

# Emerging Company Research

## Hyperion Therapeutics — Outperform (1)

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### Reports Q2:12

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**Summary:** Last night Hyperion reported Q2:12 financials, including a net loss of \$7.2MM. Following the company's July IPO, Hyperion is comfortably funded, and we project it will have a cash balance of \$57MM at the end of Q3:12. Just as important is the progress of Hyperion's pipeline. On Wednesday Hyperion announced that Ravicti's FDA review was extended by 3 months, and now has a January 23, 2012 PDUFA. We remain optimistic that Ravicti will be approved during H1:13, and read little into this week's PDUFA change. Our opinion of Ravicti and Hyperion's stock remains the same. Ravicti has been shown to be at least as potent as the current standard of care, but with much better tolerability and dosing convenience. Our consultants expect Ravicti to be approved based on its current filing, and for it to quickly capture majority share of the UCD market. Based on Ravicti's potential in UCD alone, we think Hyperion is significantly undervalued, and remain at Outperform.

- **Reports Q2:12 Financials.** Hyperion ended Q2 with \$7.3MM in cash, and subsequently raised \$53.5MM in its July IPO.
- **Several Milestones Expected Over The Next 3 - 6 Months.** Key upcoming events include the presentation of Ravicti's Phase II data in hepatic encephalopathy (HE) at AASLD in November, the end of Phase II meeting with FDA to discuss Ravicti's HE data and Phase III program around YE:12, Ravicti's U.S. PDUFA date of January 23, 2012, and the exercise of Hyperion's right to purchase Buphenyl and Ammonul (H1:13).

<b>HPTX (09/06)</b>	<b>\$10.75</b>	<b>Revenue \$MM</b>						
<b>Mkt cap</b>	<b>\$166.6MM</b>	<b>FY</b>	<b>2011</b>	<b>2012E</b>	<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	
Dil shares out	15.5MM	<b>Dec</b>	<b>Actual</b>	<b>Prior</b>	<b>Current</b>	<b>Prior</b>	<b>Current</b>	<b>Current</b>
Avg daily vol	20.3K	Q1	—	—	0.0A	—	—	—
52-wk range	\$10.0-12.0	Q2	—	—	0.0A	—	—	—
Dividend	Nil	Q3	—	—	0.0	—	—	—
Dividend yield	Nil	Q4	—	—	0.0	—	—	—
BV/sh	NA	Year	<b>0.0</b>	—	<b>0.0</b>	—	<b>49.8</b>	<b>114.0</b>
Net cash/sh	\$3.03	EV/S	—	—	—	—	<b>2.3x</b>	<b>1.0x</b>
Debt/cap	6.0%							
ROE (LTM)	NA							
5-yr fwd EPS growth (Norm)	NA							
<b>S&amp;P 500</b>	<b>1432.1</b>	<b>EPS \$</b>	<b>2011</b>	<b>2012E</b>	<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	
		<b>FY</b>	<b>Actual</b>	<b>Prior</b>	<b>Current</b>	<b>Prior</b>	<b>Current</b>	<b>Current</b>
		<b>Dec</b>						
		Q1	—	—	(1.14)A	—	—	—
		Q2	—	—	(0.68)A	—	—	—
		Q3	—	—	(0.50)	—	—	—
		Q4	—	—	(0.43)	—	—	—
		Year	<b>3.34</b>	<b>(2.51)</b>	<b>(2.58)</b>	—	<b>0.30</b>	<b>2.15</b>
		P/E	—	—	—	—	<b>35.8x</b>	<b>5.0x</b>

## Investment Summary

Hyperion is focused on the development of treatments in the areas of orphan disorders and hepatology. Hyperion's lead program includes a suite of products to treat urea cycle disorders. Urea cycle disorders, or UCDs, are a constellation of diseases in which the body lacks the ability to clear ammonia, a byproduct of protein digestion. Approximately 2,000 people in the United States have a UCD, and just over 500 are receiving pharmacotherapy. If left untreated UCDs can cause learning disabilities, mental retardation, and even death. Hyperion owns an option to purchase the leading FDA-approved therapy for the chronic management of UCDs, Buphenyl, and will begin marketing it by mid-2013. While Buphenyl can rescue patients from death, it has an excessive pill burden, a foul taste, and causes GI side effects in most patients. Hyperion has developed Ravicti to replace Buphenyl. Ravicti has succeeded in four Phase II and III trials, and is on file at the FDA with a January 23, 2013 PDUFA date. In a pooled analysis of all four studies, Ravicti has been shown to have significantly better ammonia control compared to Buphenyl. More important, Ravicti has far superior palatability in a dramatically reduced drug volume (1 tablespoon or less) with few GI side effects, making it much more tolerable for patients. Our checks suggest that Hyperion will successfully transfer the vast majority of treated UCD patients from Buphenyl to Ravicti over the next few years and we project it will achieve \$100MM+ in sales by 2016. Outside of UCD, Ravicti has shown intriguing Phase II data in Hepatic Encephalopathy (HE), a potential \$1B market. Hyperion expects to meet with FDA by YE:2012 to define Ravicti's future HE trials. We believe that Hyperion is undervalued based on Ravicti's potential in UCD, without any contribution from other indications. We expect the stock to outperform the market by 30%+ over the next 12-18 months as Ravicti is approved, and investors better appreciate its commercial potential.

### Upcoming Hyperion Milestones

Event	Timing
Presentation of Ravicti's Phase II HE data at AASLD	November 2012
End Of Phase II meeting with FDA to discuss Ravicti in HE	Q4:12
Ravicti's U.S. PDUFA date	January 23, 2013
HPTX to exercise option to purchase Buphenyl, Ammonul from MRX	H1:13
Ravicti's U.S. commercial launch	H1:13
Potential initiation of Ravicti's pivotal trials in HE	2013

Source: Cowen and Company

## Hyperion Quarterly P&amp;L (\$MM)

	Q1:12A	Q2:12A	Q3:12E	Q4:12E	2012E
Ravicti					
Buphenyl					
Ammonul					
License and Other					
Total Revenue	-	-	-	-	-
COGS					
<i>Gross Margin</i>					
R&D	8.9	2.7	3.1	3.2	17.9
SG&A	2.3	2.0	2.8	3.1	10.2
Other					
Operating Expenses	11.2	4.8	5.9	6.3	28.2
Operating Income / (Loss)	(11.2)	(4.8)	(5.9)	(6.3)	(28.2)
Interest and other income, net	(0.7)	(2.4)	(0.8)	(0.8)	(4.7)
Pretax net income	(11.9)	(7.2)	(6.7)	(7.1)	(32.8)
Taxes					
<i>Tax Rate</i>					
GAAP Net Income	(11.9)	(7.2)	(6.7)	(7.1)	(32.8)
<b>GAAP EPS</b>	<b>\$(1.14)</b>	<b>\$(0.68)</b>	<b>\$(0.50)</b>	<b>\$(0.43)</b>	<b>\$(2.58)</b>
Diluted Shares Outstanding (MM)	10.4	10.5	13.5	16.6	12.8

Source: Cowen and Company

## Hyperion Annual P&amp;L (\$MM)

	2011A	2012E	2013E	2014E	2015E	2016E
Ravicti	-	-	13.3	60.0	85.0	110.0
Buphenyl	-	-	32.5	35.0	20.0	5.0
Ammonul	-	-	4.0	8.5	9.0	9.5
License and Other	-	-	-	-	-	-
Total Revenue	-	-	49.8	103.5	114.0	124.5
COGS	-	-	3.4	8.6	10.4	12.2
<i>Gross Margin</i>			93%	92%	91%	90%
R&D	17.2	17.9	19.3	22.0	24.0	24.5
SG&A	8.9	10.2	21.5	25.0	27.5	28.0
Other	-	-	-	-	-	-
Operating Expenses	26.2	28.2	44.2	55.6	61.9	64.7
Operating Income / (Loss)	(26.2)	(28.2)	5.7	47.9	52.1	59.8
Interest and other income, net	(3.3)	(4.7)	(0.5)	(2.2)	0.0	4.0
Pretax net income	(29.4)	(32.8)	5.2	45.7	52.1	63.8
Taxes	-	-	-	2.5	7.8	19.1
<i>Tax Rate</i>	-	-	-	6%	15%	30%
GAAP Net Income	(29.4)	(32.8)	5.2	43.2	44.3	44.7
<b>GAAP EPS</b>	<b>(3.34)</b>	<b>(2.58)</b>	<b>0.30</b>	<b>2.15</b>	<b>2.15</b>	<b>2.15</b>
Diluted Shares Outstanding (MM)	8.8	12.8	17.0	20.1	20.6	20.8

Source: Cowen and Company

## Positives

1. With a purchase option on two approved products, Hyperion is very likely to begin generating revenue in 2013.

2. Ravicti has successfully completed Phase III trials in UCD, so its clinical development risk in UCD is low.
3. Our DCF analysis suggests Hyperion is substantially undervalued for Ravicti's potential in UCD.
4. Ravicti has produced promising Phase II data in a second indication, HE.

## **Negatives**

1. The length of exclusivity for Ravicti in UCD is unclear, and may be limited to 7 years of orphan drug exclusivity in the United States.
2. UCD is an ultra-orphan condition, and so there is a limited number of patients addressable by Ravicti with the condition in the U.S.
3. While Ravicti's early HE data is interesting, much clinical development and commercial risk remain.
4. Should Hyperion pursue Ravicti in HE, the company would likely need to finance again.

## Addendum

### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
HPTX	Hyperion Therapeutics

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(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

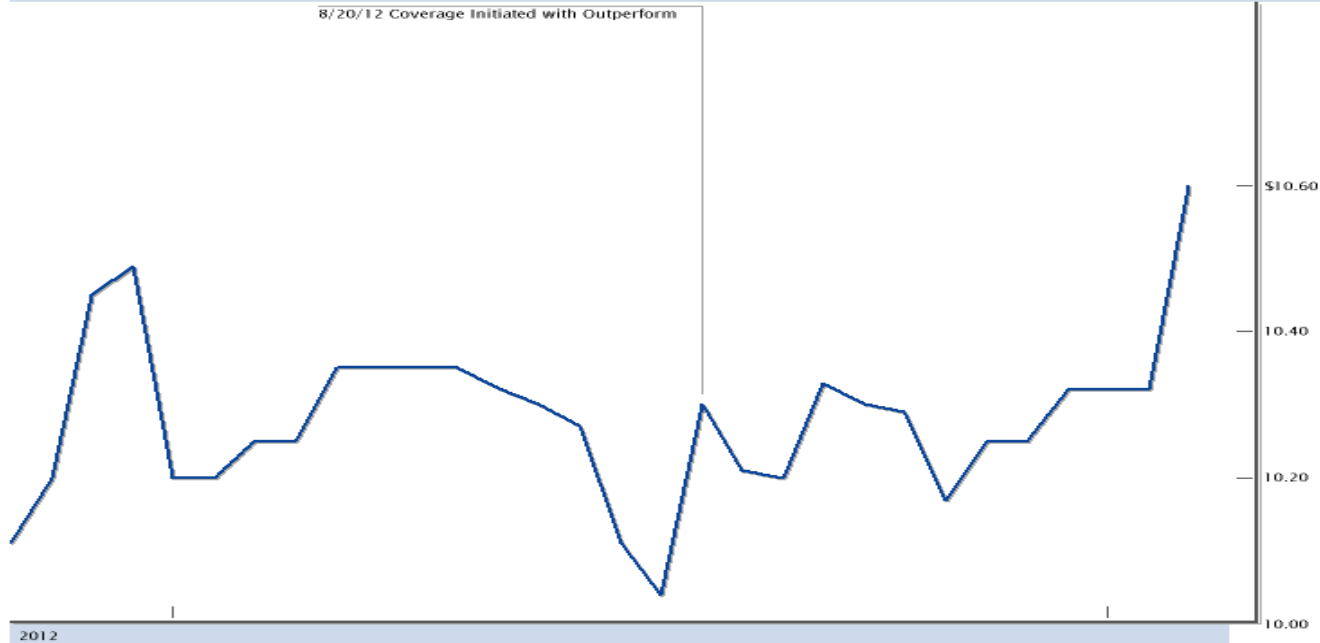
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**Hyperion Therapeutics - HPTX**



Pricing data provided by Reuters America. Chart as of 9/5/12 in USD.