

Mast Therapeutics (MSTX - \$ 0.54)

4Q14: EPIC Study Remains On-Track for Completing Patient Recruitment by 4Q15, Additional Clinical Studies Underway

This morning, MSTX reported 4Q14 financial results with a net loss of (\$7.3MM), or (\$0.05) net loss per share. The company ended 4Q14 with cash of ~\$57MM enough to support its operation deep into 2016, in our opinion.

- EPIC study patient enrollment remains on-track.** MSTX provided a patient recruitment update in early January (see our 2015-01-06 note). In our discussions today, management reiterated that the enrollment for the vepoloxamer (MST-188) in SCD Phase III (EPIC) study remains on track to complete in 4Q15 with top-line results available in 1Q16. We expect an EPIC extension study to start in 2Q15. Patients (both receiving treatment and placebo during the initial EPIC trial) will take repeated exposure of vepoloxamer during their subsequent vaso-occlusive crisis (VOC) episodes. Together, we believe MSTX's EPIC trial remains very much ahead of the competition in SCD treatment development and with a substantial lead time.
- Vepoloxamer in chronic heart failure Phase II trial to start in 3Q15.** MSTX is expanding the clinical development of vepoloxamer and plans to start a chronic heart failure Phase II trial in 3Q15. MSTX recently reported encouraging pre-clinical results from vepoloxamer in a heart failure animal model (see our 2015-03-02 note). The planned Phase II trial is a randomized, double-blind, two-arm, placebo-controlled and 150-patient study. The study objectives are to examine safety and efficacy, which include the drug's effect on biological markers of cardiac injury (troponin) and wall stress (NT-proBNP), as well as clinical outcomes. We estimate the top-line results could be available in 2016.
- Pipeline developments.** Investigator-sponsored clinical studies of AIR001 in WHO Group 2 pulmonary hypertension (PH) patients associated with left heart disease are underway; with preliminary data potentially available in 2H15.
- 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 (03/24/2015)	\$ 0.54
52-Week High (3/24/2014)	\$ 0.80
52-Week Low (11/6/2014)	\$ 0.40
Market Cap. (MM)	\$ 85
Shares Out. (MM)	159

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.05	-0.06	-0.06	-0.06	-0.24	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.

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Source: Laidlaw & Company estimates

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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	2H16	***
		Potential approval	2017	****
	Acute limb ischemia	Report Phase II study top-line results	2H16	***
	Chronic heart failure	Potentially report Phase II top-line results	2016	***
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 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.

Figure 1: Income Statement

Mast Therapeutics – Income Statement																		
(\$'000)	2011	2012	2013	1Q14	2Q14	3Q14	4Q14	2014	1Q15E	2Q15E	3Q15E	4Q15E	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	4,933	19,436	5,525	6,022	6,504	6,894	24,945	26,692	22,688	21,553	22,200	22,866
Selling, general and administrative	7,190	7,519	8,518	2,266	2,370	2,455	2,396	9,487	2,451	2,490	2,535	2,573	10,050	10,351	11,283	12,298	13,405	14,478
Marketing and sales															20,000	23,000	24,380	25,599
Transaction-related expenses	411	(70)	80	280	(11)	2	0	271	0	-	-	-	0	0	0	0	0	0
Depreciation and amortization	38	90	40	11	23	25	25	84	25	25	25	25	100	100	100	100	100	100
Total Operating Expenses	13,397	15,628	21,539	6,839	7,202	7,884	7,354	29,279	8,001	8,538	9,064	9,492	35,095	37,143	56,613	64,763	75,195	85,797
Operating Incomes (Losses)	(13,397)	(15,628)	(21,539)	(6,839)	(7,202)	(7,884)	(7,354)	(29,279)	(8,001)	(8,538)	(9,064)	(9,492)	(35,095)	(37,143)	(28,360)	22,032	92,691	167,025
Reduction of fair value of warrants	0	0	0	-	-	-	-	0	0	-	-	-	-	0	0	0	0	0
Investment income	66	74	60	15	15	18	18	67	17	17	17	17	68	75	82	91	100	110
Interest expense	0	0	0	-	-	-	-	0	0	-	-	-	-	0	0	0	0	0
Other income/(expense), net	71	(5)	(1)	453	35	0	23	511	50	50	50	50	200	2	(20)	24	(27)	(27)
Loss before cumulative effect of change in accounting princ	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(7,313)	(28,701)	(7,934)	(8,471)	(8,997)	(9,425)	(34,827)	(37,066)	(28,298)	22,147	92,763	167,108
Cumulative effect of change in accounting principle	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)	(7,313)	(28,701)	(7,934)	(8,471)	(8,997)	(9,425)	(34,827)	(37,066)	(28,298)	22,147	92,763	167,108
Tax	0.0	0	0	-	-	-	-	0	0	-	-	-	0	0	0	(8,194)	(34,322)	(61,830)
Net Income (Loss)	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(7,313)	(28,701)	(7,934)	(8,471)	(8,997)	(9,425)	(34,827)	(37,066)	(28,298)	13,952	58,441	105,278
Net Income (Loss) Applicable to Common Shareholders	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,866)	(7,313)	(28,701)	(7,934)	(8,471)	(8,997)	(9,425)	(34,827)	(37,066)	(28,298)	13,952	58,441	105,278
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.47)	(\$0.33)	(\$0.28)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.05)	(\$0.23)	(\$0.05)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.24)	(\$0.24)	(\$0.18)	\$0.09	\$0.37	\$0.66
Shares outstanding—basic	28,175	47,641	76,586	105,054	115,587	123,287	145,257	122,409	146,257	147,257	148,257	149,257	147,757	154,757	155,757	156,757	157,757	158,757
Shares outstanding—diluted	28,175	47,641	76,586	105,054	115,587	123,287	145,257	122,409	146,257	147,257	148,257	149,257	147,757	154,757	155,757	156,757	157,757	158,757
Margin Analysis (% of Sales/Revenue)																		
Costs of goods	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	80%	25%	13%	9%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	111%	41%	23%	16%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-100%	25%	55%	66%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-100%	26%	55%	66%
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-100%	16%	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	NA	NA	NA	NA	207%	93%	51%
R&D		40%	60%	24%	70%	74%	40%	51%	29%	25%	20%	40%	28%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	7%	13%	14%	12%	11%	8%	5%	3%	7%	6%	3%	9%	9%	9%	8%
Marketing and sales															15%	6%	5%	
Operating Income (Losses)		17%	38%	22%	45%	50%	29%	36%	17%	19%	15%	29%	20%	6%	-24%	-178%	321%	80%
Net Income		17%	38%	14%	45%	50%	28%	34%	25%	18%	14%	29%	21%	6%	-24%	-149%	319%	80%
EPS		-31%	-14%	-50%	-33%	25%	-9%	-16%	-11%	-7%	-5%	25%	1%	2%	-24%	-149%	316%	79%

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

DISCLOSURES:

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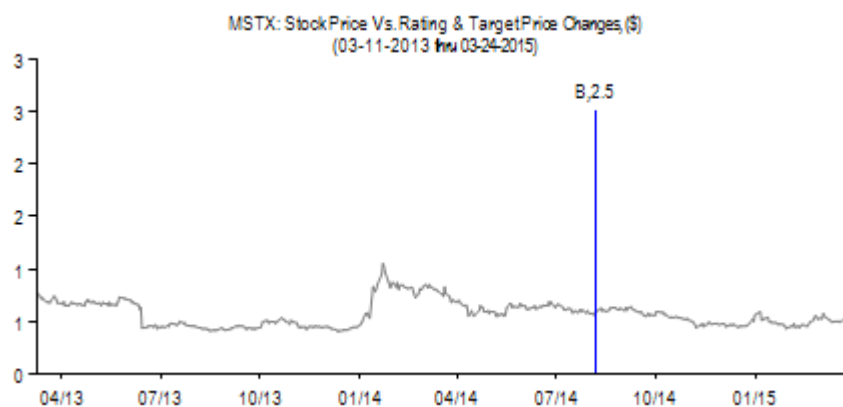
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Rating and Price Target Change History



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%
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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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