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FDA delivers crushing blows to abuse-deterrent opioids

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Pain Therapeutics investors are right to blanch at the fact that Pfizer is considering handing back rights to Pain's oxycodone formulation Remoxy. The FDA's demand for more data has set the refiling date back to mid-2015, and while Pfizer has not yet made a definite decision the market was spooked badly, halving Pain's share price to $2.68.

The trends are not good. It is true that last month the FDA updated the label for Purdue Pharma's controlled-release form of OxyContin – the only branded version currently sold – to state that it is better at deterring abuse than other formulations. But last week, the agency rejected Endo Health Solutions' claim that another putatively tamper-resistant opioid, Opana ER, was better at deterring abuse than generic versions of oxymorphone. It is possible that no other product will ever be able to match OxyContin's abuse-resistant designation.

Two-year delay

Pfizer has a history of dropping unpromising painkillers. Nine months ago it handed back the rights to three tamper-resistant painkillers developed by Acura Pharmaceuticals, though it did keep the company's oxycodone product, Oxecta (*Vantage Point – Political backing unlikely to help developers of tamper-resistant painkillers, August 9, 2012*).

Oxecta is on sale in the US already, but does not have the tamper-deterrent claim on its label. Perhaps Pfizer is now questioning the wisdom of keeping two extended-release oxycodone formulations on the books when neither is likely to get the nod as tamper-resistant.

And even if Oxecta were not already approved, Remoxy would be the one to drop: it has already been rejected by the FDA twice (*Painful damage as Remoxy is rejected again, June 24, 2011*). Pfizer met the agency in March to discuss Remoxy's future, coming away with the notion that there was a path forward.

Unfortunately, it is a long one. Pfizer said last week that it would not respond to the second complete response letter before the middle of 2015, and that it had not yet decided whether this was worth the expense.

Uncertainty

The uncertainty hit Pain Therapeutics hard, knocking $120m off its previous $241m market cap. The other partner in the project, Durect, which makes the ORADUR technology that Remoxy uses, was also bashed, suffering a 34% fall in its shares.

Without Remoxy, Pain has little to recommend it: a handful of phase I and preclinical compounds. Even after its 50% fall, though, it is valued significantly above its cash reserves of $56m, so some investors seem to be keeping faith.

If they are hoping for the drug's approval with the explicit abuse-deterrent label, this is a high-stakes, high-risk bet. There are huge amounts of money to be made – OxyContin sold nearly $3bn at its peak in 2009. Remoxy, however, is far more likely to go the way of Endo's Opana ER. An older form of this drug – extended-release, but not tamper-resistant – has been on the market since 2006, and is now off-patent.

A new, crush-resistant form was launched in December, but without the abuse-deterrent claim on its label. The agency's decision last week to deny this means that it has no sales advantage over the old version, or indeed over generics.

The FDA is sceptical in the extreme when it comes to these claims. If Remoxy makes it to market in three or four years, Pain Therapeutics will rake in the cash. Pfizer will have to weigh its chances of getting there.

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