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, 2013

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 28, 2013 was $60,272,481,253.*

The number of shares outstanding of the registrant's Common Stock on February 14, 2014 was 1,538,252,914.

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 2014 Annual Meeting of Stockholders, to be held on May 7, 2014, are incorporated by reference into Part III of this Report.

* Based on a closing price of $51.27 per share on June 28, 2013. Excludes 343,332,813 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 28, 2013. 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.

2013 Form 10-K Annual Report

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SIGNATURES 140

We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD ®, GILEAD SCIENCES®, STRIBILD®, COMPLERA®, EVIPLERA®, TRUVADA®, VIREAD®, EMTRIVA®, TYBOST®, SOVALDI®, HEPSERA®, VITEKTA®, LETAIRIS®, RANEXA®, CAYSTON®, AMBISOME®, VISTIDE®, 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 31. 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 experimental 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 B virus (HBV) infection and chronic hepatitis C virus (HCV) infection, oncology/inflammation and serious cardiovascular and respiratory conditions. Headquartered in Foster City, California, we have operations in North and South America, Europe and Asia-Pacific. 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.

2013 Highlights

Over the past year, we executed on our strategy to bring best-in-class drugs to market. In the liver diseases area, we received approval from the U.S. Food and Drug Administration (FDA) of our new drug application (NDA) for Sovaldi ® (sofosbuvir 400 mg). Sovaldi is a once-daily oral nucleotide analog polymerase inhibitor for the treatment of HCV infection as a component of a combination antiviral treatment regimen. The approval of Sovaldi represents a significant improvement in the treatment paradigm for some patients with HCV as it has shortened the duration of treatment and reduced or completely eliminated the need for pegylated interferon (peg-IFN) injections in certain viral genotype populations. In the HIV area, we expanded our single tablet regimen product offerings for the treatment of HIV with the European launch of Stribild ® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), which combines four of our medicines in a once-daily single tablet regimen. We also received approval of Tybost ® (cobicistat) and Vitekta® (elvitegravir 85 mg and 150 mg), each a component of Stribild, from the European Commission. In the oncology/inflammation area, we filed for FDA and European Medicines Agency (EMA) marketing approval of idelalisib (formerly GS-1101), an investigational, targeted, oral inhibitor of PI3K delta, for the treatment of patients with refractory indolent non-Hodgkin's lymphoma (iNHL) and relapsed chronic lymphocytic leukemia (CLL). We also continued to advanced our research and development pipeline, with more than 200 active clinical studies at the end of 2013, of which over 60 are Phase 3 clinical trials.

HIV Program

A substantial portion of our revenues is derived from our eight marketed HIV products. In 2013, we continued to be at the forefront of advancing HIV treatment through the development of new single tablet regimens. Our long-term goal is to ensure that all HIV patients have the option to 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. Because of this, we continue to focus on the development of new HIV medicines and co-formulations. 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. In December 2013, we received FDA and EMA approval for Complera/Eviplera to be used by certain adult patients switching from another stable antiretroviral regimen. Complera/Eviplera was first approved in 2011 in the United States and Europe for patients new to antiretroviral therapy.

In September 2013, we received EMA 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. This approval allows for the marketing of Tybost in all 28 countries of the European Union. In November 2013, the EMA approved Vitekta, an integrase inhibitor for the treatment of HIV-1 infection in adults without known mutations associated with resistance to elvitegravir, the active ingredient of Vitekta. Vitekta is indicated for use as part of HIV treatment regimens that include a ritonavir-boosted protease inhibitor.

We also made important progress with the clinical development of tenofovir alafenamide (TAF), formerly known as GS-7340. A Phase 2 study showed that TAF is efficacious at a fraction of a dose of Viread® (tenofovir disoproxil fumarate 300 mg) and provides potential safety advantages. Based on these results, we commenced a Phase 3 trial evaluating the single tablet regimen of TAF, elvitegravir, cobicistat and emtricitabine for the treatment of HIV infection in treatment-naïve adults. Under an agreement with Janssen R&D Ireland (Janssen), formerly Tibotec Pharmaceuticals, we are also conducting Phase 2 trials evaluating a single tablet regimen of TAF, cobicistat, darunavir and emtricitabine for the treatment of HIV infection. In the first quarter of 2013, we completed enrollment of two Phase 3 clinical trials comparing a TAF-based regimen to Stribild in patients new to HIV treatment. Data from the studies will be available in the first quarter of 2014.

Liver Diseases

The HCV therapeutic market has been and continues to be vastly underserved. Due to the limitations of available therapies, only a small fraction of individuals who are infected with HCV are diagnosed, and an even smaller fraction of those patients are treated. Prior to May 2011, when the first protease inhibitors were approved, only about half of the patients responded to the current standard of care, which involves up to 48 weeks of therapy with a peg-IFN/ribavirin (RBV)-containing regimen. The addition of protease inhibitors to the standard of care has resulted in incremental response rates for patients with genotype 1 infection; however, this regimen causes substantial side effects such as fatigue, bone marrow suppression, potentially debilitating rash, anemia and neuropsychiatric effects. As such, discontinuation rates with these triple therapy combinations are significant.

Through the acquisition of Pharmasset, Inc. (Pharmasset) in 2012, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of HCV. In December 2013, we received FDA approval for sofosbuvir under the brand name Sovaldi for the treatment of HCV as a component of a combination antiviral treatment regimen. In January 2014, we received European Commission approval of Sovaldi for the treatment of HCV. 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. U.S. recommended regimens and treatment duration for Sovaldi combination therapy in HCV mono-infected or HCV/HIV-1 co-infected patients are as follows:

	Treatment	Duration
Genotype 1 or 4	Sovaldi + peg-IFN + RBV	12 weeks
Genotype 2	Sovaldi + RBV	12 weeks
Genotype 3	Sovaldi + RBV	12 weeks
Hepatocellular carcinoma awaiting liver transplantation	Sovaldi + RBV	48 weeks or until liver transplant

As noted in the table above, compared to the current standard of care of up to 48 weeks, Sovaldi has shortened the duration of treatment to as little as 12 weeks and reduced or completely eliminated the need for peg-IFN injections in certain viral genotype populations.

As our second generation therapy for the treatment of HCV, we are advancing the fixed-dose combination of ledipasvir/sofosbuvir (LDV/SOF) for the treatment of genotype 1 patients. Our NDA for the fixed-dose combination of LDV/SOF was supported by three clinical trials and was filed in February 2014. The first study, named ION-1, evaluates the fixed-dose combination of LDV/SOF with and without RBV for either 12 or 24 weeks in treatment-naïve genotype 1 HCV-infected patients. The second Phase 3 study, named ION-2, evaluates the fixed-dose combination with RBV for 12 weeks or without RBV for 24 weeks of therapy among treatment-experienced genotype 1 HCV-infected patients. The third study, named ION-3, evaluates the fixed-dose combination of LDV/SOF with and without RBV for eight weeks or without RBV for 12 weeks in non-cirrhotic, treatment-naïve genotype 1 HCV-infected patients.

In Japan, we fully enrolled a Phase 3 study evaluating sofosbuvir in genotype 2 HCV-infected patients. We expect to file for regulatory approval of sofosbuvir in Japan in mid-2014. We also completed enrollment of Phase 3 studies evaluating the fixed-dose combination of LDV/SOF in genotype 1 infected HCV patients and sofosbuvir and RBV in genotype 2 infected HCV patients. Based on the results of these Phase 3 studies, we plan to file for regulatory approval for the fixed-dose combination of LDV/SOF in Japan in the fourth quarter of 2014.

Our long term goal is to develop an oral pan-genotypic oral therapy for all HCV patients across genotypes. The fixed-dose combination of sofosbuvir and GS-5816, a nucleotide NS5B inhibitor/pan-genotypic NS5A inhibitor, is currently in Phase 2 clinical trials.

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.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

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Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.