

# **Hyperion Therapeutics**

# Outperform (1)

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# Reports Q1, Provides Encouraging Datapoints On Ravicti's Early Launch

**Conclusion:** Last night Hyperion reported Q1:13. With Ravicti available to patients only late in Q1, sales were modest (\$0.8MM vs our \$0E). However, Hyperion provided encouraging datapoints on the launch. Most notable, Hyperion expects all 75 of Ravicti's clinical trial patients will be on commercial therapy by the end of June. We are increasing our 2013 Ravicti estimate from \$13MME to \$24MME. We believe that Hyperion is undervalued based on Ravicti's potential in UCD, without any contribution from other indications.

- **Reports Q1:13.** Hyperion reported a net loss of \$9.0MM, or \$0.52/share, in line with our estimate of a loss of \$9.3MM (\$0.55/share). Hyperion ended Q1 with \$102.7MM in cash and guided to 2013 non-GAAP Op. Ex of \$41MM \$46MM. We have made minor adjustments to our 2013 GAAP OP Ex ests, increasing them modestly from \$43MM to \$46MM.
- encouraging Datapoints On Uptake, Reimbursement. Hyperion notes that approx. one-half of the 75 clinical trial patients have already converted to commercial drug. Today private insurance companies covering about two-thirds of UCD private-pay lives are already reimbursing for Ravicti, and about one-quarter of Medicaid covered lives are reimbursed. Hyperion expects all state Medicaids to begin reimbursing after July 1. Thus far the vast majority of payors require a prior authorization confirming that a patient has a UCD, but not that the patient has been on Buphenyl, and copays for Ravicti are generally in-line with those of Buphenyl. With little difference in insurance coverage or out-of-pocket cost to the patient, we expect patient conversion from Buphenyl to Ravicti will be rapid.
- **Buphenyl Purchase To Close May 29.** With a generic to Buphenyl recently launched, we now assume that Hyperion will not increase Buphenyl's price, and have cut our 2013 Buphenyl rev. est. from \$20MM to \$10MM. We continue to anticipate that VRX will retain Ammunol.

HPTX (05/09)	\$21.09	Rever	ue \$MM						
Mkt cap	421.8MM	FY	<u>2012</u>	201	<u>3E</u>	<u>201</u>	4 <u>E</u>	2015E	2016E
Dil shares out	20.0MM	Dec	Actual	Prior	Current	Prior	Current	Current	Current
Avg daily vol	28.4K	Q1	0.0	_	0.8A	_	_	_	_
52-wk range	\$10.0-26.5	Q2	0.0	_	1.8	_	_	_	_
Dividend	Nil	Q3	0.0	14.5	13.0	_	_	_	_
Dividend yield	Nil	Q4	0.0	17.5	18.5	_	_	_	
BV/sh	\$4.49	Year	0.0	33.8	34.1	_	95.0	105.0	115.0
Net cash/sh	\$4.81	EV/S	_	_	9.5x	_	3.4x	3.1x	2.8x
Debt/cap	1.5%								
ROE (LTM)	NA								
5-yr fwd EPS	NA	EPS \$							
growth (Norm)		FY	<u>2012</u>	<u>201</u>	<u>3E</u>	<u>201</u>	<u>4E</u>	<u>2015E</u>	<u>2016E</u>
		Dec	Actual	Prior	Current	Prior	Current	Current	Current
		Q1	(1.14)	_	(0.52)A	_	_	_	_
		Q2	(0.68)	(0.50)	(0.46)	_	_	_	_
		Q3	(0.44)	0.18	0.04	_	_	_	_
S&P 500	1626.7	Q4	(0.50)	0.30	0.24	_	_	_	
		Year	(2.64)	(0.55)	(0.65)	1.80	1.25	1.30	1.40
		P/E	_	_	_	_	16.9x	16.2x	15.1x



### **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. Untreated, UCDs can cause learning disabilities, mental retardation, and death. Hyperion has exercised 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 received FDA approval on February 1, 2013 and is available to patients. Ravicti's most important advantage is its 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. With ultra-orphan pricing of \$250-290K per patient per year, we project Ravicti will achieve \$100MM+ in sales in 2015, driving Hyperion to profitability. Outside of UCD, Ravicti has shown intriguing Phase II data in Hepatic Encephalopathy (HE), a potential \$1B market. Hyperion expects to begin Phase III for HE in 2014. We believe that Hyperion is undervalued based on Ravicti's potential in UCD, without any contribution from other indications.

#### **Upcoming Hyperion Milestones**

Event	Timing
Valeant to inform Hyperion whether it will retain Ammunol	May:13
Close of acquisition of Buphenyl	May:13
Updates on Ravicti's U.S. commercial launch	2013
Secure SPA for Ravicti's pivotal trial in HE	2014
Potential initiation of Ravicti's pivotal trials in HE	2014

Source: Cowen and Company



# **UCD Revenue Model**

	2012A	2013E	2014E	2015E	2016E	2017E
U.S. Urea Cycle Disorder Market						
Chronic Therapy						
Prevalence Of Urea Cycle Disorders In U.S.	2138	2186	2234	2282	2330	2378
Annual Incidence of UCD	160	160	160	160	160	160
Annual Mortality from UCD	112	112	112	112	112	112
Total Patients With Urea Cycle Disorders In The U.S.	2186	2234	2282	2330	2378	2426
% Diagnosed	50%	50%	50%	50%	50%	50%
Number Diagnosed	1069	1093	1117	1141	1165	1189
Buphenyl						
% on Buphenyl	40%	35%	10%	7%	3%	1%
Number of Patients On Buphenyl	425	385	115	77	38	15
Average Cost per Patient per Year (\$000)	55	65	65	65	65	65
Buphenyl Revenue (\$MM)	23.4	25.0	7.5	5.0	2.5	1.0
Ravicti						
% on Ravicti		10%	35%	39%	43%	46%
Number of Patients On Ravicti		107	389	444	500	551
Average Cost per Patient per Year (\$000)		225	225	225	225	225
Ravicti Revenue		\$24.1	\$87.5	\$100.0	\$112.5	\$124.0
Y/Y Growth			263%	14%	13%	10%

Source: Cowen and Company

# Hyperion Quarterly P&L (\$MM)

	Q1:12A	Q2:12A	Q3:12A	Q4:12A	2012A	Q1:13A	Q2:13E	Q3:13E	Q4:13E	2013E
Ravicti						0.8	1.8	7.5	14.0	24.1
Buphenyl						-		5.5	4.5	10.0
Ammonul						-	-	-	-	-
License and Other										
Total Revenue	-	-	-	-	-	0.8	1.8	13.0	18.5	34.1
COGS						0.1	0.2	1.0	1.6	2.9
Gross Margin						91%	90%	92%	91%	91%
R&D	8.9	2.7	2.4	3.0	17.0	1.8	2.3	2.5	3.0	9.6
SG&A	2.3	2.0	2.4	4.8	11.5	7.9	8.5	8.5	9.0	33.9
Other										
Operating Expenses	11.2	4.8	4.8	7.8	28.5	9.9	10.9	12.0	13.6	46.4
Operating Income / (Loss)	(11.2)	(4.8)	(4.8)	(7.8)	(28.5)	(9.1)	(9.1)	1.0	4.9	(12.3)
Interest and other income, net	(0.7)	(2.4)	(0.2)	(0.5)	(3.7)	0.1	(0.1)	(0.1)	(0.1)	(0.3)
Pretax net income	(11.9)	(7.2)	(4.9)	(8.3)	(32.3)	(9.0)	(9.3)	0.9	4.8	(12.6)
Taxes						-	-	-	-	-
Tax Rate						0%	0%	0%	0%	0%
GAAP Net Income	(11.9)	(7.2)	(4.9)	(8.3)	(32.3)	(9.0)	(9.3)	0.9	4.8	(12.6)
GAAP EPS	\$(1.14)	\$(0.68)	\$(0.44)	\$(0.50)	\$(2.64)	\$(0.52)	\$(0.46)	\$ 0.04	\$ 0.24	\$(0.65)
Diluted Shares Outstanding (MM)	10.4	10.5	11.3	16.6	12.2	17.4	20.0	20.1	20.2	19.4

Source: Cowen and Company



# Hyperion Annual P&L (\$MM)

	2012A	2013E	2014E	2015E	2016E	2017E
Ravicti	-	24.1	87.5	100.0	112.5	124.0
Buphenyl	-	10.0	7.5	5.0	2.5	1.0
Ammonul	-	-	-	-	-	-
License and Other	-	-	-	-	-	-
Total Revenue	-	34.1	95.0	105.0	115.0	125.0
COGS	-	2.9	9.1	10.3	11.4	12.5
Gross Margin		91%	90%	90%	90%	90%
R&D	17.0	9.6	16.0	20.5	22.5	25.0
SG&A	11.5	33.9	37.5	40.0	42.3	44.5
Other	-	-	-	-	-	-
Operating Expenses	28.5	46.4	62.6	70.8	76.1	82.0
Operating Income / (Loss)	(28.5)	(12.3)	32.4	34.3	38.9	43.1
Interest and other income, net	(3.7)	(0.3)	(2.2)	-	4.0	4.0
Pretax net income	(32.3)	(12.6)	30.2	34.3	42.9	47.1
Taxes	-	-	4.5	6.9	12.9	14.1
Tax Rate	-	0%	15%	20%	30%	30%
GAAP Net Income	(32.3)	(12.6)	25.6	27.4	30.0	32.9
GAAP EPS	(2.64)	(0.65)	1.25	1.30	1.40	1.50
Diluted Shares Outstanding (MM)	12.2	19.4	20.5	21.0	21.5	22.0

Source: Cowen and Company



# **Hyperion DCF**

12/31/2012
5/9/2013
10.0%
-20.0%

# Hyperion: DCF Valuation

\$MM	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Ravicti Sales Growth (%)	24	<b>88</b> 263%	100 14%	<b>113</b> 13%	<b>124</b> 20%	136 10%	<b>143</b> 5%	<b>150</b> 5%	<b>158</b> 5%	<b>166</b> 5%	<b>174</b> 5%	<b>183</b> 5%	<b>192</b> 5%	<b>202</b> 5%	<b>212</b> 5%	<b>222</b> 5%	<b>233</b> 5%	<b>245</b> 5%	<b>257</b> 5%	<b>270</b> 5%	<b>216</b> -20%
Buphenyl Growth (%)	10	8 -25%	5 -33%	<b>3</b> -50%	<b>1</b> -15%	<b>1</b> -15%	<b>1</b> -15%	<b>1</b> -15%	<b>1</b> -15%	<b>0</b> -15%											
Ammonul Growth (%)	0	0	0	0	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%	<b>0</b> 0%
License and Other Growth (%)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total Revenues Growth (%)	34	<b>95</b> 179%	105 11%	115 10%	<b>125</b> 9%	137 10%	144 5%	<b>151</b> 5%	158 5%	166 5%	174 5%	<b>183</b> 5%	<b>192</b> 5%	<b>202</b> 5%	<b>212</b> 5%	<b>222</b> 5%	<b>233</b> 5%	<b>245</b> 5%	<b>257</b> 5%	<b>270</b> 5%	<b>216</b> -20%
COGS COGS as a % of sales	3 12%	9 10%	10 10%	<b>11</b> 10%	<b>12</b> 10%	<b>14</b> 10%	<b>14</b> 10%	15 10%	16 10%	<b>17</b> 10%	<b>17</b> 10%	<b>18</b> 10%	19 10%	<b>20</b> 10%	<b>21</b> 10%	<b>22</b> 10%	<b>23</b> 10%	<b>25</b> 10%	<b>26</b> 10%	<b>27</b> 10%	<b>22</b> 10%
R&D R&D as a % of Revenues	10 28%	16 17%	<b>21</b> 20%	<b>23</b> 20%	<b>25</b> 15%	18 13%	16 11%	15 10%	13 8%	13 8%	14 8%	<b>15</b> 8%	12 6%	<b>12</b> 6%	13 6%	<b>13</b> 6%	14 6%	15 6%	<b>15</b> 6%	16 6%	13 6%
SG&A SG&A as a % of Revenues	<b>34</b> 100%	<b>38</b> 39%	<b>40</b> 38%	<b>42</b> 37%	<b>45</b> 36%	<b>45</b> 33%	<b>43</b> 30%	<b>38</b> 25%	<b>32</b> 20%	<b>25</b> 15%	<b>21</b> 12%	<b>22</b> 12%	<b>23</b> 12%	<b>24</b> 12%	<b>25</b> 12%	<b>27</b> 12%	<b>28</b> 12%	<b>29</b> 12%	<b>31</b> 12%	<b>32</b> 12%	<b>26</b> 12%
Operating Income	-12	32	34	39	43	60	71	83	98	111	122	128	138	145	153	160	168	176	185	195	156
Tax Tax rate	<b>0</b> 0%	<b>5</b> 15%	<b>7</b> 20%	<b>12</b> 30%	<b>13</b> 30%	18 30%	<b>21</b> 30%	<b>25</b> 30%	<b>29</b> 30%	<b>33</b> 30%	<b>37</b> 30%	<b>38</b> 30%	<b>42</b> 30%	<b>44</b> 30%	<b>46</b> 30%	<b>48</b> 30%	<b>50</b> 30%	<b>53</b> 30%	<b>56</b> 30%	<b>58</b> 30%	<b>47</b> 30%
NOL/ Tax Assets Utilized Tax rate																					
Taxes Paid	0	5	7	12	13	18	21	25	29	33	37	38	42	44	46	48	50	53	56	58	47
Approx Free Cash Flow	(12)	28	27	27	30	42	49	58	69	78	85	90	97	102	107	112	118	124	130	136	109
Years Discount Factor	0.64 0.94	1.64 0.86	2.64 0.78	3.64 0.71	4.64 0.64	5.64 0.58	6.64 0.53	7.64 0.48	8.64 0.44	9.64 0.40	10.64 0.36	11.64 0.33	12.64 0.30	13.64 0.27	14.64 0.25	15.64 0.23	16.64 0.20	17.64 0.19	18.64 0.17	19.64 0.15	20.64 0.14
NPV of Cash flows	(12)	24	21	19	19	25	26	28	30	31	31	30	29	28	26	25	24	23	22	21	15

Terminal Value Calculation

Final year FCF	109
Perpetual Growth Rate	-20.0%
L	
Terminal Value	290
Discount Factor	0.14
Present Value of Terminal Value	41
Present Value of Cash Flows	486
Enterprise Value	527
Add: Net cash	96
Market Value	623
Fully Diluted Shares Outstanding	20.0
Value per Fully Diluted Share	\$31.16

Source: Cowen and Company





# **Addendum**

#### STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
НРТХ	Hyperion Therapeutics

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

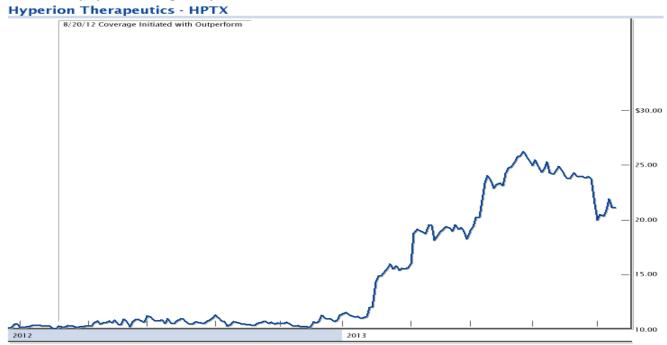
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