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New Recommendation:	**Gilead Sciences, Inc. (GILD)**	**February 11, 2016**
Recommendation:	**Buy**	**Target Price:** **$150.00**

Recent P/E: 6.8 (ftm consensus FFC) **Recent Price: $83.00** **Dividend Yield: 2.1%**

Summary:

Gilead Sciences (GILD) is a relative newcomer for a major biosciences company. It was founded, in 1987 by Dr. Michael Riordan, a graduate of the Harvard Business School and 29 years old at the time. It went public in January 1992, raising $86 million. It has shown a history of innovation, an in-depth understanding of the biochemistry in its area of expertise, and a remarkable ability to identify the potential in new drugs, particularly as those drugs might be made more effective when used in combination with other Gilead medical compounds. Its sales are projected to be over $12 billion in 2016. The overwhelming majority of that revenue is derived from sales of drugs to treat hepatitis and HIV. Gilead holds a commanding market position in these medications and has established patent protection on its product offerings. The most important of these patents are valid through 2029. The consensus earnings projection is $12.30 per share in 2016, increasing to $12.55 in 2017.

The market is severely discounting shares of Gilead Sciences (GILD) due to recent introductions of competing drugs that target hepatitis. Initial market reactions of the competitive drugs have been less than overwhelming, which has not been reflected in any rebound in Gilead stock. In addition, Gilead has four strengths, which, similarly, are not reflected in the stock price, namely: a strong balance sheet; solid earnings and cash flow; near term strength in its served markets and a well-positioned pipeline of future drugs. All of these strengths are presently discounted by the market and not well reflected in the current price. For the current market price to be comparable to its peers, Gilead would have to completely strike out on all four strengths. In the discussion below, we look at each strength.

Financials:

Gilead's balance sheet and operating cash flow are particularly strong. Operating cash flow exceeds GAAP earnings by 6%. Non-GAAP earnings are virtually the same as those reported under GAAP. The have $10 billion in cash on hand, fully one-third of their total assets. Intangible assets equal 75% of stockholder equity, which is very reasonable for a pharmaceutical company. Amortization expenses are but 7% of net income. All of the financial information points to very conservative accounting and no indications of accounting "creativity", the latter of which is common for pharmaceutical companies.

Served Markets - Hepatitis

Gilead's products address two major markets: HIV and hepatitis. Hepatitis medications are projected to account for about $19 billion in sales in 2015. HIV medications should account for

about $8 billion in sales for 2015. Total revenues for 2016 are estimated to be $31 billion – flat compared to 2015.

There are several forms of hepatitis known as Types A through E. Type C is the most debilitating, also known as HCV. An estimated 3 to 5 million Americans and 300 million people world-wide suffer from HCV. It is spread through blood to blood contact, needle stick injuries and transfusions. Untreated, it frequently leads to cirrhosis of the liver. An estimated 300,000 deaths worldwide were attributed to HCV in 2014. New infections of HCV have declined in recent years due to fairly wide-spread information on pathways for infection. However, some countries, such as Egypt and India have widespread population infections as do populations of prison inmates in the US, where roughly 1/3 are affected. Infections within Veteran Administration hospitals are also high, although not as high as within prisons. It is also estimated that there are about 30,000 new cases of HCV every year in the United States.

There are several sub-types of HCV known as genotypes 1 – 10. Gilead's drugs Sovaldi and Harvoni both treat most sub-types of Type C hepatitis and have proven very effective. Both carry a very high list price. Sovaldi must be administered along with interferon, which frequently has serious side effects. Harvoni was introduced in May, 2015. It is a once per day, stand-alone tablet, generally given over 12 weeks with a 95% cure rate.

Prior to the introduction of Sovaldi and Harvoni, treatments for HCV were very expensive, but had very bad side effects and spotty cure rates. As a result, most of diagnosed HCV individuals went untreated.

Since the introduction of Sovaldi in 2013, Gilead has estimated that 140,000 in the United States had started treatment through February of 2015 and an additional 250,000 received treatment from February 2015 through February 2016. At this treatment rate, it will be over 10 years before all the affected people in the United States are treated. Telling, is that the patent protection for Harvoni will run a bit longer than this.

Competitive Products - Hepatitis

AbbVie and Merck have both introduced new products to treat HCV. Both are multiple pill regimes. Both have reported side effects that are worse than those reported from Harvoni along with somewhat lower cure rates and an inability to treat all subtypes of the infection.

Product Pricing - Hepatitis

Product pricing is a major point of contention on all HCV medications. The list price of Sovaldi and Harvoni in the United States is very high – about $85,000 for a full regimen. This pricing is in line with older HVC treatments and much cheaper than a liver transplant. Sovaldi and Harvoni both share the benefit of higher cure rates and virtually zero reinfection rates – very favorable compared to liver transplants and older cures. However, the list price of Sovaldi and Harvoni has raised a considerable stir, because they are expensive and because the previous treatment programs were rarely used. The cost for insurers for fully implementing Harvoni on the 4 million infected people in the US would cost roughly $0.5 trillion at the list price. Total US medical expenses in 2015 were approximately $3 trillion, which would represent an increase in healthcare costs of about 16% just for the medication.

At this price level, there has been considerable push-back from insurers, along with local and federal governments and much congressional outcry. In 2015, Gilead realized sales of just under $19 billion for its HCV medications. The sales from the United States are not disclosed. Let us assume, however that 75% of the sales are US based - $14 billion. A quick division of $14

billion divided by 250,000 US treated patients yields an average actual selling price of just $57,000 per patient – a far cry from the list price of $85,000. Investors are worried about price discounting, but in fact, the discounting has already happened. Further discounts may be in the cards, but with the discounts, more patients will be treated, keeping sales flat. It will be a long time before all US patients are treated, so running out of patients is not really an issue.

Product Cost - Hepatitis

Production costs for Gilead's hepatitis drugs is less than $1,000 per regimen or less than 2% of the actual realized selling price, leaving a gross margin of 95%.

US Market Assessment -Hepatitis Products

A summary of the bottom line impact in the hepatitis market shows a large potential market, just in the US that should be unfulfilled for at least a decade. There might be some price erosion, but it will bring in new patients keeping sales at existing levels. The competitive products will make some dent in Gilead's market share, but the competitive products are simply not as good, so that impact will not be large. When we look at Gilead's pipeline, we will see they are diligently working to continuously improvement their HCV products and keep ahead of the competition.

The huge outcry that greeted the initial introduction of Gilead's products has died down, due to Gilead's willingness to negotiate with impacted parties and we do not expect to see any congressional action on the issue, given the basic inability of the US Congress to pass any meaningful legislation at all. The impact of all the factors adds up to a fairly stable US market for Gilead HVC drugs running through the patent period for the products. Our analysis does not bear out the dire predictions for dramatically lower earnings from HCV drugs that seem to be built-in to the Gilead stock price.

Worldwide Market Assessment - Hepatitis

The potential for HCV products worldwide is simply frosting on the cake for Gilead. At the moment, they have licensed manufacture in Egypt and India, where the cost of the locally produced Sovaldi equivalent treatment regimen is less than $1,000. In England and Japan, Gilead has negotiated a substantial reduction in pricing for both Sovaldi and Harvoni. However, the pricing for the medications in those countries is already built-in to the average price Gilead actually receives for the product so virtually every sales dollar of product sold in the worldwide market will fall directly to the pre-tax line on Gilead's income statement.

Market Summary - Hepatitis

The market fears for Gilead's HCV product are unfounded. It has a large unserved market in the US. Worldwide sales add virtually 100% to the pre-tax line. Competitive threats are relatively small. Discounting is already built-in and the market will be there for years. Numerically, we foresee sales to this market showing only a gradual decline from $19 billion in 2015 to $17 billion in 2018 and $10 billion in 2025.

Served Markets - HIV

Gilead markets four single-tablet regimens for HIV: Atripla, Stribild, Complera and Genvoya. All are based on their tenofovir molecule. The HIV market has been a mainstay for Gilead for a number of years. Gilead products presently command an 80% market share in the US. Patents for Atripla, Stribild and Complera begin to expire in 2018 and competitors are starting to take market share. Gilead is beginning to transfer patients from these older drugs to the newer Genvoya with longer patent protection. Genvoya is the first in a new family of HIV drugs and we expect to see further improvements in the next few years. The new drugs are based on a new

family of compounds known as Tenefovir Alafenamide Fumerate (TAF). The TAF based drugs are deemed to be safer and most doctors have plans to switch their patients to these.

There are estimated to be 1.1 million people in the US infected with the HIV virus. About 50,000 are infected each year. Worldwide, the estimate is 34 million. Most of the people treated for HIV are in the developed world and it is expected that this trend will continue. For Gilead, moving people from the older regimens to the TAF based products will allow it to maintain its market share and sales volume in that served market.

At the moment, there are no drugs that "cure" HIV, only those that suppress it, or make it non-transferable. As such, drugs to treat HIV represent an annuity to the drug company, but also leave the door open to develop a patentable drug that would offer a cure. The potential HIV cure is in Gilead's pipeline.

Competitive Products - HIV

Competitive products from Bristol-Myers Squib are set to enter the market in the 2020's. At that point, patients not transitioned to the TAF products could become patients on generic medications. However, sales for HIV products will not drop precipitously. Instead, we foresee a gradual decline in HIV product sales from about $12 billion in 2016 to around $7 billion in 2020.

Pipeline Products

Gilead's pipeline is far from empty and they do not necessarily need a blockbuster acquisition, as Wall Street seems to think, to realize some real value from their R&D. The three top executives of Gilead hold PhD's in either Organic Chemistry or Biochemistry. Gilead management has exhibited an ability to recognize valuable drugs and how they would fit in with the existing portfolio of Gilead's special expertise. I will quickly summarize these. The first few serve to enhance the viability of Gilead's market dominance in the HIV and HCV markets. Very few drug companies have been successful in defending a served market and the Street is fully discounting Gilead's ability to do so on a long term basis.

TAF Products: This new family of products will extend Gilead's HIV franchise, providing fewer side-effects and more convenience. This family of drugs is also the base for a new hepatitis B product, now in Phase 3 testing.

Gilead is various stages of development and testing of further improvements to HIV and hepatitis B with what they refer to as GS-9620 HIV cure. It is, of course unknown just how effective this will be.

They also have a set of drugs targeted to treat all subtypes of hepatitis and would eliminate the need to determine what subtype of hepatitis to target. It is believed that such a drug would open a very large opportunity in China.

Gilead has a very intense effort devoted to Non-Alcoholic Steatohepatits (NASH) which affects about 10 million Americans. NASH can lead to cirrhosis of the liver. HVC is also a liver related disease, so you can see the tie-in that is a management focus.

Gilead also has an extensive R&D effort aimed at oncology drugs. They acquired Idelalisib in a Phase 2 stage for about $600 million. This contrasts to the $20 billion that AbbVie paid for half of Imbruvica, with a similar drug. Impruvica is a single drug. In contrast, Idelalisib was part of the purchase of Calistoga Pharmaceuticals and included a full pipeline of products, including Impruvica which also target forms of lymphoma and leukemia.

Zydelig and Impruvica are intended to become the building blocks for a full family of cancer medications that build on these foundations along with Gilead's expertise in molecular biology and companion drugs that could be very effective when used in a combined therapy. It remains to be seen if Gilead can become a dominant force in oncology drugs, but it has succeeded in the past and the drugs are in the pipeline.

There is also a financial significance in Gilead's R&D work. They are expensing the costs! There is no purchased goodwill to amortize over time. Nor is there any capitalized goodwill or R&D to be amortized.

All of these drugs have a common strategy, that being, that Gilead management has recognized valuable drugs, both inside and outside of its R&D center. It has chosen those that fit into a development program building on families of products for multiple uses. It is also aiming to develop combination products. This has been a successful strategy for Gilead. It does not make for great headlines or attention grabbing, big acquisitions, but this strategy has succeeded in building one of the largest biotech companies and doing so in a very short period of time. It is a good bet they can continue this level of success. Wall Street wants to see big acquisitions – a strategy that has worked well for other big biotech companies. Gilead, however, looks to develop its new products in house or from vastly smaller acquisitions where management recognizes value long before purchased companies have blockbuster medications on-hand.

Conclusion:

We believe that Gilead is undervalued. The Street consensus heavily discounts the continued revenue stream from Gilead's medications to treat hepatitis and HIV. It also discounts Gilead's rock solid balance sheet, its promising development pipeline, and the proven ability for Gilead's management to recognize valuable compounds and turn them into successful medications. Buy the stock.