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): May 7, 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 May 7, 2020, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended March 31, 2020. 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 May 7, 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: May 7, 2020

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Reports First Quarter Ended March 31, 2020 Financial Results and Provides Corporate Update

Regulatory filings for tirbanibulin ointment for actinic keratosis submitted to both FDA and EMA

Oral Paclitaxel NDA submission is on track

2020 product sales guidance re-affirmed

Conference call & webcast today at 8:00am Eastern Time

BUFFALO, N.Y., May 7, 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 first quarter ended March 31, 2020.

“We successfully advanced our two lead product candidates towards regulatory submission. The regulatory applications for tirbanibulin have been filed and accepted in both the U.S. and E.U., and the NDA for Oral Paclitaxel is on track to be submitted soon,” stated Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex. “Both products have strong clinical data packages, a reflection of the very capable execution by our R&D and clinical teams. The commercial launches of these products, if approved, will be transformative for Athenex.”

“We are continuing with our pre-commercial activities for Oral Paclitaxel, many of which can be completed virtually, to ensure we are well positioned for commercial launch,” continued Dr. Lau. “Our team remains committed to advancing our innovative medicines, particularly Oral Paclitaxel, which we believe could be very valuable for both patients and physicians in the current environment. Our operational plans remain on track. We will continue to operate in this evolving situation with the COVID-19 pandemic and will make adjustments as necessary to ensure business continuity.”

First Quarter 2020 and Recent Business Highlights:

Clinical Programs:

Tirbanibulin ointment for actinic keratosis (AK)

- A New Drug Application (NDA) for tirbanibulin ointment for actinic keratosis was filed with the U.S. Food and Drug Administration (FDA), and the Prescription Drug User Fee Act (PDUFA) target action date has been set as December 30, 2020. Additionally, the FDA has communicated that it is not currently planning on holding an advisory committee to discuss the application.
- A Marketing Authorization Application (MAA) has been submitted to the European Medicines Agency (EMA) by our partner Almirall and validated.

Oral Paclitaxel for Metastatic Breast Cancer

- The Company participated in a constructive meeting with the FDA, as scheduled, to discuss the clinical section of the NDA for Oral Paclitaxel for the treatment of metastatic breast cancer, and is on track to submit the NDA.

Commercial Business:

- Athenex Pharmaceutical Division (APD) currently markets a total of 32 products with 59 SKUs.
- Athenex Pharma Solutions (APS) currently markets 5 products with 17 SKUs.
- Goal is to launch 7 products in 2020, including a major 503B product.

Financial Results for the First Quarter Ended March 31, 2020

Revenue from product sales were $18.5 million, a decrease of $6.6 million or 26% for the three months ended March 31, 2020, from $25.2 million for the three months ended March 31, 2019. This decrease was primarily attributable to a decrease in API and 503B product sales of $3.8 million and $3.4 million, respectively, due to the suspension of the Company's API plant and the discontinued vasopressin sales. These decreases were partially offset by an increase in specialty product revenue of $0.9 million with the launch and sales of two new products.

The Company recognized $28.3 million in license revenue for the three months ended March 31, 2020, pursuant to the license agreement entered into with Xiangxue in December 2019.

Cost of sales for the three months ended March 31, 2020 totaled $19.6 million, a decrease of $0.3 million, or 2%, as compared to $19.9 million for the three months ended March 31, 2019. The Company continued to incur fixed costs at the API plant and APS facility despite decreased production at these locations.

Research and development expenses for the three months ended March 31, 2020 totaled $17.2 million, a decrease of $7.3 million, or 30%, as compared to $24.5 million for the three months ended March 31, 2019. This was primarily due to a decrease in licensing fees and costs attributable to preclinical and clinical operations. The decrease in these R&D expenses was partially offset by an increase of $1.3 million in compensation expense and regulatory costs in connection with our NDA preparations.

SG&A expenses for the three months ended March 31, 2020 totaled $25.7 million, an increase of $10.5 million, or 70%, as compared to $15.2 million for the three months ended March 31, 2019. This was primarily due to an increase of $7.6 million related to the costs of preparing to commercialize our proprietary drugs, if approved, and an increase of $2.9 million of general administrative expense, including professional service fees and other operating expenses.

As a result of the foregoing, operating loss for the three months ended March 31, 2020 was $15.6 million, compared to $34.3 million in the same period last year.

Net loss attributable to Athenex for the three months ended March 31, 2020 was $19.4 million, or ($0.24) per diluted share, compared to a net loss of $35.2 million, or ($0.53) per diluted share, in the same period last year. Net loss attributable to Athenex for the three months ended March 31, 2020 was impacted by foreign tax withholding in relation to license revenue recognized in the period.

At March 31, 2020, the Company had cash, cash equivalents and short-term investments of $113.7 million, which included $8.7 million funded by New York State for the construction of the Dunkirk facility for which the Company has recorded a corresponding liability, compared to cash, cash equivalents and short-term investments of $160.8 million at December 31, 2019. The March 31, 2020 balance did not include the $30 million payment the Company is due to receive from Xiangxue Pharmaceutical, as part of our expanded partnership under the license agreement entered into in December 2019. Based on the current operating plan, we expect that our cash, cash equivalents and short-term investments as of March 31, 2020, together with cash to be generated from our operating activities, including the license payment from our China partner, Xiangxue Pharmaceutical, will enable us to fund our operations into the first quarter of 2021.

Outlook and Upcoming Milestones:

- An abstract for the ongoing Phase 2 study of Oral Paclitaxel in angiosarcoma has been accepted for presentation in a poster discussion session at the American Society of Clinical Oncology's (ASCO) upcoming ASCO20 Virtual Scientific Program, which will be held from May 29 to May 31, 2020.
- FDA acceptance of the NDA for Oral Paclitaxel for metastatic breast cancer.
- PDUFA date of December 30, 2020 for tirbanibulin ointment for actinic keratosis.

Financial Guidance:

The Company expects 2020 year-over-year product sales growth to be in the mid-single digits, from $80.5 million reported in 2019. 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 2019. In light of the current COVID-19 pandemic, the Company has sold and may continue to sell products that are used to treat COVID-19 patients. The Company currently does not view these revenues as recurring in nature and will provide an update at the appropriate time.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Thursday, May 7, 2020, at 8:00am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial 800-479-1004 (domestic) or 929-477-0324 (international) fifteen minutes before the conference call begins and reference the conference passcode 7976288. The live conference call and replay can also be accessed via audio webcast here http://public.viavid.com/index.php?id=139326 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 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; risks and uncertainties related to the COVID-19 pandemic and its potential impact on our operations, cash flow and financial condition; our ability to integrate CIDAL's assets into our existing operations; competition; intellectual property risks; risks relating to doing business internationally and in China; 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 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.

CONTACTS

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ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands)

	March 31, 2020	December 31, 2019
Balance sheet data:		
Cash and cash equivalents	$ 71,983	$ 127,674
Short-term investments	41,721	33,139
Goodwill	38,480	38,513
Working capital*	141,104	159,398
Total assets	297,787	309,932
Long-term debt	53,767	53,246
Total liabilities	139,551	134,077
Non-controlling interests	(12,659)	(12,370)
Total stockholders' equity	$158,236	$ 175,855

* working capital: total current assets less 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 March 31,	
	2020 (in thousands)	2019 (in thousands)
Revenue		
Product sales, net	$ 18,547	$ 25,163
License fees and other revenue	28,388	144
Total revenue	46,935	25,307
Cost of sales	(19,572)	(19,902)
Research and development expenses	(17,192)	(24,475)
Selling, general, and administrative expenses	(25,748)	(15,188)
Interest income	413	283
Interest expense	(1,673)	(1,755)
Income tax expense	(2,881)	(500)
Net loss	(19,718)	(36,230)
Less: net loss attributable to non-controlling interests	(289)	(997)
Net loss attributable to Athenex, Inc.	$ (19,429)	$ (35,233)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.24)	$ (0.53)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	81,539,548	67,011,432

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

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (45,545)	$ (32,971)
Net cash (used in) provided by investing activities	(10,451)	52,198
Net cash provided by financing activities	732	976
Net effect of foreign exchange rate changes	(427)	1,006
Net (decrease) increase in cash and cash equivalents	(55,691)	21,209
Cash and cash equivalents, at beginning of period	127,674	49,794
Cash and cash equivalents, at end of period	$ 71,983	$ 71,003