GILEAD SCIENCES INC
Form 10-K
February 26, 2019

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

FORM 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File No. 000-19731

GILEAD SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	94-3047598
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
333 Lakeside Drive, Foster City, California	94404
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 650-574-3000

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value per share	The Nasdaq Global Select Market

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes x No ¨
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company"

and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ý Accelerated filer ¨ Non-accelerated filer ¨

Smaller reporting company ¨ Emerging growth company ¨

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 29, 2018 was $79,506,595,778.*

The number of shares outstanding of the registrant’s Common Stock on February 15, 2019 was 1,275,510,558.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant’s proxy statement, which will be filed with the Commission pursuant to Regulation 14A in connection with the registrant’s 2019 Annual Meeting of Stockholders, to be held on May 8, 2019, are incorporated by reference into Part III of this Report.

* Based on a closing price of $70.84 per share on June 29, 2018. Excludes 173,576,690 shares of the registrant’s Common Stock held by executive officers, directors and any stockholders whose ownership exceeds 5% of registrant’s common stock outstanding at June 29, 2018. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, AMBISOME®, ATRIPLA®, BIKTARVY®, CAYSTON®, COMPLERA®, DESCOVY®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPSERA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, TRUVADA®, TRUVADAFORPREP®, TYBOST®, VEMLIDY®, VIREAD®, VOSEVI®, YESCARTA® and ZYDELIG®. LEXISCAN® is a registered trademark of Astellas U.S. LLC. MACUGEN® is a registered trademark of Eyetech, Inc. SYMTUZA® is a registered trademark of Janssen Sciences Ireland UC. TAMIFLU® is a registered trademark of Hoffmann-La Roche Inc. This report also includes other trademarks, service marks and trade names of other companies.

This Annual Report on Form 10-K, including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the Securities Act), and the Securities Exchange Act of 1934, as amended (the Exchange Act). Words such as “expect,” “anticipate,” “target,” “goal,” “project,” “hope,” “intend,” “plan,” “believe,” “seek,” “estimate,” “continue,” “may,” “could,” “should,” “might,” "fore such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions.

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

PART I

ITEM 1. BUSINESS

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.

2018 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 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.

Our Principal Products

Our innovative medicines represent advancements by offering enhanced modes of delivery, more convenient treatment regimens, improved resistance profiles, reduced side effects and greater efficacy. Our focus on innovation has allowed us to deliver more than 24 marketed products across our primary areas of focus: HIV/AIDS, liver diseases, hematology/oncology and inflammation/respiratory diseases.

Our principal products and the approved indications in the United States are as follows:

HIV/AIDS

- Biktarvy is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Biktarvy is a single tablet regimen of a fixed-dose combination of our antiretroviral medications, bictegravir, emtricitabine and TAF.
- Descovy® is an oral formulation indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in certain patients. Descovy is a fixed-dose combination of our antiretroviral medications, emtricitabine and TAF.
- Odefsey® is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Odefsey is a single tablet regimen of a fixed-dose combination of our antiretroviral medications, emtricitabine and TAF, and rilpivirine marketed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen).
- Genvoya® is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Genvoya is a single tablet regimen of a fixed-dose combination of our antiretroviral medicines, elvitegravir, cobicistat, emtricitabine and TAF.
- Stribild® is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Stribild is a single tablet regimen of a fixed-dose combination of our antiretroviral medications, elvitegravir, cobicistat, tenofovir disoproxil fumarate (TDF) and emtricitabine.
- Complera®/Eviplera® is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. The product, marketed in the United States as Complera and in Europe as Eviplera, is a single tablet regimen of a fixed-dose combination of our antiretroviral medications, TDF and emtricitabine, and Janssen's rilpivirine hydrochloride.
- Atripla® is an oral formulation indicated as a complete regimen for the treatment of HIV-1 infection in certain patients. Atripla is a fixed-dose combination of our antiretroviral medications, TDF and emtricitabine, and Bristol-Myers Squibb Company's (BMS's) efavirenz.
- Truvada® is an oral formulation indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in certain patients. It is a fixed-dose combination of our antiretroviral medications, TDF and emtricitabine. FDA also approved Truvada for a PrEP indication, in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in certain at-risk patients.

Liver Diseases

- Vosevi® is an oral formulation of a once-daily, single tablet regimen of sofosbuvir, velpatasvir and voxilaprevir for the re-treatment of chronic HCV infection in adults: (i) with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen or (ii) with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor.
- Vemlidy® is an oral formulation of TAF dosed once a day for the treatment of chronic HBV infection in adults with compensated liver disease.
- Epclusa® is an oral formulation of a once-daily single tablet regimen of sofosbuvir and velpatasvir for the treatment of chronic HCV infection in adults with genotype 1, 2, 3, 4, 5 or 6: (i) without cirrhosis or with compensated cirrhosis or (ii) with decompensated cirrhosis for use in combination with ribavirin.
- Harvoni® is an oral formulation of a once-daily, single tablet regimen of ledipasvir and sofosbuvir for the treatment of chronic HCV infection in: (i) adults with genotype 1, 4, 5 or 6 without cirrhosis or with compensated cirrhosis, (ii) adults with genotype 1 infection with decompensated cirrhosis, in combination with ribavirin, (ii) adults with genotype 1 or 4 who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin, or (iv) certain pediatric patients with genotype 1, 4, 5 or 6 without cirrhosis or with compensated cirrhosis.
- Viread® is an oral formulation of TDF dosed once a day for the treatment of chronic HBV infection in adults and certain pediatric patients.

Hematology/Oncology

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Yescarta (axicabtagene ciloleucel) is a 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, including DLBCL not otherwise specified, PMBCL, high-grade B-cell lymphoma and DLBCL arising from TFL.

- Zydelig® (idelalisib) is an oral formulation of a kinase inhibitor for the treatment of patients with: (i) relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, for whom rituximab alone would be considered appropriate therapy due to other co-morbidities, (ii) relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies or (iii) relapsed small lymphocytic lymphoma who have received at least two prior systemic therapies.

Other

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

For information about our product revenues, including the amount of revenue contributed by each of the products listed above for each of the last three fiscal years, see Note 2, Revenues, of the Notes to Consolidated Financial Statements included in Item 8 of our Annual Report on Form 10-K.

Commercialization and Distribution

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

We sell and distribute most of our products in the United States exclusively through the wholesale channel. Our product sales to three large wholesalers, McKesson Corporation, AmerisourceBergen Corporation and Cardinal Health, Inc., each accounted for more than 10% of total revenues for each of the years ended December 31, 2018, 2017 and 2016. On a combined basis, in 2018, these wholesalers accounted for approximately 85% of our product sales in the United States and approximately 62% of our total worldwide revenues. We sell and distribute our products in Europe and countries outside the United States where the product is approved, either through our commercial teams, third-party distributors or corporate partners.

Competition

We operate in a highly competitive environment. We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers. Our products compete with other commercially available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing. As our products mature, 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 a description of our competitors, see Item 1A - Risk Factors “We face significant competition.”

Research and Development

Our research and development (R&D) philosophy and strategy are to develop best-in-class drugs that improve safety or efficacy for unmet medical needs. We intend to continue committing significant resources to internal R&D opportunities and external business development activity.

Our product development efforts cover a wide range of medical conditions, including HIV/AIDS, liver diseases, hematology/oncology, and inflammation/respiratory diseases. We have research scientists engaged in the discovery and development of new molecules and technologies that we hope will lead to the approval of new medicines that will advance the current standard of care and address unmet medical needs.

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

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Below is a summary of our key product candidates and their corresponding current stages of development.

Product Candidates for the Treatment of HIV/AIDS

Product Candidates	Description
Product in Phase 3	
Descovy	Descovy is being evaluated for a PrEP indication.
Product in Phase 2	
GS-9131	GS-9131, a nucleoside reverse transcriptase inhibitor, is being evaluated for the treatment of HIV infection.
Products in Phase 1	
GS-6207	GS-6207, a capsid inhibitor, is being evaluated for the treatment of HIV infection.
Vesatolimod	Vesatolimod (formerly GS-9620), a TLR-7 agonist, is being evaluated as a potential cure for HIV infection.
GS-9722	GS-9722, a broadly neutralizing antibody, is being evaluated as a potential cure for HIV infection.

Product Candidates for the Treatment of Liver Diseases

Product Candidates	Description
Product in Phase 3	
Selonsertib	Selonsertib, an ASK-1 inhibitor, is being evaluated in the STELLAR-3 trial for the treatment of NASH and bridging fibrosis.
Products in Phase 2	
GS-9688	GS-9688, a TLR-8 agonist, is being evaluated for the treatment of HBV infection.
Cilofexor	Cilofexor (formerly GS-9674), a FXR agonist, is being evaluated for the treatment of NASH, primary biliary cirrhosis and primary sclerosing cholangitis.
Firsocostat	Firsocostat (formerly GS-0976), an ACC inhibitor, is being evaluated for the treatment of NASH.

Product Candidates for the Treatment of Hematology/Oncology

Product Candidates	Description
Products in Phase 3	
Axicabtagene ciloleucel	Axicabtagene ciloleucel is being evaluated for the treatment of second line diffuse large B-cell lymphoma (DLBCL).
Products in Phase 2	
Axicabtagene ciloleucel	Axicabtagene ciloleucel is being evaluated for the treatment of indolent non-Hodgkin lymphoma. Axicabtagene ciloleucel is also being evaluated for the treatment of DLBCL in combination with anti-PD-L1 mAB and first line DLBCL.
Tirabrutinib	Tirabrutinib, a BTK inhibitor, is being evaluated for the treatment of B-cell malignancies.
KTE-X19	KTE-X19, a CAR T cell therapy, is being evaluated for the treatment of mantle cell lymphoma and adult and pediatric acute lymphoblastic leukemia.
Products in Phase 1	
KITE-718	KITE-718, a MAGE A3/A6, is being evaluated for the treatment of solid tumors.

Product Candidates for the Treatment of Inflammation/Respiratory Diseases

Product Candidates	Description
Product in Phase 3	
Filgotinib	Filgotinib, a JAK1 inhibitor, is being evaluated for the treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis.
Products in Phase 2	
Filgotinib	Filgotinib is being evaluated for the treatment of various inflammatory diseases.
GS-9876	GS-9876, a Syk inhibitor, is being evaluated for the treatment of Sjogren's syndrome and lupus.
Products in Phase 1	
GS-4875	GS-4875, a TPL2 inhibitor, is being evaluated for the treatment of inflammatory bowel disease.

Other Product Candidates

Product Candidate	Description
Product in Phase 2	
Remdesivir	Remdesivir, a Nuc inhibitor, is being evaluated for the treatment of Ebola virus infection.

In addition to our internal discovery and clinical development programs, we seek to add to our portfolio of products through product acquisition, in-licensing and strategic collaborations. We completed 26 collaborations, partnerships and strategic investments in 2018, compared to 6 in 2017, 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.

Patents and Proprietary Rights

U.S. and European Patent Expiration

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

The following table shows the estimated expiration dates (including patent term extensions, supplementary protection certificates and/or pediatric exclusivity where granted) in the United States and the European Union for the primary (typically compound) patents for our Phase 3 product candidates. For our product candidates that are fixed-dose combinations of single tablet regimens, the estimated patent expirati