SANOFI SYNTHELABO SA
Form 6-K
June 16, 2003

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULES 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934

For the Month of June 2003
SANOFI-SYNTHELABO
(Exact name of registrant as specified in its charter)

174, avenue de France, 75013 Paris, FRANCE
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F X --- Form 40-F ---

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes --- No X ---

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

[SANOFI~SYNTHELABO LOGO]

~ Investor Relations

Paris, June 16, 2003

Alfuzosin Approved by the Food and Drug Administration
in the United States
Outside of the United States, alfuzosin is marketed under the name Xatral(R)

Sanofi-Synthelabo announced today that its New Drug Application (NDA) for alfuzosin HCl extended-release tablets has been approved in the United States by the Food and Drug Administration (FDA).

Alfuzosin is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia.

Alfuzosin, a compound from Sanofi-Synthelabo Research, is an alpha(1)-blocker in a 10 mg once-daily extended-release formulation.

Alfuzosin exhibits selectivity for alpha(1)-adrenergic receptors in the lower urinary tract. Blockade of these adrenoreceptors can cause smooth muscle in the bladder neck and prostate to relax, resulting in an improvement in urine flow and a reduction in symptoms of benign prostatic hyperplasia (BPH).

BPH is a very common disorder, leading to urinary symptoms of varying severity. The resulting symptoms affect 22% of men aged 50-59 years, but up to 45% of men aged 70-80 years. These symptoms may have an impact on men's day-to-day activities and may lead to serious complications such as acute urinary retention. Clinical efficacy data for alfuzosin from placebo-controlled trials have demonstrated efficacy compared to placebo in urinary flow improvement and in improvement in urinary symptoms without the need for dose titration.

In the clinical trials, the most common side effects occurring more frequently than placebo were dizziness, upper respiratory tract infection, headache and fatigue.

Alfuzosin should not be used in patients with moderate to severe hepatic insufficiency. Alfuzosin should not be co-administrated with potent inhibitors of the cytochrome P3A4. As with other alpha-blockers, some patients may experience postural hypotension or syncope. Alfuzosin should not be used in combination with other alpha-blockers. If symptoms of angina pectoris should appear or worsen, the use of alfuzosin should be discontinued.

With 15 years of clinical experience, which translates into approximately 1.35 billion days of treatment (3.7 million patient years), alfuzosin is marketed in more than 80 countries throughout Europe, Latin America, Africa and Asia. Outside of the United States, the once-daily formulation (Xatral(R) OD) is registered in 70 countries worldwide; it is currently marketed in 14 countries in Europe and in more than 35 other countries.

The launch of alfuzosin HCl extended-release tablets in the United States will occur in the second half of 2003.

Sales of alfuzosin reached 182 million euros in 2002 and 49 million euros in the first quarter of 2003.

Sanofi-Synthelabo is a major global research-based pharmaceutical group with 32,500 employees in more than 100 countries. The company is headquartered in Paris and listed in Paris (Euronext : SAN) and in New York (NYSE : SNY). With consolidated sales of EUR 7.4 billion in 2002, Sanofi-Synthelabo ranks 7th in Europe and among the world's top 20 pharmaceutical companies. With an R&D portfolio of 52 compounds in development, Sanofi-Synthelabo is focused on a core group of four therapeutic areas: cardiovascular disease and thrombosis; diseases of the central nervous system; internal medicine; and oncology.

This release contains statements that constitute forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements : the ability of Sanofi-Synthelabo to expand its presence profitably in the United States; the success of Sanofi-Synthelabo's research and development programs; the ability of Sanofi-Synthelabo to protect its intellectual property rights; and the risks associated with reimbursement of health care costs and pricing reforms, particularly in the United States and France.

Investors and security holders may obtain a free copy of documents filed by Sanofi-Synthelabo with the U.S. Securities and Exchange Commission at www.sec.gov or directly from Sanofi-Synthelabo on the web site www.sanofi-synthelabo.com

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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, thereunto duly authorized.

Dated: June 16, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay

Name: Marie-Helene Laimay
Title: Senior Vice President and Chief Financial Officer