

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2021

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

to

Commission File No. 000-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

94-3047598

(IRS Employer Identification No.)

333 Lakeside Drive, Foster City, California 94404

(Address of Principal Executive Offices, Including Zip Code)

650-574-3000

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value, \$0.001 per share	GILD	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer

Smaller reporting company Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2021 was \$62.6 billion.*

The number of shares outstanding of the registrant's Common Stock on February 18, 2022 was 1,253,886,724

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement, which will be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2022 Annual Meeting of Stockholders, to be held on May 4, 2022, are incorporated by reference into Part III of this Report.

* Based on a closing price of \$68.86 per share on June 30, 2021. Excludes 344,972,966 shares of the registrant's Common Stock held by executive officers, directors and any stockholders whose ownership exceeds 5% of registrant's common stock outstanding at June 30, 2021. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

GILEAD SCIENCES, INC.
2021 Form 10-K Annual Report
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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD[®], GILEAD SCIENCES[®], AMBISOME[®], ATRIPLA[®], BIKTARVY[®], CAYSTON[®], COMPLERA[®], DESCOVY[®], DESCOVY FOR PREP[®], EMTRIVA[®], EPCLUSA[®], EVIPLERA[®], GENVOYA[®], HARVONI[®], HEPCLUDEX[®] (BULEVIRTIDE), HEPSERA[®], JYSELECA[®] (FILGOTINIB), LETAIRIS[®], ODEFSEY[®], RANEXA[®], SOVALDI[®], STRIBILD[®], TECARTUS[®], TRODELVY[®], TRUVADA[®], TRUVADA FOR PREP[®], TYBOST[®], VEKLURY[®], VEMLIDY[®], VIREAD[®], VOSEVI[®], YESCARTA[®] and ZYDELIG[®]. This report also refers to trademarks, service marks and trade names of other companies.

This Annual Report on Form 10-K, including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the “Securities Act”), and the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Words such as “expect,” “anticipate,” “target,” “goal,” “project,” “hope,” “intend,” “plan,” “believe,” “seek,” “estimate,” “continue,” “may,” “could,” “should,” “might,” “forecast,” and variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends; operating cost and revenue trends; liquidity and capital needs; plans and expectations with respect to products, product candidates, corporate strategy, business and operations, financial projections and the use of capital; collaboration and licensing arrangements; ongoing litigation and investigation matters; statements regarding the anticipated future impact on our business of the ongoing coronavirus disease 2019 (“COVID-19”) and related public health measures; and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions.

We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified in Part I, Item 1A of this Annual Report on Form 10-K under the heading “Risk Factors.” Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof unless otherwise specified. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission (“SEC”), we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. In evaluating our business, you should carefully consider the risks described in the section entitled “Risk Factors” under Part I, Item 1A of this Annual Report on Form 10-K. Any of the risks contained herein could materially and adversely affect our business, results of operations and financial condition.

PART I

ITEM 1. BUSINESS

Gilead Sciences, Inc. (“Gilead,” “we,” “our” or “us”) 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. We are committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. We operate in more than 35 countries worldwide, with headquarters in Foster City, California.

Our Business

Products

Our innovative medicines represent advancements by offering first-in-class treatments, greater efficacy, enhanced modes of delivery, more convenient treatment regimens, improved resistance profiles and reduced side effects. Our focus on innovation has allowed us to deliver marketed products across multiple therapeutic areas.

In 2021, our primary revenue-generating products and the approved indications in the United States were as follows:

HIV/AIDS

- **Biktarvy**[®] is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Biktarvy is a single-tablet regimen of a fixed-dose combination of our antiretroviral medications, bicitgravir, emtricitabine and tenofovir alafenamide (“TAF”).
- **Genvoya**[®] is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Genvoya is a single-tablet regimen of a fixed-dose combination of our antiretroviral medicines, elvitegravir, cobicistat, emtricitabine and TAF.
- **Descovy**[®] is an oral formulation indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in certain patients. Descovy is a fixed-dose combination of our antiretroviral medications, emtricitabine and TAF. Descovy is also approved by U.S. Food and Drug Administration (“FDA”) for a pre-exposure prophylaxis (“PrEP”) indication to reduce the risk of sexually acquired HIV-1 infection in certain at-risk patients.
- **Odefsey**[®] is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Odefsey is a single-tablet regimen of a fixed-dose combination of our antiretroviral medications, emtricitabine and TAF, and rilpivirine marketed by Janssen Sciences Ireland Unlimited Company, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (“Janssen”).
- **Truvada**[®] is an oral formulation indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in certain patients. Truvada is a fixed-dose combination of our antiretroviral medications, tenofovir disoproxil fumarate (“TDF”) and emtricitabine. Truvada is also approved by FDA for a PrEP indication to reduce the risk of sexually acquired HIV-1 infection in certain at-risk patients.
- **Complera**[®]/**Eviplera**[®] is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. The product, marketed in the United States as Complera and in Europe as Eviplera, is a single-tablet regimen of a fixed-dose combination of our antiretroviral medications, TDF and emtricitabine, and Janssen’s rilpivirine hydrochloride.
- **Stribild**[®] is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Stribild is a single-tablet regimen of a fixed-dose combination of our antiretroviral medications, elvitegravir, cobicistat, TDF and emtricitabine.
- **Atripla**[®] is an oral formulation indicated as a complete regimen for the treatment of HIV-1 infection in certain patients. Atripla is a fixed-dose combination of our antiretroviral medications, TDF and emtricitabine, and Bristol-Myers Squibb Company (“BMS”)’s efavirenz.

COVID-19

- **Veklury**[®] (remdesivir), an injection for intravenous use, is a nucleotide analog RNA polymerase inhibitor indicated for the treatment of coronavirus disease 2019 (“COVID-19”) in certain adults and children 12 years of age and older and weighing at least 88 pounds (40 kg) who are (i) hospitalized or (ii) not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death*.

*This indication received expedited approval by FDA in January 2022.

Liver Diseases

- **Epclusa**[®] is an oral formulation of a once-daily single-tablet regimen of sofosbuvir and velpatasvir for the treatment of chronic hepatitis C virus (“HCV”) infection in adults and certain pediatric patients with genotype 1, 2, 3, 4, 5 or 6: (i) without cirrhosis or with compensated cirrhosis or (ii) with decompensated cirrhosis for use in combination with ribavirin. In addition, we have an authorized generic version of Epclusa distributed by our separate subsidiary, Asegua Therapeutics LLC.
- **Harvoni**[®] is an oral formulation of a once-daily, single-tablet regimen of ledipasvir and sofosbuvir for the treatment of chronic HCV infection in: (i) adults with genotype 1, 4, 5 or 6 without cirrhosis or with compensated cirrhosis, (ii) adults with genotype 1 with decompensated cirrhosis, in combination with ribavirin, (iii) adults with genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin, or (iv) certain pediatric patients with genotype 1, 4, 5 or 6 without cirrhosis or with compensated cirrhosis. In addition, we have an authorized generic version of Harvoni distributed by our separate subsidiary, Asegua Therapeutics LLC.
- **Vosevi**[®] is an oral formulation of a once-daily, single-tablet regimen of sofosbuvir, velpatasvir and voxilaprevir for the re-treatment of chronic HCV infection in adults: (i) with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen or (ii) with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor.
- **Vemlidy**[®] is an oral formulation of TAF dosed once a day for the treatment of chronic hepatitis B virus (“HBV”) infection in adults with compensated liver disease.
- **Viread**[®] is an oral formulation of TDF dosed once a day for the treatment of chronic HBV infection in adults and certain pediatric patients.

Hematology/Oncology/Cell Therapy

- **Yescarta**[®] (axicabtagene ciloleucel), a suspension for intravenous infusion, is a chimeric antigen receptor (“CAR”) T-cell therapy for the treatment of (i) adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (“DLBCL”) not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma and DLBCL arising from follicular lymphoma, and (ii) adult patients with relapsed or refractory follicular lymphoma (“FL”) after two or more lines of systemic therapy*.
*This indication is approved under accelerated approval by FDA, and continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- **Tecartus**[®] (brexucabtagene autoleucel), a suspension for intravenous infusion, is a CAR T cell therapy for the treatment of (i) adult patients with relapsed or refractory mantle cell lymphoma (“MCL”) and (ii) adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (“ALL”).
- **Trodelyv**[®] (sacituzumab govitecan-hziy), an injection for intravenous use, is a Trop-2 directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of (i) adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (“TNBC”) who have received two or more prior systemic therapies, at least one of them for metastatic disease, and (ii) adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (“PD-1”) or programmed death-ligand 1 (“PD-L1”) inhibitor*.
*This indication is approved under accelerated approval by FDA, and continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- **Zydelig**[®] (idelalisib) is an oral formulation of a kinase inhibitor for the treatment of patients with relapsed chronic lymphocytic leukemia, in combination with rituximab, for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.

Other

- **Letairis**[®] (ambrisentan) is an oral formulation of an endothelin receptor antagonist for the treatment of pulmonary arterial hypertension (“PAH”) (WHO Group I) (i) to improve exercise capacity and delay clinical worsening or (ii) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.
- **Ranexa**[®] (ranolazine) is an oral formulation of an extended-release tablet of an antianginal for the treatment of chronic angina.
- **AmBisome**[®] (amphotericin B liposome for injection) is a proprietary liposomal formulation of amphotericin B, an antifungal agent, for the treatment of serious invasive fungal infections caused by various fungal species in adults.

For information about our revenue-generating products, including the amount of revenue contributed by the products listed above, see Note 2. Revenues of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Revenue Share and Other Revenues

We also generate revenues from other activities, including revenue share from combination products, royalties for outbound licenses of our intellectual property and other payments received from our collaborations with third-party partners. For example, pursuant to our collaboration with Janssen, we receive revenue share from cobicistat, emtricitabine and TAF that are components of Symtuza (darunavir/cobicistat/emtricitabine/TAF), a fixed-dose combination product commercialized by Janssen. We include our revenue share from Symtuza in our Product sales. For a description of our collaborations with Janssen and other partners, see Note 11. Collaborations and Other Arrangements of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Commercialization and Distribution

We have U.S. and international commercial sales operations, with marketing subsidiaries in more than 35 countries. Our products are marketed through our commercial teams and/or in conjunction with third-party distributors and corporate partners. Our commercial teams promote our products through direct field contact with physicians, hospitals, clinics and other healthcare providers. We generally grant our third-party distributors the exclusive right to promote our product in a territory for a specified period of time. Most of our agreements with these distributors provide for collaborative efforts between the distributor and Gilead in obtaining and maintaining regulatory approval for the product in the specified territory.

We sell and distribute most of our products in the United States exclusively through the wholesale channel. During the year ended December 31, 2021, approximately 91% of our product sales in the United States and approximately 65% of our total worldwide revenues were to three large wholesalers, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. We sell and distribute our products in Europe and countries outside the United States where the product is approved, either through our commercial teams, third-party distributors or corporate partners.

Competition

We operate in a highly competitive environment. We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers. Our products compete with other commercially available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing. As our products mature, pricing pressures from private insurers and government payers often result in a reduction of the net product prices. Further, as new branded or generic products are introduced into major markets, our ability to maintain pricing and market share may be affected.

Research and Development

Our research and development (“R&D”) mission is to discover and develop transformational therapies in areas of high unmet medical need. Our product development efforts are focused primarily in viral diseases, inflammatory diseases and oncology. Our team of research scientists is engaged in the discovery and development of new molecules and technologies that we hope will lead to the approval of innovative medicines and therapies that will advance the current standard of care and address unmet medical needs. We intend to continue committing significant resources to internal R&D opportunities and external business development activity to drive innovation and growth of our business.

The development of product candidates and investigational therapies in our pipeline is subject to various risks and uncertainties. These risks and uncertainties include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials, including on account of clinical holds placed by regulatory authorities, or to perform additional trials and the risk of failing to obtain regulatory approvals. As a result, our product candidates and investigational therapies may never be successfully commercialized. Drug development is inherently risky, and many product candidates and investigational therapies fail during the development process.

In 2021, we continued to invest in and advance our R&D pipeline across our therapeutic areas. Below is a summary of our product candidates that were in Phase 3 or registrational Phase 2 clinical trials or pending marketing authorization review by FDA or European Medicines Agency (“EMA”) as of the end of 2021.

Product Candidates in Viral Diseases

Product Candidates	Description
Regulatory Filings	
Lenacapavir	A New Drug Application and a Marketing Authorization Application have been filed with FDA and EMA, respectively, for lenacapavir, an HIV capsid inhibitor, as a component of a long-acting regimen for the treatment of HIV infection in heavily treatment-experienced people living with HIV. It has been granted Breakthrough Therapy designation by FDA for this indication.
Bulevirtide	A Biologics License Application has been filed with FDA for bulevirtide for the treatment of chronic hepatitis delta virus (“HDV”) infection. It has been granted both Orphan Drug and Breakthrough Therapy designations by FDA for this indication. In Europe, Hepcludex [®] (bulevirtide) has been granted Conditional Marketing Authorization by the European Commission and PRIority MEDicines (PRIME) scheme eligibility by the EMA as the first approved treatment in adults with chronic HDV infection with compensated liver disease.
Phase 3	
Lenacapavir	Lenacapavir is being evaluated for an HIV PrEP indication. Program timeline is pending resolution of clinical hold placed by FDA on studies evaluating injectable lenacapavir.

Product Candidates in Inflammatory Diseases

Product Candidate	Description
Phase 3	
Cilofexor	Cilofexor, an FXR agonist, is being evaluated for the treatment of primary sclerosing cholangitis.
Filgotinib	Filgotinib, a JAK1 inhibitor, is being evaluated for the treatment of Crohn’s disease.

Product Candidates in Oncology

Product Candidates	Description
Regulatory Filings	
Yescarta (axicabtagene ciloleucel)	A supplemental Biologics License Application and a Type II Variation Marketing Authorization Application have been filed with FDA and EMA, respectively, for axicabtagene ciloleucel, a CAR T cell therapy for the treatment of second-line DLBCL. A Type II Variation Marketing Authorization Application has been filed with EMA for axicabtagene ciloleucel for the treatment of relapsed or refractory FL. Yescarta has received accelerated approval by FDA for the treatment of adult patients with relapsed or refractory FL after two or more lines of systemic therapy.
Tecartus (brexucabtagene autoleucel)	A Type II Variation Marketing Authorization Application has been filed with EMA for brexucabtagene autoleucel, a CAR T cell therapy, for the treatment of adult ALL. Tecartus has received FDA approval for the treatment of adult patients with relapsed or refractory B-cell precursor ALL.
Phase 3	
Sacituzumab govitecan-hziy	Sacituzumab govitecan-hziy, a Trop-2 directed antibody and topoisomerase inhibitor conjugate, is being evaluated for (i) hormone receptor positive (“HR+”), human epidermal growth factor receptor 2 negative (“HER2-”), metastatic breast cancer and (ii) non-small cell lung cancer (“NSCLC”) as a second-line or third-line treatment.
Magrolimab	Magrolimab, an anti-CD47, is being evaluated for (i) higher risk myelodysplastic syndrome (“MDS”) as a first-line treatment and (ii) acute myeloid leukemia (“AML”) as a first-line treatment. Program timelines are pending resolution of partial clinical holds placed by FDA on studies evaluating magrolimab.
Zimberelimab*	Zimberelimab, an anti-PD-1 monoclonal antibody, is being evaluated for NSCLC as a first-line treatment.
Domvanalimab*	Domvanalimab, an Fc-silent anti-TIGIT antibody, is being evaluated for NSCLC as a first-line treatment.
Registrational Phase 2	
Brexucabtagene autoleucel	Brexucabtagene autoleucel is being evaluated for the treatment of pediatric ALL.

*In collaboration with Arcus Biosciences, Inc. (“Arcus”). See Note 11. Collaborations and Other Arrangements of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information regarding this collaboration.

In 2021, we also received regulatory approvals or authorizations from FDA and the European Commission to expand the indications of our products, including:

Product	Regulatory Approval or Authorization
Biktarvy	FDA approved a new low-dose tablet dosage form of Biktarvy for pediatric patients weighing at least 14 kg to less than 25 kg who are virologically suppressed or new to antiretroviral therapy.
Epclusa	FDA approved an expansion of the pediatric indication of Epclusa for the treatment of chronic HCV infection to include pediatric patients 3 years of age and older, regardless of HCV genotype or liver disease severity.
Veklury	European Commission approved a variation to the Conditional Marketing Authorization for Veklury to include adults who do not require supplemental oxygen and are at an increased risk of progressing to severe COVID-19.
Yescarta	FDA granted accelerated approval of Yescarta for the treatment of adult patients with relapsed or refractory FL.
Tecartus	FDA approved Tecartus for the treatment of adult patients with relapsed or refractory B-cell precursor ALL.
Trodelvy	FDA granted full approval of Trodelvy for adult patients with unresectable locally advanced or metastatic TNBC. FDA granted accelerated approval of Trodelvy for use in adult patients with locally advanced or metastatic UC. European Commission granted marketing authorization for Trodelvy as a monotherapy indicated for the treatment of adult patients with unresectable or metastatic TNBC who have received two or more prior systemic therapies, at least one of them for advanced disease.

In addition, we seek to enhance our commercial portfolio and clinical pipeline across multiple therapeutic areas through acquisitions, in-licensing and strategic collaborations. For example, in October 2021, we entered into a clinical trial collaboration with Merck Sharp & Dohme, Corp., a subsidiary of Merck & Co., Inc. (“Merck”), to evaluate Trodelvy in combination with Merck’s Keytruda in patients with first-line metastatic TNBC. In November 2021, we expanded our research collaboration with Arcus and exercised our options to three programs in Arcus’s clinical-stage portfolio, including domvanalimab, which is in Phase 2 and 3 studies in NSCLC. Our strategic business development activity reflects our commitment to focus on transformative science, build a sustainable and diverse portfolio and position ourselves for the near-, medium- and long-term growth of our business.

Patents and Proprietary Rights

U.S. and European Patent Expiration

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

The following table shows the estimated expiration dates (including patent term extensions, supplementary protection certificates and/or pediatric exclusivity where granted) in the United States and the European Union for the primary (typically compound) patents for our key product candidates as described above. For our product candidates that are fixed-dose combinations of single-tablet regimens, the estimated patent expiration date provided corresponds to the latest expiring compound patent for one of the active ingredients in the single-tablet regimen.

Key Product Candidates	Patent Expiration	
	U.S.	E.U.
Viral Diseases:		
Lenacapavir	2037	2037
Bulevirtide	2030	2029
Inflammatory Diseases:		
Cilofexor	2032	2032
Filgotinib	2030	2030
Oncology:		
Axicabtagene ciloleucel	2031	— ⁽¹⁾
Brexucabtagene autoleucel	2027	— ⁽¹⁾
Sacituzumab govitecan-hziy	2023 ⁽²⁾	2029
Magrolimab	2031	2031
Zimberelimab ⁽³⁾	2036	2036
Domvanalimab ⁽³⁾	2037	2036

⁽¹⁾ The composition of matter patent has expired in the European Union. In the European Union and the United States, patent applications are pending relating to proprietary manufacturing processes of Kite, a Gilead company (“Kite”).

⁽²⁾ An application for patent term extension was filed in the United States that, if granted, would extend the U.S. expiration date to at least 2028. Regulatory exclusivity in the United States expires in 2032.

⁽³⁾ In collaboration with Arcus.

The following table shows the actual or estimated expiration dates (including patent term extensions, supplementary protection certificates and/or pediatric exclusivity where granted) in the United States and the European Union for the primary (typically compound) patents for our principal products. For our products that are fixed-dose combinations or single-tablet regimens, the estimated patent expiration dates provided correspond to the latest expiring compound patent for one of the active ingredients in the single-tablet regimen.

Products	Patent Expiration	
	U.S.	E.U.
Ranexa	2019 ⁽¹⁾	2023
Descovy	2025	2026
Vemlidy	2025	2026
Complera/Eviplera	2025	2026
Zydelig	2025 ⁽²⁾	2029
Odefsey	2025	2026
Yescarta	2031	— ⁽³⁾
Stribild	2029 ⁽⁴⁾	2028
Genvoya	2029 ⁽⁴⁾	2028
Harvoni	2030	2030
Epclusa	2033	2032
Biktarvy	2033	2033
Vosevi	2034	2033
Veklury	2035	2035
Tecartus	2027	— ⁽³⁾
Trodelyv	2023 ⁽⁵⁾	2029
Jyseleca	2030	2030
Hepcludex	2030	2029

These estimated expiration dates do not include any potential additional exclusivity (e.g., patent term extensions, supplementary protection certificates or pediatric exclusivity) that has not yet been granted.

⁽¹⁾ In 2013, Gilead and Lupin Limited reached an agreement to settle a patent litigation matter related to Ranexa.

⁽²⁾ Applications for patent term extensions are pending in the United States and/or SPCs are pending in one or more countries in the European Union for these products.

⁽³⁾ The composition of matter patent has expired in the European Union. In the European Union and the United States, patent applications are pending relating to proprietary manufacturing processes of Kite.

⁽⁴⁾ In 2018, Gilead and Mylan Pharmaceuticals reached an agreement to settle the patent litigation concerning patents that protect cobicistat in our Stribild and Genvoya products.

⁽⁵⁾ An application for patent term extension was filed in the United States that, if granted, would extend the U.S. expiration date to at least 2028. Regulatory exclusivity in the United States expires in 2032.

Patent Protection and Certain Challenges

Patents and other proprietary rights are very important to our business. If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.

Patents covering certain of the active pharmaceutical ingredients (“API”) of most of our HIV products as well as cell therapy products are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties.

We may obtain patents for certain products many years before marketing approval is obtained. Because patents have a limited life that may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions or supplementary protection certificates in some countries. For example, extensions for the patents or supplementary protection certificates on many of our products have been granted in the United States and in a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products we are developing, but we cannot be certain we will obtain them in some countries.

It is also important that we do not infringe the valid patents of third parties. If we infringe the valid patents of third parties, our reputation may be harmed and we may be required to pay significant monetary damages, we may be prevented from commercializing products or we may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of patents and patent applications owned by other parties that such parties may claim to cover the use of sofosbuvir, axicabtagene ciloleucel, brexucabtagene autoleucel, tenofovir disoproxil, tenofovir alafenamide and bictegravir.

Because patent applications are confidential for a period of time until a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the U.S. Patent and Trademark Office or other proceedings to determine the right to a patent or validity of any patent granted. Such litigation and proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, we may be adversely impacted.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or other proceedings regarding the enforcement or validity of our existing patents or any future patents could result in the invalidation of our patents or substantially reduce their protection. From time to time, certain individuals or entities may challenge our patents.

Our pending patent applications and the patent applications filed by our collaborative partners may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing compounds or products that are closely related to those which we have developed or are developing. In addition, certain countries do not provide effective enforcement of our patents, and third-party manufacturers may be able to sell generic versions of our products in those countries.

For a description of our significant pending legal proceedings, see Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. See also Item 1A Risk Factors “Our success depends to a significant degree on our ability to obtain and defend our patents and other intellectual property rights both domestically and internationally, and to operate without infringing upon the patents or other proprietary rights of third parties.”

Trade Secrets

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. For example, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by an individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets, internal know-how or technological innovation will not otherwise become known or be independently discovered by our competitors. Under some of our R&D agreements, inventions become jointly owned by us and our corporate partners and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions. If our trade secrets or confidential information become known or independently discovered by competitors, or if we enter into disputes over ownership of inventions, our business and results of operations could be adversely affected.

Manufacturing and Raw Materials

Our products are manufactured either at our own facilities or by third-party contract manufacturers. We depend on third parties to perform manufacturing activities for the majority of our API and drug products. For most of our products, including our HIV and HCV products, we use multiple third-party contract manufacturers so that we have primary and back-up suppliers and manufacturing sites. For our cell therapy products, we have established clinical and commercial manufacturing facilities for cell processing activities. For our future products, we continue to develop additional manufacturing capabilities and establish additional third-party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved for commercial sale.

Our Manufacturing Facilities

We own or lease manufacturing facilities to manufacture and distribute certain products and API for clinical and/or commercial uses. These facilities include:

- Foster City, California: We conduct process chemistry research and formulation development activities, manufacture API and drug product for our clinical trials and oversee our third-party contract manufacturers.
- San Dimas and La Verne, California: We manufacture AmBisome and also package and label the majority of our commercial products for distribution to the Americas and Pacific Rim.
- Oceanside, California: We utilize the facility for clinical manufacturing and process development of our biologics candidates.
- El Segundo, California: We utilize the facility for clinical and commercial manufacturing and processing of our cell therapy products.
- Frederick, Maryland: We utilize the facility for clinical manufacturing and processing of our cell therapy products.
- Morris Plains, New Jersey: We utilize the facility for manufacturing for monoclonal antibody intermediate and process optimization of our antibody drug conjugate products.
- Cork and Dublin, Ireland: We utilize the Cork facility for commercial manufacturing, packaging and labeling of our products. We also perform quality control testing, labeling, packaging and final release of many of our products at the Cork facility, which are distributed to the European Union and other international markets through our facility in Dublin. We utilize our other facility in central Dublin as a drug development hub for our pediatric programs where we perform clinical development, safety, quality, biostatistics and data sciences, regulatory and compliance functions.
- Edmonton, Canada: We conduct process chemistry research and scale-up activities for our clinical development candidates, manufacture API for both investigational and commercial products and conduct chemical development activities to improve existing commercial manufacturing processes.
- Hoofddorp, Netherlands: We utilize the facility for commercial manufacturing and processing of our cell therapy products.

Third-Party Manufacturers

We believe the technology we use to manufacture our products is proprietary. For products manufactured by our third-party contract manufacturers, we have disclosed all necessary aspects of this technology to enable them to manufacture the products for us. We have agreements with these third-party manufacturers that are intended to restrict them from using or revealing this technology, but we cannot be certain that these third-party manufacturers will comply with these restrictions.

For more information about our third-party manufacturers, see Item 1A Risk Factors “We may face manufacturing difficulties, delays or interruptions, including at our third-party manufacturers and corporate partners.”

Regulation of Manufacturing Process

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they observe do not comply with regulations. We, our third-party manufacturers and our corporate partners are subject to current Good Manufacturing Practices (“GMP”), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by FDA and the EMA. Similar regulations are in effect in other jurisdictions. Our manufacturing operations are subject to routine inspections by regulatory agencies.

For our cell therapy products, we are required by FDA to comply with the Risk Evaluation and Mitigation Strategy program, which includes educating and certifying medical personnel regarding the therapy procedures and the potential side effect profile of our therapy, such as the potential adverse side effects related to cytokine release syndrome and neurologic toxicities. Additionally, we are required to maintain a complex chain of identity and custody with respect to patient material as such material moves to the manufacturing facilities, through the manufacturing process, and back to the patient.

Access to Raw Materials

We need access to certain raw materials to conduct our clinical trials and manufacture our products. These raw materials are generally available from multiple sources, purchased worldwide and normally available in quantities adequate to meet the needs of our business. We attempt to manage the risks associated with our supply chain by inventory management, relationship management and evaluation of alternative sources when feasible. For more information, see Item 1A Risk Factors “We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues.”

Human Capital

Gilead’s success depends on the work of its dedicated employees who embrace a shared sense of purpose and a culture of excellence. Our human capital objective is to make Gilead the employer of choice for the best talent in our industry. Gilead’s key priorities for human capital management include inclusion and diversity, health and safety, total rewards, employee development and engagement. The Compensation and Talent Committee of our Board of Directors oversees our overall human capital management.

Inclusion & Diversity

Inclusion is a Gilead core value, and we believe building an inclusive and diverse workforce is critical to enabling Gilead’s mission. Our Global Inclusion and Diversity Council is responsible for governance of these matters, tracking progress on our goals and promoting a culture of inclusion. The Global Inclusion and Diversity Council is chaired by our Chairman and Chief Executive Officer and includes members of our leadership team. In 2020, we introduced our Advancing Black Leadership Strategy, a multi-year initiative that outlines our commitments to create internal and external pipelines for diverse talent and to build awareness, capabilities and accountability among our people managers. As part of this strategy, we set clear targets for representation within our overall workforce and executive populations, including goals to increase the percentage of female, Black and Hispanic employees with well-defined annual targets through 2025. Gilead also implemented multiple programs to train managers on inclusion and diversity topics, and created strategies and initiatives focused on attracting, developing and retaining diverse talent and driving an inclusive culture in our workplace, which organizational leaders were required to regularly review starting in 2021. In addition, our employee resource groups (“ERGs”) support diverse employees and aim to raise awareness of different cultures within the workplace, cultivate diversity as a business strength and support Gilead’s talent acquisition strategy to source, attract and recruit diverse candidates. Executive sponsors and leaders of our ERGs contribute to the advancement of our inclusion and diversity commitments through service on our Global Inclusion and Diversity Council.

We believe Gilead’s inclusive and diverse workforce is the foundation for innovation and productivity. Gilead’s commitment to equal employment opportunity furthers its efforts to cultivate and celebrate an equitable culture of belonging. As of December 31, 2021, Gilead had approximately 14,400 employees, and Gilead’s global workforce was approximately 52% female and 48% male. Additionally, women represented 34% of Gilead’s leadership (defined as vice president level and above). In the United States, based on our employees’ voluntary self-identification, our workforce was 40% White, 38% Asian, 11% Hispanic, 7% Black and 4% Other.

Health and Safety

Gilead is committed to providing a workplace for its employees that promotes health, safety, wellness and productivity. We have a workplace safety, training and security program together with various compliance protocols to support this commitment. We routinely train and educate our employees on workplace safety and security. In response to the COVID-19 pandemic, most Gilead sites required flexible location employees to work from home, while employees who needed to be physically present for their positions (such as laboratory technicians) continued to work at Gilead sites. In the fourth quarter of 2021, Gilead transitioned to a return-to-site phase for our U.S. flexible location employees. During the pandemic, we implemented job site enhancements and risk protocols, including health screenings, COVID-19 testing and vaccine requirements, reconfiguration of work and common spaces to allow for physical distancing, in our effort to support the safe occupancy of our sites. Gilead also maintains a robust contact tracing and notification process for any employee who reports COVID-19 infection. We continue to monitor the state of the pandemic and we remain committed to maintaining a work environment that promotes the health, safety and productivity of our workforce.

Total Rewards

Gilead's compensation and benefits programs are designed to help attract, develop and retain the industry's most talented workforce. Our Total Rewards program (which varies by country) includes competitive base salary and incentive compensation, stock awards, an employee stock purchase plan, a 401(k) savings plan with a company match that vests immediately, health and welfare and other valuable benefits, such as flexible work arrangements, flexible spending accounts, paid time off, family leave, family care resources, fertility, adoption and surrogacy assistance, student loan repayment and tuition assistance, employee assistance programs, global wellbeing reimbursement and tuition assistance, among many others. Each year, we reassess our Total Rewards package to confirm whether it offers benefits and incentives that align with our total reward philosophy.

We are a pay-for-performance company and are committed to addressing pay equity. Our employee salaries are informed by market-based ranges and are assessed annually through performance and career development reviews. Our policy is that compensation decisions are made without regard to personal characteristics such as gender, race, color, national or ethnic origin, age, disability, sexual orientation, gender identity or expression, genetic information, religion, or veteran status. We also conduct an annual pay equity review of employee compensation in an effort to strive to make our pay practices gender and race neutral.

Employee Development and Engagement

Employee development and engagement maximizes the potential and performance of each member of our workforce and is critical to achieving our business goals. Gilead offers a number of internal and external professional, management and leadership development training programs to help our employees develop technical, cross-functional and leadership skills and tools to grow their careers. In addition, employees can receive reimbursement for tuition expenses incurred while pursuing undergraduate, graduate or certificate courses at an accredited college or university.

As we strive to be the employer of choice in our industry, our listening strategy gathers input from our employees to shape our engagement strategies and programs and measure our progress. In addition to ongoing internal and external data collection, we conducted a large-scale review of the employee experience in 2021 with an employee survey. The results of this survey played a key role in determining the direction of our culture as well as the company's broader response to the continuing COVID-19 pandemic, including the meaningful benefits we provided to employees and our approach to flexible work arrangements. We believe our flexible work program positions us to be competitive for talent and support employee well-being while also creating the collaborative environment and connections that fuel innovation.

Environmental, Social and Governance (“ESG”)

Investing in corporate responsibility is core to our business strategy and reflects our values of accountability, inclusion, teamwork, excellence and integrity. This is in service to our mission to advance global health by providing innovative therapeutics in areas of unmet need in a way that is socially responsible and environmentally sustainable. Gilead's ESG programs reflect this commitment to our stakeholders. ESG strategy and performance are overseen by the Nominating and Corporate Governance Committee of its Board of Directors, and managed by a Corporate Responsibility Committee comprised of leaders from key departments across our company. The Corporate Responsibility Committee is responsible for reviewing material ESG issues and integrating them into our overall business strategy and operations. Additional information about this program and ESG highlights are available in Gilead's 2020 year in review under Gilead's website at www.gilead.com/news-and-press/annual-report/year-in-review-2020.

Our ESG goals are aspirational and may change. Statements regarding these goals and related initiatives are not guarantees or promises that they will be met.

Seasonality of Operations

Our worldwide product sales do not reflect any significant degree of seasonality in end-user demand. However, in the United States, fluctuations in wholesaler inventory levels impact our product sales. We typically observe strong wholesaler and sub-wholesaler purchases of our products in the fourth quarter resulting in inventory draw-down by wholesalers and sub-wholesalers in the subsequent first quarter. Several other factors, including government budgets, annual grant cycles for federal and state funds, the COVID-19 pandemic, and other buying patterns, also could impact the product sales recorded in a particular quarter. For more information, see Item 1A Risk Factors “We face challenges in accurately forecasting sales because of the difficulties in predicting demand for our products and fluctuations in purchasing patterns or wholesaler inventories.”

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the United States, the European Union and other countries, including laws and regulations governing the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming, which has a significant impact on our capital expenditures and results of operations. The regulatory requirements applicable to drug development and approval are subject to change. Any legal and regulatory changes may impact our operations in the future.

A country’s regulatory agency, such as FDA in the United States and the EMA and European Commission for the European Union, as well as the national authorities of the European Union Member States, must approve a drug before it can be sold in the respective country or countries. The general process for drug approval in the United States is summarized below. Many other countries, including countries in the European Union (and the European Union under a centralized procedure), have similar regulatory structures.

Preclinical Testing

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug candidate’s potential benefits and safety. We submit this data to FDA in an investigational new drug (“IND”) application seeking its approval to test the compound in humans.

Clinical Trials

If FDA accepts the IND, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

- Phase 1. The drug candidate is given to a small number of healthy human control subjects or patients suffering or at risk from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.
- Phase 2. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating or preventing the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 1 clinical trials to fail in the more rigorous and extensive Phase 2 clinical trials.
- Phase 3. If a drug candidate appears to be effective and have an appropriate safety profile in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 2 clinical trials to fail in the more rigorous and extensive Phase 3 clinical trials.

FDA Approval Process

When we believe that the data from our clinical trials show an acceptable benefit-risk profile, we submit the appropriate filing, usually in the form of a New Drug Application, Biologics License Application or supplemental application, with FDA, seeking approval to sell the drug candidate for a particular use. At FDA’s discretion, FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation to FDA that is not binding but is generally followed by FDA. If FDA agrees that the drug has met the required level of safety and efficacy for a particular use, it will approve the application and allow us to sell the drug in the United States for that use. It is not unusual, however, for FDA to decline to approve an application because it believes that the drug candidate is not safe enough or efficacious enough (i.e., does not have an appropriate benefit-risk profile) or because it does not believe that the data submitted is reliable or conclusive.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons, including safety concerns, lack of treatment benefit or manufacturing issues. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

Even after approving a drug, FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if FDA approves a drug, it could limit the uses of the drug. FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if concerns about the safety or efficacy are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by FDA. FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection. Our manufacturing facilities located in California also must be licensed by the State of California in compliance with local regulatory requirements. Our manufacturing facilities in Canada, Ireland and Netherlands also must obtain local licenses and permits in compliance with local regulatory requirements.

FDA may employ one of several tools to facilitate and expedite the development and review of a drug, including fast track designation, Breakthrough Therapy designation, accelerated approval and Priority Review designation. Fast track designation is designed to facilitate the development and review of a drug that treats a serious condition and fills an unmet medical need. Breakthrough Therapy designation is designed to expedite the development and review of a drug that treats a serious condition and preliminary clinical evidence demonstrates substantial improvement over available therapies. Accelerated approval of a drug may be granted by FDA where the drug treats a serious condition, fills an unmet medical need and has been studied for safety and efficacy. Priority Review designation means FDA's goal is to take action on an application within six months of filing. FDA may grant Priority Review designation to a drug that would provide significant improvement in the safety or effectiveness of a treatment, diagnosis or prevention of a serious condition.

European Union Regulatory System and Approval Process

In the European Union ("EU"), our products are subject to a variety of EU and EU Member State regulations governing clinical trials, commercial sales and distribution. We are required to obtain a marketing authorization in the EU before we can market our medicinal products on the relevant market. The conduct of clinical trials in the EU is governed by, among others, Directive 2001/20/EC and Directive 2005/28/EC and the EU (ICH) Good Clinical Practice rules. These impose legal and regulatory obligations that are similar to those provided in applicable U.S. laws. The conduct of clinical trials in the EU must be approved by the competent authorities of each EU Member States in which the clinical trials take place, and a positive opinion must be obtained from the relevant Ethics Committee in the relevant Member State. In 2014, the EU legislator adopted Regulation (EU) No 536/2014 to replace Directive 2001/20/EC and to introduce a coordinated procedure for authorization of clinical trials. This Regulation entered into application in January 2022.

Marketing authorization holders, manufacturers, importers, wholesalers and distributors of medicinal products placed on the market in the EU are required to comply with a number of regulatory requirements including pharmacovigilance, GMP compliance and the requirement to obtain manufacturing, import and/or distribution licenses issued by the competent authorities of the EU Member States. Failure to comply with these requirements may lead to the imposition of civil, criminal or administrative sanctions, including suspension of marketing or manufacturing authorizations.

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of third-party payer reimbursement for the cost of such products and related treatments and medical services in the markets where we sell our products. Government health authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services. A significant portion of our sales of the majority of our products are subject to substantial discounts from their list prices, including rebates we may be required to pay to Medicaid agencies or discounts we may be required to pay to 340B covered entities. As a result, the price increases we implement from time to time on certain products may have a limited effect on our net product sales in certain markets. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies.

As our products mature, pricing pressures from private insurers and government payers often result in a reduction of the net product prices. Further, as new branded or generic products are introduced into major markets, our ability to maintain pricing and market share may be affected.

For more information, see Item 1A Risk Factors “Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and other discounts on our products and other pricing pressures.” and “We face challenges in accurately forecasting sales because of the difficulties in predicting demand for our products and fluctuations in purchasing patterns or wholesaler inventories.”

Health Care Fraud and Abuse Laws; Anti-Bribery Laws

We are subject to various U.S. federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claim laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to knowingly and willingly solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business reimbursed by a federal healthcare program, including the purchase or prescription of a particular drug. False claims laws generally prohibit anyone from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by federal and certain state payers (including Medicare and Medicaid), or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. In addition, the FDA regulates written and verbal communications about our products. In addition to federal law, states also have consumer protection and false claims laws. Due to the breadth of the statutory provisions and the attention being given to them by law enforcement authorities, our sales, marketing, patient support, medical, clinical and public affairs activities may be subject to scrutiny under these laws. For example, recently there has been enhanced scrutiny by government enforcement authorities of company-sponsored patient assistance programs, including co-pay assistance programs and manufacturer donations to third-party charities that provide such assistance, reimbursement support offerings, clinical education programs and promotional speaker programs. Similarly, in Europe, interactions between pharmaceutical companies and physicians are subject to strict laws, regulations, industry self-regulation codes of conduct and physicians’ codes of professional conduct, as applicable, including the EU Member States anti-corruption laws and the UK Bribery Act 2010.

In addition, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree. In certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different than local custom.

Despite our training and compliance program, our internal control policies and procedures may not protect us from unlawful acts committed by our employees or agents. Violations of fraud and abuse laws or anti-bribery laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). Violations can also lead to the imposition of a Corporate Integrity Agreement or similar government oversight program, even if we disagree with the government’s perspective that we have violated any rules or guidance. Any similar violations by our competitors could also negatively impact the reputation of our industry and increase governmental and public scrutiny over our business and our products.

U.S. Healthcare Reform

The U.S. federal and state governments continue to propose and pass legislation designed to regulate the healthcare industry, including legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing.

For more information, see Item 1A Risk Factors “We are impacted by evolving laws, regulations and legislative or regulatory actions applicable to the health care industry.”

Environment

We are subject to a number of laws and regulations that require compliance with federal, state, and local regulations for the protection of the environment. The regulatory landscape continues to evolve, and we anticipate additional regulations in the future. Laws and regulations are implemented and under consideration to mitigate the effects of climate change mainly caused by greenhouse gas emissions. Our business is not energy intensive. Therefore, we do not anticipate being subject to a cap and trade system or other mitigation measure that would materially impact our capital expenditures, operations or competitive position.

Other Information

We are subject to the information requirements of the Securities Exchange Act of 1934 (“Exchange Act”). Therefore, we file periodic reports, proxy and information statements and other information with the SEC. The SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Our website is www.gilead.com. Through a link on the “Investors” page of our website (under the “SEC Filings” section), we make available the following filings free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our Annual Reports on Form 10-K; Quarterly Reports on Form 10-Q; Current Reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act.

Website references are provided throughout this document for convenience. The content on the referenced websites does not constitute a part of and is not incorporated by reference into this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following discussion of material risks, events and uncertainties that make an investment in us speculative or risky in addition to the other information in this Annual Report on Form 10-K. A manifestation of any of the following risks and uncertainties could, in circumstances we may or may not be able to accurately predict, materially and adversely affect our business and operations, growth, reputation (including the commercial or scientific reputation of our products), prospects, product pipeline and sales, operating and financial results, financial condition, cash flows, liquidity and stock price. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

Product and Commercialization Risks

Certain of our products subject us to additional or heightened risks.

HIV Products

We receive a substantial portion of our revenue from sales of our products for the treatment and prevention of HIV infection. During 2021, sales of our HIV products accounted for approximately 60% of our total product sales. We may be unable to sustain or increase sales of our HIV products for any number of reasons, including market share gains by competitive products, including generics, or the inability to introduce new HIV medications necessary to remain competitive. In such case, we may need to scale back our operations, including our future drug development and spending on research and development (“R&D”) efforts. For example, many of our HIV products contain tenofovir alafenamide (“TAF”), which belongs to the nucleoside class of antiviral therapeutics, and any changes to the treatment paradigm for HIV may cause nucleoside-based therapeutics to fall out of favor.

Veklury

We face risks related to our supply and distribution of Veklury, which was approved by the U.S. Food and Drug Administration (“FDA”) in October 2020 as a treatment for patients hospitalized with coronavirus disease 2019 (“COVID-19”) and in January 2022 as a treatment for non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death. While the utilization of Veklury has largely tracked rates of COVID-19 hospitalizations, we are unable to accurately predict our revenues or supply needs over the short and long term due to the dynamic nature of the pandemic, including the availability, uptake and effectiveness of vaccines and alternative treatments for COVID-19, fluctuating hospital utilization rates, the emergence of new variants and timing of surges in infection. If we do not accurately forecast demand or manufacture Veklury at levels sufficient to meet demand, then we may experience product shortages or build excess inventory that may be written off. We also remain subject to significant public attention and scrutiny over the complex decisions made regarding clinical data, supply, allocation, distribution and pricing of Veklury, all of which affects our corporate reputation.

Cell Therapy

Advancing a novel and personalized therapy such as Yescarta or Tecartus, which are chimeric antigen receptor (“CAR”) T cell therapies, creates significant challenges, including:

- educating and certifying medical personnel regarding the procedures and the potential side effects, such as cytokine release syndrome and neurologic toxicities, in compliance with the Risk Evaluation and Mitigation Strategy program required by FDA;
- securing sufficient supply of other medications to manage side effects, such as tocilizumab and corticosteroids, which may not be available in sufficient quantities, may not adequately control the side effects and/or may have detrimental impacts on the efficacy of cell therapy;
- developing and maintaining a robust and reliable process for engineering a patient’s T cells in our facilities and infusing them back into the patient; and
- conditioning patients with chemotherapy in advance of administering our therapy, which may increase the risk of adverse side effects.

The use of engineered T cells as a potential cancer treatment is a recent development and may not be broadly accepted by physicians, patients, hospitals, cancer treatment centers, payers and others in the medical community. While FDA has approved some cell therapies, including Yescarta and Tecartus, we must continue to demonstrate to the medical community the potential advantages of cell therapy compared to existing and future therapeutics. For challenges related to the reimbursement of Yescarta and Tecartus, see also “Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and other discounts on our products and other pricing pressures.”

We rely on third-party sites to collect patients’ white blood cells, known as apheresis centers, as well as shippers, couriers, and hospitals for the logistical collection of patients’ white blood cells and ultimate delivery of Yescarta or Tecartus to patients. These vendors may encounter disruptions or difficulties that could result in product loss and regulatory action. Apheresis centers may also choose not to participate in our quality certification process, or we may be unable to complete such certification in a timely manner or at all, which could delay or constrain our manufacturing and commercialization efforts.

We operate a new automated manufacturing facility in Frederick, Maryland. The facility is pending FDA approval for commercial manufacturing and, even if we obtain such approval, we have not manufactured our products in an automated facility on a commercial scale. As a result, we may not be able to produce or otherwise obtain an amount of supply sufficient to satisfy demand for our products. If we are unable to meet product demand, we will have difficulty meeting sales forecasts for products that we plan to manufacture at this facility.

Our success depends on developing and commercializing new products or expanding the indications for existing products.

If we are unable to launch commercially successful new products or new indications for existing products, our business will be adversely impacted. The launch of commercially successful products is necessary to grow our business, cover our substantial R&D expenses, and offset revenue losses when existing products lose market share due to factors such as competition and loss of patent exclusivity. There are many difficulties and uncertainties inherent in drug development and the introduction of new products. The product development cycle is characterized by significant investments of resources, long lead times and unpredictable outcomes due to the nature of developing medicines for human use. We expend significant time and resources on our product pipeline without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of new products, and failure can occur at any point in the process, including late in the process after substantial investment.

We face challenges in accurately forecasting sales because of the difficulties in predicting demand for our products and fluctuations in purchasing patterns or wholesaler inventories.

We may be unable to accurately predict demand for our products, including the uptake of new products, as demand depends on a number of factors. For example, product demand may be adversely affected if physicians do not see the benefit of our products. Additionally, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs, the U.S. Department of Veterans Affairs, correctional facilities and large health maintenance organizations, tends to be less consistent in terms of buying patterns and often causes quarter-over-quarter fluctuations that do not necessarily mirror patient demand for our products. Federal and state budget pressures, as well as the annual grant cycles for federal and state funds, may cause purchasing patterns to not reflect patient demand for our products. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers. In light of the budget crises faced by many European countries, we have observed variations in purchasing patterns induced by cost containment measures in Europe. We believe these measures have caused some government agencies and other purchasers to reduce inventory of our products in the distribution channels, and we may continue to see this trend in the future.

We sell and distribute most of our products in the United States exclusively through the wholesale channel. For the year ended December 31, 2021, approximately 91% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end-user demand and may not be completely effective in matching their inventory levels to actual end-user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end-user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions, increased competition or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers’ orders from us, even if end-user demand has not changed. In addition, we have observed that strong wholesaler and sub-wholesaler purchases of our products in the fourth quarter typically results in inventory draw-down by wholesalers and sub-wholesalers in the subsequent first quarter. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers.

New branded or generic products entering major markets affects our ability to maintain pricing and market share. Our products compete with other available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing. A number of companies are pursuing the development of technologies which are competitive with our existing products or research programs. These competing companies include large pharmaceutical and biotechnology companies and specialized pharmaceutical firms acting either independently or together with other such companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection or may establish collaborative arrangements for competitive products or programs. We may be adversely impacted if any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise.

Our existing products are subject to reimbursement pressures from government agencies and other third parties, required rebates and other discounts on our products and other pricing pressures.

Product Reimbursements

Successful commercialization of our products depends, in part, on the availability of third-party payer reimbursement for the cost of such products and related treatments and medical services in the markets where we sell our products. Government health authorities, private health insurers and other organizations generally provide reimbursement. As our products mature, pricing pressures from private insurers and government payers often result in a reduction of the net product prices.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. For example, in September 2020, FDA issued a final rule implementing a pathway for the importation of certain prescription drugs from Canada. This rule is subject to ongoing litigation. We may be adversely impacted by any such legislative and regulatory actions, though it is difficult to predict the impact, if any, on the use and reimbursement of our products.

Product Pricing, Discounts and Rebates

In the United States, the European Union (“EU”) and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services. In the United States, the volume of drug pricing-related bills has dramatically increased in recent years. For example, Congress has enacted laws requiring manufacturer refunds on certain amounts of discarded drug from single-use vials beginning in 2023 and eliminating the existing cap on Medicaid rebate amounts beginning in 2024. Congress has also proposed bills to require the Department of Health and Human Services to negotiate prices for certain drugs, impose an inflation-based rebate on Medicare Part B and D drugs when list prices for drugs grow faster than inflation, and increase manufacturer contributions in some or all of the Medicare Part D benefit phases. In addition, many state legislatures are considering, or have already passed into law, legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as requiring manufacturers to publicly report proprietary pricing information, creating review boards for prices to state agencies, and encouraging the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products, and the resulting impact on our business is uncertain. Many countries outside the United States, including the EU Member States, have established complex and lengthy procedures to obtain price approvals and coverage reimbursement and periodically review their pricing and reimbursement decisions. The outcome of this review cannot be predicted and could have an adverse effect on the pricing and reimbursement of our medicinal products in the EU member states. Reductions in the pricing of our medicinal products in one member state could affect the price in other member states and have a negative impact on our financial results.

A substantial portion of our product sales is subject to significant discounts from list price, including rebates that we may be required to pay state Medicaid agencies and discounts provided to 340B covered entities. Changes to the 340B program or the Medicaid program at the federal or state level could have a material adverse effect on our business. For example, in December 2020, Centers for Medicare & Medicaid Services (“CMS”) issued a final rule that will make certain changes to the calculation of rebates under the Medicaid Drug Rebate Program. Among other changes, effective January 1, 2023, the final rule will change the requirements for excluding manufacturer co-pay coupons from the Medicaid “best price.” These changes are subject to ongoing litigation. If these changes go into effect, they could substantially increase our Medicaid rebate obligations and decrease the prices we charge 340B covered entities. The continued growth of the 340B program also limits the prices we may charge on an increasing percentage of sales.

In addition, standard reimbursement structures may not adequately reimburse for innovative therapies. For example, beginning in fiscal year 2021, CMS established a new severity-adjusted diagnosis-related group (“DRG”) 018 for Medicare inpatient reimbursement of CAR T products such as Yescarta and Tecartus. While the new DRG has a significantly higher base payment amount than the prior DRG 016, the payment available may not be sufficient to reimburse some hospitals for their cost of care for patients receiving Yescarta and Tecartus. When reimbursement is not aligned well to account for treatment costs, Medicare beneficiaries may be denied access as this misalignment could impact the willingness of some hospitals to offer the therapy and of doctors to recommend the therapy. Additionally, in the EU, there are barriers to reimbursement in individual countries that could limit the uptake of Yescarta and Tecartus.

In addition, we estimate the rebates we will be required to pay in connection with sales during a particular quarter based on claims data from prior quarters. In the United States, actual rebate claims are typically made by payers one to three quarters in arrears. Actual claims and payments may vary significantly from our estimates.

We may experience adverse impacts resulting from the importation of our products from lower price markets or the distribution of illegally diverted or counterfeit versions of our products.

Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported and resold into those countries from lower price markets. For example, U.S. sales could also be affected if FDA permits importation of drugs from Canada. We have entered into agreements with generic drug manufacturers as well as licensing agreements with the Medicines Patent Pool, a United Nations-backed public health organization, which allows generic drug manufacturers to manufacture generic versions of certain of our products for distribution in certain low- and middle-income countries. We may be adversely affected if any generic versions of our products, whether or not produced and/or distributed under these agreements, are exported to the United States, Europe or markets with higher prices.

In the EU, we are required to permit products purchased in one EU member state to be sold in another member state. Purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high can affect the inventory level held by our wholesalers and can cause the relative sales levels in the various countries to fluctuate from quarter to quarter and not reflect the actual consumer demand in any given quarter.

Additionally, diverted products may be used in countries where they have not been approved and patients may source the diverted products outside the legitimate supply chain. These diverted products may be handled, shipped and stored inappropriately, which may affect the efficacy of the products and could harm patients and adversely impact us.

We are also aware of the existence of various suppliers around the world that source our products and generic versions of our products without Gilead’s authorization and sell them for use in countries where those products have not been approved. As a result, patients may be at risk of taking unapproved medications that may not be what they purport to be, may not have the potency they claim to have or may contain harmful substances, which could adversely impact us.

Further, third parties have illegally distributed and sold, and may continue to illegally distribute and sell, illegally diverted and counterfeit versions of our medicines, which do not meet the rigorous quality standards of our manufacturing and supply chain. For example, as part of an ongoing investigation in coordination with the U.S. Marshals and local law enforcement, we recently executed court-ordered seizures at 17 locations across eight U.S. states and seized thousands of bottles of Gilead-labeled medication with counterfeit supply chain documentation, including bottles labeled as Biktarvy and Descovy. Our investigation revealed that pharmaceutical distributors that are not authorized by Gilead to sell Gilead medicine, sold to independent pharmacies nationwide, purported genuine Gilead medicine sourced from an illegal counterfeiting scheme.

Illegally diverted and counterfeit medicines pose a serious risk to patient health and safety. Our actions to stop or prevent the distribution and sale of illegally diverted and counterfeit versions of our medicines around the world may be costly and unsuccessful, which may adversely affect our reputation and business, including our product revenues and financial results.

Product Development and Supply Chain Risks

We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption.

We are required to demonstrate the safety and efficacy of product candidates that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products.

We face numerous risks and uncertainties with our clinical trials that could result in delays or prevent completion of the development and approval of our product candidates. These risks and uncertainties include challenges in clinical trial protocol design, our ability to enroll patients in clinical trials, and the possibility of unfavorable or inadequate trial results to support further development of our product candidates, including failure to meet a trial's primary endpoint, safety issues arising from our clinical trials, and the need to modify or delay our clinical trials or to perform additional trials. For example, we recently announced clinical holds placed by FDA on clinical trials evaluating (1) injectable lenacapavir, (2) lenacapavir in combination with islatravir and (3) magrolimab, including in combination with azacitidine.

As a result, we may be unable to successfully complete our clinical trials on our anticipated timelines, or at all. Based on trial results, it is possible that FDA and other regulatory authorities may not approve our product candidates, or that any market approvals may include significant limitations on the products' use. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could adversely impact our business. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. Therefore, our product candidates may never be successfully commercialized, and we may be unable to recoup the significant R&D and clinical trial expenses incurred. In 2022, we anticipate the continued expansion of our clinical pipeline, which includes multiple planned Phase 3 study initiations in oncology and virology. We expect to expend significant time and resources on our clinical trial activities without any assurance that we will recoup our investments or that our efforts will be commercially successful.

There are also risks associated with the use of third parties in our clinical trial activities. We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third-party contract research organizations ("CROs") to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management, patient enrollment, ongoing monitoring, site management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals may be adversely affected.

We may face manufacturing difficulties, delays or interruptions, including at our third-party manufacturers and corporate partners.

Our products, which are manufactured at our own facilities or by third-party manufacturers and corporate partners, are the result of complex, highly regulated manufacturing processes. We depend on third-party manufacturers and corporate partners to perform manufacturing activities effectively and on a timely basis for the majority of our active pharmaceutical ingredients and drug products. These third parties are independent entities subject to their own unique operational and financial risks that are out of our control. We and our third-party manufacturers and corporate partners are subject to Good Manufacturing Practices ("GMP"), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by FDA and the European Medicines Agency ("EMA"), as well as comparable regulations in other jurisdictions. Manufacturing operations are also subject to routine inspections by regulatory agencies.

Any adverse developments affecting or resulting from our manufacturing operations or the operations of our third-party manufacturers and corporate partners may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the commercial supply of our products. We may also need to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications and quality standards, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such developments could increase our manufacturing costs, cause us to lose revenues or market share and damage our reputation. In addition, manufacturing issues may cause delays in our clinical trials and applications for regulatory approval. For example, if we are unable to remedy any deficiencies cited by FDA or other regulatory agencies in their inspections, our existing products and the timing of regulatory approval of product candidates in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. Our business may be adversely affected if approval of any of our product candidates were delayed or if production of our products were interrupted.

We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which could limit our ability to generate revenues.

We need access to certain supplies and products to conduct our clinical trials and to manufacture and sell our products. If we are unable to purchase sufficient quantities of these materials or find suitable alternative materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture and sell our products could be limited.

Suppliers of key components and materials must be named in the new drug application or marketing authorization application filed with the regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money and effort in the area of production and quality control to maintain full compliance with GMP. Manufacturers are subject to regular periodic inspections by regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand. In addition, if deliveries of materials from our suppliers are interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our product candidates in development for clinical trials. Also, some of our products and the materials that we utilize in our operations are manufactured by only one supplier or at only one facility, which we may not be able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers or facilities we depend on, including in the event of a disaster, such as an earthquake, equipment failure or other difficulty, may negatively impact our development and commercialization efforts.

A significant portion of the raw materials and intermediates used to manufacture our antiviral products are supplied by third-party manufacturers and corporate partners outside of the United States. As a result, any political or economic factors in a specific country or region, including any changes in or interpretations of trade regulations, compliance requirements or tax legislation, that would limit or prevent third parties outside of the United States from supplying these materials could adversely affect our ability to manufacture and supply our antiviral products to meet market needs and have a material and adverse effect on our operating results.

If we were to encounter any of these difficulties, our ability to conduct clinical trials on product candidates and to manufacture and sell our products could be impaired.

Regulatory and Other Legal Risks

Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to maintain compliance could delay or halt commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by FDA, EMA and comparable regulatory agencies in other countries. We have filed, and anticipate that we will file, for marketing approval in additional countries and for additional indications and products over the next several years. These and any future marketing applications we file may not be approved by the regulatory authorities on a timely basis, or at all. Even if marketing approval is granted for these products, there may be significant limitations on their use. We cannot state with certainty when or whether any of our product candidates under development will be approved or launched; whether we will be able to develop, license or acquire additional product candidates or products; or whether any products, once launched, will be commercially successful.

Further, how we manufacture and sell our products is subject to extensive regulation and review. For example, under FDA rules, we are often required to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk. In certain circumstances, we may be required to implement a Risk Evaluation and Mitigation Strategy program for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers, restrictions on distribution or use of a product and other elements FDA deems necessary to assure safe use of the drug. Discovery of previously unknown problems with our marketed products or product candidates, including serious safety, resistance or drug interaction issues, or problems with our manufacturing, safety reporting or promotional activities may result in regulatory approvals being delayed, denied or granted with significant restrictions on our products, including limitations on or the withdrawal of the products from the market.

Failure to comply with these or other requirements imposed by FDA could result in significant civil monetary penalties, fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecutions.

We are impacted by evolving laws, regulations and legislative or regulatory actions applicable to the health care industry.

The health care industry is subject to various federal, state and international laws and regulations pertaining to drug reimbursement, rebates, price reporting, health care fraud and abuse, and data privacy and security. In the United States, these laws include anti-kickback and false claims laws, laws and regulations relating to the Medicare and Medicaid programs and other federal and state programs, the Medicaid Rebate Statute, laws that regulate written and verbal communications about our products, individual state laws relating to pricing and sales and marketing practices, the Health Insurance Portability and Accountability Act and other federal and state laws relating to the privacy and security of health information. Actual or alleged violations of these laws or any related regulations may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, civil monetary penalties, exclusion from participation in federal and state health care programs, including Medicare, Medicaid and Department of Veterans Affairs and Department of Defense health programs, actions against executives overseeing our business and significant remediation measures, negative publicity or other consequences. These laws and regulations are broad in scope and subject to changing and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. The resulting impact on our business is uncertain and could be material.

In addition, government price reporting and payment regulations are complex, and we are continually assessing the methods by which we calculate and report pricing in accordance with these obligations. Our methodologies for calculations are inherently subjective and may be subject to review and challenge by various government agencies, which may disagree with our interpretation. If the government disagrees with our reported calculations, we may need to restate previously reported data and could be subject to additional financial and legal liability.

There also continues to be enhanced scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs, and manufacturer donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments on reimbursement and other patient support offerings, clinical education programs and promotional speaker programs. If we, or our agents and vendors, are deemed to have failed to comply with laws, regulations or government guidance in any of these areas, we could be subject to criminal or civil sanctions. Any similar violations by our competitors could also negatively impact our industry reputation and increase scrutiny over our business and our products.

For a description of our government investigations and related litigation, see Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

We are subject to risks if significant safety issues arise for our marketed products or our product candidates.

As additional studies are conducted subsequent to obtaining marketing approval for our products, and as our products are used over longer periods of time by many patients, including patients with underlying health problems or patients taking other medicines, we expect to continue finding new issues related to safety, resistance or drug interactions. Any such issues may require changes to our product labels, such as additional warnings, contraindications or even narrowed indications, or to halt sales of a product.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information and clinical trial data directly available to the public through websites and other means, such as periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action.

Our success depends to a significant degree on our ability to obtain and defend our patents and other intellectual property rights both domestically and internationally, and to operate without infringing upon the patents or other proprietary rights of third parties.

Patents and other proprietary rights are very important to our business. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. Our success depends to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets and internal know-how;
- defend against infringement of our patents and efforts to invalidate them; and
- operate without infringing on the intellectual property of others.

Because patent applications are confidential for a period of time before a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. If competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the U.S. Patent and Trademark Office or other proceedings to determine the right to a patent or validity of any patent granted. Such litigation and proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, we may be adversely impacted.

Generic manufacturers have sought, and may continue to seek, FDA approval to market generic versions of our products through an abbreviated new drug application (“ANDA”), the application process typically used by manufacturers seeking approval of a generic drug. For a description of our ANDA litigation, see Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. The entry of generic versions of our products has, and may in the future, lead to market share and price erosion.

If we are found to infringe the valid patents of third parties, we may be required to pay significant monetary damages or we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on commercially reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of patents and patent applications owned by third parties that such parties may claim cover the use of sofosbuvir, axicabtagene ciloleucel or bictegravir, as well as certain uses of combinations of emtricitabine (“FTC”) and tenofovir disoproxil fumarate (“TDF”) or TAF. For a description of our pending patent litigation, see Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. For example, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets, internal know-how or technological innovation will not otherwise become known or be independently discovered by our competitors. Under some of our R&D agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions. We could be adversely affected if our trade secrets, internal know-how, technological innovation or confidential information become known or independently discovered by competitors or if we enter into disputes over ownership of inventions.

We face potentially significant liability and increased expenses from litigation and government investigations relating to our products and operations.

We are involved in a number of litigation, investigation and other dispute-related matters that require us to expend substantial internal and financial resources. These matters could require us to pay significant monetary amounts, including royalty payments for past and future sales. For example, on February 1, 2022, we reached an agreement with ViiV Healthcare Company and related parties (collectively, “ViiV”) for a global resolution of all pending or potential claims related to our sales of Biktarvy, pursuant to which (1) ViiV granted Gilead a broad worldwide license and covenant not to sue relating to any past, present or future development or commercialization of bictegravir, and (2) Gilead agreed to make a one-time payment of \$1.25 billion and an ongoing royalty at a rate of 3% on future sales of Biktarvy and the bictegravir component of bictegravir-containing products in the United States until October 5, 2027.

We expect these matters will continue to require a high level of internal and financial resources for the foreseeable future. These matters have reduced, and are expected to continue to reduce, our earnings and require significant management attention.

In addition, the testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. We have limited insurance for product liabilities that may arise and claims may exceed our coverage.

For a description of our litigation, investigation and other dispute-related matters, see Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K. The outcome of such legal proceedings or any other legal proceedings that may be brought against us, the investigations or any other investigations that may be initiated and any other dispute-related matters, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us.

Operational Risks

Our business has been, and may in the future be, adversely affected by outbreaks of epidemic, pandemic or contagious diseases, including the ongoing COVID-19 outbreak.

Actual or threatened outbreaks of epidemic, pandemic or contagious diseases, such as COVID-19, may significantly disrupt our global operations and adversely affect our business, financial condition and results of operations. For example, the COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets and has resulted in increased risks and adverse impacts to our operations, including as described below. In addition to the developments discussed in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” we are monitoring a number of risks related to the pandemic, including the following:

- **Supply Chain:** The pandemic could result in disruptions to our global supply chain and distribution in the future. For example, quarantines, shelter-in-place and other governmental orders and policies, travel restrictions, airline capacity and route reductions, safety guidelines and health impacts of the pandemic could impact the availability or productivity of products and personnel at manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in higher costs, disruptions in our supply chain and interruptions in our distribution capabilities.
- **Clinical Trials:** The pandemic has adversely affected and may continue to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. For ongoing trials, clinical trial sites have imposed restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. There is also a risk that closures at clinical sites may be necessary as the pandemic and related guidance and restrictions continue to evolve. For the foregoing reasons, we have experienced delays with new subject enrollment for most clinical trials during the course of the pandemic, and may continue to experience overall delays in our clinical trials. There is also the risk of biased data collection if only certain clinical trial sites remain open. As a result of these challenges, our anticipated filing and marketing timelines for certain products may be adversely impacted.
- **Regulatory Reviews:** The operations of FDA, EMA or other regulatory agencies may be adversely affected. We may also experience delays in necessary interactions with regulatory authorities around the world, including with respect to any anticipated filing, which, together with other factors resulting from the pandemic, may adversely impact our ability to launch new commercial products.
- **Access to Healthcare Providers:** The pandemic has limited patients’ ability or willingness to access and seek care from healthcare providers and initiate or continue therapies, which has resulted in lower demand for our products during the course of the pandemic, particularly with respect to hepatitis C virus (“HCV”) treatment and HIV treatment and prevention. For example, we have observed lower levels of patient visits and testing volumes in HCV, resulting in fewer patient starts. In addition, at times during the pandemic, we have seen lower levels of screening and diagnosis for HIV, resulting in fewer treatment initiations, as well as higher levels of discontinuations, resulting in a reduction in prescription refills. With increased levels of unemployment at times during the pandemic, we have also experienced shifts in payer mix towards more government-funded coverage and the uninsured segment. Our field personnel have also had reduced access to healthcare personnel during the pandemic, including fewer in-person interactions, which has adversely impacted and may continue to adversely impact our commercial activities.
- **Employees:** We face risks related to the health, safety, morale and productivity of our employees, including the safe occupancy of our sites during the pandemic. In the fourth quarter of 2021, we transitioned to a return-to-site phase for our U.S. flexible location employees. Our job site enhancements and risk protocols, which include health screenings and COVID-19 testing and vaccine requirements, do not guarantee that we can maintain the continued safe occupancy of our sites and may adversely impact employee recruitment and retention. On-site employees testing positive for COVID-19 could lead to mandatory quarantines and potential site shutdowns.

- **Financial:** The pandemic has had, and may continue to have, an adverse financial impact in the short term and potentially beyond. In particular, our HCV and HIV businesses have been and continue to be adversely impacted. For example, we have observed reductions in the overall U.S. HCV treatment, HIV treatment and HIV pre-exposure prophylaxis (“PrEP”) volumes at times during the pandemic, and it is uncertain when these volumes will all return to pre-pandemic levels. We may continue to experience fluctuating revenues as infection rates rise and fall and as pandemic restrictions are periodically tightened and eased. We have also experienced, and may continue to experience, volatility in our short-term revenues due to fluctuations in inventory channel purchases during the pandemic. We could also have additional unexpected expenses related to the pandemic, which could negatively affect our results of operations. These factors together with the overall uncertainty and disruption caused by the pandemic could result in increased volatility and decreased predictability in our results of operations and volatility in our stock price.

The pandemic has also amplified many of the other risks described throughout the “Risk Factors” section of this Annual Report on Form 10-K. The extent to which the pandemic impacts our business and results will depend on future developments, which are uncertain and cannot be predicted with confidence, including any potential future waves of the pandemic, new variants of the virus that impact the severity and duration of the pandemic, the development, distribution, effectiveness and public acceptance of vaccines, and any other ongoing and future actions taken to contain the pandemic.

We face risks associated with our global operations.

Our global operations are accompanied by certain financial, political, economic and other risks, including those listed below:

- **Foreign Currency Exchange:** For the year ended December 31, 2021, approximately 29% of our product sales were outside the United States. Because a significant percentage of our product sales is denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. Overall, we are a net receiver of foreign currencies, and therefore, we benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar. Our hedging program does not eliminate our exposure to currency fluctuations. We may be adversely impacted if the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation.
- **Interest Rates and Inflation:** We hold interest-generating assets and interest-bearing liabilities, including our available-for-sale debt securities and our senior unsecured notes and credit facilities. Fluctuations in the interest rate could expose us to increased financial risk. In addition, changes in the inflation rate could also adversely impact our business and financial results.
- **Anti-Bribery:** We are subject to the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws that govern our international operations with respect to payments to government officials. Our international operations are heavily regulated and require significant interaction with foreign officials. We operate in parts of the world that have experienced governmental corruption to some degree. In certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state-controlled, in a manner that is different than local custom. It is possible that certain of our practices may be challenged under these laws. In addition, our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees and agents. Enforcement activities under anti-bribery laws could subject us to administrative and legal proceedings and actions, which could result in civil and criminal sanctions, including monetary penalties and exclusion from healthcare programs.

Other risks inherent in conducting a global business include:

- Restrictive government actions against our intellectual property and other foreign assets such as nationalization, expropriation, the imposition of compulsory licenses or similar actions, including waiver of intellectual property protections.
- Protective economic policies taken by foreign governments, such as trade protection measures and import and export licensing requirements, which may result in the imposition of trade sanctions or similar restrictions by the United States or other governments.
- Business interruptions stemming from natural or man-made disasters, such as climate change, earthquakes, hurricanes, flooding, fires, extreme heat, drought or actual or threatened public health emergencies, or efforts taken by third parties to prevent or mitigate such disasters, such as public safety power shutoffs and facility shutdowns, for which we may be uninsured or inadequately insured. For example, our corporate headquarters in Foster City and certain R&D and manufacturing facilities are located in California, a seismically active region. In the event of a major earthquake, we may not carry adequate earthquake insurance and significant recovery time could be required to resume operations.
- Political instability or disruption in a geographic region where we operate, regardless of cause, including war, terrorism, social unrest and political changes.

Our aspirations, goals and disclosures related to environmental, social and governance (“ESG”) matters expose us to numerous risks, including risks to our reputation and stock price.

Institutional and individual investors are increasingly using ESG screening criteria to determine whether Gilead qualifies for inclusion in their investment portfolios. We are frequently asked by investors and other stakeholders to set ambitious ESG goals and provide new and more robust disclosure on goals, progress toward goals and other matters of interest to ESG stakeholders. In response, we have adapted the tracking and reporting of our corporate responsibility program to various evolving ESG frameworks, and we have established and announced goals and other objectives related to ESG matters. These goal statements reflect our current plans and aspirations and are not guarantees that we will be able to achieve them. Our efforts to accomplish and accurately report on these goals and objectives present numerous operational, reputational, financial, legal and other risks, any of which could have a material negative impact, including on our reputation and stock price.

Our ability to achieve any goal or objective, including with respect to environmental and diversity initiatives, is subject to numerous risks, many of which are outside of our control. Examples of such risks include: (1) the availability and cost of low- or non-carbon-based energy sources and technologies, (2) evolving regulatory requirements affecting ESG standards or disclosures, (3) the availability of suppliers that can meet our sustainability, diversity and other standards, (4) our ability to recruit, develop and retain diverse talent in our labor markets, and (5) the impact of our organic growth and acquisitions or dispositions of businesses or operations.

The standards for tracking and reporting on ESG matters are relatively new, have not been harmonized and continue to evolve. Our selection of disclosure frameworks that seek to align with various reporting standards may change from time to time and may result in a lack of consistent or meaningful comparative data from period to period. In addition, our processes and controls may not always comply with evolving standards for identifying, measuring and reporting ESG metrics, our interpretation of reporting standards may differ from those of others and such standards may change over time, any of which could result in significant revisions to our goals or reported progress in achieving such goals.

If our ESG practices do not meet evolving investor or other stakeholder expectations and standards, then our reputation, our ability to attract or retain employees and our attractiveness as an investment, business partner or acquirer could be negatively impacted. Similarly, our failure or perceived failure to pursue or fulfill our goals, targets and objectives or to satisfy various reporting standards within the timelines we announce, or at all, could also have similar negative impacts and expose us to government enforcement actions and private litigation.

We depend on relationships with third parties for sales and marketing performance, technology, development, logistics and commercialization of products. Failure to maintain these relationships, poor performance by these companies or disputes with these third parties could negatively impact our business.

We rely on a number of collaborative relationships with third parties for our sales and marketing performance in certain territories. For example, we have collaboration arrangements with Janssen Sciences Ireland UC for Odefsey, Complera/Eviplera and Symtuza. In some countries, we rely on international distributors for sales of certain of our products. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that:

- we are unable to control the resources our corporate partners devote to our programs or products;
- disputes may arise with respect to the ownership of rights to technology developed with our corporate partners;
- disagreements with our corporate partners could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;
- our corporate partners with marketing rights may choose to pursue competing technologies or to devote fewer resources to the marketing of our products than they do to products of their own development; and
- our distributors and our corporate partners may be unable to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline.

Due to the specialized and technical nature of our business, the failure to attract, develop and retain highly qualified personnel could adversely impact us.

Our future success will depend in large part on our continued ability to attract, develop and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. Our ability to do so also depends in part on how well we maintain a strong workplace culture that is attractive to employees. In addition, competition for qualified personnel in the biopharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Additionally, changes to U.S. immigration and work authorization laws and regulations could make it more difficult for employees to work in or transfer to one of the jurisdictions in which we operate.

Significant cybersecurity incidents could give rise to legal liability and regulatory action under data protection and privacy laws and adversely affect our business and operations.

We are dependent upon information technology systems, infrastructure and data, including our Kite Konnect platform, which is critical to maintain chain of identity and chain of custody of Yescarta and Tecartus. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and ransomware attack. Likewise, data privacy or security breaches by employees or others can result in the exposure of sensitive data, including our intellectual property or trade secrets or the personal information of our employees, patients, customers or other business partners to unauthorized persons or to the public. Cybersecurity incidents are increasing in their frequency, sophistication and intensity, including during the COVID-19 pandemic. Cybersecurity incidents include, for example, the deployment of harmful malware, ransomware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business and technology partners face similar risks and any security breach of their systems could adversely affect our security posture.

Like many companies, we have experienced cybersecurity incidents, including data breaches and service interruptions. When cybersecurity incidents occur, we respond and address them in accordance with applicable governmental regulations and other legal requirements, including our cybersecurity protocols. There can be no assurance that our efforts in response to cybersecurity incidents, as well as our investments to protect our information technology infrastructure and data, will shield us from significant losses and potential liability or prevent any future interruption or breach of our systems. Such cybersecurity incidents can cause the loss of critical or sensitive information, including personal information, and could give rise to legal liability and regulatory action under data protection and privacy laws.

Regulators globally are also imposing new data privacy and security requirements, including new and greater monetary fines for privacy violations. For example, the General Data Protection Regulation (“GDPR”) established regulations regarding the handling of personal data, and non-compliance with the GDPR may result in monetary penalties of up to four percent of worldwide revenue. In addition, new domestic data privacy and security laws, such as the California Consumer Privacy Act and the California Privacy Rights Act and other laws that have been or may be passed, similarly introduce requirements with respect to personal information, and non-compliance with such laws may result in liability through private actions (subject to statutorily defined damages in the event of certain data breaches) and enforcement. Other changes or new laws or regulations associated with the enhanced protection of personal information, including, in some cases, healthcare data or other personal information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate.

Strategic and Financial Risks

We are subject to risks associated with engaging in business acquisitions, licensing arrangements, collaborations, options, equity investments, asset divestitures and other strategic transactions.

We have engaged in, and may in the future engage in, such transactions as part of our business strategy. We may not identify suitable transactions in the future and, if we do, we may not complete such transactions in a timely manner, on a cost-effective basis, or at all, and may not realize the expected benefits. If we are successful in making an acquisition or closing a licensing arrangement or collaboration, the products, intellectual property and technologies that are acquired or licensed may not be successful or may require significantly greater resources and investments than anticipated. As part of our annual impairment testing of our goodwill and other indefinite-lived intangible assets in the fourth quarter, and earlier if impairment indicators exist, as required under U.S. generally accepted accounting principles, we may need to recognize impairment charges if the products, intellectual property and technologies that are acquired or licensed are not successful. For option structured deals, there is no assurance that we will elect to exercise our option right, and it is possible that disagreements, uncertainties or other circumstances may arise, including with respect to whether our option rights have been appropriately triggered, which may hinder our ability to realize the expected benefits. For equity investments in our strategic transactions, such as in connection with our collaborations with Arcus Biosciences, Inc. and Galapagos NV, the value of our equity investments may fluctuate and decline in value. If we are not successful in the execution or implementation of these transactions, our financial condition, cash flows and results of operations may be adversely affected, and our stock price could decline.

We have paid substantial amounts of cash and incurred additional debt to finance our strategic transactions. Additional indebtedness and a lower cash balance could result in a downgrade of our credit ratings, limit our ability to borrow additional funds or refinance existing debt on favorable terms, increase our vulnerability to adverse economic or industry conditions, and reduce our financial flexibility to continue with our capital investments, stock repurchases and dividend payments. For example, as a result of the cash used and the debt issued in connection with our acquisition of Immunomedics, Inc. in 2020, S&P Global Ratings downgraded our credit rating. We may be adversely impacted by any failure to overcome these additional risks.

Changes in our effective income tax rate could reduce our earnings.

We are subject to income taxes in the United States and various foreign jurisdictions. Due to economic and political conditions, various countries are actively considering and have made changes to existing tax laws, and we cannot predict the form or timing of such changes. Our effective tax rates are affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, the introduction of new taxes, and changes in tax laws, regulations, administrative practices and interpretations, including in the United States, Germany and Ireland.

We are also subject to the examination of our tax returns and other tax matters by the U.S. Internal Revenue Service and tax authorities in various foreign jurisdictions. There are differing interpretations of tax laws and regulations and, as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We may be adversely affected by the resolution of one or more of these exposures in any reporting period.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Foster City, California, where we house our administrative, manufacturing and R&D activities. We also have R&D facilities in Emeryville, Oceanside and Santa Monica, California; Seattle, Washington; Morris Plains, New Jersey; Frederick, Maryland; Edmonton, Canada; and Dublin, Ireland. Our principal manufacturing facilities are in El Segundo, La Verne, Oceanside and San Dimas, California; Edmonton, Canada; Cork, Ireland and Hoofddorp, Netherlands. For more information about our manufacturing facilities, see Item 1. Business “*Our Manufacturing Facilities.*” Our global operations include offices in Europe, North America, Asia, South America, Africa, Australia and the Middle East.

We believe that our existing properties, including both owned and leased sites, are adequate and suitable for the conduct of our business. We believe our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs.

ITEM 3. LEGAL PROCEEDINGS

For a description of our significant pending legal proceedings, see Note 14. Commitments and Contingencies - Legal Proceedings of the Notes to Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

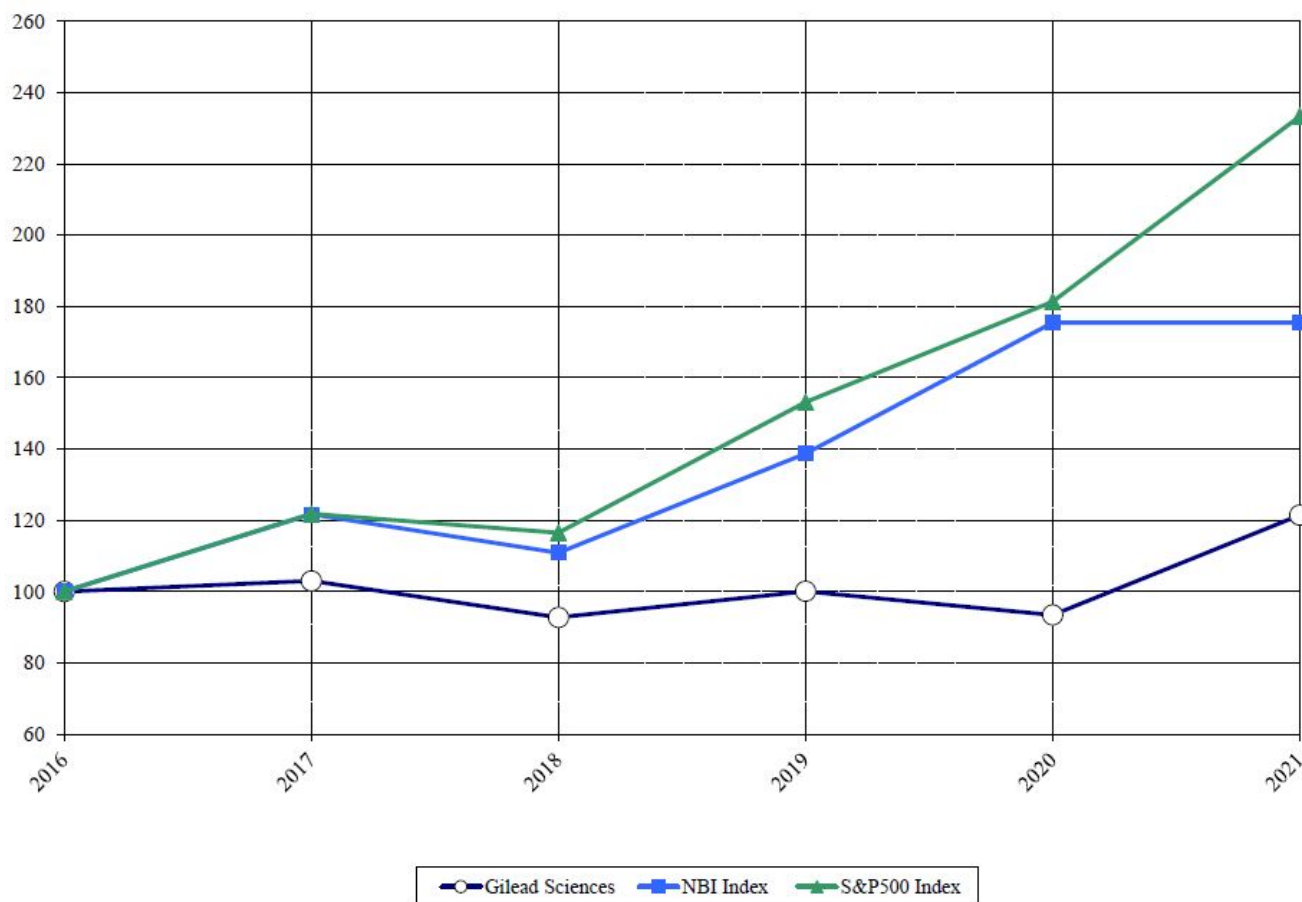
Our common stock is traded on the Nasdaq Global Select Market under the symbol “GILD.”

As of February 18, 2022, we had approximately 1,456 stockholders of record of our common stock.

Performance Graph⁽¹⁾

The following graph compares our cumulative total stockholder return for the past five years to two indices: the Standard & Poor’s 500 Stock Index (“S&P 500 Index”) and the Nasdaq Biotechnology Index (“NBI Index”). The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

Comparison of Cumulative Total Return on Investment for the Past Five Years⁽²⁾



⁽¹⁾ This section is not “soliciting material,” is not deemed “filed” with the Securities and Exchange Commission (“SEC”) and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended (the “Securities Act”) or the Securities Exchange Act of 1934 (“Exchange Act”) whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

⁽²⁾ Shows the cumulative return on investment assuming an investment of \$100 in our common stock, the NBI Index and the S&P 500 Index on December 31, 2016, and assuming that all dividends were reinvested.

Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2021:

(in millions, except per share amounts)	Number of Common Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights ⁽¹⁾	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights ⁽¹⁾	Number of Common Shares Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Plan Category	(a)	(b)	(c)
Equity compensation plans approved by security holders:			
2004 Equity Incentive Plan ⁽²⁾	15.2	\$ 70.95	74.9
Employee Stock Purchase Plan ⁽³⁾			5.1
Total equity compensation plans approved by security holders	15.2	\$ 70.95	80.0
Equity compensation plans not approved by security holders ⁽⁴⁾	1.6	\$ 67.28	6.7
Total	16.8	\$ 70.60	86.7

⁽¹⁾ Does not take into account 22 million restricted stock units, performance share awards or units and phantom shares, which have no exercise price and were granted under our 2004 and 2018 Equity Incentive Plans.

⁽²⁾ Includes awards and shares previously issuable under The Immunomedics, Inc. Amended and Restated 2014 Long-Term Incentive Plan (the “Immunomedics Plan”), which was assumed in connection with our acquisition of Immunomedics, Inc. and subsequently merged into the 2004 Equity Incentive Plan.

⁽³⁾ Under our Employee Stock Purchase Plan, participants are permitted to purchase our common stock at a discount on certain dates through payroll deductions within a pre-determined purchase period. Accordingly, these numbers are not determinable.

⁽⁴⁾ Includes awards and shares issuable under the Forty Seven, Inc. 2018 Equity Incentive Plan, which was assumed in connection with our acquisition of Forty Seven, Inc. (“Forty Seven”) and subsequently amended and restated as our 2018 Equity Incentive Plan.

Material Features of the Gilead Sciences, Inc. 2018 Equity Incentive Plan

The Forty Seven, Inc. 2018 Equity Incentive Plan was originally established by Forty Seven in June 2018. In connection with Gilead’s acquisition of Forty Seven in April 2020, Gilead assumed the Forty Seven, Inc. 2018 Equity Incentive Plan, and amended and restated it as the Gilead Sciences, Inc. 2018 Equity Incentive Plan (the “2018 Plan”). The 2018 Plan is intended to help the Gilead secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of Gilead and any affiliate, and provide a means by which the eligible recipients may benefit from increases in value of Gilead common stock. From and after April 7, 2020, only employees and consultants of Forty Seven as of immediately prior to such date and employees and consultants of Gilead hired on or following such date are eligible to receive grants of new awards under the 2018 Plan.

The 2018 Plan provides for the award of incentive stock options and non-qualified stock options, each of which must generally have an exercise price equal to at least the fair market value of our common stock on the date of grant; stock appreciation rights; restricted stock awards; restricted stock unit awards; performance stock awards; other stock awards; and performance cash awards.

As of April 7, 2020, the aggregate number of shares of common stock issuable under the 2018 Plan (from and after such date) was 12,069,378. From and after April 7, 2020, Gilead has granted restricted stock units, performance share awards or units and stock options under the 2018 Plan, and these are the only types of equity awards outstanding under the plan. As of December 31, 2021, 6.7 million shares of Gilead common stock remained available for issuance under the 2018 Plan.

Issuer Purchases of Equity Securities

In the first quarter of 2016, our Board of Directors authorized a \$12.0 billion stock repurchase program (the “2016 Program”) under which repurchases may be made in the open market or in privately negotiated transactions. We made repurchases under the 2016 Program starting in April 2016.

In the first quarter of 2020, our Board of Directors authorized a new \$5.0 billion stock repurchase program (the “2020 Program”), which will commence upon the completion of the 2016 Program. Purchases under the 2020 Program may be made in the open market or in privately negotiated transactions.

During 2021, we repurchased and retired 8 million shares of our common stock for \$546 million through open market transactions under the 2016 Program.

As of December 31, 2021, the remaining authorized repurchase amount from both programs was \$6.3 billion.

The table below summarizes our stock repurchase activity for the three months ended December 31, 2021:

	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share (in dollars)	Total Number of Shares Purchased as Part of a Publicly Announced Program (in thousands)	Maximum Fair Value of Shares that May Yet Be Purchased Under the Programs (in millions)
October 1 - October 31, 2021	309	\$ 67.47	283	\$ 6,299
November 1 - November 30, 2021	372	\$ 67.66	281	\$ 6,280
December 1 - December 31, 2021	195	\$ 70.37	155	\$ 6,269
Total	<u>876</u> ⁽¹⁾	<u>\$ 68.19</u>	<u>719</u> ⁽¹⁾	

⁽¹⁾ The difference between the total number of shares purchased and the total number of shares purchased as part of a publicly announced program is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy applicable tax withholding obligations.

Dividends

For the years ended December 31, 2021 and 2020, we paid quarterly dividends. We expect to continue to pay quarterly dividends, although the amount and timing of any future dividends are subject to declaration by our Board of Directors. Additional information is included in Item 7 Management’s Discussion and Analysis of Financial Condition and Results of Operations to the Consolidated Financial Statements.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited Consolidated Financial Statements and the accompanying Notes to Consolidated Financial Statements and other disclosures included in this Annual Report on Form 10-K (including the disclosures under Part I, Item 1A. Risk Factors). Additional information related to the comparison of our results of operations between the years 2020 and 2019 is included in Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations of our 2020 Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”). Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

MANAGEMENT OVERVIEW

Gilead Sciences, Inc. (“Gilead,” “we,” “our” or “us”) 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. We are committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. We operate in more than 35 countries worldwide, with headquarters in Foster City, California.

Our portfolio of marketed products includes AmBisome[®], Atripla[®], Biktarvy[®], Cayston[®], Complera[®], Descovy[®], Descovy for PrEP[®], Emtriva[®], Epclusa[®], Eviplera[®], Genvoya[®], Harvoni[®], Hepcludex[®] (bulevirtide), Hepsera[®], Jyseleca[®] (filgotinib), Letairis[®], Odefsey[®], Ranexa[®], Sovaldi[®], Stribild[®], Tecartus[®], Trodelvy[®], Truvada[®], Truvada for PrEP[®], Tybost[®], Veklury[®], Vemlidy[®], Viread[®], Vosevi[®], Yescarta[®] and Zydelig[®]. The approval status of Hepcludex and Jyseleca vary worldwide, and Hepcludex and Jyseleca are not approved in the United States. We also sell and distribute authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua Therapeutics, LLC. In addition, we sell and distribute certain products through our corporate partners under collaborative agreements.

Business Highlights⁽¹⁾

We delivered strong financial performance in 2021. Veklury continued to play a critical role in addressing the coronavirus disease 2019 (“COVID-19”) pandemic. Veklury’s performance helped mitigate the impacts of COVID-19 on other parts of the business, including on our HIV and chronic hepatitis C virus (“HCV”) franchises, and the impacts of the October 2020 loss of exclusivity of Truvada and Atripla in the United States. Despite these transitory headwinds, underlying demand for our virology portfolio remained strong, led by the continued growth of our Biktarvy franchise. We also received increased contributions from our oncology franchise, experiencing growth in Trodelvy, as well as our Cell Therapy franchise.

We continued to expand and strengthen both our commercial portfolio and clinical pipeline across therapeutic focus areas to drive future growth potential. During 2021, we announced an additional six filings for regulatory approval. In addition to investing in our internal pipeline programs, we also continued to enter into and leverage our existing strategic collaborations and partnerships, including opting into four additional pipeline assets from our collaboration with Arcus Biosciences, Inc. (“Arcus”) to further develop the foundation for a more sustainable and diversified business.

Viral Diseases

- In October 2021, U.S. Food and Drug Administration (“FDA”) approved a new low-dose tablet dosage form of Biktarvy for pediatric patients weighing at least 14 kg to less than 25 kg who are virologically suppressed or new to antiretroviral therapy.
- In August 2021, our Marketing Authorization Application for lenacapavir, an investigational, long-acting HIV-1 capsid inhibitor, was fully validated and is now under evaluation with the European Medicines Agency (“EMA”).
- In June 2021, FDA granted approval of a new oral pellet formulation of Epclusa, expanding the pediatric indication to treat children as young as 3 years of age with chronic HCV.
- In June 2021, we submitted a New Drug Application to FDA for lenacapavir, an investigational, long-acting agent in development for the treatment of HIV-1 in people with limited therapy options.
- In March 2021, we entered into an agreement with Merck Sharp & Dohme Corp. (“Merck”), a subsidiary of Merck & Co., Inc., to jointly develop and commercialize long-acting investigational treatments in HIV that combine Gilead’s investigational capsid inhibitor, lenacapavir, and Merck’s investigational nucleoside reverse transcriptase translocation inhibitor, islatravir.
- In March 2021, we completed the acquisition of MYR GmbH (“MYR”). The acquisition provides us with Hepcludex, which is conditionally approved by EMA for the treatment of chronic hepatitis delta virus (“HDV”) in adults with compensated liver disease.

COVID-19

- In January 2022, FDA granted expedited approval for Veklury for the treatment of non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death.
- In December 2021, the European Commission granted approval to expand the indication for Veklury for use in the earlier stages of the disease in adult patients who do not require supplemental oxygen and are at increased risk of progressing to severe COVID-19.
- In April 2021, we announced that we will (i) provide assistance and support for expansion of local manufacturing capacity of remdesivir in India and will donate the active pharmaceutical ingredient and (ii) donate a minimum of 450,000 vials of Veklury (remdesivir) to the government of India.

Oncology

Cell Therapy

- In January 2022, FDA approved an update to the prescribing information for Yescarta to include the use of prophylactic corticosteroids across all approved indications. Yescarta is now the first and only chimeric antigen receptor (“CAR”) T-cell therapy with information in the label to help physicians manage, and potentially prevent, treatment side effects.
- In October 2021, FDA approved Tecartus for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (“ALL”). Tecartus is the first and only CAR T cell therapy approved for adults with ALL.
- In September 2021, Kite, a Gilead company (“Kite”) submitted a supplemental Biologics License Application to FDA for Yescarta to expand its current indication to include the treatment of adults with relapsed or refractory large B-cell lymphoma (“LBCL”) in the second-line setting.
- In August 2021, Kite and Appia Bio, Inc. entered into a collaboration and license agreement to research and develop hematopoietic stem cell derived cell therapies directed toward hematological malignancies.
- In June 2021, Kite entered into a research collaboration and license agreement with Shoreline Biosciences, Inc. to develop novel allogeneic cell therapies across a variety of cancer targets.
- In June 2021, Fosun Kite Biotechnology Co. Ltd, a joint venture between Kite and Shanghai Fosun Pharmaceutical (Group) Co., Ltd, received approval from the China National Medical Products Administration for axicabtagene ciloleucel for the treatment of adult patients with relapsed or refractory LBCL in China.
- In March 2021, FDA granted accelerated approval of Yescarta for the treatment of adult patients with relapsed or refractory follicular lymphoma (“FL”).

Other

- In January 2022, we entered into a clinical trial collaboration agreement with Merck to evaluate Trodelvy in combination with Merck’s anti-programmed death receptor-1 (“PD-1”) therapy, Keytruda, in a first-line setting for patients with non-small cell lung cancer (“NSCLC”).
- In November 2021, the European Commission granted marketing authorization for Trodelvy for treatment of metastatic triple-negative breast cancer (“TNBC”) in adult patients with unresectable or metastatic TNBC who have received two or more prior systemic therapies, at least one of them for advanced disease.
- In November 2021, we exercised options to three programs in the clinical-stage portfolio of Arcus, including anti-TIGIT molecules domvanalimab and AB308, as well as clinical candidates etrumadenant (dual adenosine A2a/A2b receptor antagonist) and quemliclustat (small molecule CD73 inhibitor). The transaction closed in December 2021.
- In October 2021, we entered into a clinical trial collaboration and supply agreement with Merck to evaluate the efficacy of Trodelvy in combination with Keytruda as a first-line treatment for patients with locally advanced or metastatic TNBC.
- In September 2021, Health Canada approved Trodelvy for the treatment of adult patients with unresectable locally advanced or metastatic TNBC who have received two or more therapies, at least one of them for metastatic disease. Canada joined Australia, Great Britain, Switzerland and the United States among the countries that have approved Trodelvy for use under Project Orbis, a global collaborative review program for high impact oncology marketing applications across participating countries.
- In April 2021, FDA granted accelerated approval of Trodelvy for use in adult patients with locally advanced or metastatic urothelial cancer (“UC”), a new indication.
- In April 2021, FDA granted full approval of Trodelvy for adult patients with unresectable locally advanced or metastatic TNBC.

⁽¹⁾ We announced and discussed these updates in further detail in press releases available on our website at www.gilead.com. Readers are also encouraged to review all other press releases available on our website mentioned above. The content on the referenced websites does not constitute a part of and is not incorporated by reference into this Annual Report on Form 10-K.

2021 Financial Highlights

(in millions, except percentages and per share amounts)	2021	2020	Change
Total revenues	\$ 27,305	\$ 24,689	11 %
Net income attributable to Gilead	\$ 6,225	\$ 123	NM
Net income per share attributable to Gilead common stockholders - diluted	\$ 4.93	\$ 0.10	NM

NM - Not Meaningful

Total revenues increased by 11% to \$27.3 billion in 2021, compared to \$24.7 billion in 2020, primarily due to increased sales of Veklury, our FDA-approved treatment for hospitalized patients with COVID-19. The increase also reflects the continued growth of Biktarvy in all geographies and the continued uptake of Trodelvy, Cell Therapy and chronic hepatitis B virus (“HBV”) and HDV products. The increases were partially offset by the decrease in Truvada and Atripla sales in the United States, as expected, primarily due to the continued generic competition following the October 2020 loss of exclusivity in the United States.

Net income attributable to Gilead was \$6.2 billion or \$4.93 diluted earnings per share in 2021, compared to \$123 million or \$0.10 diluted earnings per share in 2020. The increase was primarily due to lower acquired in-process research and development (“IPR&D”) charges, revenue growth and lower unrealized losses from our equity investments, partially offset by a \$1.25 billion charge for a settlement related to bictegrovir litigation, and a charge of \$625 million related to the Arcus collaboration opt-in. Our acquired IPR&D expenses in 2020 were \$5.9 billion primarily related to our acquisition of Forty Seven as well as collaborations and other investments that we entered into during the year with Arcus, Pionyr Immunotherapeutics, Inc. (“Pionyr”), Tango Therapeutics, Inc. (“Tango”), Tizona Therapeutics, Inc. (“Tizona”) and Jounce Therapeutics, Inc. (“Jounce”).

Strategy and Outlook 2022

Our purpose is to deliver life-changing medications to patients in need through scientific breakthroughs, innovation and strong operational execution. Our strategic ambitions are to (i) bring 10+ transformative therapies to patients by 2030; (ii) be the biotech employer and partner of choice; and (iii) deliver shareholder value in a sustainable and responsible manner. Our strategic priorities reflect how we will deliver those ambitions: (i) expand internal and external innovation; (ii) strengthen portfolio strategy and decision making; (iii) increase patient benefit and access; and (iv) continue to evolve our culture.

In 2022, we will continue to focus on executing our strategy to expand and diversify our commercial portfolio and clinical pipelines across our three therapeutic focus areas: virology, oncology and inflammation. Specifically, we plan to significantly increase clinical development studies across our novel oncology portfolio while maintaining our leadership in antiviral medications through our work in HIV, hepatitis, the COVID-19 pandemic and emerging viruses. Our collaboration with Arcus provides additional opportunities for us to further develop the foundation for a more sustainable and diversified business. Beyond expanding our products and pipeline, we also continue to focus on our employees, the evolution of our culture and our efforts to promote racial equity and social justice. Additionally, we expect to maintain a rigorous focus on disciplined expense management.

While, the COVID-19 pandemic continues to impact our business and broader market dynamics, we expect revenue growth of between 2 – 4% in 2022 product sales, excluding Veklury, as compared to 2021. Our HIV product sales will continue to recover from the COVID-19 pandemic and demonstrate year-over-year growth, as the financial impact of the Truvada and Atripla loss of exclusivity will be largely behind us starting in the second quarter of 2022. We also expect our oncology businesses, including Cell Therapy and Trodelvy, to contribute to our growth.

Veklury sales are generated in a highly dynamic and complex global environment, which continues to evolve. As a result, Veklury sales are subject to significant volatility and uncertainty. Future product demand will depend on the nature of the COVID-19 pandemic, including duration, infection rates, hospitalizations, and availability and adoption of alternative therapies and vaccines. While we anticipate a year-over-year decline in Veklury product sales, we expect Veklury to continue to play a key role in the pandemic and contribute meaningfully to our revenue in 2022, more heavily weighted towards the beginning of the year.

Our ability to deliver on our strategy is subject to a number of uncertainties, including, but not limited to, the effects of the COVID-19 pandemic, which remains unpredictable; the uncertainty regarding the amount and timing of future Veklury sales; the continuation of an uncertain global macroeconomic environment; our ability to realize the potential benefits of our acquisitions, collaborations or licensing arrangements; our ability to initiate, progress or complete clinical trials within currently anticipated timeframes, including as a result of any current or future holds on clinical trials; the possibility of unfavorable results from new and ongoing clinical trials; our ability to submit new drug applications for new product candidates or expanded indications in the currently anticipated timelines; our ability to receive regulatory approvals in a timely manner or at all; market share and price erosion caused by the introduction of generics; loss of exclusivity of our products; higher than anticipated effects of the loss of exclusivity from Truvada and Atripla; slower than anticipated growth in Biktarvy, Trodelvy, Vemlidy and Cell Therapy products; inaccuracies in our patient start estimates; additional pricing pressures from payers and competitors; an increase in discounts, chargebacks and rebates due to ongoing contracts and future negotiations with commercial and government payers; potential government actions that could have the effect of lowering prices; a larger-than-anticipated shift in payer mix to a more highly discounted payer segment; and volatility in foreign currency exchange rates.

RESULTS OF OPERATIONS

Revenues

The following table summarizes the period-over-period changes in our revenues:

(in millions, except percentages)	Year Ended December 31, 2021				Year Ended December 31, 2020				Change
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	
Product sales:									
HIV	\$ 12,828	\$ 2,366	\$ 1,121	\$ 16,315	\$ 13,651	\$ 2,287	\$ 1,000	\$ 16,938	(4)%
Veklury	3,640	1,095	830	5,565	2,026	607	178	2,811	98 %
HCV	1,018	421	442	1,881	1,088	414	562	2,064	(9)%
HBV/HDV	397	104	468	969	380	71	409	860	13 %
Cell Therapy	542	293	36	871	396	201	10	607	43 %
Trodelvy	370	10	—	380	49	—	—	49	NM
Other	381	389	257	1,027	551	314	161	1,026	— %
Total product sales	19,176	4,678	3,154	27,008	18,141	3,894	2,320	24,355	11 %
Royalty, contract and other revenues	91	196	10	297	76	241	17	334	(11)%
Total revenues	<u>\$ 19,267</u>	<u>\$ 4,874</u>	<u>\$ 3,164</u>	<u>\$ 27,305</u>	<u>\$ 18,217</u>	<u>\$ 4,135</u>	<u>\$ 2,337</u>	<u>\$ 24,689</u>	11 %

NM - Not Meaningful

Product Sales

HIV

HIV product sales decreased by 4% to \$16.3 billion in 2021, compared to \$16.9 billion in 2020, due to the anticipated decline in sales volume of our Truvada (emtricitabine (“FTC”) and tenofovir disoproxil fumarate (“TDF”))-based products driven by the continued generic competition following the October 2020 loss of exclusivity of Truvada and Atripla in the United States. Truvada and Atripla product sales were \$1.3 billion lower in 2021, compared to 2020. The decrease was also impacted by lower sales of Genvoya driven by decrease in volume worldwide primarily due to patients switching to Biktarvy. These declines were partially offset by an increase in Biktarvy product sales worldwide driven by higher demand, higher net average selling price driven by favorable changes in estimates of government rebates and discounts in the United States. We expect that our HIV business will continue to recover from the COVID-19 pandemic in 2022. We also expect the impact of the Truvada and Atripla loss of exclusivity will be largely behind us starting in the second quarter of 2022.

Veklury

Veklury product sales were \$5.6 billion in 2021, compared to \$2.8 billion in 2020. Veklury became commercially available in the third quarter of 2020, resulting in a partial year of sales in 2020. The increase was also attributable to higher hospital demand worldwide. Sales of Veklury are generally affected by COVID-19 related rates of infections, hospitalizations and vaccinations as well as the availability, uptake and effectiveness of alternative treatments for COVID-19. As a result, future sales of Veklury are difficult to predict.

HCV

HCV product sales decreased by 9% to \$1.9 billion in 2021, compared to \$2.1 billion in 2020, primarily due to lower demand driven by fewer patient starts worldwide due to the impact of the COVID-19 pandemic. The slight increase in HCV sales in Europe in 2021 was due to a favorable change in estimate of government rebates, which offset the revenue decrease associated with lower demand.

HBV / HDV

HBV and HDV product sales increased by 13% to \$969 million in 2021, compared to \$860 million in 2020, primarily due to higher Vemlidy product sales due to higher demand in all geographies, partially offset by lower Viread product sales in Other international locations. Hepcludex sales in 2021 were \$37 million as launch activities continued across Europe following our first quarter 2021 acquisition of MYR.

Cell Therapy

Cell Therapy product sales, which include Yescarta and Tecartus, increased by 43% to \$871 million in 2021, compared to \$607 million in 2020. The growth was primarily due to the July 2020 launch of Tecartus in the United States for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (“MCL”) and the December 2020 launch of Tecartus for MCL in Europe, resulting in partial year of sales in 2020. The increase was also driven by continued higher demand for Yescarta worldwide for LBCL and volume growth related to approval of Yescarta for FL in the United States in 2021.

Trodelyv

Trodelyv product sales increased to \$380 million in 2021, compared to \$49 million in 2020. We obtained Trodelyv through the fourth quarter 2020 acquisition of Immunomedics, resulting in a partial year of sales in 2020. In addition, 2021 revenues include continued uptake of Trodelyv following the full regulatory approval for metastatic TNBC in the United States and Europe and accelerated approval for metastatic UC in the United States.

Other Product Sales

Other product sales, which include AmBisome, Cayston, Jyseleca, Letairis, Ranexa and Zydelyg, were \$1.0 billion in 2021 and remained flat as compared to 2020. AmBisome sales volume increased due to higher demand in geographies outside the United States. The increase was mostly offset by lower Letairis sales in the United States, as anticipated, due to continued generic competition following the loss of exclusivity in 2019.

Gross-to-Net Deductions

We record product sales net of estimated government and other rebates and chargebacks, cash discounts for prompt payment, distributor fees, sales returns and other related costs. These deductions totaled \$14.4 billion, or 35% of gross product sales in 2021, compared to \$15.3 billion, or 39% of gross product sales in 2020. The reduction is driven by changes in product mix, primarily due to higher Veklury sales in 2021. Of the \$14.4 billion in 2021, \$12.6 billion, or 30% of gross product sales, was related to government and other rebates and chargebacks and \$1.8 billion was related to cash discounts for prompt payment, distributor fees, sales returns and other related costs.

Foreign Currency Exchange Impact

Of our total product sales, 29% and 26% were generated outside the United States in 2021 and 2020, respectively. We generally face exposure to movements in foreign currency exchange rates, primarily in the Euro. We use foreign currency exchange contracts to hedge a portion of our foreign currency exposures. Foreign currency exchange, net of hedges, had a favorable impact on our total product sales of \$141 million in 2021, based on a comparison using foreign currency exchange rates from 2020, largely driven by Euro-based product sales.

The following table summarizes the period-over-period changes in our product sales:

(in millions, except percentages)	Year Ended December 31, 2021				Year Ended December 31, 2020				Change	
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total		
HIV Products										
Descovy (FTC/TAF) Based Products										
Biktarvy	\$ 7,049	\$ 969	\$ 606	\$ 8,624	\$ 6,095	\$ 735	\$ 429	\$ 7,259	19 %	
Descovy	1,397	164	139	1,700	1,526	197	138	1,861	(9)%	
Genvoya	2,267	391	221	2,879	2,605	490	243	3,338	(14)%	
Odefsey	1,076	440	52	1,568	1,172	450	50	1,672	(6)%	
Revenue share - Symtuza ⁽¹⁾	355	165	11	531	331	149	8	488	9 %	
Total Descovy (FTC/TAF) Based Products	12,144	2,129	1,029	15,302	11,729	2,021	868	14,618	5 %	
Truvada (FTC/TDF) Based Products										
Atripla	121	12	12	145	307	21	21	349	(58)%	
Complera/Eviplera	102	142	14	258	89	159	21	269	(4)%	
Stribild	132	43	14	189	125	54	17	196	(4)%	
Truvada	314	22	35	371	1,376	27	45	1,448	(74)%	
Total Truvada (FTC/TDF) Based Products	669	219	75	963	1,897	261	104	2,262	(57)%	
Other HIV ⁽²⁾	15	18	17	50	25	5	28	58	(14)%	
Total HIV	12,828	2,366	1,121	16,315	13,651	2,287	1,000	16,938	(4)%	
Veklury	3,640	1,095	830	5,565	2,026	607	178	2,811	98 %	
HCV Products										
Ledipasvir/Sofosbuvir ⁽³⁾	84	31	97	212	92	29	151	272	(22)%	
Sofosbuvir/Velpatasvir ⁽⁴⁾	815	316	331	1,462	864	337	398	1,599	(9)%	
Other HCV ⁽⁵⁾	119	74	14	207	132	48	13	193	7 %	
Total HCV	1,018	421	442	1,881	1,088	414	562	2,064	(9)%	
HBV/HDV Products										
Vemlidy	384	34	396	814	356	29	272	657	24 %	
Viread	11	28	72	111	14	34	137	185	(40)%	
Other HBV/HDV ⁽⁶⁾	2	42	—	44	10	8	—	18	NM	
Total HBV/HDV	397	104	468	969	380	71	409	860	13 %	
Cell Therapy Products										
Tecartus	136	40	—	176	34	10	—	44	NM	
Yescarta	406	253	36	695	362	191	10	563	23 %	
Total Cell Therapy	542	293	36	871	396	201	10	607	43 %	
Trodely	370	10	—	380	49	—	—	49	NM	
Other Products										
AmBisome	39	274	227	540	61	230	145	436	24 %	
Letairis	206	—	—	206	314	—	—	314	(34)%	
Ranexa	10	—	—	10	9	—	—	9	11 %	
Zydelig	26	35	1	62	31	39	2	72	(14)%	
Other ⁽⁷⁾	100	80	29	209	136	45	14	195	7 %	
Total Other	381	389	257	1,027	551	314	161	1,026	— %	
Total product sales	<u>19,176</u>	<u>4,678</u>	<u>3,154</u>	<u>27,008</u>	<u>\$ 18,141</u>	<u>\$ 3,894</u>	<u>\$ 2,320</u>	<u>\$ 24,355</u>	<u>11 %</u>	

NM - Not Meaningful

⁽¹⁾ Represents our revenue from cobicistat (“C”), emtricitabine FTC and tenofovir alafenamide (“TAF”) in Symtuza (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen Sciences Ireland Unlimited Company.

⁽²⁾ Includes Emtriva and Tybost.

⁽³⁾ Amounts consist of sales of Harvoni and the authorized generic version of Harvoni sold by our separate subsidiary, Asegua Therapeutics LLC.

⁽⁴⁾ Amounts consist of sales of Epclusa and the authorized generic version of Epclusa sold by our separate subsidiary, Asegua Therapeutics LLC.

⁽⁵⁾ Includes Vosevi and Sovaldi.

⁽⁶⁾ Includes Hepcludex and Hepsera.

⁽⁷⁾ Includes Cayston and Jyseleca.

Costs and Expenses

The following table summarizes the period-over-period changes in our costs and expenses:

(In millions, except percentages)	2021	2020	Change
Cost of goods sold	\$ 6,601	\$ 4,572	44 %
Product gross margin	75.6 %	81.2 %	-560 bps
Research and development (“R&D”) expenses	\$ 5,363	\$ 5,039	6 %
Acquired IPR&D expenses	\$ 177	\$ 5,856	(97)%
Selling, general and administrative (“SG&A”) expenses	\$ 5,246	\$ 5,151	2 %

Product Gross Margin

In 2021, product gross margin decreased to 75.6% as compared to 81.2% in 2020, primarily due to a \$1.25 billion charge for a settlement related to bictegravir litigation as well as an increase of \$848 million in acquisition-related expenses from amortization of finite-lived intangible assets and recognition of inventory step-up charges primarily driven by our acquisitions of Immunomedics and MYR. Product gross margin was also impacted by higher inventory write-down charges and changes in product mix. The increases were partially offset by lower royalty expenses due to lower sales of products containing emtricitabine and elvitegravir and the reversal of a previously recorded \$175 million litigation accrual following a favorable court decision related to axicabtagene ciloleucel.

Research and Development Expenses

R&D expenses consist primarily of clinical studies performed by contract research organizations, materials and supplies, payments under collaborative and other arrangements including milestone payments, licenses and fees, expense reimbursements to the collaboration partners, personnel costs including salaries, benefits and stock-based compensation expense, and overhead allocations consisting of various support and infrastructure costs.

We manage our R&D expenses by identifying the R&D activities we anticipate will be performed during a given period and then prioritizing efforts based on scientific data, probability of technical and regulatory successful development, market potential, available human and capital resources and other considerations. We continually review our R&D projects based on unmet medical need and, as necessary, reallocate resources among our internal R&D portfolio and external opportunities that we believe will best support the long-term growth of our business.

In 2021, R&D expenses increased by \$324 million compared to 2020, primarily due to the Arcus collaboration opt-in charge of \$625 million, as well as higher investments in Trodelvy and magrolimab clinical activities. These increases were partially offset by (i) a decline of approximately \$200 million in external expenses related to wind-down or completion of certain remdesivir clinical studies, (ii) \$190 million (€160 million) charge recorded in 2020 in connection with the agreement to amend the existing arrangement with Galapagos for the commercialization and development of Jyseleca, and (iii) lower stock-based compensation expense. R&D expenses for 2020 included accelerated stock-based compensation expenses of \$166 million related to our acquisitions of Immunomedics and Forty Seven.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses reflect IPR&D impairments as well as the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use, including upfront payments related to various collaborations and the initial costs of rights to IPR&D projects.

Acquired IPR&D expenses of \$177 million in 2021 were related to licensing, collaboration, investment and other arrangements we entered into during the year. Acquired IPR&D expenses of \$5.9 billion in 2020 were primarily related to our acquisition of Forty Seven as well as collaborations and other investments we entered into during the year with Arcus, Pionyr, Tango, Tizona and Jounce.

Selling, General and Administrative Expenses

SG&A expenses relate to sales and marketing, finance, human resources, legal and other administrative activities, including information technology investments. SG&A expenses consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses and other general and administrative costs. SG&A expenses also include the Branded Prescription Drug (“BPD”) fee. In the United States, we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of the BPD fee, which is estimated based on select government sales during the prior year as a percentage of total industry government sales.

In 2021, SG&A expenses increased by \$95 million compared to 2020, primarily due to an expense of \$212 million related to the donation of certain equity securities at fair value to the Gilead Foundation, a California nonprofit organization (the “Foundation”), and increased commercial activities, including higher promotional and marketing activities primarily driven by Trodelvy. SG&A expenses for 2020 included accelerated stock-based compensation expense of \$204 million related to our acquisitions of Immunomedics and Forty Seven, and a charge of \$97 million related to a U.S. Department of Justice investigation, which was settled in the third quarter of 2020.

Interest Expense and Other Income (Expense), Net

The following table summarizes the period-over-period changes in our Interest expense and Other income (expense), net:

(in millions, except percentages)	2021	2020	Change
Interest expense	\$ (1,001)	\$ (984)	2 %
Other income (expense), net	\$ (639)	\$ (1,418)	(55)%

Interest expense for 2021 increased by \$17 million, or 2%, compared to 2020, primarily due to an increase in borrowing related to the fourth quarter 2020 acquisition of Immunomedics, partially offset by lower interest expense due to debt maturities and repayments.

The changes in Other income (expense), net for 2021, compared to 2020, primarily reflects lower unrealized losses from fair value adjustments of our investments in equity securities largely driven by our investment in Galapagos, partially offset by lower interest income. Changes in the fair value of equity securities resulted in net unrealized losses of \$610 million and \$1.7 billion for the years ended December 31, 2021 and 2020, respectively.

Income Taxes

The following table summarizes the period-over-period changes in our Income tax (expense) benefit:

(in millions, except percentages)	2021	2020
Income before income taxes	\$ 8,278	\$ 1,669
Income tax expense	\$ (2,077)	\$ (1,580)
Effective tax rate	25.1 %	94.7 %

Our effective tax rate decreased in 2021, compared to 2020, primarily due to a \$4.5 billion acquired IPR&D charge recorded in connection with our acquisition of Forty Seven and \$511 million of certain other acquired IPR&D charges in 2020 that were non-deductible for tax purposes.

LIQUIDITY AND CAPITAL RESOURCES

Our cash, cash equivalents, and marketable debt securities were \$7.8 billion and \$7.9 billion as of December 31, 2021 and 2020, respectively.

Cash Flows

The following table summarizes our cash flow activities:

(in millions)	2021	2020
Net cash provided by (used in):		
Operating activities	\$ 11,384	\$ 8,168
Investing activities	\$ (3,131)	\$ (14,615)
Financing activities	\$ (8,877)	\$ 770

Operating Activities

Cash provided by operating activities represents the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net income for non-cash items and changes in operating assets and liabilities. Cash provided by operating activities increased by \$3.2 billion to \$11.4 billion in 2021 compared to 2020. The increase was primarily due to revenue growth from sales of Veklury as well as higher collection of receivables in 2021.

Investing Activities

Cash used in investing activities primarily consists of purchases, sales and maturities of our marketable debt securities, capital expenditures, acquisitions, including IPR&D, net of cash acquired, purchases of equity securities and other investments. Cash used in investing activities was \$3.1 billion in 2021 compared to \$14.6 billion in 2020. The decrease in cash used in investing activities was primarily due to a decrease in cash outflows related to acquisitions, including IPR&D, net of cash acquired. We made a \$1.2 billion payment in the first quarter of 2021 for our acquisition of MYR as compared to the \$4.7 billion and \$20.6 billion payments made in 2020 related to our acquisitions of Forty Seven and Immunomedics, respectively. The decrease was partially offset by net cash generated by investing activities in 2020 related to proceeds from sales and maturities of marketable debt securities used to partially fund these acquisitions.

Financing Activities

Cash used in financing activities for the year ended December 31, 2021 was \$8.9 billion, compared to cash provided by financing activities of \$770 million in 2020. In 2021, we utilized cash for \$4.75 billion of debt repayments, \$3.6 billion of dividend payments and \$546 million of common stock repurchases. In 2020, we obtained \$8.2 billion in proceeds from debt financing, net of issuance costs, to fund our fourth quarter 2020 acquisition of Immunomedics, partially offset by cash utilized for \$3.4 billion of dividend payments, \$2.5 billion of debt repayments and \$1.6 billion of common stock repurchases.

Debt and Credit Facilities

A summary of our borrowings under various financing arrangements is included in Note 12. Debt and Credit Facilities of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K. We may choose to repay certain of our long-term debt obligations prior to maturity dates based on our assessment of current and long-term liquidity and capital requirements.

Senior Unsecured Notes and Term Loan

In 2021, we repaid \$4.75 billion of debt, consisting of \$3.75 billion senior unsecured notes and \$1.0 billion on our senior unsecured term loan facility. We repaid \$1.0 billion of senior unsecured notes due April 2021 in the first quarter of 2021 and \$1.25 billion of senior unsecured notes due December 2021 in the third quarter of 2021. Additionally, we repaid \$500 million of senior unsecured notes due upon maturity in September 2021. In October 2021, we exercised our option to call \$500 million of senior unsecured floating rate notes and \$500 million of 0.75% senior unsecured notes, both having a final maturity date of September 2023. These two early repayments totaling \$1.0 billion principal amount were made in the fourth quarter of 2021. In December 2021, we exercised our option to call \$500 million of senior unsecured notes having a final maturity of March 2022. The notes were repaid in February 2022. No new debt was issued in 2021. We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of December 31, 2021 and 2020, we were not in violation of any covenants.

Liability Related to Future Royalties

In connection with our acquisition of Immunomedics, we assumed a liability related to a funding arrangement, which was originally entered into by Immunomedics and RPI Finance Trust prior to our acquisition of Immunomedics. The liability related to future royalties was primarily included in Long-term debt, net on our Consolidated Balance Sheets. See Note 6. Acquisitions of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Credit Facility

In June 2020, we terminated our \$2.5 billion five-year revolving credit facility maturing in May 2021 (the “2016 Revolving Credit Facility”) and entered into a new \$2.5 billion five-year revolving credit facility maturing in June 2025 (the “2020 Revolving Credit Facility”). The 2020 Revolving Credit Facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. As of December 31, 2021 and 2020, there were no amounts outstanding under the 2020 Revolving Credit Facility. The 2020 Revolving Credit Facility contains customary representations, warranties, affirmative and negative covenants and events of default. As of December 31, 2021, we were in compliance with all covenants.

Capital Return Program

The details of our Stock Repurchase Programs and Dividends are included in Note 15. Stockholders’ Equity of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

Stock Repurchase Programs

In the first quarter of 2016, our Board of Directors authorized a \$12.0 billion stock repurchase program (the “2016 Program”), under which repurchases may be made in the open market or in privately negotiated transactions. We started repurchases under the 2016 Program in April 2016.

In the first quarter of 2020, our Board of Directors authorized a new \$5.0 billion stock repurchase program (the “2020 Program”), which will commence upon the completion of the 2016 Program. Purchases under the 2020 Program may be made in the open market or in privately negotiated transactions.

We purchased 8 million and 22 million shares of our common stock under the 2016 Program for \$546 million and \$1.6 billion in 2021 and 2020, respectively.

As of December 31, 2021, the remaining authorized repurchase amount from both programs was \$6.3 billion.

Dividends

We declared and paid quarterly cash dividends for an aggregate amount of \$3.6 billion or \$2.84 per share of our common stock and \$3.4 billion or \$2.72 per share of our common stock in 2021 and 2020, respectively.

On February 1, 2022, we announced that our Board of Directors declared a quarterly cash dividend increase of 2.8% from \$0.71 to \$0.73 per share of our common stock, with a payment date of March 30, 2022 to all stockholders of record as of the close of business on March 15, 2022. Future dividends are subject to declaration by our Board of Directors.

Capital Resources

We believe our existing capital resources, supplemented by cash flows generated from our operations, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including but not limited to the following:

- the commercial performance of our current and future products;
- the progress and scope of our R&D efforts, including preclinical studies and clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the expansion of our sales and marketing capabilities;
- the possibility of acquiring additional manufacturing capabilities or office facilities;
- the possibility of acquiring other companies or new products;
- debt service requirements;
- the establishment of additional collaborative relationships with other companies; and
- costs associated with the defense, settlement and adverse results of government investigations and litigation.

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings. If such funding is required, we cannot guarantee that it will be available to us on favorable terms, if at all.

Material Cash Requirements

We continually evaluate our liquidity and capital resources, including our access to external capital to ensure that we can adequately and efficiently finance our operations. As of December 31, 2021, our material cash requirements consisted primarily of the repayment of outstanding borrowings, the remaining obligations for the one-time repatriation transition tax from the Tax Cuts and Jobs Act, our settlement related to bictegravir litigation, purchases of inventory, operating leases obligations, capital expenditures and milestone and other payments related to our collaborative agreements. See Notes 11. Collaborations and Other Arrangements, 12. Debt and Credit Facilities, 13. Leases, 14. Commitments and Contingencies and 18. Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information. We anticipate our cash requirements related to capital expenditures will increase in 2022 as compared to the prior year as we work to expand our site infrastructure and capabilities.

CRITICAL ACCOUNTING POLICIES, ESTIMATES AND JUDGMENTS

The discussion and analysis of our financial condition and results of operations is based on our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. On an ongoing basis, we evaluate and base our estimates on historical experience and on various other market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our Consolidated Financial Statements.

Government and Other Rebates and Chargebacks

Revenues from product sales are recognized net of estimated government and other rebates and chargebacks, cash discounts for prompt payment, distributor fees, sales return provisions and other related deductions. These deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Revenues from product sales, net of these deductions, are recorded only to the extent a significant reversal of the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with gross-to-net deductions is subsequently resolved.

Government and other rebates and chargebacks are subject to a complex estimation process, which requires significant judgment by management in part due to the lag between the date of the product sales and the date the related rebates or chargeback claims are settled. Government and other rebates and chargebacks include amounts payable to payers and healthcare providers under various programs, and may vary by product, by payer and by individual payer plans. For qualified programs that can purchase our products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to us the difference between their acquisition cost and the lower contractual price. Rebates and chargebacks are estimated primarily based on product sales, and expected payer mix and discount rates, which require significant estimates and judgment. Additionally, in developing our estimates of government and other rebates and chargebacks, we consider the following:

- historical and estimated payer mix;
- statutory discount requirements and contractual terms;
- historical claims experience and processing time lags;
- estimated patient population;
- known market events or trends;
- market research;
- channel inventory data obtained from our major U.S. wholesalers; and
- other pertinent internal or external information.

The following table summarizes the consolidated activities and ending balances in our government and other rebates and chargebacks accounts:

(in millions)	Balance at Beginning of Year	Decrease/ (Increase) to Product Sales	Payments	Balance at End of Year
Year ended December 31, 2021:				
Activity related to 2021 sales	\$ —	\$ 13,211	\$ (9,714)	\$ 3,497
Activity related to sales prior to 2021	4,012	(617)	(2,977)	418
Total	\$ 4,012	\$ 12,594	\$ (12,691)	\$ 3,915
Year ended December 31, 2020:				
Activity related to 2020 sales	\$ —	\$ 13,199	\$ (9,500)	\$ 3,699
Activity related to sales prior to 2020	4,108	(235)	(3,560)	313
Total	\$ 4,108	\$ 12,964	\$ (13,060)	\$ 4,012

Product sales in 2021 include the impact of \$617 million for changes in estimates related to our 2020 product sales, primarily in the United States. In 2020, we had assumed higher rebate claims from government payer segments resulting in part from the COVID-19 pandemic and its anticipated impacts, which did not materialize.

We assess and update our estimates each reporting period to reflect actual claims and other current information. We believe the methodology that we use to estimate our government and other rebates and chargebacks is reasonable and appropriate given the current facts and circumstances. However, actual results may differ significantly from our estimates. Historically, our actual government and other rebates and chargebacks claimed for prior periods have varied by less than 5% from our estimates.

Government and other chargebacks that are payable to our direct customers are classified as reductions of Accounts receivable in our Consolidated Balance Sheets and totaled \$671 million and \$552 million as of December 31, 2021 and 2020, respectively. See Note 10. Other Financial Information of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information. Government and other rebates that are payable to third party payers and healthcare providers are generally recorded in Accrued government and other rebates on our Consolidated Balance Sheets and totaled \$3.2 billion and \$3.5 billion as of December 31, 2021 and 2020, respectively.

Acquisitions and Valuation of Intangibles

We make certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. We evaluate the inputs, processes, and outputs associated with the acquired set of activities and assets. If the assets in a transaction include an input and a substantive process that together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business.

We account for business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed generally be recorded at their fair values as of the acquisition date. Excess of consideration over the fair value of net assets acquired is recorded as goodwill. Estimating fair value requires us to make significant judgments and assumptions. We perform impairment testing of goodwill annually or more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired.

In transactions accounted for as acquisitions of assets, no goodwill is recorded and contingent consideration, such as payments upon achievement of various developmental, regulatory and commercial milestones, generally is not recognized at the acquisition date. In an asset acquisition, upfront payments allocated to IPR&D projects at the acquisition date are expensed unless there is an alternative future use. In addition, product development milestones are expensed upon achievement.

Valuation of Intangible Assets

We have acquired, and expect to continue to acquire, intangible assets through asset acquisitions or business combinations. The identifiable intangible assets are measured at their respective fair values as of the acquisition date. Intangible assets acquired through business combinations are subject to potential adjustments within the measurement period, which may be up to one year from the acquisition date. The fair values of the intangible assets are generally determined using a probability-weighted income approach that discounts expected future cash flows to present value. The estimated net cash flows are discounted using a discount rate that is based on the estimated weighted-average cost of capital for companies with profiles similar to our profile and represents the rate that market participants would use to value the intangible assets. The discounted cash flow models used in valuing these intangible assets require the use of significant estimates and assumptions including but not limited to:

- identification of product candidates with sufficient substance requiring separate recognition;
- estimates of projected future cash flows including revenues and operating profits related to the products or product candidates;
- the probability of technical and regulatory success for unapproved product candidates considering their stages of development;
- the time and resources needed to complete the development and approval of product candidates;
- appropriate discount rate;
- the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining FDA and other regulatory approvals; and
- risks related to the viability of and potential alternative treatments in any future target markets.

We believe the fair values used to record intangible assets acquired are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Impairment and Amortization of Intangible Assets

Intangible assets related to IPR&D projects acquired in a business combination are capitalized as indefinite-lived intangible assets until the completion or abandonment of the associated R&D efforts. During the period the assets are considered indefinite-lived, they are not amortized. When development is successfully completed, which generally occurs when regulatory approval is obtained, the associated assets are deemed finite-lived and amortized over their respective estimated useful lives beginning at that point in time primarily on a straight-line basis.

Indefinite-lived intangible assets, composed of IPR&D projects acquired in a business combination that lack regulatory approval at the time of acquisition, are tested for impairment annually, whenever events or changes in circumstances indicate that it is more likely than not that the assets are impaired and upon regulatory approval. Estimates of fair value result from a complex series of judgments about future events and uncertainties and make assumptions at a point in time (acquisition date or subsequent impairment assessment date). Changes in estimates and assumptions, including the timing of product launch, pricing reductions, failure to obtain anticipated regulatory approval, deterioration in U.S. and global financial markets or other unanticipated events and circumstances, may decrease the projected cash flows or increase the discount rate and could potentially result in an impairment charge.

The eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition. If the carrying value of an intangible asset exceeds its estimated fair value, an impairment charge is recorded to write down the intangible asset to its estimated fair value. For example, in 2019, we recognized an \$800 million impairment charge related to IPR&D projects primarily for the treatment of indolent B-cell non-Hodgkin lymphoma due to changes in estimated market opportunities. A high rate of failure is inherent in the discovery and development of new products.

Intangible assets are also periodically reviewed for changes in facts or circumstances resulting in a reduction to the estimated useful life of the asset, requiring the acceleration of amortization.

See Note 9. Goodwill and Intangible Assets of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Legal Contingencies

We are a party to various legal actions. The most significant of these are described in Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K. It is not possible to determine the outcome of these matters. We recognize accruals for such actions to the extent that we conclude that a loss is both probable and reasonably estimable. We accrue for the best estimate of a loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible, we disclose the possible loss or range of loss, or that the amount of loss cannot be estimated at this time.

Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of the inherent uncertainty and unpredictability related to these matters, accruals are based on what we believe to be the best information available at the time of our assessment, including the legal facts and circumstances of the case, status of the proceedings, applicable law and the views of legal counsel. Upon the final resolution of such matters, it is possible that there may be a loss in excess of the amount recorded, and such amounts could have a material adverse effect on our results of operations, cash flows or financial position. We periodically reassess these matters when additional information becomes available and adjust our estimates and assumptions when facts and circumstances indicate the need for any changes. In the fourth quarter of 2021, we recorded an accrual of \$1.25 billion in Accrued and other current liabilities on our Consolidated Balance Sheets for the settlement related to bictegravir litigation. See Note 14. Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Income Taxes

We estimate our income tax provision, including deferred tax assets and liabilities, based on significant management judgment. We evaluate the realization of our deferred tax assets each reporting period. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance. If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made.

We are subject to income taxes in the United States and various foreign jurisdictions, including Ireland. Due to economic and political conditions, various countries are actively considering or have made changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. In addition, significant judgment is required in determining our worldwide provision for income taxes.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the Consolidated Financial Statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (“UTB”) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTB in Income tax (expense) benefit on our Consolidated Statements of Income.

RECENT ACCOUNTING PRONOUNCEMENTS

There have been no new accounting pronouncements issued nor adopted during the year ended December 31, 2021 that are of significance to us.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in foreign currency exchange rates, interest rates, credit risks and market prices. To reduce certain of these risks, we enter into various types of foreign currency or interest rate derivative hedging transactions, follow investment guidelines and monitor outstanding receivables as part of our risk management program.

Foreign Currency Exchange Risk

We have operations in more than 35 countries worldwide. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in foreign currency exchange rates between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. When the U.S. dollar strengthens against these currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative value of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, we benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar.

Approximately 26% of our product sales were denominated in foreign currencies during 2021. To partially mitigate the impact of changes in currency exchange rates on net cash flows from our foreign currency denominated sales, we may enter into foreign currency exchange forward or option contracts. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. In general, the market risks of these contracts are offset by corresponding gains and losses on the transactions being hedged.

As of December 31, 2021 and 2020, we had open foreign currency forward contracts with notional amounts of \$2.9 billion and \$2.4 billion, respectively. A hypothetical 10% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates as of December 31, 2021 and 2020 would have resulted in a reduction in fair value of these contracts of approximately \$333 million and \$249 million, respectively, and if realized, would have negatively affected earnings over the remaining life of the contracts. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

Interest Rate Risk

Our portfolio of available-for-sale debt securities and our senior unsecured notes create an exposure to interest rate risk. With respect to our investment portfolio, we adhere to an investment policy that requires us to limit amounts invested in securities based on credit rating, maturity, industry group and investment type and issuer, except for securities issued by the U.S. government. The goals of our investment policy, in order of priority, are as follows:

- safety and preservation of principal and diversification of risk;
- liquidity of investments sufficient to meet cash flow requirements; and
- a competitive after-tax rate of return.

The following table summarizes the expected maturities and average interest rates of our interest-generating assets and interest-bearing liabilities as of December 31, 2021:

(in millions, except percentages)	Expected Maturity						Total	Total Fair Value
	2022	2023	2024	2025	2026	Thereafter		
Assets								
Available-for-sale debt securities	\$ 1,188	\$ 599	\$ 643	\$ 37	\$ 7	\$ 23	\$ 2,497	\$ 2,497
Average interest rate	0.46 %	0.61 %	0.60 %	1.09 %	0.57 %	0.60 %		
Liabilities								
Senior unsecured fixed rate notes, including current portion ⁽¹⁾	\$ 1,500	\$ 2,250	\$ 1,750	\$ 1,750	\$ 2,750	\$ 15,750	\$ 25,750	\$ 28,599
Average interest rate	2.82 %	1.33 %	3.70 %	3.50 %	3.65 %	3.84 %		

⁽¹⁾ Amounts represent principal balances. In addition to the senior unsecured fixed rate notes, we have a \$2.5 billion five-year revolving credit facility that matures in June 2025. There were no amounts outstanding under the five-year revolving credit facility as of December 31, 2021. See Note 12. Debt and Credit Facilities of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Market Price Risk

We hold shares of common stock of certain publicly traded biotechnology companies primarily in connection with license and collaboration agreements. These equity securities are measured at fair value with any changes in fair value recognized in earnings.

The fair value of these equity securities was approximately \$1.8 billion and \$2.4 billion as of December 31, 2021 and 2020, respectively. Changes in fair value of these equity securities are impacted by the volatility of the stock market and changes in general economic conditions, among other factors. A hypothetical 20% increase or decrease in the stock prices of these equity securities would have increased or decreased their fair value as of December 31, 2021 and 2020 by approximately \$364 million and \$478 million, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

GILEAD SCIENCES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
Years ended December 31, 2021, 2020 and 2019

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Gilead Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Gilead Sciences, Inc. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 23, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Government and commercial rebates

Description of the Matter

As more fully described in Note 1, the Company estimates reductions to its revenues for amounts payable to payers and healthcare providers in the United States under various government and commercial rebate programs in the period that the related sales occur. Rebates may vary by product, payer and individual payer plans, some of which may not be known at the point of sale. Estimated reductions to revenue are based on product sales, historical and expected payer mix, discount rates, and various other estimated and actual data, adjusted for current period expectations.

Auditing the Company's estimated reductions to revenue for rebates was complex and involved significant judgment, particularly in assessing the reasonableness of estimated payer mix applied to sales during the period. This estimate relies heavily on historical data that is adjusted for changes in payer mix expectations over time.

*How We
Addressed the
Matter in Our
Audit*

We evaluated and tested the design and operating effectiveness of the Company's internal controls over management's estimation and review of reductions from revenue for rebate programs, including controls to assess the payer mix assumption. We also tested the completeness and accuracy of data utilized in the controls, and the accuracy of calculations supporting management's estimates.

To test management's estimation methodology for determining the payer mix, our audit procedures included, among others, analytically evaluating management's estimates, evaluating evidence contrary to the estimated amounts, performing a sensitivity analysis on the rates used in the estimates and performing a comparison of actual payments related to amounts accrued during the current and prior years.

Valuation of in-process research and development intangible assets acquired from Immunomedics, Inc.

*Description of
the Matter*

At December 31, 2021, the Company's in-process research and development (IPR&D) intangible assets acquired in connection with the 2020 acquisition of Immunomedics, Inc. were \$14.7 billion. As discussed in Note 1, intangible assets with indefinite useful lives related to purchased IPR&D projects are measured at their respective fair values as of the acquisition date and are considered indefinite-lived until the completion or abandonment of the associated R&D efforts. The Company tests indefinite-lived intangible assets for impairment on an annual basis and in between annual tests if they become aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts.

Auditing the impairment test of the IPR&D intangible assets acquired from Immunomedics was complex due to the significant judgment required in estimating their fair values. In particular, the fair value estimates required the use of valuation methodologies that were sensitive to significant assumptions (e.g., discount rate, probability of technical and regulatory success, addressable patient population, treatment duration and projected market share), which were affected by expected future market or economic conditions.

*How We
Addressed the
Matter in Our
Audit*

We evaluated and tested the design and operating effectiveness of the Company's internal controls over the determination of the estimated fair value of the IPR&D intangible assets acquired from Immunomedics. For example, we tested controls over management's review of the valuation methodologies and the significant assumptions used to develop the fair value estimates. We also tested management's controls to validate that the data used in the fair value estimates were complete and accurate.

To test the estimated fair value of the Company's IPR&D intangible assets acquired from Immunomedics, our audit procedures, among others, included evaluating the Company's use of appropriate valuation methodologies with assistance from a valuation specialist, evaluating sensitivity analyses to determine which assumptions had the greatest impact on the overall determination of value, and testing the completeness and accuracy of the underlying data. Our audit procedures over the most significant assumptions included comparing the assumptions to current industry, market and economic trends, to historical results of the Company's business and other guideline companies within the same industry and to other relevant factors. For example, we evaluated the probability of technical and regulatory success by considering the phase of development of the clinical projects, and the Company's history of obtaining regulatory approval. In addition, we evaluated the expected addressable patient populations by comparing the Company's estimates to external industry forecasts.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1988.
San Jose, California
February 23, 2022

GILEAD SCIENCES, INC.
Consolidated Balance Sheets

(in millions, except per share amounts)	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,338	\$ 5,997
Short-term marketable debt securities	1,182	1,411
Accounts receivable, net	4,493	4,892
Inventories	1,618	1,683
Prepaid and other current assets	2,141	2,013
Total current assets	14,772	15,996
Property, plant and equipment, net	5,121	4,967
Long-term marketable debt securities	1,309	502
Intangible assets, net	33,455	33,126
Goodwill	8,332	8,108
Other long-term assets	4,963	5,708
Total assets	\$ 67,952	\$ 68,407
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 705	\$ 844
Accrued government and other rebates	3,244	3,460
Accrued and other current liabilities	6,145	4,336
Current portion of long-term debt and other obligations, net	1,516	2,757
Total current liabilities	11,610	11,397
Long-term debt, net	25,179	28,645
Long-term income taxes payable	4,767	5,016
Deferred tax liability	4,356	3,914
Other long-term obligations	976	1,214
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 5 shares authorized; none outstanding	—	—
Common stock, par value \$0.001 per share; 5,600 authorized; 1,254 shares issued and outstanding as of December 31, 2021 and 2020	1	1
Additional paid-in capital	4,661	3,880
Accumulated other comprehensive income (loss)	83	(60)
Retained earnings	16,324	14,381
Total Gilead stockholders' equity	21,069	18,202
Noncontrolling interest	(5)	19
Total stockholders' equity	21,064	18,221
Total liabilities and stockholders' equity	\$ 67,952	\$ 68,407

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Income

(in millions, except per share amounts)	Year Ended December 31,		
	2021	2020	2019
Revenues:			
Product sales	\$ 27,008	\$ 24,355	\$ 22,119
Royalty, contract and other revenues	297	334	330
Total revenues	27,305	24,689	22,449
Costs and expenses:			
Cost of goods sold	6,601	4,572	4,675
Research and development expenses	5,363	5,039	4,055
Acquired in-process research and development expenses	177	5,856	5,051
Selling, general and administrative expenses	5,246	5,151	4,381
Total costs and expenses	17,387	20,618	18,162
Income from operations	9,918	4,071	4,287
Interest expense	(1,001)	(984)	(995)
Other income (expense), net	(639)	(1,418)	1,868
Income before income taxes	8,278	1,669	5,160
Income tax (expense) benefit	(2,077)	(1,580)	204
Net income	6,201	89	5,364
Net loss attributable to noncontrolling interest	24	34	22
Net income attributable to Gilead	\$ 6,225	\$ 123	\$ 5,386
Net income per share attributable to Gilead common stockholders - basic	\$ 4.96	\$ 0.10	\$ 4.24
Shares used in per share calculation - basic	1,256	1,257	1,270
Net income per share attributable to Gilead common stockholders - diluted	\$ 4.93	\$ 0.10	\$ 4.22
Shares used in per share calculation - diluted	1,262	1,263	1,277

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Comprehensive Income (Loss)

(in millions)	Year Ended December 31,		
	2021	2020	2019
Net income	\$ 6,201	\$ 89	\$ 5,364
Other comprehensive income (loss):			
Net foreign currency translation gain (loss), net of tax	(38)	(2)	6
Available-for-sale debt securities:			
Net unrealized gain (loss), net of tax	(6)	43	54
Reclassifications to net income, net of tax	—	(42)	(1)
Net change	(6)	1	53
Cash flow hedges:			
Net unrealized gain (loss), net of tax	129	(103)	72
Reclassifications to net income, net of tax	58	(41)	(126)
Net change	187	(144)	(54)
Other comprehensive income (loss)	143	(145)	5
Comprehensive income (loss)	6,344	(56)	5,369
Comprehensive loss attributable to noncontrolling interest	24	34	22
Comprehensive income (loss) attributable to Gilead	\$ 6,368	\$ (22)	\$ 5,391

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Stockholders' Equity

(in millions, except per share amounts)	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance as of December 31, 2018	1,282	\$ 1	\$ 2,282	\$ 80	\$ 19,024	\$ 147	\$ 21,534
Cumulative effect from the adoption of new accounting standards	—	—	—	—	8	—	8
Net income (loss)	—	—	—	—	5,386	(22)	5,364
Other comprehensive income, net of tax	—	—	—	5	—	—	5
Issuances under employee stock purchase plan	2	—	90	—	—	—	90
Issuances under equity incentive plans	10	—	118	—	—	—	118
Stock-based compensation	—	—	638	—	—	—	638
Repurchases of common stock	(28)	—	(77)	—	(1,791)	—	(1,868)
Dividends declared (\$2.52 per share)	—	—	—	—	(3,239)	—	(3,239)
Balance as of December 31, 2019	1,266	1	3,051	85	19,388	125	22,650
Cumulative effect from the adoption of new accounting standard	—	—	—	—	(7)	—	(7)
Change in noncontrolling interest	—	—	—	—	—	(72)	(72)
Net income (loss)	—	—	—	—	123	(34)	89
Other comprehensive income (loss), net of tax	—	—	1	(145)	(1)	—	(145)
Issuances under employee stock purchase plan	2	—	100	—	—	—	100
Issuances under equity incentive plans	11	—	156	—	—	—	156
Stock-based compensation	—	—	642	—	—	—	642
Repurchases of common stock	(25)	—	(70)	—	(1,658)	—	(1,728)
Dividends declared (\$2.72 per share)	—	—	—	—	(3,464)	—	(3,464)
Balance as of December 31, 2020	1,254	1	3,880	(60)	14,381	19	18,221
Net income (loss)	—	—	—	—	6,225	(24)	6,201
Other comprehensive income (loss), net of tax	—	—	—	143	—	—	143
Issuances under employee stock purchase plan	2	—	111	—	—	—	111
Issuances under equity incentive plans	9	—	58	—	—	—	58
Stock-based compensation	—	—	640	—	—	—	640
Repurchases of common stock	(11)	—	(28)	—	(664)	—	(692)
Dividends declared (\$2.84 per share)	—	—	—	—	(3,618)	—	(3,618)
Balance as of December 31, 2021	1,254	\$ 1	\$ 4,661	\$ 83	\$ 16,324	\$ (5)	\$ 21,064

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Cash Flows

(in millions)	Year Ended December 31,		
	2021	2020	2019
Operating Activities:			
Net income	\$ 6,201	\$ 89	\$ 5,364
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation expense	329	288	255
Amortization expense	1,721	1,192	1,149
Stock-based compensation expense	635	643	636
Deferred income taxes	(116)	(214)	(2,098)
Net (gain) loss from equity securities	610	1,662	(1,241)
Acquired in-process research and development expenses	177	5,856	4,251
In-process research and development impairment	—	—	800
Write-downs for slow-moving and excess raw material and work in process inventory	121	40	547
Other	1,217	250	279
Changes in operating assets and liabilities:			
Accounts receivable, net	313	(1,171)	(218)
Inventories	11	(195)	(95)
Prepaid expenses and other	(42)	(214)	(307)
Accounts payable	(118)	80	(61)
Income taxes payable	(364)	(778)	272
Accrued liabilities	689	640	(389)
Net cash provided by operating activities	11,384	8,168	9,144
Investing Activities:			
Purchases of marketable debt securities	(3,517)	(20,315)	(30,455)
Proceeds from sales of marketable debt securities	730	23,239	7,523
Proceeds from maturities of marketable debt securities	2,180	9,479	22,398
Acquisitions, including in-process research and development, net of cash acquired	(1,402)	(25,742)	(4,251)
Purchases of equity securities	(380)	(455)	(1,773)
Capital expenditures	(579)	(650)	(825)
Other	(163)	(171)	(434)
Net cash used in by investing activities	(3,131)	(14,615)	(7,817)
Financing Activities:			
Proceeds from debt financing, net of issuance costs	—	8,184	—
Proceeds from issuances of common stock	169	256	209
Repurchases of common stock	(546)	(1,583)	(1,749)
Repayments of debt and other obligations	(4,750)	(2,500)	(2,750)
Payment of dividends	(3,605)	(3,449)	(3,222)
Other	(145)	(138)	(122)
Net cash (used in) provided by financing activities	(8,877)	770	(7,634)
Effect of exchange rate changes on cash and cash equivalents	(35)	43	(2)
Net change in cash and cash equivalents	(659)	(5,634)	(6,309)
Cash and cash equivalents at beginning of period	5,997	11,631	17,940
Cash and cash equivalents at end of period	\$ 5,338	\$ 5,997	\$ 11,631
Supplemental disclosure of cash flow information:			
Interest paid, net of amounts capitalized	\$ 979	\$ 951	\$ 982
Income taxes paid	\$ 2,509	\$ 2,639	\$ 1,793

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

Gilead Sciences, Inc. (“Gilead,” “we,” “our” or “us”) 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. We are committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. We operate in more than 35 countries worldwide, with headquarters in Foster City, California.

Our portfolio of marketed products includes AmBisome[®], Atripla[®], Biktarvy[®], Cayston[®], Complera[®], Descovy[®], Descovy for PrEP[®], Emtriva[®], Epclusa[®], Eviplera[®], Genvoya[®], Harvoni[®], Hepcludex[®] (bulevirtide), Hepsera[®], Jyseleca[®] (filgotinib), Letairis[®], Odefsey[®], Ranexa[®], Sovaldi[®], Stribild[®], Tecartus[®], Trodelvy[®], Truvada[®], Truvada for PrEP[®], Tybost[®], Veklury[®], Vemlidy[®], Viread[®], Vosevi[®], Yescarta[®] and Zydelig[®]. The approval status of Hepcludex and Jyseleca vary worldwide, and Hepcludex and Jyseleca are not approved in the United States. We also sell and distribute authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua Therapeutics, LLC. In addition, we sell and distribute certain products through our corporate partners under collaborative agreements.

Basis of Presentation

The accompanying Consolidated Financial Statements include the accounts of Gilead, our wholly-owned subsidiaries and certain variable interest entities for which we are the primary beneficiary. All intercompany transactions have been eliminated. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income or loss attributable to noncontrolling interests in our Consolidated Statements of Income equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties.

We assess whether we are the primary beneficiary of a variable interest entity (“VIE”) at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE’s economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. We did not have any material VIEs as of December 31, 2021.

Certain reclassifications have been made to prior periods in the Consolidated Financial Statements and accompanying notes to conform with the current presentation. Beginning 2020, acquired in-process research and development (“IPR&D”) expenses are reported separately from Research and development expenses on our Consolidated Statements of Income. Our Consolidated Statements of Income for the year ended December 31, 2019 was conformed to separately present acquired IPR&D expenses.

Segment Information

We have one operating segment which primarily focuses on the discovery, development and commercialization of innovative medicines in areas of unmet medical need. Our Chief Executive Officer, as the chief operating decision-maker (“CODM”), manages and allocates resources to the operations of our company on an entity-wide basis. Managing and allocating resources on an entity-wide basis enables our CODM to assess the overall level of resources available and how to best deploy these resources across functions and research and development (“R&D”) projects based on unmet medical need and, as necessary, reallocate resources among our internal R&D portfolio and external opportunities to best support the long-term growth of our business. See Note 2. Revenues for a summary of disaggregated revenues by product and geographic region.

Significant Accounting Policies, Estimates and Judgments

The preparation of these Consolidated Financial Statements in accordance with U.S. generally accepted accounting principles requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. On an ongoing basis, we evaluate our significant accounting policies and estimates. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that the coronavirus disease (“COVID-19”) could have on our significant accounting estimates. Actual results may differ significantly from these estimates.

Revenue Recognition

Product Sales

We recognize revenue from product sales when control of the product transfers, generally upon shipment or delivery, to the customer, or in certain cases, upon the corresponding sales by our customer to a third party. The revenues are recognized net of estimated government and other rebates and chargebacks, cash discounts for prompt payment, distributor fees, sales return provisions and other related deductions. These deductions to product sales are referred to as gross-to-net deductions and are estimated and recorded in the period in which the related product sales occur. Our payment terms to customers generally range from 30 to 90 days; however, payment terms differ by jurisdiction, by customer and, in some instances, by type of product. Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with gross-to-net deductions is subsequently resolved. Taxes assessed by governmental authorities and collected from customers are excluded from product sales. If we expect, at contract inception, that the period between the transfer of control and corresponding payment from the customer will be one year or less, we do not adjust the amount of consideration for the effects of a financing component.

Gross-to-Net Deductions

Rebates and Chargebacks

Government and other rebates and chargebacks include amounts payable to payers and healthcare providers under various programs, and may vary by product, by payer and individual payer plans. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, payer and individual payer plans. For qualified programs that can purchase our products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to us the difference between their acquisition cost and the lower contractual price.

Rebates and chargebacks are estimated primarily based on product sales, and expected payer mix and discount rates, which require significant estimates and judgment. Additionally, in developing our estimates, we consider: historical and estimated payer mix; statutory discount requirements and contractual terms; historical claims experience and processing time lags; estimated patient population; known market events or trends; market research; channel inventory data obtained from our major U.S. wholesalers; and other pertinent internal or external information. We assess and update our estimates each reporting period to reflect actual claims and other current information.

Government and other chargebacks that are payable to our direct customers are generally classified as reductions of Accounts receivable on our Consolidated Balance Sheets. Government and other rebates that are payable to third party payers and healthcare providers are recorded in Accrued government and other rebates on our Consolidated Balance Sheets.

Cash Discounts

We estimate cash discounts based on contractual terms, historical customer payment patterns and our expectations regarding future customer payment patterns.

Distributor Fees

Under our inventory management agreements with our significant U.S. wholesalers, we pay the wholesalers a fee primarily for compliance with certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These distributor fees are based on a contractually determined fixed percentage of sales.

Allowance for Sales Returns

Allowances are made for estimated sales returns by our customers and are recorded in the period the related revenue is recognized. We typically permit returns if the product is damaged, defective, or otherwise cannot be used by the customer. In the United States, we typically permit returns six months prior to and up to one year after the product expiration date. Outside the United States, returns are only allowed in certain countries on a limited basis.

Our estimates of sales returns are based primarily on analysis of our historical product return patterns, industry information reporting the return rates for similar products and contractual agreement terms. We also take into consideration known or expected changes in the marketplace specific to each product.

Shipping and Handling

Shipping and handling activities are considered to be fulfillment activities and not considered to be a separate performance obligation.

Royalty, Contract and Other Revenues

Royalty revenue is recognized in the period in which the obligation is satisfied and the corresponding sales by our corporate partners occur.

Research and Development Expenses

R&D expenses consist primarily of clinical studies performed by contract research organizations (“CROs”), materials and supplies, payments under collaborative and other arrangements including milestone payments, licenses and fees, expense reimbursements to the collaboration partners, personnel costs including salaries, benefits and stock-based compensation expense, and overhead allocations consisting of various support and infrastructure costs. Milestone payments made to third-party collaborators are expensed as incurred up to the point of regulatory approval. Milestone payments made upon regulatory approval are capitalized and amortized over the remaining useful life of the related product. From time to time, we enter into development and collaboration agreements in which we share expenses with a collaborative partner. We record payments received from our collaborative partners for their share of the development costs as a reduction of R&D expenses.

We charge R&D costs, including clinical study costs, to expense when incurred. Clinical study costs are a significant component of R&D expenses. Most of our clinical studies are performed by third-party CROs. We monitor levels of performance under each significant contract including the extent of patient enrollment and other activities through communications with our CROs. We accrue costs for clinical studies performed by CROs over the service periods specified in the contracts and adjust our estimates, if required, based upon our ongoing review of the level of effort and costs actually incurred by the CROs. All of our material CRO contracts are terminable by us upon written notice and we are generally only liable for actual services completed by the CRO and certain non-cancelable expenses incurred at any point of termination. Payments we make for R&D services prior to the services being rendered are recorded as prepaid assets in our Consolidated Balance Sheets and are expensed as the services are provided.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses reflect IPR&D impairments as well as the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use, including upfront payments related to various collaborations and the initial costs of rights to IPR&D projects. The acquired IPR&D is expensed on acquisition date. Future costs to develop these IPR&D projects are recorded in Research and development expenses on our Consolidated Statements of Income as incurred.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses relate to sales and marketing, finance, human resources, legal and other administrative activities. SG&A expenses consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses, and other general and administrative costs. SG&A expenses also include the Branded Prescription Drug (“BPD”) fee. In the United States, we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of the BPD fee, which is estimated based on select government sales during the prior year as a percentage of total industry government sales.

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$735 million, \$795 million and \$784 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Cash and Cash Equivalents

We consider highly liquid investments with insignificant interest rate risk and an original maturity of three months or less on the purchase date to be cash equivalents.

Marketable and Non-Marketable Securities

Marketable Debt Securities

We determine the appropriate classification of our marketable debt securities at the time of purchase and reevaluate such designation at each balance sheet date. All of our marketable debt securities are considered available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term marketable debt securities or long-term marketable debt securities. Unrealized gains and losses on available-for-sale debt securities are excluded from net income and reported in Accumulated other comprehensive income (loss) (“AOCI”) as a separate component of stockholders’ equity. Other income (expense), net, includes interest, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and expected credit losses, if any. The cost of securities sold is based on the specific identification method. We regularly review our investments for declines in fair value below their amortized cost basis to determine whether the impairment is due to credit-related factors or noncredit-related factors. Our review includes the creditworthiness of the security issuers, the severity of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost bases. When we determine that a portion of the unrealized loss is due to an expected credit loss, we recognize the loss amount in Other income (expense), net, with a corresponding allowance against the carrying value of the security we hold. The portion of the unrealized loss related to factors other than credit losses is recognized in AOCI.

Marketable and Non-Marketable Equity Securities

Investments in equity securities, other than equity method investments, are recorded at fair market value if fair value is readily determinable, and unrealized gains and losses are included in Other income (expense), net on our Consolidated Statements of Income.

For investments in entities over which we have significant influence but do not meet the requirements for consolidation and have not elected the fair value option, we use the equity method of accounting with our share of the underlying income or loss of such entities reported in Other income (expense), net on our Consolidated Statements of Income. We have elected the fair value option to account for our equity investments in Arcus Biosciences, Inc. (“Arcus”) and Galapagos NV (“Galapagos”) over which we have significant influence. We believe the fair value option best reflects the underlying economics of these investments. See Note 11. Collaborations and Other Arrangements for additional information.

Equity securities without readily determinable fair values are recorded using the measurement alternative of cost less impairment, if any, adjusted for observable price changes in orderly transactions for identical or similar investments of the same issuer. Certain investments in equity securities of non-public companies are accounted for using the equity method based on our ownership percentage and other factors that indicate we have significant influence over the investee. See Note 11. Collaborations and Other Arrangements for additional information.

Our investments in equity securities are recorded in Prepaid and other current assets or Other long-term assets on our Consolidated Balance Sheets. We regularly review our securities for indicators of impairment.

Concentrations of Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government and other programs, cash discounts for prompt payment and credit losses. Estimates of our allowance for credit losses consider a number of factors including existing contractual payment terms, individual customer circumstances, historical payment patterns of our customers, a review of the local economic environment and its potential impact on expected future customer payment patterns and government funding and reimbursement practices. The majority of our trade accounts receivable arises from product sales in the United States and Europe. Additions to the allowance for credit losses, write-offs and recoveries of customer receivables were not material for the years ended December 31, 2021, 2020 and 2019.

Inventories

Inventories are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. We periodically review our inventories to identify obsolete, slow-moving, excess or otherwise unsaleable items. If obsolete, slow-moving, excess or unsaleable items are observed and there are no alternate uses for the inventory, we record a write-down to net realizable value through a charge to Cost of goods sold on our Consolidated Statements of Income. The determination of net realizable value requires judgment, including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions and potential product obsolescence, among others.

When future commercialization is considered probable and the future economic benefit is expected to be realized, based on management’s judgment, we capitalize pre-launch inventory costs prior to regulatory approval. A number of factors are considered, including the current status in the regulatory approval process, potential impediments to the approval process such as safety or efficacy, anticipated R&D initiatives that could impact the indication in which the compound will be used, viability of commercialization and marketplace trends.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized using the straight-line method. Repairs and maintenance costs are expensed as incurred. Estimated useful lives in years are generally as follows:

<u>Description</u>	<u>Estimated Useful Life</u>
Buildings and improvements	Shorter of 35 years or useful life
Laboratory and manufacturing equipment	4-10
Office, computer equipment and other	3-15
Leasehold improvements	Shorter of useful life or lease term

Leases

We determine if an arrangement contains a lease at inception. Right-of-use assets and lease liabilities are recognized at the commencement date based on the present value of the lease payments over the lease term, which is the non-cancelable period stated in the contract adjusted for any options to extend or terminate when it is reasonably certain that we will exercise that option. Right-of-use assets are adjusted for prepaid lease payments, lease incentives and initial direct costs incurred. Operating lease expense for the minimum lease payments is recognized on a straight-line basis over the lease term.

We account for lease and nonlease components in our lease agreements as a single lease component in determining lease assets and liabilities. In addition, we do not recognize the right-of-use assets and liabilities for leases with lease terms of one year or less.

As most of our operating leases do not provide an implicit interest rate, we generally utilize a collateralized incremental borrowing rate, applied in a portfolio approach when relevant, based on the information available at the commencement date to determine the lease liability.

Acquisitions

We account for business combinations using the acquisition method of accounting, which generally requires that assets acquired, including IPR&D projects, and liabilities assumed be recorded at their fair values as of the acquisition date on our Consolidated Balance Sheets. Any excess of consideration over the fair value of net assets acquired is recorded as goodwill. The determination of estimated fair value requires us to make significant estimates and assumptions. As a result, we may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period, which may be up to one year from the acquisition date, with the corresponding offset to goodwill. Transaction costs associated with business combinations are expensed as they are incurred.

When we determine net assets acquired do not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an acquisition of assets and, therefore, no goodwill is recorded and contingent consideration, such as payments upon achievement of various developmental, regulatory and commercial milestones, generally is not recognized at the acquisition date. In an asset acquisition, upfront payments allocated to IPR&D projects at the acquisition date and subsequent milestone payments are expensed as incurred on our Consolidated Statements of Income unless there is an alternative future use.

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets are measured at their respective fair values as of the acquisition date and may be subject to adjustment within the measurement period, which may be up to one year from the acquisition date. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. We do not amortize goodwill and intangible assets with indefinite useful lives. Goodwill and indefinite-lived intangible assets are tested for impairment annually or more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired.

When development is successfully completed, which generally occurs when regulatory approval is obtained, the associated assets are deemed finite-lived and amortized over their respective estimated useful lives beginning at that point in time. Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis, and are reviewed for impairment when facts or circumstances indicate that the carrying value of these assets may not be recoverable.

Impairment of Long-Lived Assets

Long-lived assets, including property, plant and equipment and finite-lived intangible assets, are reviewed for impairment whenever facts or circumstances either internally or externally may indicate that the carrying value of an asset may not be recoverable. Should there be an indication of impairment, we test for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset to the carrying amount of the asset or asset group. If the asset or asset group is determined to be impaired, any excess of the carrying value of the asset or asset group over its estimated fair value is recognized as an impairment loss.

Valuation of Contingent Consideration Resulting from a Business Combination

In connection with certain acquisitions, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. We record contingent consideration resulting from a business combination at its fair value on the acquisition date. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value in Research and development expenses on our Consolidated Statements of Income until such time that the related product candidate receives marketing approval.

Increases or decreases in fair value of the contingent consideration liabilities can result from updates to assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues or changes in discount rates. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period. Actual results may differ from estimates.

Foreign Currency Translation, Transaction Gains and Losses, and Hedging Contracts

Non-U.S. entity operations are recorded in the functional currency of each entity. Results of operations for non-U.S. dollar functional currency entities are translated into U.S. dollars using average currency rates. Assets and liabilities are translated using currency rates at period end. Foreign currency translation adjustments are recorded as a component of AOCI within stockholders' equity. Foreign currency transaction gains and losses are recorded in Other income (expense), net, on our Consolidated Statements of Income. Net foreign currency transaction gains and losses were not material for the years ended December 31, 2021, 2020 and 2019.

We hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates and, as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we seek to limit the risk that counterparties to these contracts may be unable to perform. We also seek to limit our risk of loss by entering into contracts that permit net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrealized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative contracts for trading purposes.

Fair Value of Financial Instruments

We apply fair value accounting for all financial and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. We define fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risks.

Derivative Financial Instruments

We recognize all derivative instruments as either assets or liabilities at fair value on our Consolidated Balance Sheets. Unrealized changes in the fair value of derivatives designated as part of a hedge transaction are recorded in AOCI. The unrealized gains or losses in AOCI are reclassified into Product sales on our Consolidated Statements of Income when the respective hedged transactions affect earnings. Changes in the fair value of derivatives that are not part of a hedge transaction are recorded each period in Other income (expense), net on our Consolidated Statements of Income.

We assess, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are effective in offsetting the changes in cash flows or fair values of the hedged items. If we determine that a forecasted transaction is probable of not occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in Other income (expense), net on our Consolidated Statements of Income.

Share-Based Compensation

We provide share-based compensation in the form of various types of equity-based awards, including restricted stock units (“RSU”s), performance share awards or units (“PSU”s) and stock options. Compensation expense is recognized on the Consolidated Statements of Income based on the estimated fair value of the award on the grant date. The estimated fair value of RSUs is based on the closing price of our common stock. For PSUs, depending on the terms of the award, fair value on the date of grant is determined based on either the Monte Carlo valuation methodology or the closing stock price on the date of grant. For stock option awards, estimated fair value is based on the Black-Scholes option valuation model.

Contingencies

We are a party to various legal actions. We recognize accruals for such actions to the extent that we conclude that a loss is both probable and reasonably estimable. We accrue the best estimate of loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible, we disclose the possible loss or range of loss, or that the amount of loss cannot be estimated at this time.

Income Taxes

Our income tax provision is computed under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of applicable tax laws or regulations.

We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by tax authorities based on the technical merits of the position. The tax benefit recognized in the Consolidated Financial Statements for a particular tax position is based on the largest benefit that is more likely than not to be realized. The amount of unrecognized tax benefits (“UTB”) is adjusted as appropriate for changes in facts and circumstances, such as significant amendments to existing tax law, new regulations or interpretations by tax authorities, new information obtained during a tax examination or resolution of an examination. We recognize both accrued interest and penalties, where appropriate, related to UTB in Income tax (expense) benefit on our Consolidated Statements of Income.

We have elected to account for the tax on Global Intangible Low-Taxed Income, enacted as part of the Tax Cuts and Jobs Act, as a component of tax expense in the period in which the tax is incurred.

Other Significant Accounting Policies

Our other significant accounting policies are described in the remaining appropriate Notes to the Consolidated Financial Statements.

2. REVENUES

Disaggregation of Revenues

Revenues were as follows:

(in millions)	Year Ended December 31, 2021				Year Ended December 31, 2020				Year Ended December 31, 2019			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product Sales:												
HIV												
Atripla	\$ 121	\$ 12	\$ 12	\$ 145	\$ 307	\$ 21	\$ 21	\$ 349	\$ 501	\$ 60	\$ 39	\$ 600
Biktarvy	7,049	969	606	8,624	6,095	735	429	7,259	4,225	370	143	4,738
Complera/ Eviplera	102	142	14	258	89	159	21	269	160	214	32	406
Descovy	1,397	164	139	1,700	1,526	197	138	1,861	1,078	255	167	1,500
Genvoya	2,267	391	221	2,879	2,605	490	243	3,338	2,984	664	283	3,931
Odefsey	1,076	440	52	1,568	1,172	450	50	1,672	1,180	438	37	1,655
Stribild	132	43	14	189	125	54	17	196	268	75	26	369
Truvada	314	22	35	371	1,376	27	45	1,448	2,640	101	72	2,813
Revenue share - Symtuza ⁽¹⁾	355	165	11	531	331	149	8	488	249	130	—	379
Other HIV ⁽²⁾	15	18	17	50	25	5	28	58	30	5	12	47
Total HIV	12,828	2,366	1,121	16,315	13,651	2,287	1,000	16,938	13,315	2,312	811	16,438
Veklury	3,640	1,095	830	5,565	2,026	607	178	2,811	—	—	—	—
Hepatitis C virus (“HCV”)												
Ledipasvir/ Sofosbuvir ⁽³⁾	84	31	97	212	92	29	151	272	312	71	260	643
Sofosbuvir/ Velpatasvir ⁽⁴⁾	815	316	331	1,462	864	337	398	1,599	971	553	441	1,965
Other HCV ⁽⁵⁾	119	74	14	207	132	48	13	193	182	118	28	328
Total HCV	1,018	421	442	1,881	1,088	414	562	2,064	1,465	742	729	2,936
Hepatitis B virus (“HBV”) / Hepatitis Delta virus (“HDV”)												
Vemlidy	384	34	396	814	356	29	272	657	309	21	158	488
Viread	11	28	72	111	14	34	137	185	32	69	142	243
Other HBV/ HDV ⁽⁶⁾	2	42	—	44	10	8	—	18	2	9	—	11
Total HBV/ HDV	397	104	468	969	380	71	409	860	343	99	300	742
Cell Therapy												
Tecartus	136	40	—	176	34	10	—	44	—	—	—	—
Yescarta	406	253	36	695	362	191	10	563	373	83	—	456
Total Cell Therapy	542	293	36	871	396	201	10	607	373	83	—	456
Trodely	370	10	—	380	49	—	—	49	—	—	—	—
Other												
AmBisome	39	274	227	540	61	230	145	436	37	234	136	407
Letairis	206	—	—	206	314	—	—	314	618	—	—	618
Ranexa	10	—	—	10	9	—	—	9	216	—	—	216
Zydelig	26	35	1	62	31	39	2	72	47	54	2	103
Other ⁽⁷⁾	100	80	29	209	136	45	14	195	151	43	9	203
Total Other	381	389	257	1,027	551	314	161	1,026	1,069	331	147	1,547
Total product sales	19,176	4,678	3,154	27,008	18,141	3,894	2,320	24,355	16,565	3,567	1,987	22,119
Royalty, contract and other revenues	91	196	10	297	76	241	17	334	80	244	6	330
Total revenues	\$ 19,267	\$ 4,874	\$ 3,164	\$ 27,305	\$ 18,217	\$ 4,135	\$ 2,337	\$ 24,689	\$ 16,645	\$ 3,811	\$ 1,993	\$ 22,449

(1) Represents our revenue from cobicistat (“C”), emtricitabine (“FTC”) and tenofovir alafenamide (“TAF”) in Symtuza (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen Sciences Ireland Unlimited Company (“Janssen”).

(2) Includes Emtriva and Tybost.

(3) Amounts consist of sales of Harvoni and the authorized generic version of Harvoni sold by our separate subsidiary, Asegua Therapeutics LLC.

(4) Amounts consist of sales of Eplusa and the authorized generic version of Eplusa sold by our separate subsidiary, Asegua Therapeutics LLC.

(5) Includes Vosevi and Sovaldi.

(6) Includes Hepcludex and Hepsera.

(7) Includes Cayston and Jyseleca.

Revenues From Major Customers

The following table summarizes revenues from each of our customers who individually accounted for 10% or more of our total revenues:

(as a percentage of total revenues)	Year Ended December 31,		
	2021	2020	2019
AmerisourceBergen Corporation	23 %	27 %	21 %
Cardinal Health, Inc.	22 %	21 %	21 %
McKesson Corporation	20 %	20 %	22 %

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

Revenues recognized from performance obligations satisfied in prior years related to our revenue share with Janssen, as described in Note 11. Collaborations and Other Arrangements, and royalties for licenses of our intellectual property were \$851 million, \$841 million and \$741 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Revenues from product sales, net of gross-to-net deductions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable of occurring when the uncertainty associated with gross-to-net deductions is subsequently resolved. Estimates are assessed each period and updated to reflect current information. Changes in estimates related to sales made in prior years resulted in \$856 million, \$101 million and \$257 million increase in revenues for the years ended December 31, 2021, 2020 and 2019, respectively. This was primarily related to changes in estimates for accrued government and other rebates and allowances for sales returns upon product expiration.

Contract Balances

Our contract assets, which consist of unbilled amounts primarily from arrangements where the licensing of intellectual property is the only or predominant performance obligation, totaled \$174 million and \$198 million as of December 31, 2021 and 2020, respectively. Contract liabilities, which generally result from receipt of advance payment before our performance under the contract, were not material as of December 31, 2021 and 2020, respectively. Revenue expected to be recognized in the future from contract liabilities as the related performance obligations are satisfied is not expected to be material in any one year.

3. FAIR VALUE MEASUREMENTS

We determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3 inputs include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Our Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

Our financial instruments consist primarily of cash and cash equivalents, marketable debt securities, accounts receivable, foreign currency exchange contracts, equity securities, accounts payable and short-term and long-term debt. Cash and cash equivalents, marketable debt securities, certain equity securities, and foreign currency exchange contracts are reported at their respective fair values on our Consolidated Balance Sheets. Equity securities without readily determinable fair values are recorded using the measurement alternative of cost less impairment, if any, adjusted for observable price changes in orderly transactions for identical or similar investments of the same issuer. Short-term and long-term debt are reported at their amortized costs on our Consolidated Balance Sheets. The remaining financial instruments are reported on our Consolidated Balance Sheets at amounts that approximate current fair values. There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

The following table summarizes the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

(in millions)	December 31, 2021				December 31, 2020			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	\$ 407	\$ —	\$ —	\$ 407	\$ 309	\$ —	\$ —	\$ 309
U.S. government agencies securities	—	4	—	4	—	—	—	—
Non-U.S. government securities	—	50	—	50	—	43	—	43
Certificates of deposit	—	249	—	249	—	216	—	216
Corporate debt securities	—	1,363	—	1,363	—	1,142	—	1,142
Residential mortgage and asset-backed securities	—	424	—	424	—	316	—	316
Equity securities:								
Money market funds	3,661	—	—	3,661	4,361	—	—	4,361
Equity investment in Galapagos ⁽¹⁾	931	—	—	931	1,648	—	—	1,648
Equity investment in Arcus ⁽¹⁾	559	—	—	559	212	—	—	212
Other publicly traded equity securities	331	—	—	331	531	—	—	531
Deferred compensation plan	261	—	—	261	218	—	—	218
Foreign currency derivative contracts	—	80	—	80	—	12	—	12
Total	<u>\$ 6,150</u>	<u>\$ 2,170</u>	<u>\$ —</u>	<u>\$ 8,320</u>	<u>\$ 7,279</u>	<u>\$ 1,729</u>	<u>\$ —</u>	<u>\$ 9,008</u>
Liabilities:								
Liability for MYR GmbH (“MYR”) contingent consideration	\$ —	\$ —	\$ 317	\$ 317	\$ —	\$ —	\$ —	\$ —
Deferred compensation plan	261	—	—	261	218	—	—	218
Foreign currency derivative contracts	—	5	—	5	—	121	—	121
Total	<u>\$ 261</u>	<u>\$ 5</u>	<u>\$ 317</u>	<u>\$ 583</u>	<u>\$ 218</u>	<u>\$ 121</u>	<u>\$ —</u>	<u>\$ 339</u>

⁽¹⁾ See Note 11. Collaborations and Other Arrangements for additional information.

Equity Securities

The following table summarizes the classification of our equity securities measured at fair value on a recurring basis on our Consolidated Balance Sheets:

(in millions)	December 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 3,661	\$ 4,361
Prepaid and other current assets	885	853
Other long-term assets	1,197	1,756
Total	<u>\$ 5,743</u>	<u>\$ 6,970</u>

Changes in the fair value of equity securities resulted in net unrealized losses of \$610 million and \$1.7 billion and net unrealized gains of \$1.2 billion for the years ended December 31, 2021, 2020 and 2019 respectively, which were included in Other income (expense), net, on our Consolidated Statements of Income.

Other Equity Securities

Equity method investments and other equity investments without readily determinable fair values were \$338 million and \$262 million as of December 31, 2021 and 2020, respectively, and were excluded from the above tables. These amounts were included in Other long-term assets on our Consolidated Balance Sheets.

Related Party Transaction

During the second quarter of 2021, we donated certain equity securities at fair value to the Gilead Foundation, a California nonprofit organization (the “Foundation”). The Foundation is a related party as certain officers of the company also serve as directors of the Foundation. The donation expense of \$212 million was recorded within Selling, general and administrative expenses on our Consolidated Statements of Income for the year ended December 31, 2021.

Level 2 Inputs

We estimate the fair values of Level 2 investments by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

For our marketable securities, we review trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data.

Substantially all of our foreign currency derivative contracts have maturities within an 18-month time horizon and all are with counterparties that have a minimum credit rating of A- or equivalent by S&P Global Ratings, Moody's Investors Service, Inc. or Fitch Ratings, Inc. We estimate the fair values of these contracts by taking into consideration the valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency exchange rates, London Interbank Offered Rates ("LIBOR") and swap rates. These inputs, where applicable, are observable at commonly quoted intervals.

The total estimated fair values of our aggregate short-term and long-term debt, determined using Level 2 inputs based on their quoted market values, were approximately \$28.6 billion and \$34.6 billion as of December 31, 2021 and 2020, respectively, and the carrying values were \$25.6 billion and \$30.3 billion as of December 31, 2021 and 2020, respectively.

Level 3 Inputs

In connection with our first quarter 2021 acquisition of MYR, we measured assets acquired and liabilities assumed at fair value on a nonrecurring basis, except for the liability for contingent consideration. The estimated fair value of the liability for contingent consideration was \$341 million and \$317 million as of the acquisition date and December 31, 2021, respectively. The change in estimated fair value from the acquisition date was primarily due to the effect of foreign exchange remeasurement. The contingent consideration was estimated using probability-weighted scenarios for U.S. Food and Drug Administration ("FDA") approval of Hepcludex. See Note 6. Acquisitions for additional information.

In connection with our fourth quarter 2020 acquisition of Immunomedics, Inc. ("Immunomedics"), we measured assets acquired and liabilities assumed at fair value on a nonrecurring basis. The liability assumed related to the sale of future royalties is subsequently amortized using the effective interest method over the remaining estimated life. The fair values of the liability related to the sale of future royalties were \$1.3 billion and \$1.1 billion as of December 31, 2021 and 2020, respectively, and the carrying value was \$1.1 billion as of December 31, 2021 and 2020. See Note 6. Acquisitions and Note 12. Debt and Credit Facilities for additional information.

In 2020, in connection with collaborations and other equity arrangements we entered into with Pionyr Immunotherapeutics Inc. ("Pionyr") and Tizona Therapeutics, Inc. ("Tizona"), we also measured fair values of our exclusive options to acquire the remaining outstanding capital stock of Pionyr and Tizona on a nonrecurring basis. See Note 11. Collaborations and Other Arrangements for additional information.

In 2019, we measured IPR&D intangible assets acquired in connection with the acquisition of Kite Pharma, Inc. ("Kite") at fair value on a nonrecurring basis, and recognized a pre-tax impairment charge of \$800 million. The fair values of the acquired IPR&D assets are estimated based on probability-adjusted discounted cash flow calculations using Level 3 fair value measurements, and inputs include estimated revenues, costs, probability of technical and regulatory success and discount rates. Amounts capitalized as IPR&D are subject to impairment testing until the completion or abandonment of the associated R&D efforts. See Note 9. Goodwill and Intangible Assets for additional information.

Our policy is to recognize transfers into or out of Level 3 classification as of the actual date of the event or change in circumstances that caused the transfer. There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

4. AVAILABLE-FOR-SALE DEBT SECURITIES

The following table summarizes our available-for-sale debt securities:

(in millions)	December 31, 2021				December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	\$ 408	\$ —	\$ (1)	\$ 407	\$ 308	\$ 1	\$ —	\$ 309
U.S. government agencies securities	4	—	—	4	—	—	—	—
Non-U.S. government securities	50	—	—	50	43	—	—	43
Certificates of deposit	249	—	—	249	216	—	—	216
Corporate debt securities	1,365	—	(2)	1,363	1,140	2	—	1,142
Residential mortgage and asset-backed securities	425	—	(1)	424	316	—	—	316
Total	\$ 2,501	\$ —	\$ (4)	\$ 2,497	\$ 2,023	\$ 3	\$ —	\$ 2,026

The following table summarizes the classification of our available-for-sale debt securities in our Consolidated Balance Sheets:

(in millions)	December 31, 2021	December 31, 2020
Cash and cash equivalents	\$ 6	\$ 113
Short-term marketable debt securities	1,182	1,411
Long-term marketable debt securities	1,309	502
Total	\$ 2,497	\$ 2,026

The following table summarizes our available-for-sale debt securities by contractual maturity:

(in millions)	December 31, 2021	
	Amortized Cost	Fair Value
Within one year	\$ 1,189	\$ 1,188
After one year through five years	1,288	1,286
After five years	24	23
Total	\$ 2,501	\$ 2,497

We held a total of 534 and 75 positions which were in unrealized loss positions as of December 31, 2021 and 2020, respectively. Aggregated gross unrealized losses on available-for-sale debt securities were not material for the years ended December 31, 2021 and 2020. No impairment was recognized for the years ended December 31, 2021, 2020 and 2019.

5. DERIVATIVE FINANCIAL INSTRUMENTS

Our operations in foreign countries expose us to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, primarily the Euro. To manage this risk, we may hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward or option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates, and as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we seek to limit the risk that counterparties to these contracts may be unable to perform. We also seek to limit our risk of loss by entering into contracts that permit net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrealized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative contracts for trading purposes.

We hedge our exposure to foreign currency exchange rate fluctuations for certain monetary assets and liabilities that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are not designated as hedges, and as a result, changes in their fair value are recorded in Other income (expense), net, on our Consolidated Statements of Income.

We hedge our exposure to foreign currency exchange rate fluctuations for forecasted product sales that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are designated as cash flow hedges and have maturities of 18 months or less. Upon executing a hedging contract and each reporting period thereafter, we assess hedge effectiveness using regression analysis. The unrealized gains or losses in AOCI are reclassified into Product sales on our Consolidated Statements of Income when the respective hedged transactions affect earnings. The majority of gains and losses related to the hedged forecasted transactions reported in AOCI as of December 31, 2021 are expected to be reclassified to Product sales within 12 months.

The cash flow effects of our derivative contracts for the years ended December 31, 2021, 2020 and 2019 were included within Net cash provided by operating activities on our Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of \$2.9 billion and \$2.4 billion as of December 31, 2021 and 2020, respectively.

While all our derivative contracts allow us the right to offset assets and liabilities, we have presented amounts on a gross basis. The following table summarizes the classification and fair values of derivative instruments in our Consolidated Balance Sheets:

December 31, 2021				
(in millions)	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ 75	Accrued and other current liabilities	\$ 4
Foreign currency exchange contracts	Other long-term assets	5	Other long-term obligations	1
Total derivatives designated as hedges		80		
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	—	Accrued and other current liabilities	—
Total derivatives not designated as hedges		—		
Total derivatives		\$ 80		
December 31, 2020				
(in millions)	Derivative Assets		Derivative Liabilities	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	\$ —	Accrued and other current liabilities	\$ 113
Foreign currency exchange contracts	Other long-term assets	—	Other long-term obligations	7
Total derivatives designated as hedges		—		
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Prepaid and other current assets	12	Accrued and other current liabilities	1
Total derivatives not designated as hedges		12		
Total derivatives		\$ 12		

The following table summarizes the effect of our foreign currency exchange contracts on our Consolidated Financial Statements:

(in millions)	Year Ended December 31,		
	2021	2020	2019
Derivatives designated as hedges:			
Gain (loss) recognized in AOCI	\$ 147	\$ (118)	\$ 76
Gain (loss) reclassified from AOCI into Product sales	\$ (67)	\$ 47	\$ 127
Derivatives not designated as hedges:			
Gain (loss) recognized in Other income (expense), net	\$ 21	\$ (51)	\$ 22

From time to time, we may discontinue cash flow hedges and, as a result, record related amounts in Other income (expense), net on our Consolidated Statements of Income. There were no discontinuances of cash flow hedges for the years presented.

As of December 31, 2021 and 2020, we only held foreign currency exchange contracts. The following table summarizes the potential effect of offsetting our foreign currency exchange contracts on our Consolidated Balance Sheets:

(in millions)	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset on the Consolidated Balance Sheets	Amounts of Assets/Liabilities Presented on the Consolidated Balance Sheets	Gross Amounts Not Offset on the Consolidated Balance Sheets		
				Derivative Financial Instruments	Cash Collateral Received/Pledged	Net Amount (Legal Offset)
As of December 31, 2021						
Derivative assets	\$ 80	\$ —	\$ 80	\$ (4)	\$ —	\$ 76
Derivative liabilities	\$ 5	\$ —	\$ 5	\$ (4)	\$ —	\$ 1
As of December 31, 2020						
Derivative assets	\$ 12	\$ —	\$ 12	\$ (12)	\$ —	\$ —
Derivative liabilities	\$ 121	\$ —	\$ 121	\$ (12)	\$ —	\$ 109

6. ACQUISITIONS

MYR

In the first quarter of 2021, we completed the acquisition of MYR, a German biotechnology company. MYR focuses on the development and commercialization of therapeutics for the treatment of HDV. The acquisition provided Gilead with Hepcludex, which was conditionally approved by the European Medicines Agency (“EMA”) in July 2020 for the treatment of chronic HDV infection in adults with compensated liver disease. Upon closing, MYR became a wholly-owned subsidiary of Gilead. The financial results of MYR were included in our Consolidated Financial Statements from the date of the acquisition. Acquisition-related expenses were not material for the year ended December 31, 2021.

The aggregate consideration for this acquisition of €1.3 billion (or \$1.6 billion) primarily consisted of €1.0 billion (or \$1.2 billion) paid upon closing and contingent consideration of up to €300 million, subject to customary adjustments, representing a potential future milestone payment upon FDA approval of Hepcludex. The fair value of this contingent liability, estimated using probability-weighted scenarios for FDA approval, was \$341 million as of the acquisition date and was initially recorded in Other long-term obligations on our Consolidated Balance Sheets. In the second quarter of 2021, the balance was reclassified to Accrued and other current liabilities on our Consolidated Balance Sheets. The estimated fair value of this contingent liability was \$317 million as of December 31, 2021. The change in estimated fair value from the acquisition date was primarily due to the effect of foreign exchange remeasurement.

The acquisition of MYR was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be generally recognized at fair value as of the acquisition date. The fair value estimates for the assets acquired and liabilities assumed were based upon valuations using information known and knowable as of the date of this filing. Changes to these assumptions and estimates could cause an impact to the valuation of assets acquired, including intangible assets, goodwill and the related tax impacts of the acquisition, as well as legal and other contingencies. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the acquisition date.

The following table summarizes estimated fair values of assets acquired and liabilities assumed as of the acquisition date:

(in millions)	Amount
Intangible assets:	
Finite-lived intangible asset	\$ 845
Acquired IPR&D	1,190
Deferred income taxes, net	(513)
Other assets (and liabilities), net	(187)
Total identifiable net assets	1,335
Goodwill	226
Total consideration	<u>\$ 1,561</u>

Intangible Assets

The finite-lived intangible asset of \$845 million represents the estimated fair value of Hepcludex for HDV in Europe as of the acquisition date. The fair value was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to Hepcludex for HDV in Europe and a discount rate of 12%. The discount rate used represents the estimated rate that market participants would use to value this intangible asset. This intangible asset is being amortized over an estimated useful life of 10 years.

Acquired IPR&D consists of Hepcludex for HDV in all other regions without regulatory approval, including the United States. The estimated aggregate fair value of \$1.19 billion as of the acquisition date was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to this asset and a discount rate of 12%. The discount rate used represents the estimated rate that market participants would use to value this intangible asset.

Some of the more significant assumptions inherent in the development of intangible asset fair values include: estimates of projected future cash flows, including revenues and operating profits; probability of success; the discount rate selected; the life of the potential commercialized products and the risks related to the viability of and potential alternative treatments in any future target markets, among other factors.

The inputs used for valuing these identifiable intangibles are unobservable and considered Level 3 under the fair value measurement and disclosure guidance. See Note 3. Fair Value Measurements for additional information.

Deferred Income Taxes

The net deferred tax liability was based upon the difference between the estimated financial statement basis and tax basis of net assets acquired and an estimate for the final pre-acquisition net operating losses of MYR.

Goodwill

The excess of the consideration transferred over the fair values of assets acquired and liabilities assumed of \$226 million was recorded as goodwill, which primarily reflects the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Goodwill recognized for MYR is not expected to be deductible for income tax purposes.

There were no material measurement period adjustments recorded to the fair values of assets acquired and liabilities assumed during the year ended December 31, 2021.

Immunomedics

In the fourth quarter of 2020, we completed the acquisition of Immunomedics, a company focused on the development of antibody-drug conjugate technology, for cash consideration of \$20.6 billion. Upon closing, Immunomedics became a wholly-owned subsidiary of Gilead. The acquisition was financed with the majority of the proceeds from the September 2020 senior unsecured notes offering, an additional \$1.0 billion borrowing under a new senior unsecured term loan facility and cash on hand. In 2021, we repaid the borrowing under the senior unsecured term loan facility. See Note 12. Debt and Credit Facilities for additional information.

We recorded share-based compensation expense of \$289 million related to the cash settlement of the accelerated share-based compensation expense attributable to the post-combination period, which was primarily recorded in Selling, general and administrative expenses and Research and development expenses on our Consolidated Statements of Income for the year ended December 31, 2020. We also recorded other acquisition-related expenses of \$39 million, primarily representing closing costs and related fees, in Selling, general and administrative expenses on our Consolidated Statements of Income for the year ended December 31, 2020.

The acquisition of Immunomedics was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be generally recognized at fair value as of the acquisition date. There were no material measurement period adjustments recorded to the fair values of assets acquired and liabilities assumed during the year ended December 31, 2021. The fair value estimates for the assets acquired and liabilities assumed have been completed.

The following table summarizes fair values of assets acquired and liabilities assumed as of the acquisition date:

(in millions)	Amount
Cash and cash equivalents	\$ 726
Inventories	946
Intangible assets:	
Finite-lived intangible asset	4,600
Acquired IPR&D	15,760
Outlicense contract	175
Deferred tax liabilities	(4,565)
Liability related to future royalties	(1,100)
Other assets (and liabilities), net	64
Total identifiable net assets	16,606
Goodwill	3,991
Total consideration transferred	<u>\$ 20,597</u>

Inventories

The fair value step-up adjustment of \$881 million, included in inventories of \$946 million as of the acquisition date, was primarily determined by the estimated selling price of finished inventory less the cost to complete the manufacturing process and selling effort. The step-up adjustment is recorded in Cost of goods sold on our Consolidated Statements of Income as the inventory is sold to customers and in Research and development expenses on our Consolidated Statements of Income for inventory used for clinical purposes.

Intangible Assets

The finite-lived intangible asset of \$4.6 billion represents the estimated fair value of Trodelvy for metastatic triple-negative breast cancer (“TNBC”) as of the acquisition date. The fair value was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to Trodelvy for metastatic TNBC and a discount rate of 7.0%. The discount rate used represents the estimated rate that market participants would use to value this intangible asset. This intangible asset is being amortized over an estimated useful life of 12 years.

Acquired IPR&D assets consist of Trodelvy for hormone receptor positive, human epidermal growth factor receptor 2 negative, metastatic breast cancer, Trodelvy for non-small cell lung cancer and Trodelvy for urothelial cancer (“UC”). The estimated aggregate fair value of \$15.8 billion as of the acquisition date was determined by applying the income approach using unobservable inputs to estimate probability-weighted net cash flows attributable to these assets and a discount rate of 7.0%. The discount rate used represents the estimated rate that market participants would use to value these intangible assets. Trodelvy for UC was granted accelerated approval by FDA in April 2021 and \$1.0 billion was reclassified to finite-lived intangibles from IPR&D. See Note 9. Goodwill and Intangible Assets for additional information.

Some of the more significant assumptions inherent in the development of intangible asset fair values include: the amount and timing of projected future cash flows (including revenue, cost of sales, research and development costs, and sales and marketing expenses); probability of success; the discount rate selected to measure the inherent risk of future cash flows; the assessment of the asset’s life cycle and the competitive trends impacting the asset, among other factors.

We also recorded an intangible asset related to a license and supply agreement with a third party, which was entered into by Immunomedics prior to the acquisition. Under the agreement, the third party was granted an exclusive license to develop and commercialize Trodelvy in certain territories in Asia and make certain sales milestones and royalty payments to us. The acquisition date fair value of \$175 million was determined by estimating the probability-weighted net cash flows attributable to the outlicense and a discount rate of 7.0%. The discount rate represents the estimated rate that market participants would use to value this intangible asset. This intangible asset is being amortized over an estimated useful life of 15 years on a straight-line basis.

The inputs used for valuing these identifiable intangibles are unobservable and considered Level 3 under the fair value measurement and disclosure guidance.

Deferred Income Taxes

The net deferred tax liability was based upon the difference between the estimated financial statement basis and tax basis of net assets acquired and an estimate for the final pre-acquisition net operating losses of Immunomedics.

Liability Related to Future Royalties

We assumed a liability related to a funding arrangement, which was originally entered into by Immunomedics and RPI Finance Trust (“RPI”), prior to our acquisition of Immunomedics. Under the funding agreement, RPI has the right to receive certain royalty amounts, subject to certain reductions, based on the net sales of Trodelvy for each calendar quarter during the term of the agreement through approximately 2036. The acquisition date fair value of the liability was estimated as \$1.1 billion, which was primarily determined based on current estimates of future royalty payments to RPI over the life of the arrangement using the real options method and an effective annual interest rate of 2.5%. The liability is amortized using the effective interest rate method, resulting in recognition of interest expense over 16 years. The estimated timing and amount of future expected royalty payments over the estimated term will be re-assessed each reporting period. The impact from changes in estimates will be recognized in the liability and the related interest expense prospectively. The inputs used for valuation of this liability are unobservable and are considered Level 3 under the fair value measurement and disclosure guidance. See Note 3. Fair Value Measurements for additional information. The liability related to future royalties was categorized as debt and primarily included in Long-term debt, net on our Consolidated Balance Sheets. See Note 12. Debt and Credit Facilities for additional information.

Goodwill

The excess of the consideration transferred over the fair values of assets acquired and liabilities assumed of \$4.0 billion was recorded as goodwill, which primarily reflects the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. Goodwill recognized for Immunomedics is not expected to be deductible for income tax purposes.

Forty Seven, Inc. (“Forty Seven”)

In the second quarter of 2020, we completed the acquisition of Forty Seven, a clinical-stage immuno-oncology company focused on developing therapies targeting cancer immune evasion pathways and specific cell targeting approaches, for total consideration of \$4.7 billion, net of acquired cash. Upon closing, Forty Seven became a wholly-owned subsidiary of Gilead. We accounted for the transaction as an asset acquisition since the lead asset, magrolimab, represented substantially all the fair value of the gross assets acquired. During the year ended December 31, 2020, we recorded a \$4.5 billion charge representing an acquired IPR&D asset with no alternative future use in Acquired in-process research and development expenses, and stock-based compensation expense of \$144 million primarily in Research and development expenses on our Consolidated Statements of Income.

7. INVENTORIES

The following table summarizes our Inventories:

(in millions)	December 31,	
	2021	2020
Raw materials	\$ 1,112	\$ 1,080
Work in process	590	976
Finished goods	1,032	958
Total	<u>\$ 2,734</u>	<u>\$ 3,014</u>
Reported as:		
Inventories	\$ 1,618	\$ 1,683
Other long-term assets	1,116	1,331
Total	<u>\$ 2,734</u>	<u>\$ 3,014</u>

Amounts reported as Other long-term assets primarily consisted of raw materials as of December 31, 2021 and 2020. Total inventories as of December 31, 2021 and 2020 include \$294 million and \$797 million, respectively, of fair value adjustments resulting from the Immunomedics acquisition.

Inventory write-down charges were \$228 million, \$86 million and \$649 million for the years ended December 31, 2021, 2020 and 2019, respectively. During the year ended December 31, 2019, \$547 million of the \$649 million inventory write-down charges was related to slow-moving and excess raw material and work in process inventory primarily due to lower long-term demand for our HCV products.

8. PROPERTY, PLANT AND EQUIPMENT

The following table summarizes our Property, plant and equipment, net:

(in millions)	December 31,	
	2021	2020
Land and land improvements	\$ 404	\$ 404
Buildings and improvements (including leasehold improvements)	3,794	3,678
Laboratory and manufacturing equipment	952	904
Office, computer equipment and other	807	793
Construction in progress	1,057	856
Subtotal	7,014	6,635
Less: accumulated depreciation and amortization	1,893	1,668
Total	<u>\$ 5,121</u>	<u>\$ 4,967</u>

We had unamortized capitalized software costs, included in Office, computer equipment and other, of \$131 million and \$124 million as of December 31, 2021 and 2020, respectively. Capitalized interest on construction in progress is included in Property, plant and equipment, net on our Consolidated Balance Sheets. Interest capitalized in 2021 and 2020 was not material.

The net book value of our property, plant and equipment in the United States was \$4.1 billion and \$4.0 billion as of December 31, 2021 and 2020, respectively. The corresponding amount in international locations was \$963 million and \$940 million as of December 31, 2021 and 2020, respectively. All individual international locations accounted for less than 10% of the total balances.

9. GOODWILL AND INTANGIBLE ASSETS

Goodwill

The following table summarizes the changes in the carrying amount of Goodwill:

(in millions)	December 31,	
	2021	2020
Beginning balance	\$ 8,108	\$ 4,117
Goodwill resulting from acquisitions	226	3,991
Measurement period adjustments	(2)	—
Ending balance	<u>\$ 8,332</u>	<u>\$ 8,108</u>

We perform an annual goodwill impairment assessment in the fourth quarter or earlier if impairment indicators exist. As of December 31, 2021, there were no accumulated goodwill impairment losses.

Intangible Assets

The following table summarizes our Intangible assets, net:

(in millions)	December 31, 2021				December 31, 2020			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount
Finite-lived assets								
Intangible asset - sofosbuvir	\$ 10,720	\$ (5,651)	\$ —	\$ 5,069	\$ 10,720	\$ (4,952)	\$ —	\$ 5,768
Intangible asset - axicabtagene ciloleucel ⁽¹⁾	7,110	(1,501)	—	5,609	6,200	(1,105)	—	5,095
Intangible asset - Trodelvy ⁽²⁾	5,630	(507)	—	5,123	4,600	(63)	—	4,537
Intangible asset - Hepcludex	845	(72)	—	773	—	—	—	—
Other ⁽³⁾	1,610	(650)	1	961	1,377	(540)	(1)	836
Total finite-lived assets	25,915	(8,381)	1	17,535	22,897	(6,660)	(1)	16,236
Indefinite-lived assets - IPR&D ⁽⁴⁾	15,920	—	—	15,920	16,890	—	—	16,890
Total intangible assets	<u>\$ 41,835</u>	<u>\$ (8,381)</u>	<u>\$ 1</u>	<u>\$ 33,455</u>	<u>\$ 39,787</u>	<u>\$ (6,660)</u>	<u>\$ (1)</u>	<u>\$ 33,126</u>

⁽¹⁾ Gross carrying amount as of December 31, 2021 includes \$910 million reclassified in the first quarter of 2021 from indefinite-lived assets - IPR&D following the March 2021 FDA approval of Yescarta for the treatment of adult patients with relapsed or refractory follicular lymphoma.

⁽²⁾ Gross carrying amount as of December 31, 2021 includes Trodelvy for metastatic TNBC and Trodelvy for use in adult patients with locally advanced or metastatic UC. The amount related to UC of \$1.0 billion was reclassified to finite-lived assets from indefinite-lived assets - IPR&D upon the accelerated approval by FDA in April 2021.

⁽³⁾ In October 2021, FDA granted approval of Tecartus for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Accordingly, the related amount of \$200 million was reclassified to finite-lived assets in the fourth quarter of 2021.

⁽⁴⁾ Gross carrying amount as of December 31, 2021 includes IPR&D from our 2021 acquisition of MYR and remaining IPR&D from our 2020 acquisition of Immunomedics. Gross carrying amount as of December 31, 2020 includes IPR&D from our 2020 acquisition of Immunomedics and remaining IPR&D from our 2017 acquisition of Kite.

Aggregate amortization expense related to finite-lived intangible assets was \$1.7 billion, \$1.2 billion and \$1.1 billion for the years ended December 31, 2021, 2020 and 2019, respectively, and is primarily included in Cost of goods sold on our Consolidated Statements of Income.

Amounts capitalized as IPR&D are subject to impairment testing until the completion or abandonment of the associated R&D efforts. During 2021, we performed a qualitative assessment of our IPR&D intangible asset obtained in connection with our first quarter 2021 acquisition of MYR and did not identify any indicators of impairment. During 2021, 2020 and 2019, we performed quantitative impairment testing of our IPR&D intangible assets, other than the MYR asset described above, using a probability-weighted income approach that discounts expected future cash flows to present value using discount rates of 6.5%, 8.0% and 9.5%, respectively. The discount rates are based on the estimated weighted-average cost of capital for companies with profiles similar to our profile and represents the rate that market participants would use to value the intangible assets. The discounted cash flow models used in valuing these intangible assets also require the use of Level 3 fair value measurements and inputs including estimated revenues, costs, and probability of technical and regulatory success. No IPR&D impairment charges were recorded in 2021 and 2020.

During 2019, we lowered our estimated revenues related to our IPR&D intangible asset - axicabtagene ciloleucel for the treatment of indolent B-cell non-Hodgkin lymphoma due to changes in the estimated market opportunities as new therapies or combinations of existing therapies were approved. The lower estimated revenues reduced the fair value of the IPR&D intangible assets below carrying value resulting in the recognition of an impairment charge of \$800 million, which was recorded within Acquired in-process research and development expenses on our Consolidated Statements of Income.

The following table summarizes the estimated future amortization expense associated with our finite-lived intangible assets as of December 31, 2021:

(in millions)	Amount
2022	\$ 1,778
2023	1,778
2024	1,778
2025	1,773
2026	1,765
Thereafter	8,663
Total	\$ 17,535

10. OTHER FINANCIAL INFORMATION

Accounts receivable, net

The following table summarizes our Accounts receivable, net:

(in millions)	December 31,	
	2021	2020
Accounts receivable	\$ 5,278	\$ 5,560
Less: chargebacks	671	552
Less: cash discounts and other	67	72
Less: allowances for credit losses	47	44
Accounts receivable, net	\$ 4,493	\$ 4,892

Accrued and other current liabilities

The following table summarizes the components of Accrued and other current liabilities:

(in millions)	December 31,	
	2021	2020
Compensation and employee benefits	\$ 927	\$ 864
Income taxes payable	539	598
Allowance for sales returns	499	587
Accrual for settlement related to bictegravir litigation ⁽¹⁾	1,250	—
Other accrued liabilities	2,930	2,287
Accrued and other current liabilities	\$ 6,145	\$ 4,336

⁽¹⁾ See Note 14. Commitments and Contingencies for additional information.

11. COLLABORATIONS AND OTHER ARRANGEMENTS

We enter into licensing and strategic collaborations and other similar arrangements with third parties for the development and commercialization of certain products and product candidates. These arrangements may involve two or more parties who are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities. These arrangements may include non-refundable upfront payments, expense reimbursements or payments by us for options to acquire certain rights, contingent obligations by us for potential development and regulatory milestone payments and/or sales-based milestone payments, royalty payments, revenue or profit-sharing arrangements and cost-sharing arrangements. We also have equity investments in third parties focused on the development and commercialization of products and product candidates.

Merck & Co, Inc. (“Merck”)

On March 13, 2021, we entered into a license and collaboration agreement with Merck Sharp & Dohme Corp., a subsidiary of Merck to jointly develop and commercialize long-acting investigational treatments in HIV that combine Gilead’s investigational capsid inhibitor, lenacapavir, and Merck’s investigational nucleoside reverse transcriptase translocation inhibitor, islatravir. The collaboration will initially focus on long-acting oral and injectable formulations.

Under the terms of the agreement, Gilead and Merck will share global development and commercialization costs at 60% and 40%, respectively, across the oral and injectable formulation programs. For long-acting oral products, if approved, Gilead would lead commercialization in the United States, and Merck would lead commercialization in the European Union (“EU”) and rest of the world. For long-acting injectable products, if approved, Merck would lead commercialization in the United States and Gilead would lead commercialization in the EU and rest of the world. Under the terms of the agreement, Gilead and Merck would jointly promote the combination products in the United States and certain other major markets. If successful, we would share global product revenues with Merck equally until product revenues surpass certain pre-determined per formulation revenue tiers. Upon passing \$2.0 billion in net product sales for the oral combination in a given calendar year, our share of revenue would increase to 65% for any revenues above the threshold for such calendar year. Upon passing \$3.5 billion in net product sales for the injectable combination in a given calendar year, our share of revenue will increase to 65% for any revenues above the threshold for such calendar year. Reimbursements of research and development costs to or from Merck are recorded within Research and development expenses on our Consolidated Statements of Income. Expenses recognized under the agreement were not material for the year ended December 31, 2021. No revenues have been recognized under the agreement for the year ended December 31, 2021.

We will also have the option to license certain of Merck’s investigational oral integrase inhibitors to develop in combination with lenacapavir. Reciprocally, Merck will have the option to license certain of Gilead’s investigational oral integrase inhibitors to develop in combination with islatravir. Each company may exercise its option for such investigational oral integrase inhibitor of the other company within the first five years after execution of the agreement, following completion of the first Phase 1 clinical trial of that integrase inhibitor. Upon exercise of an option, the companies will split development costs and revenues, unless the non-exercising company decides to opt-out, in which case the non-exercising company will be paid a royalty.

In December 2021, Merck announced the decision of the parties to stop all dosing of participants in the Phase 2 clinical study evaluating an oral-weekly combination treatment regimen of lenacapavir and islatravir following the decision of FDA to place clinical holds on the investigational new drug applications for certain formulations of islatravir.

Arcus

On May 27, 2020, we entered into a transaction with Arcus, a publicly traded oncology-focused biopharmaceutical company, which included entry into an option, license and collaboration agreement (the “Collaboration Agreement”) and a common stock purchase agreement and an investor rights agreement (together, and as subsequently amended the “Stock Purchase Agreements”). In accordance with the terms of the Collaboration Agreement and Stock Purchase Agreements, which closed on July 13, 2020, we made an upfront payment of \$175 million and acquired approximately 6.0 million shares of Arcus common stock for approximately \$200 million. Of the total \$391 million initial cash payments, including transactional costs, made under the agreements, we recorded \$135 million as an equity investment which was calculated based on Arcus’ closing stock price on the closing date of the transaction. The remaining \$256 million was attributed to (i) the acquired license and option rights of \$175 million representing IPR&D assets with no alternative future use, (ii) \$65 million of an issuance premium for the equity purchase and (iii) \$16 million of direct transactional costs. These amounts were expensed as Acquired in-process research and development expenses during the year ended December 31, 2020 on our Consolidated Statements of Income.

Under the Stock Purchase Agreements, we have the right to purchase additional shares of Arcus from Arcus over the five-year period beginning on the closing of the Stock Purchase Agreements, up to a maximum of 35% of the outstanding voting stock. We are subject to a three-year standstill, restricting our ability to acquire voting stock of Arcus exceeding more than 35% of the then-issued and outstanding voting stock of Arcus, subject to certain exceptions. Additionally, we agreed not to dispose of any equity securities of Arcus prior to the second anniversary of the closing of the Stock Purchase Agreements without the prior consent of Arcus, subject to certain exceptions. On May 29, 2020, in a separate secondary equity offering, we acquired 2.2 million shares of common stock of Arcus for approximately \$61 million. In the first quarter of 2021, we also acquired approximately 5.7 million additional shares of Arcus common stock for \$220 million. As a result, we currently own a total of 13.8 million shares of Arcus, which represented approximately 19.5% of the issued and outstanding voting stock of Arcus immediately following the closing of the first quarter 2021 transaction.

Pursuant to the Collaboration Agreement, Gilead had the right to opt in to all current and future clinical-stage product candidates for up to ten years following the closing of the transaction. In November 2021, we exercised our options to three of Arcus' clinical stage programs and amended the Collaboration Agreement. The option exercise and amendment transaction closed in December 2021, triggering collaboration opt-in payments of \$725 million and waiving the \$100 million option continuation payment which would have been due to Arcus in the third quarter of 2022. The net option charge of \$625 million was recorded within Research and development expenses on our Consolidated Statements of Income for the year ended December 31, 2021. The collaboration opt-in payments of \$725 million were recorded in Accrued and other current liabilities on our Consolidated Balance Sheets as of December 31, 2021 and paid to Arcus in January 2022. Our payments to Arcus will be included within Net cash provided by investing activities on our Consolidated Statements of Cash Flows in the first quarter of 2022. Under the amended Collaboration Agreement, the companies will co-develop and share the global costs related to these clinical programs. If the optioned molecules achieve regulatory approval, the companies will co-commercialize and equally share profits in the U.S. Gilead will hold exclusive commercialization rights outside the U.S., subject to any rights of Arcus's existing collaboration partners, and will pay to Arcus tiered royalties as a percentage of net sales ranging from the mid-teens and low twenties. Under the Collaboration Agreement, we may also pay an additional \$100 million at our option on each of the fourth, sixth and eighth anniversaries of the agreement, unless terminated early, to maintain the rights to opt-in to future Arcus programs for the duration of the contact term.

We elected and applied the fair value option to account for our equity investment in Arcus whereby the investment is marked to market each reporting period based on the market price of Arcus shares. We believe the fair value option best reflects the underlying economics of the investment. During the years ended December 31, 2021 and 2020, we recorded pre-tax unrealized gains of \$127 million and \$80 million, respectively, related to our investment in Arcus in Other income (expense), net on our Consolidated Statements of Income. We initially recorded our equity investments in Arcus in Other long-term assets on our Consolidated Balance Sheets as the investments were subject to contractual lock-up provisions for a period of two years from the closing date of the Stock Purchase Agreements, subject to certain conditions. In the third quarter of 2021, we reclassified our equity investments in Arcus to Prepaid and other current assets on our Consolidated Balance Sheets as the contractual lock-up provisions are expected to expire in July 2022. Our equity investment in Arcus was \$559 million and \$212 million as of December 31, 2021 and 2020, respectively.

Pionyr

On June 19, 2020, we entered into a transaction with Pionyr, a privately held company pursuing novel biology in the field of immuno-oncology, which included entry into two separate merger agreements, one contemplating the initial acquisition of a 49.9% equity interest in Pionyr, and the other providing us the exclusive option, subject to certain terms and conditions, to acquire the remaining outstanding capital stock of Pionyr (together, the "Pionyr Merger and Option Agreements") and a research and development service agreement.

On July 13, 2020, we closed the transaction and made cash payments of \$269 million. We account for our investment in Pionyr using the equity method of accounting because our equity interest provides us with the ability to exercise significant influence over Pionyr. Our investment in Pionyr, consisting of the transaction price noted above and transaction costs, exceeded our pro-rata portion of Pionyr's net assets at transaction closing. We determined that the resulting basis difference primarily relates to Pionyr's IPR&D which has no alternative future use and that Pionyr is not a business as defined in ASC 805, "Business Combinations." As a result, we immediately recorded a charge for this basis difference of \$215 million in Acquired in-process research and development expenses on our Consolidated Statements of Income during the year ended December 31, 2020. The carrying value of our equity method investment in Pionyr was zero as of December 31, 2021 and 2020.

The estimated fair value of our exclusive option to acquire the remaining outstanding capital stock of Pionyr is approximately \$70 million based on a probability-weighted option pricing model using unobservable inputs, which are considered Level 3 under the fair value measurement and disclosure guidance. The estimated amount is recorded in Other long-term assets on our Consolidated Balance Sheets. We may choose to exercise our exclusive option to purchase the remaining equity interest from Pionyr's current shareholders for a \$315 million option exercise fee and up to \$1.2 billion in potential future milestone payments upon achievement of certain development and regulatory milestones. Such option to purchase will expire following the earliest occurrence of specified events, including the delivery of data following completion of certain Phase 1b trials by Pionyr.

Under the research and development service agreement, we made an initial cash funding of \$80 million and recorded a charge in Acquired in-process research and development expenses on our Consolidated Statements of Income during the year ended December 31, 2020. In addition, we committed to provide additional payments of up to \$115 million to Pionyr upon achievement of certain development milestones. We accrued \$70 million in milestone payments, related to the initiation of two Phase 1 studies, with a charge to Research and development expenses on our Consolidated Statements of Income during the year ended December 31, 2020, and the payment was made in the first quarter of 2021.

Tizona

On July 17, 2020, we entered into a transaction with Tizona, a privately held company developing cancer immunotherapies, which included entry into two separate merger agreements, one contemplating the initial acquisition of a 49.9% equity interest in Tizona, and the other providing us the exclusive option, subject to certain terms and conditions, to acquire the remaining outstanding capital stock of Tizona (together, the “Tizona Merger and Option Agreements”) and a development agreement.

On August 25, 2020, we closed the transaction with Tizona and made cash payments of \$302 million to Tizona’s shareholders in accordance with the terms of the Tizona Merger and Option Agreements. We account for our investment in Tizona using the equity method of accounting because our equity interest provides us with the ability to exercise significant influence over Tizona. Our investment in Tizona, consisting of the transaction price noted above and transaction costs, exceeded our pro-rata portion of Tizona’s net assets at transaction closing. We determined that the resulting basis difference primarily relates to Tizona’s IPR&D with no alternative future use and that Tizona is not a business as defined in ASC 805, “Business Combinations.” As a result, during the year ended December 31, 2020, we immediately recorded a charge for this basis difference of \$272 million in Acquired in-process research and development expenses on our Consolidated Statements of Income. The carrying value of our equity method investment in Tizona was zero as of December 31, 2021 and 2020.

The estimated fair value of our exclusive option to acquire the remaining outstanding capital stock of Tizona is approximately \$41 million based on a probability-weighted option pricing model using unobservable inputs, which are considered Level 3 under the fair value measurement and disclosure guidance. The estimated amount is recorded in Other long-term assets on our Consolidated Balance Sheets. We may choose to exercise our exclusive option to purchase the remaining equity interest from Tizona’s current shareholders for a \$100 million option exercise fee and up to \$1.2 billion in potential future milestone payments upon achievement of certain development and regulatory milestones. Such option to purchase will expire following the earliest occurrence of specified events, including the delivery of data following completion of certain Phase 1b trials by Tizona.

Under the development agreement, we committed to provide funding to Tizona of \$115 million, which was recorded in Acquired in-process research and development expenses on our Consolidated Statements of Income during the year ended December 31, 2020.

Tango Therapeutics, Inc. (“Tango”)

On August 17, 2020, we entered into a transaction with Tango, a privately held company pursuing innovative targeted immune evasion therapies for patients with cancer through its proprietary, CRISPR-enabled functional genomics target discovery platform, which included entry into an amended and restated research collaboration and license agreement and a stock purchase agreement (together, the “Tango Collaboration and Stock Purchase Agreements”).

Upon entering into this transaction, we made an upfront payment of \$125 million and a \$20 million equity investment in Tango. During the year ended December 31, 2020, we recorded the \$125 million upfront expense in Acquired in-process research and development expenses on our Consolidated Statements of Income. In the third quarter of 2021, we made an additional \$13 million equity investment. Tango became a publicly traded company in the third quarter of 2021, and accordingly our equity investment is recorded in Prepaid and other current assets on our Consolidated Balance Sheets at fair market value as of December 31, 2021.

Under the Tango Collaboration and Stock Purchase Agreements, Gilead has the right to option up to 15 programs over the seven-year collaboration for up to \$410 million per program in opt-in, extension and milestone payments. For the products that Tango opts to co-develop and co-promote, the parties will equally split profits and losses, as well as development costs in the U.S. For products that Tango does not opt to co-develop and co-promote, we will pay Tango up to low double-digit tiered royalties on net sales. We will provide Tango milestone payments and royalties on sales outside of the U.S.

Jounce Therapeutics, Inc. (“Jounce”)

On September 1, 2020, we entered into a transaction with Jounce, a publicly traded company developing novel cancer immunotherapies, which included entry into license, registration rights and stock purchase agreements (together, “Jounce License and Stock Purchase Agreement”). In October 2020, we closed this transaction and made a total payment of \$120 million. We recorded \$64 million upfront expense in Acquired in-process research and development expenses on our Consolidated Statements of Income and \$56 million as an equity investment in Other long-term assets on our Consolidated Balance Sheets, representing approximately 14% of the issued and outstanding voting stock of Jounce immediately following the transaction, which was calculated based on Jounce’s closing stock price on the closing date of the transaction. As of December 31, 2021, Jounce was eligible to receive from us up to \$660 million in future potential clinical, regulatory and commercial milestone payments upon achievement of certain milestones, and royalties ranging from high single digit to mid-teens based upon worldwide sales, subject to certain adjustments.

Galapagos

Filgotinib Collaboration

In 2016, we closed a license and collaboration agreement with Galapagos, a clinical-stage biotechnology company based in Belgium, for the development and commercialization of filgotinib, a JAK1-selective inhibitor being evaluated for inflammatory disease indications (the “filgotinib agreement”). Upon closing, we made an upfront license fee payment and an equity investment in Galapagos by subscribing for 6.8 million new ordinary shares of Galapagos at a price of €58 per share. We amended the terms of the agreement in 2019, 2020 and 2021.

Under the terms of the filgotinib agreement, as amended in 2019 (the “2019 Agreement”), we obtained an exclusive, worldwide, royalty-bearing, sublicensable license for filgotinib and products containing filgotinib.

In December 2020, following a Type A meeting with FDA to discuss the points raised in the Complete Response Letter related to the New Drug Application for filgotinib in the treatment of rheumatoid arthritis, Gilead and Galapagos agreed to amend the 2019 Agreement to allow Galapagos to assume development, manufacturing, commercialization and certain other rights for filgotinib in Europe which the parties reflected in an amendment to the 2019 Agreement in December 2021.

Beginning on January 1, 2021, Galapagos bore the development costs for certain studies, in lieu of the equal cost split contemplated by the 2019 Agreement. The parties transferred filgotinib’s marketing authorizations in the EU and Great Britain to Galapagos in December 2021. As of January 1, 2022, all commercial economics on filgotinib in Europe transferred to Galapagos, subject to payment of tiered royalties of 8% to 15% of net sales in Europe to Gilead, starting in 2024. In connection with the amendments to the 2019 Agreement, Gilead agreed to irrevocably pay Galapagos €160 million (or approximately \$190 million), which is subject to certain adjustments for higher-than-budgeted development costs. Of this total amount, Gilead paid €35 million (or approximately \$43 million) in January 2021 and paid an additional €75 million (or approximately \$88 million) in April 2021 and will pay €50 million (or approximately \$60 million) in 2022. We accrued the full amount of this liability with a charge to Research and development expenses on our Consolidated Statements of Income for the year ended December 31, 2020. In addition, Galapagos will no longer be eligible to receive any future milestone payments relating to filgotinib in Europe.

Global Collaboration

In August 2019, we closed an option, license and collaboration Agreement (the “Galapagos Collaboration Agreement”) and a subscription agreement (the “Galapagos Subscription Agreement”), each with Galapagos, pursuant to which the parties entered into a global collaboration that covers Galapagos’ current and future product portfolio (other than filgotinib). Upon closing, we paid \$5.05 billion for the license and option rights and for 6.8 million new ordinary shares of Galapagos at a subscription price of €140.59 per share with a fair value of \$1.13 billion, which included an issuance discount of \$63 million calculated based on Galapagos’ closing stock price on the date of closing of the Galapagos Subscription Agreement. The remaining \$3.92 billion of the payment was recorded within Acquired in-process research and development expenses on our Consolidated Statements of Income for the year ended December 31, 2019.

Pursuant to the Galapagos Subscription Agreement, we were issued warrants that confer the right to subscribe, from time to time, for a number of new shares to be issued by Galapagos sufficient to bring the number of shares owned by us to 29.9% of the issued and outstanding shares at the time of our exercises. In 2019, we exercised a warrant to subscribe for 2.6 million ordinary shares of Galapagos at €140.59 per share and purchased shares on the open market with an aggregate fair value of \$586 million, which brought the number of shares owned by us to 16.7 million or approximately 25.8% of the shares then issued and outstanding.

We are subject to a 10-year standstill restricting our ability to acquire voting securities of Galapagos exceeding more than 29.9% of the then-issued and outstanding voting securities of Galapagos. We agreed not to, without the prior consent of Galapagos, dispose of any equity securities of Galapagos prior to the second anniversary of the closing of the Galapagos Subscription Agreement or dispose of any equity securities of Galapagos thereafter until the fifth anniversary of the closing of the Galapagos Subscription Agreement, if after such disposal we would own less than 20.1% of the then-issued and outstanding voting securities of Galapagos, subject to certain exceptions and termination events. In April 2021, we amended the Galapagos Subscription Agreement to extend the initial lock-up provision for certain Galapagos shares from August 2021 to August 2024. We have two designees appointed to Galapagos’ board of directors.

The initial contractual lock-up provision for certain Galapagos shares was due to expire in August 2021. As such, \$351 million was included within Prepaid and other current assets on our Consolidated Balance Sheets and the remainder of \$1.3 billion was included within Other long-term assets on our Consolidated Balance Sheets as of December 31, 2020. Subsequent to the extension of the contractual lock-up period, all of our equity investment in Galapagos was classified to Other long-term assets on our Consolidated Balance Sheets, and was \$931 million as of December 31, 2021.

We have elected the fair value option to account for our equity investment in Galapagos whereby the investment is marked to market through earnings each reporting period based on the market price of Galapagos' shares. We believe the fair value option best reflects the underlying economics of the investment. During the years ended December 31, 2021, 2020 and 2019, we recorded pre-tax unrealized losses of \$717 million and \$1.8 billion and a pre-tax unrealized gain of \$1.2 billion, respectively, related to our investment in Galapagos in Other income (expense), net on our Consolidated Statements of Income due to changes in Galapagos' stock price.

Under the Galapagos Collaboration Agreement, we had an exclusive license for the development and commercialization of GLPG-1690, a late-stage candidate for idiopathic pulmonary fibrosis, in our territories and had an option to participate in the development and commercialization of Galapagos' other current and future clinical programs that have entered clinical development during the first ten years of the collaboration, subject to extension in certain circumstances. Gilead and Galapagos terminated the Phase 3 clinical studies with GLPG-1690 in February 2021.

With respect to all other programs in Galapagos' current and future pipeline, if we exercise our option to a program, we will pay a \$150 million option exercise fee per program. In addition, Galapagos will receive tiered royalties ranging from 20% to 24% on net sales in our territories of each Galapagos product optioned by us. If we exercise our option for a program, the parties will share equally in development costs and mutually agreed commercialization costs incurred subsequent to our exercise of the option. We may terminate the collaboration in its entirety or on a program-by-program and country-by-country basis with advance notice as well as following other customary termination events.

Janssen

Complera/Eviplera and Odefsey

In 2009, we entered into a license and collaboration agreement with Janssen, formerly Tibotec Pharmaceuticals, to develop and commercialize a fixed-dose combination of our Truvada and Janssen's non-nucleoside reverse transcriptase inhibitor, rilpivirine. This combination was approved in the U.S. and EU in 2011 and is sold under the brand name Complera in the U.S. and Eviplera in the EU.

The agreement was amended in 2014 to expand the collaboration to include another product containing Janssen's rilpivirine and our emtricitabine and tenofovir alafenamide ("Odefsey").

Under the amended agreement, Janssen granted us an exclusive license to Complera/Eviplera and Odefsey worldwide, but retained rights to distribute both combination products in certain countries outside of the U.S. Neither party is restricted from combining its drugs with any other drug products except those which are similar to the components of Complera/Eviplera and Odefsey.

We are responsible for manufacturing Complera/Eviplera and Odefsey and have the lead role in registration, distribution and commercialization of both products except in the countries where Janssen distributes. Janssen has exercised a right to co-detail the combination product in some of the countries where we are the selling party.

Under the financial provisions of the 2014 amendment, the selling party sets the price of the combined products and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. We retain a specified percentage of Janssen's share of revenues, including up to 30% in major markets. Sales of these products are included in Product sales and Janssen's share of revenues is included in Cost of goods sold on our Consolidated Statements of Income. Cost of goods sold relating to Janssen's share was \$530 million, \$570 million and \$574 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Termination of the agreement may be on a product or country basis and will depend on the circumstances, including withdrawal of a product from the market, material breach by either party or expiry of the revenue share payment term. We may terminate the agreement without cause with respect to the countries where we sell the products, in which case Janssen has the right to become the selling party for such country if the product has launched but has been on the market for fewer than 10 years.

Symtuza

In 2014, we amended a license and collaboration agreement with Janssen to develop and commercialize a fixed-dose combination of Janssen's darunavir and our cobicistat, emtricitabine and tenofovir alafenamide ("Gilead Compounds"). This combination was approved in the U.S. and EU in July 2018 and September 2017, respectively, and is sold under the brand name Symtuza.

Under the terms of the 2014 amendment, we granted Janssen an exclusive license to Symtuza worldwide. Janssen is responsible for manufacturing, registration, distribution and commercialization of Symtuza worldwide. We are responsible for the intellectual property related to the Gilead Compounds and are the exclusive supplier of the Gilead Compounds. Neither party is restricted from combining its drugs with any other drug products except those which are similar to the components of Symtuza.

Janssen sets the price of Symtuza and the parties share revenue based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. The intellectual property license and supply obligations related to the Gilead Compounds are accounted for as a single performance obligation. As the license was deemed to be the predominant item to which the revenue share relates, we recognize our share of the Symtuza revenue in the period when the corresponding sales of Symtuza by Janssen occur. We record our share of the Symtuza revenue as Product sales on our Consolidated Statements of Income primarily because we supply the Gilead Compounds to Janssen for Symtuza.

Termination of the agreement may be on a product or country basis and will depend on the circumstances, including withdrawal of a product from the market, material breach by either party or expiry of the revenue share payment term. Janssen may terminate the agreement without cause on a country-by-country basis, in which case Gilead has the right to become the selling party for such country(ies) if the product has launched but has been on the market for fewer than 10 years. Janssen may also terminate the entire agreement without cause.

Japan Tobacco, Inc. (“Japan Tobacco”)

In 2005, Japan Tobacco granted us exclusive rights to develop and commercialize elvitegravir, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco retained such rights. Effective December 2018, we entered into an agreement with Japan Tobacco to acquire the rights to market and distribute certain products in our HIV portfolio in Japan and to expand our rights to develop and commercialize elvitegravir to include Japan. We are responsible for the marketing of the products as of January 1, 2019.

We are responsible for seeking regulatory approval in our territories and are required to use diligent efforts to commercialize elvitegravir for the treatment of HIV infection. We bear all costs and expenses associated with such commercialization efforts and pay a royalty to Japan Tobacco based on our product sales. Our sales of these products are included in Product sales on our Consolidated Statements of Income. Royalties due to Japan Tobacco are included in Cost of goods sold on our Consolidated Statements of Income. Royalty expenses recognized were \$250 million, \$291 million and \$358 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Under the terms of the 2018 agreement, we paid Japan Tobacco \$559 million in cash and recognized an intangible asset of \$550 million reflecting the estimated fair value of the marketing-related rights acquired from Japan Tobacco. The intangible asset is being amortized over nine years, representing the period over which the majority of the benefits are expected to be derived from the applicable products in our HIV portfolio. The amortization expense is classified as selling expense and recorded as Selling, general and administrative expenses on our Consolidated Statements of Income.

Termination of the agreement may be on a product or country basis and will depend on the circumstances, including material breach by either party or expiry of royalty payment term. We may also terminate the entire agreement without cause.

Gadeta B.V. (“Gadeta”)

In July 2018, we entered into a collaboration arrangement with Gadeta and made a purchase of equity in Gadeta from Gadeta's shareholders. We determined that Gadeta was a VIE, and we were its primary beneficiary because we had the power to direct the activities of Gadeta that most significantly impact its economic performance. Upon the initial consolidation of Gadeta, we recorded \$82 million to Noncontrolling interest, primarily reflecting acquired intangible assets related to IPR&D, on our Consolidated Balance Sheets.

During the year ended December 31, 2020, we effectively terminated the agreement with Gadeta. Upon the effective termination, we ceased to have a controlling interest and deconsolidated this VIE by removing the related net assets and noncontrolling interest of \$82 million from our Consolidated Balance Sheets. The net loss from the deconsolidation was not material.

Other Collaboration Arrangements That Are Not Individually Significant

During 2021, 2020 and 2019, we entered into several collaborations, equity investments and licensing arrangements as well as other similar arrangements that we do not consider to be individually material. We recorded upfront collaboration expenses related to these arrangements of \$177 million, \$129 million and \$331 million for the years ended December 31, 2021, 2020 and 2019, respectively, within Acquired in-process research and development expenses on our Consolidated Statements of Income. Cash payments for our equity investments, other than those noted above, during the years ended December 31, 2021, 2020 and 2019 were \$147 million, \$72 million and \$118 million, respectively, which were primarily recorded within Prepaid and other current assets and Other long-term assets on our Consolidated Balance Sheets.

Under the financial terms of these arrangements, we may be required to make payments upon achievement of various developmental, regulatory and commercial milestones, which could be significant. Future milestone payments, if any, will be reflected in our Consolidated Statements of Income when the corresponding events become probable. In connection with the regulatory approvals, milestone payments made will be capitalized as intangible assets and will be amortized to Cost of goods sold through the terms of these collaboration arrangements. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty.

12. DEBT AND CREDIT FACILITIES

The following table summarizes the carrying amount of our borrowings under various financing arrangements:

(in millions)				December 31,	
Type of Borrowing	Issue Date	Due Date	Interest Rate	2021	2020
Senior Unsecured	March 2011	April 2021	4.50%	\$ —	\$ 1,000
			3-month LIBOR		
Senior Unsecured	September 2020	September 2021	+ 0.15%	—	499
Senior Unsecured	December 2011	December 2021	4.40%	—	1,249
Senior Unsecured	September 2016	March 2022	1.95%	500	499
Senior Unsecured	September 2015	September 2022	3.25%	999	998
Senior Unsecured	September 2016	September 2023	2.50%	748	748
			3-month LIBOR		
Senior Unsecured	September 2020	September 2023	+ 0.52%	—	498
Senior Unsecured	September 2020	September 2023	0.75%	1,496	1,992
Term Loan	October 2020	October 2023	variable	—	998
Senior Unsecured	March 2014	April 2024	3.70%	1,747	1,746
Senior Unsecured	November 2014	February 2025	3.50%	1,747	1,746
Senior Unsecured	September 2015	March 2026	3.65%	2,739	2,737
Senior Unsecured	September 2016	March 2027	2.95%	1,247	1,246
Senior Unsecured	September 2020	October 2027	1.20%	746	745
Senior Unsecured	September 2020	October 2030	1.65%	993	992
Senior Unsecured	September 2015	September 2035	4.60%	992	991
Senior Unsecured	September 2016	September 2036	4.00%	742	741
Senior Unsecured	September 2020	October 2040	2.60%	987	986
Senior Unsecured	December 2011	December 2041	5.65%	996	996
Senior Unsecured	March 2014	April 2044	4.80%	1,736	1,735
Senior Unsecured	November 2014	February 2045	4.50%	1,733	1,732
Senior Unsecured	September 2015	March 2046	4.75%	2,220	2,219
Senior Unsecured	September 2016	March 2047	4.15%	1,727	1,726
Senior Unsecured	September 2020	October 2050	2.80%	1,476	1,476
Total senior unsecured notes and term loan facility				25,571	30,295
Liability related to future royalties				1,124	1,107
Total debt, net				26,695	31,402
Less: current portion of long-term debt and other obligations, net				1,516	2,757
Total long-term debt, net				\$ 25,179	\$ 28,645

Senior Unsecured Notes and Term Loan Facility

In 2021, we repaid \$4.75 billion of debt, consisting of \$3.75 billion senior unsecured notes and \$1.0 billion of our senior unsecured term loan facility. We repaid \$1.0 billion of senior unsecured notes due April 2021 in the first quarter of 2021 and \$1.25 billion of senior unsecured notes due December 2021 in the third quarter of 2021. Additionally, we repaid \$500 million of senior unsecured floating rate notes due upon maturity in September 2021. In October 2021, we exercised our option to call \$500 million of senior unsecured floating rate notes and \$500 million of 0.75% senior unsecured notes, both having a final maturity date of September 2023. These two early repayments totaling \$1.0 billion principal amount were made in the fourth quarter of 2021. In December 2021, we exercised our option to call \$500 million of senior unsecured notes having a final maturity of March 2022. The notes were repaid in February 2022. No new debt was issued in 2021.

Our senior unsecured fixed rate notes may be redeemed at our option at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an independent investment banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a semiannual basis at the Treasury Rate, plus a make-whole premium as defined in the indenture. The senior unsecured fixed rate notes also have a call feature, exercisable at our option, to redeem the notes at par in whole, or in part, on dates ranging from one month to two years prior to maturity. In each case, accrued and unpaid interest is also required to be redeemed to the date of redemption. The \$1.5 billion of 0.75% senior unsecured notes due September 2023 also have a call feature, exercisable at our option, to redeem the notes at par, in whole or in part, after September 2021.

In the event of the occurrence of a change in control and a downgrade in the rating of our senior unsecured notes below investment grade by Moody’s Investors Service, Inc. and S&P Global Ratings, the holders may require us to purchase all or a portion of their notes at a price equal to 101% of the aggregate principal amount of the notes repurchased, plus accrued and unpaid interest to the date of repurchase. We are required to comply with certain covenants under our note indentures governing our senior unsecured notes. As of December 31, 2021 and 2020, we were not in violation of any covenants.

In September 2020, we entered into a commitment letter with a group of institutional lenders to provide for a three-year senior unsecured term loan facility in an aggregate principal amount of \$1.0 billion. In October 2020, in connection with our acquisition of Immunomedics, we entered into a term loan credit agreement (the “Term Loan Facility”) and borrowed an aggregate principal amount of \$1.0 billion. In 2021, we repaid \$1.0 billion principal amount outstanding under the Term Loan Facility which was due upon maturity in October 2023.

Liability Related to Future Royalties

In connection with our acquisition of Immunomedics, we assumed a liability related to a funding arrangement, which was originally entered into by Immunomedics and RPI, prior to our acquisition of Immunomedics. The liability related to future royalties was primarily included in Long-term debt, net on our Consolidated Balance Sheets. See Note 6. Acquisitions for additional information.

Revolving Credit Facilities

In June 2020, we terminated our \$2.5 billion five-year revolving credit facility maturing in May 2021 (the “2016 Revolving Credit Facility”) and entered into a new \$2.5 billion five-year revolving credit facility maturing in June 2025 (the “2020 Revolving Credit Facility”). The 2020 Revolving Credit Facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. As of December 31, 2021 and 2020, there were no amounts outstanding under the 2020 Revolving Credit facility.

The 2020 Revolving Credit Facility contains customary representations, warranties, affirmative and negative covenants and events of default. As of December 31, 2021, we were in compliance with all covenants. Loans under the 2020 Revolving Credit Facility bear interest at either (i) the Eurodollar Rate plus the Applicable Percentage, or (ii) the Base Rate plus the Applicable Percentage, each as defined in the 2020 Revolving Credit Facility agreement. We may terminate or reduce the commitments, and may prepay any loans under the credit facility in whole or in part at any time without premium or penalty.

Contractual Maturities of Financing Obligations

The following table summarizes the aggregate future principal maturities of our senior unsecured notes as of December 31, 2021:

(in millions)	Amount
2022	\$ 1,500
2023	2,250
2024	1,750
2025	1,750
2026	2,750
Thereafter	15,750
Total	<u>\$ 25,750</u>

Interest Expense

Interest expense on our debt and credit facilities related to the contractual coupon rates and amortization of the debt discount and issuance costs was \$1.0 billion in 2021, 2020 and 2019.

13. LEASES

Our operating leases consist primarily of properties and equipment for our administrative, manufacturing and R&D activities. Some of our leases include options to extend the terms for up to 15 years and some include options to terminate the lease within one year after the lease commencement date. As of December 31, 2021 and 2020, we did not have material finance leases. Operating lease expense, including variable costs and short-term leases, was \$156 million, \$171 million and \$162 million in 2021, 2020 and 2019, respectively.

The following table summarizes balance sheet and other information related to our operating leases:

(in millions, except weighted average amounts)	Classification	December 31,	
		2021	2020
Right-of-use assets, net	Other long-term assets	\$ 542	\$ 646
Lease liabilities - current	Accrued and other current liabilities	\$ 101	\$ 107
Lease liabilities - noncurrent	Other long-term obligations	\$ 489	\$ 608
Weighted average remaining lease term		8.5 years	8.6 years
Weighted average discount rate		3.00 %	3.32 %

The following table summarizes other supplemental information related to our operating leases:

(in millions)	Year Ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities	\$ 123	\$ 66
Right-of-use assets obtained in exchange for lease liabilities	\$ 88	\$ 88

The following table summarizes a maturity analysis of our operating lease liabilities showing the aggregate lease payments as of December 31, 2021:

(in millions)	Amount
2022	\$ 117
2023	108
2024	92
2025	61
2026	50
Thereafter	249
Total undiscounted lease payments	677
Less: imputed interest	87
Total discounted lease payments	<u>\$ 590</u>

14. COMMITMENTS AND CONTINGENCIES

Legal Proceedings

We are a party to various legal actions. The most significant of these are described below. We recognize accruals for such actions to the extent that we conclude that a loss is both probable and reasonably estimable. We accrue for the best estimate of a loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a material loss is reasonably possible and the loss or range of loss can be estimated, we disclose the possible loss. Unless otherwise noted, the outcome of these matters either is not expected to be material or is not possible to determine such that we cannot reasonably estimate the maximum potential exposure or the range of possible loss.

In the third quarter of 2021, we reversed a \$175 million previously recorded litigation accrual following a favorable court decision for the litigation related to axicabtagene ciloleucel described below. In the fourth quarter of 2021, we recorded an accrual of \$1.25 billion in Accrued and other current liabilities on our Consolidated Balance Sheets for the settlement related to bictegravir litigation described below.

Litigation Related to Sofosbuvir

In 2012, we acquired Pharmasset, Inc. Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of HCV. In 2013, we received approval from FDA for sofosbuvir, now known commercially as Sovaldi. Sofosbuvir is also included in all of our marketed HCV products. We have received a number of litigation claims regarding sofosbuvir. While we have carefully considered these claims both prior to and following the acquisition and believe they are without merit, we cannot predict the ultimate outcome of such claims or range of loss.

We are aware of patents and patent applications owned by third parties that have been or may in the future be alleged by such parties to cover the use of our HCV products. If third parties obtain valid and enforceable patents, and successfully prove infringement of those patents by our HCV products, we could be required to pay significant monetary damages. We cannot predict the ultimate outcome of intellectual property claims related to our HCV products. We have spent, and will continue to spend, significant resources defending against these claims.

Litigation with the University of Minnesota

The University of Minnesota (the “University”) has obtained U.S. Patent No. 8,815,830 (the “’830 patent”), which purports to broadly cover nucleosides with antiviral and anticancer activity. In 2016, the University filed a lawsuit against us in the U.S. District Court for the District of Minnesota, alleging that the commercialization of sofosbuvir-containing products infringes the ’830 patent. We believe the ’830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir. In 2017, the court granted our motion to transfer the case to California. We have also filed petitions for inter partes review with the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“PTAB”) alleging that all asserted claims are invalid for anticipation and obviousness. The PTAB instituted one of these petitions and a merits hearing was held in February 2021. In 2018, the U.S. District Court for the Northern District of California stayed the litigation until after the PTAB concludes the inter partes review that it has initiated. In May 2021, the PTAB issued a written decision finding the asserted claims of the University’s patent invalid. In July 2021, the University appealed this decision. The litigation in the U.S. District Court will remain stayed through the appeal proceedings.

Litigation with NuCana plc. (“NuCana”)

NuCana has obtained European Patent No. 2,955,190 (the “EP ’190 patent”) that allegedly covers sofosbuvir. In opposition proceedings before the European Patent Office (“EPO”) held in February 2021, the EPO Opposition Division upheld the validity of the EP ’190 patent in amended form. We believe that the amended EP ’190 patent claims are invalid. Subsequently, we initiated proceedings to invalidate the UK counterpart of the EP ’190 patent in the High Court of England & Wales. In March 2021, NuCana filed a counterclaim against us in the High Court of England & Wales alleging patent infringement of the UK counterpart and seeking damages and other relief. In April 2021, NuCana also filed a lawsuit against us in Germany at the Landgericht Düsseldorf alleging patent infringement of the German counterpart of the EP ’190 patent and seeking damages and injunctive relief. The hearing date for the German NuCana case has been scheduled for May 2022. The hearing date for the UK NuCana case has been scheduled for January 2023.

Litigation Related to Axicabtagene Ciloleuce

In October 2017, Juno Therapeutics, Inc. and Sloan Kettering Cancer Center (collectively, “Juno”) filed a lawsuit against us in the U.S. District Court for the Central District of California, alleging that the commercialization of axicabtagene ciloleuce, sold commercially as Yescarta, infringes on U.S. Patent No. 7,446,190 (the “’190 patent”). A jury trial was held on the ’190 patent, and in December 2019, the jury found that the asserted claims of the ’190 patent were valid, and that we willfully infringed the asserted claims of the ’190 patent. The jury also awarded Juno damages in amounts of \$585 million in an upfront payment and a 27.6% running royalty from October 2017 through the date of the jury’s verdict. The parties filed post-trial motions in the first quarter of 2020, and the trial judge entered a judgment in April 2020. The trial judge affirmed the jury’s verdict, enhanced the past damages by 50% and maintained the royalties on future Yescarta sales at 27.6%. In April 2020, we filed an appeal seeking to reverse the judgment or obtain a new trial due to errors made by the trial judge, and in July 2021, the appeals court heard oral arguments. In August 2021, the Court of Appeals for the Federal Circuit (the “CAFC”) reversed the jury verdict, finding the asserted claims of Juno’s patent invalid. In October 2021, Juno filed a petition for rehearing with the CAFC. In January 2022, the CAFC denied Juno’s petition for rehearing. We believe that the likelihood of a material adverse outcome in this matter is remote.

Litigation Related to Bictegravir

In 2018, ViiV Healthcare Company (“VHC”) filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, sold commercially in combination with tenofovir alafenamide and emtricitabine as Biktarvy, infringes VHC’s U.S. Patent No. 8,129,385 (the “’385 patent”) covering VHC’s dolutegravir. Bictegravir is structurally different from dolutegravir, and we believe that bictegravir does not infringe the claims of the ’385 patent. In its lawsuit, VHC was seeking billions of dollars for alleged damages comprised of VHC’s lost profits and a royalty on U.S. sales of bictegravir from launch through the trial. In addition, should a court find that we are liable for infringement, we also expected VHC to seek a royalty on U.S. sales after the trial.

In 2018, VHC also filed a lawsuit against us in the Federal Court of Canada, alleging that our activities relating to our bictegravir compound infringes VHC's Canadian Patent No. 2,606,282 (the "'282 patent"), which was issued to Shionogi & Co. Ltd. and VHC. The '282 patent is the compound patent covering VHC's dolutegravir. We believe that bictegravir does not infringe the claims of the '282 patent. In November and December 2019, VHC filed lawsuits in France, Germany, Ireland and the UK asserting the relevant national designations of European Patent No. 3 045 206; in Australia asserting Australian Patent No. 2006239177; in Japan asserting Japanese Patent No. 4295353; and in Korea asserting Korean Patent Nos. 1848819 and 1363875. These patents all relate to molecules that VHC claims would act as integrase inhibitors. We believe that bictegravir does not infringe any valid claims of VHC's patents and have prevailed in court proceedings to date in Canada and Germany.

On February 1, 2022, Gilead reached an agreement (the "Settlement") with VHC, ViiV Healthcare UK (No.3) Limited, ViiV Healthcare UK Limited, Shionogi & Co., Ltd. and GlaxoSmithKline Mercury Limited (collectively, "ViiV") for a global resolution of all pending or potential claims related to Gilead's sales of Biktarvy, including the litigation pending in the U.S. District Court of Delaware and other jurisdictions outside the United States as described above. In February 2022, the lawsuit pending in the United States was dismissed as well as the lawsuits in Canada, France, Ireland, the UK, Australia, Japan and Korea.

Pursuant to the terms of the Settlement, ViiV grants Gilead a broad worldwide license and covenant not to sue relating to any past, present or future development or commercialization of bictegravir. In connection with the Settlement, Gilead (1) made a one-time payment to ViiV of \$1.25 billion in the first quarter of 2022, and (2) will provide ViiV an ongoing royalty at a rate of 3% on future sales of Biktarvy and the bictegravir component of bictegravir-containing products in the United States until October 5, 2027. In connection with the Settlement, Gilead recorded a pre-tax charge of \$1.25 billion to Cost of goods sold on our Consolidated Statements of Income in the fourth quarter of 2021.

Litigation Relating to Pre-Exposure Prophylaxis

In August 2019, we filed petitions requesting inter partes review of U.S. Patent Nos. 9,044,509, 9,579,333, 9,937,191 and 10,335,423 (collectively, "HHS Patents") by PTAB. The HHS Patents are assigned to the U.S. Department of Health and Human Services ("HHS") and purport to claim a process of protecting a primate host from infection by an immunodeficiency retrovirus by administering a combination of emtricitabine or tenofovir disoproxil fumarate ("TDF") prior to exposure of the host to the immunodeficiency retrovirus, a process commonly known as pre-exposure prophylaxis ("PrEP"). In November 2019, the U.S. Department of Justice filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the sale of Truvada and Descovy for use as PrEP infringes the HHS Patents. In February 2020, PTAB declined to institute our petitions for inter partes review of the HHS Patents. In April 2020, we filed a breach of contract lawsuit against the U.S. federal government in the U.S. Court of Federal Claims, alleging violations of four material transfer agreements ("MTAs") related to the research underlying the HHS Patents and a clinical trial agreement ("CTA") by the U.S. Centers for Disease Control and Prevention related to PrEP research. Although we cannot predict with certainty the ultimate outcome of these litigation matters, we believe that the U.S. federal government breached the MTAs and CTA, that Truvada and Descovy do not infringe the HHS Patents and that the HHS Patents are invalid over prior art descriptions of Truvada's use for PrEP and post-exposure prophylaxis as well because physicians and patients were using the claimed methods years before HHS filed the applications for the patents. A trial date for the lawsuit in the Court of Federal Claims has been set for June 2022, and a trial date for the lawsuit in the District Court of Delaware has been set for May 2023.

Litigation with Generic Manufacturers

As part of the approval process for some of our products, FDA granted us a New Chemical Entity ("NCE") exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application ("ANDA"), the application form typically used by manufacturers seeking approval of a generic drug. The sale of generic versions of our products prior to their patent expiration would have a significant negative effect on our revenues and results of operations. To seek approval for a generic version of a product having NCE status, a generic company may submit its ANDA to FDA four years after the branded product's approval.

Starting in December 2019, we received letters from Lupin Ltd., Apotex Inc., Shilpa Medicare Ltd. ("Shilpa"), Sunshine Lake Pharma Co. Ltd. ("Sunshine Lake"), Laurus Labs, Natco Pharma Ltd., Macleods Pharma Ltd., Hetero Labs Ltd. and Cipla Ltd. (collectively, "Generic Manufacturers") indicating that they have submitted ANDAs to FDA requesting permission to market and manufacture generic versions of certain of our TAF-containing products. Between them, these Generic Manufacturers seek to market generic versions of Odefsey, Descovy and Vemlidy. The Generic Manufacturers have challenged the validity of two to four patents listed on the Orange Book and associated with TAF. We filed lawsuits against the Generic Manufacturers, and we intend to enforce and defend our intellectual property. In November 2021, we reached an agreement with Shilpa to resolve the lawsuit against Shilpa. In addition, in January 2022, we reached an agreement with Sunshine Lake to resolve the lawsuit against Sunshine Lake. The settlement agreements have been filed with the U.S. Federal Trade Commission and the U.S. Department of Justice as required by law.

In October 2021, we received a letter from Lupin Ltd. (“Lupin”) indicating that it has submitted an ANDA to FDA requesting permission to market and manufacture a generic version of Symtuza, a product commercialized by Janssen and for which Gilead shares in revenues. In November 2021, we, along with Janssen Products, L.P. and Janssen, filed a patent infringement lawsuit against Lupin as co-plaintiffs in the U.S. District Court of Delaware. We separately filed an additional lawsuit against Lupin asserting infringement of two additional patents in the same court.

European Patent Claims

In 2015, several parties filed oppositions in the EPO requesting revocation of one of our granted European patents covering sofosbuvir that expires in 2028. In 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We have appealed this decision, seeking to restore all of the original claims, and several of the original opposing parties have also appealed, requesting full revocation. An appeal hearing originally scheduled for July 2021 has been canceled and a new date has not yet been set by the EPO.

In 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to sofosbuvir that expires in 2024. The EPO conducted an oral hearing for this opposition in 2018 and upheld the claims. Two of the original opposing parties have appealed, requesting full revocation.

In 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2026. In 2017, the EPO upheld the validity of the claims of our TAF patent. Three parties have appealed this decision. The appeal hearing was held in March 2021, and the validity of all claims were upheld.

In 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to TAF hemifumarate that expires in 2032. In 2019, the EPO upheld the validity of the claims of our TAF hemifumarate patent. Three parties have appealed this decision.

In 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. In 2017, the EPO upheld the validity of the claims of our cobicistat patent. Two parties have appealed this decision.

The appeal process may take several years for all EPO opposition proceedings. While we are confident in the strength of our patents, we cannot predict the ultimate outcome of these oppositions. If we are unsuccessful in defending these oppositions, some or all of our patent claims may be narrowed or revoked and the patent protection for sofosbuvir, TAF, TAF hemifumarate and cobicistat in the EU could be substantially shortened or eliminated entirely. If our patents are revoked, and no other European patents are granted covering these compounds, our exclusivity may be based entirely on regulatory exclusivity granted by EMA. If we lose patent protection for any of these compounds, our revenues and results of operations could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost.

Antitrust and Consumer Protection

We (along with Bristol-Myers Squibb Company (“BMS”) and Johnson & Johnson, Inc.) have been named as defendants in class action lawsuits filed in 2019 and 2020 related to various drugs used to treat HIV, including drugs used in combination antiretroviral therapy. Plaintiffs allege that we (and the other defendants) engaged in various conduct to restrain competition in violation of federal and state antitrust laws and state consumer protection laws. The lawsuits, which have been consolidated, are pending in the U.S. District Court for the Northern District of California. The lawsuits seek to bring claims on behalf of two nationwide classes—one of direct purchasers consisting largely of wholesalers, and another of indirect or end-payor purchasers, including health insurers and individual patients. Plaintiffs seek damages, permanent injunctive relief and other relief. In the fall of 2021, several plaintiffs filed separate lawsuits effectively opting out of the class action cases, asserting claims that are substantively the same as the putative classes. These cases have been coordinated with the class actions. Trial is set for March 2023.

In September 2020, we, along with generic manufacturers Cipla Ltd. and Cipla USA Inc. (together, “Cipla”), were named as defendants in a class action lawsuit filed in the U.S. District Court for the Northern District of California by Jacksonville Police Officers and Fire Fighters Health Insurance Trust (“Jacksonville Trust”) on behalf of end-payor purchasers. Jacksonville Trust claims that the 2014 settlement agreement between us and Cipla, which settled a patent dispute relating to patents covering our Emtriva, Truvada and Atripla products and permitted generic entry prior to patent expiry, violates certain federal and state antitrust and consumer protection laws. The Plaintiff seeks damages, permanent injunctive relief and other relief.

In February 2021, we along with BMS and Teva Pharmaceutical Industries Ltd. were named as defendants in a lawsuit filed in the First Judicial District Court for the State of New Mexico, County of Santa Fe by the New Mexico Attorney General. The New Mexico Attorney General alleges that we (and the other defendants) restrained competition in violation of New Mexico antitrust and consumer protection laws. The New Mexico Attorney General seeks damages and other relief.

While we believe these cases are without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages or could be subject to permanent injunctive relief awarded in favor of plaintiffs.

Product Liability

We have been named as a defendant in one class action lawsuit and various product liability lawsuits related to Viread, Truvada, Atripla, Complera and Stribild. Plaintiffs allege that Viread, Truvada, Atripla, Complera and/or Stribild caused them to experience kidney, bone and/or tooth injuries. The lawsuits, which are pending in state or federal court in California, Delaware, Maryland, Missouri and New Jersey, involve more than 27,000 plaintiffs. Plaintiffs in these cases seek damages and other relief on various grounds for alleged personal injury and economic loss. We intend to vigorously defend ourselves in these actions. While we believe these cases are without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

Government Investigation

In 2017, we received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents related to our promotional speaker programs for HIV. We are cooperating with this inquiry.

Qui Tam Litigation

A former sales employee filed a qui tam lawsuit against Gilead in March 2017 in U.S. District Court for the Eastern District of Pennsylvania. Following the government's decision not to intervene in the suit, the case was unsealed in December 2020. The lawsuit alleges that certain of Gilead's HCV sales and marketing activities violated the federal False Claims Act and various state false claims acts. The relator seeks all available relief under these statutes.

Two former employees filed a qui tam lawsuit against Gilead in April 2020 in California state court. Following the California Attorney General's Office's decision not to intervene, relators served Gilead with their complaint in August 2020. The complaint alleges violations of the California False Claims Act ("CFCA") and employment law claims. Relators seek all available relief under the CFCA. In December 2021, Gilead and relators executed a settlement agreement to resolve the lawsuit, and in February 2022, the court issued an order dismissing the lawsuit with prejudice. The settlement does not have a material impact to our Consolidated Financial Statements.

Health Choice Advocates, LLC ("Health Choice") filed a qui tam lawsuit against Gilead in April 2020 in New Jersey state court. Following the New Jersey Attorney General's Office's decision not to intervene in the suit, Health Choice served us with their original complaint in August 2020. The lawsuit alleges that Gilead violated the New Jersey False Claims Act through our clinical educator programs for Sovaldi and Harvoni and our HCV and HIV patient access programs. The lawsuit seeks all available relief under the New Jersey False Claims Act. In April 2021, the trial court granted our motion to dismiss with prejudice. Health Choice has appealed the trial court's dismissal.

Health Choice filed another qui tam lawsuit against Gilead in May 2020 making similar allegations in Texas state court. Following the Texas Attorney General's Office's decision not to intervene in the suit, Health Choice served us with their original complaint in October 2020. The lawsuit alleges that Gilead violated the Texas Medicare Fraud Prevention Act ("TMFPA") through our clinical educator programs for Sovaldi and Harvoni and our HCV and HIV patient access programs. The lawsuit seeks all available relief under the TMFPA. In September 2021, the Texas Court of Appeals for the Sixth Court Appeals District granted our request to stay the Texas litigation. The case is stayed pending final judgment in the Eastern District of Pennsylvania lawsuit filed in March 2017, as discussed above.

We intend to vigorously defend ourselves in these actions. While we believe these cases are without merit, we cannot predict the ultimate outcomes. If any of these plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

Securities Litigation

Immunomedics and several of its former officers and directors have been named as defendants in putative class actions filed in 2018 and 2019, which were consolidated in September 2019. Plaintiffs filed a consolidated complaint in November 2019 and an amended complaint in July 2021. Plaintiffs allege that Immunomedics and the individual defendants violated the federal securities laws in connection with Immunomedics' Biologics License Application for Trodelvy, and seek certification of a class of shareholders, damages and other relief. The consolidated lawsuit is pending in the U.S. District Court for the District of New Jersey. While we believe this case is without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

Other Matters

We are a party to various legal actions that arose in the ordinary course of our business. We do not believe that these other legal actions will have a material adverse impact on our consolidated business, financial position or results of operations.

Other Commitments

In the normal course of business, we enter into firm purchase commitments related to inventory. As of December 31, 2021, these commitments for the next five years were approximately \$1.1 billion in 2022, \$450 million in 2023, \$243 million in 2024, \$60 million in 2025 and \$31 million in 2026.

15. STOCKHOLDERS' EQUITY

Stock Repurchase Programs

In the first quarter of 2016, our Board of Directors authorized a \$12.0 billion stock repurchase program ("2016 Program") under which repurchases may be made in the open market or in privately negotiated transactions. We started repurchases under the 2016 Program in April 2016.

In the first quarter of 2020, our Board of Directors authorized a new \$5.0 billion stock repurchase program ("2020 Program"), which will commence upon the completion of the 2016 Program. Purchases under the 2020 Program may be made in the open market or in privately negotiated transactions.

As of December 31, 2021, the remaining authorized repurchase amount under both programs was \$6.3 billion.

The following table summarizes our stock repurchases under the 2016 Program:

(in millions, except per share amounts)	Year Ended December 31,		
	2021	2020	2019
Shares repurchased and retired	8	22	26
Amount	\$ 546	\$ 1,583	\$ 1,749
Average price per share	\$ 66.58	\$ 70.64	\$ 66.36

In addition to repurchases from the 2016 Program and 2020 Program, we repurchased shares of common stock withheld by us from employee restricted stock awards to satisfy our applicable tax withholding obligations. These shares are excluded from the table above.

We use the par value method of accounting for our stock repurchases. Under the par value method, common stock is first charged with the par value of the shares involved. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital based on an estimated average sales price per issued share with the excess amounts charged to retained earnings.

Dividends

The following table summarizes cash dividends declared on our common stock:

(in millions, except per share amounts)	2021		2020	
	Dividend Per Share	Amount	Dividend Per Share	Amount
First quarter	\$ 0.71	\$ 906	\$ 0.68	\$ 867
Second quarter	0.71	903	0.68	866
Third quarter	0.71	905	0.68	866
Fourth quarter	0.71	904	0.68	865
Total	\$ 2.84	\$ 3,618	\$ 2.72	\$ 3,464

Our restricted stock and performance share awards or units have dividend equivalent rights entitling holders to dividend equivalents to be paid upon vesting for each share of the underlying unit.

On February 1, 2022, we announced that our Board of Directors declared a quarterly cash dividend of \$0.73 per share of our common stock, with a payment date of March 30, 2022 to all stockholders of record as of the close of business on March 15, 2022. Future dividends are subject to declaration by our Board of Directors.

Preferred Stock

We have 5 million shares of authorized preferred stock issuable in series. Our Board is authorized to determine the designation, powers, preferences and rights of any such series. There was no preferred stock outstanding as of December 31, 2021 and 2020.

Accumulated Other Comprehensive Income

The following table summarizes the changes in AOCI by component, net of tax:

(in millions)	Foreign Currency Translation, Net of Tax	Unrealized Gains and Losses on Available-for-Sale Debt Securities, Net of Tax	Unrealized Gains and Losses on Cash Flow Hedges, Net of Tax	Total
Balance as of December 31, 2018	\$ 47	\$ (52)	\$ 85	\$ 80
Net unrealized gain	6	54	72	132
Reclassifications to net income	—	(1)	(126)	(127)
Net current period other comprehensive income (loss)	6	53	(54)	5
Balance as of December 31, 2019	<u>\$ 53</u>	<u>\$ 1</u>	<u>\$ 31</u>	<u>\$ 85</u>
Net unrealized gain (loss)	(2)	43	(103)	(62)
Reclassifications to net income	—	(42)	(41)	(83)
Net current period other comprehensive income (loss)	(2)	1	(144)	(145)
Balance as of December 31, 2020	<u>\$ 51</u>	<u>\$ 2</u>	<u>\$ (113)</u>	<u>\$ (60)</u>
Net unrealized gain (loss)	\$ (38)	\$ (6)	\$ 129	\$ 85
Reclassifications to net income	—	—	58	58
Net current period other comprehensive income (loss)	(38)	(6)	187	143
Balance as of December 31, 2021	<u>\$ 13</u>	<u>\$ (4)</u>	<u>\$ 74</u>	<u>\$ 83</u>

The amounts reclassified to net income for gains and losses on cash flow hedges are recorded as part of Product sales on our Consolidated Statements of Income. See Note 5. Derivative Financial Instruments for additional information. The amounts reclassified to net income for gains and losses on available-for-sale debt securities are recorded as part of Other income (expense), net, on our Consolidated Statements of Income. The income tax impact allocated to each component of other comprehensive income was not material for the periods presented.

16. EMPLOYEE BENEFITS

Equity Incentive Plans

In May 2004, our stockholders approved and we adopted the Gilead Sciences, Inc. 2004 Equity Incentive Plan (as amended, the “2004 Plan”). The 2004 Plan authorized the issuance of a total of 309 million shares of common stock.

As part of the Forty Seven acquisition, we assumed the Forty Seven, Inc. 2018 Equity Incentive Plan, which we subsequently amended and restated as the Gilead Sciences, Inc. 2018 Equity Incentive Plan (as amended and restated, the “2018 Plan”). The aggregate amount of shares that may be issued under the 2018 Plan on or after the assumption date will not exceed 12 million shares. As part of the Immunomedics acquisition, we assumed the Immunomedics Amended and Restated 2014 Long-Term Incentive Plan (the “Immunomedics Plan” and referred together with the 2004 Plan and 2018 Plan as the “Plans”), which we subsequently merged into the 2004 Plan. The aggregate amount of shares that may be issued under the Immunomedics Plan on or after the assumption date will not exceed 26 million shares. See Note 6. Acquisitions for additional information on the settlement of stock awards.

The Plans are broad based incentive plans that provide for the grant of equity-based awards, including stock options, restricted stock units, restricted stock awards and performance share awards, to employees, directors and consultants. As of December 31, 2021, a total of 82 million shares remain available for future grant under the Plans.

Stock Options

The Plans provide for option grants designated as either non-qualified or incentive stock options. All stock options granted after January 1, 2006 have been non-qualified stock options. Employee stock options generally vest over three or four years. All options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices not less than the fair market value of our common stock on the grant date. Stock option exercises are settled with common stock from the Plans’ previously authorized and available pool of shares.

The following table summarizes activity and related information under our stock option plans. All option grants presented in the table had exercise prices not less than the fair value of the underlying common stock on the grant date:

	Shares (in millions)	Weighted- Average Exercise Price (in dollars)	Weighted- Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in millions)
Outstanding as of December 31, 2020	16.6	\$ 69.40		
Granted	3.8	\$ 64.77		
Forfeited	(0.9)	\$ 67.67		
Expired	(1.1)	\$ 82.11		
Exercised	<u>(1.6)</u>	\$ 37.46		
Outstanding as of December 31, 2021	<u>16.8</u>	\$ 70.60	5.34	\$ 101
Exercisable as of December 31, 2021	11.2	\$ 72.43	3.67	\$ 68
Expected to vest, net of estimated forfeitures as of December 31, 2021	5.3	\$ 67.01	8.61	\$ 32

Aggregate intrinsic value represents the value of our closing stock price on the last trading day of the year in excess of the weighted-average exercise price multiplied by the number of options outstanding or exercisable. Total intrinsic value of options exercised was \$48 million, \$179 million and \$209 million for 2021, 2020 and 2019, respectively.

The weighted-average grant date fair value of the stock options granted was \$10.05 per share, \$11.69 per share and \$12.15 per share for 2021, 2020 and 2019, respectively.

As of December 31, 2021, there was \$47 million of unrecognized compensation cost related to stock options, which is expected to be recognized over an estimated weighted-average period of 2.3 years.

Restricted Stock and Performance Share Awards

We grant time-based RSUs to certain employees as part of our annual employee equity compensation review program as well as to new hire employees and to non-employee members of our Board. RSUs are share-based awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. RSUs generally vest over three or four years from the date of grant. The fair value of an RSU is equal to the closing price of our common stock on the grant date.

We grant PSUs which vest upon the achievement of specified market or performance goals, which could include achieving a total shareholder return compared to a pre-determined peer group or achieving revenue targets. The actual number of common shares ultimately issued is calculated by multiplying the number of PSUs by a payout percentage ranging from 0% to 200%, and these awards generally vest only when a committee (or subcommittee) of our Board has determined that the specified market and performance goals have been achieved. The fair value of each PSU is estimated at the date of grant or when performance objectives are defined for the grants. Depending on the terms of the award, fair value on the date of grant is determined based on either the Monte Carlo valuation methodology or the closing stock price on the date of grant.

In addition, we have also granted other PSUs to certain of our employees under the 2004 Plan. The vesting of these awards is subject to the achievement of specified individual performance goals, typically within a one to two year period. The fair value of such an award is equal to the closing price of our common stock on the grant date.

The following table summarizes our RSU and PSU activity and related information:

(in millions, except per share amounts)	RSUs		PSUs	
	Shares	Weighted- Average Grant Date Fair Value Per Share	Shares ⁽¹⁾	Weighted- Average Grant Date Fair Value Per Share ⁽¹⁾
Outstanding as of December 31, 2020	19.5	\$ 69.80	0.6	\$ 84.87
Granted	11.9	\$ 65.42	0.3	\$ 71.31
Vested	(7.0)	\$ 70.30	(0.1)	\$ 88.36
Forfeited	(3.5)	\$ 67.77	(0.1)	\$ 78.37
Outstanding as of December 31, 2021	<u>20.9</u>	\$ 67.48	<u>0.7</u>	\$ 79.13

⁽¹⁾ Weighted-average grant-date fair value per share excludes shares related to grants that currently have no grant date as the performance objectives have not yet been defined.

The weighted-average grant date fair value of RSUs granted was \$65.42 per share, \$70.94 per share and \$64.31 per share for 2021, 2020 and 2019, respectively. The weighted-average grant date fair value of PSUs granted was \$71.31 per share, \$83.64 per share and \$68.30 per share for 2021, 2020 and 2019, respectively. The total grant date fair value of our vested RSUs and PSUs was \$503 million, \$479 million and \$450 million for 2021, 2020 and 2019, respectively, and total fair value as of the respective vesting dates was \$471 million, \$459 million and \$372 million for 2021, 2020 and 2019, respectively.

As of December 31, 2021, there was \$917 million of unrecognized compensation cost related to unvested RSUs and PSUs, which is expected to be recognized over a weighted-average period of 2.2 years.

Employee Stock Purchase Plan

Under our Employee Stock Purchase Plan and the International Employee Stock Purchase Plan (together, as amended, the “ESPP”), employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of our common stock on the offering date or the purchase date. The ESPP offers a six-month look-back feature as well as an automatic reset feature that provides for an offering period to be reset to a new lower-priced offering if the offering price of the new offering period is less than that of the current offering period. ESPP purchases are settled with common stock from the ESPP’s previously authorized and available pool of shares. During 2021, 2 million shares were issued under the ESPP for \$111 million. A total of 79 million shares of common stock have been authorized for issuance under the ESPP, and there were 5 million shares available for issuance under the ESPP as of December 31, 2021.

Stock-Based Compensation

The following table summarizes total stock-based compensation expenses included on our Consolidated Statements of Income:

(in millions)	Year Ended December 31,		
	2021	2020	2019
Cost of goods sold	\$ 40	\$ 109	\$ 48
Research and development expenses	287	462	289
Selling, general and administrative expenses	308	505	299
Stock-based compensation expense included in total costs and expenses ⁽¹⁾	635	1,076	636
Income tax effect ⁽²⁾	(100)	(222)	2
Stock-based compensation expense, net of tax	<u>\$ 535</u>	<u>\$ 854</u>	<u>\$ 638</u>

⁽¹⁾ Pre-tax stock-based compensation expense for the year ended December 31, 2020 of \$1.1 billion included \$643 million non-cash stock-based expense and \$289 million and \$144 million of accelerated post-acquisition stock-based expense related to the acquisitions of Immunomedics and Forty Seven, respectively. See Note 6. Acquisitions for additional information.

⁽²⁾ Income tax effect for the year ended December 31, 2019 included a \$114 million income tax expense following the U.S. Court of Appeals decision in *Altera Corp v. Commissioner*, which requires related parties in an intercompany cost sharing arrangement to share expenses related to stock-based compensation.

Stock-based compensation is recognized as expense over the requisite service periods on our Consolidated Statements of Income using the straight-line expense attribution approach, reduced for estimated forfeitures. We estimate forfeitures based on our historical experience. The requisite service period could be shorter than the vesting period if an employee is retirement eligible.

Valuation Assumptions

Fair value of options granted under our Plans and purchases under our ESPP were estimated at grant or purchase dates using a Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including expected stock price volatility and expected award life.

We used the following assumptions to calculate the estimated fair value of the awards:

	Year Ended December 31,		
	2021	2020	2019
Expected volatility:			
Stock options	29 %	29 %	27 %
ESPP	25 %	28 %	27 %
Expected term in years:			
Stock options	5.0	5.0	5.5
ESPP	0.5	0.5	0.5
Risk-free interest rate:			
Stock options	0.8 %	0.8 %	2.3 %
ESPP	0.1 %	0.6 %	1.8 %
Expected dividend yield	4.4 %	4.0 %	3.6 %

The fair value of stock options granted was calculated using the single option approach. We use a blend of historical volatility along with implied volatility for traded options on our common stock to determine our expected volatility. The expected term of stock-based awards represents the weighted-average period the awards are expected to remain outstanding. We estimate the weighted-average expected term based on historical cancellation and historical exercise data related to our stock options as well as the contractual term and vesting terms of the awards. The risk-free interest rate is based upon observed interest rates appropriate for the term of the stock-based awards. The dividend yield is based on our history and expectation of dividend payouts.

Deferred Compensation

We maintain a retirement saving plan under which eligible U.S. employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code (the Gilead Sciences 401k Plan). In certain foreign subsidiaries, we maintain defined benefit plans as required by local regulatory requirements. Our total matching contribution expense under the Gilead Sciences 401k Plan and other defined benefit plans was \$166 million, \$144 million and \$110 million during 2021, 2020 and 2019, respectively.

We maintain a deferred compensation plan under which our directors and key employees may defer compensation. Amounts deferred by participants are deposited into a rabbi trust. The total assets and liabilities associated with the deferred compensation plan were \$261 million and \$218 million as of December 31, 2021 and 2020, respectively.

17. NET INCOME PER SHARE ATTRIBUTABLE TO GILEAD COMMON STOCKHOLDERS

Basic net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock and other dilutive securities outstanding during the period. The potentially dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options and equivalents were determined under the treasury stock method.

Potential shares of common stock excluded from the computation of diluted net income per share attributable to Gilead common shareholders because their effect would have been antidilutive were 15 million, 13 million and 14 million during 2021, 2020 and 2019, respectively.

The following table shows the calculation of basic and diluted net income per share attributable to Gilead common stockholders:

(in millions, except per share amounts)	Year Ended December 31,		
	2021	2020	2019
Net income attributable to Gilead	\$ 6,225	\$ 123	\$ 5,386
Shares used in per share calculation - basic	1,256	1,257	1,270
Dilutive effect of stock options and equivalents	6	6	7
Shares used in per share calculation - diluted	1,262	1,263	1,277
Net income per share attributable to Gilead common stockholders - basic	\$ 4.96	\$ 0.10	\$ 4.24
Net income per share attributable to Gilead common stockholders - diluted	\$ 4.93	\$ 0.10	\$ 4.22

18. INCOME TAXES

Income before income taxes consists of the following:

(in millions)	Year Ended December 31,		
	2021	2020	2019
Domestic	\$ 8,587	\$ 2,505	\$ 4,112
Foreign	(309)	(836)	1,048
Income before income taxes	<u>\$ 8,278</u>	<u>\$ 1,669</u>	<u>\$ 5,160</u>

The Income tax (expense) benefit consists of the following:

(in millions)	Year Ended December 31,		
	2021	2020	2019
Federal:			
Current	\$ (1,776)	\$ (1,450)	\$ (1,646)
Deferred	250	164	843
	<u>(1,526)</u>	<u>(1,286)</u>	<u>(803)</u>
State:			
Current	(228)	(198)	(135)
Deferred	(185)	97	42
	<u>(413)</u>	<u>(101)</u>	<u>(93)</u>
Foreign:			
Current	(185)	(155)	(124)
Deferred	47	(38)	1,224
	<u>(138)</u>	<u>(193)</u>	<u>1,100</u>
Income tax (expense) benefit	<u>\$ (2,077)</u>	<u>\$ (1,580)</u>	<u>\$ 204</u>

The 2019 income tax benefit included a \$1.2 billion deferred tax benefit related to intangible asset transfers from a foreign subsidiary to Ireland and the United States. In the fourth quarter of 2019, we completed an intra-entity asset transfer of certain intangible assets from a foreign subsidiary to Ireland. The transaction resulted in a step-up of the Irish tax-deductible basis in the transferred assets, and accordingly, created a temporary difference where the tax basis exceeded the financial statement basis of such intangible assets. As a result, we recognized a deferred tax asset of \$1.2 billion on our Consolidated Financial Statements. We expect to be able to realize the deferred tax asset resulting from this intra-entity asset transfer. The impact of the intangible asset transfer from a foreign subsidiary to the United States was not material.

The reconciliation between the federal statutory tax rate applied to income before income taxes and our effective tax rate is summarized as follows:

	Year Ended December 31,		
	2021	2020	2019
Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	2.5 %	4.2 %	0.4 %
Foreign earnings at different rates	(0.3)%	(10.0)%	2.5 %
Research and other credits	(1.6)%	(6.9)%	(1.9)%
US tax on foreign earnings	1.1 %	7.2 %	4.3 %
Foreign-derived intangible income deduction	(1.6)%	(8.0)%	(3.2)%
Deferred tax - intra-entity transfer of intangible assets	(0.7)%	0.6 %	(24.0)%
Settlement of tax examinations	(0.7)%	(10.2)%	(2.4)%
Acquired IPR&D and related charges	— %	56.2 %	— %
Changes in valuation allowance	1.5 %	6.7 %	— %
Non-taxable unrealized (gain) loss on investment	1.8 %	23.0 %	(5.0)%
Other	2.1 %	10.9 %	4.3 %
Effective tax rate	<u>25.1 %</u>	<u>94.7 %</u>	<u>(4.0)%</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows:

(in millions)	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 413	\$ 587
Stock-based compensation	117	113
Reserves and accruals not currently deductible	700	444
Excess of tax basis over book basis of intangible assets	1,157	1,177
Upfront and milestone payments	1,310	1,144
Research and other credit carryforwards	249	219
Equity investments	117	116
Liability related to future royalties	274	247
Other, net	292	311
Total deferred tax assets before valuation allowance	4,629	4,358
Valuation allowance	(520)	(398)
Total deferred tax assets	4,109	3,960
Deferred tax liabilities:		
Property, plant and equipment	(227)	(202)
Excess of book basis over tax basis of intangible assets	(6,719)	(6,168)
Other	(180)	(202)
Total deferred tax liabilities	(7,126)	(6,572)
Net deferred tax assets (liabilities)	<u>\$ (3,017)</u>	<u>\$ (2,612)</u>

The valuation allowance was \$520 million and \$398 million as of December 31, 2021 and 2020, respectively. The increase of our valuation allowance in 2021 was primarily related to California research and development tax credits.

The valuation allowance was \$398 million and \$217 million as of December 31, 2020 and 2019, respectively. The increase of our valuation allowance in 2020 was primarily related to acquired attributes related to Forty Seven and Immunomedics acquisitions, and capital losses related to our equity method investments.

As of December 31, 2021, we had U.S. federal net operating loss and tax credit carryforwards of approximately \$250 million and \$8 million, respectively, which will start to expire in 2022, if not utilized. In addition, we had state net operating loss and tax credit carryforwards of approximately \$2.8 billion and \$768 million, respectively. The state net operating loss and state tax credit carryforwards will start to expire in 2022 if not utilized.

Utilization of net operating losses and tax credits may be subject to an annual limitation due to ownership change limitations provided in the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

We file federal, state and foreign income tax returns in the United States and in many foreign jurisdictions. For federal income tax purposes, the statute of limitations is open for 2016 and onwards and 2013 and onwards for California income tax purposes. For certain acquired entities, the statute of limitations is open for all years from inception due to our utilization of their net operating losses and credits carried over from prior years.

Our income tax returns are subject to audit by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service and Irish tax authorities for our 2016 to 2018 tax years. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

Of the total unrecognized tax benefits, \$800 million and \$1.2 billion as of December 31, 2021 and 2020, respectively, if recognized, would reduce our effective tax rate in the period of recognition. Interest and penalties related to unrecognized tax benefits included income tax expense of \$41 million, income tax benefit of \$82 million and income tax expense of \$105 million on our Consolidated Statements of Income for the years ended December 31, 2021, 2020 and 2019 respectively. Accrued interest and penalties related to unrecognized tax benefits were \$218 million and \$177 million as of December 31, 2021 and 2020, respectively. As of December 31, 2021, we believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$100 million in the next 12 months due to potential settlements with various taxing authorities.

The following is a rollforward of our total gross unrecognized tax benefits:

(in millions)	Year Ended December 31,		
	2021	2020	2019
Balance, beginning of period	\$ 1,614	\$ 2,031	\$ 1,595
Tax positions related to current year:			
Additions	147	121	138
Reductions	—	—	—
Tax positions related to prior years:			
Additions	161	398	405
Reductions	(179)	(481)	—
Settlements	(28)	(454)	(104)
Lapse of statute of limitations	(2)	(1)	(3)
Balance, end of period	<u>\$ 1,713</u>	<u>\$ 1,614</u>	<u>\$ 2,031</u>

In connection with the Tax Cuts and Jobs Act, we recorded a federal income tax payable for transition tax on the mandatory deemed repatriation of foreign earnings that is payable over an eight-year period. As of December 31, 2021 and 2020, we have accrued \$4.0 billion and \$4.5 billion, respectively, for transition tax. Of the amounts accrued as of December 31, 2021, approximately \$473 million is expected to be paid within one year.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Gilead Sciences, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Gilead Sciences, Inc.'s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Gilead Sciences, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 23, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Jose, California

February 23, 2022

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2021 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures,” which are defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to the company’s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

(b) Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2021.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K and have issued a report on our internal control over financial reporting as of December 31, 2021. Its report on the audit of internal control over financial reporting appears above.

(c) Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2021, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2022 Annual Meeting of Stockholders (the “Proxy Statement”) under the headings “The Gilead Board of Directors - Nominees,” “Board Structure,” “Executive Officers,” and, if applicable, “Delinquent Section 16(a) Reports.”

Our written Code of Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at www.gilead.com in the “Investors” section under “Corporate Governance.” We intend to disclose future amendments to certain provisions of the Code of Ethics, and waivers of the Code of Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings “Executive Compensation,” “Committees of our Board of Directors,” “Compensation and Talent Committee Report,” and “Compensation of Non-Employee Board Members.”

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to Item 5 of our Annual Report on Form 10-K under the heading “Equity Compensation Plan Information” and the section of the Proxy Statement under the heading “Security Ownership of Certain Beneficial Owners and Management.”

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings “The Gilead Board of Directors,” and “Board Processes.”

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the heading “Principal Accountant Fees and Services.”

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Index list to Consolidated Financial Statements:

Report of Independent Registered Public Accounting Firm (PCAOB ID: 42)	50
Audited Consolidated Financial Statements:	
Consolidated Balance Sheets	52
Consolidated Statements of Income	53
Consolidated Statements of Comprehensive Income (Loss)	54
Consolidated Statements of Stockholders’ Equity	55
Consolidated Statements of Cash Flows	56
Notes to Consolidated Financial Statements	57

(2) All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits.

The following exhibits are filed herewith or incorporated by reference:

Exhibit Footnote	Exhibit Number	Description of Document
(1)	2.1	Agreement and Plan of Merger, dated September 13, 2020, among Immunomedics, Inc., Gilead Sciences, Inc. and Maui Merger Sub, Inc.
(2)	2.2	Agreement and Plan of Merger, by and among Forty Seven, Inc., Registrant and Toro Merger Sub, Inc., dated March 1, 2020
(3)	3.1	Restated Certificate of Incorporation of Registrant
(3)	3.2	Amended and Restated Bylaws of Registrant
(4)	4.1	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(4)	4.2	First Supplemental Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including form of Senior Notes)
(5)	4.3	Second Supplemental Indenture related to Senior Notes, dated as of December 13, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2041 Note)
(6)	4.4	Third Supplemental Indenture related to Senior Notes, dated as of March 7, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2024 Note and Form of 2044 Note)

(7)	4.5	Fourth Supplemental Indenture related to Senior Notes, dated as of November 17, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2025 Note and Form of 2045 Note)
(8)	4.6	Fifth Supplemental Indenture, dated as of September 14, 2015, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2026 Note, Form of 2035 Note and Form of 2046 Note)
(9)	4.7	Sixth Supplemental Indenture, dated as of September 20, 2016, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2023 Note, Form of 2027 Note, Form of 2036 Note and Form of 2047 Note)
(10)	4.8	Eighth Supplemental Indenture, dated as of September 30, 2020, between the Registrant and Wells Fargo Bank, National Association, as Trustee (including form of notes)
(11)	4.9	Description of Registrant's Securities
(12)	10.1*	Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017
(13)	10.2*	Amendment No. 1 to Gilead Sciences, Inc. 2004 Equity Incentive Plan, amended and restated May 10, 2017
(14)	10.3*	Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)
(15)	10.4*	Form of employee stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(16)	10.5*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)
(17)	10.6*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)
(18)	10.7*	Form of global employee stock option agreement under 2004 Equity Incentive Plan (4 year vest) (for grants commencing in 2021)
(19)	10.8*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2009 through 2012)
(20)	10.9*	Form of non-employee director stock option agreement (U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)
(20)	10.10*	Form of non-employee director stock option agreement (non-U.S.) under 2004 Equity Incentive Plan (for grants made in 2013)
(21)	10.11*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2014 through 2018)
(15)	10.12*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(22)	10.13*	Form of non-employee director stock option agreement under 2004 Equity Incentive Plan (for grants commencing in 2020)
(15)	10.14*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)
(17)	10.15*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)
(18)	10.16*	Form of performance share award agreement - TSR Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2021)
(15)	10.17*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2019)
(17)	10.18*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants made in 2020)
(18)	10.19*	Form of performance share award agreement - Revenue Goals (U.S.) under 2004 Equity Incentive Plan (for grants commencing in 2021)
(14)	10.20*	Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2011 through 2018)
(15)	10.21*	Form of employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants made in 2019)
(16)	10.22*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2019)
(17)	10.23*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants made in 2020)
(18)	10.24*	Form of global employee restricted stock unit issuance agreement under 2004 Equity Incentive Plan (4 year vest) (for grants commencing in 2021)
(22)	10.25*	Form of non-employee director restricted stock unit issuance agreement under 2004 Equity Incentive Plan (for grants commencing in 2020)
(22)	10.26*	Gilead Sciences, Inc. 2018 Equity Incentive Plan, amended and restated April 7, 2020
(23)	10.27*	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated January 22, 2015
(15)	10.28*	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, amended and restated April 19, 2016
(22)	10.29*	Gilead Sciences, Inc. Severance Plan, amended and restated May 5, 2020
(17)	10.30*	Gilead Sciences, Inc. Corporate Annual Incentive Plan, amended and restated January 1, 2020
(24)	10.31*	Offer Letter between Registrant and Daniel O'Day, dated November 30, 2018
(15)	10.32*	Stock option agreement for Daniel O'Day under 2004 Equity Incentive Plan
(15)	10.33*	Performance share award agreement for Daniel O'Day (for TSR Goals in 2019) under 2004 Equity Incentive Plan
(15)	10.34*	Performance share award agreement for Daniel O'Day (for Revenue Goals in 2019) under 2004 Equity Incentive Plan
(15)	10.35*	Form of restricted stock unit issuance agreement for Daniel O'Day (in 2019) under 2004 Equity Incentive Plan

(15)	10.36*	Offer Letter between Registrant and Johanna Mercier, dated May 21, 2019
(22)	10.37*	Letter Agreement between Registrant and Johanna Mercier, dated May 4, 2020
(17)	10.38*	Global stock option agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan
(17)	10.39*	Restricted stock unit issuance agreement for Johanna Mercier (for Performance Objectives in 2019-2020) under 2004 Equity Incentive Plan
(17)	10.40*	Global restricted stock unit issuance agreement for Johanna Mercier (in 2019) under 2004 Equity Incentive Plan
(17)	10.41*	Offer Letter between Registrant and Merdad Parsey, dated September 29, 2019
(17)	10.42*	Global stock option agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan
(17)	10.43*	Global restricted stock unit issuance agreement for Merdad Parsey (in 2019) under 2004 Equity Incentive Plan
(25)	10.44*	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
(25)	10.45*	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
(26)	10.46*	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised September 2006)
+ (27)	10.47	Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement); the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement); and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)
+ (28)	10.48	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000, amending the 1991 License Agreement and the December 1992 License Agreement
+ (29)	10.49	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006, amending the October 1992 License Agreement and the December 1992 License Agreement
+ (30)	10.50	Seventh Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated July 1, 2013, amending the October 1992 License Agreement and the December 1992 License Agreement
+ (31)	10.51	Exclusive License Agreement by and between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999
+ (32)	10.52	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005
+ (32)	10.53	Amended and Restated License Agreement by and between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
++ (33)	10.54	Amended and Restated EVG License Agreement by and between Japan Tobacco Inc. and Registrant, dated November 29, 2018
++ (33)	10.55	Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018
+ (34)	10.56	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland, dated December 23, 2014
+ (35)	10.57	License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013
++ (16)	10.58	Option, License and Collaboration Agreement by and between Galapagos NV and Registrant, dated July 14, 2019
	21.1**	<u>Subsidiaries of Registrant</u>
	23.1**	<u>Consent of Independent Registered Public Accounting Firm</u>
	24.1**	Power of Attorney (included on the signature page of this report)
	31.1**	<u>Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
	31.2**	<u>Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended</u>
	32***	<u>Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)</u>
	101.INS**	XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
	101.SCH**	Inline XBRL Taxonomy Extension Schema Document
	101.CAL**	Inline XBRL Taxonomy Extension Calculation Linkbase Document
	101.DEF**	Inline XBRL Taxonomy Extension Definition Linkbase Document
	101.LAB**	Inline XBRL Taxonomy Extension Label Linkbase Document
	101.PRE**	Inline XBRL Taxonomy Extension Presentation Linkbase Document
	104	Cover Page Interactive Data File, formatted in Inline XBRL (included as Exhibit 101)

- (1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2020, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 2, 2020, and incorporated herein by reference.
- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2019, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 30, 2020, and incorporated herein by reference.
- (11) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and incorporated herein by reference.
- (12) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 12, 2017, and incorporated herein by reference.
- (13) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and incorporated herein by reference.
- (15) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, and incorporated herein by reference.
- (16) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, and incorporated herein by reference.
- (17) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.
- (24) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 10, 2018, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (28) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (29) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
- (30) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.
- (31) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
- (32) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Amendment No. 1 to Annual Report on Form 10-K/A filed on April 18, 2019, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.
- (35) Filed as an exhibit to Kite Pharma, Inc.'s Registration Statement on Form S-1/A (No. 333-196081) filed on June 17, 2014, and incorporated herein by reference.
- * Management contract or compensatory plan or arrangement.
- ** Filed herewith.
- *** Furnished herewith.
- + Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the Mark pursuant to Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.
- ++ Certain confidential portions of this Exhibit were omitted by means of marking such portions with the Mark because the identified confidential portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

ITEM 16. FORM 10-K SUMMARY

None.

Signature	Title	Date
/s/ DANIEL P. O'DAY Daniel P. O'Day	Chairman and Chief Executive Officer <i>(Principal Executive Officer)</i>	February 23, 2022
/s/ ANDREW D. DICKINSON Andrew D. Dickinson	Chief Financial Officer <i>(Principal Financial Officer)</i>	February 23, 2022
/s/ DIANE E. WILFONG Diane E. Wilfong	Senior Vice President and Chief Accounting Officer <i>(Principal Accounting Officer)</i>	February 23, 2022
/s/ JACQUELINE K. BARTON Jacqueline K. Barton, Ph.D.	Director	February 23, 2022
/s/ JEFFREY A. BLUESTONE Jeffrey A. Bluestone, Ph.D.	Director	February 23, 2022
/s/ SANDRA J. HORNING Sandra J. Horning, M.D.	Director	February 23, 2022
/s/ KELLY A. KRAMER Kelly A. Kramer	Director	February 23, 2022
/s/ KEVIN E. LOFTON Kevin E. Lofton	Director	February 23, 2022
/s/ HARISH MANWANI Harish Manwani	Director	February 23, 2022
/s/ JAVIER J. RODRIGUEZ Javier J. Rodriguez	Director	February 23, 2022
/s/ ANTHONY WELTERS Anthony Welters	Director	February 23, 2022