

Mast Therapeutics (MSTX - \$ 0.54)

Encouraging Vepoloxamer in Advanced Heart Failure Pre-clinical Study Results

MSTX reported encouraging pre-clinical results this morning. Performed in a dog advanced heart failure model, the results suggested repeated vepoloxamer dosing (every three weeks) improved LV systolic and diastolic function. The therapeutic impact could sustain for at least 6 weeks.

- Details.** This morning, MSTX announced positive results from a pre-clinical study that examined vepoloxamer vs. saline in a dog advanced heart failure model. The vepoloxamer treatment exhibited superior improvements in left ventricular (LV) systolic and diastolic function. With repeated dosing at the third week, the positive therapeutic impact could be sustained for at least 6 weeks (Figure 1, page 2). This outcome is consistent with the earlier positive single dosing study results. In addition, the study also suggested one of the mechanisms by which vepoloxamer restores heart function is by its ability to seal the damaged cell membrane of cardiomyocytes (Figure 2, page 2).
- Implications.** We view the vepoloxamer improving advanced heart failure pre-clinical results as encouraging. It is also logical that by repairing damaged cardiomyocytes, heart function could be restored. The positive results also suggest that MSTX could further explore the therapeutic utilities of vepoloxamer in heart failure going forward.
- 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. We view the MSTX story as under-exposed and the shares as under-valued, in our opinion.

Healthcare/Biotechnology

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

Trading Data:

Last Price (03/02/2015)	\$ 0.54
52-Week High (3/20/2014)	\$ 0.93
52-Week Low (11/6/2014)	\$ 0.40
Market Cap. (MM)	\$ 86
Shares Out. (MM)	159

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.06A	-0.06A	-0.06A	-0.06	-0.25	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.
FY-11A	NA	NA	NA	NA	-0.47	N.A.

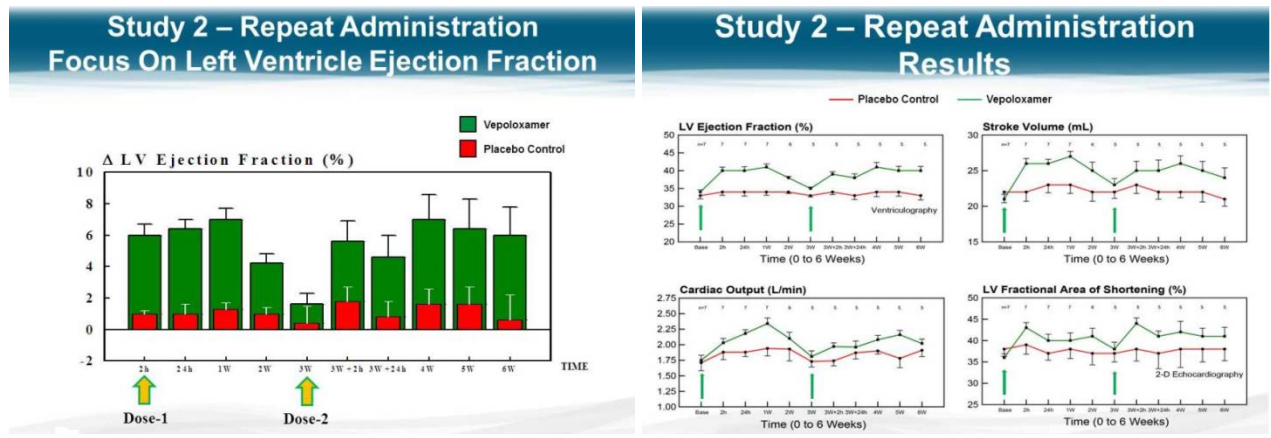
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Source: Laidlaw & Company estimates

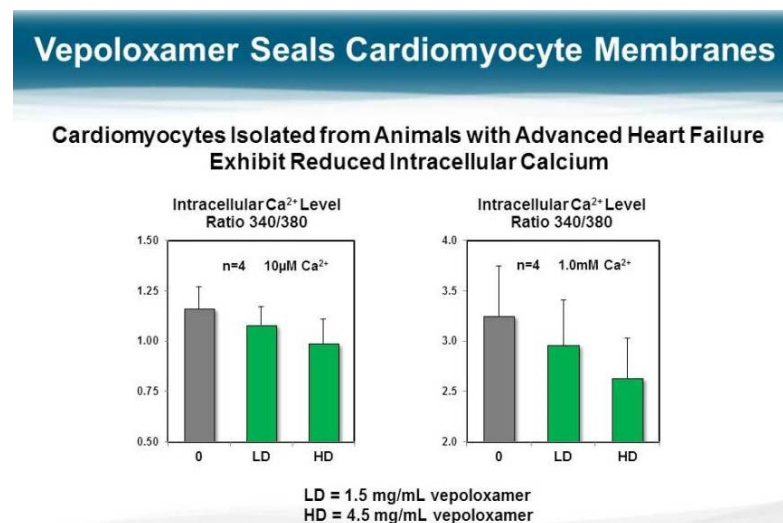
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Figure 1: Repeat Vepoloxamer administration results



Source: Company presentation

Figure 2: Vepoloxamer seals cardiomyocyte membranes and reduced intracellular calcium



Source: Company presentation

Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
MST-188	Vaso-occlusive crisis (VOC) in sickle cell disease (SCD)	Periodical updates on Phase III trial progress	2014/2015	***
		Start EPIC extension (repeat exposure);study	1H15	***
		Completion of Phase III (EPIC) study	4Q15	***
		Report of Phase III study top-line results	1Q16	****
		Potential NDA filing	1H16	***
		Potential approval	2017	****
	Acute limb ischemia	Report Phase II study top-line results	2H16	***
	Heart failure	Start Phase II study	1H15	***
		Potentially report Phase II interim results	2H15	***
AIR001	PH associated with heart failure with preserved ejection fraction (HFpEF),	Potentially start investigator-sponsored Phase II study	2015	***
		Report preliminary results	2H15	****

**** / ***** 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 outcome for the prior Phase III study, and a potentially favorable trial design of the ongoing EPIC Phase III study; risks still exist. 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 based on the assumption that a positive EPIC study outcome could lead to MST-188 approval. 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. We recognize that the substantial unmet medical need of shortening the VOC in SCD patients. However we cannot fully predict the market acceptance and potential revenue ramp up for the product. 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 to me-too competitors. Competitors might develop a method to generate a 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 processes to produce a similar, or even better, product than MST-188. As such, the company might not enjoy the competitive edge and this might damage MST-188's commercial outlook.

Limited product diversity could increase overall risk. In its nascent stage of the corporate development, the majority of the product pipeline value resides in MST-188 in SCD development. The second potential pipeline product, AIR001, remains in a very early development stage for indications such as in pulmonary arterial hypertension, acute limb ischemia, stroke, and acute heart failure. These potentially could be addressed by MST-188. 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 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 issue 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)	2011	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue														
MST-188 revenue	0	0	0					0	0	0	28,253	86,796	167,886	252,822
Net sales	0	0	0	-	-	-	-	0	0	0	0	0	0	0
Licensing revenue	0	0	0	-	-	-	-	0	0	0	0	0	0	0
Grant revenue	0	0	0	-	-	-	-	0	0	0	0	0	0	0
Total revenue	0	0	0	-	-	-	-	0	0	0	28,253	86,796	167,886	252,822
Costs of goods	0	0		-							2,543	7,812	15,110	22,754
Research and development	5,758	8,088	12,902	4,281	4,820	5,402	5,456	19,959	22,753	24,346	20,694	19,659	20,249	20,856
Selling, general and administrative	7,190	7,519	8,518	2,266	2,370	2,455	2,553	9,644	10,320	10,629	11,586	12,628	13,765	14,866
Marketing and sales											20,000	23,000	24,380	25,599
Transaction-related expenses	411	(70)	80	280	(11)	2	18	289			0	0	0	0
Depreciation and amortization	38	90	40	11	23	25	25	84	84	84	84	84	84	84
Total Operating Expenses	13,397	15,628	21,539	6,839	7,202	7,884	8,052	29,977	33,157	35,059	54,907	63,184	73,588	84,160
Operating Incomes (losses)	(13,397)	(15,628)	(21,539)	(6,839)	(7,202)	(7,884)	(8,052)	(29,977)	(33,157)	(35,059)	(26,654)	(23,612)	(94,298)	(168,662)
Reduction of fair value of warrants	0	0	0	-	-	-	0	0	0	0	0	0	0	0
Investment income	66	74	60	15	15	18	18	67	73	81	89	98	107	118
Interest expense	0	0	0	-	0	0	0	0	0	0	0	0	0	0
Other income/(expense), net	71	(5)	(1)	453	35	0	0	488	2	2	(20)	24	(27)	(27)
Loss before cumulative effect of change in accounting principle	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(8,034)	(29,422)	(33,081)	(34,977)	(26,585)	(23,734)	(94,378)	(168,753)
Cumulative effect of change in accounting principle	0	0	0	-	0	0	0	0	0	0	0	0	0	0
Income before tax	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(8,034)	(29,422)	(33,081)	(34,977)	(26,585)	(23,734)	(94,378)	(168,753)
Tax	0.0	0	0	-	0	0	0	0	0	0	0	(8,781)	(34,920)	(62,439)
Net Income (Loss)	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(8,034)	(29,422)	(33,081)	(34,977)	(26,585)	(14,952)	(59,458)	(106,314)
Net Income (Loss) Applicable to Common Shareholders	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(8,034)	(29,422)	(33,081)	(34,977)	(26,585)	(14,952)	(59,458)	(106,314)
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.47)	(\$0.33)	(\$0.28)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)	(\$0.25)	(\$0.25)	(\$0.19)	\$0.11	\$0.42	\$0.75
Shares outstanding—basic	28,175	47,641	76,586	105,054	115,587	123,287	125,287	117,304	130,287	137,287	138,287	139,287	140,287	141,287
Shares outstanding—diluted	28,175	47,641	76,586	105,054	115,587	123,287	125,287	117,304	130,287	137,287	138,287	139,287	140,287	141,287
Margin Analysis (% of Sales/Revenue)														
Costs of goods										9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	73%	23%	12%	8%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	112%	41%	23%	16%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-94%	27%	56%	67%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-94%	27%	56%	67%
Tax Rate											37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-94%	17%	35%	42%
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%	24%	70%	74%	55%	55%	14%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	7%	13%	14%	19%	13%	7%	3%	9%	9%	9%	8%
Marketing and sales												15%	6%	5%
Operating Income (Losses)		17%	38%	22%	45%	50%	41%	39%	11%	6%	-24%	-189%	299%	79%
Net Income		17%	38%	14%	45%	50%	41%	37%	12%	6%	-24%	-156%	298%	79%
EPS		-31%	-14%	-50%	-33%	25%	16%	-11%	1%	0%	-25%	-156%	295%	78%

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

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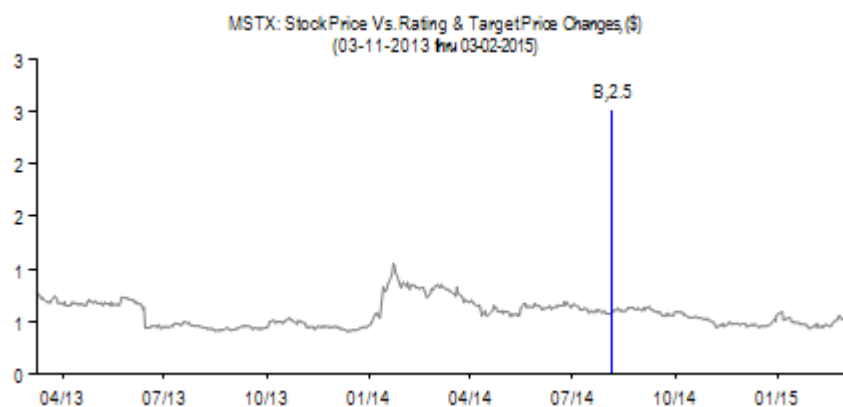
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Rating and Price Target Change History



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

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.	81.82%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.55%	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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