Evaluate Vantage

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Wins all around at CombinatoRx with Exalgo approval

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The owners of the former Neuromed got their wish. The FDA's approval of Exalgo, the extended release formulation of opiate pain reliever, hydromorphone hydrocholoride, means that under the terms of Neuromed's merger with CombinatoRx, which owns the drug as a result of the transaction, Neuromed's pre-merger shareholders will hold 60% of the combined company (*Event - Milestones from Exalgo approval will boost CombinatoRx's fortunes, February 8, 2010*).

With a $40m milestone from commercialisation partner Covidien also due with the approval, CombinatoRx will be in a better position to use its drug combination platform to develop its stable of pain, anti-inflammatory and diabetic agents now in phase II trials. The knowledge that the company may get some more shots on goal surely must make the terms of the merger seem sweeter to the former shareholders of privately held Neuromed, who would have seen their share of the company fall to 40% had the FDA delayed Exalgo's approval past September 30.

Just as sweet must have been watching the performance of the shares on Tuesday, when they rose 33% to close at $1.48. Just a year ago, pre-merger CombinatoRx closed at a little more than one-third of Tuesday's close, 51 cents, and on December 22, the day after the merger closed, CombinatoRx shares were worth 91 cents.

Merging to survive

Neuromed's reverse merger with CombinatoRx has turned out, for now, to be a winning strategy for CombinatoRx. Neuromed brought the development rights to Exalgo to the merger table, while CombinatoRx was struggling through a period in which it cut its R&D budget and sacked two-thirds of its workforce. The merger aimed to give CombinatoRx enough money to survive through 2012, and it appears to have worked, particularly with the approval of Exalgo (*CombinatoRx finds that reversing is the way forward, July 3, 2009*).

Analysts at Wells Fargo securities estimate a $200m-a-year sales opportunity for licensing partner Covidien. That may not be far off the mark, as Jurnista, the identical drug marketed in the European Union by Johnson & Johnson, is forecast to ring up $280m in sales by 2014, according to consensus forecasts from *EvaluatePharma.*

Without doubt, royalties of that scale will be welcome to CombinatoRx as it works on developing and commercialising its pipeline drugs. One, prednisporin for conjunctivitis, was licensed in phase II to Fovea Pharmaceuticals in Japan and Taiwan.

Three others may still be seeking partners: CRx-401, a diabetes treatment, has shown success in lowering blood sugar levels; Synavive for osteoarthritis, which despite its failure in a phase IIb trial in 2008 the company still continues to test; and CRx-191, a selective steroid amplifier for psoriasis, which although it showed safety and efficacy in a phase II trial the company has not talked about since 2008.

The phrase win-win is tossed around indiscriminately in the business world, but the Exalgo approval is an instance where the label should apply. In merging with Neuromed, CombinatoRx won a product that will now be taken to the market and aid in the development of its pipeline products, while the former Neuromed shareholders won a bigger share of the company based on regulatory approval of their product.

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