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): June 6, 2019

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))

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. ☒

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**

Item 8.01 Other Events.

On June 6, 2019, Athenex, Inc. (the "Company") issued a press release to announce preliminary positive clinical activity signals in a Phase I clinical trial of KX2-391, or tirbanibulin, for the treatment of psoriasis. Also on June 6, 2019, the Company issued a press release to announce that it has voluntarily temporarily suspended production activities at its active pharmaceutical ingredient plant in Chongqing, China. These press releases are filed as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release regarding KX2-391 issued by the Company on June 6, 2019
99.2	Press release regarding Chongqing plant issued by the Company on June 6, 2019

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: June 6, 2019

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex and PharmaEssentia Announce Positive Early Signals of Clinical Activity of KX2-391 (INN: tirbanibulin) in Patients with Psoriasis

BUFFALO, NY and TAIPEI, Taiwan, June 6, 2019 (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, and PharmaEssentia Corp. (Taipei Exchange: 6446), a global biopharmaceutical company delivering efficacious, safe and cost-effective therapeutic products for the treatment of human diseases, today announced preliminary positive clinical activity signals observed in a cohort of patients with psoriasis treated with KX2-391 (INN: tirbanibulin) 1% ointment once daily for 5 days in a Phase I clinical trial.

Six patients with mild to moderate psoriasis were studied. All patients showed some improvement. One patient had complete resolution of skin scaling and another patient had improvement of psoriatic plaque thickness. The treatment was found to be well-tolerated. Only mild (grade-1) skin burning sensation and irritation were observed in one patient each.

Tirbanibulin (KX2-391) ointment has been well tolerated in patients with psoriasis and also in trials treating patients with actinic keratosis. Positive topline efficacy and safety results from two Phase III studies of tirbanibulin ointment 1% in the treatment of actinic keratosis were presented at the 2019 American Academy of Dermatology Annual Meeting in a late breaker oral presentation.

Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex, commented, “We are delighted to observe positive early clinical signals in this small cohort of patients. Based on the results from our Phase II and III studies of this product in actinic keratosis, we are confident about its safety profile for psoriasis, which is treated according to a similar protocol. We are working closely with our partner, PharmaEssentia, to further evaluate the optimal treatment regimen for psoriasis using this novel molecule.”

Athenex licensed the rights to tirbanibulin (KX2-391) to PharmaEssentia for psoriasis and non-malignant skin conditions (excluding actinic keratosis) in Mainland China, Taiwan, Hong Kong, Macau, Singapore and Malaysia, as well as the rights for actinic keratosis in Taiwan. PharmaEssentia is sponsoring this Phase I clinical trial in psoriasis. Athenex also licensed the rights to tirbanibulin for any skin disorder or skin disease in humans, including any skin cancer treated by dermatologists (but excluding any other forms of cancer), in the U.S. and European countries, including Russia, to Almirall, S.A.

The World Health Organization has recommended “tirbanibulin” as the International Nonproprietary Name (INN) for KX2-391. The Company may use the nomenclature “tirbanibulin” in future communications.

Tirbanibulin: Novel Mechanism(s) of Action

Tirbanibulin (KX2-391) is a novel small molecule, discovered and developed by Athenex. It has dual mechanisms of action consisting of Src kinase inhibition (non-ATP competitive) and tubulin polymerization inhibition resulting in upregulation of apoptosis in proliferating cells, including anti-proliferative action in skin cells.

About Psoriasis

Psoriasis is a chronic autoimmune skin disease that speeds up the growth cycle of skin cells. Psoriasis causes localized or generalized patches of red papules and plaques, covered with white or silver scales and itching. According to the World Health Organization, psoriasis may affect at least 100 million individuals worldwide.

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 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 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," "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 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 forward-looking statements, except as required by law.

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Exhibit 99.2

Athenex Provides an Update on its Chongqing API Plant

BUFFALO, N.Y., June 6, 2019 — Athenex, Inc. (Nasdaq: ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer, today announced that its active pharmaceutical ingredient (API) plant in Chongqing, China has voluntarily suspended production activities. The voluntary temporary suspension occurred last month, and the Company expects to have a resolution by the end of the third quarter of 2019, subject to inspection and evaluation by the Department of Emergency Management of Chongqing. This voluntary action came after tragic accidents at other chemical plants in March and April 2019 in certain provinces of China that led to industry-wide plant inspections focused on production safety. Athenex believes that this self-imposed action demonstrates the Company's good faith in working with the Department of Emergency Management of Chongqing and that the Company takes work safety very seriously.

The Company has communicated its decision to voluntarily suspend production to its customers. The Company plans to continue selling existing API inventories through at least the third quarter of this year. The Company believes that it has sufficient API inventory for all ongoing and near term planned clinical studies, and for its registration activities for late-stage clinical products. In addition, the Company is in the process of working with its secondary suppliers and securing additional suppliers subject to its needs, as part of normal course supply chain activities. The build-out of the new API plant in Chongqing is near completion and the plant is expected to commence operations in the first half of 2020. Athenex re-affirms its product sales guidance of a 25% to 30% increase in 2019 from the product sales revenue of $56.4 million reported in 2018.

The decision to voluntarily suspend production activities at the API plant was made to ease concerns from the Department of Emergency Management of Chongqing, which has been evaluating the safety of all chemical and other plants in the region after the recent tragic accidents at other plants in the region. The Company believes the API plant has been in compliance from a safety and regulatory perspective. The Company will continue to work closely with the department and aims to conclude the inspection as soon as practicable.

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