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): November 9, 2017

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

(Former name or former address, if changed since last report.)

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 November 9, 2017, Athenex, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release titled "Athenex, Inc. Announces Third Quarter 2017 Results" issued by the Company on November 9, 2017.

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: November 9, 2017

/s/ J. Nick Riehle
Name: J. Nick Riehle
Title: Chief Financial Officer

- Encouraging results of 1st interim analysis of the Oraxol Phase III clinical trial for breast cancer
- Commencement of the KX-01 ointment Phase III clinical trials for Actinic Keratosis
- Launched Oxaliplatin Injection, Terbutaline Sulfate Injection, and Ketorolac Tromethamine Injection in the Athenex Pharmaceutical Division, further expanding the APD product portfolio
- Revenue of $14 million for the third quarter 2017, up 149% year-over-year
- Company raises full-year revenue guidance to the range of $33 million - $35 million

BUFFALO, N.Y., November 9, 2017 — 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 third quarter of 2017.

"We are pleased to report a strong third quarter, advancing our lead candidates through Phase III clinical trials in our Orascovery and Src Kinase platforms, as well as delivering healthy revenue through our commercial platform," stated Johnson Lau, Athenex's Chairman and Chief Executive Officer. "During the quarter, we announced the unanimous recommendation from an independent Drug Safety Monitoring Board to continue the Phase III clinical trial for Oraxol, as well as the first patient recruitment for the Phase III clinical trial for KX-01 ointment, a testament to the strength of our novel research platforms and the progress we are making in moving our proprietary drug candidates forward through key clinical trials."

Dr. Lau continued, "These aforementioned achievements underscore the capabilities of our clinical development platforms, which are the primary focuses of Athenex. We are acutely focused on the discovery, development, and commercialization of novel and efficacious treatment of cancer and related conditions. In parallel to our clinical efforts, we believe we are laying an extremely solid foundation of commercial capabilities, as exhibited by strong revenue performance in the third quarter. We continue to view the commercial platform as both an important opportunity to generate revenue to fund our R&D efforts in the clinical platform and vital to the eventual commercialization of those platforms, as we work to make Athenex a leading provider of proprietary oncology treatments. We are excited about the opportunities created for us by our unique business model, and confident that we are favorably positioned to capitalize on these opportunities to create value for our shareholders."

Third Quarter 2017 and Recent Business Highlights:

Clinical Platforms:

- Orascovery:
  - An independent Drug Safety Monitoring Board (DSMB) reviewed the clinical efficacy and safety of 90 patients in the Oraxol Phase III Clinical Trial for breast cancer in a pre-planned 1st interim analysis in September 2017. The DSMB was impressed by the good response rates and very low incidence of neuropathy as compared to IV paclitaxel control. The DSMB unanimously recommended continuation and the rapid patient recruitment for this study.
- Src Kinase Inhibition
  - KX-01 ointment Phase II clinical trial showed excellent efficacy with a dramatic decrease in the frequency of severe local skin reactions compared with published

data of the current standard of topical therapy for actinic keratosis. After consultation with the FDA, two Phase III randomized double-blind controlled clinical trials of KX-01 ointment for Actinic Keratosis are commenced in USA.

Commercial Business:

- Launched Oxaliplatin Injection, Terbutaline Sulfate injection, and Ketorolac Tromethamine Injection
- Athenex Pharmaceutical Division ("APD") currently markets 14 products in the U.S. with 24 SKUs
- Athenex Pharma Solutions ("APS"), our 503(b) outsourced facility, currently markets 5 products with 14 SKUs

Corporate Updates:

- Entered Grant Disbursement Agreement with New York State Urban Development Corporation to receive up to $200 million for construction of Dunkirk Facility.

Third Quarter and Year to Date 2017 Financial Results:

Revenue for the three months ended September 30, 2017 was $14.0 million, an increase of $8.4 million, or 149%, as compared to $5.6 million for the three months ended September 30, 2016. The increase was primarily attributable to our Specialty Platform, which contributed revenue of $7.4 million during the period, due largely to the sales of sodium bicarbonate in response to the U.S. shortage, as well as the launch of 11 specialty products since inception. API sales increased $1.3 million over the prior year period. This was offset by a $0.3 million decrease in contract manufacturing revenue.

Revenue for the nine months ended September 30, 2017 was $23.2 million, an increase of $7.7 million, or 50%, as compared to $15.4 million for the nine months ended September 30, 2016. The increase was primarily attributable to the launch of 11 specialty drugs since March 2017, which together contributed $9.3 million of the revenue increase in the current year. Revenue from proprietary products, primarily licensing fees from such products, increased $0.7 million over the prior year period. These were offset by the decreases of $1.4 million in API sales, $0.4 million in medical devices sales, $0.3 million in contract manufacturing revenue and $0.2 million in grant revenue.

Cash, cash equivalents and short-term investments were $69.0 million as of September 30, 2017, compared to $85.3 million as of June 30, 2017 and $41.8 million as of December 31, 2016.

Cash used in operations for the nine months ended September 30, 2017 was $63.6 million, compared to $35.2 million for the same period in 2016. The increase was primarily due to the payment of certain license fees related to the launch of our specialty drug business, as well as higher operating expenses as described below. Capital expenditures for the nine months ended September 30, 2017 were $4.4 million, compared to $1.1 million for the same period in 2016, with the increase primarily attributable to manufacturing projects, including those associated with the launch of our 503(b) business.

Research and development (R&D) expenses for the three months ended September 30, 2017 were $11.9 million, compared to $18.1 million in the same period in 2016. The decrease in R&D expenses reflects the decreased spending on drug licensing for our specialty products in the most recent quarter, a shift in focus for the specialty pharma team as they have begun marketing their products and reduced spending for preclinical studies, offset by modest increases for our clinical studies and for spending on 503(b) and API products.

R&D expenses for the nine months ended September 30, 2017 were $55.9 million, compared to $33.4 million in the same period in 2016, primarily due to the increased costs of drug licensing with Hanmi, Gland and Amphastar and the costs related to the advancement of our clinical pipeline. The increase was somewhat offset to an extent by a decrease in employee compensation of $3.5 million as the specialty pharma team has shifted their focus from product development to marketing and a $2.1 million decrease in preclinical study costs as our proprietary drugs entered clinical stages.

Selling, General, and Administrative expenses for the three months ended September 30, 2017 were $10.4 million compared to $6.8 million in the same period in 2016. The increase in SG&A expenses was primarily attributable to the expansion of our sales and marketing force and the shift in focus of certain specialty pharma personnel from product development to marketing, in addition to professional fees and other expenses related to public company administration.

SG&A expenses for the nine months ended September 30, 2017 increased to $33.8 million compared to $15.7 million in the same period in 2016, primarily due to an increase in employee compensation, office expenses, and selling and marketing expenses associated with the buildup of the Commercial Platform, as well as stock grants made at the time of the IPO and increases in professional fees and other expenses related to public company administration.

Outlook and Upcoming Milestones:

Clinical Platforms:

- Paclitaxel is one of the most commonly used and effective anti-cancer drugs worldwide. Neuropathy is a severe dose limiting side-effect of IV paclitaxel. If the superior clinical efficacy and the very low rate of neuropathy of Oraxol versus IV paclitaxel can be confirmed in this randomized controlled Phase III clinical trial, it may represent a breakthrough treatment for therapy of cancer. The pre-scheduled 2nd interim analysis of this Oraxol Phase III clinical trial at 180 patients is expected to be in 2018.
- Actinic keratosis is a common skin condition affecting more than 50 million people in the United States. The Phase II clinical trial for KX-01 ointment showed excellent activity and a dramatic decrease in the frequency of severe local skin reactions compared with published data of the current standard of topical therapy for actinic keratosis. If the Phase III clinical trials of KX-01 ointment for Actinic Keratosis confirm the Phase II results, KX-01 ointment has the potential to change the paradigm of topical therapy for actinic keratosis.
- Data release for the positive results of KX-01 Phase II clinical trial in actinic keratosis is expected in 4Q 2017.
- Completion of patient recruitment for the two KX-01 Phase III clinical trials totaling 600 patients is expected to be in eight months.

Commercial Business:

- Increased expectations for full-year revenue in the range of $33 million to $35 million, inclusive of opportunity created by the U.S. Sodium Bicarbonate Shortage; and
- Anticipate the launch of four additional products in Athenex Pharmaceutical Division and two products in Athenex Pharma Solutions in 4Q’17.

Corporate Updates:

- Groundbreaking on Dunkirk facility expected in 1H’18.

Conference Call and Webcast Information:

The Company will host a conference call and audio webcast on Thursday, November 9, 2017 at 9:00 a.m. Eastern Time. To participate in the call, dial (855) 227-0567 (domestic) or (612) 979-9912 (international) fifteen minutes before the conference call begins and reference the conference passcode 4869599. A replay will be available approximately one hour after the recording through Thursday, November 16, 2017 and can be accessed by dialing (855) 859-2056. The live conference call and replay can also be accessed via audio webcast at the Investor Relations section of the Company's website, located at www.athenex.com. An archive will be available at this website until December 9, 2017.

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. Athenex's Oncology Innovation Platform generates clinical candidates through an extensive understanding of kinases, including novel binding sites and human absorption biology, as well as through the application of Athenex's proprietary research and selection processes in the lab. The Company's current clinical pipeline is derived from two different platform technologies Athenex calls Orascovery and Src Kinase Inhibition. The Orascovery platform is based on the novel oral P-glycoprotein pump inhibitor molecule HM30181A, through which Athenex is able to facilitate oral absorption of traditional cytotoxics, which Athene believes may offer improved patient tolerability and efficacy as compared to IV administration of the same cytotoxics. The Orascovery platform was developed by Hanmi Pharmaceuticals and licensed exclusively to Athenex for all major worldwide territories except Korea, which is retained by Hanmi. The Src Kinase Inhibition platform refers to novel small molecule compounds that have multiple mechanisms of action, including the inhibition of the activity of Src Kinase and the inhibition of tubulin polymerization during cell division. Athenex believes the combination of these mechanisms of action provides a broader range of anti-cancer activity as compared to either mechanism of action alone. 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.

Forward-Looking Statement Disclaimer/Safe Harbor Statement

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. 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 need to raise additional capital; 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. We assume no obligation and do not intend to update these forward-looking statements, except as required by law.

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	Three Months Ended September 30,			
	2017	2016	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 13,994	$ 5,616	$ 8,378	149%
Cost of product sales	(8,082)	(5,416)	$ (2,666)	49%
Research and development expenses	(11,944)	(18,052)	$ 6,108	-34%
Selling, general, and administrative expenses	(10,364)	(6,790)	$ (3,574)	53%
Interest expense	(353)	(5)	$ (348)	NM
Unrealized loss on derivative liability	(6,548)	—	$ (6,548)	NM
Income tax (expense) benefit	(11)	(9)	$ (2)	22%
Net loss	(23,308)	(24,656)	1,348	
Less: net loss attributable to non-controlling interests	(34)	(34)	—	0%
Net loss attributable to Athenex, Inc.	$ (23,274)	$ (24,622)	$ 1,348	

	Nine Months Ended September 30,			
	2017	2016	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 23,170	$ 15,438	$ 7,732	50%
Cost of product sales	(15,058)	(14,392)	$ (666)	5%
Research and development expenses	(55,949)	(33,443)	$ (22,506)	67%
Selling, general, and administrative expenses	(33,795)	(15,694)	$ (18,101)	115%
Interest expense	(6,010)	(8)	$ (6,002)	NM
Unrealized loss on derivative liability	(15,411)	—	$ (15,411)	NM
Income tax benefit	52	294	$ (242)	-82%
Net loss	(103,001)	(47,805)	(55,196)	
Less: net loss attributable to non-controlling interests	(114)	(144)	30	-21%
Net loss attributable to Athenex, Inc.	$ (102,887)	$ (47,661)	$ (55,226)	

	September 30, 2017	December 31, 2016
	(in thousands)	
Balance sheet data:		
Cash, cash equivalents and shot-term investments	$ 69,043	$ 41,753
Goodwill	37,691	37,552
Working capital *	63,176	23,904
Total assets	148,758	105,890
Long-term debt	1,800	41,807
Total liabilities	33,858	71,221
Non-controlling interests	797	862
Total stockholders' equity	$ 114,900	$ 34,669

* Working capital: total current assets - total current liabilities

	Nine Months Ended September 30,	
	2017	2016
	(in thousands)	
Cash Flow Summary:		
Net cash (used in) operating activities	$ (63,644)	$ (35,166)
Net cash (used in) investing activities	(47,022)	(2,244)
Net cash provided by financing activities	96,093	37,623
Net effect of foreign exchange rate changes	710	(177)
Net increase (decrease) in cash and cash equivalents	$ (13,863)	$ 36