



# Hyperion Therapeutics

## Outperform (1)

November 8, 2012

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## Reports Q3:12; AASLD Presentation Of Ravicti's HE Data Next Milestone

**Conclusion:** Last night Hyperion reported Q3:12 financials. The next milestone for Hyperion will be the presentation of data from Ravicti's Phase II trial in hepatic encephalopathy at the AASLD meeting on Monday, November 12, with an end of Phase II meeting with the FDA expected by YE:12. Ravicti's review in urea cycle disorders (UCD) continues, and we expect Ravicti to be approved on or around its January 2013 PDUFA. 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. We believe that Hyperion is undervalued based on Ravicti's potential in UCD, without any contribution from other indications.

- **Q3:12 Financials.** Hyperion reported a net loss of \$4.9MM. Following its recent IPO, Hyperion is well funded, ending Q3 with \$56.5MM in cash.
- **HE Phase II Data Intriguing.** Hyperion's Phase II trial enrolled 178 HE patients and randomized them to Ravicti (n = 90) or placebo (n = 88) on top of standard of care (lactulose and/or rifaximin). Hyperion has reported that the trial succeeded on its primary endpoint: Ravicti significantly reduced the proportion of patients experiencing at least one HE event, with 19 of 90 Ravicti patients (21%) experiencing an event vs. 32 of 88 (36%) of placebo patients (42% reduction, p = 0.02). Ravicti also significantly reduced the total HE events on study, and produced a numerical reduction in the total HE-related hospitalizations. Consultants believe Ravicti's efficacy data on the background of lactulose alone convincingly show that the drug is active at lowering the risk of HE attacks. We expect focus at AASLD will be on evidence that Ravicti produces additive efficacy on top of rifaximin. Ravicti's data will be presented at a Presidential Plenary on Monday morning (11/12), and Hyperion will host an analyst meeting Monday evening.
- **Ravicti's Filing In UCD Has A January 23, 2013 PDUFA.**

<b>HPTX (11/07)</b>	<b>\$10.32</b>	<b>Revenue \$MM</b>							
<b>Mkt cap</b>	<b>169.2MM</b>	<b>FY</b>	<b>2011</b>	<b>2012E</b>		<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	
Dil shares out	16.4MM	<b>Dec</b>	<b>Actual</b>	<b>Prior</b>	<b>Current</b>	<b>Prior</b>	<b>Current</b>	<b>Current</b>	<b>Current</b>
Avg daily vol	21.1K	Q1	—	—	0.0A	—	0.0	—	—
52-wk range	\$10.0-12.0	Q2	—	—	0.0A	—	13.3	—	—
Dividend	Nil	Q3	—	—	0.0A	—	12.3	—	—
Dividend yield	Nil	Q4	—	—	0.0	—	10.9	—	—
BV/sh	\$2.57	Year	<b>0.0</b>	—	<b>0.0</b>	—	<b>49.8</b>	<b>103.5</b>	<b>114.0</b>
Net cash/sh	\$2.90	EV/S	—	—	—	—	2.4x	1.2x	1.1x
Debt/cap	5.0%								
ROE (LTM)	NA								
5-yr fwd EPS growth (Norm)	NA								
		<b>EPS \$</b>	<b>2011</b>	<b>2012E</b>		<b>2013E</b>	<b>2014E</b>	<b>2015E</b>	
		<b>Dec</b>	<b>Actual</b>	<b>Prior</b>	<b>Current</b>	<b>Prior</b>	<b>Current</b>	<b>Current</b>	<b>Current</b>
Price Target		Q1	—	—	(1.14)A	—	(0.55)	—	—
		Q2	—	—	(0.68)A	—	0.13	—	—
		Q3	—	—	(0.44)A	—	0.04	—	—
<b>S&amp;P 500</b>	<b>1394.5</b>	Q4	—	(0.43)	(0.35)	—	(0.09)	—	—
		Year	<b>3.34</b>	<b>(2.58)</b>	<b>(2.45)</b>	—	<b>0.30</b>	<b>2.15</b>	<b>2.15</b>
		P/E	—	—	—	—	34.4x	4.8x	4.8x

## Investment Thesis

Hyperion is developing treatments in the areas of orphan disorders and hepatology. Hyperion's lead program includes a suite of products to treat urea cycle disorders (UCDs). 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. Left untreated, UCDs can cause learning disabilities, mental retardation, and 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.

### Upcoming Hyperion Milestones

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

Source: Company data, Cowen and Company

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

	Q1:12A	Q2:12A	Q3:12A	Q4:12E	2012E	Q1:13E	Q2:13E	Q3:13E	Q4:13E	2013E
Ravicti						-	1.8	3.5	8.0	13.3
Buphenyl						-	12.0	11.0	9.5	32.5
Ammonul						-	1.3	1.3	1.4	4.0
License and Other										
Total Revenue	-	-	-	-	-	-	13.3	12.3	10.9	49.8
COGS						-	0.9	1.0	1.4	3.4
Gross Margin							94%	93%	93%	93%
R&D	8.9	2.7	2.4	2.5	16.5	4.0	4.8	5.0	5.5	19.3
SG&A	2.3	2.0	2.4	3.1	9.8	5.2	5.3	5.4	5.5	21.4
Other										
Operating Expenses	11.2	4.8	4.8	5.6	26.3	9.2	11.0	11.4	12.4	44.1
Operating Income / (Loss)	(11.2)	(4.8)	(4.8)	(5.6)	(26.3)	(9.2)	2.3	0.9	(1.5)	5.7
Interest and other income, net	(0.7)	(2.4)	(0.2)	(0.2)	(3.4)	(0.1)	(0.1)	(0.1)	(0.1)	(0.5)
Pretax net income	(11.9)	(7.2)	(4.9)	(5.8)	(29.8)	(9.3)	2.2	0.7	(1.6)	5.2
Taxes						-	-	-	-	-
Tax Rate						0%	0%	0%	0%	0%
GAAP Net Income	(11.9)	(7.2)	(4.9)	(5.8)	(29.8)	(9.3)	2.2	0.7	(1.6)	5.2
GAAP EPS	\$(1.14)	\$(0.68)	\$(0.44)	\$(0.35)	\$(2.45)	\$(0.55)	\$ 0.13	\$ 0.04	\$(0.09)	\$ 0.30
Diluted Shares Outstanding (MM)	10.4	10.5	11.3	16.4	12.2	17.0	17.3	17.5	17.8	17.4

Source: Company data, Cowen and Company estimates

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

	2011A	2012E	2013E	2014E	2015E	2016E	2017E
Ravicti	-	-	13.3	60.0	85.0	110.0	125.0
Buphenyl	-	-	32.5	35.0	20.0	5.0	2.0
Ammonul	-	-	4.0	8.5	9.0	9.5	10.0
License and Other	-	-	-	-	-	-	-
Total Revenue	-	-	49.8	103.5	114.0	124.5	137.0
COGS	-	-	3.4	8.6	10.4	12.2	13.6
Gross Margin			93%	92%	91%	90%	90%
R&D	17.2	16.5	19.3	22.0	24.0	24.5	25.0
SG&A	8.9	9.8	21.4	25.0	27.5	28.0	29.0
Other	-	-	-	-	-	-	-
Operating Expenses	26.2	26.3	44.1	55.6	61.9	64.7	67.6
Operating Income / (Loss)	(26.2)	(26.3)	5.7	47.9	52.1	59.8	69.4
Interest and other income, net	(3.3)	(3.4)	(0.5)	(2.2)	-	4.0	4.0
Pretax net income	(29.4)	(29.8)	5.2	45.7	52.1	63.8	73.4
Taxes	-	-	-	2.5	7.8	19.1	22.0
Tax Rate	-	-	0%	6%	15%	30%	30%
GAAP Net Income	(29.4)	(29.8)	5.2	43.2	44.3	44.7	51.4
GAAP EPS	(3.34)	(2.45)	0.30	2.15	2.15	2.15	2.40
Diluted Shares Outstanding (MM)	8.8	12.2	17.4	20.1	20.6	20.8	21.4

Source: Company data, Cowen and Company estimates

## Hyperion DCF Analysis

Financial Year End	12/31/2011
Valuation Date	11/7/2012
Discount Rate	10.0%
Terminal Growth Rate	-10.0%

### Hyperion: DCF Valuation Wednesday, November 07, 2012

SMM	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
<b>Ravicti Sales</b>	0	13	60	85	110	125	138	144	116	92	74	59	47	38	30
Growth (%)			351%	42%	29%	20%	10%	5%	-20%	-20%	-20%	-20%	-20%	-20%	-20%
<b>Buphenyl</b>	0	33	35	20	5	2	2	1	1	1	1	1	1	1	0
Growth (%)			8%	-43%	-75%	-15%	-15%	-15%	-15%	-15%	-15%	-15%	-15%	-15%	-15%
<b>Ammonul</b>	0	4	9	9	10	10	10	10	10	10	10	10	10	10	10
Growth (%)			113%	6%	6%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
<b>License and Other</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Growth (%)															
<b>Total Revenues</b>	0	50	104	114	125	137	149	156	127	103	85	70	58	48	41
Growth (%)			108%	10%	9%	10%	9%	4%	-19%	-18%	-18%	-18%	-17%	-16%	-16%
<b>COGS</b>	0	3	9	10	12	14	15	16	13	10	8	7	6	5	4
COGS as a % of sales		25%	14%	12%	11%	11%	11%	11%	11%	11%	11%	12%	12%	13%	13%
<b>R&amp;D</b>	17	19	22	24	25	25	19	17	13	10	8	7	6	5	4
R&D as a % of Revenues		39%	21%	21%	20%	15%	13%	11%	10%	10%	10%	10%	10%	10%	10%
<b>SG&amp;A</b>	10	21	25	28	28	29	27	25	15	12	10	8	7	6	5
SG&A as a % of Revenues		43%	24%	24%	22%	20%	18%	16%	12%	12%	12%	12%	12%	12%	12%
<b>Operating Income</b>	-26	-31	4	23	45	57	76	87	75	59	47	37	29	22	17
<b>Tax</b>	0	0	0	3	14	17	23	26	23	18	14	11	9	7	5
Tax rate	0%	0%	6%	15%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
NOL/ Tax Assets Utilized															
Tax rate															
<b>Taxes Paid</b>	0	0	0	3	14	17	23	26	23	18	14	11	9	7	5
<b>Approx Free Cash Flow</b>	(26)	(31)	4	20	32	40	53	61	53	42	33	26	20	16	12
Years	0.14	1.14	2.14	3.14	4.14	5.14	6.14	7.14	8.14	9.14	10.14	11.14	12.14	13.14	14.14
Discount Factor	0.99	0.90	0.82	0.74	0.67	0.61	0.56	0.51	0.46	0.42	0.38	0.35	0.31	0.29	0.26
<b>NPV of Cash flows</b>	(26)	(28)	3	15	21	25	30	31	24	17	12	9	6	4	3

#### Terminal Value Calculation

Final year FCF	12
Perpetual Growth Rate	-10.0%
<b>Terminal Value</b>	54
Discount Factor	0.26
<b>Present Value of Terminal Value</b>	14
<b>Present Value of Cash Flows</b>	167
<b>Enterprise Value</b>	181
Add: Net cash	48
<b>Market Value</b>	229
Fully Diluted Shares Outstanding	16.4
<b>Value per Fully Diluted Share</b>	\$13.96

Source: Cowen and Company estimates



## 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.

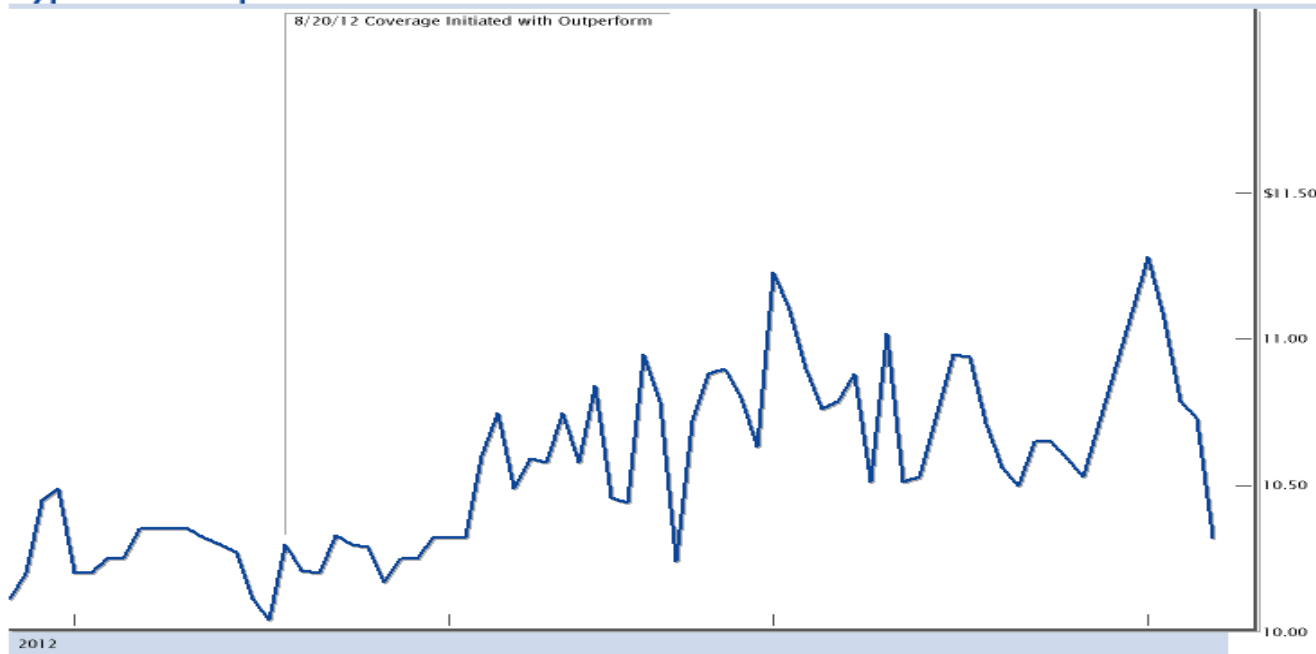
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Cowen and Company Price and Ratings History

### Hyperion Therapeutics - HPTX



Pricing data provided by Reuters America. Chart as of 11/7/12 in USD.

