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Novartis seeks new respiratory bride in Oriel

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Novartis believes it has found another way to skin a cat. The Swiss company's Sandoz generics unit is acquiring Oriel Therapeutics, a North Carolina firm, which is developing a drug delivery platform that Novartis says may be able to jump the ever-higher US regulatory hurdles for inhaled respiratory drugs.

Coming as it does a month after Novartis handed back to UK-based Vectura the US marketing rights to VR315, widely believed to be a generic version of Advair, the Oriel purchase seems to signal that Novartis reckons it has found a better pathway to approval of a generic challenger to the world's second-biggest drug. Advair is scheduled to lose patent protection in 2011, but hurdles constructed by the FDA has made it appear to be one of the better-protected products in a post-patent-cliff era (*Glaxo's Advair looks increasingly bullet proof as Sandoz backs away from US, March 18, 2010*).

Regulatory challenges

It is a sign of the difficulties with the FDA that when Novartis renegotiated its deal with Vectura, it retained marketing rights in Europe, where the pathway for generic inhalation products is clearer. Add on top of that the ever-increasing concern about the use in asthma of long-acting beta agonists (LABAs), one of the two components of Advair, and the regulatory path is far from clear (*FDA takes tough stance on asthma drugs, February 19, 2010*).

Although Novartis did not disclose the price it paid for privately held Oriel, it said the purchase will give it access to Oriel's proprietary Solis dry powder inhaler, which is based on its FreePath technology. Novartis said the technology "has the potential to address some of the hurdles facing regulatory approval of generic inhaled medicines in the US".

Analysts from Piper Jaffray noted that while not much is known about Oriel and its technology, the inhaler is based on electronics that analyze patients' breath and adjust dispersion to make dosing more accurate. However, they added that proving bioequivalence in real-world dosing still remains a challenge, as well as the true substitutability of the device.

Vectura slides

Suffering collateral damage from the deal was Vectura, which has secured a $9.5m fee and $25m loan facility from Novartis to fund US development of VR315, following the cancellation of the US marketing deal. Its share price fell 4%, to 42.25p, in afternoon trading, an 18-month low.

Speaking to *EP Vantage*, Julia Wilson, Vectura's investor relations director, said Novartis' deal with Oriel had not altered the company's plan to push forward alone with VR315 in the US if necessary, and noted that Novartis still has an option for co-promotion rights to the product if Vectura is successful in winning approval with the Vectura GyroHaler.

GlaxoSmithKline, meanwhile, has expressed confidence that Advair will remain an important part of its portfolio past its patent expiry; US sales of the drug are set to peak at $4.23bn next year according to *EvaluatePharma*. While the regulatory environment may be giving Glaxo an assist, the size of the market opportunity seems to keep generic companies' interests alive and Novartis' deal with Oriel is a sign that interest is not waning.