Evaluate Vantage

June 24, 2011

Painful damage as Remoxy is rejected again

Jonathan Gardner

Investors in Pain Therapeutics and Durect who took as a positive sign the FDA's approval of Oxecta last Friday are gnashing their teeth today (*Oxecta FDA approval tempered by lack of abuse resistance claim, June 21, 2011).* The regulator has rejected the companies' abuse-resistant oxycodone pill Remoxy, causing shares in both to tumble in early trade today.

The second complete response letter raises the spectre of Pfizer pulling the plug on development of the extended-release pain reliever. Such a scenario would leave Texas-based Pain with a tough decision over whether to try a third time for approval of its lead product on its own, or re-focus on its early-stage assets.

Damage

Shares in Pain plummeted 42% to a 20-month low of $5.40 in early trade this morning. Durect, which supplied the abuse-resistance technology, was down 28% to $2.24, a 10-month low.

In retrospect, the signs were not that encouraging when the FDA granted approval to Acura Pharmaceuticals' Oxecta but refused to allow a claim on its label that the pill reduces the risk of abuse. In essence, the agency is saying that the pill shows evidence of pain reduction but does little beyond that.

The addition of a request for an epidemiological trial of Oxecta to study the issue was a further sign of the regulators' scepticism about the strategies both Oxecta and Remoxy apply – resistance to crushing or dissolving that makes the tablets difficult to snort or inject, as well as aversion techniques.

Pain and Pfizer, which acquired rights to Remoxy with its purchase of King Pharmaceuticals, did not disclose the FDA's reasons for the rejection, so much is still a mystery – including the big issue of whether new trials are necessary. The chief difference between Oxecta and Remoxy is that the former is a fast-acting pain reliever.

Good position

For a company with no marketed products, Pain is in a decent position financially. It had $54.9m in cash available at March 31, and the deal with King extended to phase I candidate PTI-202 and other abuse resistant opioids in its pipeline. In the absence of a Remoxy approval it has said its cash needs are just $5m in 2011.

However, Remoxy's rejection virtually ensures the company will continue to lose money in coming years. Royalties on Remoxy were forecast at $12m starting in 2012, escalating to $120m in 2016 for Pain, and potentially $114m in 2016 for Durect, according to *EvaluatePharma* data. Even if Pfizer or Pain presses ahead in the hopes that Remoxy is third time lucky, it could be years before Pain and Durect will see a regular revenue flow from it.

Despite Pfizer's commitment to pain-relief medicines, it is not a company looking to add to its R&D burden (*Pfizer's R&D cull yet to take shape, February 7, 2011*). As such it would not be a surprise to see Remoxy shelved in the not too distant future.