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, 2015

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, 2015 was $140,034,139,655.*

The number of shares outstanding of the registrant's Common Stock on February 12, 2016 was 1,366,845,691.

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 2016 Annual Meeting of Stockholders, to be held on May 11, 2016, are incorporated by reference into Part III of this Report.

* Based on a closing price of $117.08 per share on June 30, 2015. Excludes 276,651,262 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, 2015. 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.

2015 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®, EMTRIVA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPSERA®, LETAIRIS®, RANEXA®, RAPISCAN®, SOVALDI®, STRIBILD®, TRUVADA®, TYBOST®, VIREAD®, VITEKTA®, VOLIBRIS®, and ZYDELIG®. ATRIPLA® is a registered trademark belonging to Bristol-Myers Squibb & Gilead Sciences, LLC. LEXISCAN® is a registered trademark belonging to Astellas U.S. LLC. MACUGEN® is a registered trademark belonging to Eyetech, Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Pharma Company. TAMIFLU® is a registered trademark belonging to 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. 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, cardiovascular, hematology/oncology and inflammation/respiratory. We have operations in more than 30 countries worldwide, with headquarters in Foster City, California. We continue to add to our existing portfolio of products through our internal discovery and clinical development programs and through a product acquisition and in-licensing strategy.

2015 Highlights

Over the past year, we worked 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 HIV area, we received approval from U.S. Food and Drug Administration (FDA) and the European Commission of Genvoya® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir alafenamide 10 mg or E/C/F/TAF), a once-daily single tablet regimen for the treatment of HIV-1 infection. Two other TAF-based regimens are currently under evaluation by FDA and the European Medicines Agency (EMA). The first is an investigational, fixed-dose combination of emtricitabine 200 mg and tenofovir alafenamide 25 or 10 mg (F/TAF) for use in combination with other antiretroviral agents. The second is an investigational, once-daily single tablet regimen that combines emtricitabine 200 mg, tenofovir alafenamide 25 mg and rilpivirine 25 mg (R/F/TAF). In the liver diseases area, we received approval from FDA to expand the use of Harvoni® in patients with genotype 4, 5 and 6 chronic HCV infection and in patients co-infected with HIV. In addition, Harvoni plus ribavirin (RBV) for 12 weeks was approved as an alternate therapy to 24 weeks of Harvoni for treatment-experienced, genotype 1 patients with cirrhosis. We also submitted marketing applications to FDA and the EMA for the approval of a once-daily fixed-dose combination of sofosbuvir (SOF), approved as Sovaldi® in December 2013, and velpatasvir (VEL), an investigational pan-genotypic NS5A inhibitor, for the treatment of chronic genotype 1-6 HCV. If approved, SOF/VEL would become the first pan-genotypic, all-oral single tablet regimen for the treatment of HCV and would complement our current HCV portfolio of Sovaldi and Harvoni, offering high cure rates and the potential to simplify treatment and eliminate the need for HCV genotype testing. In the hematology/oncology area, we submitted supplemental new drug applications to FDA and the EMA for approval of Zydelig® (idelalisib) in combination with ofatumumab in previously-treated patients with chronic lymphocytic leukemia (CLL). Zydelig was originally approved in combination with rituximab for the treatment of certain patients with CLL, small lymphocytic lymphoma and follicular lymphoma, the most common type of indolent non-Hodgkin's lymphoma (iNHL). We also advanced our research and development pipeline, with 180 active clinical studies at the end of 2015, 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. During 2015, we expanded our generic licensing agreements with our India-based manufacturing partners to include SOF/VEL, once approved, for distribution in developing countries. A pan-genotypic therapeutic option for the treatment of HCV is particularly important for developing countries, where genotype testing is often unreliable or not readily available. We also expanded the geographic scope of our licensing agreements with our India-based manufacturing partners to include 101 developing countries. In 2015, we also updated our tiered pricing strategy to make our branded HCV medicines available at a significantly reduced public/government price in all of these 101 countries. By making our pricing in these countries clear and transparent, we hope to facilitate planning and encourage a meaningful public health response to HCV.

HIV Program

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.

We look forward to introducing this new generation of TAF single tablet regimens that we have created to address the evolving needs of people living with HIV. 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 in clinical trials to TDF in combination with other antiretroviral agents. With the launch of our first TAF-based regimen, Genvoya, we now have four single tablet regimens available for the treatment of HIV. Marketing approvals for two additional TAF-based product candidates, F/TAF and R/F/TAF, are pending in the United States and European Union. Our product candidate R/F/TAF has been assigned an approval date under the Prescription Drug User Fee Act (PDUFA) of March 1, 2016 and a European Commission decision is expected in the third quarter of 2016. F/TAF has been assigned a PDUFA date of April 7, 2016 and a European Commission decision is expected in the second quarter of 2016. Emtricitabine and TAF are from Gilead and rilpivirine is from Janssen Sciences Ireland UC (Janssen).

In addition, we are investigating two additional TAF-based single tablet regimens; TAF, emtricitabine and GS-9883, our proprietary integrase inhibitor currently in Phase 3 clinical studies; and TAF, emtricitabine, cobicistat and Janssen's darunavir (D/C/F/TAF), which is being developed and commercialized by Janssen.

Liver Diseases

Our goal is to advance the treatment options and standard of care for the underserved HCV market. With the approval of Sovaldi, compared to the prior standard of care of up to 48 weeks, the duration of treatment has been shortened to as few as 12 weeks and the need for peg-interferon (peg-IFN) injections in certain viral genotype populations has been reduced or eliminated completely. In 2014, we received FDA and European Commission approval of Harvoni, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infected patients, the most prevalent genotype in the United States. We received approval of Harvoni in Japan in 2015. Harvoni combines the NS5A inhibitor ledipasvir with sofosbuvir and is indicated for an eight, 12 or 24 week treatment duration depending on prior treatment history, cirrhosis status and baseline viral load and eliminates the need for peg-IFN and RBV, which can be challenging to take and tolerate. In 2015, FDA expanded the use of Harvoni to include patients with genotype 4, 5 and 6 chronic HCV infection and in patients co-infected with HIV. In addition, Harvoni plus ribavirin for 12 weeks was approved as an alternate therapy to 24 weeks of Harvoni for treatment-experienced, genotype 1 patients with cirrhosis.

Our long term goal is to develop an oral therapy for all HCV patients across genotypes. In the fourth quarter of 2015, we submitted marketing applications to FDA and the EMA for the approval of a once-daily fixed-dose combination of SOF/VEL for the treatment of chronic genotype 1-6 HCV. In the fourth quarter of 2015, we also initiated Phase 3 clinical trials evaluating the once-daily fixed-dose combination of SOF, VEL and GS-9857, an investigational NS3 protease inhibitor, for the treatment of chronic genotype 1-6 HCV.

We are evaluating TAF for the treatment of chronic HBV infection and based on data from two Phase 3 clinical trials, we filed marketing applications to FDA and the EMA in the first quarter of 2016. We are also conducting Phase 2 clinical trials of GS-9620, an oral TLR-7 agonist, and GS-4774, a Tarmogen T cell immunity stimulator, for the treatment of HBV.

We are evaluating simtuzumab, a monoclonal antibody, for the treatment of nonalcoholic steatohepatitis (NASH) and primary sclerosing cholangitis in Phase 2 clinical trials. We are also evaluating GS-4977, an ASK-1 inhibitor, for NASH in Phase 2 clinical trials. We are also evaluating GS-9674, a FXR Agonist, for NASH in Phase 1 clinical trials.

Cardiovascular

In 2015, we received FDA approval of the use of Letairis® (ambrisentan) in combination with tadalafil for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Letairis is an endothelin receptor antagonist that was first approved in 2007 in the United States as monotherapy for PAH to improve exercise ability and delay clinical worsening. Tadalafil is a PDE5 inhibitor that was initially approved for PAH in the United States in 2009 to improve exercise ability.

Eleclazine, formerly known as GS-6615, a late sodium channel inhibitor, is being evaluated in Phase 3 clinical trials for the treatment of Long QT-3 Syndrome. Eleclazine is also being evaluated in Phase 2 clinical trials for the treatment of hypertrophic cardiomyopathy and ventricular tachycardia/ventricular fibrillation. We are also evaluating GS-4977, an ASK-1 inhibitor, for pulmonary arterial hypertension in Phase 2 clinical trials.

Hematology/Oncology

In the oncology area, we are seeking to expand the use of Zydelig (idelalisib), a first-in-class PI3K delta inhibitor, for the treatment of patients with certain blood cancers. In 2015, we submitted supplemental new drug applications with FDA and the EMA for approval of Zydelig in combination with ofatumumab in previously-treated patients with CLL. Idelalisib is in Phase 3 clinical trials for the treatment of patients with frontline and relapsed refractory CLL and relapsed refractory

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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