INCYTE CORP
Form 8-K
July 25, 2005

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: July 25, 2005
(Date of earliest event reported)

INCYTE CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**0-27488**	**94-3136539**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

Experimental Station, Route 141 & Henry Clay Road, **Building E336** **Wilmington, DE** (Address of principal executive offices)	**19880** (Zip Code)

(302) 498-6700

(Registrant s telephone number,
including area code)

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:

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01 OTHER EVENTS.

On July 25, 2005 Incyte Corporation (Incyte) publicly announced results from Study 203, a six-month randomized double-blind Phase IIb trial, involving 199 patients and 25 clinical sites in the U.S. and Europe to evaluate the efficacy, dose response, safety and tolerability of Reverset in treatment-experienced human immunodeficiency virus (HIV) infected patients who are failing their current treatment regimens. Results from the first two stages of Study 203 presented at the 3rd International AIDS Society (IAS) Conference on HIV Pathogenesis and Treatment, in Rio de Janeiro, suggest that the highest of three once-daily doses of Reverset provided the greatest antiviral suppression in these highly treatment-experienced patients who have a wide variety of HIV mutations.

The protocol for Study 203 was divided into three stages. The first two stages of the study were designed to evaluate three different doses of Reverset (50, 100 and 200 mg once daily) versus placebo at two different time points, at week two (prior to any optimization of background therapy) and week 16 (after potential optimization of background therapy at the end of week two). The third stage of the trial, which begins at week 16 and ends at week 24, allows all placebo patients to crossover to receive either the 100 or 200 mg dose of Reverset, and permits an additional optimization of background therapy and allows for additional longer-term safety data.

Summary of Results

Two- and 16-week results presented at the IAS conference demonstrated that patients receiving the 200 mg dose of Reverset experienced significant antiviral benefit.

At two weeks, when the 200 mg dose of Reverset was used as add-on therapy in patients who were failing their current treatment, patients who received Reverset achieved:

a 0.7 log drop in viral load overall as compared to placebo patients who did not achieve any change in viral load; and

a 1.1 log drop in viral load in the subset of patients not using 3TC or FTC in their background treatment regimen.

At 16 weeks in the overall group, when the 200 mg dose of Reverset was used as add-on therapy in either an optimized or non-optimized regimen, patients who received Reverset achieved:

a 1.2 log drop in viral load versus a 0.8 log drop for the placebo patients;

a 1.4 log drop in viral load in the subset of patients who were not receiving 3TC or FTC in their background treatment regimen versus a 0.5 log drop for the placebo patients; and

a 54% response rate versus a 40% response rate as compared to placebo with response defined as more than a 1.0 log drop in viral load. The response rate among patients not receiving 3TC or FTC in their background treatment regimen was 80% versus 25% on placebo.

At 16 weeks, in the non-optimized group, patients who received the 200 mg dose of Reverset achieved:

a 0.6 log drop in viral load as compared to non-optimized placebo patients who achieved a 0.1 log drop; and

a 1.5 log drop in viral load in the subset of patients who were not receiving 3TC or FTC in their background treatment regimen as compared to a 0.3 log increase in the non-optimized placebo patients not receiving 3TC or FTC.

In this trial the 100 mg and 50 mg daily doses of Reverset were less effective than the 200 mg dose, with viral load decreases of 0.3 to 0.4 log during the two week add-on phase and viral load decreases of 0.8 to 0.9 log at week 16 following the optimized background phase of the study.

Effects Against HIV Mutations

Reverset was also shown to be effective in patients with virus resistant to other commonly used nucleoside analog reverse transcriptase inhibitors (NRTIs), including viruses harboring multiple thymidine analog mutations (TAMS), including the M41L and L210W mutations, and the L74V and M184V mutations. Sixty-six percent of

the patients had the M184V mutation; 46% had the M41L and L210W mutations; 44% had 4 to 6 TAMS; and 6% had K65R. There were too few instances of virus with the K65R mutation in patients receiving the 200 mg dose to draw firm conclusions; however, the viral load reduction in patients with the K65R mutation treated with lower doses of Reverset suggests that the compound is also active against this mutation.

Tolerability

Reverset was generally well tolerated in this study. Clinical adverse events were generally mild, with the only possibly related events of at least moderate severity reported in more than one of the 151 Reverset-treated patients at any dose being nausea (4 patients, 2.6%), headache (4 patients, 2.6%), diarrhea (3 patients, 2.0%), pancreatitis (2 patients, 1.3%), and myalgia (2 patients, 1.3%). During up to 24 weeks of therapy, asymptomatic increases in serum lipase to greater than 5 times the upper limit of the normal range (Grade 4) were seen in 50% of patients receiving 200 mg Reverset with ddI (didanosine), and it has been concluded Reverset should not be used with ddI. Two patients receiving Reverset 100 mg with ddI and tenofovir in combination at higher than recommended doses of ddI or tenofovir developed symptoms of pancreatitis which resolved within days of discontinuation of ddI, tenofovir and Reverset. Didanosine labeling states that the dose of ddI should be reduced when co-administered with tenofovir because of increased risks of ddI toxicity, including pancreatitis. Importantly, in patients who were not also receiving didanosine (ddI), asymptomatic hyperlipasemia was reported in 2 patients (5%) receiving 200 mg Reverset and in one placebo-treated subject (3%).

About Study 203

Study 203 was designed to assess the efficacy, safety and tolerability of Reverset over a six-month period, to determine the most appropriate dose of Reverset, and to identify patients for whom Reverset is likely to provide the greatest benefit.

The study involves 199 treatment-experienced patients who were failing their current treatment regimen. Patients in Study 203 had a mean baseline viral load of 4.5 log10. At entry, patients were randomized to receive one of three doses of Reverset (50, 100 and 200mg) once a day or placebo. During the first 14 days of the trial, study medication was added to a patient s failing regimen. At the end of 14 days, physicians had the option to optimize the background regimen of any patient based on their prior treatment history and the results of a viral genotype obtained during the screening period. In approximately seventy percent of the patients in the study, the physician optimized the background regimen at this point, with the remaining thirty percent continuing the original failing regimen plus randomized study medication (these latter patients were defined as non-optimizers). At week 16, all placebo patients were randomized to either the 100 or 200 mg dose of Reverset and study physicians were again given the option to reoptimize the background therapy of any patient if appropriate.

Forward Looking Statements

Except for the historical information contained herein, the matters set forth in this Form 8-K, including statements as to the potential benefits and value of Reverset, serious adverse events, and the expected initiation of Phase III trials and potential for Reverset, are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including the high degree of risk associated with drug development, the risk that additional clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, results of further research, the impact of competition and of technical advances, and other risks detailed from time to time in Incyte s Securities and Exchange Commission reports, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2005. Incyte disclaims any intent or obligation to update these forward-looking statements.

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.

Dated: July 25, 2005

INCYTE CORPORATION

By: /s/ Patricia A. Schreck

Patricia A. Schreck

Executive Vice President and

General Counsel