SANOFI SYNTHELABO SA
Form 6-K
June 04, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

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

For the month of June 2004

Commission File Number: 001-31368

SANOFI-SYNTHELABO
(Translation of registrant's name into English)

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

This Report on Form 6-K shall be deemed to be incorporated by reference into Sanofi-Synthelabo's Registration Statement on Form F-4 (Registration No. 333-112314), as post-effectively amended and declared effective on May 13, 2004 by the United States Securities Exchange Commission, and the related prospectus, dated April 9, 2004, and the prospectus supplement, dated May 27, 2004, each filed pursuant to Rule 424(b) under the United States Securities Act of 1933, as amended, and shall be part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

[SANOFI-SYNTHELABO LOGO]

[GRAPHIC] INVESTOR RELATIONS

Paris, June 4, 2004

NEW INDICATIONS FOR ARIXTRA(R) IN THE UNITED STATES:
THE TREATMENT OF ACUTE DEEP VENOUS THROMBOSIS
AND ACUTE PULMONARY EMBOLISM.

Sanofi-Synthelabo announced today that the synthetic, selective factor Xa inhibitor Arixtra(R) (fondaparinux sodium) has been approved by the US Food and Drug Administration (FDA) for two new indications:

- THE TREATMENT OF ACUTE DEEP VENOUS THROMBOSIS WHEN ADMINISTERED IN CONJUNCTION WITH WARFARIN SODIUM, AND

- THE TREATMENT OF ACUTE PULMONARY EMBOLISM WHEN ADMINISTERED IN CONJUNCTION WITH WARFARIN SODIUM WHEN INITIAL THERAPY IS ADMINISTERED IN THE HOSPITAL.

Arixtra(R) is already indicated in the United-States for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism in patients undergoing hip fracture surgery, including extended prophylaxis, hip replacement surgery and knee replacement surgery.

The file for the new indications for Arixtra(R) was submitted to the FDA July 31, 2003. The clinical dossier was based upon the findings of the MATISSE PE and MATISSE DVT studies which demonstrated that a new strength of Arixtra(R) 7.5 mg* given as a once daily subcutaneous injection, when administered in conjunction with warfarin sodium, can effectively and safely treat the acute phases of both deep vein thrombosis and pulmonary embolism.
Arixtra(R) is the first antithrombotic agent to be registered in the US specifically for the treatment of acute PE since the introduction of unfractionated heparin (UFH).

The MATISSE PE study is the largest worldwide trial ever performed in the treatment of pulmonary embolism. This open label trial involved 2,213 patients with symptomatic PE enrolled in 214 centres in 20 countries worldwide, including 67 centres in the US. The study showed that a fixed once daily subcutaneous dose of Arixtra(R) 7.5mg*, without need for coagulation monitoring, appears to be at least as effective and as safe as continuous intravenous and dose-adjusted UFH. Moreover, in the study, 15% of patients, (26.4% in the US**), received Arixtra(R) on an outpatient basis, after receiving the first dose in the hospital, compared to none with UFH.

The MATISSE DVT trial involved 2,205 patients in 23 countries in a total of 154 centers around the world with symptomatic DVT without symptomatic PE. The study showed that Arixtra(R) 7.5mg*, given once daily in a fixed subcutaneous dose appears to be at least as effective and safe as dose-adjusted low molecular weight heparin (LMWH) administered subcutaneously twice a day.

DVT and PE represent two manifestations of the same disease known as Venous Thromboembolism (VTE), a condition in which blood clots in the lower limbs (DVT) may travel to the lungs where they can cause a PE. VTE is the third most common cardiovascular disease after heart attack and stroke. VTE affects about two million Americans annually, at least 60,000 of whom will die of PE. VTE represents an annual cost of at least $2.9 billion in the US alone.

As with other antithrombotics, the most common side effect during Arixtra(R) administration is bleeding. Arixtra(R) is contraindicated in patients with severely impaired kidney function. Arixtra(R) prophylactic therapy is contraindicated in patients who weigh less than 50 kg (110 pounds), undergoing hip fracture, hip replacement and knee replacement surgery because they may have an increased risk for major bleeding. Patients greater than 75 years of age also may be more likely to experience major bleeding complications. As with other antithrombotics, labeling for Arixtra(R) includes a Boxed Warning regarding possible spinal/epidural haematomas when spinal anaesthesia or spinal puncture is used.

Arixtra(R) was launched in the United States on February 8, 2002, and in Europe as from March 27, 2002.

On April 13, 2004, Sanofi-Synthelabo signed an agreement with GlaxoSmithKline Group (GSK) regarding the divestment by Sanofi-Synthelabo, on a worldwide basis, of Arixtra(R), Fraxiparine(R) and related assets including the manufacturing facility located in Notre-Dame de Bondeville, France. The deal is conditional on completion of Sanofi-Synthelabo's offer for Aventis.

*5mg in patients with a body weight