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 5, 2017

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

(Former name or former address, if changed since last report.)

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 8.01 Other Events.

On October 5, 2017, the Company issued a press release announcing that the planned interim analysis of the Oraxol 001 Phase III Clinical Trial has been conducted and reviewed by an independent Drug Safety Monitoring Board. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "Athenex Announces Positive Recommendations from the Drug Safety Monitoring Board to Continue the Oraxol Phase III Program" issued by the Company on October 5, 2017.

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 5, 2017

/s/ J. Nick Riehle
Name: J. Nick Riehle
Title: Chief Financial Officer

Exhibit 99.1

Athenex Announces Positive Recommendations from the Drug Safety Monitoring Board to Continue the Oraxol Phase III Program

Buffalo, NY, October 5, 2017 — 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 a planned interim analysis of the Oraxol 001 Phase III Clinical Trial has been conducted and reviewed by an independent Drug Safety Monitoring Board (DSMB). The DSMB unanimously recommended continuation of the study. The DSMB was impressed by the conduct of the study in achieving a good overall response rate. The DSMB was reassured by the expected difference in safety profile between Oraxol and IV paclitaxel. In particular, the adverse event of painful neuropathy was uncommon with Oraxol treatment. The DSMB encouraged the rapid patient recruitment toward the scheduled second interim analysis at 180 patients.

The Oraxol 001 Phase III Clinical Trial is a randomized controlled clinical trial comparing Oraxol monotherapy against intravenous (IV) paclitaxel monotherapy in patients with metastatic breast cancer, with target enrollment of 360 patients. The study is designed to show a safety comparison and superiority of Oraxol over IV paclitaxel based on confirmed response rate as assessed by RECIST Criteria, a generally accepted clinical response criteria for efficacy in tumor reduction. Confirmed treatment response rates are made by a blinded independent radiologic imaging analysis center. The protocol allows the first interim analysis to be conducted when 90 patients completed 18 weeks of treatment or discontinued.

Dr. Rudolf Kwan, Athenex's Chief Medical Officer, commented, "After comprehensive review of the efficacy and safety data of this Oraxol Phase III clinical trial, the unanimous recommendation by the DSMB to continue this study full speed ahead represents an important milestone achieved. Neuropathy is a severe dose limiting side-effect of IV paclitaxel. The very low incidence of neuropathy with Oraxol therapy may represent an advance in effective and less toxic treatment for cancer patients and is an important step towards a new chapter of oral therapy based on paclitaxel, potentially establishing a path towards long-term maintenance therapy (metronomic dosing) for the control of cancer based on orally delivered taxanes. We expect this clinical trial to proceed on track with rapid patient recruitment timelines and a scheduled second interim analysis at 180 patients in 2018."

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. Athenex's Oncology Innovation Platform generates clinical candidates through an extensive understanding of kinases, including novel binding sites and human absorption biology, as well as through the application of Athenex's proprietary research and selection processes in the lab. The Company's current clinical pipeline is derived from two different platform technologies Athenex calls Orascovery and Src Kinase Inhibition. The Orascovery platform is based on the novel oral P-glycoprotein pump inhibitor molecule HM30181A, through which Athenex is able to facilitate oral absorption of traditional cytotoxics, which Athenex believes may offer

improved patient tolerability and efficacy as compared to IV administration of the same cytotoxics. The Orascovery platform was developed by Hanmi Pharmaceuticals and licensed exclusively to Athenex for all major worldwide territories except Korea that is retained by Hanmi. The Src Kinase Inhibition platform refers to novel small molecule compounds that have multiple mechanisms of action, including the inhibition of the activity of Src Kinase and the inhibition of tubulin polymerization during cell division. Athenex believes the combination of these mechanisms of action provides a broader range of anti-cancer activity as compared to either mechanism of action alone. 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.

Forward-Looking Statement Disclaimer/Safe Harbor 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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Athenex, Inc.