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EQUITY RESEARCH
Company Report

August 9, 2016

Mast Therapeutics (MSTX - $ 0.35)

Healthcare/Biotechnology

2Q16: EPIC Trial Phase III Top-line Results Reporting Just Weeks Away

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

MSTX recently reported 2Q16 financial results with a net loss of ($10.7MM), vs. estimates of Laidlaw ($11.4MM) and the Street ($11.3MM). Net loss per share equated to ($0.05), vs. ($0.06) estimates of Laidlaw and the Street. MSTX reported cash of ~$35MM at the end of 2Q16, enough to support its operations into 2H17, in our opinion.

- **EPIC Phase III study results available in September are main focus.** MSTX indicated that the EPIC Phase III study of Vepoloxamer (MST-188) in patients with sickle cell disease (SCD) experiencing vaso-occlusive crisis (VOC) top-line results will be reported in September – a binary event for MSTX shares, in our opinion. As a reminder, MSTX reported that the EPIC trial (when ~80% of patients had been recruited) included high percentages of pediatric (~72%) and hydroxyurea (HU) treated (61%) patients – the two patient cohorts that had demonstrated statistically significant improvements by drug treatment from the prior Phase III study. As such, it should bode well for a potentially positive outcome. EPIC trial is a 388-patient, randomized, multi-center, placebo controlled study. The primary endpoint is reduction of the duration of VOC mainly based on completion of parenteral analgesic use (time from randomization to the last dose of parenteral analgesic or opioid for the treatment of VOC prior to hospital discharge). MSTX is on the path for a NDA filing, potentially in 4Q16 or early 2017 in our estimates. MSTX continues to enroll EPIC patients into its repeat exposure EPIC-E study and in a clinical PK study in individuals with varying degrees of renal insufficiency. We believe an AdCom meeting by the FDA could be in place before the PDUFA decision (both likely in late 2017/ early 2018) should the data be positive and MSTX files for approval. MSTX's second asset, AIR001 recently started a Phase II study (INDIE-HFpEF) sponsored by Heart Failure Clinical Research Network (HFN). It includes~100 patients with heart failure with preserved ejection fraction (HFpEF), and we estimate top-line results could be available in 2017/2018. Primary endpoint is the peak oxygen consumption (VO_2) after four weeks of treatment with nebulized inhaled AIR001 or placebo as assessed by CPET performed at peak drug levels.
- **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 (08/09/2016)	$ 0.35
52–Week High (9/30/2015)	$ 0.60
52–Week Low (2/10/2016)	$ 0.21
Market Cap. (MM)	$ 67
Shares Out. (MM)	193

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.06A	-0.05A	-0.04	-0.04	-0.20	N.A.
FY-15A	-0.06	-0.06	-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.

Source: Laidlaw & Company estimates

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
Vepoloxamer (MST-188)	Vaso-occlusive crisis (VOC) in sickle cell disease (SCD)	Report of Phase III study top-line results	**Sep. 2016**	*****
		Potential NDA filing	**1H17**	***
		Potential AdComm meeting	**Late 2017/ Early 2018**	*****
		Potential approval and the U.S. launch	**Late 2017/ Early 2018**	****
	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 report Phase II (INDIE-HFpEF) top-line results	**2017/2018**	****

***** / ***** 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 2Q16 with ~$35MM 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	2015	1Q16	2Q16	3Q16E	4Q16E	2016E	2017E
Revenue										
Vepoloxamer revenue	0	0	0	0	-	-	-	-	0	28,253
Net sales	0	0	0	0	-	-	-	-	0	0
Licensing revenue	0	0	0	0	-	-	-	-	0	0
Grant revenue	0	0	0	0	-	-	-	-		0
Total revenue	0	0	0	0	-	-	-	-	0	28,253
Costs of goods	0									2,543
Research and development	8,088	12,902	19,436	28,264	7,875	7,752	5,581	4,688	25,897	22,012
Selling, general and administrative	7,519	8,518	9,487	10,963	2,835	2,439	2,512	2,550	10,336	11,266
Marketing and sales										20,000
Transaction-related expenses	(70)	80	271	0					0	0
Depreciation and amortization	90	40	84	146	32	30	30	30	122	122
Total Operating Expenses	15,628	21,539	29,279	39,373	10,742	10,221	8,124	7,268	36,355	55,943
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(39,373)	(10,742)	(10,221)	(8,124)	(7,268)	(36,355)	(27,690)
Reduction of fair value of warrants	0	0	0	0	0	0	0	-	0	0
Investment income	74	60	67	47	39	0	0	0	39	43
Interest expense	0	0	0	0	(519)	(485)	(485)	(485)	(1,974)	(2,171)
Other income/(expense), net	(5)	(1)	511	(516)	15		2	2	19	(20)
Loss before cumulative effect of change in accounting princ	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(10,706)	(8,607)	(7,751)	(38,271)	(29,839)
Cumulative effect of change in accounting principle	0	0	0	0	0	0	0	-		
Income before tax	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(10,706)	(8,607)	(7,751)	(38,271)	(29,839)
Tax	0	0	0	0	0	0	0	-	0	0
Net Income (Loss)	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(10,706)	(8,607)	(7,751)	(38,271)	(29,839)
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(10,706)	(8,607)	(7,751)	(38,271)	(29,839)
Net Earnings (Losses) Per Share—Basic and Diluted	($0.33)	($0.28)	($0.23)	($0.25)	($0.06)	($0.05)	($0.04)	($0.04)	($0.20)	($0.15)
Shares outstanding—basic	47,641	76,586	122,409	162,204	178,115	196,554	197,554	198,554	192,694	193,694
Shares outstanding—diluted	47,641	76,586	122,409	162,204	178,115	196,554	197,554	198,554	192,694	193,694
Margin Analysis (% of Sales/Revenue)										
Costs of goods									9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	78%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	111%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-98%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-106%
Tax Rate										37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-106%
Financial Indicator Growth Analysis (YoY%)										
Licensing revenue				0%					0%	0%
Grant revenue				0%					0%	0%
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	40%	60%	51%	45%	30%	0%	-24%	-38%	-8%	-15%
SG&A	5%	13%	11%	16%	-21%	1%	2%	1%	-6%	9%
Marketing and sales										
Operating Income (Losses)	17%	38%	36%	34%	11%	0%	-17%	-25%	-8%	-24%
Net Income	17%	38%	34%	39%	17%	5%	-13%	-24%	-4%	-22%
EPS	-31%	-14%	-16%	5%	4%	-20%	-28%	-37%	-19%	-22%

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

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Additional information available upon request.

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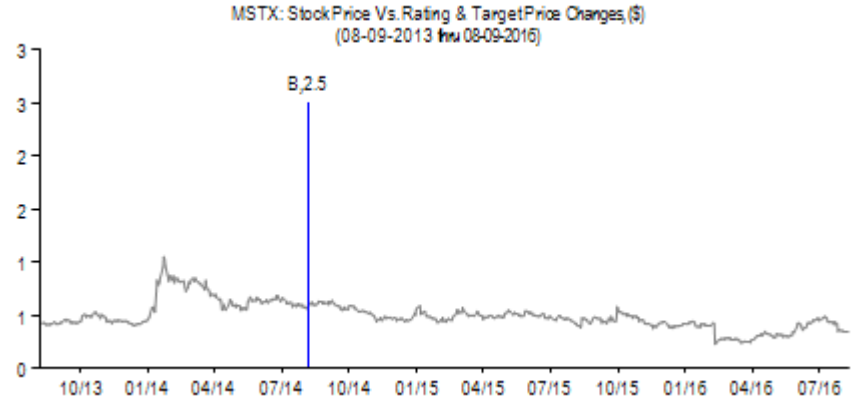
Rating and Price Target Change History



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.	62.16%	27.03%	2.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

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