
**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 22, 2018

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

Delaware
(State or other jurisdiction
of incorporation)

001-38112
(Commission
File Number)

43-1985966
(IRS Employer
Identification No.)

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

14203
(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))

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 22, 2018, Athenex, Inc. (the “Company”) issued a press release to announce that the Company presented encouraging clinical trial efficacy and safety results of Oraxol in the treatment of metastatic breast cancer at the European Society for Medical Oncology Congress on October 21, 2018 in Munich, Germany. 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 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 U.S. Securities and Exchange Commission (the “SEC”) 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 Issued by the Company on October 22, 2018](#)

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 22, 2018

/s/ Teresa Bair

Name: Teresa Bair

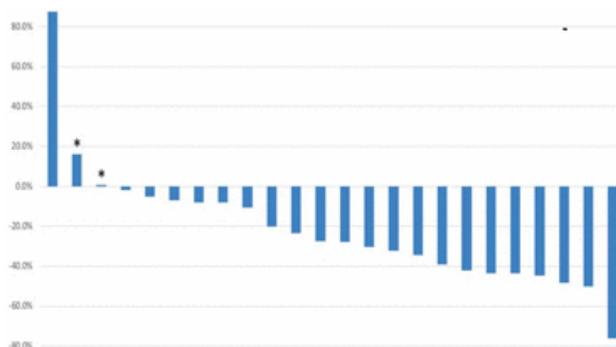
Title: Vice President, Legal Affairs and Corporate Development

ESMO 2018: Athenex Presented Encouraging Clinical Trial Efficacy and Safety Results of Oraxol in the Treatment of Metastatic Breast Cancer

BUFFALO, N.Y., October 22, 2018 — 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 the presentation of encouraging efficacy and safety data of Oraxol in the treatment of metastatic breast cancer patients who failed previous chemotherapies in a pharmacokinetics (PK) and phase II clinical trial conducted in Taiwan. The data were presented at the European Society for Medical Oncology (ESMO) Congress on October 21, 2018 in Munich, Germany. Oraxol is an innovative oral formulation of paclitaxel, a very effective and commonly used anti-cancer chemotherapy, combined with HM30181A (a novel gastrointestinal tract specific P-glycoprotein pump inhibitor).

Results from twenty four patients with metastatic breast cancer were reported. Common metastatic sites included bone (n=12), liver (n=9), lungs (n=9), lymph nodes (n=9) and 6 patients had \leq 3 metastasis. These patients failed a median of two previous chemotherapies.

Eleven patients (45.8%) achieved partial remission (PR), 10 patients (41.7%) had stable disease (SD) (two patients with SD will have their last CT scans conducted in early November and therefore, the overall PR rate may be higher), and 3 patients had progressive disease (PD), as shown in the waterfall plot of tumor responses below:



Note that two patients with PD showed small tumor size changes of <30% but were classified as PD because new metastatic lesions were identified by CT scans (* indicates the two patients). Two SD patients are expected to complete their last CT scans in early November and the overall PR rate may be higher in the final analysis.

Drug-related serious adverse events consisting of Grade 4 neutropenia were observed in 3 patients and all recovered completely. There was no dose-limiting neuropathy observed. The Oraxol pharmacokinetic profiles at week 1 were reproducible at week 4, and the plasma AUC exposure is similar to those reported for intravenous paclitaxel at 80mg/kg weekly.

Dr. Rudolf Kwan, Chief Medical Officer of Athenex, stated, “The encouraging pharmacokinetic profile and the positive Phase II clinical efficacy and safety data showed the excellent potential of Oraxol. We are advancing our Phase III program rapidly.”

Dr. Ko-Chung Lin, Chief Executive Officer of PharmaEssentia, the licensee of Oraxol for Taiwan, Singapore and Vietnam, commented, “Athenex has been an excellent partner to PharmaEssentia. We have been working closely together on the clinical studies and on our discussions with the regulatory authorities. We are delighted to see such a wonderful set of encouraging results and we are fully committed to support the development of Oraxol in the territory we have licensed from Athenex.”

The Orascovery program was initially discovered by Hanmi Pharmaceuticals and licensed to Athenex. PharmaEssentia Corporation (Taiwan Stock Exchange: 6446), licensed the Taiwan, Singapore and Vietnam commercialization rights of Oraxol from Athenex and is a close partner, particularly in the clinical developments of Oraxol in Taiwan.

About Athenex, Inc.

Founded in 2003, Athenex, Inc. is a global clinical stage biopharmaceutical company dedicated to becoming a leader in the discovery and development 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 non-absorbed 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 and multiple locations in Chongqing, China. For more information, please visit www.athenex.com.

Forward-Looking Statement

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. 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; our need to raise additional capital; competition; intellectual property risks; risks relating to doing business in China; 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. We assume no obligation and do not intend to update these forward-looking statements, except as required by law.

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