GILEAD SCIENCES INC
Form 8-K
January 10, 2011

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): January 7, 2011

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 7.01 Regulation FD Disclosure.

Gilead Sciences, Inc. (Gilead) has decided, per the recommendation of the U.S. Food and Drug Administration (FDA), to amend the design of its ongoing Phase III clinical study of elvitegravir, the company's investigational integrase inhibitor in treatment experienced patients (GS-US-183-0145, "A Multicenter, Randomized, Double-Blind, Double-Dummy, Phase III Study of the Safety and Efficacy of Ritonavir-Boosted Elvitegravir Versus Raltegravir Each Administered With a Background Regimen in HIV-1 Infected, Antitretroviral Treatment Experienced Adults"), to extend the double-blinded study period to up to 96 weeks, rather than the initially planned 48-week duration.

This change will be implemented to allow Gilead to obtain safety and efficacy data from a longer controlled and blinded study, the first clinical trial directly comparing two integrase inhibitors. Gilead has not been informed of any issues with the ongoing study that would cause Gilead to halt or otherwise amend the study design.

Gilead does not expect this planned change to have any impact on timelines for availability of data from ongoing pivotal studies in support of the investigational "Quad" combination of Truvada® (emtricitabine and tenofovir disoproxil fumarate), elvitegravir and cobicistat, or timelines, pending a positive outcome of these studies, for regulatory submissions of the Quad, cobicistat or elvitegravir.

Forward-Looking Statement

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 that could cause actual results to differ materially from those referred to in the forward-looking statements, including risks that timelines for receiving data from the pivotal studies in support of the Quad or for filing of regulatory submissions related to the Quad, cobicistat or elvitegravir could be delayed due to unforeseen events, or the data from clinical trials for the Quad, cobicistat or elvitegravir could indicate safety or efficacy concerns that limit the potential market for these products or cause Gilead to modify, delay such clinical trials or cease development of one or more of them. Further, Gilead may ultimately be unable to obtain the FDA or other regulatory body approvals, and as a result, the Quad, cobicistat or elvitegravir may never be successfully commercialized. 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 quarter ended September 30, 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.

January 10, 2011

By: /s/ Robin L. Washington

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