

## Mast Therapeutics (MSTX - \$ 0.49)

### Patient Recruitment for Vepoloxamer Pivotal (EPIC) Trial is On-track to Complete as Projected

This morning, MSTX provided an update on patient recruitment for the vepoloxamer in resolving vaso-occlusive crisis (VOC) in sickle cell disease (SCD) patient pivotal (EPIC) trial. 205 patients are enrolled as of April 20, 2015.

- Details.** MSTX this morning provided an update on the patient recruitment for the vepoloxamer in resolving VOC in SCD patient pivotal (EPIC) trial with 205 patients enrolled as of April 20, 2015. Accordingly, the company reiterated its projection of reporting top-line results in 1Q16. MSTX also indicated that the trial now includes 70 clinical sites in ten countries, with greater than two-thirds of clinical sites located in the U.S. The company also plans to open new sites over the next few months in at least four additional countries. Additional information reported this morning includes: 1) >70% of the clinical sites have enrolled at least one patient and >52% of sites have enrolled two or more patients; 2) the majority of enrolled patients were from the U.S.; and 3) the average age of randomized patients is 14, while ~20% of the randomized patients are 18 and over.
- Implications.** We view today's update on patient recruitment as a very positive development. Recall that the company's earlier patient enrollment update (in January 6<sup>th</sup> this year) indicated a total of ~130 patients were enrolled then. During the three and half months since the last update, the study enrolled ~75 patients. With the projected a total of 388 patients needed, it might be an additional eight to nine months for patient enrollment to reach the target (December 2015 or January 2016); if the future patient recruitment pace is identical to that of the last three and half months. Given that patient recruitment usually picks up its pace as the trial enters the later stages since most sites are better ready to accept patients. We believe patient recruitment completion could occur in 4Q15 as guided by the company. We also view the age distribution of the patients (~20% of 18 or older) bodes well for the drug use not being limited only to pediatric patients if it receives approval.
- 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 (04/20/2015)	\$ 0.49
52-Week High (6/24/2014)	\$ 0.73
52-Week Low (11/6/2014)	\$ 0.40
Market Cap. (MM)	\$ 78
Shares Out. (MM)	159

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-15E</b>	-0.05	-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.

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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

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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										
					1Q15E	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
Costs of goods	0	0									2,543	7,812	15,110	22,754
Research and development	5,758	8,088	12,902	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	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	271	0	-	-	-	0	0	0	0	0	0
Depreciation and amortization	38	90	40	84	25	25	25	25	100	100	100	100	100	100
<b>Total Operating Expenses</b>	<b>13,397</b>	<b>15,628</b>	<b>21,539</b>	<b>29,279</b>	<b>8,001</b>	<b>8,538</b>	<b>9,064</b>	<b>9,492</b>	<b>35,095</b>	<b>37,143</b>	<b>56,613</b>	<b>64,763</b>	<b>75,195</b>	<b>85,797</b>
Operating Incomes (losses)	(13,397)	(15,628)	(21,539)	(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	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
Other income/(expense), net	71	(5)	(1)	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)	(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
<b>Income before tax</b>	<b>(13,260)</b>	<b>(15,559)</b>	<b>(21,480)</b>	<b>(28,701)</b>	<b>(7,934)</b>	<b>(8,471)</b>	<b>(8,997)</b>	<b>(9,425)</b>	<b>(34,827)</b>	<b>(37,066)</b>	<b>(28,298)</b>	<b>22,147</b>	<b>92,763</b>	<b>167,108</b>
Tax	0.0	0	0	0	0	-	-	-	0	0	0	(8,194)	(34,322)	(61,830)
<b>Net Income (Loss)</b>	<b>(13,260)</b>	<b>(15,559)</b>	<b>(21,480)</b>	<b>(28,701)</b>	<b>(7,934)</b>	<b>(8,471)</b>	<b>(8,997)</b>	<b>(9,425)</b>	<b>(34,827)</b>	<b>(37,066)</b>	<b>(28,298)</b>	<b>13,952</b>	<b>58,441</b>	<b>105,278</b>
Net Income (Loss) Applicable to Common Shareholders	(13,260)	(15,559)	(21,480)	(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)	(\$0.23)	(\$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	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	122,409	146,257	147,257	148,257	149,257	147,757	154,757	155,757	156,757	157,757	158,757
<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	80%	25%	13%	9%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	11%	41%	23%	16%
Operating Income (loss)	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	-100%	26%	55%	66%
Tax Rate											37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-100%	16%	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%	51%	29%	25%	20%	40%	28%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	11%	8%	5%	3%	7%	6%	3%	9%	9%	9%	8%
Marketing and sales											15%	6%	5%	
Operating Income (Losses)		17%	38%	36%	17%	19%	15%	29%	20%	6%	-24%	-178%	321%	80%
Net Income		17%	38%	34%	25%	18%	14%	29%	21%	6%	-24%	-149%	319%	80%
EPS		-31%	-14%	-16%	-11%	-7%	-5%	25%	1%	2%	-24%	-149%	316%	79%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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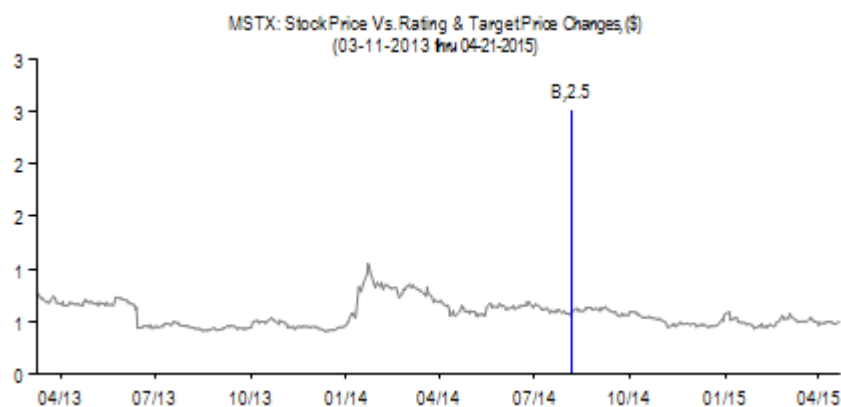
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*Additional information available upon request.*

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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.	69.57%	30.43%	8.70%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.35%	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)  
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