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Oblivion beckons for Remodulin as FDA again says no

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The US filing for UT-15C Sustained Release, the oral version of United Therapeutics' blood pressure drug Remodulin, has once again been kicked into the long grass by the FDA. With the original, infused form of Remodulin accounting for half of United's revenue but coming off patent next year, United is now in trouble.

This is the second time the FDA has turned UT-15C down, but it might not be the last; the eternally optimistic United has said that it remains confident and wants to discuss the path forward with the agency. But few drugs have been approved on the third time of asking – Purdue Pharma and Transcept Pharmaceuticals' insomnia therapy Intermezzo being a rare exception – and anyway, time is running out.

The FDA's decision is hardly surprising given that in its previous complete response letter it had said that even further trial data were unlikely to sway its decision – and no such data were included in the new submission, United instead supplying a reanalysis of its previous, rather poor, trial results (*United's oral Remodulin slighted with poor data cited, October 24, 2012*).

With this proviso in mind it is perhaps strange that the agency decided last month to accept United's resubmission of the drug, known generically as treprostinil, as a treatment for pulmonary arterial hypertension (PAH).

Pressure

Mark Schoenebaum, an analyst at ISI Group, says he believes that this time around the FDA had not raised any new issues, and optimistically added that United might have been able to resolve a few of the problems highlighted in the first complete response letter.

Be that as it may, clearly not all of them were, and now United has little hope of getting an oral, extended-release Remodulin on the US market before the patent on the infused form expires and its worldwide sales drop from a peak of $479 next year to $302 in 2018.

Worse, the market is becoming saturated. Bayer's Riociguat and Actelion's Opsumit are due to hit the US this year and will become the top-selling PAH drugs in 2018, according to consensus data from *EvaluatePharma*.

United is not done for yet. Its inhaled version of Remodulin, Tyvaso, remains secure for another five years, although an interim look at a phase III trial of its competitor, Actelion's selexipag, could put further pressure on the stock, Mr Schoenebaum warned. He added that the company could use some of its cash to buy back stock, and could bolster its late stage pipeline through M&A.

The company's share price has fallen just 3% so far today as clearly the FDA's verdict was not unexpected. Investors are not yet deserting the company, but, in PAH at least, United is at risk of coming untied.

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