SANOFI SYNTHELABO SA
Form 6-K
June 02, 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
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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
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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 2, 2003

Major Results on oxaliplatin presented at the
American Society of Clinical Oncology (ASCO).

Oxaliplatin clearly demonstrates consistent superiority in the treatment of colorectal cancer in all settings of the disease:

from early stage, adjuvant treatment after surgery, to the metastatic setting.

Sanofi-Synthelabo announced today major results on oxaliplatin presented at the 39th annual meeting of the American Society of Clinical Oncology (ASCO).

136 abstracts on oxaliplatin were published at the meeting and important new data were presented: from early stage of the disease, adjuvant treatment following surgery, to metastatic setting, 1st and 2nd /3rd line treatment. These results show that oxaliplatin is effective in all stages of the disease and hence significantly improve the quality and length of life for colorectal cancer patients.

In early stage:

- Results from the MOSAIC trial for the use oxaliplatin as adjuvant therapy following surgery, presented by A. de Gramont

In metastatic setting:

- Results from an NCI-sponsored 1st-line colorectal cancer trial - N 9741 - presented by R. Goldberg
- Results from a 2nd-line colorectal cancer trial - EFC 4584 - presented by M. Rothenberg
- Results from a 3rd-line colorectal cancer trial - EFC 4760 - presented by N. Kemeny

Here is a brief overview of the results:

MOSAIC study (adjuvant therapy)
Efficacy results of the MOSAIC study demonstrated that the addition of oxaliplatin to the current post surgery standard chemotherapy, 5-Fluorouracil/Leucovorin (5-FU/LV), for colon cancer reduces the risk of recurrence by 23% vs. current standard treatment alone. This strong achievement, 15 years after 5-FU/LV was established as standard adjuvant treatment, is a major step towards curing more patients and was obtained without dramatically impacting safety.

N 9741 study (1st line treatment for metastatic colorectal cancer)
The results of this NCI-sponsored trial clearly show the superiority of the FOLFOX regimen (oxaliplatin + 5-FU/LV) versus the IFL regimen (irinotecan + 5-FU/LV), in terms of response rate (RR), progression free survival (PFS), overall survival (OS) and safety profile. The overall survival was 19.5 months with the FOLFOX regimen versus 14.8 months with the IFL regimen (p = 0.0001) giving an improvement of 4.7 months in favor of oxaliplatin-based treatment, representing a survival gain of more than 30%.

EFC 4584 study (2nd line treatment for metastatic colorectal cancer)
The study compared the FOLFOX regimen versus 5-FU/LV, as 2nd line treatment for metastatic colorectal cancer, after IFL regimen failure. The response rate and the progression free survival were significantly superior in the FOLFOX group. The overall survival was 9.8 months in the FOLFOX group versus 8.7 months in the 5-FU/LV group (p=0.07), clearly suggesting a trend for survival improvement, in this very difficult-to-treat patient population for which no viable option is available.
In addition, this study clearly shows a superiority of oxaliplatin as far as clinical benefit is concerned as demonstrated by the significant improvement of disease-related symptoms.

With these very promising results, Sanofi-Synthelabo should file oxaliplatin in the United States, for the 1st line treatment for metastatic colorectal cancer (MCRC) in the early second half of the year 2003 and for the adjuvant treatment of colorectal cancer towards the end of the year 2003. The filing in Europe for the adjuvant treatment of colorectal cancer should occur in the second half of the year 2003.

In the US, ELOXATIN(R) (oxaliplatin for injection) is approved for use in combination with infusional 5-fluorouracil (5-FU) and leucovorin (LV), is currently indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed during or within six months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan. The approval of ELOXATIN(R) was based on the response rate and time to tumor progression observed in an ongoing trial. Data that demonstrate a clinical benefit, such as improvement of disease-related symptoms or increased survival were not available at approval.

ELOXATIN(R) (oxaliplatin for injection) is a chemotherapeutic cancer agent and as such should be administered under the supervision of a qualified physician experienced in the use of such products.

ELOXATIN(R) should not be administered to patients with a history of known allergy to ELOXATIN(R) or other platinum compounds. Women of childbearing potential should be advised not to become pregnant while receiving treatment with ELOXATIN(R). As with other platinum compounds, hypersensitivity and anaphylactic/anaphylactoid reactions have been reported. ELOXATIN(R) is associated with pulmonary toxicity, which may be fatal and two distinct types of primarily peripheral sensory neuropathies: an acute, reversible type of early onset and a persistent type (>14 days). An acute syndrome of pharyngolaryngeal dysesthesia seen in 1-2% of patients characterized by subjective sensations of dysphagia or dyspnea, without any laryngospasm or bronchospasm (no stridor or wheezing) may also occur.

Both 5-FU and ELOXATIN(R) are associated with gastrointestinal and hematologic adverse events. When ELOXATIN(R) is administered in combination with 5-FU, the incidence of these events is increased. The most frequently reported adverse events with ELOXATIN(R) in combination with infusional 5-FU/LV are acute neuropathy (56%), persistent neuropathy (48%), fatigue (68%), diarrhea (67%), nausea (65%) and vomiting (40%). Changes in hematology parameters were also seen: anemia (81%), leukopenia (76%), neutropenia (73%), and thrombocytopenia (64%).

Full prescribing information including boxed warning is available through www.eloxatin.com.

About one million new cases of colorectal cancer are diagnosed worldwide, and about 150,000 new cases in the U.S. According to the American Cancer Society, colorectal cancer is the second leading cause of malignancy-related death in the U.S., accounting for 10 to 15% of all cancer death. Over a lifetime, about one in 18 people develop colorectal cancer, and, each year, about 56,000 people die from it in the U.S.

ELOXATIN(R)is currently marketed by Sanofi-Synthelabo in more than 60 countries for 1st and/or 2nd line metastatic colorectal cancer and is undergoing extensive worldwide clinical development for new indications. Global sales of ELOXATIN(R) reached EUR 389 million in 2002. Sales for the first quarter 2003 were EUR 185 million. Oxaliplatin was developed in association with Debiopharm S.A.

About Sanofi-Synthelabo
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.

Forward Looking Statement
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

Conference Call

To discuss the data presented at the at the American Society of Clinical Oncology (ASCO), a conference call has been organised on Monday, June 2nd 2003 at 3:00 pm (Paris time).

The conference call will be chaired by:

Dr. Alain HERRERA, Vice President,
Oncology Franchise of Sanofi-Synthelabo,

In order to participate in the conference call, please dial the following numbers 10 minutes before it starts:

France:	00 33 (0) 1 70 70 81 99	code: 420295
United Kingdom:	00 44 (0) 207 984 75 76	code: 420295
USA:	00 1 719 457 26 37	code: 598646

A recorded version of the conference will be made available through Friday June 13th, 2003 by dialing:

France:	00 33 (0) 1 70 70 82 10	code: 420295#
United Kingdom:	00 44 (0) 207 784 10 24	code: 420295#
USA:	00 1 719 457 08 20	code: 420295#

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Investor Relations

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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 2, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay

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