

Fusilev shock hits low end of investors' tolerance spectrum



[Lisa Urquhart](#)

It would have been a big enough shock for Spectrum Pharmaceuticals to warn that sales of its most important drug, Fusilev, were expected to crash by 60% this year, but to reveal this less than three weeks after promising "continued growth" must be particularly humiliating.

Spectrum's shares fell 35% to \$8.08 in late morning trading, hitting lows not seen for two years. The US company's two other marketed products generate negligible revenue, and it will be interesting to see whether its CEO, Rajesh Shrotriya, can survive such a gaffe.

Surprisingly, though, the Fusilev collapse seems not to have been due to the most obvious threat that had hung over the drug since its launch five years ago. The bear case was that doctors would simply prescribe generic leucovorin in preference to Fusilev – leucovorin's patented and much more expensive L-enantiomer.

But instead, the company looks to have fallen victim to a US government campaign to force it to cut Fusilev's price.

Available since 1952

Leucovorin, also known as folinic acid, has been available since 1952 as an adjuvant in cancer chemotherapy involving methotrexate, and in combination with 5FU. Use of Fusilev (levoleucovorin) reflects that of the racemic drug: rescue after methotrexate therapy in osteosarcoma and combination with 5FU in palliative treatment of metastatic colorectal cancer.

Fusilev revenue surged in 2011 after Spectrum secured approval for the colorectal cancer indication at a time when the US was suffering a shortage of generic leucovorin. So bad was the problem that the US FDA actually highlighted the "ample" availability of levoleucovorin, and directed doctors to the Spectrum website.

Thus it would be logical to expect an end to the shortage to hit Fusilev; but the FDA advice, as well as the leucovorin shortage, remains in effect.

The FDA website states that, of the four leucovorin makers, Bedford Laboratories has discontinued manufacture and Teva is suffering a regulatory delay, while APP Pharmaceuticals and Sagent Pharmaceuticals are struggling to meet increased demand.

Spectrum only grudgingly admitted on a call today that wholesaler orders for Fusilev were down in the current quarter. The main thrust of its argument is that end-user demand remains stable, and what has hurt has been the mix of Fusilev sales, which has had shifted towards accounts that qualify for significant government-mandated discounts.

But it remains hugely embarrassing for management that as recently as last month it was claiming that all was well, the shift in mix was "largely complete", and "stable future demand" was expected. Some 75% of sales were generated through community doctors – a "sticky" segment that rarely returns to generic leucovorin, Spectrum had said.

On February 21 Mr Shrotriya stated that Fusilev revenues were expected to "continue to grow, and to be higher than in 2012".

Instead, 2013 sales are now expected to fall 58% to \$80-90m, Spectrum said yesterday, while Q1 would see a quarter-on-quarter collapse of 72% to \$10-15m.

Analysts' consensus, as compiled by *EvaluatePharma*, had forecast only an 8% dip in Fusilev sales this year, followed by steady revenue growth to reach \$221m in 2018. Clearly these forecasts will now have to be slashed.

Spectrum has tried to put on a brave face, pointing to its other two marketed drugs, Zevalin and Folutyn, the second of which was acquired through last September's takeover of Allos Therapeutics, but clearly the minimal

sales of these two cannot make up for Fusilev.

Profitability in doubt

Last year was Spectrum's second as a profitable company, thanks to Fusilev sales of \$204m – 76% of the group total. Spectrum now admits that 2013 will be profitable only on a pro forma basis.

What is perhaps worst of all is that if Spectrum's argument about government discounting is true then the risk of generic use – when leucovorin shortages end – remains, threatening to deal it a second blow.

Investors will now have Mr Shrotriya, and perhaps the rest of Spectrum's senior management, in the crosshairs. If he does survive this debacle, he is unlikely to survive a second.

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