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): February 15, 2021

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))

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**

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 February 15, 2021, Athenex, Inc. (the "Company") entered into a Second Amendment (the "Second Amendment") to the License Agreement (the "License") dated December 8, 2011, between the Company and PharmaEssentia Corp. ("PharmaEssentia"). The Second Amendment, among other things, expands the territory covered by the License for tirbanibulin ointment (formerly known as KX01 or KX2-391) to include two additional territories, Japan and South Korea, and expands the existing field under the license to Taiwan, Singapore and Malaysia to include dermatology indications and skin cancer.

Under the expanded License, the Company will receive an upfront payment of $500,000 (the "Upfront Payment"). The Company will also be eligible to receive milestone payments of up to $13 million associated with the achievement of certain development and sales milestones. Further, the Company will be eligible to receive tiered double-digit royalties ranging from the low to high twenties on net sales of tirbanibulin ointment in Japan and South Korea. The Company will supply the licensed products under a supply agreement for a separate fee.

The foregoing summary of the Second Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Second Amendment, a copy of which will be filed as an exhibit to the Company's next Quarterly Report on Form 10-Q and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On February 18, 2021, the Company issued a press release to announce the entry into the Second Amendment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated February 18, 2021 (the attached reflects updated footnotes to correct the attribution of the statements they support)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 18, 2021

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex Announces U.S. Launch of Klisyri® and Licensing of Additional Territories for Tirbanibulin

- *Athenex Announces Licensing of Additional Territories for the Development and Commercialization of Tirbanibulin in Japan and South Korea.*
- *PharmaEssentia Expands Tirbanibulin Partnership by Adding Japan and South Korea to Already Licensed Territories of Taiwan, Singapore, and Malaysia*
- *Athenex's Existing Partners Include Almirall, S.A., in the United States, Europe, and Russia; and Guangzhou Xiangxue Pharmaceutical in China*
- *Almirall launches Klisyri® for actinic keratosis in the U.S. today*

Buffalo, N.Y., February 18, 2021 (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, announced that today marks the U.S. launch of Klisyri® (tirbanibulin) in the United States, led by the Company's partner Almirall. Athenex announced the licensing of additional territories for tirbanibulin to its partner PharmaEssentia Corp. (Taiwan Exchange: 6446). Athenex received approval from the U.S. Food and Drug Administration (FDA) for Klisyri® for the topical treatment of actinic keratosis of the face or scalp on December 14, 2020.

"We are thrilled to announce the U.S. launch of Klisyri® and the expansion of our successful collaboration with PharmaEssentia to now include the Japanese and South Korean markets," said Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex. "Throughout our partnership, PharmaEssentia has demonstrated strong execution and a commitment to drug research and development. We are confident that this will further our mission to bring a valuable treatment option to benefit patients globally."

PharmaEssentia (PEC) adds licensing rights to tirbanibulin for Japan and South Korea to already licensed territories, which include Taiwan, Singapore, and Malaysia. Under the expanded agreement, Athenex will receive an upfront payment from PharmaEssentia, and will be eligible to receive milestone payments associated with the achievement of certain development and sales milestones. Athenex will also be eligible to receive tiered double-digit royalties on net sales of tirbanibulin in Japan and South Korea.

Dr. Ko-Chung Lin, Chief Executive Officer of PharmaEssentia, added, "We are delighted by the news of the U.S. FDA approval of Klisyri®. We believe that Klisyri® will disrupt and change the AK treatment paradigm and provide good options for patients in Asia, particularly for those in Taiwan, Japan, Korea, Vietnam, Malaysia and Singapore."

Klisyri® launched today in the U.S., led by our partner Almirall. Under the terms of the license agreement with Almirall, Athenex is eligible to receive up to $65 million in milestone payments associated with today's launch and expansion into additional indications. Additionally, Athenex is eligible for additional sales-related milestone payments. The agreement includes tiered royalties starting at 15% based on annual net sales.

About PharmaEssentia (PEC)

PharmaEssentia Corporation (Taipei Exchange: 6446) is a fully integrated global biopharmaceutical company delivering efficacious, safe and cost-effective therapeutic products for the treatment of human diseases while aiming to bring long lasting value to stakeholders. PharmaEssentia, based in Taipei, began operations in 2003 with subsidiaries across Asia and the U.S., and was founded 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.

For further information on Klisyri visit www.klisyri.com.

About Klisyri®

Klisyri® (tirbanibulin) is a microtubule inhibitor indicated for the topical treatment of actinic keratosis of the face or scalp. The two double-blind, vehicle-controlled, randomized, parallel group, multicenter, Phase III studies (KX01-AK-003 and KX01-AK-004) evaluated the efficacy and safety of tirbanibulin ointment 1% (10 mg/g) in adults with actinic keratosis on the face or scalp.

The studies enrolled a total of 702 patients across 62 sites in the US. Tirbanibulin ointment 1% (10 mg/g) or vehicle (randomized 1:1) was self-administered to 25 cm2 of the face or scalp encompassing 4-8 typical AK lesions, once daily for 5 consecutive days.

Both Phase III studies, KX01-AK-003 and KX01-AK-004, achieved their primary endpoint, which was defined as 100% clearance of the AK lesions at Day 57 within the face or scalp treatment areas, each study achieving statistical significance ($p<0.0001$) on this endpoint. In the KX01-AK-003 study, complete clearance was observed in 44% of the patients treated with tirbanibulin versus 5% for vehicle treated groups. In the KX01-AK-004 study, complete clearance was observed in 54% of the patients treated with tirbanibulin versus 13% for vehicle treated groups.

About Actinic Keratosis

Actinic keratosis or solar keratosis is a chronic and precancerous skin disease that occurs primarily in areas that have been exposed to ultraviolet (UV) radiation for a long period of time. It is usually found on the face, ears, lips, bald scalp, forearms, the posterior part of the hands, and lower legs. It is not possible to predict which AK lesions will develop into squamous cell carcinoma, so all lesions should be treated by a dermatologist. Actinic keratosis is the most common pre-cancerous dermatological condition. AK is the second most common diagnosis made by dermatologists in the United States[1]. The reported prevalence of AK is between 11% and 25%[2].

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Ophthalmic Adverse Reactions

KLISYRI may cause eye irritation. Avoid transfer of the drug into the eyes and to the periocular area during and after application. Wash hands immediately after application. If accidental exposure occurs, instruct patient to flush eyes with water and seek medical care as soon as possible.

Local Skin Reactions

Local skin reactions, including severe reactions (erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation and erosion/ulceration) in the treated area can occur after topical application of KLISYRI. Avoid use until skin is healed from any previous drug, procedure, or surgical treatment. Occlusion after topical application of KLISYRI is more likely to result in irritation.

ADVERSE REACTIONS

The most common adverse reactions (incidence ³2%) were local skin reactions, application site pruritus, and application site pain.

Please see Full Prescribing Information for Klisyri at **https://www.klisyri.com/**.

Athenex and Almirall Partnership

Athenex, Inc. (NASDAQ: ATNX) and Almirall entered into a strategic partnership in December 2017 to develop and market tirbanibulin for the treatment of actinic keratosis and other skin conditions in the United States and Europe, including Russia. Athenex has been responsible for conducting all preclinical and clinical studies in order to gain FDA approval of tirbanibulin. Almirall will leverage its expertise to support development in Europe and to market the product in all licensed territories.

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 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; multiple locations in Chongqing, China; Manchester, UK; Guatemala City, Guatemala and Buenos Aires, Argentina. 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,” “goal,” “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; uncertainties around our ability to meet funding conditions under our financing agreements and access to capital thereunder; risks and uncertainties related to the COVID-19 pandemic and its potential impact on our operations, cash flow and financial condition; competition; intellectual property risks; risks relating to doing business internationally and in China; the risk of production slowdowns or stoppages or other interruptions at our Chongqing facilities; 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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[2] Stockfeth, E., Fernandiz, C, Grob JJ, et al., Development of a treatment algorithm for actinic keratoses: a European Consensus. Eur J Dermatol. 2008;18(6):651-659