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, 2012

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 29, 2012 was $32,606,069,397.*

The number of shares outstanding of the registrant's Common Stock on February 15, 2013 was 1,522,392,518.

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 2013 Annual Meeting of Stockholders, to be held on May 8, 2013, are incorporated by reference into Part III of this Report.

* Based on a closing price of $25.64 per share on June 29, 2012. Excludes 226,596,532 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, 2012. 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.

2012 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®, STRIBILD®, COMPLERA®, EVIPLERA®, TRUVADA®, VIREAD®, HEPSERA®, AMBISOME®, EMTRIVA®, VISTIDE®, LETAIRIS®, VOLIBRIS®, RANEXA®, CAYSTON® 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 decl ine, 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 seek to improve the care of patients suffering from life-threatening diseases around the world. Gilead's primary areas of focus include human immunodeficiency virus (HIV), liver diseases such as hepatitis B virus (HBV) and hepatitis C virus (HCV), serious cardiovascular and respiratory conditions, and oncology/inflammation. Headquartered in Foster City, California, we have operations in North America, Europe and Asia. 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.

2012 Highlights

Over the past year, we executed on our strategy to bring best-in-class drugs to market. We completed our acquisition of Pharmasset, Inc. (Pharmasset), which accelerated our timeline to develop the first all-oral HCV regimen and entered into an agreement to acquire YM Biosciences Inc. (YM Biosciences), which closed in February 2013 and expands our growing oncology/inflammation pipeline. We also expanded our single tablet regimen product offerings for the treatment of HIV with the launch of Stribild in the United States, which combines four of our medicines in a once-daily single tablet regimen, and expanded worldwide access to Complera/Eviplera, which is now available in 21 countries. We also advanced our research and development pipeline, with over 50 active Phase 3 clinical trials at the end of 2012 and filed marketing applications for two of the components of Stribild, elvitegravir and cobicistat, as single agents.

HIV Program

A substantial portion of our revenues is derived from our six marketed HIV products. In 2012, 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, Complera/Eviplera in 2011 and Atripla in 2006, we now have three single tablet regimens available.

During 2012, we submitted marketing applications in the United States and European Union for elvitegravir, an integrase inhibitor for the treatment of HIV-1 infection in treatment-experienced adults, and cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels to allow once-daily dosing of certain HIV medicines. The U.S. Food and Drug Administration (FDA) has set target review dates of April 2013 under the Prescription Drug User Fee Act.

In 2012, we also obtained FDA approval for once-daily oral Truvada, in combination with safer sex practices, for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection among uninfected adults. Truvada is the first antiretroviral has been approved for the prevention of HIV infection in adults.

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 one-tenth the dose of Viread and provides potential safety advantages. Based on these results, a Phase 3 trial evaluating the single tablet regimen of TAF, elvitegravir, cobicistat and emtricitabine treatment of HIV infection in treatment-naïve adults commenced earlier this year. Under an agreement with Janssen R&D Ireland (Janssen), we are also conducting Phase 2 trials evaluating a single tablet regimen of TAF, cobicistat, darunavir and emtricitabine for the treatment of HIV infection.

HCV Program

In January 2012, we acquired Pharmasset. Through the acquisition, we acquired sofosbuvir (formerly known as GS-7977), an investigational nucleotide analog that acts to inhibit the replication of HCV. This product candidate is currently in Phase 2 and Phase 3 clinical trials. 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 standard of care combination of pegylated interferon (peg-IFN) and ribavirin. 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 have significantly increased.

During 2013, we expect to receive a significant amount of data from clinical trials evaluating sofosbuvir, alone or in combination with other direct acting antivirals in HCV-infected individuals across all genotypes. Our initial new drug application (NDA) for sofosbuvir will be supported by four Phase 3 studies named Fission, Positron, Fusion and Neutrino. Fission is a study in genotype 2 and 3-treatment naïve patients comparing 12 weeks of sofosbuvir and ribavirin to the current standard of care of 24 weeks of treatment with interferon and ribavirin. Positron compares 12 weeks of treatment with sofosbuvir and ribavirin in genotype 2 and 3 interferon intolerant/ineligible patients to placebo. The Fusion study explores 12 or 16 weeks duration of treatment with sofosbuvir and ribavirin among genotype 2 and 3 treatment-experienced patients. Neutrino is a single arm study evaluating a 12-week course of sofosbuvir, interferon and ribavirin in genotype 1, 4, 5 and 6 infected-patients. We announced data from the four studies in late 2012 and during the first quarter of 2013.

We anticipate filing for regulatory approvals for sofosbuvir by the second quarter of 2013. We expect the initial indication to be for 12 to 16 weeks of treatment with sofosbuvir and ribavirin in treatment-naive, interferon-intolerant and experienced genotype 2 and 3 patients and for 12 weeks of treatment with sofosbuvir, peg-IFN and ribavirin in treatment-naive genotype 1, 4, 5 and 6 patients.

In parallel, we are also advancing a fixed-dose combination of sofosbuvir and ledipasvir (formerly GS-5885) for the treatment of genotype 1 patients. Our NDA for the fixed dose combination of sofosbuvir and ledipasvir will be supported by two clinical trials. The first study, named ION-1, evaluates the fixed-dose combination of sofosbuvir and ledipasvir with and without ribavirin for either 12 or 24 weeks in treatment-naïve genotype 1 infected patients. Pending a review of results from the two 12-week arms of an initial enrollment of 200 patients, by the second quarter of 2013, we expect to enroll additional patients in the ION-1 study to assess the fixed dose combination of sofosbuvir and ledipasvir in a total of 800 individuals. In January 2013, we also started screening patients for the second Phase 3 study, named ION-2, which evaluates the fixed-dose combination with ribavirin for 12 weeks and with and without ribavirin for 24 weeks of therapy among treatment-experienced genotype 1 HCV patients.

See the Risk Factor entitled “The public announcement of data from clinical studies evaluating sofosbuvir and the fixed dose combination of sofosbuvir and ledipasvir in HCV-infected patients is likely to cause significant volatility in our stock price” on page 31.

Oncology/Inflammation

Over the last five years we have worked to advance our oncology franchise. Idelalisib, is a PI3K delta inhibitor antibody formerly known as GS-1101, that advanced into five Phase 3 trials during 2012. The compound is being evaluated for the treatment of chronic lymphocytic leukemia and indolent non-Hodgkin's lymphoma. Simtuzumab, a monoclonal antibody formerly known as GS-6624, is being evaluated in various Phase 2 trials for the treatment of myelofibrosis, colorectal cancer and pancreatic cancer. With the acquisition of YM Biosciences, we acquired momelotinib or GS-0387, formerly known as CYT387. Momelotinib is a JAK inhibitor being evaluated in Phase 2 clinical trials for the treatment of myelofibrosis. We expect to advance the compound to Phase 3 trials later in 2013.

Our Products

HIV/AIDS

- **Stribild** (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a complete once-daily single tablet regimen for HIV-1 infection for treatment-naive adults. Stribild combines four compounds in one daily tablet and was approved by the FDA in August 2012. We filed a marketing authorization application for Stribild with the European Medicines Agency (EMA) in December 2011. We expect to receive approval from the European Commission in the second quarter of 2013.

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.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
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.