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 14, 2018

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 November 14, 2018, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended September 30, 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 November 14, 2018

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 14, 2018

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

Exhibit 99.1

Athenex, Inc. Announces Third Quarter 2018 Financial Results and Provides Corporate Update

Third quarter revenue increased to $18.4 million compared to $14.0 million in 3Q 2017

Positive recommendation by DSMB upon second interim analysis for Oraxol Phase III program

KX2-391 Phase III pivotal studies achieved primary endpoints

Oratecan and Oradoxel are ready to advance to Phase II

Conference call and live audio webcast at 8:00 a.m. Eastern Time today

BUFFALO, N.Y., November 14, 2018 — 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 three- and nine-months ended September 30, 2018.

"We achieved continued positive momentum at Athenex in the third quarter in our strategy to build a global biopharmaceutical business and to create more effective, safer and tolerable treatments for cancer patients," stated Dr. Johnson Lau, Chief Executive Officer of Athenex. "Our Phase III Oraxol program reached an important milestone with the second positive DSMB review in September and we remain on track to complete enrollment and report data from this study in 2019. We also continue to make progress with other drug candidates in our Orascovery platform, with Oratecan and Oradoxel ready to advance to Phase II studies. The addition of the cellular immunotherapy and biologic platforms have expanded our oncology-focused product pipeline. For KX2-391, the most advanced candidate in our Src kinase program, we are working with our partner Almirall on developing a commercial plan for this product."

Third Quarter 2018 and Recent Business Highlights:

Clinical Platforms:

- Announced that the Data and Safety Monitoring Board (DSMB) overseeing the Company's ongoing randomized, controlled Phase III trial of Oraxol in metastatic breast cancer recommended unanimously that the study continue as planned. The DSMB also congratulated the Company on the rapid patient recruitment and promising results achieved.
- Presented updated encouraging efficacy and safety data of Oraxol in the treatment of metastatic breast cancer patients who had failed previous chemotherapies in a pharmacokinetics (PK) and Phase II study conducted in Taiwan at the European Society for Medical Oncology (ESMO) Congress in Munich, Germany.
- Announced acceptance of an Investigational New Drug (IND) application for Eribulin ORA, Athenex's oral version of Eribulin. Initiation of clinical trials is currently planned for the first half of 2019. This is the eighth US IND allowance that Athenex has obtained.
- Identified suitable dosing regimens of Oratecan and Oradoxel for advancement into Phase II studies, based on recent PK data.
- 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. Axis Therapeutics Limited, a joint venture between Athenex and Xiangxue Life Sciences established in September 2018, owns the worldwide (excluding China) rights to research, develop and commercialize T-cell receptor-engineered T cells (TCR-T), including TAEST technology.

- Announced positive data from two Phase III pivotal efficacy studies of KX2-391 in the treatment of actinic keratosis (AK).

Commercial Business

- Developed detailed launch plans for Oraxol and KX2-391.
- Athenex Pharmaceutical Division ("APD") currently markets a total of 25 products with 48 SKUs and is planning to launch 2 new products before year end with 4 additional new SKUs.
- Athenex Pharma Solutions ("APS") currently markets 6 products in total with 16 SKUs.

Corporate and Strategic Highlights:

- Promoted Mr. Randoll Sze to Chief Financial Officer.
- Announced a strategic realignment of joint projects between Athenex and its collaborative partner, Hanmi Pharmaceutical.

Third Quarter 2018 Financial Results:

Revenue for the three months ended September 30, 2018 was $18.4 million, an increase of $4.4 million, or 32%, as compared to $14.0 million for the three months ended September 30, 2017. The increase was primarily attributable to an increase in licensing revenue of $5.0 million, a $1.0 million increase in sales of the Company's 503B products, and a $0.8 million increase in medical device sales. This was offset by decreases in API sales of $1.7 million, contract manufacturing revenue of $0.2 million, grant revenue of $0.2 million, and other product sales of $0.2 million.

Cost of sales for the three months ended September 30, 2018 totaled $12.0 million, an increase of $3.9 million, or 48%, as compared to $8.1 million for the three months ended September 30, 2017. This was primarily due to the increase of $1.9 million cost of sales from the recently launched specialty products and $2.0 million cost of sales from 503B and API products. The increase in gross profit was primarily due to the licensing revenue in the current year.

Research and development expenses for the three months ended September 30, 2018 totaled $51.2 million, an increase of $39.3 million, or 329%, as compared to $11.9 million for the three months ended September 30, 2017. This was primarily due to an increase in licensing fees and clinical expenses. In particular, there was a $29.5 million non-cash license fee related to the purchase of TCR-T in connection with the establishment of Axis Therapeutics, of which $24.5 million related to the fair value of the IPR&D and $5.0 million related to the Company's common stock issued to Xiangxue Life Sciences.

SG&A expenses for the three months ended September 30, 2018 totaled $11.5 million, an increase of $1.1 million, or 11%, as compared to $10.4 million for the three months ended September 30, 2017. This was primarily due to an increase in professional fees of $0.9 million from legal fees incurred in conjunction with the launch of 503B products and an increase in employee compensation of $0.5 million, offset by a decrease of $0.3 million in selling and marketing expenses related to the launch of specialty products.

Net loss attributable to Athenex for the third quarter ended September 30, 2018 was $46.2 million, or ($0.70) per diluted share, compared to a net loss of $23.3 million, or ($0.41) per diluted share, in the same period last year. Excluding the non-cash license fee of $24.5 million, the net loss attributable to Athenex for the third quarter ended September 30, 2018 was $21.6 million.

In July 2018, Athenex closed a privately placed debt and equity financing deal with Perceptive Advisors, LLC for gross proceeds of $100.0 million and aggregate net proceeds of $97.1 million, net of fees and offering expenses. The Company entered into a 5-year senior secured loan for $50.0 million of this financing and issued 2,679,528 shares of its common stock at a purchase price of $18.66 per share for the remaining $50.0 million.

Cash, cash equivalents and short-term investments were $141.4 million at September 30, 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 September 30, 2018, together with cash to be generated from operating activities, will enable it to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2019.

Nine Months Ended September 30, 2018 Financial Results

Revenue for the nine months ended September 30, 2018 was $67.8 million, an increase of $44.7 million, or 193%, as compared to $23.2 million for the nine months ended September 30, 2017. The increase was primarily attributable to $30.0 million in upfront license fees, a $13.7 million increase in specialty products sold through the Company's Commercial Platform, a $2.0 million increase in sales of 503B products, and a $0.4 million increase in API and medical device sales.

Cost of sales for the nine months ended September 30, 2018 totaled $32.7 million, an increase of $17.6 million, or 117%, as compared to $15.1 million for the nine months ended September 30, 2017. This was primarily due to the increase of $13.2 million cost of sales from the specialty products and $4.4 million cost of sales from 503B and API products.

Research and development expenses for the nine months ended September 30, 2018 totaled $99.1 million, an increase of $43.1 million, or 77%, as compared to $55.9 million for the nine months ended September 30, 2017. This was primarily due to an increase in licensing fees and clinical expenses. In particular, there was a $29.5 million non-cash license fee related to the purchase of TCR-T in connection with the establishment of Axis Therapeutics, of which $24.5 million related to the fair value of the IPR&D and $5.0 million related to the Company's common stock issued to Xiangxue Life Sciences.

SG&A expenses for the nine months ended September 30, 2018 totaled $37.4 million, an increase of $3.6 million, or 11%, as compared to $33.8 million for the nine months ended September 30, 2017. This was primarily due to an increase in costs related to operating as a public company.

Net loss attributable to Athenex for the nine months ended September 30, 2018 was $90.3 million, or ($1.42) per diluted share, compared to a net loss of $102.9 million, or ($2.18) per diluted share, for the nine months ended September 30, 2017. Excluding the non-cash license fee of $24.5 million, the net loss attributable to Athenex for the nine months ended September 30, 2018 was $65.8 million.

Outlook and Upcoming Milestones:

Due to the timing of a collaborative payment from a partner, the Company currently expects its full year 2018 revenue to be in the lower end of the guidance range of $100 million to $125 million, inclusive of licensing-fee revenue. The operational business is on track and the Company expects to receive the collaborative payment in the first half of 2019.

Clinical Platforms:

- 12 month follow-up data from KX2-391 Phase III studies for the treatment of AK are expected in the second quarter of 2019.
- Oraxol Phase III clinical trial in metastatic breast cancer is expected to complete target enrollment by the end of 2018, with top line data expected in mid-2019.
- Oratecan and Oradoxel Phase II studies are expected to initiate in the first half of 2019.
- Expect to file INDs for TCR-T candidates and Pegtomarginase by mid-2019.

Corporate Updates:

- The Company will be hosting a Research and Development Day for the investment community on December 17, 2018 to provide an update on its major clinical programs.
- The exterior of the Dunkirk facility is expected to be completed by the first half of 2019. The facility is expected to be completed by the end of 2019 and operational in mid-2020.
- Construction of the Chongqing API plant is expected to be completed by the end of 2018, with completion of the facility expected by mid-2019.
- Construction of the Chongqing dosage plant is expected to break ground in the first half of 2019.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Wednesday, November 14, 2018 at 8:00 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 13683946.

To join the webcast, click on https://edge.media-server.com/m6/p/i58pm3en.

A replay of the call will be accessible two hours after its completion through November 21 by dialing 844-512-2921 (in the U.S.) or 412-317-6671 (outside the U.S.) and entering passcode 13683946. The live conference call and replay can also be accessed via audio webcast on the Investor Relations section of the Company's website, located at www.athenex.com.

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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ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	September 30, 2018	December 31, 2017
Balance sheet data:	(In thousands)	
Cash and cash equivalents	$ 51,108	$ 39,284
Short-term investments	90,309	11,753
Goodwill	37,501	37,795
Working capital*	145,606	38,615
Total assets	244,467	140,413
Long-term debt	46,527	1,981
Total liabilities	92,410	49,691
Non-controlling interests	(10,537)	685
Total stockholders' equity	$ 152,057	$ 90,722

*Working capital: total current assets — total current liabilities

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30			
	2018	2017	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 18,428	$ 13,994	$ 4,434	32%
Cost of product sales	(11,965)	(8,082)	(3,883)	48%
Research and development expenses	(51,204)	(11,944)	(39,260)	329%
Selling, general, and administrative expenses	(11,493)	(10,364)	(1,129)	11%
Interest expense	(1,058)	(353)	(705)	200%
Unrealized loss on derivative liability	—	(6,548)	6,548	-100%
Income tax benefit (expense)	30	(11)	41	NM
Net loss	(57,262)	(23,308)	(33,954)	146%
Less: net loss attributable to non-controlling interests	(11,091)	(34)	(11,057)	NM
Net loss attributable to Athenex, Inc.	$ (46,171)	$ (23,274)	$ (22,897)	

	Nine Months Ended September 30			
	2018	2017	Change	
	(in thousands)	(in thousands)	(in thousands)	%
Revenue	$ 67,829	$ 23,170	$ 44,659	193%
Cost of product sales	(32,734)	(15,058)	(17,676)	117%
Research and development expenses	(99,077)	(55,949)	(43,128)	77%
Selling, general, and administrative expenses	(37,390)	(33,795)	(3,595)	11%
Interest expense	(463)	(6,010)	5,547	-92%
Unrealized loss on derivative liability	—	(15,411)	15,411	100%
Income tax benefit	286	52	234	450%
Net loss	(101,549)	(103,001)	1,452	-1%
Less: net loss attributable to non-controlling interests	(11,222)	(114)	(11,108)	NM
Net loss attributable to Athenex, Inc.	$ (90,327)	$ (102,887)	$ 12,560	