

**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 10, 2022

ATHENEX, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38112
(Commission
File Number)

43-1985966
(IRS Employer
Identification No.)

1001 Main Street, Suite 600, Buffalo, New York
(Address of principal executive offices)

14203
(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 May 10, 2022, Athenex, Inc. (the “Company”) issued a press release to report financial results for the quarter ended March 31, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the Company on May 10, 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: May 10, 2022

/s/ Joe Annoni

Name: Joe Annoni

Title: Chief Financial Officer

Athenex Provides First Quarter 2022 Financial Results and Business Update

- *Reports 1Q product sales of \$29.0M, up 42% year-over-year*
- *Encouraging interim update from ANCHOR study of KUR-502 presented at ASTCT with 60% overall response rate (ORR) and 6-month complete response (CR) rate of 29% in the NHL cohort*
- *Abstract for KUR-501 in GINAKIT2 study accepted at ASGCT; 25% (3/12) ORR with 2 out of 3 responses at dose level 4 (1x10⁸ cells/m²)*
- *Corporate reorganization and cost savings initiatives well underway, demonstrated by 28% and 39% reduction in SG&A expenses and R&D expenses, respectively, over the prior year period*
- *Raising full-year 2022 product revenue guidance range to 20-25% growth from previous range of 15-20% growth compared to 2021*
- *Management to host conference call and webcast today at 8:00 a.m. ET*

Buffalo, N.Y., May 10, 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 first quarter ended March 31, 2022.

“Our focus for 2022 continues to be on transforming Athenex into a robust, well-positioned cell therapy company with a solid balance sheet. We are proud of the progress we have made since announcing our strategic pivot and remain committed to delivering on cutting operating expenses and executing on additional monetization of noncore assets” said Johnson Lau, Chief Executive Officer of Athenex. “Our cell therapy programs continue to generate exciting data, which we are looking forward to presenting throughout the year. We believe our NKT cell therapy platform will be the main driver of future growth and will position us to be a differentiated leader in cell therapy space. Our corporate initiatives continue to set us up for successful value creation and allow us to further execute on our ultimate mission of bringing innovative treatments to cancer patients.”

Corporate Developments

Business Updates

- Lowered operating expenses in the first quarter of 2022 by 34% versus the prior year period, with additional cost-cutting underway
- APD/APS division delivered four new product launches and generated 42% growth in product revenues during the first quarter of 2022 versus the prior year period
- Plan to monetize non-core assets to support development of cell therapy pipeline

Key Anticipated Milestones

- Oral presentation of interim analysis of Phase 1 GINAKIT2 study of KUR-501, our autologous GD2 CAR NKT program in pediatric relapsed/refractory high-risk neuroblastoma, at the American Society of Gene & Cell Therapy (ASGCT) annual meeting on May 16, 2022 at 2:30 p.m. ET
- Online presentation of KUR-503 preclinical data, our allogeneic GPC3 CAR-NKT cell program in liver cancer, at the American Society of Clinical Oncology (ASCO) on June 3-7, 2022
- Multi-center expansion of CD19 CAR-NKT ANCHOR study of KUR-502 permitted under the newly allowed IND
- Data update from ANCHOR study evaluating allogeneic CD19 CAR NKT therapy KUR-502 at American Society of Hematology (ASH) expected in December 2022
- Regulatory interactions with MHRA for Oral Paclitaxel in advanced breast cancer in UK
- Phase 2 data from I-SPY 2 trial of Oral Paclitaxel in combination with dostarlimab in neoadjuvant breast cancer expected in 2H 2022
- IND filing for KUR-503, our allogeneic CAR-NKT program in liver cancer planned in 2023

First Quarter 2022 and Recent Business Highlights

Clinical Programs

Cell Therapy

- Presented interim analysis from ANCHOR study of KUR-502 at the American Society of Transplantation and Cellular Therapy (ASTCT). Reported 60% ORR and 6-month CR rate of 40% in five patients of the NHL cohort, including 1 ongoing CR at 34 weeks. Allogeneic CD19 CAR-NKT cells well tolerated with no cases of cytokine release syndrome (CRS) in the NHL cohort, no immune effector cell-associated neurotoxicity syndrome (ICANS) and no graft versus host disease (GvHD)
- Upcoming presentation of abstract from interim analysis of Phase 1 GINAKIT2 study of KUR-501, an autologous GD2 CAR-NKT cell therapy for relapsed/refractory high risk neuroblastoma at ASGCT. Data presented shows dose response at low doses of 1×10^8 cells/m², including a durable complete response persisting 12 months. Analysis of results found that response correlates with CD62L+ NKT frequency as well as CAR-NKT area under the curve (AUC). Treatment remains well-tolerated with no dose-limiting toxicity, no ICANS, and one case of grade 2 CRS.

Commercial Update

Klisyri® (tirbanibulin)

- Commercial partner Almirall reported 3.6% market share in the U.S.
- Klisyri® was granted Medicare coverage and now has 40% coverage
- Uptake remains strong in German market, and pre-launch activities in place to support the continued rollout in Europe
- American Academy of Dermatology guidelines for the management of actinic keratosis included Klisyri® receiving the strongest recommendation

- Athenex Pharmaceutical Division (APD) currently markets a total of 29 products with 54 SKUs.
- Athenex Pharma Solutions (APS) currently markets 6 products with 16 SKUs

First Quarter 2022 Financial Highlights

Revenues from product sales increased to \$29.0 million for the three months ended March 31, 2022, from \$20.4 million for the three months ended March 31, 2021, an increase of \$8.6 million or 42%. This increase was primarily attributable to an increase in APD specialty product sales, which increased by \$9.5 million as the result of increases in shortage product sales and product launches during 2022.

License fees and other revenue for three months ended March 31, 2022 was \$0.8 million, compared to \$20.7 million for the same period in 2021, a decrease of \$19.9 million. This decrease was primarily due to the recognition of \$20.0 million of license revenue pursuant to the 2017 Almirall License Agreement upon the launch of Klisyri in the U.S. during the three months ended March 31, 2021.

Cost of sales for the three months ended March 31, 2022 totaled \$23.3 million, an increase of \$6.9 million, or 42%, as compared to \$16.4 million for the three months ended March 31, 2021. The increase in our cost of specialty product sales was primarily due to an increase in cost of APD and 503B product sales, of \$5.7 million and \$2.5 million, respectively. These were partially offset by a \$1.3 million decrease in cost of API product sales.

R&D expenses totaled \$14.0 million for the three months ended March 31, 2022, a decrease of \$9.1 million, or 39%, as compared to \$23.1 million for the three months ended March 31, 2021. This decrease was primarily due to a decrease in Oral Paclitaxel product development and medical affairs costs, costs of clinical and regulatory operations, and costs of preclinical operations.

SG&A expenses totaled \$14.9 million for the three months ended March 31, 2022, a decrease of 28% as compared to \$20.7 million for the three months ended March 31, 2021. The decrease was primarily due to a \$6.7 million decrease of costs for preparing to commercialize Oral Paclitaxel as significant pre-launch activities occurred in 2020, partially offset by a \$1.3 million increase in operating costs.

Interest income and interest expense totaled \$0.1 million and \$4.5 million, respectively, for the three months ended March 31, 2022. Interest income and interest expense for three months ended March 31, 2021 totaled less than \$0.1 million and \$4.9 million, respectively. Interest expense in both periods was incurred from the Senior Credit Agreement with Oaktree.

Income tax expense for the three months ended March 31, 2022 amounted to less than \$0.1 million, compared to \$0.2 million for the same period in 2021. We did not record a provision for U.S. federal income taxes for the three months ended March 31, 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 March 31, 2022 was \$17.4 million, or (\$0.16) per diluted share, as compared to a net loss of \$25.1 million, or (\$0.27) 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 March 31, 2022, refer to the Form 10Q filed with the SEC.

2022 Financial Guidance

Athenex now expects product sales growth to be in the range of 20-25% over the prior year period, versus the prior range of 15-20% growth, year-over-year, due to the strong performance of Athenex's APD/APS division, earlier than expected NY State license, and the robust pipeline of launches planned for the remainder of 2022.

Cash Conservation Update

As of March 31, 2022, the Company had cash and cash equivalents of \$27.2 million, restricted cash of \$13.8 million, and short-term investments of \$10.2 million, for a total of \$51.2 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, Tuesday, May 10, 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: 10018962

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 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 (2) Orascovery, based on a P-glycoprotein inhibitor, and (3) Src Kinase Inhibition. 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," "believe," "continue," "could," "expect," "guidance," "implementing," "intend," "may," "plan," "underway," "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 history of operating losses and our need and ability to raise additional capital to continue as a going concern; our ability to successfully redirect our resources and reduce our operating expenses; our ability to 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; 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; 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; 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; 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; whether we enter into a preferred contract manufacturing agreement with ImmunityBio; 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

Investors

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

	March 31, 2022	December 31, 2021
Selected Balance sheet data:		
Cash, cash equivalents, and restricted cash	\$ 40,974	\$ 51,702
Short-term investments	10,235	10,207
Working capital ⁽¹⁾	50,804	37,349
Total assets	236,862	267,448
Long-term debt	126,911	150,337
Total liabilities	216,063	232,996
Non-controlling interests	(17,191)	(16,679)
Total stockholders' equity	20,799	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 March 31,	
	2022	2021
Revenue		
Product sales, net	\$ 28,950	\$ 20,360
License and other revenue	774	20,665
Total revenue	29,724	41,025
Cost of sales	(23,295)	(16,405)
Gross profit	6,429	24,620
Research and development expenses	(13,990)	(23,070)
Selling, general, and administrative expenses	(14,935)	(20,736)
Interest income	77	29
Interest expense	(4,521)	(4,908)
Loss on partial extinguishment of debt	(3,501)	—
Income tax expense	(28)	(154)
Net loss from continuing operations	(30,469)	(24,219)
Gain (loss) from discontinued operations	12,537	(1,384)
Net loss	(17,932)	(25,603)
Less: net loss attributable to non-controlling interests	(512)	(553)
Net loss attributable to Athenex, Inc.	(17,420)	(25,050)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	(0.16)	(0.27)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	110,504,076	93,429,935