Evaluate Vantage

December 15, 2009

# Gilead has little to show for its expensive CV push

Amy Brown

Hopes were not particularly high for Gilead Science's hard-to-treat hypertension treatment, darusentan, but news that the phase III drug is heading for the R&D dustbin is certainly disappointing. Consensus for sales in 2014 had already come down by almost a third to $164m since dubious results were announced from the first pivotal trial in April, and the product looks set to be scrubbed from analysts' models completely.

Relatively speaking the drug was not viewed as a hugely important future growth driver for Gilead, so in this sense its loss will not hurt that much. However, the failure does represent a damaging blow to the company's attempts to diversify away from HIV, a drive that has cost a lot of money but has yet to generate tangible returns, as the analysis below reveals.

**Nothing to show?**

Gilead's attempt to break into the cardiovascular space has centred on two acquisitions, Myogen in 2006 for $2.6bn and CV Therapeutics earlier this year, for $1.4bn.

The former was mainly struck over Letairis, or Volibris, a treatment for pulmonary hypertension, which has roundly disappointed since it reached the market in the middle of 2007, as it has struggled to take share from Actelion's blockbuster Tracleer. Archived forecasts reveal that since it was launched consensus for sales in 2012 have more than halved, from $734m to $343m today.

The Myogen acquisition also brought with it the now fated darusentan, which has always had its doubters. The results of the first pivotal trial were announced with great fanfare in April, but the detailed read out that followed revealed some worrying cardiovascular side effects, prompting a round of sales forecast downgrades from already sceptical financial analysts.

Whilst the first trial met both primary endpoints of a significant decrease in systolic and diastolic blood pressure over 14 weeks, patients in the second trial did not demonstrate any change from baseline to week 14 in trough sitting systolic blood pressure and diastolic blood pressure, compared with placebo. As the second trial was much larger, conducted in 849 patients compared with 379, these results are unlikely to be the outlier.

**Value erosion**

Gilead did not mention any safety measures in the press release yesterday, but the first set of data linked the drug with heart complaints, including peripheral oedema. Whether this was also seen in this later trial remains to be seen.

Either way, with the value of darusentan now likely to drop to zero, the acquisition of Myogen is not looking like money well spent.

The table below uses *EvaluatePharma's*NPV Analyzer to compare today's value of acquired products to the price of their acquisition, an analysis that reveals a big discrepancy in the case of Myogen.

| Gilead Sciences - Product NPVs of Acquired CV Companies | | | | | |
|---|---|---|---|---|---|
| **Acquisition** | **Product** | **Indication Summary** | **Today's NPV ($m)** | **Status on Acquisition** | **Phase (Current)** |
| CV Therapeutics (April 09) | Ranexa | Angina, chronic stable [Marketed]; Coronary artery disease (CAD) [Filed]; | 647 | Marketed | Marketed |
| | Lexiscan | Myocardial perfusion imaging (MPI) [Marketed] | 525 | Marketed | Marketed |
| ***Total NPV*** | | | **1,172** | | |
| ***Acquisition cost*** | | | **1,400** | | |
| Myogen (Nov 06) | Letairis/Volibris | Pulmonary hypertension [Marketed]; Pulmonary fibrosis, idiopathic [Phase III]; | 692 | Marketed | Marketed |
| | Darusentan | Hypertension (HTN) [Phase III] | 259 | Phase III | Phase III |
| | Flolan | Thrombosis, deep vein (DVT) [Marketed]; Pulmonary hypertension [Marketed] | 2 | Marketed | Marketed |
| ***Total NPV*** | | | **953** | | |
| ***Total NPV minus darusentan*** | | | **694** | | |
| ***Acquisition cost*** | | | **2,500** | | |

The acquisition of CV Therapeutics was only struck this year so it is probably a bit early to make a call on whether Gilead overpaid in this case, although at the moment the figures are not looking encouraging. Still, consensus for Ranexa, for chronic angina, has stayed fairly static since it was taken into the fold, albeit dipping slightly, and analysts are probably reserving judgement for the time being.

At the time of the takeover the company was incredibly bullish about its chances of turning the drug around, saying that with a bit more marketing muscle, and investment, the product should be able to become much bigger. As the sales effort continues to ramp up next year, sales of this product will be closely watched.

Unfortunately, the whole premise behind the CV Therapeutics acquisition was that the sales reps promoting Ranexa would be able to take on darusentan when it reached the market, as both would be targeted at specialist cardiologists (*Gilead follows its heart and sweeps CV away for $1.4bn, March 12, 2009*).

Gilead is now left supporting a growing sales force, with a gaping hole in their repertoire. It has a couple of other cardiovascular products in development – CVT-510 in phase III trials for supraventricular arrhythmia, and cicletanine in phase II for pulmonary hypertension – but none have yet impressed analysts to warrant sales forecasts.

Despite the fact that darusentan was not a big product for Gilead, shares in the company were trading 3.5% lower in early trade, at $45.42. Many were already concerned about Gilead's attempts to break into the cardiovascular world, and today's news only serves to highlight that the $2.5bn for Myogen looks like money down the drain. Fears that the CV money will follow are no doubt growing.

Evaluate APAC
+81-(0)80-1164-4754