GILEAD SCIENCES INC
Form 8-K
September 29, 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): September 24, 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))

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Item 8.01 Other Events.

Gilead s San Dimas, Calif. Manufacturing Facility Receives FDA Warning Letter

On September 24, 2010, Gilead s San Dimas, Calif. manufacturing facility received a Warning Letter from the U.S. Food and Drug Administration (FDA). The Warning Letter is connected with an FDA current Good Manufacturing Practices (cGMP) inspection of that facility, which took place in January and February of this year. At the conclusion of that inspection, the FDA issued Form 483 Inspectional Observations, to which Gilead responded in March 2010. In May 2010, we learned that FDA may be considering issuing a Warning Letter to us resulting from this inspection.

The letter details the following inadequacies identified by the FDA in the AmBisome manufacturing environment, including control systems and monitoring, procedures to prevent microbiological contamination and preventative cleaning and equipment maintenance. Referencing certain Viread lots, the letter also states concerns connected with quality procedures and controls and investigation procedures. Finally, the letter expresses a generalized concern over the effectiveness of the San Dimas quality unit in carrying out its responsibilities.

Gilead believes that, since our initial written response sent to the FDA in March 2010, we have addressed the Form 483 observations, and we are working diligently to resolve any outstanding FDA concerns listed in the Warning Letter.

Unless and until we are able to correct outstanding issues to the FDA s satisfaction, the FDA may withhold permission to export AmBisome to certain countries outside the United States and Europe. The FDA may also withhold approval of pending drug applications listing the San Dimas facility. Since, as required, we have notified appropriate international regulatory authorities of the letter s issuance, it is possible that the letter may impact our ability to supply our aseptic products manufactured at San Dimas (AmBisome, Cayston and Macugen) outside the United States. We do not believe the letter will impact our ability to supply any of our solid dosage form products: Atripla, Emtriva, Hepsera, Letairis, Ranexa, Truvada or Viread. In the event our solid dosage form products were affected, we have alternate sites from which we could supply such products.

Forward looking statements:

This 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 related to whether the FDA or other international regulatory authorities will agree that steps taken or to be taken by Gilead to correct matters described in the Warning Letter are adequate, whether Gilead can resolve any continuing concerns that may be expressed by the FDA or other international regulatory authorities in a timely manner and whether the FDA or other international regulatory authorities decide to take further corrective or disciplinary actions against Gilead. 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 Gilead s Quarterly Report on Form 10-Q for the first and second quarters of 2010, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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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.

September 29, 2010

By: /s/ Robin L. Washington

Name: Robin L. Washington
Title: Senior Vice President and Chief Financial Officer