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 5, 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

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 5, 2020, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended September 30, 2020. A copy of 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 November 5, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 5, 2020

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Reports Third Quarter Ended September 30, 2020 Financial Results and Provides Corporate Update

FDA accepted and granted priority review of NDA for Oral Paclitaxel in metastatic breast cancer

PDUFA dates for tirbanibulin ointment and Oral Paclitaxel set for December 30, 2020 and February 28, 2021, respectively

Four abstracts featuring Oral Paclitaxel accepted for presentation at San Antonio Breast Cancer Virtual Symposium

Product sales in Q3 2020 were $24.8 million, up 29% y/y — raising full year 2020 guidance to low 20% growth

Conference call and live webcast at 8.00 am ET today

BUFFALO, N.Y., November 5, 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 third quarter ended September 30, 2020.

“Our New Drug Application (NDA) filing for Oral Paclitaxel was accepted with priority review and a target action date of February 28, 2021,” stated Dr. Johnson Lau, Chairman and Chief Executive Officer of Athenex. “Oral Paclitaxel has a compelling efficacy, and tolerability profile that we believe positions it to potentially become the chemotherapy of choice in metastatic breast cancer. Our supply chain is in place and we are finalizing our commercial plans, with the goal of launching in the U.S. upon approval in the first quarter of 2021.”

“During the quarter, we strengthened our balance sheet with a successful equity financing, raising net proceeds of $118.7 million,” continued Dr. Lau. “This provides us with additional resources and financial flexibility to invest in and expand our commercial infrastructure, as well as to pursue label expansion initiatives for Oral Paclitaxel and continued development of our pipeline. The planned commercial launch of Oral Paclitaxel will also be funded by the other financings we recently announced with Oaktree and Sagard Healthcare Royalty Partners, which provide a total of $225 million and $50 million, respectively, based on associated milestones.”

Third Quarter 2020 and Recent Business Highlights:

Clinical Programs:

Oral Paclitaxel for Breast Cancer

- The U.S. Food and Drug Administration (FDA) accepted an NDA for Oral Paclitaxel for the treatment of metastatic breast cancer and has granted the application Priority Review. Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target action date of February 28, 2021.
- Launched two new study arms of the I-SPY 2 TRIAL, sponsored by Quantum Leap Healthcare Collaborative, to evaluate Oral Paclitaxel in combination with GSK’s dostarlimab in Stage 2/3 HER2+ and HER2- breast cancer patients.

Tirbanibulin Ointment for Actinic Keratosis

- Under the PDUFA, the FDA has set a target action date for tirbanibulin ointment as December 30, 2020.

TCRT-ESO-A2, a TCR-T cell therapy, for NY-ESO-1 positive solid tumors

- FDA has allowed the investigational new drug (IND) application for TCRT-ESO-A2, an autologous T-cell receptor (TCR)-T cell therapy. TCRT-ESO-A2 is being developed by Axis Therapeutics Limited, a joint venture between Athenex and Xiangxue Life Sciences Limited.

Commercial Business:

- Product sales growth in the third quarter was primarily driven by sales of specialty pharmaceutical products used to treat patients hospitalized with COVID-19.
- Athenex Pharmaceutical Division (APD) currently markets a total of 30 products with 54 SKUs.
- Athenex Pharma Solutions (APS) currently markets 6 products with 18 SKUs.

Corporate Financing Highlights:

- Completed an underwritten follow-on public offering of a total of 11.5 million shares generating net proceeds of $118.7 million.
- Entered into a $50 million revenue interest financing agreement with Sagard Healthcare Royalty Partners, LP. (“Sagard”).

Financial Results for the Third Quarter Ended September 30, 2020

Revenue from product sales increased to $24.8 million for the three months ended September 30, 2020, up from $19.2 million for the three months ended September 30, 2019, which represents an increase of $5.6 million or 29%. The increase was primarily attributable to a significant increase in specialty product sales of $9.7 million, driven by the impact of the global health pandemic which led to the increased demand for COVID-19 related drugs. The revenue increase was partially offset by a decrease in API and 503B products sales, totaling $3.3 million and $0.8 million, respectively. The decrease in API and 503B sales was attributable to the suspension of production of commercial batches at our API facility and the discontinued vasopressin sales, respectively.

Pursuant to the 2019 Xiangxue License Agreement and an out-licensing agreement with PharmaEssentia, we recognized $9.4 million in license revenue, net of $0.6 million VAT, and $1.0 million in license revenue, respectively, for the three months ended September 30, 2020.

Cost of sales totaled $24.5 million for the three months ended September 30, 2020, an increase of $7.4 million, or 44%, as compared to $17.1 million for the three months ended September 30, 2019. The increase in cost of specialty product sales was in-line with the increase in revenue, and we continued to incur fixed costs despite decreased production at our API and APS facilities. Out of the $24.5 million costs of sales, approximately $2.4 million was attributable to the sublicense fees payable to Hanmi, in relation to the license revenue recognized in the quarter pursuant to the 2019 Xiangxue License Agreement.

R&D expenses totaled $18.4 million for the three months ended September 30, 2020, a decrease of $1.2 million, or 6%, as compared to $19.6 million for the three months ended September 30, 2019. The decline was attributable to a decrease in clinical operations, drug licensing costs, regulatory costs, and preclinical operations. The decrease in R&D expenses were partially offset by a $1.8 million increase in medical affairs and API development costs, and a $1.2 million increase in compensation expenses.

SG&A expenses totaled $22.2 million for the three months ended September 30, 2020, an increase of $5.9 million, or 36%, as compared to $16.3 million for the three months ended September 30, 2019. The increase was attributable to increasing commercial preparations costs associated with the possible approval of our proprietary drugs, and an increase in general and administrative costs related to professional fees, IT costs, and other operational costs.

Interest income consisted of interest earned on our short-term investments, which totaled $0.1 million and $0.7 million for the three months ended September 30, 2020 and 2019, respectively. Interest expense totaled $3.6 million and $1.7 million for the three months ended September 30, 2020 and 2019, respectively. The majority of the interest expense in the current period was incurred from the Senior Credit Agreement with Oaktree, while the majority of the interest expense in the prior period was incurred from the variable-rate, long-term debt with Perceptive.

In the three months ended September 30, 2020, we recognized a $3.0 million loss on the partial extinguishment of debt related to the assignment of a portion of the senior secured loan from Oaktree's co-investors to Sagard. We did not incur expenses of similar nature for the three months ended September 30, 2019.

For the three months ended September 30, 2020, we incurred income tax expense of $1.1 million, compared to $0.1 million for the three months ended September 30, 2019. The increase was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Net loss attributable to Athenex for the three months ended September 30, 2020 was $36.8 million, or ($0.44) per diluted share, compared to a net loss of $34.8 million, or ($0.45) per diluted share, for the three months ended September 30, 2019. Excluding the one-time debt extinguishment expenses of $3.0 million, the net loss attributable to Athenex for the three months ended September 30, 2020 was $33.8 million, or ($0.40) per diluted share.

As of September 30, 2020, the Company had cash and cash equivalents of $143.6 million, restricted cash of $13.8 million and short-term investments of $84.8 million.

On August 4, 2020, Athenex entered into a Revenue Interest Financing (RIF) agreement with Sagard Healthcare Royalty Partners, LP. The agreement provides Athenex with $50 million of capital upon FDA approval of Oral Paclitaxel for the treatment of metastatic breast cancer. In exchange for funding this capital, Sagard will receive quarterly payments equal to a mid-single digit royalty of worldwide net sales of Oral Paclitaxel. The Company expects that the proceeds from the financing will be used to fund the development and commercialization of Oral Paclitaxel and other general corporate purposes. Also, in connection with this agreement, Sagard and certain of its co-investors have purchased by assignment $50 million of outstanding loans and undrawn commitments from funds managed by Oaktree, becoming lenders under Athenex's $225 million term loan facility entered into between Oaktree and Athenex in June 2020.

In September 2020, Athenex completed an underwritten follow-on public offering in which it sold 11.5 million shares of its common stock, including 1.5 million shares of common stock pursuant to underwriters' option to purchase additional shares, at a public offering price of $11.00 per share and received net proceeds of $118.7 million, after deducting underwriting discounts and commissions and offering expenses.

Outlook and Upcoming Milestones:

- Four abstracts featuring Oral Paclitaxel have been accepted for presentation at the San Antonio Breast Cancer Virtual Symposium, to take place December 8-11, 2020.
- FDA has set a PDUFA target action date of December 30, 2020 for tirbanibulin ointment for the treatment of actinic keratosis.
- FDA has set a PDUFA target action date of February 28, 2021 for Oral Paclitaxel for the treatment of metastatic breast cancer.

Upcoming Investor Events (each to be conducted virtually):

- SVB Leerink's Oncology 1x1 Day, November 19, 2020
- Evercore ISI 3rd Annual HealthCONx, December 1-3, 2020

Financial Guidance:

Athenex provides revenue guidance for product sales only. The Company is raising its product sales guidance for the full year 2020 from mid-teens growth as previously communicated to at least low twenties percentage growth year-over-year, from $80.5 million of product sales revenue reported in

2019. This takes into account the Company's sales performance year to date as well as the outlook for the remainder of the year. The Company's product mix may continue to include products that are used to treat patients hospitalized with COVID-19, although the Company does not view these revenues as recurring in nature.

The Company believes that the existing cash, cash equivalents, restricted cash, and short-term investments will be sufficient to fund current operating plans into the second quarter of 2022. The Company plans to access additional milestone-based, non-dilutive capital available under the Senior Credit Agreement with Oaktree and Revenue Interest Financing Agreement with Sagard upon achievement of such funding milestones, and if such funding milestones are achieved, the additional capital provided by such is expected to further extend the Company's cash runway into 2023.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Thursday, November 5, 2020, before the market opens, at 8:00 am Eastern Time to discuss 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 13711719. The live conference call and replay can also be accessed via audio webcast here and also 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; uncertainties around our ability to meet funding conditions under our financing agreements and access to capital thereunder; risks and uncertainties related to the COVID-19 pandemic and its potential impact on our operations, cash flow and financial condition; competition; intellectual property risks; risks relating to doing business internationally and in China; the risk of production slowdowns or stoppages or other interruptions at our Chongqing facilities; 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)

	September 30, 2020	December 31, 2019
Balance sheet data:		
Cash, cash equivalents, and restricted cash	$ 157,309	$ 127,674
Short-term investments	84,751	33,139
Goodwill	38,692	38,513
Working capital*	257,653	159,398
Total assets	409,640	309,932
Long-term debt	123,614	53,246
Total liabilities	197,405	134,077
Non-controlling interests	(13,523)	(12,370)
Total stockholders' equity	$ 212,235	$ 175,855

* working capital: total current assets less total current liabilities

ATHENEX, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020 (in thousands)	2019 (in thousands)	2020 (in thousands)	2019 (in thousands)
Revenue				
Product sales, net	$ 24,780	$ 19,237	$ 83,494	$ 66,433
License fees and other revenue	10,696	127	39,089	435
Total revenue	35,476	19,364	122,583	66,868
Cost of sales	(24,510)	(17,071)	(77,088)	(53,915)
Gross profit	10,966	2,293	45,495	12,953
Research and development expenses	(18,390)	(19,588)	(57,597)	(62,570)
Selling, general, and administrative expenses	(22,220)	(16,283)	(65,454)	(48,640)
Interest income	112	650	710	1,408
Interest expense	(3,595)	(1,745)	(6,833)	(5,254)
Loss on extinguishment of debt	(3,048)	—	(10,278)	—
Income tax expense	(1,093)	(114)	(4,080)	(1,019)
Net loss	(37,268)	(34,787)	(98,037)	(103,122)
Less: net loss attributable to non-controlling interests	(462)	(29)	(1,351)	(1,100)
Net loss attributable to Athenex, Inc.	$ (36,806)	$ (34,758)	$ (96,686)	$ (102,022)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.44)	$ (0.45)	$ (1.17)	$ (1.41)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	83,712,060	77,297,555	82,314,802	72,552,248

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

	Nine Months Ended September 30,	
	2020	2019
Net cash used in operating activities	$ (97,088)	$ (74,120)
Net cash (used in) provided by investing activities	(58,404)	2,588
Net cash provided by financing activities	185,328	108,051
Net increase in cash, cash equivalents, and restricted cash	29,836	36,519
Cash, cash equivalents, and restricted cash, at beginning of period	127,674	49,794
Net effect of foreign exchange rate changes	(201)	592
Cash, cash equivalents, and restricted cash, at end of period	$ 157,309	$ 86,905