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EQUITY RESEARCH
Company Report

November 13, 2015

Mast Therapeutics (MSTX - $ 0.43)

Healthcare/Biotechnology

Ticker:	**MSTX**
Rating:	**Buy**
Price Target:	**$ 2.50**

3Q15: EPIC Trial Ongoing and Top-line Results Are Likely Available in 2Q16

Yesterday, MSTX reported 3Q15 financial results with a net loss of ($9.9MM) vs. Laidlaw ($10.3MM) and the Street ($10MM) estimates. Net loss per share equated to ($0.06), which is identical to that of Laidlaw and the Street. MSTX ended 3Q15 with cash of ~$50MM, enough to support its operation into 2017, in our opinion.

- **EPIC study patient enrollments continue.** Patient recruitment of EPIC trial slowed down in October but picked up pace in November with >80% of expected patients already enrolled so far. MSTX adjusted the guidance slightly with enrollment completion now expected in 1Q16 with top-line results anticipated in 2Q16. From the fundamental prospective, we view this minor delay immaterial. Management also pointed out that the Phase III trial started to enroll patients in the UK and France. More than half of the European SCD patients (~40k) reside in these countries, the majority of them located in major metropolitan areas like London and Paris. We believe conducting clinical trials in these regions not only could increase patient recruitment, but also potentially expands the awareness of the drug among physicians and patients. The EPIC trial is conducted in ~75 clinical sites with ~40% outside of the U.S. If the outcome of the EPIC trial is positive and MSTX files for approval, we believe an FDA AdCom meeting is possible given vepoloxamer is a novel chemical entity there has been no SCD drug approval for nearly two decades. Vepoloxamer remains clinically the most advanced and broadly applicable SCD therapy in development to date.
- **Pipeline development update.** The vepoloxamer in chronic heart failure Phase II trial is underway with top-line results potentially available in late 2016. The study evaluates the drug's potential for improving left ventricle contractile function by restoring cardiomyocyte membrane integrity and increasing cardiomyocyte survival. The study measures echocardiograms (i.e. ejection fraction), 6MWD and blood-based markers (i.e. troponin I and NT-proBNP). In addition, two investigator-sponsored trials that evaluate AIR001 in WHO Group 2 pulmonary hypertension (PH) patients associated with left heart disease are ongoing. We estimate MSTX will report interim and final results in 2016.
- **Action.** We are reiterating our Buy rating and our $2.50 target price based on peer comparable probability adjusted DCF analyses to reflect the continued execution of corporate developments.

Trading Data:

Last Price (11/12/2015)	$ 0.43
52–Week High (1/5/2015)	$ 0.63
52–Week Low (8/10/2015)	$ 0.38
Market Cap. (MM)	$ 70
Shares Out. (MM)	164

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.06A	-0.06A	-0.06A	-0.06	-0.25	N.A.
FY-14A	-0.06	-0.06	-0.06	-0.05	-0.23	N.A
FY-13A	-0.12	-0.09	-0.05	-0.06	-0.28	N.A.
FY-12A	-0.09	NA	-0.07	-0.08	-0.33	N.A

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
Vepoloxamer (MST-188)	Vaso-occlusive crisis (VOC) in sickle cell disease (SCD)	Completion of Phase III (EPIC) study	**1Q16**	***
		Report of Phase III study top-line results	**2Q16**	****
		Potential NDA filing	**2H16**	***
		Potential AdComm meeting	**2017**	****
		Potential approval	**2H17**	****
	Stroke	Potentially start Phase II trial	**2016**	***
	Chronic heart failure	Potentially report Phase II top-line results	**4Q16**	****
AIR001	PH associated with heart failure with preserved ejection fraction (HFpEF),	Report preliminary and top-line results	**2016**	****

***** / ***** 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

Risks of clinical study failure could have a major impact on MSTX share value. Despite an encouraging prior Phase III study outcome and potentially favorable trial design of the ongoing EPIC Phase III study, risks still exist that MST-188 might not receive approval by the FDA if the pivotal study does not meet its endpoints. Given that the majority of upside for MSTX shares is currently based on the assumption that a positive EPIC study outcome could lead to MST-188 approval before its commercial potential can be realized; a failure of the EPIC study would have a significant negative impact on MSTX share value.

Commercial success of the MST-188 in resolving vaso-occlusive crisis in sickle cell disease (SCD) patients is less predictable. Although we recognize that the substantial unmet medical need of shortening the VOC in SCD patients, we cannot fully predict the market acceptance and potential revenue ramp up for the product; as the actual clinical performance will play an important role even if the product is approved. In addition, we cannot fully foresee the market dynamic if competitors also enter the market since such dynamic could be affected by multiple factors. Together, commercial performance of MST-188 may not meet expectations, and if so, MSTX share value could also be impacted negatively.

Lack of patent protection could make MST-188 vulnerable if competitors develop method to generate a me-too product that might not require complete clinical studies but as generic. Although the production processes of MST-188 are protected on several fronts, including proprietary technology, trade secrets and know-how, it remains possible that other competitors could develop similar or alternative processes to produce a similar, or even better, product like MST-188. As such, the company might not enjoy the competitive edge and potentially damage MST-188's commercial outlook.

Limited product diversity could increase overall risk. Given the nascent stage of the corporate development, majority of the product pipeline value mainly resides on MST-188 in SCD development. The second potential pipeline product, AIR001 in pulmonary arterial hypertension and additional indications (acute limb ischemia, stroke and acute heart failure), potentially could be addressed by MST-188 remains in very early development stage. As such, we believe the company at the current stage has very limited diversification potential in its product pipeline.

Additional financing could dilute shareholder value. Although the company ended 3Q14 with ~$43MM cash, MSTX could potentially need more financial resources going forward if they want to expand and further develop its pipeline and/or commercialize MST-188 in SCD. Should the product not receive FDA approval or product revenue does not reach expectations, the company might need to increase its financial resources, which includes issuing 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

Mast Therapeutics – Income Statement

($'000)	2012	2013	2014	1Q15	2Q15	3Q15	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
MST-188 revenue	0	0	0					0	0	28,253	86,796	167,886	252,822
Net sales	0	0	0	-	-	-	-	0	0	0	0	0	0
Licensing revenue	0	0	0	-	-	-	-	0	0	0	0	0	0
Grant revenue	0	0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	0	-	-	-	-	0	0	28,253	86,796	167,886	252,822
Costs of goods	0									2,543	7,812	15,110	22,754
Research and development	8,088	12,902	19,436	6,042	7,734	7,330	7,697	28,803	30,819	26,196	24,886	25,633	26,402
Selling, general and administrative	7,519	8,518	9,487	3,578	2,410	2,460	2,497	10,945	11,273	12,288	13,394	14,599	15,767
Marketing and sales										20,000	23,000	24,380	25,599
Transaction-related expenses	(70)	80	271	-	-	0	0	0	0	0	0	0	0
Depreciation and amortization	90	40	84	30	37	38	38	143	143	143	143	143	143
Total Operating Expenses	15,628	21,539	29,279	9,650	10,181	9,828	10,231	39,890	42,235	61,169	69,234	79,865	90,665
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(9,650)	(10,181)	(9,828)	(10,231)	(39,890)	(42,235)	(32,916)	17,561	88,021	162,157
Reduction of fair value of warrants	0	0	0	-	-	0	0	0	0	0	0	0	0
Investment income	74	60	67	17	30	0	17	64	70	77	85	94	103
Interest expense	0	0	0	0	0	0	0	0	0	0	0	0	0
Other income/(expense), net	(5)	(1)	511	17	0	(84)	(23)	(90)	2	(20)	24	(27)	(27)
Loss before cumulative effect of change in accounting princ	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,237)	(39,916)	(42,163)	(32,859)	17,670	88,088	162,233
Cumulative effect of change in accounting principle	0	0	0	-	0	0	0	0					
Income before tax	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,237)	(39,916)	(42,163)	(32,859)	17,670	88,088	162,233
Tax	0	0	0	-	-	0	0	0	0	0	(6,538)	(32,593)	(60,026)
Net Income (Loss)	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,237)	(39,916)	(42,163)	(32,859)	11,132	55,495	102,207
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,237)	(39,916)	(42,163)	(32,859)	11,132	55,495	102,207
Net Earnings (Losses) Per Share—Basic and Diluted	($0.33)	($0.28)	($0.23)	($0.06)	($0.06)	($0.06)	($0.06)	($0.25)	($0.25)	($0.19)	$0.06	$0.32	$0.59
Shares outstanding—basic	47,641	76,586	122,409	159,459	162,128	163,614	164,614	162,454	169,454	170,454	171,454	172,454	173,454
Shares outstanding—diluted	47,641	76,586	122,409	159,459	162,128	163,614	164,614	162,454	169,454	170,454	171,454	172,454	173,454
Margin Analysis (% of Sales/Revenue)													
Costs of goods									9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	93%	29%	15%	10%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	114%	42%	23%	16%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-117%	20%	52%	64%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-116%	20%	52%	64%
Tax Rate										37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-116%	13%	33%	40%
Financial Indicator Growth Analysis (YoY%)													
Licensing revenue								0%	0%	0%	0%	0%	0%
Grant revenue								0%	0%	0%	0%	0%	0%
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	207%	93%	51%
R&D	40%	60%	51%	41%	60%	36%	56%	48%	7%	-15%	-5%	3%	3%
SG&A	5%	13%	11%	58%	2%	0%	4%	15%	3%	9%	9%	9%	8%
Marketing and sales											15%	6%	5%
Operating Income (Losses)	17%	38%	36%	41%	41%	25%	39%	36%	6%	-22%	-153%	401%	84%
Net Income	17%	38%	34%	51%	42%	26%	40%	39%	6%	-22%	-134%	399%	84%
EPS	-31%	-14%	-16%	-1%	1%	-5%	24%	5%	1%	-23%	-134%	396%	83%

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

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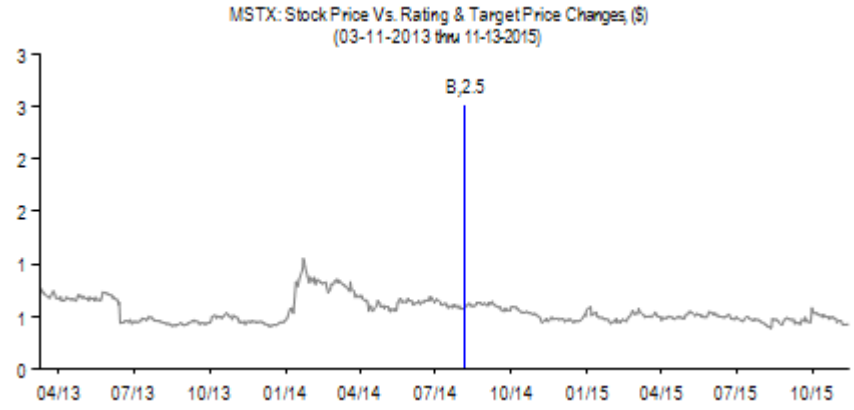
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/06/2014	Buy (B)	0.60

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/06/2014	2.50	0.60

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.	71.88%	25.00%	6.25%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	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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