Evaluate Vantage

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Steering post-Advair Glaxo will be left to Witty’s successor

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GlaxoSmithKline can start the countdown to the end of the Advair era. The FDA has accepted Hikma's application for a substitutable version of the asthma drug, with May 10, 2017 the regulator’s deadline for rendering a decision.

Glaxo’s lead franchise has already been battered by price competition with its branded rivals, and the next-generation respiratory products Breo and Anoro Ellipta have been massive disappointments. Its outgoing chief executive, Sir Andrew Witty, will be leaving his successor quite a task, as the next head of the UK’s biggest drugmaker will be taking the job just as Advair falls.

Wall breached

A decision on Hikma’s project, code-named VR315, should appear at much the same time as that on Mylan’s generic Advair, firing the starting gun on what should be significant price and sales erosion for Glaxo’s biggest seller.

EvaluatePharma’s consensus forecasts see Advair revenues dropping from a peak of $8.3bn in 2013 to $2.1bn in 2020 – a period that will see Glaxo’s topline prescription sales drop from $33bn to $28bn.

Glaxo had once believed the inhaler technology would help defend sales of the long-acting beta-2 agonist and steroid combination – Teva, for one, has struggled with the inhaler – but the submission of two generic drug applications suggests that this was not a sustainable strategy.

As this loss of sales has been long expected, Glaxo’s London-based shares did not react to Hikma’s announcement, falling less than 1% in mid-afternoon trading today. Hikma, likewise was up less than 1%, although the VR315 licensor Vectura saw a 5% rise, thanks in part to a $10m milestone and anticipation of an $11m payout on FDA approval.

Whether or not Advair generics were expected, the now very real probability of approval next year underscores a major investor theme about Glaxo: its need for a strategic shift. Newly launched products like Nucala and late-stage research projects like sirikumab could generate growth, but probably not enough to make up for the $6bn hole left by Advair.

Deal making

Sir Andrew is famously averse to megamergers, and instead has sought to unlock short-term value through calculated divestments, such as the asset swap with Novartis in 2014, and now-shelved plans to sell its share in the HIV joint venture Viiv. Glaxo has spent $11bn on 15 deals in the past five years – $7bn of this on the Novartis asset swap, and $3bn to buy Human Genome Sciences.

However, Sir Andrew will not be in the C-suite as of April 1, 2017. With the collapse of Pfizer’s acquisition of Allergan, Glaxo re-entered the M&A frame as it might be more difficult for the US Treasury to come up with a rule that would block a potential tax-benefiting inversion around a UK domicile. But just as likely might be Glaxo's entry as a buyer rather than target.

Analysts from Socgen recently suggested a scenario in which Glaxo sells to Novartis its share of the two groups’ consumer health joint venture – part of that 2014 asset swap – and cuts dividends to raise the money for M&A.

What it would buy is a big question: primary-care respiratory products like Advair have turned into commodities. Despite giving up on many marketed oncology products Glaxo remains active in R&D, and as it has limited presence in the hot immuno-oncology space a play on CAR-T might be in store.

Those immuno-oncology assets remain expensive, although the popping of the biotech bubble has brought valuations down, and they could decline further by the time Sir Andrew formally steps down.

Perhaps by then a perfect storm of valuation declines, Advair generics and a new chief executive could turn Glaxo into a bigger dealmaker.

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