LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Stamford
Ft. Lauderdale

EQUITY RESEARCH
Company Report

January 6, 2015

Mast Therapeutics (MSTX - $ 0.51)

Healthcare/Biotechnology

EPIC Trial Patient Recruitment Update with Top-line Results Reporting On-track in 1Q16

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

MSTX provided an update yesterday after the market close and also at this morning's conference call on the progression of patient enrollment for the Phase III (EPIC) study, which evaluates vepoloxamer in sickle cell disease patients.

- **Details.** Management indicated that the EPIC study has already enrolled more than one-third of patients (of a total 388 projected) which is ahead of the company's projection. Accordingly, MSTX indicated patient recruitment for the trial remains on track with completion expected by year-end 2015, and topline results potentially available in 1Q16 as previously guided. A total of 69 clinical sites (>50 in the U.S.) currently are active in patient recruitment. Among them, ~60% have recruited at least one patient; while ~40% have recruited two or more patients. Patient recruitment rate has accelerated substantially since inception with n=3, 34 and 82 patients for 2013, 1H14 and 2H14, respectively. Average time from site open to first patient recruited was 7 months and 3.5 months for the U.S. and non-U.S. sites, respectively. Total clinical sites could potentially reach 75-80. MSTX expects average patient age would be ≤18 years (currently, 14) once the study is completed, as study inclusion criteria have expanded from pediatric more than a year ago. MSTX also expects to start an EPIC extension study (EPIC-E) in 1H15 for patients (both receiving treatment and placebo during the regular EPIC trial) to take repeated exposure of vepoloxamer during their subsequent VOC episodes. MSTX ended 2014 with $57MM cash, sufficient for operation into 2016 potentially after data release, in our opinion.

- **Implication.** We view this study update as positive for MSTX share value given 1) the timeline for study completion and data reporting is likely on-track, supported by an accelerated patient recruitment rate; 2) overall younger patients included in the study increases the probability of study success based on the positive experience of a similar patient cohort from the prior Phase III study; while inclusion of adult patients could potentially support a broader usage label if clinically successful; and 3) comfortable cash position could alleviate some overhang.

- **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.

Trading Data:

Last Price (01/06/2015)	$ 0.51
52–Week High (1/22/2014)	$ 1.10
52–Week Low (11/6/2014)	$ 0.40
Market Cap. (MM)	$ 83
Shares Out. (MM)	159

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

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

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	Potentially complete discussion with the FDA for trial design	**4Q14**	***
		Report pre-clinical data	**1Q15**	***
		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-sponsed Phase II studies	**4Q14**	***
		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

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)	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	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 princi	(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%

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

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

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

DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

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.	80.95%	33.33%	9.52%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.76%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%lyco

ADDITIONAL COMPANIES MENTIONED

ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

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

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices. market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at www.Laidlawltd.com, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

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

NOTES:

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