LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

January 16, 2018

Athenex Inc. (ATNX - $16.49)

Healthcare/Biotechnology

Ticker:	**ATNX**
Rating:	**Buy**
Price Target: ↑Raise	**$38.00**

FDA Accepted the Study Design of Oraxol in Metastatic Breast Cancer Phase III Trial

ATNX reported this morning that the FDA has accepted the study design of Oraxol in metastatic breast cancer (mBC) Phase III trial.

- **Details.** ATNX indicated that the agency has suggested that a single comparative trial could be adequate, if it meets the primary endpoint with an acceptable benefit/risk profile, for supporting the registration of Oraxol for a mBC indication in the U.S. As a reminder, the ongoing Phase III trial is a randomized controlled study intended to show superiority of response rates of Oraxol over IV paclitaxel in mBC patients. Response rate will be measured by radiological scans utilizing RECIST v1.1 guidelines conducted by centralized blinded radiologist group at weeks 10, 16, and 19. The study plans to recruit 360 patients with 2:1 randomization between the treatment and comparator arm. Two interim analyses were planned when 90 and 180 patients have received treatment, respectively. The first interim analysis was completed in Oct. 2017 with a positive response from the DSMB and the second interim analysis is expected in mid-2018. Further, our discussion with management indicated that the patient recruitment of the Phase III is on track.
- **Implications.** We view today's announcement a very positive development for ATNX. Some investors might have concern regarding the lack of a typical EOP2 meeting with the FDA prior to the company starting the Phase III trial; and we believe today's news could alleviate that overhang. The company's strategy from the beginning has been to first generate some clinical data from the Phase III trial before discussing with the FDA, instead of having an EOP2 meeting beforehand. Management believes this approach could provide more credible clinical material for the discussion with the agency since they could have a peek on the interim data. In addition, several recent developments, including receiving Promising Innovative Medicine (PIN) designation from UK and commencement of Phase I study in China all bode well for the development of Oraxol globally.
- **Action.** We are reiterating our Buy rating and increasing our target price to $38 from $36 (mainly from increasing the probability of success of both lead programs) to reflect our more bullish view on two promising lead late stage products and multiple potentially positive catalysts over the next 18 months. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Trading Data:

Last Price (1/12/2018)	$15.87
52-Week High (7/5/2017)	$20.79
52–Week Low (6/14/2017)	$11.21
Market Cap. (MM)	$920
Shares Out. (MM)	58.121

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-1.01A	-0.88A	-0.41A	-0.47	-2.61	NM
FY-16A	-0.27	-0.31	N.A.	N.A.	-2.19	NM
FY-15A	N.A.	N.A.	N.A.	N.A.	-1.50	NM
FY-14A	N.A.	N.A.	N.A.	N.A.	N.A.	NM

Source: Laidlaw & Company estimates

Yale Jen, Ph.D.
Managing Director /
Senior Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

- **Multiple positive events late last year boost our confidence.** We continue to view ANTX as a successful execution story with:
  - **Partnership with Almirall of KX2-391 gained an experienced dermatology partner with favorable terms and allowing ANTX continuing focus on oncology.** For the deal, Almirall will gain the rights to market KX2-391 (KX-01) in the U.S. and Europe, including Russia. In exchange, ANTX is entitled to up to $55MM up-front and near-term payments. In addition, ANTX could receive regulatory and developmental milestone payments of $65MM and sale-based milestone payments up to $155MM. ANTX also is entitled for sales-based tiered royalties starting from 15%. Almirall is a Barcelona, Spain-based global specialty pharmaceutical company with strong focus on dermatology and a sales footprint in the U.S. via its subsidiary, Aqua. Almirall generated €860MM (~$1 billion) revenue in 2016. We anticipate KX2-391 in actinic keratosis, if approved, would be a critical element of Almirall's growth strategy after the company announced a more measured guidance update in mid-2017. The more detailed KX-01 in actinic keratosis Phase II data will be presented at the American Academy of Dermatology meeting on Feb. 17, 2018. Further, our discussion with management indicated that the patient recruitment of the Phase III is on track with potential completion in 1H18.
  - **Additional developments of Oraxol and other Orascovery-based programs are very encouraging.** Oraxol recently received a Promising Innovative Medicine (PIN) designation from the UK Medicine and Healthcare Products Regulatory Agency (MHRA), which we believe demonstrates the recognition of Oraxol's potential for a positive benefit-risk balance and its capability of fulfilling unmet need. A tangible benefit of the PIN designation is to qualify Oraxol to apply for Early Access to Medicine Scheme (EAMS), and allow Oraxol to be prescribed to patients prior to being approved. We believe prior to Oraxol, only four PIN designations were issued and among them, three are checkpoint inhibitors and one is a tyrosine kinase regulator. In addition, ATNX will start a Phase I study of Oraxol and initiated the development of oral eribulin in China. Eribulin is one of the lead oncology products sold by Eisai with 2016 annual sales of ~$335MM (¥37.3 billion). Given eribulin (Halaven) is the only chemotherapy that increases OS as monotherapy in metastatic breast cancer and soft tissue sarcoma, potential success of the oral eribulin could potentially provide ATNX a broader therapy options (along with Oraxol and eribulin is indicated for second line metastatic breast cancer) in managing breast cancer.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Oraxol	Metastatic breast cancer	Potential discussion with the FDA regarding path forward	**1H18**	***
		Potential second interim (n=180) Phase III trial data readout	**Mid-18**	****
		Potential topline Phase III trial data readout	**4Q19**	****
KX-01	Actinic keratosis (AK)	Potentially report full Phase II results at the American Academy of Dermatology meeting	**Feb. 17, 2018**	***
		Potential completion of patient recruitment of Phase III trial	**1Q18**	***
		Potential topline Phase III trial data readout	**Mid- to 3Q18**	****
		Potential approval	**2H19**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Major risks

Clinical study failure could have a major negative impact on ATNX share value. Despite ATNX's two lead products have demonstrated different degrees of promising efficacy and safety, clinical risks remain for either drug or future pipeline products as they might fail in the late stage clinical trials. For Oraxol, it is still too early to determine whether the drug can demonstrate a better safety or more efficacious vs. IV paclitaxel given the superiority in ORR is the primary endpoint of the Phase III trial. Further, the outcome might not be available until the topline data readout later unless the DSMB has decided to un-blind the results. Although the risk-reward profile of KX-01 in AK could be more favorable with reported positive Phase II results, it remains possible that the Phase III trial fails due to recognized and unidentifiable factors. Since the major value drivers for drug development company is the success of late stage clinical trials and drug approvals by regulatory agencies, unable to achieve such goal would usually impair the share value very significantly.

Commercial risks remain difficult to handicap. Although the potential benefits of ATNX's products in development can be easily recognized and appreciated, it is still too early to determine their commercial potential more accurately. For Oraxol, the balance between the safety and efficacy would likely to determine uptake of the drug by physicians and patients. A safer but less robust medication might not gain greater market shares since eradication of cancer cells remain the main objective of a cancer therapy. In addition, various types of modified chemotherapies are in development globally, while novel non-chemo treatment modalities are coming to the market. Such rapidly evolving cancer treatment market could further limit the market expansion of Oraxol. For KX-01, given the current AK topical treatment market has multiple lower cost medications available, it might be challenging for a more premium-priced product to gain greater market shares despite the drug might be better overall. Together, if the company's sales substantially fall short, we believe shareholder disappointment could negatively impact the company's valuation.

Yet-to-be-clinically-validated technology platforms could impact on future pipeline developments. Although ATNX's two technology platforms: Orascovery and Src kinase inhibition, have helped to create promising drug candidates currently in development, it remains too early to judge the validity of the platform of whether they can generate approvable clinical therapeutics. If such validation cannot be achieved, the value of these platforms could be in question. Such scenario can also diminish shareholder value.

Commercial infrastructure might not create high margin for ATNX unless it starts selling proprietary products. Although ATNX's commercial infrastructure could provide positive strategic value near term as well as later when the company's proprietary products are approved and launched, it remains uncertain as whether this scenario could be realized in a reasonable timeframe. If proprietary high margin products are not available for long period, the valuation

Yale Jen, Ph.D.
yjen@laidlawltd.com

metric of the company could be shifted to the lower multiples specialty pharma group. As such, the shareholders might not gain the potential upsides anticipated.

Additional financings could dilute shareholder value. The company currently has ~$69MM total cash as of the end of 3Q17. As such, ATNX would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can successfully explore non-dilutive financial sources. With additional equity offerings, the value of current shareholder might be reduced unless the share price increase if the upsides created due to greater financial source could offset the dilution of current shareholders.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Figure 1: Income Statement

Athenex Inc. – Income Statement

($'000)	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue															
Oraxol revenues										95,430	222,146	385,352	574,494	775,746	959,574
KX-01 in actinic keratosis revenues										12,682	33,440	52,890	71,198	92,785	114,401
Total proprietary product revenues	0	0	0	0	0	0	0	0	0	**108,112**	**255,586**	**438,242**	**645,692**	**868,530**	**1,073,975**
Other product revenues	12,816	19,394	3,900	4,416	13,662	11,749	33,727	53,250	58,042	60,364	62,778	65,289	67,901	70,617	73,442
License fees and consulting revenue	314	392	598	98	60	120	876	485	501	511	521	532	542	553	564
Grant revenue	814	765	83	81	272	81	517	320	330	333	337	340	343	347	350
Total revenue	13,944	20,551	4,581	4,595	13,994	11,950	35,120	54,055	58,873	169,320	319,222	504,403	714,479	940,047	1,148,331
COGS	13,153	19,718	2,839	4,137	8,082	8,007	23,065	44,030	47,098	48,974	50,924	52,952	55,061	57,254	59,533
Total gross profit	791	833	1,742	458	5,912	3,944	12,056	10,025	11,775	120,346	268,298	451,451	659,418	882,793	1,088,799
Research and development	24,463	60,624	26,408	17,597	11,944	12,900	68,849	62,806	73,483	76,422	89,414	95,673	99,499	96,514	86,863
Selling, general, and administrative expenses	27,036	25,956	9,799	13,632	10,364	10,675	44,470	46,000	50,140	64,179	68,671	72,105	75,710	79,496	83,470
Total operating expenses	51,499	86,580	36,207	31,229	22,308	23,574	113,318	108,805	123,622	140,601	158,085	167,777	175,210	176,010	170,333
Operating Incomes (losses)	(50,708)	(85,747)	(34,465)	(30,771)	(16,396)	(19,631)	(101,263)	(98,781)	(111,848)	(20,254)	110,213	283,673	484,209	706,783	918,465
Other Income/(Expense)															
Interest expense (income)	1	1,891	2,376	3,281	353	2,649	8,659	12,070	13,277	14,605	16,065	17,672	19,439	21,383	23,521
Unrealized loss on derivative liability	0	533	4,276	4,587	6,548	4,397	19,808	17,228	17,198	17,370	17,544	17,719	17,896	18,075	18,256
Total other income (expense), net	1	2,424	6,652	7,868	6,901	7,046	28,467	29,298	30,475	31,975	33,609	35,391	37,335	39,458	41,777
Pretax income	**(50,709)**	**(88,171)**	**(41,117)**	**(38,639)**	**(23,297)**	**(26,677)**	**(129,730)**	**(128,079)**	**(81,373)**	**11,720**	**143,822**	**319,064**	**521,544**	**746,241**	**960,242**
Tax on income	(54)	(265)	(92)	29	11	33	(19)	103	100	110	(53,214)	(118,054)	(192,971)	(276,109)	(355,290)
Net Income (Loss)	(50,655)	(87,906)	(41,025)	(38,668)	(23,308)	(26,710)	(129,711)	(128,182)	(81,473)	11,610	197,036	437,118	714,515	1,022,350	1,315,532
net loss attributable to non-controlling interests	(55)	(191)	(37)	(43)	(34)	(39)	(153)	(162)	(161)	(163)	(164)	(166)	(168)	(169)	(171)
Net loss attributable to Athenex	**(50,600)**	**(87,715)**	**(40,988)**	**(38,625)**	**(23,274)**	**(26,671)**	**(129,558)**	**(128,020)**	**(81,312)**	**11,773**	**197,200**	**437,284**	**714,683**	**1,022,520**	**1,315,703**
Unrealized gain (loss) on investment, net of income taxes	91	(33)	3	(37)	9	30	5	9	8	8	8	8	8	8	8
Foreign currency translation adjustment, net of income taxes	(397)	(1,048)	499	181	200	199	1,079	801	915	924	933	943	952	962	971
Net Income (Loss)	**(50,906)**	**(88,796)**	**(40,486)**	**(38,481)**	**(23,065)**	**(26,442)**	**(128,474)**	**(127,210)**	**(80,389)**	**12,705**	**198,142**	**438,235**	**715,643**	**1,023,490**	**1,316,683**
Basic and diluted net loss per share	($1.50)	($2.19)	($1.01)	($0.88)	($0.41)	($0.47)	($2.61)	($2.34)	($1.34)	$0.19	$3.19	$7.03	$11.39	$16.17	$20.65
Shares outstanding: basic and undiluted	33,766	40,121	40,693	43,741	57,135	57,335	49,726	54,726	60,726	61,226	61,726	62,226	62,726	63,226	63,726
Margin Analysis (% of Sales/Revenue)															
Costs of goods	94%	96%	62%	90%	58%	67%	66%	81%	80%	29%	16%	10%	8%	6%	5%
R&D	175%	295%	576%	383%	85%	108%	196%	116%	125%	45%	28%	19%	14%	10%	8%
SG&A	194%	126%	214%	297%	74%	89%	127%	85%	85%	38%	22%	14%	11%	8%	7%
Operating Income (loss)	-364%	-417%	-752%	-670%	-117%	-164%	-288%	-183%	-190%	-12%	35%	56%	68%	75%	80%
Pretax	-364%	-429%	-898%	-841%	-166%	-223%	-369%	-237%	-138%	7%	45%	63%	73%	79%	84%
Tax Rate	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income	-363%	-427%	-895%	-841%	-166%	-223%	-369%	-237%	-138%	7%	62%	87%	100%	109%	115%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue		47%	-1%	-12%	NA	NA	71%	54%	9%	188%	89%	58%	42%	32%	22%
Gross Profit		5%	258%	28%	NA	NA	1347%	-17%	17%	922%	123%	68%	46%	34%	23%
Cost of Goods		50%	-31%	-14%	NA	NA	17%	91%	7%	4%	4%	4%	4%	4%	4%
R&D		148%	291%	104%	-20693%	-72%	14%	-9%	17%	4%	17%	7%	4%	-3%	-10%
SG&A		-4%	126%	58%	-11745%	-2169%	71%	3%	9%	28%	7%	5%	5%	5%	5%
Operating Income (Losses)		68%	227%	136%	-15276%	-47%	31%	-4%	14%	14%	12%	6%	4%	0%	-3%
Pretax Income		74%	290%	199%	13445%	-42%	47%	-1%	-36%	-114%	1127%	122%	63%	43%	29%
Net Income		74%	280%	202%	12104%	-43%	45%	-1%	-37%	-116%	1460%	121%	63%	43%	29%
EPS		46%	269%	183%	376%	-98%	19%	-10%	-43%	-114%	1561%	120%	62%	42%	28%

Yale Jen, Ph.D. 212-953-4978

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

Yale Jen, Ph.D.
yjen@laidlawltd.com

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

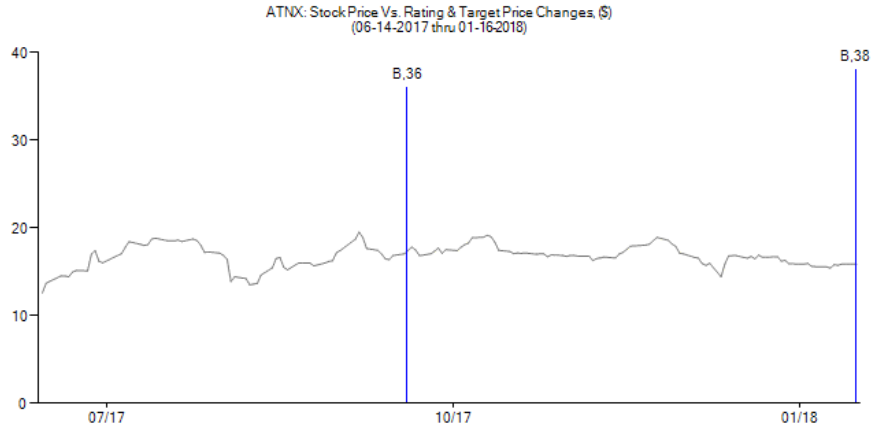
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
09/19/...	Buy (B)	17.42

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
09/19/...	36.00	17.42
01/16/...	38.00	15.87*

** Previous Close1/12/2018*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	29.41%	1.96%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.96%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate

in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com