

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

SANOFI SYNTHELABO SA
Form 6-K
April 24, 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 April 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 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
--- ---

(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, April 24th, 2003

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

 STRONG GROWTH IN CONSOLIDATED SALES

IN THE FIRST QUARTER OF 2003

+13.4% ON A COMPARABLE BASIS (1)
 +5.6% ON A REPORTED BASIS

WORLDWIDE SUCCESS OF ELOXATIN

FORECAST FOR 2003 EPS (2) GROWTH CONFIRMED

Sanofi-Synthelabo generated consolidated sales of 1,959 million euros in the first quarter of 2003, an increase of 13.4% on a comparable basis(1) and 5.6% on a reported basis.

Changes in Group structure(3) had an unfavorable impact of 0.5 of a percentage point. Currency fluctuations had an unfavorable impact of 7.3 percentage points over the quarter. Of this, more than half was due to the weakening of the US dollar; the rest was due to the weakness of in some Latin American and Asian currencies.

Consolidated sales by geographical region

In million euros	Consolidated sales Q1 2003	Consolidated sales Q1 2002 (comparable)	Consolidated sales Q1 2002 (reported)	Change on a comparable basis
Europe	1,155	1,064	1,070	+8.5%
United States	471	358	424	+31.6%
Rest of the world	333	305	361	+9.2%
Total	1,959	1,727	1,855	+13.4%

 (1) Comparable basis means constant Group structure and exchange rates (see explanatory note).

(2) Before exceptional items and goodwill amortization

(3) Primarily, change from 100% to 51% consolidation of Sanofi-Synthelabo-Fujisawa (Taiwan) in May 2002

- In Europe, consolidated sales reached 1,155 million euros, representing a growth rate of 8.5% on a comparable basis, once again outperforming market growth.

- In the United States, consolidated sales were 471 million euros, an increase of 31.6% on a comparable basis and 11.1% on a reported basis, the

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

difference being entirely due to fluctuations in the exchange rate between the dollar and the euro. The level of comparable-basis growth was due to the success of Eloxatin(R), which generated sales of 100 million euros, and to the advance made by Ambien(R), which posted a 22.8% rise in sales on a comparable basis to 285 million euros. During the period, sales of Primacor(R) almost disappeared (2 million euros, vs. 49 million euros in the first quarter of 2002) following the introduction of generics in May 2002.

- In the rest of the world, strong growth in Asia and a recovery of the operations in Latin America resulted in sales of 333 million euros, up 9.2% on a comparable basis but down 7.8% on a reported basis. The fall in reported-basis figures was due to the change from 100% to 51% consolidation of Sanofi-Synthelabo-Fujisawa (Taiwan) and the weakness of some Latin American and Asian currencies.

Consolidated sales by product

Consolidated sales of the top 10 products came to 1,285 million euros, an increase of 30.4% on a comparable basis and 21.4% on a reported basis.

The top 10 products accounted for 65.6% of consolidated sales, compared with 57.1% in the first quarter of 2002.

Sales of other products in the portfolio were 9.1% lower on a comparable basis at 673 million euros. Setting aside the decline in sales of Ticlid(R) and the fall in sales of Primacor(R) in the United States, sales of other products in the portfolio remained stable (-0.3%).

In million euros	Consolidated sales Q1 2003	Consolidated sales Q1 2002 (comparable)	Change on a comparable basis	Chan repor
Stilnox(R)/Ambien(R)	342	282	+21.2% (4)	+
Plavix(R)	289	230	+25.5%	+2
Eloxatin(R)	185	57	+225.8%	+21
Aprovel(R)	164	121	+35.6%	+3
Fraxiparine(R)	85	80	+6.5%	+
Depakine(R)	68	65	+4.0%	+
Xatral(R)	49	43	+14.0%	+1
Cordarone(R)	37	39	-5.4%	-1
Solian(R)	35	33	+5.1%	+
Tildiem(R)	33	37	-9.6%	-1
Total	1,285	986	+30.4%	+2

- (4) Difference resulting from dollar fluctuations, most sales of this product being generated in the United States

- Consolidated sales of Stilnox(R)/Ambien(R)/Myslee(R) totaled 342 million euros, a rise of 21.2% on a comparable basis. In the United States, this

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

product generated sales of 285 million euros, up 22.8% on a comparable basis. In Japan, developed sales of Myslee(R) came to 16 million euros, an increase of 45.3% on a comparable basis.

- Consolidated sales of Plavix(R) reached 289 million euros, an increase of 25.5% on a comparable basis, including sales of the active ingredient and finished products to Bristol-Myers Squibb. Without those sales between the two groups, consolidated sales growth for Plavix(R) rises to 39.3%.
- Consolidated sales of Aprovel(R) amounted to 164 million euros, an increase of 35.6% on a comparable basis, underlining the success of this product especially in Europe, where it ranks second in its class.
- Consolidated sales of Eloxatin(R) were 185 million euros, a rise of 225.8% on a comparable basis. This very strong growth reflects the success of Eloxatin(R) in the United States, where it achieved sales of 100 million euros. Growth outside the United States also remains robust, with sales up 49.2% on a comparable basis.
- Consolidated sales of Arixtra(R) remained low at 3.6 million euros, due to the current narrow range of indications. The program aimed at extending indications for Arixtra(R) is on track.

Developed sales(5)

Developed sales, which represent the worldwide market presence of Sanofi-Synthelabo products, came to 2,397 million euros, a rise of 9.8% on a comparable basis. This lower-than-expected growth rate was due to the weakness of Plavix(R) invoicing in the United States.

In million euros	Plavix(R) /Iscover(R)		Aprovel(R) /Avapro(R) /Karvea(R)	
	Developed sales		Developed sales	
	Q1 2003	Change(6)	Q1 2003	Change(6)
Europe	233	+29%	146	+26%
United States	287	-14%	98	+3%
Rest of the world	73	+61%	46	+46%
Total	593	+6%	290	+20%

Developed sales of Plavix(R)/Iscover(R) came to 593 million euros. Outside the United States, sales rose by 35% on a comparable basis.

-
- (5) Developed sales include Sanofi-Synthelabo consolidated sales and sales generated under the agreements with Bristol-Myers Squibb on Plavix(R)/Iscover(R) (clopidogrel) and Aprovel(R)/Avapro(R)/Karvea(R) (irbesartan), with Fujisawa on Stilnox(R)/Myslee(R) (zolpidem), and with Organon on Arixtra(R) (fondaparinux) (see explanatory note)
- (6) On a comparable basis

In the United States, although demand continues to grow at a sustained pace with prescriptions (IMS YTD 03/03 retail + mail order + long term care) up 27.2%, coupled with a favorable price effect, Plavix invoicing decreased 14% on a comparable basis. This trend, which results in a strong decline of the level of

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

inventory at the wholesalers level, was due to the combined effect of the three following factors:

- an unfavorable basis for growth comparison, Bristol-Myers Squibb having initiated the inventory workdown plan for Plavix as from second quarter 2002;
- a destocking by certain wholesalers, who had anticipated a price increase of Plavix(R) in January 2003;
- Bristol-Myers Squibb's significant reduction in incentives to American wholesalers at the beginning of 2003.

Given the very strong growth in prescriptions and the current level of inventories held by American wholesalers, full-year invoiced sales should be close to prescription demand.

Developed sales of Aprovel(R)/Avapro(R)/Karvea(R) totaled 290 million euros. Outside the United States, sales growth reached 30% on a comparable basis. In the United States, Avapro(R) sales reached 98 million euros over the quarter, in line with our forecasts and with demand which grew +15% in volume terms (Prescriptions IMS YTD 03/03 retail + mail order + long term care) coupled with a favorable price effect. First-quarter invoiced sales were 3% higher on a comparable basis, due to an unfavorable comparison basis, as 30% of 2002 Avapro(R) annual sales were generated in the first quarter of that year.

Highlights of the first quarter of 2003

- Discontinuation on January 16th, 2003, following a recommendation from the independent data safety and monitoring board, of the ANDROMEDA study evaluating tolerance of dronedarone in high risk patients with severe congestive heart failure. Subsequently, on February 12th, 2003, the independent data safety and monitoring board recommended the continuation of the two pivotal effectiveness trials (EURIDIS and ADONIS) which are evaluating dronedarone in patients with atrial fibrillation.
- Approval in February 2003 by the US Food and Drug Administration for Eligard 30 mg (4-month formulation of leuprolide acetate for subcutaneous injection) in the treatment of advanced prostate cancer.
- Following the filing of an application in December 2002, granting by the US Food and Drug Administration in March 2003 of a priority review for Arixtra(R) in a new indication: long-term prevention of deep venous thrombosis in patients undergoing hip fracture surgery.
- Following the publication by Bristol-Myers-Squibb of restated accounts for the years 1999 to 2002, Sanofi-Synthelabo confirmed on March 12th, 2003 that there was no need to modify either the Group's financial statements prepared in compliance with French accounting principles or the growth forecasts for 2003 announced on February 18th, 2003.
- Under the authority granted by the General Meeting of Shareholders and the Board of Directors on May 22nd, 2002, Sanofi-Synthelabo continued the share buy back program initiated in 2002. As of March 31st, 2003, Sanofi-Synthelabo held 28 million shares acquired under this program for a total amount of 1.5 billion euros which correspond to 3.8% of the share capital.

Outlook

In a generally tougher environment, the expected growth in sales of Plavix(R), Aprovel(R)/Avapro(R) and Stilnox(R)/Ambien(R)/Myslee(R) and the

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

better-than-forecast success of Eloxatin(R), allow to confirm the forecasts for growth in sales and earnings per share(7) for 2003 as announced on February 18th, 2003.

Barring major adverse events, Sanofi-Synthelabo should achieve in 2003:

- a similar level of consolidated sales growth, on a comparable basis, to that achieved in 2002.
- at an exchange rate of one euro per dollar, an increase in earnings per share close to 20%, before exceptional items and goodwill amortization, the sensitivity of this growth rate being 1% for a 3 cent movement in the dollar exchange rate.

Explanatory Notes:

All figures in this press release are in French GAAP.

In this press release, we refer to our historical sales as "reported " sales. In addition to reported sales, we also present and discuss two other non-GAAP indicators that we believe are useful measurement tools to explain changes in our reported net sales :

Comparable Sales. When we refer to the change in our net sales on a <<comparable >> basis, we mean fluctuations and changes in perimeter (acquisitions and divestitures of entities and rights to products as well as change in consolidation ratio for consolidated entities).

For any two periods, we exclude the impact of exchange rates by recalculating net sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition. Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product.

For a change in the consolidation ratio of a consolidated entities the prior period is recalculated on the basis of the consolidation scheme retained for the current period

Developed sales. When we refer to <<developed sales >> of a product, we mean consolidated sales, excluding sales of products to our alliance partners, but including those that are made through our alliances and which are not included in our consolidated net sales (with Bristol-Myers Squibb on Plavix(R)/Iscover(R) (clopidogrel) and Aprovel(R)/Avapro(R)/Karvea(R) (irbesartan), with Fujisawa on Stilnox(R)/Myslee(R) (zolpidem), and with Organon on Arixtra(R) (fondaparinux)). Our alliance partners provide us information regarding their sales in order to allow us to calculate developed sales.

We believe that developed sales are useful measurement tool because they demonstrate trends in the overall presence of our products in the market.

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

(7) Before exceptional items and goodwill amortization

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.

REMINDER

A conference call is organised today, Thursday April 24th at 3.30 pm (Paris time) to comment the Q1 2003 sales. In order to participate in the conference call, the following numbers are to be dialed 10 minutes before it starts:

France:	00 33 (0) 1 70 70 81 98	code: 546664
United Kingdom:	00 44 (0) 207 984 75 82	code: 546664
USA:	00 1 719 457 26 79	code: 546664

A recorded version of the conference will be made available through Wednesday April 30th, 2003 by dialing:

France:	00 33 (0) 1 70 70 82 10	code: 546664#
United Kingdom:	00 44 (0) 207 784 10 24	code: 546664#
USA:	00 1 719 457 08 20	code: 546664#

A live audio webcast of this conference will be made available at our internet site (www.sanofi-synthelabo.com) and a recorded version will be archived through Wednesday, April 30th, 2003.

Investor Relations Department

Philippe Goupit	Director of Investor Relations
Isabelle Laurent	Investor Relations Europe
Arnaud Delepine	Investor Relations Europe
Sanjay Gupta	Investor Relations US

Contacts:

E-mail: investor-relations@sanofi-synthelabo.com

Europe	US
Tel: + 33 1 53 77 45 45	Tel.: 1 212 551 42 93
Fax: + 33 1 53 77 42 96	Fax: 1 212 551 49 92

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

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: April 24, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay

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