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 7, 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))

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 2.02 Results of Operations and Financial Condition.

On November 7, 2019, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended September 30, 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 November 7, 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: November 7, 2019

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

Exhibit 99.1

Athenex, Inc. Announces Third Quarter 2019 Financial Results

Oral presentation of Phase III Oral Paclitaxel data at the San Antonio Breast Cancer Symposium

NDA submissions for Oral Paclitaxel and tirbanibulin ointment are on track

$19.2 million of product sales in Q3 2019, a 45% year-over-year increase

Raising full year 2019 guidance to 35% to 40% year-over-year growth

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

BUFFALO, N.Y., November 7, 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 third quarter of 2019.

"We continue to make strong progress across the board, bringing us closer to our goal of becoming a fully integrated global pharma company," stated Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex. "We have several major catalysts upcoming, including two anticipated NDA submissions. We are also scheduled to deliver an oral presentation to discuss the Phase III data for Oral Paclitaxel in metastatic breast cancer at the San Antonio Breast Cancer Symposium in December. We have been strategic in building out and integrating our clinical and manufacturing operations in order to maximize the commercial opportunities of our rapidly advancing pipeline. We believe we are in a strong position to develop multiple, potentially successful therapies in the future."

Mr. Jeffrey Yordon, Chief Operating Officer of Athenex, commented, "We are continually optimizing our commercial infrastructure, developing the market, and building awareness of our Athenex Oncology brand in anticipation of commercial launch of Oral Paclitaxel. We have finalized our staffing and organizational plan, and intend to make additional key hires next year, including medical science liaisons and regional sales leaders, with the full sales team expected to come on board in the months leading up to potential approval. In addition to late-stage pipeline progress, we once again achieved strong revenue growth for our existing commercial business. We plan to continue launching additional products in the remainder of 2019 and into next year."

Third Quarter 2019 and Recent Business Highlights:

Clinical Programs:

Phase III Study of Oral Paclitaxel and Encequidar for Metastatic Breast Cancer

- Study met primary endpoint showing statistically significant improvement in overall response rate for oral paclitaxel and encequidar ("Oral Paclitaxel") compared to IV paclitaxel.
- Strong trend in progression-free survival (PFS) and overall survival (OS) of Oral Paclitaxel compared to IV paclitaxel.
- Proportion of confirmed responders with duration of response >150 days was 2.5 times higher for Oral Paclitaxel than IV paclitaxel.
- Neuropathy was less frequent with Oral Paclitaxel compared to IV paclitaxel.
- Planning to meet with the FDA and present data at SABCS.

Other Oral Paclitaxel Developments

- European Commission granted orphan designations for paclitaxel and for encequidar for the treatment of soft tissue sarcoma.

- Presented three posters at European Society for Medical Oncology Congress 2019 demonstrating the results from clinical studies of Oral Paclitaxel for patients with a number of advanced solid tumor types as well as in combination with ramucirumab, an anti-VEGFR2 antibody therapy.

Tirbanibulin Ointment for Actinic Keratosis (AK)

- Partner Almirall announced a progress update on the program, including AK recurrence rates in those patients who had complete clearance at the primary evaluation endpoint on day 57 and who were followed quarterly in the 12-month extension period.
- Athenex completed pre-NDA consultation with the FDA.
- Partner Almirall reiterated its expectations for launch of tirbanibulin ointment in the US and Europe in Q1 2021 and Q2 2021, respectively.

Phase I Clinical Study of KX2-361 Oral

- Partner Xiangxue Pharmaceutical initiated a Phase I study in China. KX2-361 is the second compound derived from Athenex's Src kinase inhibition platform, for the treatment of glioblastoma multiforme.

Corporate Announcements:

- Appointed Daniel Lang, MD, as President of Axis Therapeutics Limited (Axis) and Senior Director of Corporate Development at Athenex.
- Completed construction of new API (active pharmaceutical ingredients) facility in Chongqing, China.
  - The 440,000-square-foot facility is expected to commence operations in the first half of 2020.
  - The construction of the facility is part of Athenex's strategy for vertical integration to capture value across the supply chain.

Commercial Business:

- Athenex Pharmaceutical Division (APD) currently markets a total of 31 products with 59 SKUs.
- Athenex Pharma Solutions (APS) currently markets 5 products with 13 SKUs.
- Goal is to launch 3-5 products in the remainder of 2019.

Financial Results for the Quarter Ended September 30, 2019

Product sales for the three months ended September 30, 2019 were $19.2 million, compared with $13.3 million for the three months ended September 30, 2018, an increase of $5.9 million or 45%. This increase was primarily attributable to an increase in specialty product revenue and 503B revenue of $4.7 million and $2.5 million, respectively. The licensing fees and consulting revenue recorded in the three months ended September 30, 2018 primarily related to our tirbanibulin license agreement with Almirall.

Cost of sales for the three months ended September 30, 2019 totaled $17.1 million, an increase of $5.1 million, or 43%, as compared to $12.0 million for the three months ended September 30, 2018. The increase in cost of sales was in line with the increase in product sales.

Research and development expenses for the three months ended September 30, 2019 were $19.6 million as compared to $51.2 million for the three months ended September 30, 2018. This was primarily due to a decrease in licensing fees, product development, clinical operations, and R&D related compensation. The licensing fee decrease mainly resulted from a $29.5 million non-cash license fee related to the license of TCR-T technology in connection with the establishment of Axis, recorded in the third quarter of 2018 and which did not recur. The decrease in R&D expenses was offset primarily by an increase in preclinical development costs related to the Arginine Deprivation Therapy and TCR-T Immunotherapy platforms.

Selling, general and administrative expenses for the three months ended September 30, 2019 totaled $16.3 million, compared to $11.5 million for the three months ended September 30, 2018. This was primarily due to an increase in costs of preparing to commercialize our proprietary drugs, if approved, and an increase in general administrative expenses including legal fees and other professional service fees. Administrative-related compensation expense remained consistent with the prior year.

Net loss attributable to Athenex for the three months ended September 30, 2019 was $34.8 million, or ($0.45) per diluted share, compared to a net loss of $46.2 million, or ($0.70) per diluted share, in the same period last year.

The Company received a $20 million milestone payment from Almirall during the second quarter of 2019 in connection with the partnership on tirbanibulin and expects this payment to be recorded as revenue in the fourth quarter of 2019.

At September 30, 2019, the Company had cash, cash equivalents, restricted cash and short-term investments of $129.2 million, compared to $107.4 million at December 31, 2018. Based on the current operating plan, we expect that our cash, cash equivalents, and restricted cash as of September 30, 2019, together with cash to be generated from our operating activities, will enable us to fund our operations into the third quarter of 2020.

Financial Results for the Nine Months Ended September 30, 2019

Product sales increased to $66.4 million for the nine months ended September 30, 2019, from $37.4 million for the nine months ended September 30, 2018.

Total revenue for the nine months ended September 30, 2019 decreased by $1.0 million, to $66.9 million, as compared to $67.8 million for the nine months ended September 30, 2018. The decrease was primarily due to $30.0 million related to license milestone revenue earned during 2018, and $2.3 million decrease in medical device product sales and contract manufacturing revenue, offset by a $15.2 million increase in specialty product sales, a $13.4 million increase in 503B sales, and a $2.7 million increase in sales of API. Revenue from 503B and API sales is expected to decline for the remainder of the year as we ceased sales of vasopressin in August 2019 and suspended production of API in the second quarter of 2019.

Cost of sales for the nine months ended September 30, 2019 totaled $53.9 million, an increase of $21.2 million, or 65%, as compared to $32.7 million for the nine months ended September 30, 2018. This was primarily due to the increase of $16.9 million in cost of sales from the sale of specialty products and $4.3 million in cost of sales from 503B and API products. The increase in cost of sales was lower than that in product sales, primarily as a result of changes in our product portfolio.

Research and development expenses for the nine months ended September 30, 2019 totaled $62.6 million, as compared to $99.1 million for the nine months ended September 30, 2018. This was primarily due to a decrease in licensing fees, as well as expenses in relation to clinical operations and product development, partially offset by an increase in preclinical development costs related to the Arginine Deprivation Therapy and TCR-T Immunotherapy platforms, and an increase of R&D related compensation expense.

Selling, general and administrative expenses for the nine months ended September 30, 2019 totaled $48.6 million, as compared to $37.4 million for the nine months ended September 30, 2018. This was primarily due to an increase related to the costs of preparing to commercialize our proprietary drugs, if approved, and an increase in general administrative expenses including legal fees and other professional service fees, partially offset by a decrease of in administrative related compensation expense.

Net loss attributable to Athenex for the nine months ended September 30, 2019 was $102.0 million, or ($1.41) per diluted share, compared to a net loss of $90.3 million, or ($1.42) per diluted share, in the same period last year.

Outlook and Upcoming Milestones:

- Oral presentation of Phase III results for Oral Paclitaxel at the San Antonio Breast Cancer Symposium (December 13, 2019)
- Expect to submit an NDA for tirbanibulin ointment in actinic keratosis (Q1 2020)
- Expect to submit an NDA for Oral Paclitaxel in metastatic breast cancer (Q1 2020)

Raising Financial Guidance:

Athenex provides revenue guidance for product sales only. The Company is raising its product sales guidance for the full year 2019 to an increase of 35% to 40% year-over-year from $56.4 million in 2018, versus prior guidance of 30% to 35% year-over-year. This new revenue guidance has taken into account our discontinuation of vasopressin sales and the suspension of operations at our Taihao API plant. The revenue guidance excludes license and collaboration fees.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Thursday, November 7, 2019, at 8:00am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial877-407-0784 (domestic) or 201-689-8560 (international) fifteen minutes before the conference call begins and reference the conference passcode 13694941. The live conference call and replay can also be accessed via audio webcast here and on the Investor Relations section of the Company's website, located at http://ir.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, 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; multiple locations in Chongqing, China; Manchester, UK; Guatemala City, Guatemala and Buenos Aires, Argentina. 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," "goal," "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; our ability to integrate CIDAL's assets into our existing operations; competition; intellectual property risks; risks relating to doing business in China; the uncertainty of when, if at all, we will be able to resume producing API in our Chongqing plant; 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, 2019	December 31, 2018
Balance sheet data:	**(in thousands)**	
Cash, cash equivalents, and restricted cash	$ 86,905	$ 49,794
Short-term investments	42,273	57,629
Goodwill	37,293	37,495
Working capital *	123,573	119,143
Total assets	287,595	231,095
Long-term debt	53,639	46,764
Total liabilities	152,769	102,326
Non-controlling interests	(11,686)	(10,586)
Total stockholders' equity	$ 134,826	$ 128,769

* Working capital: total current assets—total current liabilities

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)	(in thousands)	(in thousands)	(in thousands)
Revenue				
Product sales, net	$ 19,237	$ 13,309	$ 66,433	$ 37,385
License fees and consulting revenue	115	5,096	325	30,278
Grant revenue	12	23	110	166
Total revenue	19,364	18,428	66,868	67,829
Cost of sales	(17,071)	(11,965)	(53,915)	(32,734)
Research and development expenses	(19,588)	(51,202)	(62,570)	(99,077)
Selling, general, and administrative expenses	(16,283)	(11,493)	(48,640)	(37,390)
Interest income	650	654	1,408	1,314
Interest expense	(1,745)	(1,712)	(5,254)	(1,777)
Income tax (expense) benefit	(114)	30	(1,019)	286
Net loss	(34,787)	(57,260)	(103,122)	(101,549)
Less: net loss attributable tonon-controlling interests	(29)	(11,090)	(1,100)	(11,222)
Net loss attributable to Athenex, Inc.	$ (34,758)	$ (46,170)	$ (102,022)	$ (90,327)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.45)	$ (0.70)	$ (1.41)	$ (1.42)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	77,297,555	66,399,091	72,552,248	63,806,787

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (74,120)	$ (75,315)
Net cash provided by (used in) investing activities	2,588	(81,125)
Net cash provided by financing activities	108,051	168,364
Net effect of foreign exchange rate changes	592	(100)
Net increase in cash and cash equivalents	37,111	11,824
Cash, cash equivalents, and restricted cash at beginning of period	49,794	39,284
Cash, cash equivalents, and restricted cash at end of period	$ 86,905	$ 51,108