

Asterias Biotherapeutics (AST - \$3.40)

Management Updates and Enrollment/Dosing Completion of AIS-B SCI 10x10⁶ Cell and AIS-A SCI 20x10⁶ Cell Cohorts

Sandwiched between the announcements of completed enrollment and dosing of 10x10⁶ AST-OPC1 cells in AIS-B SCI (cohort 4), and 20x10⁶ AST-OPC1 cells in AIS-A SCI (cohort 3) cohorts, we hosted meetings with AST management and investors. Key takeaways include:

- **Cohorts 3 and 4 topline results expected in 1Q18.** AST reported that the patient enrollment and dosing of 10x10⁶ AST-OPC1 cells in AIS-B SCI cohort (n=5) and 20x10⁶ AST-OPC1 cells in AIS-A SCI cohort (n=5) of the ongoing Phase I/IIa trial have completed. Top-line six-month follow-up results are expected in January 2018. Safety, improvements of upper extremity motor score (UEMS) and motor level (by ISNCSCI examinations) are the major endpoints.
- **Maturation and expansion of SCiStar study data are the key focus of investors.** The overall consensus of many investors is that the potential completion and success of the SCiStar trial would be critical for enhancing AST share value and for gaining a greater buy-in on the AST-OPC1 platform. As such, data readouts in 1Q18 could be critical, not only for potentially positive data from an additional AIS-B SCI cohort, but also having reported efficacy data from a larger number of patients (from 6 to 15). In addition, the 12-month follow-up results of cohort 2 (AIS-A SCI 10x10⁶ cells) could be available in early 4Q17 with data from all six patients instead of five. Should the outcome be positive, which we believe is likely, it would demonstrate continued persistency of treatment effect. This is important given that a competitor program failed to show enduring effect at 12 months despite earlier promising data. Under the recently announced modified recruitment criteria (C4- injured included and therapy window of 21-42 days) more patients could be enrolled into cohort 5.
- **Phase IIb trial could start in 2H18.** Should the ongoing SCiStar trial show a promising outcome and receive more FDA feedback, AST could start a placebo-controlled Phase IIb trial in 2018, possibly in mid- to 2H18. AST could potentially incur much less costs for the study if they apply for and successfully receive funding support from the California Institute of Regeneration Medicine (CIRM).
- **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 are undervalued given its differentiated and promising SCI treatment modality, and potentially positive multiple catalysts in next 18 months.

Earnings Estimates: (per share)

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

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	AST
Rating:	Buy
Price Target:	\$12.00

Trading Data:

Last Price (7/14/2017)	\$3.40
52-Week High (11/18/2016)	\$5.80
52-Week Low (8/26/2016)	\$2.54
Market Cap. (MM)	\$172
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	3Q17	***
		Report 10MM cell 12-month results	4Q17	****
		Report 20MM cell 6-month results	1Q18	****
		Report 20MM cell 12-month results	4Q18	***
	Subacute spinal cord injury (SCI) cervical incomplete (AIS-B at C5-C7)	Report 10MM cell 6-month results	1Q18	****
		Complete patient enrollment of 20MM cell trial	1Q18	***
		Report 10MM cell 12-month results	4Q18	****
		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

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
Revenue																
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													10,466	30,891	82,584	189,881
AST-VAC1 in AML revenues															37,131	95,994
AST-VAC2 in NSCLC revenues																85,629
Total product revenues													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
Total revenue	1,224	3,582	6,953	2,010	1,830	1,669	1,829	7,338	7,646	7,952	8,270	8,600	19,411	40,194	129,389	381,566
COGS of therapeutic products													(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)
Total gross profit	1,129	3,314	6,826	1,957	1,784	1,632	1,762	7,135	7,433	7,730	8,039	8,361	19,660	36,810	106,803	266,345
Expenses																
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)	(20,000)	(25,000)	(29,250)	(31,298)
Marketing and sales													(20,000)	(25,000)	(29,250)	(31,298)
Total operating costs and expenses	(18,590)	(25,222)	(40,949)	(11,064)	(9,866)	(10,073)	(10,375)	(41,378)	(46,740)	(54,319)	(63,881)	(73,207)	(98,004)	(106,296)	(109,554)	(106,419)
Operating Incomes (losses)	(17,461)	(21,908)	(34,123)	(9,107)	(8,082)	(8,441)	(8,613)	(34,243)	(39,308)	(46,589)	(55,841)	(64,846)	(78,344)	(69,486)	(2,751)	159,926
Other Income/(Expense)																
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	28	40	50	118	130	143	157	173	190	209	230	253
Total other income (expense), net	(12)	(347)	(3,691)	2,820	(331)	(516)	(640)	1,333	(2,758)	(2,656)	(2,641)	(2,624)	(2,639)	(2,652)	(2,665)	(2,676)
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)
Net Income (Loss)	(10,097)	(15,003)	(35,490)	(6,287)	(7,683)	(8,207)	(8,555)	(30,732)	(39,276)	(46,385)	(55,622)	(64,611)	(78,122)	(69,278)	(3,412)	99,068
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
Margin Analysis (% of Sales/Revenue)																
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%
Financial Indicator Growth Analysis (YoY%)																
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%	7%	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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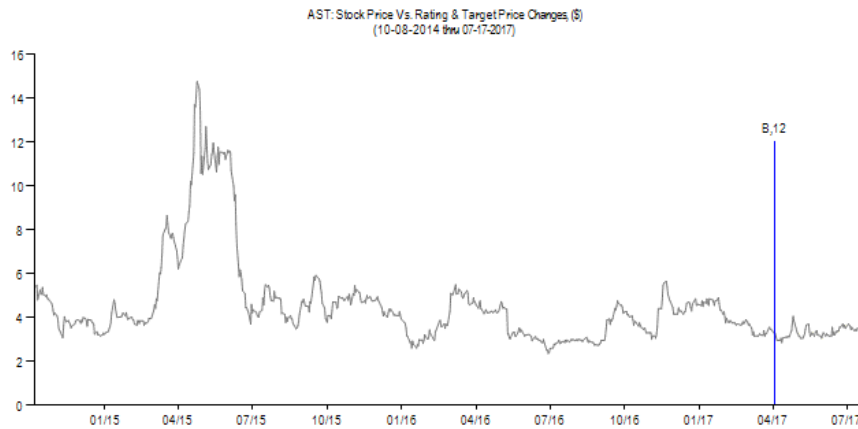
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/03/2...	Buy (B)	3.25

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
04/03/2...	12.00	3.25

Source: Laidlaw & Company

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			Investment Banking	Brokerage
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