

DBV Technologies investors go into shock with filing withdrawal



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DBV Technologies' decision to pull its Viaskin Peanut filing leaves the door open for Aimmune Therapeutics to clean up.

The rollercoaster ride for peanut allergy investors took another unexpected turn yesterday when DBV Technologies said after market close that it would withdraw the filing for its lead asset, Viaskin Peanut. The move, which has potentially saved DBV from a complete response letter further down the road, caused shares in the French biotech to tank.

With the launch of Viaskin Peanut potentially delayed by at least a year, DBV's stumble also leaves the way clear for Aimmune Therapeutics. Aimmune is expected to submit a BLA in the next few weeks for AR101, and if successful this will be first to market in the peanut immunotherapy space, securing a valuable competitive and commercial advantage.

Negative sentiment

DBV was quick to point out that the decision to withdraw the BLA, after discussions with the FDA, was related to insufficient detail on data for manufacturing and quality controls rather than clinical issues. But, coming on top of other slip-ups from management, the withdrawal led to a stinging rebuke from analysts at Stifel, who described the stock as "un-investible at the current time".

This sentiment was clearly shared by stockholders who have sent shares in DBV down more than 63% so far today. In contrast, Aimmune shares are up 13% in early trading in New York.

What appears to have particularly irked investors in DBV was management's lack of clarity around potential timelines for remedying the manufacturing issues and re-filing Viaskin Peanut.

Additionally, Viaskin Peanut had been granted fast-track and breakthrough designation by the FDA, a processes that usually guarantees greater access to the US regulator to smooth the path to approval. The fact that DBV has hit the buffers here has only served to deepen questions around DBV's operational and management processes following a phase III disappointment in late 2017 ([DBV's peanut problems open the door for Aimmune, October 23, 2017](#)).

Also-ran

Even before this latest mishap, Aimmune's AR101 had been the bookmakers' favourite in the peanut allergy treatment race, despite its issues with systemic hypersensitivity and GI side effects. The only hope Viaskin Peanut had to make up ground was its cleaner safety profile, which compensated for a longer onset of action, and the fact that it was likely to get to market first.

With the launch of Viaskin Peanut not expected until 2021, AR101 will have plenty of time to consolidate its dominant position, potentially leaving DBV with the option to compete on price when it does launch, or play heavily on its safety credentials to gain market share.

An update from DBV on progress with the regulator could come in the first quarter. If the group misses that deadline, or the news it has to report does not satisfy the remaining shareholder base, then the last shreds of credibility the management currently have will be stripped away.