

## Mast Therapeutics (MSTX - \$ 0.28)

### 4Q15: All Eyes Are Focusing on EPIC Trial Top-line Results Anticipated in 2Q16

This morning, MSTX reported 4Q15 financial results with a net loss of (\$10.2MM), which is essentially identical to Laidlaw and the Street's estimates of (\$10.2MM). Net loss per share equated to (\$0.06), which is also identical to the estimates of Laidlaw and the Street. We estimate MSTX currently should have ~\$40MM (pro forma) in cash, which includes ~\$8MM from recent financing adjusted for estimated expenses of the last two months. MSTX's cash is enough to support its operation into 2017, in our opinion.

- Patient enrollment completed and top-line results expected in 2Q16.** MSTX reported last month the completion of patient enrollment of the Vepoloxamer in sickle cell disease (SCD) experiencing vaso-occlusive crisis (VOC) Phase III (EPIC) study. The company guided the top-line results would be available in 2Q16 – a binary event for the MSTX shares, in our opinion, given that the EPIC trial is Vepoloxamer's most advanced clinical development. A positive result, we believe, could afford substantial upside for the share value given the low current MSTX share valuation (<\$15MM enterprise value). We remain encouraged for potentially positive outcome since the trial has recruited high percentages of pediatric (~72%) and hydroxyurea (HU) treated (61%) patients according to the report provided during MSTX Analyst Day (on 2015-10-08 when patient recruitment had reached ~80%). Both patient cohorts have demonstrated statistically significant improvements from the prior Phase III study. The primary endpoint is reduction of the duration of VOC mainly based on completion of parenteral analgesic use (time from randomization to the last dose of parenteral analgesic or opioid for the treatment of VOC prior to hospital discharge). Should the outcome be positive and MSTX files for approval, we believe the FDA will hold an AdCom meeting before the PDUFA decision — both likely in 2017.
- AIR001 in HFpEF update.** MSTX is scheduled to start a randomized, double-blind, placebo-controlled Phase II (INDIE-HFpEF) study (n~100) in 3Q16. Interim data from a second investigator sponsored AIR001 in HFpEF Phase IIa study could be available mid-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.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.06	-0.06	-0.05	-0.05	-0.22	N.A.
<b>FY-15A</b>	-0.06	-0.06	-0.06	-0.06	-0.25	N.A.
<b>FY-14A</b>	-0.06	-0.06	-0.06	-0.05	-0.23	N.A.
<b>FY-13A</b>	-0.12	-0.09	-0.05	-0.06	-0.28	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>MSTX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 2.50</b>

#### Trading Data:

Last Price (03/14/2016)	\$ 0.28
52-Week High (9/30/2015)	\$ 0.60
52-Week Low (2/10/2016)	\$ 0.21
Market Cap. (MM)	\$ 53
Shares Out. (MM)	193

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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	2Q16	*****
		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)	Present initial patient cohort preliminary results at a scientific conference	May 2016	****
		Commence Phase II (INDIE-HFpEF) trial	3Q16	***

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

Source: Laidlaw & Company and company presentation

## Major Risks

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**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)	2012	2013	2014	1Q15	2Q15	3Q15	4Q15	2015	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E
<b>Revenue</b>														
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	6,042	7,734	7,330	7,518	28,264	7,593	7,631	5,723	4,922	25,870	21,989
Selling, general and administrative	7,519	8,518	9,487	3,578	2,410	2,460	2,515	10,963	2,641	2,746	2,939	2,983	11,308	12,326
Marketing and sales														20,000
Transaction-related expenses	(70)	80	271	-	-	0	0	0					0	0
Depreciation and amortization	90	40	84	30	37	38	41	146	41	41	41	41	164	164
<b>Total Operating Expenses</b>	<b>15,628</b>	<b>21,539</b>	<b>29,279</b>	<b>9,650</b>	<b>10,181</b>	<b>9,828</b>	<b>9,714</b>	<b>39,373</b>	<b>10,275</b>	<b>10,419</b>	<b>8,703</b>	<b>7,946</b>	<b>37,342</b>	<b>57,022</b>
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(9,650)	(10,181)	(9,828)	(9,714)	(39,373)	(10,275)	(10,419)	(8,703)	(7,946)	(37,342)	(28,769)
Reduction of fair value of warrants	0	0	0	-	-	-	0	0	0	-	-	-	0	0
Investment income	74	60	67	17	30	0	0	47	0	0	0	0	0	0
Interest expense	0	0	0	-	-	-	-	0	0	-	-	-	0	0
Other income/(expense), net	(5)	(1)	511	17	0	(84)	(449)	(516)	2	2	2	2	8	(20)
Loss before cumulative effect of change in accounting principle	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,163)	(39,842)	(10,273)	(10,417)	(8,701)	(7,944)	(37,334)	(28,789)
Cumulative effect of change in accounting principle	0	0	0	-	0	0	0	0	0	-	-	-	-	-
<b>Income before tax</b>	<b>(15,559)</b>	<b>(21,480)</b>	<b>(28,701)</b>	<b>(9,616)</b>	<b>(10,151)</b>	<b>(9,912)</b>	<b>(10,163)</b>	<b>(39,842)</b>	<b>(10,273)</b>	<b>(10,417)</b>	<b>(8,701)</b>	<b>(7,944)</b>	<b>(37,334)</b>	<b>(28,789)</b>
Tax	0	0	0	-	-	0	0	0	0	-	-	-	0	0
<b>Net Income (Loss)</b>	<b>(15,559)</b>	<b>(21,480)</b>	<b>(28,701)</b>	<b>(9,616)</b>	<b>(10,151)</b>	<b>(9,912)</b>	<b>(10,163)</b>	<b>(39,842)</b>	<b>(10,273)</b>	<b>(10,417)</b>	<b>(8,701)</b>	<b>(7,944)</b>	<b>(37,334)</b>	<b>(28,789)</b>
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(9,912)	(10,163)	(39,842)	(10,273)	(10,417)	(8,701)	(7,944)	(37,334)	(28,789)
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.33)	(\$0.28)	(\$0.23)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.25)	(\$0.06)	(\$0.06)	(\$0.05)	(\$0.05)	(\$0.22)	(\$0.17)
Shares outstanding—basic	47,641	76,586	122,409	159,459	162,128	163,614	163,614	162,204	164,614	165,614	166,614	167,614	166,114	167,114
Shares outstanding—diluted	47,641	76,586	122,409	159,459	162,128	163,614	163,614	162,204	164,614	165,614	166,614	167,614	166,114	167,114
<b>Margin Analysis (% of Sales/Revenue)</b>														
Costs of goods													9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	78%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	114%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-102%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-102%
Tax Rate														37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-102%
<b>Financial Indicator Growth Analysis (YoY%)</b>														
Licensing revenue								0%					0%	0%
Grant revenue								0%					0%	0%
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	40%	60%	51%	41%	60%	36%	52%	45%	26%	-1%	-22%	-35%	-8%	-15%
SG&A	5%	13%	11%	58%	2%	0%	5%	16%	-26%	14%	19%	19%	3%	9%
Marketing and sales														
Operating Income (Losses)	17%	38%	36%	41%	41%	25%	32%	34%	6%	2%	-11%	-18%	-5%	-23%
Net Income	17%	38%	34%	51%	42%	26%	39%	39%	7%	3%	-12%	-22%	-6%	-23%
EPS	-31%	-14%	-16%	-1%	1%	-5%	23%	5%	3%	0%	-14%	-24%	-9%	-23%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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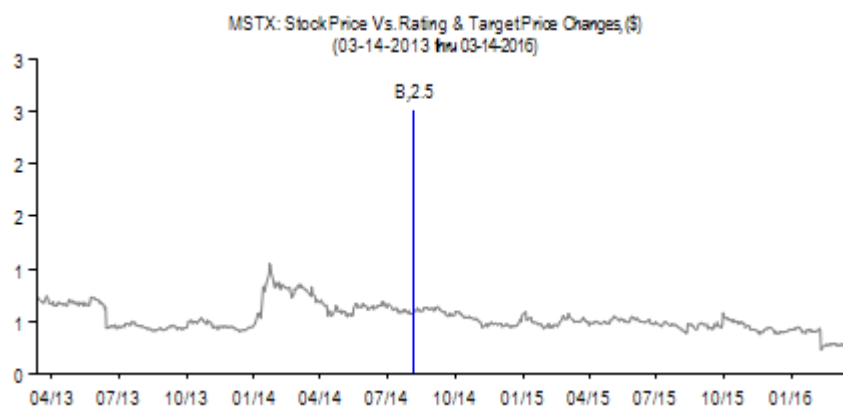
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#### 3 Year Rating Change History

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

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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