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GILEAD

Information Report Compiled by Jennifer Schneider Malamud April 10th, 2023

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Executive Summary

Founded by Michael Riordan in 1987 as a biotechnology company, Gilead Sciences Inc. began manufacturing drug treatments in Foster City, California, with a venture capital of \$10 million. Since then, the company established itself as the most prolific HIV treatments manufacturer in the U.S. and expanded into the fields of COVID-19 and oncology through the acquisition of minor pharmaceutical companies. Gilead produces and markets Veklury, the first COVID-19 treatment approved by the FDA, and Biktarvy, and all-inclusive HIV treatment and Gilead's best-selling medication. In the future, Gilead aims to open a new oncology-focused research center to expand its portfolio of over 15 products. Some risks the company faces include competition and patent disputes with other pharmaceutical companies, plus a high debt.

Company Overview

- Researches, develops and commercializes antiviral drugs with a focus on HIV/AIDS, liver diseases, serious respiratory and cardiovascular conditions, cancer and inflammation
- Founded by Michael Riordan, as a biotechnology company in Foster City, California, on June 22, 1987
- Changed the name from Oligogen, a reference to small strands of DNA called oligomers, to Gilead, a reference to the elixir of life
- Launched the drug Truvada, the first once-a-day, single-tablet HIV treatment
- Produced Veklury (remdesivir), the first antiviral drug approved by the FDA to treat COVID-19
- Ranked 129 in the 2022 edition of the Fortune 500 Companies
- Runs operations in the United States, Canada, Mexico, Argentina, Brazil, Western and Eastern Europe, Africa, the Middle East, and the Asia-Pacific region
- Listed as GILD in the Nasdaq stock change

Company History

- 1987: Founded Gilead Sciences Inc
- 1989: Raised \$10 million in venture capital
- 1991: Developed antiviral therapeutics like tenofovir, and generated revenue for the first time
- 1992: Made its initial public offering (IPO) and debuted on NASDAQ
- 1997: Launched AmBisome and Vistide into the market, after FDA approval
- 1999: Acquired NeXstar Pharmaceuticals and established European operations
- 2003: Acquired Triangle Pharmaceuticals
- 2009: Acquired CV Therapeutics
- 2010: Acquired CGI Pharmaceuticals
- 2011: Acquired Arresto Biosciences and Calistoga Pharmaceuticals
- 2012: Acquired Pharmaset
- 2015: Donated over \$440 million for HIV/AIDS
- 2016: Acquired Nimbus Apollo
- 2017: Acquired Kite Pharma for \$11.9 billion
- 2020: Acquired Forty-Seven Inc. for \$95.50 a share (\$4.9 billion in total)
- 2021: Paid \$1.25 billion to Viiv Healthcare to settle patent lawsuit over drug Biktarvy
- 2022: Experienced its strongest full year of growth, through COVID-19 and oncology medications

Key Persons (13,000 employees worldwide)

Daniel O'Day (Chairman and Chief Executive Officer)

- Joined Gilead Sciences in 2019, to spearhead the company in its oncology efforts
- Rewarded a \$19.2 million package after the company's revenue increased 11% in 2021, due to the COVID-19 response
- Worked for more than three decades at Roche Pharmaceuticals, where he became CEO

Andrew Dickison (Chief Financial Officer)

- Joined Gilead in 2016, and prior to his current role, he served as the head of the company's development and strategy groups
- Managed the company's licensing, partnership and acquisition transactions and investments
- Worked as global co-head of healthcare investment banking at Lazard

Stacey Ma (Executive Vice President, Pharmaceutical Development and Manufacturing)

- Worked as Executive Vice President of Technical Operations at Sana Biotechnology and as Global Head of Innovation, Manufacturing Science and Technology at Genentech/Roche
- Oversees all the company's investigational compounds and marketed products

Annual Financial Statements (all numbers in millions, except per share amounts)

December 31, 2022	December 31, 2021
Revenue: \$27,281	Revenue: \$27,305
Net Income: \$4,592	Net Income: \$6,225
Net Earnings Per Share: \$3.66	Net Earnings Per Share: \$4.96
Annual Gross Profit: \$21,624	Annual Gross Profit: \$20,704
Total Assets: \$63,171	Total Assets: \$67,952
Total Liabilities: \$41,962	Total Liabilities: \$46,888
Current Assets: \$14,443	Current Assets: \$14,772
Current Liabilities: \$11,237	Current Liabilities: \$11,610
Equity: \$21,209	Equity: \$21,064
Cash: \$9,072	Cash: \$11,384
Total Debt: \$22,957	Total Debt: \$25,179
Total Common Shares: \$1,255	Total Common Shares: 1,256

Primary Products (plus 15 others in the market)

Veklury

- VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients) with positive results of SARS-CoV-2 viral testing, hospitalized or not hospitalized
- Veklury was the first COVID-19 medication approved by the FDA for treatment in the United States

Biktarvy

- BIKTARVY® is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients
- Biktarvy is Gilead Science's best-selling medication, with a total of \$10,390 million in revenue, in 2022.
- •

Truvada

- TRUVADA is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg
- Truvada is the first drug approved for HIV prevention in uninfected adults at high-risk, a treatment known as pre-exposure prophylaxis (PrEP)

Trodelvy

• TRODELVY® is an antibody inhibitor indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer









Yescarta

• YESCARTA® is an immunotherapy indicated for the treatment of adult patients with lymphoma

Tamiflu

- Tam Tamiflu® is an influenza inhibitor indicated for the treatment of acute illness due to influenza infection in patients more than one year old
- Tamiflu was the first antiviral medicine discovered by Gilead researchers and was approved by the FDA in 1999





Revenue Generation

- Product Sales Excluding Veklury Increased Year-Over-Year by 8% for Full Year 2022
- Biktarvy Sales Increased Year-Over-Year by 20% for Full Year 2022
- Trodelvy sales increased 79% to \$680 million for the full year 2022
- Veklury sales decreased 30% to \$3.9 billion for the full year 2022
- Oncology Sales Increased Year-Over-Year by 71% for Full Year 2022
- HIV product sales increased 5% to \$17.2 billion for the full year 2022
- HCV product sales decreased 4% to \$1.8 billion for the full year 2022
- HBV and HDV product sales increased 2% to \$988 million for the full year 2022
- Cell Therapy product sales increased 68% to \$1.5 billion for the full year 2022

Social Impact Initiatives

Zeroing InTM: Ending the HIV Epidemic (EHE)

- Supports over 116 healthcare organizations helping the fight against HIV, across 47 countries
- Funds non-clinical testing, supportive service programs, and biomedical HIV prevention programs
- Granted over \$24 million to local communities impacted the HIV and COVID-19 pandemics, to advance healthcare and medical education

Creating Possible Fund

- Gives grants to medical institutes, to advance education equity, health strategies and to build a pipeline for Black medical leaders
- Gave past grants to Brown University, Kingmakers of Oakland, KQED, Morehouse College, Oakland Fund for Public Innovation, the Trevor Project Inc., and others

Sustainability Initiatives

- Adheres to the construction parameters of the LEED and BREEAM green building certifications, which include eliminating waste and conserving natural resources
- Developed a greenhouse gas (GHG) reduction plan, to invest in renewable energy
- Upholds waste management operational standards to avoid pharmaceuticals in the environment (PiE), as a member of the Pharmaceutical Product Stewardship Work Group (PPSWG)
- Reduced 74% of Biktarvy manufacturing waste, using green chemistry techniques like enzymatic catalysis, flow chemistry, and greener solvents in active pharmaceutical ingredient (API) synthesis
- Joined the Pharmaceutical Supply Chain Initiative (PSCI) in 2018
- Mandates all their suppliers follow the good manufacturing practices (GMP) put forth by the Food and Drug Administration (FDA)

Opportunities

- Expand HIV Portfolio following the approval of Sunleca (lenacapavir), a twice-a-year injectable treatment for patients with multi-drug resistant HIV (see Appendix H)
- Capitalize on the 81% 2019 to 2022 increase in their pipeline portfolio, in the areas of oncology, virology, and inflammation (see appendix H)
- Maximize the impact of their most recent products, including Trodelvy, Yescarta, Veklury, Tecartus, Hepcludex, and Sunleca
- Maintain HIV Leadership (see Appendix H)
- Accelerate oncology business, with a \$2 billion annual run-rate and with a new oncologyfocused research facility expected to begin operations in 2026 (see Appendix F)

Risks

Patent Risk

• Prompts legal disputes among companies over drug's components and hinders medical research (see Appendix G)

Regulatory Risk

• Impedes marketing and launching of non-FDA approved treatments (see Appendix B) Competition Risk

• Competes with other biopharmaceuticals like Merck & Co., Johnson & Johnson, and Viiv Healthcare (GlaxoSmithKline) in the HIV/AIDS treatments industry (see Appendix C)

Product Liability Risk

• Faced court allegations for delaying the launch and shelving newer, safer HIV treatments, to finish the stock of medicines harmful to kidneys and bones

Key Person Risk

• Searching for new leadership to replace Christi Shaw, former CEO of Kite Pharma; Gilead Science's oncology and cell therapy company

Geopolitical Risk

• Established headquarters in Foster City California, a city with a major risk of flooding over the next 30 years

Pandemic Risk

• Faced with the risk of the manufacturing, production, monetary, competition and research costs of another pandemic outbreak

Financial Risk

• Adds up to a high \$22,957 in total debt

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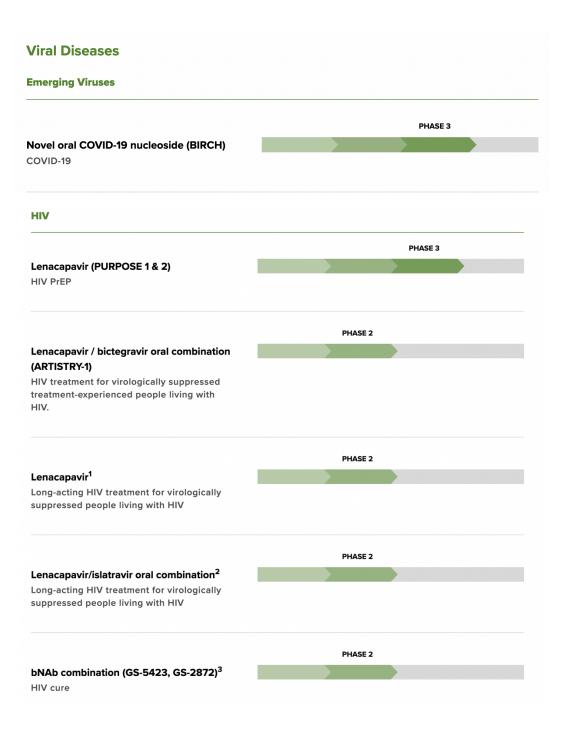
Appendix A: Share Price and Volume History



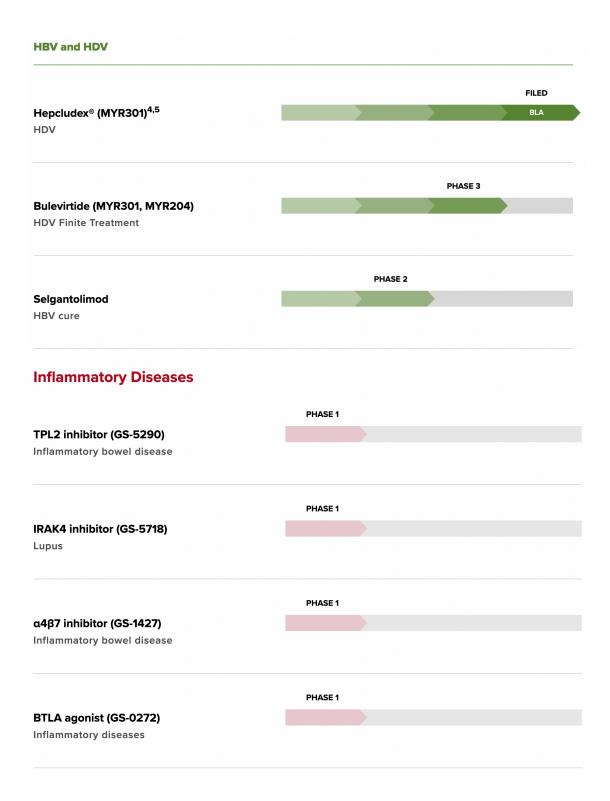
Stock from December 31, 2019, to April 5, 2023

- April 13, 2020 Gilead announces positive results from Phase 3 trials of COVID-19 drug Remdesivir. Stock rises 7.9% seven days after the announcement
- October 25, 2020 Gilead stock drops 25% between July 5 to October 25, as demand for hepatitis and other non-coronavirus related drugs falls
- January 18, 2021 Gilead stock rises 19.9 % between December 20 to January 31, after healthcare company Daiichi Sankyo returns drug Yescarta marketing rights to Gilead Sciences and its Kite Pharma subsidiary
- August 15, 2021 Gilead stock peaks at 72.44 points that same day, after releasing press release demonstrating continued effective antiviral activity of the drug Veklury (remdesivir) in COVID-19 Omicron subvariants
- November 28, 2022 Gilead stock rises 44% between September 25 and November 27, after releasing report of third quarter of 2022, and publishing a press release of the transformative impact of cell therapy and the deliverables of their blood cancer portfolio

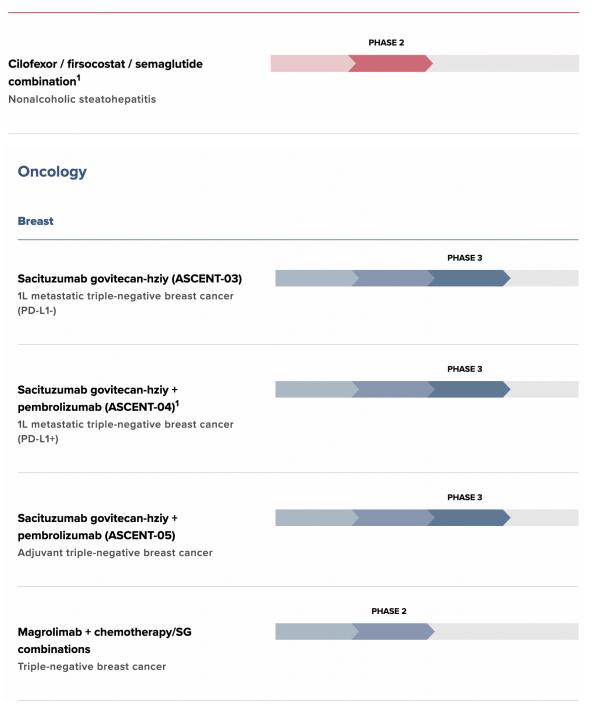
Appendix B: Virology, Oncology and Inflammation Drugs Pipeline



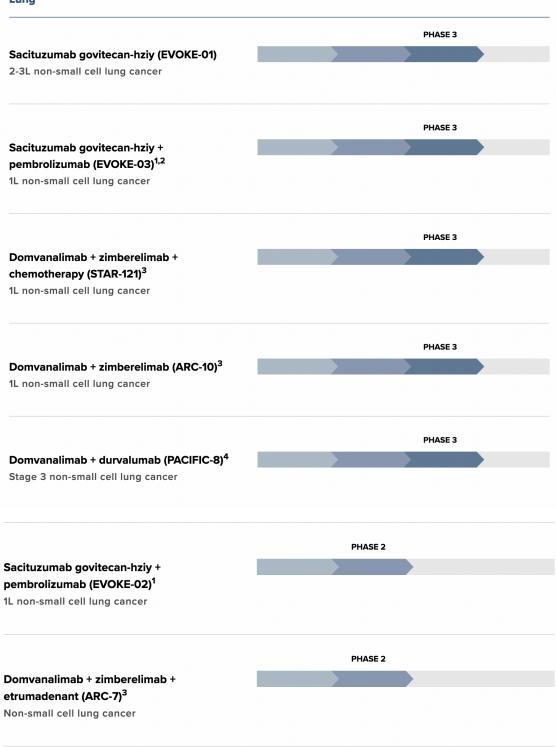
	PHASE 2
Lefitolimod ³	
HIV cure	
	PHASE 2
Vesatolimod	
HIV cure	
	PHASE 1
HIV bispecific T-cell engager (GS-8588)	
HIV cure	
	PHASE 1
Lenacapavir / bNAb combination	
Long-acting HIV treatment for virologically suppressed people living with HIV	
	PHASE 1
HIV long-acting injectable INSTI (GS-6212)	
Long-acting HIV treatment	
	PHASE 1
HIV long-acting oral NNRTI (GS-5894)	
Long-acting HIV treatment	
	PHASE 1
IV long-acting oral INSTI (GS-1720)	
ong-acting HIV treatment	

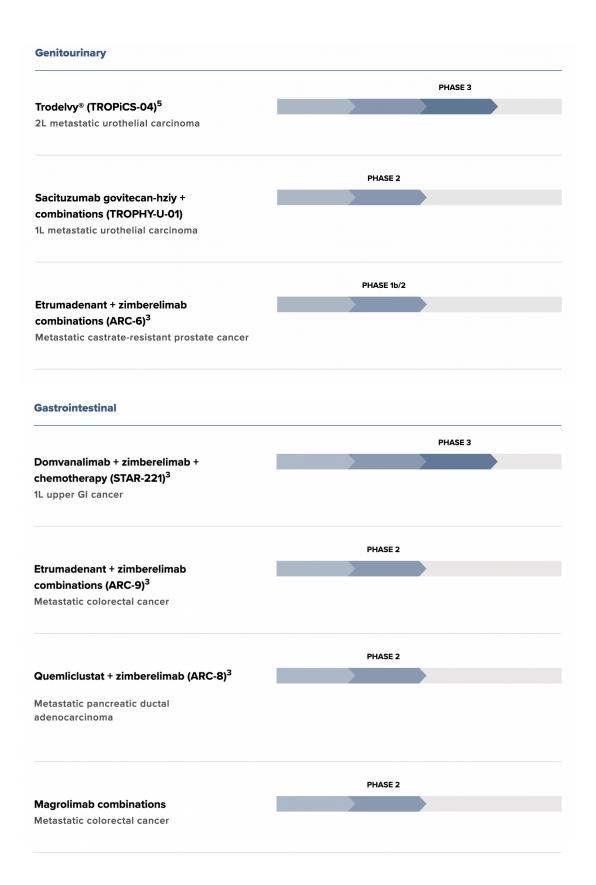


Fibrotic Diseases

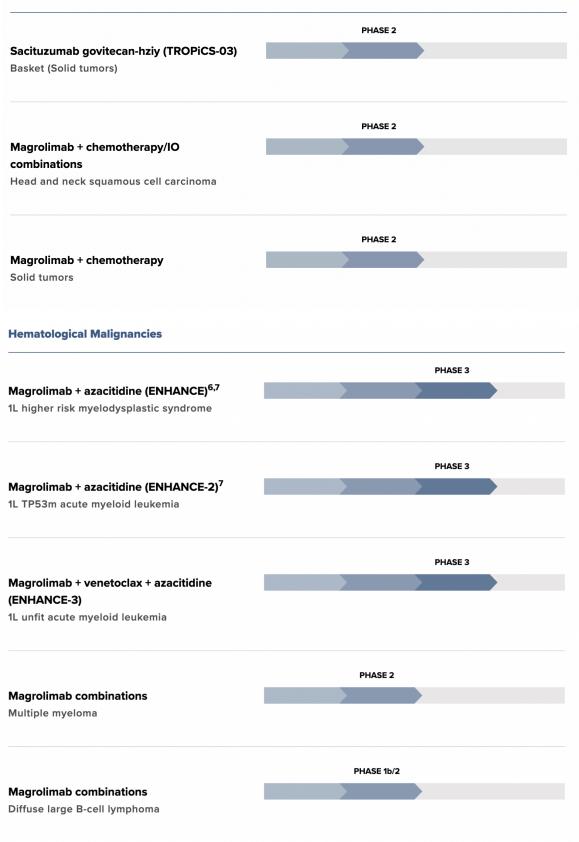


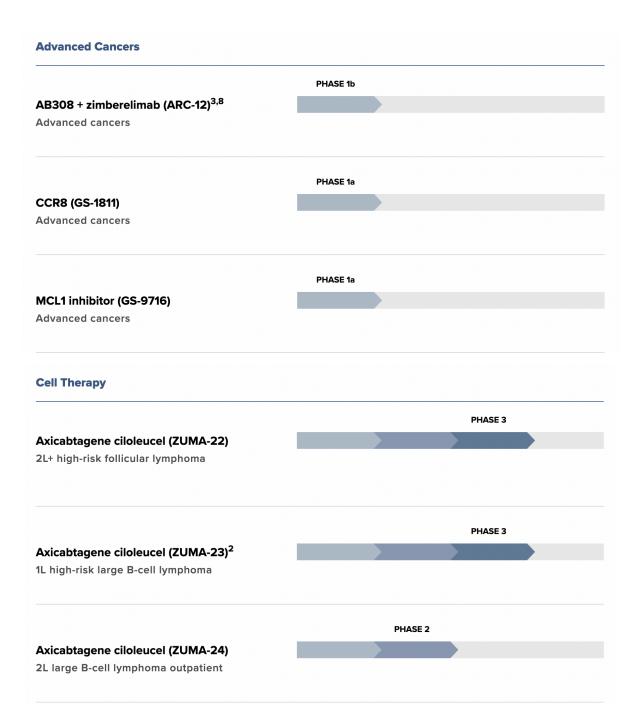
Lung

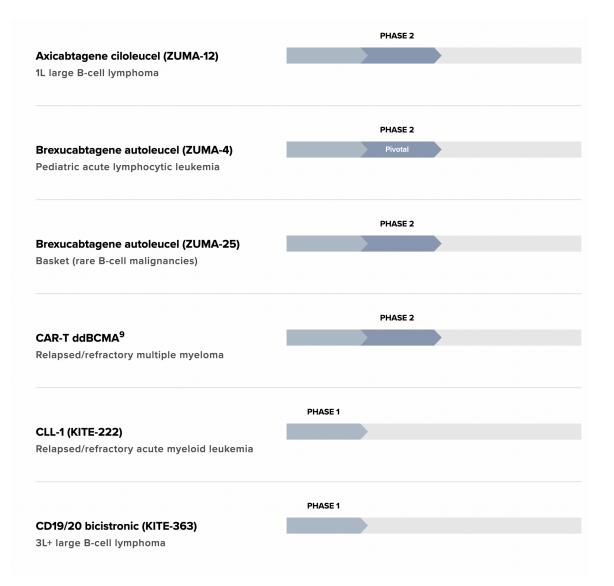




Other Solid Tumors







Appendix C: Main Competitors (all numbers in million US dollars)

Viiv Healthcare (GlaxoSmithKline)

- Net Income from Continuous Operations: \$4,195
- Cash Flow: \$29,027
- Working Capital: \$26,630

Johnson & Johnson

- Net Income from Continuous Operations: \$17,941
- Cash Flow: \$23,519
- Working Capital: \$76,804

Merck & Co

- Net Income from Continuous Operations: \$14,519
- Cash Flow: \$8,096
- Working Capital: \$38,257



Working together in HIV

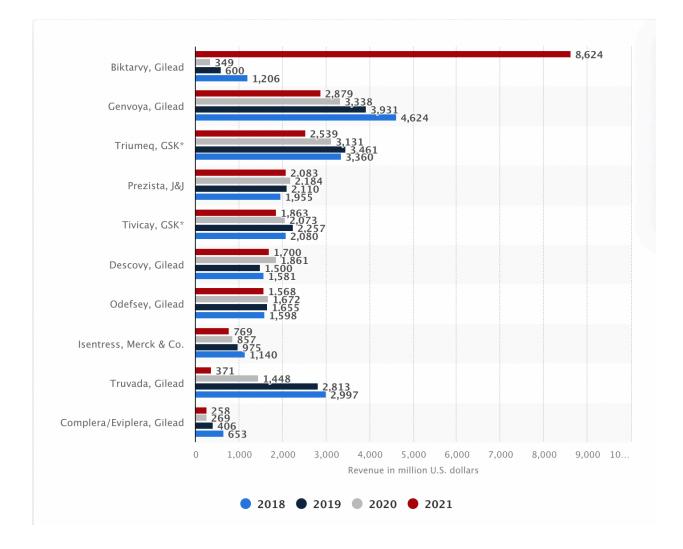
Johnson & Johnson



In contrast, Gilead Sciences Inc. has \$4,592 in net income from continuous operations, \$7,630 in operating cash flow and \$21,209 of working capital.

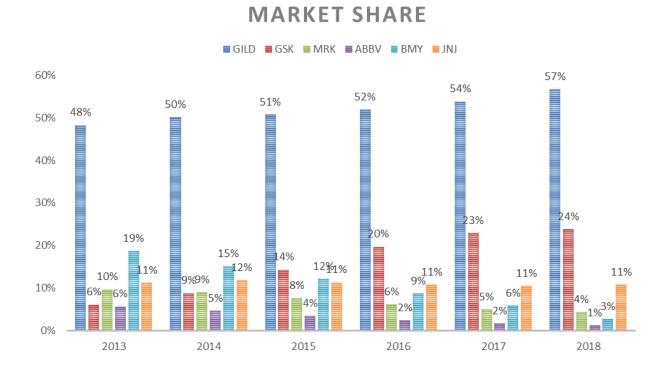
Appendix D: Global Best-Selling HIV Medications

Gilead Sciences Inc. has sold 6 of the top 6 of the 10 bestselling HIV medications in the U.S. (Statista, 2023).



Appendix E: Market Share

Gilead Sciences Inc. produced more than half of the total bestselling HIV medications in the U.S. between 2014 and 2019 (Seeking Alpha, 2019).



Appendix F: New Research Center in Foster City, California

- Spent \$200 million to open a 175,000 feet research center by 2026, next to Foster City, California, headquarters
- Focus on manufacturing and developing over 10 drug treatments, in oncology, virology and inflammation
- Will house between 300 and 350 workers and power through renewable energy solar panels, with a LEED Gold certificate

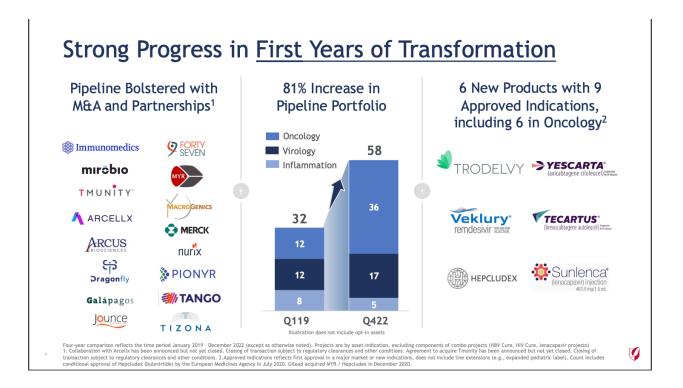


3D Architectural Plan of the New Gilead Sciences Research Center

Appendix G: Patent Lawsuit Dispute

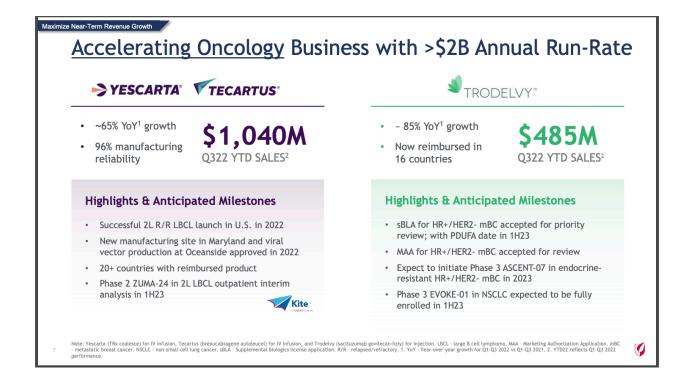
- Paid \$1.25 billion to Viiv Healthcare to settle a legal patent lawsuit in 2021
- Settled dispute over the intellectual rights for Gilead to use the compound Dolutegravir in their drug Biktarvy, which comines 3 different HIV treatments
- Generated \$7.05 billion in Biktarvy sales, in 2021
- Will pay 3% of royalties Biktarvy, Gilead's highest selling drug, to the GlaxoSmithKline conglomerate until 2027
- Projected to generate \$50 billion in Biktarvy sales in the U.S. between February 2022, and October 2027

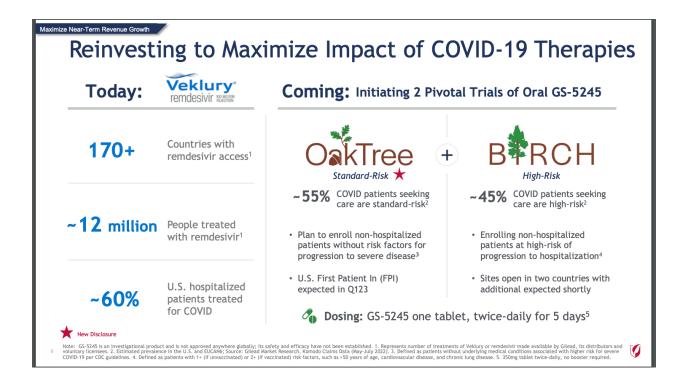
Appendix H: Treatments Progress Portfolio

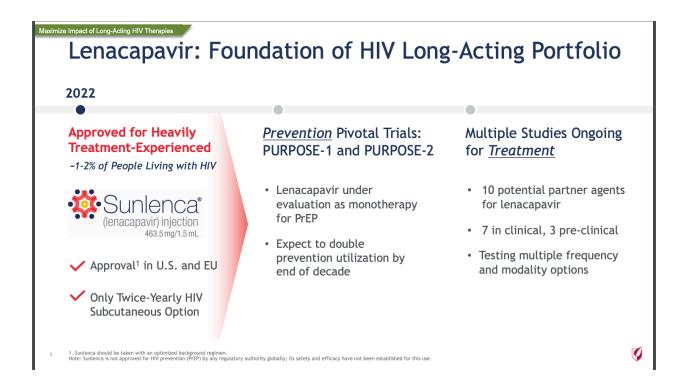


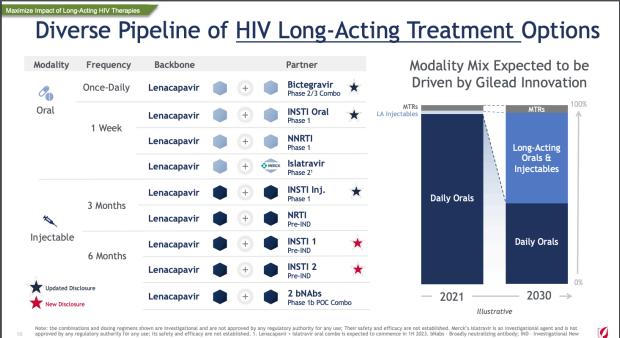


Note: 322 YTD reflects 01-03 2022 performance. 3231 YTD reflects 01-03 2021 performance. Y07 - Year-verv-grag growth for 01-03 2022 vs 01-03 2021. Biktary (bictegravir, emtricitable, and tend/orv laidenamide) tablets. 1. Estimated parter topity corresponds to the latest expiring compound patent for one of the active ingredentis in the single tablet regimen. 2. Dispetember 2022, Glied and five generic manufactures (Lupit Alaceast Pharma Ltd., Hetero Labs Ltd., and Cipla Ltd.) reached agreements to settle the patent litigation concerning patents that protect tendorivi alafenamide in our Descovy product. 3. Source: Monthly IQVIA NPA AND Regimen Market (NRTI Market, exct., IPF v 2-Dug Combos). 4. IQVIA NAD Weekly; National data incluides RAV 4. Reflects HIV PEP TBs from (UQVIA NPA retail a mail order).









te: the combinations and dosing regimens shown are investigational and are not approve roved by any regulatory authority for any use; its safety and efficacy are not establishe ig; INSTI - Integrase strand transfer inhibitor; LA - Long-acting; MTR - Multi-tablet regim egulatory authority for any use; Their safety and efficacy are not established. Merck's islatravir is an in capavir + Islatravir oral combo is expected to commence in 1H 2023. bNabs - Broadly neutralizing antib - Non-nucleoside reverse transcriptase inhibitor: NRT1 - Nucleoside reverse transcriptase inhibitor: POC vestigational agent and is not ody; IND - Investigational New ind are not approved by any reg y are not established. 1. Lenaca neutralizing antibody; איז - איז - איז - mesca ase inhibitor; POC - Proof of concept