Evaluate Vantage

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Bad news on Xifaxan gives Salix investors indigestion

Jonathan Gardner

No matter how it is pitched, the expected FDA rejection of Xifaxan for irritable bowel syndrome (IBS) is a huge setback for Salix Pharmaceuticals. Acknowledging that there will be a delay in marketing its biggest potential drug in its biggest indication resulted in a market blow today, with shares falling 23% to $32 in early trading and erasing all the gains of the preceding 12 months.

As the announcement was based on a telephone conversation with agency officials ahead of what looks like will be a complete response letter, Salix has not been able to disclose many details other than that the regulator is probably going to ask for data on retreatment. While much more is unknown than known, the revelation suggests the FDA wants to see more long-term data before approval is granted to treat a condition that for many patients is a lifetime affliction.

Terse

In a short conference call in which she did not take questions, Salix chief executive Carolyn Logan said that despite the setback the North Carolina group is well positioned to withstand it. Leaving off forecasts of $29m in the non-constipation IBS (non-C IBS) indication, Salix is still poised to sell $511m this year thanks to a stable of marketed gastrointestinal products, according to *EvaluatePharma* forecasts.

Moreover, after a $300m fundraising last year, the company was sitting on a war chest of $491.5m as of September 30, 2010, which certainly is sufficient to withstand a delay (*Who were the cash call kings of 2010?, December 21, 2010*). If additional trials are necessary, it has the funds to pay for them and likely still have enough to make strategic decisions, such as its reacquisition of full rights to Relistor (*Salix takes Relistor's commercial reins from Pfizer, February 8, 2011*).

Yet the reasons for the market reaction are clear. Xifaxan is projected to be a blockbuster product, forecast to be far and away Salix's biggest seller at $1.4bn in 2016. As such its net present value of $2.68bn exceeded Salix's market capitalisation of $2.4bn at Wednesday's market close (*Event – Salix needs Xifaxan IBS win to justify valuation, February 14, 2011*).

The $601m in non-C IBS sales projected in 2016 represents about half of Xifaxan sales – it also is approved in hepatic encephalopathy and travellers' diarrhoea - and more than one-third of overall company sales.

Thus, expectations have been building for Xifaxan – Salix shares had risen by 62% over the preceding year – and news of a delay to a hugely valuable indication is clearly unwelcome.

Clarity needed

The contents of the complete response letter, expected by March 7, will likely clarify Salix's situation a little bit more. Results from the pivotal Target 1 and 2 studies showed that patients taking Xifaxan experienced significantly more relief from IBS symptoms in a three-month period that included a two-week treatment period and 10 weeks of follow-up, suggesting duration of relief.

However, the proportion of patients with adequate relief declined throughout the 10-week follow-up, according to trial results published in the *New England Journal of Medicine*. This suggests that retreatment would be necessary for a significant number of Xifaxan users over the long term.

In a note published today, analysts from Roth Capital Markets write that the data on retreatment is available. How long a delay this request will cause is unclear, however, and is the crucial question.

Until this is known, a great deal of uncertainty will hang over Salix and Xifaxan. The Roth analysts write that a standard nine-month delay to refile the new drug application with additional retreatment data would trim $5 from its current price target of $55. However, they remain bullish on Salix as Xifaxan's growth in hepatic encephalopathy remains healthy.

But uncertainty is never good, particularly when it clouds a company’s biggest hope. All eyes will be on the details of the FDA’s demands, to gauge how big a set back this is.

Trial IDs	Target-1	NCT00731679
	Target-2	NCT00724126

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Evaluate HQ
44-(0)20-7377-0800

Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754

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