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): December 27, 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 December 27, 2017, Athenex, Inc. (the "Company") issued a press release announcing that the UK Medicines and Healthcare Products Regulatory Agency granted a Promising Innovative Medicine designation for Oraxol in the treatment of paclitaxel-responsive cancers.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release titled "Athenex Receives Promising Innovative Medicine Designation from the United Kingdom MHRA for Oraxol, An Innovative Oral Form of Paclitaxel" issued by the Company on December 27, 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: December 28, 2017

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

Exhibit 99.1

Athenex Receives Promising Innovative Medicine Designation from the United Kingdom MHRA for Oraxol, An Innovative Oral Form of Paclitaxel

BUFFALO, N.Y., December 27, 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 the UK Medicines and Healthcare Products Regulatory Agency (MHRA) granted a Promising Innovative Medicine (PIM) designation for Oraxol in the treatment of paclitaxel-responsive cancers.

Oraxol is an innovative development in the treatment of cancer, in that it is an oral formulation of paclitaxel, a very effective and commonly used chemotherapy treatment for many cancers. The existing marketed form of paclitaxel can only be administered intravenously. It cannot be absorbed orally because it is excreted by gastrointestinal cells via the P-glycoprotein (P-gp) pump before it can be absorbed. Athenex had enabled oral administration of paclitaxel by combining HM30181A with oral paclitaxel (called Oraxol), which was initially discovered by Hanmi Pharmaceuticals and licensed to Athenex in the establishment of a strategic partnership. Oraxol is currently in Phase III studies being managed by Athenex.

A PIM designation recognizes Oraxol as a promising and innovative drug based on early clinical data. Drugs recognized with a PIM designation must address life-threatening or seriously debilitating conditions, have a high unmet need and demonstrate a positive benefit-risk balance. The designation is the first of two steps in the Early Access to Medicines Scheme (EAMS). The PIM designation now qualifies Athenex to apply for Step II of EAMS, which would allow Athenex to provide patients early access to Oraxol, prior to receiving marketing authorization, because it addresses a high unmet need. This will be based on the Step II EAMS scientific opinion that describes the benefits and risks of the medicine and supports both prescriber and patient in making a decision on using the medicine before its license is approved.

The EAMS program was launched in 2014 by the UK government to accelerate patient access to promising medicines. Marketed drugs that successfully went through the EAMS program include Pembrolizumab, Nivolumab, Osimertinib and Atezolizumab.

“We are pleased that Oraxol has been granted a PIM designation and that the MHRA has recognized the innovation in shifting from IV to oral delivery across paclitaxel-responsive cancers,” stated Dr. Rudolf Kwan, Athenex’s Chief Medical Officer. “Oraxol will be a break-through treatment if paclitaxel chemotherapy can be given orally instead of intravenously, with similar or better anti-cancer efficacy, less toxicities and a better quality of life. It also offers cancer patients on IV paclitaxel the opportunity for home treatment, something many of these patients would prefer. In addition, Oraxol may provide major cost savings to the healthcare system by eliminating the expensive weekly IV paclitaxel chemotherapy infusion at hospitals.”

Dr. Johnson Lau, Athenex’s Chief Executive Officer, added, “We are delighted with the positive recommendation by the MHRA and the PIM designation for Oraxol, which provides further validation of the progress of our Orascovery platform through an independent review from another well-respected regulatory authority. The designation was given to Oraxol for the treatment for the entire class of

paclitaxel-responsive cancers instead of a narrow specific cancer indication, highlighting the endorsement by the MHRA on the positive scientific merits in Oraxol. This designation is an important milestone that may provide a streamlined path for the development of Oraxol not just for the UK, but also for the European market as part of our planned strategy for global outreach."

The PIM designation follows the independent Data Safety Monitoring Board's first interim analysis of the Oraxol 001 Phase III Clinical Trial, where they unanimously recommended continuation of the study and encouraged rapid recruitment toward the scheduled second interim analysis, which Athenex previously announced on October 5, 2017. The recommendation was based on a positive overall response rate and particularly the relatively limited number of occurrences of the adverse event of painful neuropathy with Oraxol, which is currently a severe dose-limiting side-effect of IV paclitaxel.

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, which 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; 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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