

Mast Therapeutics (MSTX - \$ 0.47)

AIR001 in Heart Failure with Preserved Ejection Fraction (HFpEF) Phase II Studies Started

MSTX reported this morning the commencement of two institutional-sponsored AIR001 in heart failure with preserved ejection fraction (HFpEF) Phase IIa studies.

- Details.** This morning, MSTX announced the commencement of patient dosing of two institutional-sponsored AIR001 in heart failure with preserved ejection fraction (HFpEF) Phase IIa studies. The studies will be conducted at Mayo Clinic and the University of Pittsburgh. Both trials will evaluate the hemodynamic effects of AIR001 in acute and exercise conditions. The studies also will examine the change in submaximal oxygen consumption before and after AIR001 vs. placebo. MSTX will start a third institutional-sponsored AIR001 in HFpEF Phase IIa study later this year with the objective to compare hemodynamic benefits vs. the formation of methemoglobin between AIR001 (inhaled sodium nitrite solution) and intravenous nitrite. According to clinicaltrials.gov (clinicalTrials.gov identifier: NCT02262078), the Mayo study is a randomized, double-blind trial that expects to recruit 30 HFpEF patients referred to the catheterization lab. The primary endpoints are exercise pulmonary capillary wedge pressure 4 minutes after starting exercise; and cardiac filling pressure measured in mmHg. Top-line results are expected by year-end 2015.
- Implications.** We view the start of clinical development of AIR001 in HFpEF is a positive development for MSTX shareholders as the company now has a second clinical product in their development pipeline. HFpEF is a major public health problem that has no proven effective treatment. Although the major focus for most investors might remain on the advancement of the vepoloxamer (MST-188) in resolving vaso-occlusive crisis (VOC) in sickle cell disease (SCD) Phase III (EPIC) trial; we believe the clinical progress of AIR001 could provide MSTX shareholders a second value driver; and AIR001 clinical advancement potentially represents more diversification for overall risks.
- 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
FY-14E	-0.06A	-0.06A	-0.06A	-0.06	-0.25	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.
FY-11A	NA	NA	NA	NA	-0.47	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	MSTX
Rating:	Buy
Price Target:	\$ 2.50

Trading Data:

Last Price (02/04/2015)	\$ 0.47
52-Week High (3/20/2014)	\$ 0.93
52-Week Low (11/6/2014)	\$ 0.40
Market Cap. (MM)	\$ 75
Shares Out. (MM)	159

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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	1H16	***
		Potential approval	2017	****
	Acute limb ischemia	Report Phase II study top-line results	2H16	***
	Embolic stroke	Report pre-clinical data	2Q15	***
	Heart failure	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 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	4Q14E	2014E	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	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
Total Operating Expenses	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						
Income before tax	(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)
Net Income (Loss)	(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
Margin Analysis (% of Sales/Revenue)														
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%
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	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%	9%	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 & Company estimates

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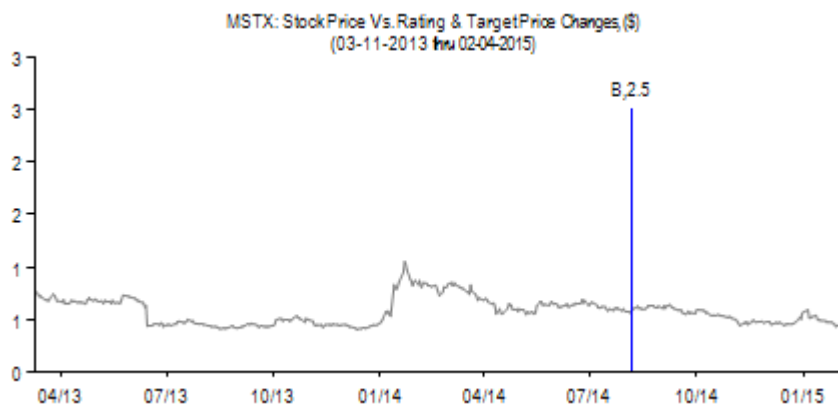
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Rating and Price Target Change History



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%
Buy (B)	Expected to outperform the sector average over 12 months.	81.82%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.55%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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