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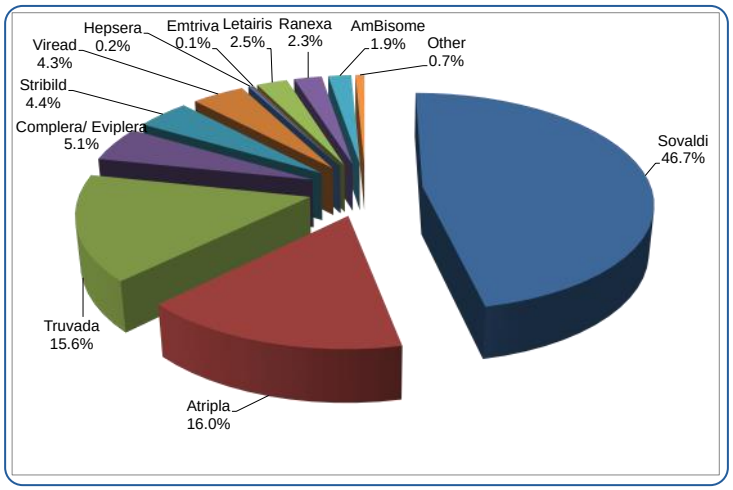
Gilead Sciences: Exploding profit base on new blockbuster drug

Gilead Sciences is a biopharmaceutical company that discovers, develops and commercialises innovative therapeutics in areas of unmet medical needs. The company is headquartered in California and has operations in North and South America, Europe and Asia Pacific.

Gilead's core product lines are a number of HIV antiretroviral drugs ([ARVs], including licensing Truvada and Viread to Aspen in exchange for royalties) and some oncology products. However, the key for the company seems to be a massive bet on its new Hepatitis C drug called Sovaldi which Gilead has patented. This is a single-dose drug that cuts the treatment regime of the disease down from 48 weeks to 12 weeks, but at a cost of $84,000 for the 3-month treatment this is also quite an expensive drug. Gilead received US Federal Drug Administration (FDA) approval for Sovaldi in December 2013 and European approval in February 2014. The drug already accounted for $2.3bn of sales (c. 47% of the group total) in the quarter ended March 2014 (1Q14). In the prior comparable period, it was zero and so this drug alone accounted for the fact that Gilead's revenue basically doubled in this quarter and its profit swelled from $0.43/share in 1Q13 to $1.33 in 1Q14.

Sales by product, 1Q14:



Source: Company data, Anchor Capital

This week Gilead's President and COO John Milligan gave a presentation at the *34th Annual William Blair Growth Stock Conference* where he addressed what he saw as Gilead's major growth drivers (Sovaldi, oncology treatment and HIV). Speaking about Gilead's potential opportunity in the Hepatitis C space, Milligan highlighted that while Sovaldi has already sold $2bn+ in 1Q14, this could prove to be what he termed "the tip of the iceberg" given that a small number of the total patient population in the US has thus far been treated. Milligan noted that in the US there are slightly over 4mn people infected and, based on data from the Centre for Disease Control (CDC) and others, Gilead believes c. 1.7mn people are diagnosed and only about 380,000 patients are under care. In 1Q14 only c. 30,000 patients were treated with Sovaldi—showing there is significant upside potential for the drug. Sales will also likely rocket as Sovaldi's continues its roll-out in Europe (at present it is only available in Germany and France). According to Milligan, Gilead is currently going through pricing and reimbursement discussions across the European Union (EU). Japan was mentioned as another important market and although it has a lower prevalence of Hepatitis C than the US (for example) there are still over 1mn people infected. Gilead foresees entering that market next year (one year earlier than the company had initially expected).

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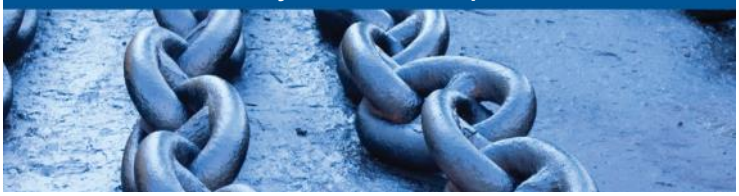
We scan the globe looking for good opportunities. We provide our model portfolios, as well as news and views on our watchlist, which is continually reviewed and updated.



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In his presentation Milligan also touched on the high cost of the treatment pointing out that the cost of care with Sovaldi was actually less than the standard of care prior to its launch. As an example he highlighted that using other treatment regimens was more expensive (including interferon and ribavirin which costs c. $94,000 for a 12-week course, and $96,000-$97,000 to treat patients with Incivek plus peg interferon plus ribavirin over 24-48 weeks). From his comments it would seem Gilead does not plan on reducing the cost of Sovaldi anytime soon. It could also suggests that the Group's next-generation ledipasvir and Sovaldi combination drug could carry a similarly high price (FDA approval is expected in October).

In terms of oncology treatments Gilead has three drug candidates (idelalisib, GS-9973, and momelotinib) which the company sees as promising and which it hopes to release over the next few years. Among the three. Idelalisib is closest to market (a decision on approval is due August/ September). Gilead intends creating combination therapies across these drugs.

Gilead is also a major force in HIV treatment with HIV drug sales of $9bn+ in 2013 and a large percentage of these sales coming from single-tablet combination drugs (the Gilead single-tablet drug is included in all five of the most widely prescribed US HIV treatment regimens, according to the company). As HIV patients live longer drug manufacturers will also need to create new drugs that reduce side effects of HIV treatments (such as loss of kidney function and bone density) and here Gilead could also benefit. It is studying tenofovir alafenamide (TAF) in two phase-3 trials as a way of delivering tenofovir at a very low dose to prevent side effects. The company expects these results to be available by year-end and, if positive, an FDA filing for TAF could happen in 2015.

For the whole of last year, Gilead's EPS amounted to $1.80 on a diluted basis. At this rate it seems highly likely, in our view, that Deutsche Bank's FY14 target of $10.6bn of revenue from Sovaldi could be quite realistic. This would represent almost half the group total and make Sovaldi truly a blockbuster drug. Deutsche estimates EPS of $6.65 this year and close to $10 next year - and judging by 1Q results these numbers (certainly for FY14) could well be fair. The annualised rate of earnings from that quarter's run-rate would be $5.30/share, but bear in mind that, as mentioned earlier, Sovaldi will likely still be ramping up throughout the year. These earnings figures would place the share at a 12-month forward P/E of 9.5x - very cheap for a large global pharma company.

However, the high level of product concentration risk should also be noted. Merck has just paid $3.85bn for rival Hepatitis C drugmaker Idenix and there is a statement under the 'litigation' section of Gilead's 10k filing which alludes to the fact that Abbvie has obtained patents for certain combinations of ledipasvir and sofosbuvir (active ingredient for Sovaldi) that Gilead believes it has applied for patents prior. The two companies are now suing each other and it is now up to the courts to decide. Gilead does not expect this to hamper its ability to commercialise its products, but it notes that it may have to obtain licences for/ pay royalties to Abbvie for these combination products if the lawsuit goes against them. We also note either party can appeal a ruling. In addition to this, it seems there are a few similar patent-related lawsuits outstanding with Merck and Idenix (acquired by Merck) so we expect a bit of noise in this space.

Nevertheless, the bottom-line is that this is a hugely profitable company whose profit base is exploding further (>50% operating margin, 60% RoE...such are the returns when you discover and commercialise a major new drug!) and this may not yet be fully reflected in the valuation. Although it is not without risk and competition, we believe Gilead has good growth prospects and the share could present an attractive risk/reward equation for investors

Gilead's metrics are as follows:

Spot	$80.58
MKT Cap	$123.7bn
12M trailing P/E	28.99
12M fwd P/E	11.53
10-year average P/E	20.1
FYE	31-Dec
P/Book Ratio	9.22
12M fwd DY	0.00

Source: Bloomberg, Company data, Anchor Capital

Sean Ashton

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