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IOI ChartBook – Gilead Sciences (GILD)

Gilead is like a specialized hedge fund with high investment concentration

September 27, 2016

Three Things You Should Know About Gilead

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- **It doesn't matter what the PE Ratio is – Gilead is not necessarily undervalued at present prices.**

  Many value investors seem to be enamored with Gilead because it is trading at a "low PE." However, looking at uncertainties related to opportunities for Gilead's future growth and considering that its single largest revenue source – its hepatitis c virus (HCV) treatment franchise – is likely to continue to shrink in the near-term, we believe the present price is easily justified by fundamentals. Using a PE ratio or any other multiple to value a firm only obfuscates assumptions for the rate of growth of future cash flows. Gilead's shares are a perfect case in point why multiples-based valuations are often deeply flawed.

  We do find several scenarios where Gilead's intrinsic value would be considerably higher than its price is trading today, but also one where it's value is about 34% lower than it is today. We are unable to handicap the likelihood of these outcomes, but upside scenarios are slightly undervalued by the option market.

- **Gilead is essentially a very specialized, highly-regulated biotechnology hedge fund.**

  A hedge fund engages in proprietary financial research and invests capital in investments that it believes has the best chance of generating large cash flows within its investment time horizon (which is usually determined by its investors). Most hedge funds are only lightly regulated, but are subject to legislative risk.

  Gilead engages in proprietary biotechnological research and invests capital in investments that it believes has the best chance of generating large cash flows within its investment time horizon (which is legally determined by patent law). Gilead is in one of the most tightly regulated industries in the world and is subject to regulatory and legislative risk.

  Gilead's product portfolio (equivalent to a hedge fund's investment portfolio) is highly concentrated in two related areas – treatment of HCV and of HIV. As any investor who has studied Bill Ackman or Bill Miller's career will know, concentration is a double-edged sword. Gilead's investments throw off a lot more cash than Ackman's or Miller's do, and in that respect, are much more robust. However, if Gilead's future investment projects are not very successful, the company's value is less than its present price.

- **Investment success hinges upon factors that are impossible for anyone alive to know today.**

  Gilead's business hinges on its ability to consistently invest in research or acquisitions that will generate blockbuster drugs in the future. We think that Gilead may have an advantage in assessing antiviral drugs, but even with this acuity, commercial success relies upon what its competitors are doing and the results of trials and regulatory reviews. Many opine. No one really knows.

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Valuation Overview

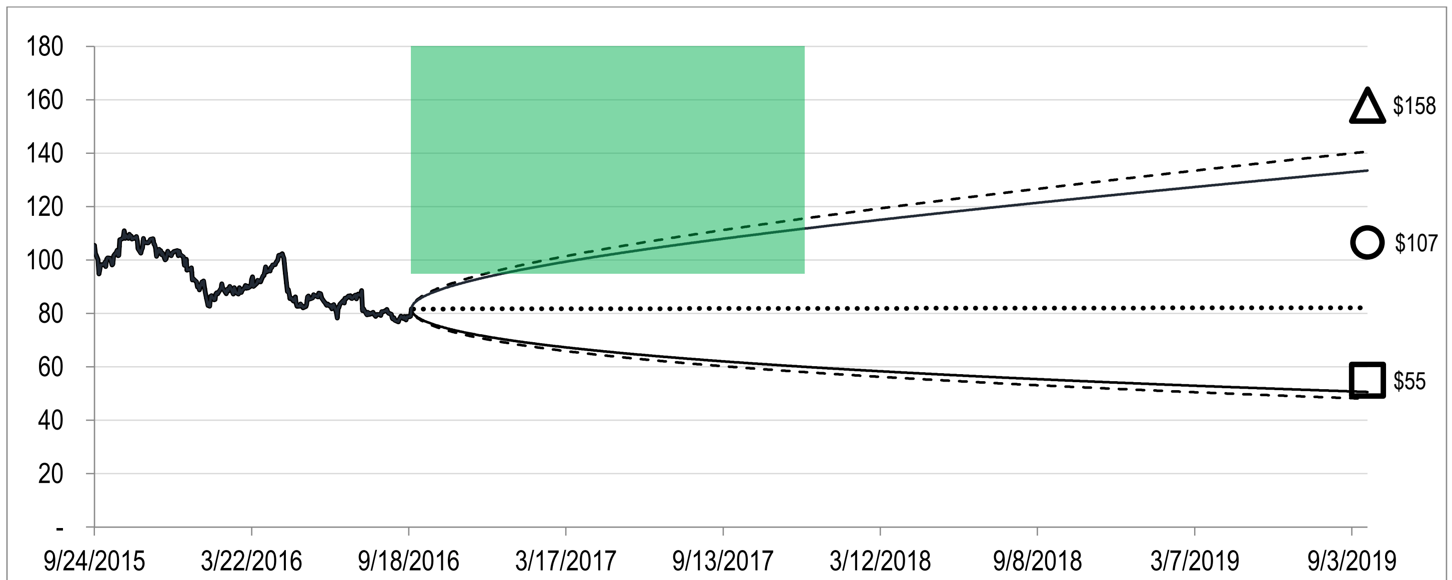

Figure 1. Source: YCharts, CBOE, IOI Analysis. Geometrical markers show IOI's best-case (triangle), worst-case (square), and equally-weighted average value (circle). Cone-shaped region indicates option market's projection of Gilead's future stock price (dotted line represents ask price projection, solid line, bid price projection). Shaded region represents the purchase of a call option on Gilead's stock.

	IOI Best Case	IOI Worst Case	Historical Median
Year 1-5 Average Revenue Growth	10%	-4%	16%, 26% (5, 10-year)
Year 1-5 Average Profitability	50%	33%	40% (5 & 10-year)
Year 6-10 Cash Flow Growth	10%	-4%	71%

Usually, we use the most heavily traded options to form the above BSM Cone, but we did not believe the near-term options accurately reflected the market's uncertainty regarding Gilead's future price levels. Looking at the implied volatility for LEAPS expiring in 2018, we found that the implied volatility was about six percentage points higher. We opted for the cone corresponding to the higher implied volatility. IOI members are welcome to contact us for an explanation.

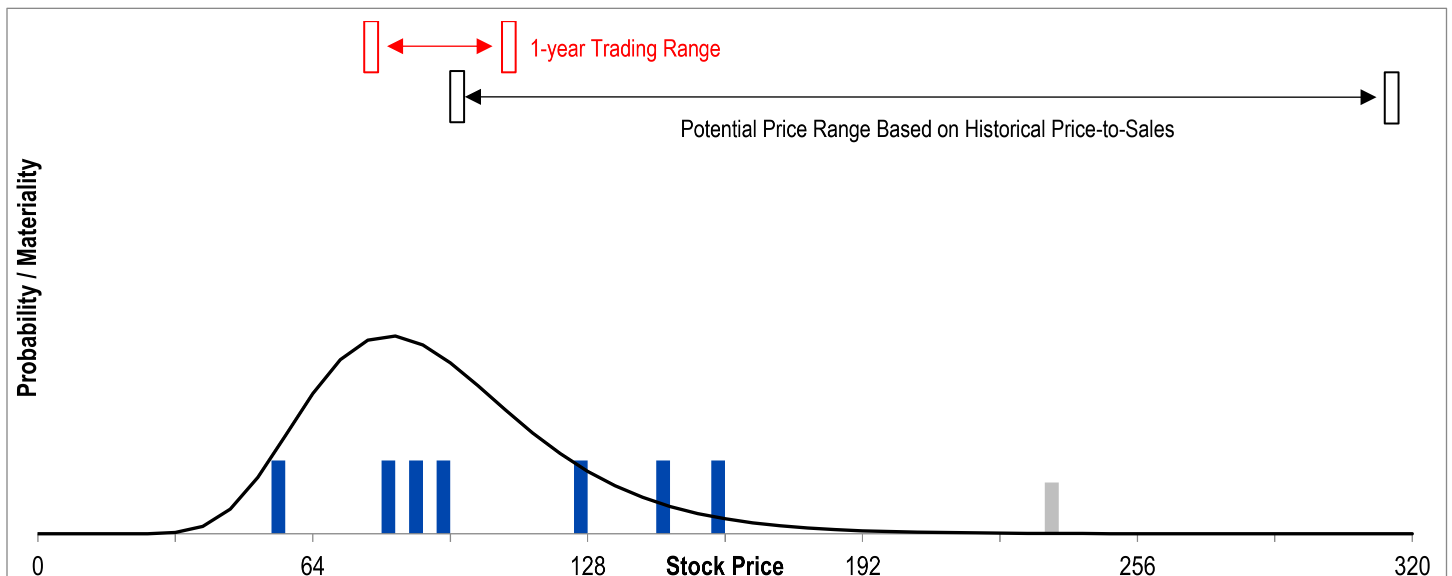

Figure 2. Source: CBOE, IOI Analysis

The firm looks relatively fairly valued, though several scenarios are in the $130-$160 / share price range. As we shall see in the pages below, the valuation will be affected mainly by the success or failure of the drugs in its pipeline. The price range implied by the PS Ratio above is certainly too wide and skewed too far to the right; this is an artifact of Gilead's sudden historical revenue growth.

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Valuation Drivers

Revenue Growth

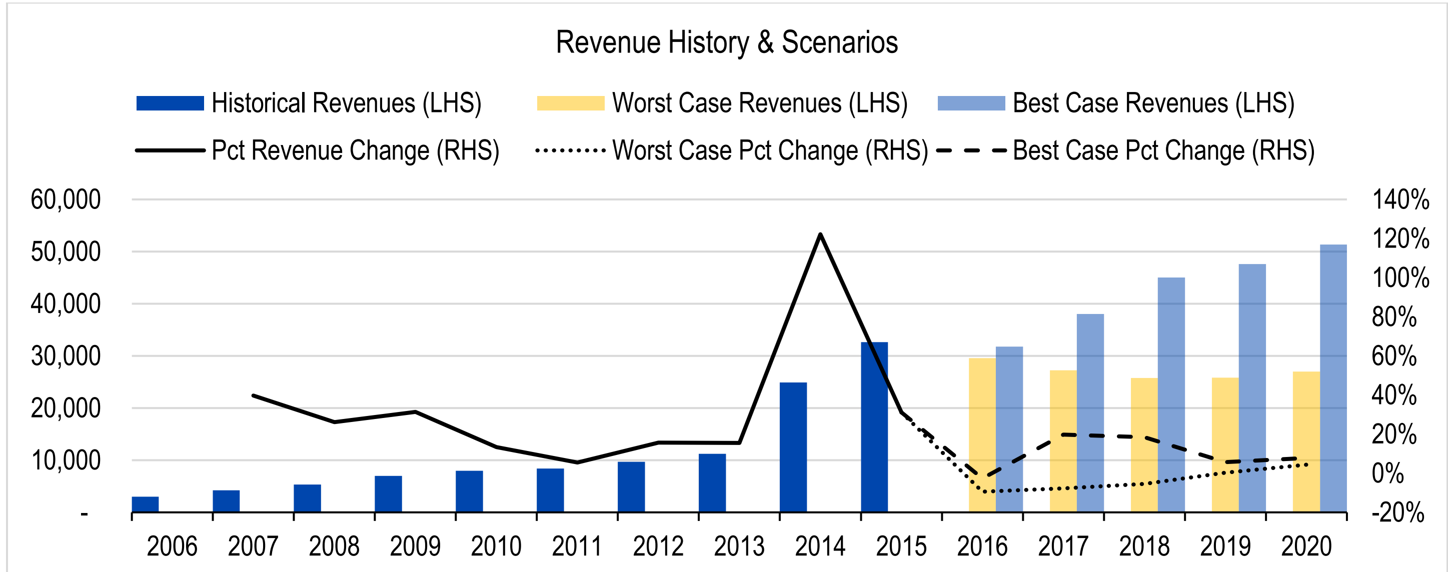

Figure 3. Source: Company Statements, IOI Analysis

Our best case scenario assumes that Gilead is able to produce another $10 billion blockbuster drug over the next five years. Gilead's revenues are generated by three main product lines, each of which we have forecast separately. Please see the diagrams and commentary below for details.

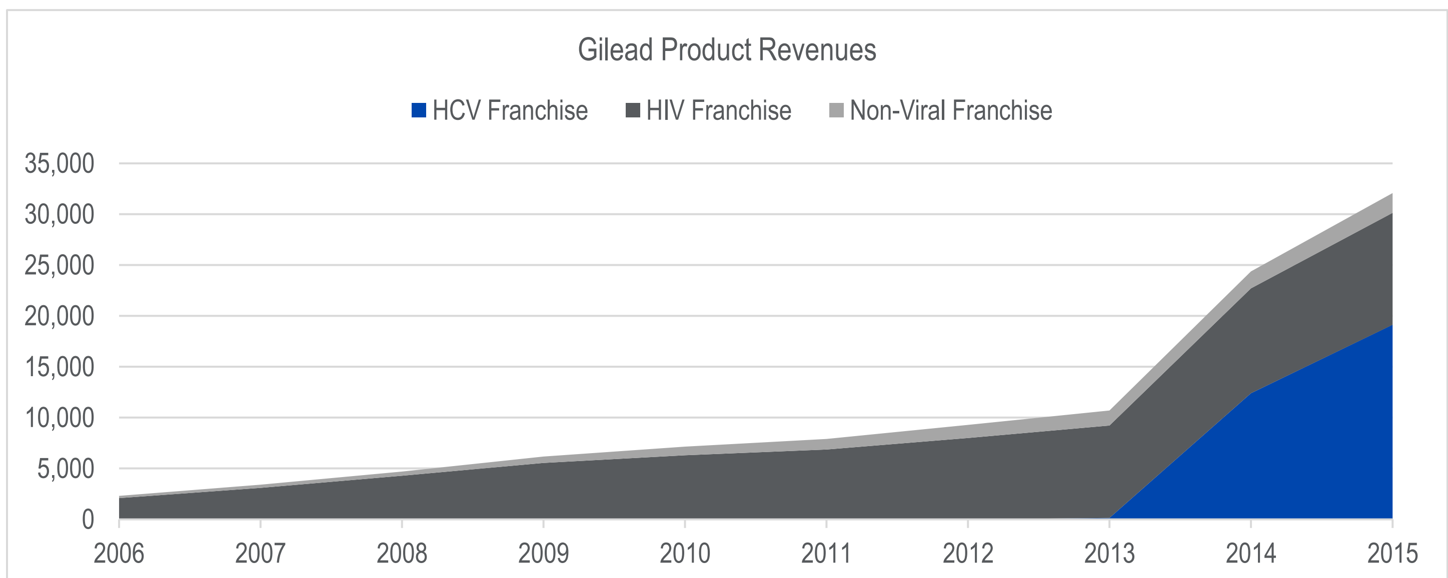

Figure 4. Source: Company Statements, IOI Analysis

Before Gilead's purchase of Pharmasset in 2011, the company's largest product line was its antiviral HIV treatment franchise, led by its compound known as Truvada. The 2011 Pharmasset acquisition allowed Gilead access to a drug known as Solvadi, a truly revolutionary treatment for hepatitis C virus (HCV) discussed below. The Non-Viral franchise is a stable of treatments for various ailments, including one of the first drugs to really put Gilead on the map, AmBosome, a treatment for fungal infections that Gilead acquired when it bought NeXstar Pharmaceuticals in 1999. Both the NeXstar and Pharmasset acquisitions were transformational to Gilead. NeXstar's revenues were three times that of Gilead at the time of the purchase; Pharmasset's acquisition cost of $11 billion was worth nearly five of the preceding years' worth of Owners' Cash Profits (OCP) – IOI's preferred measure of profitability.

Gilead has one more revenue line related to its licensing of drugs. This presently represents a small proportion of product revenues – around 1.5% – so we exclude it from these charts but have built it into our valuation model.

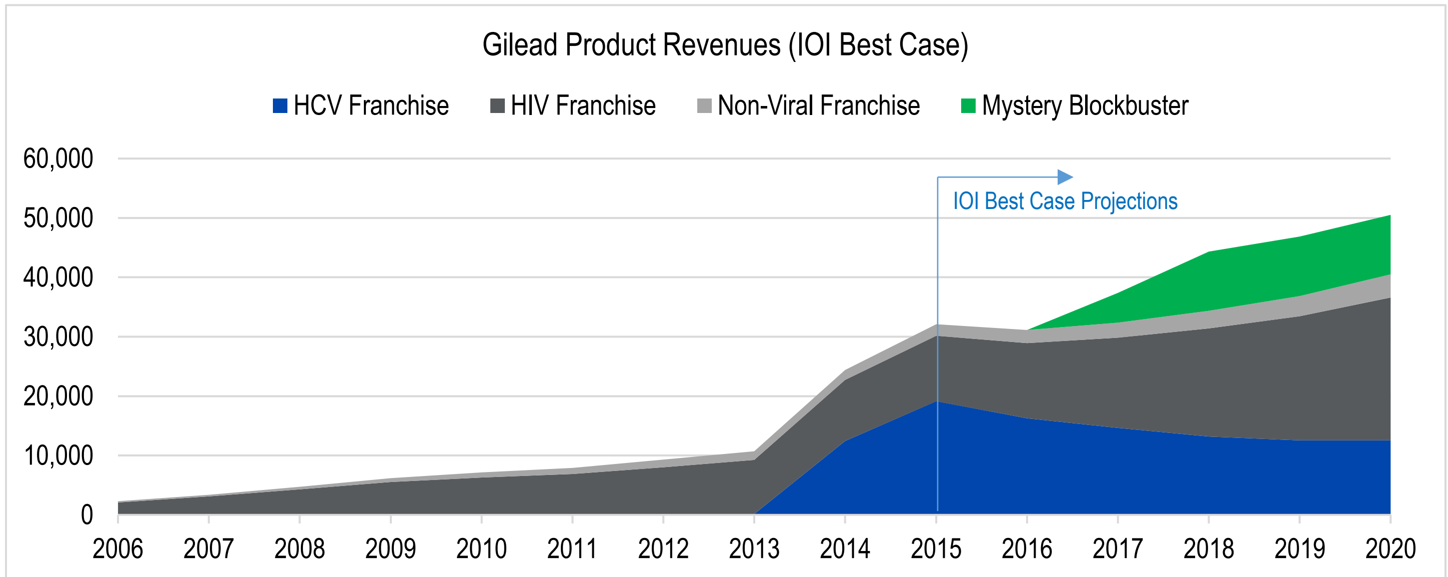

Figure 5. Source: Company Statements, IOI Analysis

We discuss the specific assumptions of our best case scenario in the following diagrams and pages, but as a 30,000-foot overview, the figure above is what we have modeled for the company's future revenues in the best case. The HCV franchise has characteristics that we think will cause it to trend downward in the future. HIV will again become dominant, and non-viral treatments will increase at a good clip. If Gilead can pull off a coup and discover another super-blockbuster (candidates for this are discussed below), worth at least ten billion dollars of revenue each year, the firm will be generating about $50 billion worth of product revenues in 2020 compared to about $30 billion today.

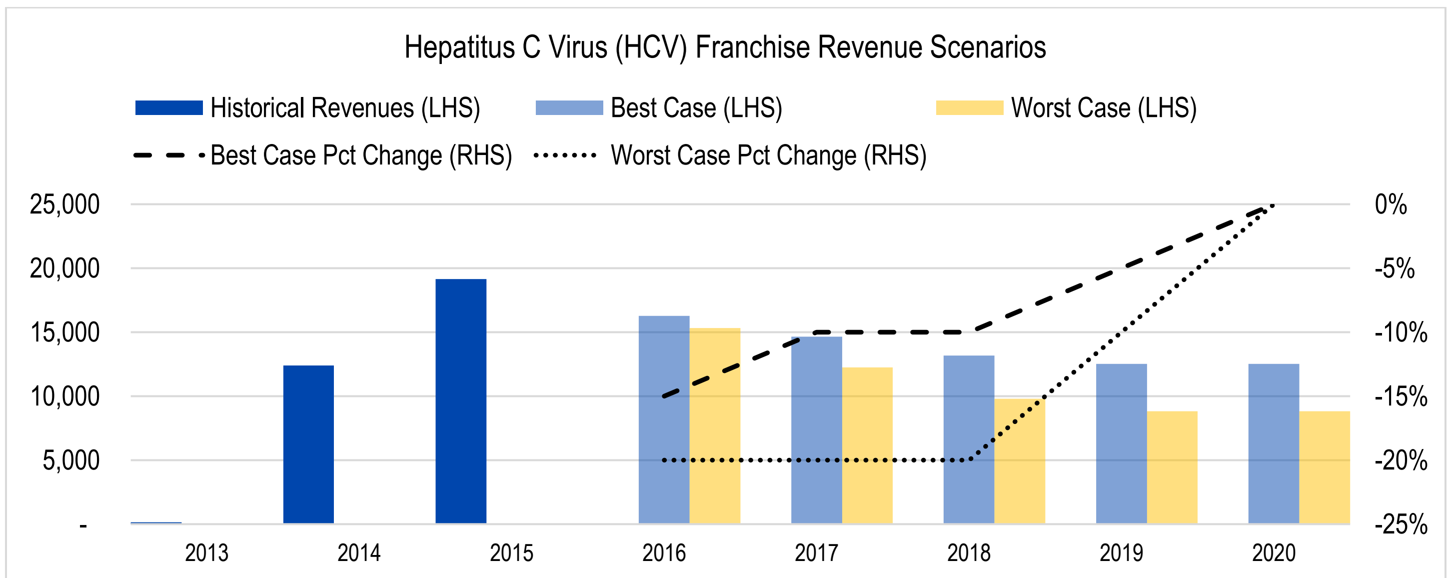

Figure 6. Source: Company Statements, IOI Analysis

Previous treatments for HCV involved interferon injections that would slow the progress of the disease but not cure it in the vast majority of cases (on the order of 20% cure rates). The interferon injections have the additional drawback that they are associated with severe side effects (essentially, the patient has symptoms similar to the flu for months at a time), and many times HCV patients would eventually have to have a liver transplant if they did not respond to repeated treatments. Gilead's Solvadi, a pill rather than an injection, is able to cure the disease (90% and higher cure rates) with minimal side effects in only a matter of weeks. Gilead priced the drug at $84,000 per average treatment course, arguing that while expensive, the Sovaldi treatment option saved money in the long run because the costs of repeated treatments of interferon, liver transplants, and the like could be avoided were Sovaldi to be used. Sovaldi was the first compound of this sort, but competitive products have since been developed. The first true competitor to Sovaldi is a drug from Merck called Zepatier, which Merck priced at $55,000 per average treatment. Gilead began rebating Sovaldi and its successor, Harvoni (the key component of

which is the same as Sovaldi), which is part of the reason for the revenue declines in both best- and worst-case scenarios in the figure above. Another partial reason for the decline is that Gilead started selling the drug into the U.S. Veterans' Administration which, unlike Medicare, is able to negotiate the price of the drugs it buys.

Gilead, to preserve its market position, has continued to develop its HCV franchise. Its newest HCV drug, known as Epclusa, is astounding, with very high cure rates, shorter treatment times, and the ability to treat all six genetic variations of HCV (genotype 1a, 1b, 2, 3, 4, 5). The last characteristic means that genetic pre-screening is unnecessary – a seemingly small but significant advance for HCV treatment.

Even with these improvements, though, Gilead's HCV franchise will shrink, in our opinion, due to 1) competition from other drugs (Merck, Achilion, AbbVie, and other firms are all working on alternative treatments) 2) regulatory and payor pressure to cut the price of the drug, and 3) the lifecycle of the disease (this last point requires some explanation – IOI members are invited to contact me for an explanation). In the end, HCV will be a very good business for Gilead for the next 10 years or more, but its peak, in our opinion, has passed.

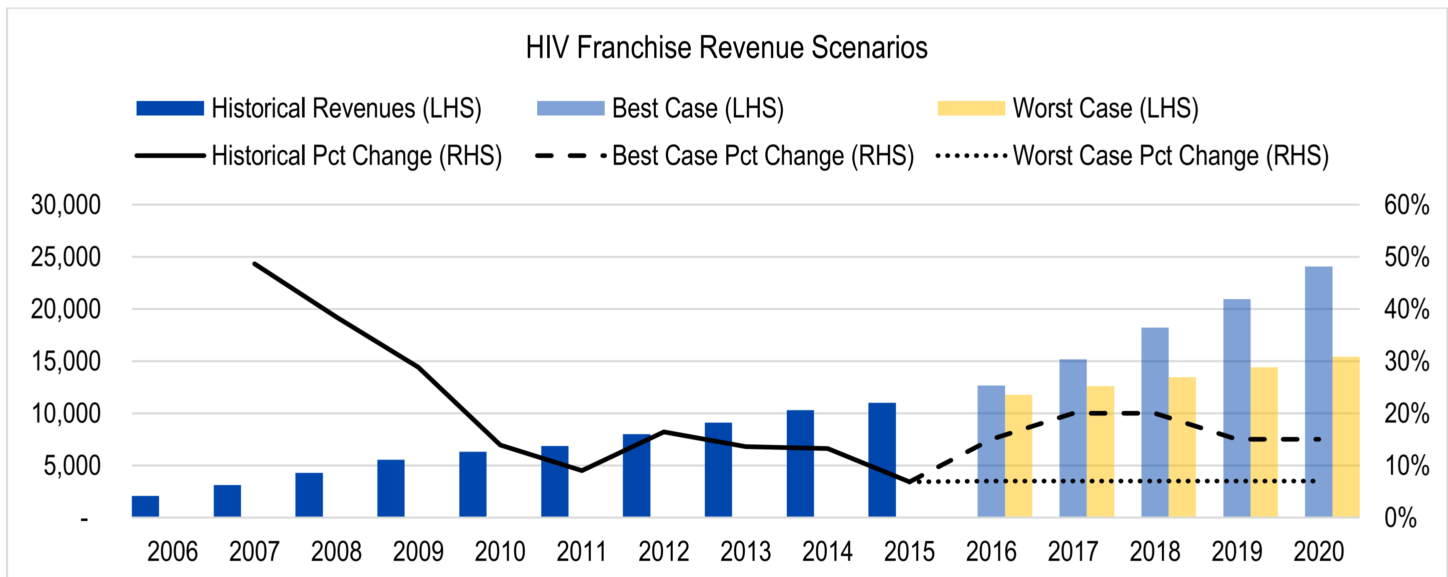

Figure 7. Source: Statista.com

Gilead's HIV franchise, while eclipsed by the HCV franchise over the past few years, is remarkable as well. The compound names are confusing, but in essence, there are two different families of HIV treatments at Gilead: TDF is the older line, the most talked about drug is named Truvada. TAF is a new line, just approved at the end of 2015 and in 2016, the active compound of which is derived from a modification of the compound used in TDF; the most mature of the TAF drugs is named Genvoya (released in 2015).

TDF drugs require a larger dosage than TAF and are associated in some cases with a loss in bone density and in reduced liver function. The TAF drugs use lower dosages, so it is less likely for patients to experience harmful interactions with other medicines and also to show as severe side effects as the TDF line. TAF looks like a great drug line, but it is an evolutionary product extension that is being sold into a market in which competitors also have plausible, efficacious substitutes. In the case of HCV, Gilead's treatments stood out because they represented a quantum leap improvement to any other treatment on the market. That dynamic is muted in Gilead's HIV line.

One of the most potentially exciting developments regarding Gilead's treatment line is the eventual possibility of an eradication of HIV/AIDS. Truvada has shown to be efficacious in the prevention of the transmission of HIV even among people engaging in risky sexual or intravenous drug use behavior. Pre-Exposure Prophylaxis (PrEP) is the buzzword in the gay community these days – daily use of Truvada appears to be highly (perfectly?) efficacious in preventing the spread of HIV. If the newer TAF drugs are also similarly efficacious, Gilead will be able to enjoy years of strong demand for its HIV franchise. Truvada's European patent protections are due to expire in 2018 and its American ones in 2020; if TAF drugs can be used instead of Truvada for PrEP, they will likely be more popular due to the lack of side effects and harmful drug interactions mentioned above.

From a humanitarian standpoint, Gilead's scientific advances are amazing. One terminal, wasting disease (HCV) cured within a decade, another (HIV) potentially cured or practically controlled within a generation. From a commercial standpoint, the HIV franchise, which carries with it the potential for ongoing treatments in the form of PrEP, is the more attractive.

Our best-case assumption is that the TAF drugs create robust demand for Gilead's HIV treatments over the next five years. Worst case is that essentially, the TAF line simply replaces the revenues of the older TDF line, growing at an average rate of 7% per year.

Gilead's TAF drugs also can be used to treat hepatitis b, a matter we will discuss more below.

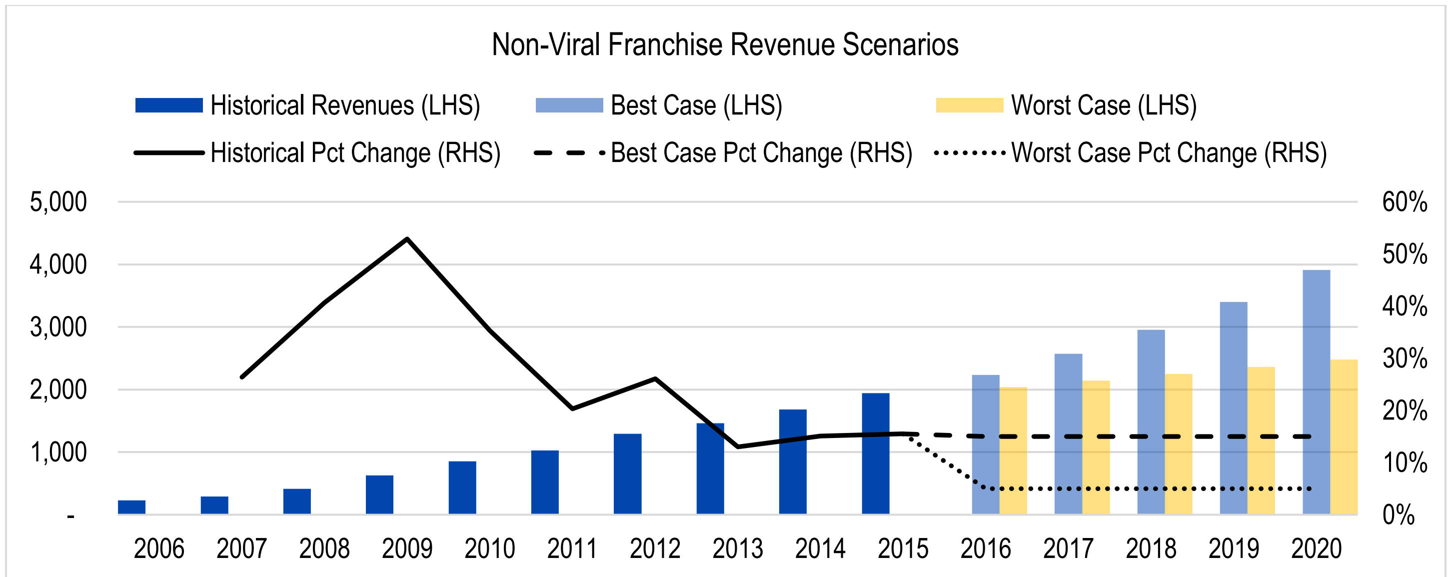

Figure 8. Source: Statista.com

Gilead's non-viral treatment franchise generates revenues from several drugs to treat several different conditions. While all of these drugs have respectable revenue lines and revenue growth has been good, none are in the $1 billion plus per year "blockbuster" category. Also, one of these drugs lost U.S. patent protection last year, another is losing it this year, and yet another is losing it in 2019. In the best-case, Gilead's pipeline for non-viral treatments (in the fields of cardiovascular, oncological, and inflammatory conditions) drive robust revenue growth for this franchise. In the worst-case, revenue growth will be at the run rate for the segment in the first half of this year – 5%.

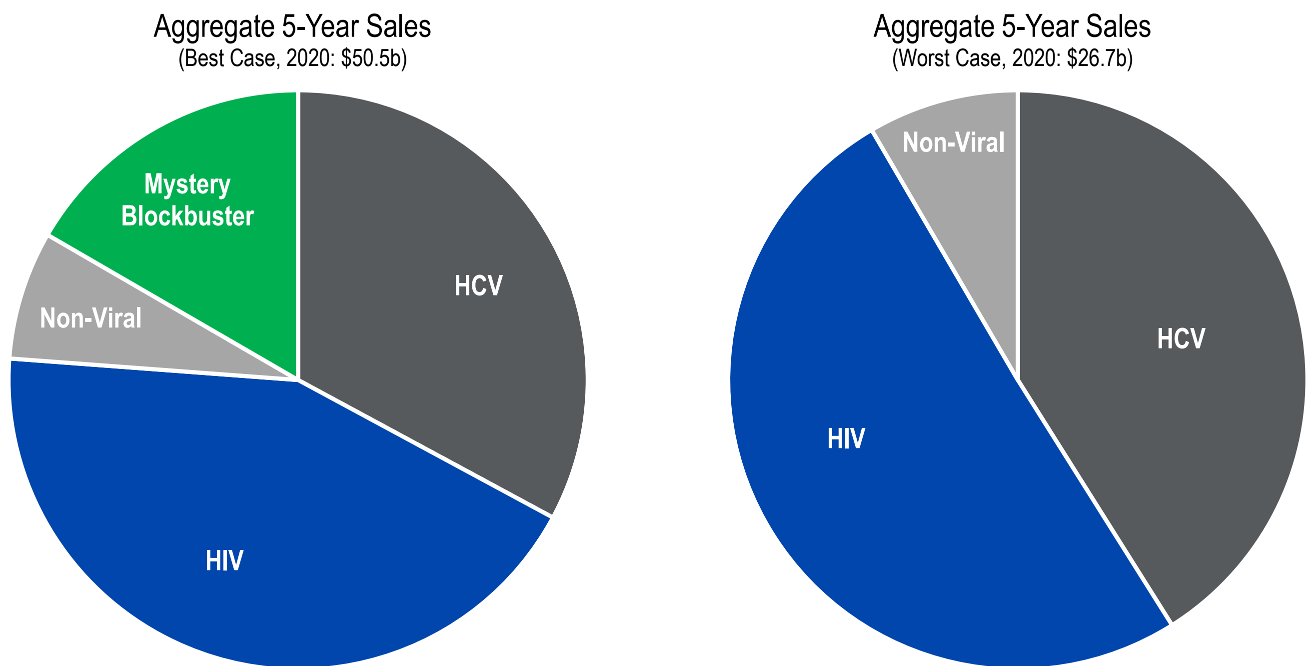

Figure 9. Source: Company Statements, IOI Analysis. This shows our model's aggregate revenues over our short-term period (2016-2020) under best- and worst-case scenarios.

The crucial determinant of Gilead's value will be the efficacy of its short- and medium-term investments in new drug development and / or drug company acquisitions. The HCV franchise acquisition from Pharmasset was truly one of the greatest, boldest investments I have ever seen. Put in context, this acquisition would be equivalent to you or me spending 20% more of our prior year's *gross* salary on a single investment.

The boldness of the Pharmasset acquisition paid off in spades, but we are suspicious the firm being able to replicate this success in the short-term (i.e., the next five years) and much more suspicious that it would be able to do so yet again in the medium-term (years 6-10).

Common wisdom in the investing world is that Gilead has some magical ability to spot biotech winners. While we acknowledge that the company appears to have a particularly good understanding of antiviral treatments, its ability to successfully commercialize this understanding is subject to constraints that are largely out of its control. Particularly, it is unable to control the timing or the success of a competitor's drug, nor can it control the regulatory approval process.

At present, Gilead is working very hard to develop drugs to treat non-alcoholic steatohepatitis (NASH, a form of fatty liver disease). The term "hepatitis" in this disease name simply means inflammation of the liver and its causes are not the same as hepatitis b or c, which are viral infections. The investing community is excited about the possibility of a Gilead NASH treatment, but in fact, there are several companies with competitive treatments, and Gilead's product does not appear to be the most compelling for several reasons (this Seeking Alpha article has a good summary of NASH development pipelines, this presentation is also helpful). First, Gilead's drug does not seek to treat NASH itself, but to treat the effects of NASH (cirrhosis and inflammation). Second, Gilead's drug is a combination of injectable and subcutaneous injections, rather than a pill (pills are easiest for patients to take, so compliance and cure rates are higher for pills versus injections). Third, Gilead's drug is still not in Phase III trials, and according to the articles linked above, it is likely that definitive results from clinical trials will take a long time due to peculiarities of NASH as a condition. In our view, Gilead's drug may someday become an important portion of the treatment of NASH, it is unlikely that it will be a blockbuster. Also, it is unlikely, given the uncertainties surrounding the causes of NASH, that Gilead scientists have special insight into what competitors' research may be particularly promising. This implies that the chance of a failed investment in the acquisition of a competitive NASH treatment is relatively high.

While Gilead's research touches on a number of fields – inflammatory conditions, liver disease, and antiviral treatments – we believe it is likely strongest in the antiviral field. If this assumption is true (we have phrased this question five different ways so far to Gilead's management, but have yet to receive a helpful response), we believe that the best hope for the development of a super-blockbuster lies not in NASH, but in the extension of the TAF-based HIV drugs to treat the hepatitis b virus (HBV). The CDC estimates that the number of HBV sufferers in the U.S. is on the order of 1.5 million people, roughly half the number of sufferers of HCV. HBV prevalence in Asia and Africa are high, but Gilead reduces its prices drastically in developing markets, so the commercial potential for worldwide sales is lower. Judging by U.S. market size, we estimate the revenue potential for a HBV treatment to be roughly half that of HCV. There are other drugs in development to treat hepatitis b, but in our best case, we simply assume that Gilead wins and is generating $10 billion per year in two years (starting in 2018).

Profitability

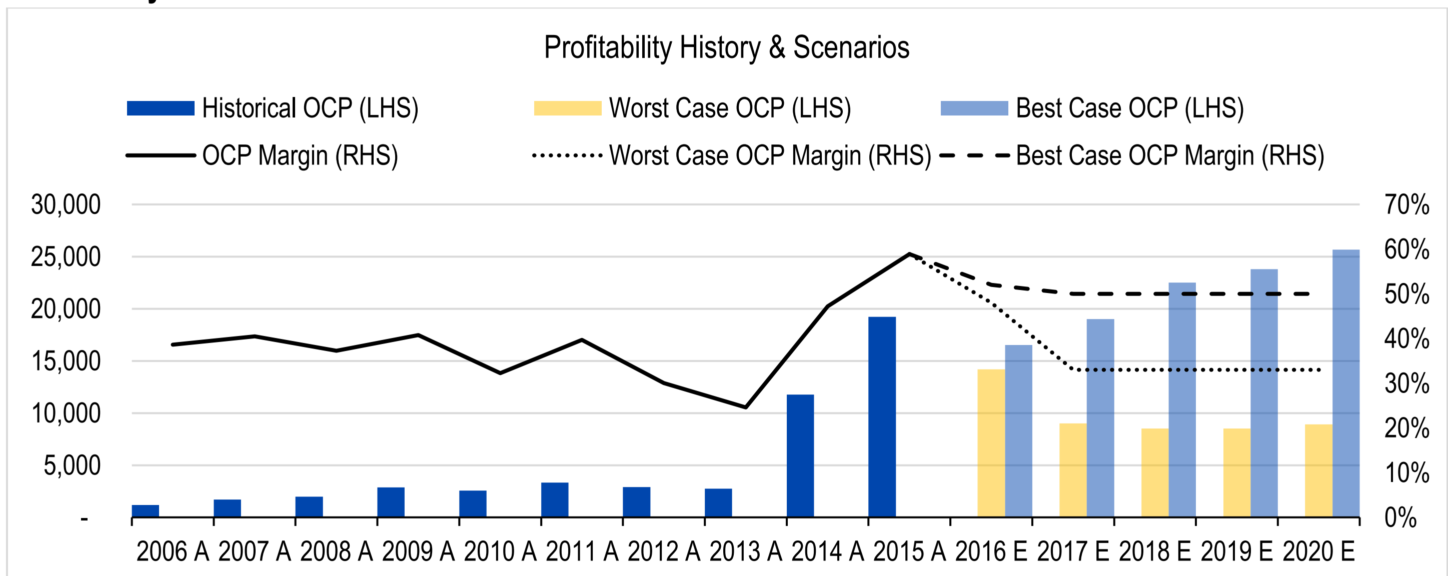

Figure 10. Source: Company Statements, IOI Analysis

Not only is Gilead's profit model very similar to a biotech hedge fund, its cost structure is very similar as well; it is a lean organization, so its profitability is very high. As a market becomes more competitive and mature, price competition ensues and profitability drops (note drop from 2009-2013 in the figure above). HCV treatments, while under competitive attack, are still phenomenally profitable and 1H 2016 OCP margins are still in the low-50% range. One possibility in this world of cost-conscious insurance companies and smirking pharma execs like Martin Shkreli is that regulatory action will be undertaken to disgorge some "excess" pharma profits. This is unlikely, but not implausible, especially considering worst-case scenarios. Gilead focuses on finding cures for heretofore incurable conditions, and this focus allows, in our opinion, the firm the ability to push back harder on regulators and legislators looking for pharma company scapegoats. It does not, however, make it immune from such pressures.

Investment Level

Expansionary Cash Flow is IOI's measure of investment spending net of asset sales and divestments.

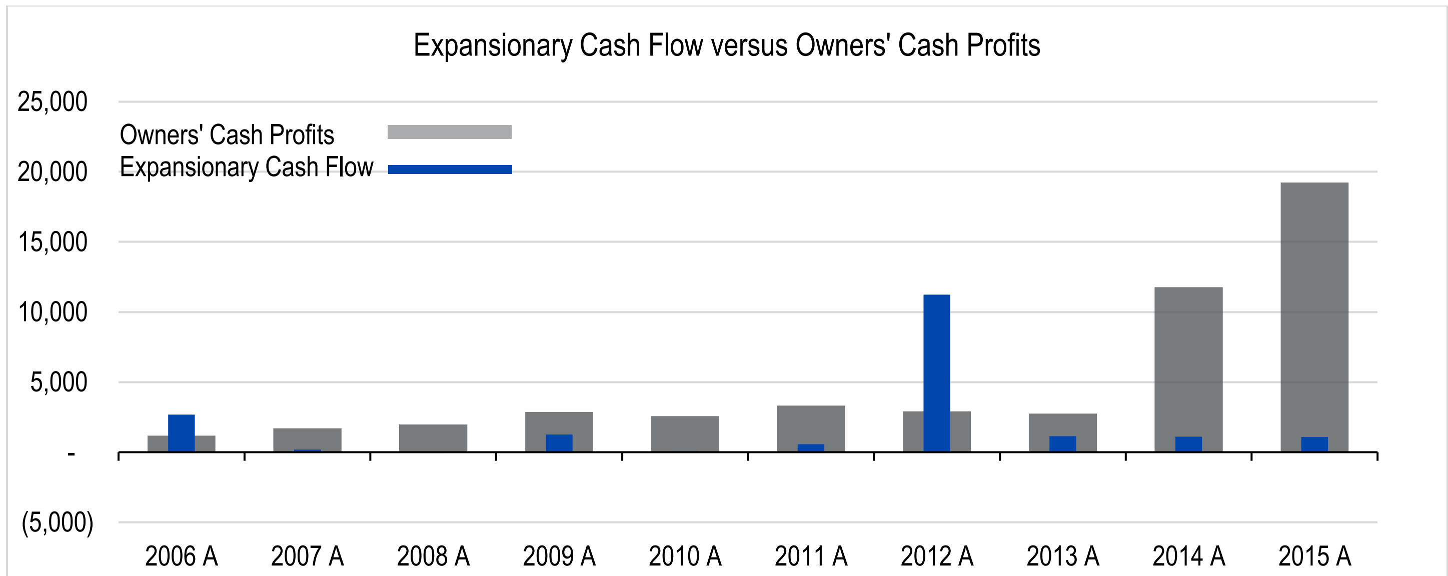

Figure 11. Source: Company Statements, IOI Analysis

Over the last 10 years, Gilead has spent a median 40% of its OCP on investment projects. Large acquisitions in 2006 (Myogen) and 2012 (Pharmasset) drove this spending. The Myogen deal, through which Gilead acquired several cardiovascular drugs, was only a very modest success. Gilead paid $2.5 billion for Myogen to acquire a drug called Letairis, which has only generated revenues of $3.5 billion over the past 10 years and the Letaris patent expired in 2015.

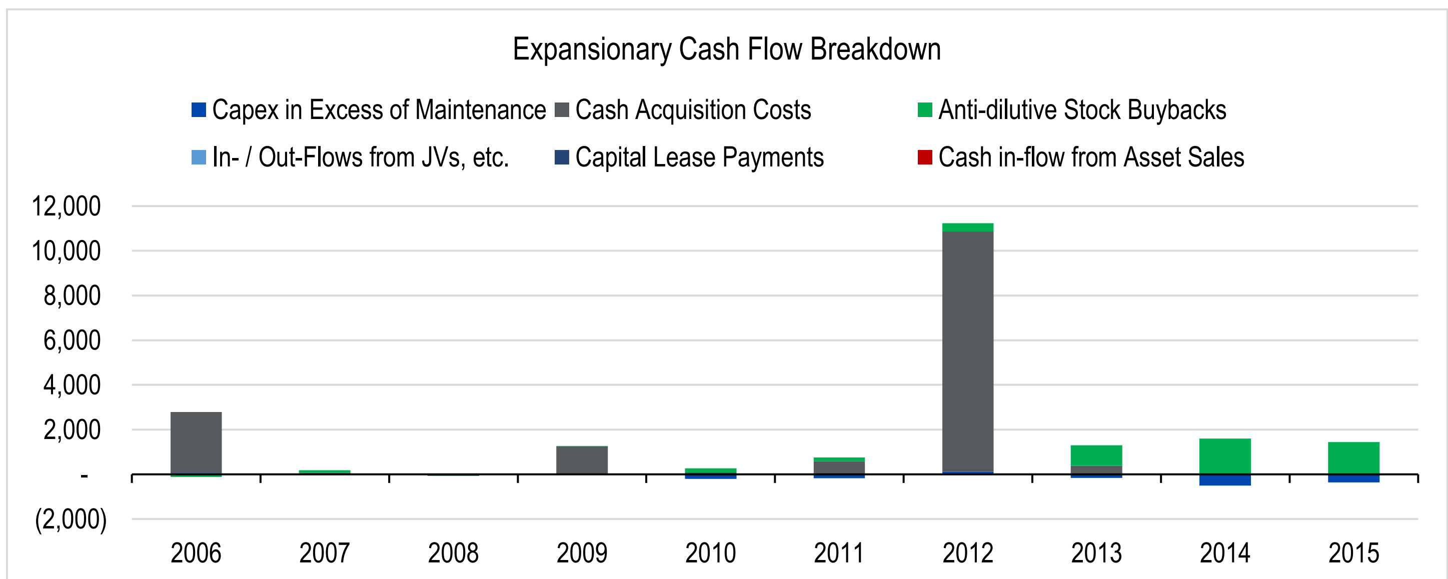

Figure 12. Source: Company Statements, IOI Analysis

The big jump up in what we term anti-dilutive stock buybacks is partially due to increase issues of shares since 2012 (average issuance, 27.4 million shares versus an average of 17.8 million shares issued in the previous six years) and partially due to Gilead's soaring stock price.

Investment Efficacy

Corporate investments lead to profit growth. IOI measures profit growth versus the standard yardstick of nominal GDP growth to assess the efficacy of the company's past investments.

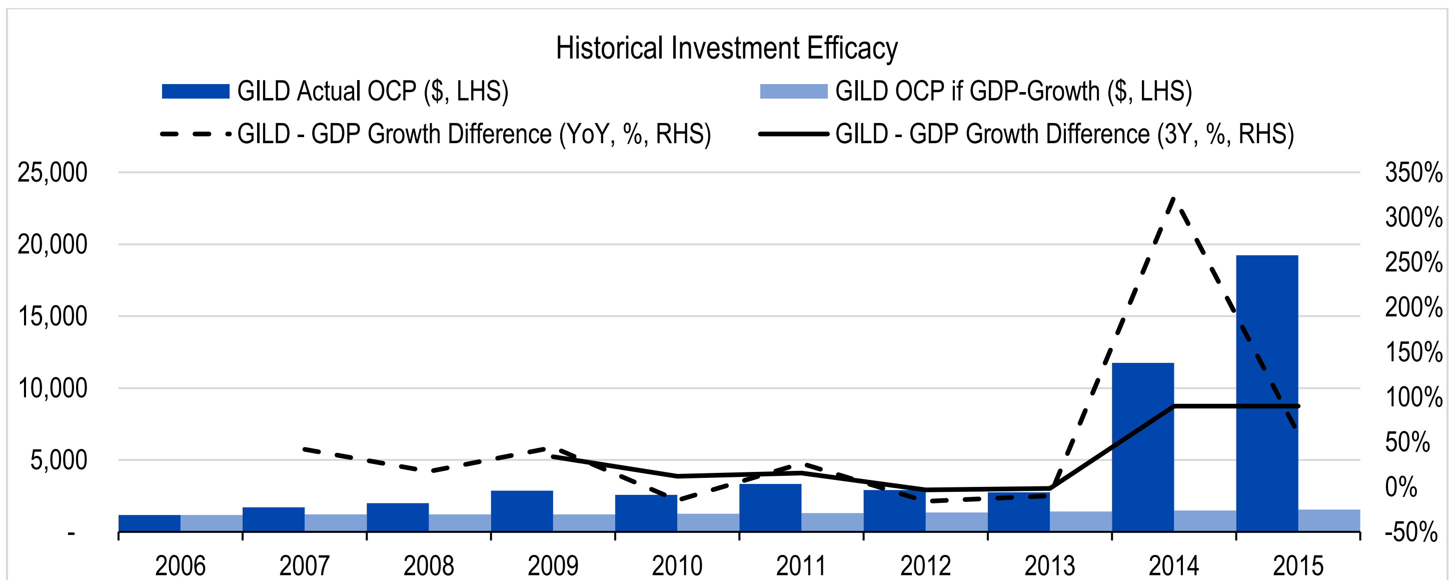

Figure 13. Source: Company Statements, Bureau of Economic Analysis, IOI Analysis

The above efficacy chart is simply outstanding. Gilead's Pharmasset investment and its investment in its HIV technology before that were so outstanding, it's enough to make Warren Buffett blush in embarrassment. That said, it is clear that Gilead's investment prowess is not perfect. Non-viral investments have been only modestly successful, for instance. We believe that Gilead's investment efficacy is highest in the antiviral field and that its success in HCV was, while not purely luck, aided by a confluence of favorable occurrences. The assumption that Gilead will meet another favorable confluence twice in the next 10 years (as implied by our best-best case scenario) is, in our opinion, very unlikely.

Free Cash Flow to Owners

Free Cash Flow to Owners (FCFO) is the metric IOI uses to value companies. It equals Owners' Cash Profits less Net Expansionary Cash Flow.

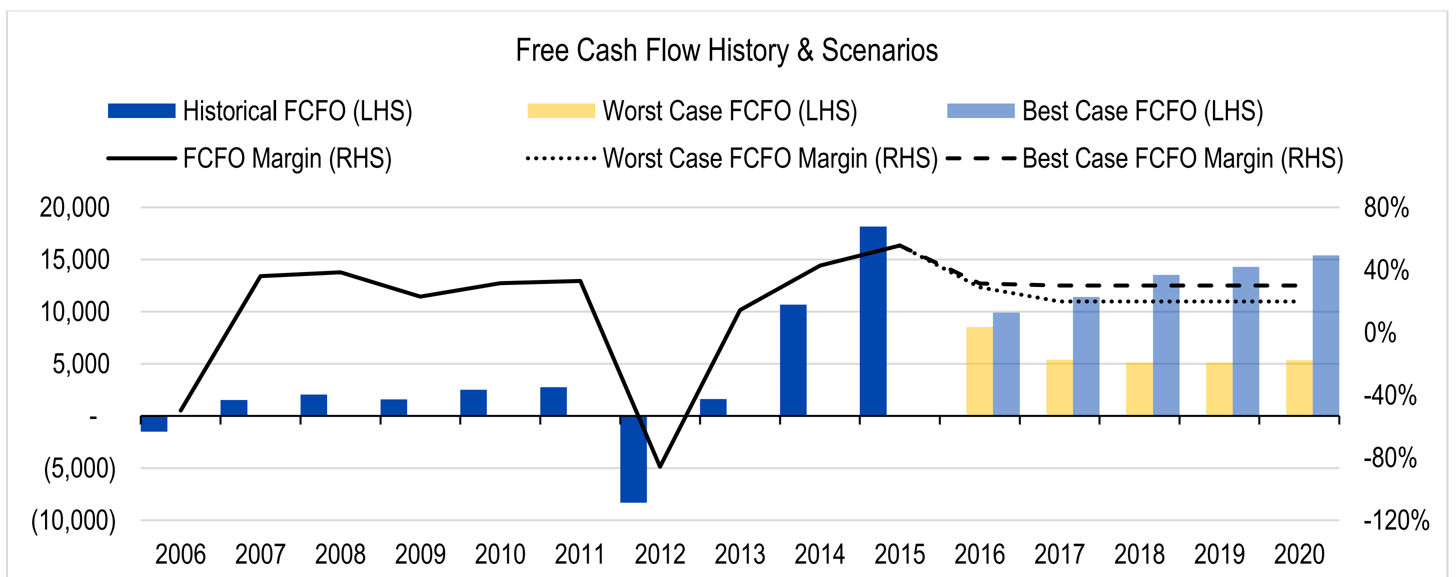

Figure 14. Source: Company Statements, IOI Analysis

While investment spending will likely be lumpier than what is shown in our model, our best-case scenario sees the firm generating $65 billion of FCFO over the next five years versus generating $31 billion over last 10 years and $29 billion over the last two.

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Valuation Waterfall

Revenue Growth

Declines in the HCV business – presently Gilead's largest franchise proportionally – will dominate revenue growth in both best and worst cases. Worst case assumes no super-blockbuster in the next five years; Best case assumes one. If one comes, we believe it will be in the treatment of hepatitis b.

Profitability

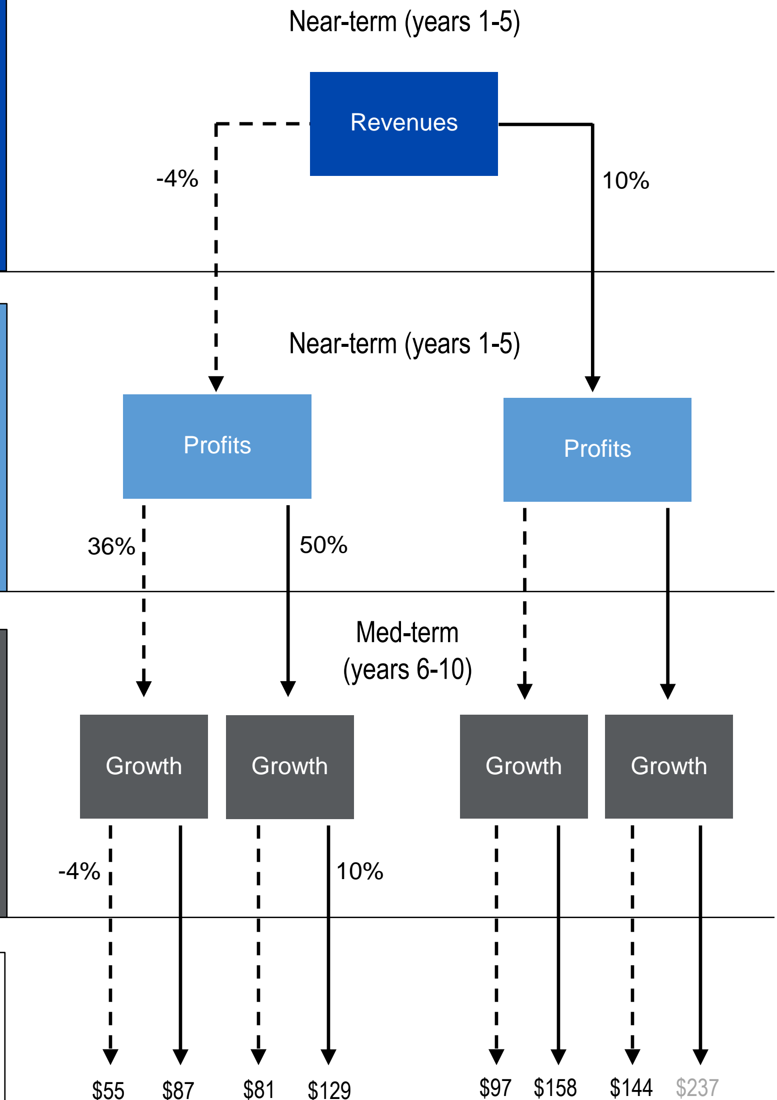
We believe profitability is more likely to be near the 50% best-case level than near the 33% worst-case one, but issues of regulation and competition make this hard to handicap. 33% was the average OCP margin in the five years between 2009-2013 – just before the HCV franchise took off.

Medium-Term Cash Flow Growth

For medium-term growth to average 10% per year, the company will likely need to develop and market another super-blockbuster during years 6-10. If it cannot, FCFO is likely to fall as its drugs mature and competition heats up. We think two super-blockbuster drugs in 10 years is very unlikely.

Fair Value Range

Our fair value range extends from $53 to $156 / share and excludes the most extreme valuation scenario. We believe the present stock price reflects the market's opinion that 1) near-term revenues are likely to fall, 2) near-term profitability is likely to be high, and 3) the firm is unlikely to develop a super-blockbuster in the 5 years starting in 2021.



Methodology

IOI analyses focus on three main valuation drivers: revenue growth, profitability, and medium-term cash flow growth. We estimate a best- and worst-case scenario for each of these drivers resulting in a total of 2^3 = 8 fair value scenarios based on discounted cash flow methodology. Profitability is measured by Owners' Cash Profit (OCP) margin. We use a discount rate of 10% for large capitalization stocks.

A wide spread of lowest and highest fair values indicates a firm whose value is uncertain. Risk depends on the stock price's relationship to the valuation range.

Best-case scenarios are represented with a solid line; worst-case scenarios, with a dotted one.

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