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EQUITY RESEARCH
Company Report

September 29, 2014

Mast Therapeutics (MSTX - $ 0.56)

Healthcare/Biotechnology

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

Rivipansel (GMI-1070) in Resolving Vaso-occlusive Crisis (VOC) of SCD Patient Phase III Study Commencement Delayed

Last Friday, GlycoMimetics and Pfizer reported that the commencement of the rivipansel (GMI-1070) in SCD Phase III clinical trial will be "significantly delayed" due to a manufacturing development issue impacting the formulated drug supply.

- **Details.** Last Friday, Pfizer informed GlycoMimetics that initiation of rivipansel (GMI-1070) in resolving vaso-occlusive crisis (VOC) of SCD patient Phase III clinical trial will be "significantly delayed" due to a manufacturing development issue impacting formulated drug supply. Earlier, Pfizer guided that they expected to start Phase III study before year-end 2014. According to clinicaltrial.gov, the Phase III study might take three years to complete.
- **Implications.** Although Pfizer did not specify what might be the duration of "significantly delayed," we speculate it may take two quarters or more. Possible competition for recruiting patients once Pfizer started its Phase III study was a potential modest shadow overhanging MSTX shares. If so, it could potentially prolong the time needed for MSTX to complete its pivotal (EPIC) study. The delay in starting the rivipansel (GMI-1070) in SCD Phase III trial, in our opinion, should increase the likelihood that MSTX completes the EPIC study as management indicated. It is also possible that MSTX could potentially increase recruitment of patients from clinical sites that initially committed to the rivipansel trial; as this study might not take place for a while. In addition, some recent investor feedback suggested that, if clinically successful, MST-188 potentially might only be indicated in pediatric SCD patients, given the substantial patient recruitment from pediatric clinics and children's hospitals. Our discussion with MSTX management indicated MST-188 should potentially be eligible as a treatment for both pediatric and adult SCD patients since non-pediatric patients may account for 30% or more of the participant in the ongoing EPIC study.
- **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 is both under-exposed and the shares are under-valued, in our opinion.

Trading Data:

Last Price (09/26/2014)	$ 0.56
52–Week High (1/22/2014)	$ 1.10
52–Week Low (12/12/2013)	$ 0.40
Market Cap. (MM)	$ 68
Shares Out. (MM)	122

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-14E	-0.06A	-0.06A	-0.06	-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

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Anticipated milestones in 2014 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**	***
		Completion of Phase III (EPIC) study	**4Q15**	***
		Report of Phase III study top-line results	**Late 2015**	****
		Potential NDA filing	**1H16**	***
		Potential approval	**2017**	****
	Acute limb ischemia	Report of Phase II study top-line results	**Late 2015**	***
	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**	***

***** / ***** 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 as 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 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 the expectation, 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 by several fronts, including proprietary technology, trade secrets and know-how, it remains possible that other competitors develop similar or alternative processes to produce 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 remain 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's ended 1Q14 with ~$49MM 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)	2011	2012	2013	1Q14	2Q14	3Q14E	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	4,868	5,014	18,983	21,641	23,156	19,682	18,698	19,259	19,837
Selling, general and administrative	7,190	7,519	8,518	2,266	2,370	2,441	2,539	9,616	10,289	10,598	11,552	12,591	13,725	14,823
Marketing and sales											20,000	23,000	24,380	25,599
Transaction-related expenses	411	(70)	80	280	(11)	10	18	297			0	0	0	0
Depreciation and amortization	38	90	40	11	23	23	23	80	80	80	80	80	80	80
Total Operating Expenses	13,397	15,628	21,539	6,839	7,202	7,342	7,594	28,977	32,011	33,834	53,857	62,182	72,554	83,093
Operating Incomes (losses)	(13,397)	(15,628)	(21,539)	(6,839)	(7,202)	(7,342)	(7,594)	(28,977)	(32,011)	(33,834)	(25,604)	24,614	95,332	169,729
Reduction of fair value of warrants	0	0	0	-	0	0	-	0	0	0	0	0	0	0
Investment income	66	74	60	15	15	15	15	61	68	74	82	90	99	109
Interest expense	0	0	0	-	0	0	-	0	0	0	0	0	0	0
Other income/(expense), net	71	(5)	(1)	453	35	1	0	489	2	2	(20)	24	(27)	(27)
Loss before cumulative effect of change in accounting princ	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,326)	(7,578)	(28,427)	(31,941)	(33,758)	(25,542)	24,728	95,404	169,811
Cumulative effect of change in accounting principle	0	0	0	-	0	0	-	0						
Income before tax	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,326)	(7,578)	(28,427)	(31,941)	(33,758)	(25,542)	24,728	95,404	169,811
Tax Rate								*37%*	*37%*	*37%*	*37%*	*37%*	*37%*	*37%*
Tax	0.0	0	0	-	0	0	-	0	0	0	0	(9,149)	(35,299)	(62,830)
Net Income (Loss)	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,326)	(7,578)	(28,427)	(31,941)	(33,758)	(25,542)	15,579	60,104	106,981
Net Income (Loss) Applicable to Common Shareholders	(13,260)	(15,559)	(21,480)	(6,371)	(7,152)	(7,326)	(7,578)	(28,427)	(31,941)	(33,758)	(25,542)	15,579	60,104	106,981
Net Earnings (Losses) Per Share—Basic and Diluted	($0.47)	($0.33)	($0.28)	($0.06)	($0.06)	($0.06)	($0.06)	($0.25)	($0.26)	($0.26)	($0.20)	$0.12	$0.45	$0.80
Shares outstanding—basic	28,175	47,641	76,586	105,054	115,587	115,987	117,987	113,654	122,987	129,987	130,987	131,987	132,987	133,987
Shares outstanding—diluted	28,175	47,641	76,586	105,054	115,587	115,987	117,987	113,654	122,987	129,987	130,987	131,987	132,987	133,987
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	70%	22%	11%	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	-91%	28%	57%	67%
Pretax	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-90%	28%	57%	67%
Tax Rate											37%	37%	37%	37%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-90%	18%	36%	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%	57%	42%	47%	14%	7%	-15%	-5%	3%	3%
SG&A		5%	13%	7%	13%	13%	18%	13%	7%	3%	9%	9%	9%	8%
Marketing and sales												15%	6%	5%
Operating Income (Losses)		17%	38%	22%	45%	39%	33%	35%	10%	6%	-24%	-196%	287%	78%
Pretax Income			38%	14%	45%	39%	33%	32%	12%	6%	-24%	-197%	286%	78%
Net Income		17%	38%	14%	45%	39%	33%	32%	12%	6%	-24%	-161%	286%	78%
EPS		-31%	-14%	-50%	-33%	23%	17%	-11%	4%	0%	-25%	-161%	283%	77%

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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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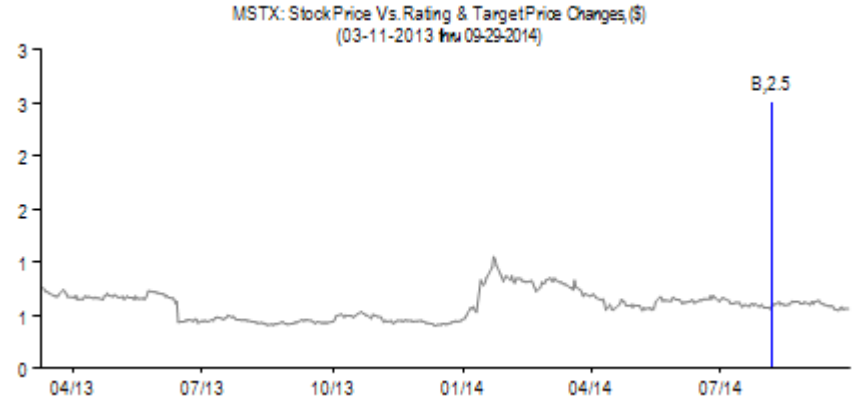
Rating and Price Target Change History



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.	95.00%	30.00%	10.00%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

GlycoMimetics (GLCY: Not Rated)
Pfizer (PFE: Not: Rated)

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