

Quick Take

Hyperion Therapeutics — Outperform (1)

HPTX: \$13.00

Quick Take: FDA Action On Ravicti Delayed; We Remain Confident In Approval

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This morning, Hyperion announced that the FDA has notified the company that it does not expect to meet the PDUFA date of January 23 on Ravicti's NDA. The FDA stated that it has not had sufficient time to complete labeling and determination of Ravicti's post-marketing requirements. While the delay is an annoyance, we have spoken with management and are now, if anything, even more confident that Ravicti remains on track for approval than we were before this news.

Management reports that the FDA admitted it would not be able to get Ravicti's labeling done by January 23 at the end of an otherwise very positive conference call to discuss the label that took place yesterday evening. Hyperion does not expect to receive a CRL on the 23rd, rather there will simply be no decision from the FDA on the PDUFA date. Because the FDA has already pushed out Ravicti's PDUFA by 3 months, there is actually no official mechanism remaining to set a new PDUFA date, so the precise timing of FDA action is now somewhat unclear. Nevertheless, we remain confident that Ravicti will eventually be approved. We note that a similar situation occurred with Salix's Fulyzaq, which had its original PDUFA pushed back 3 months from June 2012 to September, after which the FDA missed the revised PDUFA date, eventually approving the drug at year end. Management continues to feel very confident about Ravicti's approval chances, noting that while it cannot disclose everything the FDA has communicated, it is comfortable that there is no undisclosed material bad news.

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 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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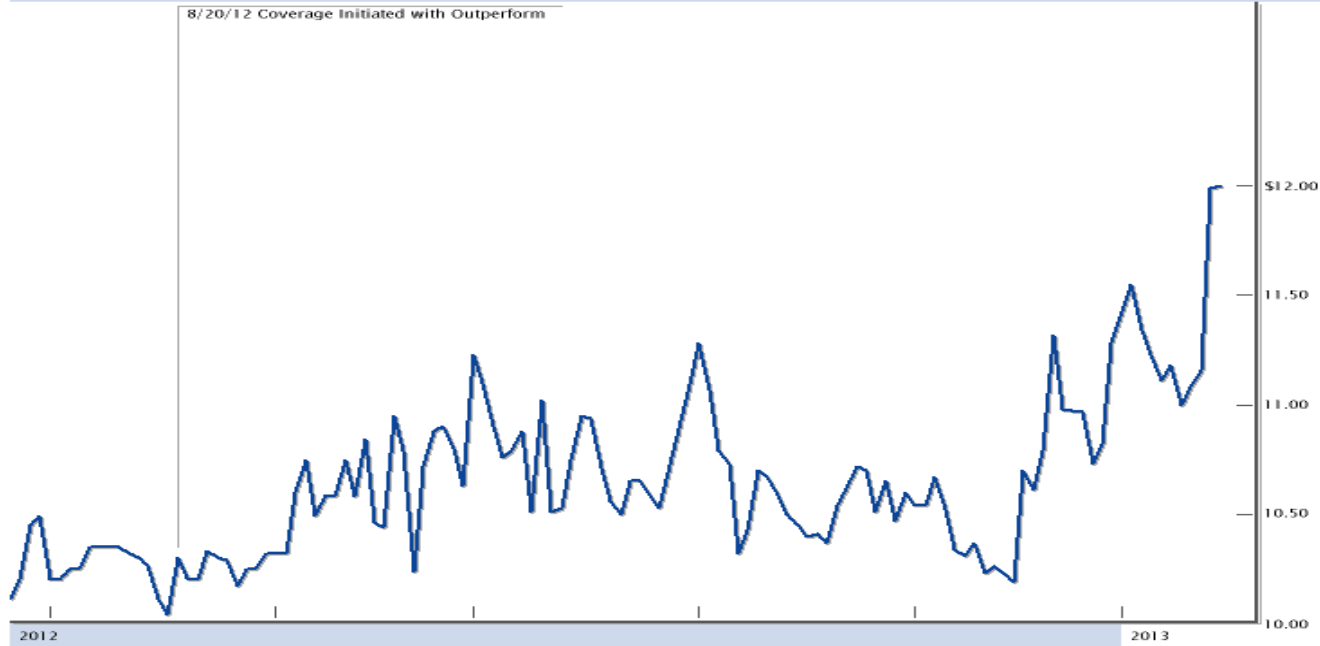
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Hyperion Therapeutics - HPTX



Pricing data provided by Reuters America. Chart as of 1/15/13 in USD.