Jennifer Schneider, 1006257471

WRI360: Finance and Writing

Prof. Guy Allen April 10, 2023

Article 1b [The COVID-19 Response of Gilead Sciences Inc.]

In November 2019, a virus turned pandemic outbreak would affect the financial revenue of and give center stage to pharmaceutical companies. Gilead Sciences Inc., "developed the first antiviral drug approved to treat COVID-19."

Before the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic, Gilead Sciences Inc. began to examine the effects of their antiviral medicine Veklury on COVID-19, after it showed potential against the treatment of other coronaviruses within preclinical experiments. "In early 2020, the first patient received Veklury for the treatment of COVID-19 through a special regulatory emergency use process, and we prepared for the possibility of rapidly initiating clinical trials to evaluate Veklury as an investigational treatment for COVID-19," Gilead said.

In May of 2020, the Food and Drug Administration (FDA) granted permission for the emergency use of Veklury, and by October of that year, the FDA approved the use of Veklury on hospitalized COVID-19 patients. Gilead sold each vial in the US for \$520 but donated an entire supply of Veklury for clinical trials in June of 2020. The current cost of a 5-day treatment of Veklury in Canada is \$3,122. To take effect each treatment of Veklury should last a minimum of 5 days and a maximum of 10.

Backlash

In a Fierce Pharma report, Arlene Weintraub said that a new study by the WHO overrode Gilead's results, which claimed that the drug Veklury cut patient's recovery time by 31%. In a preliminary study that measured 11,266 COVID-19 patients in 30 countries, the WHO concluded that remdesivir—the antiviral substance within the pharmaceutical drug Veklury—had little to no effect in COVID-19 patients. To measure the effects of the remdesivir substance, the WHO measured "the need for ventilation, the length of hospital stay and overall mortality."

In response, Gilead doubted the validity of of the study, calling the sample size heterogenous and the results inconclusive. Furthermore, Gilead released the following statement: "We are concerned that the data from this open label global trial have not undergone the rigorous review required to allow for constructive scientific discussion, particularly given the limitations of the trial design."

After then President Donald Trump said he was treated with Veklury for Covid-19– and the FDA expanded the authorization for remdesivir in treatment to include all hospitalized COVID-19 patients, despite the severity of their disease–Gilead projected the antiviral to make a profit of \$3.5 billion and dupped its revenue expectation from 23 to 25 billion dollars.

By the end of 2020, Gilead made a total revenue of \$24,689,000 billion and a net profit of \$123,000 billion.

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On February 2, 2021, Gilead Sciences Inc. issued a press release announcing its collaboration with the Human Rights Campaign (HRC) to combat the HIV epidemic and promote transgender justice. The pharmaceutical company leads the research and production of HIV medicines. By giving a two-years \$3.2 million grant to the HRC—the largest LGBTQ+ civil rights organization in the US—the HIV giant reinforced its commitment to addressing healthcare disparities. "The grant to HRC builds on our commitment to advance equity in healthcare, particularly in Black communities and other communities of color that are disproportionately affected by HIV and other diseases," said Daniel O'Day, Gilead Science's chairman and chief executive officer.

#### A Redemption Arc

Despite its recent efforts to support social justice initiatives, Gilead Sciences Inc. has a subpar track record when showing allyship to the LBTQ+ community, one of the demographic groups most affected by the HIV epidemic. According to an HRC study, if current numbers continue, 1 in 6 gay men will be affected by HIV in their lifetimes.

The first of such offenses occurred in 2016, when the AIDS Healthcare Foundation (AHF) issued an advertising campaign against Gilead Sciences, following a Los Angeles Times article titled, "Gilead Scandal: Gay Men, we don't care about your kidneys and bones, only the money." Both the campaign and the article exposed Gilead's manipulation of the patent of their bestselling HIV drug, tenofovir. Tenofovir has grave secondary effects like bone loss and kidney damage. In order to extend its patent and expand the revenue of tenofovir, Gilead's higher ups halted research of other less dangerous alternatives for HIV medication in 2004. As a

response, the AIDS Healthcare Foundation asked the Federal Drugs Administration and the US congress to conduct formal research into the viability of Gilead's patents.

In 2020, Gilead faced further backlash for having donated \$12,000 to the senators that supported the "Don't Say Gay" bill in Florida, between 2014 and 2018. Ironically enough, Gilead's first effort in supporting the LBTQ+ community encompassed airing television ads for its HIV prevention medication, pre-exposure prophylaxis (PrEP), that same year. PrEP, also known as its brand version Truvada, is a safer form of the drug tenofovir, which shows the positive impact of the AIDS Healthcare Foundation in advancing safer alternatives of HIV medication.

Gilead's television campaign *Healthysexual* featured a gay couple, a transgender woman, and a young couple of colour, three demographics disproportionately affected by HIV. The ad led viewers to a site that featured resources to get tested for HIV, LGBTQ+ friendly doctors approved to give prescription medicines, and places that give free condoms.

In a statement regarding the campaign, Gilead said: "When developing this campaign, it was important to us that the materials feature a diverse group of individuals who are representative of the communities most impacted by HIV, including young Black and Latino gay men, as well as cis-gender and transgender women."

Dr. Antony Fauci, the head of the National Institute of Allergy and Infectious Diseases, praised the ad's realistic portrayal of HIV, plus its emphasis on promoting HIV testing and preventive resources. Regardless, taking Gilead's preventive HIV medicines is not affordable, with the monthly price for PrEP coming in at a hefty \$1000 a month.

Fierce Pharma writer Natalie Missakian found that the outreach campaign helped increase a positive response from gay and cisgender men in a survey commissioned by the Human Rights

Campaign and Wells Fargo, regarding the efforts of pharmaceutical companies towards understanding the specific needs of the LGBTQ+ community. Missakian said that Gilead's preventive HIV prompted 21% of the 15,000 surveyed bisexual and gay cisgender men to agree with the statement, "Pharmaceutical companies adequately outreach to and understand my identity as a lesbian, gay, bisexual, transgender, non-binary and/or queer individual."

#### Allyship and Marketing

The COVID-19 pandemic had a positive impact on pharmaceutical efforts to help charitable organizations. Accordingly, Gilead foundation's board decided to allocate \$200 million to three areas: funding health justice initiatives, funding local community groups, and matching employee donations to eligible non-profits at a higher rate.

On the first front, Gilead launched the Creating Possible Fund, which Gilead's higher ups say will give grants to organizations working on "innovative approaches to complex social issues, especially those affecting the most underserved members of society, including people of color and LGBTQ+ youth." On the second front, Gilead higher ups plan to award funds to disaster relief and humanitarian efforts, in the places where their employees live. On the last front, they plan to continue their Giving Together Program, which matches employee donations to eligible non-profits. Gilead allocated an additional \$15,000 to their 12,000 employees for this initiative.

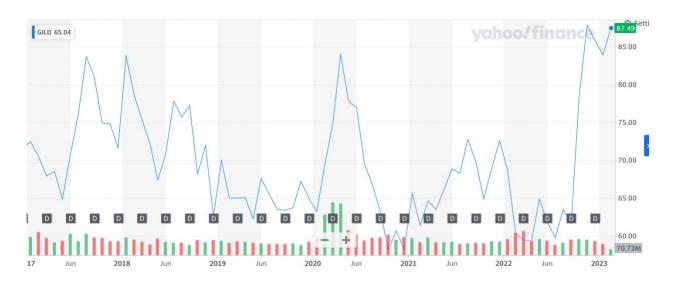
In 2022, Gilead joined GLAAD, the HRC, the National Black Justice Coalition (NBJC), the National Center for Lesbian Rights (NCLR), and the National Minority AIDS Council (NMAC) to address the monkeypox pandemic outbreak. Gilead allotted \$5 million to a public education regarding vaccine hesitancy, a public policy response, and a global outbreak

emergency funding. GLAAD reported that, "The Global Monkeypox Outbreak Emergency Fund will provide grants of up to \$50,000 to existing Gilead grantee organizations working in regions with active MPV outbreaks to respond to this growing emergency." In a press release, Gilead reported that "of that group, 98% of the cases were among gay or bisexual men and 41% were living with HIV."

Other than their efforts to address misinformation in relation to the LGBTQ+ community, Gilead has made strides to address the high prices and the access gap of their HIV medication, boosting their co-pay assistance program payment from \$4,800 to \$7,200 per patient each year.

Gilead added 'inclusion' as part of its core values, while its general counsel and executive vice president of corporate affairs, Ben Pletcher, created a Pride group currently attended by 1,000 out of Gilead's 11,000 employees. "It gives people the confidence, the voice and the platform to speak out," Pletcher said. Due to these strides and its work developing lifesaving HIV drugs, the San Francisco Business Times awarded Gilead Sciences Inc. with the 2020 Corporate Pride Award.

As of 2023, Gilead has partnered with Gay Games 11 Hong Kong 2023 (GGHK) for the Colours of Life Campaign, meant to jumpstart conversations about the Diversity, Equity and Inclusion (DEI) agenda in Asia. The campaign will feature stories by para-badminton player Daniel Chan Ho-yuen, award-winning stand-up comedian Vivek Mahbubani, the co-chair of GGHK Lisa Lam, and Gilead's vice-president and general manager of Asia Dustin Haines. The stock price of Gilead Sciences Inc. increased from \$69.36 billion since February 2020 to \$87.49 billion in February 2023, showing the profitability of their new inclusive approach to business.



Source: Yahoo Finance (NasdaqGS - NasdaqGS Real-time price, 2023). Gilead's stock has increased due to their social responsibility efforts to grow as allies to the LGBTQ+ Community.

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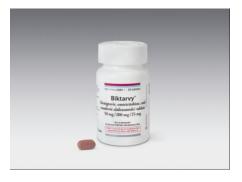
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The healthcare companies Gilead and Viiv Healthcare fought over the legal patent for an HIV medication. Viiv Healthcare, a company owned by GlaxoSmithKline, Pfizer Inc. and Shionogi & Co., claims to act as "the global specialist company in HIV care." Gilead Sciences Inc. similarly aims to "overcome the barriers to HIV care that still exist around the world" and to "help end the epidemic for everyone, everywhere."

Gilead Science Inc. is Viiv Healthcare's biggest competitor. The drug Biktarvy, manufactured by Gilead, produced a revenue of \$7.05 billion in 2021, acting as one of Gilead's top selling treatments. Biktarvy combines three different HIV medicines into one daily tablet.

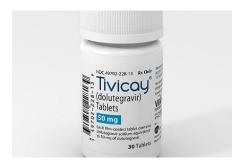


Source: POZ Digital (2019). Gilead Sciences Inc. produces Biktarvy to treat HIV.

In an article sponsored by the Canadian AIDS treatment information exchange, which compared Gilead Science's drug Biktarvy to Viiv Healtcare's drug Dolutregravir, Sean R. Hosein found "that both regimens were highly effective and tolerated over the course of one year. Side effects were less common among bictegravir users (18%) compared to dolutegravir users (26%)." The study involved over 600 hundred participants in ten different countries, over a one-year timeline.

# Legal Battle and Financial Implications

Viiv Healthcare and partners alleged that Biktarvy infringed certain of their patents regarding dolutegravir. They entered a settlement and patent license agreements to grant Gilead a worldwide license to certain Viiv Healthcare patents, and for Viiv Healthcare not to enforce their patents to any future Gilead product containing bictegravir or dolutegravir, all under the hefty price of \$1.25 billion.



Source: Pharmaceutical Technology (Admin, 2013). Viiv Healthcare has the US patent for HIV inhibitor dolutegravir.

In a statement by Viiv Healthcare, the pharmaceutical company announced that other than the upfront payment of \$1.25 billion, Gilead will also pay a 3% royalty for all future US sales of Biktarvy, which amounted to \$6.09 billion in 2020. Regarding Gilead products containing the chemical bictegravir, Gilead started paying these royalties February 1<sup>st</sup>, 2022, and will do so until Viiv Healthcare's patent No. 8,129,385 expires on October 5<sup>th</sup>, 2027. In addition, the statement explained that the stakeholders would distribute upfront payment and upcoming royalties, in proportion to the shareholder percentages for Viiv Healthcare: 78.3% for GSK, 11.7% for Pfizer and 10% for Shionogi.

A corresponding statement by Gilead Sciences reinforced this information and added that settlement dismisses all pending lawsuits regarding the drug bictegravir, ensuirng"Gilead's

ability to obtain and defend its patents and other intellectual property rights and to operate without infringing upon the patents or other proprietary rights of third parties."

### Media Coverage and Ramifications

In an article by science newspaper *The Lancet*, Nayanah Siva reported the legal patent battle and ensuing financial ramifications as "one of the largest pharmaceutical settlements."

While pointing out the differences between the two drugs, Siva added that the legal battle shows the complexity that intellectual property patents can add to drug discovery and production.

In a statement for *Litigate*, Andrew Moeser claims to have given Gilead legal counsel regarding Biktarvy's patent infringement action.

"Gilead to fork over \$1.25B, pay 3% royalty on blockbuster Biktarvy in GSK patent settlement," Eric Sagonowsky titled a *Fierce Pharma* article, about the dispute. Sagonowsky says that the deal favors Viiv Healthcare, considering that Biktarvy was projected to generate \$50 billion in revenue between February 2022 and October 2027 in the US alone.

In the third quarter of 2022, Gilead Science's Biktarvy sales increased 22% to 2.8 billion.

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### Article 4b [Gilead Delves into Oncology]

When Daniel O'Day took over as Gilead's Chief Executive Officer in 2019, his focus on oncology plus the development of twenty new Cancer treatments, made Gilead's stock accelerate every quarter. According to *Investors* writer Allison Gatlin, sales from the oncology drug Yescarta soared 82%, bringing in \$317 million during the September quarter of 2022. Yescarta sales helped Gilead's oncology business grow 79% coming into 2023.

The success came after Gilead acquired Yescarta's producer Kite Pharma in 2017. Even after the Food and Drugs Administration (FDA) approved Yescarta for patients with late-stage blood Cancer, Yescarta sales did not increase until the fourth quarter of 2018, due to insurers debating whether to imburse patients for the treatments amid manufacturing challenges.

Since the fourth quarter of 2018, Yescarta sales have beat expectations 56% of the time. In 2022 specifically, Yescarta sales grew 31% in the first quarter, 66% in the second, and 82% in the third. The Yescarta treatment works by reprogramming a patient's cells through a drug named *chimeric antigen receptor T-cell therapy*, or CAR-T for short.

### Cash Flow

Due to the financial success of their oncology medications, Gilead Sciences plans to expand their portfolio by augmenting its late-stage clinical pipeline, corresponding to the four stages of drug trials for a new treatment to launch into the market: discovery and development (1), preclinical research (2), clinical research (3), and FDA drug review (4).

With a current value of \$30 billion and having spent \$12 billion on the acquisition of Kite Pharma, Gilead plans to develop the clinical trials of non-alcoholic steatohepatitis (NASH) and

off-the-shelf therapy tabelecleucel, in collaboration with pharmaceuticals Novo Nordisk and Atara Biotherapeutics.

By turning away from low-risk licensing deals and acquisitions, and towards bigger collaborations and buy-ins, clinical trials, and off-the-shelf-cell therapies, Gilead seeks to ensure its stop in the competitive field of oncology pharmaceutical drugs.

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Article 5c [Gilead to Develop a New Research Centre as a Result of 2022 Financial Growth]

The HIV focused pharmaceutical Gilead Sciences Inc. plans to build a 175,000 square feet research center in their headquarters in Foster City, California, with the aim to expand their portfolio of drugs pertaining to oncology and hepatitis C.

With the additional goal to convert their 250,000 square feet of campus office space into labs, their growth in collaborations, internal research and acquisitions has allowed Gilead to spend over \$200 million building a research center that will open in 2026. "It's a significant investment," said Joydeep Ganguly, the senior vice president of corporate operations at Gilead. "It is the largest capital investment that we will be making in our master plan in the last four years."

Gilead Sciences Inc. made such financial investments and internal expansion possible as a result of the growth the company experienced in 2022. "2022 marked Gilead's strongest full year growth in our base business since HCV sales peaked in 2015. This return to growth was driven by consistent and high quality commercial and clinical execution across our portfolio," said Gilead's Chairman and Chief Executive Officer Daniel O'Day.

# Financial Growth

Gilead's financial results for the fourth quarter of 2022 showed the total revenue increase by 2% compared to that same quarter in 2021, with a total revenue of \$7.4 billion. Diluted earnings per share—meaning the measurement of a company's earnings when converting all securities to common stocks and a shareholder's existing equity stake—increased from \$0.30 in the fourth quarter of 2021 to \$1.30 in the fourth quarter of 2022.

In 2021, Gilead Sciences Inc. had to pay \$1.25 billion to HIV competitor Viiv Healthcare—a subsection of the GlaxoSmithKline conglomerate—in a legal patent settlement and spent a \$625 million to opt in to a collaboration with Arcus Biosciences Inc. to co-develop and commercialize next generation cancer immunotherapies.

In the fourth quarter of 2022, Gilead expenses included acquiring new assets, including buying the immunotherapy GS-1811 from Jounce Therapeutics, Inc., a collaboration with antibody-based pharmaceutical company MacroGenics. In 2022, Gilead invested in higher research and development, and terminated of the collaboration with licensing pharmaceutical company Everest Medicines for drug Trodelvy. As a result, Gilead generated \$2.6 billion in operating cash flow and utilized \$791 million to repurchase common stock in the fourth quarter of 2022.

Ganguy attributes Gilead's growth to a variety of factors, particularly a focus on research, which acts as an important financial reason to invest on the new Foster City, California research quarters. "In HIV, Biktarvy gained market share in the U.S. as it has every quarter since launch, while our long-acting HIV agent, lenacapavir, received its first regulatory approvals," Ganguy said. "The strong full year growth in oncology was driven by continued increase in demand for Trodelvy and our Cell Therapies. We look forward to building on this momentum in 2023 and further increasing our impact for people and communities worldwide."



Source: Yahoo Finance (NasdaqGS - NasdaqGS Real-time price, 2023). Gilead showed great growth in the fourth quarter of 2023 as a result of their focus on internal research.

## *Internal Research and Sustainability*

The new California Research Centre will house between 300 and 350 workers, and contribute to Gilead's efforts for internal research, with the aim to develop more than ten new transformative drug treatments across the therapeutic areas of virology, oncology and inflammation by 2030. Other than addressing issues with the company's technological capabilities, and with the capacity needs for Gilead's growing oncology and inflammation research teams, Gilead wants to ensure the new campus is socially responsible, by implementing renewable energy solar panels and will become one of the only research centers classified LEED Gold for sustainability in the biotech industry.

"Positioning people at the center of the research and development process is helping us to fuel the next wave of innovation in virology," said Frank Duff the Senior Vice

President of Virology Therapeutic in Gilead Sciences. "Our scientific advances are grounded in collaboration with community and research partners around the world."

According to the Executive Vice President of Research Flavius Martin, the decision of build a new research center lies on the company's plan to "redefine sustainability standards for research buildings and allow us to attract and retain top scientific talent," continuing its financial growth prompted by research in oncology, virology and inflammation, and allowing the company to expand its currently HIV-focused portfolio.

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