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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File No. 0-19731

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 ☒ 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 ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 ☒ 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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-Accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2016 was $103,455,508,531.*

The number of shares outstanding of the registrant's Common Stock on February 16, 2017 was 1,307,066,900.

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 2017 Annual Meeting of Stockholders, to be held on May 10, 2017, are incorporated by reference into Part III of this Report.

* Based on a closing price of $83.42 per share on June 30, 2016. Excludes 90,648,083 shares of the registrant's Common Stock held by executive officers, directors and any stockholders whose ownership exceeds 5% of registrant's common stock outstanding at June 30, 2016. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

GILEAD SCIENCES, INC.

2016 Form 10-K Annual Report

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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, AMBISOME®, CAYSTON®, COMPLERA®, DESCOVY®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPSERA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, TRUVADA®, TYBOST®, VEMLIDY®, VIREAD®, VITEKTA®, VOLIBRIS® and ZYDELIG®. ATRIPLA® is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC. LEXISCAN® is a registered trademark of Astellas U.S. LLC. MACUGEN® is a registered trademark of Eyetech, Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Pharma Company. 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," variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs 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 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 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 30 countries worldwide, with headquarters in Foster City, California. Gilead's primary areas of focus include human immunodeficiency virus (HIV), liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, hematology/oncology, cardiovascular and inflammation/respiratory diseases. We seek to add to our existing portfolio of products through our internal discovery and clinical development programs and through product acquisition and in-licensing strategies.

2016 Highlights

Over the past year, we continued to bring best-in-class drugs to market that advance the standard of care by offering enhanced modes of delivery, more convenient treatment regimens, improved resistance profiles, reduced side effects and greater efficacy. In the area of HIV, U.S. Food and Drug Administration (FDA) and the European Commission approved two tenofovir alafenamide (TAF)-based regimens: Odefsey® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg) for the treatment of HIV-1 infection in certain patients and Descovy® (emtricitabine 200 mg/tenofovir alafenamide 25 mg), a fixed-dose combination for the treatment of HIV-1 infection. In the liver diseases area, we received FDA and European Commission approval of Epclusa® (sofosbuvir 400 mg/velpatasvir 100 mg), the first all-oral, pan-genotypic, single-tablet regimen for the treatment of adults with genotype 1-6 chronic HCV infection. Epclusa is also the first single-tablet regimen approved for the treatment of patients with HCV genotype 2 and 3, without the need for ribavirin. We also received FDA approval of Vemlidy® (tenofovir alafenamide 25 mg), a once-daily treatment for adults with HBV infection with compensated liver disease. In the inflammation/respiratory area, we advanced filgotinib, a JAK1 inhibitor we are developing with Galapagos NV (Galapagos) to Phase 3 clinical trials for the potential treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis. At the end of 2016, our research and development pipeline included 167 active clinical studies, of which 61 were Phase 3 clinical trials.

In addition to advancing treatment options across therapeutic areas, we also enabled access to our medications for people who need them around the world. We continued to expand access to our medicines in low- and middle-income countries by pursuing multiple strategies, including entering into collaborations with governments, generic manufacturers, regional business partners, policy makers, healthcare providers, patient groups and public health entities. Today, 10 million people are receiving Gilead HIV medicines in low- and middle-income countries. In 2016, we also entered into a partnership with the World Health Organization (WHO) to provide $20 million in funding and drug donations over five years to expand access to diagnostic services and treatment for visceral leishmaniasis, the world's second-deadliest parasitic infectious disease that affects up to 300,000 people annually in resource-limited countries.

HIV

Our goal is to ensure that all HIV patients can choose a single-tablet regimen that is right for them. Single-tablet regimens allow patients to adhere to a fully suppressive course of therapy more easily and consistently, which is critical for the successful management of the disease. HIV patients are living longer, thus facing additional health challenges to those experienced by newly diagnosed patients. We are motivated to continue improving on existing treatment options. The need for efficacy together with improved long-term safety has driven our development programs and the design of the studies we have completed and those that are planned.

Our TAF single-tablet regimens seek to address the diverse needs of HIV patients worldwide. TAF is a novel targeted prodrug of tenofovir that has demonstrated high antiviral efficacy similar to and at a dose less than one-tenth that of Viread® (tenofovir disoproxil fumarate, TDF), as well as improvement in surrogate laboratory markers of renal and bone safety as compared to TDF in clinical trials in combination with other antiretroviral agents. With the launch of our two TAF-based single-tablet regimens, Genvoya® (elvitegravir 150mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg) and Odefsey, we now have five single-tablet regimens available for the treatment of HIV. Odefsey is currently the smallest pill of any single-tablet regimen for the treatment of HIV. Descovy, a fixed-dose combination for the treatment of HIV, also represents an important evolution in HIV care, as it is the first new HIV treatment backbone approved by FDA in more than a decade.

In addition, we are evaluating bictegravir/emtricitabine/TAF in Phase 3 studies for the treatment of HIV. We anticipate completing these studies in the third quarter of 2017.

Liver Diseases

Our goal is to advance the treatment options and standard of care for the HCV market. With the approval of Sovaldi® (sofosbuvir 400 mg), compared to the prior standard of care of up to 48 weeks, the duration of treatment was shortened to as few as 12 weeks and the need for peg-interferon injections in certain viral genotype populations was reduced or eliminated completely. Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg) is the first once-daily single-tablet regimen for the treatment of HCV genotype 1-infected patients, the most prevalent genotype in the United States. In 2016, we received approval of Epclusa, the first all-oral, pan-genotypic, single-tablet regimen for the treatment of adults with genotype 1-6 chronic HCV infection. Epclusa is also the first single-tablet regimen approved for the treatment of patients with HCV genotype 2 and 3, without the need for ribavirin. In the fourth quarter of 2016, we submitted a new drug application to FDA for the approval of an investigational, once-daily, single-tablet regimen containing sofosbuvir 400 mg, velpatasvir 100 mg and voxilaprevir 100 mg (SOF/VEL/VOX), for the treatment of HCV. The product, if approved, would offer an effective cure for patients who have failed prior therapy with other highly effective regimens.

In 2016, we received FDA approval of Vemlidy, a once-daily treatment for adults with HBV infection with compensated liver disease.

We are also evaluating selonsertib, an investigational small-molecule inhibitor of apoptosis signal-regulating kinase 1, or ASK-1, for the treatment of nonalcoholic steatohepatitis (NASH) in Phase 3 clinical trials. Based on the Phase 2 results, we intend to evaluate selonsertib in patients with NASH and moderate to severe fibrosis. We have two other compounds with different mechanisms currently in two Phase 2 studies in patients with NASH and fibrosis - GS-9674, an FXR agonist, and GS-0976, an acetyl-CoA carboxylase (ACC) inhibitor. Pending demonstration of single agent efficacy and safety in these Phase 2 studies, we plan to initiate combination studies with the three agents in 2017.

Hematology/Oncology

In the hematology/oncology area, we continued to progress our product candidates through clinical trials. Idelalisib, a PI3K delta inhibitor, is in Phase 3 clinical trials for the treatment of patients with relapsed refractory chronic lymphocytic leukemia (CLL). We are also evaluating GS-5745, an investigational anti-MMP9 antibody, in a Phase 3 study for the treatment of gastric cancer.

Inflammation/Respiratory

In 2016, we closed on a license and collaboration agreement with Galapagos, a clinical-stage biotechnology company based in Belgium, for the development and commercialization of filgotinib, a JAK1 inhibitor being evaluated in Phase 3 trials for three inflammatory disease indications - rheumatoid arthritis, Crohn's disease and ulcerative colitis. In 2017, we also expect to initiate Phase 2 clinical trials evaluating filgotinib in combination with GS-9876, a Syk inhibitor, and GS-4059, a BTK inhibitor, for the potential treatment of rheumatoid arthritis.

Our Products

HIV

- **Descovy** is an oral formulation indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age or older. Descovy is a fixed-dose combination of our antiretroviral medications, Emtriva® (emtricitabine) and TAF. Descovy was approved by FDA and the European Commission in April 2016.
- **Odefsey** is an oral formulation dosed once a day for the treatment of HIV-1 infection in certain patients. Odefsey is a fixed-dose combination of our antiretroviral medications, Emtriva and TAF, and rilpivirine marketed by Janssen Sciences Ireland UC (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Odefsey represents the smallest pill of any single-tablet regimen for the treatment of HIV. Odefsey was approved by FDA in March 2016 and the European Commission in June 2016.
- **Genvoya** is an oral formulation dosed once a day for the treatment of HIV-1 infection in adults. Genvoya is a single-tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medicines, Vitekta® (elvitegravir), Tybost® (cobicistat), Emtriva and TAF.
- **Stribild®** (elvitegravir/cobicistat/emtricitabine/TDF) is an oral formulation dosed once a day for the treatment of HIV-1 infection in treatment-naive adults. Stribild is a single-tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medications, Vitekta, Tybost, Viread and Emtriva.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

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Sync your system to PACER to automate legal marketing.