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Orexigen trades one problem for another

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Orexigen stock climbing 9% yesterday despite the group's confirmation that it would be stung with the $210m cost of running a second cardiovascular outcomes study of the obesity drug Contrave shows just how much worse things could have been.

Takeda might, for instance, have pulled the plug on the companies' deal, something that has been averted. However, Orexigen's standing with the US FDA still lies in tatters, and its shares will continue to be depressed by an urgent need to raise cash; a new trial cannot start without the funds to complete it, and Orexigen has only $175m in the bank.

Indeed, while the restructuring of the Takeda deal removes an overhang on Orexigen's shares, the stock is still 51% below where it stood in early March. That was before news broke of Orexigen's unorthodox disclosure of interim data from Light, Contrave's original 9,000-patient cardiovascular outcomes trial.

With Orexigen's reputation damaged Takeda started a formal dispute against the US company over the cost of funding a second post-approval study, and sought to terminate the 2010 deal, claiming that Orexigen was in material breach (*Orexigen's heavy price for Light miscalculation, May 13, 2015*).

Disaster averted

Yesterday's settlement draws a line under the dispute, but loads Orexigen with most of the up-front costs of the new trial, showing the strength of Takeda's negotiating position.

True, the Japanese group has agreed to pick up the remaining costs of Light, but since the trial has been terminated these will be low. 900 Takeda reps will continue to promote the drug, and the company will be liable for an extra $105m of milestones to Orexigen, though these are back-end loaded and depend partly on Contrave's label reflecting superiority claims.

After the farrago around Light's interim data disclosure it is far from clear whether this is possible, or even whether sufficient patients can be recruited into a second large trial once Contrave secures enough cash to enable it to start.

A study to rule out increased risk of heart attack or stroke had been mandated by the FDA as a condition of Contrave's US approval. In the event Light's first interim analysis not only ruled out an increased risk but showed a 41% reduction in cardiovascular events, but by the second analysis this benefit had evaporated.

It would be logical for the second cardiovascular outcomes study to mirror Light, and to seek to rule in or out similar scenarios at similar interim analyses, though for now Orexigen will reveal nothing about its design.

Ironically, Contrave has quietly been doing rather well in the market, edging out Vivus's Qsymia and Arena's Belviq to become the most prescribed US branded obesity drug within eight months of launch. Second-quarter in-market sales were $18m, and sellside consensus for 2020 stands at $219m, *EvaluatePharma* calculates.

At least Contrave is still on the market, with a negligible risk of being pulled from it. And in terms of reputation there is another reason to be optimistic: beyond funding the new cardiovascular study Orexigen will have nothing to do with its running. This is now in the hands of Takeda.

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