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 11, 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 2.02 Results of Operations and Financial Condition.

On March 11, 2019, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter and year ended December 31, 2018. 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 March 11, 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 11, 2019

/s/ Randoll Sze
Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Announces Fourth Quarter and Year Ended December 31, 2018 Financial Results and Provides Corporate Update

Oraxol Phase III clinical trial in metastatic breast cancer fully enrolled

Positive Phase III topline results of KX2-391 in actinic keratosis featured in late breaker session at recent 2019 AAD Annual Meeting

A number of abstracts submitted for presentation at ASCO on six of our products, highlighting data across the entire pipeline

Full year 2018 revenue was $89.1 million (after accounting for termination of the KX2-391 licensing arrangement in China that would have contributed to $14.5 million licensing fee revenue), compared to $38.0 million in 2017

4Q 2018 revenue was $21.3 million, compared to $14.9 million in 4Q 2017

Conference call and live audio webcast at 8:30 a.m. Eastern Time today

BUFFALO, N.Y., March 11, 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 fourth quarter and year ended December 31, 2018.

"In 2018, we made substantial progress in advancing our pipeline and expanding our technology platforms in oncology as we work towards building a global biopharmaceutical business," stated Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex. "We are on track to continue this positive momentum in 2019, with the expected completion of our Phase III study of Oraxol in metastatic breast cancer and preparations underway for regulatory filings for KX2-391 in actinic keratosis. We now have a total of 8 product candidates in the clinic, with INDs on 2 further candidates scheduled by mid-year, and we are committed to continuing our strong clinical execution. On the operational front, we continue to build out our commercial infrastructure and global supply chain as we put the plans in place to launch our proprietary products."

Fourth Quarter 2018 and Recent Business Highlights:

Clinical Programs:

- KX2-391 ointment in actinic keratosis: Positive topline results from two pivotal Phase III studies were featured in a late breaker session at the 2019 American Academy of Dermatology Annual Meeting
    - In studies KX01-AK-003 and KX01-AK-004, 44% and 54% of patients, respectively, achieved 100% AK lesion clearance at Day 57. The results were highly statistically significant.
    - Safety profile of KX2-391 ointment may be an important competitive advantage; adherence to treatment was greater than 99%
- Oraxol Phase III studies in metastatic breast cancer: Achieved target enrollment of 360 patients. Topline results are expected to be available in mid-2019
- Other Oraxol studies:
    - Announced positive results from the second cohort of patients in a global Phase Ib clinical trial of Oraxol plus ramucirumab in gastric cancer patients who failed previous chemotherapies. The Oraxol dose is currently being further escalated to 300 mg/m^2 in the third cohort of patients and the study is ongoing.

- Initiated a Phase I/II clinical study to assess the safety, tolerability and activity of Oraxol in combination with anti-PD1 antibody (pembrolizumab) in patients with advanced solid malignancies.
- Initiated a Phase I clinical study of Oraxol in angiosarcomas. Oraxol received Orphan Drug Designation from the U.S. FDA for this indication. Preclinical data to be presented in a poster session at American Association for Cancer Research (AACR) Annual Meeting 2019

- Orascovery platform:
  - Licensed the rights to develop and commercialize Oradoxel (Oral Docetaxel) in Taiwan, Singapore, and Vietnam to PharmaEssentia.
  - Announced acceptance of an Investigational New Drug (IND) application for Eribulin ORA, Athenex's oral version of Eribulin.
- TCR-T immunotherapy: Announced positive results from pilot studies conducted in China by Xiangxue Life Sciences in end-stage cancer patients who were treated with T-cell receptor affinity enhancing specific T-cell therapy (TAEST), a form of cancer immunotherapy.

Commercial Business:

- Athenex Pharmaceutical Division ("APD") currently markets a total of 28 products with 53 SKUs.
- Athenex Pharma Solutions ("APS") currently markets 6 products in total with 16 SKUs.
- Commercial platform is planning to launch 12 new products in 2019.
- Dunkirk manufacturing facility achieved a significant construction milestone with the steel and concrete work complete and the final beam raised into place.

Financial Results for the Fourth Quarter Ended December 31, 2018

Revenue for the three months ended December 31, 2018 was $21.3 million, as compared to $14.9 million for the three months ended December 31, 2017, an increase of $6.4 million, or 43%. Product sales were $19.0 million and $14.1 million for the three months ended in December 31, 2018 and December 31, 2017, respectively. The increase was primarily attributable to an increase of $3.5 million in API revenue, $3.1 million in 503B revenue, offset by $1.8 million decrease in medical device and CMO revenue. There was a $2.0 million licensing fee revenue in the three months ended December 31, 2018, pursuant to a licensing agreement we entered into with PharmaEssentia, for rights to Oral Docetaxel in certain Asian territories.

Cost of sales for the three months ended December 31, 2018 totaled $14.3 million, as compared to $10.1 million for the three months ended December 31, 2017, an increase of $4.2 million, or 42%. The increase was primarily due to a change in our product mix. As we continue to develop our product portfolio, the gross margin might fluctuate over time.

Research and development expenses for the three months ended December 31, 2018 totaled $20.8 million. Our various clinical programs accounted for the majority of our R&D expenses. The R&D expenses for the three months ended December 31, 2018 were in line with the $20.8 million for the three months ended December 31, 2017.

Selling, general, and administrative expenses for the three months ended December 31, 2018 totaled $11.6 million, as compared to $12.3 million for the three months ended December 31, 2017, a decrease of $0.7 million, or 6%.

Net loss attributable to Athenex for the three months ended December 31, 2018 was $27.1 million, or ($0.41) per diluted share, compared to a net loss of $28.3 million, or ($0.49) per diluted share, in the same period last year.

Financial Results for the Year Ended December 31, 2018:

Revenue for the year ended December 31, 2018 was $89.1 million, as compared to $38.0 million for the year ended December 31, 2017, an increase of $51.1 million, or 134%. The increase was primarily attributable to the $30.0 million license fees related to the collaboration agreement with Almirall. Revenue from product sales also increased from $36.1 million in the year ended December 31, 2017 to $56.4 million in the year ended December 31, 2018. The increase was primarily attributable to an increase in specialty product revenue of $13.2 million, an increase in 503B revenue of $5.1 million, an increase in API revenue of $2.6 million, and an increase in medical device sales of $0.6 million, offset by a decrease in contract manufacturing revenue and other revenue of $1.7 million.

Cost of sales for the year ended December 31, 2018 totaled $47.0 million, as compared to $25.1 million for the year ended December 31, 2017, an increase of $21.9 million, or 87%. The increase in specialty product revenue, 503B revenue, and API revenue increased cost of sales by $15.2 million, $3.7 million, and $3.0 million, respectively.

Research and development expenses for the year ended December 31, 2018 totaled $119.9 million, as compared to $76.8 million for the year ended December 31, 2017, an increase of $43.1 million, or 56%. This increase was primarily due to the advancement of the Company's clinical pipeline and additional drug licensing fees, and included the following: $18.6 million increase of clinical trial costs with the progression of the Phase 3 trials of KX2-391 Ointment and Oraxol; $15.7 million increase in drug licensing fees primarily due to a $29.5 million non-cash license fee related to the purchase of TCR-T technology in connection with the establishment of Axis Therapeutics Limited, of which $24.5 million related to the fair value of the in-process research and development (IPR&D) and $5.0 million was paid for in the Company's common stock. This was offset by a decrease in drug licensing fees paid to Hanmi, Gland and Amphastar; a $5.4 million increase of employee salary and benefits, which was primarily attributable to hiring more research and development personnel to support our expanding research and clinical activities, including the expansion of our clinical R&D team in Taiwan; a $2.8 million increase in general product development of 503B products as they were introduced and production was scaled-up to a commercial level and product development of our proprietary products; and a $0.6 million increase in the cost of preclinical studies as research was performed on an oral formulation of Eribulin.

Selling, general, and administrative expenses for the year ended December 31, 2018 totaled $49.0 million, as compared to $46.1 million for the year ended December 31, 2017, an increase of $2.9 million, or 6%. This was primarily due to an increase in operating activities and professional fees and included the following: a $2.9 million increase in professional fees

including legal fees related to the launch of 503B products and consulting fees related to the manufacturing facility in Dunkirk, NY; and a $2.2 million increase in other office expenses including property and sales taxes, insurance expenses, rent and utilities, and others. These costs were offset by a decrease in employee compensation of $1.6 million from the stock-based compensation incurred in the prior year in connection with the Company's IPO and a decrease in marketing costs of $0.6 million.

Net loss attributable to Athenex for the year ended December 31, 2018 was $117.4 million, or ($1.82) per diluted share, compared to a net loss of $131.2 million, or ($2.63) per diluted share, for the year ended December 31, 2017.

Excluding the non-cash license fee of $24.5 million in connection with the establishment of Axis Therapeutics Limited in July 2018, the net loss attributable to Athenex for the year ended December 31, 2018 was $92.9 million, or ($1.44) per diluted share.

The Company had cash, cash equivalents and short-term investments aggregating $107.4 million at December 31, 2018, compared to $51.0 million at December 31, 2017. Based on the current operating plan, the Company expects that its cash, cash equivalents and short-term investments as of December 31, 2018, together with cash to be generated from operating activities, will enable it to fund its operating expenses and capital expenditure requirements through at least the fourth quarter of 2019.

Outlook and Upcoming Milestones:

Clinical Platforms:

- Complete third cohort of patients for Oraxol with ramucirumab study in gastric cancer.
- Presentation of preclinical data for Oraxol in angiosarcomas at American Association for Cancer Research (AACR) Annual Meeting, April 3, 2019.
- Expect to file INDs for TCR-T candidates and Pegtomarginase by mid-2019.
- Presentations at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting, May 31 - June 4, 2019
- Top line results from Phase 3 trial of Oraxol in metastatic breast cancer, mid-2019

Financial Guidance:

Going forward, the company's revenue guidance will be on product sales only, and will exclude estimates for license and collaborative fees. More importantly, we will continue to provide regular updates on our clinical progress and results, and business development activities, which remain to be the core value drivers of our Company.

We had previously provided guidance for full year 2018 revenue to be in the lower end of the guidance range, inclusive of licensing-fee revenue. In our licensing fee revenue guidance we accounted for an upfront payment of US$14.5 million from Chongqing Jingdong Pharmaceutical. As announced in early March 2019, the agreement with Chongqing Jingdong Pharmaceutical was terminated by mutual consent, leading to our 2018 reported revenue.

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, Monday, March 11, 2018 at 8:30 a.m. 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 13687139.

The live conference call and replay can also be accessed via audio webcast at https://edge.media-server.com/m6/p/adkpa7kq and also on the Investor Relations section of the Company's website, located at www.athenex.com.

A replay of the call will be accessible two hours after its completion through March 18, 2019 by dialing 844-512-2921 (domestic) or 412-317-6671 (international) and entering passcode 13687139.

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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Financial Summary

Selected Condensed Consolidated Statements of Operations

	Three Months Ended December 31,			
	2018	2017	Change	
	(in thousands, except per share data)			%
Revenue				
Product sales	$ 19,009	$ 14,128	$ 4,881	35%
License fees and consulting revenue	2,109	349	1,760	NM
Grant revenue	153	396	(243)	-61%
Total revenue	21,271	14,873	6,398	
Cost of sales	(14,271)	(10,064)	(4,207)	42%
Research and development expenses	(20,828)	(20,848)	20	0%
Selling, general, and administrative expenses	(11,618)	(12,317)	699	-6%
Interest (expense) income	(1,330)	98	(1,428)	NM
Income tax expense	(386)	(137)	(249)	182%
Net loss	(27,162)	(28,395)	1,233	
Less: net loss attributable to non-controlling interests	(49)	(112)	63	-56%
Net loss attributable to Athenex, Inc.	$(27,113)	$(28,283)	$ 1,170	
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.41)	$ (0.49)		

	Year ended December 31,			
	2018	2017	Change	
	(in thousands, except per share data)			%
Revenue				
Product sales	$ 56,394	$ 36,106	$ 20,288	56%
License fees and consulting revenue	32,387	1,105	31,282	NM
Grant revenue	319	832	-513	-62%
Total revenue	89,100	38,043	51,057	
Cost of sales	(47,005)	(25,122)	(21,883)	87%
Research and development expenses	(119,905)	(76,797)	(43,108)	56%
Selling, general, and administrative expenses	(49,008)	(46,112)	(2,896)	6%
Interest expense	(1,793)	(5,912)	4,119	-70%
Unrealized loss on derivative liability	—	(15,411)	15,411	NM
Income tax (benefit) expense	100	85	15	18%
Net loss	(128,711)	(131,396)	2,685	
Less: net loss attributable to non-controlling interests	(11,271)	(226)	(11,045)	NM
Net loss attributable to Athenex, Inc.	$(117,440)	$(131,170)	$ 13,730	
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (1.82)	$ (2.63)		

Selected Condensed Consolidated Balance Sheet

	December 31,	
	2018	2017
	(In thousands)	
Selected Balance sheet data:		
Cash and cash equivalents	$ 49,794	$ 39,284
Short-term investments	57,629	11,753
Goodwill	37,495	37,795
Working capital(1)	119,143	38,615
Total assets	231,095	140,413
Long-term debt	46,764	1,981
Total liabilities	102,326	49,691
Non-controlling interests	(10,586)	685
Total stockholders' equity	$128,769	$ 90,722

(1) Working capital: total current assets - total current liabilities

Selected Condensed Consolidated Statements of Cash

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Selected Cash flow data:			
Net cash used in operating activities	$(109,387)	$(81,512)	$(47,870)
Net cash (used in) provided by investing activities	(48,963)	(10,018)	2,659
Net cash provided by financing activities	169,035	96,896	35,272
Net effect of foreign exchange rate changes	(175)	793	(431)
Net increase (decrease) in cash and cash equivalents	10,510	6,159	(10,370)

Cash and cash equivalents at beginning of period	39,284	33,125	43,495
Cash and cash equivalents at end of period	$ 49,794	$ 39,284	$ 33,125