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EQUITY RESEARCH
Company Report

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Asterias Biotherapeutics (AST - $2.47)

Healthcare/Biotechnology

Issued 2018 Milestone Targets Are In-line with Our Estimate

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

Yesterday, AST announced the 2018 milestone targets with several clinical data readouts and upcoming FDA discussions as highlights.

- **Details.** AST issued guidance about major milestone events for 2018 yesterday. The highlights include: 1) For the AST-OPC1 SCiStar study, the cohort three ($20x10^6$ AST-OPC1 cells in AIS-A SCI) and four ($10x10^6$ AST-OPC1 cells in AIS-B SCI) 6-month clinical data readouts are expected in February 2018, and 12-month data in August 2018; 2) The cohort five ($20x10^6$ AST-OPC1 cells in AIS-B SCI) in combination with all other completed cohorts 6- and 12-month data readouts are expected in June and December 2018, respectively; 3) Conduct a meeting with the FDA in 2018 to establish next clinical study protocols. We believe that will occur once the cohort three and four data readouts are available; 4) AST-VAC2 in non-small cell lung cancer (NSCLC) Phase I/IIa study could start in 1H18, and if so, initial data readout, mainly on the safety and immunogenicity, could be available in late 2H18; and 5) AST has ended 4Q17 with total cash of ~$21.6MM.
- **Implications.** We view the milestone target guidance overall in line with our expectation. As such in our opinion, 2018 will be a critical inflection year for AST shareholders as the outcomes of the SCiStar study would likely be the basis for the future development of AST OPC1 in SCI program. We especially anticipate the outcomes from the cohort three and four 6- and 12-month readouts to be most critical, potentially demonstrating the likely utility of AST OPC1 in treating SCI. We estimate major readouts could include safety, improvements of upper extremity motor score (UEMS) and motor level (by ISNCSCI examinations). In addition to motor function improvement, potential improvements of sensory function (also by ISNCSCI) in AIS-B SCI patients can also be examined. We also anticipate the FDA feedback could possibly provide visibility regarding approvable clinical endpoints for the future clinical studies. We estimate AST could potentially start a placebo-controlled Phase IIb trial in 2H18. A potential funding from the California Institute of Regeneration Medicine (CIRM) could significantly reduce costs by AST. We also view the commencement of AST-VAC2 in NSCLC Phase I/IIa study could diversify the clinical risks and increase value for AST shareholders.
- **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 SCI treatment modality and potentially positive multiple catalysts in next 18 months.

Trading Data:

Last Price (1/4/2018)	$2.45
52–Week High (1/24/2017)	$5.00
52–Week Low (12/8/2017)	$1.95
Market Cap. (MM)	$135
Shares Out. (MM)	54.15

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.13A	-0.18A	-0.14A	-0.16	-0.61	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 2018 and beyond

Product	Indication	Event	Timing	Importance
AST-OPC1	Subacute spinal cord injury (SCI) cervical complete (AIS-A at C5-C7)	Report 20MM cell 6-month results	**Feb. '18**	****
		Report 20MM cell 12-month results	**Aug. 18**	***
	Subacute spinal cord injury (SCI) cervical incomplete (AIS-B at C5-C7)	Report 10MM cell 6-month results	**Feb. '18**	****
		Report 10MM cell 12-month results	**Aug. 18**	****
		Report 20MM cell 6-month results	**June, 18**	****
		Report 20MM cell 12-month results	**Dec. 18**	***
	Subacute spinal cord injury (SCI) cervical	More formal discussion with the FDA for possible Phase II and III trial	**1H18**	***
		Potentially finalize Phase IIb trial design after FDA discussion	**1H18**	***
		Potentially start Phase IIb trial	**2H18**	***
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	**1H18**	***

***** / ***** 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 ~$25MM total cash, 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)	2016	1Q17	2Q17	3Q17	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	381	116	25	162	159	462	494	514	535	556	578	601	625	651
Sale of cell lines	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Grant income	6,572	1,894	291	1,526	370	4,081	0	0	0	0	0	0	0	0
Total revenue	6,953	2,010	316	1,688	529	4,543	494	514	535	556	11,045	31,493	120,340	372,155
COGS of therapeutic products											(2,093)	(6,178)	(24,489)	(76,744)
Cost of sales	(127)	(53)	(18)	(81)	(72)	(224)	(208)	(216)	(225)	(234)	243	(5,926)	(24,226)	(76,471)
Total gross profit	6,826	1,957	298	1,607	457	4,319	287	298	310	323	11,288	36,817	106,810	266,353
Expenses														
Research and development	(25,468)	(6,598)	(6,984)	(6,624)	(6,690)	(26,896)	(22,862)	(27,206)	(32,919)	(38,515)	(41,211)	(42,859)	(41,574)	(37,416)
General and administrative	(15,481)	(4,466)	(1,847)	(2,046)	(2,073)	(10,432)	(8,554)	(9,324)	(10,070)	(10,775)	(11,313)	(11,879)	(12,473)	(13,097)
Marketing and sales											(20,000)	(25,000)	(29,250)	(31,298)
Total operating costs and expenses	(40,949)	(11,064)	(8,831)	(8,670)	(8,763)	(37,328)	(31,416)	(36,529)	(42,988)	(49,289)	(72,524)	(79,738)	(83,296)	(81,810)
Operating Incomes (losses)	(34,123)	(9,107)	(8,533)	(7,063)	(8,305)	(33,008)	(31,129)	(36,231)	(42,678)	(48,967)	(61,237)	(42,921)	23,514	184,542
Other Income/(Expense)														
Change in fair value on warrant liability	(3,107)	2,954	(56)	506	(450)	2,954	(2,100)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)	(1,200)
Interest expense, net	(548)	(134)	(114)	(112)	(140)	(500)	(525)	(1,599)	(1,598)	(1,597)	(1,629)	(1,662)	(1,695)	(1,729)
Other income (expense), net	(36)		(25)	(140)	50	(115)	(127)	(139)	(153)	(168)	(185)	(204)	(224)	(247)
Total other income (expense), net	(3,691)	2,820	(195)	254	(540)	2,339	(2,752)	(2,938)	(2,951)	(2,965)	(3,014)	(3,065)	(3,119)	(3,175)
Pretax income	(37,814)	(6,287)	(8,728)	(6,809)	(8,845)	(30,669)	(33,880)	(39,169)	(45,629)	(51,932)	(64,251)	(45,987)	20,395	181,367
Deferred income tax benefit	2,324	0	0	0	0	0	0	0	0	0	0	0	(7,546)	(67,106)
Net Income (Loss)	**(35,490)**	**(6,287)**	**(8,728)**	**(6,809)**	**(8,845)**	**(30,669)**	**(33,880)**	**(39,169)**	**(45,629)**	**(51,932)**	**(64,251)**	**(45,987)**	**12,849**	**114,261**
Basic and diluted net loss per share	($0.83)	($0.13)	($0.18)	($0.14)	($0.16)	($0.61)	($0.61)	($0.67)	($0.75)	($0.82)	($0.94)	($0.67)	$0.19	$1.67
Weighted average common shares outstanding: basic and undiluted	42,943	48,357	48,511	49,771	53,771	50,103	55,103	58,103	61,103	63,103	68,103	68,203	68,303	68,403
Margin Analysis (% of Sales/Revenue)														
Costs of goods	-33%	-46%	-72%	-50%	-45%	-48%	-42%	-42%	-42%	-42%	-42%	-42%	-42%	-42%
R&D	-366%	-328%	-2210%	-392%	-1265%	-592%	-4625%	-5292%	-6157%	-6926%	-373%	-136%	-35%	-10%
SG&A	-223%	-222%	-584%	-121%	-392%	-230%	-1730%	-1814%	-1883%	-1938%	-102%	-38%	-10%	-4%
Operating Income (loss)	-491%	-453%	-2700%	-418%	-1570%	-727%	-6297%	-7047%	-7982%	-8806%	-554%	-136%	20%	50%
Pretax	-544%	-313%	-2762%	-403%	-1672%	-675%	-6854%	-7619%	-8534%	-9339%	-582%	-146%	17%	49%
Tax Rate											37%	37%	37%	37%
Net Income	-510%	-313%	-2762%	-403%	-1672%	-675%	-6854%	-7619%	-8534%	-9339%	-582%	-146%	11%	31%
Financial Indicator Growth Analysis (YoY%)														
Total Revenue	94%	26%	-79%	-19%	-70%	-35%	-89%	4%	4%	4%	1886%	185%	282%	209%
R&D	47%	4%	16%	27%	-15%	6%	-15%	19%	21%	17%	7%	4%	-3%	-10%
SG&A	96%	-29%	-28%	-51%	-14%	-33%	-18%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)	62%	-12%	3%	-8%	-15%	-9%	-16%	16%	18%	15%	47%	10%	4%	-2%
Pretax Income	70%	-44%	56%	-41%	-6%	-19%	10%	16%	16%	14%	24%	-28%	-144%	789%
Net Income	137%	-39%	69%	-36%	-5%	-14%	10%	16%	16%	14%	24%	-28%	-128%	789%
EPS	97%	-52%	46%	-42%	-19%	-26%	0%	10%	11%	10%	15%	-29%	-128%	788%

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

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Additional information available upon request.

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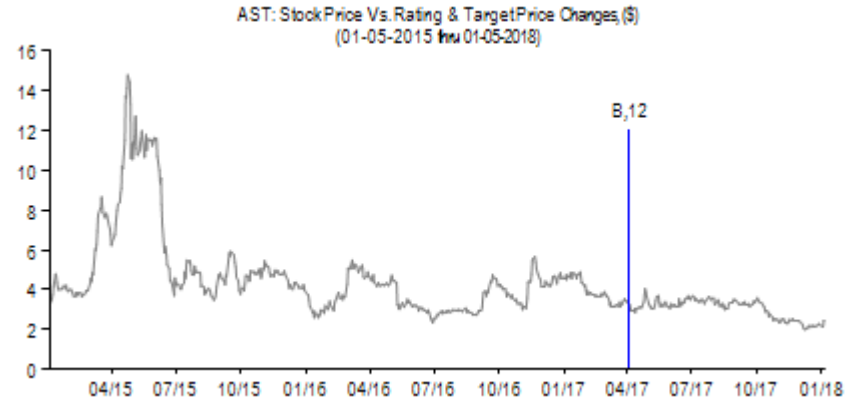
Rating and Price Target Change History



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.	66.67%	29.41%	1.96%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.96%	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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