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EQUITY RESEARCH
Company Report

September 25, 2017

Athenex Inc. (ATNX - $16.83)

Healthcare/Biotechnology

Ticker:	**ATNX**
Rating:	**Buy**
Price Target:	**$36.00**

KX-01 in Actinic Keratosis (AK) Pivotal Trial Started and More Detailed Phase II Results should be Available in 1H18

This morning, ATNX announced the commencement of one of the two KX-01 in actinic keratosis (AK) Phase III trials with the first patient recruted. The company also reiterated that more detailed results of the completed Phase II study will be presented at a major dermatological meeting, likely in 1H18.

- **Details.** This morning, ATNX announced the recruitment of the first patient for the KX-01 in actinic keratosis (AK) Phase III trial. The Phase III trial includes two double-blind, vehicle-controlled, 600-patient randomized studies. Patients will be randomized 1:1 between the treatment and placebo group, and will be treated for five days with a post-treatment follow-up. Primary endpoint is complete response rate, which is defined as the proportion of subjects achieving 100% complete clearance of all treated AK lesions on the face or scalp at day 57. Both studies are being conducted in the U.S. The statistical powering is based on a conservative assumption of complete response rate of 30% of treatment and 10% of placebo group. The confidence interval (CI) of the study is +90%. ATNX expects to complete patient recruitment within eight months. If so, we estimate ATNX could potentially report Phase III trial topline results in mid-2018, and if positive, file an NDA with possible FDA approval decision in 2H19. In addition, the company reiterated that a more detailed clinical data from the earlier Phase IIa trial will be reported at a major dermatological conference, and we believe it is likely in 1H18, possibly 1Q18.
- **Implications.** We view this development an important and positive event for ATNX to advance their second lead value driver and management demonstrating their timely execution. We have been bullish on the potential positive outcome from the ongoing Phase III trials given the robust preliminary Phase IIa results (both on efficacy and safety), and the fact that the pivotal trial design is very similar to that of the Phase II trial. Should the Phase III outcome be similar to that of the Phase IIa trial, we also believe the commercial outlook of KX-01 in AK could be promising given the marketed product with less tolerable side effects has experienced limited uptake by patients and physicians.
- **Action.** We are reiterating our Buy rating and $36 target price to reflect our bullish view on two promising lead products in late stage development 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 (9/22/2017)	$16.83
52-Week High (7/5/2017)	$20.79
52–Week Low (6/14/2017)	$11.21
Market Cap. (MM)	$973
Shares Out. (MM)	40.121

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-1.01A	-0.88A	-0.86	-0.87	-3.61	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

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
Oraxol	Metastatic breast cancer	Potential first interim (n=90) Phase III trial data readout	**Late 3Q17**	****
		Potential discussion with the FDA regarding path forward	**4Q17**	***
		Potential second interim (n=180) Phase III trial data readout	**4Q18**	****
		Potential topline Phase III trial data readout	**4Q19**	****
KX-01	Actinic keratosis (AK)	Potentially report full Phase II results at a medical conference	**1Q18**	***
		Potential topline Phase III trial data readout	**Mid- to 3Q18**	****
		Potential approval	**2H19**	****
		Potential IPR decision on first generics challenge	**Late 4Q17**	***

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

Source: Laidlaw & Company estimates and company presentation.

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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

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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 ~$85MM total cash as of the end of 2Q17. 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.

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Figure 1: Income Statement

Athenex Inc. – Income Statement

($'000)	2015	2016	1Q17	2Q17	3Q17E	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										50,730	119,430	165,280	203,423	231,961	254,224
Total proprietary product revenues	0	0	0	0	0	0	0	0	0	**146,159**	**341,576**	**550,632**	**777,917**	**1,007,707**	**1,213,798**
Other product revenues	12,816	19,394	3,900	4,416	8,346	16,609	33,271	75,274	82,049	85,331	88,744	92,294	95,986	99,825	103,818
License fees and consulting revenue	314	392	598	98	100	120	916	485	501	511	521	532	542	553	564
Grant revenue	814	765	83	81	82	81	327	320	330	333	337	340	343	347	350
Total revenue	13,944	20,551	4,581	4,595	8,528	16,810	34,514	76,079	82,880	232,335	431,178	643,798	874,789	1,108,432	1,318,531
COGS	13,153	19,718	2,839	4,137	7,420	14,625	29,020	62,150	66,304	68,948	71,697	74,556	77,529	80,621	83,834
Total gross profit	791	833	1,742	458	1,109	2,185	5,494	13,930	16,576	163,387	359,481	569,242	797,261	1,027,812	1,234,697
Research and development	24,463	60,624	26,408	17,597	19,181	20,715	83,901	97,164	113,682	118,230	138,329	148,012	153,932	149,314	134,383
Selling, general, and administrative expenses	27,036	25,956	9,799	13,632	12,541	12,918	48,890	55,664	60,674	89,797	96,083	100,887	105,932	111,228	116,790
Total operating expenses	51,499	86,580	36,207	31,229	31,722	33,633	132,791	152,828	174,356	208,027	234,412	248,899	259,864	260,542	251,172
Operating Incomes (losses)	(50,708)	(85,747)	(34,465)	(30,771)	(30,613)	(31,448)	(127,297)	(138,899)	(157,780)	(44,640)	125,069	320,343	537,397	767,269	983,525
Other Income/(Expense)															
Interest expense (income)	1	1,891	2,376	3,281	2,800	2,649	11,106	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	4,402	4,397	17,662	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	7,202	7,046	28,768	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)**	**(37,815)**	**(38,494)**	**(156,065)**	**(168,197)**	**(127,305)**	**(12,665)**	**158,678**	**355,734**	**574,732**	**806,727**	**1,025,302**
Tax on income	(54)	(265)	(92)	29	25	33	(5)	103	100	110	(58,711)	(131,622)	(212,651)	(298,489)	(379,362)
Net Income (Loss)	(50,655)	(87,906)	(41,025)	(38,668)	(37,840)	(38,527)	(156,060)	(168,300)	(127,405)	(12,775)	217,389	487,356	787,383	1,105,217	1,404,663
net loss attributable to non-controlling interests	(55)	(191)	(37)	(43)	(41)	(39)	(160)	(162)	(161)	(163)	(164)	(166)	(168)	(169)	(171)
Net loss attributable to Athenex	**(50,600)**	**(87,715)**	**(40,988)**	**(38,625)**	**(37,799)**	**(38,488)**	**(155,900)**	**(168,138)**	**(127,244)**	**(12,613)**	**217,553**	**487,522**	**787,550**	**1,105,386**	**1,404,834**
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)**	**(37,590)**	**(38,259)**	**(154,816)**	**(167,328)**	**(126,321)**	**(11,680)**	**218,494**	**488,473**	**788,511**	**1,106,356**	**1,405,814**
Basic and diluted net loss per share	($1.50)	($2.19)	($1.01)	($0.88)	($0.86)	($0.87)	($3.61)	($3.49)	($2.35)	($0.23)	$3.95	$8.76	$14.03	$19.52	$24.59
Shares outstanding: basic and undiluted	33,766	40,121	40,693	43,741	43,941	44,141	43,129	48,129	54,129	54,629	55,129	55,629	56,129	56,629	57,129
Margin Analysis (% of Sales/Revenue)															
Costs of goods	94%	96%	62%	90%	87%	87%	84%	82%	80%	30%	17%	12%	9%	7%	6%
R&D	175%	295%	576%	383%	225%	123%	243%	128%	137%	51%	32%	23%	18%	13%	10%
SG&A	194%	126%	214%	297%	147%	77%	142%	73%	73%	39%	22%	16%	12%	10%	9%
Operating Income (loss)	-364%	-417%	-752%	-670%	-359%	-187%	-369%	-183%	-190%	-19%	29%	50%	61%	69%	75%
Pretax	-364%	-429%	-898%	-841%	-443%	-229%	-452%	-221%	-154%	-5%	37%	55%	66%	73%	78%
Tax Rate	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income	-363%	-427%	-895%	-841%	-443%	-229%	-452%	-221%	-154%	-5%	50%	76%	90%	100%	107%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue		47%	-1%	-12%	NA	NA	68%	120%	9%	180%	86%	49%	36%	27%	19%
Gross Profit		5%	258%	28%	NA	NA	560%	154%	19%	886%	120%	58%	40%	29%	20%
Cost of Goods		50%	-31%	-14%	NA	NA	47%	114%	7%	4%	4%	4%	4%	4%	4%
R&D		148%	291%	104%	-33170%	-54%	38%	16%	17%	4%	17%	7%	4%	-3%	-10%
SG&A		-4%	126%	58%	-14192%	-2603%	88%	14%	9%	48%	7%	5%	5%	5%	5%
Operating Income (Losses)		68%	227%	136%	-21680%	-25%	53%	15%	14%	19%	13%	6%	4%	0%	-4%
Pretax Income		74%	290%	199%	21886%	-17%	77%	8%	-24%	-90%	-1353%	124%	62%	40%	27%
Net Income		74%	280%	202%	19789%	-17%	74%	8%	-25%	-91%	-1971%	124%	61%	40%	27%
EPS		46%	269%	183%	905%	-96%	65%	-3%	-33%	-90%	-1809%	122%	60%	39%	26%

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

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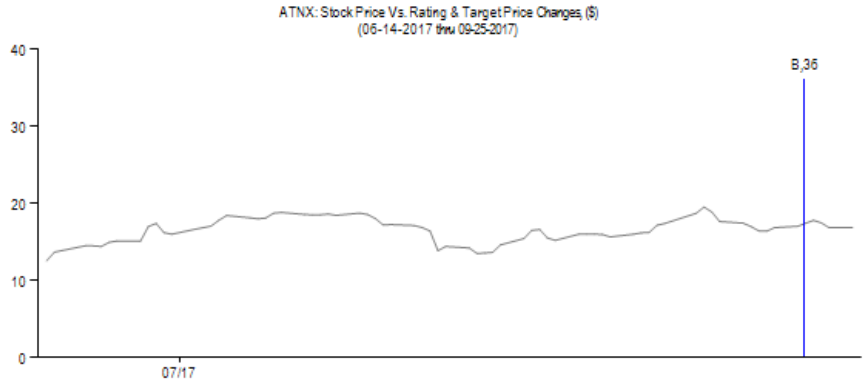
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
09/19/2017	Buy (B)	17.42

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
09/19/2017	36.00	17.42

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

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			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.	64.58%	31.25%	2.08%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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