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): March 1, 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. ☒

Item 1.02 Termination of a Material Definitive Agreement.

Effective as of March 6, 2019, Athenex, Inc. (the "Company") terminated the license agreement, dated as of December 30, 2018, between the Company as licensor and one of the Company's subsidiaries, Chongqing Taihao Pharmaceutical Co Ltd, as licensee and the sublicense agreement, dated as of December 30, 2018, between Chongqing Taihao Pharmaceutical Co Ltd, as sublicensor and Chongqing Jingdong Junzhuo Pharmaceutical Co., Ltd as sublicensee.

Pursuant to the original agreements, we granted to Chongqing Jingdong Junzhuo Pharmaceutical Co., Ltd the rights to exclusively commercialize KX2-391 for the treatment of actinic keratosis and oncology indications in humans in mainland China (excluding Hong Kong, Macau and Taiwan). Under the terms of the termination agreements, we have regained the right to commercialize KX2-391 in mainland China. We are not subject to any termination penalties related to the termination of the license and sublicense agreements.

On March 7, 2019, the Company issued a press release announcing the termination of these license and sublicense arrangements. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01 Other Events.

On March 1, 2019, the U.S. Food and Drug Administration (the "FDA") announced that it had determined not to list vasopressin on its list of bulk drug substances for which there is a clinical need ("503B Bulks List") pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act (the "FDCA").

On March 4, 2019, the Company and two of its wholly-owned subsidiaries, Athenex Pharma Solutions, LLC and Athenex Pharmaceutical Division, LLC, filed a complaint in the United States District Court for the District of Columbia (the "Court") against the FDA, the U.S. Department of Health and Human Services and certain governmental officials seeking to vacate the FDA decision not to include vasopressin on the 503B Bulks List. On March 7, 2019, the FDA agreed that pending the Court's decision on the merits of the Company's complaint, the FDA will not initiate enforcement action against the Company based solely on its use of the bulk drug substance vasopressin to compound drugs and distribute those drugs. Accordingly, the Company intends to continue selling its compounded vasopressin product. The Court is expected to hold a hearing on the merits of the Company's claim in late April or May 2019.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Athenex, Inc. dated March 7, 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: March 7, 2019

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex Regains Rights to KX2-391 in China

BUFFALO, N.Y., Mar. 7, 2019 — 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 upon Athenex's request, Athenex and Chongqing Jingdong Junzhuo Pharmaceutical Co., Ltd. ("Chonqing Jingdong Pharmaceutical") have mutually agreed to terminate the licensing and partnership agreement entered into on December 30, 2018.

Pursuant to the original agreement, Athenex, via Chongqing Taihao Pharmaceutical Co., Ltd. (an Athenex subsidiary in China), granted to Chongqing Jingdong Pharmaceutical the rights to exclusively commercialize KX2-391 for the treatment of actinic keratosis and oncology indications in humans in mainland China (excluding Hong Kong, Macau and Taiwan). Under the terms of the termination agreement, Athenex has regained the rights to commercialize KX2-391 in mainland China. The decision of both parties to terminate the licensing and partnership agreement has no connection with the progress or the results of any of the clinical studies of the KX2-391 program.

Johnson Lau, Chief Executive Officer of Athenex, commented, "We believe KX2-391 is an important drug candidate with the potential to drive significant economic value for Athenex. We remain committed to the global development and commercialization efforts. The compelling clinical profile of KX2-391 ointment was highlighted in the Late-Breaking Program at the recent 2019 American Academy of Dermatology Annual Meeting, where the topline results of our two pivotal Phase III studies were presented. We believe we are well positioned to align our development strategies in mainland China as we continue to evaluate options for KX2-391 globally."

For further information on the topline results from the two pivotal Phase III studies of KX2-391 ointment in the treatment of actinic keratosis released on March 4, 2019, please visit the Press Releases page of the Investor Relations section of Athenex's website at www.athenex.com and review SEC filings on www.sec.gov.

KX2-391, also known as KX-01, is a first-in-class dual Src kinase and tubulin polymerization inhibitor. KX2-391 ointment is a topical medicinal product for the treatment of actinic keratosis that is in late stage Phase III development. Actinic keratosis is a common skin condition that is induced through ultra-violet light damage, resulting in patches of thick, scaly, or crusty skin. Other drug candidates with KX2-391 as the active ingredient are also being developed for oncology indications.

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

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