

# **Quick Take**

# **Hyperion Therapeutics — Outperform (1)**

**HPTX: \$16.13** 

**Quick Take: Ravicti FDA Approved With Broad Label** 

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Analysts
Phil Nadeau, Ph.D.
(646) 562-1336
phil.nadeau@cowen.com

Nicholas Bishop, Ph.D. (646) 562-1378 nicholas.bishop @cowen.com

This afternoon, the FDA approved Ravicti for management of UCD disorders. This was widely expected following the passage of the January 23<sup>rd</sup> PDUFA without a CRL, but perhaps a bit earlier than some had feared. Two minor uncertainties that were resolved positively in the approval are: (1) the inclusion of pediatric patients ages 2 years and older (rather than 6 and over), despite the incomplete 12-month safety followup of Hyperion's pediatric trial, and (2) the granting of an orphan designation, which we believe means that Ravicti has received orphan market exclusivity.

We expect Hyperion is likely to hold a conference call today. We would anticipate pricing and launch details to be key points of investor focus.

We expect Hyperion will trigger its option to purchase Buphenyl and Ammonul from Medicis shortly. The option can be exercised for a period of 90 days beginning today. Hyperion management has indicated that it will exercise this option at the first opportunity. Hyperion will make a \$22MM upfront payment to Medicis, plus future milestones and royalties. Hyperion can fund the purchase via a loan from Medicis that is payable over 8 quarters. When Hyperion exercises its option, Medicis will have the option to retain Ammonul for a price of \$32MM. If Medicis retains Ammonul, the price of Buphenyl for Hyperion is reduced to \$19MM, meaning that Medicis would need to make a net payment to Hyperion of \$13MM.

We assume that Ravicti will be launched in mid-2013, and that Hyperion gets rights to Buphenyl at the same time. Our model projects that 67 patients will be on Ravicti during 2013, which we believe is conservative given our consultants' expectations for a rapid switch of the market, the fact that there are 90 patients in Ravicti's extension studies, and Hyperion's label for patients aged 2 and up. We project that Hyperion will recognize \$32.5MM in Buphenyl revenue in 2013, and \$13MM in Ravicti revenue. We expect that over time Ravicti will capture the vast majority of UCD treated patients, and expand the market modestly by capturing newly diagnosed patients, as well as some that have dropped off Buphenyl because they cannot tolerate it. We project that by 2017 there will be 625 patients on Ravicti, and only 15 on Buphenyl, yielding \$125MM in Ravicti revenue, and \$2MM in Buphenyl revenue.

Our view of HTPX remains unchanged. Ravicti has been shown to be at least as potent as the current standard of care, but with much better tolerability and dosing convenience, in the treatment of urea cycle disorders (UCD). Our consultants expect Ravicti to be approved based on its current filing, and for it to quickly capture

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majority share of the UCD market. Based on Ravicti's potential in UCD alone, with no contribution from HE, we think Hyperion is undervalued, and remain at Outperform.



# **Addendum**

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Ticker	Company Name	
HPTX	Hyperion Therapeutics	

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Cowen and Company, LLC. New York (646) 562-1000 Boston (617) 946-3700 San Francisco (415) 646-7200 Chicago (312) 577-2240 Cleveland (440) 331-3531 Atlanta (866) 544-7009 London (affiliate) 44-207-071-7500

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

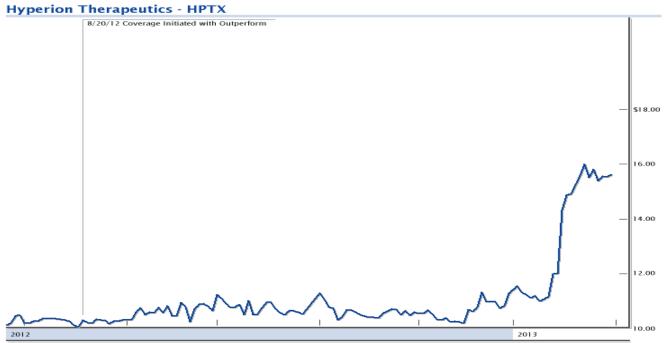
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