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Merck calls time on US allergy market



[Amy Brown](#)

Two years into a disappointing launch, Merck & Co has decided that the US allergy market is no longer worth the effort. The US pharma giant has handed three products back to its partner ALK-Abello, ending a decade-long partnership.

Shares in the Danish company slumped 18% today on the news, although it probably suspected that the writing was on the wall. ALK must now decide whether to find a new partner or go it alone in the US. Given the track record of the unwinding partnership and others in this space, neither represents an easy option.

Merck inherited the deal, sealed back in January 2007, from Schering-Plough. Grastek and Ragwitek, under-the-tongue immunotherapy tablets, were approved to desensitise hay fever sufferers to grass and ragweed pollens in 2014, and a similar house dust mite product was filed for US approval in February.

Sales have never been disclosed by Merck, and ALK does not split out royalties on the products from other income received under the partnership. In 2015 it said Merck income climbed 22% to Dkr44m (\$6.5m), without specifying how much of that could be attributed to Grastek or Ragwitek. Very little is probably a fair assumption.

Analysts at Jefferies commented recently that US adoption had been sluggish, with Grastek prescriptions up 45% year on year in the first quarter, implying less than \$2m of in-market sales. The bank had high hopes nonetheless, forecasting peak US sales of \$800m, albeit around 15 years from now.

For ALK those projections are worth fighting for, but Merck justifiably thinks on a different scale. Historically the pharma giant was not an illogical partner given its respiratory franchise and former blockbuster Nasonex, but the company's focus has increasingly turned away from this space.

Structural barriers

Those attempting to crack the US allergy market face very particular barriers. Allergy specialists widely use "home brew" shots made from compounded allergen extracts – a lucrative business for them – and are thus not incentivised to switch to off-the shelf products. Add to this the novel concept of pre-allergy season treatments and an onerous schedule that requires daily administration for up to 12 weeks, and it is not surprising that uptake has been slow.

The main competitor, Stallergenes Greer, has also struggled to crack the market with this type of product. In its 2015 results it admitted that sales of Oralair – a direct competitor to Grastek – were below initial expectations, and that the US market continued to be dominated by allergen extracts.

ALK has been pinning its hopes on approval of the house dust mite treatment Acarizax to give Merck a fuller suite of products, but also reckons that approval for allergic asthma is critical to the success of these.

Acarizax is specifically approved to treat this condition in adults in Europe, but the company's attempts to establish the other products' ability to control asthma have been less successful.

A large phase III trial looking at asthma prevention in children with [Grastek failed earlier this year](#), although the company still hoped to get some data onto the label. The outcome of talks with regulators is not yet known, and it is not beyond the realm of possibility that the FDA will want to see firmer evidence.

Maybe Merck decided that it did not have the patience to wait for all this to unfold. And maybe ALK suspected this. In its statement today it said "the timing of this move is unexpected" – that it happened at all was apparently not a revelation – and acknowledged that US sales over the past two years have been below expectations.

Tellingly, in its financial reports over the past couple of years, the Danish company has excluded the Merck partnership from the numbers on its "base business" elsewhere. Whether or not it knew the dissolution of the partnership was coming, ALK's US ambitions just got a lot harder to realise.

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