Table of Contents

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, 2011

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, 2011 was $ 29,933,970,092.*

The number of shares outstanding of the registrant's Common Stock on February 10, 2012 was 757,315,361.

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 2012 Annual Meeting of Stockholders, to be held on May 10, 2012, are incorporated by reference into Part III of this Report.

* Based on a closing price of $41.41 per share on June 30, 2011. Excludes 48,586,996 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, 2011. 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.

Table of Contents

GILEAD SCIENCES, INC.

2011 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®, TRUVADA®, VIREAD®, HEPSERA®, AMBISOME®, EMTRIVA®, COMPLERA®, EVIPLERA®, 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 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 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)/AIDS, liver diseases such as hepatitis B and C and serious cardiovascular/metabolic and respiratory conditions. Headquartered in Foster City, California, we have operations in North America, Europe and Asia Pacific. We continue to seek 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.

Over the past year, we executed our philosophy and strategy to bring best-in-class drugs to market. In keeping with this strategy, we completed several acquisitions and licensing transactions to enhance our pipeline. We also expanded our single-tablet regimen product offerings for the treatment of HIV with the launch of Complera/Eviplera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) and the anticipated 2012 launch of Quad, which combines four of our HIV medicines in a once-daily single-tablet regimen and is pending Food and Drug Administration (FDA) approval.

Our largest transaction was the acquisition of Pharmasset, Inc. in January 2012 for $11.1 billion. For several years, we have focused a large proportion of our research and development effort on discovering and advancing direct-acting antivirals for the treatment of chronic hepatitis C virus (HCV). 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 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.

Over the last two years, we have progressed several early stage HCV molecules with various mechanisms of action into clinical development. During 2011, the field of HCV research evolved rapidly, and it became clear our HCV portfolio of oral antiviral development compounds would have difficulty competing because it was behind the development programs of many of our competitors. Through our acquisition of Pharmasset, we gained ownership of GS-7977, the most advanced, and to date the most potent, nucleotide analog that acts to inhibit the replication of HCV with limited safety or resistance concerns detected thus far. The compound has been studied extensively in Phase 2 studies in genotype 2 and 3 infected patients in combination with ribavirin with or without pegylated interferon and is currently being studied in genotype 1 infected patients. The first of two Phase 3 trials, known as FISSION, evaluating GS-7977 in genotype 2 and 3 patients is currently enrolling. A second Phase 3 study of genotype 2 and 3 patients is scheduled to begin enrolling in the next few weeks. If Phase 3 data for genotype 2 and 3 patients is consistent with data from our Phase 2 trials, we would expect to file a new drug application (NDA) for the treatment of genotype 2 and 3 patients in 2013 for potential approval in late 2013 or early 2014.

Two thirds of HCV-infected individuals in the United States and Europe are infected with HCV genotype 1. We are conducting Phase 2 studies to determine the efficacy of GS-7977 plus ribavirin in this population. Results from these studies will be available over the next several months. We expect the first data evaluating GS-7977 plus ribavirin for 12 weeks in genotype 1 treatment-naïve patients from an arm of the QUANTUM study with 25 patients will be available at the end of the first quarter of 2012. We expect that this will be followed in the second quarter by data from an arm of the ELECTRON study involving 25 treatment-naïve patients treated for 12 weeks and, early in the third quarter, data on GS-7977 and ribavirin treatment for 24 weeks from an arm of the QUANTUM study will become available.

On February 17, 2012, we announced that the majority of HCV genotype 1 patients with a prior "null" response to an interferon-containing regimen enrolled in an arm of our ongoing ELECTRON study experienced viral relapse within four weeks of completing 12 weeks of treatment with GS-7977 plus ribavirin. Ten patients were randomized to this arm of the ELECTRON study and data were available for eight of the ten patients at the time of the announcement. Among these eight patients, six experienced viral relapse. Two patients had not relapsed; however, they had only reached the two week post-treatment time point. These data indicate that treatment of genotype 1 patients classified as null responders with GS-7977 plus ribavirin for 12 weeks will not be sufficient to cure their disease. Regulatory authorities require that patients have a sustained viral response for 12 weeks after the cessation of therapy to be considered "cured" of the disease.

To the extent data from the ELECTRON and QUANTUM studies indicate genotype 1 treatment-naïve patients can be effectively treated using GS-7977 and ribavirin, larger Phase 3 studies in genotype 1 patients are expected to commence in 2012. If we are able to commence Phase 3 trials on that timeline and the results of those trials are positive, we expect to file a NDA that includes data for genotype 1 patients in 2013 for potential approval in 2014. If GS-7977 with ribavirin is not sufficiently effective in treating genotype 1 treatment-naïve patients, we would need to explore combination therapy using GS-7977 and other direct acting antiviral compounds from our or others' portfolios, which would delay development and approval of GS-7977 for use in genotype 1 treatment-naïve patients. We expect to begin clinical studies evaluating GS-7977 in combination with our GS-5885 NS5A inhibitor in genotype 1 treatment-naïve patients in the second quarter of 2012.

See the Risk Factor entitled "The public announcement of data from clinical studies evaluating GS-7977 in HCV-infected patients is likely to cause significant volatility in our stock price" on page 30.

Our Products

HIV/AIDS

- **Atripla** (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) is an oral formulation dosed once a day for the treatment of HIV infection in adults. Atripla is the first once-daily single-tablet regimen for HIV intended as a stand alone therapy or in combination with other antiretrovirals. It is a fixed-dose combination of our antiretroviral medications, Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine), and Bristol Myers-Squibb Company's (BMS) non-nucleoside reverse transcriptase inhibitor, Sustiva (efavirenz).
- **Truvada** (emtricitabine and tenofovir disoproxil fumarate) is an oral formulation dosed once a day as part of combination therapy to treat HIV infection in adults. It is a fixed-dose combination of our antiretroviral medications, Viread and Emtriva.
- **Viread** is an oral formulation of a nucleotide analog reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in patients 2 years of age and older. Viread is also approved for the treatment of chronic hepatitis B in adults.
- **Complera/Eviplera** is an oral formulation dosed once a day for the treatment of HIV-1 infection in treatment-naïve adults. The product, marketed in the United States as Complera and in Europe as Eviplera, is the second complete single-tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medications, Viread and Emtriva, and Tibotec Pharmaceuticals' non-nucleoside reverse transcriptase inhibitor, Edurant (rilpivirine).
- **Emtriva** is an oral formulation of a nucleoside analog reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults. In the United States and Europe, Emtriva is also available as an oral solution approved as part of combination therapy to treat HIV infection in children.

Liver Disease

- **Viread** is an oral formulation of a nucleotide analog reverse transcriptase inhibitor, dosed once a day for the treatment of chronic hepatitis B in adults with compensated and decompensated liver disease.

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.