GILEAD SCIENCES INC
Form 8-K
July 20, 2007

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 19, 2007

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))

Top of the Form

Item 8.01 Other Events.

In October 2006, Gilead Sciences, Inc., a Delaware corporation (the Company), along with its partners Bristol-Myers Squibb Company and Merck & Co., Inc. announced the submission of a marketing authorisation application (MAA) seeking approval of Atripla™ (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in the European Union to the European Medicines Agency (EMEA). On July 19, 2007, the Company provided an update on the status of the MAA during its conference call to discuss financial results for the second quarter of 2007. The Company announced that the main issue it is discussing with the EMEA relates to the method of administration of Atripla -- dosing with or without food. Unlike in the United States, the current European prescribing information states that Truvada® (emtricitabine and tenofovir disoproxil fumarate) should be administered with food, whereas efavirenz should be administered on an empty stomach. The Company has proposed to the EMEA that Atripla should be administered like efavirenz, on an empty stomach. The Company believes this is supported by data from two clinical studies and its post-marketing experience with Atripla in the United States. The Company has been working to resolve this issue with the EMEA to keep the approval of Atripla on track for the end of 2007. Requirements for additional data would delay the approval of Atripla in the European Union.

This Current Report on 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 and uncertainties related to the Company's ability to obtain marketing approval for Atripla in the European Union under the timelines currently anticipated or at all. Discussions with the EMEA may impact the amount of data needed and timelines for review, which may differ materially from the Company's current projections. Depending on the data required by the EMEA, the Company may be required to perform additional clinical trials. The Company may not be able to successfully enroll patients in such clinical trials and safety and efficacy data from additional clinical studies may not be sufficient to support the approval of Atripla by the EMEA. In addition, to the extent discussion with the EMEA indicate that the approval of Atripla would be substantially delayed or that required clinical trials would not be feasible, the Company may decide to cease its efforts to commercialize Atripla for sales in the European Union. Further, marketing approval, if granted, may have significant limitations on its use. 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. These and other risks are described in detail in the Company's Annual Report on Form 10-K for the year ended December 31, 2006 and its Quarterly Report on Form 10-Q for the first quarter of 2007, filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to the Company, and the Company assumes no obligation to update any such forward-looking statements.

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 19, 2007

By: /s/ John F. Milligan, Ph.D.

Name: John F. Milligan, Ph.D.
Title: Chief Operating Officer and Chief Financial Officer