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Shire needs pipeline focus to recover from early Adderall blow

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It has taken seven years, but on Friday Shire was forced to hand back its get-out-of-jail card for Adderall XR when in a surprise move the FDA finally approved Actavis' ANDA for a generic version of the drug, answering Shire's citizen petition. Shares in Shire plunged 13% on the first day of trading following the news, dropping to £17.20 as the first unauthorised generic version of the drug started shipping.

While the outcome had been one of the overhangs for Shire's stock, the deep falls were all about the timing of unauthorised generic erosion, which has come a year sooner than many had forecast. With analysts now expecting the impact on earnings per share growth for this year to be as much as five percentage points and significantly more next year if other generics enter the space, Shire will now need the rest of its pipeline and in particular Vyvanse to perform strongly.

Although there are currently two other generic versions of Adderall XR on the market, these are authorised versions sold by Teva Pharmaceutical Industries and Impax Laboratories, both of which pay Shire royalties. This arrangement has limited the impact on sales, which last year actually rose to $533m, making up 14% of group revenue. The margins on the product are probably high given that it now carries few associated promotional costs - another factor that might have affected the shares.

Effective barriers

Watson Pharmaceuticals, which now owns Actavis, had been expected to be the first generic entrant in August 2013, having filed its own ANDA. Now that it has achieved its goal through Actavis this filing is expected to be abandoned.

But Shire had done well to keep any unauthorised competition off the market for this long. The group also appears to have dodged a large bullet in that the FDA has so far only seen fit to approve Actavis's version of the drug, rather than multiple copies.

This implies that the FDA's bioequivalence bar - partial area under the curve measurements at five and beyond five hours - is still providing a significant deterrent for other wannabe challengers. Shire executives, however, will be waiting anxiously in the coming days to see if this has indeed been a significant enough hurdle and whether the FDA has any other surprise approvals waiting in the wings.

The future

While the market appears to have reacted quickly and decisively on the news, how much of a blow the entry of Actavis will be is harder to gauge and depends on a multitude of factors. Chief among the issues is how much Actavis will be able to charge for the drug, which in turn will determine how much market share will be lost to the new challenger and also the level of cost savings Shire can squeeze out of the broader business.

What will also be important is how Shire makes use of the rest of its pipeline to pick up the shortfall; many see Vyvanse as the key product to do this.

Arguably, Vyvanse might still be underappreciated by the market, despite its sales being forecast to hit $2.07bn by 2018, according to EvaluatePharma. It is currently only prescribed for ADHD, and Shire is looking to expand its use into a raft of new CNS indications such as negative symptoms of schizophrenia, major depressive disorders (MDD), binge eating and excessive daytime sleepiness.

If any of these disorders, which are currently inadequately managed by existing therapies, come off there could be significant upside for Shire. Positive data have already been reported from a phase II trial in MDD and interim data from phase III studies could come before the end of the year. If the results are positive this could represent a major opportunity for Shire.

Vyvanse is also set to receive European approval by the end of the year. If there are no trip-ups in the data points, Shire could start to see some recovery.

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