

Gilead Sciences Inc GILD | ★★★

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Gilead's winning R&D strategy gives us confidence in its long-term competitive advantages.



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Investment Thesis 11/07/2014

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Gilead's focus on infectious disease has paid off in spades. With a small salesforce, inexpensive manufacturing, and selective research and development, it generates stellar profit margins, and the firm's pipeline is extending its reach into other high-margin markets like hepatitis C and hematological oncology. With the approval of hepatitis C drug Sovaldi in late 2013, we think Gilead's competitive advantages have strengthened, moving it into wide-moat territory.

Gilead's tenofovir molecule--in Viread, Truvada, and all single-tablet regimens--forms the heart of the firm's \$9 billion HIV franchise. Its newest single-tablet regimens, Complera and Stribild, are seeing rapid uptake and strong reimbursement. Such regimens offer patients convenience and affordability, as they are less likely to miss doses and develop drug resistance, and they only need to make one copayment. Gilead will see new competitive threats in HIV; Glaxo could introduce a Truvada/Tivicay single-tablet regimen once Truvada patents begin to expire in 2018, and generic versions of Atripla should be available beyond 2021. However, we think Complera and Stribild will have a strong grasp on the market by this time, resetting the firm's HIV patent cliff into the 2020s. Gilead's pipeline drug TAF appears to have bone and renal safety advantages over tenofovir, and the potential for a single-tablet regimen with protease inhibitors like J&J's Prezista could lengthen Gilead's HIV profits.

Management is diversifying with acquisitions, including the \$11 billion Pharmasset deal and key hepatitis C drug Sovaldi. While competitors like AbbVie, Bristol, and Merck also look capable of launching competitive all-oral regimens by 2016 (AbbVie in late 2014), Gilead's regimens set a high bar. Sovaldi saw \$8.5 billion in sales in the first nine months of 2014, and the Sovaldi/ledipasvir combination--Harvoni--was launched in the U.S. in October. We think Gilead will see hepatitis C sales in 2014 of close to \$12 billion, or 70% of our global market estimate this year. Finally, Gilead's first cancer drug, Zydrelig (idelalisib), launched in 2014, and we forecast almost \$3 billion in peak sales in CLL and NHL combined.

Economic Moat 11/07/2014

We assign Gilead a wide economic moat rating. We think patent protection on newer HIV regimens as well as the recent Food and Drug Administration approval of Gilead's oral hepatitis C drug Sovaldi (sofosbuvir) will be enough to ensure strong returns for the next couple of decades, making visibility on profits clearer at Gilead than at many of its large-cap biotech peers. We think Gilead is capable of gaining \$12 billion in hepatitis C-related sales in 2014, or roughly 70% of our estimate of the global market this year. Gilead's expertise in infectious diseases and single-pill formulations is a part of its research and development strategy, which we see as one of the strongest intangible assets supporting the firm's wide moat.

Gilead's moat was formed by its leadership position in the treatment of HIV, with three patented products that form the backbone of today's treatment regimens. Despite numerous competitors, the company has established leading market share and spectacular profitability with its convenient, effective, and safe treatments. Gilead now serves about 85% of treated HIV patients in the United States. Management has done an excellent job of maximizing sales of the tenofovir molecule, which is present in Viread, Truvada, Atripla, Complera, and Stribild. That said, key patents begin to expire in 2018, and improvement beyond the firm's most recently approved products such as Stribild and Complera will be difficult to achieve, limiting the profit potential for this franchise beyond the 2020s.

However, we think the firm has shown that it can translate its extensive understanding of the drug discovery and development process in HIV into new therapeutic areas, allowing it to achieve wide-moat status. Despite initial criticism of the high price that Gilead paid for Pharmasset in early 2012, we think the \$11 billion acquisition gave Gilead the most valuable hepatitis C drug in the industry and also demonstrated the firm's ability to recognize the potentially unique nature of Sovaldi's safety and efficacy profile compared with other, toxic nucleotide analogs. We think the firm's experience with another nucleotide analog, tenofovir, a key ingredient in all of Gilead's HIV combination regimens, probably contributed to its recognition of Sovaldi's value at an early stage in its development.

We think Sovaldi could redefine Gilead as a powerhouse in the broader infectious disease market. The drug is leading the way for all-oral treatments in the fast-growing hepatitis C market, and we expect Gilead has a multi-billion-dollar product, with longevity extending as far as 2029. We think the low resistance potential and pan-genotypic efficacy of Sovaldi will allow Gilead to retain a significant portion of its dominant market share following the late 2013 launch, despite emerging competition from firms like AbbVie and Bristol.

Morningstar's Take GILD

Analyst		
Price 12-17-2014 99.84 USD	Fair Value Estimate 106 USD	Uncertainty ⓘ Medium
Consider Buy ⓘ 74.2 USD	Consider Sell ⓘ 143.1 USD	Economic Moat ⓘ Wide
Morningstar Credit Rating ⓘ A+	Stewardship Rating ⓘ Exemplary	

Bulls Say

- Gilead markets the three single-tablet regimens for HIV: Atripla, Stribild, and Complera. Once-daily dosing greatly increases patient compliance and reduces the risk of drug resistance.
- Guidelines that aim to improve diagnosis and treatment rates provide strong tailwinds for growth in the HIV and hepatitis C markets.
- With the approval of Sovaldi and Harvoni, Gilead holds the only all-oral hepatitis C treatment regimens. None of Gilead's competitors have other proven nucleotide analogs approaching the market, making the \$11 billion acquisition of Pharmasset look like a bargain.

Bears Say

- Gilead's HIV franchise historically provided three fourths of sales. Heavy dependence on tenofovir, which loses exclusivity in 2018, puts pressure on Gilead's hepatitis C portfolio to support long-term growth.
- Pricing pressure and reduced willingness to pay for convenience could weigh on Gilead's growth. Atripla will become a formidable generic competitor to Gilead's newer HIV products by 2021, and hepatitis C regimens from Bristol and AbbVie could spark price wars if PBMs negotiate aggressively.
- Ongoing litigation with Merck and AbbVie could shave off some of Gilead's Sovaldi profits.

Competitors GILD

More...

Name	Price	% Chg	TTM Sales \$ mil
Gilead Sciences Inc	\$99.86	-0.64 ↓	20,696
Roche Holding AG Dividend Right Cert.	\$290.69	0.17 ↑	48,392
Roche Holding AG ADR	\$36.31	0.55 ↑	48,392
Roche Holding AG	\$287.20	-0.28 ↓	48,392
Amgen Inc	\$159.13	-0.39 ↓	19,743
Novo Nordisk A/S Class B	\$43.47	-2.21 ↓	14,444

Valuation 11/07/2014

We're raising our fair value estimate to \$106 per share from \$100 on the basis of slightly higher sales estimates for Sovaldi and Harvoni in 2014 and 2015. The impact on our valuation is accentuated by Sovaldi's high gross margins and tax-lowering impact. Overall, we now include global Gilead hepatitis C sales of \$11.8 billion in 2014 (up from \$10.9 billion) and \$11.5 billion in 2015 (up from \$10.6 billion) in our valuation. We expect Gilead's hepatitis C sales to peak in 2014, with sales declining to \$8.6 billion in 2016 and then slowly declining to \$7.3 billion by 2023. We think treatment rates could dip in 2016 as warehoused patients and those with cirrhosis will have been treated, and we think market growth beyond this year--due to improved diagnosis and treatment rates--will be spread among more competitors. We also think U.S. rebates are poised to increase with the launch of AbbVie's competing regimen, and we expect 30% rebates to list prices by 2017. Harvoni was approved in schedule in the U.S., and we think our assumed net global average price of roughly \$80,000 for Harvoni (more than \$90,000 in the U.S.) corresponds well with the \$95,000 list price for a 12-week regimen. Overall, we think Gilead's HIV franchise will peak at \$11.7 billion in 2018, with relatively flat sales from 2018 until heavier generic competition begins in 2022. We assume a 70% probability of approval for TAF, the next-generation version of Viread, as the product has been filed with the FDA. We expect top-line growth to average 17% through 2018, and Sovaldi's high gross margins, strong operating leverage, and lower tax rate, as well as share buybacks (as Gilead will have to put massive cash flows to work either via acquisitions or returns to shareholders) should allow for 38% EPS growth during this time. However, the vast majority of this growth comes in 2014, as we expect revenue to more than double. Gilead will easily surpass its previous peak operating margin (around 55%) beginning this year, and we see operating margins approaching 65% in the long run. We assume an 8% cost of equity based on Gilead's below-average exposure to systematic risk.

Risk 11/07/2014

Increasing competition and pricing pressures in the HIV and hepatitis C markets are risks for Gilead. If Gilead's HIV franchise does not maintain its superior efficacy and safety status, a large portion of its sales foundation could be at risk. Key patents on Gilead's top marketed HIV products will expire by 2021, and the firm will need to see significant switching to newer products Complera and Stribild to counter the negative impact from generic competitors. More than 60% of Gilead's U.S.-based HIV sales volume represents government purchases, and higher rebates on some of these sales were implemented in 2010. Austerity measures also had a higher-than-average impact on prices in Europe in 2010, and escalating overall health-care costs and tight budgets could lead to continued, elevated pricing pressure in both the U.S. and Europe. Gilead also paid a significant premium to acquire Myogen, and the failure of darusentan puts even more pressure on Letairis to make this deal accretive. That said, the \$11 billion Pharmasset acquisition is largely derisked, as Sovaldi brought in \$8.5 billion in revenue in the first three months of 2014. However, growth beyond 2014 is still uncertain, as strong competition could emerge from firms like Bristol and AbbVie, and pharmacy benefit managers like Express Scripts could aggressively negotiate pricing once more all-oral treatment options reach the market.

Management 11/07/2014

We assign Gilead exemplary marks for stewardship based on its moat-building investment strategies, good allocation of capital, and superior board independence and qualifications. Gilead has made several acquisitions and collaborative deals over the years that have supported its infectious disease portfolio. For example, the acquisition of Triangle in 2003 brought Emtriva, a critical component of Truvada and all of the firm's single-tablet HIV regimens. While outside of Gilead's therapeutic area focus, the acquisition of CV Therapeutics was also a wise investment, as angina drug Ranexa is growing strongly. In addition, our investment thesis rests on the (now largely proven) theory that the \$11 billion bet on Pharmasset--and hepatitis C drug Sovaldi--was an excellent use of capital.

Chairman and CEO John Martin is the only insider on Gilead's 11-member board, which has an independent lead director. Experienced board members offer a diverse skill set, including expertise in public policy, infectious disease, and global health initiatives. Martin, who was previously Bristol-Myers' director of antiviral chemistry and has more than a quarter-century of experience, replaced Gilead's founder as CEO in 1996. We like that management is rewarded for R&D progress rather than earnings per share. Gilead's decision to boost share repurchases has been a smart one, in our view, as shares have traded below our fair value estimate over the past two years.

Overview

Profile:

Gilead Sciences develops and markets therapies to treat life-threatening infectious diseases, with the core of its portfolio focused on HIV and hepatitis B and C. The acquisitions of Corus Pharma, Myogen, CV Therapeutics, Arresto Biosciences, and Callistoga have broadened this focus to include pulmonary and cardiovascular diseases and cancer. Gilead's acquisition of Pharmasset brought rights to hepatitis C drug Sovaldi, which is also part of the recently approved combination regimen Harvoni.

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