GILEAD SCIENCES (NYSE:GILD) INVESTMENT CASE JULY 2017

Benedikt Olesch, CFA

WertArt Capital

b.olesch@wertartcapital.com

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"We are a small company and we intend to stay small and limit on what we spend on R&D and therefore we keep the hurdle bar very high and work on only a few things that give us a higher probability of success."

"We are not into empire building. … It is ingrained in our DNA to stay lean."

"We want to have the best molecule for treating certain disease that could come internally or externally. I do want to point out that our R&D budget even though it is close to a billion dollars a year is less than 1% of global R&D and less than 20 new drugs are approved every year. So statistics are against you if you only focus internally. You need to focus externally. Internally you need the very good science that allows you as an organization to identify what that best molecule is."

John Martin, current Chairman and former CEO of Gilead Sciences from an interview with bcg.perspectives in November 2010

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1. Executive Summary

Gilead Sciences (GILD) is an USD 84.5 bn market cap[1] biotech company and one of the largest biopharmaceutical companies globally. Last year, GILD generated revenues of USD 30.4 bn and reached net profits of USD 13.5 bn realizing a 44% net profit margin.

My conviction for GILD is mostly based on the company's HIV segment. GILD has been an innovator for the treatment of this disease for years and is by far the most important provider of drugs to HIV patients. Given the lifelong treatment requirement, increasing life expectancy and a steady flow of new patients, GILD dominates a highly attractive market. This is specifically the case for the US where the company's drugs treat 3 out of 4 patients.

Based on my valuation, I bought this segment at eight times net profit, while ascribing little value to GILD's other revenue generating segments and the company's new product pipeline. For instance, my valuation of the company's other important segment HCV is 40% covered by expected 2017 free cash flow generation.

The major known risk emerges from GILD's HIV regimens becoming obsolete. However, GILD has proven more than once that they can make themselves redundant before the competition is able to. Management is currently demonstrating this with the successful conversion from older TDF based regimens towards recently introduced less toxic TAF based HIV regimens. Ten years from now HIV might have become a curable disease and GILD's revenue might have vanished. This scenario has already been reflected in the market value. Evidently, expectations for the HIV segment to continue to prosper are low.

Based on the latest forecast from a leading research house,[2] GILD will be the only top 20 pharmaceutical company with negative sales growth until 2022. The negative outlook seems to be fully reflected in the company's market valuation. However, in the pharma industry success and failure are closely related and today's high flying expectations for many potential blockbuster drugs will disappoint in the future. At the same time, seemingly unspectacular development programs will turn out to be highly effective game changers for the industry. I believe that the market ascribes a modest probability to the potential development of a third blockbuster franchise like for instance NASH, Cohn disease or rheumatoid arthritis. I expect GILD's focused strategy on a small number of therapies to continue to pay off in the future. I also consider current expectations for future HCV sales to be moderate.

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[1] I bought a 3.5% position for the portfolio on May 23, 2017 for an average price of USD 64.5 per share. With 1.31 bn shares outstanding this equals a USD 84.5 bn market cap. http://wertartcapital.com/2017/05/23/gilead-sciences-nasdaqgild/

[2] World preview 2017, outlook 2022 from Evaluate Pharma

Over the long term, management has a strong track record in generating value for shareholders. Recently there have been setbacks with untimely share buybacks and the market waiting for an in-organic play to boost the revenue outlook. Management might be less responsive to market claims than CEOs of similar sized US companies. However, I believe that they are acting for the long term benefit of shareholders.

A corporate action like GILD continuing its highly value creative acquisition path or the involvement of an activist investor might provide a catalyst for the stock price. In addition, insiders have recently reduced selling stock to a large extent. This might indicate that the share price has bottomed out now.

My analysis excludes an in-depth discussion of the prospects of any potential health care reform in the US. Without a doubt, this topic is of importance to the health care industry. I believe that uncertainty about future reforms has negatively affected the equity values of pharma companies over the last year. I also believe that the pharma lobby is very well positioned to fight for their economic benefit. It is also noteworthy that drug expenses compose only a fraction of total US health care spending. Therefore, significant reductions in prescription costs on its own will not solve the problem of an overblown US health care system. Companies like GILD that invest large amounts of capital in drug development require an adequate return on capital. According to Deloitte,[3] the average IRR for new drug development (including failures) ranged from 4% to 10% between 2010 and 2015 for a cohort of 12 large biopharma companies.[4] This does not seem to be excessive and therefore I believe that pharma companies will either be able to defend current drug pricing to a large extent or that the cost of developing new drugs, currently at an annual rate of USD 1.5 bn, will go down.

[3] Measuring the return from pharmaceutical innovation – Transforming R&D returns in uncertain times, Deloitte 2015

[4] The cohort includes Amgen, AstraZeneca, Bristol-Myers Squibb, Eli Lilly. GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Roche, Sanofi and Takeda.

2. Introduction

In 1996, a combination-based antiretroviral therapy first demonstrated durable, effective and sustained control of the human immunodeficiency virus (HIV). While the dosing was complex requiring the patient to take a handful of pills every day, within the next ten years, intense competition between drug companies led to the development of the first single daily pill regimens (STR). Since then, companies like GILD, GlaxoSmithKline and Merck introduced a number of products that also transformed the HIV infection from a fatal and debilitating disease into a chronic manageable condition. Today more than 18 m patients (roughly 50% of total prevalence) are receiving an antiretroviral therapy. With 10 m patients taking prescription drugs from GILD, the company is by far the largest provider of HIV drug regimens.[5]

With the acquisition of Pharmasset in 2011, GILD prepared for the entrance in the hepatitis C (HCV) market with a global prevalence of roughly 180 m people.[6] At the end of 2013, GILD was the first to launch a set of drugs that are able to cure HCV with a higher than 90% probability. The development and approval of these drugs marked an inflection point. For the first time, patients could rely on an effective and oral cure with limited side effects. So far Gilead HCV regimens treated 1.4 m patients successfully around the world.

The HIV and HCV segment make up more than 90% of Gilead's revenue. Both segments are driven by different economics - one treating patients with a chronic disease over a long time while the other provides a cure for a life-threatening disease within a couple of weeks.

[5] http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

[6] http://www.healthline.com/health/hepatitis-c/facts-statistics-infographic#3

3. The HIV segment

In 2016, GILD generated revenues of USD 12.8 bn (42% of total) from 8 marketed HIV drugs.[7] Roughly three quarter of revenue come from the US. The rest is mostly generated in the large five European markets including Germany, France, Italy Spain and UK.

HIV is a virus infection that can over time turn into acquired immunodeficiency syndrome (AIDS). AIDS is a condition in humans in which progressive failure of the immune system allows life-threatening opportunistic infections and cancers to thrive. Without treatment, average survival time after infection with HIV is estimated to be 9 to 11 years, depending on the HIV subtype. HIV infects vital cells in the human immune system such as CD4+ T cells. When CD4+ T cell numbers decline below a critical level, cell-mediated immunity is lost, and the body becomes progressively more susceptible to opportunistic infections.[8]

In 2015, roughly 36.7 m people were living with HIV globally and about 2.1 m people became newly infected. 1.1 m people died from AIDS-related illness. About 18.2 m people have access to antiretroviral therapy.[9]

3.1 HIV product portfolio and the conversion from TDF to TAF

The following table gives you an overview of sales per quarter for GILD's HIV products:

	Revenue in USD million	2014	2015				2016				2017
	Product	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
TDF-based	Truvada	897	771	849	903	936	898	942	858	868	714
TDF-based	Viread	311	234	271	297	306	272	287	303	324	260
TDF-based	Atripla	925	734	782	818	800	675	673	650	607	452
TDF-based	Complera Eviplera	348	320	367	360	380	381	368	411	297	253
TDF-based	Stribild	385	356	447	511	511	477	429	621	387	309
TAF-based	Genvoya	-	-	-	-	45	158	302	461	563	769
TAF-based	Descovy	-	-	-	-	-	0	61	88	149	251
TAF-based	Odefsey	-	-	-	-	-	11	58	105	155	227
	Total	2,866	2,415	2,716	2,889	2,978	2,872	3,120	3,497	3,350	3,235

In 2015 and 2016, three new GILD drugs were granted with marketing clearance by the FDA and EU Commission. The new coformulations Genvoya, Descovy and Odefsey are updated versions of

[7] Part of the sales stem from HBV medication where the same medication as for HIV is used.

[8] http://www.imshealth.com/en/thought-leadership/webinar-library/replay/prep-pipelines-and-payer-pressure-next-decade-of-hiv-treatment

[9] http://www.unaids.org/sites/default/files/media_asset/UNAIDS_FactSheet_en.pdf

Truvada, Complera and Stribild. They replaced *tenofovir disoproxil fumarate* (TDF) with *tenofovir alafenamide fumarate* (TAF).

GILD forestalled upcoming patent expiries of TDF in the EU in 2017 and the US in 2021 with the introduction of TAF. TAF based drugs need lower dosage and therefore provide for (i) smaller size tablets (ii) lower generic equivalent production costs and prices for low-income countries, and (iii) reduced kidney and bone toxicity. Overall, TAF seems to be a safer drug having a statistically superior bone and renal safety profile compared to TDF.[10]

Since patients are on HIV drugs for life, long term safety considerations are important. Given that half of HIV patients on antiretroviral treatment in the US and Europe are over the age of 50, physicians are looking for drugs that have minimal side effects for an aging population.

TAF is a *nucleotide reverse transcriptase inhibitor* (NRTI)[11]. NRTIs belong to a group of four important drug classes that have been developed for HIV treatment:

1. **NRTIs** was the first drug class to be discovered in 1987 and is still the backbone of HIV treatment. They block the reverse transcriptase enzyme. HIV uses reverse transcriptase to convert its RNA into DNA (transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.[12]
2. *Protease inhibitors* (**PIs**)[13] were discovered in 1995. PIs prevent the breakdown and reassembly of viral RNA[14] chains. PIs have drawbacks like side effects and they also require boosting. Without boosting, PIs would not work effectively against the virus. Boosting can negatively interact with other drugs[15]
3. *Non nucleotide reverse transcriptase inhibitor* (**NNRTI**)[16] were first marketed in 1996. NNRTIs are comparable to NRTIs but have a different binding site. They form an effective one-tablet combination alongside the NRTI backbone.
4. *Integrase inhibitors* (**INIs**)[17] have a significantly impact on survival times in combination with NRTIs. They were first launched in 2007. INIs stop HIV from being able to make integrase.

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[10] http://www.croiconference.org/sessions/significant-efficacy-long-term-safety-difference-taf-based-str-na%C3%AFve-adults

[11] Truvada (TDF) and Genvoya (TAF) from Gilead

[12] https://aidsinfo.nih.gov/understanding-hiv-aids/glossary/902/nucleoside-reverse-transcriptase-inhibitor

[13] Prezista (*darunavir*) from Jannssen Pharmaceutical and Reyataz (*atazanir*) from BMS

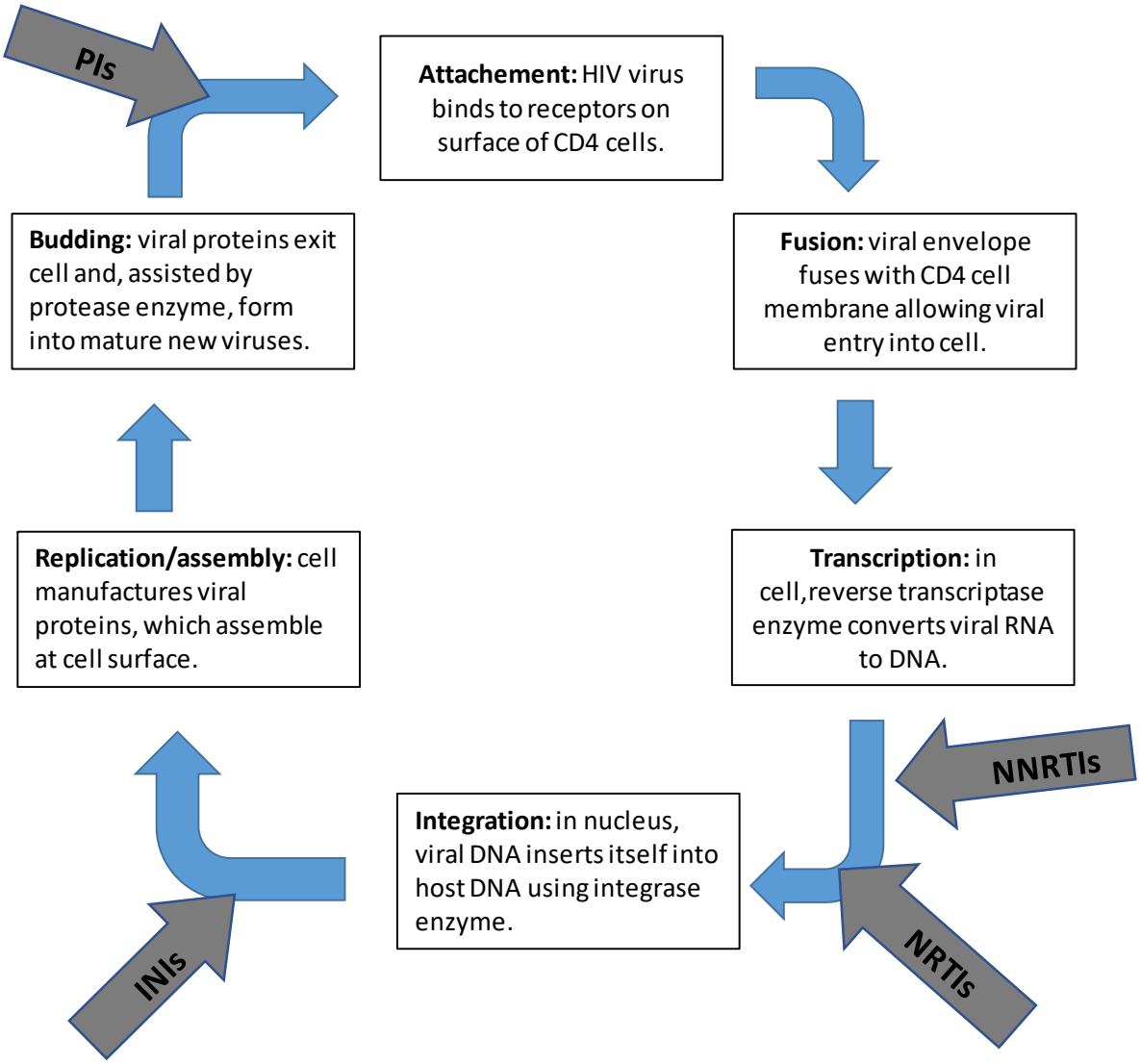
[14] RNA: Ribonucleic acid

[15] http://www.aidsmap.com/Protease-inhibitors-PIs/page/1060148/

[16] Intelence (*Etravirine*), from Janssen, Sutiva (*efavirenz*) from BMS and Edurant (*rilpivirine*) from Janssen

[17] Ticivay (*dolutegravir*) from ViiV, Vitekta (*elvitegravir*) from GILD and Isentress (*raltegravir*) from Merck

Without the help of this enzyme, HIV cannot take over the body's T-cells to copy itself. Until recently, INIs had to be taken either twice daily or with a boosting agent. ViiV Healthcare's[18] *dolutegravir* is the first INI that does not require boosting and can be safely taken once daily.



Source: IMS Health

[18] ViiV is an affiliate of GlaxoSmithKline

GILD combines different drug classes in its HIV regimens. The backbones are TAF (replacing TDF) and *emtricitabin*[19]*.* Odefsey combines the NRTI backbone with Janssen's NNRTI *rilpivirin.* Genvoya replaces Stribild, which uses the same combination except for TAF.

Drug classes	Odefsey	Genvoya	Descovy
NRTI	Emtricitabin, TAF	Emtricitabin, TAF	Emtricitabin, TAF
NNRTI	Rilpivirin	-	-
INI	-	Elvitegravir	-
Booster	-	Cobicistat	-
STR	Yes	Yes	No

So far GILD's TAF portfolio has achieved preferred status and inclusion in the treatment guidelines in the US and in four of the five major EU markets. This is important, because historically, payers and physicians have been following official treatment guidelines. Management anticipates to receive preferred status in France, the largest market after the US, until the end of 2017. At the same time, TDF-backed regimes have been downgraded from preferred to alternative status in many countries.

In addition, as the new TAF-based coformulations became available, GILD has been undercutting the prices for its existing TDF-based products. It seems that this is likely a strategy to retain market share before TDF goes off patent, as it will be more difficult to switch patients back to a generic version of a drug that they were previously tolerating well. However, GILD had already increased list pricing for the older regimes briefly before the introduction of the new TAF regimes.

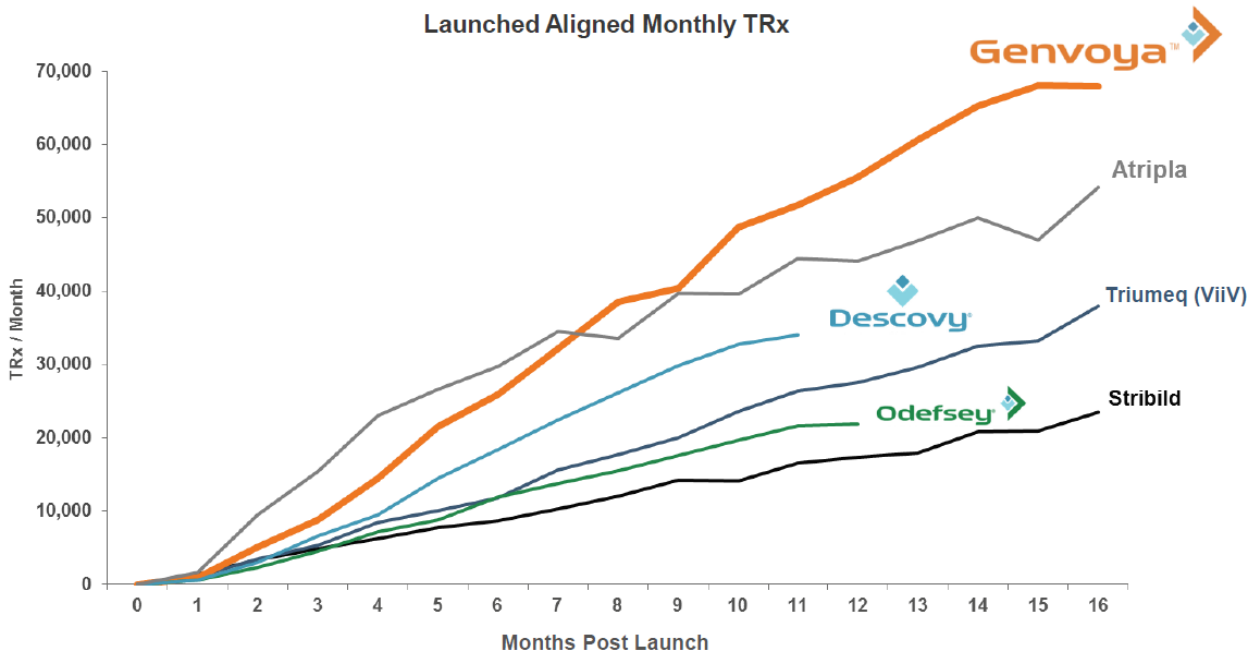
Following these marketing efforts, at the end of 2016, TAF-based regimens already made up 37% of GILD's HIV prescription volume in the treatment market.

According to management, most patients switch from GILD's older regimens to TAF based regimens due to the improved safety profile of TAF. Additionally, an estimated 10% of patient switches are coming from existing non-GILD therapies, resulting in incremental growth for GILD's HIV segment.

The chart below shows TAF portfolio uptake after product launch in the US relative to TDF regimes and ViiV Healthcare's *dolutegravir* based regimen Triumeq:[20]

[19] Emtricitabin is also used in Truvada.

[20] TRx/month: total prescriptions per month.



Source: Based on data derived from IMS NPA Monthly.

The patent for TDF will expire in the EU in 2017.This affects Atripla, Truvada and Viread. Consequently, GILD might lose patients who have not been transferred to TAF based regimens yet, as cheaper generics enter the market. From a pricing perspective, the normal impact of a generic entry is a big change from where the product has been before.

However, management has mentioned on several occasions that in particular for the old products like Atripla that are going to be off patent, the difference between current prices and potential generic pricing will be not that large. According to management, this is "just very unique" with the HIV market. Consequently, the patent cliff might be less severe than with other types of drugs.

In the case of Atripla the run off might have a positive effect on profitability anyway. GILD is paying royalties of one third of revenues from Atripla to Bristol-Myers Squibb (BMS). Consequently, there is an incremental upside on earnings with any patient switching from Atripla to TAF based regimens.

Moreover, for instance in the US due to deeply-discounted segments and the CPI-U penalties[21] that companies face over time, management believes that the HIV market has mostly been driven by patient volume. According to management, net pricing (listing prices less all kind of rebates) has

[21] CMS discourages manufacturers from what the government would deem to be excessive price increases by requiring manufacturers of single source and innovator multiple source drugs to pay an additional rebate for increases in AMP that outpace inflation. https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

deteriorated so much over time that generic competition will have a less severe affect than for other drugs.

Nevertheless, I believe that management is too optimistic in this regard. In particular for Truvada, I expect pricing to decrease by 50% once there will be generics available. Therefore, the acceptance of TAF based regimens by patients, physicians and payers is most important to keep GILD's HIV franchise alive. Given the market penetration of TAF based regimens so far, I think chances to accomplish that are very good.

3.2 Competitive landscape and industry characteristics

The HIV market has been consolidating to the hands of a few companies. Recent HIV research and development has been undertaken by only a handful of companies including ViiV Healthcare[22], Janssen Pharmaceutica[23], Merck, and GILD. Large drug manufacturers like Roche, Boehringer Ingelheim and BMS[24] withdrew from drug development as treatment guidelines have selected only the few best combinations.

GILD's HIV products mostly compete with ViiV Healthcare. ViiV's Triumeq has adversely impacted GILD's HIV sales recently. Nevertheless, GILD significantly outperformed ViiV based on average gross revenue (USD 1.2 bn vs USD 0.3 bn) over the last five years.[25]

An overview of the industry in terms of global revenue can be found below:

HIV segment of	**Revenue 2016** ***in million USD***	**Share in %**
Gilead	12,839	55.1%
ViiV Healthcare	4,623	19.8%
Janssen	2,496	10.7%
Bristol-Myers Squibb	1,977	8.5%
Merck	1,387	5.9%
Total	23,322	100%

[22] ViiV Healthcare is a JV formed in 2009 owned 78.3% by GlaxoSmithKline with Pfizer and Shionogi the other shareholders.

[23] 100% owned by Johnson & Johnson.

[24] In February 2016, BMS sold its HIV pipeline to ViiV Healthcare which includes a number of programs at different stages of discovery, preclinical and clinical development. The transaction excluded BMS's HIV marketed medicines. BMS receives up to USD 6 bn future tiered royalties if the products are approved and commercialized.

[25] According to IMS Health.

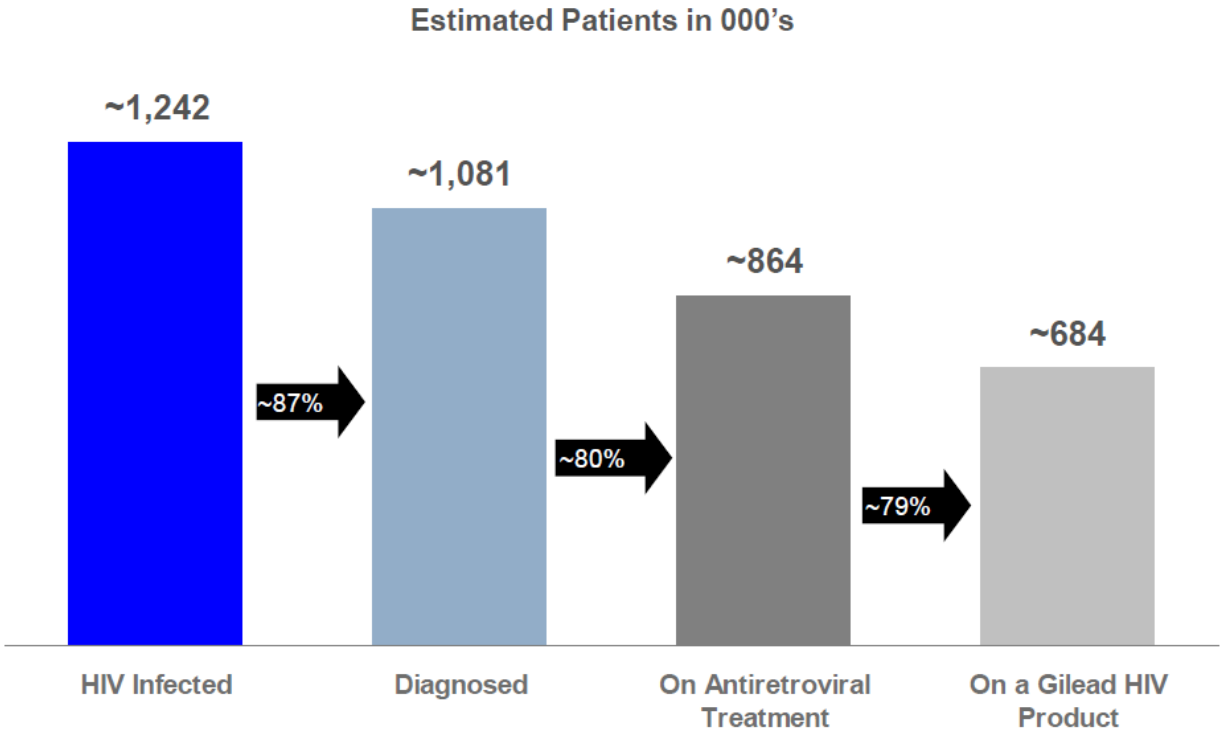
GILD's revenues include sales of Viread for hepatitis B patients. Hence, GILD's actual HIV-only sales are lower than presented in the table above. I assume that Viread sales for patients with HBV or HIV and HBV generate up to USD 1 bn in sales.

GILD's products are treating the bulk of HIV patients receiving antiretroviral therapy. The company has dominated the antiretroviral therapy for years due to the successful launch of STRs. As long as they can keep or extend this dominance they own a very attractive market. The only other company offering an STR is ViiV. Janssen and Merck are in a different position as they do not have a complete set of drugs of their own. In the past, they collaborated with GILD on different pipeline projects.

Taking into account that for instance a 20-year-old patient diagnosed with HIV today, when being treated with antiretroviral drugs, has a life expectancy of another 50 years, any new patient offers a highly predictive revenue stream over a long term period. There is also a trend to more aggressive treatment approaches with an increasing consensus to embrace immediate treatment of HIV[26] and treatment as a prevention approach. According to the Center for Disease Control and Prevention (CDC), the number of patients diagnosed with HIV in the US increased by roughly 3% per annum between 2010 and 2014. According to IMS Health, revenues from antiretroviral treatment grew by 10.5% per annum between 2011 and 2015.

[26] Regardless of CD4 count.

The vast majority of global HIV sales comes from the US.[27]Here, GILD's position in treating diagnosed patients who are on antiretroviral treatment is almost monopolistic. GILD product's have a market share of 79% in terms of patients treated:



Sources: CDC and Ipsos Healthcare HIV U.S. Therapy Monitor/Scope Q4 2016.

[27] Close to 75%.

GILD's dominance can also be seen from the table below. The company provides four out of the top five prescribed HIV regimes in the US:

Rank	Naïve	All Patients
1	Genvoya	Genvoya
2	Other STR	Atripla
3	Stribild	Other STR
4	Odefsey	Stribild
5	Complera	Complera

US Source: Ipsos Healthcare HIV U.S. Therapy Monitor/Scope Q4 2016.

Genvoya became the leader in prescriptions for both naïve and total number of patients within less than one year after product launch in the US. The "Other STR" is ViiV Healthcare single tablet regimen Triumeq.[28] Unlike Genvoya, Triumeq doesn't need a booster. Genvoya contains *cobicistat*, a booster (to provide for fast circulation of the drug) that interacts with many other medications. That is an important issue as with patients getting older, many of them need to take other medicine as well. However, Triumeq also has its disadvantages. It contains *abacavir*. There is still a lingering debate about whether *abacavir* increases the risk of heart attack. Current guidelines recommend avoiding abacavir (including Triumeq) if the patient has heart disease or a lot of risk factors for heart disease. Pre-screening for abacavir hypersensitivity is therefore a necessity before starting Triumeq.

[28] Triumeq is backed by *dolutegravir* a newly developed *integrase inhibitor.*

Consequently, each of the two STRs have drawbacks. Triumeq has *dolutegravir*, currently the best integrase inhibitor in the market, but it requires taking *abacavir*, which has some disadvantages over tenofovir, especially now that TAF is available. Genvoya on the other hand contains TAF, the best NRTI on the market, but requires the *cobicistat* booster, which has drug interactions.

Triumeq's revenue in the US in 2016, which was approved by the FDA in August 2014, was roughly USD 1.5 bn. Genvoya, which was launched at the end of 2015, reached revenues of roughly USD 1.3 bn in 2016.

Looking at the situation before the launch of Gilead's TAF backed regimes as of Q3 2015 provides the following picture:

Rank	Naïve	All Patients
1	Stribild	Atripla
2	Other STR	Stribild
3	Complera	Complera
4	Atripla	Other STR
5	Truvada + other 3rd Agent	Truvada + other 3rd Agent

US Naïve Source: Ipsos Healthcare HIV U.S. Scope Q3 2015.
US All Patient Source: Ipsos Healthcare HIV U.S. Monitor Q3 2015.

Note that in Q3 2015 the situation looked entirely different with Triumeq putting pressure on GILD's existing TDF regimens. With Genvoya being in the market for one year now, Triumeq has fallen behind and Genvoya seems to be able to foster GILD's leading position.

In Europe, at first glance the picture looks somehow differently:

Rank	Naïve	All Patients
1	Other STR	Other STR
2	Stribild	Eviplera
3	Eviplera	Atripla
4	Genvoya	Stribild
5	Truvada + other 3rd Agent	Truvada + other 3rd Agent

EU Naïve Source: Ipsos Healthcare HIV EU Scope Q4 2016.
EU All Patient Source: Ipsos Healthcare HIV EU Therapy Monitor Q3 2016.
*Europe-5 comprised of France, Spain, Italy, UK, and Germany.

Triumeq is dominating the market with Genvoya being almost non-existent. This is basically due to later launches of Genvoya in Europe than in the US. GILD just recently launched Genvoya in France and Italy. On the other hand, in Germany the conversion rate from TDF to TAF has already reached 60% as of Q1 2017. Hence, I expect the number of prescriptions to change in Genvoya's favor over the next quarters.

Triumeq's revenue in Europe in 2016, which was approved by the European Medicines Agency in September 2014, was roughly USD 0.5 bn.[29] Genvoya, which was still in the roll out phase in 2016, has reached revenues of roughly USD 0.2 bn during the same period.[30]

[29] Based on USD/GBP 1.3.

[30] Estimation based on TAF Regimes generating USD 0.3 bn in Europe out of 2.1 bn in total as shown in 10-K 2016.

3.3 Hepatitis B treatment as part of the HIV segment

Viread is also approved for the treatment of Hepattis B (HBV). Therefore, HBV is included as a sub segment in HIV. HBV infects more than 300 m people worldwide and is a common cause of liver disease and liver cancer. Recently, GILD launched an improved substitute for Viread called Vemlidy to treat chronic HBV adults with stable liver disease. Vemlidy is a TAF based regimen and the first new drug launch in nearly a decade to treat chronic HBV. It is also following GILD's Hepsera which lost patent protection in 2014 in the US. Comparable to HIV treatment, TAF based Vemlidy can be given at a lower dose than TFD based Viread thus resulting in improved renal and bone laboratory safety parameters.[31] I believe that like in HIV, the majority of patients will switch from Viread to Vemlidy. The current revenue from HBV is around USD 1 bn.[32]

3.4 Potential for strengthening competitive position with PrEP

With Truvada, GILD owns the only medication being FDA approved for pre-exposure prophylaxis (PrEP),[33] to reduce the risk of sexually acquired HIV infection in adults at high risk. People that face a high permanent risk of an HIV infection can take Truvada to reduce the probability of an infection.

At the end of the first quarter 2017, an estimated 125 k patients were using Truvada to prevent from HIV transmission in the US. This is an increase of more than 100% since the beginning of 2016. In comparison, 684 k diagnosed HIV patients were treated with a GILD drug in the US. Hence, the market for PrEP is already significant and offers further growth potential.

According to management, 90% of PrEP prescribing has come out of only five cities in the US in 2016. And these were not the cities where HIV is most pronounced. Recently, GILD installed a team working on increasing PrEP usage in other urban areas. Moreover, management is starting to see persistency that is similar to patients taking antiretroviral therapy for treatment.

Management believes that Truvada for PrEP will help to grow revenues from HIV in the U.S., as communities embrace the public health benefits of prevention. Currently, coverage from commercial payers is fairly good and the goal is to receive coverage from a number of public payers as well.

While patent protection will be lost in Europe in 2017, the Truvada patent will expire In the US in 2021. More than 95% of PrEP prescriptions come from the US. The introduction of competing PrEP

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[31] https://www.hepmag.com/article/gileads-hepatitis-b-treatment-vemlidy-safer-bones-kidneys-viread

[32] I do not know the exact number HBV revenue on a stand alone basis is not reported by management.

[33] https://www.drugs.com/newdrugs/fda-approves-truvada-reducing-risk-sexually-acquired-hiv-infection-3383.html

pharmaceuticals[34] poses a threat to Truvada to further grow sales in this sub market. GILD plans to extend its PrEP franchise by evaluating the potential of Descovy in a Phase 3 trial. If approved by regulators, the TAF-based regimen could provide an alternative to Truvada as an HIV PrEP therapy.

Despite being a relatively old drug having been approved in the US in 2004[35], due to increasing PrEP usage sales might hold up steady for some time despite the ongoing conversion from TDF to TAF:

Revenue in USD million	2014	2015				2016				2017
Product	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Truvada - total sales	897	771	849	903	936	898	942	858	868	714
Truvada - US only	548	409	500	561	587	576	631	573	604	464
% of total Truvada sales	61%	53%	59%	62%	63%	64%	67%	67%	70%	65%

3.5 HIV candidates under development

I have already outlined that Genvoya has an advantage and a disadvantage against ViiV Healthcare's Triumeq. Genvoya uses TAF which seems to be superior to Triumeq's usage of *abacavir.* On the other hand however, Triumeq's integrase inhibitor *dolutegravir* comes without a booster leading to less drug interaction.

Therefore, Gilead has been working on the development of a non-boosted INI to regain full leadership in the market. With *bictegravir* Gilead has a non-boosted INI in Phase III development. Recent results have shown *bictegravir* being non-inferior to *dolutegravir.* While market participants had hoped for superiority of *bictegravir,* I believe that a near term launch of a triple treatment including *bictegravir*, TAF and *emtricitabine* will in combination provide a superior HIV regimen compared to Triumeq.

However, ViiV Healthcare is currently working on a two drug-regimen. To date, HIV STRs consist of at least three different drugs. ViiV started this development process to find an alternative treatment which does not require the use of *abacavir*. While a two drug regimen might have a number of advantages like less drug-drug interactions and lower side effects it is not clear whether it might lead to an increase in patient resistance over a long period of treatment. Currently, ViiV is testing *dolutegravir* in combination with a NRTI and in combination with a NNRTI to develop the first two drug STR. Both testings are currently in phase III.

[34] http://i-base.info/htb/30828

[35] https://www.drugs.com/newdrugs/truvada-gilead-sciences-inc-hiv-infection-188.html

Also in phase III testing is ViiV's injectable regimen based on INI *cabotegravir.* The drug is closely related to *dolutegravir.* The company is currently testing the drug in combination with Janssen's *rilpivirine.* Another drug from Taimed for injection every two weeks has been granted with priority review from the FDA in June 2017. In addition, Merck's EFdA, a long-acting NRTI showed results that as an injectable it may maintain effective drug levels for up to 6 months.[36]

Still, an injection might be more inconvenient for many patients than taking a daily pill. In addition, any injectable drug will face strong competition from established oral STRs.

There is also a vast number of vaccines under development. However, there is still no breakthrough in eliciting effective immune response to the virus. This also includes a potential cure of the disease. However, until a breakthrough will be reached, PrEP might turn out to be a valuable substitute.

In summary, there will be a range of treatment alternatives on the market after 2020. However, it is important to note that existing treatments are already very good and that the incremental increase in effectiveness, safety and convenience is getting smaller and smaller.

3.6 Potential future HIV market shifts

Over the next years, I expect the market volume to grow, but at a lower rate than over the last years as effective and safe drugs have already penetrated the market to a large extend particularly in the US.

Over the mid to long term generics are likely to play a more significant role. There are some HIV generics available at the moment but they make very little impact in the US and Europe due to the large benefits of newer drugs. In 2021, there is an important shift when Atripla and Truvada will lose patent protection in the US. In the following year, the first TAF based combinations including Descovy and Odefsey will become open to generic challenge. In 2023, the first INIs will become available generically. That will be the first time that there is a real generic option on the market. Genvoya will keep protection until 2028/2029. The same applies to a *bictegravir*/TAF backed regimen.

At that point in time, treatment options will likely be greater than today with injectable drugs, possibly vaccines, and imaginably a cure available. However, I believe that the most important breakthrough with highly effective STRs and PrEP medicine has already been made.

Apart from that, new retroviral diseases might evolve that can be treated similar to HIV as it is the case with HBV treatment today.

[36] http://www.eatg.org/news/several-new-candidates-in-hiv-drug-pipeline-discussed-at-conference/
https://www.reuters.com/article/us-gsk-hiv-idUSKBN19Q0Y4

In summary, GILD might lose the dominance it has today over the next decade. However, I believe that their current and future drugs will shape antiretroviral treatment for quite a long time.

4. HCV segment

In 2016, Gilead generated revenues of USD 14.8 bn (49% out of total) from 3 marketed Hepatitis C (HCV) drugs.

HCV is a blood-borne liver disease caused by the hepatitis C virus. HCV belongs to the *Flaviviridae* virus family and is a communicable disease spread primarily through direct contact with the blood or the bodily fluids of an infected individual, including sexual and mother-to-child transmission. HCV infection normally does not produce signs or symptoms and, as such, most people who are infected do not know they have the disease.

Approx. 15% of infected individuals are able to clear the virus and are free from associated complications. The remaining 85% of individuals are at risk of developing hepatic fibrosis and complications associated with chronic infection, such as scarring, liver cancer, and liver failure. An estimated 20–30% of chronic HCV patients go on to develop cirrhosis, while 1–5% will develop liver cancer. Physicians categorize hepatic fibrosis by differentiating between five stages of the disease from patients with a fibrosis score of F0 (no fibrosis) to patients with a score of F4 (cirrhosis).

The HCV virus is variable and can be divided into seven types. Genotype 1 is the most common HCV genotype and is estimated to account for 83.4 m infections (46% of total), with wide geographical distribution, in Northern and Western Europe, Asia, North and South America, and Australia. HCV genotype 2 is mostly present in West and Central Africa, as its endemic place of origin. HCV genotype 3 is the next most common genotype after genotype 1 and accounts for 54.3 million (31%) cases globally, about 75% of these occur in south Asia. Genotype 4 is characteristic for the Middle East especially Egypt. Genotype 5 is present only in South Africa. Genotype 6 is endemic in South East Asia especially in Hong Kong and Southern China. Genotypes 2, 4, and 6 are responsible for the majority of the remaining cases of HCV worldwide after cases caused by genotype 1and 3, with an estimated 16.5 million (9%), 15.0 million (8%), and 9.8 million (5%) cases, respectively. To date, only one genotype 7 infection has been reported.[37]

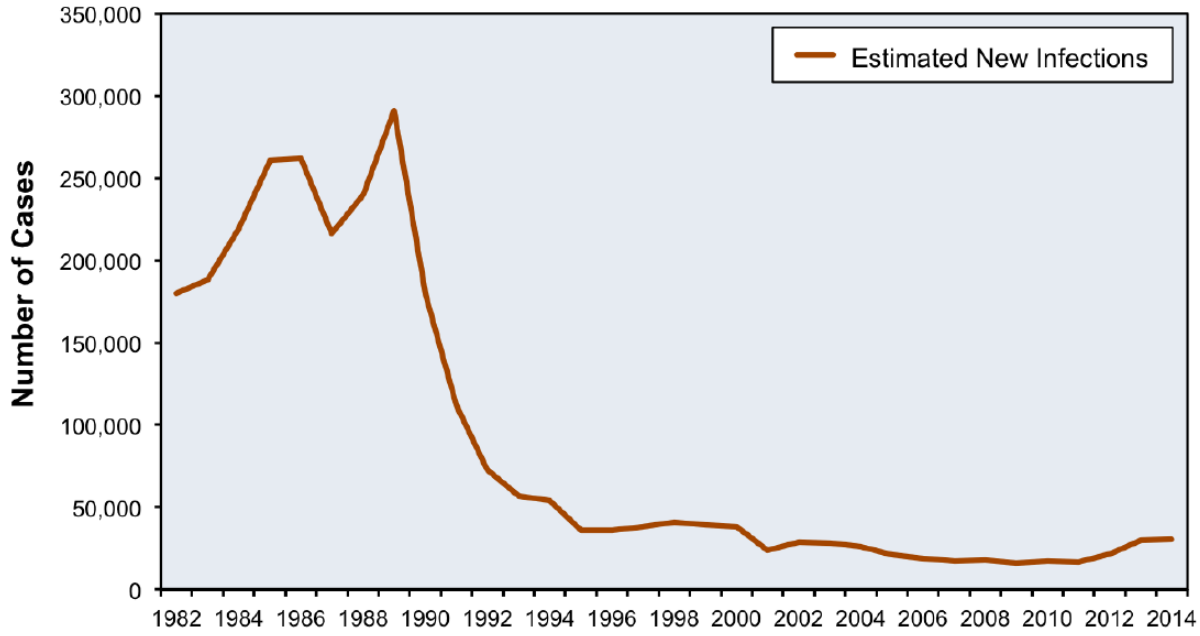
4.1 The entrance into a curative market

GILD was the first biopharma company to launch a direct-acting antiviral (DAA) with (i) the ability to cure around 90% of many patient populations, (ii) shortening treatment durations to only 24 weeks or even less with a once-daily single pill and (iii) almost eliminating severe adverse events for the patient.

[37] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4651911/

GILD's Sovaldi backed by the NS5B inhibitor *sofosbuvir* was the first to launch in 2013 shortly followed by Harvoni (a fixed-dose combination of *sofosbuvir* and *ledipasvir*). With the launch of Epclusa (*sofosbuvir* and *velpatasvir*) in 2016, GILD was eliminating some of the treatment complexity of the former drugs and provided a solution for patients that were formerly regarded as difficult to cure (mostly genotype 2 and 3 patients).

As shown in the chart below, estimated HCV infections reached its peak in the US in 1989 following a sharp decline over the next two decades[38]:



With the launch of Sovaldi and Harvoni there was a warehoused pool of older patients cued-up and ready for therapy in 2014 and 2015. They were given preferential treatment given the advanced live threatening state of the disease expressed in high fibrosis scores.

The following table gives you an overview of sales per product and per quarter since Q4 2014:

Revenue in USD million	2014	2015				2016				2017
Product	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Harvoni	2,107	3,597	3,608	3,332	3,345	3,017	2,564	1,860	1,640	1,371
Sovaldi	1,732	972	1,291	1,466	1,547	1,277	1,358	825	541	313
Epclusa	-	-	-	-	-	-	64	640	1,048	892
Total	3,839	4,569	4,899	4,798	4,892	4,294	3,986	3,325	3,229	2,576

[38] http://www.hepatitisc.uw.edu/pdf/screening-diagnosis/epidemiology-us/core-concept/all

The lumpiness of sales in the HCV segment is illustrated below:

Revenue per product in USD million

Product	Launch	Patent Expiry (US / Europe)	2013	2014	2015	2016	2017 guidance
Harvoni		2030/ 2030	-	2,127	13,864	9,081	n/a
Sovaldi		2029 / 2028	139	10,283	5,276	4,001	n/a
Epclusa		2032 / 2032	-	-	-	1,752	n/a
Total			139	12,410	19,140	14,834	7,500 to 9,000

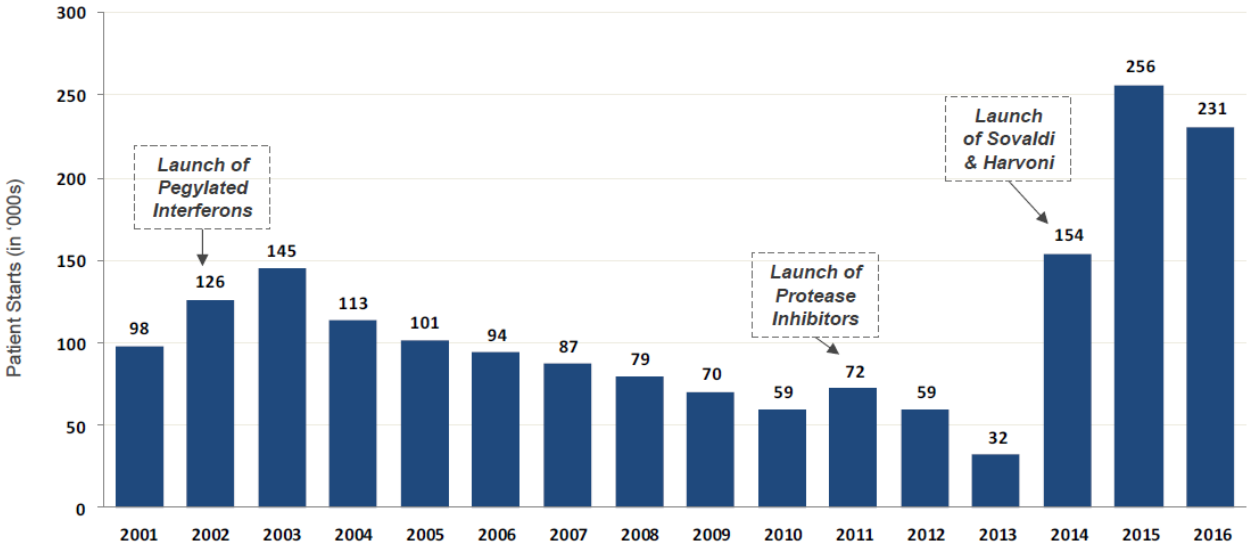
Sales went from zero to more than USD 19 bn in 2015 where they most likely reached their all-time high.[39] The volatility in sales results from the curative nature of HCV treatment.

Now, with many of high fibrosis score patients cured the profile of patients coming into treated care has changed. A greater number of patients have less advanced disease (fibrosis scores F0-F2). As the proportion of early disease patients increases the average treatment period decreases. In addition, patients with low fibrosis scores are less likely to get clearance from payer schemes. Management also expects a decline in market share due to increased competition from new HCV products that enter the market. Moreover, pricing pressures evolves from a shift in payer mix to more highly discounted payer segments and geographic regions and a decrease in the average duration of treatment as fewer patients are treated for 24 or 12 weeks and more patients are treated for 8 weeks.

As a result, revenues are trending downward with management's guidance for 2017 expecting revenues to decrease between 39% and 49% compared to last year.

[39] Harvoni was the drug generating largest sales globally in 2015 before AbbVie's Humira. http://www.imshealth.com/en/about-us/news/top-line-market-data

The table below shows the sharp increase in US patient starts after the launch of GILD's HCV medications at the end of 2013:



Since the second quarter of 2015, the number of new patient starts has diminished, and management expects patient starts to decline relative to 2016 in all major markets. GILD forecasts patient starts to decrease to between 150 k and 175 k in the US for 2017 (75 k to 85 k in Europe and 30 k to 40 k in Japan).

4.2 Modelling the value of GILD's HCV segment

According to management, it is extremely difficult to forecast the remaining market potential of the existing HCV regimens. I will give it a try anyway. In the following sections, I will forecast total patient starts, pricing and GILD's market share. Apart from treatment period, these are the main value drivers in a curative market. At the end of this chapter, I will come up with GILD's cumulative revenue prospect, that will lead to a valuation for GILD's HCV segment.

4.2.1 Patient starts

Worldwide, around 180 m people are estimated to suffer from chronic HCV. For GILD, the most relevant markets are the US, Western Europe, Japan and some countries with smaller HCV population like Canada and Australia.

In the US, management estimates that 3 m people are infected with HCV and 1.5 m diagnosed.

With many of the patients with high fibrosis scores having received successful treatment, this leaves a larger share of patients who have low fibrosis scores and thus there is less urgency for immediate treatment. Getting access to treatment for this patient group is more burdensome as insurance

companies and health care schemes tend to deny treatment for this group of patients.[40] For instance, management estimated that in the second quarter 2016 only 13% of US patients starting treatment had F4 fibrosis scores compared with more than 21% the year prior to that.

Apart from that, an increasing percentage of untreated patients faces circumstances that favor delay such as ongoing drug or alcohol use, co-morbidities or unstable living conditions. The US, countries in Western Europe and Japan are all exhibiting these characteristics with Southern Europe facing budgetary constraints and even more limited treatment of F0 to F2 patients. Going forward, this speaks for a lower number of patient starts.

On the other hand, access has improved, and almost all major commercial payers in the US are now providing open access to HCV treatment. Management estimates that up to 90% of all commercial covered lives have access without regard to fibrosis score. In terms of all new HCV treatment starts, approx. 55% come from the commercial payer system.

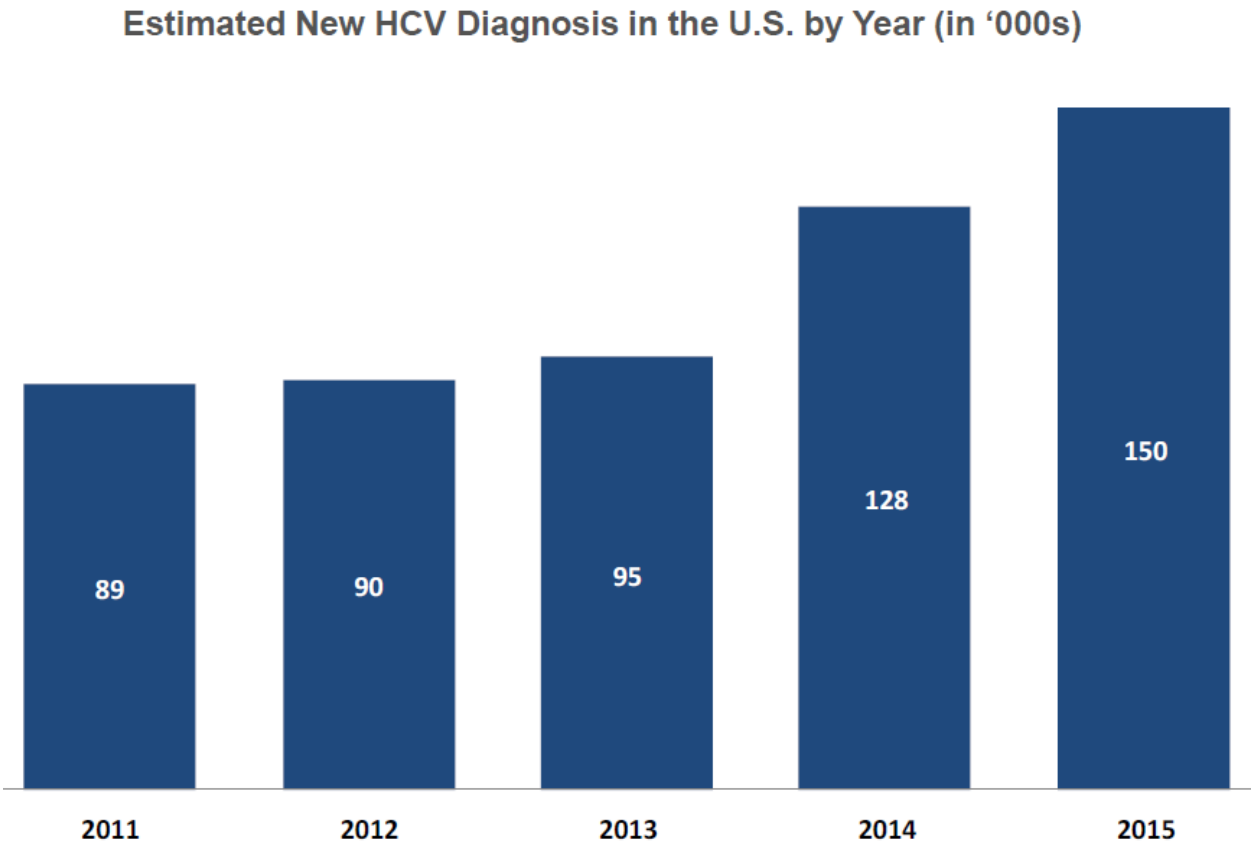
In addition, Medicaid remains the only payer segment where use is still generally restricted to the sicker patients. This is mostly due to the fact that Medicaid has relatively young members who will switch automatically to Medicare at some point in time. Hence, treatment might be postponed to a point in time when patients are aging from Medicaid to Medicare.

Despite recent successes in treating patients in the US and Europe, the disease is still affecting a large part of societies.

While the number of F3/F4 fibrosis score patients has declined since 2014 due to successful treatment, according to GILD still 42% out of the 1.5 m diagnosed HCV patients in the US were in an advanced state of the disease.

[40] https://www.hepmag.com/blog/hep-c-treatment-viekira-pak-helps-cure-hep-c-patient-denise-part-1

Moreover, new infections are on the rise again[41] and as the chart below shows new diagnosis in the US has increased:



Source: Analysis of Quest and Medivo lab data.
Projected data based on Quest and Medivo data capturing ~70% of lab tests.

According to management, heightened diagnosis is a consequence of more HCV testing over the last years. The advance in screening seems to be caused by the launch of curative drugs and GILD campaigning for HCV testing.[42] According to GILD, while the total number of diagnosed patients has grown, the proportion however of newly diagnosed HCV patients with F3/F4 fibrosis scores and therefore high treatment urgency has dropped from 51% in 2011 to 42% in 2015.

In summary, while new diagnosis will lead to a steady flow of patients who will need a cure at some point in time, the immediate urgency of treatment has slowed down with a smaller share of high fibrosis score patients. Much will depend on the progress that can be made to further simplify the

[41] https://www.bloomberg.com/news/articles/2017-05-11/new-u-s-hepatitis-c-infections-soar-to-15-year-high-cdc-says

[42] http://www.fiercepharma.com/marketing/baby-boomers-targeted-gilead-hepatitis-c-awareness-campaign-even-as-drug-s-fortunes-drop

access for patients with less advanced liver disease. Patients who are early in their disease have the highest cure rates and often require only eight weeks of treatment, resulting in lower costs per cure.

When estimating patient starts, I am using management's 2017 guidance as a reference point. Management's low end of the guidance for 2017 are 150 k patient starts for the US, 75 k for Europe and 30 k for Japan.

I can now model one scenario based on the following parameters:

1) For 2017, I assume that 15% of US patients with a F3/F4 fibrosis score and 5% of US patients with a F0/F2 fibrosis score will be treated.
2) For the remaining forecast period, I assume that 10% of total US patients with a F3/F4 fibrosis score and 5% of total US patients with a F0/F2 fibrosis score will be treated each year. I expect the portion of newly diagnosed HCV patients in the US with a F3 fibrosis score or higher to gradually decrease from 40% in 2017 to 32% over the next five years. At the same time, I expect the total number of newly diagnosed patients in the US to decrease from 150 k in 2017 to around 60 k within the next five years.
3) I extrapolate the US numbers to get to European patient starts. Both regions have similar patient characteristics.
4) Other countries including Japan, Australia and Canada will see a large drop in 2018 mostly due to a foreseeable decline in Japan after initial treatments of warehoused patients have been completed. In Japan, up to 40% of the remaining HCV infected population is over 80 years old and according to GILD often under the care of a general practitioner, who does not understand the importance of treating patients regardless of age. In Japan, there is also a low awareness of HCV and the fact that there is a cure among the general Japanese population. On the other hand, Canada for instance is approaching universal treatment for HCV[43] From 2018, I estimate that other country patient starts will make up 10% of US and Europe patient starts combined.
5) The forecast period goes from 2017 to 2030. I assume that GILD will lose patent protection for all HCV drugs in 2030.

Based on these assumptions, the following scenario evolves for patient starts in the major markets until 2030:

[43] https://www.hepmag.com/article/canada-moves-one-step-closer-universal-hepatitis-c-treatment

numbers in '000	2017		2018		2019		2020		2021		2030	
Diagnosed HCV patients US	**1,504**	100%	**1,513**	100%	**1,524**	100%	**1,512**	100%	**1,483**	100%	**972**	100%
thereof fibrosis F0/F2	917	61%	944	62%	970	64%	982	65%	982	66%	754	78%
thereof fibrosis F3/F4	587	39%	569	38%	554	36%	531	35%	502	34%	218	22%
New HCV diagnosis	150	100%	120	100%	96	100%	77	100%	61	100%	8	100%
thereof fibrosis F0/F2	90	60%	74	62%	61	64%	51	66%	42	68%	7	86%
thereof fibrosis F3/F4	60	40%	46	38%	35	36%	26	34%	20	32%	1	14%
Patient starts US	**146**	100%	**110**	100%	**109**	100%	**108**	100%	**106**	100%	**80**	100%
thereof fibrosis F0/F2	43	29%	47	43%	49	45%	50	46%	51	48%	41	52%
thereof fibrosis F3/F4	104	71%	63	57%	60	55%	58	54%	55	52%	38	48%
Patients starts US as a % of total	**9.7%**		**7.3%**		**7.2%**		**7.1%**		**7.1%**		**8.2%**	
Patient starts Europe	**75**	100%	**57**	100%	**56**	100%	**55**	100%	**54**	100%	**41**	100%
thereof fibrosis F0/F2	22	29%	24	43%	25	45%	26	46%	26	48%	21	52%
thereof fibrosis F3/F4	53	71%	32	57%	31	55%	30	54%	28	52%	20	48%
Patient starts other countries	**50**	100%	**17**	100%	**17**	100%	**16**	100%	**16**	100%	**12**	100%
thereof fibrosis F0/F2	15	29%	7	43%	7	45%	8	46%	8	48%	6	52%
thereof fibrosis F3/F4	35	71%	10	57%	9	55%	9	54%	8	52%	6	48%
Total patient starts	**271**		**184**		**182**		**179**		**176**		**133**	

Under this scenario patient starts will stabilize in 2018 at less than half the number of patients treated at the peak in 2015 and will then gradually decline by another 24% until 2030. Total patient starts until 2030 sum up to 2.3 m.

Estimating that there are around 6 m people infected with HCV in the US and Europe alone, this is not a large proportion to be treated. Hence, this scenario might for instance suggest that prices will stay high and that selective treatment continues. For F3/F4 fibrosis score US patients this implies a large remaining share of patients that do not ask for a treatment, receive alternative treatment, or do not qualify for treatment either due to health issues or missing coverage.

For Europe, the result might be at the low end of a realistic outcome. GILD has now agreements with 14 European countries in place, including four of the five major markets, that allow patient access regardless of disease severity. In France for instance the total spending is capped at EUR 0.7 bn per annum for HCV treatment. However, depending on pricing this opens access for 15 k to 30 k patients per year in France alone.

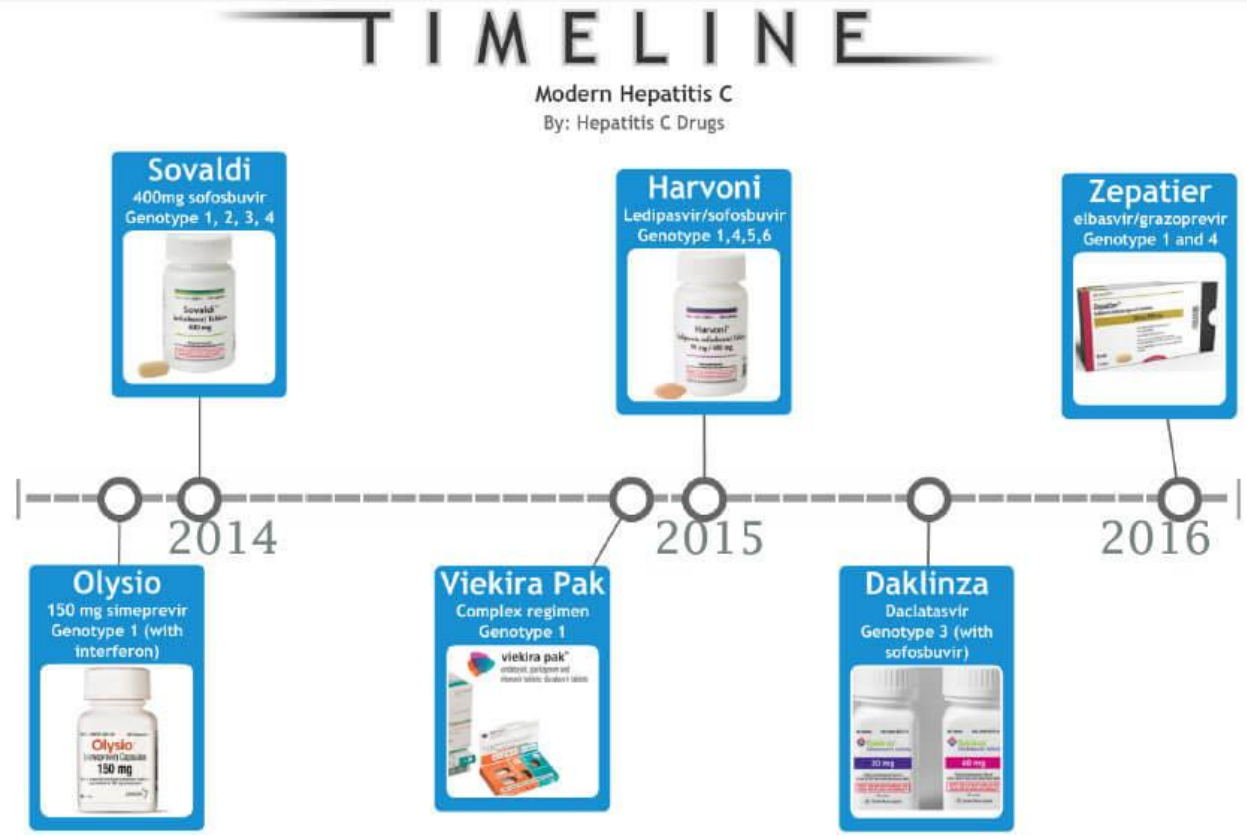
For the moment, I will leave it like that and will return to this variable, when I will have discussed the two other defining factors- market share and pricing.

4.2.2 Market share

Close to 90% of patient starts in the US included a GILD's HCV regimen since the advent of DAA's. In terms of global revenue in the HCV market, GILD holds a 76% share as of first quarter 2017:

Company	Products	Revenue *in million USD* / market share in %							
		Q1 2017		2016		2015		2014	
Gilead	Sovaldi / Harvoni / Epclusa	2,576	76%	14,834	80%	19,158	83%	3,839	60%
Bristol-Myers Squibb	Daklinza / Sunrepra / Beclabuvir	162	5%	1,578	8%	1,603	7%	256	4%
AbbVie	Viekira / Technivie	263	8%	1,522	8%	1,639	7%	48	1%
Merck	Zepatier	378	11%	555	3%	-	0%	-	0%
Johnson & Johnson	Olysio	n/a	0%	106	1%	621	3%	2,302	36%
Total		3,379	100%	18,595	100%	23,021	100%	6,445	100%

The chart below illustrates the launch dates of the most important medications in the market (apart from Epclusa which was launched in June 2016):



Differentiation in HCV drugs comes from cure rate, treatment duration, side effects, pricing and most predominantly the genotype the drug is used for. In the US, approx. 70% of chronic HCV infections are caused by hepatitis C genotype 1, 15% to 20% by genotype 2, 10% to 12% genotype 3, 1% genotype 4, and less than 1% genotype 5 or 6. Among the genotype 1 infections, approximately 55% are genotype 1a and 35% 1b.

Hepatitis C genotypes differ from region to region. In Japan, genotype 1b is most common. Genotype 3 is predominant in South Asia, including India and Pakistan, while genotype 2 is the most common

genotype in several Western African nations. There are also considerable numbers of people with genotypes 2 and 3 in China and genotype 2 in Russia; both countries with a large hep C population.[44]

Hence, apart from checking the viral load and the fibrosis score of a patient, a physician will also test for the genotype to identify the appropriate drug.

The following table provides an industry overview per medication in terms of the genotype that can be cured, cure rate and list prices:

Drug	Company	Genotype	Cure Rate[1]	Wholesale acquisition
Sovaldi	Gilead	1,2,3,4	84%+	USD 84 k
Harvoni	Gilead	1,3,4,5,6	95%+	USD 95 k
Epclusa	Gilead	All	98%+	USD 75 k
Daklinza	Bristol-Myers	1,2,3	90%+	USD 150 k[2]
Viekira	AbbVie	1	94%+	USD 83 k
Zepatier	Merck	1,4	94%+	USD 54 k
Olysio	Johnson & Johnson	1	91%+	USD 150 k[2]

1) Source: http://www.hepatitisc.uw.edu/

2) Daklinza and Olysio are paired with Sovaldi

As far as I understand, the only potential threat to GILD's HCV drug regimens in the current market is Merck's[45] Zepatier. Despite an additional test for genotype 1a patients required[46], the drug seems to be non-inferior to the best alternative treatment methods from Gilead for genotype 1 and 4 patients. The list price is lower for Zepatier than for competing medication. Still, Harvoni generated revenues in the first quarter 2017 that were more than 3 times larger than Zepatier's.

I believe that for the time being physicians have stayed with GILD's HCV regimens given their proven empirical success rate over the last years. Harvoni for genotype 1 is still the preferred drug to prescribe with an 8 and 12 weeks treatment available. According to management, Harvoni is about 50% of the patients that are using 8 weeks treatment in genotype 1.

Epclusa and Zepatier were both launched roughly at the same time. Still Epclusa revenues were more than two times larger than Zepatier's during the first quarter 2017. While Zepatier entered the

[44] http://www.hepatitisc.uw.edu/go/screening-diagnosis

[45] Please note that in December 2016, a jury found that Gilead willfully infringed a patent of Idenix Pharmaceuticals, Inc., which has since been acquired by Merck. This patent relates to any sofosbuvir-containing products through the expiration of Idenix's patent in 2021. Idenix might be awarded with up to USD 8.5 bn. It is however unlikely that this amount will have to be transferred by GILD in a process that might take many years. In addition, GILD was recently able to invalidate one of three patents in dispute.

[46] http://www.natap.org/2016/HCV/020516_07.htm

competitive sub market of genotype 1 patients, Epclusa on the other hand is the first pan-genotypic once-daily single-tablet option. Right now, Epclusa seems to be the best treatment option in the U.S. for an estimated 20% to 25% of HCV patients having genotype 2 and genotype 3. And equally across Europe, there are some countries that have up to 30% of patients with genotype 3. In this part of the market there has been little competition so far. In addition, patients with genotype 3 have more rapid disease progression.[47]

Beyond the recent approval of Epclusa, GILD has been working on a third single-tablet regimen that combines the two active ingredients in Epclusa with a third investigational compound, voxilaprevir. This combination known as Vosevi has recently been evaluated in four Phase 3 clinical trials among patients who have previously failed direct-acting antiviral treatments. It is also being studied for its potential to offer 8 weeks treatment duration for treatment-naïve patients of all genotypes.

On July 18, 2017 GILD announced that the FDA has approved Vosevi for the re-treatment HCV infection in adults with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. The approval is based on a 12 weeks treatment for patients without cirrhosis.

In summary, GILD seems to be a step ahead of competition first in DAAs, then in pan-genotypic cures and now for failed prior DAA treatment patients.

However, the current situation might be changing with AbbVie releasing another pan-genotypic cure consisting of *glecaprevir/pibrentasvir* (G/P) most likely this year. G/P seems to be at least non-inferior to Vosevi. In February, the FDA granted priority review status to G/P. With 8 weeks, G/P might have a shorter treatment duration than Epclusa with 12 weeks[48], specifically for those patients without F4 fibrosis score who have not been treated for HCV before. G/P is also intended to address the needs of patients with specific treatment challenges, including those with severe chronic kidney disease and those with failed prior DAA treatment.

Johnson & Johnson with its affiliate Janssen Pharmaceutica and Merck are behind GILD and AbbVie in getting new treatments to market. Both companies have new drugs in phase II trials. BMS has already dropped out of HCV drug development.

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[47] Apart from that, a major potential advantage for the future that Epclusa has to offer the global epidemic is the chance for a one-size-fits-all regimen that does not require genotype testing, which is expensive in many middle income and developing countries.

[48] Harvoni has an 8 weeks treatment period for naïve genotype 1 patients in place.

The launch of AbbVie's new drug regimen will result in more intense competition and GILD might feel more pressure even with Vosevi entering the market. GILD is currently not working on a more advanced HCV drug regimen as a follow up to Vosevi. I think that this makes sense given that HCV has become a curable disease and that existing drugs are working very well.

In addition to that, with increasing competition for patients coming into care whose nature is changing (i.e. less advanced fibrosis, co-morbidities, unstable living conditions and drug abuse) the return potential of the HCV market is diminishing. Therefore, the economics of developing superior drugs for smaller samples of patients having a curative disease is getting less attractive for incumbents and new entrants.

I expect GILD and AbbVie to provide the standard care in HCV curation going forward with Merck offering a potential alternative for a smaller set of patients. A fourth alternative might enter the market from Johnson & Johnson or Merck. However, this will take a couple of years from now. GILD has been the first mover and created the largest data by treating nine out of ten patients in the US.

In conclusion, I expect GILD's market share in terms of global revenue to stay above 40% and more likely to stabilize somewhere between 50% and 60%.

4.2.3 Pricing

Harvoni has become a standard care for naïve genotype 1 patients for 8 weeks treatment at more than 80% discount to list price in some public payer schemes (e.g. Medicaid) in the US.

Consequently, it will be interesting to see how AbbVie will price G/P in the market depending on whether they target to compete in the overall market including the well covered treatment of genotype 1 patients or whether they will focus on other genotypes and uncovered treatment indications. The later should led to less pricing pressure for the existing drugs.

Nevertheless, pricing pressure comes from payer schemes anyway. For most payer schemes list prices are of marginal importance given the large discounts that are negotiated. These discounts can reach 50%+ on the list price. Hence, while Merck put in place a much lower list price for Zepatier than the competition the price difference gets less pronounced when adjusted for discounts and rebates.

While GILD has been criticized for charging USD 1,000 for one pill of Sovaldi[49] this is getting less of an issue with prices falling. According to management, the volume-weighted average price for Harvoni was reduced to less than USD 15 k per bottle[50] inclusive of discounts and rebates in 2016.

[49] https://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html

[50] One bottle has 28 pills and provides treatment for 4 weeks or half the treatment period of a naïve genotype 1 patient.

The price goes down to less than USD 10 k in some states in the US where access is opened to all patients.

Apart from that, it is noteworthy that the opportunity costs of not treating fibrosis caused by HCV is usually higher than curing fibrosis at the current price level. Hence, for most patients or their payer schemes there is an economic benefit from curing the disease. According to this study[51], before the introduction of DAA's the lifetime cost of an individual infected with HCV was estimated to be at least USD 65k depending on life expectancy.

GILD's average global pricing per patient decreased by 20% from USD 45.1 k in 2015 to USD 35.9 k in 2016. In the US revenue per patient declined from USD 52.7 k in 2015 to USD 41.0 k in 2016 or by 22%. In Europe price reduction reached 13% from USD 32.5 k in 2015 to USD 28.3 k in 2016. In the US, about 45% of HCV patients are coming from the public and about 55% from the less price sensitive commercial payer schemes. Since the introduction of DAA's, there has been a shift in payer mix to more highly discounted payer segments which is likely to continue. In Europe pricing pressure comes from a shift from the patients in the north to the patients in the south, where prices are lower than they are in northern Europe.

Overall, I expect prices to further decrease over the forecast period.

4.2.4 HCV market volume until 2030

After discussing the major value drivers, I will now define the total HCV market volume from 2017 until 2030. This is simply a function of price and patient starts.

With lower pricing, more patients will be eligible for treatment until patent expiry. I expect the average price[52] from 2017 until 2030 to be in a range of USD 5 k to USD 20 k which implies a 44% to 86% reduction from global 2016 pricing.

I also assume that with each USD 5 k reduction in pricing the number of annual patient starts will increase by 500 bps starting from 15% of F3/F4 fibrosis score patients and 5% of F0/F2 fibrosis diagnosis at an USD 20 k average price. This goes up to 30% of F3/F4 fibrosis score patients and 15% of F0/F2 fibrosis patients at an USD 5 k average price.[53]

Up to now, more than 90% of GILD's revenue from HCV was generated in the US, Europe and Japan alone. However, there is a tipping point in pricing where middle income country governments will

[51] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3763475/

[52] For the US, Europe and other developed markets.

[53] To quantify the number of patients starts, I am using the model which I presented under 4.2.1

prefer direct access to Harvoni and Epclusa (among others) over cheap imitations. I think that this tipping point might be reached at a price of USD 2 k per treatment.

Globally, about 180 m people are infected with HCV. Assuming that half of them life in middle income countries and that a maximum of 20% will be cured with DAA's after reaching a price tag of USD 2k per treatment this could add 18 m patient starts until 2030. I assume that this pool of patients will be eligible, if the average price of an HCV treatment in the US, Europe and other developed countries reaches USD 10 k. In this case, I expect the cumulative market volume for middle income countries to be USD 18 bn until 2030.

I have now defined the total cumulative market volume. In terms of GILD's market share, the launch of competitive drugs will most likely give GILD a smaller piece of the pie going forward. Nevertheless, GILD has a stronghold position and with AbbVie's G/P being the only real competitor for many of the remaining patients who require either short term treatment (8 weeks or below) or special treatment (e.g. due to failed treatment, other than genotype 1), I believe that GILD will be able to grab a market share of 40% to 60% until patent expiry.

The following table summarizes the market potential of HCV treatment until 2030 and GILD's cumulative revenue share based on the different scenarios previously discussed:

Established markets including US, Europe and other countries like Japan, Australia and Canada			Middle income countries		Cum. Market volume	GLD cumulative revenue based on market share		
Avg price per treatment	Reduction from 2016 pricing	Patient starts	Avg Price per treatment	Patient starts	until 2030	60%	50%	40%
USD 20 k	44%	2.4 m	-	-	USD 48.9 bn	USD 29.4 bn	USD 24.5 bn	USD 19.6 bn
USD 15 k	58%	3.1 m	-	-	USD 46.6 bn	USD 28.0 bn	USD 23.3 bn	USD 18.6 bn
USD 10 k	72%	3.5 m	USD 2 k	9.0 m	USD 52.9 bn	USD 31.7 bn	USD 26.4 bn	USD 21.1 bn
USD 5 k	86%	3.7 m	USD 1 k	18.0 m	USD 36.4 bn	USD 21.9 bn	USD 18.2 bn	USD 14.6 bn

4.2.5 Resulting valuation of the HCV segment

After defining the revenue potential for GILD, I need to make three more assumptions to obtain a valuation for Gilead's HCV segment.

First, I assume the segment's net profit margin will be steady at 70%. This implies a higher proportion in costs of goods sold and selling, general & administrative expenses than in 2016 given lower revenue and therefore scale in the future. It also does not include research and development expenses for this segment as the launch of Vosevi should mark the end point of GILD'S HCV drug development. Net profit after tax will be 56% of revenue considering a 20% tax rate.

Second, I assume that cash conversion averages 100%. This is in line with historic numbers and a testament of Gilead's excellent earnings quality.

Third, I estimate a discount factor of 0.7 times. Over a total forecast period of 13 years (from 2017 to 2030) this might seem aggressive. However, most of the revenue will be frontloaded. For instance, I assume that revenues in 2017 will reach at least USD 7 bn according to management's guidance. That is already between 24% and 48% of total cumulative revenue depending on the three variables (average price, patient starts and market share).

The following table provides the result of this last step in modelling the value of GILD's HCV business:

NPV of GLD's HCV franchise varying by market share		
60%	50%	40%
USD 11.6 bn	USD 9.6 bn	USD 7.7 bn
USD 11.0 bn	USD 9.2 bn	USD 7.3 bn
USD 12.5 bn	USD 10.4 bn	USD 8.3 bn
USD 8.6 bn	USD 7.2 bn	USD 5.7 bn
Best case	**Base case**	**Worst case**
USD 11.6 bn	USD 8.7 bn	USD 5.7 bn

In conclusion, I arrive at a net present value of USD 8.7 bn for GILD's HCV franchise.

5. Other segments and new product development

GILD will spend between USD 3.1 bn and USD 3.4 bn on research and development of new drugs (R&D spending) in 2017. This is up to 17.0% of 2017 estimated revenue and 2.2% of global pharmaceutical R&D spending.[54] As of YE 2016, the research pipeline included 167 active clinical studies, of which 61 were Phase 3 clinical trials.

The two corner stones, liver disease and HIV receive the bulk of R&D spending with 31% and 27% respectively. Regarding liver disease, management has been moving away from HCV to testing drugs for non-alcoholic steatohepatitis (NASH) and to a smaller degree HBV. Management is also trying to establish franchises for inflammatory diseases and oncology. Both receive roughly 20% of R&D spending each. But first I will briefly turn to GILD's small cardiovascular segment before discussing GILD's other segments.

5.1 Cardiovascular

Outside of the major segments including HIV and HCV, GILD's top drugs are Letairis and Ranexa, which are used to treat cardiovascular diseases. Revenues from these two drugs were USD 1.5 bn in 2016 compared to USD 1.3 bn in 2015. Letairis loses patent protection in 2018 in the US and in 2020 in the EU. Ranexa loses patent protection in the US in 2019 and in the EU in 2023. R&D spending for development of cardiovascular drugs has been reduced substantially over the last years.

In total, I assume that this segment has an after tax net present value of USD 2.3 bn being generated by free cash for the two drugs until patent expiration less minor R&D spending.

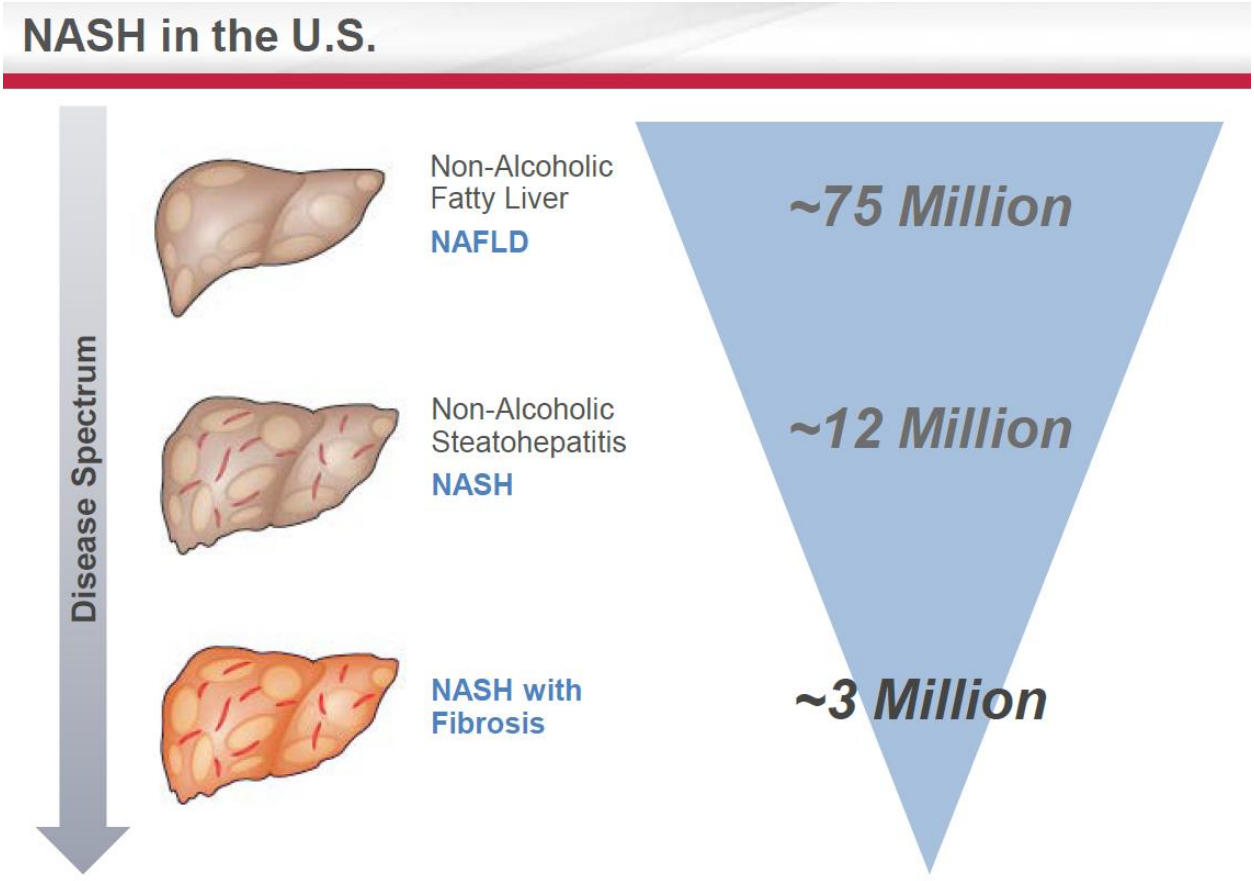
5.2 NASH

NASH is resulting from non-alcoholic fatty liver disease (NAFLD). NAFLD is a broad-spectrum condition that contains several disease states beginning with the accumulation of fat in the liver and ultimately progressing as far as cirrhosis. In this disease, hepatic fat accumulation, or steatosis, is not due to alcohol use, but rather, is caused by sedentary lifestyle, western diet, and genetic predisposition.

The clinical progression of NAFLD, begins with steatosis, leading to inflammation and fibrosis, cirrhosis, and eventually hepatocellular carcinoma (HCC) and/or hepatic failure in more advanced stages. Non-alcoholic steatohepatitis (NASH) is the second stage of NAFLD, characterized by inflammation.

[54] World preview 2016, outlook 2022 from Evaluate Pharma

So far, no treatment option for NASH has been developed. Management estimates that 2% to 3% of the US population are suffering from NASH with roughly one quarter having NASH with fibrosis and requiring urgent treatment. However, the number of NASH patients is likely to increase as already roughly 75 m are suffering from NAFLD which will turn for many of them into NASH. In addition, the number of people with NAFLD is likely to increase:

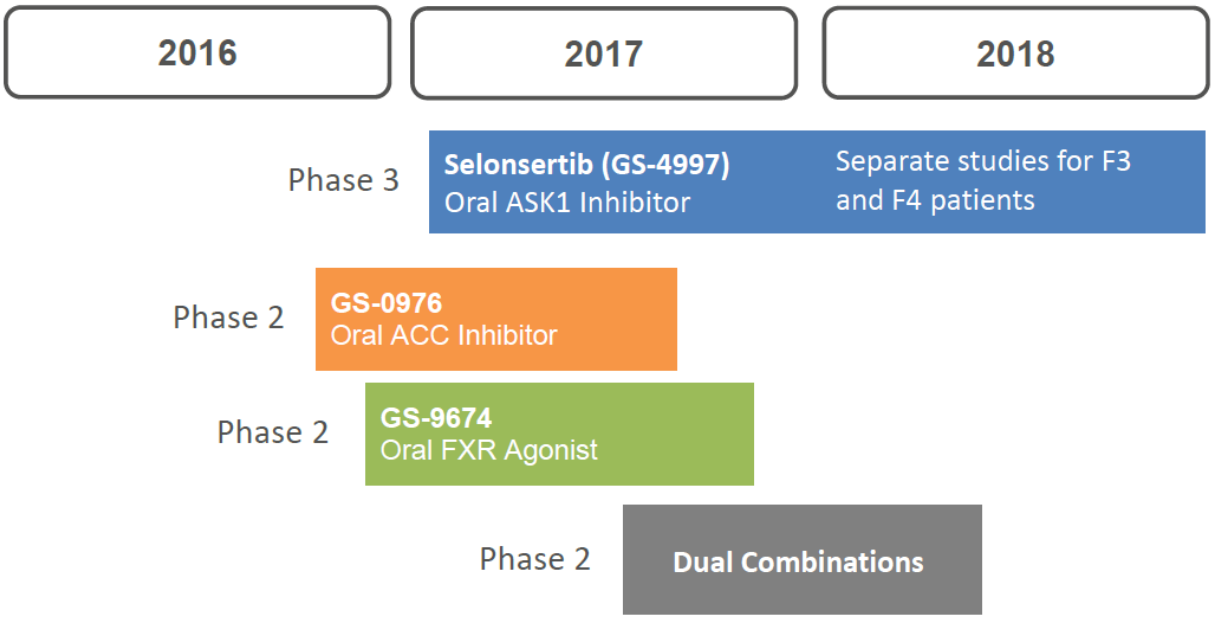


5.2.1 NASH development pipeline and competitive landscape

GILD has been focusing research mostly on the fibrotic (F3/F4) stage of the disease. For instance, the median survival for a NASH patient with cirrhosis (F4) is only five years. Management had high hopes for *simtuzumab*, but drug development was halted at the beginning of last year after disappointing results.

Currently, the company has two Phase III trials underway evaluating their ASK-1 inhibitor *selonsertib* in NASH patients with bridging fibrosis and cirrhosis. Major competitors in this area are Allergan[55] and smaller names like Conatus[56], Inventiva and Galectin.

Apart from that, GILD has two other medications in Phase II studies. They are also working on a combination therapy which is currently in phase II. Two out of the three substances currently under development were acquired through M&A and one was developed in-house.[57]



The absence of treatment on the market and the need to seek a treatment quickly, eliminates the need to prove in Phase III a greater effect than a drug already on the market. Hence, this improves the probability of obtaining approval once a developer reaches phase III. At the same time, unlike for other diseases, NASH will require a long-term treatment approach that will need to demonstrate efficacy and safety for a long period of time. At the moment, GILD's management like other participants in the market believe that any solution will be a combination therapy as NASH involves

[55] Allergan became a top NASH contender with its acquisition of Tobira Therapeutics and a deal with private Akarna Therapeutics in 2016 together for roughly USD 1.8 bn. Tobira was acquired at a 700% premium to market.

[56] Conatus recently signed a license agreement with Novartis.

[57] GILD acquired Phenex Pharmaceutical's NASH program in 2015 for USD 470 m and Nimbus Therapeutics NASH program in 2016 for USD 400 m.

multiple pathways. Also, the number of companies involved in this market has risen very fast over the last years.[58]

Therefore, I believe that GILD will enter into additional collaborations or acquisitions with smaller players that have promising drugs under development to identify a combination treatment. From an industry perspective Intercept and Genfit are the two companies that are leading the development of NASH drugs and they might present a beneficial contribution to GILD's NASH portfolio.[59]

5.2.2 Valuing the NASH pipeline

Due to the untapped nature of NASH treatment and the growing number of patient, the market potential is huge. Assuming that there is a similar number of NASH patients in Europe like in the US, this results in a patient pool of roughly 25 m. The introduction of NASH treatments will not only benefit the patients but might also reduce health expenses. The annual patient burden for each stage of NAFLD is substantial. Costs can range from a couple of thousand USD for patients with fibrosis to a couple of hundred thousand USD for those needing a liver transplant. Therefore, payer schemes might be willing to pay relatively high prices for drugs.

Unlike HCV, treatments for NASH will not cure the disease and patients might have to take the medicine for the rest of their life's. Assuming that 30% of NASH patients in the US and Europe receive treatment at an average cost of USD 5 k per patient, the annual market size will be USD 37.5 bn.[60]

Given that the market potential is large and no treatment has been approved so far, competition in development activity has increased rapidly over the last years. I counted 21 companies which have their substances currently being tested between phase I and phase III.

With GILD's former success in treating liver diseases and an untouched and enormous market potential for NASH, GILD's investment in this market is plausible. With the fierce competition for the first drugs being approved, it is impossible to predict who will be the main beneficiary. I believe that GILD has good chances to grab a 10% market share. Nevertheless, it seems unlikely for them to obtain the dominance they have for treatment in HIV and HCV.

At 10% market share annual revenue from NASH could reach USD 3.8 bn. Assuming that they own patent protection for ten years and that any treatment(s) will be approved in 2020 total revenue

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[58] Other big drugmakers with licensing deals or options on future deals in the space include Novartis, Merck, BMS and Janssen. In addition, there are more than 20 smaller companies currently working in this field.

[59] Genfit and Intercept are focusing on the metabolic dysfunction of the liver, whereas GILD has so far focused on fibrosis.

[60] This does not take into account any future growth in patient numbers.

could reach USD 37.5 bn over that period. At a 70% operating margin and 20% tax rate, this translates into USD 2.1 bn annual net operating profit after tax (NOPAT). Taking into account R&D expenses, discounting cash flows at 8% and assuming a 50% success rate NASH's NPV is roughly USD 3.6 bn.

in million USD	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
R&D spending	-1,054	-1,054	-1,054	-1,054										
Revenue				3,750	3,750	3,750	3,750	3,750	3,750	3,750	3,750	3,750	3,750	3,750
Operating profit	-1,054	-1,054	-1,054	1,887	2,625	2,625	2,625	2,625	2,625	2,625	2,625	2,625	2,625	2,625
NOPAT	-843	-843	-843	1,510	2,100	2,100	2,100	2,100	2,100	2,100	2,100	2,100	2,100	2,100
NPV @8%	-781	-723	-669	1,110	1,429	1,323	1,225	1,135	1,051	973	901	834	772	715
NPV success	9,294													
NPV failure	-2,173													
Success rate	50%													
NPV NASH	**3,561**													

5.3 Oncology

GILD's only current drug within oncology is Zydelig, which is used for the treatment of certain blood cancers. Zydelig had sales of USD 168 m in 2016 compared to sales of USD 132 min 2015.

5.3.1 Oncology pipeline

Cancer treatment is an area GILD hopes to further diversify in. 20% of annual R&D spending are currently allocated to this segment. Recently, Alessandro Riva joined from Novartis. Mr. Riva spent 12 years at Novartis where he led the development of more than 20 cancer drugs.[61]

GILD currently has seven clinical trials involving cancer drugs, with two in Phase III. The company is testing a substance for relapsed refractory chronic lymphocytic leukemia and a substance for gastric cancer in phase III development.

So far results have been mixed and there have been a number of setbacks. For me this is a black box with a certain degree of optionality. With the hiring of Alessandro Riva, I expect this segment to receive even more resources in the future than it is already the case. Oncology is a very attractive field for new drug development, but it is also crowded with large drug developers.

5.3.2 Valuing the oncology segment

I keep it simple and assume that any profit from current / future drugs will be absorbed by development costs. Therefore, I attribute a zero value to this segment. To assume that one of the new segments will tumble is highly likely given the high failure rates in drug development.

[61] https://pharmaphorum.com/news/gilead-hires-novartis-oncology-specialist-riva/

5.4 Inflammation

Like in Oncology, GILD is working on establishing a franchise in inflammation / autoimmune diseases. They are allocating 20% of total R&D spending to this segment in 2017.

5.4.1 Inflammation pipeline

Filgotinib, a JAK 1 inhibitor[62], is the most important substance in this segment being tested in a wide variety of autoimmune indications including Crohn disease and rheumatoid arthritis.

Filgotinib has been developed by Galapagos, a Belgian biotech start-up. In December 2015, GILD and Galapagos announced a partnership on filgotinib in which GILD payed USD 300 m in cash and made an USD 425 m equity investment in Galapagos. In addition, GILD committed to up to USD 1.35 bn in milestones payments split approx. between USD 750 m in development and USD 600 m in sales milestones.

Interestingly, AbbVie handed back their rights in filgotinib to Galapagos in September 2015 and GILD took the opportunity to enter into an agreement with Galapagos one year later. As far as I can see, AbbVie has a comparable in-house substance and they decided to focus on that one. AbbVie also owns Humira the top selling drug for treatment of RA and might want to preserve its Humira franchise for as long as possible. In addition, at the time of AbbVie's retreat positive phase II results for the treatment of Crohn's disease were not known.

Currently, filgotinib is being tested in phase III as an oral treatment for Crohn's disease and Ulcerative Colitis. The phase 2 study of filgotinib in Crohn's met the primary endpoint of showing significantly higher clinical remission compared to a placebo with a good safety profile and less side effects than comparable enzymes (JAK2 and JAK 3).

Ulcerative Colitis is a gastrointestinal disease that is localized to the large intestine, or colon, where inflammation can affect either the entire organ or a portion of it. Approx. 1.9 bn patients have been diagnosed with UC globally.

Crohn's disease can affect any part of the gastrointestinal tract, but most commonly involves both the large and small intestines. Although Crohn's disease is more severe than Ulcerative Colitis, the global prevalence is much lower, with only 1.3 million patients diagnosed.[63]

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[62] The JAK family of enzymes (JAK1, JAK2, JAK3 and TYK2) is a group of intracellular kinases that allow receptors on the cell surface to signal inside the cell. Inhibition of these enzymes with JAK inhibitors is associated with modulation of the immune system and hence these drugs have application in a variety of autoimmune diseases.

[63] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4123809/

Filgotinib as part of the oral JAK class could also become an alternative treatment option for Rheumatoid Arthritis(RA) patients, many of whom do not respond to current treatments. JAK inhibitor for RA treatment can be taken orally, rather than through injection. This brings more convenient delivery to the patient than available drugs on the market.

The first and so far, only JAK based RA treatment is Pfizer's Xeljanz. Despite being associated with infections and liver toxicity, revenues reached USD 927 m in 2016. The launch of further JAK inhibitors in the coming years should expand this class of treatment. Eli Lilly and Incyte's *baricitinib* has already shown clinical superiority over the market leader Humira. Apart from that, GILD / Galapagos and AbbVie have JAK inhibitors for RA treatment in phase III testing.

5.4.2 Valuing the inflammation segment

Traditional therapies have yielded roughly USD 4 bn in global annual sales for Ulcerative Colitis and USD 3 bn for Crohn's disease.[64] With an effective drug coming to the market, I assume that global sales volume from both diseases will grow to USD 8 bn annually. At 30% market share annual revenue from Ulcerative Colitis and Crohn's disease could reach USD 2.4 bn. Assuming that patent protection will last for ten years and that any treatment(s) will be approved in 2020 total revenue could reach USD 24 bn over that period. At a 70% operating margin and 20% tax rate, this translates into USD 1.3 bn of annual net operating profit after tax. Taking into account half of R&D expenses allocated to the inflammation segment, discounting cash flows at 8% and assuming a 50% success rate the NPV is roughly USD 3.0 bn.

in million USD	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
R&D spending	-340	-340	-340	-340										
Revenue				2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400
Operating profit	-340	-340	-340	1,442	1,680	1,680	1,680	1,680	1,680	1,680	1,680	1,680	1,680	1,680
NOPAT	-272	-272	-272	1,154	1,344	1,344	1,344	1,344	1,344	1,344	1,344	1,344	1,344	1,344
NPV @8%	-252	-233	-216	848	915	847	784	726	672	623	576	534	494	458
NPV success	6,776													
NPV failure	-701													
Success rate	50%													
NPV Crohn / UC	**3,037**													

The total annual market size of anti-rheumatics is roughly USD 50 bn and expected to grow by 2% per annum.[65] At a 3.5% market share and 20% of revenues attributable to Galapagos annual revenue from RA could reach USD 1.4 bn. Assuming that patent protection will last for ten years and that any treatment(s) will be approved in 2020 total revenue could reach USD 14 bn over that period. At a

[64] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4123809/

[65] Evaluate Pharma August 2016

70% operating margin and a 20% tax rate, this translates into USD 0.8 bn of annual net operating profit. Taking into account half of R&D expenses allocated to the inflammation segment, discounting cash flows at 8% and assuming a 50% success rate the NPV is roughly USD 1.4 bn.

in million USD	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
R&D spending	-340	-340	-340	-340										
Revenue				1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400
Operating profit	-340	-340	-340	742	980	980	980	980	980	980	980	980	980	980
NOPAT	-272	-272	-272	594	784	784	784	784	784	784	784	784	784	784
NPV @8%	-252	-233	-216	436	534	494	457	424	392	363	336	311	288	267

NPV success	3,602
NPV failure	-701
Success rate	50%
NPV RA	**1,451**

This brings the combined value of the inflammation segment to USD 4.5 bn.

5.5 Validating the valuation of GILD's drug pipeline

I have now put together a value for GILD's pipeline excluding HIV and HCV. The valuation only includes the most promising drugs excluding many phase I/phase II molecules currently being tested as well. In combination, the drug pipeline has a value of USD 8.1 bn.[66] To substantiate this valuation, I use a research piece from EvaluatePharma[67]. In this study EvaluatePharma provides a valuation of the ten most valuable pipelines as of August 2016:

Value Creators: Top 10 Pipelines NPV, $m

Rank	Company	Pipeline NPV, $m
1.	**Roche**	43,171
2.	**Novartis**	24,091
3.	**AstraZeneca**	23,160
4.	**Eli Lilly**	19,677
5.	**AbbVie**	19,364
6.	**Pfizer**	18,214
7.	**Sanofi**	17,699
8.	**Celgene**	16,246
9.	**Biogen**	13,621
10.	**Johnson & Johnson**	13,157

Unfortunately, they do not provide their assumptions. So, I have no idea what discount rate, success rate or product lifetime they used. This narrows the comparability to my valuation of GILD's pipeline.

[66] NASH: USD 3.6 bn; Inflammation: USD 4.5 bn.

[67] World preview 2016, outlook 2022, http://www.evaluategroup.com/public/EvaluatePharma-Overview.aspx

Nevertheless, I think it is still helpful to compose some ratios that can indicate whether my valuation is adequate.

Pipeline NPV in relation to annual R&D spending and pipeline NPV in relation to market capitalization should be conducive in this regard.

Annual 2016 R&D spending for the peer group ranges from USD 8.7 bn in the case of Roche to USD 2.0 bn for Biogen. Pipeline NPV in relation to R&D spending ranges from 6.8 times for Celgene to 1.9 times for Johnson & Johnson. The average is 4.1 times and the median is 4.1 times. I have valued GILD's pipeline at 3.2 times 2017 R&D expenses (adjusted for R&D expenses allocated to HIV).[68] Provided that the underlying assumptions regarding NPV calculation are comparable, this translates into a discount of 23% to the peer group. However, the top ten pipelines as shown in the table above obviously prefer the winners. Consequently, for the industry as a whole the multiple might be lower.

Pipeline NPV in relation to market cap as of August 2016 ranges from 9.0% for Pfizer to 27.4% for AstraZeneca. The average is 17.9% and the median is 18.5%.[69] Based on my valuation, GILD's pipeline composes 9.5% of GILD's market cap as of the time of my investment. This excludes the product pipeline in HIV. While Evaluate Pharma is not providing a NPV estimate for GILD's pipeline as a whole, they recently prepared an estimate for GILD's most promising phase III HIV regimen (*bictegravir*, TAF and *emtricitabine*).[70] Including their valuation of GILD's new HIV STR of USD 7.2 bn the ratio advances from 9.5% to 18.1%.

As already mentioned it is difficult to say whether this makes sense without knowing the underlying assumptions. However, the results of this exercise at least indicate that GILD's pipeline valuation should be at the lower end of the average pharma company.

[68] Management expects to allocate 27% of R&D to HIV development in 2017.

[69] I have excluded Johnson & Johnson from the sample as its market cap is also reflecting a large chunk of other businesses outside pharma.

[70] World preview 2016, outlook 2022, http://www.evaluategroup.com/public/EvaluatePharma-Overview.aspx

6. Management

John Martin[71], the current chairman and former CEO, John Milligan, the current CEO, and Norbert Bischofberger, the Chief Scientific Officer, all joined Gilead in 1990. Hence, the pillars of the current management team have been in place for almost 30 years. Over their tenure the stock price has risen by more than 10,000%. Without a doubt, they have done many things right.

6.1 Evaluating management's capital allocation decisions

Two capital allocation decisions made by management in the past stand out as being highly value creative.

First, the acquisition of Triangle Pharmaceuticals in 2003 for USD 0.5 bn. This transaction played a major role in creating the HIV segment as it presents itself today. Triangle brought in an important component for the development of successful drugs like Atripla and Truvada.

Second, the acquisition of Pharmasset for USD 11 bn assisted significantly in the evolution of today's HCV segment. While a good portion of these achievements can be attributed to luck, it also implies that management has a good skillset in identifying attractive acquisition targets.

However, over the last years management also destroyed value for shareholders due to poorly executed capital allocation.

Over the last three years, the company generated free cash flow from operations of USD 47.7 bn. This equals an astonishing 38% of GILD's market cap at yearend 2013. Nevertheless, the share price is back at the same level where it started three and a half years ago.

Management was eager to return cash to shareholders as soon as possible. At first glance, this will be in line with shareholder interests, if there are no investment opportunities with an adequate return on capital available. So, management spent USD 26.4 n to repurchase 287 m shares at an average share price of USD 92 from 2014 to 2016. This equals 18% of shares outstanding at yearend 2013. With the share price trading now in the low seventies, timing of the repurchase decision has turned out to be unfortunate.

[71] https://www.bcgperspectives.com/content/videos/biopharma_medical_devices_technology_innovation_creating_value_through_innovation/

Even worse, now with the share price being down, the company has slowed down share repurchases as well. In the first quarter 2017, they spent only USD 0.5 bn or 94% less on stock repurchases than during the same period last year despite the share price trading 25% lower.[72]

Apart from that, management has been criticized for limited M&A activity since the Pharmasset acquisition. According to Bloomberg[73], only one large pharma company has spent less money on acquisitions than GILD since the firm announced the acquisition of Pharmasset in 2011. While the average pharm company[74] spent USD 15 bn on 36 licensing agreements and 25 acquisitions, GILD spent only USD 2 bn on 13 licensing agreements and 7 acquisitions.

As a result, GILD has a drug pipeline which consists of two to three blockbuster candidates outside of HIV and HCV[75]. The focus on in-house product development and very strict acquisition criteria fatigued market participants. For instance, two years ago when the share price reached a peak of USD 120, shares could have been used to finance a deal at more attractive conditions than today.[76] New drugs except for HIV / HCV are not expected to launch before 2019. Consequently, management has not been able to deliver a substitute that compensates for falling HCV sales. However, I believe that the recent punishment expressed in the falling stock price is overdone and that management has still significant leeway in enhancing the pipeline as many potential candidates to strengthen the pipeline are still available at reasonable prices.

6.2 Management Compensation

Not only long term shareholders profited handsomely from the development of the business. Also, the management team was able to realize an enormous profit. The basic salary of the management is in line with its peers. However, many members of the management team have become very wealthy due to the exercise of stock options.

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[72] In 2015, the company started to pay dividends and the stock currently yields 3%.

[73] https://www.bloomberg.com/gadfly/articles/2017-05-31/gilead-cancer-drug-m-a-muddying-the-waters

[74] Sample including Janssen, Pfizer, AbbVie, Novartis, Merck, AstraZeneca, Glaxo, Roche, Celgene, Amgen, BMS, Eli, Biogen, Sanofi, GILD and NovoNordisk.

[75] Namely filgotinib and a combination treatment for NASH.

[76] While GILD shares lost 42% of their value since reaching an all-time high in July 2015, the I shares NASDAQ Biotechnology ETF lost only 23%.

Since 2012, the company issued 114 m shares under its equity incentive plan. From 2012 to 2016, the three top executives acquired 16.1 m shares on the exercise of stock options with a total value of USD 1.0 bn[77].

The following table summarizes insider selling for the years 2015, 2016 and until June 5, 2017 almost entirely resulting from the exercise of stock options:

Insider selling	Total amount sold *in USD m*	Avg share price realized *in USD*	Number of shares sold *in m*
2017 YTD	35.5	69.3	0.5
2016	174.2	84.8	2.1
2015	429.9	106.6	4.0

For instance, the current Chairman and former CEO, John Martin, sold 1.9 m shares realizing USD 190 m just in 2015 from option exercising. To my knowledge, insiders have not bought shares directly in the market during this period. Insider selling has slowed down since 2015.

Option awards as of December 2016 for the CEO, John Milligan, are summarized in the table below:

	Option Awards(1)			
Name	Number of Securities Underlying Unexercised Options(1) Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price(2)	Option Expiration Date
John F. Milligan	320,000	—	$ 21.58	1/30/2018
	80,000	—	$ 27.07	5/7/2018
	280,000	—	$ 23.60	1/21/2019
	280,000	—	$ 23.76	1/28/2020
	384,000	—	$ 19.09	1/20/2021
	302,500	—	$ 24.30	1/26/2022
	140,268	9,352	$ 40.56	2/1/2023
	44,625	20,285	$ 80.65	2/1/2024
	30,752	39,538	$ 104.83	2/1/2025
	—	235,820(4)	$ 84.05	2/1/2026
	—	—	—	—
	—	—	—	—
	—	—	—	—

[77] Defined as the difference between stock price and exercise price at the time of exercise.

John Milligan's exercisable options have to a large degree exercise prices that are well below the current share price. The characteristics of the CEO's option awards are similar to those of his executive colleagues. In total, insiders were holding 6.0 m of exercisable options with an exercise price of less than USD 40 per share as of YE 2016. At a share price of USD 70 (as of the beginning of 2017) and an average exercise price of USD 25 the total realizable value is USD 276 m.

In comparison to that, less than 10% of these exercisable options have been exercised and shares sold to date. It is also noteworthy that 88% of options turned into shares and sold to date were coming from the Chairman John Martin. At the same time, he was only holding 51% of exercisable options with an exercise price below USD 40 per share at yearend 2016. The current Chairman is 64 years old and he might already prepare for retirement, which might explain part of the motivation for his disproportionately high insider selling.

Consequently, I believe that insiders have become more optimistic with regard to future share price performance. With insider selling slowing down despite of a large number of exercisable options at relatively low exercise prices, I see this as an indication of the stock price bottoming out.

At the same time, managements huge realized compensation packages imply to question their motivation to continue the mostly excellent work of the last 30 years. Of course, there are leaders who are passionate about their work and do not get up in the morning just for the money. I am not sure whether GILD's management belongs to this group of executives. However, I expect that in the case of GILD a sluggish management team will be replaced sooner than later either due to GILD becoming an acquisition target or the involvement of an activist investor.

7. Valuation

I will first come back to the results I prepared for the HCV and the other segments including Cardiovascular, NASH, Oncology and Inflammation[78]. This helps me to invert the current market valuation of the HIV segment. I will then try to validate the valuation of the HIV segment with the assistance of a competitor's financials.

7.1 Inverse valuation of HIV segment

The following table summarizes the previous segment valuations:

Segment	**Value** ***in USD bn***
HCV	8.7
Cardiovascular	2.3
NASH	3.6
Oncology	0.0
Inflammation	4.5
Total Value ex HIV	**19.0**

This brings me to a valuation for GILD excluding HIV of USD 19.0 bn.

I believe that this value is conservative for two reasons. First HCV is expected to reach USD 4 bn in profit for 2017. This equals already 45% of my valuation for the HCV segment. Second, the pipeline valued at USD 8.7 bn implies a moderate value compared to the peer group as shown under section 5.5.[79]

At the time of my investment, GILD had a market cap of USD 84.5 bn.[80] At the end of March 2017, the company had a net cash position of USD 7.7 bn. The enterprise value is therefore USD 76.8 bn.

Hence, the implied value given by the market to the HIV segment is USD 57.8 bn.

[78] Please see section xxxxxfor reference.

[79] http://www.hiddenpipeline.com/relative-price-and-value-of-pre-phase-iii-pipelines-for-the-22-largest-drug-biotech-companies/

[80] I bought a 3.5% position for the portfolio on May 23, 2017 for an average price of USD 64.5 per share. With 1.31 bn shares outstanding this equals a USD 84.5 bn market cap.

Let's have a closer look at the earnings power of this segment:

P&L- HIV	Amount *in USD bn*	Comment
Revenue	12.8	2016 revenue
COGS	2.2	17%
SG&A	1.7	13%
Operating profit before R&D	9.0	70% margin
R&D expenses	0.9	27% out of USD3.4 bn total 2017 R&D spending or 7% of revenue
Operating profit after R&D	**8.1**	**63% margin**
Income taxes	1.6	20% tax rate
Net profit	**6.5**	**50% margin**

The table above shows GILD's 2016 revenue from HIV/HBV product sales less normalized expenses for costs of goods sold (COGS), selling, general and administrative (SG&A) as well as R&D expenses. For COGS and SG&A, I used a slightly higher percentage than in the consolidated P&L given the positive scale effect from HCV selling in 2016[81]. Overall, I assume the same operating margin before R&D as for the other segments. R&D expenses are derived from management's 2017 guidance.

My estimation of operating profit after R&D equals USD 8.1 bn. Net profit is USD 6.5 bn. Consequently, I bought the HIV segment at 7.1 times operating profit or 8.9 times net profit.

7.2 Back testing the HIV segment valuation

A different approach is provided for by Glaxo SmithKline's (GSK). GSK owns 78.3% of ViiV Healthcare. The following is an excerpt from GSK's 2016 annual report:

"ViiV Healthcare put options: In 2009 and 2012, both Pfizer and Shionogi were granted written put options by the Group that enabled each to put its non-controlling interest back to the Group in the future. Up to and including 31 December 2015, no financial liabilities were recorded for these two options as each arrangement contained clauses that enabled the Group to avoid acquiring these

[81] COGS in 2016 was 14.2% of product sales and SG&A was 11.3%.

interests if certain conditions were met. In February 2016, the Group unilaterally waived certain of its rights. As a result, liabilities with an aggregate value of £2,172 million were recognised. In December 2016, agreement was reached with Shionogi, whereby it agreed to forego its rights to exercise its written put option. As a result, the Group's associated liability of £1,244 million was de recognised during December 2016. At 31 December 2016, the liability in respect of Pfizer's written put option had a carrying value of £1,319 million."

Pfizer is holding an 11.7% interest in ViiV. Taking into account the value of the put option, this implies a valuation of USD 14.7 bn at a GBP/USD 1.3 exchange rate for 100% of ViiV. With ViiV's 2016 revenues of USD 4.6 bn this implies a 3.2 times sales multiple. The same multiple attributed to GILD leads to a valuation of USD 41.0 bn. This is below GILD's HIV segment's current market value. However, from my perspective there are a number of reasons why this valuation approach clearly undervalues GILD's HIV segment.

First, Pfizer holds a minority stake which is subject to a discount to intrinsic value. In addition, the option value might only be an approximation of the agreed sales price given the use of accounting rules and option pricing methods. More importantly, ViiV has been growing at a slower rate than GILD and has a much smaller franchise. Apart from that, with Shionogi foregoing its right to exercise its put option and Pfizer not exercising it, this is also an indication that the price might not be attractive to them despite owning only a small share in the JV. Moreover, two years ago GSK was said to plan a carve-out for ViiV that was said to fetch a market valuation between GBP 12 bn and GBP 18 bn.[82] Since then, ViiV has increased its value by further enhancing the product portfolio.

I believe that GILD's current market valuation is attractive. The market value for the HIV segment implies that the business keeps existing at the current earnings level for roughly the next ten years. Growth is not included. It is hard to say how the pharmaceutical HIV industry will look like ten years from now. However, the expectation for the HIV segment to grow or to exist beyond 2027 is quite low. In my view, this offers optionality for good things to happen. In addition, a USD 19 bn valuation for the ex HIV businesses seems to provide additional room for positive surprises.

[82] https://www.forbes.com/sites/joecornell/2015/02/10/glaxosmithkline-gsk-may-ipo-viiv-healthcare-in-2016/#74cc0940a3db

8. Strategic Alternatives and catalysts for the stock price

Expectations expressed in the stock price and valuation of the company are low.

Management has followed an in-house development strategy with very selective acquisitions. In contrast, most peers have actively grown their pipeline through buying smaller competitors over the last years. As I have shown the value of the pipeline makes up only 9.5% of the current market cap. Optionality is coming from any positive results in drug development which will increase the pipeline's NPV and therefore the stock price.

In addition, HCV sales might stabilize at a higher level than currently expected. Also, HIV could surprise with stable top line growth over the coming years.

Alternatively, the company could easily bear a number of acquisitions. With a clean balance sheet and ample free cash flow to be expected over the next years, a multi-billion acquisition could lead to the evolvement of a more attractive development pipeline.

Apart from that, GILD can become an acquisition target. I think in the current environment, GILD's low valuation is highly attractive to a financial engineering strategy involving the take up of low priced debt. Though this means an enormous debt load for any buyer, future expected cash flow streams can justify this decision. At a 6% to 7% free cash flow yield, which implies USD 6 bn to USD 7 bn at a USD 100 bn valuation or 25% premium to my entry point, paying 3% to 4% on debt might look like a good deal to some executives in the industry.

Lastly, the involvement of an activist investor pushing for a merger/sale and/or the replacement of management can become a reality if the share price continuous to languish. This might unlock value for existing shareholders, but it should definitely have a short term positive impact on GILD's market price. Depending on the activist investor's strategy and chances of success, I can then evaluate the situation once again.

Consequently, apart from the attractive valuation I think that various catalysts exist not being reflected in the current stock price.