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): November 27, 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 2	30.425)	
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- □ 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 1.01 Entry into a Material Definitive Agreement.

On November 27, 2018, Athenex, Inc. (the "Company") and PharmaEssentia Corp. ("PharmaEssentia") entered into a second amendment to their December 2013 out-licensing agreement of Oraxol and Oratecan, which was previously amended in December 2016. In addition to those products, this amendment (the "Amendment") provides for PharmaEssentia to license Oradoxel from the Company for use in Singapore, Taiwan and Vietnam. The Company will receive a payment of \$2.0 million from PharmaEssentia on or prior to December 15, 2018 in consideration for entering into the Amendment. In addition, the Amendment provides for the Company to receive up to \$8.5 million in additional development and regulatory milestone payments related to Oradoxel.

The Company intends to file the Amendment with its Annual Report on Form 10-K for the fiscal year ending December 31, 2018.

In addition to the December 2013 out-licensing agreement, the Company and PharmaEssentia are also party to an out-licensing agreement for KX-01 and KX-02 for use in treating psoriasis or other non-malignant skin conditions in a territory that includes China, Taiwan, Macau, Hong Kong, Singapore and Malaysia. The Company also owns 68,000 shares of PharmaEssentia, which is a company publicly traded on the Taiwan OTC Exchange.

Item 8.01 Other Events.

On November 29, 2018, the Company issued a press release to report entering into the Amendment. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No. Description

99.1 Press release issued by the Company on November 29, 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: December 4, 2018 /s/ Randoll Sze

Name: Randoll Sze

Title: Chief Financial Officer

Athenex Announces Licensing Agreement with PharmaEssentia for Rights to Oradoxel (Oral Docetaxel) in Certain Asian Territories

BUFFALO, N.Y., Nov. 29, 2018 (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 it has entered into an agreement with PharmaEssentia Corporation (Taipei Exchange:6446) to license the rights to develop and commercialize Athenex's Oradoxel in Taiwan, Singapore and Vietnam. The existing licensing agreement for Oraxol (oral paclitaxel) and Oratecan (oral irinotecan) with PharmaEssentia is being expanded to account for additional considerations, including milestone payments, for Oradoxel (oral docetaxel). In December 2013, Athenex and PharmaEssentia entered into a license agreement, pursuant to which PharmaEssentia was granted a license to develop and commercialize Oraxol and Oratecan in Taiwan and Singapore. The agreement was amended in December 2016 to also include Vietnam in the territories covered by the license.

Under the terms of the expanded agreement, which includes Oradoxel, Athenex will receive a cash payment as well as the potential to receive additional milestone payments for certain development and regulatory milestones of Oradoxel in the territories. PharmaEssentia will be responsible for all activities and expenses relating to clinical development, regulatory approval, and commercialization of Oradoxel in the territories.

Docetaxel is an anti-cancer chemotherapeutic agent that is used widely in the treatment of breast, prostate, gastric, head and neck, and lung cancers. Oradoxel is an oral formulation of Docetaxel combined with HM30181A, a novel gastrointestinal tract specific P-glycoprotein pump inhibitor. Oradoxel is currently in Phase I clinical studies in the U.S. and New Zealand, and is ready to advance to Phase II with studies expected to begin in the first half of 2019.

Dr. Kochung Lin, Chief Executive Officer of PharmaEssentia, commented, "We are excited with the encouraging results so far from clinical trials of Athenex's Orascovery drug candidates, particularly Oraxol. The potential of oral chemotherapy drugs to improve efficacy and safety, and improve patients' quality of life, cannot be overstated. Athenex has generated promising Phase I data with both Oratecan and Oradoxel, and we are pleased to participate in the development of these exciting products in Taiwan, Singapore and Vietnam to help realize the full potential of this platform. We have been impressed by the Athenex team in their execution and are delighted to continue and expand our excellent partnership with the addition of Oradoxel."

Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex, stated, "This agreement builds on our longstanding relationship with PharmaEssentia has demonstrated strong commitment to cancer drug research and development, and we are confident they have the capabilities for successfully delivering Oradoxel to patients in the licensed territories."

The Orascovery platform was initially developed by Hanmi Pharmaceuticals and licensed exclusively to Athenex for all major worldwide territories except Korea, which is retained by Hanmi.

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.

About PharmaEssentia Corporation

PharmaEssentia Corporation (Taipei Exchange: 6446) is a fully integrated global biopharmaceutical company delivering efficacious, safe and costeffective therapeutic products for the treatment of human diseases while aiming to bring long lasting value to stakeholders. PharmaEssentia was founded in 2003 by a group of Taiwanese-American executives and high-ranking scientists from leading U.S. biotechnology and pharmaceutical companies in order to develop treatments for myeloproliferative neoplasms, hepatitis and other diseases. The company is committed to the improvement of health and quality of life for patients suffering from these diseases. The company's world-class cGMP biologics facility in Taichung is certified by the Taiwan Food and Drug Administration (TFDA) and is designed and operated to be compliant with all U.S. FDA and EMA requirements.

Forward-Looking Statement

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," "guidance," "intend," "likely," "may," "plan," "potential," "predict," "probable," "project," "seek," "should," "will," 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; 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 to continue as a going concern; 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. All information provided in this release is as of the date hereof and we assume no obligation and do not intend to update these forwardlooking statements, except as required by law.

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