

Mast Therapeutics (MSTX - \$ 0.35)

INDIE-HFpEF Phase II Study of AIR001 in Patients with Heart Failure with Preserved Ejection Fraction (HFpEF) Started

This morning, MSTX announced the initiation of a 100-patient Phase II study of AIR001 assessing inorganic nitrite delivery to improve exercise capacity in HFpEF (INDIE-HFpEF). The study is sponsored by the Duke Clinical Research Institute as the coordinating center for the Heart Failure Clinical Research Network (HFN).

- Details.** It is a multicenter, randomized, double-blinded, placebo-controlled crossover Phase II study that evaluates AIR001 in patients with HFpEF. The trial intends to enroll 100 patients in ~20 clinical sites. The study will assess AIR001's effect on aerobic capacity (peak VO₂) after four weeks of dosing. Primary endpoint is to compare the peak oxygen consumption (VO₂) after four weeks of treatment between the AIR001 and placebo treatment arms. Peak VO₂ will be assessed by cardiopulmonary exercise testing (CPET) performed at peak drug levels. In addition to safety and tolerability, other secondary outcomes measures include submaximal activity tolerance chronically, quality of life, chronic filling pressures as assessed by echocardiography and natriuretic peptide levels, and ventilator efficiency or submaximal exercise capacity at peak drug levels. Quality of life will be evaluated via a heart failure specific patient-reported outcome measure called Kansas City Cardiomyopathy Questionnaire (KCCQ).
- Implications.** On the heels of an earlier promising Phase IIa study result, we view today's news as a positive step for the progression of the AIR001 program. We are encouraged by HFN's sponsorship and commencement of this Phase II study for validating the potential value of MSTX's second asset. Despite investor focus near-term is mainly on the potential success of the EPIC study of Vepoloxamer (MST-188) in vaso-occlusive crisis (VOC) in sickle cell disease (SCD) (top-line data expected in September 2016), the continued clinical development and success of AIR001 in HFpEF would further diversify the overall risks of MSTX shares.
- 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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (08/01/2016)	\$ 0.35
52-Week High (9/30/2015)	\$ 0.60
52-Week Low (2/10/2016)	\$ 0.21
Market Cap. (MM)	\$ 67
Shares Out. (MM)	193

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.06A	-0.06	-0.05	-0.05	-0.22	N.A.
FY-15A	-0.06	-0.06	-0.06	-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.

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
Vepoloxamer (MST-188)	Vaso-occlusive crisis (VOC) in sickle cell disease (SCD)	Report of Phase III study top-line results	Sep. 2016	*****
		Potential NDA filing	2H16	***
		Potential AdComm meeting	2017	*****
		Potential approval and the U.S. launch	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)	Potentially report Phase II (INDIE-HFpEF) top-line results	2017/2018	****

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company and company presentation

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 2Q16 with ~\$35MM 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.

Figure 1: Income Statement

Mast Therapeutics – Income Statement										
(\$'000)	2012	2013	2014	2015	1Q16	2Q16E	3Q16E	4Q16E	2016E	2017E
Revenue										
Vepoloxamer revenue	0	0	0	0	-	-	-	-	0	28,253
Net sales	0	0	0	0	-	-	-	-	0	0
Licensing revenue	0	0	0	0	-	-	-	-	0	0
Grant revenue	0	0	0	0	-	-	-	-	0	0
Total revenue	0	0	0	0	-	-	-	-	0	28,253
Costs of goods	0									2,543
Research and development	8,088	12,902	19,436	28,264	7,875	7,914	5,698	4,787	26,274	22,333
Selling, general and administrative	7,519	8,518	9,487	10,963	2,835	2,948	3,037	3,082	11,903	12,974
Marketing and sales										20,000
Transaction-related expenses	(70)	80	271	0					0	0
Depreciation and amortization	90	40	84	146	32	32	32	32	128	128
Total Operating Expenses	15,628	21,539	29,279	39,373	10,742	10,895	8,767	7,901	38,305	57,978
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(39,373)	(10,742)	(10,895)	(8,767)	(7,901)	(38,305)	(29,725)
Reduction of fair value of warrants	0	0	0	0	0	0	-	-	0	0
Investment income	74	60	67	47	39	0	0	0	39	43
Interest expense	0	0	0	0	(519)	(519)	(519)	(519)	(2,076)	(2,284)
Other income/(expense), net	(5)	(1)	511	(516)	15	2	2	2	21	(20)
Loss before cumulative effect of change in accounting principle	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Cumulative effect of change in accounting principle	0	0	0	0	0	0	-	-		
Income before tax	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Tax	0	0	0	0	0	0	-	-	0	0
Net Income (Loss)	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.33)	(\$0.28)	(\$0.23)	(\$0.25)	(\$0.06)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.22)	(\$0.18)
Shares outstanding—basic	47,641	76,586	122,409	162,204	178,115	179,115	180,115	181,115	179,615	180,615
Shares outstanding—diluted	47,641	76,586	122,409	162,204	178,115	179,115	180,115	181,115	179,615	180,615
Margin Analysis (% of Sales/Revenue)										
Costs of goods									9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	79%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	117%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-105%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-113%
Tax Rate										37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-113%
Financial Indicator Growth Analysis (YoY%)										
Licensing revenue				0%					0%	0%
Grant revenue				0%					0%	0%
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	40%	60%	51%	45%	30%	2%	-22%	-36%	-7%	-15%
SG&A	5%	13%	11%	16%	-21%	22%	23%	23%	9%	9%
Marketing and sales										
Operating Income (Losses)	17%	38%	36%	34%	11%	7%	-11%	-19%	-3%	-22%
Net Income	17%	38%	34%	39%	17%	12%	-6%	-17%	1%	-21%
EPS	-31%	-14%	-16%	5%	4%	2%	-15%	-25%	-9%	-21%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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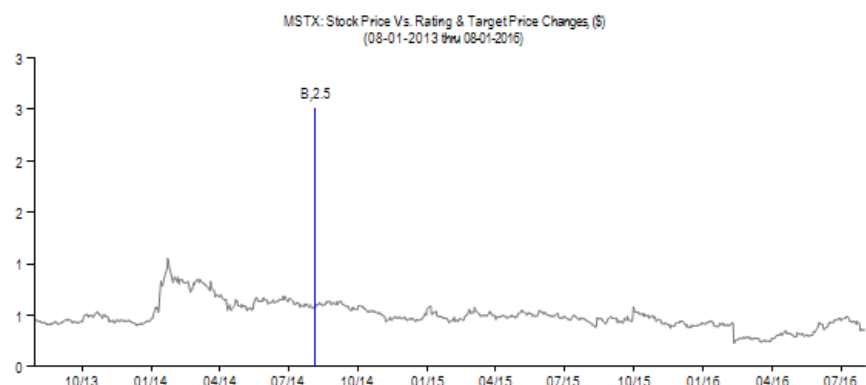
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Rating and Price Target Change History



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

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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.	64.86%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	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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