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EQUITY RESEARCH
Company Report

October 27, 2015

Mast Therapeutics (MSTX - $ 0.49)

Healthcare/Biotechnology

Vepoloxamer in Chronic Heart Failure Phase II Study Started - Top-line Results Possible in Late 2016

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

Yesterday, MSTX announced the initiation of its vepoloxamer in chronic heart failure (CHF) Phase II study. The vepoloxamer formulation for the CHF clinical study is different from that for the sickle cell disease (SCD) trial.

- **Details.** The trial is a randomized, double-blind, multicenter, placebo-controlled Phase II study that expects to recruit 150 New York Heart Association functional Class II or III CHF patients, who are stable and well-managed on an established guideline-based medication regimen for at least four weeks. The eligible patients will have a recently documented ⩽35% left ventricular ejection fraction (LVEF) within the last 12 months, and have an elevated plasma cardiac troponin I (cTnI). Patients will be randomized into either one of two different dose treatment arms or a placebo group. In addition to standard medical therapy, patient will receive a single intravenous infusion of vepoloxamer over a three hour period. The study will evaluate vepoloxamer's potential for improving left ventricle contractile function by restoring cardiomyocyte membrane integrity and increasing cardiomyocyte survival. The study will measure echocardiograms (i.e. ejection fraction), 6MWD and blood-based markers (i.e. troponin I and NT-proBNP). We estimate the top-line results for the study could be available in late 2016.
- **Implication.** Based on prior encouraging pre-clinical data (see our 2015-03-02 note), CHF is the second indication for which vepoloxamer could potentially provide clinical benefit. It is vepoloxamer's second shot on goal in addition to the leading SCD development (EPIC trial). The CHF Phase II trial would be a POC study and is critical, in our opinion, to demonstrate whether vepoloxamer has clinical utility in this much larger indication. We believe investors' current focus remains on the success of the EPIC study (with top-line results expected in 1Q16). However, we expect greater attention could shift to the pipeline development of CHF and stroke if the EPIC study is positive. Stroke is the third indication with a Phase II study which might start in 2016. Further, given the formulation for the CHF trial is different from that of SCD, it potentially could provide added IP protection for vepoloxamer.
- **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.

Trading Data:

Last Price (10/26/2015)	$ 0.49
52–Week High (1/5/2015)	$ 0.63
52–Week Low (8/10/2015)	$ 0.38
Market Cap. (MM)	$ 80
Shares Out. (MM)	164

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.06A	-0.06A	-0.06	-0.06	-0.25	N.A.
FY-14A	-0.06	-0.06	-0.06	-0.05	-0.23	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

Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

MST-188	Vaso-occlusive crisis (VOC) in sickle cell disease (SCD)	Periodical updates on Phase III trial progress	**2015**	***
		Completion of Phase III (EPIC) study	**4Q15**	***
		Report of Phase III study top-line results	**1Q16**	****
		Potential NDA filing	**2H16**	***
		Potential approval	**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),	Potentially start investigator-sponsed 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

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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.

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Figure 1: Income Statement

Mast Therapeutics – Income Statement

($'000)	2012	2013	2014	1Q15	2Q15	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Revenue														
MST-188 revenue	0	0	0					0	0	28,253	86,796	167,886	252,822	331,386
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	28,253	86,796	167,886	252,822	331,386
Costs of goods	0									2,543	7,812	15,110	22,754	29,825
Research and development	8,088	12,902	19,436	6,042	7,734	7,889	8,046	29,711	31,791	27,022	25,671	26,441	27,235	28,052
Selling, general and administrative	7,519	8,518	9,487	3,578	2,410	2,453	2,490	10,932	11,260	12,273	13,377	14,581	15,748	16,850
Marketing and sales										20,000	23,000	24,380	25,599	26,367
Transaction-related expenses	(70)	80	271	-	-	0	-	0	0	0	0	0	0	0
Depreciation and amortization	90	40	84	30	37	37	37	141	141	141	141	141	141	141
Total Operating Expenses	15,628	21,539	29,279	9,650	10,181	10,379	10,574	40,784	43,191	61,979	70,001	80,653	91,476	101,235
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(9,650)	(10,181)	(10,379)	(10,574)	(40,784)	(43,191)	(33,726)	16,794	87,232	161,346	230,152
Reduction of fair value of warrants	0	0	0	-	-	0	-	0	0	0	0	0	0	0
Investment income	74	60	67	17	30	17	17	81	89	98	108	119	130	143
Interest expense	0	0	0	0	0	0	-	0	0	0	0	0	0	0
Other income/(expense), net	(5)	(1)	511	17	0	20	23	60	2	(20)	24	(27)	(27)	(27)
Loss before cumulative effect of change in accounting princ	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(10,342)	(10,534)	(40,643)	(43,100)	(33,648)	16,926	87,324	161,449	230,268
Cumulative effect of change in accounting principle	0	0	0	-	0	0	-	0						
Income before tax	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(10,342)	(10,534)	(40,643)	(43,100)	(33,648)	16,926	87,324	161,449	230,268
Tax	0	0	0	-	-	0	-	0	0	0	(6,263)	(32,310)	(59,736)	(85,199)
Net Income (Loss)	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(10,342)	(10,534)	(40,643)	(43,100)	(33,648)	10,664	55,014	101,713	145,069
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(9,616)	(10,151)	(10,342)	(10,534)	(40,643)	(43,100)	(33,648)	10,664	55,014	101,713	145,069
Net Earnings (Losses) Per Share—Basic and Diluted	($0.33)	($0.28)	($0.23)	($0.06)	($0.06)	($0.06)	($0.06)	($0.25)	($0.25)	($0.20)	$0.06	$0.32	$0.59	$0.83
Shares outstanding—basic	47,641	76,586	122,409	159,459	162,128	163,128	164,128	162,211	169,211	170,211	171,211	172,211	173,211	174,211
Shares outstanding—diluted	47,641	76,586	122,409	159,459	162,128	163,128	164,128	162,211	169,211	170,211	171,211	172,211	173,211	174,211
Margin Analysis (% of Sales/Revenue)														
Costs of goods									9%	9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	96%	30%	16%	11%	8%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	114%	42%	23%	16%	13%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-119%	19%	52%	64%	69%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-119%	20%	52%	64%	69%
Tax Rate										37%	37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-119%	12%	33%	40%	44%
Financial Indicator Growth Analysis (YoY%)														
Licensing revenue								0%	0%	0%	0%	0%	0%	0%
Grant revenue								0%	0%	0%	0%	0%	0%	0%
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	207%	93%	51%	31%
R&D	40%	60%	51%	41%	60%	46%	63%	53%	7%	-15%	-5%	3%	3%	3%
SG&A	5%	13%	11%	58%	2%	0%	4%	15%	3%	9%	9%	9%	8%	7%
Marketing and sales											15%	6%	5%	3%
Operating Income (Losses)	17%	38%	36%	41%	41%	32%	44%	39%	6%	-22%	-150%	419%	85%	43%
Net Income	17%	38%	34%	51%	42%	31%	44%	42%	6%	-22%	-132%	416%	85%	43%
EPS	-31%	-14%	-16%	-1%	1%	-1%	27%	7%	2%	-22%	-132%	413%	84%	42%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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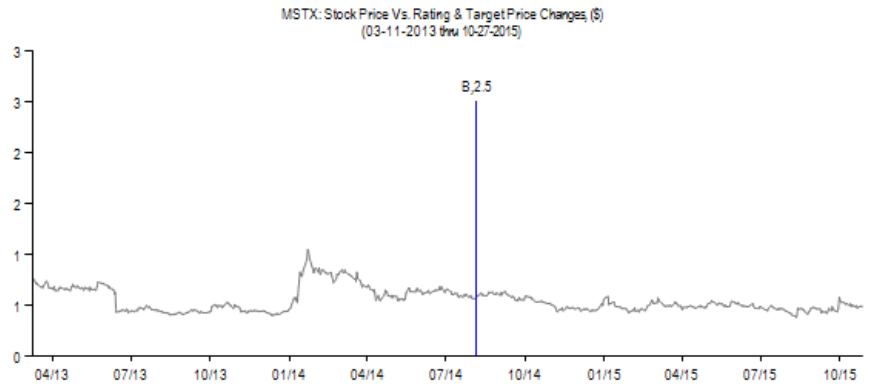
Rating and Price Target Change History



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 **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
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.	74.19%	25.81%	6.45%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.23%	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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