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Pharma regulatory and development news over Christmas 2016

Jacob Plieth

The doom-mongers' worst year-end predictions failed to come to pass and, rather than seeing a selloff, the Nasdaq biotechnology index enjoyed a positive uplift to finish 2015.

This was in spite of several setbacks, which hit the share prices of companies including Valeant, Flamel Technologies and Chimerix. Had these disappointments not occurred during the Christmas shutdown the reactions might have been even more severe, though positive sector sentiment hinges on the US FDA's willingness to approve new drugs – and this seems unlikely to change.

December 31

Flamel's disappointment came courtesy of the FDA approving Hikma's neostigmine, a muscle relaxant reversal agent for surgical use – a generic version of Flamel's Bloxiverz – on December 28.

While this was a great result for Hikma it was clearly less good for Flamel, which suffered a 16% share price slump in a delayed reaction on December 31. Bloxiverz is expected to have recorded sales of just under $200m last year, according to *EvaluatePharma*, and Hikma today said its generic had been launched.

Another company whose executive team had its New Year's Eve celebrations spoiled was Vivus, which had rights to its me-too erectile dysfunction drug Stendra handed back by Endo. Two years ago Vivus had offloaded Stendra to Auxilium, a group subsequently bought by Endo, but the new licencee failed to stimulate sales (*Vivus ticks the US Stendra box, October 14, 2013*).

December 30

As the year drew to a close it became clear that the writing was on the wall for KaloBios, notwithstanding a brief resurrection thanks to Martin Shkreli taking a majority stake in the group in November and becoming its chief executive.

Of course, in the intervening period Mr Shkreli had been arrested on fraud charges and subsequently fired, and on December 30 KaloBios applied for bankruptcy protection. This drew a veil over the delisting notice the company had received from Nasdaq, though the day before KalaBios said it would appeal against this, with a hearing set for February 25.

The delisting notice actually came on December 18 – explaining why KaloBios stock had not traded since then – though the group managed to take five days before disclosing this, along with the fact that its accountants had resigned. Nasdaq has subsequently given additional reasons for delisting KaloBios.

December 29

Puma Biotechnology, which lost 60% of its value in 2015, also finds itself in investors' firing line, most recently from Fredric Eshelman, a 1% equity holder. In October he filed a consent statement seeking investor support to increase Puma's board from five to nine, and to elect him and three other dissidents as directors.

Mr Eshelman's main point of contention is the value destruction over which current management has presided. Puma has now sought and published the opinion of three advisory firms, which have all recommended that investors vote against the proposal.

December 28

However, the annus horribilis truly belonged to Valeant, which in 2015 came under pressure over its pricing strategies and links to speciality pharmacies, as revealed by the Southern Investigative Reporting Foundation, an investigative journalism outfit, and the short-selling fund Citron Research.

This has led to Valeant's market cap losing over $10bn of valuation year to date, and the stock fell a further 10% on news that its chief executive, Michael Pearson, was being put on medical leave. Mr Pearson had been

hospitalised with a severe case of pneumonia, and in his absence Valeant has convened a temporary leadership team.

The year also ended on a sour note for Chimerix, which crashed 81% on the phase III failure of its cytomegalovirus (CMV) prophylaxis project brincidofovir.

Patients in the active arm did see a reduction in CMV infections, but this reversed during the following 10 weeks off treatment, and more worryingly there was a numerical increase in mortality for patients on brincidofovir versus control. Earlier this year the group's valuation had breached the $2bn mark on hopes of brincidofovir's potential in Ebola.

December 23

Another company also not having a great time – Northwest Biotherapeutics – slipped out a quiet announcement the day before Christmas Eve to say it was raising $12.6m in stock and warrants,

Northwest is mired in a clinical trial halt amid a tussle with its 28% shareholder, Neil Woodford, over allegations made by Phase Five Research. These have already led to a Northwest director, Navid Malik, being suspended from his job as analyst at the UK broker Cenkos.

There was better news from Sanofi, which filed its fixed-dose combo of lixisenatide and insulin glargine in the US, along with a priority review voucher it had bought from Retrophin for $245m. Meanwhile, Cellectis requested approval to start UK clinical trials with UCART19, though since Pfizer picked up rights to this asset from Servier it is no longer Cellectis's responsibility.

And despite a serious dip in September, which wiped out the Nasdaq biotech index's entire gains over 2015, the index fought back to end the year up 10%. The FDA is still approving drugs – the December 22 green light for AstraZeneca's Lesinurad made it 45 NCEs for the year – and Shire's continued pursuit of Baxalta suggests plenty more work for investment bankers.

And with the industry's annual knees-up, the JP Morgan conference, kicking off in San Francisco next week comes the hope for more positive business development news.

To contact the writer of this story email Jacob Plieth in London at jacobp@epvantage.com or follow @JacobPlieth on Twitter