GILEAD SCIENCES INC
Form 8-K
July 26, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

Current Report

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): July 26, 2010

Gilead Sciences, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**0-19731**	**94-3047598**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Other Events.

In connection with a proposed offering of convertible senior notes, Gilead Sciences, Inc. (the Company) has provided to potential investors a description of certain risk factors affecting the Company and its business, which are attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In 2009, the Company licensed from Tibotec Pharmaceuticals the right to coformulate TMC278 (rilpivirine) with Truvada to create a single tablet, once daily regimen to treat HIV. On July 22, 2010, Tibotec Pharmaceuticals announced results from two pivotal Phase 3, double-blind, randomized clinical trials comparing the efficacy, safety and tolerability of its investigational non-nucleoside reverse transcriptase inhibitor (NNRTI) TMC278 (rilpivirine) versus efavirenz (EFV), each administered once daily with a nucleoside/nucleotide background regimen in treatment-naive, HIV-1-infected adults.

Tibotec Pharmaceuticals announced the following information:

These global trials, known as ECHO and THRIVE, reached their primary objective, which was to demonstrate non-inferiority of TMC278 vs. EFV in the proportion of patients achieving an undetectable viral load (less than 50 copies/mL) at week 48 (with a maximum allowable difference of 12 percent). A pooled analysis of ECHO and THRIVE was presented on July 22, 2010 at the XVIII International AIDS Conference in Vienna, Austria.

ECHO and THRIVE pooled results showed that 84.3 percent of patients (n=686) in the TMC278 group reached an undetectable viral load, compared with 82.3 percent of patients (n=682) in the EFV group. The difference between the treatment groups was not significant. Patients received TMC278 (25 mg) or EFV (600 mg), each administered once daily in combination with a nucleoside/nucleotide background regimen. The virologic failure rate was 9 percent in the TMC278 group and 4.8 percent in the EFV group.

TMC278 is an investigational product, and the safety and efficacy has not yet been established. Tibotec plans to submit these results to the U.S. Food and Drug Administration (FDA) to support approval of TMC278 for use in treatment-naive adult patients.

Adverse events (AEs) leading to discontinuation in the TMC278 group were 3.4 percent compared to 7.6 percent in the EFV group, and Grade 2-4 AEs at least possibly related to treatment were 15.9 percent in the TMC278 group versus 31.1 percent in the EFV group. Grade 2-4 AEs of interest by organ class reported among patients in the TMC278 group versus the EFV group were psychiatric (14.9 percent vs. 22.7 percent), neurological (17.1 percent vs. 37.8 percent) and rash-all types (3.1 percent vs. 13.6 percent). Grade 3/4 lipid abnormalities were also reported among patients in the TMC278 group versus the EFV group for increases in total cholesterol (0.1 percent vs. 2.5 percent), LDL-cholesterol (0.7 percent vs. 4.1 percent) and triglycerides (0.3 percent vs. 2.2 percent).

ECHO (TMC278-TiDP6-C209) and THRIVE (TMC278-TiDP6-C215) are pivotal Phase 3, double-blind, randomized studies that evaluated the efficacy, safety and tolerability of TMC278 in 1,368 treatment-naive, HIV-1-infected adults. ECHO (Efficacy Comparison in treatment-naive HIV-infected subjects Of TMC278 and EFV) evaluated TMC278 (25 mg) once daily, versus EFV (600 mg) once daily, combined with a fixed background regimen consisting of emtricitabine + tenofovir disoproxil fumarate. THRIVE (TMC278 against HIV, in a once daily RegImen Versus Efavirenz) evaluated TMC278 (25 mg) once daily versus EFV (600 mg) once daily, combined with an investigator-selected background regimen consisting of two N[t]RTIs (abacavir + lamivudine or emtricitabine + tenofovir disoproxil fumarate or zidovudine + lamivudine).

Each study is being conducted at more than 100 sites, in more than 20 countries. The studies will last for a total of 104 weeks, which includes a four-week screening period, a 96-week treatment period and a four-week follow-up period.

Tibotec Pharmaceuticals plans to file the 48-week findings from ECHO and THRIVE with the FDA when seeking marketing authorization for TMC278. Pending approval, Tibotec Therapeutics will commercialize TMC278 in the United States. Tibotec has also entered into a license and collaboration agreement with the Company for the development and commercialization of a

once-daily, fixed-dose combination of TMC278 and the Company s Truvada® (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg).

The information contained in Item 7.01 of this Current Report on Form 8-K relating to the Tibotec Pharmaceuticals announcement dated July 22, 2010 (including the data and results referred to therein) reflects the data contained in Tibotec Pharmaceuticals announcement. The data was not prepared by the Company, and the Company has not had an opportunity to verify its accuracy.

The information in this Form 8-K includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including risks related to the Company s ability to obtain regulatory approval for the fixed-dose combination of Truvada and TMC278. Regulatory agencies may not approve the fixed-dose combination, and marketing approval, if granted, may have significant limitations on its use. In addition, safety and efficacy data from additional clinical studies may not warrant further development of the fixed-dose combination and as a result, the fixed-dose combination may never be successfully commercialized. Further, even if the fixed-dose combination is approved, commercialization of the product may not be successful if physicians do not see advantages of the fixed-dose combination over other therapies and are therefore reluctant to prescribe the product. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. The Company directs readers to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2010. The Company claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. All forward-looking statements made by the Company are based on information currently available to the Company, and the Company assumes no obligation to update any such forward-looking statements.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 8.01. Other Events.

In a press release on July 26, 2010, the Company announced that it intends to offer convertible senior notes in a private offering. A copy of the press release is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Risk Factors

99.2 Press Release dated July 26, 2010, issued by Gilead Sciences, Inc.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GILEAD SCIENCES, INC.

By: /s/ Robin L. Washington
Name: **Robin L. Washington**
Title: **Senior Vice President and Chief Financial Officer**

Dated: July 26, 2010

Exhibit Index

Exhibit No.	Description
99.1	Risk Factors
99.2	Press Release dated July 26, 2010, issued by Gilead Sciences, Inc.