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): August 7, 2019

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 August 7, 2019, Athenex, Inc. (the "Company") issued a press release to report financial results for the quarter ended June 30, 2019. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

Also on August 7, 2019, the Company issued a press release to report positive results from its Phase 3 study of oral paclitaxel and encequidar in patients with metastatic breast cancer. This press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Items 2.02 and 7.01 of this Form 8-K and Exhibits 99.1 and 99.2 attached hereto 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 of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on August 7, 2019 regarding financial results for the quarter ended June 30, 2019
99.2	Press release issued by the Company on August 7, 2019 regarding results from Phase 3 study of oral paclitaxel and encequidar in patients with metastatic breast cancer

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: August 7, 2019

/s/ Randoll Sze

Name: Randoll Sze
Title: Chief Financial Officer

Exhibit 99.1

Athenex, Inc. Announces Second Quarter 2019 Financial Results, Positive Phase III Results on Oral Paclitaxel plus Encequidar and Increased Product Sales Guidance

Positive Phase III results of Oral Paclitaxel show statistically significant improvement in overall response rate in metastatic breast cancer

Company is preparing two NDA submissions following successful Phase III studies announced within the last twelve months

Expanded clinical pipeline with FDA's allowance of the IND application for PT01 (Pegtomarginase)

Approximately 92% year/year increase in Q2 product sales

Raising product sales guidance to 30% - 35% year/year growth in 2019

Conference call and live audio webcast at 8:00 a.m. Eastern Time today

BUFFALO, N.Y., August 7, 2019 — Athenex, Inc. (NASDAQ: ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer, today announced its financial results and business highlights for the second quarter of 2019.

"Athenex has continued to execute successfully across all of our strategic objectives in our development programs as well as our commercial operations and readiness," stated Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex. "We are particularly excited about today's announcement of success in our Phase III study of oral paclitaxel and encequidar in metastatic breast cancer. We believe the success of this program serves to derisk our technology platform and provides further validation as we continue advancing our other Orascovery candidates (including docetaxel, cabazitaxel, irinotecan, topotecan and eribulin) and combination therapies."

Mr. Jeffrey Yordon, Chief Operating Officer of Athenex, commented, "We have been building the commercial infrastructure in manufacturing (active pharmaceutical ingredient and dosage-form), logistics and marketing to support the potential launch of oral paclitaxel and encequidar, which, based on the Phase III results announced, we believe has significant potential. Athenex is in the process of transforming from a clinical stage company to a fully integrated, commercial organization focused on delivering innovative cancer treatments that can improve patient outcomes."

Second Quarter 2019 and Recent Business Highlights:

Clinical Programs:

Phase III study of oral paclitaxel and encequidar for metastatic breast cancer

- Primary efficacy endpoint met in Phase III clinical trial of oral paclitaxel and encequidar (Oral Paclitaxel) versus IV paclitaxel in patients with metastatic breast cancer. Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel with an ORR of 36% compared to 24% based on intention-to-treat analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with $p \leq 0.01$ in all analyses.
- Results also showed that the proportion of confirmed responders with a duration of response more than 150 days was 2.5 times higher in Oral Paclitaxel versus IV paclitaxel.

- There were strong trends in progression-free survival (p = 0.077) and overall survival (p = 0.11) favoring Oral Paclitaxel over IV paclitaxel.
- Neuropathy was less frequent with Oral Paclitaxel compared to IV paclitaxel.
- Plan to request a pre-NDA meeting as soon as possible and present data at a major upcoming scientific meeting.

Other

- Reported promising clinical results from a clinical study of oral paclitaxel and encequidar in cutaneous angiosarcoma. Preliminary data show rapid, visible response to oral paclitaxel and encequidar monotherapy in the first seven subjects, including three complete responses.
- Four posters featuring the Company's products/technologies were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Preliminary positive clinical activity signals observed in a cohort of patients with psoriasis treated with tirbanibulin ointment (formerly known as KX2-391) in a Phase I clinical trial.
- The U.S. Food and Drug Administration (FDA) allowed the Company's Investigational New Drug (IND) application for the clinical investigation of PT01 (Pegtomarginase) for the treatment of patients with advanced malignancies.

Corporate Announcements:

- Launched new brand, Athenex Oncology, and corresponding website, AthenexOncology.com, during the 2019 ASCO Annual Meeting.
- Strategically expanded presence in Europe and Latin America to grow the Company's global clinical research and development capacity and maximize the global potential of its pipeline.
    - Formed a subsidiary in the U.K. and established offices in Manchester.
    - Entered into a definitive agreement to acquire certain assets of CIDAL Limited, a contract research organization (CRO) with headquarters in Guatemala and operations in various countries in Latin America.
- Voluntarily suspended production activities at its active pharmaceutical ingredient (API) plant in Chongqing (Taihao API plant). This decision was made based on discussions with the Department of Emergency Management of Chongqing (DEMC) related to concerns raised about the location of our plant. The DEMC has been evaluating the safety of all chemical and other plants in the region after recent accidents at other plants. In the meantime, the Company has been working on the build-out of the new API plant in Chongqing, and the plant is expected to commence operations in the first half of 2020.

Commercial Business:

- Athenex Pharmaceutical Division (APD) currently markets a total of 30 products with 58 SKUs.
- Athenex Pharma Solutions (APS) currently markets 5 products in total with 13 SKUs.
- Goal is to launch 9-12 products in 2019.

Financial Results for the Quarter Ended June 30, 2019

Product sales for the three months ended June 30, 2019 were $22.0 million, compared with $11.5 million for the three months ended June 30, 2018, an increase of $10.6 million or 92%. This increase was primarily attributable to an increase in 503B revenue of $6.0 million, an increase in specialty product revenue of $4.6 million, and an increase in API sales of $0.6 million.

Cost of sales for the three months ended June 30, 2019 totaled $16.9 million, an increase of $7.5 million, or 79%, as compared to $9.4 million for the three months ended June 30, 2018. This was primarily due to an increase of $5.8 million in cost of sales from the sale of specialty products and $1.7 million from 503B and API products. Gross margin attributable to product sales increased from 17.7% in the three months ended June 30, 2018 to 23.1% in the three months ended June 30, 2019, primarily as a result of change in product mix.

Research and development expenses for the three months ended June 30, 2019 were $18.5 million as compared to $26.6 million for the three months ended June 30, 2018. This was primarily due to a decrease in licensing fees, as well as expenses in relation to clinical operations and product development. The decrease in these R&D expenses was offset primarily by an increase of $1.1 million of preclinical development costs related to the arginase and TCR-T platforms.

Selling, general and administrative expenses for the three months ended June 30, 2019 were $17.2 million as compared to $12.8 million for the three months ended June 30, 2018. This was primarily due to an increase of $3.7 million related to the costs of preparing to commercialize our proprietary drugs, if approved, and an increase of $1.3 million in general administrative expenses including legal fees and other professional service fees, offset by a decrease of $0.6 million in administrative related compensation expense.

Net loss attributable to Athenex for the three months ended June 30, 2019 was $32.0 million, or $0.44 per diluted share, compared to a net loss of $36.9 million, or $0.58 per diluted share, in the same period last year.

On May 7, 2019, the Company closed a private placement transaction in which it issued 10 million shares of common stock to three institutional investors (Perceptive Advisors, Avoro Capital Advisors (formerly known as venBio Select Advisor) and OrbiMed) at a purchase price of $10.00 per share, for net proceeds of approximately $99.9 million to Athenex.

The Company received a $20 million milestone payment from Almirall S.A. during the second quarter of 2019 in connection with the partnership on tirbanibulin and expects this payment to be recorded as revenue in the second half of 2019.

At June 30, 2019, the Company had cash, cash equivalents, restricted cash and short-term investments of $165.9 million, compared to $107.4 million at December 31, 2018. Based on the current operating plan, we expect that our cash, cash equivalents, restricted cash and short-term investments as of June 30, 2019, together with cash to be generated from our operating activities, will enable us to fund our operations into the third quarter in 2020.

Financial Results for the Six Months Ended June 30, 2019

Product sales reached $47.2 million for the six months ended June 30, 2019, compared with $24.1 million for the six months ended June 30, 2018, an increase of $23.1 million or 96%.

Total revenue for the six months ended June 30, 2019 was $47.5 million, a decrease of $1.9 million, or 4%, as compared to $49.4 million for the six months ended June 30, 2018. The decrease was primarily due to $25.0 million related to license milestone revenue earned in the

first quarter of 2018, and $1.1 million decrease in medical device product sales and contract manufacturing revenue, offset by a $24.3 million the increase in product sales, of which $10.9 million was from the sales of 503B products, $10.5 million was from sales of specialty products, and $2.8 million was from API.

Cost of sales for the six months ended June 30, 2019 totaled $36.8 million, an increase of $16.1 million, or 77%, as compared to $20.8 million for the six months ended June 30, 2018. This was primarily due to the increase of $12.0 million in cost of sales from the sale of specialty products and $4.1 million in cost of sales from 503B and API products. Gross margin attributable to product sales increased from 13.7% in the six months ended June 30, 2018 to 21.9% in the six months ended June 30, 2019, primarily as a result of change in product mix.

Research and development expenses for the six months ended June 30, 2019 were $43.0 million as compared to $47.9 million for the six months ended June 30, 2018. This was primarily due to a decrease in licensing fees, as well as expenses in relation to clinical operations and product development. The decrease in these R&D expenses was offset by an increase of $2.8 million of preclinical development costs related to the arginase and TCR-T platforms, and a $1.7 million increase of R&D related compensation.

Selling, general and administrative expenses for the six months ended June 30, 2019 were $32.4 million as compared to $25.9 million for the six months ended June 30, 2018. This was primarily due to an increase of $6.2 million related to the costs of preparing to commercialize our proprietary drugs, if approved, and an increase of $1.3 million of general administrative expenses including legal fees and other professional service fees, offset by a decrease of $1.3 million in administrative related compensation expense.

Net loss attributable to Athenex for the six months ended June 30, 2019 was $67.3 million, or $0.96 per diluted share, compared to a net loss of $44.2 million, or $0.71 per diluted share, in the same period last year.

Outlook and Upcoming Milestones:

- Intend to submit results from Phase III clinical trial of oral paclitaxel and encequidar in metastatic breast cancer for presentation at a major upcoming scientific meeting and for peer review publication (Q4 2019 / H1 2020)
- Expect to request a pre-NDA meeting as soon as possible for oral paclitaxel and encequidar in metastatic breast cancer (Q4 2019)
- Expect to file an NDA for tirbanibulin ointment in actinic keratosis (Q1 2020)

Financial Guidance:

Athenex provides revenue guidance for product sales only. The Company is raising its product sales guidance for 2019 and is now forecasting that product sales this year will increase by between 30% and 35% year-over-year from $56.4 million in 2018 (versus previous guidance of 25% – 30% annual growth). This new revenue guidance has taken into account the court's latest decision in the Vasopressin proceeding and the suspension of operations at our Taihao API plant. The revenue guidance excludes license and collaboration fees.

Conference Call and Webcast Information:

The Company will host a conference call and live audio webcast today, Wednesday, August 7, 2019, at 8:00am Eastern Time to discuss the 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 13691069. The live conference call and replay can be accessed via audio webcast at http://public.viavid.com/index.php?id=134662 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 non-absorbed 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; and Manchester, U.K. 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; our ability to integrate CIDAL's assets into our existing operations; competition; intellectual property risks; risks relating to doing business in China; the uncertainty of when, if at all, we will be able to resume producing API in our Chongqing plant; 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

Investor Relations:
Tim McCarthy
Managing Director, LifeSci Advisors, LLC
Tel: +1 716-427-2952
Direct: +1 212-915-2564

Athenex, Inc.:
Randoll Sze
Chief Financial Officer
Email: randollsze@athenex.com

Jacqueline Li
Corporate Development and Investor Relations
Email: jacquelineli@athenex.com

ATHENEX, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	June 30, 2019	December 31, 2018
	(in thousands)	
Balance sheet data:		
Cash, cash equivalents, and restricted cash	$122,198	$ 49,794
Short-term investments	43,718	57,629
Goodwill	37,528	37,495
Working capital *	154,372	119,143
Total assets	322,273	231,095
Long-term debt	50,811	46,764
Total liabilities	155,066	102,326
Non-controlling interests	(11,657)	(10,586)
Total stockholders' equity	$167,207	$ 128,769

* Working capital: total current assets — 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands)	(in thousands)	(in thousands)	(in thousands)
Revenue				
Product sales, net	$ 22,033	$ 11,471	$ 47,196	$ 24,076
License fees and consulting revenue	105	91	210	25,182
Grant revenue	59	3	98	143
Total revenue	22,197	11,565	47,504	49,401
Cost of sales	(16,942)	(9,443)	(36,844)	(20,769)
Gross profit	5,255	2,122	10,660	28,632
Research and development expenses	(18,507)	(26,572)	(42,982)	(47,875)
Selling, general, and administrative expenses	(17,169)	(12,817)	(32,357)	(25,897)
Interest (expense) income	(1,279)	368	(2,751)	595
Income tax (expense) benefit	(405)	(51)	(905)	256
Net loss	(32,105)	(36,950)	(68,335)	(44,289)
Less: net loss attributable to non-controlling interests	(74)	(91)	(1,071)	(132)
Net loss attributable to Athenex, Inc.	$ (32,031)	$ (36,859)	$ (67,264)	$ (44,157)
Net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	$ (0.44)	$ (0.58)	$ (0.96)	$ (0.71)
Weighted-average shares used in computing net loss per share attributable to Athenex, Inc. common stockholders, basic and diluted	73,114,392	63,310,219	70,079,771	62,487,328

ATHENEX, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2019	**2018**
	(in thousands)	
Net cash used in operating activities	$ (37,773)	$ (38,029)
Net cash provided by (used in) investing activities	4,764	(56,553)
Net cash provided by financing activities	104,698	69,099
Net effect of foreign exchange rate changes	715	267
Net increase (decrease) in cash and cash equivalents	72,404	(25,216)
Cash, cash equivalents, and restricted cash at beginning of period	49,794	39,284
Cash, cash equivalents, and restricted cash at end of period	$ 122,198	$ 14,068

Exhibit 99.2

Athenex Announces Oral Paclitaxel and Encequidar had a Significantly Higher Response Rate Over IV Paclitaxel in a Phase III Pivotal Study in Metastatic Breast Cancer

- *Study met primary endpoint showing statistically significant improvement in overall response rate for oral paclitaxel and encequidar (Oral Paclitaxel) compared to IV paclitaxel based on intention-to-treat (ITT) analysis*
- *Strong trend in progression-free survival (PFS) and overall survival (OS) of Oral Paclitaxel compared to IV paclitaxel*
- *Proportion of confirmed responders with duration of response >150 days was 2.5 times higher for Oral Paclitaxel than IV paclitaxel*
- *Neuropathy was less frequent with Oral Paclitaxel compared to IV paclitaxel*

****

Plan to request a pre-NDA meeting as soon as possible and present data at a major upcoming scientific meeting

ATNX to discuss the results on the earnings conference call today at 8:00am Eastern Time

BUFFALO, N.Y., August 07, 2019 — Athenex, Inc. (Nasdaq: ATNX), a global biopharmaceutical company dedicated to the discovery, development and commercialization of novel therapies for the treatment of cancer, today announced topline data showing that oral paclitaxel and encequidar (Oral Paclitaxel) met the primary efficacy endpoint with statistically significant improvement over IV paclitaxel in a Phase III pivotal study in metastatic breast cancer.

A total of 402 typical metastatic breast cancer patients were enrolled in a 2 to 1 ratio of Oral Paclitaxel to IV paclitaxel in the ITT population (265 in the Oral Paclitaxel group versus 137 in the IV paclitaxel group). Patient demographics were balanced in the two treatment groups. The primary efficacy endpoint was overall tumor response rate (ORR) confirmed at two consecutive timepoints using RECIST v1.1 criteria. Blinded assessments of tumor response were made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.

Oral Paclitaxel showed a statistically significant improvement compared to IV paclitaxel on the primary efficacy endpoint, with an ORR of 36% for the Oral Paclitaxel group compared to 24% for IV paclitaxel patients based on ITT analysis ($p = 0.01$). Oral Paclitaxel also showed statistically significant improvement compared to IV paclitaxel based on other analyses on populations excluding non-evaluable patients (which would give higher response rates), with p-values ≤ 0.01 in all analyses. In addition, the results showed that the proportion of confirmed responders with a duration of response of more than 150 days was 2.5 times higher in the Oral Paclitaxel group than in the IV paclitaxel group.

Based on the data cut-off on July 25, 2019, there was a strong trend in progression-free survival ($p = 0.077$) favoring Oral Paclitaxel over IV paclitaxel, and a strong trend in overall survival (p =

0.11) favoring Oral Paclitaxel over IV paclitaxel. At the cut-off date, a higher proportion of patients on Oral Paclitaxel compared with IV paclitaxel remained progression-free and Athenex expects the PFS and OS trend will continue to improve upon follow-up.

In the study, the Oral Paclitaxel group had lower incidence and severity of neuropathy compared to IV paclitaxel: 57% of IV paclitaxel patients experienced neuropathy (all grades) versus 17% of Oral Paclitaxel patients, with grade 3 neuropathy observed in 8% of IV paclitaxel patients versus 1% of Oral Paclitaxel patients. The results also showed lower incidence of alopecia, arthralgia and myalgia in the Oral Paclitaxel group. The incidence of neutropenia was similar in both groups, but there were more incidents of grade 4 neutropenia and infection in the Oral Paclitaxel group. There were also more gastro-intestinal side effects in the Oral Paclitaxel group.

Dr. Rudolf Kwan, Chief Medical Officer of Athenex, stated, “This is the second successful Phase III clinical program accomplished by the clinical team this year. We are excited by the positive results in the Phase III pivotal study, demonstrating improved ORR for Oral Paclitaxel compared to IV paclitaxel across a full spectrum of analyses and lower incidence of neuropathy in the Oral Paclitaxel group. We will be preparing our NDA submission as soon as possible. We are also investigating additional indications for Oral Paclitaxel as well as combinations with other anti-cancer drugs, including biologics and immuno-oncology drugs. With a longer duration of response observed in this trial, we will look into the potential of this drug candidate in metronomic dosing and maintenance therapy. Based on these results, we will aggressively advance the other oral chemotherapy programs.”

Dr. Johnson Lau, Chief Executive Officer and Chairman of Athenex, commented, “Based on the results of the Phase III study, together with the preliminary results generated in the angiosarcoma study, Athenex believes that Oral Paclitaxel has the potential to represent a new class of oral anti-cancer drugs, if approved, based on the findings from this Phase III study showing statistically significant improvement in ORR as monotherapy and longer duration of response over IV paclitaxel, as well as strong trends in improved PFS and OS in patients with metastatic breast cancer. There is also evidence of early onset of activity in angiosarcoma. Adding to this potential are the favorable safety data from this study showing lower incidence of neuropathy, which is currently a major reason for discontinuing IV paclitaxel treatment. There is a potential for Oral Paclitaxel, which is not designed to require steroid pre-medication for immunosuppression, to serve as a cornerstone in chemotherapy in combination with other small molecule anti-cancer drugs, biologics, and immuno-oncology treatment approaches, including other drug candidates in our oncology pipeline.”

“We believe the success of the Oral Paclitaxel program serves as a validation for our Orascovery technology platform, which also includes the oral delivery of docetaxel, cabazitaxel, irinotecan, topotecan and eribulin,” continued Dr. Lau. “Athenex is transforming from a clinical stage company into a fully integrated company with late-stage oncology product candidates and capabilities across the pharmaceutical value chain, including manufacturing and marketing.”

Athenex is also evaluating Oral Paclitaxel in combination with ramucirumab in patients with gastric cancer in an expansion phase of a Phase 1b study, which has shown encouraging preliminary data. Oral Paclitaxel also showed encouraging clinical activity in a pilot study of patients with angiosarcoma. The company is also testing the combination of Oral Paclitaxel with an anti-PD1, pembrolizumab, in patients with advanced solid malignancies.

The Orascovery platform was initially developed by Hanmi Pharmaceuticals and licensed exclusively to Athenex for all major worldwide territories except Korea, which is retained by Hanmi. PharmaEssentia Corp. licensed the Taiwan, Singapore and Vietnam rights of Oral Paclitaxel and ZenRx licensed the Australia and New Zealand rights of Oral Paclitaxel from Athenex.

About the Phase III Study of Oral Paclitaxel and Encequidar

The Phase III pivotal study is a randomized, controlled clinical trial designed to compare the the safety and efficacy of Oral Paclitaxel monotherapy against intravenous paclitaxel monotherapy in patients with metastatic breast cancer. The primary endpoint was tumor response rate (confirmed by scans at two consecutive timepoints) as assessed by RECIST v1.1 criteria, a generally accepted method for assessing tumor response. Blinded assessments of tumor response are made by two independent radiologists and an independent adjudicator, using a computer algorithm to assign responses.

Conference Call and Webcast Information

Company management will discuss the Phase III results during its quarterly earnings conference call, today, Wednesday, August 7, 2019, at 8:00am Eastern Time. 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 13691069. The live conference call and replay can be accessed via audio webcast at http://public.viavid.com/index.php?id=134662 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 non-absorbed 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; and Manchester, UK. 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," "evaluate," "expect," "foresee," "guidance," "intend," "investigate," "likely," "may," "plan," "potential," "predict," "preliminary," "prepare," "potential," "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; competition; intellectual property risks; risks relating to doing business in China; the uncertainty of when, if at all, we will be able to resume producing API in our Chongqing plant; 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

Investor Relations:
Tim McCarthy
Managing Director, LifeSci Advisors, LLC
Tel: +1 716-427-2952
Direct: +1 212-915-2564

Athenex, Inc.:
Randoll Sze
Chief Financial Officer
Email: randollsze@athenex.com

Jacqueline Li
Corporate Development and Investor Relations
Email: jacquelineli@athenex.com