

## Mast Therapeutics (MSTX - \$ 0.51)

### 3Q14: Uneventful Quarter as EPIC Study Remains On-Track for Patient Recruitment Completion by 4Q15

This morning, MSTX reported 3Q14 financial results with a net loss of (\$7.7MM), or (\$0.06) net loss per share. With cash of ~\$43MM by the end of 3Q14, we believe the company has sufficient capital for operations through early 2016.

- EPIC study patient enrollment on-track.** Management indicated that patient enrollment for the MST-188 in SCD Phase III (EPIC) study remains on track with completion potentially in 4Q15. Currently, there are more than 60 active clinical sites (50 in the U.S. and >10 ex-U.S.) with an expected goal totaling an estimated 70 sites. The company also announced to start an EPIC extension study in 1H15 for patients (both receiving treatment and placebo during the regulator EPIC trial) to take repeated exposure of MST-188 during their subsequent vaso-occlusive crisis (VOC) episodes. We view this development as positive given it could potentially provide additional clinical information on repeated exposure to MST-188 treatment, and also provide a greater incentive for patients participating in the EPIC clinical study. Even patients that have been randomized into the placebo group could potentially benefit from MST-188 treatment during their subsequent VOCs. The recent filing by GlycoMimetics suggested that Pfizer was still working through the manufacturing development issue affecting the formulated drug supply of rivipansel (GMI-1070) before they can start the Phase III study. We believe MSTX's EPIC trial is still in a comfortable position with substantial lead time ahead of rivipansel development. In addition, we also anticipate MSTX to further enhance the intellectual property position of MST-188 going forward to fend off potential competitors.
- Pipeline developments.** MSTX is preparing several investigator-sponsored clinical studies of AIR001 in WHO Group 2 pulmonary hypertension (PH) patients associated with left heart disease; with preliminary data potentially available in 2H15. Further, patient enrollment of MST-188 in a heart failure Phase II study could start in 1H15, while interim safety analysis results may 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-14E</b>	-0.06A	-0.06A	-0.06A	-0.06	-0.25	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.
<b>FY-11A</b>	NA	NA	NA	NA	-0.47	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 (10/31/2014)	\$ 0.51
52-Week High (1/22/2014)	\$ 1.10
52-Week Low (12/12/2013)	\$ 0.40
Market Cap. (MM)	\$ 61
Shares Out. (MM)	122

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### Anticipated milestones in 2014 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	***
	Embolic stroke	Report pre-clinical data	2Q15	***
	Heart failure	Potentially complete discussion with the FDA for trial design	4Q14	***
		Report pre-clinical data	1Q15	***
		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 studies	4Q14
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	1Q14	2Q14	3Q14	4Q14E	2014E	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
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
<b>Total Operating Expenses</b>	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
<b>Income before tax</b>	(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)
<b>Net Income (Loss)</b>	(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
<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	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%
<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%	24%	70%	74%	55%	55%	14%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	7%	13%	14%	19%	13%	7%	3%	9%	9%	8%	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 &amp; Company estimates

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*Additional information available upon request.*

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Date	Rating	Closing Price (\$)
08/06/2014	Buy (B)	0.60

Date	Target Price (\$)	Closing Price, (\$)
08/06/2014	2.50	0.60

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			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.	95.24%	33.33%	14.29%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.76%	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%

### ADDITIONAL COMPANIES MENTIONED

GlycoMimetics (GLCY: Not Rated)  
Pfizer (PFE: Not: Rated)

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