

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

SANOFI SYNTHELABO SA  
Form 6-K  
July 23, 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 July 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, July 23rd, 2003

-----  
STRONG GROWTH IN CONSOLIDATED SALES

# Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

IN THE FIRST HALF OF 2003

+14.4% ON A COMPARABLE BASIS(1)

+6.1% ON A REPORTED BASIS

- o Acceleration in sales growth in the second quarter on a comparable basis (1) (+15.4%)
- o Second-quarter invoiced US sales of Plavix(R) in line with demand
- o Continuing success for Eloxatin(R)
- o 2003 EPS(2) growth forecast confirmed

-----  
Sanofi-Synthelabo generated consolidated sales of 3,903 million euros in the first half of 2003, an increase of 14.4% on a comparable basis(1) and 6.1% on a reported basis. Consolidated sales for the second quarter of 2003 were 1,944 million euros, a rise of 15.4% on a comparable basis(1) and 6.5% on a reported basis.

Currency fluctuations had an unfavorable impact of 7.8 percentage points over the half-year. Of this, half was due to the weakening of the US dollar (in the first half of 2003, the euro appreciated against the dollar by an average of over 20% relative to the first half of 2002), and the rest was due to the weakness of some Latin American and Asian currencies. Changes in Group structure(3) had an unfavorable impact of 0.5 of a percentage point.

Consolidated sales by geographical region  
-----

In millions of euros	Consolidated sales H1 2003	Change on a comparable basis	Change on a reported basis
Europe	2,320	+7.9%	+6.6%
United States	884	+40.1%	+16.9%
Rest of the world	699	+11.0%	-6.7%
Total	3,903	+14.4%	+6.1%

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

(2) Before exceptional items and goodwill amortization

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

- In Europe, first-half consolidated sales were 2,320 million euros, up 7.9% on a comparable basis. Excluding sales of finished products to Bristol-Myers Squibb, comparable-basis growth was 8.2% in the first half, a higher growth rate than that of the market (7.3% IMS YTD retail to end May). In the second quarter, consolidated sales advanced by 7.2% on a comparable basis (or 8.0% excluding sales of finished products to Bristol-Myers Squibb).

## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

- In the United States, first-half consolidated sales reached 884 million euros, an increase of 40.1% on a comparable basis and 16.9% on a reported basis, the difference being entirely due to fluctuations in the dollar/euro exchange rate. This performance was due to the success of Eloxatin(R), which generated sales of 213 million euros, and to the progress made by Ambien(R), which posted 516 million euros in sales, an increase of 24.0% on a comparable basis. Second-quarter consolidated sales in the United States were 51.3% higher on a comparable basis.
- In the rest of the world, sustained growth in Asia and a recovery in Latin American operations led to first-half sales of 699 million euros, up 11.0% on a comparable basis but down 6.7% on a reported basis. The fall in reported-basis figures was due to the weakness of some Latin American and Asian currencies during the first half, and to the change to proportionate consolidation of Sanofi-Synthelabo-Fujisawa (Taiwan). Second-quarter sales rose by 12.6% on a comparable basis.

### Consolidated sales by product

First-half consolidated sales of the top 10 products totaled 2,574 million euros, an increase of 30.4% on a comparable basis and 21.1% on a reported basis. The comparable-basis growth rate for the top 10 products during the second quarter (30.5%) was the same as for the first quarter (30.3%).

The top 10 products accounted for 65.9% of first-half consolidated sales, compared with 57.9% on a comparable basis in the first half of 2002.

In millions of euros	Consolidated sales H1 2003	Change on a comparable basis	Change on a reported basis
Stilnox (R)/Ambien (R)	627	+20.8%	+0.6%
Plavix (R)	612	+27.0%	+23.4%
Eloxatin (R)	384	+220.0%	+209.7%
Aprovel (R)	334	+29.5%	+25.6%
Fraxiparine (R)	166	+3.8%	+0.0%
Depakine (R)	137	+5.4%	+1.5%
Xatral (R)	103	+19.8%	+15.7%
Cordarone (R)	73	-8.8%	-14.1%
Solian (R)	71	+6.0%	+4.4%
Tildiem (R)	67	-6.9%	-8.2%
<b>Total</b>	<b>2,574</b>	<b>+30.4%</b>	<b>+21.1%</b>

During the first half of 2003:

- Consolidated sales of Stilnox(R)/Ambien(R)/Myslee(R) were 627 million euros, a rise of 20.8% on a comparable basis and 0.6% on a reported basis. This difference is related to the impact of movements in the dollar/euro exchange rate, most of the product's sales being generated in the United States. In the United States, the product recorded sales of 516 million euros, up 24.0% on a comparable basis. In Japan, consolidated sales of Myslee(R) reached 23 million euros growing by 23.7% on a comparable basis.
- Consolidated sales of Plavix(R) totaled 612 million euros, a rise of 27.0% on a comparable basis. Without sales of active ingredient and finished

## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

products to Bristol-Myers Squibb, consolidated sales growth for Plavix(R) is 38.3%.

- Consolidated sales of Eloxatin(R) came to 384 million euros, up 220.0% on a comparable basis. This very strong growth reflects the continuing success of Eloxatin(R) in the United States, where it achieved sales of 213 million euros. Outside the United States, sales advanced by 43.4% on a comparable basis.
- Consolidated sales of Aprovel(R) were 334 million euros, a rise of 29.5% on a comparable basis, underlining the success of this product, especially in Europe.
- Consolidated sales of Arixtra(R) remained low at 8 million euros, due to the current narrow range of indications. The program aimed at extending indications for Arixtra(R) is on track.

Apart from the top 10 products, the rest of the portfolio generated sales of 1,329 million euros in the first half of 2003, a decline of 7.6% on a comparable basis. Stripping out the fall in sales of Ticlid(R) and the virtual disappearance of sales of Corotrope(R)/Primacor(R) (since the introduction of generics in the United States in May 2002), sales of the other products in the portfolio were almost unchanged (- 0.4%).

### Developed sales (4)

-----

First half developed sales, which represent the worldwide market presence of Sanofi-Synthelabo products, reached 4,913 million euros, an increase of 15.0% on a comparable basis. Second-quarter developed sales rose by 20.5% on a comparable basis, thanks notably to a performance by Plavix(R) in the United States in line with demand.

-----

(4) 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)

### Developed sales of Plavix(R)/Iscover(R)

-----

In millions of euros	Q1 2003	Change (5)	Q2 2003	Change (5)	H1 2003	Change
Europe	233	+28.7%	243	+24.0%	476	+26.
United States	287	-14.1%	426	+50.5%	713	+15.
Rest of the world	73	+62.2%	84	+61.5%	157	+61.
<b>Total</b>	<b>593</b>	<b>+5.9%</b>	<b>753</b>	<b>+41.8%</b>	<b>1,346</b>	<b>+23.</b>

## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Developed sales of Plavix(R)/Iscover(R) amounted to 1,346 million euros in the first half of 2003. In the United States:

- Second-quarter invoiced sales of Plavix (426 million euros) recorded a strong rise of 50.5% on a comparable basis. This growth corresponds to invoiced sales in line with demand, and also reflects a favorable comparative base, since Bristol-Myers Squibb only began its inventory workdown in the second quarter of 2002.
- Over the first half, demand for Plavix continues to grow at a sustained pace, with prescriptions up 26.7% (Prescription IMS YTD June 2003 retail + mail order + long term care), coupled with a favorable price effect.
- 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 demand.

Outside the United States, second-quarter sales rose by 31.9 % on a comparable basis.

Developed sales of Aprovel(R)/Avapro(R)/Karvea(R)

In millions of euros	Q1 2003	Change(5)	Q2 2003	Change(5)	H1 2003	Change
Europe	146	+27.0%	160	+25.0%	306	+25.
United States	98	+3.2%	90	-2.2%	188	+0.
Rest of the world	46	+43.8%	51	+37.8%	97	+40.
<b>Total</b>	<b>290</b>	<b>+19.8%</b>	<b>301</b>	<b>+17.1%</b>	<b>591</b>	<b>+18.</b>

Developed sales of Aprovel(R)/Avapro(R)/Karvea(R) amounted to 591 million euros in the first half of 2003.

In the United States, second-quarter sales of Avapro(R) reached 90 million euros. Over the first half, prescriptions grew by 14.0% (Prescriptions IMS YTD June 2003 retail + mail order + long term care), coupled with a favorable price effect. Invoiced sales were in line with demand over the first half. The lack of comparable-basis growth was due to an unfavorable comparative base, the inventory workdown being implemented by Bristol-Myers Squibb from the second half of 2002. Outside the United States, second-quarter sales rose by 27.9% on a comparable basis.

-----  
(5) On a comparable basis

### Recent events

- Announcement in June 2003 at the 39th annual conference of the ASCO (American Society of Clinical Oncology) of major results with Oxaliplatin (Eloxatin(R)), clearly demonstrating consistent superiority in the treatment of colorectal cancer in all settings of the disease (early stage,

## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

adjuvant treatment after surgery, metastatic settings).

- Approval in June 2003 by the US Food and Drug Administration of Uroxatral(R) in the treatment of the signs and symptoms of benign prostatic hypertrophy.
- Approval in June 2003 by the US Food and Drug Administration of Arixtra(R) in the long-term prevention of deep venous thrombosis in patients undergoing hip fracture surgery.
- Announcement in July 2003 at the 19th conference of the ISTH (International Society on Thrombosis and Haemostasis) of favorable results with Arixtra(R), demonstrating a significant reduction of the risk of deep venous thrombosis in medical patients (ARTEMIS study) and benefits in prevention of deep venous thrombosis after major abdominal surgery (PEGASUS study).

### Outlook

-----

Based on the strong activity during the first half of 2003, in a globally tougher environment, the Group is able:

- o to confirm the forecasts for growth in 2003 sales and earnings per share before exceptional items and goodwill amortization as announced on February 18th, 2003: barring major adverse events, Sanofi-Synthelabo should achieve in 2003:
  - a similar level of comparable-basis consolidated sales growth 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.
- o to anticipate for the first half of 2003, growth in earnings per share before exceptional items and goodwill amortization, in line with the full-year forecasts announced for 2003.

-----  
Detailed figures for the first quarter of 2003  
-----

### First-quarter consolidated sales by geographical region

-----

In millions of euros	Consolidated sales sales Q1 2003	Consolidated sales Q1 2002 (comparable)	Consolidated sales Q1 2002 (reported)	Change on a comparable basis
Europe	1,155	1,064	1,073	+8.6%
United States	471	358	424	+31.6%
Rest of the world	333	305	358	+9.2%
Total	1,959	1,727	1,855	+13.4%

-----

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

First-quarter consolidated sales by product

In millions of euros	Consolidated sales sales Q1 2003	Consolidated sales Q1 2002 (comparable)	Consolidated sales Q1 2002 (reported)	Change on a comparable basis
Stilnox (R) /Ambien (R)	342	282	335	+21.3%
Plavix (R)	289	230	236	+25.7%
Eloxatin (R)	185	57	59	+224.6%
Aprovel (R)	164	121	124	+35.5%
Fraxiparine (R)	85	80	83	+6.3%
Depakine (R)	68	65	67	+4.6%
Xatral (R)	49	43	44	+14.0%
Cordarone (R)	37	39	41	-5.1%
Solian (R)	35	33	33	+6.1%
Tildiem (R)	33	37	37	-10.8%
<b>Total</b>	<b>1,285</b>	<b>986</b>	<b>1,059</b>	<b>+30.3%</b>

Detailed figures for the second quarter of 2003

Second-quarter consolidated sales by geographical region

In millions of euros	Consolidated sales sales Q2 2003	Consolidated sales Q2 2002 (comparable)	Consolidated sales Q2 2002 (reported)	Change on a comparable basis
Europe	1,165	1,087	1,103	+7.2%
United States	413	273	332	+51.3%
Rest of the world	366	325	391	+12.6%
<b>Total</b>	<b>1,944</b>	<b>1,685</b>	<b>1,825</b>	<b>+15.4%</b>

Second-quarter consolidated sales by product

In millions of euros	Consolidated sales sales Q2 2003	Consolidated sales Q2 2002 (comparable)	Consolidated sales Q2 2002 (reported)	Change on a comparable basis
Stilnox (R) /Ambien (R)	285	237	288	+20.3%
Plavix (R)	323	252	260	+28.2%

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Eloxatin (R)	199	63	65	+215.9%
Aprovel (R)	170	137	142	+24.1%
Fraxiparine (R)	81	80	83	+1.3%
Depakine (R)	69	65	68	+6.2%
Xatral (R)	54	43	45	+25.6%
Cordarone (R)	36	41	44	-12.2%
Solian (R)	36	34	35	+5.9%
Tildiem (R)	34	35	36	-2.9%
Total	1,289	988	1,066	+30.5%

Detailed figures for the first half of 2003

First-half consolidated sales by geographical region

In millions of euros	Consolidated sales sales H1 2003	Consolidated sales H1 2002 (comparable)	Consolidated sales H1 2002 (reported)	Change on a comparable basis
Europe	2,320	2,151	2,176	+7.9%
United States	884	631	756	+40.1%
Rest of the world	699	630	749	+11.0%
Total	3,903	3,412	3,680	+14.4%

First-half consolidated sales by product

In millions of euros	Consolidated sales sales H1 2003	Consolidated sales H1 2002 (comparable)	Consolidated sales H1 2002 (reported)	Change on a comparable basis
Stilnox (R) /Ambien (R)	627	519	623	+20.8%
Plavix (R)	612	482	496	+27.0%
Eloxatin (R)	384	120	124	+220.0%
Aprovel (R)	334	258	266	+29.5%
Fraxiparine (R)	166	160	166	+3.8%
Depakine (R)	137	130	135	+5.4%
Xatral (R)	103	86	89	+19.8%
Cordarone (R)	73	80	85	-8.8%
Solian (R)	71	67	68	+6.0%
Tildiem (R)	67	72	73	-6.9%
Total	2,574	1,974	2,125	+30.4%



## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

-----  
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 sales:

**Comparable sales:** When we refer to the change in our sales on a "comparable" basis, we mean that we exclude the impact of exchange rate fluctuations and changes in Group structure (acquisitions and divestitures of entities and rights to products as well as change in the consolidation percentage for consolidated entities).

For any two periods, we exclude the impact of exchange rates by recalculating 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 percentage of a consolidated entity, the prior period is recalculated on the basis of the consolidation method used 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 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 with 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.

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 US Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov), or directly from Sanofi-Synthelabo on the web site [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com).

-----  
REMINDER

## Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

A conference call is arranged for financial analysts, institutional investors and journalists, today on Wednesday July 23rd, 2003 at 9.30 a.m. Paris time. The conference call will be in English.

To take part in the conference call, please call the following numbers 10 minutes before the presentation is due to start:

in France:	01 70 70 81 98	code: 163469
in the United Kingdom:	00 44 (0) 207 984 75 82	code: 163469
in the United States:	00 1 719 457 26 79	code: 163469

A recording of the conference call will be released at 11.30 a.m. Paris time, and will be available until August 15, 2003, by calling the following numbers:

in France:	01 70 70 82 10	code: 163469 #
in the United Kingdom:	00 44 (0) 207 784 10 24	code: 163469 #
in the United States:	00 1 719 457 08 20	code: 163469 #

A live audio webcast of the conference call will be available on [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com), and a recording will be archived on this website from 11.30 a.m. the same day until August 15th, 2003.

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

Contacts:  
E-mail: [investor-relations@sanofi-synthelabo.com](mailto:investor-relations@sanofi-synthelabo.com)  
Europe United States  
Tel: + 33 1 53 77 45 45 Tel.: 00 1 212 551 42 93  
Fax: + 33 1 53 77 42 96 Fax: 00 1 212 551 49 92

### 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: July 23, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay  
-----

Name: Marie-Helene Laimay  
Title: Senior Vice President and

