

Quick Take

Hyperion Therapeutics — Outperform (1)

HPTX: \$10.60

Quick Take: Ravicti's PDUFA Pushed To January 23, 2013

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Last night Hyperion announced that the FDA has extended Ravicti's PDUFA date by 3 months, from October 23, 2012 to January 23, 2013. Hyperion had recently responded to FDA questions, and the FDA characterized those responses as a "major amendment" to the filing, triggering the PDUFA change. We read little into this PDUFA date change as such extensions have become relatively common. In fact, management characterized the FDA's questions as routine, and remains confident in Ravicti's approvability.

Hyperion has previously said it expected to launch Ravicti during H1:13 following the completion of its acquisition of Buphenyl from Medicis (Hyperion's option to acquire Buphenyl begins on January 1, 2013), and our model assumes a launch around mid-2013. Therefore we have not changed any of our estimates following last night's announcement. In fact, there is one positive element to the change in Ravicti's PDUFA. Ravicti's strongest protection from generic competition is likely its orphan drug exclusivity. The 7-year period of orphan exclusivity begins on the day of FDA approval. Therefore, the extension could reduce the number of months during which Ravicti is approved but not launched, in effect preserving more of the orphan exclusivity period.

Our opinion of Ravicti and Hyperion's stock is 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. 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.

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.

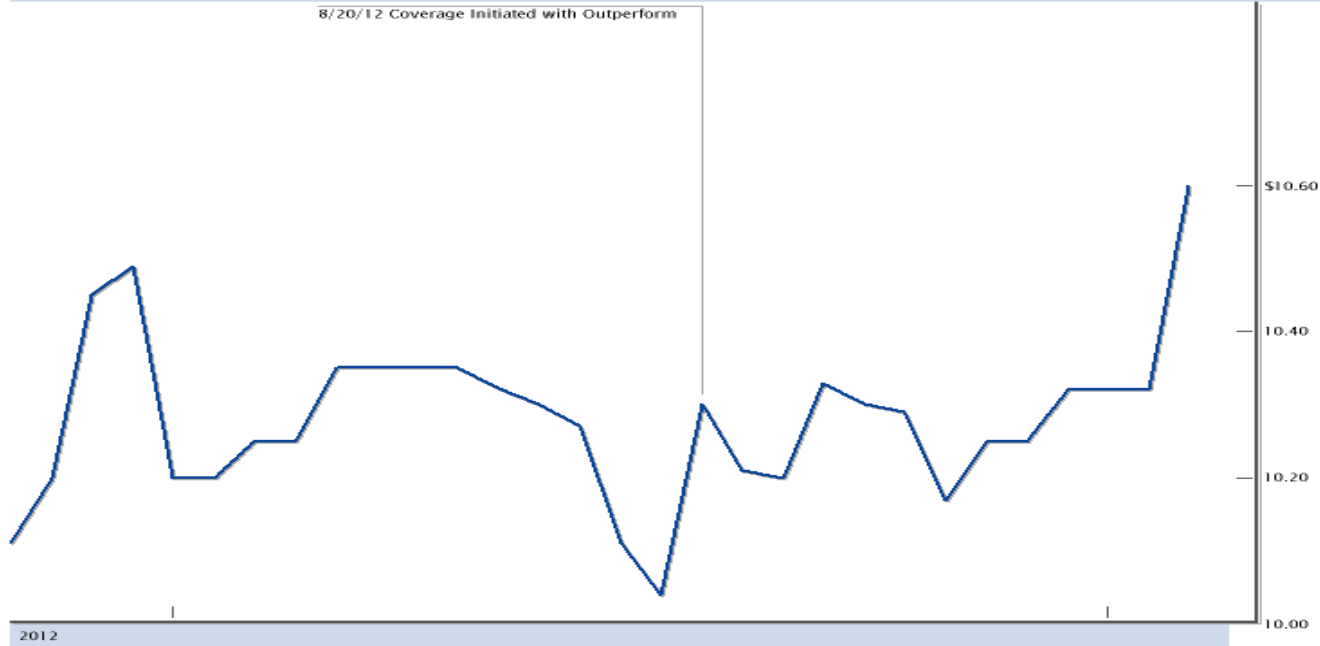
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Hyperion Therapeutics - HPTX



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