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): July 28, 2022

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 July 28, 2022, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended June 30, 2022. 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 July 28, 2022
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: July 28, 2022

/s/ Joe Annoni

Name: Joe Annoni
Title: Chief Financial Officer

Athenex Provides Second Quarter 2022 Financial Results and Business Update

- *Reports 2Q product sales of $25.8 million, up 26% year-over-year*
- *Raised $85 million in total transaction value in 2Q for total of $125 million in proceeds from sales of non-core assets in 1H 2022, and reduced Senior Credit Facility balance from $150 million to $57.5 million*
- *Cash used in operating activities for 1H 2022 was reduced 42% over the prior year*
- *Presented promising early Phase 1 clinical trial data for CD19 and GD2 CAR-NKT cell products at ASTCT/CIBMTR Tandem Meetings and ASGCT annual meeting in 2Q 2022, respectively*
- *Maintains full-year 2022 product revenue guidance range of 20-25% growth year-over-year*
- *Management to host conference call and webcast today at 8:00 a.m. EDT*

Buffalo, N.Y., July 28, 2022 (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 second quarter ended June 30, 2022.

“Our team has made significant progress advancing our new strategy this quarter. I am proud of our operational execution in the first half of 2022 and pleased to say we are continuing this momentum into the second half of the year,” said Dr. Johnson Lau, Chief Executive Officer of Athenex. “By monetizing non-core assets, we have paid down a significant amount of our senior secured debt and extended our cash runway. Athenex remains focused on advancing our NKT cell therapy platform during this transformational period and is highly encouraged by the clinical trial data to date demonstrating the potential of CAR-NKT cells to offer a more durable, safe, and effective cell therapy option for patients with advanced solid tumors or hematological malignancies.”

Second Quarter 2022 and Recent Business Highlights

Business Updates

- APD/APS division delivered new product launches and generated 26% growth in product revenues during the second quarter of 2022 versus the prior year
- Announced sale of revenues from U.S. and European royalty and milestone interests in Klisyri® (tirbanibulin) for a total transaction value of $85 million in June
- Entered into an agreement in July to sell China API Business for approximately $19 million
- Appointed Darrel P. Cohen, MD, PhD as new Chief Medical Officer of Cell Therapy

- Entered a clinical collaboration with Merck to support the expansion of the Phase 1 clinical trial to evaluate Oral Paclitaxel plus KEYTRUDA® (pembrolizumab) in patients with non-small cell lung cancer (NSCLC)

Clinical Programs

NKT Cell Therapy

- Presented early Phase 1 ANCHOR dose escalation data for KUR-502, an allogeneic CD19 CAR-NKT therapy at the American Society of Transplantation and Cellular Therapy (ASTCT)/Center for International Blood & Marrow Transplant Research (CIBMTR) Tandem Meetings in April 2022. Data demonstrated a 60% ORR and 6-month CR rate of 40% in 5 patients from the Non-Hodgkin's Lymphoma (NHL) cohort, including 1 ongoing CR at 34 weeks. Encouraging response rates were observed at low doses, including 2 durable responses in patients who failed prior autologous CAR-T cell therapy. KUR-502 remains well-tolerated without cytokine release syndrome (CRS) in the NHL cohort, immune effector cell-associated neurotoxicity syndrome (ICANS), or graft versus host disease (GvHD).
- Presented early Phase 1 GINAKIT2 dose escalation data for KUR-501, an autologous GD2 CAR-NKT cell therapy for relapsed/refractory high-risk neuroblastoma at the American Society of Gene & Cell Therapy (ASGCT) annual meeting in May 2022. Study demonstrated expansion of CAR-NKT cells in all patients and dose response, with 2 out of 3 responses observed at the $1x10^8$ cells/m^2 dose level, including a durable complete response lasting at least 12 months. Analysis of results found that responses correlated with CD62L+ NKT cell expression as well as CAR-NKT cell area under the curve (AUC). Treatment remains well-tolerated without any dose-limiting toxicity, no ICANS, and 1 case of Grade 2 CRS.
- Presented pre-clinical data for KUR-503, an allogeneic GPC3 CAR-NKT cell therapy, at the ASCO Annual Meeting in June 2022. Study demonstrated CAR-NKT cells overexpressing BATF3 enhanced NKT cell proliferation, long-term tumor control, and survival compared to IL-15 CAR-NKT cells.
- Made the strategic decision to deprioritize development of AX-TCRT-001 and plan to close the Phase 1 open-label study of TCRT-ESO-A2 autologous T cells expressing TCR specific for NY-ESO-1 in patients with advanced solid tumors.

Commercial Update

Specialty Pharmaceutical Business

- Athenex Pharmaceutical Division (APD) currently markets a total of 31 products with 57 SKUs.
- Athenex Pharma Solutions (APS) currently markets 6 products with 16 SKUs.

Key Anticipated Milestones

- *Oral Paclitaxel:*
  - Phase 2 data from I-SPY 2 trial evaluating Oral Paclitaxel in combination with dostarlimab in neoadjuvant breast cancer expected in 2H 2022

- Regulatory interactions with UK MHRA for Oral Paclitaxel in advanced breast cancer in UK remain on track with responses to questions expected later this quarter

- *KUR-501:* autologous GD2 CAR-NKT cell therapy for relapsed/refractory high-risk neuroblastoma
  - Ongoing enrollment of additional patients in single-institution Phase 1 dose escalation GINAKIT2 study at the 2 highest dose levels (DL5: $3x10^8$ cells/m^2; DL6: $1x10^9$ cells/m^2)
  - Next data update from the ongoing GINAKIT2 study expected in 2023

- *KUR-502:* allogeneic CD19 CAR-NKT cell therapy for relapsed/refractory B-cell malignancies
  - Ongoing multicenter expansion of Phase 1 dose escalation ANCHOR study
  - Next clinical trial data update from the ongoing ANCHOR study anticipated in 4Q 2022 or 1Q 2023

- *KUR-503*: allogeneic GPC3 CAR-NKT cell therapy for hepatocellular carcinoma
  - IND filing for KUR-503 in GPC3-expressing hepatocellular carcinoma planned in 2023

Second Quarter 2022 Financial Highlights

Revenues from product sales increased to $25.8 million for the three months ended June 30, 2022, from $20.4 million for the three months ended June 30, 2021, an increase of $5.4 million or 26%. This increase was primarily attributable to an increase in APD specialty product sales, which increased by $4.2 million as the result of increases in shortage product sales and product launches during 2022.

License fees and other revenue for the three months ended June 30, 2022, was $5.7 million, compared to $0.3 million for the same period in 2021, an increase of $5.4 million. This increase was primarily due to the recognition of $5.0 million of license revenue pursuant to the 2017 Almirall License Agreement upon the commencement of a line extension trial for Klisyri in the U.S.

Cost of sales for the three months ended June 30, 2022, totaled $23.1 million, an increase of $4.0 million, or 21%, as compared to $19.1 million for the three months ended June 30, 2021. The increase was primarily due to an increase of $1.3 million in cost of APD product sales and an increase of $2.7 million in cost of 503B product sales.

R&D expenses totaled $13.1 million for the three months ended June 30, 2022, a decrease of $7.6 million, or 37%, as compared to $20.6 million for the three months ended June 30, 2021. This decrease was primarily due to a decrease in Oral Paclitaxel product development and medical affairs costs, costs of clinical and regulatory operations, compensation costs, and costs of preclinical operations.

SG&A expenses totaled $17.2 million for the three months ended June 30, 2022, a decrease of $0.5 million, or 3%, as compared to $17.6 million for the three months ended June 30, 2021. The decrease was primarily due to a $2.5 million decrease of costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020 and a $0.2 million decrease in compensation related costs. These decreases were partially offset by a $2.2 million increase in operating costs.

Interest expense totaled $4.3 million and $5.6 million, respectively, for the three months ended June 30, 2022, and 2021. Interest expense in both periods was incurred from the Senior Credit Agreement with Oaktree, and the decrease in 2Q 2022 was due to principal repayments made to the Agreement.

Income tax benefit for the three months ended June 30, 2022, amounted to less than $0.1 million, compared to an $11.0 million benefit for the same period in 2021. The income tax benefit in 2Q21 was the result of a taxable temporary difference due to the deferred tax liability recognized for the indefinite lived intangible assets acquired in connection with the acquisition of Kuur's IPR&D. We did not record a provision for U.S. federal income taxes for the three months ended June 30, 2022, because we expect to generate a loss for the year ending December 31, 2022.

Net loss attributable to Athenex for the three months ended June 30, 2022, was $32.2 million, or ($0.28) per diluted share, as compared to a net loss of $34.3 million, or ($0.33) per diluted share, for the same period in 2021.

For further details on the Company's financial results, including the results for the three months ended June 30, 2022, refer to the Form 10Q filed with the SEC.

2022 Financial Guidance

Athenex continues to expect product sales from continuing operations growth to be in the range of 20-25% over the prior year period.

Cash Conservation Update

As of June 30, 2022, the Company had cash and cash equivalents, restricted cash, and short-term investments of $37.1 million. The Company is implementing cost savings programs and monetizing non-core assets, and as the Company completes such activities, the Company plans to extend its cash runway into next year.

Conference Call and Webcast Information

Athenex will host a conference call and live audio webcast today, Thursday, July 28, 2022, at 8:00 a.m. 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:	1-855-327-6837
International:	1-631-891-4304
Passcode:	10019801

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 https://ir.athenex.com/investor-calendar.

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 cell therapy drugs for the treatment of cancer. In pursuit of this mission, Athenex leverages years of experience in research and development, clinical trials, regulatory standards, and manufacturing. The Company's current clinical pipeline is derived mainly from the following core technologies: (1) Cell therapy, based on NKT cells and (2) Orascovery, based on a P-glycoprotein inhibitor. Athenex's employees worldwide are dedicated to improving the lives of cancer patients by creating more active, accessible, 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," "continue," "could," "expect," "intend," "may," "plan," "potential," "strategy" "will," 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: our ability to complete the sale of our equity interests in our China subsidiaries; our history of operating losses and the substantial doubt about our ability to continue as a going concern; our strategic pivot to focus on our cell therapy platform and our plan to dispose of non-core assets; our ability to obtain financing to fund operations, successfully redirect our resources and reduce our operating expenses; our ability to refinance, extend or repay our substantial indebtedness owed to our senior secured lender; 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; the preclinical and clinical results for Athenex's drug candidates, which may not support further development of such drug candidates; the Company's 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 uncertainty of ongoing legal proceedings; risks related to our ability to successfully integrate the business of Kuur Therapeutics 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; risks and uncertainties inherent in litigation, including purported stockholder class actions; the impact of the COVID-19 pandemic and other macroeconomic factors, such as the war in Ukraine, and their ongoing impact on our operations, supply chain, cash flow, and financial condition; competition; intellectual property risks; 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 facility as well as our ability to find alternative sources of supply to meet our obligations and requirements; the risk that our common stock will be delisted from the Nasdaq Global Market if we are unable to regain compliance with its continued listing standards, 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.

Athenex Contacts

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ATHENEX, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	June 30, 2022	December 31, 2021
Selected Balance sheet data:		
Cash, cash equivalents, and restricted cash	$ 35,964	$ 51,702
Short-term investments	1,189	10,207
Working capital[(1)]	27,575	37,349
Total assets attibutable to discontinued operations	26,542	63,210
Total assets	221,887	267,448
Long-term debt	51,939	148,507
Royalty financing liability	75,006	—
Total liabilities attibutable to discontinued operations	11,164	17,205
Total liabilities	227,360	232,996
Non-controlling interests	(17,408)	(16,679)
Total stockholders' (deficit) equity	(5,473)	34,452

([1]) working capital: total current assets less total current liabilities

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

	Three Months ended June 30,		Six Months ended June 30,	
	2022	2021	2022	2021
Revenue				
Product sales, net	$ 25,786	$ 20,394	54,154	38,881
License and other revenue	5,730	304	6,504	20,969
Total revenue	31,516	20,698	60,658	59,850
Cost of sales	(23,092)	(19,117)	(45,613)	(34,158)
Gross profit	8,424	1,581	15,045	25,692
Research and development expenses	(13,094)	(20,646)	(27,179)	(42,390)
Selling, general, and administrative expenses	(17,172)	(17,641)	(30,979)	(36,840)
Interest income	46	32	122	61
Interest expense	(4,307)	(5,608)	(8,820)	(10,538)
Gain (loss) on partial extinguishment of debt	2,051	—	(1,450)	—
Income tax benefit (expense)	19	11,035	(8)	10,881
Net loss from continuing operations	(24,033)	(31,247)	(53,269)	(53,134)
Gain (loss) from discontinued operations	(8,341)	(3,368)	2,963	(7,084)
Net loss	(32,374)	(34,615)	(50,306)	(60,218)
Less: net loss attributable to non-controlling interests	(217)	(341)	(729)	(894)
Net loss attributable to Athenex, Inc.	(32,157)	(34,274)	(49,577)	(59,324)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	(0.28)	(0.33)	(0.44)	(0.60)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	113,006,158	103,370,268	111,762,029	98,427,561