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): May 9, 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 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended March 31, 2019. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on May 9, 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: May 9, 2019

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Announces First Quarter 2019 Financial Results and Provides Corporate Update

Positive Phase 3 data for KX2-391 featured at 2019 AAD Annual Meeting
Promising early and complete response data reported for Oraxol in cutaneous angiosarcoma
Topline results from Oraxol Phase III clinical trial expected August 2019
Presenting four abstracts featuring Athenex product candidates at 2019 ASCO Annual Meeting
Approximately 100% year-over-year increase in Q1 product sales
Conference Call and Live Audio Webcast at 8:00 a.m. Eastern Time today

BUFFALO, N.Y., May 9, 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 its financial results and business highlights for the first quarter ended March 31, 2019.

"In the first quarter of 2019 we continued to make progress across our all our technology platforms and business units as we execute on our corporate strategy to build a global oncology company delivering more effective, safer and tolerable treatments for cancer patients," stated Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex. "Most notably, we recently reported promising preliminary data from our ongoing pilot study of Oraxol in angiosarcoma, which included three complete responses from the first seven patients to receive at least six weeks of Oraxol monotherapy, all of whom showed visible improvements in the angiosarcoma lesions within one to two weeks. We believe the high response rate and strong safety profile further support the rationale that oral paclitaxel can potentially achieve a more desirable pharmacokinetic profile and a better clinical outcome, giving us greater confidence in our all of our Oraxol clinical programs."

Dr. Lau continued, "Having achieved target enrollment in our Phase III trial of Oraxol in metastatic breast cancer we look forward to announcing top line results in August. Preparations are underway for regulatory filings for our partnered product KX2-391 in actinic keratosis. We are also working to build out our commercial and manufacturing infrastructure and develop our corporate brand in advance of anticipated proprietary product launches. Finally, we have added to our Board of Directors with four key appointments."

"We have also strengthened our balance sheet, with a private placement equity offering, completed on May 7, 2019, in which we raised gross proceeds of $100 million. We are very grateful for the support from the three leading healthcare investment firms who participated in this transaction," concluded Dr. Lau.

First Quarter 2019 and Recent Business Highlights:

Clinical Programs:

- Presented positive Phase 3 data on KX2-391 in actinic keratosis (AK) at the American Academy of Dermatology (AAD) annual meeting. Both Phase 3 studies are nearing completion of the one-year follow-up of patients who had complete responses and the final top-line data will be discussed with the FDA at an upcoming pre-NDA meeting.
- Oraxol Phase III studies in metastatic breast cancer: Achieved target enrollment of more than 360 patients. Topline results are expected to be available in August 2019.

- Announced Investigational New Drug (IND) allowance by China's National Medical Products Administration (NMPA) to begin registrational related clinical studies in China of TAEST16001 injection in patients with solid tumors
    - TAEST16001 is a cancer immunotherapy product candidate based on Athenex's T-cell receptor Affinity Enhanced Specific T-cell (TAEST) technology
    - TEAST technology is being developed by Axis Therapeutics, a joint venture between Athenex and Xiangxue Life Sciences (XLifeSc)
- Reported promising clinical results from a clinical study of Oraxol in cutaneous angiosarcoma. Preliminary data show rapid, visible response to Oraxol monotherapy in the first seven subjects, including three complete responses.
- Presented preclinical data on Oraxol in the treatment of angiosarcoma at the American Association for Cancer Research (AACR) annual meeting on April 3, 2019
- Announced acceptance of four abstracts for presentation at the 2019 American Society of Clinical Oncology (ASCO) annual meeting. Abstract topics include:
    - Oraxol program in metastatic breast cancer, including information about ongoing Phase III trial and about Phase II trial in Taiwan (two abstracts)
    - Preliminary results from Oratecan Phase I study
    - Preclinical proof of concept data on Arginine Deprivation Therapy platform

Corporate Announcements:

- Appointed new members to the Board of Directors:
    - John Moore Vierling, MD, FACP, FAASLD, AGAF, tenured Professor of Medicine and Surgery at the Baylor College of Medicine
    - Stephanie Davis, Senior Client Partner at Korn Ferry
    - Jordan S. Kanfer, Managing Director, Convertible and Equity Research at Opti Capital Management
    - John Koh, an independent director of NSL Ltd.; Mapletree Industrial Trust, a Singapore listed REIT; Kris Energy; and Aurora Mobile Limited (JG)

Commercial Business:

- Athenex Pharmaceutical Division ("APD") currently markets a total of 29 products with 54 SKUs
- Athenex Pharma Solutions ("APS") currently markets 6 products in total with 16 SKUs

Financial Results for the First Quarter Ended March 31, 2019

Athenex is on track to achieve its revenue guidance on products sales issued in March 2019. Product sales for the three months ended March 31, 2019 were $25.2 million, compared with $12.6 million for the three months ended March 31, 2018, an increase of $12.6 million or approximately 100%. The increase was attributable to a $6.0 million increase in specialty product sales, a $5.0 million increase in 503B product sales driven significantly by Vasopressin, and a $2.1 million increase in API product sales.

Total revenue for the three months ended March 31, 2019 was $25.3 million, a decrease of $12.5 million, or 33%, as compared to $37.8 million for the three months ended March 31, 2018. The decrease was primarily due to a decrease in licensing revenue of $25.0 million. This decrease was offset by the increases in product sales described above.

Cost of sales for the three months ended March 31, 2019 totaled $19.9 million, an increase of $8.6 million, or 76%, as compared to $11.3 million for the three months ended March 31, 2018. This was primarily due to the increase of $6.2 million cost of sales from the specialty products and $2.4 million cost of sales from 503B and API products. The decrease in gross profit and gross margin was primarily due to the absence of licensing revenue in the interim period.

Research and development expenses for the three months ended March 31, 2019 were $24.5 million as compared to $21.3 million for the three months ended March 31, 2018. This was primarily due to an increase in licensing fees and preclinical development activities.

Selling, general and administrative expenses for the three months ended March 31, 2019 were $15.2 million as compared to $13.1 million for the three months ended March 31, 2018. This was primarily due to an increase of $2.6 million related to the pre-launch costs of the Company's proprietary drugs, offset by a decrease of $0.5 million in general administrative expenses.

Net loss attributable to Athenex for the three months ended March 31, 2019 was $35.2 million, or $0.53 per diluted share, compared to a net loss of $7.3 million, or $0.12 per diluted share, in the same period last year.

At March 31, 2019, the Company had cash, cash equivalents and short-term investments aggregating $71.3 million, compared to $107.4 million at December 31, 2018. Based on the current operating plan, the Company expects that its cash, cash equivalents and short-term investments as of March 31, 2019, together with proceeds it has recently raised from the private placement and cash to be generated from operating activities, will enable it to fund its operating expenses and capital expenditure requirements through at least the next twelve months.

On May 7, 2019, the Company closed a private placement agreement in which it issued 10 million shares of common stock to three institutional investors (Perceptive Advisors, Avoro Capital Advisors (formerly known as venBio Select Advisor) and OrbiMed) at a purchase price of $10.00 per share, for aggregate gross proceeds of $100 million to Athenex, before deducting offering expenses.

Outlook and Upcoming Milestones:

- Presentations at the 2019 American Society of Clinical Oncology (ASCO) annual meeting
- Expect to file an IND for Pegtomarginase by mid-2019
- Top line results from Phase 3 trial of Oraxol in metastatic breast cancer, August 2019
- Expect to conduct a pre-IND meeting with the U.S. FDA for TAEST16001 injection product under the TCR-T immunotherapy program

Financial Guidance:

The company provides revenue guidance for product sales only. The revenue guidance excludes license and collaboration fees. Athenex reaffirms the product sales guidance issued in March 2019. Athenex is forecasting that product sales in 2019 will increase by between 25% and 30% year-over-year from $56.4 million in 2018.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Thursday, May 9, 2019, at 8:00am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial 877-407-0784 (domestic) or 201-689-8560 (international) fifteen minutes before the conference call begins and reference the conference passcode 13689379. The live conference call and replay can also be accessed via audio webcast at https://edge.media-server.com/m6/p/ohu4cnks and on the Investor Relations section of the Company's website, located at http://ir.athenex.com/, under "Events and Presentations."

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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Athenex, Inc. & Subsidiaries
Condensed Consolidated Balance Sheets

	March 31, 2019	December 31, 2018
	(in thousands)	
Balance sheet data:		
Cash, cash equivalents	$ 71,003	$ 49,794
Short-term investments	341	57,629
Goodwill	37,589	37,495
Working capital	82,933	119,143
Total assets	220,307	231,095
Long-term debt	47,732	46,764
Total liabilities	124,726	102,326
Non-controlling interests	(11,583)	(10,586)
Total stockholders' equity	$ 95,581	$ 128,769

Athenex, Inc. & Subsidiaries
Condensed Consolidated Statement of Operations

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	(in thousands)
Revenue		
Product sales, net	$ 25,163	$ 12,605
License fees and consulting revenue	105	25,091
Grant revenue	39	140
Total revenue	25,307	37,836
Cost of sales	(19,902)	(11,326)
Gross profit	5,405	26,510
Research and development expenses	(24,475)	(21,303)
Selling, general, and administrative expenses	(15,188)	(13,080)
Interest (expense) income	(1,472)	227
Income tax (expense) benefit	(500)	307
Net loss	(36,230)	(7,339)
Less: net loss attributable to non-controlling interests	(997)	(41)
Net loss attributable to Athenex, Inc.	$ (35,233)	$ (7,298)

Athenex, Inc. & Subsidiaries
Condensed Consolidated Statement of Cash Flows

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash (used in) operating activities	$(32,971)	$(12,726)
Net cash provided by investing activities	52,198	(56,800)
Net cash provided by financing activities	976	68,981
Net effect of foreign exchange rate changes	1,006	478
Net increase (decrease) in cash and cash equivalents	21,209	(67)
Cash and cash equivalents at beginning of period	49,794	39,284
Cash and cash equivalents at end of period	$ 71,003	$ 39,217