

GILEAD SCIENCES INC
Form 8-K
July 16, 2009

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 16, 2009

Gilead Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

0-19731

(Commission
File Number)

94-3047598

(I.R.S. Employer
Identification No.)

333 Lakeside Drive, Foster City, California

(Address of principal executive offices)

94404

(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))
-

Top of the Form

Item 1.01 Entry into a Material Definitive Agreement.

On July 16, 2009, Gilead Sciences, Inc. (Gilead) and its wholly owned subsidiary, Gilead Sciences Limited, entered into a License and Collaboration Agreement with Tibotec Pharmaceuticals (Tibotec), a wholly owned subsidiary of Johnson & Johnson, which sets forth the terms and conditions under which Gilead will develop and commercialize a fixed-dose combination (the Combination Product") of Gilead's Truvada (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) and Tibotec's non-nucleoside reverse transcriptase inhibitor, TMC278 (25 mg rilpivirine hydrochloride), which is currently in phase III clinical trials. Under the agreement, Tibotec granted Gilead an exclusive, license to the Combination Product for administration to adults in a once daily, oral dosage form, worldwide excluding low-income countries and Japan. Neither party is restricted from combining its drugs with any other drugs.

Gilead will pay up to €71,450,000 million of Tibotec's development costs for TMC-278, and is required to use commercially reasonable efforts to develop and formulate the fixed-dose combination, including completion of bioequivalence studies. Tibotec is required to use commercially reasonable efforts to develop TMC-278 and obtain its approval in the United States and Europe. Gilead will manufacture the Combination Product and assume the lead role in registration, distribution and, subject to regulatory approval, commercialization of the Combination Product in the licensed countries. Tibotec will have the right to detail the Combination Product in the licensed countries, and, at its option, can request that it be the distributor of the Combination Product in a limited number of such countries. The price of the Combination Product is expected to be the sum of the price of Truvada and the price of TMC278 purchased separately. Gilead expects to recognize product sales revenue from future sales of the Combination Product if it is approved. The cost of TMC278 purchased by Gilead from Tibotec for the Combination Product will approximate the market price of TMC278, less a specified percentage of up to thirty percent (30%) which recognizes Gilead for its investment in the development of TMC278 and the Combination Product.

Either party may terminate the License and Collaboration Agreement if the Combination Product is withdrawn from the market, if a party materially breaches the agreement, if the TMC278 program fails to meet its primary clinical endpoints, if the Combination Product is not approved within three years of the approval of TMC278 in the United States or Europe and if additional clinical studies are required by the U.S. Food and Drug Administration or the European Medicines Agency as a condition to approval and Gilead is unwilling to conduct the additional clinical studies pertaining to the Combination Product. Gilead may terminate the agreement in the United States and Canada on or after the expiration of the last to expire patent for tenofovir disoproxil fumarate in the United States, and may terminate the agreement in any other country on or after the expiration of the last to expire patent for tenofovir disoproxil fumarate in a country of the European Union. Tibotec may terminate the agreement in the United States and Canada on or after the expiration of the last to expire patent for TMC278 in the United States, and may terminate the agreement in any other country on or after the expiration of the last to expire patent for TMC278 in a country of the European Union.

Item 8.01 Other Events.

On July 16, 2009, Gilead issued a press release, a copy of which is filed as Exhibit 99.1 hereto, announcing the execution of the License and Collaboration Agreement.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press Release, issued by Gilead Sciences, Inc. on July 16, 2009

Top of the Form

SIGNATURES

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.

July 16, 2009

By: */s/ Robin L. Washington*

Name: Robin L. Washington

Title: Senior Vice President and Chief Financial Officer

Edgar Filing: GILEAD SCIENCES INC - Form 8-K

Top of the Form

Exhibit Index

Exhibit No.	Description
99.1	Press Release, issued by Gilead Sciences, Inc. on July 16, 2009