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EQUITY RESEARCH
Company Report

July 10, 2017

Asterias Biotherapeutics (AST - $3.55)

Healthcare/Biotechnology

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

SCiStar Study Enrollment Criteria Modifications Could Fulfill a Greater Unmet Need and Expand Market Potential

This morning, AST announced that the FDA has accepted a protocol amendment to the SCiStar clinical trial with expansions of 1) eligible patients to include those with C4 level SCI from prior C5; and 2) dosing window from 14-30 days to 21-42 days post-injury.

- **Details.** The company offered more details regarding the study protocol modifications. The basis for the FDA's decision of expanding eligible patients with C4 level injuries is the existing good safety profile of AST-OPC1 and the procedure from the ongoing studies. Rationale for the dosing window expansion is based on supportive evidence from the recent preclinical research indicating AST-OPC1 cells can durably engraft at a patient's injury site when administered up to two months post injury.
- **Implications.** Overall, we view today's news as a positive development given the protocol modifications could potentially benefit more SCI patients and expand the market potential of AST-OPC1 therapy. The C4 is the lowest part of the high cervical nerves, which is associated with breathing (C1-C4) and head and neck movement (C2). In addition, the heart rate is controlled by nerves associated with C4-C6. SCI patients with injury in the high cervical nerves usually incur substantially higher costs and patients with SCI at the C4 level could be paralyzed from the neck down, typically requiring around-the-clock care. Based on the NSCISC 2016 annual report, approximately 46% of the discharged SCI patients of the National SCI database were with cervical lesions with 15.0% at C4, 15.2% at C5, 10.2% at C6 and 5.1% at C7. As such, if AST-OPC1 could be successful in treating C4 patients, it not only fulfills a major unmet medical need but also expands its market potential. In addition, we believe the expansion of the dosing window to three to six weeks could provide study investigators more time to screen patients to determine if they are eligible to participate in the SCiStar study. Given the SCiStar trial is a Phase I/II study, it would be valuable to cast a bigger net to fully explore the potential of AST-OPC1 therapy in order to potentially better shape the study design of the future Phase IIb and III trials.
- **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 treatment modality, and potentially positive multiple catalysts in next 18 months.

Trading Data:

Last Price (7/7/2017)	$3.55
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

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

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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

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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.

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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)	(17,224)	(18,085)	(18,989)	(19,939)
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	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	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%	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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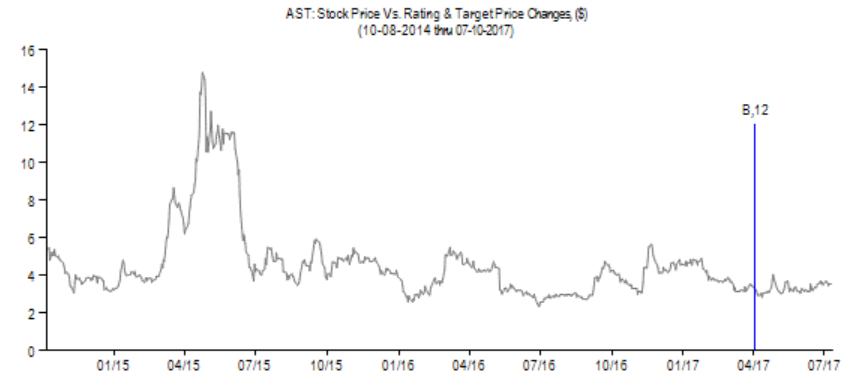
Rating and Price Target Change History



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
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.	64.44%	31.11%	2.22%
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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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