

# Healthcare Biotechnology Gilead Sciences (GILD)

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Rating: Underweight

## Manish Desai

manish.desai@yale.edu  
MBA Candidate, Class of 2007

## Robert Goldman

robert.goldman@yale.edu  
MBA Candidate, Class of 2007

## David Kaczorowski

david.kaczorowski@yale.edu  
MBA Candidate, Class of 2007

## 1 Year Performance Chart



Source: www.gilead.com

## Market Data

|                    |               |
|--------------------|---------------|
| Current Price      | \$61.43       |
| Market Cap         | \$28.16B      |
| Shares Outstanding | 457.92M       |
| 52 Wk High/Low     | \$65 – \$34.8 |
| Price to Earnings  | 35.76         |
| Price to Book      | 10            |

- We value the shares of Gilead at \$31.05 and rate the stock a strong sell.
- Gilead boasts the most impressive HIV franchise of any drug company, with Viread, Truvada, and Emtriva grossing almost 1.4B in sales in 2005.
- A successful outcome to a dispute with Roche over the successful Tamiflu treatment for Influenza A and B boosted revenues in the 4<sup>th</sup> quarter of 2005 by 81 million. Gilead anticipates receiving 18-19% of Tamiflu revenues going forward in the form of royalties and a greater role in the marketing, manufacturing, and distribution of the drug.
- Although Gilead's enormously successful HIV franchise will drive earnings in the short-term, a barren pipeline will force the Company to acquire smaller firms with drugs in Phase II and III clinical trials to bolster their weak long-term growth story.



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## Company Overview

### Description

Gilead Sciences is a biopharmaceutical company that develops and markets treatments and therapeutics for a variety of infectious diseases. The Company has a truly global presence, employing almost 1,900 employees in 11 countries worldwide and has an enormous sales presence in North America as well as Europe.

Gilead currently has the premier portfolio of drugs for the treatment of HIV and has a significant presence in the areas of fungal infections, chronic Hepatitis B, and Influenza A and B.

Current research focuses mainly on virology and liposomal technology. The broad area of virology includes a number of cutting edge drugs therapies that Gilead has pioneered including protease inhibitors for treatments against HIV, nucleotide and nucleoside analogues for therapeutics to treat HIV and Hepatitis B and C, and neuraminidase inhibitors that show potential in treating influenza patients.

Moreover, Gilead has led the way in liposomal technologies, which is a new drug delivery system where the compound is actually placed inside a liposome (a tiny molecule 1/1000<sup>th</sup> the size of a human hair) to more efficiently and effectively deliver treatment to patients.

### Comparison to the Biotech Industry

| Industry Comparison    | Market Cap   | LTG Forecast  | P/E - trailing | P/E - forward | PEG - forward | Annual Revenues |
|------------------------|--------------|---------------|----------------|---------------|---------------|-----------------|
| Genentech              | 89.1B        | 30.70%        | 42.8           | 32.1          | 1.3           | 6.6B            |
| Amgen                  | 86.2B        | 15.00%        | 19.6           | 17.2          | 1.3           | 12.4B           |
| <b>Gilead Sciences</b> | <b>28.5B</b> | <b>19.30%</b> | <b>29.4</b>    | <b>25.3</b>   | <b>1.5</b>    | <b>2.0B</b>     |
| Genzyme                | 17.5B        | 18.40%        | 23.9           | 20.5          | 1.4           | 2.7B            |
| Chiron                 | 9.0B         | 16.30%        | 26             | 25.5          | 1.6           | 1.9B            |
| Industry Average       | 24.9B        | 23.50%        | 35.4           | 24.9          | 1.5           | 3.1B            |

Source: Thomson Financial

### Financial Results

Gilead has been an outstanding performer for investors over the last three years, posting positive earnings surprises in 10 of the last 12 quarters and in 2005 the Company reached a number of important milestones. For the first time, Gilead topped 2 billion in revenues, up 53% from 2004, and experienced drug sales north of 1.8 billion, 1.4 of which resulted from its exemplary HIV line. Their HIV drugs grew in every market worldwide, including successful launches in many European countries.

On a quarter-to-quarter basis, revenues increased 65% from the 4<sup>th</sup> quarter of 2004 to 2005, driven by explosive sales in their HIV drugs and a substantial increase in royalty payments from partnerships and collaborations. A sizable portion of the rise in royalty payments arose from a dispute settlement with Roche over the Influenza drug, Tamiflu. More about this partnership and the dispute will be discussed later in the report.



Below is a table that summarizes the sales growth of Gilead's drug portfolio over the last few years:

**Total Product Sales, 2003-2005 (\$MM)**

|                    |             |      |             |      |           |      | Annual Percent Change |           |
|--------------------|-------------|------|-------------|------|-----------|------|-----------------------|-----------|
|                    | 2005        |      | 2004        |      | 2003      |      | 2005/2004             | 2004/2003 |
| Viread             | \$778,783   | 43%  | \$782,915   | 63%  | \$566,478 | 68%  | (0.5%)                | 38.2%     |
| Truvada            | \$567,829   | 31%  | \$67,865    | 5%   |           |      | 736.7%                |           |
| Emtriva            | \$47,486    | 3%   | \$57,600    | 5%   | \$10,021  | 1%   | (17.6%)               | 474.8%    |
| Total HIV products | \$1,394,098 | 77%  | \$908,380   | 73%  | \$576,499 | 69%  | 53.5%                 | 57.6%     |
| AmBisome           | \$220,753   | 12%  | \$211,688   | 17%  | \$198,350 | 24%  | 4.3%                  | 6.7%      |
| Hepsera            | \$186,532   | 10%  | \$112,525   | 9%   | \$50,506  | 6%   | 65.8%                 | 122.8%    |
| Vistide            | \$6,629     | 0%   | \$7,904     | 1%   | \$7,576   | 1%   | (16.1%)               | 4.3%      |
| DaunoXome          | \$1,287     | 0%   | \$1,727     | 0%   | \$3,410   | 0%   | (25.5%)               | (49.4%)   |
| Total              | \$1,809,299 | 100% | \$1,242,224 | 100% | \$836,341 | 100% |                       |           |

Source: Gilead Sciences 2005 Annual Report

## Drug Portfolio and Pipeline

Compared to other biotech firms that we have analyzed, Gilead has a relatively modest portfolio of just 7 drugs on the market (not including Tamiflu that is marketed by Roche). The lineup is also quite concentrated, offering treatments for just three categories of infectious diseases: HIV, Hepatitis, and fungal infections.

Moreover, Gilead's HIV franchise: Viread, Truvada, and Emtriva, dominate the overall drug sales and the total revenues of the Company, accounting for over 77% of total drug sales in 2005. This percentage is expected to grow in subsequent years as Truvada gains a foothold in Europe where saturation is still quite low.

Gilead's pipeline is an area of concern when analyzing the Company's prospects for long-term growth. Other than a joint venture with Bristol-Myers Squibb to produce once-daily, fixed-dose pill for HIV patients, Gilead has virtually no promising drug in their mid to late stage pipeline. Tenofovir, a drug to treat Hepatitis B and C, is the only drug solely sponsored by Gilead that is in Phase III clinical trials. However, Tenofovir will join one of their existing drugs, Hepsera, in treating Hepatitis and it does very little to diversify the company's concentration in just three disease categories. Another mid-stage drug is the GS9137 compound that Gilead discusses with great excitement. However, this drug still adds just another treatment to an already strong HIV portfolio and does little to diversify Gilead's portfolio. We feel that the only way Gilead can improve their long-term growth outlook is by acquiring smaller companies with promising drugs in late-stage clinical trials.



Below is a chart that outlines Gilead's current lineup and their drugs in development:

| Product/Candidate  | Research | Preclinical | Phase I | Phase II | Phase III | New Drug Application | Cleared for Marketing |
|--|----------|-------------|---------|----------|-----------|----------------------|-----------------------|
| <b><u>Truvada<sup>®</sup></u></b><br>(emtricitabine and tenofovir disoproxil fumarate)                                     |          |             |         |          |           |                      |                       |
| <b><u>Viread<sup>®</sup></u></b><br>(tenofovir disoproxil fumarate)  |          |             |         |          |           |                      |                       |
| <b><u>AmBisome<sup>®</sup></u></b><br>(amphotericin B) liposome for injection  |          |             |         |          |           |                      |                       |
| <b><u>Hepsera<sup>®</sup></u></b><br>(adefovir dipivoxil)  |          |             |         |          |           |                      |                       |
| <b><u>Emtriva<sup>®</sup></u></b><br>(emtricitabine)   |          |             |         |          |           |                      |                       |
| <b><u>Vistide<sup>®</sup></u></b><br>(cidofovir injection)   |          |             |         |          |           |                      |                       |
| <b><u>Tamiflu<sup>®</sup></u></b><br>(oseltamivir phosphate)   |          |             |         |          |           |                      |                       |
| <b><u>Macugen<sup>®</sup></u></b><br>(pegaptanib sodium injection)   |          |             |         |          |           |                      |                       |
| <b>Co-formulation of Truvada<br/>(emtricitabine and tenofovir disoproxil fumarate) and Sustiva<sup>®</sup> (efavirenz)</b> |          |             |         |          |           |                      |                       |
| <b>Tenofovir disoproxil fumarate</b>   |          |             |         |          |           |                      |                       |



GS 9137

HIV/AIDS



GS 9132

Hepatitis C



GS 9160

HIV/AIDS



Protease and Polymerase Inhibitors

Hepatitis C



Small Molecule  
Therapeutics

Viral Infections



Small Molecule  
Therapeutics

Diseases of Lymphatic System



Source: [www.gilead.com](http://www.gilead.com)

## Partnerships, Collaborations, and Investments

### Investment in Corus Pharma, Inc.

On April 12, 2006, Gilead announced a 25M investment in Corus Pharma, Inc., a small, privately held company. This purchase makes Gilead the second largest shareholder with an option to purchase the rest of the shares at a specific price in the near future.

Corus is an attractive buyout candidate because of Cayston<sup>TM</sup>, an inhaled antibiotic that fights bacterial lung infections in patients with cystic fibrosis (CF). Cayston<sup>TM</sup> is currently enrolling in Phase III FDA trials and would potentially boost Gilead's weak late-stage pipeline lineup.

Although Corus is involved in a lawsuit with Chiron over trade secret misappropriations, we agree with the Wall Street consensus opinion that this small investment will have little to no effect on Gilead's financial statements and Gilead would not have made the investment if the lawsuit represented a serious threat.



## Partnership with Bristol-Myers Squibb

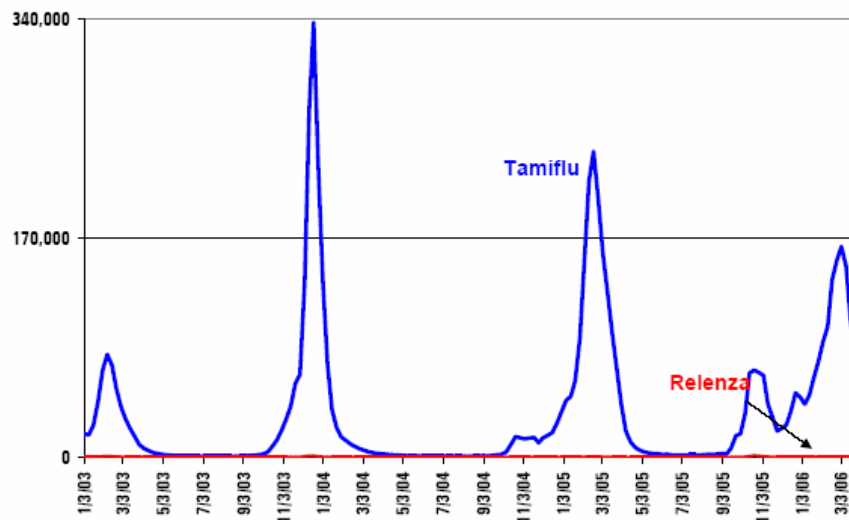
Gilead and Bristol-Myers recently announced that they overcame formulation concerns over combining their two HIV drugs, Truvada and Sustiva, in a single pill treatment by using an innovative bi-layer technology. This “triple-pill” as it has come to be known in the industry will be 1500mg in size and the companies are expected to file with the FDA in the second quarter of 2006. The excitement over this pill lies with the fact that it will become the first fixed-dose, once daily, one pill treatment for HIV patients.

Although neither company has announced a tentative timeline for this drug to be approved, it is expected to take the accelerated track through the approval process due to its application to a life threatening illness like HIV and the fact that the three drugs that comprise the one drug are already approved and marketed by the two companies. Most analysts feel approval will be finalized by the end of this year or early in 2007.

## Partnership with Hoffman-La Roche: Tamiflu

In November, 2005, Gilead won a dispute with Roche over disputed royalty payments from Tamiflu sales from 2001 to 2003. Gilead received \$116 million in royalty payments in the 4<sup>th</sup> quarter of 2005 and as a result of the favorable resolution, they also gained additional collaboration rights and will participate in the strategic planning and distribution of the drug. Royalties in the future are expected to be collected at 18% - 19% of Tamiflu sales.

Part of the reason why Gilead is excited over this ruling is because of the recent animal tests on the avian influenza virus, or “bird flu.” When administered no more than 4 hours after infection, Tamiflu prevented death in animals 100% of the time. However, it proved less effective when the drug was given more than 24 hours after infection. This study is evidence that the “stockpiling” effect of Tamiflu may continue through 2007 as hype about the pandemic continues to spread and sustain the explosive sales growth.



Source: IMS Health, Prudential Securities



## Competitive Analysis

### Pipeline Yield & Approved Drug Revenues

Unlike some of its competitors, Gilead has virtually no late-stage pipeline drugs that show a great deal of promise in terms of propelling future growth. The majority of the Company's pipeline consists of drugs that are currently in Phase I/II of clinical trials, and aside from a few improved versions of existing therapies (e.g., drug combinations), we do not see any signs of sustainable long-term growth at very high rates. New treatments like HIV therapy using the new and improved "triple pill" do offer benefits and will help Gilead distinguish itself from its competitors. However, they do not have any drugs on the short-term horizon that introduce innovative techniques or molecules to the market.

Truvada will be the primary driver of sales over the next two years and will further augment their already impressive HIV segment. Adoption in the U.S. is still growing, as this pill offers a number of advantages over its closest competitor – safer, easier to use, greater effectiveness (to some degree). In addition, the drug was recently approved for use in the E.U., where the Company expects adoption to gradually increase over the course of the year, possibly at a rate similar to U.S. adoption in 2005. However, following the initial boom in sales, there will be fewer "switchers" as the majority of physicians and patients willing to convert will already have switched therapies. Also, Gilead expects growth of the Truvada to come primarily from new prescriptions rather than switchers. On the negative side, if there were to be a paradigm shift in the search for the most effective HIV treatment, and demand for NRTIs or combination drugs declined, Gilead would suddenly be in trouble because that is where the firm's competitive advantage lies, and it is heavily dependent on sales of this type of product to maintain market share.

Development of each drug requires significant capital expenditure with no guarantee of success. Preclinical tests may show the product to be toxic, clinical trials may show the drug to be less effective than anticipated. FDA approval may be slowed by additional requests for information, or the patent could be denied outright. This is not as important of an issue for Gilead, considering that its primary revenue drivers going forward have either already been approved, or are not likely to be denied since they are simply improved versions of existing approved medications.

Gilead's existing products, coupled with planned improvements, will still produce sales growth in the next few years, primarily in the HIV therapy segment, but we do not expect this trend to continue well into the future for reasons that are discussed below.





## Competition/Cannibalization

As is common in the industry, Gilead faces stiff competition on individual drugs:

### Competing Biotech Drugs

| Drug     |       | Competing products   | Competitor                                 |
|----------|-------|----------------------|--|
| Truvada  | NRTIs | Cambivir             | GlaxoSmithKline                            |
| Emtriva  |       | Epzicom              | GlaxoSmithKline                            |
| Viread   |       | Trizivir             | GlaxoSmithKline                            |
| Ambisome |       | Vfend                | Pfizer                                     |
|          |       | Cancidas             | Merck                                      |
|          |       | Ablecet              | Enzon Pharmaceuticals                      |
|          |       | Amphotec             | Three Rivers Pharmaceuticals               |
|          |       | Noxafil*             | Schering-Plough                            |
|          |       | anidulafungin*       | Pfizer                                     |
| Hepsera  |       | Baraclude            | Bristol-Meyers Squibb                      |
|          |       | Epivir-HBV           | GlaxoSmithKline /<br>Shire Pharmaceuticals |
|          |       | telbuvudine*         | Novartis Pharmaceuticals /<br>Idenix       |
|          |       | pradafovir mesylate* | Valeant Pharmaceuticals                    |
| Vistide  |       | Cytovene             | Roche Pharmaceuticals                      |
|          |       | Valcyte              | Roche Pharmaceuticals                      |
|          |       | Foscavir             | AstraZeneca                                |
|          |       | Vitravene            | CibaVision                                 |
| Tamiflu  |       | Relenza              | GlaxoSmithKline                            |
| Macugen  |       | Visudyne             | Novartis Pharmaceuticals                   |
|          |       | Lucentis             | Genentech                                  |

\* In clinical trials

Source: Gilead Sciences 2005 Annual Report

## Patent protection and expiration

As with any drug manufacturer, patent infringement can have a significant negative impact on sales, even if only one major drug is affected. Compulsory licensing, which is discussed below, essentially allows for “legal patent infringement” in developing countries if mandated by foreign governments. Gilead does not face any serious near-term threat, with respect to patent infringement, other than the loss of the European AmBisome patent in 2008. Revenues from Vistide and DaunoXome sales do not constitute a significant portion of total sales, so the expiration of these patents in the US and Europe should not be cause for concern.



## Patents Currently Held by Amgen

| Patented Drug | Patent Expiration |        |
|---------------|-------------------|--------|
|               | U.S.              | Europe |
| Truvada       | 2021              | 2018   |
| Emtriva       | 2021              | 2016   |
| Viread        | 2017              | 2018   |
| Macugen       | 2017              | 2017   |
| Tamiflu       | 2016              | 2016   |
| AmBisome      | 2016              | 2008   |
| Hepsera       | 2014              | 2011   |
| Vistide       | 2010              | 2012   |
| DaunoXome     | 2009              | 2008   |

Source: Gilead Sciences 2005 Annual Report

## Supply & Manufacturing concerns

One of the key risks Gilead faces from a manufacturing perspective is that it does not own any commercial-scale manufacturing facilities, and that it relies very heavily on third-party contractors for drug development for both clinical and commercial purposes. This exposes the Company to risks that are out of its control, but this risk is somewhat mitigated through multiple contracts for each drug. By doing so, production issues at any one facility can only have a limited effect on sales. However, by spreading itself so thin across many different partnerships and research collaborations, the Company is also cutting into the revenues generated by each drug. The ability to maintain good relationships with these manufacturers is critical to maintaining profitability in the future.

If problems do arise, this would be a major concern because it would set Gilead back in terms of product development, manufacturing and shipments. The nature of such problems could be related to actual operations (physical plant issues), hold ups on the supplier end, or changes in regulatory specifications

## Government Intervention & Reimbursement

One major issue facing Gilead is reimbursement through government medical assistance plans. This is not as much of a concern in the U.S. as it is in other markets, such as Europe. European governments may not provide reimbursement for the cost of these drugs, and even if they do, the approved reimbursement amount may not be sufficient for Gilead to cover the costs of its R&D which can have a significant impact on the Company's profitability. Also, Europeans are less likely to purchase drugs that are not reimbursed, which will open the door for competitors that produce cheaper alternatives to capture a greater percentage of the market. This will place pricing pressure on Gilead, which will prevent them from maintaining historic profit levels.



Furthermore, governments of certain developing countries can force drug manufacturers to grant compulsory licenses to local companies in order to make drugs more affordable for the local population. This undermines the intended effect of a patent, and for HIV treatments, which are in high demand in underdeveloped parts of the world, this can have a significant negative impact on revenue-generating ability. This is especially a concern for Gilead, since over 50% of its sales are derived from international markets.

On the positive side, the U.S. government supports the manufacturers of drugs intended to treat serious life-threatening conditions, such as HIV. Under the U.S. Presidential Emergency Plan for AIDS Relief, companies developing HIV treatments are eligible for expedited/priority review by the FDA, which can speed up the drug approval process considerably and allow the firm to save money on R&D costs and start to bring in revenue on new drugs sooner. It is under this plan that Gilead will be granted priority review for its triple pill, thereby enabling the firm to move through the entire FDA approval process in less than one year.

## Earnings Drivers

### Truvada

Sales of Truvada totaled close to \$568 million in 2005, which was the first full year that the drug was on the market. This was an increase of almost \$500 million over 2004 sales, which is impressive considering that the 2004 figure represents drug sales for two quarters. In February 2005, Truvada was approved for use in Europe, a large market that will propel sales of the drug even more over the next few years. The drug is a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) developed by Gilead: Viread (US approval in 10/01) and Emtriva (US approval in 7/03). Most of the sales growth comes from growth in the new patient population, but cannibalization of Viread and Emtriva has contributed significantly to the increased use of this drug. The company believes that the conversion to Truvada has stabilized, and that growth in the immunotherapy market and new prescriptions will be the primary drivers of sales going forward.

In addition, Gilead is currently working with Bristol-Myers Squibb (BMS) to develop a “triple-combination” pill that combines Truvada and BMS’ Sustiva to form a more effective HIV treatment. The company filed a new drug application (NDA) earlier this year, and if the drug is granted priority review by the FDA, it could be on the market by the end of the 2006. Approval of this combination drug, coupled with recent data from a study giving strong evidence that Truvada is superior to Combivir (a competing drug developed by GlaxoSmithKline), will make GILD the dominant player in HIV treatment and will help capture a greater percentage of market share. Currently, Truvada is being administered to over 60% of new patients seeking HIV therapy.



## **Viread**

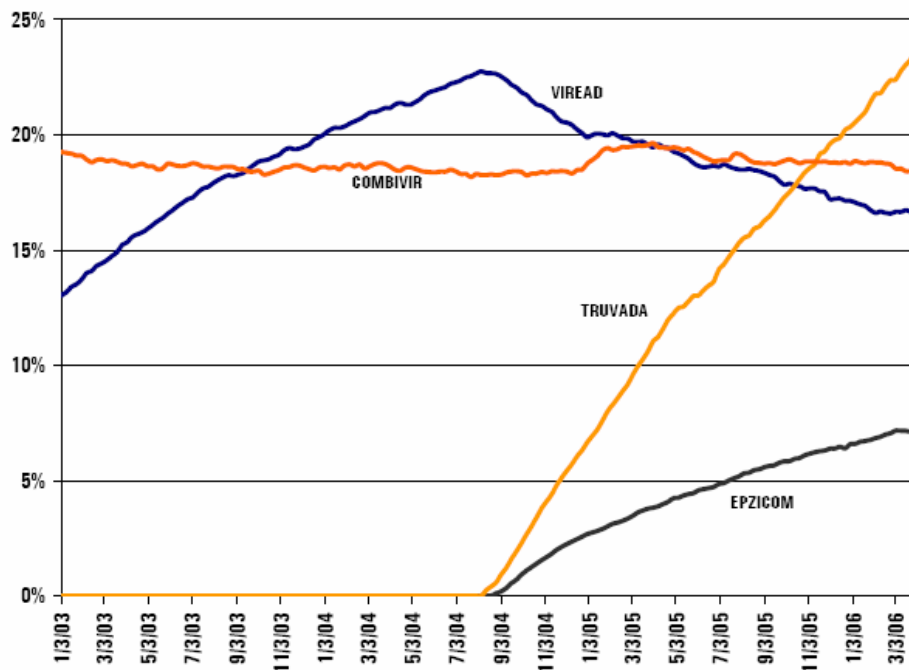
Viread 2005 sales fell less than 1% from 2004 levels, but the drug saw a 20% decrease in sales as a percentage of total revenue. This was due mostly to the dramatic increase in Truvada sales following the 2004 launch. The company expects sales to remain strong for this drug, primarily in areas of the world where Truvada has not yet been introduced. The effects of Truvada cannibalization will continue into 2006 due to the recent approval of Truvada for use in the EU but is expected to stabilize by the end of the year. At the end of 2005, Viread had captured approximately 21% of the market, and since the drug is still used as a standalone treatment for later lines of HIV therapy, it should be able to maintain its position in the market in the short term. Further, recent positive data from studies on Truvada (a combination of Viread and Emtriva) will reinforce results from a Viread study conducted two years ago that proved it was better than the #1 NRTI at the time (Zerit), which will help maintain strong sales. Also, clinical trials are also being conducted on the use of tenofovir, the active ingredient in Viread, for treatment of hepatitis B (HBV) in combination with Truvada.

## **Emtriva**

Sales of Emtriva in 2005 were approximately \$47 million, down 17.6% from the previous year. As with Viread, this decline is due in large part to cannibalization by Truvada. Use of Emtriva should continue into 2006, especially in the EU where Truvada is still being rolled out. The company did not offer any insights that were particularly optimistic, and this is also reflected in analyst estimates for sales going forward. Currently, there are no planned or on-going clinical trials involving the use of this drug for new and/or improved therapies, so it is unlikely that this drug will continue to be a major contributor to the firm's revenues. In 2005, Emtriva comprised only 3% of total product sales, and this is expected to fall to less than 1% by 2009 (average of analyst estimates).

Based on the growth in the HIV market and the near-term prospects for Gilead in this segment, we feel that the company has a competitive advantage in this niche and should be able to capitalize on that, at least in the next few years. Management has forecasted revenues in the range of \$1.65-1.75 billion for total HIV product sales in 2006 (Truvada, Viread, Emtriva), however we believe that is a conservative estimate based on the following factors:

- Potential to dominate market by cooperating with competitor (BMS) to produce the once-daily triple pill (not factored into management estimate)
- Studies prove Gilead products are superior to those of leading competitor's top HIV drug (GSK)
- Approval of Truvada for use in EU opens up new market and may result similar sales trend as seen in 2005 in US)



Source: IMS Health, Prudential Securities

An average of Wall Street estimates also produces a slightly bullish near-term forecast for the HIV product segment (relative to guidance), which we feel is more indicative of the firm's future performance. However, a variety of factors, including competition, potential new developments, resistance to switching therapies, reimbursement issues, development of generics (mandated by foreign governments), uncertainty of success in clinical trials, etc. may inhibit the company's ability to maintain such explosive growth, and we agree that while sales will remain strong in this segment, growth in sales will begin to taper off by 2008.

## AmBisome

Sales in 2005 totaled approximately \$221 million with year over year growth of 4.3% compared to 2004. Gilead believes that AmBisome is the premier drug used in the treatment of fungal infections, particularly in the EU, but despite this, it still faces stiff competition from other products in the market. The company claims that the high competition was offset by higher than expected volume, however pricing pressure in the market led to lower than expected margins on this product. As with Emtriva, the company did not present any compelling evidence that foreshadowed sustained high revenues for AmBisome, and sales of this product are expected to decline slowly over the next few years according to analyst estimates. Physicians seem to prefer AmBisome over certain alternatives because of recent data confirming that the efficacy is virtually the same at both high and low doses, and while this is positive news, it is not sufficient to produce growth in sales.



According to management guidance, 2006 projected revenue for AmBiosome is \$205 million, which is in line with Wall Street estimates and our expectations (\$211 million) based on past performance and future earnings potential.

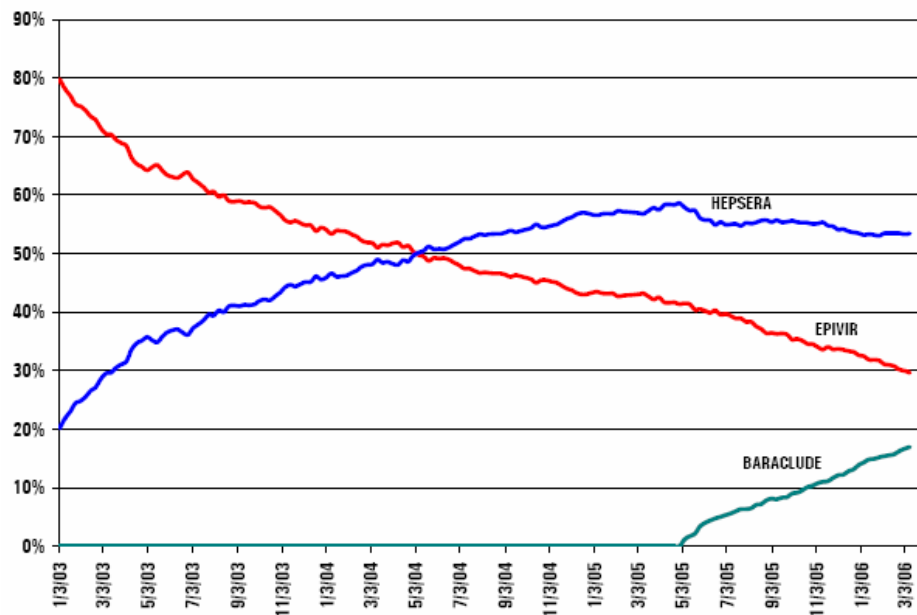
## **Hepsera**

In 2005, Hepsera generated \$186.5 million in sales, an increase of 65% over 2004 levels, however margins remained relatively unchanged as a percentage of total product sales. 2005 sales were driven primarily by growth in international markets, especially in southern Europe. The drug currently faces competition from Bristol-Meyers Squibb's drug, entecavir (Baraclude), and things will only get tougher for Gilead in 2006 with the potential launch of telbivudine (Idenix/Novartis Pharmaceuticals) in the second half of the year. That being said, the introduction of these two products contributes to growth in the market, and to the extent that Gilead is able to capture significant market share, they are indirectly benefiting from this competition.

At the end of 2005, the company presented data from a study showing positive data regarding the reversal of liver damage after 5-years of Hepsera treatment. This will have a tremendous impact on the ability of Hepsera to compete with the numerous alternatives available on the market, as it is the only antiviral drug that is supported by long-term data. This is a great selling point when marketing the drug to both physicians and patients, given that HBV is a chronic condition that can require years of therapy to treat.

There is the possibility that Hepsera sales could be cannibalized by Gilead's own products in the future, as the company is currently conducting clinical trials for the use tenofovir and Truvada to treat the same condition (HBV).

Management expects to generate \$205 million in Hepsera sales in 2006, which is in line with Wall Street estimates and our expectations (\$206 million) based on past performance and future earnings potential. The HBV segment is very competitive, and growth in the market alone may not be sufficient to maintain high levels of sales growth in the coming years. Competition from firms such as Bristol-Meyers Squibb and Novartis will prove challenging as well, however Gilead's ability to distinguish itself from competitors in this market (long-term data) should still be an asset and help drive sales going forward.



Source: IMS Health, Prudential Securities

## Other risks

- With 50% of sales coming from international markets, the effects of currency fluctuation could potentially have an adverse effect on Gilead's top line growth.
- Were there to be a paradigm shift in the search for the best HIV treatment and demand for NRTIs or combination drugs declined, Gilead would suddenly be in trouble because that is where the firm's competitive advantage lies, and its future growth prospects are heavily dependent on sales of this type of product.



## Valuation

### Beta

Beta was determined using 60-period regression analysis of monthly equity return against the market return minus the risk free rate. The analysis estimated the beta at 0.89, comparable to consensus estimates.

Asset beta was assumed to be the same as equity beta since Gilead's current overall debt is less than 1% of the market value of equity and we forecasted zero debt in our model since most of the debt is contained in a term loan unconnected to core operations and will be paid off within five years.

The risk free rate was calculated at the 10-year treasury rate (5.049%) less the standard 1% risk premium, per instruction. Market return was estimated to be the long-term average return of the S&P 500 (10.6%) that allowed us to use the typical market risk premium of 6.6%. Since we forecasted zero debt going forward, Gilead's cost of capital was equal to its cost of equity, which was calculated to be 9.9% by applying the CAPM equation.

### Model Assumptions

- Core items on balance sheet and income statements were considered in proportion to sales and grown at the same rate. Several small miscellaneous items were held constant.
- We obtained the tax rate (32%) from the Company's 2005 10-K report. We assume the rate will remain constant over the full time horizon of the projections since there was nothing in their earnings call to indicate that their operations going forward would change their tax situation.
- Per instructions, Property Plant and Equipment was used as a proxy for Capital Expenditure. The PP&E figure was included in the free cash flow projections as net of depreciation, effectively eliminating the need to include depreciation in the model. The net PP&E figure was assumed to grow at the same rate as sales and was subtracted from adjusted net income.
- Balance Sheet line item "Deferred Tax" represents extra-ordinary items in connection with litigation involving Hoffman-La Roche and a repatriation of foreign earnings. The figure is treated as a one-time item and is not grown with sales or the rest of the accounts.
- Balance sheet and income statement items "Minority Interest in Joint Venture" are grown at the same rate as sales. The Company's 2005 10-K reports that the joint venture with Bristol Myers Squibb is expected to grow. No further company guidance is given so the growth is assumed at the same rate as core operations.





## **Growth Rate Assumptions**

Early year growth rates ('06 and '07) are predicted to be in excess of 20%, slightly above the Company guidance of 18%. We bumped the rates up a bit due to the fact that the guidance does not take into account potential sales from the “triple pill”, Gilead’s latest innovation in partnership with Bristol-Myers Squibb. As discussed earlier in the report, the NDA (New Drug Application) will be filed shortly and we feel the drug will be approved by the end of this year in time to possibly affect earnings in 2006 and boost sales to a larger extent in 2007. Moreover, Gilead did not include royalties in their sales growth estimates and we chose to roll the growth in royalties with sales growth which also caused our numbers to be slightly higher.

Growth projections drop off considerably beginning in 2008 primarily due to loss of royalty income from Tamiflu. Company guidance states that the drug is designed to treat the current strains of influenza and avian flu, and that within two years these strains will have mutated beyond the scope of this drug. Moreover, competition in this market will severely threaten any ongoing competitive advantage gained through Tamiflu-related research. The Company estimates that revenue from Tamiflu will be cut in half in 2008, resulting in a drop of 4% in the overall growth rate.

Our growth rates for Gilead’s five to ten year outlook reflect a scenario that is bleak. The Company’s barren drug pipeline, especially in the latter stages, shows little hope of increasing overall revenue and sustaining an impressive growth rate. Several of Gilead’s major portfolio drugs will come off patent within ten years, and in the interim will suffer from increased competition as other major drug companies enter the lucrative HIV market. Growth rates for the latter half of the model are predicted at less than 10% per year and terminal growth is assumed to be 3.5%, a value in line with the growth of a mature company.

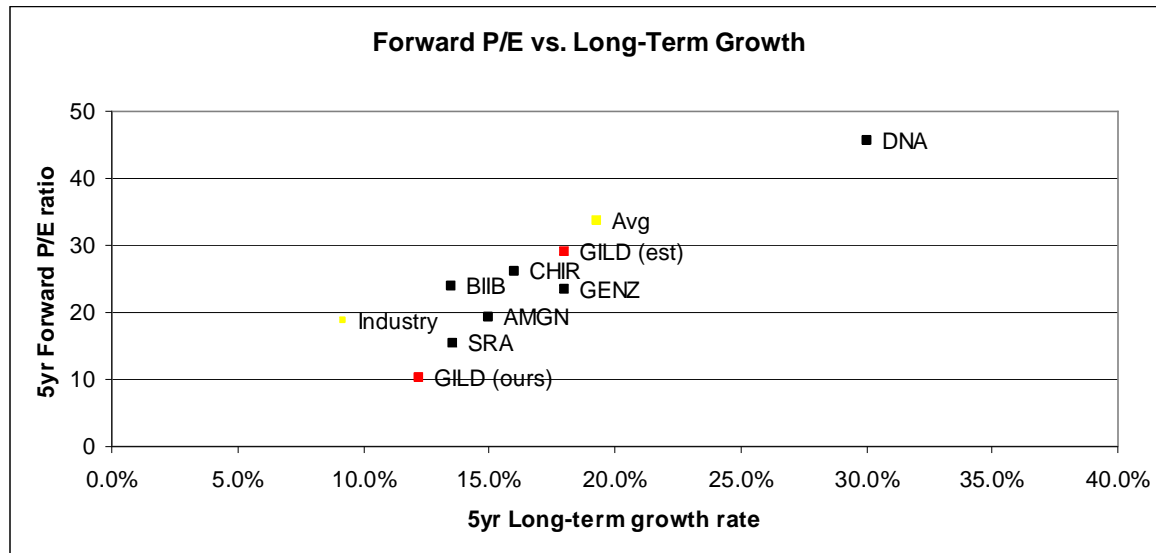
## **Recommendation**

For the reasons outlined above, and the fact that a fiercely competitive landscape and patent expiration will severely compromise their leadership position in the HIV market that currently represents almost 80% of their revenue income, we rate the shares of Gilead a strong sell. In order for Gilead’s long-term growth story to improve, the Company will need to employ a number of strategies that would include acquiring companies with potential blockbuster drugs in the later stages of FDA approval and capitalizing on their recent success and committing a large portion of cash to R&D in hopes of fostering a fertile pipeline in the next few years.

Although we made rather optimistic growth assumptions in the short-term, our valuation is significantly lower than some firms on Wall Street and about 50% lower than the current market price. However, we attribute this discrepancy to the fact that some analysts may be buying into the momentum story of the last few years when sales growth has been consistently over 50% and the star HIV drugs have enjoyed unparalleled success. We feel that some analysts, and certainly most individual investors, don’t recognize the competitive forces that will undoubtedly impact Gilead’s HIV franchise and lower margins to a fraction of where they are today. Once this point



is observed by the general market and analysts and investors begin to focus not only on the past and current success of Gilead's star drugs, but also on the potential of future drugs that will be counted on to justify this market value, we feel the stock will converge to our valuation. The chart below summarizes our investment thesis and shows that our growth estimates over the next 5 years are about in line with the entire industry but significantly less than the consensus Wall Street estimates for Gilead and the growth rates of major competitors.





## Balance Sheet Projections

| ASSETS                               | 2006      | 2007      | 2008      | 2009      | 2010      | 2011      | 2012      | 2013       | 2014       | 2015       |
|--------------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|------------|------------|
| Cash, Equivalents & Securities       | 2,456,927 | 2,997,451 | 3,536,993 | 3,979,117 | 4,377,028 | 4,770,961 | 5,152,638 | 5,513,322  | 5,706,289  | 5,906,009  |
| Receivables                          | 630,988   | 769,806   | 908,371   | 1,021,917 | 1,124,109 | 1,225,279 | 1,323,301 | 1,415,932  | 1,465,490  | 1,516,782  |
| Inventories                          | 272,681   | 332,671   | 392,551   | 441,620   | 485,782   | 529,503   | 571,863   | 611,893    | 633,310    | 655,476    |
| Other Current Assets                 | 340,802   | 415,778   | 490,618   | 551,945   | 607,140   | 661,782   | 714,725   | 764,756    | 791,522    | 819,225    |
| Current Assets - Total               | 3,701,398 | 4,515,706 | 5,328,533 | 5,994,599 | 6,594,059 | 7,187,525 | 7,762,527 | 8,305,903  | 8,596,610  | 8,897,491  |
| PPE (net)                            | 436,438   | 532,454   | 628,296   | 706,833   | 777,517   | 847,493   | 915,292   | 979,363    | 1,013,641  | 1,049,118  |
| Other Noncurrent Assets              | 320,430   | 390,925   | 461,291   | 518,953   | 570,848   | 622,224   | 672,002   | 719,042    | 744,209    | 770,256    |
| TOTAL ASSETS                         | 4,458,266 | 5,439,085 | 6,418,120 | 7,220,385 | 7,942,424 | 8,657,242 | 9,349,821 | 10,004,309 | 10,354,460 | 10,716,866 |
| LIABILITIES                          |           |           |           |           |           |           |           |            |            |            |
| Total Accrued liabilities            | 345,524   | 421,539   | 497,416   | 559,593   | 615,552   | 670,952   | 724,628   | 775,352    | 802,489    | 830,576    |
| Accounts Payable                     | 90,508    | 110,420   | 130,296   | 146,583   | 161,241   | 175,753   | 189,813   | 203,100    | 210,208    | 217,565    |
| Deferred taxes                       |           |           |           |           |           |           |           |            |            |            |
| Deferred revenue                     | 25,662    | 31,308    | 36,943    | 41,561    | 45,717    | 49,832    | 53,819    | 57,586     | 59,601     | 61,687     |
| Current Maturities of LT debt        | 60,000    | 60,000    | 60,000    | 60,000    |           |           |           |            |            |            |
| Other LT obligations Due Within 1    | 442       | 442       | 442       | 442       | 442       | 442       | 442       | 442        | 442        | 442        |
| Total Current Liabilities            | 522,137   | 623,709   | 725,097   | 808,179   | 822,953   | 896,979   | 968,702   | 1,036,480  | 1,072,741  | 1,110,272  |
| LT deferred revenue                  | 53,666    | 65,472    | 77,257    | 86,914    | 95,606    | 104,210   | 112,547   | 120,425    | 124,640    | 129,003    |
| Accrued litigation settlement exp.   | -         | -         | -         | -         | -         | -         | -         | -          | -          | -          |
| LT debt                              | 180,000   | 120,000   | 60,000    |           |           |           |           |            |            |            |
| other LT obligations due after 1 Yr. | 374       | 374       | 374       | 374       | 374       | 374       | 374       | 374        | 374        | 374        |
| Minority interest in joint venture   | 10,200    | 12,444    | 14,684    | 16,519    | 18,171    | 19,807    | 21,391    | 22,889     | 23,690     | 24,519     |
| TOTAL LIABILITIES                    | 766,376   | 821,999   | 877,412   | 911,987   | 937,104   | 1,021,369 | 1,103,014 | 1,180,167  | 1,221,445  | 1,264,167  |
| Total LT debt from all sources       | 240,816   | 180,816   | 120,816   | 60,816    | 816       | 816       | 816       | 816        | 816        | 816        |
| Liabilities less LT debt             | 525,560   | 641,183   | 756,596   | 851,170   | 936,287   | 1,020,553 | 1,102,197 | 1,179,351  | 1,220,629  | 1,263,351  |
| TOTAL EQUITY                         | 3,691,890 | 4,617,086 | 5,540,708 | 6,308,399 | 7,005,320 | 7,635,873 | 8,246,808 | 8,824,141  | 9,133,015  | 9,452,699  |
| Debt + equity                        | 3,932,707 | 4,797,902 | 5,661,524 | 6,369,215 | 7,006,137 | 7,636,689 | 8,247,624 | 8,824,958  | 9,133,831  | 9,453,515  |
| TOTAL LIABILITIES & EQUITY           | 4,458,266 | 5,439,085 | 6,418,120 | 7,220,385 | 7,942,424 | 8,657,242 | 9,349,821 | 10,004,309 | 10,354,460 | 10,716,866 |

## Free Cash Flow Projections

|                                  | 2006      | 2007      | 2008      | 2009      | 2010      | 2011      | 2012      | 2013      | 2014      | 2015      |
|----------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Sales (Net)                      | 2,535,500 | 3,093,310 | 3,650,106 | 4,106,369 | 4,517,006 | 4,923,536 | 5,317,419 | 5,689,639 | 5,888,776 | 6,094,883 |
| COGS                             | 325,408   | 396,997   | 468,457   | 527,014   | 579,715   | 631,889   | 682,441   | 730,211   | 755,769   | 782,221   |
| R&D                              | 435,365   | 531,145   | 626,751   | 705,095   | 775,605   | 845,409   | 913,042   | 976,955   | 1,011,148 | 1,046,538 |
| SG&A                             | 578,381   | 705,625   | 832,637   | 936,717   | 1,030,388 | 1,123,123 | 1,212,973 | 1,297,881 | 1,343,307 | 1,390,323 |
| Special Items                    | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| EBIT                             | 1,196,347 | 1,459,543 | 1,722,261 | 1,937,544 | 2,131,298 | 2,323,115 | 2,508,964 | 2,684,591 | 2,778,552 | 2,875,801 |
| Interest Expense                 | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Interest & Other Income          | 44,085    | 53,784    | 63,465    | 71,398    | 78,538    | 85,606    | 92,455    | 98,927    | 102,389   | 105,973   |
| Special Items                    | 4,994     | 6,092     | 7,189     | 8,088     | 8,896     | 9,697     | 10,473    | 11,206    | 11,598    | 12,004    |
| Pretax Income                    | 1,245,426 | 1,519,419 | 1,792,915 | 2,017,029 | 2,218,732 | 2,418,418 | 2,611,892 | 2,794,724 | 2,892,539 | 2,993,778 |
| Income Taxes                     | 398,536   | 486,214   | 573,733   | 645,449   | 709,994   | 773,894   | 835,805   | 894,312   | 925,613   | 958,009   |
| Extraordinary items              | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| Net Income (Loss)                | 846,890   | 1,033,205 | 1,219,182 | 1,371,580 | 1,508,738 | 1,644,524 | 1,776,086 | 1,900,412 | 1,966,927 | 2,035,769 |
| change in current assets         | 609,190   | 814,308   | 812,827   | 666,067   | 599,460   | 593,465   | 575,002   | 543,377   | 290,707   | 300,881   |
| change in PPE (net)              | 193,870   | 96,016    | 95,842    | 78,537    | 70,683    | 69,976    | 67,799    | 64,070    | 34,278    | 35,477    |
| Change in noncurrent assets      | (109,445) | 70,495    | 70,366    | 57,661    | 51,895    | 51,376    | 49,778    | 47,040    | 25,166    | 26,047    |
| change in liabilities ex LT debt | 89,543    | 115,623   | 115,413   | 94,574    | 85,117    | 84,266    | 81,644    | 77,154    | 41,277    | 42,722    |
| fcf to D+E                       | 242,817   | 168,010   | 355,560   | 663,889   | 871,816   | 1,013,972 | 1,165,151 | 1,323,079 | 1,658,053 | 1,716,085 |

Cost of Capital 9.9%  
 Terminal Value 26,959,639  
 PV(terminal) 10,522,167  
 PV of FCF 4,142,557  
 Total PV less debt and minority interest 14,355,708  
 Shares Outstanding 462,280

Price/Share 31.05



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