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): October 11, 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 7.01 Regulation FD Disclosure.

On October 11, 2021, Athenex, Inc. (the "Company") issued a press release to announce that after holding a Type A meeting with the U.S. Food and Drug Administration regarding the New Drug Application for oral paclitaxel and encequidar ("Oral Paclitaxel") in metastatic breast cancer, the Company has determined to redeploy its resources to focus on other ongoing studies of Oral Paclitaxel. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information in this Item 7.01 is not incorporated by reference into any filing with the Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated October 11, 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: October 11, 2021

/s/ Steven Adams

Name: Steven Adams
Title: Interim Chief Accounting Officer

Athenex Provides Update from FDA Type A Meeting Regarding Oral Paclitaxel + Encequidar in Metastatic Breast Cancer

BUFFALO, N.Y., Oct. 11, 2021 (GLOBE NEWSWIRE) – **Athenex** (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 it recently held a Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for oral paclitaxel and encequidar (Oral Paclitaxel) in metastatic breast cancer (mBC). The purpose of the meeting was to review with the FDA a proposed design for a new clinical trial intended to address the deficiencies raised in the Complete Response Letter received in February 2021 and discuss the potential regulatory path forward for Oral Paclitaxel in mBC in the U.S.

“We had an informative meeting with the FDA, which was an important step to assessing the U.S. regulatory pathway for Oral Paclitaxel in mBC,” said Dr. Johnson Lau, Chief Executive Officer of Athenex. “After careful consideration of the FDA feedback, we have determined to redeploy our resources to focus on other ongoing studies of Oral Paclitaxel and our promising CAR-NKT and TCR-T cell therapies to maximize value for all stakeholders. We also remain committed to serving patients utilizing products manufactured by our specialty pharmaceutical business (APS and APD).”

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 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, including NKT Cell Therapy and related risks involved in drug development, clinical trials, regulation, uncertainties around regulatory reviews and approvals; our

ability to pivot our business and to find new uses for the capacity at our Dunkirk manufacturing facility, once operational 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 our ability to successfully integrate the business of Kuur into our existing businesses, including uncertainties associated with maintaining relationships with customers, vendors and employees, as well as differences in operations, cultures, and management philosophies that may delay successful integration and our ability to support the added cost burden of Kuur's business; 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 enter into new financing agreements as we are unable to meet funding conditions under our existing 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 ongoing 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 as well as our ability to find alternative sources of supply to meet our obligations and requirements; 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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