

---

---

**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): August 1, 2019**

---

**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 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 8.01 Other Events.**

On August 2, 2019, Athenex, Inc. (the “Company”) issued a press release to announce that the U.S. District Court for the District of Columbia issued a decision on August 1, 2019 finding against the Company on the merits of the Company’s motion for summary judgment in its lawsuit against the U.S. Food and Drug Administration (“FDA”), the U.S. Department of Health and Human Services and against certain governmental officials seeking to vacate the FDA’s decision that vasopressin is not a bulk drug substance for which there is a clinical need for outsourcing facility compounding under Section of the Federal Food, Drug and Cosmetic Act. This press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

**Exhibit**

<u>No.</u>	<u>Description</u>
99.1	<a href="#">Press release dated August 2, 2019</a>

---

**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: August 2, 2019

/s/ Randoll Sze

Name: Randoll Sze

Title: Chief Financial Officer

### Athenex Provides an Update Regarding the Vasopressin Case

BUFFALO, N.Y., August 02, 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 the U.S. District Court for the District of Columbia issued a decision in Athenex's litigation against the U.S. Food and Drug Administration (FDA) denying Athenex's motion for summary judgment and granting the FDA's cross-motion for summary judgment. Athenex plans to appeal the ruling and seek a stay of ruling pending its appeal. Athenex will cease producing and marketing its compounded vasopressin product until it is permitted to recommence production by the Court and FDA.

The latest court decision follows an FDA decision on March 4, 2019 not to list vasopressin on the list of bulk drug substances permitted to be compounded under Section 503B of the Federal Food, Drug and Cosmetic Act. Subsequent to the FDA decision, the company commenced a lawsuit against the FDA in the U.S. District Court for the District of Columbia contesting the FDA's decision not to include vasopressin on the bulk drug substances list. In its decision, the court found in favor of the FDA, upholding the agency's determination that vasopressin is not a bulk drug substance for which there is a clinical need for outsourcing facility compounding under Section 503B.

Jeffrey Yordon, Chief Operating Officer of Athenex, stated, "While we are disappointed by the court's decision, it does not come unexpected. We believe our vasopressin product helps to meet an important clinical need, so while we will comply with the court's and FDA's decision, we may explore additional actions, including an appeal. Vasopressin is part of a portfolio of specialty pharmaceutical and 503B products sold by Athenex, and we will continue to seek opportunities to add to this portfolio, in order to drive further growth and leverage the brand recognition and relationships we have built in oncology. In parallel, we remain focused on the progress of our proprietary oncology pipeline."

#### 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](http://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; the uncertain impact of inspections to be performed by the Department of Emergency Management of Chongqing on the production of API in our Chongqing plant and our business generally; 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.

## CONTACTS

Investor Relations:

Tim McCarthy

Managing Director, LifeSci Advisors, LLC

Tel: +1 716-427-2952

Direct: +1 212-915-2564

Athenex, Inc.:

Randoll Sze

Chief Financial Officer

Email: [randollsze@athenex.com](mailto:randollsze@athenex.com)

Jacqueline Li

Corporate Development and Investor Relations

Email: [jacquelineli@athenex.com](mailto:jacquelineli@athenex.com)