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Alimera gets unwelcome Christmas message from FDA

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At this stage the details released by Alimera Sciences on the complete response letter for Iluvien, a treatment for diabetic macular oedema, point to a delay rather than anything more terminal.

But with expectations high for US approval and launch early next year, even a delay is a big disappointment for the newly-listed company, which is likely to see its shares fall substantially below their IPO price after the Christmas break. Such a reaction is understandable; the Georgia company was forecast to turn a profit next year, an eventuality which now looks very unlikely, and raises the possibility that additional funds will have to be found.

Red flags

Iluvien is an implant inserted in to the back of the eye that slowly releases a corticosteroid, fluocinolone acetonide, over three years. The active agent lessens the swelling in the centre of the retina, the cause of diabetic macular oedema.

Equity analysts that follow Alimera were largely confident in a nod from regulators, based on a successful pivotal trial programme, the fact that other intravitreal inserts have been approved, and lack of other therapies on the market (*Event – Alimera hopes for the first 'aye' in DME, September 30, 2010*).

One red flag that had been raised was the phase III trial's failure on one statistical measure. Two different techniques were used to analyse the data; the primary endpoint was met when the full study set was included, but it was narrowly missed when data from a modified patient set was analysed.

Few analysts believed this would cause the FDA to rebuff the drug, although it feasibly could explain why the regulator has asked to see longer-term data.

Complete response

Alimera said as part of the complete response letter the FDA has asked to see 36-month follow up data from the study, called Fame. The application for approval was submitted with 24-month data and this extra year of data has already been collected; Alimera was slated to present this in February.

As well as this confirmation of longer term safety and efficacy, the regulator has asked for new analyses of the data to further assess the relative benefits and risks of Iluvien. No further studies are required, which is encouraging, but the company has not indicated how long it will take to fulfil these requests. More information should be available after a meeting with the FDA.

Another blow came with news of deficiencies at third-party manufacturers; again how long this will take to resolve is unclear.

Question marks

With US markets closed for the holiday the true reaction from Alimera investors has yet to be seen, although after hours trading gave an inkling of the disappointment. The stock dropped 29% to $8 in extended trading, well below the $11 the shares floated at back in April.

The news also hurt pSivida, which licensed Iluvian to Alimera, potentially earning itself a 20% royalty on sales and a valuable $25m milestone payment on approval. The company's Nasdaq-listed shares plunged 35% to $4.15 in after hours trading, while its Australian-listed stock sank 29% to A$4.25.

Alimera ended September with $55m in the bank, and in October obtained a $32.5m senior secured credit facility, to "help fund working capital requirements". It projected this would be sufficient until revenues started flowing next year.

Consensus data from *EvaluatePharma*shows revenues of $68m were expected next year. Assuming a six

month delay, which is probably the best case scenario, a cash shortfall is possible.

Respite could come in the shape of European approval, but that is not expected until mid-2011. A partner could also be found for the region, bringing in funds. But with a foggy path forward in the US, this delay is not the Christmas present Alimera was hoping for.

Trial ID	Acronym
NCT00344968	Fame