

## Asterias Biotherapeutics (AST - \$3.70)

### Recent Updates from Management Suggest that Near-term Events Could Have Significant Impact on AST Valuation

After our recent meetings with AST management and investors, we remain confident in the significant potential of AST-OPC1 in SCI treatment. An imminent start of AST-VAC-2 in non-small cell lung cancer (NSCLC) Phase I/II trial in mid-2017 could afford a second value driver. Highlights of the meetings include:

- **Near-term catalysts remain on-track.** The 12-month follow-up data from the AST-OPC1 10x10<sup>6</sup> cell cohort (cohort 2) in AIS-A Phase I/IIa trial is expected in 3Q17. If positive, it could exhibit the continued persistency of treatment effect after earlier reported robust 9-month data. The 9-month data showed 50% of patients (vs. 29% in 12-month of historical control) achieved two levels of motor function recovery. Further, treated patients achieved an average UEMS improvement of 11.2 points (9.7 points at 6 months). AST is scheduled to report the 6-month results from the AIS-A 20x10<sup>6</sup> cell (cohort 3) and AIS-B 10x10<sup>6</sup> cell (cohort 4) cohorts in late 2017 and possibly in 1Q18. We believe the outcomes from these two cohorts, if positive, could substantially strengthen AST-OPC1's value based on larger patient size and broad spectrum of utility. We believe that the cohort 3 outcome would be a winner if it is on par with the cohort 2 results, and an added bonus if it is superior. This is based on the very robust outcomes reported so far from cohort 2, in addition to the cell therapy generally not exhibiting a rigid proportionality in dose titration as that of a small molecular weight compound treatment. The effective dose range was initially hypothesized to be 10-20x10<sup>6</sup> AST-OPC1 cells. The success of cohort 4 would expand the market potential for AST-OPC1. In addition, investors' feedback suggested that the primary endpoints of the SCiStar trial make a lot of sense given that they could demonstrate meaningful clinical benefits.
- **Take off of AST-VAC2 in NSCLC trial could add value.** AST believes that the commencement of AST-VAC2 in NSCLC Phase I/II trial in mid-2017 could afford AST shareholders a second value driver. Although the NSCLC treatment landscape is undergoing substantial changes due to the presence of CPIs, AST-VAC2 could potentially afford a maintenance role if the outcome is positive. Interim data readouts could be available in 2018. Further, positive AST-VAC1 in AML data could also clinically de-risk the program.
- **Action.** We are reiterating our Buy rating and \$12 target price. Our valuation is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses. We believe AST shares remain undervalued given its differentiated and promising SCI therapy modality, and multiple catalysts in next 18 months.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	-0.13A	-0.16	-0.17	-0.16	-0.62	N.A.
<b>FY-16A</b>	-0.27	-0.12	-0.24	-0.20	-0.83	N.A.
<b>FY-15A</b>	-0.09	-0.10	-0.09	-0.13	-0.42	N.A.
<b>FY-14A</b>	-0.07	-0.09	-0.05	-0.11	-0.33	N.A.

Source: Laidlaw & Company estimates

#### Healthcare/Biotechnology

Ticker:	<b>AST</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$12.00</b>

#### Trading Data:

Last Price (7/3/2017)	\$3.70
52-Week High (11/18/2016)	\$5.80
52-Week Low (7/5/2016)	\$2.52
Market Cap. (MM)	\$177
Shares Out. (MM)	42.934

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## Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
AST-OPC1	Subacute spinal cord injury (SCI) cervical complete (AIS-A at C5-C7)	Complete patient enrollment of 20MM cell trial	2Q17	***
		Report 10MM cell 12-month results	3Q17	****
		Report 20MM cell 6-month results	4Q17	***
		Report 20MM cell 12-month results	3Q18	****
	Subacute spinal cord injury (SCI) cervical incomplete (AIS-B at C5-C7)	Complete patient enrollment of 10MM cell trial	2Q17	***
		Report 10MM cell 6-month results	4Q17	****
		Complete patient enrollment of 20MM cell trial	1Q18	***
		Report 10MM cell 12-month results	3Q18	****
		Report 20MM cell 6-month results	3Q18	****
	Subacute spinal cord injury (SCI) cervical	Conduct discussion with the FDA for possible Phase III trial	Mid-2017	***
		Potentially finalize Phase IIb trial design after FDA discussion	2H17	***
		Potentially start Phase IIb trial	2018	***
AST-VAC1	Acute myeloid leukemia (AML)	Potentially start Phase IIb confirmatory trial	2018	***
AST-VAC2	Non-small cell lung cancer (NSCLC)	Potentially start Phase I/IIa trial	Mid-17	***

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

Source: Laidlaw & Company and company presentation

## Major Risks

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**Clinical study failure could have a major impact on AST share value.** Despite promising pre-clinical and clinical results of the company's lead product, AST-OPC1, it remains too early to predict the long-term safety and efficacy outcomes from the upcoming clinical studies. Given that clinical validation has not been fully established, near term, it would be critical for the additional studies of the ongoing Phase I/II trial to demonstrate efficacy and a positive safety profile after a longer follow-up, higher dosage and broader patient population in order to increase the assets and shareholder value. Negative results of ongoing and future clinical studies could have a materially negative impact on the shareholder value; especially since the company has a relatively diverse-limited pipeline profile. In addition, given there has been very limited progress over the last two decades in developing therapeutics for treating SCI, the overall risks in developing an effective treatment in this area could be higher than in other disease areas.

**Yet-to-be-validated pluripotent stem cell platform could remain uncertain.** Although stem cell-based therapies have been tested in many clinical trials in recent years; there is currently no pluripotent stem cell-based therapy approved for the treatment of spinal cord injury or other disease indications. As such, clinical risks for pluripotent stem cell-based therapies are higher than similar products generated from other more proven development platforms.

**Product may not be approved or reach anticipated sales.** Although AST's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and the possible changes in pricing flexibility that could potentially have a negative impact on payer reimbursement. Other potential commercial risks also include the societal or political pressure that could limit premium pricing capability for many orphan drugs moving forward. Further, a below expectation revenue outlook could also negatively affect AST shareholder value.

**Additional financings could dilute shareholder value.** Although the company currently has ~\$34MM total cash as of the end of February 2017, AST would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can continuously explore un-dilutive financial sources. Should the future operational expenses significantly increase, especially in the areas of R&D and SG&A, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Figure 1: Income Statement

Asterias Biotherapeutics – Income Statement																
(\$'000)	2014	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
<b>Revenue</b>																
AST-OPC1 US sales													10,466	30,891	79,246	174,950
AST-OPC1 ex-US royalties and COGS													0	0	3,338	14,931
AST-OPC1 total revenue													<b>10,466</b>	<b>30,891</b>	<b>82,584</b>	<b>189,881</b>
AST-VAC1 in AML revenues															95,994	85,629
AST-VAC2 in NSCLC revenues															37,131	371,505
<b>Total product revenues</b>													10,466	30,891	119,714	371,505
Royalties from product sales	189	535	381	116	110	89	159	474	507	527	549	571	593	617	642	667
Sale of cell lines		40	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grant income	1,034	3,007	6,572	1,894	1,720	1,580	1,670	6,864	7,139	7,424	7,721	8,030	8,351	8,685	9,033	9,394
<b>Total revenue</b>	<b>1,224</b>	<b>3,582</b>	<b>6,953</b>	<b>2,010</b>	<b>1,830</b>	<b>1,669</b>	<b>1,829</b>	<b>7,338</b>	<b>7,646</b>	<b>7,952</b>	<b>8,270</b>	<b>8,600</b>	<b>19,411</b>	<b>40,194</b>	<b>129,389</b>	<b>381,566</b>
<b>COGS of therapeutic products</b>													(2,093)	(6,178)	(24,489)	(76,744)
Cost of sales	(95)	(268)	(127)	(53)	(46)	(37)	(67)	(203)	(213)	(222)	(230)	(240)	249	(5,919)	(24,220)	(76,464)
<b>Total gross profit</b>	<b>1,129</b>	<b>3,314</b>	<b>6,826</b>	<b>1,957</b>	<b>1,784</b>	<b>1,632</b>	<b>1,762</b>	<b>7,135</b>	<b>7,433</b>	<b>7,730</b>	<b>8,039</b>	<b>8,361</b>	<b>19,660</b>	<b>36,810</b>	<b>106,803</b>	<b>266,345</b>
<b>Expenses</b>																
Research and development	(13,310)	(17,321)	(25,468)	(6,598)	(7,410)	(7,543)	(7,769)	(29,320)	(33,718)	(40,124)	(48,550)	(56,804)	(60,780)	(63,211)	(61,315)	(55,183)
General and administrative	(5,280)	(7,901)	(15,481)	(4,466)	(2,456)	(2,530)	(2,606)	(12,058)	(13,023)	(14,195)	(15,330)	(16,404)	(17,224)	(18,085)	(18,989)	(19,939)
Marketing and sales													(20,000)	(25,000)	(29,250)	(31,298)
<b>Total operating costs and expenses</b>	<b>(18,590)</b>	<b>(25,222)</b>	<b>(40,949)</b>	<b>(11,064)</b>	<b>(9,866)</b>	<b>(10,073)</b>	<b>(10,375)</b>	<b>(41,378)</b>	<b>(46,740)</b>	<b>(54,319)</b>	<b>(63,881)</b>	<b>(73,207)</b>	<b>(98,004)</b>	<b>(106,296)</b>	<b>(109,554)</b>	<b>(106,419)</b>
<b>Operating Incomes (losses)</b>	<b>(17,461)</b>	<b>(21,908)</b>	<b>(34,123)</b>	<b>(9,107)</b>	<b>(8,082)</b>	<b>(8,441)</b>	<b>(8,613)</b>	<b>(34,243)</b>	<b>(39,308)</b>	<b>(46,589)</b>	<b>(55,841)</b>	<b>(64,846)</b>	<b>(78,344)</b>	<b>(69,486)</b>	<b>(2,751)</b>	<b>159,926</b>
<b>Other Income/(Expense)</b>																
Change in fair value on warrant liability			(3,107)	2,954	(190)	(349)	(450)	1,965	(2,100)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)
Interest expense, net	(10)	(341)	(548)	(134)	(169)	(207)	(240)	(750)	(788)	(1,599)	(1,598)	(1,597)	(1,629)	(1,662)	(1,695)	(1,729)
Other income (expense), net	(2)	(6)	(36)	28	40	50	118	130	143	157	173	190	209	230	253	
<b>Total other income (expense), net</b>	<b>(12)</b>	<b>(347)</b>	<b>(3,691)</b>	<b>2,820</b>	<b>(331)</b>	<b>(516)</b>	<b>(640)</b>	<b>1,333</b>	<b>(2,758)</b>	<b>(2,656)</b>	<b>(2,641)</b>	<b>(2,624)</b>	<b>(2,639)</b>	<b>(2,652)</b>	<b>(2,665)</b>	<b>(2,676)</b>
Pretax income	(17,473)	(22,255)	(37,814)	(6,287)	(8,413)	(8,957)	(9,253)	(32,910)	(42,065)	(49,245)	(58,482)	(67,471)	(80,982)	(72,138)	(5,415)	157,250
Deferred income tax benefit	7,376	7,252	2,324	730	730	750	698	2,178	2,789	2,860	2,860	2,860	2,860	2,860	2,004	(58,183)
<b>Net Income (Loss)</b>	<b>(10,097)</b>	<b>(15,003)</b>	<b>(35,490)</b>	<b>(6,287)</b>	<b>(7,683)</b>	<b>(8,207)</b>	<b>(8,555)</b>	<b>(30,732)</b>	<b>(39,276)</b>	<b>(46,385)</b>	<b>(55,622)</b>	<b>(64,611)</b>	<b>(78,122)</b>	<b>(69,278)</b>	<b>(3,412)</b>	<b>99,068</b>
Basic and diluted net loss per share	(\$0.33)	(\$0.42)	(\$0.83)	(\$0.13)	(\$0.16)	(\$0.17)	(\$0.16)	(\$0.62)	(\$0.72)	(\$0.81)	(\$0.92)	(\$1.04)	(\$1.16)	(\$1.03)	(\$0.05)	\$1.46
Weighted average common shares outstanding: basic and undiluted	30,720	35,443	42,943	48,357	48,377	48,417	52,417	49,392	54,392	57,392	60,392	62,392	67,392	67,492	67,592	67,692
<b>Margin Analysis (% of Sales/Revenue)</b>																
Costs of goods	-50%	-50%	-33%	-42%	-42%	-42%	-42%	-43%	-42%	-42%	-42%	-42%	-42%	-42%	-42%	-42%
R&D	-1088%	-484%	-366%	-328%	-405%	-452%	-425%	-400%	-441%	-505%	-587%	-660%	-313%	-157%	-47%	-14%
SG&A	-431%	-221%	-223%	-222%	-134%	-152%	-142%	-164%	-170%	-179%	-185%	-191%	-89%	-45%	-15%	-5%
Operating Income (loss)	-1427%	-612%	-491%	-453%	-442%	-506%	-471%	-467%	-514%	-586%	-675%	-754%	-404%	-173%	-2%	42%
Pretax	-1428%	-621%	-544%	-313%	-460%	-537%	-506%	-448%	-550%	-619%	-707%	-785%	-417%	-179%	-4%	41%
Tax Rate													37%	37%	37%	37%
Net Income	-825%	-419%	-510%	-313%	-420%	-492%	-468%	-419%	-514%	-583%	-673%	-751%	-402%	-172%	-3%	26%
<b>Financial Indicator Growth Analysis (YoY%)</b>																
Total Revenue	NA	193%	94%	26%	19%	-20%	4%	6%	4%	4%	4%	4%	126%	107%	222%	195%
R&D	NA	30%	47%	4%	23%	44%	-1%	15%	15%	19%	21%	17%	7%	4%	-3%	-10%
SG&A	NA	50%	96%	-29%	-5%	-40%	9%	-22%	8%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)	NA	25%	62%	-12%	15%	7%	1%	1%	13%	16%	18%	15%	34%	8%	3%	-3%
Pretax Income	NA	27%	70%	-44%	50%	-22%	-2%	-13%	28%	17%	19%	15%	20%	-11%	-92%	-3004%
Net Income	NA	49%	137%	-39%	49%	-23%	-8%	-13%	28%	18%	20%	16%	21%	-11%	-95%	-3004%
EPS	NA	29%	97%	-52%	29%	-28%	-20%	-25%	16%	12%	14%	12%	12%	-11%	-95%	-2999%

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

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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/03/2017	Buy (B)	3.25

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price (\$)
04/03/2017	12.00	3.25

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			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.	64.44%	31.11%	2.22%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	2.22%	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%

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