

Athenex Inc. (ATNX - \$17.47)

Management Updates with Focus on Two Phase III Data Readouts in 3Q18

After recent meetings with ATNX management and investors, we walked away with renewed confidence that Oraxol would be a leading oral taxane, with mBC Phase III trial 2nd interim data readout on track for 2H18. Key takeaways from the meetings include:

- **Oraxol in mBC Phase III trial 2nd interim data readout is on track and patient enrollment progress well.** ATNX reiterated that the 2nd interim data readout of the Oraxol in mBC Phase III trial is on track for 3Q18. Further, management indicated that patient recruitment is progressing well (reaching ~240 recently) and anticipates potential completion before year-end 2018. Recall that the primary endpoint of the Phase III study is to show superior response rates to IV paclitaxel. We also learned that with the two interim looks for the study, the statistical penalty is rather minimal (0.004) and as such, the p value for demonstrating statistical significance is 0.045.
- **Additional Oraxol in mBC clinical data readouts.** One of the frequent questions is to know more about Oraxol in metastatic breast cancer clinical data. ATNX reported the Oraxol in mBC Phase I/II clinical trial (n=24) in Taiwan. Topline results indicated that in 12 patients, Oraxol treatment showed 50% PR and 50% SD after 2.6 months follow-up. On the safety side, 25% (3/12) patients experienced Grade 4 neutropenia and no neuropathy was found. ATNX indicated a more comprehensive data readout is scheduled to be presented at the upcoming ASCO meeting (June 1-5) and the ESMO meeting (Oct., 19-23). Although currently there are two oral taxanes in clinical development, we view Oraxol is likely in a leading position based on its clinical stage and potential safety/efficacy profile.
- **KX-01 development updates.** Similar to Oraxol, patient enrollment of KX-01 in actinic keratosis (AK) Phase III study is also on track for data readout in 3Q18. In addition, the final Phase III readout, including the 12-month follow-up will be available in 4Q19. Management indicated that the commercial partner, Ammiral, is fully committed to launch KX-01 in AK in the U.S. if approved – a scenario we believe is very likely.
- **Action.** We are reiterating our Buy rating and our target price of \$38 to reflect our bullish view on two promising lead late stage products and multiple potentially positive catalysts over the next 12 months. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.05	-0.54	-0.50	-0.10	-1.37	NM
FY-17A	-1.01	-0.88	-0.41	-0.49	-2.63	NM
FY-16A	-0.27	-0.31	-0.61	-0.96	-2.19	NM
FY-15A	N.A.	N.A.	N.A.	N.A.	-1.50	NM

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	ATNX
Rating:	Buy
Price Target:	\$38.00

Trading Data:

Last Price (3/29/2018)	\$17.47
52-Week High (7/5/2017)	\$20.79
52-Week Low (6/14/2017)	\$11.21
Market Cap. (MM)	\$1,080
Shares Out. (MM)	49.96

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Oraxol	Metastatic breast cancer	Potential second interim (n=180) Phase III trial data readout	Mid- to 3Q18	****
		Potential topline Phase III trial data readout	4Q19	****
KX-01	Actinic keratosis (AK)	Potential topline Phase III trial data readout	Mid- to 3Q18	****
		Potential NDA filing	2H18	***
		Potential approval	2H19	****
Additional pipeline development of the Orascovery platform	Oncology	Potentially advancing into Phase I studies	2018	***

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

Source: Laidlaw & Company estimates and company presentation.

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: Orascovey 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

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 had ~\$85MM (proforma) total cash currently. 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.

Figure 1: Income Statement

Athenex Inc. – Income Statement															
(\$'000)	2015	2016	2017	1Q18E	2Q18E	3Q18E	4Q18E	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	36,106	15,117	15,722	16,351	16,841	64,030	69,793	72,585	75,488	78,507	81,648	84,914	88,310
License fees and consulting revenue	314	392	1,105	30,110	120	125	25,130	55,485	501	511	521	532	542	553	564
Grant revenue	814	765	832	380	480	520	580	1,960	330	333	337	340	343	347	350
Total revenue	13,944	20,551	38,043	45,607	16,322	16,996	42,551	121,475	70,624	181,541	331,932	517,621	728,226	954,344	1,163,200
COGS	13,153	19,718	25,122	12,547	12,892	13,244	13,473	52,156	55,834	58,075	60,406	62,829	65,349	67,971	70,696
Total gross profit	791	833	12,921	33,060	3,430	3,752	29,078	69,320	14,790	123,466	271,526	454,792	662,876	886,373	1,092,504
Research and development	24,463	60,624	76,797	23,141	24,298	22,111	21,426	90,977	106,443	110,701	129,520	138,587	144,130	139,806	125,826
Selling, general, and administrative expenses	27,036	25,956	46,112	12,687	13,067	13,459	13,863	53,076	57,852	74,051	79,235	83,196	87,356	91,724	96,310
Total operating expenses	51,499	86,580	122,909	35,828	37,365	35,571	35,289	144,053	164,296	184,752	208,755	221,783	231,486	231,530	222,136
Operating Incomes (losses)	(50,708)	(85,747)	(109,988)	(2,768)	(33,936)	(31,819)	(6,211)	(74,733)	(149,506)	(61,286)	62,771	233,009	431,390	654,842	870,368
Other Income/(Expense)															
Interest expense (income)	1	1,891	6,108	140	125	110	98	473	520	572	630	693	762	838	922
Unrealized loss on derivative liability	0	533	15,411	0	0	0	0	0	0	0	0	0	0	0	0
Total other income (expense), net	1	2,424	21,519	140	125	110	98	473	520	572	630	693	762	838	922
Pretax income	(50,709)	(88,171)	(131,507)	(2,908)	(34,061)	(31,929)	(6,309)	(75,206)	(148,986)	(60,714)	63,401	233,701	432,152	655,680	871,290
Tax on income	(54)	(265)	85	23	25	26	29	103	100	110	(23,458)	(86,469)	(159,896)	(242,602)	(322,377)
Net Income (Loss)	(50,655)	(87,906)	(131,396)	(2,931)	(34,086)	(31,955)	(6,338)	(75,309)	(149,086)	(60,824)	86,859	320,171	592,048	898,282	1,193,667
net loss attributable to non-controlling interests	(55)	(191)	(226)	(41)	(42)	(39)	(40)	(162)	(161)	(163)	(164)	(166)	(168)	(169)	(171)
Net loss attributable to Athenex	(50,600)	(87,715)	(131,170)	(2,890)	(34,044)	(31,916)	(6,298)	(75,147)	(148,925)	(60,661)	87,023	320,337	592,215	898,451	1,193,838
Unrealized gain (loss) on investment, net of income taxes	91	(33)	(26)	1	2	2	4	9	8	8	8	8	8	8	8
Foreign currency translation adjustment, net of income taxes	(397)	(1,048)	1,184	200	210	197	194	801	915	924	933	943	952	962	971
Net Income (Loss)	(50,906)	(88,796)	(130,012)	(2,689)	(33,832)	(31,717)	(6,100)	(74,337)	(148,002)	(59,729)	87,965	321,288	593,176	899,421	1,194,818
Basic and diluted net loss per share	(\$1.50)	(\$2.19)	(\$2.63)	(\$0.05)	(\$0.54)	(\$0.50)	(\$0.10)	(\$1.37)	(\$2.44)	(\$0.99)	\$1.40	\$5.13	\$9.41	\$14.16	\$18.67
Shares outstanding: basic and undiluted	33,766	40,121	49,961	63,040	63,340	63,640	63,890	54,961	60,961	61,461	61,961	62,461	62,961	63,461	63,961
Margin Analysis (% of Sales/Revenue)															
Costs of goods	94%	96%	66%	83%	82%	81%	80%	43%	80%	32%	18%	12%	9%	7%	6%
R&D	175%	295%	202%	51%	149%	130%	50%	75%	151%	61%	39%	27%	20%	15%	11%
SG&A	194%	126%	121%	28%	80%	79%	33%	44%	82%	41%	24%	16%	12%	10%	8%
Operating Income (loss)	-364%	-417%	-289%	-6%	-208%	-187%	-15%	-62%	-212%	-34%	19%	45%	59%	69%	75%
Pretax	-364%	-429%	-346%	-6%	-209%	-188%	-15%	-62%	-211%	-33%	19%	45%	59%	69%	75%
Tax Rate	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income	-363%	-427%	-345%	-6%	-209%	-188%	-15%	-62%	-211%	-33%	26%	62%	81%	94%	103%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue	47%	85%	896%	255%	21%	186%	219%	-42%	157%	83%	56%	41%	31%	22%	
Gross Profit	5%	1451%	1798%	649%	-37%	505%	436%	-79%	735%	120%	67%	46%	34%	23%	
Cost of Goods	50%	27%	342%	212%	64%	34%	108%	7%	4%	4%	4%	4%	4%	4%	
R&D	148%	27%	-12%	38%	85%	3%	18%	17%	4%	17%	7%	4%	-3%	-10%	
SG&A	-4%	78%	29%	-26%	30%	13%	15%	9%	28%	7%	5%	5%	5%	5%	
Operating Income (Losses)	68%	42%	-1%	20%	59%	6%	17%	14%	12%	13%	6%	4%	0%	-4%	
Pretax Income	74%	49%	-93%	-12%	37%	-78%	-43%	98%	-59%	-204%	269%	85%	52%	33%	
Net Income	74%	46%	-93%	-12%	38%	-78%	-43%	99%	-60%	-247%	265%	85%	52%	33%	
EPS	46%	20%	-95%	-39%	23%	-80%	-48%	79%	-60%	-242%	265%	83%	51%	32%	

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

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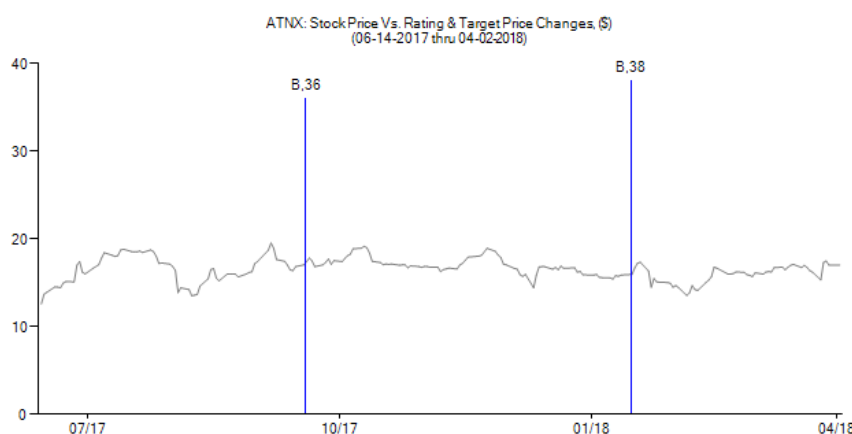
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Date	Rating	Closing Price (\$)
09/19/...	Buy (B)	17.42

Date	Target Price (\$)	Closing Price, (\$)
09/19/...	36.00	17.42
01/16/...	38.00	15.95

Source: Laidlaw & Company

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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.	65.38%	26.92%	3.85%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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Almirall SA (ALM – Not Rated)

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