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 4, 2021

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 4, 2021, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended September 30, 2021. 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 4, 2021
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 4, 2021

/s/ Steve Adams

Name: Steve Adams
Title: Interim Chief Accounting Officer

Exhibit 99.1

Athenex Provides Third Quarter 2021 Corporate and Financial Update

Held FDA Type A Meeting for oral paclitaxel in metastatic breast cancer

Klisyri® launched in Europe

ANCHOR Phase 1 interim results accepted for poster presentation at 2021 ASH

3Q product sales were $27.0M, up 9% year-over-year

Company now expects full year product sales revenue in 2021 to decrease by 6-12% compared to 2020

Management to host conference call and webcast today at 10:00 a.m. ET

Buffalo, N.Y., November 4, 2021 (GLOBE NEWSWIRE) – 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 provided a corporate and financial update for the third quarter ended September 30, 2021.

"Following our recent Type A meeting with U.S. FDA to discuss our New Drug Application for oral paclitaxel and encequidar (Oral Paclitaxel) in metastatic breast cancer, we determined that deploying our resources towards other ongoing clinical programs of Oral Paclitaxel and our cell therapy programs would be a better way to maximize value for all of our shareholders and stakeholders," said Johnson Lau, Chief Executive Officer of Athenex. "Our management team is focused on advancing the clinical pipeline where we believe Athenex has a strong competitive advantage, as well as exploring various other approaches for our assets that will unlock shareholder value. We are particularly pleased with the continued positive momentum and increasing visibility of our cell therapy programs."

Third Quarter 2021 and Recent Business Highlights

Clinical Programs

Orascovery

- Held a Type A meeting with the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for Oral Paclitaxel in metastatic breast cancer.

- Presented positive interim data from a Phase 1 trial evaluating Oral Paclitaxel in combination with pembrolizumab in patients with advanced solid malignancies at ESMO 2021.

- Received confirmation from the Innovative Licensing and Access Pathway (ILAP) in the UK that encequidar in combination with oral anticancer medicines has been awarded the innovative medicine designation, the Innovation Passport. ILAP was set up by the UK Medicines & Healthcare products Regulatory Agency (MHRA) and other UK government agencies to efficiently accelerate the time to market and facilitating patient access to innovative medicines.

Cell Therapy

- Interim data from the ongoing Phase 1 ANCHOR trial evaluating KUR-502 in patients with CD19-positive relapsed or refractory lymphoma and leukemia have been accepted for poster presentation at the 2021 ASH Annual Meeting.

- The U.S. Patent and Trademark Office allowed patent claims around the NKT cellular immunotherapy platform developed by Athenex and the Center for Cell and Gene Therapy at Baylor College of Medicine, Texas Children's Hospital and Houston Methodist Hospital.

- Opened enrollment in Phase 1 trial to evaluate TCRT-ESO-A2 (high-affinity TCR-T targeting NY-ESO-1 solid tumors).

Commercial Update

Klisyri® (tirbanibulin)

- Athenex's partner, Almirall (Almirall, S.A., BME: ALM), launched Klisyri® (tirbanibulin) in Germany and the UK. Klisyri received approval by the European Commission and the UK MHRA in July and August of 2021, respectively, for the topical treatment of actinic keratosis (AK) of the face and scalp in adults.

Specialty Pharmaceutical Business

- Athenex Pharmaceutical Division (APD) currently markets a total of 33 products with 64 SKUs.
- Athenex Pharma Solutions (APS) currently markets 5 products with 16 SKUs.

Corporate

- Dr. Michael Smolinski promoted to Chief Scientific Officer. Dr. Smolinski has been with Athenex for 13 years and previously served as Vice President of Preclinical Operations.

Key Anticipated Milestones

- ANCHOR Phase 1 poster presentation at 2021 ASH in December
- Results from the I-SPY 2 trial of oral paclitaxel plus anti PD-1 expected in 2022
- Almirall to continue phased roll-out of Klisyri in other European countries in 2022

Third Quarter 2021 Financial Highlights

Revenues from product sales increased to $27.0 million for the three months ended September 30, 2021, from $24.8 million for the three months ended September 30, 2020, an increase of $2.2 million or 9%. This increase was primarily attributable to an increase in 503B product sales of $2.1 million as the result of the increase in demand for certain drugs used to treat patients hospitalized with COVID-19. API product sales and contract manufacturing sales each experienced an increase of $0.4 million. These increases were offset by a decrease in APD product sales of $0.7 million, resulting primarily from a significant prior year increase in demand for COVID-19 related drugs and for FDA shortage products during 2020, including some significant non-recurring orders.

License fees and other revenue decreased by $5.4 million, for the three months ended September 30, 2021. This decrease was primarily due to the recognition of $5.1 million in license and royalty revenue from Almirall for the launch of Klisyri in Europe in

September 2021, while we recognized $10.4 million in license revenue during the three months ended September 30, 2020, pursuant to license agreements with Xiangxue and PharmaEssentia.

Cost of sales for the three months ended September 30, 2021 totaled $25.6 million, an increase of $1.1 million, or 5%, as compared to $24.5 million for the three months ended September 30, 2020. The increase was primarily due to an increase of $2.9 million in cost of 503B product sales as production levels increased. Cost of APD product sales increased by $0.9 million, while the cost of API product sales decreased by $0.1 million. Additionally, cost of sales related to royalties for license income decreased by $2.5 million due to the royalty payment that incurred in 2020 on the license revenue from Xiangxue.

R&D expenses for the three months ended September 30, 2021 totaled $17.7 million, a decrease of $0.7 million, or 4%, as compared to $18.4 million for the three months ended September 30, 2020. This was primarily due to a decrease in costs of clinical operations of $2.4 million after the completion of the Phase 3 studies for tirbanibulin ointment and Oral Paclitaxel, a decrease in Oral Paclitaxel product development and medical affairs costs of $1.8 million incurred in connection with the potential product launch, a decrease in costs of preclinical operations of $1.0 million, and a decrease in R&D related compensation expenses of $0.4 million. The decrease in these R&D expenses was partially offset by a $2.6 million increase in cell therapy development costs, a $2.0 million increase in drug licensing costs related to licenses for specialty drug products, and a $0.3 million increase in costs of other product development.

SG&A expenses for the three months ended September 30, 2021 totaled $22.8 million, an increase of $0.6 million, or 3%, as compared to $22.2 million for the three months ended September 30, 2020. This was primarily due to a $3.2 million increase from the change in fair value of contingent consideration, a $2.1 million increase in operating costs including insurance and IT costs and professional fees, a $1.9 million increase in compensation related costs, and a $1.1 million increase in site preparation costs related to the manufacturing facility in Dunkirk. The increase was partially offset by a $7.7 million decrease in costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020 and slowed upon receipt of the Complete Response Letter in February 2021.

Interest expense totaled $5.1 million and $3.6 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense in the current period was incurred from the Senior Credit Agreement with Oaktree, while interest expense in the prior period was primarily incurred from debt under a former credit agreement with Perceptive Advisors LLC and its affiliates.

Income tax expense for the three months ended September 30, 2021 amounted to $0.3 million, compared to income tax expense of $1.1 million for the same period in 2020. The income tax expense in the prior year was primarily attributable to foreign income tax withholdings on our revenue earned under our out-license arrangements.

Net loss attributable to Athenex for the third quarter was $36.1 million or 33 cents per diluted share, as compared to a net loss of $36.8 million or 44 cents per diluted share, for the same period in 2020.

For further details on the Company's financial results, including the results for the nine months ended September 30, 2021, refer to the Form 10Q filed with the SEC.

Financial Guidance

In terms of product sales guidance, the Company is limiting financial guidance to the existing Athenex product portfolio only. In 2020, the Company recorded a significant amount of revenues from international customers as a result of the global pandemic. However, it does not see these revenues as recurring in nature. In the first nine months of 2021, the Company experienced significant COVID-related challenges in our Indian supply chain and to a lesser extent China, which slowed down APD product sales during the period. As a result, the Company now expects its full year product sales in 2021, excluding any royalties from Klisyri®, to decline by 6% to 12% year-over-year compared with 2020 levels.

Cash Conservation Update

As of September 30, 2021, the company had cash and cash equivalents of $73.6 million, restricted cash of $16.5 million, and short-term investments of $14.9 million, for a total of $105.0 million. Given the earlier uncertainty stemming from the CRL for Oral Paclitaxel in metastatic breast cancer, the Company has already identified and adopted certain cash conservation measures. The Company is seeking additional cash conservation and funding opportunities to further extend the cash runway.

Conference Call and Webcast Information

Athenex will host a conference call and live audio webcast today, Thursday, November 4, 2021, at 10:00 am Eastern Time to discuss the financial results and provide a business update.

To participate in the call, dial either the domestic or international number fifteen minutes before the conference call begins:

Domestic: (855) 227-0567
International: (612) 979-9912
Passcode: 7292300

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 under "Events and Presentations", 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 technologies: (1) Orascovery, based on P-glycoprotein inhibitor, (2) Src kinase inhibition, (3) Cell therapy, 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. 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, including NKT Cell Therapy and related risks involved in drug development, clinical trials, regulation, uncertainties around regulatory reviews and approvals; our ability to pivot our business and to find new uses for the capacity at our Dunkirk manufacturing facility, once operational; our ability to scale our manufacturing and commercial supply operations for current and future approved products, and ability to commercialize our products, once approved; ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the preclinical and clinical results for Athenex's drug candidates, which may not support further development of such drug candidates; risks related to our ability to successfully integrate the business of Kuur into our existing businesses, including uncertainties associated with maintaining relationships with customers, vendors and employees, as well as differences in operations, cultures, and management philosophies that may delay successful integration and our ability to support the added cost burden of Kuur's business; risks related to counterparty performance, including our reliance on third parties for success in certain areas of Athenex's business; our history of operating losses and our need and ability to raise additional capital to continue as a going concern; uncertainties around our ability to enter into new financing agreements as we are unable to meet funding conditions under our existing financing agreements and access to capital thereunder; risks and uncertainties inherent in litigation, including purported stockholder class actions; risks and uncertainties related to the COVID-19 pandemic and its ongoing impact on our operations, supply chain, cash flow and financial condition; competition; intellectual property risks; uncertainties around our ability to successfully integrate acquired and merged businesses in a timely and cost-effective manner and to achieve synergies; risks relating to doing business internationally and in China; the risk of development, operational delays, production slowdowns or stoppages or other interruptions at our manufacturing facilities as well as our ability to find alternative sources of supply to meet our obligations and requirements; 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
(In thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
	(In thousands)	
Selected Balance sheet data:		
Cash, cash equivalents, and restricted cash	$ 90,094	$ 86,087
Short-term investments	14,918	138,636
Goodwill	67,617	38,891
Working capital[(1)]	111,303	229,820
Total assets	386,894	384,329
Long-term debt	150,594	148,587
Total liabilities	250,015	218,981
Non-controlling interests	(16,000)	(14,427)
Total stockholders' equity	$ 135,879	$ 165,348

*working capital: total current assets less total current liabilities

ATHENEX, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(In thousands)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2021 (in thousands)	2020 (in thousands)	2021 (in thousands)	2020 (in thousands)
Revenue				
Product sales, net	$ 27,035	$ 24,780	$ 68,780	$ 83,494
License and other revenue	5,262	10,696	26,465	39,089
Total revenue	32,297	35,476	95,245	122,583
Cost of sales	(25,644)	(24,510)	(61,712)	(77,088)
Gross profit	6,653	10,966	33,533	45,495
Research and development expenses	(17,731)	(18,390)	(61,928)	(57,597)
Selling, general, and administrative expenses	(22,794)	(22,220)	(66,145)	(65,454)
Interest income	39	112	200	710
Income from government grant	2,459	—	2,459	—
Interest expense	(5,100)	(3,595)	(15,692)	(6,833)
Loss on extinguishment of debt	—	(3,048)	—	(10,278)
Income tax benefit (expense)	(262)	(1,093)	10,619	(4,080)
Net loss	(36,736)	(37,268)	(96,954)	(98,037)
Less: net loss attributable to non-controlling interests	(679)	(462)	(1,573)	(1,351)
Net loss attributable to Athenex, Inc.	$ (36,057)	$ (36,806)	$ (95,381)	$ (96,686)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.33)	$ (0.44)	$ (0.93)	$ (1.17)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	109,292,740	83,712,060	102,111,218	82,314,802