MARINEMAX INC
Form CT ORDER
March 03, 2017

on date provided corresponds to the latest expiring compound patent for one of the active ingredients in the single tablet regimen.

Phase 3 Product Candidates	Patent Expiration	
Product Candidate for the Treatment of HIV/AIDS	U.S.	E.U.
Descovy for PrEP	2022*	2021*
Product Candidate for the Treatment of Liver Diseases		
Selonsertib for the treatment of NASH	2033	2033
Product Candidates for the Treatment of Hematology/Oncology		
Axicabtagene ciloleucel for the treatment of second line diffuse large B-cell lymphoma	2027	**
Product Candidate for the Treatment of Inflammation/Respiratory Diseases		
Filgotinib for the treatment of rheumatoid arthritis, Crohn’s disease and ulcerative colitis	2030	2030

*An application for patent term extension was filed in the United States that if granted would extend the U.S. expiration date to 2025. Applications for supplementary protection certificates were filed in the European Union that if granted would extend the E.U. expiration date to 2026.

** 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 Kite’s proprietary manufacturing processes.

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.
Letairis	2018 (1)	2020
Ranexa	2019 (2)	2023
Atripla	2021 (3)	2017
Truvada	2021 (3)	2017 (4)
Descovy	2022 (7)	2021 (7)
Vemlidy	2022 (7)	2021 (7)
Complera/Eviplera	2025	2022 (6)
Zydelig	2025 (6)	2025 (6)
Odefsey	2025	2022 (6)
Yescarta	2027 (6)	- (5)
Stribild	2029	2027 (6)
Genvoya	2029	2027 (6)
Harvoni	2030	2030 (6)
Epclusa	2032	2032
Biktarvy	2033	2033
Vosevi	2034	2033

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.

Notes:

(1) In 2017, Gilead and Watson Laboratories, Inc. reached an agreement to settle a patent litigation matter related to Letairis.

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

(3) In 2014, Gilead and Teva Pharmaceuticals reached an agreement to settle the patent litigation concerning patents that protect emtricitabine in our Truvada and Atripla products.

(4) Supplementary protection certificates (SPCs) have been granted in several European countries. The validity of these SPCs has been challenged by several generic manufacturers, many of whom launched their competing product in 2017. The validity of these SPCs is being considered in national courts and by the Court of Justice for the European Union.

(5) 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 Kite's proprietary manufacturing processes.

(6) 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.

(7) An application for patent term extension was filed in the United States that, if granted, would extend the U.S. expiration date to 2025. Applications for SPCs were filed in the European Union that, if granted, would extend the E.U. expiration date to 2026.

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 Yescarta, Letairis and Ranexa are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties. We do not own patents covering ranolazine, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained-release formulation of ranolazine would achieve therapeutic plasma levels, we obtained patents on those formulations and the characteristic plasma levels they achieve.

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

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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 reputations 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 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 interference/derivation proceedings or litigation to determine the right to a patent. Litigation and interference/derivation proceedings are unpredictable and expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

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 13, Commitments and Contingencies - Legal Proceedings of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K.

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 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. 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 Letairis, we are the exclusive manufacturer of the ambrisentan API, but we have another qualified supplier to make this API. For Yescarta, we have established clinical and commercial manufacturing facilities for the 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.

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Our Manufacturing Facilities

We own or lease manufacturing facilities in Foster City, San Dimas, La Verne, Oceanside and El Segundo, California; Dublin and Cork, Ireland; and Edmonton, Alberta, Canada, where we manufacture and distribute certain products and API for clinical and/or commercial uses.

- Foster City, California: We conduct process chemistry research and development activities, manufacture API for our clinical trials and oversee our third-party contract manufacturers.
- San Dimas and La Verne, California: We manufacture AmBisome (in San Dimas), package and label the majority of our commercial products and distribute our products to the Americas and Pacific Rim.
- Oceanside, California: We utilize the facility for clinical manufacture and process development of our biologics candidates.
- El Segundo, California: We utilize the facility for clinical and commercial manufacture and processing of Yescarta.
- Cork and Dublin, Ireland: We utilize the Cork facility for commercial manufacture, packaging and labeling of our antiviral products. We also perform quality control testing, labeling, packaging and final release of many of our products for distribution to the European Union and other international markets. The Dublin facility is also responsible for distribution activities of our products.
- Edmonton, Alberta, Canada: We conduct process chemistry research and scale-up activities of our clinical development candidates, manufacture API for both investigational and commercial products and conduct chemical development activities to improve existing commercial manufacturing processes.

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. In addition, these third-party manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products. We could be required to enter into additional agreements with these third-party manufacturers if we want to use that technology ourselves or allow another manufacturer to use that technology. The third-party manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable to us.

For more information about our third-party manufacturers, see Item 1A - Risk Factors "Manufacturing problems, including at our third-party manufacturers and corporate partners, could cause inventory shortages and delay product shipments and regulatory approvals, which may adversely affect our results of operations."

Regulation of Manufacturing Process

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

For Yescarta, 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 would limit our ability to generate revenues.”

Seasonality of Operations and Backlog

Our worldwide product sales do not reflect any significant degree of seasonality in end-user demand. In the United States, fluctuations in wholesaler inventory levels have impacted our product sales. We have observed that strong wholesaler and sub-wholesaler purchases of our products in the fourth quarter have resulted 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 and other buying patterns, have impacted the product sales recorded in a particular quarter. For more information, see Item 1A - Risk Factors “Our inability to accurately predict demand for our products, uptake of new products or fluctuations in customer inventories makes it difficult for us to accurately forecast sales and may cause our forecasted revenues and earnings to fluctuate, which could adversely affect our financial results and our stock price.”

For the most part, we operate in markets characterized by short lead times and the absence of significant backlogs. We do not believe that backlog information is material to our business as a whole.

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. 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 EMA/European Commission for the European Union, 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, 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 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 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 safe 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 (NDA) or supplemental NDA, with FDA seeking approval to sell the drug candidate for a particular use. 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 compound has met the required level of safety and efficacy for a particular use, it will allow us to sell the drug candidate in the United States for that use. It is not unusual, however, for FDA to reject an application because it believes that the drug candidate is not safe enough or efficacious enough 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 and lack of treatment benefit. 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 the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

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 problems 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 and Ireland also must obtain local licenses and permits in compliance with local regulatory requirements.

Drugs that treat serious or life-threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track candidates by FDA and may be eligible for priority review. Drugs for the treatment of HIV infection that are designated for use under the U.S. President’s Emergency Plan for AIDS Relief may also qualify for an expedited review.

European Union Approval Process

Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union. If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries. The European Union also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payer reimbursement for the cost of such products and related treatments 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 the list prices. As a result, the price increases we implement from time to time on certain products may have a limited effect on our product sales in certain markets. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies.

As our products mature, private insurers and government payers often reduce the amount they will reimburse patients, which increases pressure on us to reduce 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 from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may reduce profitability.” and “Our inability to accurately predict demand for our products, uptake of new products or fluctuations in customer inventories make it difficult for us to accurately forecast sales and may cause our forecasted revenues and earnings to fluctuate, which could adversely affect our financial results and our stock price.”

Patient Assistance Programs

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

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Health Care Fraud and Abuse Laws; Anti-Bribery Laws

We are subject to various 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 solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the increasing attention being given to them by law enforcement authorities, it is possible that certain of our practices may be challenged under anti-kickback or similar laws. 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. Our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws.

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 reckless or criminal 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.

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 “Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions” and “Laws and regulations applicable to the health care industry could impose new obligations on us, require us to change our business practices and restrict our operations in the future.”

Employees

As of January 31, 2019, we had approximately 11,000 employees. We believe we have good relations with our employees.

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 near 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 Exchange Act. Therefore, we file periodic reports, proxy and information statements and other information with the SEC. The SEC maintains a website (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

The mailing address of our headquarters is 333 Lakeside Drive, Foster City, California 94404, and our telephone number at that location is 650-574-3000. Our website is www.gilead.com. Through a link on the “Investors” page of our website (under “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.

Transactions with Iran

We did not engage in any transactions within Iran during 2018 that would require disclosure in this Annual Report on Form 10-K.

Item 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following risks in addition to the other information in this Annual Report on Form 10-K. A manifestation of any of the following risks could materially and adversely affect our business, results of operations and financial condition. 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 and, therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

A substantial portion of our revenues is derived from sales of products to treat HIV and HCV. If we are unable to increase HIV sales or if HCV sales decrease more than anticipated, then our results of operations may be adversely affected.

We receive a substantial portion of our revenue from sales of our products for the treatment of HIV infection. During the year ended December 31, 2018, sales of our HIV products accounted for approximately 67% of our total product sales, and we expect our HIV products to account for a higher percentage of our total product sales in 2019 than in 2018. Most of our HIV products contain tenofovir alafenamide (TAF), tenofovir disoproxil fumarate (TDF) and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. If the treatment paradigm for HIV changes, causing nucleoside-based therapeutics to fall out of favor, or if we are unable to maintain or increase our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our future drug development and spending on research and development (R&D) efforts.

During the year ended December 31, 2018, sales of our products for the treatment of chronic hepatitis C virus (HCV) infection accounted for approximately 17% of our total product sales. Our HCV revenues have declined, and we expect a further decline in product sales in 2019, compared to 2018, in major markets. The drivers of our HCV product revenues are patient starts, net pricing, market share and treatment duration. With treatment duration stabilizing and pricing largely stabilizing, we expect to continue to compete for market share across market segments and geographies. We anticipate patient starts to continue to steadily decline and be more predictable. Any unexpected and adverse changes to these drivers, including any larger than anticipated shifts, may adversely impact our HCV product revenues.

In addition, future sales of our HIV and HCV products depend, in part, on the extent of reimbursement of our products by private and public payers. We may continue to experience global pricing pressure that could result in larger discounts or rebates on our products or delayed reimbursement, which negatively impacts our product sales and results of operations. Also, private and public payers can choose to exclude our products from their formulary coverage lists or limit the types of patients for whom coverage will be provided, which would negatively impact the demand for, and revenues of, our products. Any change in the formulary coverage, reimbursement levels or discounts or rebates offered on our products to payers may impact our anticipated revenues. If we are unable to achieve our forecasted HIV and HCV sales, our stock price could be adversely impacted.

We may be unable to sustain or increase sales of our HIV or HCV products for any number of reasons including, but not limited to, the reasons discussed above and the following:

- As our products are used over a longer period of time in many patients and in combination with other products, and additional studies are conducted, new issues with respect to safety, resistance and interactions with other drugs may arise, which could cause us to provide additional warnings or contraindications on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.
- As our products mature, private insurers and government payers often reduce the amount they will reimburse patients for these products, which increases pressure on us to reduce prices.
- If physicians do not see the benefit of our HIV or HCV products, the sales of our HIV or HCV products will be limited.
- As new branded or generic products are introduced into major markets, our ability to maintain pricing and market share may be affected.

If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues and our results of operations may be adversely affected.

If we do not introduce new products or increase sales of our existing products, we will not be able to increase or maintain our total revenues nor continue to expand our R&D efforts, and our results of operations may be adversely affected. Drug development is inherently risky and many product candidates fail during the drug development process. We may decide to terminate product development after expending significant resources and effort. For example, we recently announced that our KITE-585, an anti- B-cell maturation antigen (anti-BCMA) being evaluated for the treatment of multiple myeloma, will not be moving forward. We also recently announced that STELLAR-4, a Phase 3 study evaluating the safety and efficacy of selonsertib in patients with compensated cirrhosis due to nonalcoholic steatohepatitis (NASH), did not meet the pre-specified week 48 primary endpoint. In addition, if we are unable to obtain regulatory approval for product candidates, our future revenue growth and results of operations may be adversely impacted.

Further, 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, there may be significant limitations on their use.

Our inability to accurately predict demand for our products, uptake of new products or fluctuations in customer inventories makes it difficult for us to accurately forecast sales and may cause our forecasted revenues and earnings to fluctuate, which could adversely affect our financial results and stock price.

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, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAPs), the U.S. Department of Veterans Affairs, correctional facilities and large health maintenance organizations, tends to be even 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 of our products. For example, in the first quarters of 2018 and certain prior years, we observed large non-retail purchases of our HIV products by a number of state ADAPs that exceeded patient demand. We believe such purchases were driven by the grant cycle for federal ADAP funds. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in fluctuations in our product sales, revenues and earnings in the future. 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, which has decreased our revenues and caused fluctuations in our product sales and earnings. 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. During the year ended December 31, 2018, approximately 85% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., Cardinal Health, Inc. and McKesson Corp. 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. For example, during the fourth quarter of 2017, strong wholesaler and sub-wholesaler purchases of our products resulted in inventory draw-down by wholesalers and sub-wholesalers in the first quarter of 2018. 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.

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 may vary significantly from our estimates which can cause an adjustment to our product revenues. To the extent our actual or anticipated product revenues exceed or fall short of investors' expectations, our stock price could be adversely impacted.

Yescarta, a chimeric antigen receptor (CAR) T cell therapy, represents a novel approach to cancer treatment that creates significant challenges for us, which may impact our ability to increase sales of Yescarta.

Yescarta, a CAR T cell therapy, involves (i) harvesting T cells from the patient's blood, (ii) engineering T cells to express cancer-specific receptors, (iii) increasing the number of engineered T cells and (iv) infusing the functional cancer-specific T cells back into the patient. Advancing this novel and personalized therapy creates significant challenges, including:

- educating and certifying medical personnel regarding the 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, in compliance with the Risk Evaluation and Mitigation Strategy (REMS) program required by FDA for Yescarta;

- using medicines to manage adverse side effects of our therapy, such as tocilizumab and corticosteroids, which may not be available in sufficient quantities, may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- developing a robust and reliable process, while limiting contamination risks, for engineering a patient's T cells ex vivo and infusing the engineered T cells 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. We may not be able to establish or demonstrate to the medical community or commercial or governmental payers the safety and efficacy of Yescarta and the potential advantages compared to existing and future therapeutics. If we fail to overcome these significant challenges, our sales of Yescarta, results of operations and stock price could be adversely affected.

We face significant competition.

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

Our TAF-containing HIV products compete primarily with products from ViiV Healthcare Company (ViiV). We also face competition from generic HIV products. Generic versions of efavirenz, a component of Atripla, are available in the United States, Canada and Europe. We have observed some pricing pressure related to the efavirenz component of our Atripla sales. TDF, one of the active pharmaceutical ingredients in Truvada, Atripla, Complera/Eviplera and Stribild, faces generic competition in the European Union, the United States and certain other countries. In addition, because emtricitabine, the other active pharmaceutical ingredient of Truvada, faces generic competition in the European Union, Truvada also faces generic competition in the European Union and certain other countries outside of the United States.

Our HCV products compete primarily with products marketed by AbbVie and Merck.

Our HBV products face competition from existing therapies for treating patients with HBV as well as generic versions of TDF. Our HBV products also compete with products marketed by Bristol-Myers Squibb Company and Novartis Pharmaceuticals Corporation (Novartis).

Yescarta competes with a CAR T cell therapy marketed by Novartis and is expected to compete with products from other companies developing advanced T cell therapies.

Letairis competes with products marketed by Actelion Pharmaceuticals US, Inc., United Therapeutics Corporation and Pfizer Inc. Because the U.S. patent for ambrisentan, the active pharmaceutical ingredient in Letairis, expired in July 2018, Letairis is expected to face competition from manufacturers of generic versions of Letairis in the United States.

Ranexa competes predominantly with generic compounds from three distinct classes of drugs for the treatment of chronic angina in the United States, including generic and/or branded beta-blockers, calcium channel blockers and long-acting nitrates. Ranexa is expected to face competition from manufacturers of generic versions of Ranexa in the United States starting in the first quarter of 2019.

In addition, a number of companies are pursuing the development of technologies which are competitive with our existing products or research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs. If any of these competitors gain market share as a result of new technologies, commercialization strategies or otherwise, it could adversely affect our results of operations and stock price.

Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the Affordable Care Act (the ACA) was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a Texas federal district court struck down the ACA on the ground that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges to the ACA have resulted in uncertainty regarding its future viability and destabilization of the health insurance market. The resulting impact on our business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services (HHS) released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. The Trump administration also proposed to establish an “international pricing index” that would be used as a benchmark to determine the costs of drugs under Medicare Part B. In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Similar bills have been introduced at the federal level. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. For example, in December 2018, HHS proposed a rule that would modify the Medicare Part D protected class policy to provide Part D Plan Sponsors broader authority to impose step therapy, prior authorization and other utilization management controls on products in the Part D protected classes, including our HIV products. In January 2019, HHS also proposed a rule that would remove regulatory protection under the Discount Safe Harbor to the Federal Anti-Kickback Statute for manufacturer rebates paid to Part D Plan Sponsors, Medicaid managed care organizations and pharmacy benefit managers under contract with them, and would create new safe harbors for arrangements with these entities. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely affected.

Our existing products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may reduce profitability.

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payer reimbursement for the cost of such products and related treatments 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 substantial portion of sales of the majority of our products is subject to significant discounts from list price. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies.

For example, effective October 2018, the Centers for Medicare and Medicaid Services (CMS) established inpatient reimbursement for patients receiving Yescarta. The reimbursement includes payment for a severity adjusted diagnosis related group (DRG) 016, a new technology add-on payment (NTAP) for Yescarta that at most will cover one half the cost of Yescarta and may cover less than that, and, in some cases, an outlier payment. Taken together, the total payment may not be sufficient to reimburse hospitals for their cost of care for patients receiving Yescarta. This payment methodology is likely to be in effect until at least September 2020. Limited payments such as this could impact the willingness of some hospitals to offer the therapy and of doctors to recommend the therapy and could lessen the attractiveness of our therapy to patients, which could have an adverse effect on sales of Yescarta and on our results of operations. CMS has also proposed a National Coverage Decision on CAR T cells and would impose certain coverage limitations on that therapy. These coverage limitations would apply to the entire Medicare program and includes, among other things, a requirement for patients to be enrolled in a clinical trial or registry in order for the hospital and physician to be paid for CAR T cell therapy. Further, commercial payers may follow Medicare coverage policies and could impose similar limitations. Additionally, in the European Union, there are barriers to reimbursement in individual countries that could limit the uptake of Yescarta.

Laws and regulations applicable to the health care industry could impose new obligations on us, require us to change our business practices and restrict our operations in the future.

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, individual state laws relating to pricing and sales and marketing practices, the Health Insurance Portability and Accountability Act (HIPAA) and other federal and state laws relating to the privacy and security of health information.

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, Veterans Administration health programs, and federal employee health benefit programs, actions against executives overseeing our business and burdensome remediation measures. In addition, these laws and regulations are broad in scope and they are subject to change 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. Violations of these laws, or allegations of such violations, could also result in negative publicity or other consequences that could harm our reputation, disrupt our business or adversely affect our results of operations. If any or all of these events occur, our business and stock price could be materially and adversely affected.
Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments on reimbursement support offerings, clinical education programs and promotional speaker programs. If we, or our agents, vendors or donation recipients, 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 13, Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K.
We have engaged in, and may in the future engage in, business acquisitions, licensing arrangements, strategic collaborations or disposal of our assets, which could cause us to incur significant expenses and could adversely affect our financial condition and results of operations.
We have engaged in, and may in the future engage in, business acquisitions, licensing arrangements, strategic collaborations or disposal of our assets, 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, the products and technologies that are acquired may not be successful or may require significantly greater resources and investments than originally anticipated. We may not be able to integrate acquisitions successfully into our existing business and could incur or assume significant debt and unknown or contingent liabilities. We also conduct annual impairment testing of our goodwill and other indefinite lived intangible assets in the fourth quarter, or earlier if impairment indicators exist, as required under U.S. generally accepted accounting principles. If we fail to overcome these risks, it could cause us to incur significant expenses and negatively affect profitability, which could have an adverse effect on our results of operations. We could also experience negative effects on our reported results of operations from acquisition or disposition-related charges, amortization of expenses related to intangibles and charges for impairment of long-term assets.
Approximately 25% of our product sales occur outside the United States, and currency fluctuations and hedging expenses may cause our earnings to fluctuate, which could adversely affect our stock price.
Because a significant percentage of our product sales are denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. When the U.S. dollar strengthens against these foreign 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 increases. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar.
We use foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. 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 cash is collected or paid. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $94 million for the year ended December 31, 2018, compared to the same period in 2017.

We cannot predict future fluctuations in the foreign currency exchange rates of the U.S. dollar. If the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation, our results of operations will be adversely affected and our stock price may decline. Additionally, the expenses that we recognize in relation to our hedging activities can also cause our earnings to fluctuate. The level of hedging expenses that we recognize in a particular period is impacted by the changes in interest rate spreads between the foreign currencies that we hedge and the U.S. dollar.

If significant safety issues arise for our marketed products or our product candidates, our reputation may be harmed and our future sales may be reduced, which would adversely affect our results of operations.
The data supporting the marketing approvals for our products and forming the basis for the safety warnings in our product labels were obtained in controlled clinical trials of limited duration and, in some cases, from post-approval use. As our products are used over longer periods of time by many patients with underlying health problems, taking numerous other medicines, we expect to continue to find new issues such as safety, resistance or drug interaction issues, which may require us to provide additional warnings or contraindications on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products.
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 which may potentially cause our product sales or stock price to decline.
Further, if serious safety, resistance or drug interaction issues arise with our marketed products, sales of these products could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected.
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, the European Medicines Agency (EMA) and comparable regulatory agencies in other countries. We are continuing clinical trials for many of our products for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional indications and products over the next several years. These products may fail to receive such marketing approvals on a timely basis, or at all.
Further, how we manufacture and sell our products is subject to extensive regulation and review. Discovery of previously unknown problems with our marketed products or problems with our manufacturing, safety reporting or promotional activities may result in restrictions on our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, including those related to promotion and manufacturing, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.
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 and implement a REMS for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers or other elements as FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on the distribution or use of a product. Failure to comply with these or other requirements imposed by FDA could result in significant civil monetary penalties and our operating results may be adversely affected.
We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption, which would adversely affect our prospects for future revenue growth and our results of operations.
We are required to demonstrate the safety and efficacy of products 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. For example, we recently announced that our KITE-585, an anti-BCMA being evaluated for the treatment of multiple myeloma, will not be moving forward. We also recently announced that STELLAR-4, a Phase 3 study evaluating the safety and efficacy of selonsertib in patients with compensated cirrhosis due to NASH, did not meet the pre-specified week 48 primary endpoint. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. In addition, we may also face challenges in clinical trial protocol design.
If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth and our results of operations would be adversely impacted. For example, we face numerous risks and

uncertainties with our product candidates, including Descovy for pre-exposure prophylaxis (PrEP); selonsertib for the treatment of NASH; axicabtagene ciloleucel for the treatment of second line diffuse large B-cell lymphoma; and filgotinib for the treatment of rheumatoid arthritis, Crohn’s disease and ulcerative colitis, each currently in Phase 3 clinical trials, that could prevent completion of development of these product candidates. These risks 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 or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates may never be successfully commercialized. For example, FDA has requested that we conduct a safety study of filgotinib in men with ulcerative colitis (MANTA study), and enrollment in this MANTA study will likely be the rate limiting factor to filing an NDA for filgotinib in the United States. 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. If these programs and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth and our results of operations may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn adversely affect our results of operations and harm our business.

In addition, 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 could be adversely affected.

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.

In addition, we rely on third party sites to collect patient white blood cells, known as apheresis centers, shippers, couriers, and hospitals for the logistical collection of patient's white blood cells and ultimate delivery of Yescarta to patients. Any disruption or difficulties incurred by any of these vendors could result in product loss and regulatory action and harm our Yescarta business and our reputation. To ensure that any apheresis center is prepared to ship cells to our manufacturing facilities, we plan to conduct quality certifications of each apheresis center. However, apheresis centers may choose not to participate in the certification process or we may be unable to complete certification in a timely manner or at all, which could delay or restrain our manufacturing and commercialization efforts. As a result, our sales of Yescarta may be limited which could harm our results of operations.

Our success depends to a significant degree on our ability to defend our patents and other intellectual property rights both domestically and internationally. We may not be able to obtain effective patents to protect our technologies from

use by competitors.
Patents and other proprietary rights are very important to our business. 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

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- operate without infringing on the intellectual property of others.

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.

Patent applications are confidential for a period of time before a patent is issued. As a result, we may not know if our competitors 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. 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. Litigation, post-grant proceedings before the U.S. Patent and Trademark Office or other proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

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 13, Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K. The entry of generic versions of our products may lead to market share and price erosion and have a negative impact on our business and results of operations.

Our success depends in large part on our ability to operate without infringing upon the patents or other proprietary rights of third parties.

If we 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 and bictegravir. See also a description of our litigation regarding sofosbuvir, axicabtagene ciloleucel and bictegravir in Note 13, Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K. We are also aware of U.S. Patent Nos. 9,044,509, 9,579,333 and 9,937,191 assigned to the U.S. Department of Health and Human Services that purport to claim a process of protecting a primate host from infection by an immunodeficiency retrovirus by administering a combination of emtricitabine and tenofovir or TDF prior to exposure of the host to the immunodeficiency retrovirus. We have been in contact with the U.S. Department of Health and Human Services about the scope and relevance of the patents and have explained that we do not believe that these patents are valid because the patent office was not given the most relevant prior art and because physicians and patients were using the claimed methods years before the Centers for Disease Control and Prevention filed the applications for the patents.

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. 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, our business and results of operations could be adversely affected.

Manufacturing problems, including at our third-party manufacturers and corporate partners, could cause inventory shortages and delay product shipments and regulatory approvals, which may adversely affect our results of operations.

In order to generate revenue from our products, we must be able to produce sufficient quantities of our products to satisfy demand. Many of our products are the result of complex manufacturing processes. The manufacturing process for pharmaceutical products is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Our products are either manufactured at our own facilities or by third-party manufacturers or corporate partners. We depend on third parties to perform manufacturing activities effectively and on a timely basis for the majority of our solid dose products.

We, our third-party manufacturers and our 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 EMA. Similar regulations are in effect in other jurisdictions.

Our third-party manufacturers and corporate partners are independent entities subject to their own unique operational and financial risks that are out of our control. If we or any of these third-party manufacturers or corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or could cause delays in our clinical trials and applications for regulatory approval. Further, we may have to write-off the costs of manufacturing any batch that fails to pass quality inspection or meet regulatory approval. In addition, we, our third-party manufacturers and our corporate partners may only be able to produce some of our products at one or a limited number of facilities and, therefore, have limited manufacturing capacity for certain products, and we may not be able to locate additional or replacement facilities on a reasonable basis or at all. Our sales of such products could also be adversely impacted by our reliance on such limited number of facilities. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

Our manufacturing operations are subject to routine inspections by regulatory agencies. If we are unable to remedy any deficiencies cited by FDA in these inspections, our currently marketed products and the timing of regulatory approval of products 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. If approval of any of our product candidates were delayed or if production of our marketed products was interrupted, our anticipated revenues and our stock price would be adversely affected.

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

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

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 ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the 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, which would in turn decrease our revenues and harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made 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 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 would 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 provide our products and product candidates to patients would be jeopardized.

Imports from countries where our products are available at lower prices and unapproved generic or counterfeit versions of our products could have a negative impact on our reputation and business.

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 into those or other countries from lower price markets. If our HIV, HBV and HCV products, which we have agreed to make available at substantially reduced prices to certain low- and middle-income countries participating in our Gilead Access Program, are re-exported from these low- and

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middle-income countries into the United States, Europe or other higher price markets, our revenues would be adversely affected. In addition, we have entered into voluntary licensing agreements with generic drug companies in India, South Africa and China, as well as a licensing agreement with the Medicines Patent Pool, a United Nations-backed public health organization, which allows generic drug companies to manufacture generic versions of HIV and HBV products incorporating our licensed compounds, TAF, cobicistat, elvitegravir and bictegravir, for distribution in certain low- and middle-income countries. We have also entered into agreements with generic manufacturers in India, Egypt and Pakistan allowing them to produce and/or distribute generic versions of our HCV products in certain low- and middle-income countries. If generic versions of our HIV, HBV and HCV products produced and/or distributed under these agreements are then re-exported to the United States, Europe or other markets outside of these low- and middle-income countries, our revenues would be adversely affected. In addition, 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 may adversely impact our revenues and gross margin and may cause our sales to fluctuate from quarter to quarter. Additionally, use of these diverted products could occur in countries where they have not been approved and patients could source the product outside the legitimate supply chain. Therefore, the products may be handled, shipped and stored inappropriately, which may affect the efficacy of the product and could harm patients, our brands or the commercial or scientific reputation of our products.

In the European Union, we are required to permit products purchased in one EU member state to be sold in another EU 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. These quarterly fluctuations may impact our earnings, which could adversely affect our stock price and harm our business.

We are also aware of the existence of various “Buyers Clubs” around the world that promote the personal importation of generic versions of our HCV and HIV products that have not been approved for use in the countries into which they are imported. As a result, patients may be at risk of taking unapproved medications which may not be what they purport to be, may not have the potency they claim to have or may contain harmful substances. To the extent patients take unapproved generic versions of one or more of our medications and are injured by these generic products, our brands or the commercial or scientific reputation of our HCV and HIV products could be harmed.

Further, third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous quality standards of our manufacturing and supply chain. For example, in 2017 and 2018, there were reports that a product labeled as Epclusa was available in multiple countries, which we determined was not authentic product based on sample analysis and the lot number. We have cooperated and continue to cooperate with regulatory authorities to investigate this matter. We actively take actions to discourage counterfeits of our products around the world, including working with local regulatory and legal authorities to enforce laws against counterfeit drugs, raising public awareness of the dangers of counterfeit drugs and promoting public policies to hinder the sale and availability of counterfeit drugs. Counterfeit drugs pose a serious risk to patient health and safety and may raise the risk of product recalls. Our reputation and business could suffer as a result of counterfeit drugs sold under our brand name.

Expensive litigation and government investigations have increased our expenses which may continue to reduce our earnings.

We are involved in a number of litigation, investigation and other dispute-related matters that require us to expend substantial internal and financial resources. 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 will continue to reduce our earnings and require significant management attention. For a description of our litigation, investigation and other dispute-related matters, see Note 13, Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of our 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 that could significantly reduce our earnings and cash flows and harm our business.

We may face significant liability resulting from our products and such liability could materially reduce our earnings. 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. If we do not maintain adequate coverage or if claims exceed our coverage, our financial condition will be adversely affected. In addition, negative publicity associated with any claims, regardless of their merit, may decrease the future demand for our products and impair our financial condition. For a description of our products liability matters, see Note 13, Commitments and Contingencies of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K.

If we fail to attract and retain highly qualified personnel, we may be unable to successfully develop new product candidates, conduct our clinical trials and commercialize our product candidates.

Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Competition for qualified personnel in the biopharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. We may not be able to attract and retain quality personnel on acceptable terms. 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 jurisdictions in which we have operations and could impair our ability to attract and retain qualified personnel. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.

At the end of 2018, John F. Milligan stepped down as our President and Chief Executive Officer following 28 years of service. We announced that Daniel P. O'Day will serve as our Chief Executive Officer, effective March 1, 2019. If we do not successfully manage the transition to a new Chief Executive Officer in 2019, our business may be negatively impacted.

Business disruptions from natural or man-made disasters may harm our future revenues.

Our worldwide operations, third party manufacturers or corporate partners could be subject to business interruptions stemming from natural or man-made disasters, including those related to climate change, for which we or they may be uninsured or inadequately insured. Our corporate headquarters in Foster City and our Santa Monica location, which together house a majority of our R&D activities, and our San Dimas, La Verne, Oceanside and El Segundo manufacturing facilities are located in California, a seismically active region. As we may not carry adequate earthquake insurance and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake.

We are dependent on information technology systems, infrastructure and data, which may be subject to cyberattacks and security breaches.

We are dependent upon information technology systems, infrastructure and data, including our Kite Konnect platform, which is critical to ensure chain of identity and chain of custody of Yescarta. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others pose a risk that sensitive data, including our intellectual property or trade secrets or the personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, 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. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions or identify breaches in our systems. Such interruptions or breaches could adversely affect our business and operations and/or cause the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our insurance may not be sufficient in type or amount to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Regulators globally are also imposing new data security requirements, including greater monetary fines for privacy violations. For example, the General Data Protection Regulation (GDPR) that became effective in Europe in 2018 established new 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, we may be subject to additional data privacy and security laws, such as the California Consumer Privacy Act of 2018. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, including 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.

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 including Ireland. Due to economic and political conditions, various countries are actively considering and have made changes to existing tax laws. We cannot predict the form or timing of potential legislative and regulatory changes that could have a material adverse impact on our results of operations. For example, the United States enacted significant tax reform, and certain provisions of the new law are complex and will continue to significantly affect us.

In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to, changes in forecasted demand for our HCV products, our portion of the non-tax deductible annual branded prescription drug fee, the accounting for stock options and other share-based awards, mergers and acquisitions, the ability to manufacture product in our Cork, Ireland facility, the amortization of certain acquisition related intangibles for which we receive no tax benefit, future levels of R&D spending, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings, resolution of federal, state and foreign income tax audits, and potential changes to our legal entity structure. The impact on our income tax provision resulting from the above mentioned factors may be significant and could have a negative impact on our consolidated results of operations.

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 for the tax years from 2013 to 2015 and by various state and 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. Resolution of one or more of these exposures in any reporting period could have a material impact on the results of operations for that period.

See Note 18, Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for additional details.

There can be no assurance that we will pay dividends or continue to repurchase stock.

Our Board of Directors authorized a dividend program under which we intend to pay quarterly dividends of $0.63 per share, subject to quarterly declarations by our Board of Directors. Our Board of Directors also approved the repurchase of up to $12.0 billion of our common stock, of which $5.1 billion is available for repurchase as of December 31, 2018. Any future declarations, amount and timing of any dividends and/or the amount and timing of such stock repurchases are subject to capital availability and determinations by our Board of Directors that cash dividends and/or stock repurchases are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the declaration and payment of cash dividends and the repurchase of stock. Our ability to pay dividends and/or repurchase stock will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, including acquisitions, debt service requirements, results of operations, financial condition and other factors beyond our control that our Board of Directors may deem relevant. A reduction in or elimination of our dividend payments, our dividend program and/or stock repurchases could have a negative effect on our stock price.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Foster City, California, where we house our administrative, manufacturing and R&D activities. We also have R&D facilities in Emeryville, Oceanside, Santa Monica, California; Gaithersburg, Maryland; Seattle, Washington; Edmonton, Alberta, Canada; and Amsterdam, Netherlands and manufacturing facilities in El Segundo, La Verne, Oceanside, San Dimas, California; Alberta, Canada; and Dublin and Cork, Ireland. 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 in good condition 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, please see Note 13, Commitments and Contingencies - Legal Proceedings of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K, which is incorporated herein by reference.

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 15, 2019, we had 1,275,510,558 shares of common stock outstanding held by approximately 375 stockholders of record, which include shares held by a broker, bank or other nominee.

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]

Notes:

(1) This section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the 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, 2013, 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, 2018:

Plan Category	Number of Common Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a) (in thousands)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b) [1] (in dollars)	Number of Common Shares Remaining Available for Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a) (c) (in thousands)
Equity Compensation plans approved by security holders :			
2004 Equity Incentive Plan	23,524	$ 53.80	91,441
Employee Stock Purchase Plan [2]			10,491
Total equity compensation plans approved by security holders	23,524	$ 53.80	101,932
Equity Compensation plans not approved by security holders	—	—	—
Total	23,524	$ 53.80	101,932

Notes:

(1) Does not take into account 16 million restricted stock and stock unit awards, performance share units and phantom shares granted under our 2004 Equity Incentive Plan.

(2) 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.

Issuer Purchases of Equity Securities

In the first quarter of 2016, our Board of Directors authorized a $12.0 billion share 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.

During 2018, we repurchased and retired 40 million shares of our common stock for $2.9 billion through open market transactions under the 2016 Program.

The table below summarizes our stock repurchase activity for the three months ended December 31, 2018:

	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 Program (in millions)

October 1 - October 31, 2018	804		$ 73.96	751		$ 6,053
November 1 - November 30, 2018	5,922		$ 69.16	5,696		$ 5,660
December 1 - December 31, 2018	7,642		$ 67.39	7,608		$ 5,147
Total	14,368	(1)	$ 68.49	14,055	(1)	

Notes:

(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 unit awards in order to satisfy applicable tax withholding obligations.

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ITEM 6. SELECTED FINANCIAL DATA
GILEAD SCIENCES, INC.
SELECTED CONSOLIDATED FINANCIAL DATA
(in millions, except per share data)

	Year Ended December 31,				
	2018	2017	2016	2015	2014
CONSOLIDATED STATEMENT OF INCOME DATA[1]:					
Total revenues [2]	$22,127	$26,107	$30,390	$32,639	$24,890
Total costs and expenses	$13,927	$11,983	$12,757	$10,446	$9,625
Income from operations	$8,200	$14,124	$17,633	$22,193	$15,265
Provision for income taxes[3]	$2,339	$8,885	$3,609	$3,553	$2,797
Net income[2][3]	$5,460	$4,644	$13,488	$18,106	$12,059
Net income attributable to Gilead[2][3]	$5,455	$4,628	$13,501	$18,108	$12,101
Net income per share attributable to Gilead common stockholders - basic[2][3]	$4.20	$3.54	$10.08	$12.37	$7.95
Shares used in per share calculation - basic	1,298	1,307	1,339	1,464	1,522
Net income per share attributable to Gilead common stockholders - diluted[2][3]	$4.17	$3.51	$9.94	$11.91	$7.35
Shares used in per share calculation - diluted	1,308	1,319	1,358	1,521	1,647
Cash dividends declared per share	$2.28	$2.08	$1.84	$1.29	$—

	December 31,				
	2018	2017	2016	2015	2014
CONSOLIDATED BALANCE SHEET DATA[1]:					
Cash, cash equivalents and marketable debt securities[4]	$31,512	$36,694	$32,380	$26,208	$11,726
Working capital[4][5]	$25,231	$20,188	$10,370	$14,044	$11,453
Total assets[4][6]	$63,675	$70,283	$56,977	$51,716	$34,601
Other long-term obligations[5]	$1,040	$558	$297	$395	$594
Long-term debt, including current portion[4][6]	$27,322	$33,542	$26,346	$22,055	$12,341
Retained earnings[2][3]	$19,024	$19,012	$18,154	$18,001	$12,732
Total stockholders' equity[2][3]	$21,534	$20,501	$19,363	$19,113	$15,819

Notes:

(1) See Management's Discussion and Analysis of Financial Condition and Results of Operations included in Item 7 of this Annual Report on Form 10-K for a description of our results of operations for 2018.

(2) In 2018, we adopted Accounting Standards Update No. 2014-09 (Topic 606) "Revenue from Contracts with Customers" using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. As such, results for 2018 are presented under Topic 606, while the information for prior periods has not been adjusted and continues to be reported in accordance with our historical accounting under Topic 605 "Revenue Recognition". The impact as a result of applying Topic 606 in place of Topic 605 was not material for the year ended December 31, 2018. See Note 1, Organization and Summary of Significant Accounting Policies, and Note 2, Revenues, of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for further information.

(3) In December 2017, we recorded an estimated $5.5 billion net charge related to the enactment of the Tax Cuts and Jobs Act. See Note 18, Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional details.

(4) In 2018, we repaid $1.8 billion principal amount of our senior unsecured notes at maturity and repaid $4.5 billion of term loans borrowed in connection with our acquisition of Kite Pharma, Inc. (Kite).
In 2017, in connection with the acquisition of Kite, we issued $3.0 billion aggregate principal amount of senior unsecured notes in a registered offering and drew on a $6.0 billion aggregate principal amount term loan facility

credit agreement, of which $1.5 billion was repaid in December 2017.
In 2016, we issued $5.0 billion principal amount of senior unsecured notes in a registered offering. We also repaid $285 million of principal balance of convertible senior notes due in May 2016 and $700 million of principal balance of senior unsecured notes due in December 2016.
In 2015, we issued $10.0 billion principal amount of senior unsecured notes in a registered offering. We also repaid $213 million of principal balance of convertible senior notes due in May 2016.
In 2014, we issued $8.0 billion principal amount of senior unsecured notes in registered offerings. We also repaid $912 million of principal balance of convertible senior notes due in May 2014, $750 million of principal balance of senior unsecured notes due in December 2014 and $600 million under our five-year revolving credit facility agreement.

(5) In 2017, we retrospectively adopted Accounting Standards Update No. 2015-17 “Balance Sheet Classification of Deferred Taxes,” which requires deferred tax assets and liabilities be classified as noncurrent on the balance sheet. As a result, we reclassified deferred tax assets from Total current assets to Other long-term assets and our deferred tax liabilities from Other accrued liabilities to Other long-term obligations for each of the years presented.

(6) In 2016, we retrospectively adopted Accounting Standards Update No. 2015-03 “Simplifying the Presentation of Debt Issuance Costs,” which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet. As a result, we reclassified unamortized debt issuance costs from assets to Long-term debt, including current portion for each of the years presented.

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"). 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), incorporated in Delaware on June 22, 1987, is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. With each new discovery and investigational drug candidate, we strive to transform and simplify care for people with life-threatening illnesses around the world. We have operations in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead's primary areas of focus include HIV/AIDS, liver diseases, hematology/oncology and inflammation/respiratory diseases. We seek to add to our existing portfolio of products through our internal discovery and clinical development programs, product acquisition, in-licensing and strategic collaborations.

Our portfolio of marketed products includes AmBisome®, Atripla®, Biktarvy®, Cayston®, Complera®/Eviplera®, Descovy®, Emtriva®, Epclusa®, Genvoya®, Harvoni®, Hepsera®, Letairis®, Odefsey®, Ranexa®, Sovaldi®, Stribild®, Truvada®, Tybost®, Vemlidy®, Viread®, Vosevi®, Yescarta® and Zydelig®. We also sell and distribute certain products through our corporate partners under collaborative agreements.

2018 Business Highlights

2018 was marked by operational excellence and transition as we positioned ourselves for the future growth of our business. We continued to develop and deliver innovative medicines to help people with life-threatening illnesses around the world. Highlights of our 2018 performance include:

- HIV: We achieved record sales of our HIV products in 2018, with HIV product revenues increasing by 19% in the United States and 12% worldwide compared to 2017. This growth was driven by the successful launch of Biktarvy and the continued strong uptake of our single tablet regimens containing tenofovir alafenamide (TAF) for the treatment of HIV infection as well as Truvada for a pre-exposure prophylaxis (PrEP) indication for HIV prevention. Biktarvy, a once-daily single tablet regimen containing bictegravir, emtricitabine (FTC) and TAF for the treatment of HIV infection in adults, was approved by the U.S. Food and Drug Administration (FDA) in February and by the European Commission in June.
- Liver Diseases: Our revenues from our chronic hepatitis C virus (HCV) products became more predictable in 2018. Because we wanted to introduce a lower-priced alternative to our HCV products without significant disruption to the healthcare system and our business, we authorized the launch of generic versions of Epclusa and Harvoni in the United States starting in January 2019 through our separate subsidiary, Asegua Therapeutics LLC (Asegua). We also continued to advance our clinical trials for the treatment of chronic hepatitis B virus (HBV) and nonalcoholic steatohepatitis (NASH), including completing enrollment of Phase 3 clinical trials of NASH.
- Cell Therapy and Immuno-Oncology: We advanced our pipeline of cancer therapies and positioned ourselves as a leader in cell therapy. Yescarta was approved by the European Commission in August for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) after two or more lines of systemic therapy. We certified additional centers in the United States and Europe to provide treatment for Yescarta. In order to advance and accelerate research and development efforts in cell therapy and immuno-oncology, during the year, we entered into key strategic collaborations with the National Cancer Institute, Pfizer, Inc. (Pfizer), Sangamo Therapeutics, Inc. (Sangamo), Gadeta B.V. (Gadeta), HiFiBiO Therapeutics (HiFiBiO), Tango Therapeutics (Tango) and Agenus Inc. (Agenus).
- Inflammation: We continued to advance our pipeline of novel investigational agents for inflammatory diseases, including announcing positive data on filgotinib in ongoing Phase 2 and 3 clinical trials. We also entered into a

strategic collaboration with Verily Life Sciences LLC, an Alphabet company (Verily), using Verily's Immunoscape platform to identify and better understand the immunological basis of inflammatory diseases.

During the year, we continued to invest in and advance our research and development pipeline across our therapeutic areas. At the end of 2018, our research and development pipeline included 119 active clinical studies, of which 41 were Phase 3 clinical trials. Additionally, we completed 26 collaborations, partnerships and strategic investments in 2018, which reflects our commitment to enabling our access to new technologies and drug candidates with the potential to evolve care for people with life-threatening illnesses. Our investments in research and development reflect our commitment to expanding our pipeline across a range of diseases to address areas of significant unmet medical need and positioning ourselves for the long-term growth of our business.

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Recent key announcements include:

HIV and Liver Diseases Programs

- FDA and European Commission granted marketing authorization for Biktarvy for the treatment of HIV-1 infection.
- FDA approved Truvada - in combination with safer sex practices - to reduce the risk of sexually acquired HIV-1 in at-risk adolescents.
- China National Drug Administration (CDA, succeeded by China National Medical Products Administration (NMPA)) approved Genvoya in China for the treatment of HIV-1 infection.
- NMPA approved Descovy in China for the treatment of HIV-1 infection in adults and adolescents.
- We entered into an agreement with Japan Tobacco Inc. (Japan Tobacco) to expand our rights to develop and commercialize elvitegravir to include Japan and to acquire from Japan Tobacco the rights to market and distribute certain products in our HIV portfolio in Japan effective January 1, 2019.
- We entered into a research collaboration and license agreement with Hookipa Biotech AG (Hookipa) that grants us exclusive rights to Hookipa's TheraT® and Vaxwave® arenavirus vector-based immunization technologies for chronic HBV infection and HIV infection.
- We announced plans to launch authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua.
- NMPA approved Harvoni in China for the treatment of chronic HCV infection with genotype 1-6 in adults and adolescents aged 12 to 18 years.
- CDA approved Epclusa in China for the treatment of adults with genotype 1-6 chronic HCV infection. The CDA also approved Epclusa in combination with ribavirin for adults with chronic HCV infection and decompensated cirrhosis.
- NMPA approved Vemlidy in China for the treatment of chronic HBV infection in adults and adolescents.
- We entered into a strategic collaboration with Precision BioSciences (Precision) to develop therapies targeting the in vivo elimination of chronic HBV infection with Precision's proprietary genome editing platform, ARCUS.
- We announced that STELLAR-4, a Phase 3, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of selonsertib, an investigational, once-daily, oral inhibitor of apoptosis signal-regulating kinase 1 (ASK1), in patients with compensated cirrhosis (F4) due to NASH, did not meet the pre-specified week 48 primary endpoint of a ≥ 1-stage histologic improvement in fibrosis without worsening of NASH.

Oncology and Cell Therapy Programs

- We entered into an immuno-oncology partnership with Agenus focused on the development and commercialization of up to five novel immuno-oncology therapies.
- We entered into a global strategic collaboration with Tango to discover, develop and commercialize a pipeline of targeted immuno-oncology treatments for patients with cancer.
- European Commission granted marketing authorization for Yescarta as a treatment for adult patients with relapsed or refractory DLBCL and PMBCL after two or more lines of systemic therapy.
- We announced new worldwide facilities to advance manufacturing of cell therapies for people with cancer.
- We entered into a research collaboration with Gadeta to advance gamma delta T cell receptor technology for solid tumors. This collaboration adds an additional new platform to our current capabilities in research and cell manufacturing.
- We entered into a research collaboration and license agreement with HiFiBiO to develop technology supporting the discovery of neoantigen-reactive T cell receptors for the potential treatment of various cancers, including solid tumors.
- We entered into a license agreement with Trianni, Inc. (Trianni) that grants us the use of the Trianni transgenic human monoclonal antibody discovery platform to support our drug discovery efforts.
- We announced a new cooperative research and development agreement with the National Cancer Institute to develop adoptive cell therapies targeting patient-specific tumor neoantigens.
- We entered into a worldwide collaboration with Sangamo using Sangamo's zinc finger nuclease technology platform for the development of next-generation ex vivo cell therapies in oncology.
- We entered into a clinical trial collaboration with Pfizer to evaluate the safety and efficacy of the investigational combination of Yescarta and Pfizer's utomilumab, a fully humanized 4-1BB agonist monoclonal antibody, in patients

with refractory large B-cell lymphoma.

Inflammation Programs

- We entered into a strategic collaboration with Scholar Rock Holding Corporation to discover and develop highly specific inhibitors of transforming growth factor beta activation for the treatment of fibrotic diseases.

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- We entered into a scientific collaboration with Verily, using Verily's Immunoscape platform to identify and better understand the immunological basis of three common and serious inflammatory diseases: rheumatoid arthritis, inflammatory bowel disease and lupus-related diseases.

Transition

- Following 28 years of service, John F. Milligan, Ph.D., stepped down from his role as President and Chief Executive Officer (CEO) effective December 31, 2018. Our Board announced the selection of Daniel O'Day to be our new Chairman and CEO effective March 1, 2019. Mr. O'Day brings more than 30 years of executive management, creative leadership and operational excellence. Most recently, Mr. O'Day served as the CEO of Roche Pharmaceuticals, the pharma division of Roche Group. We had other leadership transitions throughout the year resulting from planned successions and normal industry turnover.

2018 Financial Highlights

Total revenues decreased to $22.1 billion and total product sales decreased to $21.7 billion in 2018, compared to $26.1 billion and $25.7 billion in 2017, respectively, primarily due to lower sales of our HCV products, partially offset by higher sales of our HIV products. In the United States, product sales were $16.2 billion in 2018, compared to $18.1 billion in 2017. In Europe, product sales were $3.7 billion in 2018, compared to $5.0 billion in 2017. Product sales in other international locations were $1.8 billion in 2018, compared to $2.6 billion in 2017.

Cost of goods sold increased to $4.9 billion in 2018, compared to $4.4 billion in 2017, primarily due to reserves for excess raw material inventory, and higher amortization related to intangible assets acquired in connection with our acquisition of Kite Pharma, Inc. (Kite). In 2018, inventory reserves of $440 million were recorded for excess raw materials primarily due to a sustained decrease in demand for Harvoni as a result of a shift in the market from Harvoni to Epclusa.

Research and development (R&D) expenses increased to $5.0 billion in 2018, compared to $3.7 billion in 2017, primarily due to an $820 million impairment charge related to in-process R&D (IPR&D) for the KITE-585 program (an anti-BCMA being evaluated for the treatment of multiple myeloma), an increase in up-front collaboration expenses to further enhance our pipeline, a full year of investments to support the growth of our business following the acquisition of Kite and higher stock-based compensation expenses associated with the acquisition of Kite.

Selling, general and administrative (SG&A) expenses increased to $4.1 billion for 2018, compared to $3.9 billion in 2017, primarily due to a full year of investments to support the growth of our business following the acquisition of Kite, partially offset by lower acquisition-related costs associated with the acquisition of Kite and lower branded prescription drug (BPD) fees.

Net income attributable to Gilead was $5.5 billion or $4.17 per diluted share in 2018, compared to $4.6 billion or $3.51 per diluted share in 2017. The increase was primarily due to a $5.5 billion charge to income tax expense related to the enactment of the Tax Cuts and Jobs Act (Tax Reform) recorded in 2017 and higher HIV product sales in 2018, partially offset by lower HCV product sales and higher operating expenses associated with advancement of our pipeline and investments to support the growth of our business following the acquisition of Kite in 2018.

As of December 31, 2018, we had $31.5 billion of cash, cash equivalents and marketable debt securities compared to $36.7 billion as of December 31, 2017. During 2018, we generated $8.4 billion in operating cash flow, repaid $6.3 billion of principal amount of debt, paid cash dividends of $3.0 billion and repurchased a total of 40 million shares for $2.9 billion through open market transactions.

Outlook 2019

In 2019, we expect to continue to maintain our strong focus on operational excellence and financial discipline. From an R&D perspective, we expect to continue to invest in new and ongoing clinical studies that support both our existing products and product candidates. We expect data read-outs in 2019 including selonsertib or STELLAR-3 for the treatment of NASH, filgotinib for the treatment of rheumatoid arthritis, and Descovy for PrEP indication. In order to further augment our product pipeline, we continue to pursue opportunities for collaborations, partnerships and strategic investments that fit into our long term strategic plan.

From a commercial perspective, we expect to continue to promote Biktarvy and other HIV regimens containing TAF. In addition, we believe Truvada for PrEP will continue to be an integral part of our growth in HIV in the United States as communities continue to embrace the public health benefits of prevention. In HCV, we expect a decline in product sales as a result of lower patient starts across all markets and competitive factors, although at a lower rate than in 2018. We believe the launch of authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua, will increase access to the medications for patients at lower prices. In cell therapy, we expect to continue to promote Yescarta in the United States and support its launch in Europe.

We will continue to help promote patient access to our products around the world, including through our Gilead Access Program, under which more than 11 million people receive our HIV medicines in low- and middle-income countries.

Our progress on all of these initiatives is subject to a number of uncertainties, including, but not limited to, the possibility of unfavorable results from new and ongoing clinical trials (for example, we recently announced that STELLAR-4, a Phase 3 study evaluating the safety and efficacy of selonsertib in patients with compensated cirrhosis due to NASH, did not meet the pre-specified week 48 primary endpoint); the continuation of an uncertain global macroeconomic environment; additional pricing pressures from payers and competitors; slower than anticipated growth in our HIV products; an increase in discounts, chargebacks and rebates due to ongoing contracts and future negotiations with commercial and government payers; market share and price erosion caused by the introduction of generic versions of products containing tenofovir disoproxil fumarate (TDF) outside the United States and Viread, Letairis and Ranexa in the United States; inaccuracies in our HCV patient start estimates; potential amendments to the Affordable Care Act or other government action that could have the effect of lowering prices; a larger-than-anticipated shift in payer mix to more highly discounted payer segment; and volatility in foreign currency exchange rates.

2018 Results of Operations

Total Revenues

The following table summarizes the period-over-period changes in our product sales and royalty, contract and other revenues:

(In millions, except percentages)	2018	Change	2017	Change	2016
Revenues:					
Product sales	$21,677	(16)%	$25,662	(14)%	$29,953
Royalty, contract and other revenues	450	1 %	445	2 %	437
Total revenues	$22,127	(15)%	$26,107	(14)%	$30,390

On January 1, 2018, we adopted Accounting Standards Update No. 2014-09 “Revenue from Contracts with Customers” (Topic 606) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. As such, results for 2018 are presented under Topic 606, while the information for prior periods has not been adjusted and continues to be reported in accordance with our historical accounting under Topic 605 “Revenue Recognition” (Topic 605). The impact as a result of applying Topic 606 in place of Topic 605 was not material for the year ended December 31, 2018. See Note 1, Organization and Summary of Significant Accounting Policies, and Note 2, Revenues, of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for further information.

Product Sales

2018 Compared to 2017

Total product sales decreased by 16% to $21.7 billion in 2018, compared to $25.7 billion in 2017, primarily due to lower sales of our HCV products, partially offset by increased sales of our HIV products.

HIV product sales increased by 12% to $14.6 billion in 2018, compared to $13.0 billion in 2017, primarily due to the launch of Biktarvy in 2018 and the continued uptake of Descovy, Genvoya and Odefsey.

HCV product sales decreased by 60% to $3.7 billion in 2018, compared to $9.1 billion in 2017, primarily due to lower average net selling price and lower sales volume across all major markets as a result of increased competition and lower patient starts.

Yescarta generated $264 million in sales in 2018, compared to $7 million in sales in 2017.

Other product sales, which include products from our HBV, cardiovascular, oncology and other categories inclusive of Vemlidy, Viread, Letairis, Ranexa, Zydelig and AmBisome, decreased by 12% to $3.1 billion in 2018, compared to $3.5 billion in 2017. Sales of Viread, which is primarily used for the treatment of chronic HBV infection, decreased due to the availability of generic versions of the product. Letairis is expected to face generic competition in the United States because the U.S. patent for ambrisentan, the active pharmaceutical ingredient in Letairis, expired in July 2018. Ranexa is also expected to face generic competition in the United States. We expect a decline in our Letairis and Ranexa sales in the United States after the generic entries.

Of our total product sales, 25% were generated outside the United States in 2018. We faced exposure to movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $94 million in 2018, compared to 2017.

We record product sales net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, including rebates, chargebacks, cash discounts for prompt payment, distributor fees and other related costs. These deductions are generally referred to as gross-to-net deductions, which totaled $16.5 billion, or 43% of gross product sales in 2018, compared to $17.2 billion, or 40% of gross products sales in 2017. Of the $16.5 billion in 2018, $14.8 billion or 39% of gross product sales was related to government and other rebates and chargebacks, and $1.7 billion was related to cash discounts for prompt payment, distributor fees and other related costs.

Product sales in the United States decreased by 11% to $16.2 billion in 2018, compared to $18.1 billion in 2017. The decrease was primarily due to lower sales of our HCV products, partially offset by higher sales of our HIV products. The decrease in sales of our HCV products was primarily due to lower average net selling price and lower sales volume as a result of increased competition. The increase in the sales of our HIV products was primarily due to the launch of Biktarvy in 2018, the continued uptake of Descovy, Genvoya and Odefsey, the increased usage of Truvada for PrEP and higher average net selling price, partially offset by the decreases in sales volume of Atripla, Complera and Stribild.

Product sales in Europe decreased by 26% to $3.7 billion in 2018, compared to $5.0 billion in 2017. The decrease was primarily due to lower sales of our HCV products and the availability of generic versions of Truvada, Atripla and Viread. The decrease in sales of our HCV products was primarily due to lower sales volume and average net selling price as a result of increased competition. The decrease was partially offset by our launch of Biktarvy in 2018 and the continued uptake of Descovy, Genvoya and Odefsey. Foreign currency exchange, net of hedges, had a favorable impact on our product sales in Europe of $68 million in 2018, compared to 2017.

Product sales in other international locations decreased by 30% to $1.8 billion in 2018, compared to $2.6 billion in 2017, primarily due to lower sales of our HCV products in Japan. Sales of our HCV products in Japan decreased to $167 million for 2018, compared to $692 million in 2017, primarily due to lower market share as a result of increased competition.

2017 Compared to 2016

Total product sales decreased by 14% to $25.7 billion in 2017, compared to $30.0 billion in 2016, primarily due to lower sales of our HCV products, partially offset by increased sales of our HIV products.

HIV product sales increased by 11% to $13.0 billion in 2017, compared to $11.7 billion in 2016, primarily driven by the continued uptake of Descovy, Genvoya and Odefsey, partially offset by decreases in sales of Truvada, Atripla, Complera and Stribild.

HCV product sales decreased by 38% to $9.1 billion in 2017, compared to $14.8 billion in 2016, primarily due to declines across all major markets as a result of increased competition and lower total market patient starts.

Other product sales, which include products from our HBV, cardiovascular, oncology and other categories inclusive of Vemlidy, Viread, Letairis, Ranexa, Zydelig and AmBisome, increased by 2% to $3.5 billion in 2017, compared to $3.4 billion in 2016.

Of our total product sales, 29% were generated outside the United States in 2017. We faced exposure to movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales of $117 million in 2017, compared to 2016.

Our gross-to-net deductions totaled $17.2 billion, or 40% of gross product sales in 2017, compared to $20.3 billion, or 40% of gross products sales in 2016. Of the $17.2 billion in 2017, $15.5 billion or 36% of gross product sales was related to government and other rebates and chargebacks, and $1.7 billion was related to cash discounts for prompt payment, distributor fees and other related costs.

Product sales in the United States decreased by 6% to $18.1 billion in 2017, compared to $19.3 billion in 2016. The declines in sales of our HCV products was partially offset by the increase in sales of our HIV products. The declines in sales of our HCV products was primarily due to lower Harvoni and Sovaldi sales volume as a result of increased competition and lower total market patient starts. Additionally, increases in Epclusa and Vosevi sales volume were partially offset by lower average net selling price for Epclusa as pricing of all regimens has gravitated towards the 8-week regimen price. The increase in the sales of our HIV products was primarily due to the continued uptake of Descovy, Genvoya and Odefsey and higher average net selling prices, partially offset by decreases of Truvada, Atripla, Complera and Stribild and the prior year favorable impact of a revision to our rebate reserves of $332 million, primarily related to Truvada, Atripla, Complera and Stribild.

Product sales in Europe decreased by 18% to $5.0 billion in 2017, compared to $6.1 billion in 2016, primarily due to lower Harvoni and Sovaldi sales volume, partially offset by higher Epclusa sales volume. Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales in Europe of $89 million in 2017 compared to 2016. Product sales in other international locations decreased by 45% to $2.6 billion in 2017, compared to $4.6 billion in 2016, primarily due to lower sales in Japan. Sales of our HCV products in Japan decreased to $692 million in 2017, compared to $2.5 billion in 2016, primarily due to lower sales volume as a result of lower total market patient starts and increased competition.

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

(In millions, except percentages)	2018	Change	2017	Change	2016
Atripla	$1,206	(33)%	$1,806	(31)%	$2,605
Biktarvy	1,184	*	—	*	—
Complera/Eviplera	653	(32)%	966	(34)%	1,457
Descovy	1,581	30 %	1,218	*	298
Genvoya	4,624	26 %	3,674	*	1,484
Odefsey	1,598	44 %	1,106	*	329
Stribild	644	(39)%	1,053	(45)%	1,914
Truvada	2,997	(4)%	3,134	(12)%	3,566
Other HIV(1)	61	5 %	58	23 %	47
Revenue share - Symtuza(2)	79	*	—	*	—
Total HIV	14,627	12 %	13,015	11 %	11,700
AmBisome	420	15 %	366	3 %	356
Epclusa	1,966	(44)%	3,510	100 %	1,752
Harvoni	1,222	(72)%	4,370	(52)%	9,081
Letairis	943	6 %	887	8 %	819
Ranexa	758	6 %	717	6 %	677
Vemlidy	321	*	122	*	3
Viread	307	(71)%	1,046	(12)%	1,186
Vosevi	396	35 %	293	*	—
Yescarta	264	*	7	*	—
Zydelig	133	(11)%	149	(11)%	168
Other(3)	320	(73)%	1,180	(72)%	4,211
Total product sales	$21,677	(16)%	$25,662	(14)%	$29,953

Notes:
* Percentage not meaningful
(1) Includes Emtriva and Tybost
(2) Represents our revenue from cobicistat (C), FTC and TAF in Symtuza® (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen
(3) Includes Cayston, Hepsera and Sovaldi

The following is additional discussion of our results on certain products:

• Descovy (FTC/TAF)-based products - Biktarvy, Descovy, Genvoya and Odefsey

Product sales of our Descovy (FTC/TAF)-based products were $9.0 billion, $6.0 billion and $2.1 billion, and were 41%, 23% and 7% of our total product sales in 2018, 2017 and 2016, respectively.

In 2018, sales of our Descovy (FTC/TAF)-based products were $7.2 billion in the United States and $1.5 billion in Europe, compared to $5.0 billion in the United States and $892 million in Europe in 2017 and $1.8 billion in the United States and $256 million in Europe in 2016.

The increase in 2018 compared to 2017 in all major markets was primarily driven by higher sales volume reflecting our launch of Biktarvy in 2018 and the continued uptake of Genvoya, Odefsey and Descovy.

The increase in 2017 compared to 2016 in all major markets was primarily driven by higher sales volume as patients shifted away from Truvada (FTC/TDF)-based regimens.

• Truvada (FTC/TDF)-based products - Atripla, Complera/Eviplera, Stribild and Truvada

Product sales of our Truvada (FTC/TDF)-based products were $5.5 billion, $7.0 billion and $9.5 billion, and were 25%, 27% and 32% of our total product sales in 2018, 2017 and 2016, respectively.

In 2018, sales of our Truvada (FTC/TDF)-based products were $4.4 billion in the United States and $815 million in Europe, compared to $4.8 billion in the United States and $1.7 billion in Europe in 2017 and $6.6 billion in the United States and $2.3 billion in Europe in 2016.

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In the United States, the decrease in 2018 compared to 2017 was primarily due to lower sales volume as a result of patients switching to newer regimens containing TAF, partially offset by the increased usage of Truvada for PrEP and higher average net selling price of certain of our Truvada (FTC/TDF)-based products. In Europe, the decrease in 2018 compared to 2017 was primarily due to lower sales volume as a result of the availability of generic versions of Truvada and Atripla and patients switching to newer regimens containing TAF.
In the United States, the decrease in 2017 compared to 2016 was primarily due to lower sales volume as a result of patients switching to newer regimens containing TAF, partially offset by the increased usage of Truvada for PrEP. In Europe, the decreases in 2017 compared to 2016 was primarily due to lower sales volume as a result of the availability of generic versions of Truvada in several countries and patients switching to newer regimens containing TAF.
•HCV products - Epclusa, Harvoni, Sovaldi and Vosevi
HCV product sales were $3.7 billion, $9.1 billion and $14.8 billion, and were 17%, 36% and 50% of our total product sales in 2018, 2017 and 2016, respectively.
In 2018, sales of our HCV products were $2.0 billion in the United States, $896 million in Europe and $767 million in other international locations. In 2017, sales of our HCV products were $5.9 billion in the United States, $1.9 billion in Europe and $1.4 billion in other international locations. In 2016, sales of our HCV products were $8.4 billion in the United States, $2.8 billion in Europe and $3.6 billion in other international locations.
The decrease in 2018 compared to 2017 in all major markets was primarily due to lower sales volume and lower average net selling price as a result of increased competition and lower total market patient starts. Harvoni and Sovaldi product sales also decreased as a result of a shift in the market from Harvoni and Sovaldi to Epclusa.
The decrease in 2017 compared to 2016 in all major markets was primarily due to lower sales volume and lower average net selling price as a result of increased competition and lower total market patient starts. Harvoni and Sovaldi product sales also decreased as a result of a shift in the market from Harvoni and Sovaldi to Epclusa. Epclusa product sales increased in 2017 compared to 2016 primarily due to a full year of sales. Epclusa was approved by FDA and European Commission in June and July 2016, respectively.
Cost of Goods Sold and Product Gross Margin
The following table summarizes the period-over-period changes in our product sales, cost of goods sold and product gross margin:

(In millions, except percentages)	2018	Change	2017	Change	2016
Total product sales	$21,677	(16)%	$25,662	(14)%	$29,953
Cost of goods sold	$4,853	11 %	$4,371	3 %	$4,261
Product gross margin	78 %		83 %		86 %

Our cost of goods sold for 2018 increased by $482 million or 11%, compared to 2017, primarily due to higher inventory reserves. In 2018, we recorded inventory reserves of $572 million, of which $440 million was related to excess raw materials primarily due to a sustained decrease in demand for Harvoni as a result of a shift in the market from Harvoni to Epclusa. Inventory reserves recorded for the years ended December 31, 2017 and 2016 were not material. Cost of goods sold also increased due to a full year of amortization expense related to intangible assets acquired in connection with our acquisition of Kite in October 2017. The increases were partially offset by lower costs of efavirenz, a component of Atripla, as a result of the termination of a collaboration arrangement with Bristol-Myers Squibb Company on December 31, 2017.
The decrease in our product gross margin in 2018 compared to 2017 was primarily due to the factors impacting cost of goods sold noted above and changes in product mix.
The decrease in our product gross margin in 2017 compared to 2016 was primarily due to changes in product mix, as our HCV product sales decreased as a percentage of total product sales.
Research and Development Expenses
The following table summarizes the period-over-period changes in R&D expenses:

(In millions, except percentages)	2018	Change	2017	Change	2016
R&D expenses	$5,018	34 %	$3,734	(27)%	$5,098

R&D expenses consist primarily of clinical studies performed by contract research organizations, materials and supplies, licenses and fees, up-front and milestone payments under collaboration agreements, personnel costs, including salaries, benefits and stock-based compensation and overhead allocations consisting of various support and facilities-related costs.

We do not track total R&D expenses by product candidate, therapeutic area or development phase. However, 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 successful development, market potential, available human and capital resources and other considerations. We continually review our R&D pipeline and the status of development and, as necessary, reallocate resources among the R&D portfolio that we believe will best support the future growth of our business.

The following table provides a breakout of R&D expenses by major cost type (in millions):

	2018	2017	2016
Clinical studies and outside services	$1,665	$1,881	$2,446
Personnel, infrastructure and other expenses	1,876	1,399	1,271
IPR&D impairment charges	820	—	432
Up-front collaboration expenses	278	—	373
Acquired IPR&D	—	222	400
Stock-based compensation expenses	379	232	176
Total	$5,018	$3,734	$5,098

In 2018, R&D expenses increased by $1.3 billion or 34%, compared to 2017, primarily due to an $820 million impairment charge related to the IPR&D for the KITE-585 program due to its discontinuance, an increase in up-front collaboration expenses and higher personnel and facilities-related costs to support the growth of our business following the acquisition of Kite, partially offset by higher acquired IPR&D expense in 2017 as a result of our purchase of Cell Design Labs, Inc.

In 2017, R&D expenses decreased by $1.4 billion or 27%, compared to 2016, primarily due to the 2016 impacts of business development activities resulting in up-front collaboration expense related to our license and collaboration agreement with Galapagos NV and acquired IPR&D expense related to our purchase of Nimbus Apollo, Inc., IPR&D impairment charges and ongoing milestone payments, partially offset by acquired IPR&D expense related to our purchase of Cell Design Labs, Inc. in 2017.

Selling, General and Administrative Expenses

The following table summarizes the period-over-period changes in SG&A expenses:

(In millions, except percentages)	2018	Change	2017	Change	2016
SG&A expenses	$4,056	5 %	$3,878	14 %	$3,398

SG&A expenses relate to sales and marketing, finance, human resources, legal and other administrative activities. 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 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 and is trued-up upon receipt of invoices from the Internal Revenue Service.

In 2018, SG&A expenses increased by $178 million or 5%, compared to 2017, primarily due to a full year of expense to support the growth of our business following the acquisition of Kite, partially offset by lower acquisition-related costs associated with the acquisition of Kite and lower BPD fees.

In 2017, SG&A expenses increased by $480 million or 14%, compared to 2016, primarily due to costs associated with our acquisition of Kite, which primarily consist of stock-based compensation and transaction costs, as well as higher BPD fee expenses resulting from a favorable adjustment of $191 million in the first quarter of 2016.

BPD fee expenses were $229 million, $385 million and $270 million in 2018, 2017 and 2016, respectively. BPD fee expenses are not tax-deductible.

Other Income (Expense), Net

Other income (expense), net, was $676 million, $523 million and $428 million in 2018, 2017 and 2016, respectively. The increase in 2018 compared to 2017 was primarily due to unrealized gains from changes in the fair value of our marketable equity securities. Starting in January 2018, we recorded unrealized gains (losses) from changes in the fair value of our marketable equity securities in Other income (expense), net, on our Consolidated Statements of Income as a result of the adoption of Accounting Standards Update No. 2016-01 “Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities". See Note 1, Organization and Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for further information.

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The increase in other income (expense), net, in 2017 compared to 2016 was primarily due to our cash, cash equivalents and marketable securities earning a higher yield and higher cash balances.

Provision for Income Taxes

Provision for income taxes was $2.3 billion in 2018 compared to $8.9 billion in 2017. The 2018 effective tax rate decreased to 30.0% from the 2017 effective tax rate of 65.7%, primarily due to a $5.5 billion net tax charge in 2017 and a reduction to the U.S. corporate tax rate in 2018 as a result of the enactment of Tax Reform in December 2017. In addition, the 2018 effective tax rate was further decreased due to a $202 million tax benefit recorded in 2018 related to settlement of tax examinations, offset by a $588 million deferred tax charge in 2018 resulting from a transfer of acquired intangible assets between wholly owned subsidiaries, changes to the geographic mix of earnings and the tax on Global Intangible Low-Taxed Income (enacted as part of Tax Reform). We are continuing to evaluate certain changes to our legal entity structure in response to guidelines and requirements in various international tax jurisdictions where we conduct business. These changes may take multiple reporting periods to implement and may result in certain material, but non-recurring, adjustments to our deferred tax assets and/or liabilities, which will cause an offsetting increase or decrease to our tax provision. Estimates of these adjustments cannot be reasonably determined at this time and are dependent on the changes actually implemented.

Our provision for income taxes was $8.9 billion in 2017 compared to $3.6 billion in 2016. The 2017 effective tax rate increased to 65.7% from the 2016 effective tax rate of 21.1%, primarily due to the enactment of Tax Reform in December 2017. Changes to the geographic mix of earnings also contributed to the increase in the 2017 effective tax rate.

See Note 18, Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional details on Tax Reform.

Liquidity and Capital Resources

The following table summarizes our cash, cash equivalents, and marketable debt securities and working capital (in millions):

	December 31,	
	2018	2017
Cash, cash equivalents and marketable debt securities	$31,512	$36,694
Working capital	$25,231	$20,188

Cash, Cash Equivalents and Marketable debt Securities

Cash, cash equivalents and marketable debt securities decreased by $5.2 billion, or 14%, compared to December 31, 2017. During 2018, we generated $8.4 billion in operating cash flow, repaid $1.8 billion principal amount of senior unsecured notes at maturity, repaid $4.5 billion of term loans borrowed in connection with our acquisition of Kite, paid cash dividends of $3.0 billion and utilized $2.9 billion on stock repurchases.

Working Capital

Working capital increased by $5.0 billion, or 25%, compared to December 31, 2017, primarily driven by an increase in cash and cash equivalents resulting from a shift in the average remaining term to maturity of our marketable debt securities portfolio to reduce interest rate risk.

Cash Flows

The following table summarizes our cash flow activities (in millions):

	2018	2017	2016
Cash provided			

by (used in):			
Operating activities	$8,400	$11,898	$17,047
Investing activities	$14,355	$(16,069)	$(11,985)
Financing activities	$(12,318)	$3,393	$(9,725)

Cash Provided by 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 decreased by $3.5 billion to $8.4 billion in 2018 compared to 2017, primarily due to lower cash receipts as a result of lower product sales and higher tax payments. The tax payments made

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in 2018 included a $500 million payment related to the first annual installment of the Tax Reform transition tax, a $771 million deemed early payment of the Tax Reform transition tax and a $514 million settlement of a tax examination.

Cash provided by operating activities decreased by $5.1 billion to $11.9 billion in 2017 compared to 2016, primarily due to lower cash receipts as a result of lower product sales and higher tax payments.

Cash Provided by (Used in) Investing Activities

Cash provided by (used in) investing activities primarily consists of purchases, sales and maturities of our marketable debt securities, capital expenditures, acquisitions (net of cash acquired) and other investments.

Cash provided by investing activities was $14.4 billion in 2018 compared to cash used in investing activities of $16.1 billion in 2017. The change in cash provided by (used in) investing activities was primarily due to higher proceeds from maturities of our marketable debt securities and lower purchases of marketable debt securities, partially offset by lower proceeds from sales of our marketable debt securities. In addition, $10.4 billion cash was used to acquire Kite in 2017, whereas no cash was used for acquisitions in 2018.

Cash used in investing activities increased by $4.1 billion to $16.1 billion in 2017 compared to 2016, primarily due to our acquisition of Kite, partially offset by higher proceeds from maturities and sales of marketable debt securities and lower purchases of marketable debt securities.

Cash Provided by (Used in) Financing Activities

Cash used in financing activities was $12.3 billion in 2018, compared to cash provided by financing activities of $3.4 billion in 2017. The change in cash provided by (used in) financing activities was primarily due to higher repayment of debt and repurchases of our common stock in 2018. In addition, we had $9.0 billion net proceeds from debt issuances to partially fund our acquisition of Kite in 2017, whereas no debt was issued in 2018.

Cash provided by financing activities was $3.4 billion in 2017, compared to cash used in financing activities of $9.7 billion in 2016, primarily due to lower repurchases of our common stock and higher proceeds from the issuances of debt.

Debt and Credit Facilities

Long-Term Obligations

The 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 our Annual Report on Form 10-K.

Senior Unsecured Notes

In 2018, we repaid at maturity $1.0 billion principal amount of senior unsecured notes that were issued in September 2015 and $750 million of principal amount of senior unsecured notes that were issued in September 2017.

In 2017, in connection with our acquisition of Kite, we issued $3.0 billion aggregate principal amount of senior unsecured notes consisting of $750 million principal amount of floating rate notes due September 2018, $750 million principal amount of floating rate notes due March 2019, and $500 million principal amount of floating rate notes due September 2019 (collectively, the Floating Rate Notes) and $1.0 billion principal amount of 1.85% senior notes due September 2019 (the Fixed Rate Notes, and collectively with the Floating Rate Notes, the 2017 Notes). The Floating Rate Notes bear interest rates equal to three month London Interbank Offered Rates (LIBOR), plus 0.17% with respect to the Floating Rate Notes due September 2018, 0.22% with respect to the Floating Rate Notes due March 2019 and 0.25% with respect to the Floating Rate Notes due September 2019. The Fixed Rate Notes pay interest semiannually and the Floating Rate Notes pay interest quarterly.

We are required to comply with certain covenants under our notes indentures and as of December 31, 2018, we were not in violation of any covenants.

Term Loan Facilities

In September 2017, we entered into a $6.0 billion aggregate principal amount term loan facility credit agreement consisting of a $1.0 billion principal amount 364-day senior unsecured term loan facility, a $2.5 billion principal amount three-year senior unsecured term loan facility and a $2.5 billion principal amount five-year senior unsecured term loan facility (collectively, the Term Loan Facilities). In October 2017, we drew $6.0 billion aggregate principal amount on the Term Loan Facilities and used the proceeds to finance our acquisition of Kite, of which $1.5 billion was repaid in 2017 and the remaining $4.5 billion was repaid in 2018. The term loan facility credit agreement was terminated in 2018.

Credit Facilities

In 2016, we entered into a $2.5 billion five-year revolving credit facility maturing in May 2021 (the Five-Year Revolving Credit Agreement). The revolving credit facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. We are required to comply with certain covenants under the Five-Year Revolving Credit Agreement and as of December 31, 2018, we were not in violation of any covenants, and no amounts were outstanding under the Five-Year Revolving Credit Agreement.

Capital Return Program

The details of our Stock Repurchase Programs and Dividends are included in Note 14, Stockholders' Equity of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

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.

Repurchases under the 2016 Program were 40 million and 13 million shares of our common stock for $2.9 billion and $954 million in 2018 and 2017, respectively. As of December 31, 2018, the remaining authorized repurchase amount under the 2016 Program was $5.1 billion.

Dividends

We declared and paid quarterly cash dividends for an aggregate amount of $3.0 billion or $2.28 per common share and $2.7 billion or $2.08 per common share in 2018 and 2017, respectively.

On February 4, 2019, we announced that our Board of Directors declared a quarterly cash dividend increase of 11% from $0.57 to $0.63 per share of our common stock, with a payment date of March 28, 2019 to all stockholders of record as of the close of business on March 15, 2019. Future dividends are subject to declaration by the 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.

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.

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

Revenue Recognition

Adoption of ASC Topic 606, “Revenue from Contracts with Customers”

On January 1, 2018, we adopted Topic 606 using the modified retrospective method whereby results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605. Under Topic 606, an entity recognizes revenue when it transfers control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We recorded the cumulative effect of applying the new revenue standard as a net increase of $190 million to the opening balance of retained earnings. The impact as a result of applying Topic 606 in place of Topic 605 was not material for the year ended December 31, 2018.

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. We record product sales net of estimated mandatory and supplemental discounts to government and private payers, in addition to discounts to private payers, and other related charges. These are generally accounted for as variable consideration estimated in the same period the related sales occur. Government and other rebates and chargebacks represent the majority of our variable consideration and require complex and significant judgment by management. Estimates are assessed each period and updated to reflect current information.

Government and Other Rebates and Chargebacks

Government and other rebates and chargebacks include amounts paid to payers and healthcare providers in the United States, including Medicaid rebates, AIDS Drug Assistance Program rebates and chargebacks, Veterans Administration and Public Health Service chargebacks and other rebates, as well as foreign government rebates. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, by 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.

Our allowances for government and other rebates and chargebacks are estimated based on products sold, historical payer mix, pertinent third-party industry information, estimated patient population, known market events or trends, channel inventory data and/or other market data. We also consider new information regarding changes in programs' regulations and guidelines that would impact the amount of the actual rebates and/or our expectations regarding future payer mix for these programs. 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 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 on our Consolidated Balance Sheets and totaled $492 million and $340 million at December 31, 2018 and 2017, respectively. Government and other rebates that are invoiced directly to us are recorded in Accrued government and other rebates on our Consolidated Balance Sheets and totaled $3.9 billion and $4.7 billion at December 31, 2018 and 2017, respectively. The following table summarizes the consolidated activities and ending balances in our government and other rebates and chargebacks accounts (in millions):

Accrued government and other rebates and chargebacks:	Balance at Beginning of Year	Decrease/(Increase) to Product Sales	Payments	Balance at End of Year
Year ended December 31, 2018:				
Activity related to 2018 sales	$ —	$ 14,784	$ (10,953)	$ 3,831
Activity related to sales prior to 2018	5,044	41	(4,496)	589

Total	$ 5,044	$ 14,825	$(15,449)	$4,420
Year ended December 31, 2017:				
Activity related to 2017 sales	$ —	$ 15,809	$(11,170)	$4,639
Activity related to sales prior to 2017	5,657	(264)	(4,988)	405
Total	$ 5,657	$ 15,545	$(16,158)	$5,044

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Legal Contingencies

We are a party to various legal actions. The most significant of these are described in Note 13, Commitments and Contingencies - Legal Proceedings 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 loss is reasonably possible and the loss or range of loss can be estimated, we disclose the possible loss.

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.

We did not recognize any accruals in our Consolidated Balance Sheets for such matters as of December 31, 2018 and 2017 as we did not believe losses were probable.

Valuation of Intangible Assets

The identifiable intangible assets are measured at their respective fair values as of the acquisition date and may be subject to revision within the measurement period, which may be up to one year from the acquisition date. The models used in valuing these intangible assets require the use of significant estimates and assumptions including but not limited to:

- estimates of revenues and operating profits related to the products or product candidates;
- the probability of success for unapproved product candidates considering their stages of development;
- the time and resources needed to complete the development and approval of product candidates;
- 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 in connection with a business combination using information known and knowable and are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During the period the assets are considered indefinite-lived, they are not amortized but are tested for impairment on an annual basis as well as between annual tests if we become aware of any events or changes that would indicate that it is more likely than not that the fair values of the IPR&D projects are below their respective carrying amounts. The fair value of our indefinite-lived intangible assets is dependent on 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 and changes to our assumptions could have a significant impact on our results of operations in any given period.

Intangible assets with finite useful lives are amortized over their estimated useful lives primarily on a straight-line basis. Intangible assets with finite useful lives are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

On October 3, 2017, in connection with our Kite acquisition, we acquired intangible assets primarily related to IPR&D for axicabtagene ciloleucel, KITE-585 (an anti-BCMA, being evaluated for the treatment of multiple myeloma) and KTE-X19 (being evaluated for the treatment of adult and pediatric acute lymphoblastic leukemia), which had an estimated aggregate fair value of $9.0 billion. On October 18, 2017, FDA approved axicabtagene ciloleucel, now known commercially as Yescarta, making it the first CAR T cell therapy for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, which includes diffuse large B-cell lymphoma, transformed follicular lymphoma and primary mediastinal B-cell lymphoma. Upon approval, we reclassified $6.2 billion of the purchased IPR&D as a finite-lived intangible asset. We are amortizing this asset over an estimated useful life of 18 years using the straight-line method.

During the fourth quarter of 2018, we concluded that the efficacy profile of the KITE-585 program did not justify further efforts based on the totality of the clinical data gathered and made a decision to discontinue the KITE-585 program. As a result,

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the estimated fair value of the IPR&D relating to the KITE-585 program was written down to zero and we recorded an impairment charge of $820 million within Research and development expenses on our Consolidated Statements of Income included in Item 8 of this Annual Report on Form 10-K.

Provision for Income Taxes

We estimate our income tax provision, including deferred tax assets and liabilities, based on significant management judgment. We evaluate the realization of all or a portion of our deferred tax assets on a quarterly basis. 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. The valuation allowance was $331 million and $162 million at December 31, 2018 and 2017, respectively. The increase of our valuation allowance in 2018 was primarily related to certain Kite tax attributes and certain foreign jurisdictions, which do not have sufficient history of profit to realize the benefit of the losses on a more-likely-than-not basis.

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 and have made changes to existing tax laws (for example, the United States enacted significant tax reform, and certain provisions of the new law will continue to significantly affect us). 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 record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise’s financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. An adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

Of the total unrecognized tax benefits, $1.3 billion and $1.8 billion at December 31, 2018 and 2017, if recognized, would reduce our effective tax rate in the period of recognition. As of December 31, 2018, 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 taxing authorities.

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 2013 and onwards and 2010 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 IRS for the tax years from 2013 to 2015 and by various state and 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 periodically evaluate our exposures associated with our tax filing positions.

See Note 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.

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Contractual Obligations

Our contractual obligations consist of debt obligations, operating leases, capital commitments, purchase obligations for active pharmaceutical ingredients and inventory-related items and clinical trials contracts. The following table summarizes our significant enforceable and legally binding obligations, future commitments and obligations related to all contracts that we are likely to continue regardless of the fact that certain of these obligations may be cancelable as of December 31, 2018 (in millions):

	Payments due by Period				
Contractual Obligations	Total	Less than one year	1-3 years	3-5 years	More than 5 years
Debt [(1)]	$41,876	$ 3,753	$ 6,582	$3,801	$ 27,740
Operating lease obligations	574	89	144	112	229
Capital commitments [(2)]	336	336	—	—	—
Purchase obligations [(3)]	1,629	1,280	214	72	63
Clinical trials [(5)]	1,678	930	505	207	36
Transition Tax Payable [(6)]	4,639	—	621	1,359	2,659
Total [(4)(7)]	$50,732	$ 6,388	$ 8,066	$5,551	$ 30,727

Notes:

(1) Debt consists of senior unsecured notes and includes principal and interest payments. Interest payments for our fixed rate senior unsecured notes are incurred and calculated based on terms of the related notes. Interest payments for our variable rate debt are calculated based on the interest rates on the last reset date in 2018 for each debt instrument. 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.

(2) Amounts include capital project commitments primarily relating to construction of new buildings.

(3) Amounts include purchase commitments primarily relating to active pharmaceutical ingredients with minimum purchase requirements and certain inventory-related items. These amounts also include a $365 million accrued payment to Japan Tobacco, Inc. as a result of a collaboration arrangement. See Note 11, Collaborative Arrangements of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional information.

(4) In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing, collaboration and development arrangements. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheets and have not been included in the table above.

(5) At December 31, 2018, we had several clinical studies in various clinical trial phases. Our most significant clinical trial expenditures are to contract research organizations (CROs). Although all of our material contracts with CROs are cancelable, we historically have not canceled such contracts. These amounts reflect commitments based on existing contracts and do not reflect any future modifications to, or terminations of, existing contracts or anticipated or potential new contracts.

(6) In connection with Tax Reform, as of December 31, 2017, we recorded a federal income tax payable for transition tax on the mandatory deemed repatriation of foreign earnings that will be payable over an eight-year period. The amounts included in the table above represent the remaining federal income tax payable after applying the first year's installment payment and early payments of future installments. See Note 18, Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional details on Tax Reform.

(7) As of December 31, 2018, our long-term income taxes payable includes unrecognized tax benefits, interest and penalties totaling $1.3 billion. Due to the high degree of uncertainty on the timing of future cash settlement and other events that could extinguish these unrecognized tax benefits, we are unable to estimate the period of cash settlement and therefore we have excluded these unrecognized tax benefits from the table above.

Recent Accounting Pronouncements

The information required by this item is included in Note 1, Organization and Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K.

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 price. 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

Our operations include manufacturing and sales activities in the United States, Canada and Ireland as well as sales activities in countries outside the United States, including Europe and Asia Pacific. 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 amounts of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business. Approximately 25% of our product sales were denominated in foreign currencies during 2018. 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 and 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, 2018 and 2017, we had open foreign currency forward contracts with notional amounts of $2.2 billion and $2.8 billion, respectively. A hypothetical 10% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2018 would have resulted in a reduction in fair value of these contracts of approximately $218 million on this date and, if realized, would negatively affect earnings over the remaining life of the contracts. The same hypothetical movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2017, would have resulted in a reduction in fair value of these contracts of approximately $285 million on this date and, if realized, would negatively affect 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 marketable debt securities and our fixed and variable rate liabilities 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
- 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 at December 31, 2018 (in millions, except percentages):

	Expected Maturity							Total
	2019	2020	2021	2022	2023	Thereafter	Total	Fair Value
Assets								
Available-for-sale debt securities	$22,741	$1,001	$311	$16	$30	$65	$24,164	$24,164
Average interest rate	2.61 %	3.10 %	2.97 %	2.89 %	2.54%	3.47 %		
Liabilities								
Long-term debt, including current portion[1]:								
Fixed rate	$1,500	$2,500	$2,250	$1,500	$750	$17,750	$26,250	$25,886
Average interest rate	1.92 %	2.51 %	4.44 %	2.82 %	2.50%	4.16 %		
Variable rate	$1,250	$—	$—	$—	$—	$—	$1,250	$1,250
Average interest rate[2]	3.02 %	— %	— %	— %	— %	— %		

Notes:

(1) Amounts represent principal balances. In addition to these fixed and variable rate long-term debt, we have a $2.5 billion five-year revolving credit facility. There were no amounts outstanding under the five-year revolving credit

facility as of December 31, 2018. 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.

(2) Average interest rates for our variable rate debt were based on the interest rates on the last reset date in 2018 for each debt instrument and are dependent upon several factors subject to change, including but not limited to LIBOR, the principal amount of debt outstanding and credit ratings on each reset date.

Credit Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable debt 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

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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. The majority of our trade accounts receivable arises from product sales in the United States and Europe.

As of December 31, 2018, our accounts receivable, net, in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $161 million, of which $31 million were greater than 120 days past due, including $27 million greater than 365 days past due. As of December 31, 2017, our accounts receivable, net, in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $326 million, of which $131 million were greater than 120 days past due, including $52 million greater than 365 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable.

Market Price Risk

We hold shares of common stock of certain publicly traded biotechnology companies in connection with license and collaboration agreements. These equity securities are measured at fair value with any changes in fair value recognized in earnings starting on January 1, 2018 as a result of our adoption of Accounting Standards Update No. 2016-01 “Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities”. See Note 1, Organization and Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K for further information.

The fair value of these equity securities was approximately $881 million and $635 million as of December 31, 2018 and 2017, respectively. Changes in fair value of these equity securities are primarily due to 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 increase or decrease their fair value at December 31, 2018 and 2017 by approximately $176 million and $127 million, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

GILEAD SCIENCES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
Years ended December 31, 2018, 2017 and 2016

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Shareholders 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, 2018 and 2017, 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, 2018, and the related notes and financial statement schedule listed in the index at Item 15(a) (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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 25, 2019 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.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1988.

San Jose, California
February 25, 2019

GILEAD SCIENCES, INC.
Consolidated Balance Sheets
(in millions, except per share amounts)

	December 31, 2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$17,940	$7,588
Short-term marketable securities	12,149	17,922
Accounts receivable, net of allowances of $583 and $455, respectively	3,327	3,851
Inventories	814	801
Prepaid and other current assets	1,606	1,661
Total current assets	35,836	31,823
Property, plant and equipment, net	4,006	3,295
Long-term marketable securities	1,423	11,184
Intangible assets, net	15,738	17,100
Goodwill	4,117	4,159
Other long-term assets	2,555	2,722
Total assets	$63,675	$70,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$790	$814
Accrued government and other rebates	3,928	4,704
Other accrued liabilities	3,139	3,370
Current portion of long-term debt and other obligations, net	2,748	2,747
Total current liabilities	10,605	11,635
Long-term debt, net	24,574	30,795
Long-term income taxes payable	5,922	6,794
Other long-term obligations	1,040	558
Commitments and contingencies (Note 13)		
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; 1,282 and 1,308 shares issued and outstanding, respectively	1	1
Additional paid-in capital	2,282	1,264
Accumulated other comprehensive income	80	165
Retained earnings	19,024	19,012
Total Gilead stockholders' equity	21,387	20,442
Noncontrolling interest	147	59
Total stockholders' equity	21,534	20,501
Total liabilities and stockholders' equity	$63,675	$70,283

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Income
(in millions, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales	$21,677	$25,662	$29,953
Royalty, contract and other revenues	450	445	437
Total revenues	22,127	26,107	30,390
Costs and expenses:			
Cost of goods sold	4,853	4,371	4,261
Research and development expenses	5,018	3,734	5,098
Selling, general and administrative expenses	4,056	3,878	3,398
Total costs and expenses	13,927	11,983	12,757
Income from operations	8,200	14,124	17,633
Interest expense	(1,077)	(1,118)	(964)
Other income (expense), net	676	523	428
Income before provision for income taxes	7,799	13,529	17,097
Provision for income taxes	2,339	8,885	3,609
Net income	5,460	4,644	13,488
Net income (loss) attributable to noncontrolling interest	5	16	(13)
Net income attributable to Gilead	$5,455	$4,628	$13,501
Net income per share attributable to Gilead common stockholders - basic	$4.20	$3.54	$10.08
Shares used in per share calculation - basic	1,298	1,307	1,339
Net income per share attributable to Gilead common stockholders - diluted	$4.17	$3.51	$9.94
Shares used in per share calculation - diluted	1,308	1,319	1,358

See accompanying notes.

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

	Year Ended December 31,		
	2018	2017	2016
Net income	$5,460	$4,644	$13,488
Other comprehensive income (loss):			
Net foreign currency translation gain (loss), net of tax	(38)	(47)	177
Available-for-sale securities:			
Net unrealized gain, net of tax impact of $0, $6 and $19, respectively	43	218	7
Reclassifications to net income (loss), net of tax impact of $0, ($9) and $0, respectively	4	(8)	(7)
Net change	47	210	—
Cash flow hedges:			
Net unrealized gain (loss), net of tax impact of $2, ($11) and $0, respectively	112	(304)	5
Reclassification to net income, net of tax impact of $0, $0 and $(8), respectively	87	28	8
Net change	199	(276)	13
Other comprehensive income (loss)	208	(113)	190
Comprehensive income	5,668	4,531	13,678
Comprehensive income (loss) attributable to noncontrolling interest	5	16	(13)
Comprehensive income attributable to Gilead	$5,663	$4,515	$13,691

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 at December 31, 2015	1,422	1	444	88	18,001	579	19,113
Change in noncontrolling interest	—	—	—	—	—	(90)	(90)
Net income (loss)	—	—	—	—	13,501	(13)	13,488
Other comprehensive income, net of tax	—	—	—	190	—	—	190
Issuances under employee stock purchase plan	1	—	84	—	—	—	84
Issuances under equity incentive plans	13	—	128	—	—	—	128
Tax benefits from employee stock plans	—	—	186	—	—	—	186
Stock-based compensation	—	—	381	—	—	—	381
Repurchases of common stock	(126)	—	(302)	—	(10,883)	—	(11,185)
Warrants settlement	—	—	(469)	—	—	—	(469)
Convertible notes settlement	—	—	(95)	—	—	—	(95)
Convertible note hedges settlement	—	—	95	—	—	—	95
Dividends declared ($1.84 per share)	—	—	—	—	(2,465)	—	(2,465)
Reclassification of conversion spread of convertible notes	—	—	(733)	—	—	—	(733)
Reclassification of convertible note hedges	—	—	733	—	—	—	733
Reclassification to equity component of currently redeemable convertible notes	—	—	2	—	—	—	2
Balance at December 31, 2016	1,310	1	454	278	18,154	476	19,363
Change in noncontrolling interest	—	—	(3)	—	—	(433)	(436)
Net income	—	—	—	—	4,628	16	4,644
Other comprehensive loss, net of tax	—	—	—	(113)	—	—	(113)
Issuances under employee stock purchase plan	1	—	83	—	—	—	83
Issuances under equity incentive plans	11	—	146	—	—	—	146
Stock-based compensation	—	—	618	—	—	—	618
Repurchases of common stock	(14)	—	(34)	—	(1,028)	—	(1,062)
Dividends declared ($2.08 per share)	—	—	—	—	(2,742)	—	(2,742)
Balance at December 31, 2017	1,308	1	1,264	165	19,012	59	20,501
Change in noncontrolling interest	—	—	—	—	—	83	83
Net income	—	—	—	—	5,455	5	5,460
Other comprehensive income, net of tax	—	—	—	208	—	—	208
Issuances under employee stock purchase plan	2	—	91	—	—	—	91
Issuances under equity incentive plans	14	—	197	—	—	—	197
Stock-based compensation	—	—	842	—	—	—	842
Repurchases of common stock	(42)	—	(112)	—	(2,940)	—	(3,052)
Dividends declared ($2.28 per share)	—	—	—	—	(2,986)	—	(2,986)
	—	—	—	(293)	483	—	190

Cumulative effect from the adoption of new accounting standards							
Balance at December 31, 2018	1,282	$ 1	$ 2,282	$ 80	$ 19,024	$ 147	$ 21,534

See accompanying notes.

GILEAD SCIENCES, INC.
Consolidated Statements of Cash Flows
(in millions)

	Year Ended December 31,		
	2018	2017	2016
Operating Activities:			
Net income	$5,460	$4,644	$13,488
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation expense	226	233	177
Amortization expense	1,203	1,053	981
Stock-based compensation expense	845	638	380
Deferred income taxes	289	(82)	(119)
In-process research and development impairment	820	—	432
Inventory reserves for excess raw materials	440	—	—
Other	56	304	162
Changes in operating assets and liabilities:			
Accounts receivable, net	480	754	1,192
Inventories	(310)	(253)	(488)
Prepaid expenses and other	903	358	(520)
Accounts payable	(39)	(430)	47
Income taxes payable	(1,459)	5,497	1,010
Accrued liabilities	(514)	(818)	305
Net cash provided by operating activities	8,400	11,898	17,047
Investing Activities:			
Purchases of marketable securities	(10,233)	(23,314)	(25,619)
Proceeds from sales of marketable securities	1,522	10,440	13,039
Proceeds from maturities of marketable securities	24,336	7,821	1,700
Other investments	(346)	—	(357)
Acquisitions, net of cash acquired	—	(10,426)	—
Capital expenditures	(924)	(590)	(748)
Net cash provided by (used in) investing activities	14,355	(16,069)	(11,985)
Financing Activities:			
Proceeds from debt financing, net of issuance costs	—	8,985	5,293
Proceeds from convertible note hedges	—	—	956
Proceeds from issuances of common stock	289	234	208
Repurchases of common stock	(2,900)	(954)	(11,001)
Repayments of debt and other obligations	(6,250)	(1,811)	(1,981)
Payments to settle warrants	—	—	(469)
Payment of dividends	(2,971)	(2,731)	(2,455)
Other	(486)	(330)	(276)
Net cash provided by (used in) financing activities	(12,318)	3,393	(9,725)
Effect of exchange rate changes on cash and cash equivalents	(85)	137	41
Net change in cash and cash equivalents	10,352	(641)	(4,622)
Cash and cash equivalents at beginning of period	7,588	8,229	12,851
Cash and cash equivalents at end of period	$17,940	$7,588	$8,229

Supplemental disclosure of cash flow information:

Interest paid, net of amounts capitalized	$1,070	$1,038	$885
Income taxes paid	$3,198	$3,342	$2,436

See accompanying notes.

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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), incorporated in Delaware on June 22, 1987, is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. With each new discovery and investigational drug candidate, we strive to transform and simplify care for people with life-threatening illnesses around the world. We have operations in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead's primary areas of focus include HIV/AIDS, liver diseases, hematology/oncology and inflammation/respiratory diseases. We seek to add to our existing portfolio of products through our internal discovery and clinical development programs, product acquisition, in-licensing and strategic collaborations.
Our portfolio of marketed products includes AmBisome®, Atripla®, Biktarvy®, Cayston®, Complera®/Eviplera®, Descovy®, Emtriva®, Epclusa®, Genvoya®, Harvoni®, Hepsera®, Letairis®, Odefsey®, Ranexa®, Sovaldi®, Stribild®, Truvada®, Tybost®, Vemlidy®, Viread®, Vosevi®, Yescarta® and Zydelig®. We also 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 (loss) attributable to noncontrolling interests on 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. As of December 31, 2018, we did not have any material VIEs.
Significant Accounting Policies, Estimates and Judgments
The preparation of these Consolidated 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 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. Actual results may differ significantly from these estimates.
Revenue Recognition
On January 1, 2018, we adopted Accounting Standards Update No. 2014-09 "Revenue from Contracts with Customers" (Topic 606) using the modified retrospective method. Topic 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition" (Topic 605). As a result, we have changed our accounting policies for revenue recognition as detailed below.
Policy Elections and Practical Expedients Taken

- We account for shipping and handling activities that are performed after a customer has obtained control of a good as fulfillment costs rather than as separate performance obligations; and
- 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 significant financing component.

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. Upon recognition of revenue from product sales, provisions are made for various forms of variable consideration, which include

government and other rebates such as Medicaid reimbursements, customer incentives such as cash discounts for prompt payment, distributor fees and expected returns of expired products, as appropriate. Our payment terms to customers generally range from 30 to 90 days.

Variable Consideration
Rebates and Chargebacks
We estimate reductions to our revenues for amounts paid to payers and healthcare providers in the United States, including Medicaid rebates, AIDS Drug Assistance Program rebates and chargebacks, Veterans Administration and Public Health Service chargebacks and other rebates, as well as foreign government rebates. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, payer and individual payer plans. Our estimates are based on products sold, historical payer mix, and as available, pertinent third-party industry information, estimated patient population, known market events or trends, and for our U.S. product sales, channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. We also take into consideration, as available, new information regarding changes in programs' regulations and guidelines that would impact the amount of the actual rebates and/or our expectations regarding future payer mix for these programs. Government and other chargebacks that are payable to our direct customers are classified as reductions of Accounts receivable on our Consolidated Balance Sheets. Government and other rebates that are invoiced directly to us 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.
Product Returns
We do not provide our customers with a general right of product return, but typically permit returns if the product is damaged, defective, or otherwise cannot be used when received by the customer, or in the case of product sold in the United States and certain other countries, if the product has expired. We will accept returns for product that will expire within six months or that have expired up to one year after their expiration dates. Our estimates for expected returns of expired products are based primarily on an ongoing analysis of our historical return patterns, historical industry information reporting the return rates for similar products and contractual agreements intended to limit the amount of inventory maintained by our wholesalers.
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
Research and development (R&D) expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations (CROs), materials and supplies, licenses and fees, up-front and milestone payments under collaboration arrangements and overhead allocations consisting of various support and facility-related costs.
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.
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 fee.
We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $587 million, $600 million and $618 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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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 Nonmarketable 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 securities or long-term marketable 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, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration 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 basis. When we determine that the decline in fair value of an investment is below our accounting basis and the decline is other-than-temporary, we reduce the carrying value of the security we hold and record a loss for the amount of such decline.
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. Equity securities with no 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. Our investments in equity securities are recorded in Prepaid and other current assets or Other long term assets on our Consolidated Balance Sheet. Unrealized gains and losses are recorded as part of Other income (expense), net. We regularly review our securities for indicators of impairment. Investments in non-public companies are not material for the periods presented.
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. The majority of our trade accounts receivable arises from product sales in the United States, Europe and Japan. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at December 31, 2018.
Certain of the raw materials and components that we utilize in our operations are obtained through single suppliers. Certain of the raw materials that we utilize in our operations are made at only one facility. Since the suppliers of key components and raw materials must be named in a new drug application filed with U.S. Food and Drug Administration (FDA) for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from our suppliers was interrupted for any reason, we may be unable to ship our commercial products or to supply our product candidates for clinical trials.
Accounts Receivable

Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government and other programs, cash discounts for prompt payment and doubtful accounts. Estimates for wholesaler chargebacks for government and other programs and cash discounts are based on contractual terms, historical trends and our expectations regarding the utilization rates for these programs. Estimates of our allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by geographic region and a review of the local economic environment and its potential impact on government funding and reimbursement practices. Historically, the amounts of uncollectible accounts receivable that have been written off have been insignificant.

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, excess or unsaleable items are observed and there are no alternate uses for the inventory, we record an inventory valuation reserve through a charge to Cost of goods sold on our Consolidated Statements of Income. The establishment of inventory valuation reserves, together with the calculation of the amount of such reserves, 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 taken into consideration, 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. As of December 31, 2018 and 2017, the amount of pre-launch inventory on our Consolidated Balance Sheets was not significant.

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:

Description	Estimated Useful Life
Buildings and improvements	Shorter of 35 years or useful life
Laboratory and manufacturing equipment	4-10
Office and computer equipment	3-7
Leasehold improvements	Shorter of useful life or lease term

Acquisitions

We account for business combinations using the acquisition method of accounting, which requires that assets acquired, including in-process research and development (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 purchase price 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 (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 rather than a business combination and, therefore, no goodwill is recorded.

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 with indefinite useful lives are related to purchased IPR&D projects and are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time. We test goodwill and other indefinite-lived intangible assets for impairment on an annual basis and in between annual tests if we become aware of any events or circumstances that would indicate the fair values of the assets are below their carrying amounts.

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 suggest 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 suggest 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. Any excess of the carrying value of the asset or asset group over its estimated fair value is recognized as an impairment loss.
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 immaterial for the years ended December 31, 2018, 2017 and 2016.
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 assets and liabilities 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. Changes in the fair value of derivatives are recorded each period in current earnings or AOCI, depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction.
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.
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 record liabilities related to unrecognized tax benefits in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax

position taken or expected to be taken in a tax return. An adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

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

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Topic 606. Entities adopting Topic 606 had the option of using either a full retrospective or a modified retrospective approach.

On January 1, 2018, we adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. As such, results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605.

As discussed further above, our product sales are recognized when control of the product transfers, generally upon shipment or delivery to the customer, or in certain cases, upon the corresponding sale by our customer to a third party. Certain product sales that were deferred under the sell-through or cash basis methods of accounting because fees were not fixed or determinable prior to the adoption of Topic 606 are now recognized upon transfer of control. Royalty revenue is recognized in the period in which the corresponding sales by our corporate partners occur. Prior to the adoption of Topic 606, royalty revenue was generally recognized in the quarter following the quarter in which the corresponding sales by our corporate partners occurred.

The cumulative effect of the changes made to our Consolidated Balance Sheets as of January 1, 2018 for the adoption of Topic 606 was as follows (in millions):

	December 31, 2017	Adjustments Due to Topic 606	January 1, 2018
Prepaid and other current assets	$ 1,661	$ 96	$ 1,757
Other long-term assets	$ 2,722	$ 10	$ 2,732
Other accrued liabilities	$ 3,370	$ (115)	$ 3,255
Other long-term obligations	$ 558	$ 31	$ 589
Retained earnings	$ 19,012	$ 190	$ 19,202

In 2018, the impact to our Consolidated Financial Statements as a result of applying Topic 606 in place of Topic 605 was not material.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01 “Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities” (ASU 2016-01). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. Additionally, ASU 2016-01 clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. On January 1, 2018, we adopted this standard using a modified retrospective approach. The standard requires that equity investments with readily determinable fair values be measured at fair value with any changes in fair value recognized in earnings. As a result of the adoption, we reclassified $293 million of unrealized net gain from AOCI to retained earnings on January 1, 2018, which primarily consisted of $278 million unrealized gain from our equity investment in Galapagos NV.

In August 2017, the FASB issued Accounting Standards Update No. 2017-12 “Derivatives and Hedging: Targeted Improvements to Accounting for Hedging Activities” (ASU 2017-12). The amendments in ASU 2017-12 more closely align the results of hedge accounting with risk management activities. ASU 2017-12 also amends the presentation and disclosure requirements and eases documentation and effectiveness assessment requirements. On January 1, 2018, we early adopted this standard on a prospective basis. Upon adoption of ASU 2017-12, we no longer recognize hedge ineffectiveness in our Consolidated Statements of Income, but we instead recognize the entire change in the fair value of the hedge contract in AOCI. The adoption did not have a material impact on our Consolidated Financial Statements. The primary impact of adoption was required disclosure changes. See Note 5, Derivative Financial Instruments, for additional information.

In March 2018, the FASB issued Accounting Standards Update No. 2018-05 “Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118” (ASU 2018-05). ASU 2018-05 amends Topic 740 by incorporating the SEC Staff Accounting Bulletin No. 118 (SAB 118) issued on December 22, 2017. SAB 118 provides guidance on accounting for the effects of Tax Reform and allows a company to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. See Note 18, Income Taxes, for additional information.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 “Leases” (Topic 842). Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. In July 2018, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10 “Codification Improvements to Topic 842, Leases” and ASU 2018-11 “Leases (Topic 842): Targeted Improvements.” The guidance will become effective for us beginning in the first quarter of 2019. The modified retrospective transition approach is required. We plan to adopt these standards on the effective date by recording a cumulative effect adjustment to the opening balance of retained earnings on January 1, 2019.

Based on our lease portfolio as of December 31, 2018, we anticipate recognition of lease assets and liabilities of approximately $500 million on our consolidated balance sheet upon adoption with no material impact to our consolidated statements of income. We will elect the practical expedients upon transition to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs. We will also elect the practical expedient for lessees to combine lease and nonlease components for all asset classes. We are in the process of finalizing key system functionality and updating our controls and procedures for maintaining and accounting for our lease portfolio under the new guidance.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 “Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments” (ASU 2016-13). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for us beginning in the first quarter of 2020 and must be adopted using a modified retrospective approach, with certain exceptions. Early adoption is permitted beginning in the first quarter of 2019. We are evaluating the impact of the adoption of this standard on our Consolidated Financial Statements.

In November 2018, the FASB issued Accounting Standards Update No. 2018-18 “Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606” (ASU 2018-18). ASU 2018-18 clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account, adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606, and precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless those transactions are directly related to third-party sales. This guidance will become effective for us beginning in the first quarter of 2020 and should be applied retrospectively to January 1, 2018 when we initially adopted Topic 606. Early adoption is permitted. We are evaluating the impact of the adoption of this standard but we currently do not expect a material impact on our revenue.

2. REVENUES

Disaggregation of Revenues

The following table disaggregates our product sales by product and geographic region and disaggregates our royalty, contract and other revenues by geographic region for the years ended December 31, 2018, 2017 and 2016. The information for the years ended December 31, 2017 and 2016 has not been adjusted in accordance with our modified retrospective adoption of Topic 606 and continues to be reported in accordance with our historical accounting under Topic 605.

	Year Ended December 31, 2018				Year Ended December 31, 2017				Year Ended December 31, 2016			
(In millions)	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product Sales:												
Atripla	$967	$131	$108	$1,206	$1,288	$335	$183	$1,806	$1,898	$520	$187	$2,605
Biktarvy	1,144	39	1	1,184	—	—	—	—	—	—	—	—
Complera/Eviplera	276	327	50	653	406	503	57	966	821	580	56	1,457
Descovy	1,217	308	56	1,581	958	226	34	1,218	226	69	3	298
Genvoya	3,631	794	199	4,624	3,033	534	107	3,674	1,301	160	23	1,484
Odefsey	1,242	335	21	1,598	964	132	10	1,106	302	27	—	329
Stribild	505	97	42	644	811	195	47	1,053	1,523	314	77	1,914
Truvada	2,605	260	132	2,997	2,266	644	224	3,134	2,384	913	269	3,566
Other HIV(1)	40	7	14	61	43	6	9	58	41	6	—	47
Revenue share - Symtuza(2)	27	52	—	79	—	—	—	—	—	—	—	—
AmBisome	46	229	145	420	28	207	131	366	20	209	127	356
Epclusa	934	654	378	1,966	2,404	869	237	3,510	1,591	141	20	1,752
Harvoni	802	144	276	1,222	3,053	704	613	4,370	4,941	1,810	2,330	9,081
Letairis	943	—	—	943	887	—	—	887	819	—	—	819
Ranexa	758	—	—	758	717	—	—	717	677	—	—	677
Vemlidy	245	12	64	321	111	5	6	122	3	—	—	3
Viread	50	82	175	307	514	238	294	1,046	591	302	293	1,186
Vosevi	304	78	14	396	267	22	4	293	—	—	—	—
Yescarta	263	1	—	264	7	—	—	7	—	—	—	—
Zydelig	61	70	2	133	69	77	3	149	91	76	1	168
Other(3)	137	76	107	320	283	314	583	1,180	2,036	949	1,226	4,211
Total product sales	16,197	3,696	1,784	21,677	18,109	5,011	2,542	25,662	19,265	6,076	4,612	29,953
Royalty, contract and other revenues	72	310	68	450	85	300	60	445	89	289	59	437
Total revenues	$16,269	$4,006	$1,852	$22,127	$18,194	$5,311	$2,602	$26,107	$19,354	$6,365	$4,671	$30,390

Notes:

(1) Includes Emtriva and Tybost

(2) Represents Gilead’s 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 UC (Janssen)

(3) Includes Cayston, Hepsera and Sovaldi

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

During the year ended December 31, 2018, revenues recognized from performance obligations satisfied in prior years related to royalties for licenses of our intellectual property were $541 million. Changes in estimates for variable consideration related to sales made in prior years resulted in a $56 million decrease in revenues during the year ended December 31, 2018.

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 $125 million and $132 million as of December 31, 2018 and January 1, 2018, respectively.

Contract liabilities were not material as of December 31, 2018 and January 1, 2018.

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. 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; 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 and equity securities, and foreign currency exchange contracts are reported at their respective fair values on our Consolidated Balance Sheets. Short-term and long-term debt are reported at their amortized costs in our Consolidated Balance Sheets. The remaining financial instruments are reported in our Consolidated Balance Sheets at amounts that approximate current fair values.

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, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	$3,969	$—	$ —	$3,969	$4,061	$—	$ —	$4,061
Certificates of deposit	—	4,361	—	4,361	—	5,131	—	5,131
U.S. government agencies securities	—	938	—	938	—	926	—	926
Non-U.S. government securities	—	305	—	305	—	664	—	664
Corporate debt securities	—	13,067	—	13,067	—	14,747	—	14,747
Residential mortgage and asset-backed securities	—	1,524	—	1,524	—	4,058	—	4,058
Marketable equity securities:								
Money market funds	5,305	—	—	5,305	4,714	—	—	4,714
Equity securities	881	—	—	881	635	—	—	635
Deferred compensation plan	124	—	—	124	116	—	—	116
Foreign currency derivative contracts	—	78	—	78	—	13	—	13
Total	$10,279	$20,273	$ —	$30,552	$9,526	$25,539	$ —	$35,065
Liabilities:								
Deferred compensation plan	$124	$—	$ —	$124	$116	$—	$ —	$116
Foreign currency derivative contracts	—	1	—	1	—	93	—	93
Total	$124	$1	$ —	$125	$116	$93	$ —	$209

For the year ended December 31, 2018, changes in the fair value of marketable equity securities resulted in net unrealized gains of $115 million, which were included in Other income (expense), net, on our Consolidated Statements of Income.

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The following table summarizes the classification of our marketable equity securities in our Consolidated Balance Sheets (in millions):

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 5,305	$ 4,714
Prepaid and other current assets	863	637
Other long-term assets	142	114
Total	$ 6,310	$ 5,465

Our available-for-sale debt securities are classified as cash equivalents, short-term marketable securities and long-term marketable securities on our Consolidated Balance Sheets. See Note 4, Available-for-Sale Debt Securities, for additional information.

Level 2 Inputs

We estimate the fair values of Level 2 instruments 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 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.

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 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 short-term and long-term debt, determined using Level 2 inputs based on their quoted market values, were approximately $27.1 billion and $35.5 billion at December 31, 2018 and 2017, respectively, and the carrying values were $27.3 billion and $33.5 billion at December 31, 2018 and 2017, respectively.

Level 3 Inputs

As of December 31, 2018 and 2017, the only assets or liabilities that were measured using Level 3 inputs on a recurring basis were our contingent consideration liabilities, which were immaterial. On a nonrecurring basis, we measure certain assets including intangible assets at fair value when the carrying value of the asset exceeds its fair value. In 2018, we recorded an impairment charge of $820 million to write down to zero the carrying value of the KITE-585 program (an anti-BCMA being evaluated for the treatment of multiple myeloma). See Note 9, 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, 2018				December 31, 2017			
	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	$3,978	$ —	$ (9)	$3,969	$4,090	$ —	$ (29)	$4,061
Certificates of deposit	4,361	—	—	4,361	5,131	—	—	5,131
U.S. government agencies securities	943	—	(5)	938	934	—	(8)	926
Non-U.S. government securities	307	—	(2)	305	668	—	(4)	664
Corporate debt securities	13,095	1	(29)	13,067	14,790	3	(46)	14,747
Residential mortgage and asset-backed securities	1,532	—	(8)	1,524	4,072	1	(15)	4,058
Total	$24,216	$ 1	$ (53)	$24,164	$29,685	$ 4	$ (102)	$29,587

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

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 10,592	$ 481
Short-term marketable securities	12,149	17,922
Long-term marketable securities	1,423	11,184
Total	$ 24,164	$ 29,587

The following table summarizes our available-for-sale debt securities by contractual maturity (in millions):

	December 31, 2018	
	Amortized Cost	Fair Value
Within one year	$22,786	$22,741
After one year through five years	1,364	1,358
After five years through ten years	46	45
After ten years	20	20
Total	$24,216	$24,164

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The following table summarizes our available-for-sale debt securities that were in a continuous unrealized loss position, but were not deemed to be other-than-temporarily impaired (in millions):

	Less Than 12 Months		12 Months or Greater		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
December 31, 2018						
U.S. treasury securities	$—	$ 896	$(9)	$ 1,383	$(9)	$ 2,279
U.S. government agencies securities	—	30	(5)	553	(5)	583
Non-U.S. government securities	—	86	(2)	192	(2)	278
Corporate debt securities	(1)	1,600	(28)	4,204	(29)	5,804
Residential mortgage and asset-backed securities	—	192	(8)	1,186	(8)	1,378
Total	$(1)	$ 2,804	$(52)	$ 7,518	$(53)	$ 10,322
December 31, 2017						
U.S. treasury securities	$(2)	$ 821	$(27)	$ 3,240	$(29)	$ 4,061
U.S. government agencies securities	(1)	206	(7)	700	(8)	906
Non-U.S. government securities	(1)	203	(3)	461	(4)	664
Corporate debt securities	(14)	7,674	(32)	3,561	(46)	11,235
Residential mortgage and asset-backed securities	(4)	2,245	(11)	1,206	(15)	3,451
Total	$(22)	$ 11,149	$(80)	$ 9,168	$(102)	$ 20,317

We held a total of 1,348 and 2,957 positions, which were in an unrealized loss position as of December 31, 2018 and 2017, respectively.

Based on our review of these securities, we believe we had no other-than-temporary impairments as of December 31, 2018 and 2017, because we do not intend to sell these securities nor do we believe that we will be required to sell these securities before the recovery of their amortized cost basis. Gross realized gains and gross realized losses were not material for the years presented.

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. In order 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 unrecognized 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 of our entities 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 quarterly thereafter, we assess hedge effectiveness using regression analysis. Prior to January 2018, we excluded time value from our effectiveness testing and recognized changes in the time value of the hedge in Other income (expense), net, on our Consolidated Statements of Income. Starting in January 2018, we include time value in our effectiveness testing and the entire change in the value of hedge contracts is recorded as unrealized gains or losses in AOCI within Stockholders' equity on our Consolidated Balance Sheets. The unrealized gains or losses in AOCI are reclassified into product sales when the respective hedged transactions affect earnings. The majority of gains and losses related to the hedged forecasted transactions reported in AOCI at December 31, 2018 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, 2018, 2017 and 2016 are 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 $2.2 billion and $2.8 billion at December 31, 2018 and 2017, respectively.

While all of 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 (in millions):

	December 31, 2018			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 73	Other accrued liabilities	$ (1)
Foreign currency exchange contracts	Other long-term assets	5	Other long-term obligations	—
Total derivatives designated as hedges		78		(1)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	—	Other accrued liabilities	—
Total derivatives not designated as hedges		—		—
Total derivatives		$ 78		$ (1)

	December 31, 2017			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 2	Other accrued liabilities	$ (89)
Foreign currency exchange contracts	Other long-term assets	1	Other long-term obligations	(3)
Total derivatives designated as hedges		3		(92)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	10	Other accrued liabilities	(1)
Total derivatives not designated as hedges		10		(1)
Total derivatives		$ 13		$ (93)

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

	Year Ended December 31,		
	2018	2017	2016
Derivatives designated as hedges:			
Gains (losses) recognized in AOCI	$ 114	$ (315)	$ 5
Gains (losses) reclassified from AOCI into product sales	$ (87)	$ (28)	$ 73
Gains (losses) recognized in Other income (expense), net	$ —	$ 41	$ (32)
Derivatives not designated as hedges:			
Gains (losses) recognized in Other income (expense), net	$ (2)	$ (113)	$ 206

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 material amounts recorded in Other income (expense), net, on our Consolidated Statements of Income for the years presented as a result of the discontinuance of cash flow hedges.

As of December 31, 2018 and 2017, we only held foreign currency exchange contracts. The following table summarizes the potential effect of offsetting derivatives by type of financial instrument on our Consolidated Balance Sheets (in millions):
As of December 31, 2018
Offsetting of Derivative Assets/Liabilities

Description	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		Net Amount (Legal Offset)
				Derivative Financial Instruments	Cash Collateral Received/Pledged	
Derivative assets	$ 78	$ —	$ 78	$ (1)	$ —	$ 77
Derivative liabilities	(1)	—	(1)	1	—	—

As of December 31, 2017
Offsetting of Derivative Assets/Liabilities

Description	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		Net Amount (Legal Offset)
				Derivative Financial Instruments	Cash Collateral Received/Pledged	
Derivative assets	$ 13	$ —	$ 13	$ (8)	$ —	$ 5
Derivative liabilities	(93)	—	(93)	8	—	(85)

6. ACQUISITIONS

Kite Pharma, Inc.

On October 3, 2017 (the Acquisition Date), we completed a tender offer for all of the outstanding common stock of Kite Pharma, Inc. (Kite) for $180 per share in cash. As a result, Kite became our wholly-owned subsidiary. The acquisition of Kite helps establish our foundation for improving the treatment of hematological malignancies and solid tumors.

The consideration transferred for the acquisition was $11,155 million, consisting of $10,420 million in cash to the outstanding Kite common stockholders, $645 million cash payment to vested equity award holders, $15 million to warrant holders and $75 million representing the portion of the replaced stock-based awards attributable to the pre-combination period. In addition, $733 million was excluded from the consideration transferred, representing the portion of the replaced stock-based awards attributable to the post combination period, which is expected to be recognized through 2021.

The acquisition of Kite 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 recognized at fair value as of the acquisition date. The determination of estimated fair value requires us to make significant estimates and assumptions. During 2018, we recorded a $42 million reduction to goodwill primarily due to revision of deferred income taxes as a result of finalization of Kite’s pre-acquisition federal income tax return. The fair value estimates for the assets acquired and liabilities assumed have been completed.

The following table summarizes the acquisition date fair values of assets acquired and liabilities assumed, and the consideration transferred (in millions):

Cash and cash equivalents	$652
Identifiable intangible assets	
Indefinite-lived intangible assets - IPR&D	8,950
Outlicense acquired	91
Deferred income taxes	(1,564)
Other assets acquired (liabilities assumed), net	81
Total identifiable net assets	8,210
Goodwill	2,945
Total consideration transferred	$11,155

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Identifiable Intangible Assets
We acquired intangible assets primarily related to IPR&D for axicabtagene ciloleucel, KITE-585, and KTE-X19 (formerly KTE-C19, being evaluated for the treatment of adult and pediatric acute lymphoblastic leukemia), which had an estimated aggregate fair value of $8,950 million as of the Acquisition Date.
Intangible assets related to IPR&D projects are considered to be indefinite-lived assets until the completion or abandonment of the associated R&D efforts. In October 2017, upon FDA approval of Yescarta for the treatment of adult patients with relapsed or refractory DLBCL after two or more lines of systemic therapy, $6,200 million of the purchased IPR&D was reclassified as a finite-lived intangible asset and is being amortized over an estimated useful life of 18 years using the straight-line method. In 2018, we recorded an impairment charge of $820 million to write down to zero the estimated fair value of the KITE-585 program. See Note 9, Intangible Assets, for additional information.
Additionally, we acquired an outlicensing arrangement with Daiichi Sankyo Company Limited, which had an estimated fair value of $91 million as of the Acquisition Date. This definite-lived intangible asset is being amortized over an estimated useful life of 14 years on a straight-line basis. The fair value was determined by estimating the probability-weighted net cash flows attributable to the outlicense discounted to present value using a discount rate that represents the estimated rate that market participants would use to value this intangible asset.
Goodwill
The $2,945 million goodwill represents the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and represents the future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. None of the goodwill is deductible for income tax purposes.
Cell Design Labs, Inc.
In December 2017, we acquired all of the issued and outstanding stock of Cell Design Labs, Inc., a privately held company (Cell Design Labs), which was in addition to the approximately 12.2% of shares in Cell Design Labs we obtained in the acquisition of Kite. With this acquisition, we gained new technology platforms that will enhance research and development efforts in cellular therapy.
The cash consideration totaled $150 million, net of acquired cash. Additionally, the shareholders of Cell Design Labs, other than us, are eligible to receive contingent development and regulatory milestone-based payments of up to $322 million. Our 12.2% equity interest in Cell Design Labs had a carrying value of $30 million. The transaction was accounted for as an asset acquisition. As a result, $172 million was expensed as acquired IPR&D within Research and development expenses on our Consolidated Statements of Income.
Nimbus Apollo, Inc.
In May 2016, we acquired Nimbus Apollo, Inc., a privately held company, and its Acetyl-CoA Carboxylase inhibitor program, which is being evaluated for the potential treatment of non-alcoholic steatohepatitis, hepatocellular carcinoma and other diseases. The consideration included a payment of $400 million and contingent development and regulatory milestone-based payments of up to $800 million. The transaction was accounted for as an asset acquisition. As a result, the payment of $400 million was expensed as acquired IPR&D within Research and development expenses on our Consolidated Statements of Income. During 2016, based on the achievement of certain clinical development milestones, we recorded a $200 million expense within Research and development expenses on our Consolidated Statements of Income.

7. INVENTORIES

Inventories are summarized as follows (in millions):

	December 31,	
	2018	2017
Raw materials	$1,888	$1,880
Work in process	235	352
Finished goods	507	670
Total	$2,630	$2,902
Reported as:		
Inventories	$814	$801
Other long-term assets	1,816	2,101
Total	$2,630	$2,902

Amounts reported as other long-term assets primarily consisted of raw materials as of December 31, 2018 and 2017. During the year ended December 31, 2018, we recorded inventory reserves of $572 million, of which $440 million was related to excess raw materials primarily due to a sustained decrease in demand for Harvoni. Inventory reserves recorded for the years ended December 31, 2017 and 2016 were not material.

8. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment is summarized as follows (in millions):

	December 31,	
	2018	2017
Land and land improvements	$404	$396
Buildings and improvements (including leasehold improvements)	2,344	2,176
Laboratory and manufacturing equipment	697	533
Office and computer equipment	558	494
Construction in progress	1,194	690
Subtotal	5,197	4,289
Less accumulated depreciation and amortization	(1,191)	(994)
Total	$4,006	$3,295

Office and computer equipment includes capitalized software. We had unamortized capitalized software costs on our Consolidated Balance Sheets of $121 million and $129 million as of December 31, 2018 and 2017, respectively. Capitalized interest on construction in-progress is included in property, plant and equipment. Interest capitalized in 2018, 2017 and 2016 was not material.

9. INTANGIBLE ASSETS

The following table summarizes our intangible assets, net (in millions):

	December 31, 2018				December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived assets							
Intangible asset - sofosbuvir	$10,720	$ (3,554)	$ —	$7,166	$10,720	$ (2,855)	$7,865
Intangible asset - axicabtagene ciloleucel (DLBCL)	6,200	(416)	—	5,784	6,200	(72)	6,128
Intangible asset - Ranexa	688	(678)	—	10	688	(566)	122
Other	1,096	(359)	(3)	734	546	(311)	235
Total finite-lived assets	18,704	(5,007)	(3)	13,694	18,154	(3,804)	14,350
Indefinite-lived assets - IPR&D	2,047	—	(3)	2,044	2,750	—	2,750
Total intangible assets	$20,751	$ (5,007)	$ (6)	$15,738	$20,904	$ (3,804)	$17,100

Amortization expense related to finite-lived intangible assets is included in Cost of goods sold on our Consolidated Statements of Income and totaled $1.2 billion, $912 million and $844 million for the years ended December 31, 2018, 2017 and 2016, respectively.

In 2018, we entered into an agreement with Japan Tobacco Inc. (Japan Tobacco) to acquire the rights to market and distribute certain products in our HIV portfolio in Japan. In connection with this agreement, we recorded an intangible asset of $550 million reflecting the estimated fair value of the marketing-related rights acquired from Japan Tobacco. The intangible asset will be amortized over nine years beginning January 1, 2019. The amortization expense will be classified as selling expense and recorded as Selling, general and administrative expenses on our Consolidated Statements of Income. See Note 11, Collaborative Arrangements, for additional information.

In 2018, we concluded that the KITE-585 program did not justify further efforts based on the totality of the clinical data gathered and discontinued the program. As a result, the carrying value of the IPR&D relating to the KITE-585 program was written down to zero and we recorded an impairment charge of $820 million within Research and development expenses on our Consolidated Statements of Income. No IPR&D impairment charges were recorded in 2017 and $432 million of IPR&D impairment charges were recorded in 2016 within Research and development expenses on our Consolidated Statements of Income.

In 2018, we entered into a collaboration agreement with Gadeta B.V. (Gadeta) to develop gamma delta T cell receptor therapies for various cancers. Gadeta is a VIE that we consolidate. Upon consolidation, we recognized a $117 million indefinite-lived intangible asset relating to IPR&D. See Note 11, Collaborative Arrangements, for additional information.

As of December 31, 2018, estimated future amortization expense associated with our finite-lived intangible assets is as follows (in millions):

Fiscal Year	Amount
2019	$1,149
2020	1,125
2021	1,124
2022	1,124
2023	1,124
Thereafter	8,048
Total	$13,694

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10. OTHER FINANCIAL INFORMATION
Other Accrued Liabilities
The components of Other accrued liabilities are summarized as follows (in millions):

	December 31,	
	2018	2017
Compensation and employee benefits	$555	$455
Accrued payment for marketing-related rights acquired from Japan Tobacco	365	—
Income taxes payable	190	713
Other accrued expenses	2,029	2,202
Total	$3,139	$3,370

11. COLLABORATIVE ARRANGEMENTS
We enter into collaborative arrangements with third parties for the development and commercialization of certain products and product candidates. These arrangements 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, up-front payments, 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, cost-sharing arrangements, equity investments, or a combination of these terms.
Janssen
Complera/Eviplera and Odefsey
In 2009, we entered into a license and collaboration agreement with Janssen Sciences Ireland UC (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 United States and European Union in 2011 and is sold under the brand name Complera in the United States and Eviplera in the European Union.
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 United States. 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, up to 30% in major markets. Sales of these products are included in Product sales and Janssen's shares of revenues are included in Cost of goods sold on our Consolidated Statements of Income. Cost of goods sold relating to Janssen's shares were $608 million, $561 million and $459 million for the years ended December 31, 2018, 2017 and 2016, 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 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. This combination was approved in the United States and European Union 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 cobicistat, emtricitabine and tenofovir alafenamide (Gilead Compounds) and are the exclusive

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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. See Note 2, Revenues, for revenue recognized for the periods presented.

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 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

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 and paid a royalty to us based on its product sales in Japan. Under the agreement, 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. Japan Tobacco also marketed and distributed certain other products in our HIV portfolio in Japan and paid a royalty to us based on these product sales.

We received approval for Stribild and Genvoya (elvitegravir-containing products) in 2012 and 2015, respectively. Our sales of these products are included in Product sales, royalties due to Japan Tobacco based on our product sales are included in Cost of goods sold, and royalties due from Japan Tobacco based on its product sales in Japan are included in Royalty, contract and other revenues on our Consolidated Statements of Income. Royalty expenses recognized were $452 million, $400 million and $282 million for the years ended December 31, 2018, 2017 and 2016, respectively. Royalty income recognized was not material for the periods presented.

Effective in 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.

Under the terms of the agreement, we are obligated to pay Japan Tobacco $559 million in cash, of which $194 million was paid as an up-front payment and the remaining $365 million was reflected in Other accrued liabilities on our Consolidated Balance Sheets at December 31, 2018. We recognized an intangible asset of $550 million reflecting the estimated fair value of the marketing-related rights acquired from Japan Tobacco with the remaining $9 million recorded as Prepaid and other current assets on our Consolidated Balance Sheets. The intangible asset will be 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 will be 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.

Galapagos

In 2016, we closed on a license and collaboration agreement with Galapagos NV (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.

Upon closing of the license and collaboration agreement, we made an up-front license fee payment of $300 million and a $425 million equity investment in Galapagos by subscribing for new shares at a price of €58 per share, including an issuance premium. As a result, we received 6.8 million new shares of Galapagos, representing 14.75% of its

outstanding share capital at the closing of the license and collaboration agreement. The license fee payment of $300 million and the issuance premium on the equity investment of $68 million were recorded within Research and development expenses on our Consolidated Statements of Income in 2016. The equity investment, net of issuance premium, was recorded in Prepaid and other current assets on our Consolidated Balance Sheets. As of December 31, 2018, the fair value of the investment was $622 million.
Galapagos is eligible to receive from us development and regulatory milestone-based payments of up to $755 million, sales-based milestone payments of up to $600 million, plus tiered royalties on global net sales ranging from 20% to 30%, with the exception of certain co-promotion territories where profits would be shared equally. For the years ended December 31, 2018 and

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2017, milestone payments made to Galapagos were not material. For the year ended December 31, 2016, we recorded a $60 million expense based on the achievement of certain clinical development milestones within Research and development expenses on our Consolidated Statements of Income.

Under the terms of the agreement, we have an exclusive, worldwide, royalty-bearing, sublicensable license for filgotinib and products containing filgotinib. We are primarily responsible for development and seeking regulatory approval related to filgotinib. We are responsible for 80% and Galapagos is responsible for 20% of the development costs incurred. For the years presented, the payments between Galapagos and us for the development costs were not material. We are also responsible for the manufacturing and commercialization activities. In 2017, Galapagos exercised its option to co-promote filgotinib in the UK, Germany, France, Italy, Spain, the Netherlands, Belgium and Luxembourg, and in these territories we and Galapagos will share profits equally.

Termination of the agreement may be on a country basis and will depend on the circumstances, including expiration of royalty term or in the co-promotion territory, sale of a generic product, or material breach by either party. We may also terminate the entire agreement without cause following a certain period.

Gadeta

In July 2018, we entered into a collaboration arrangement with Gadeta, a privately-held company based in Utrecht, the Netherlands, to develop gamma delta T cell receptor therapies for various cancers. Under the financial terms, we provide R&D funding for the collaboration, and Gadeta is eligible to receive future payments upon achievement of certain regulatory milestones. In addition, we made an upfront purchase of equity in Gadeta from Gadeta's shareholders and may acquire additional equity in Gadeta upon achievement of certain R&D milestones. We also have the exclusive option to acquire the remaining equity in Gadeta for €300 million, adjusted for closing cash, transaction expenses and closing indebtedness. The option is exercisable at our discretion.

Gadeta is a VIE, and we are its primary beneficiary because we have the power to direct the activities of Gadeta that most significantly impact its economic performance and as a result of the financial terms described above. Upon the initial consolidation of Gadeta, we recorded assets of $117 million, primarily intangible assets related to IPR&D and $82 million to Noncontrolling interest on our Consolidated Balance Sheets. Gadeta does not meet the definition of a business as defined in ASC 805, "Business Combinations", and as a result, no goodwill was recognized.

Bristol-Myers Squibb Company

North America

In 2004, we entered into a collaboration arrangement with Bristol-Myers Squibb Company (BMS) to develop and commercialize a single tablet regimen containing our Truvada and BMS's Sustiva (efavirenz) in the United States and Canada. This combination was approved for use in the United States in 2006 and is sold under the brand name Atripla. We and BMS structured this collaboration as a joint venture that operated as a limited liability company, which we consolidated.

On December 31, 2017, we terminated BMS's participation in the collaboration following the launch of a generic version of Sustiva in the U.S. and became the sole owner of the joint venture. BMS is not permitted to commercialize Atripla in the United States and Canada but is entitled to receive from us certain fees based on net sales of Atripla in 2018, 2019 and 2020 on a declining annual scale. We may continue to purchase efavirenz from BMS at cost plus a markup as needed to continue manufacturing Atripla for the United States and Canada markets. For the year ended December 31, 2018, we recorded $198 million of fee expenses within Cost of goods sold on our Consolidated Statements of Income.

Europe

In 2007, Gilead Sciences Ireland UC, our wholly-owned subsidiary, and BMS entered into a collaboration agreement which sets forth the terms and conditions under which we and BMS commercialize and distribute Atripla in the European Union, Iceland, Liechtenstein, Norway and Switzerland (collectively, the European Territory). The parties formed a limited liability company which we consolidate, to manufacture Atripla for distribution in the European Territory using efavirenz that it purchases from BMS at BMS's estimated net selling price of efavirenz in the European Territory. We are responsible for manufacturing, product distribution, inventory management and warehousing. Through our local subsidiaries, we have primary responsibility for order fulfillment, collection of receivables, customer relations and handling of sales returns in all the territories where we and BMS promote Atripla. In general, the parties share revenues and out-of-pocket expenses in proportion to the net selling prices of the components of Atripla, Truvada and efavirenz.

Starting in 2012, except for a limited number of activities that are jointly managed, the parties no longer coordinate detailing and promotional activities in the European Territory. We are responsible for accounting, financial reporting and tax reporting for the collaboration. As of December 31, 2018 and 2017, efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory was included in Inventories on our Consolidated Balance Sheets.

The parties also formed a limited liability company to hold the marketing authorization for Atripla in the European Territory. We have primary responsibility for regulatory activities. In the major market countries, both parties have agreed to independently continue to use commercially reasonable efforts to promote Atripla.

The agreement will terminate upon the expiration of the last-to-expire patent which affords market exclusivity to Atripla or one of its components in the European Territory. In addition, since December 31, 2013, either party may terminate the agreement for any reason and such termination will be effective two calendar quarters after notice of termination. The non-terminating party has the right to continue to sell Atripla and become the continuing party, but will be obligated to pay the terminating party certain fees based on net sales for a three-year period following the effective date of the termination. In the event the continuing party decides not to sell Atripla, the effective date of the termination will be the date Atripla is withdrawn in each country or the date on which a third party assumes distribution of Atripla, whichever is earlier.

Other collaboration arrangements that are not individually significant

During 2018, we entered into several other collaboration arrangements that resulted in cash payments of $474 million, of which $278 million was recorded as up-front collaboration expense within Research and development expenses on our Consolidated Statements of Income and the remaining amounts were recorded in current and other long-term assets on our Consolidated Balance Sheets. We do not consider any of these collaborations arrangements to be individually material. We made no material initial cash payments related to individually insignificant collaboration arrangements in 2017 or 2016.

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. 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 of occurrence. Future milestone payments and royalties, if any, will be reflected on our Consolidated Statements of Income when the corresponding events become probable.

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	2018	2017
Senior Unsecured	September 2015	September 2018	1.85%	$—	$999
Senior Unsecured	September 2017	September 2018	3-month LIBOR + 0.17%	—	749
Term Loan	October 2017	October 2018	Variable	—	999
Senior Unsecured	September 2017	March 2019	3-month LIBOR + 0.22%	750	748
Senior Unsecured	March 2014	April 2019	2.05%	500	499
Senior Unsecured	September 2017	September 2019	1.85%	999	997
Senior Unsecured	September 2017	September 2019	3-month LIBOR + 0.25%	499	499
Senior Unsecured	November 2014	February 2020	2.35%	499	499
Senior Unsecured	September 2015	September 2020	2.55%	1,996	1,994
Term Loan	October 2017	October 2020	Variable	—	998
Senior Unsecured	March 2011	April 2021	4.50%	997	995
Senior Unsecured	December 2011	December 2021	4.40%	1,247	1,246
Senior Unsecured	September 2016	March 2022	1.95%	498	497
Senior Unsecured	September 2015	September 2022	3.25%	997	996
Term Loan	October 2017	October 2022	Variable	—	2,497
Senior Unsecured	September 2016	September 2023	2.50%	746	745
Senior Unsecured	March 2014	April 2024	3.70%	1,744	1,742
Senior Unsecured	November 2014	February 2025	3.50%	1,745	1,744
Senior Unsecured	September 2015	March 2026	3.65%	2,731	2,729
Senior Unsecured	September 2016	March 2027	2.95%	1,245	1,244
Senior Unsecured	September 2015	September 2035	4.60%	990	990
Senior Unsecured	September 2016	September 2036	4.00%	740	740
Senior Unsecured	December 2011	December 2041	5.65%	995	995
Senior Unsecured	March 2014	April 2044	4.80%	1,734	1,733
Senior Unsecured	November 2014	February 2045	4.50%	1,730	1,730
Senior Unsecured	September 2015	March 2046	4.75%	2,216	2,215
Senior Unsecured	September 2016	March 2047	4.15%	1,724	1,723
Total debt, net				27,322	33,542
Less current portion				2,748	2,747
Total long-term debt, net				$24,574	$30,795

Senior Unsecured Notes

In 2017, in connection with our acquisition of Kite, we issued $3.0 billion aggregate principal amount of senior unsecured notes in a registered offering consisting of $750 million principal amount of floating rate notes due September 2018, $750 million principal amount of floating rate notes due March 2019, and $500 million principal amount of floating rate notes due September 2019 (collectively, the Floating Rate Notes) and $1.0 billion principal amount of 1.85% senior notes due September 2019 (the Fixed Rate Notes, and collectively with the Floating Rate Notes, the 2017 Notes), the terms of which are summarized in the table above. In 2018, we repaid at maturity $750 million of principal balance related to the Floating Rate Notes.

We collectively refer to the 2017 Notes, and our senior unsecured notes issued in September 2016 (the 2016 Notes), in September 2015 (the 2015 Notes), in March and November 2014 (the 2014 Notes) and in March and December 2011 (the 2011 Notes) as our Senior Notes. In 2018, we repaid at maturity $1.0 billion of principal balance related to the 2015 Notes.

Our Senior Notes, except for the Floating 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

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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. Our Senior Notes maturing after 2020 also have a call feature, exercisable at our option, to redeem the notes at par in whole or in part one to six months immediately preceding maturity. In each case, accrued and unpaid interest is also required to be redeemed to the date of redemption. We do not have the option to redeem any series of the Floating Rate Notes, in whole or in part, prior to the maturity date.

In the event of the occurrence of a change in control and a downgrade in the rating of our Senior 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 Senior Notes and as of December 31, 2018 and 2017, we were not in violation of any covenants.

Interest expense on our Senior Notes related to the contractual coupon rates and amortization of the debt discount and issuance costs was $1.1 billion, $1.0 billion and $907 million in 2018, 2017 and 2016, respectively.

Term Loan Facilities

In September 2017, we entered into a $6.0 billion aggregate principal amount term loan facility credit agreement consisting of a $1.0 billion principal amount 364-day senior unsecured term loan facility, a $2.5 billion principal amount three-year senior unsecured term loan facility and a $2.5 billion principal amount five-year senior unsecured term loan facility (collectively, the Term Loan Facilities). In October 2017, we drew $6.0 billion principal amount on the Term Loan Facilities and used the proceeds to finance our acquisition of Kite, of which $1.5 billion was repaid in 2017 and the remaining $4.5 billion was repaid in 2018. The term loan facility credit agreement was terminated in 2018.

Credit Facilities

In 2016, we entered into a $2.5 billion five-year revolving credit facility agreement maturing in May 2021 (the Five-Year Revolving Credit Agreement). The revolving credit facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. As of December 31, 2018 and 2017, there were no amounts outstanding under the Five-Year Revolving Credit Agreement.

The Five-Year Revolving Credit Agreement contains customary representations, warranties, affirmative and negative covenants and events of default. At December 31, 2018, we were not in violation of any covenants. Loans under the Five-Year Revolving Credit Agreement 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 Five-Year Revolving Credit Agreement. We may terminate or reduce the commitments, and may prepay any loans under the Five-Year Revolving Credit Agreement in whole or in part at any time without premium or penalty.

Contractual Maturities of Financing Obligations

As of December 31, 2018, the aggregate future principal maturities of financing obligations for each of the next five years, based on contractual due dates, are as follows (in millions):

	2019	2020	2021	2022	2023
Contractual Maturities	$2,750	$2,500	$2,250	$1,500	$750

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13. COMMITMENTS AND CONTINGENCIES
Lease Arrangements
We lease facilities and equipment related primarily to administrative, R&D, sales and marketing activities under various long-term non-cancelable operating leases in the United States and international markets. Our leases expire on various dates between 2018 and 2068, with many of our leases containing options to renew. Lease expense under our operating leases was $109 million, $84 million and $81 million in 2018, 2017 and 2016, respectively.
Aggregate undiscounted non-cancelable future minimum rental payments under operating leases are as follows (in millions):

2019	$89
2020	78
2021	66
2022	60
2023	52
Thereafter	229
Total	$574

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 loss is reasonably possible and the loss or range of loss can be estimated, we disclose the possible loss. Unless otherwise noted, it is not possible to determine the outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss.
We did not recognize any accruals for the actions described below in our Consolidated Balance Sheets as of December 31, 2018 and 2017, as we did not believe losses were probable.
Litigation Related to Sofosbuvir
In January 2012, we acquired Pharmasset, Inc. (Pharmasset). Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of the hepatitis C virus (HCV). In December 2013, we received approval from U.S. Food and Drug Administration (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 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 Idenix Pharmaceuticals, Inc. (Idenix), Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L'Universite Montpellier II
In 2013, Idenix, UDSG, Centre National de la Recherche Scientifique and L'Université Montpellier II sued us in U.S. District Court for the District of Delaware alleging that the commercialization of sofosbuvir will infringe U.S. Patent No. 7,608,600 (the '600 patent). Also in 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir will infringe U.S. Patent Nos. 6,914,054 (the '054 patent) and 7,608,597 (the '597 patent). In 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware.
Prior to trial in 2016, Idenix committed to give us a covenant not to sue with respect to any claims arising out of the '054 patent related to sofosbuvir and withdrew that patent from the trial. A jury trial was held in 2016 on the '597 patent, and the jury found that we willfully infringed the asserted claims of the '597 patent and awarded Idenix $2.54 billion in past damages. In 2018, the judge invalidated Idenix's '597 patent and vacated the jury's award of $2.54 billion in past damages. Idenix appealed this decision to the U.S. Court of Appeals for the Federal Circuit (CAFC), and

briefing is now complete. We believe the Delaware

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court’s decision correctly found that, as a matter of law, the ‘597 patent is invalid, and we remain confident in the merits of our case on appeal. We believe that the possibility of a material adverse outcome on this matter is remote.

In 2014, the European Patent Office (EPO) granted Idenix's European Patent No. 1 523 489 (the ‘489 patent), which corresponds to the ‘600 patent. The same day that the ‘489 patent was granted, we filed an opposition with the EPO seeking to revoke the ‘489 patent. An opposition hearing was held in 2016, and the EPO ruled in our favor and revoked the ‘489 patent. Idenix has appealed. In 2014, Idenix also initiated infringement proceedings against us in Germany and France alleging that the commercialization of Sovaldi would infringe the German and French counterparts of the ‘489 patent. In 2015, the German court in Düsseldorf determined that the Idenix patent was highly likely to be invalid and stayed the infringement proceedings pending the outcome of the opposition hearing held by the EPO in 2016. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix’s request, the French proceedings have been stayed.

Litigation with Merck & Co. Inc. (Merck)

In 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent No. 7,105,499 (the ‘499 patent) and U.S. Patent No. 8,481,712 (the ‘712 patent), which it co-owns with Ionis Pharmaceuticals, Inc. The ‘499 and ‘712 patents cover compounds which do not include, but may relate to, sofosbuvir. We filed a lawsuit in 2013 in the U.S. District Court for the Northern District of California seeking a declaratory judgment that the Merck patents are invalid and not infringed. Initially, in 2016, a jury determined that we had not established that Merck’s patents are invalid and awarded Merck $200 million in damages. However, in 2016, the court ruled in our favor on our defense of unclean hands and determined that Merck may not recover any damages from us for the ‘499 and ‘712 patents.

In 2018, the CAFC affirmed the court’s decision on unclean hands. In 2019, the U.S. Supreme Court denied Merck’s petition for review. The merits portion of this case is now final.

Litigation with the University of Minnesota

The University of Minnesota (the University) has obtained 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 four petitions for inter partes review with the USPTO Patent Trial and Appeal Board (PTAB) alleging that all asserted claims are invalid for anticipation and obviousness. In 2018, the District Court stayed the litigation until after the PTAB rules on our petitions for inter partes review.

Litigation Related to Axicabtagene Ciloleucel

In 2017, we acquired Kite, which is now our wholly-owned subsidiary. Through the acquisition, we acquired axicabtagene ciloleucel, a chimeric antigen receptor (CAR) T cell therapy. We received approval from FDA in 2017 for axicabtagene ciloleucel, now known commercially as Yescarta.

We own patents and patent applications that claim axicabtagene ciloleucel chimeric DNA segments. Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing axicabtagene ciloleucel or to require us to obtain a license in order to commercialize axicabtagene ciloleucel. For example, we are aware that Juno Therapeutics, Inc. (Juno) has exclusively licensed Patent No. 7,446,190 (the ‘190 patent), which was issued to Sloan Kettering Cancer Center. In September 2017, Juno and Sloan Kettering Cancer Center filed a lawsuit against Kite in the U.S. District Court for the Central District of California, alleging that the commercialization of axicabtagene ciloleucel infringes the ‘190 patent. In October 2017, following FDA approval for Yescarta, Juno filed a second complaint alleging that axicabtagene ciloleucel infringes the ‘190 patent. Juno subsequently moved to dismiss the September 2017 complaint and has maintained the October 2017 complaint. The court has set a trial date of December 2019 for this lawsuit.

We cannot predict the ultimate outcome of intellectual property claims related to axicabtagene ciloleucel. If Juno’s patent is upheld as valid and Juno successfully proves infringement of that patent by axicabtagene ciloleucel, we could be required to pay significant monetary damages or we could be prevented from selling Yescarta unless we were able to obtain a license to this patent. Such a license may not be available on commercially reasonable terms or at all.

Litigation Related to Bictegravir

In 2018, ViiV Healthcare Company (ViiV) filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, now known commercially as Biktarvy, infringes ViiV’s U.S. Patent No. 8,129,385 (the ‘385 patent), which was issued to Shionogi & Co. Ltd. & GlaxoSmithKline LLC. The ‘385 patent is the compound patent covering ViiV’s dolutegravir. Bictegravir is structurally different from dolutegravir, and we believe that bictegravir does not infringe the claims of the ‘385 patent. To the extent that ViiV’s patent claims are interpreted to cover bictegravir, we believe those claims are invalid. The U.S. Patent and Trademark Office (USPTO) has granted us patents covering bictegravir. The court has set a trial date of September 2020 for this lawsuit.

In 2018, ViiV also filed a lawsuit against us in the Federal Court of Canada, alleging that our activities relating to our bictegravir product have infringed ViiV's Canadian Patent No. 2,606,282 (the '282 patent), which was issued to Shionogi & Co. Ltd. and ViiV. The '282 patent is the compound patent covering ViiV's dolutegravir. We believe that bictegravir does not infringe the claims of the '282 patent. To the extent that ViiV's patent claims are interpreted to cover bictegravir, we believe those claims are invalid.

We cannot predict the ultimate outcome of intellectual property claims related to bictegravir. If ViiV's patents are upheld as valid and ViiV successfully proves infringement of those patents by bictegravir, we could be required to pay significant monetary damages.

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 earlier than 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.

Current legal proceedings of significance with generic manufacturers include:

HIV Products

In 2018, we received notice that Strides Pharma Inc. (Strides) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Strides alleges that two patents associated with emtricitabine and four patents associated with the emtricitabine and tenofovir disoproxil fumarate fixed-dose combination are invalid, unenforceable and/or will not be infringed by Strides' manufacture, use or sale of a generic version of Truvada. In response, we filed a lawsuit against Strides in the U.S. District Court for the District of New Jersey for infringement of our patents. In 2018, we reached an agreement with Strides to resolve the lawsuit, which has been dismissed. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

In 2018, we received notice that Zydus Pharmaceuticals (USA) Inc. (Zydus) submitted an ANDA to FDA requesting permission to manufacture and market generic versions of Truvada at various dosage strengths. In the notice, Zydus alleges that two patents associated with emtricitabine and four patents associated with the emtricitabine and tenofovir disoproxil fumarate fixed-dose combination are invalid, unenforceable and/or will not be infringed by Zydus' manufacture, use or sale of generic versions of Truvada at various dosage strengths. In response, we filed a lawsuit against Zydus in the U.S. District Court for the District of New Jersey for infringement of our patents.

In 2018, we received notice that Mylan Pharmaceuticals Inc. (Mylan) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Stribild. In the notice, Mylan alleges that one patent owned by Japan Tobacco Inc. (JT) and associated with elvitegravir is invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Stribild. In 2019, JT filed a lawsuit against Mylan in the U.S. District Court for the Northern District of West Virginia for infringement of its patent.

HCV Products

In 2018, we received notices from Natco Pharma Limited (Natco) and Teva Pharmaceuticals (Teva) that they have each submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Sovaldi. In Teva's notice, it alleges that nine patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of generic versions of Sovaldi. In response, we filed lawsuits against Teva in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents. In Natco's notice, it alleges that two patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of generic versions of Sovaldi. Natco did not challenge all patents listed on the Orange Book for Sovaldi. We also filed lawsuits against Natco in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents. In 2018, we reached an agreement with Teva to resolve the lawsuit, which has been dismissed. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

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. The appeal process may take several years.

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. The appeal process may take several years.

In 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2021. In 2017, the EPO upheld the validity of the claims of our TAF patent. Three parties have appealed this decision. The appeal process may take several years.

In 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to TAF hemifumarate that expires in 2032. We responded to these oppositions, and a hearing was held in February 2019. The patent was upheld at this hearing. The opposing parties may choose to appeal this decision, which could take several years to conclude.

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. One of the original opposing parties has appealed this decision. The appeal process may take several years.

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 and cobicistat in the European Union 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 the European Medicines Agency. Sovaldi has been granted regulatory exclusivity that will prevent generic sofosbuvir from entering the European Union for 10 years following approval of Sovaldi, or January 2024. If we lose patent protection for sofosbuvir prior to 2028, our revenues and results of operations could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost, which may cause our stock price to decline.

Government Investigations and Related Litigation

In 2011, we received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Complera, Atripla, Truvada, Viread, Emtriva, Hepsera and Letairis. We cooperated with the government's inquiry. In 2014, the U.S. Department of Justice informed us that, following an investigation, it declined to intervene in a False Claims Act lawsuit filed by two former employees. Also in 2014, the former employees served a First Amended Complaint, and the U.S. District Court for the Northern District of California issued an order granting in its entirety, without prejudice, our motion to dismiss the First Amended Complaint. In 2015, the plaintiffs filed a Second Amended Complaint, and the District Court issued an order granting our motion to dismiss the Second Amended Complaint. The plaintiffs then filed a notice of appeal in the U.S. Court of Appeals for the Ninth Circuit. In 2017, the Ninth Circuit granted our motion to stay the case pending an appeal to the U.S. Supreme Court, and we filed a Petition for a Writ of Certiorari to the U.S. Supreme Court. In 2018, the Solicitor General submitted a brief for the United States to the Supreme Court stating its intention to file a motion to dismiss under the federal False Claims Act. In January 2019, the Supreme Court denied the Petition and the case has been remanded to the District Court.

In 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients and documents concerning our provision of financial assistance to patients for our HCV products. We are cooperating with this inquiry. In 2017, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our copay coupon program and Medicaid price reporting methodology. We are cooperating with this inquiry.

In 2017, we received a voluntary request for information from the U.S. Attorney's Office for the Eastern District of Pennsylvania requesting information related to our reimbursement support offerings, clinical education programs and interactions with specialty pharmacies for Sovaldi and Harvoni. In 2018, we received another voluntary request for information related to our speaker programs and advisory boards for our HCV and hepatitis B virus (HBV) products. We are cooperating with these voluntary requests.

In 2017, we received a subpoena from the California Department of Insurance and the Alameda County District Attorney's Office requesting documents related to our marketing activities, reimbursement support offerings, clinical education programs and interactions with specialty pharmacies for Harvoni and Sovaldi. We are cooperating with this inquiry.

In 2017, we received a subpoena from the U.S. Department of Health and Human Services requesting documents related to our Frontlines of Communities in the United States (FOCUS) program. We cooperated with the inquiry, and in February 2019, the government informed us that it declined to intervene in the False Claims Act qui tam lawsuit related to the inquiry.

In 2017, we also 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.

Products Liability

In 2018, plaintiffs filed a purported mass action against us in the U.S. District Court for the Northern District of California (the Holley action). Plaintiffs alleged that they suffered kidney and/or bone injuries as a result of using Viread, Truvada, Atripla, Complera and/or Stribild, and alleged that: (1) we should have altered the design of these medications by replacing one of their active ingredients, tenofovir disoproxil fumarate (TDF), with an allegedly superior ingredient, tenofovir alafenamide fumarate, and/or by reducing the dose of TDF in Stribild; and (2) we failed to adequately warn plaintiffs or their physicians about kidney and bone risks from Viread, Truvada, Atripla, Complera and Stribild and the need to monitor patients for those risks. Based on those allegations, plaintiffs asserted claims for products liability, negligence, fraud, breach of warranty and violations of state consumer protection laws. Plaintiffs seek compensatory, statutory and punitive damages and restitution. Four other federal lawsuits are pending in the U.S. District Court for the Central District of California (the Dechow action), the U.S. District Court for the Middle District of Louisiana (the Hills action), the U.S. District Court for the Western District of Louisiana (the Pierot action) and the U.S. District Court for the Northern District of California (the Dowdy action) based on allegations similar to those raised in the Holley action.

In addition to the five pending federal actions, there are three lawsuits based on plaintiffs' allegations similar to those raised in the Holley action, pending in California state court (the Lujano, Martinez and Grim actions).

We filed motions to dismiss in the Holley, Dowdy, Hills, Pierot and Lujano actions. The motion to dismiss in the Lujano action was granted as to plaintiffs' strict products liability claim but denied as to the remaining claims. The other motions to dismiss remain pending. We also plan to file motions to dismiss in the Dechow, Martinez and Grim actions. 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.

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 various firm purchase commitments primarily related to active pharmaceutical ingredients and certain inventory related items. As of December 31, 2018, these commitments for the next five years were approximately $503 million in 2019, $54 million in 2020, $51 million in 2021, $30 million in 2022 and $27 million in 2023. The amounts related to active pharmaceutical ingredients represent minimum purchase commitments. Actual payments for the purchases related to active pharmaceutical ingredients and certain inventory related items were $1.0 billion in 2018, $1.7 billion in 2017 and $2.0 billion in 2016.

14. 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. The 2016 Program commenced in April 2016 after the $15.0 billion stock repurchase program authorized by our Board of Directors in January 2015 (2015 Program) was completed. As of December 31, 2018, the remaining authorized repurchase amount under the 2016 Program was $5.1 billion.

The following table summarizes our stock repurchases under the above-described programs (in millions, except per share data):

	Year ended December 31,		
	2018 (1)	2017 (1)	2016 (2)
Shares repurchased and retired	40	13	123
Amount	$2,900	$954	$11,001
Average price per share	$72.95	$71.79	$89.15

Notes:

(1) All repurchases were under the 2016 Program.

(2) Includes 36 million shares repurchased for $3.0 billion under the 2016 Program and 87 million shares repurchased for $8.0 billion under the 2015 Program.

In addition to repurchases from our stock repurchase programs, we repurchased shares of common stock withheld by us from employee restricted stock awards to satisfy our applicable tax withholding obligations, which are immaterial and 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 APIC based on an estimated average sales price per issued share with the excess amounts charged to retained earnings.

The following table summarizes the reduction of common stock and APIC and the charge to retained earnings as a result of our stock repurchases (in millions):

	Year ended December 31,		
	2018	2017	2016
Reduction of common stock and APIC	$112	$34	$302
Charge to retained earnings	2,940	$1,028	$10,883

Dividends

The following table summarizes cash dividends declared on our common stock (in millions, except per share data):

	2018		2017	
	Dividend Per Share	Amount	Dividend Per Share	Amount
First quarter	$0.57	$752	$0.52	$685
Second quarter	0.57	747	0.52	685
Third quarter	0.57	746	0.52	685
Fourth quarter	0.57	741	0.52	687
Total	$2.28	$2,986	$2.08	$2,742

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

On February 4, 2019, we announced that our Board of Directors declared a quarterly cash dividend of $0.63 per share of our common stock, with a payment date of March 28, 2019 to all stockholders of record as of the close of business on March 15, 2019. Future dividends are subject to declaration by the 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, 2018 and 2017.

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Accumulated Other Comprehensive Income (Loss)

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

	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Securities	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2016	$ 132	$ (16)	$ 162	$278
Other comprehensive income (loss) before reclassifications	(47)	218	(304)	(133)
Amounts reclassified from accumulated other comprehensive income	—	(8)	28	20
Net current period other comprehensive income (loss)	(47)	210	(276)	(113)
Balance at December 31, 2017	$ 85	$ 194	$ (114)	$165
Reclassifications to retained earnings as a result of the adoption of new accounting standards	—	(293)	—	(293)
Balance at January 1, 2018	$ 85	$ (99)	$ (114)	$(128)
Net unrealized gain (loss)	(38)	43	112	117
Reclassifications to net income	—	4	87	91
Net current period other comprehensive income (loss)	(38)	47	199	208
Balance at December 31, 2018	$ 47	$ (52)	$ 85	$80

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.

15. EMPLOYEE BENEFITS

We provide share based compensation in the form of various types of equity-based awards, including restricted stock units (RSUs), performance-based restricted stock units (PSUs) 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, estimated fair value is based on either the Monte Carlo valuation methodology or the stock price on the date of grant. For stock option awards, estimated fair value is based on the Black-Scholes option valuation model.

2004 Equity Incentive Plan

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 is a broad based incentive plan that provides for the grant of equity-based awards, including stock options, restricted stock units, restricted stock awards and performance awards, to employees, directors and consultants. The 2004 Plan authorized the issuance of a total of 309 million shares of common stock. As of December 31, 2018, a total of 91 million shares remain available for future grant under the 2004 Plan.

Stock Options

The 2004 Plan provides for option grants designated as either non-qualified or incentive stock options. Prior to January 1, 2006, we granted both non-qualified and incentive stock options, but all stock options granted after January 1, 2006 have been non-qualified stock options. Under the 2004 Plan, employee stock options granted prior to 2011 generally vest over five years and stock options granted starting in 2011 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 2004 Plan's 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 thousands)	Weighted-Average Exercise Price (in dollars)	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2017	30,220	$ 43.93		
Granted	3,659	$ 79.49		
Forfeited	(1,943)	$ 70.23		
Expired	(284)	$ 71.09		
Exercised	(8,128)	$ 24.16		
Outstanding at December 31, 2018	23,524	$ 53.80	5.63	$ 417
Exercisable at December 31, 2018	15,521	$ 45.67	4.21	$ 372
Expected to vest, net of estimated forfeitures at December 31, 2018	7,629	$ 69.34	8.37	$ 43

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 $412 million for 2018, $337 million for 2017 and $452 million for 2016.

The weighted-average grant date fair value of the stock options granted was $17.03 per share for 2018, $38.78 per share for 2017 and $20.04 per share for 2016. The weighted-average grant date fair value of stock options granted in 2017 was higher due to replacement awards granted in connection with our acquisitions of Kite and Cell Design Labs.

As of December 31, 2018, there was $173 million of unrecognized compensation cost related to stock options, which is expected to be recognized over an estimated weighted-average period of 2.4 years.

Performance-Based Restricted Stock Units

Under the 2004 Plan, 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 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 activity and related information for our PSUs:

	Shares [(1)] (in thousands)	Weighted-Average Grant Date Fair Value Per Share [(1)] (in dollars)
Outstanding at December 31, 2017	757	$ 82.80
Granted	452	$ 88.76
Vested	(228)	$ 83.75

Forfeited	(149)	$ 103.80
Outstanding at December 31, 2018	832	$ 82.42

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Note:

(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 our PSUs granted was $88.76 per share for 2018, $74.42 per share for 2017 and $71.60 per share for 2016. The total grant date fair value of our vested PSUs was $19 million for 2018, $4 million for 2017

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and $33 million for 2016, and total fair value as of the respective vesting dates was $18 million for 2018, $3 million for 2017 and $45 million for 2016.

We recognized stock-based compensation expenses of $31 million in 2018, $24 million in 2017 and $20 million in 2016 related to these PSUs. As of December 31, 2018, there was $33 million of unrecognized compensation costs related to these PSUs, which is expected to be recognized over an estimated weighted-average period of 1.1 years.

Restricted Stock Units

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 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. The following table summarizes our RSU activities and related information:

	Shares (in thousands)	Weighted-Average Grant Date Fair Value Per Share (in dollars)
Outstanding at December 31, 2017	15,005	$ 79.37
Granted	7,196	$ 77.98
Vested	(5,619)	$ 82.22
Forfeited	(1,688)	$ 78.48
Outstanding at December 31, 2018	14,894	$ 77.72

The weighted-average grant date fair value of RSUs granted was $77.98 per share for 2018, $73.56 per share for 2017, and $84.51 per share for 2016. The total grant date fair value of our vested RSUs was $462 million for 2018, $325 million for 2017 and $284 million for 2016, and total fair value as of the respective vesting dates was $428 million for 2018, $285 million for 2017 and $408 million for 2016.

As of December 31, 2018, there was $789 million of unrecognized compensation cost related to unvested RSUs which is expected to be recognized over a weighted-average period of 2.4 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. Prior to 2016, the ESPP offered a two-year 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. Beginning in the first quarter of 2016, the look-back feature for ESPP offering periods became six-months. ESPP purchases are settled with common stock from the ESPP's previously authorized and available pool of shares. During 2018, 2 million shares were issued under the ESPP for $91 million. A total of 79 million shares of common stock have been authorized for issuance under the ESPP, and there were 10 million shares available for issuance under the ESPP as of December 31, 2018.

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,		
	2018	2017	2016

Cost of goods sold	$61	$24	$14
Research and development expenses	379	232	176
Selling, general and administrative expenses	405	393	190
Stock-based compensation expense included in total costs and expenses	845	649	380
Income tax effect	(164)	(280)	(104)
Stock-based compensation expense, net of tax	$681	$369	$276

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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.

Valuation Assumptions

Fair value of options granted under our 2004 Plan 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,		
	2018	2017	2016
Expected volatility:			
Stock options	28 %	28 %	30 %
ESPP	28 %	28 %	30 %
Expected term in years:			
Stock options	5.2	4.6	5.5
ESPP	0.5	0.5	0.5
Risk-free interest rate:			
Stock options	2.5 %	2.1 %	1.4 %
ESPP	2.6 %	1.8 %	1.1 %
Expected dividend yield	2.8 %	2.7 %	1.9 %

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 $91 million during 2018, $74 million during 2017 and $69 million during 2016.

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 $124 million as of December 31, 2018 and $116 million as of December 31, 2017.

16. 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 outstanding 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, the assumed conversion of our outstanding Convertible Notes and the assumed exercise of the warrants related to our outstanding Convertible Notes were determined under the treasury stock method. Both the Convertible Notes and the associated warrants were settled in 2016.

We excluded stock options and equivalents of approximately 13 million, 11 million and 3 million weighted-average shares of our common stock that were outstanding during 2018, 2017 and 2016, respectively, in the computation of diluted net income per share attributable to Gilead common stockholders because their effect was antidilutive.

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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,		
	2018	2017	2016
Net income attributable to Gilead	$5,455	$4,628	$13,501
Shares used in per share calculation - basic	1,298	1,307	1,339
Effect of dilutive securities:			
Stock options and equivalents	10	12	13
Conversion spread related to the Convertible Notes	—	—	2
Warrants related to the Convertible Notes	—	—	4
Shares used in per share calculation - diluted	1,308	1,319	1,358
Net income per share attributable to Gilead common stockholders - basic	$4.20	$3.54	$10.08
Net income per share attributable to Gilead common stockholders - diluted	$4.17	$3.51	$9.94

17. 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. Therefore, our results of operations are reported on a consolidated basis consistent with internal management reporting reviewed by our chief operating decision maker, who is our chief executive officer or interim chief executive officer. See Note 2, Revenues, for a summary of disaggregated revenues by product and geographic region.

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,		
	2018	2017	2016
AmerisourceBergen Corp.	20 %	20 %	18 %
Cardinal Health, Inc.	21 %	19 %	16 %
McKesson Corp.	21 %	23 %	22 %

Long-Lived Assets

The net book value of our property, plant and equipment (less office and computer equipment) in the United States was $3.2 billion as of December 31, 2018, $2.6 billion as of December 31, 2017 and $2.2 billion as of December 31, 2016. The corresponding amount in international locations was $620 million as of December 31, 2018, $520 million as of December 31, 2017 and $430 million as of December 31, 2016. All individual international locations accounted for less than ten percent of the total balances.

18. INCOME TAXES

Income before provision for income taxes consists of the following (in millions):

	Year Ended December 31,		
	2018	2017	2016
Domestic	$7,074	$8,099	$7,646
Foreign	725	5,430	9,451
Total income before provision for income taxes	$7,799	$13,529	$17,097

The provision for income taxes consists of the following (in millions):

	Year Ended December 31,		
	2018	2017	2016
Federal:			
Current	$1,716	$8,817	$3,351
Deferred	324	(123)	(85)
	2,040	8,694	3,266
State:			
Current	162	97	131
Deferred	(17)	(20)	28
	145	77	159
Foreign:			
Current	175	54	261
Deferred	(21)	60	(77)
	154	114	184
Provision for income taxes	$2,339	$8,885	$3,609

The 2018 provision for income taxes included a $588 million deferred tax charge on previously acquired intangible assets resulting from a transfer of these assets between wholly owned subsidiaries. The 2017 provision for income taxes included a $5.5 billion provisional charge to income tax expense related to Tax Reform enacted in December 2017.

On December 22, 2017, Tax Reform was signed into law making significant changes to the Internal Revenue Code of 1986, as amended. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, a repatriation tax on deemed repatriated earnings of foreign subsidiaries, implementation of a modified territorial tax system, which has the effect of subjecting earnings of our foreign subsidiaries to U.S. taxation on Global Intangible Low-Taxed Income (GILTI). As a result, we recorded a provisional charge to income tax expense of $5.5 billion in December 2017, which included a provisional $308 million deferred tax benefit related to the re-measurement of certain deferred tax assets and liabilities and a $5.8 billion provisional charge related to the transition tax on the mandatory deemed repatriation of accumulated foreign earnings.

The accounting for the income tax effects of Tax Reform was completed in accordance with SAB 118 in 2018 and as a result, we recorded a $4 million net tax charge to our income tax provision primarily relating to the deferred tax revaluation partially offset by the refinement to the provisional estimate of transition tax.

As of December 31, 2017, the accrued federal liability for transition tax was $6.1 billion, which was payable over an eight year period. As of December 31, 2018, the accrued federal liability for transition tax was $4.6 billion, which was included in Long-term income taxes payable on our Consolidated Balance Sheets. The decrease of $1.5 billion was primarily due to $1.3 billion of payments in 2018 and $174 million of refinements to the provisional estimate.

For the year ended December 31, 2018, we repatriated $30.4 billion of cash, cash equivalents and marketable securities to our parent company headquartered in the United States. Prior to the enactment of Tax Reform, these earnings were considered indefinitely reinvested and no U.S. taxes had been provided. In 2017 U.S. taxes have been provided on these earnings through the accrual of the transition tax.

Additionally, we completed our evaluation of the accounting policy election required with regard to the tax on GILTI. The FASB allows companies to adopt a policy election to account for the tax on GILTI under one of two methods: (i) account for the tax on GILTI as a component of tax expense in the period in which the tax is incurred (the period cost method), or (ii) account for the tax on GILTI in a company’s measurement of deferred taxes (the deferred method). We have elected to account for the tax on GILTI under the period cost method.

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

	Year Ended December 31,		
	2018	2017	2016
Federal statutory rate	21.0 %	35.0 %	35.0 %
State taxes, net of federal benefit	0.6 %	0.1 %	0.7 %
Foreign earnings at different rates	(0.9)%	(11.2)%	(16.0)%
Research and other credits	(1.1)%	(0.6)%	(0.7)%
US tax on foreign earnings	2.1 %	1.2 %	0.7 %
Deferred tax charge on acquired intangibles	7.5 %	— %	— %
Transition tax	(0.7)%	42.9 %	— %
Deferred tax revaluation	0.8 %	(2.3)%	— %
Settlement of tax examinations	(1.9)%	— %	— %
Other	2.6 %	0.6 %	1.4 %
Effective tax rate	30.0 %	65.7 %	21.1 %

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,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$344	$322
Stock-based compensation	163	165
Reserves and accruals not currently deductible	426	336
Deferred revenue	—	27
Depreciation related	61	56
Research and other credit carryforwards	363	293
Other, net	183	102
Total deferred tax assets before valuation allowance	1,540	1,301
Valuation allowance	(331)	(162)
Total deferred tax assets	1,209	1,139
Deferred tax liabilities:		
Intangibles	(1,667)	(1,316)
Other	(80)	(70)
Total deferred tax liabilities	(1,747)	(1,386)
Net deferred tax assets (liabilities)	$(538)	$(247)

The valuation allowance was $331 million and $162 million at December 31, 2018 and 2017, respectively. The increase of our valuation allowance in 2018 was primarily related to certain Kite tax attributes and certain foreign jurisdictions, which do not have sufficient history of profit to realize the benefit of the losses on a more-likely-than-not basis.

At December 31, 2018, we had U.S. federal net operating loss carryforwards of approximately $494 million. The federal net operating loss carryforwards will start to expire in 2021, if not utilized. We also had federal tax credit carryforwards of approximately $179 million which will start to expire in 2020, if not utilized. In addition, we had state net operating loss and tax credit carryforwards of approximately $1.5 billion and $414 million, respectively. The state net operating loss and tax credit carryforwards will start to expire in 2019 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 2013 and onwards and 2010 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 IRS for the tax years from 2013 to 2015 and by various state and 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 periodically evaluate our exposures associated with our tax filing positions.

Of the total unrecognized tax benefits, $1.3 billion and $1.8 billion at December 31, 2018 and 2017, if recognized, would reduce our effective tax rate in the period of recognition. We include interest and penalties related to unrecognized tax benefits as part of Provision for income taxes on our Consolidated Statements of Income. We had accrued interest and penalties related to unrecognized tax benefits of $154 million and $112 million at December 31, 2018 and 2017, respectively.

As of December 31, 2018, 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 taxing authorities.

The following is a rollforward of our total gross unrecognized tax benefits (in millions):

	December 31,		
	2018	2017	2016
Balance, beginning of period	$2,181	$1,852	$1,350
Tax positions related to current year:			
Additions	64	299	522
Reductions	—	—	—
Tax positions related to prior years:			
Additions	125	67	33
Reductions	—	(16)	(3)
Settlements	(774)	(12)	(49)
Lapse of statute of limitations	(1)	(9)	(1)
Balance, end of period	$1,595	$2,181	$1,852

SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following amounts are in millions, except per share amounts:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2018				
Total revenues	$ 5,088	$ 5,648	$ 5,596	$ 5,795
Gross profit on product sales	$ 4,000	$ 4,344	$ 4,369	$ 4,111
Net income[1]	$ 1,539	$ 1,819	$ 2,099	$ 3
Net income attributable to Gilead[1]	$ 1,538	$ 1,817	$ 2,097	$ 3
Net income per share attributable to Gilead common stockholders - basic[2]	$ 1.18	$ 1.40	$ 1.62	$ —
Net income per share attributable to Gilead common stockholders - diluted[2]	$ 1.17	$ 1.39	$ 1.60	$ —
2017				
Total revenues	$ 6,505	$ 7,141	$ 6,512	$ 5,949
Gross profit on product sales	$ 5,420	$ 5,920	$ 5,370	$ 4,581
Net income (loss)[3]	$ 2,699	$ 3,069	$ 2,712	$ (3,836)
Net income (loss) attributable to Gilead[3]	$ 2,702	$ 3,073	$ 2,718	$ (3,865)
Net income (loss) per share attributable to Gilead common stockholders - basic[3]	$ 2.07	$ 2.35	$ 2.08	$ (2.96)
Net income (loss) per share attributable to Gilead common stockholders - diluted[3]	$ 2.05	$ 2.33	$ 2.06	$ (2.96)

Notes:

(1) Amounts for the fourth quarter of 2018 included $820 million and $588 million from an impairment and a non-cash tax charge related to intangible assets acquired from Kite Pharma, Inc., respectively, and inventory reserves of $410 million for excess raw materials primarily due to a sustained decrease in demand for Harvoni. See Note 7, Inventories, Note 9, Intangible Assets and Note 18, Income Taxes, of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional details.

(2) Amounts for the fourth quarter of 2018 included an unfavorable impact of $1.31 per basic share and $1.30 per diluted share from the factors noted above.

(3) In December 2017, we recorded a $5.5 billion net charge, or $4.20 per basic share and $4.16 per diluted share, related to the enactment of the Tax Cuts and Jobs Act. See Note 18, Income Taxes of the Notes to Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K for additional details.

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GILEAD SCIENCES, INC.
Schedule II: Valuation and Qualifying Accounts
(in millions)

	Balance at Beginning of Period	Additions/Charged to Expense	Deductions	Balance at End of Period
Year ended December 31, 2018:				
Accounts receivable allowances[1]	$ 455	$ 7,572	$ 7,444	$ 583
Sales return allowance	$ 162	$ 85	$ 88	$ 159
Valuation allowances for deferred tax assets	$ 162	$ 170	$ 1	$ 331
Year ended December 31, 2017:				
Accounts receivable allowances[1]	$ 763	$ 7,682	$ 7,990	$ 455
Sales return allowance	$ 195	$ 23	$ 56	$ 162
Valuation allowances for deferred tax assets	$ 126	$ 72	$ 36	$ 162
Year ended December 31, 2016:				
Accounts receivable allowances[1]	$ 1,032	$ 9,287	$ 9,556	$ 763
Sales return allowance	$ 371	$ (141)	$ 35	$ 195
Valuation allowances for deferred tax assets	$ 6	$ 120	$ —	$ 126

Notes:
(1) Allowances are for doubtful accounts, cash discounts and chargebacks.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2018 was carried out under the supervision and with the participation of our management, including our interim Chief Executive Officer and Chief Financial Officer, of the effectiveness of our “disclosure controls and procedures,” which are defined in Rule 13a-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 interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at December 31, 2018.

(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) 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 interim 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, 2018.

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, 2018. Their report on the audit of internal control over financial reporting appears below.

(c) Changes in Internal Control over Financial Reporting

Our management, including our interim 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, 2018, 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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2018, 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, 2018, 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, 2018 and 2017, 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, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a) and our report dated February 25, 2019 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 25, 2019

ITEM 9B. OTHER INFORMATION

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 2019 Annual Meeting of Stockholders (the Proxy Statement) under the headings “The Gilead Board of Directors - Nominees,” “Board Structure,” “Executive Officers,” and “Section 16(a) Beneficial Ownership Reporting Compliance.”

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 http://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 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:

(2) Schedule II is included on page 91 of this report. 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)	3.1	Restated Certificate of Incorporation of Registrant
(2)	3.2	Amended and Restated Bylaws of Registrant
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(3)	4.2	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(3)	4.3	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)
(4)	4.4	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 2014 Note, Form of 2016 Note, Form of 2021 Note, Form of 2041 Note)
(5)	4.5	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 2019 Note, Form of 2024 Note, Form of 2044 Note)
(6)	4.6	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 2020 Note, Form of 2025 Note, Form of 2045 Note)
(7)	4.7	Fifth Supplemental Indenture, dated as of September 14, 2015, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2018 Note, Form of 2020 Note, Form of 2022 Note, Form of 2026 Note, Form of 2035 Note and Form of 2046 Note)
(8)	4.8	Sixth Supplemental Indenture, dated as of September 20, 2016, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2022 Note, Form of 2023 Note, Form of 2027 Note, Form of 2036 Note and Form of 2047 Note)
(9)	4.9	Seventh Supplemental Indenture, dated as of September 21, 2017, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of Fixed Rate Note, Form of Form of September 2018 Note, Form of March 2019 Note and Form of September 2019 Note)
*(10)	10.1	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended and restated May 10, 2017
*(11)	10.2	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(12)	10.3	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(13)	10.4	

		Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(14)	10.5	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(12)	10.6	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(15)	10.7	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(15)	10.8	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(16)	10.9	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in and after May 2014)
*(15)	10.10	Form of restricted stock unit issuance agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(17)	10.11	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) in 2016)
*(17)	10.12	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) with Director Retirement Provisions in 2016)
*(17)	10.13	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) in 2016)
*(17)	10.14	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) with Director Retirement Provisions in 2016)
*(18)	10.15	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals - Non-US in 2015)
*(17)	10.16	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals -Non-US in 2016)
*(18)	10.17	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2015)
*(17)	10.18	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2016)
*(14)	10.19	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(19)	10.20	Gilead Sciences, Inc. Employee Stock Purchase Plan, restated on January 22, 2015
*(20)	10.21	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document

*(20)	10.22	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement

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*(20)	10.23	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(21)	10.24	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(22)	10.25	Gilead Sciences, Inc. Severance Plan, as amended on March 8, 2016
*(23)	10.26	Gilead Sciences, Inc. Corporate Bonus Plan, as amended and restated on January 1, 2019
*(24)	10.27	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(25)	10.28	Gilead Sciences, Inc. Retention Program for Executive Officers
*(26)	10.29	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(27)	10.30	Separation Agreement and Release dated August 6, 2018 between Registrant and John F. Milligan, Ph.D.
*(28)	10.31	Offer Letter dated November 30, 2018 between Registrant and Daniel O'Day
*(29)	10.32	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(29)	10.33	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(30)	10.34	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(31)	10.35	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)
+(32)	10.36	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+(33)	10.37	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
+(34)	10.38	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
+(35)	10.39	

		Exclusive License Agreement 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
+(36)	10.40	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
+(36)	10.41	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
+	10.42	Amended and Restated EVG License Agreement between Japan Tobacco Inc., and Registrant, dated November 29, 2018
+	10.43	Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018
+(37)	10.44	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
+(38)	10.45	License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013
	21.1	Subsidiaries of Registrant
	23.1	Consent of Independent Registered Public Accounting Firm
	31.1	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
	31.2	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
	32.1**	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)
	101.INS***	XBRL Instance Document
	101.SCH***	XBRL Taxonomy Extension Schema Document
	101.CAL***	XBRL Taxonomy Extension Calculation Linkbase Document
	101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document
	101.LAB***	XBRL Taxonomy Extension Label Linkbase Document
	101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2014, and incorporated herein by reference.

(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 23, 2015, and incorporated herein by reference.

(3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
(4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.
(5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.
(6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.
(7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, and incorporated herein by reference.
(8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference.
(9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 21, 2017, and incorporated herein by reference.
(10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 12, 2017, 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, 2007, and incorporated herein by reference.
(12) 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.
(13) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, 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, 2013, and incorporated herein by reference
(16) 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.
(17) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, 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, 2015, and incorporated herein by reference.
(19) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.
(20) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
(21) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.
(22) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 11, 2016, and incorporated herein by reference.
(23) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, and incorporated herein by reference.
(24) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 17, 2016, and incorporated herein by reference.
(25) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, and incorporated herein by reference.
(26) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
(27)

Filed as an exhibit to Registrant’s Current Report on Form 8-K filed on August 7, 2018, and incorporated herein by reference.

(28) Filed as an exhibit to Registrant’s Current Report on Form 8-K filed on December 10, 2018, and incorporated herein by reference.

(29) Filed as an exhibit to Registrant’s Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.

(30) 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.

(31) 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.

(32) 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.

(33) 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.

(34) 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.

(35) 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.

(36) 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.

(37) 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.

(38) 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.

** Furnished herewith.

*** Filed 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.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GILEAD SCIENCES, INC.

By: /S/ GREGG H. ALTON
Gregg H. Alton
Interim Chief Executive Officer and Chief Patient Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gregg H. Alton and Brett A. Pletcher, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ GREGG H. ALTON Gregg H. Alton	Interim Chief Executive Officer and Chief Patient Officer (Principal Executive Officer)	February 25, 2019
/S/ ROBIN L. WASHINGTON Robin L. Washington	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2019
/S/ JOHN C. MARTIN John C. Martin, Ph.D.	Chairman of the Board of Directors	February 25, 2019
/S/ JACQUELINE K. BARTON Jacqueline K. Barton, Ph.D.	Director	February 25, 2019
/S/ JOHN F. COGAN John F. Cogan, Ph.D.	Director	February 25, 2019
/S/ KELLY A. KRAMER Kelly A. Kramer	Director	February 25, 2019
/S/ KEVIN E. LOFTON Kevin E. Lofton	Director	February 25, 2019
/S/ NICHOLAS G. MOORE Harish Manwani	Director	February 25, 2019
/S/ RICHARD J. WHITLEY Richard J. Whitley, M.D.	Director	February 25, 2019
/S/ GAYLE E. WILSON Gayle E. Wilson	Director	February 25, 2019
/S/ PER WOLD-OLSEN Per Wold-Olsen	Director	February 25, 2019