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With Abstral approval ProStrakan breathing easier

Jonathan Gardner

There may be a collective wipe of the brow at ProStrakan's headquarters today. The FDA approved the reformulated fentanyl candidate Abstral/Rapinyl, the second US approval the Scottish group has received in 12 days, helping to erase some of the worries that have overshadowed the company in recent months (*ProStrakan's debt pile casts dark shadow on drug delays, September 7, 2010*).

Shares rose 11% to a one-year high of 115.3p on the news today – and boosted shares of Orexo, ProStrakan's Swedish-based partner, by 14% - as Abstral joined Fortesta in getting the regulator's stamp of approval (*Clinical and regulatory events over the Christmas period, January 4, 2011*). Investor confidence gradually returned to the specialty group in the fourth quarter as private UK group Norgine bought a partial stake and Candian partner Paladin Labs assumed ProStrakan's debt in return for expanded commercial rights.

Tilted playing field

ProStrakan's biggest growth driver and second most valuable product with a net present value of $154m, Abstral is a sublingual treatment for breakthrough pain in cancer patients already on constant opioid therapy. It has been on the European market since 2008, where it booked $9m in sales in 2009. US sales account for half of the $119m in worldwide sales forecast for 2016, according to *EvaluatePharma* data, making the FDA a key obstacle to success.

Abstral will be the only sublingual product on the market but will be competing with Cephalon's transmucosal products, Fentora, a slowly dissolving lozenge that patients slip between cheek and upper gum, and Actiq, a lozenge on a plastic stick that patients consume much like a lollipop.

As an opioid to treat pain, Abstral will be subject to one of the increasingly strict risk evaluation and management strategies (REMS) that the FDA has imposed in recent years on drugs thought to have safety concerns or present a risk for abuse. Analysts for Nomura Code note that Fentora and Actiq are not subject to such surveillance as yet, which may mean Abstral experiences a slow takeup as partner Orexo implements requirements such as pharmacy and physician authorisation and patient registries.

Happiness

If there was any concern about slow takeup, it could not be heard from ProStrakan executives today. In an interview, chief financial officer Allan Watson said the company felt it had addressed the many concerns that investors had in autumn 2010.

Shares dropped one third on September 7 with the news that Abstral's PDUFA date had been pushed back a second time and concerns mounted about £46.5m ($71.2m) in debts coming due at the end of 2010. Longtime chief executive Wilson Totten resigned at that time.

After a failed attempt by Norgine to buy the company – although it did managed to acquire a 12.6% stake – Paladin Labs became ProStrakan's white knight by assuming £50m of debt in exchange for commercial rights to Abstral, Sancuso, Rectogesic, Xomolix and Tostran in territories in which they have not been partnered. The Montreal group has an option to convert the debt into a 20% stake in the company in the next three years.

"All the things that the market was concerned about at that time have really been resolved," Mr Watson says. "People clearly were concerned about what would happen in 2011 when we had to start making capital repayments. We always believed that we could get things resolved and I think it was a case of having to be patient."

Given that it is already being manufactured for the European market, Mr Watson said Abstral will be reaching the company's 50 US representatives "in the next few weeks" where it will join Sancuso, marketed for chemotherapy-induced vomiting, in the sales pitch to oncology specialists.

After a series of blows in 2010, ProStrakan is breathing easier in 2011. Although its board has rejected the Norgine bid, the group confirmed today it is still evaluating other takeover offers and bids for company assets, meaning a trade sale may yet happen. And with a REMS expected by some to hamper a quick US launch of Abstral the drama may not be over just yet.