

Hyperion Therapeutics, Inc. (HPTX)

Catching up with Hyperion

MARKET DATA	
Price	\$20.80
52-Week Range:	\$9.95 - \$26.50
Shares Out. (M):	20.3
Market Cap (\$M):	\$422.2
Average Daily Vol. (000):	91.0
Cash (M):	\$102
LT Debt (M):	\$8
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2012A	2013E	2014E
Revenue (\$M)	1Q	\$0.0	\$0.8A	
	2Q	\$0.0	\$1.9	
	3Q	\$0.0	\$8.1	
	4Q	\$0.0	\$11.8	
	FY	\$0.0	\$22.5	\$78.0
EPS	1Q	(\$25.16)	(\$0.52)A	
	2Q	(\$15.26)	(\$0.17)	
	3Q	(\$0.44)	(\$0.26)	
	4Q	(\$0.50)	(\$0.10)	
	FY	(\$4.45)	(\$1.05)	(\$0.05)
Previous	FY	NC	(\$0.31)	\$0.96
Source: Company reports and JMP Securities LLC				



MARKET OUTPERFORM | Price: \$20.80 | Target Price: \$30.00

INVESTMENT HIGHLIGHTS

Catching up with Hyperion; reiterate Market Outperform rating and \$30 price target based on a risk-adjusted, discounted cash flow analysis. We recently got an update from management on the early stages of the Ravicti launch for urea cycle disorders (UCDs) and progress with regulators on a Phase 3 design for hepatic encephalopathy (HE). We are encouraged that Hyperion is making good progress with reimbursement for Ravicti and working to transition patients from clinical trial material to commercial drug. We estimate \$15M for 2013 Ravicti revenue that is back-end loaded as patients only see their physicians once or twice a year and are generally unlikely to come in ahead of a scheduled visit to receive a Ravicti prescription. We continue to like shares of Hyperion as we anticipate steady Ravicti revenue growth and the opportunity for increased value as the company begins a pivotal study in HE in 2014.

Ravicti launch color. About half the patients on clinical trial material have been converted to commercial drug so far and we anticipate the other half will switch over as they meet with their physicians during the year. We are encouraged that physicians not involved in clinical trials are prescribing the drug and outnumber physicians at clinical trial sites, suggesting to us that the message of benefit from Ravicti is resonating with the target population. We estimate \$15M of Ravicti revenue in 2013, increasing to \$67M in 2014. About a third of Medicaid lives are covered so far and more states will begin coverage on July 1, 2013. As a reminder, close to 40% of UCD patients are covered by Medicaid. Two-thirds of commercial lives are covered so far and we are pleased with the initial response from payors with about half of Ravicti prescriptions are going through on the first try with very few requests to provide evidence of a Buphenyl failure to receive Ravicti.

Buphenyl acquisition to close May 29. As anticipated, Valeant (Ucyclyd) exercised the option to retain Ammonul, the IV acute therapy for UCD, triggering a \$13M payment to Hyperion when the deal for Buphenyl closes. A generic form of Buphenyl powder was approved in March, which may impact the pricing of Buphenyl, but in our view, should not impact Ravicti revenue as patients are unlikely to switch to a generic form and if they switch, are likely to upgrade to Ravicti.

SEALD working on HE endpoints. The study endpoint and label development group at FDA (SEALD) has been working to create a more objective measure of patient and physician-reported outcomes for HE to standardize data. This process has delayed Hyperion from receiving a special protocol assessment for an HE study in 1H14 with a trial likely to begin later that year.

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Company Description

Hyperion Therapeutics is a San Francisco-based biopharmaceutical company focused on the development of Ravicti, a delayed release formulation of buphenyl, an ammonia scavenger approved for use in UCD with the potential to be used in other diseases characterized by ammonia toxicity, notably HE.

Investment Risks

Clinical risk. Ravicti is currently being evaluated for use in children under age 2. Should a safety issue arise, ramifications could include approval extension into this age group and potentially for the broader age group. Ravicti could underperform in forthcoming clinical studies in hepatic encephalopathy (HE) or safety issues could arise.

Regulatory risk. The FDA is currently revising endpoints for HE. We expect the process to wrap up by year end, but it is conceivable that it could take longer, which would push back the start of pivotal studies for Ravicti in this indication. Hyperion has indicated that it will pursue a special protocol assessment (SPA) in advance of starting its pivotal program and it is possible that the FDA may disagree with development plans for Ravicti in HE.

Intellectual Property risk. The composition of matter patent for Ravicti expires in 2015, with market exclusivity extended to 2018 with Hatch Waxman. Hyperion may or may not receive orphan exclusivity, which, if granted, would extend the exclusivity period until 2020. Hyperion recently received notice that new patents will be allowed which cover instructions on how to monitor and adjust dosing, which management believes will extend protection until 2028. It is possible that a generic competitor could attempt a work around to these patents, which could put Ravicti revenue at risk, as early as 2018.

Commercial risk. As a small company, Hyperion may not be able to maximize the marketplace and bring non-treated UCD patients on board. Insurers may provide more push-back than anticipated in allowing patients to switch from Buphenyl to Ravicti. Patients may chose other alternatives such as generic sodium phenylbuterate powder or a tasteless formulation currently moving through the European regulatory process. Newer technological breakthroughs may occur rendering Hyperion's compound obsolete. Hyperion may have a harder time gaining traction in HE given the dominance of lactulose and Salix's Xifaxan in the marketplace.

Sector risk. Valuation of biopharmaceutical stocks is subject to both investors' assessments of the prospects of the underlying companies, as well as investor tolerance for risk and confidence in the prospects of pharmaceutical stocks as a group. Therefore, Hyperion's stock price may fall even while the company meets or exceeds investor expectations.

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JMP Securities was manager or co-manager of a public offering for Hyperion Therapeutics, Inc. in the past 12 months.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

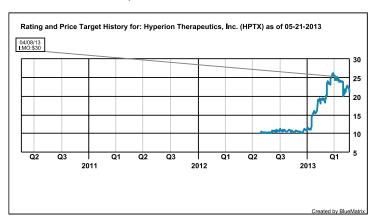
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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							# Co's Receiving IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	223	59.31%	Buy	223	59.31%	68	30.49%
MARKET PERFORM	Hold	148	39.36%	Hold	148	39.36%	18	12.16%
MARKET UNDERPERFORM	Sell	5	1.33%	Sell	5	1.33%	0	0%
TOTAL:		376	100%		376	100%	86	22.87%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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