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EQUITY RESEARCH
Company Report

November 15, 2017

Asterias Biotherapeutics (AST - $2.35)

Healthcare/Biotechnology

3Q17: All Eyes are on Cohorts Three and Four 6-Month Clinical Data Readouts in 1Q18

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

Yesterday after the market close, AST reported 3Q17 financial results with a net loss of ($6.8MM) vs. Laidlaw ($7.9MM) and the Street ($7.2MM) estimates. Net loss/share was ($0.14) vs. ($0.16) and ($0.14) for Laidlaw and the Street. AST has $27MM cash by Oct. 2017, sufficient to support operations into 1H19, in our opinion.

- **SCiStar study updates.** AST reiterated that 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 on-track for 1Q18, possibly in late January or February, in our estimate. Safety, improvements of upper extremity motor score (UEMS) and motor level (by ISNCSCI examinations) are the major endpoints. In addition to motor function improvement, potential improvements of sensory function (also by ISNCSCI) in AIS-B SCI patients can also be examined, but we do not anticipate these readouts will be a critical part for potential approval. The cohort three and four 12-month data readouts are slated to mid-2H18. In addition, AST anticipates cohort five ($20x10^6$ AST-OPC1 cells in AIS-B SCI) patient enrollment could complete by YE2017 with 6-month data readout in mid-2018. AST will have an informal meeting with the FDA later this year with a formal (Type B) meeting in late 1Q18 after the data readout of the two cohorts. AST could start a placebo-controlled Phase IIb trial in 2018, possibly in mid- to 2H18. AST could potentially incur much lower costs for the study if they apply for and successfully receive funding from the California Institute of Regeneration Medicine (CIRM).
- **Regenerative Medicine Advanced Therapy (RMAT) designation received.** The OPC1 in SCI program recently received a RMAT designation by the FDA under the 21st Century Cures Act. Besides the recognition of program's merit, this designation expedites communications with the FDA at earlier stages of development, and as such, could potentially facilitate a priority review as well as accelerated approval.
- **AST-VAC2 updates.** We believe AST-VAC2 in non-small cell lung cancer Phase I/IIa study could start in mid-to late 1H18, and if so, initial data readout, mainly on the safety, could be available in late 2018.
- **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 (11/14/2017)	$2.35
52–Week High (11/18/2016)	$5.80
52–Week Low (11/14/2017)	$2.20
Market Cap. (MM)	$125
Shares Out. (MM)	42.934

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

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

- **Strengthen AST's financial operation and cash position**. To better utilize their financial resources, AST will tighten its financial operation, reducing operating expenditures and is supported by a recent completion of a capital raise. The cash burn will be reduced ~40% to $1.3MM from $2.0MM per month in 2018.

Table 1: Estimated and reported 3Q17 results

3Q17 Estimates and Reported Results			
($,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$1,589**	**$1,688**	**$1,500**
Total op. profit (loss)	**($8,889)**	**($8,670)**	**($7,000)**
R&D	($7,005)	($6,624)	
SG&A	($1,884)	($2,046)	
EPS	**($0.16)**	**($0.14)**	**($0.14)**
Net income (loss)	($7,853)	($6,809)	($7,200)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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)	Report 20MM cell 6-month results	**Jan. '18**	****
		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	**Jan. '18**	****
		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	More formal discussion with the FDA for possible Phase II and III trial	**1Q18**	***
		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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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%

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

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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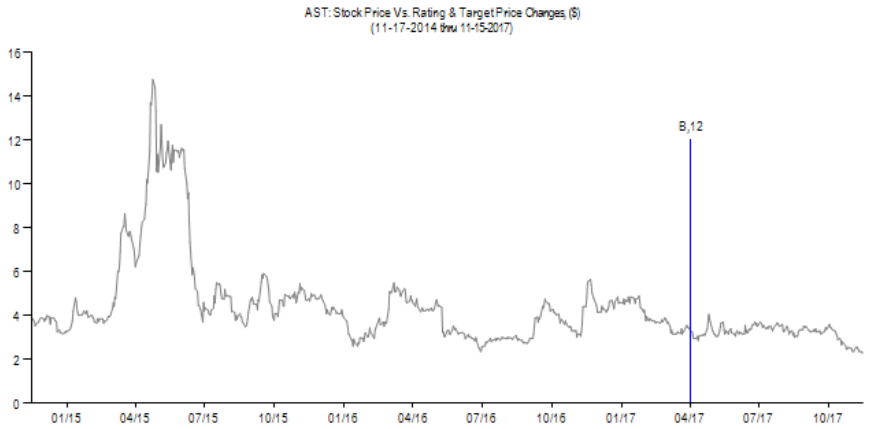

3 Year Rating Change History

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 **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
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.	65.31%	30.61%	2.04%
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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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NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com