

## Mast Therapeutics (MSTX - \$ 0.52)

1Q15: Uneventful on the Financial Side, EPIC Study Remains On-Track for Completing Patient Recruitment by 4Q15 With Top-line Results Available in 1Q16

This morning, MSTX reported 1Q15 financial results with a net loss of (\$9.6MM), or (\$0.06) net loss per share. The company ended 1Q15 with cash of ~\$50MM enough to support its operation deep into 2016, in our opinion.

- EPIC study patient enrollment remains on-track.** Last month, MSTX provided an update on patient recruitment indicating that the EPIC trial already enrolled more than half of the patients (205/388) needed. At the recruitment pace between January and April, we believe patient enrollment is on-track to complete in 4Q15 per company guidance. We expect top-line results to be available in 1Q16 (see our 2015-04-21 note). In addition, we view the prior update illustrating the age distribution of the patients recruited so far (~20% of 18 or older) bodes well for the potential that the drug use might not be limited only to pediatric patients if it receives approval. We also expect an EPIC extension study to start in 2Q15. In this study, all 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. The extension study could help to expand the safety database.
- Pipeline developments.** MSTX recently reported encouraging pre-clinical study results of vepoloxamer in several indications, which include sickle cell disease, heart failure and stroke. MSTX plans to start a vepoloxamer in chronic heart failure Phase II trial in 3Q15 with top-line results potentially available in 2016. This would be a randomized, double-blind, two-arm, placebo-controlled and 150-patient study. The objectives of the trial are to examine safety and efficacy, which include the drug's effect on biological markers of cardiac injury (troponin), wall stress (NT-proBNP), and clinical outcomes. We also expect the preliminary data of an investigator-sponsored trial that evaluates AIR001 in WHO Group 2 pulmonary hypertension (PH) patients associated with left heart disease potentially be 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.

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-0.06A	-0.06	-0.06	-0.06	-0.24	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.
<b>FY-12A</b>	-0.09	NA	-0.07	-0.08	-0.33	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 (05/11/2015)	\$ 0.52
52-Week High (6/24/2014)	\$ 0.73
52-Week Low (11/6/2014)	\$ 0.40
Market Cap. (MM)	\$ 84
Shares Out. (MM)	160

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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

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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)	2011	2012	2013	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenue</b>														
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
<b>Costs of goods</b>	0	0									2,543	7,812	15,110	22,754
Research and development	5,758	8,088	12,902	19,436	6,042	6,163	6,594	6,990	25,789	27,594	23,455	22,282	22,951	23,639
Selling, general and administrative	7,190	7,519	8,518	9,487	3,578	2,862	2,914	2,958	12,312	12,681	13,823	15,067	16,423	17,736
Marketing and sales											20,000	23,000	24,380	25,599
Transaction-related expenses	411	(70)	80	271	-	0	-	-	0	0	0	0	0	0
Depreciation and amortization	38	90	40	84	30	30	30	30	120	120	120	120	120	120
<b>Total Operating Expenses</b>	13,397	15,628	21,539	29,279	9,650	9,055	9,538	9,978	38,221	40,396	59,940	68,281	78,983	89,849
Operating Incomes (losses)	(13,397)	(15,628)	(21,539)	(29,279)	(9,650)	(9,055)	(9,538)	(9,978)	(38,221)	(40,396)	(31,687)	18,515	88,903	162,973
Reduction of fair value of warrants	0	0	0	0	-	0	-	-	0	0	0	0	0	0
Investment income	66	74	60	67	17	17	17	17	68	75	82	91	100	110
Interest expense	0	0	0	0	0	0	-	-	0	0	0	0	0	0
Other income/(expense), net	71	(5)	(1)	511	17	20	20	23	80	2	(20)	24	(27)	(27)
Loss before cumulative effect of change in accounting princ	(13,260)	(15,559)	(21,480)	(28,701)	(9,616)	(9,018)	(9,501)	(9,938)	(38,073)	(40,319)	(31,625)	18,630	88,975	163,056
Cumulative effect of change in accounting principle	0	0	0	0	-	0	-	-	0	0	0	0	0	0
<b>Income before tax</b>	(13,260)	(15,559)	(21,480)	(28,701)	(9,616)	(9,018)	(9,501)	(9,938)	(38,073)	(40,319)	(31,625)	18,630	88,975	163,056
Tax	0.0	0	0	0	-	0	-	-	0	0	0	(6,893)	(32,921)	(60,331)
<b>Net Income (Loss)</b>	(13,260)	(15,559)	(21,480)	(28,701)	(9,616)	(9,018)	(9,501)	(9,938)	(38,073)	(40,319)	(31,625)	11,737	56,054	102,725
Net Income (Loss) Applicable to Common Shareholders	(13,260)	(15,559)	(21,480)	(28,701)	(9,616)	(9,018)	(9,501)	(9,938)	(38,073)	(40,319)	(31,625)	11,737	56,054	102,725
Net Earnings (Losses) Per Share—Basic and Diluted	(\$0.47)	(\$0.33)	(\$0.28)	(\$0.23)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.06)	(\$0.24)	(\$0.24)	(\$0.19)	\$0.07	\$0.33	\$0.60
Shares outstanding—basic	28,175	47,641	76,586	122,409	159,459	160,459	161,459	162,459	160,959	167,959	168,959	169,959	170,959	171,959
Shares outstanding—diluted	28,175	47,641	76,586	122,409	159,459	160,459	161,459	162,459	160,959	167,959	168,959	169,959	170,959	171,959
<b>Margin Analysis (% of Sales/Revenue)</b>														
Costs of goods										9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	83%	26%	14%	9%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	120%	44%	24%	17%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-112%	21%	53%	64%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-112%	21%	53%	64%
Tax Rate											37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-112%	14%	33%	41%
<b>Financial Indicator Growth Analysis (YoY%)</b>														
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%	28%	22%	42%	33%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	11%	58%	21%	19%	23%	30%	3%	9%	9%	9%	8%
Marketing and sales												15%	6%	5%
Operating Income (Losses)		17%	38%	36%	41%	26%	21%	36%	31%	6%	-22%	-158%	380%	83%
Net Income		17%	38%	34%	51%	26%	21%	36%	33%	6%	-22%	-137%	378%	83%
EPS		-31%	-14%	-16%	-1%	-9%	-8%	21%	1%	1%	-22%	-137%	375%	82%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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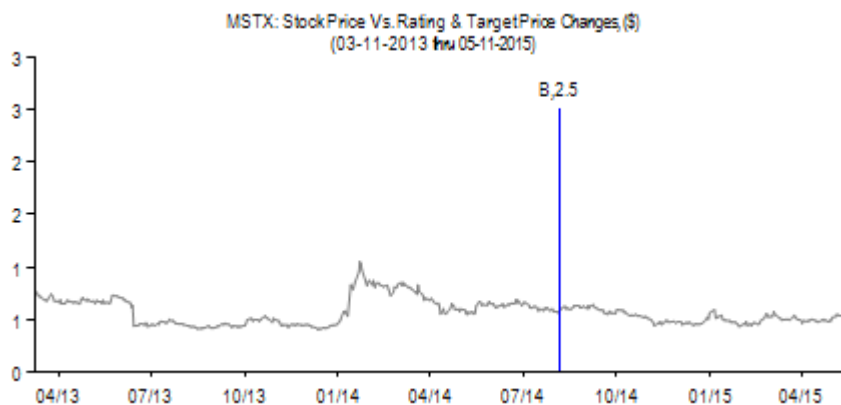
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#### 3 Year Rating Change History

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

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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.	73.08%	30.77%	7.69%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.85%	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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