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EQUITY RESEARCH
Company Report

October 8, 2015

Mast Therapeutics (MSTX - $ 0.52)

Healthcare/Biotechnology

Encouraging Analyst Day Updates

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

Yesterday, MSTX hosted an Analyst day and provided updates on the EPIC Phase III study, vepoloxamer in SCD commercialization plan and additional pipeline development. We walked away with renewed confidence of potential bullish outcomes of the EPIC study. Highlights of the event were:

- **Greater details of the EPIC study boost our confidence.** MSTX reported that the EPIC trial patient recruitment has reached ~80% (75 clinical sites with ~50 in the U.S.) and is on-track to report top-line results in 1Q16. The average patient age is 15 and 28% patients are >18. 61% of patients have been treated with hydroxyurea (HU). The U.S. patients account for >50% of the total patients enrolled. In the prior trial, patients <16 years old exhibited a benefit of 22 hours (p=0.01) and those on HU had a benefit of 16 hours (p =0.02). Patient makeup of the EPIC trial, in our opinion, bodes well for positive outcome since the percentage of younger and HU-treated patients is greater than that of the prior study (pediatric: 28% vs. 72% and HU user: 21% vs. 61%) With 28% adult patients in the study, we believe vepoloxamer could receive a label for adult and pediatric if the outcome is positive.
- **Interim statistical analyses are encouraging.** MSTX conducted an interim statistical analysis (of the initial 250 patients) and demonstrated that current data support: 1) sample size estimates and confirm the study is performing to prior assumptions; and 2) variability for the primary outcome across U.S. and non-U.S. regions are similar. Although these analyses cannot provide greater certainty of whether vepoloxamer affords statistically significant activities over a placebo, they do suggest that the study design is appropriate and is consistent with the scenario that the drug is active. Given the data remained blinded, these are no statistical penalties.
- **SCD in the EU is another significant commercial opportunity.** Similar to the U.S., SCD patient distribution pattern in Europe is highly concentrated with 54% in UK and France. Within them, most patients are in the metro areas like London (75%) and Paris (70%). The EU could be another market beside the U.S. where MSTX believes they could commercialize vepoloxamer by themselves. Potential launch could slate to 2019.
- **Action.** We are reiterating our Buy rating and $2.50 target price based on peer comparable probability adjusted DCF analyses to reflect the continued execution of corporate developments.

Trading Data:

Last Price (10/07/2015)	$ 0.52
52–Week High (1/5/2015)	$ 0.63
52–Week Low (8/10/2015)	$ 0.38
Market Cap. (MM)	$ 87
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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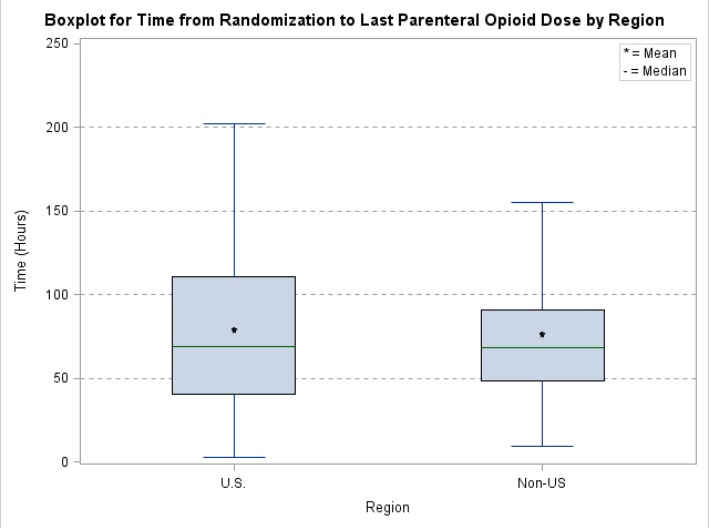
- **Interim statistical analyses.** The interim statistical analyses were conducted by Dr. Bruce A. Barton of University of Mass Medical School, and he also presented the outcomes at the Analyst day. The first analysis is based on the assumption that the mean time from randomization to last dose of parenteral opioid analgesic (or the primary outcome) for placebo is 96 hours with standard deviation (S.D.) of 51 hours. Management indicated that the information is mainly derived from a recent clinical study, called Preventing Acute Chest Syndrome by Transfusion Feasibility Study (PROACTIVE), which is intended to test blood transfusions as a treatment option for ACS. The primary outcome of the 250 patients (both treated and placebo) is 79 hours with S.D. of 47 hours. It is encouraging that the S.D. in both cases is similar (51 vs. 47) as they demonstrate consistency between current data and assumptions for initial sample size. The lower mean duration (79 vs. 96) between the two groups is interesting with two possible explanations: 1) vepoloxamer is very active, or 2) the baseline duration decreased compared with the earlier assumption. The second analysis indicates that variability for the primary outcome across U.S. and non-U.S. regions are similar (Figure 1).

Figure 1: Boxplot for time from randomization to last parenteral opioid dose by region



Source: Company presentation

- **Vepoloxamer in SCD regulatory timeline.** MSTX indicated that vepoloxamer in SCD in Europe could be an opportunity that the company can realize by themselves. Management provided a timeline for the regulatory development in the U.S. and EU (Figure 2). If the EPIC results are positive, MSTX plans to file for NDA possibly in late 2016. Given vepoloxamer is a new chemical entity and the first newly developed SCD drug over more than a decade, management believes it is likely that the FDA would conduct an AdCom meeting to review the approval. We estimate such meeting could be scheduled in 2017 with potential market entry in 2H17. On the safety side of vepoloxamer, MSTX indicated that it would not be necessary for additional DSMB review for the EPIC study. DSMB had made four reviews during the trial when the study recruited 25, 58, 145 and 250 patients.

  For the regulatory plan in Europe, MSTX plans to submit a Pediatric investigation plans (PIP) to EMEA possibly in 1H16, followed by EU national authority meetings in 2H16. If positive, MSTX could potentially file for MAA submission in 2017.

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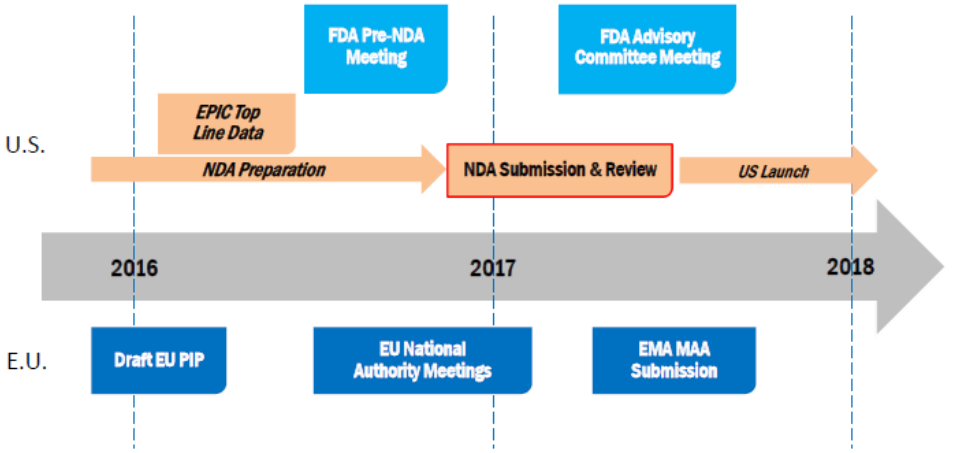
Figure 2: Vepoloxamer in SCD development timeline of the U.S. and Europe



Source: Company presentation

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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	**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 start Phase II trial	**4Q15**	***
		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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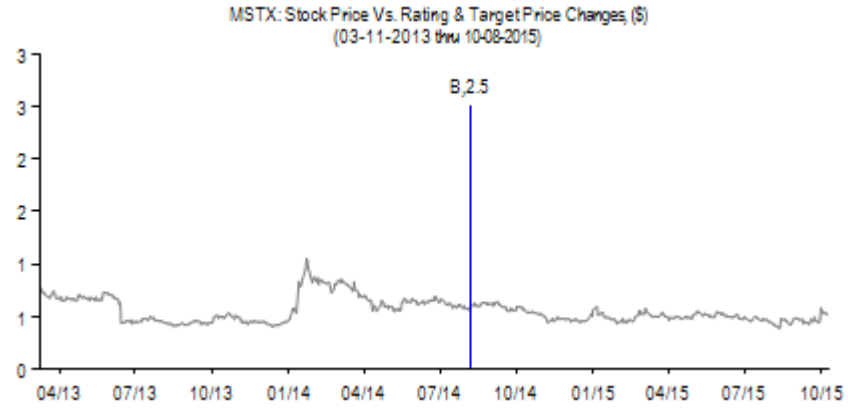

3 Year Rating Change History

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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