Gilead Sciences, Inc. GILD

by Karen Andersen

Analyst Note 04-21-2009

Gilead GILD reported first-quarter financial results that were largely in line with our expectations, and we're not making any changes to our fair value estimate. Total revenue grew 22% to surpass $1.5 billion in the quarter, driven largely by $1.3 billion in revenue related to Gilead's HIV franchise. An impressive $641 million of revenue was recorded as operating cash flow, and Gilead's operating margin reached almost 53%. Atripla is on track to launch in France, the biggest of the European HIV markets, by the middle of the year, and 31% of treated HIV patients already receive the drug in the U.S. Consistent with our expectations, it does not appear that the recession has impacted the use of Gilead's life-saving drugs; the company may actually benefit from the results of a study--to be published later this month--that show the importance of beginning HIV treatment early in the course of the disease. We also like the fact that Gilead has been proactive about pricing pressure in the U.S. The firm has voluntarily frozen prices through 2010 for the 35% of U.S. HIV sales that are booked through federal payers, such as public health organizations and drug assistance programs. This could make Gilead even less vulnerable to pricing pressure in the U.S., a scenario that we already consider unlikely given the clear cost effectiveness of Gilead's drugs.

Thesis 03-31-2009

Gilead Sciences' focus on infectious disease has paid off in spades, and the firm's HIV franchise continues to dominate a growing, global market and drive impressive profitability. Although Gilead has 10 years until key patents begin to expire, management is diversifying with the $2.5 billion acquisition of Myogen in 2006 and the pending $1.4 billion acquisition of CV Therapeutics CVTX. If Gilead proves it can play in other markets, we think its competitive advantage could extend into wide-moat territory.

The heart of Gilead's product portfolio--its HIV franchise--represented 81% of the firm's total revenue in 2008. Sales for Viread, Emtriva, and combo drug Truvada remain key drivers, but sales of the all-in-one triple combination pill, known as Atripla, now make up more than a quarter of Gilead's top line. Atripla, which combines Truvada with Bristol-Myers Squibb's BMY Sustiva, offers convenience and affordability; patients are less likely to miss doses and develop drug resistance, and they only need to make one copayment. Atripla does cannibalize sales of Gilead's other drugs, but we think this is trumped by new prescriptions and patients who switch from older drugs such as GlaxoSmithKline's GSK Combivir. We're optimistic about Atripla's ongoing launch in Europe, and we're eager to see if Gilead's next HIV drug--an integrase inhibitor going head-to-head against Merck's MRK Isentress in Phase III trials this year--can live up to the firm's spotless record.

When Gilead acquired Myogen and its cardiovascular drug candidates, it moved out of familiar infectious disease territory, broadening its portfolio and potentially reducing its

Morningstar Rating
★★★

Stock Price
As of 04-21-2009
$43.73

Fair Value Estimate
$48.00

Consider Buying
$24.00

Consider Selling
$96.00

Fair Value Uncertainty
High

Economic Moat
Narrow

Stewardship Grade
B

Bulls Say

- Atripla, which contains Truvada and Bristol-Myers' Sustiva, is the first pill approved by the Food and Drug Administration as an all-in-one HIV treatment. Once-daily dosing greatly increases patient compliance because of the relative ease of program maintenance, and it could slow the development of drug resistance.
- The Centers for Disease Control and Prevention recently recommended that HIV testing become part of routine medical care, which could lead many of the 250,000 undiagnosed HIV-positive Americans to begin treatment with Gilead's therapeutics.
- With the purchase of Myogen and pending acquisition of CV Therapeutics, Gilead is creating a portfolio of cardiovascular drugs to bolster internal drug-development efforts.
- Gilead faces minimal exposure to patent expirations, compared to its larger pharmaceutical peers; key patents for Viread don't expire until 2017.
- After Sustiva's patent protection ends in 2013, the economics of Gilead's deal

heavy reliance on its HIV franchise. Letairis, approved to treat pulmonary arterial hypertension, should gain traction in a market with few alternatives that can match its safety, efficacy, and convenience. Although it's still in its early days, we think Gilead's experience with HIV market dynamics--involving a small number of prescribing physicians and growing use of combination therapy--will serve it well. Myogen's second drug candidate, darusentan, is in Phase III trials for resistant hypertension, and we think both of these products have billion-dollar potential. The pending acquisition of CV Therapeutics--which brings chronic angina drug Ranexa and a 170-person cardiologist-focused salesforce--reinforces Gilead's move outside its infectious disease foundation.

Gilead has translated successful products into a strong, profitable business, boasting $2.2 billion in operating cash flows in 2008. However, with much of its success based on the molecule in Viread, we're anxious to see evidence that the firm's pipeline can pass through trials and succeed in the market.

Valuation

We're raising our fair value estimate to $48 per share from $45 as a result of cash flows generated since our last report. Because of better diagnosis and earlier treatment, we expect the high growth in treated HIV patients and Gilead's sales of HIV therapies to continue. We believe Atripla's approval will inspire more patients to switch or begin HIV treatment. Gilead's most recent market data show that 71% of all treated HIV patients in the United States take Atripla, Truvada, or Viread. We forecast 11% 10-year average sales growth, and we see Gilead maintaining operating margins around 50% for the next 10 years. We still assume that the probability of approval for GS 9137 (elvitegravir) is 60%. Letairis sales have fallen slightly behind our expectations, and we now think that the Myogen acquisition deal could be accretive by 2012 and that U.S. sales of the drug that year could approach $400 million. If Letairis sales continue to disappoint or darusentan fails in Phase III trials, our view of this acquisition's potential could become more pessimistic. We think U.S. sales of chronic angina drug Ranexa, assuming the firm's pending acquisition of CV Therapeutics goes as planned, should peak at roughly $500 million, assuming that formulation patents expiring in 2019 can successfully protect exclusivity.

Risk

Increasing competition and pricing pressures within the HIV market are risks for Gilead. If Viread/Truvada/Atripla do not maintain their superior efficacy and safety status, a large portion of Gilead's sales growth could be at risk. Competition in the hepatitis B market could slow Hepsera and Viread sales growth significantly. Also, the company paid a significant premium to acquire Myogen, and if Letairis sales remain slow and darusentan disappoints in Phase III trials, the acquisition could prove costly.

Close Competitors	TTM Sales $Mil	Market Cap $Mil
Gilead Sciences, Inc.	**5,608**	**40,280**
* Abbott Laboratories	29,480	70,179
* GlaxoSmithKline PLC	48,704	99,583
* Bristol-Myers Squibb Company	20,721	38,370

* Morningstar Analyst Report Available

Data as of 03-31-09

Strategy

Gilead Sciences focuses on developing drugs to fight infectious diseases. The company conducts research and development in HIV, as well as hepatitis B and C, and has stretched its focus to include pulmonary and cardiovascular-with Bristol for Atripla--and Gilead's overall gross margin--should improve significantly.

Bears Say

- Gilead's HIV franchise provided 81% of sales in 2008. If resistance to tenofovir (a molecule in Viread, Truvada, and now Atripla) should become more prevalent, Gilead would be severely crippled.
- While Gilead gains chronic angina drug Ranexa with the acquisition of CV Therapeutics, it also brings on 170 cardiologist-focused salespeople. If hypertension drug darusentan fails in Phase III trials, Gilead may not see significant synergies from this acquisition.
- Gilead's HIV pipeline centers on integrase inhibitor GS 9137, and the firm is taking a substantial risk by putting its candidate head-to-head with Merck's newly approved integrase inhibitor Isentress in Phase III trials.
- Roche's sales of Tamiflu have dropped significantly, and Gilead may see fewer royalties in the future, as government orders for pandemic preparedness dry up.
- Hepatitis B drug Hepsera is starting to see competition from new products such as Bristol-Myers' Baraclude, and sales of Viread--recently approved in this indication--could cannibalize those of Hepsera.

related indications with the acquisitions of Corus Pharma and Myogen and the pending acquisition of CV Therapeutics. Gilead uses a specialized niche salesforce to market its drugs and maintains international marketing rights for most approved products.

Management & Stewardship

On the basis of Gilead's superior board independence and qualifications, we assign the company a Stewardship Grade of B. Chairman and CEO John Martin is one of only two insiders on Gilead's board, which has an independent lead director. Experienced board members offer a diverse skill set, and directors include experts in public policy, emerging markets, and technology, as well as Nobel Prize winner Paul Berg. 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 research and development progress rather than earnings per share. Martin began prescheduling monthly option exercises in 2006, which alleviates any concern over the timing and size of these actions. Although he exercises close to a half million options annually under this plan, we believe he has retained a respectable level of ownership. We applaud recent efforts to keep option issuance below 3% of shares outstanding, and Gilead's decision to boost share repurchases should protect investors from dilution (almost 45 million in-the-money options were exercisable as of the end of 2008). Executive compensation is above average for the company's peer group (Martin received almost $3 million in cash alone in 2008), but so is performance.

Profile

Gilead Sciences develops and markets therapies to treat life-threatening infectious diseases, and acquisitions are broadening this focus to include pulmonary and cardiovascular diseases. The company has four products--Viread, Emtriva, combination pill Truvada, and triple combination Atripla--in its HIV franchise, as well as Hepsera and Viread for hepatitis B. Gilead markets pulmonary hypertension drug Letairis and is acquiring CV Therapeutics and its angina drug Ranexa.

Growth

Gilead's HIV franchise should continue to drive revenue growth. Including Bristol-Myers' share of Atripla revenue, we expect sales growth to gradually decline but average 11% annually over the next 10 years.

Profitability

Gilead's HIV franchise has boosted the firm to strong profitability. Even though Atripla's accounting will artificially deflate gross margins until Sustiva's patent expires in 2013, we think Gilead's operating margins will hover at a respectable 50% in the longer term.

Financial Health

At the end of 2008, Gilead had about $3.2 billion in cash and marketable securities. The firm's high cash flows from operations helped fund almost $2 billion in share repurchases in 2008, and even after the $1.4 billion acquisition of CV Therapeutics, we think Gilead will have plenty of spare change for additional internal development and global expansion.

Authors can be reached at analyst feedback.