August 02, 2022

Gilead Sciences Announces Second Quarter 2022 Financial Results

– Biktarvy Sales Increased 28% Year-Over-Year to $2.6 billion –

– Oncology Sales Increased 71% Year-Over-Year to $527 million –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today its results of operations for the second quarter of 2022.

“This was a very strong quarter for Gilead, with solid commercial and clinical execution,” said Daniel O’Day, Chairman and Chief Executive Officer, Gilead Sciences. “Excluding Veklury, product sales grew 7% year-over-year. There was continued strong demand for our HIV portfolio with further share growth for Biktarvy, and oncology revenues reached an all-time high, driven by cell therapy and Trodelvy.”

Second Quarter 2022 Financial Results

- Total second quarter 2022 revenue increased 1% to $6.3 billion compared to the same period in 2021, primarily due to increased sales in HIV and oncology products, offset partially by decreased sales of Veklury® (remdesivir) and hepatitis C virus (“HCV”) products.
- Diluted Earnings Per Share (“EPS”) decreased to $0.91 for the second quarter of 2022 compared to $1.21 for the same period in 2021. The decrease was primarily due to higher acquired in-process research & development (“IPR&D”) expenses from an upfront payment of $300 million, or $0.18 on a post-tax per share basis, related to the Dragonfly Therapeutics, Inc. (“Dragonfly”) collaboration and higher net unrealized losses from our strategic equity investments.
- Non-GAAP diluted EPS decreased 13% to $1.58 for the second quarter of 2022 compared to $1.81(1) for the same period in 2021, primarily reflecting the Dragonfly upfront payment and Biktarvy® (bictegravir 50mg/emtricitabine 200mg (“FTC”)/tenofovir alafenamide 25mg (“TAF”))-related royalty expense that began in the first quarter of 2022, offset partially by higher revenues.
- As of June 30, 2022, Gilead had $7.0 billion of cash, cash equivalents and marketable debt securities down from $7.8 billion as of December 31, 2021

primarily due to payment associated with the settlement of the bictegravir-related litigation, paid dividends, acquired IPR&D payments related to collaborations, debt repayments, stock repurchases and capital expenditures, partially offset by net cash provided by operations.

- During the second quarter of 2022, Gilead generated $1.8 billion in operating cash flow.
- During the second quarter of 2022, Gilead made a $300 million collaboration upfront payment to Dragonfly, paid dividends of $920 million and repurchased $72 million of common stock.

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(1) Non-GAAP diluted EPS has been recast due to an update to our non-GAAP policy in the first quarter 2022, resulting in a $0.06 reduction of previously-reported non-GAAP diluted EPS for the second quarter 2021. Refer to Non-GAAP Financial Information section below for further information.

Product Sales Performance

Total second quarter 2022 product sales were $6.1 billion, flat compared to the same period in 2021. Total product sales, excluding Veklury, increased 7% to $5.7 billion in the second quarter of 2022 compared to the same period in 2021, primarily due to growth in the HIV, Cell Therapy and Trodelvy® (sacituzumab govitecan-hziy) businesses, offset partially by declining revenue in HCV.

HIV product sales increased 7% to $4.2 billion in the second quarter of 2022 compared to the same period in 2021, primarily reflecting changes in channel mix leading to higher average realized price as well as higher demand for treatment and pre-exposure prophylaxis ("PrEP") medicines.

- Biktarvy sales increased 28% year-over-year in the second quarter of 2022, primarily due to higher demand and channel mix.
- Descovy® (FTC 200mg/TAF 25mg) sales increased 6% year-over-year in the second quarter of 2022, primarily driven by channel mix and increased demand, partially offset by inventory dynamics.

HCV product sales decreased 18% to $448 million in the second quarter of 2022 compared to the same period in 2021, primarily driven by channel mix leading to lower average realized price and fewer patient starts.

Hepatitis B virus ("HBV") and hepatitis delta virus ("HDV") product sales decreased 1% to $234 million in the second quarter of 2022 compared to the same period in 2021. Vemlidy® (TAF 25mg) sales decreased 3% in the second quarter of 2022

compared to the same period in 2021, primarily driven by China Volume Based Procurement update, offset in part by volume growth in all other regions.

Cell therapy product sales increased 68% to $368 million in the second quarter of 2022 compared to the same period in 2021.

- Yescarta® (axicabtagene ciloleucel) sales increased 66% to $295 million in the second quarter of 2022, primarily driven by demand for relapsed or refractory ("R/R") large B-cell lymphoma ("LBCL") in the United States and Europe and R/R follicular lymphoma ("FL") in the United States.
- Tecartus® (brexucabtagene autoleucel) sales increased 78% to $73 million in the second quarter of 2022, primarily driven by demand for R/R mantle cell lymphoma ("MCL") in the United States and Europe and for adult patients with R/R B-cell precursor acute lymphoblastic leukemia ("ALL") in the United States.

Trodelvy sales increased by 79% to $159 million in the second quarter of 2022 compared to the same period in 2021, primarily reflecting adoption in both the second- and third-line settings for the treatment of metastatic triple-negative breast cancer ("TNBC") in the United States and Europe as well as for metastatic urothelial cancer in the United States.

Veklury sales decreased by 46% to $445 millionfor the second quarter of 2022 compared to the same period in 2021. Veklury revenue generally reflects COVID-19 related rates and severity of infections and hospitalizations, as well as the availability, uptake and effectiveness of vaccinations and alternative treatments for COVID-19.

Second Quarter 2022 Product Gross Margin, Operating Expenses and Effective Tax Rate

- Product gross margin was 76.5% for the second quarter of 2022 compared to 77.4% for the same period in 2021. Non-GAAP product gross margin was 85.6% for the second quarter of 2022 compared to 86.4% in the same period in 2021. The decreases were primarily driven by Biktarvy-related royalty expense that began in the first quarter of 2022.
- Research and development ("R&D") expenses for the second quarter of 2022 were $1.1 billion, relatively flat with the same period in 2021. Non-GAAP R&D expenses for the second quarter of 2022 were $1.1 billion compared to $1.0 billion(2) in the same period in 2021. GAAP and Non-GAAP R&D expenses primarily reflect increased investment in development activities and timing of clinical trial activities, primarily for oncology. GAAP R&D expenses were offset by lower restructuring expenses as compared to the prior year.
- Acquired IPR&D expenses for the second quarter of 2022 were $330 million compared to $138 million(2) in the same period in 2021. The increase primarily reflects an upfront payment related to the Dragonfly collaboration.

- Selling, general and administrative ("SG&A") expenses for the second quarter of 2022 were $1.4 billion, relatively flat with the same period in 2021. Non-GAAP SG&A expenses for the second quarter of 2022 were $1.3 billion compared to $1.1 billion in the same period in 2021. GAAP and Non-GAAP SG&A expenses primarily reflect increased promotional and marketing investment, including for Trodelvy, as well as higher corporate activities, including information technology projects and grants. GAAP SG&A expenses were offset by lower donations to Gilead Foundation as compared to the prior year.
- The effective tax rate ("ETR") for the second quarter of 2022 was 24.5% compared to 16.5% for the same period in 2021, primarily due to a discrete tax benefit related to an intra-entity transfer of intangible assets in the three months ended June 30, 2021, and higher net unrealized losses from equity investments that are non-deductible for income tax purposes. Non-GAAP ETR for the second quarter of 2022 was 19.3% compared to 19.5% for the same period in 2021.

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(2) Beginning in the second quarter of 2022, expenses related to development milestones and other collaboration payments made prior to regulatory approval of a developed product were reclassified from R&D expenses to Acquired IPR&D expenses in the Condensed Consolidated Statements of Income. We believe this presentation assists users of the financial statements to better understand the total costs incurred to acquire IPR&D projects. Prior periods have been recast for both GAAP and Non-GAAP reporting to reflect this classification, resulting in a reduction of previously-reported R&D expenses of $42 million and $47 million for the three and six months ended June 30, 2021, respectively, and $8 million for the three months ended March 31, 2022.

Guidance and Outlook

For the full-year, Gilead has updated its guidance and now expects:

- Total product sales between $24.5 billion and $25.0 billion, compared to $23.8 billion and $24.3 billion previously.
- Total product sales, excluding Veklury, between $22.0 billion to $22.5 billion, compared to $21.8 billion and $22.3 billion previously.
- Total Veklury sales of approximately $2.5 billion, compared to approximately $2.0 billion previously.
- Non-GAAP earnings per share between $6.35 and $6.75, compared to $6.20 and $6.70 previously.

- Earnings per share between $2.90 and $3.30, compared to $3.00 and $3.50 previously.

This financial guidance excludes the impact of any expenses related to potential acquisitions or business development transactions that have not been executed, fair value adjustments of equity securities and discrete tax charges or benefits associated with changes in tax related laws and guidelines as Gilead is unable to project such amounts. A reconciliation between GAAP and non-GAAP financial information for the 2022 guidance is provided in the accompanying tables. Also see the Forward-Looking Statements described below. The financial guidance is subject to a number of risks and uncertainties, including uncertainty around the duration and magnitude of the COVID-19 pandemic. While the pandemic can be expected to continue to impact Gilead's business and broader market dynamics, the rate and degree of these impacts as well as the corresponding recovery from the pandemic may vary across Gilead's business.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.