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, 2014

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, 2014 was $99,821,731,329.*

The number of shares outstanding of the registrant's Common Stock on February 13, 2015 was 1,489,401,683.

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 2015 Annual Meeting of Stockholders, to be held on May 6, 2015, are incorporated by reference into Part III of this Report.

* Based on a closing price of $82.91 per share on June 30, 2014. Excludes 310,054,509 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, 2014. 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.

2014 Form 10-K Annual Report

Table of Contents

We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, SOVALDI®, TRUVADA®, HARVONI®, COMPLERA®, EVIPLERA®, STRIBILD®, VIREAD®, LETAIRIS®, RANEXA®, AMBISOME®, ZYDELIG®, EMTRIVA®, TYBOST®, HEPSERA®, VITEKTA®, CAYSTON®, VOLIBRIS® and RAPISCAN®. 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 below under "Risk Factors," beginning at page 30. 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, oncology and inflammation, and serious cardiovascular and respiratory conditions. 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.

2014 Highlights

Over the past year, we brought best-in-class drugs to market that advanced 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 liver diseases area, we received approval from the U.S. Food and Drug Administration (FDA) and the European Commission of Harvoni®, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults. Harvoni combines the NS5A inhibitor ledipasvir with the nucleotide analog polymerase inhibitor sofosbuvir, which was approved under the tradename Sovaldi® in December 2013. The approval of Harvoni represents a significant improvement in the treatment paradigm for the majority of HCV genotype 1 infected patients because it eliminates the need for pegylated interferon (peg-IFN) injections and ribavirin (RBV). In clinical studies, Harvoni demonstrated very high cure rates of 94% to 99% in eight or twelve weeks. In the HIV area, we submitted a new drug application (NDA) for a once-daily single tablet regimen containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide (TAF) 10 mg (E/C/F/TAF) for the treatment of HIV-1 infection in adults. We also received approval in the United States of Tybost® (cobicistat) and Vitekta® (elvitegravir 85 mg and 150 mg), each a component of Stribild®. In the oncology area, we received approval of Zydelig® (idelalisib), a first-in-class, targeted, oral inhibitor of PI3K delta, in combination with rituximab for the treatment of certain patients with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) and follicular lymphoma (FL), the most common type of indolent non-Hodgkin's lymphoma (iNHL). We also advanced our research and development pipeline, with 225 active clinical studies at the end of 2014, of which more than 54 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 2014, we signed non-exclusive license agreements with seven India-based generic drug companies to manufacture Sovaldi and Harvoni for distribution in 91 developing countries. We also announced an agreement with the Medicines Patent Pool (the MPP) under which the MPP can sublicense TAF to generic drug companies in India and China for manufacturing and distribution in 112 developing countries. These efforts extend ongoing programs to enable access for people in the most resource-limited parts of the world, where diseases like HIV and HCV affect the highest numbers of individuals.

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. We are focused on the development of new HIV medicines and co-formulations of products into complete regimens. With the launch of Stribild in the United States in 2012 and in Europe in 2013, Complera®/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) in 2011 and Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in 2006, we now have three single tablet regimens available for the treatment of HIV.

In 2014, we advanced the development of a new single tablet regimen, E/C/F/TAF, for the treatment of HIV-1 infection in adults. Marketing applications for E/C/F/TAF are pending in the United States and European Union. The FDA has established a target review date, under the Prescription Drug User Fee Act, of November 5, 2015.

Phase 3 clinical studies demonstrated that patients taking E/C/F/TAF experienced favorable renal and bone safety compared to Stribild patients. We are also conducting Phase 3 clinical trials of the fixed-dose co-formulation of TAF and emtricitabine. Under an agreement with Janssen R&D Ireland (Janssen), formerly Tibotec Pharmaceuticals, we are evaluating a single tablet regimen of TAF, cobicistat, darunavir and emtricitabine for the treatment of HIV infection. We also amended our agreement with Janssen to collaborate on a single tablet regimen of rilpivirine, emtricitabine and TAF.

In 2014, we received FDA approval for Tybost, a pharmacokinetic enhancer that boosts blood levels of certain HIV medicines. Tybost is indicated as a boosting agent for the HIV protease inhibitors atazanavir (300 mg once daily) and darunavir (800 mg once daily) as part of antiretroviral combination therapy in adults with HIV-1 infection. In 2014, the FDA also approved Vitekta, an integrase inhibitor for the treatment of HIV-1 infection in adults without known mutations associated with resistance to elvitegravir. Vitekta is indicated for use as part of HIV treatment regimens that include a ritonavir-boosted protease inhibitor.

Liver Diseases

Our goal is to advance the treatment options and standard of care for the underserved HCV market. In 2013, we received approval of Sovaldi for the treatment of HCV as a component of a combination antiviral treatment regimen. Sovaldi's efficacy has been established in patients with HCV genotypes 1, 2, 3 or 4 infection (in United States and Europe) and genotypes 5 and 6 infection (in Europe), including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. Compared to the prior standard of care of up to 48 weeks, Sovaldi has shortened the duration of treatment to as few as 12 weeks and reduced or completely eliminated the need for peg-IFN injections in certain viral genotype populations.

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. 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.

Marketing applications for sofosbuvir and the fixed-dose combination of ledipasvir and sofosbuvir are pending in Japan.

Our long term goal is to develop an oral therapy for all HCV patients across genotypes. Our fixed-dose combination of sofosbuvir and GS-5816, a pan-genotypic NS5A inhibitor, is currently in Phase 3 clinical trials. We are also evaluating a single tablet regimen of GS-9857, GS-5816 and sofosbuvir in Phase 2 trials for the potential treatment of HCV genotype 1 and 3 infected patients in four and six weeks.

We are evaluating TAF for the treatment of HBV and have completed enrollment of Phase 3 clinical trials. We are also conducting Phase 2 clinical studies of GS-4774, a Tarmogen T cell immunity stimulator, and GS-9620, an oral TLR-7 agonist, being evaluated as a potential cure for HBV.

We are evaluating simtuzumab for nonalcoholic steatohepatitis (NASH) in Phase 2 clinical trials. In December 2014, we also entered into an agreement with Phenex Pharmaceuticals AG (Phenex) under which we acquired Phenex's Farnesoid X Receptor (FXR) program comprised of small molecule FXR agonists for the treatment of liver diseases including NASH.

Oncology and Inflammation

In the oncology area, in 2014 we received FDA and European Commission approval of Zydelig (idelalisib), a first-in-class PI3K delta inhibitor, in combination with rituximab, for the treatment of patients with certain blood cancers. In the fourth quarter of 2014, we also initiated Phase 3 clinical studies to evaluate idelalisib as a treatment for patients with iNHL and a frontline treatment for patients with CLL.

In December 2014, we entered into an exclusive license agreement with ONO Pharmaceutical Co., Ltd. for the development and commercialization of ONO-4059 (now known as GS-4059), an oral Bruton's tyrosine kinase inhibitor for the treatment of B-cell malignancies and other diseases.

Cardiovascular

In 2014, we released positive results from the AMBITION study (a randomized, double-blind, multicenter study of first-line combination therapy with Letairis® (ambrisentan) and tadalafil in patients with pulmonary arterial hypertension), which was conducted in collaboration with GlaxoSmithKline plc. In AMBITION, first-line treatment of pulmonary arterial hypertension with the combination of ambrisentan 10 mg and tadalafil 40 mg reduced the risk of clinical failure by 50 percent compared to the pooled ambrisentan and tadalafil monotherapy arm. The combination was also statistically significant versus the individual ambrisentan and tadalafil monotherapy groups for the primary endpoint. We have filed a supplemental NDA in the United States to cover the use of ambrisentan in combination with tadalafil.

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.