLC, a corporation organized and existing under the laws of the state of Delaware, USA, with a principal place of business at 1001 Main Street, Suite 600, Buffalo, New York 14203 (“Athenex”), and PharmaEssentia Corp., a publicly traded company organized and existing under the laws of Taiwan with a principal place of business at 13F., No. 3 YuanQu Street, Nankang District, Taipei 115, Taiwan (“PharmaEssentia” and, together with Athenex, the “Parties” and each, a “Party”).

WITNESSETH:

WHEREAS, the Parties entered into a License Agreement on December 8, 2011 (the “License”), as the same has been amended by that certain First Amendment to the License dated as of December 23, 2016 (the “First Amendment”) pursuant to which Athenex licensed to PharmaEssentia certain rights with respect to Athenex’s KX01 and KX02 compounds, subject to the restrictions and solely within the territory set forth therein; and

WHEREAS, the Parties now wish to further amend the terms of the License to expand the territory in the License for KX01 ointment (hereinafter referred to herein as “Tirbanibulin”) to include Japan and South Korea (the “Tirbanibulin Territory Expansion”) and to further provide for certain additional rights and obligations of the Parties with respect to the Tirbanibulin Territory Expansion through the addition of an addendum to the License (the “Addendum”) which shall set forth such additional rights and obligations of the Parties as they relate to the Tirbanibulin Territory Expansion, as more fully set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and intending to be legally bound hereby, the Parties hereby agree as follows:

1. The recitals set forth above are incorporated herein by this reference. All capitalized terms used in this Amendment and not defined herein shall have the meaning given to them in the License. Except as amended by this Amendment, the License shall continue in full force and effect.
2. Amendments.
 - (a) Notwithstanding anything in the License to the contrary, the Parties agree that the following provisions shall apply to the supply of Licensed Products under the License:
 - i. Unless otherwise agreed by the Parties in writing, during the Term, Athenex shall engage one or more of its Affiliates to supply Licensed Products in the quantities and at the prices agreed to by the Parties from time to time. Athenex or its Affiliates will obtain and maintain all required registrations and licenses filings in order to manufacture the Licensed Products in compliance with all applicable Law.
 - ii. In the event the Parties desire to use a third party manufacturer to supply Licensed Products, such third party shall be mutually agreed upon by the Parties (a “Third Party Manufacturer”) to supply one or more Licensed Products under the License pursuant to a manufacture and supply agreement with such Third Party Manufacturer (the “Third Party Supply Agreement”). The Parties shall also collaborate in good faith in connection with the preparation and completion of the Third Party Supply Agreement which collaboration shall include affording other Party the opportunity to review and comment upon drafts of the Third Party Supply Agreement and accommodating to the extent practicable the reasonable comments of the other Party on such agreement.

- (b) The Field and Territory set forth in below table shall control and supersede any conflicting terms set forth in the License with respect to the Development and Commercialization of Tirbanibulin by the Parties for all dermatology indications, including actinic keratosis, skin cancer, and psoriasis and other nonmalignant skin conditions (added per chart below)(collectively, the “Expanded Field”) such that, from and after the Effective Date until the expiration of the last patent / patent application granted, the Parties agree that the Territory covered by the License by Field is as follows:

FIELD	TERRITORY
Actinic keratosis:	Taiwan, Japan, South Korea
Psoriasis and other non-malignant skin conditions:	Taiwan, Japan, South Korea, Mainland China, Hong Kong, Macau, Singapore, Malaysia
Skin cancer:	Japan, South Korea, Taiwan, Singapore, Malaysia
All dermatology indications:	Japan, South Korea, Taiwan, Singapore, Malaysia

For avoidance of doubt, Athenex hereby grants to PharmaEssentia an exclusive right and license in the above tabulated Field throughout above tabulated Territory with the patents/patent applications as listed in the **Exhibit A** hereto and the Section 1.36 of the License shall be replaced and superseded by this Exhibit A.

- (c) While the Article 4 of the License remains fully effective, and solely as it relates to the Tirbanibulin Territory Expansion, the terms set forth in the Addendum to the License attached hereto as **Exhibit B** shall control and supersede any conflicting terms set forth in the License with respect to the Development and Commercialization of Tirbanibulin by the Parties in Japan and South Korea (together, the “Expanded Territory”) for the Expanded Field.

3. Miscellaneous.

- (a) Entire Agreement. The License, as amended to date by the provisions contained in the First Amendment, this Amendment and the Addendum, contains the entire agreement among the Parties with respect to the transactions contemplated thereby and herein and supersedes any prior agreements, understandings or arrangements between them, whether oral or in writing. Except as expressly amended, modified and supplemented hereby, the provisions of the License are and shall remain in full force and effect and shall be read with the First Amendment, this Amendment and the Addendum, *mutatis mutandis*. Where the terms of this Amendment are inconsistent with the terms of the License or First Amendment (prior to their amendment hereby), the terms of this Amendment, including the terms set forth in the Addendum, shall govern solely with respect to the subject matter hereof to the extent of such inconsistency.
- (b) Further Assurances. Each of the Parties hereto will from time to time execute and deliver all such further documents and instruments and do all acts and things as the other Party may reasonably require to effectively carry out or better evidence or perfect the full intent and meaning of this Amendment.
- (c) Amendments; No Waiver. This Amendment may not be amended, modified, altered or supplemented except by means of a written agreement or other instrument executed by both of the Parties. No course of conduct or dealing between the Parties shall act as a modification or waiver of any provisions of this Amendment.
- (d) Counterparts. This Amendment shall be executed in two originals and may be executed in separate counterparts. Each Party keeps one original as evidence.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment as of the date first above written.

ATHENEX, INC.

By: /s/ Johnson Y.N. Lau

Name: Johnson Y.N. Lau

Title: Chief Executive Officer

PHARMAESSENTIA CORP

By: /s/ Ching-Leou Teng

Name: Ching-Leou Teng

Title: Chairperson

EXHIBIT B
Additional Territory Addendum

Definitions; Rights and Obligations Generally.	<p>The following terms shall apply to the Parties' obligations under the License with respect to Tirbanibulin:</p> <ol style="list-style-type: none">1. The Expanded Territory shall be added to the definition of "Territory" under the License, as context requires, solely with respect to Tirbanibulin;2. The Expanded Field shall be added to the definition of "Field" under the License (as amended by the First Amendment), as context requires, solely with respect to Tirbanibulin; and3. Products developed in the Expanded Territory with Tirbanibulin as the Compound shall constitute Licensed Products for purposes of the License and solely with respect to the Tirbanibulin Territory Expansion, the additional rights and obligations of the Parties set forth below in this Addendum shall apply with respect to the Development and Commercialization of Tirbanibulin under the License. <p>All other capitalized terms used and not defined in the Amendment or below shall have the meaning given to them in the License.</p>
PharmaEssentia Responsibilities:	<p>Solely with respect to the Tirbanibulin Territory Expansion, PharmaEssentia shall be responsible for conducting and shall itself, or through its Affiliates or sublicensees, conduct the following activities in the Expanded Territory in the Expanded Field during the Agreement Term:</p> <ol style="list-style-type: none">1. Conduct, administer and complete any and all Clinical Studies to obtain Regulatory Approval for Licensed Products in the Expanded Territory, including, without limitation, any:<ol style="list-style-type: none">(i) required Bridging Clinical Studies for actinic keratosis in the Expanded Territory; and(ii) Phase II Clinical Studies for psoriasis and skin cancer in the Expanded Territory by December 31, 2023. <p>For purposes hereof, "Bridging Clinical Studies" means additional Clinical Studies consisting of patients from the Expanded Territory that allows extrapolation of a foreign pivotal data package to support Regulatory Approvals of such Licensed Product in the Expanded Territory.</p> <ol style="list-style-type: none">2. Except as otherwise set forth above, the provisions of Article 3 of the License shall apply <i>mutatis mutandis</i> to the Commercialization of Tirbanibulin in the Expanded Territory.

Upfront & Milestone Payments:	<p>In consideration of the rights granted by Athenex hereunder to the Expanded Territory, PharmaEssentia shall pay Athenex the following milestone fees, contingent upon occurrence of the specified event, with each milestone fee to be paid no more than once with respect to the achievement of such milestone event (but payable within 30 days of the first time such milestone event is achieved):</p> <ol style="list-style-type: none"> Upfront Payment: PharmaEssentia shall pay \$500,000 (the “Upfront Payment”) within 30 days of execution of this Amendment. Regulatory Milestone Payments: <table border="0" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><u>Milestone Events for Actinic Keratosis (“AK”):</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Milestone Payment</u></th> </tr> </thead> <tbody> <tr> <td><u>Milestone 1:</u> NDA submitted to Japanese Regulatory Authority (MOHW) for AK</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 2:</u> NDA submitted to Korean Regulatory Authority (KFDA) for AK</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 3:</u> NDA approved by Japanese Regulatory Authority for AK</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 4:</u> NDA approved by Korean Regulatory Authority for AK</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"><u>Milestone Events for skin cancer related indications:</u></td> </tr> <tr> <td><u>Milestone 1:</u> NDA approval for squamous cell carcinoma in Japan</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 2:</u> NDA approval for basal cell carcinoma in Japan</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td colspan="2" style="padding-top: 10px;"><u>Milestone Events for psoriasis:</u></td> </tr> <tr> <td><u>Milestone 1:</u> Showing positive Phase II Clinical Study data in psoriasis (such as indicating improvement from baseline severity or affected surface area)</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 2:</u> NDA submission to Japanese Regulatory Authority for psoriasis</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 3:</u> NDA submission to Korean Regulatory Authority for psoriasis</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 4:</u> NDA accepted by Japanese Regulatory Authority for psoriasis</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td><u>Milestone 5:</u> NDA accepted by Korean Regulatory Authority for psoriasis</td> <td style="text-align: right;">\$ [*]</td> </tr> </tbody> </table> 	<u>Milestone Events for Actinic Keratosis (“AK”):</u>	<u>Milestone Payment</u>	<u>Milestone 1:</u> NDA submitted to Japanese Regulatory Authority (MOHW) for AK	\$ [*]	<u>Milestone 2:</u> NDA submitted to Korean Regulatory Authority (KFDA) for AK	\$ [*]	<u>Milestone 3:</u> NDA approved by Japanese Regulatory Authority for AK	\$ [*]	<u>Milestone 4:</u> NDA approved by Korean Regulatory Authority for AK	\$ [*]	<u>Milestone Events for skin cancer related indications:</u>		<u>Milestone 1:</u> NDA approval for squamous cell carcinoma in Japan	\$ [*]	<u>Milestone 2:</u> NDA approval for basal cell carcinoma in Japan	\$ [*]	<u>Milestone Events for psoriasis:</u>		<u>Milestone 1:</u> Showing positive Phase II Clinical Study data in psoriasis (such as indicating improvement from baseline severity or affected surface area)	\$ [*]	<u>Milestone 2:</u> NDA submission to Japanese Regulatory Authority for psoriasis	\$ [*]	<u>Milestone 3:</u> NDA submission to Korean Regulatory Authority for psoriasis	\$ [*]	<u>Milestone 4:</u> NDA accepted by Japanese Regulatory Authority for psoriasis	\$ [*]	<u>Milestone 5:</u> NDA accepted by Korean Regulatory Authority for psoriasis	\$ [*]
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Sales Milestones:	<p>PharmaEssentia shall pay the following milestone fees to Athenex set out in the table below upon the achievement of the corresponding sales milestones. Each milestone fee shall be deemed earned as of the achievement of the related milestone event and shall be paid by PharmaEssentia within 30 days of the date when the milestone event is first achieved.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;"><u>On the aggregate Net Sales of the Licensed Products in the Expanded Territory reaching the following levels of the Net Sales for the first time in a given Calendar Year period. Each milestone is only to be paid once:</u></th> <th style="text-align: right; border-bottom: 1px solid black;"><u>Milestone Payment</u></th> </tr> </thead> <tbody> <tr> <td>Milestone 1: First time total Net Sales in Japan and South Korea in a Calendar Year are at least \$10,000,000</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td>Milestone 2: First time total Net Sales in Japan and South Korea in a Calendar Year are at least \$20,000,000</td> <td style="text-align: right;">\$ [*]</td> </tr> <tr> <td colspan="2">Total Milestone Payments (Including Regulatory Milestones and Sales Milestones): \$13,000,000</td> </tr> </tbody> </table>	<u>On the aggregate Net Sales of the Licensed Products in the Expanded Territory reaching the following levels of the Net Sales for the first time in a given Calendar Year period. Each milestone is only to be paid once:</u>	<u>Milestone Payment</u>	Milestone 1: First time total Net Sales in Japan and South Korea in a Calendar Year are at least \$10,000,000	\$ [*]	Milestone 2: First time total Net Sales in Japan and South Korea in a Calendar Year are at least \$20,000,000	\$ [*]	Total Milestone Payments (Including Regulatory Milestones and Sales Milestones): \$13,000,000																					
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Royalties:	<p>PharmaEssentia shall pay Royalties to Athenex on the aggregate annual (Calendar Year) Net Sales of Licensed Products in the Expanded Territory, in accordance with the provisions of Article 4 of the License except as otherwise set forth herein, at the following royalty rates (as a percentage of aggregate Net Sales of the Licensed Products), based upon the following royalty rates:</p> <table border="1" data-bbox="478 190 1356 405"> <thead> <tr> <th data-bbox="478 190 1085 224"><u>Portion of Net Sales in a Calendar Year</u></th> <th data-bbox="1085 190 1356 224"><u>Royalty Rate</u></th> </tr> </thead> <tbody> <tr> <td data-bbox="478 224 1085 257">Less than or equal to \$10,000,000</td> <td data-bbox="1085 224 1356 257">[*]%</td> </tr> <tr> <td data-bbox="478 257 1085 313">Greater than \$10,000,000 and less than or equal to \$30,000,000</td> <td data-bbox="1085 257 1356 313">[*]%</td> </tr> <tr> <td data-bbox="478 313 1085 369">Greater than \$30,000,000 and less than or equal to \$100,000,000</td> <td data-bbox="1085 313 1356 369">[*]%</td> </tr> <tr> <td data-bbox="478 369 1085 405">Greater than \$100,000,000</td> <td data-bbox="1085 369 1356 405">[*]%</td> </tr> </tbody> </table>	<u>Portion of Net Sales in a Calendar Year</u>	<u>Royalty Rate</u>	Less than or equal to \$10,000,000	[*]%	Greater than \$10,000,000 and less than or equal to \$30,000,000	[*]%	Greater than \$30,000,000 and less than or equal to \$100,000,000	[*]%	Greater than \$100,000,000	[*]%
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Cost of Goods:	<p>Athenex to supply Licensed Products in the Expanded Territory at its Cost of Goods plus [*]%. For purposes hereof, “Cost of Goods” shall mean the fully burdened cost of manufacturing and/or supplying finished Licensed Products and related inputs and services, such costs to include the cost of direct materials and labor, conversion, packaging and labeling, quality assurance/control and other services such as release testing, stability testing, associated freight expenses, and attributable portion of all indirect and overhead amounts (including depreciation and amortization expenses) attributable to such manufacturing, delivery, and related inputs and services). Costs shall be calculated in accordance with US GAAP or IFRS and allocations shall be commercially justifiable consistent with fair industry practices.</p>										

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: May 6, 2021

/s/ Johnson Y.N. Lau

Name: Johnson Y.N. Lau

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

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

I, Randall Sze, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Athenex, Inc. (the registrant);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2021

/s/ Randall Sze

Name: Randall Sze

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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

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

1. The registrant’s Quarterly Report on Form 10-Q for the period ended March 31, 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: May 6, 2021

/s/ Johnson Y.N. Lau

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

/s/ Randoll Sze

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