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): February 27, 2020

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

Not Applicable
(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))

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 February 27, 2020, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter and year ended December 31, 2019. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished pursuant to 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, as amended (the "Exchange Act") or otherwise subject to the liabilities under such section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on February 27, 2020

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: February 27, 2020

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Reports Fourth Quarter and Year Ended December 31, 2019 Financial Results and Provides Corporate Update

- *Tirbanibulin ointment NDA for actinic keratosis was submitted*
- *Oral Paclitaxel NDA submission is on track; Final FDA meeting scheduled for early April*
- *Presentation of Oral Paclitaxel Phase 3 results at SABCS received broad positive reception*
- *43% y/y increase in product revenue and 14% y/y increase in total revenue for 2019*
- *Conference call & webcast today at 8:00am Eastern Time*

BUFFALO, N.Y., February 27, 2020 — 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 ended December 31, 2019.

“Following a very successful and productive 2019, our team’s immediate focus is to execute on regulatory approval of our two most advanced candidates, Oral Paclitaxel and tirbanibulin ointment. Both of these products have the potential to change the standard of care in their respective markets,” stated Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex. “We have been making the necessary investments in our manufacturing and commercial infrastructure to ensure a successful launch for Oral Paclitaxel upon approval. Our goal is to establish Oral Paclitaxel as the treatment of choice for patients receiving chemotherapy for metastatic breast cancer.”

Fourth Quarter 2019 and Recent Business Highlights:

Clinical Programs:

Tirbanibulin ointment for actinic keratosis (AK)

- A New Drug Application (NDA) was submitted to the FDA.

Oral Paclitaxel for metastatic breast cancer

- Results presented at 2019 San Antonio Breast Cancer Symposium (SABCS) showed that Oral Paclitaxel had superior response and overall survival benefit compared to IV paclitaxel in the treatment of metastatic breast cancer.
- Incidence and severity of neuropathy were less frequent with Oral Paclitaxel compared to IV paclitaxel.
- Oral Paclitaxel abstract accepted for Press Program at SABCS.
- Final FDA meeting has been scheduled for early April and the Company plans to submit an NDA in the US shortly thereafter.

Corporate Announcements:

- Expanded strategic partnership with Guangzhou Xiangxue Pharmaceutical through a licensing agreement for Oral Paclitaxel, Oral Irinotecan, and tirbanibulin ointment, in China, Hong Kong and Macao. Athenex is entitled to receive aggregate payments of up to $200 million, including an initial license payment of $30 million, and double-digit tiered royalties on commercial sales.
- In December 2019, closed a private placement equity offering of 3.95 million shares of common stock at a price of $15.30 per share. Net proceeds from the offering were approximately $59.4 million.

Commercial Business:

- Athenex Pharmaceutical Division (APD) currently markets a total of 30 products with 59 SKUs.
- Athenex Pharma Solutions (APS) currently markets 5 products with 16 SKUs.
- Goal is to launch 7 products in 2020, including a major 503B product.

Financial Results for the Quarter Ended December 31, 2019

Product sales for the three months ended December 31, 2019 were $14.1 million, compared with $19.0 million for the three months ended December 31, 2018, a decrease of $4.9 million or 26%. This decrease was primarily attributable to lower sales of vasopressin and Chongqing API. License and other revenue recorded in the three months ended December 31, 2019 was $20.3 million, compared to $2.3 million in the same period in 2018. The increase was primarily due to a $20.0 million milestone achieved during the three-months ended December 31, 2019 in connection with the Almirall license agreement.

Cost of sales for the three months ended December 31, 2019 totaled $15.7 million, an increase of $1.4 million, or 10%, as compared to $14.3 million for the three months ended December 31, 2018. The increase in cost of sales was primarily due to an increase in the cost of specialty product sales of $4.6 million, offset by a decrease in the cost of 503B and API sales of $3.2 million. The increase in cost of specialty product sales was in line with the increase in specialty product revenue, while the cost of 503B and API sales decreased at a slower rate than the respective sales due to continued fixed costs despite decreased production. Changes in availability of products and market demand could increase or decrease our revenue and gross profit in the future.

Research and development expenses for the three months ended December 31, 2019 were $21.8 million as compared to $20.8 million for the three months ended December 31, 2018. This was primarily due to an increase in clinical and preclinical costs related to encequidar, tirbanibulin ointment, and TCR-T development, offset by a decrease in product development costs related to the scale up of 503B operations, API research and development, and the launch of certain specialty products in 2018.

Selling, general and administrative expenses for the three months ended December 31, 2019 totaled $18.1 million, as compared to $11.6 million for the three months ended December 31, 2018, an increase of $6.5 million, or 56%. This was primarily due to an increase of $6.3 million related to the costs of preparing to commercialize our proprietary drugs, together with a small increase in general administrative expenses including professional fees, rent, utilities, insurance, and office expenses.

Net loss attributable to Athenex for the three months ended December 31, 2019 was $21.7 million, or ($0.28) per diluted share, compared to a net loss of $27.1 million, or ($0.41) per diluted share, in the same period last year.

At December 31, 2019, the Company had cash, cash equivalents and short-term investments of $160.8 million, which included $7.8 million funded by New York State for the construction of the Dunkirk facility for which the company has recorded a corresponding liability, compared to $107.4 million of cash, cash equivalents and short-term investments at December 31, 2018. The amount at December 31, 2019 does not include the $30 million license fee payment the Company expects to receive as part of the expanded license agreement with Guangzhou Xiangxue Pharmaceutical. Based on the current operating plan, the Company expects that its cash and cash equivalents and short-term investments as of December 31, 2019, will enable it to fund operations into the first quarter of 2021.

Financial Results for the Year Ended December 31, 2019

Product sales for the year ended December 31, 2019 were $80.5 million, an increase of $24.1 million, or 43%, as compared to $56.4 million for the year ended December 31, 2018. The increase was due to a $20.0 million increase in specialty product sales from growing sales volume of existing products and the launch and sales of new products along with an $11.8 million increase in 503B sales mainly attributable to vasopressin sales in the first half of 2019, offset by a $5.2 million decrease in sales of API products and a $2.5 million decrease in medical device sales.

Total revenue for the year ended December 31, 2019 was $101.2 million, an increase of $12.1 million as compared to $89.1 million for the year ended December 31, 2018.

We recognized $20.0 million and $30.0 million in collaboration and license revenue for the years ended December 31, 2019 and 2018, respectively, pursuant to the license agreement entered into with Almirall in December 2017. We recognized zero and $2.0 million in collaboration and license revenue for the years ended December 31, 2019 and 2018, respectively, pursuant to the license agreement we entered into with PharmaEssentia to develop and commercialize oral paclitaxel, oral irinotecan, and oral docetaxel in Taiwan, Singapore, and Vietnam.

Cost of sales totaled $69.6 million for the year ended December 31, 2019, an increase of $22.6 million, or 48%, as compared to $47.0 million for the year ended December 31, 2018. This was primarily due to an increase in the cost of specialty product sales and 503B product sales of $21.5 million and $7.0 million, respectively, and was offset by a decrease in cost of API product sales of $5.9 million. The increase in cost of sales was in line with the increase in product sales. Changes in availability of products and market demand could increase or decrease our revenue and gross profit in the future.

Research and development expenses totaled $84.4 million for the year ended December 31, 2019, a decrease of $35.5 million, or 30%, as compared to $119.9 million for the year ended December 31, 2018. This was primarily due to a decrease in licensing fees, product development, and clinical operations and included the following: $30.0 million decrease in drug in-licensing fees primarily related to a $29.5 million license fee related to the license of TCR-T technology in connection with the establishment of Axis; $8.4 million decrease of product development costs related to the scale up of 503B operations, API research and development, and the launch of certain specialty products in 2018; and $3.7 million decrease of clinical development costs related to encequidar and tirbanibulin ointment due to the winding down of the two AK Phase 3 studies. The decrease in these R&D expenses was offset by an increase of $4.7 million of preclinical development costs related to the Arginine Deprivation Therapy and TCR-T Immunotherapy platforms and a $1.9 million increase of R&D related compensation expense.

Selling, general, and administrative expenses totaled $66.7 million for the year ended December 31, 2019, an increase of $17.7 million, or 36%, as compared to $49.0 million for the year ended December 31, 2018. This was primarily due to an increase of $15.6 million related to the costs of preparing to commercialize our proprietary drugs, an increase of $1.3 million of general administrative expenses including rent, utilities, insurance, and office expenses, and an increase of $0.9 million of professional fees including legal and accounting fees.

Net loss attributable to Athenex for the year ended December 31, 2019 was $123.7 million, or ($1.67) per diluted share, compared to a net loss of $117.4 million, or ($1.82) per diluted share, for the year ended December 31, 2018.

Outlook and Upcoming Milestones:

- Final FDA meeting for Oral Paclitaxel in metastatic breast cancer has been scheduled for early April and the Company plans to submit an NDA in the US shortly thereafter.
- Plan to submit additional data from ongoing Phase 1 study of Oral Paclitaxel in cutaneous angiosarcoma for presentation at a medical meeting (H1-2020).
- Enroll patients in dose expansion part of Phase 1 trial of Oral Paclitaxel in combination with pembrolizumab for the treatment of advanced solid tumors (H2-2020).

Financial Guidance:

Athenex's product sales in 2019 amounted to $80.5 million, representing a 43% year-over-year increase which was above the 35%-40% guidance range provided on the last earnings call in November 2019. The Company expects 2020 year-over-year product sales growth to be in the mid-single digits, from $80.5 million in 2019. While the Company does not give quarterly guidance, product sales are expected to be back-end loaded in 2020. The product sales guidance for 2020 has taken into account the discontinuation of vasopressin sales and the suspension of operations at the Taihao API plant in 2019, which had meaningful contributions in the first nine months of 2019.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Thursday, February 27, 2020, 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 13698005. The live conference call and replay can also be accessed via audio webcast at this link http://public.viavid.com/index.php?id=137607 and also via 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 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 internationally and in China, including the impact of public health epidemics such as the coronavirus; the uncertainty of when, if at all, we will be able to resume full API production operations in Chongqing; 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 https://ir.athenex.com/financial-information/sec-filings?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 STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019 (in thousands)	2018 (in thousands)	2019 (in thousands)	2018 (in thousands)
Revenue				
Product sales, net	$ 14,102	$ 19,009	$ 80,535	$ 56,394
License and other revenue	20,259	2,262	20,694	32,706
Total revenue	34,361	21,271	101,229	89,100
Cost of sales	(15,704)	(14,271)	(69,619)	(47,005)
Research and development expenses	(21,823)	(20,828)	(84,393)	(119,905)
Selling, general, and administrative expenses	(18,109)	(11,618)	(66,749)	(49,008)
Interest income	1,231	474	1,881	1,788
Interest expense	(2,458)	(1,804)	(6,954)	(3,581)
Income tax benefit (expense)	91	(386)	(928)	(100)
Net loss	(22,411)	(27,162)	(125,533)	(128,711)
Less: net loss attributable to non-controlling interests	(684)	(49)	(1,784)	(11,271)
Net loss attributable to Athenex, Inc.	$ (21,727)	$ (27,113)	$ (123,749)	$ (117,440)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.28)	$ (0.41)	$ (1.67)	$ (1.82)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	78,550,995	66,915,173	74,054,261	64,590,270

ATHENEX, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	December 31,	
	2019	2018
	(In thousands)	
Cash and cash equivalents	$127,674	$ 49,794
Short-term investments	33,139	57,629
Goodwill	38,513	37,495
Working capital*	159,398	119,143
Total assets	309,932	231,095
Long-term debt	53,246	46,764
Total liabilities	134,077	102,326
Non-controlling interests	(12,370)	(10,586)
Total stockholders' equity	$175,855	$128,769

* working capital: total current assets less total current liabilities.