

## Athenex Inc. (ATNX - \$ 20.61)

### KX2-391 in Actinic Keratosis Phase III Studies Met Primary Endpoints with Regulatory Filing Going Forward

ATNX announced this morning that the two current Phase III studies, KX-AK-003 and KX-AK-004, that evaluate KX2-391 in actinic keratosis met their primary endpoints.

- Details.** Specifically, the study demonstrated that KX2-391 (1% ointment) has achieved 100% clearance of actinic keratosis (AK) lesions at day 57 within the face or scalp treatment areas vs. vehicle control with  $p < 0.0001$ . In addition, statistical significance ( $p < 0.001$ ) was achieved for both face and scalp subgroups as well. On the safety side, the studies showed that the local skin reaction (LSR) profile was within expectations, in line with the Phase II study results reported in 1Q18. Both Phase III studies are still ongoing in order to complete the one-year follow-up of the patients who had complete responses. ATNX expects to present the Phase III studies results at an upcoming scientific meeting. We estimate ATNX might file for approval possibly in mid-2019 with potential product launch in 2020. In addition to the U.S. and EU, ATNX remains owner of the commercial rights in other regions, like Japan, New Zealand and Australia.
- Implications.** Despite a more bullish expectation regarding a positive outcome from the KX2-391 in AK Phase III studies already exist in the Street, we believe the robust readouts (based on the very low p values) remain a positive surprise for ATNX shares. Although the information still limited, by combining the efficacy and safety profile of KX2-391, we believe the drug could be a major player in AK treatment, especially in the hands of a very capable dermatological company, like Almirall, S.A. ATNX is scheduled to conduct a pre-NDA meeting with the FDA. A regulatory filing might be accelerated if rolling NDA submission is granted given the very robust Phase III clinical data. We also view the pace of reaching the Phase III topline study readout as testament of ATNX management's execution efficiency given these two large studies (total  $n=702$ ) were completed within only ~9 months (initiated in late 09/2017). In addition, the next major catalyst for ATNX shares will be the second interim analysis results of Oraxol in metastatic breast cancer Phase III trial, which could occur in late 3Q18 (possibly in September).
- 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
<b>FY-18E</b>	-0.12A	-0.51	-0.40	-0.07	-1.10	NM
<b>FY-17A</b>	-1.01	-0.88	-0.41	-0.49	-2.63	NM
<b>FY-16A</b>	-0.27	-0.31	-0.61	-0.96	-2.19	NM
<b>FY-15A</b>	N.A.	N.A.	N.A.	N.A.	-1.50	NM

Source: Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>ATNX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 38.00</b>

#### Trading Data:

Last Price (07/26/2018)	\$ 20.61
52-Week High (7/26/2018)	\$ 20.90
52-Week Low (8/8/2017)	\$ 13.16
Market Cap. (MM)	\$ 1,367
Shares Out. (MM)	66

#### Yale Jen, Ph.D.

Managing Director /  
Senior Biotechnology Analyst  
(212) 953-4978  
yjen@laidlawltd.com

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

## 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	3Q18	****
		Potentially completed patient enrollment for the Phase III study	2Q19	***
		Potential topline Phase III trial data readout	4Q19	****
	Angiosarcoma	Potentially start Phase I/II trial	2H18/2019	***
KX2-391	Actinic keratosis (AK)	Potential NDA filing	Mid-2019	***
		Potential approval	2020	****
Additional pipeline development of the Orascovery platform	Oncology	Potentially advancing into Phase I studies	2018	***
HATac (NY-ESO-1/HLA-0201)	Solid tumors	Potentially start Phase I trial in China	2H18	***
		Potentially start Phase I trial in the U.S.	1H19	***
Pegtomarginase	Oncology	Potentially start Phase I trial in the U.S.	2Q19	***

\*\*\*\* / \*\*\*\*\* 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 ~\$200MM total cash (proforma) 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	1Q18	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
<b>Revenue</b>															
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
<b>Total proprietary product revenues</b>	0	0	0	0	0	0	0	0	0	<b>108,112</b>	<b>255,586</b>	<b>438,242</b>	<b>645,692</b>	<b>868,530</b>	<b>1,073,975</b>
Other product revenues	12,816	19,394	36,106	12,836	16,045	17,489	18,014	64,384	70,178	72,985	75,905	78,941	82,099	85,383	88,798
License fees and consulting revenue	314	392	1,105	25,000	120	125	25,130	50,375	501	511	521	532	542	553	564
Deferred revenue						5,000		5,000							
Grant revenue	814	765	832	0	480	520	580	1,580	330	333	337	340	343	347	350
<b>Total revenue</b>	<b>13,944</b>	<b>20,551</b>	<b>38,043</b>	<b>37,836</b>	<b>16,645</b>	<b>23,134</b>	<b>43,724</b>	<b>121,339</b>	<b>71,009</b>	<b>181,942</b>	<b>332,349</b>	<b>518,054</b>	<b>728,677</b>	<b>954,813</b>	<b>1,163,688</b>
<b>COGS</b>	<b>13,153</b>	<b>19,718</b>	<b>25,122</b>	<b>11,326</b>	<b>13,157</b>	<b>14,166</b>	<b>14,411</b>	<b>53,060</b>	<b>56,143</b>	<b>58,396</b>	<b>60,739</b>	<b>63,176</b>	<b>65,710</b>	<b>68,346</b>	<b>71,086</b>
<b>Total gross profit</b>	<b>791</b>	<b>833</b>	<b>12,921</b>	<b>26,510</b>	<b>3,488</b>	<b>8,968</b>	<b>29,313</b>	<b>68,279</b>	<b>14,867</b>	<b>123,546</b>	<b>271,610</b>	<b>454,878</b>	<b>662,966</b>	<b>886,466</b>	<b>1,092,601</b>
Research and development	24,463	60,624	76,797	21,303	22,368	20,355	19,724	83,750	97,988	101,907	119,231	127,578	132,681	128,700	115,830
Selling, general, and administrative expenses	27,036	25,956	46,112	13,080	13,472	13,877	14,293	54,722	59,647	76,348	81,692	85,777	90,066	94,569	99,297
<b>Total operating expenses</b>	<b>51,499</b>	<b>86,580</b>	<b>122,909</b>	<b>34,383</b>	<b>35,841</b>	<b>34,232</b>	<b>34,017</b>	<b>138,472</b>	<b>157,635</b>	<b>178,255</b>	<b>200,924</b>	<b>213,355</b>	<b>222,746</b>	<b>223,269</b>	<b>215,128</b>
<b>Operating Incomes (losses)</b>	<b>(50,708)</b>	<b>(85,747)</b>	<b>(109,988)</b>	<b>(7,873)</b>	<b>(32,352)</b>	<b>(25,264)</b>	<b>(4,704)</b>	<b>(70,193)</b>	<b>(142,768)</b>	<b>(54,709)</b>	<b>70,686</b>	<b>241,524</b>	<b>440,220</b>	<b>663,197</b>	<b>877,474</b>
<b>Other Income/(Expense)</b>															
Interest expense (income)	1	1,891	6,108	(227)	125	110	98	106	117	128	141	155	171	188	207
Unrealized loss on derivative liability	0	533	15,411	0	0	0	0	0	0	0	0	0	0	0	0
<b>Total other income (expense), net</b>	<b>1</b>	<b>2,424</b>	<b>21,519</b>	<b>(227)</b>	<b>125</b>	<b>110</b>	<b>98</b>	<b>106</b>	<b>117</b>	<b>128</b>	<b>141</b>	<b>155</b>	<b>171</b>	<b>188</b>	<b>207</b>
<b>Pretax income</b>	<b>(50,709)</b>	<b>(88,171)</b>	<b>(131,507)</b>	<b>(7,646)</b>	<b>(32,477)</b>	<b>(25,374)</b>	<b>(4,802)</b>	<b>(70,299)</b>	<b>(142,651)</b>	<b>(54,581)</b>	<b>70,827</b>	<b>241,679</b>	<b>440,391</b>	<b>663,385</b>	<b>877,680</b>
Tax on income	(54)	(265)	85	(307)	25	26	29	(227)	100	(26,206)	(89,421)	(162,945)	(245,452)	(324,742)	
Net Income (Loss)	(50,655)	(87,906)	(131,396)	(7,339)	(32,502)	(25,400)	(4,831)	(70,072)	(142,751)	(54,691)	97,033	331,100	603,335	908,837	1,202,422
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	<b>(50,600)</b>	<b>(87,715)</b>	<b>(131,170)</b>	<b>(7,298)</b>	<b>(32,460)</b>	<b>(25,361)</b>	<b>(4,791)</b>	<b>(69,910)</b>	<b>(142,590)</b>	<b>(54,528)</b>	<b>97,197</b>	<b>331,266</b>	<b>603,503</b>	<b>909,006</b>	<b>1,202,593</b>
Unrealized gain (loss) on investment, net of income taxes	91	(33)	(26)	0	2	2	4	8	8	8	8	8	8	8	8
Foreign currency translation adjustment, net of income taxes	(397)	(1,048)	1,184	0	210	197	194	601	915	924	933	943	952	962	971
<b>Net Income (Loss)</b>	<b>(50,906)</b>	<b>(88,796)</b>	<b>(130,012)</b>	<b>(7,298)</b>	<b>(32,248)</b>	<b>(25,162)</b>	<b>(4,593)</b>	<b>(69,301)</b>	<b>(141,667)</b>	<b>(53,596)</b>	<b>98,139</b>	<b>332,217</b>	<b>604,463</b>	<b>909,976</b>	<b>1,203,573</b>
Basic and diluted net loss per share	(\$1.50)	(\$2.19)	(\$2.63)	(\$0.12)	(\$0.51)	(\$0.40)	(\$0.07)	(\$1.10)	(\$2.03)	(\$0.77)	\$1.37	\$4.62	\$8.37	\$12.52	\$16.45
Shares outstanding: basic and undiluted	33,766	40,121	49,961	63,276	63,576	63,876	64,126	63,713	70,126	70,626	71,126	71,626	72,126	72,626	73,126
<b>Margin Analysis (% of Sales/Revenue)</b>															
Costs of goods	94%	96%	66%	83%	82%	81%	80%	44%	80%	32%	18%	12%	9%	7%	6%
R&D	175%	295%	202%	56%	134%	88%	45%	69%	138%	56%	36%	25%	18%	13%	10%
SG&A	194%	126%	121%	35%	81%	60%	33%	45%	84%	42%	25%	17%	12%	10%	9%
Operating Income (loss)	-364%	-417%	-289%	-21%	-194%	-109%	-11%	-58%	-201%	-30%	21%	47%	60%	69%	75%
Pretax	-364%	-429%	-346%	-20%	-195%	-110%	-11%	-58%	-201%	-30%	21%	47%	60%	69%	75%
Tax Rate	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income	-363%	-427%	-345%	-19%	-195%	-110%	-11%	-58%	-201%	-30%	29%	64%	83%	95%	103%
<b>Financial Indicator Growth Analysis (YoY%)</b>															
Total Revenue	47%	85%	726%	262%	65%	194%	219%	-41%	156%	83%	56%	41%	31%	22%	
Gross Profit	5%	1451%	1422%	662%	52%	510%	428%	-78%	731%	120%	67%	46%	34%	23%	
Cost of Goods	50%	27%	299%	218%	75%	43%	111%	6%	4%	4%	4%	4%	4%	4%	
R&D	148%	27%	-19%	27%	70%	-5%	9%	17%	4%	17%	7%	4%	-3%	-10%	
SG&A	-4%	78%	33%	-23%	34%	16%	19%	9%	28%	7%	5%	5%	5%	5%	
Operating Income (Losses)	68%	42%	-5%	15%	53%	3%	13%	14%	13%	13%	6%	4%	0%	-4%	
Pretax Income	74%	49%	-81%	-16%	9%	-83%	-47%	103%	-62%	-230%	241%	82%	51%	32%	
Net Income	74%	46%	-82%	-16%	9%	-84%	-47%	104%	-62%	-283%	239%	82%	51%	32%	
EPS	46%	20%	-89%	-42%	-3%	-85%	-58%	85%	-62%	-277%	238%	81%	50%	31%	

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

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

## 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

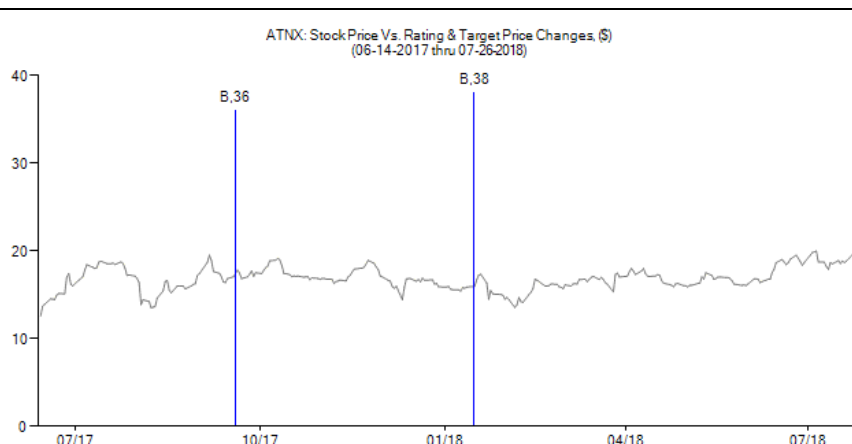
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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 & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three 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	15.95

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	67.27%	25.45%	3.64%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Almirall SA (ALM – Not Rated)

### 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](http://www.LaidlawLtd.com), or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2018 Laidlaw & Co. (UK), Ltd.

**NOTES:**