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): March 1, 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 March 1, 2021, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter and year ended December 31, 2020. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On March 1, 2021, the Company issued a press release announcing the receipt of a complete response letter from the U.S. Food and Drug Administration (FDA) for the Company's New Drug Application (NDA) for oral paclitaxel plus encequidar for the treatment of metastatic breast cancer. A copy of the Company's press release is attached hereto as Exhibit 99.2 and incorporated into this Item 7.01 by reference.

The information in Items 2.02 and 7.01 of this Form 8-K and Exhibits 99.1 and 99.2 attached hereto 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 of that Section, or incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on March 1, 2021 announcing earnings results for the quarter and year ended December 31, 2020
99.2	Press release issued by the Company on March 1, 2021 announcing receipt of a complete response letter from the FDA
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: March 1, 2021

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Athenex Provides Fourth Quarter and Full Year 2020 Corporate and Financial Update

- Receipt of Complete Response Letter from the FDA for Oral Paclitaxel Plus Encequidar
- Klisyri® (tirbanibulin) received FDA approval and launched commercially on February 18, 2021
- The New England Journal of Medicine published Phase III trial data on the efficacy and safety of Klisyri®
- Product sales in 4Q20 grew 54.4% Y/Y to $21.8 million
- 2021 product sales (excluding proprietary products) expected to be in line with 2020
- Management to host conference call and webcast today at 8:00 a.m. ET

Buffalo, N.Y., March 1, 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 fourth quarter and full year ended December 31, 2020.

Oral Paclitaxel Plus Encequidar Update

As announced by Athenex in a separate press release this morning, the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the Company's New Drug Application (NDA) for oral paclitaxel and encequidar for the treatment of metastatic breast cancer. In the CRL, the FDA expressed the following:

- Concerns about safety risks associated with increase in neutropenia-related sequelae
- Concerns regarding the primary endpoint assessment conducted by the Blinded Independent Central Review (BICR)
- Recommendation that Athenex conduct a new clinical trial in a patient population with metastatic breast cancer representative of the population in the U.S.

"We are surprised and disappointed by the FDA's decision to issue a complete response letter for oral paclitaxel and encequidar," said Johnson Lau, Chief Executive Officer of Athenex. "Based on the clinical benefits demonstrated by the Phase III trial results, we are committed to exploring our available options to obtain approval for oral paclitaxel and encequidar. Additionally, we will undertake a thorough review of our organization to best position ourselves to create value for all stakeholders as we move forward."

Fourth Quarter 2020 and Recent Business Updates

Clinical Programs:

Oral Paclitaxel Plus Encequidar for Metastatic Breast Cancer

- Athenex received a Complete Response Letter from the FDA for the NDA for oral paclitaxel for metastatic breast cancer

- On December 9, 2020, the Company presented four abstracts associated with oral paclitaxel plus encequidar for the treatment of metastatic breast cancer and angiosarcoma at the 2020 San Antonio Breast Cancer Symposium

Klisyri® for Actinic Keratosis

- On December 14, 2020, the U.S. Food and Drug Administration (FDA) approved Klisyri® (tirbanibulin), 1% for the treatment of actinic keratosis of the face or scalp
- 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
- Almirall, S.A. (BLM: ALM), Athenex's U.S. partner, launched Klisyri® in the U.S. on February 18, 2021

Commercial Business:

- Product sales growth in the fourth quarter were primarily driven by sales of specialty pharmaceutical products used to treat patients hospitalized with COVID-19
- Athenex Pharmaceutical Division (APD) currently markets a total of 34 products with 63 SKUs
- Athenex Pharma Solutions (APS) currently markets 6 products with 19 SKUs

Key Anticipated Future Milestones

- Request a meeting with the FDA to discuss and align on next steps to obtain approval for oral paclitaxel plus encequidar in metastatic breast cancer
- Identify and undertake appropriate adjustments for the company pending the outcome of the FDA meeting
- Begin expansion portion of the oral paclitaxel plus pembrolizumab Phase I trial
- Present the oral paclitaxel plus pembrolizumab Phase I trial data at a medical conference in 2021
- Anticipate EMA approval of Klisyri® in 2021
- TCR-T NY-ESO-1 IRB approval and initiate P1 trial enrollment in 1H 2021
- Anticipate results from the I-SPY 2 trial of oral paclitaxel plus anti PD-1 in 2022

Fourth Quarter and Full Year 2020 Financial Highlights

Product sales for the three months ended December 31, 2020 were $21.8 million, up from $14.1 million for the three months ended December 31, 2019, which represents a 54% increase. Product sales for the full year in 2020 were $105.3 million, up from $80.5 million for the full year in 2019, which represents a 31% increase. The increase was primarily driven by the impact of the global health pandemic which led to the increased demand for COVID-19 related drugs, and the launch of additional products, resulting in a significant increase in specialty product sales. The product sales increase was partially offset by a decrease in API and 503B products sales, which was attributable to the reduced production and external sales of API, and the discontinued vasopressin sales.

Collaboration and license revenue for the three months and year ended December 31, 2020 were $28 thousand and $39.1 million, respectively, compared to $20.3 million and $20.7 million, respectively, for the same periods in 2019. The collaboration and license revenue recognized in the full year of 2020 was primarily attributable to the 2019 Xiangxue License Agreement, while the revenue in the full year of 2019 was primarily attributable to a milestone achieved pursuant to the license agreement entered with Almirall in December 2017.

Total revenues for the three months and year ended December 31, 2020 were $21.8 million and $144.4 million, respectively, compared to $34.4 million and $101.2 million, respectively, for the same periods in 2019.

Cost of sales totaled $18.3 million for the three months ended December 31, 2020, an increase of 16%, as compared to $15.7 million for the three months ended December 31, 2019. Cost of sales totaled $95.4 million for the full year in 2020, an increase of 37%, as compared to $69.6 million for the full year in 2019. The increase in cost of specialty product sales was generally in-line with the increase in revenue, and we continued to incur fixed costs despite decreased production at our API and 503B facilities. in the fourth quarter, the increase in product sales outpaced that of cost of sales, primarily as a result of an uptake in the blended product margin of our specialty product portfolio.

Research & Development (R&D) expenses totaled $18.3 million for the three months ended December 31, 2020, a decrease of 16%, as compared to $21.8 million for the three months ended December 31, 2019. R&D expenses totaled $75.9 million for the full year in 2020, a decrease of 10%, as compared to $84.4 million for the full year in 2019. This was primarily attributable to a decrease in clinical operations expenses, drug development costs for specialty products and certain licensing costs. The decrease in R&D expenses in the full year of 2020 was partially offset by an increase in medical affairs expenses related to preparing our proprietary drugs for commercialization, API development costs, and expenses related to the expansion of our R&D teams in Latin America and Taiwan.

Selling, General & Administrative (SG&A) expenses totaled $31.4 million for the three months ended December 31, 2020, an increase of 73%, as compared to $18.1 million for the three months ended December 31, 2019. SG&A expenses totaled $96.9 million for the full year in 2020, an increase of 45%, as compared to $66.7 million for the full year in 2019. This was primarily attributable to an increase in commercial preparations costs associated with the possible approval of Oral Paclitaxel, expanded work forces at our manufacturing facilities and an increase in general and administrative costs related to professional service fees, IT costs, insurance and other operational costs. In addition, in the three months ended December 31, 2020, we recorded a provision for a potential credit loss of $8.9 million related to an outstanding balance due from Xiangxue and associated expenses resulting from currency conversion. This provision is related to the license revenue we recognized in the third quarter of 2020. As of February 28, 2021, we have received $1.5 million from Xiangxue.

Interest expense totaled $4.4 million and $1.7 million for the three months ended December 31, 2020 and 2019, respectively. Interest expense totaled $11.2 million and $7.0 million for the full year in 2020 and 2019, respectively. In June 2020, we refinanced the $50 million long-term debt with Perceptive, with an up to $225 million long-term credit facility with Oaktree. In the three months ended December 31, 2020, we received net proceeds of $24.25 million from the Oaktree facility upon achievement of the tirbanibulin FDA approval milestone. As of December 31, 2020, we had drawn down $150 million, out of the $225 million Oaktree facility.

We recognized a $7.2 million loss on the extinguishment of debt related to the termination of the senior secured loan agreement with Perceptive and a $3.0 million loss on the partial extinguishment of debt related to the assignment of a portion of the senior secured loan from Oaktree's co-investors to Sagard during the year ended December 31, 2020. We did not incur expenses of similar nature in 2019.

For the full year in 2020, we incurred income tax expense of $4.1 million, compared to $0.9 million for the same period in 2019. The increase was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Net losses attributable to Athenex for the three months and year ended December 31, 2020 were $49.5 million and $146.2 million, respectively, or ($0.53) and ($1.72) per diluted share, respectively, as compared to a net loss of $21.7 million and $123.7 million, or ($0.28) and ($1.67) per diluted share, for the same periods in 2019. Excluding the credit loss provision of $8.9 million during the three months ended December 31, 2020, net loss attributable to Athenex for the quarter was $40.6 million or ($0.43) per diluted share. Excluding the one-time debt extinguishment expenses of $10.3 million and the $8.9 million credit loss provision during the year ended December 31, 2020, net loss attributable to Athenex for the full year in 2020 was $127.0 million, or ($1.49) per diluted share.

As of December 31, 2020, the Company had cash, cash equivalents and restricted cash of $86.1 million and short-term investments of $138.6 million.

2021 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®) becomes 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, while it has been continuing to expand its product portfolio. The Company currently expects its product sales in 2021, excluding any royalties from Klisyri®, to be in line with 2020 levels.

The Company expects that its cash, cash equivalents, restricted cash, and short-term investments as of December 31, 2020, will enable it to meet its current operational liquidity needs and fund operations into the second quarter 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. The cash runway described above does not reflect additional funding available through the existing Senior Credit Agreement with Oaktree, or the Revenue Interest Financing Agreement with Sagard.

Conference Call and Webcast Information

Athenex will host a conference call and live audio webcast today, Monday, March 1, 2021, before the market open, at 8:00 am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial **(877) 407-0784 (domestic)** or **(201) 689-8560 (international)** fifteen minutes before the conference call begins and reference the conference passcode **13715950**. 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) T-cell receptor-engineered T-cells (TCR-T), 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. Athenex has offices in Buffalo and Clarence, New York; Cranford, New Jersey; Houston, Texas; Chicago, Illinois; Hong Kong; Taipei, Taiwan; multiple locations in Chongqing, China; Manchester, UK; Guatemala City, Guatemala and Buenos Aires, Argentina. 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, manufacturing and commercialization; 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 need to raise additional capital; uncertainties around our ability to meet funding conditions under our financing agreements and access to capital thereunder; risks and uncertainties related to the COVID-19 pandemic and its potential impact on our operations, cash flow and financial condition; competition; intellectual property risks; risks relating to doing business internationally and in China; the risk of production slowdowns or stoppages or other interruptions at our Chongqing 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.

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

	December 31,	
	2020	2019
	(In thousands)	
Selected Balance sheet data:		
Cash, cash equivalents, and restricted cash	$ 86,087	$ 127,674
Short-term investments	138,636	33,139
Goodwill	38,891	38,513
Working capital(1)	229,820	159,398
Total assets	384,329	309,932
Long-term debt	148,587	53,246
Total liabilities	218,981	134,077
Non-controlling interests	(14,427)	(12,370)
Total stockholders' equity	$ 165,348	$ 175,855

(1) 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 December 31,		Year ended December 31,	
	2020 (in thousands)	2019 (in thousands)	2020 (in thousands)	2019 (in thousands)
Revenue				
Product sales, net	$ 21,780	$ 14,102	$ 105,274	$ 80,535
License and other revenue	28	20,259	39,117	20,694
Total revenue	21,808	34,361	144,391	101,229
Cost of sales	(18,267)	(15,704)	(95,355)	(69,619)
Gross profit	3,541	18,657	49,036	31,610
Research and development expenses	(18,307)	(21,823)	(75,904)	(84,393)
Selling, general, and administrative expenses	(31,401)	(18,109)	(96,855)	(66,749)
Interest income	164	473	874	1,881
Interest expense	(4,386)	(1,700)	(11,219)	(6,954)
Loss on extinguishment of debt	—	—	(10,278)	—
Income tax (expense) benefit	(8)	91	(4,088)	(928)
Net loss	(50,397)	(22,411)	(148,434)	(125,533)
Less: net loss attributable to non-controlling interests	(904)	(684)	(2,255)	(1,784)
Net loss attributable to Athenex, Inc.	$ (49,493)	$ (21,727)	$ (146,179)	$ (123,749)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.53)	$ (0.28)	$ (1.72)	$ (1.67)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	93,326,892	78,550,995	85,082,868	74,054,261

Exhibit 99.2

Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer

- *Conference call and webcast scheduled for today at 8:00 a.m. ET*

Buffalo, N.Y., March 1, 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 announced that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) for the company's New Drug Application (NDA) for oral paclitaxel plus encequidar 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.

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 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 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.

Athenex plans to request a meeting with the FDA to discuss the Agency's response, 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.

"Our clinical and regulatory teams are disappointed by the complete response letter," said Dr. Rudolf Kwan, Chief Medical Officer of Athenex. "We plan to work with the Agency to resolve the issues raised in the CRL and to obtain approval for oral paclitaxel plus encequidar in metastatic breast cancer."

Dr. Johnson Lau, Chief Executive Officer of Athenex, added, "We remain committed to the breast cancer community and will explore the best path forward to obtain regulatory approval. In the interim, we will identify and undertake the appropriate internal organizational adjustments accordingly."

Webcast and Conference Call

Athenex will host a webcast and conference call today Monday, March 1, 2021, at 8 a.m. ET to discuss this regulatory update for oral paclitaxel, as well as the company's fourth quarter and full year 2020 financial results. The live call may be access by dialing **(877) 407 – 0784 (domestic)** or **(201) 689-8560 (international)** fifteen minutes before the conference call begins and reference the passcode **13715950**. The live conference call and replay can also be accessed via audio webcast at the Investor Relations section of the Company's website, located at http://ir.athenex.com/.

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