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EQUITY RESEARCH
Company Report

May 9, 2016

Mast Therapeutics (MSTX - $ 0.32)

Healthcare/Biotechnology

1Q16: EPIC Trial Top-line Result Reporting Is Potentially Just Weeks Away

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

MSTX recently reported 1Q16 financial results with a net loss of ($11.2MM), vs. estimates of Laidlaw ($10.3MM) and the Street ($11.0MM). Net loss per share equated to ($0.06), which matched the estimates of Laidlaw and the Street. MSTX reported cash of $37MM at the end of 1Q16, enough to support its operation into 2H17, in our opinion.

Trading Data:

Last Price (05/06/2016)	$ 0.32
52–Week High (9/30/2015)	$ 0.60
52–Week Low (2/10/2016)	$ 0.21
Market Cap. (MM)	$ 61
Shares Out. (MM)	193

- **Phase III EPIC study results are primary focus.** After MSTX announced the completion of patient enrollment of the Vepoloxamer in sickle cell disease (SCD) experiencing vaso-occlusive crisis (VOC) Phase III (EPIC) study in early February, the main focus of investors is on the reporting of the outcome. MSTX expects the top-line results will be in this quarter – a binary event for the MSTX shares, in our opinion. 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. 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). We believe an AdCom meeting by the FDA could be in place before the PDUFA decision (both likely in 2017) if the outcome be positive and MSTX files for approval since Vepoloxamer is potentially the first new SCD drug for more than a decade.
- **AIR001 in HFpEF updates.** MSTX reported positive top-line results from the AIR001 in HFpEF Phase IIa study which met the primary endpoint in 1Q16. The company plans to present more detailed results at a scientific meeting, possibly this month. Additionally, AIR001 was selected by the Heart Failure Clinical Research Network (HFN) for a double-blind, placebo-controlled Phase IIa (INDIE-HFpEF) study in ~100 HFpEF patients. The study potentially begin in 3Q16. 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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.06A	-0.06	-0.05	-0.05	-0.22	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

Yale Jen, Ph.D.
Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Table 1: Estimated and reported 1Q16 results

1Q16 Estimates and Reported Results			
($,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**$0.0**	**$0.0**	**$0.0**
Total op. profit (loss)	**($10,275)**	**($10,742)**	**($10,900)**
R&D	$7,593	$7,875	
SG&A	$2,641	$2,835	
EPS	**($0.06)**	**($0.06)**	**($0.06)**
Net income (loss)	($10,273)	($11,207)	($11,000)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Yale Jen, Ph.D.
yjen@laidlawltd.com

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	**2Q16**	*****
		Potential NDA filing	**2H16**	***
		Potential AdComm meeting	**2017**	*****
		Potential approval and the U.S. launch	**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),	Present initial patient cohort preliminary results at a scientific conference	**May 2016**	****
		Commence Phase II (INDIE-HFpEF) trial	**3Q16**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

Yale Jen, Ph.D.
yjen@laidlawltd.com

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.

Yale Jen, Ph.D.
yjen@laidlawltd.com

Figure 1: Income Statement

Mast Therapeutics – Income Statement

($'000)	2012	2013	2014	2015	1Q16	2Q16E	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	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	7,914	5,698	4,787	26,274	22,333
Selling, general and administrative	7,519	8,518	9,487	10,963	2,835	2,948	3,037	3,082	11,903	12,974
Marketing and sales										20,000
Transaction-related expenses	(70)	80	271	0					0	0
Depreciation and amortization	90	40	84	146	32	32	32	32	128	128
Total Operating Expenses	15,628	21,539	29,279	39,373	10,742	10,895	8,767	7,901	38,305	57,978
Operating Incomes (losses)	(15,628)	(21,539)	(29,279)	(39,373)	(10,742)	(10,895)	(8,767)	(7,901)	(38,305)	(29,725)
Reduction of fair value of warrants	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)	(519)	(519)	(519)	(2,076)	(2,284)
Other income/(expense), net	(5)	(1)	511	(516)	15	2	2	2	21	(20)
Loss before cumulative effect of change in accounting princ	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Cumulative effect of change in accounting principle	0	0	0	0	0	0	-	-		
Income before tax	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Tax	0	0	0	0	0	0	-	-	0	0
Net Income (Loss)	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Net Income (Loss) Applicable to Common Shareholders	(15,559)	(21,480)	(28,701)	(39,842)	(11,207)	(11,412)	(9,284)	(8,418)	(40,321)	(31,985)
Net Earnings (Losses) Per Share—Basic and Diluted	($0.33)	($0.28)	($0.23)	($0.25)	($0.06)	($0.06)	($0.05)	($0.05)	($0.22)	($0.18)
Shares outstanding—basic	47,641	76,586	122,409	162,204	178,115	179,115	180,115	181,115	179,615	180,615
Shares outstanding—diluted	47,641	76,586	122,409	162,204	178,115	179,115	180,115	181,115	179,615	180,615
Margin Analysis (% of Sales/Revenue)										
Costs of goods									9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	79%
MG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	117%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-105%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	-113%
Tax Rate										37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-113%
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%	2%	-22%	-36%	-7%	-15%
SG&A	5%	13%	11%	16%	-21%	22%	23%	23%	9%	9%
Marketing and sales										
Operating Income (Losses)	17%	38%	36%	34%	11%	7%	-11%	-19%	-3%	-22%
Net Income	17%	38%	34%	39%	17%	12%	-6%	-17%	1%	-21%
EPS	-31%	-14%	-16%	5%	4%	2%	-15%	-25%	-9%	-21%

Yale Jen, Ph.D. 212-953-4978

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

Yale Jen, Ph.D.
yjen@laidlawltd.com

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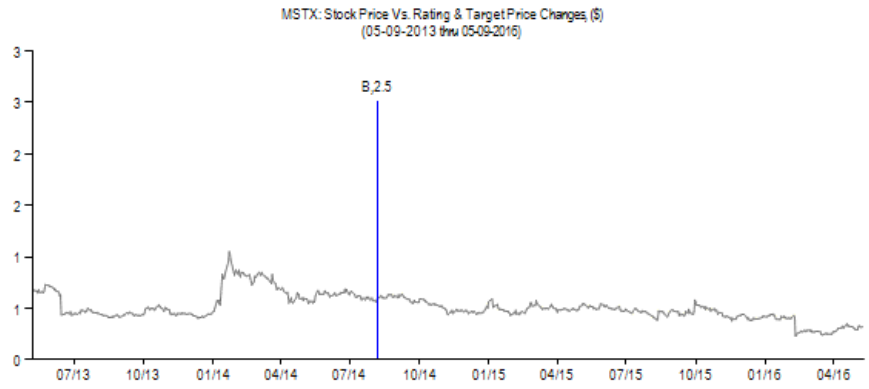

3 Year Rating Change History

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.	66.67%	27.78%	2.78%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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Yale Jen, Ph.D.
yjen@laidlawltd.com

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Yale Jen, Ph.D.
yjen@laidlawltd.com

NOTES:

Yale Jen, Ph.D.
yjen@laidlawltd.com