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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 6, 2021

ATHENEX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38112**	**43-1985966**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1001 Main Street, Suite 600, Buffalo, New York	**14203**
(Address of principal executive offices)	**(Zip Code)**

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under such section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on May 6, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

ATHENEX, INC.

Date: May 6, 2021

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex Provides First Quarter 2021 Corporate and Financial Update

Plan to Request Type A Meeting with the FDA for Oral Paclitaxel by the End of May
Klisyri® Launched in the U.S. in February 2021

Acquired Kuur Therapeutics to Expand Cell Therapy Development with Off-the-Shelf Engineered CAR-NKT Platform in May 2021

Management to Host Conference Call and Webcast at 8:00 a.m. ET

Buffalo, N.Y., May 6, 2021 (GLOBE NEWSWIRE) – Athenex, Inc., (NASDAQ: ATNX), a global biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies for the treatment of cancer and related conditions, today provided a corporate and financial update for the first quarter ended March 31, 2021.

“We continue to work diligently with our advisers to analyze and respond to the complete response letter received from the FDA on oral paclitaxel plus encequidar (oral paclitaxel). We are collecting additional data and doing additional analyses in support of our application. We expect to have a type A meeting with the FDA before end of the second quarter.” said Johnson Lau, CEO and Chairman of Athenex. “We remain committed to pursuing regulatory approval of oral paclitaxel and aim to bring this important product to market to benefit metastatic breast cancer patients. We hope to align with the FDA, work to resolve its concerns and reach agreement on the path forward required to obtain approval. In parallel, we continue our efforts to deepen our pipeline and are excited to add Kuur Therapeutics and its innovative allogeneic CAR-NKT technology to the Athenex platform.”

First Quarter 2021 and Recent Business Highlights

Clinical Programs

Oral Paclitaxel for Metastatic Breast Cancer

- Athenex received a Complete Response Letter (CRL) from the US Food & Drug Administration (FDA) for the New Drug Application (NDA) for oral paclitaxel in metastatic breast cancer on February 26, 2021.

Klisyri® in actinic keratosis

- Almirall, S.A. (BLM: ALM), Athenex’s U.S. partner, launched Klisyri® in the U.S. on February 18, 2021, triggering a $20 million milestone payment from Almirall
- In February 2021, the New England Journal of Medicine published Phase 3 trial results on the efficacy and safety of tirbanibulin ointment for the topical treatment of actinic keratosis of the face or scalp

Cell Therapy

- Acquired Kuur Therapeutics (privately held), a leading developer of off-the-shelf CAR-NKT cell immunotherapies for the treatment of solid and hematological malignancies in May 2021
- Athenex will pay $70 million upfront, comprised primarily of equity in Athenex common stock, to Kuur shareholders and certain of its former employees and directors

- Additionally, Kuur shareholders and certain of its former employees and directors are eligible to receive up to $115 million of milestone payments, which Athenex may elect to pay in cash, additional Athenex common stock, or a combination of both
- Acquisition provides an allogeneic NKT platform that can be applied to our high affinity TCR in solid tumors
- High-affinity TCR-T in NY-ESO-1 to enter the clinic in a Phase 1 trial at Baylor in 1H 2021

Commercial Business

- Product sales growth in the first quarter was primarily attributable to an increase in sales of 503B products
- Athenex Pharmaceutical Division (APD) currently markets a total of 34 products with 61 SKUs
- Athenex Pharma Solutions (APS) currently markets 6 products with 19 SKUs

Key Anticipated 2021 Milestones

- Request a meeting with the FDA to discuss and align on next steps to obtain approval for oral paclitaxel in metastatic breast cancer
- Begin expansion portion of the oral paclitaxel plus pembrolizumab Phase I trial into lung cancer and gastric cancer
- Present oral paclitaxel plus pembrolizumab Phase I trial data at a medical conference
- EMA approval of Klisyri® in 2021
- Present abstract on oral docetaxel in metastatic prostate cancer at ASCO 2021
- Present abstract on oral paclitaxel plus encequidar in metastatic breast cancer at ASCO 2021
- Expect TCR-T NY-ESO-1 IRB approval and to initiate Phase 1 trial enrollment in 1H 2021
- Additional GINAKIT2 Phase I data to be presented at the American Society of Gene & Cell Therapy (ASGCT) 24th Annual Meeting on May 14, 2021
- Results from the I-SPY 2 trial of oral paclitaxel plus anti PD-1 expected in 2022

Clinical Data Presentations

American Society of Gene & Cell Therapy (ASGCT) 2021

- **Natural Killer T Cells Expressing a GD2- CAR and IL-15 Are Safe and Can Induce Complete Remission in Children with Relapsed Neuroblastoma – A First-in-Human, Phase I Trial**
- Dr. Andrus Heczey is the principal investigator. The abstract and work were selected for presentation at this year’s Clinical Trials Spotlight Symposium at ASGCT on May 14, 2021, at 11 am ET

American Society of Clinical Oncology (ASCO) 2021

- **An open-label, pharmacokinetic study to determine the bioavailability, safety and tolerability of single dose oral docetaxel (Oradoxel) in metastatic prostate cancer (mPC) patients treated with IV docetaxel**

- Dr. Christopher Jackson is the primary author of the abstract, #5050, to be presented during the Genitourinary Cancer – Prostate, Testicular, and Penile, poster session
- **Confirmed tumor response by molecular subtype in patients with metastatic breast cancer: Sub-analysis from a phase 3 clinical study comparing oral paclitaxel and encequidar to IV paclitaxel**
- Dr. Gerardo Umanzor is the primary author of the abstract, #1073, to be presented during the Breast Cancer – Metastatic, poster session
- **An open-label, fixed-sequence study to evaluate the effect of encequidar (HM30181) an oral P-gp inhibitor, on the pharmacokinetics of dabigatran etexilate (a P-gp substrate) in healthy male volunteers**
- Dr. Christopher Jackson is the primary author of the abstract, #E15060, an online publication
- The virtual scientific program of the ASCO will be held June 4-8, 2021

First Quarter 2021 Financial Highlights

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. 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 partially 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 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 royalty payment to Hanmi 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.

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, particularly in the first two months of 2021 prior to the receipt of the CRL, preclinical operations costs, drug licensing costs in relation to our specialty drug product in-licenses, and R&D related compensation expenses. The increase in these R&D expenses was partially offset by a decrease in clinical studies and patient costs on oral paclitaxel after completion of the Phase 3 studies and regulatory, API development, and 503B development costs.

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 CRL in 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 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 the debt with Perceptive.

Income tax expense for the three months ended March 31, 2021, was $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.

Net loss attributable to Athenex for the three months ended March 31, 2021, was $25.1 million or ($0.27) per diluted share, respectively, as compared to a net loss of $19.4 million or ($0.24) per diluted share, for the same period in 2020.

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.

Financial Guidance

In terms of product sales guidance, the Company is limiting financial guidance to only the existing product portfolio, which excludes any proprietary products, until meaningful sales data from the proprietary product, Klisyri®, become available. In 2020, the Company recorded a significant amount of revenues from international customers as a result of the global pandemic. However, the Company does not see these revenues as recurring in nature. The Company continues to expand its product portfolio. The Company is affirming the guidance it provided on March 1, 2021, as it currently expects its product sales in 2021, excluding any royalties from Klisyri®, to be in line with 2020 levels.

Cash Conservation Update

Given uncertainty stemming from the CRL for oral paclitaxel, the Company identified and adopted certain cash conservation measures. Considering these initial measures, and based on our current operating plan, we now expect that our cash and cash equivalents, restricted cash and short-term investments as of March 31, 2021, will enable us to meet our current operational liquidity needs and fund operations into 2H 2022.

Conference Call and Webcast Information

Athenex will host a conference call and live audio webcast today, Thursday, May 6, 2021, at 8:00 am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial either the domestic or international number fifteen minutes before the conference call begins:

Domestic: (888) 771-4371

International: (847) 585-4405

Passcode: 50156178

The live conference call and replay can also be accessed by audio webcast **here** and also on the Investor Relations section of the Company's website, located at https://ir.athenex.com.

About Athenex, Inc.

Founded in 2003, Athenex, Inc. is a global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery, development, and commercialization of next generation drugs for the treatment of cancer. Athenex is organized around three platforms, including an Oncology Innovation Platform, a Commercial Platform, and a Global Supply Chain Platform. The Company's current clinical pipeline is derived from four different platform technologies: (1) Orascovery, based on P-glycoprotein inhibitor, (2) Src kinase inhibition, (3) Cell therapy, and (4) Arginine deprivation therapy. Athenex's employees worldwide are dedicated to improving the lives of cancer patients by creating more active and tolerable treatments. For more information, please visit www.athenex.com.

Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. These forward-looking statements are typically identified by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "foresee," "goal," "guidance," "intend," "likely," "may," "plan," "potential," "predict," "preliminary," "probable," "project," "promising," "seek," "should," "will," "would," and similar expressions. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: the development stage of our primary clinical candidates and related risks involved in drug development, clinical trials, regulation, uncertainties around regulatory reviews and approvals; our ability to scale our manufacturing and commercial supply operations for current and future approved products, and ability to commercialize our products, once approved; ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the preclinical and clinical results for Athenex's drug candidates, which may not support further development of such drug candidates; risks related to counterparty performance, including our reliance on third parties for success in certain areas of Athenex's business; our history of operating losses and our need and ability to raise additional capital; uncertainties around our ability to meet funding conditions under our financing agreements and access to capital thereunder; risks and uncertainties inherent in litigation, including purported stockholder class actions; risks and uncertainties related to the COVID-19 pandemic and its potential impact on our operations, supply chain, cash flow and financial condition; competition; intellectual

property risks; uncertainties around our ability to successfully integrate acquired and merged businesses in a timely and cost-effective manner and to achieve synergies; risks relating to doing business internationally and in China; the risk of development, operational delays, production slowdowns or stoppages or other interruptions at our manufacturing facilities; and the other risk factors set forth from time to time in our SEC filings, copies of which are available for free in the Investor Relations section of our website at http://ir.athenex.com/phoenix.zhtml?c=254495&p=irol-sec or upon request from our Investor Relations Department. All information provided in this release is as of the date hereof and we assume no obligation and do not intend to update these forward-looking statements, except as required by law.

Contacts

Investors:

Steve Rubis
Athenex, Inc.
Email: stevenrubis@athenex.com

Daniel Lang, MD
Athenex, Inc.
Email: danlang@athenex.com

Tim McCarthy
LifeSci Advisors, LLC
Email: tim@lifesciadvisors.com

ATHENEX, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2021	December 31, 2020
	(In thousands)	
Selected Balance sheet data:		
Cash, cash equivalents, and restricted cash	$ 64,480	$ 86,087
Short-term investments	123,186	138,636
Goodwill	38,840	38,891
Working capital(1)	201,444	229,820
Total assets	349,656	384,329
Long-term debt	149,235	148,587
Total liabilities	206,532	218,981
Non-controlling interests	(14,980)	(14,427)
Total stockholders' equity	$143,124	$ 165,348

* working capital: total current assets less total current liabilities

ATHENEX, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(unaudited)

	Three months ended March 31,	
	2021 (in thousands)	2020 (in thousands)
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
Research and development expenses	(23,070)	(17,192)
Selling, general, and administrative expenses	(22,120)	(25,748)
Interest income	29	413
Interest expense	(4,908)	(1,673)
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)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.27)	$ (0.24)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	93,429,935	81,539,548