

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

SANOFI SYNTHELABO SA  
Form 6-K  
January 22, 2004

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 January 2004  
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 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

Investor Relations

Paris, January 22nd, 2004

CONTINUED STRONG CONSOLIDATED SALES GROWTH IN 2003:  
15.6% ON A COMPARABLE BASIS  
8.1% ON A REPORTED BASIS

VERY ROBUST GROWTH IN DEVELOPED SALES(1) IN 2003:  
20.4% ON A COMPARABLE BASIS

Unless otherwise indicated, growth rates are on a comparable basis

>> In 2003, Sanofi-Synthelabo once again achieved very strong sales growth:

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

- o Consolidated sales: up 15.6% (8.1% on a reported basis) to 8,048 million euros
  - o Developed sales: up 20.4% to 10,560 million euros
- >> Sales growth was particularly robust in the fourth quarter:
- o Consolidated sales: up 17.0% (10.8% on a reported basis) to 2,108 million euros
  - o Developed sales: up 28.7% to 2,919 million euros
- >> In 2003, sales growth for Plavix(R), Avapro(R), Ambien(R) was strong with particularly sound inventory levels(2) in the United States (close to 1.1 month(3) on average):
- o Plavix(R): 39.9% developed sales growth, including 37.9% in the United States and 37.9% in Europe
  - o Ambien(R): 10.4% consolidated sales growth, including 10.6% in the United States
  - o Aprovel(R): 27.5% developed sales growth, including 30.0% in the United States and 23.6% in Europe.
- >> In 2003, sales of Eloxatin(R) were 824 million euros up 125.8%.
- >> Accelerated growth of the business in the second half of 2003 confirms the forecast of 2003 EPS(4) growth despite unfavorable currency effect.

-----

(1) 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)

(2) Inventory level expressed in months' sales

(3) Internal estimates of inventories (wholesalers, hospitals, pharmacies...) as of December 31st 2003

(4) Before exceptional items and goodwill amortization

2003 consolidated sales: up 15.6% on a comparable basis

Sanofi-Synthelabo generated 2003 consolidated sales of 8,048 million euros, a rise of 15.6% on a comparable basis (8.1% on a reported basis). Currency fluctuations had an unfavorable impact of 7.2 percentage points. Of this, over half was due to the weakening of the US dollar, and the rest to the weakness of some Latin American and Asian currencies. Changes in Group structure(5) had an unfavorable impact of 0.3 of a percentage point.

Fourth-quarter consolidated sales amounted to 2,108 million euros, an increase of 17.0% on a comparable basis (10.8% on a reported basis). During the quarter, currency fluctuations had an unfavorable impact of 6.0 percentage points, and changes in Group structure an unfavorable impact of 0.2 of a percentage point.

2003 Consolidated Sales by Geographical Region: Double-digit Growth in all 3 Zones on a comparable basis

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

In millions of euros	2003 consolidated sales	Change on a comparable basis	Change on a reported basis
Europe	4,693	+10.4%	+9.0%
United States	1,912	+32.9%	+13.2%
Rest of the world	1,443	+13.1%	-0.8%
Total	8,048	+15.6%	+8.1%

- In Europe, 2003 consolidated sales totaled 4,693 million euros, an increase of 10.4% on a comparable basis (9.0% on a reported basis). Fourth-quarter consolidated sales growth achieved 13.2% on a comparable basis (11.0% on a reported basis).
- In the United States, 2003 consolidated sales were 1,912 million euros, an increase of 32.9% on a comparable basis. On a reported basis, growth was 13.2%, due to fluctuations in the dollar/euro exchange rate. Fourth-quarter consolidated sales growth was 28.3% on a comparable basis (10.9% on a reported basis).
- In the rest of the world, 2003 consolidated sales amounted to 1,443 million euros, up 13.1% on a comparable basis but down 0.8% on a reported basis. Fourth-quarter sales growth was 16.1% on a comparable basis (10.2% on a reported basis).

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

Consolidated sales by product: 26.9% growth for the top 10 products on a comparable basis

2003 consolidated sales of the Group's top 10 products were 5,420 million euros, an advance of 26.9% on a comparable basis (18.5% on a reported basis). This represents 67.3% of the Group's consolidated sales, compared to 61.3% in 2002 (on a comparable basis). Fourth-quarter growth in sales of the top 10 products was 23.1%.

In millions of euros	2003 consolidated sales	Change on a comparable basis	Change on a reported basis
Stilnox (R)/Ambien (R)	1,345	+10.4%	-5.5%
Plavix (R)	1,325	+37.4%	+34.2%
Eloxatine (R)	824	+125.8%	+111.8%
Aprovel (R)	683	+24.4%	+21.5%
Fraxiparine (R)	319	+1.6%	-1.5%
Depakine (R)	277	+7.4%	+3.7%
Xatral (R)	222	+24.7%	+22.0%
Solian (R)	148	+11.3%	+9.6%
Cordarone (R)	146	-5.2%	-9.9%
Tildiem (R)	131	-5.1%	-7.1%

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

Total	5,420	+26.9%	+18.5%
-------	-------	--------	--------

In 2003:

- Consolidated sales of Stilnox(R)/Ambien(R)/Myslee(R) were 1,345 million euros, up 10.4% on a comparable basis.  
In the United States, demand for Ambien(R) remained strong, with prescriptions up 13.4%(6), coupled with a favorable price effect. Invoiced sales of Ambien(R) grew only by 10.6% on a comparable basis due to the reduction in inventory levels(7) of approximately 0.8 months(8) on the full year.  
In Japan, Myslee(R) became the class leader after two years from its launch.
- Consolidated sales of Plavix(R) totaled 1,325 million euros, up 37.4% on a comparable basis.
- Consolidated sales of Eloxatin(R) were 824 million euros, up 125.8% on a comparable basis. This strong growth reflects the continuing success of Eloxatin(R) in the United States, where sales reached 460 million euros. Outside the United States, sales of the product increased by 37.4% on a comparable basis to 364 million euros.
- Consolidated sales of Aprovel(R) reached 683 million euros, up 24.4% on a comparable basis.
- Consolidated sales of Xatral(R)/Uroxatral(R) rose by 24.7% on a comparable basis to 222 million euros. Uroxatral(R) was launched in the United States at the start of November, and its progress is in line with our expectations.

-----

- (6) prescriptions IMS NPA+ 12/2003 retail + mail order + long term care
- (7) Inventory level expressed in months' sales
- (8) Internal estimates of inventories (wholesalers, hospitals, pharmacies...) as of December 31st 2003

Apart from the top 10 products, the rest of the portfolio generated sales of 2,628 million euros in 2003, a decline of 2.4% on a comparable basis. Notwithstanding the fall in sales of Ticlid(R) (replaced by Plavix(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 rose 2.2%.

Pending additional indications, Arixtra(R), the sole synthetic product of its therapeutic class, achieved consolidated sales of 19 million euros.

2003 Developed Sales(9): up 20.4% on a Comparable Basis

In 2003, developed sales, which represent the worldwide market presence of Sanofi-Synthelabo products, reached 10,560 million euros, an increase of 20.4% on a comparable basis. Fourth-quarter developed sales rose by 28.7% on a comparable basis.

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

Developed Sales of Plavix(R)/Iscover(R) in 2003: Up 39.9% on a Comparable Basis

In millions of euros	2003	Change on a comparable basis	Q4 2003	Change on a comparable basis
Europe	1,056	+37.9%	305	+45.9%
United States	1,817	+37.9%	577	+73.3%
Rest of the world	352	+59.3%	103	+58.5%
	3,225	+39.9%	985	+62.3%

2003 developed sales of Plavix(R)/Iscover(R) reached 3,225 million euros. In the United States, demand for Plavix(R) again grew at a very strong pace in 2003, with prescriptions up 26.8%(10), coupled with a favorable price effect. Invoiced sales of Plavix(R) advanced by 37.9% on a comparable basis.

(9) 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)

(10) prescriptions IMS NPA + 12/2003 retail + mail order + long term care

Developed Sales of Aprovel(R)/Avapro(R)/Karvea(R): Up 27.5% on a Comparable Basis

In millions of euros	2003	Change on a comparable basis	Q4 2003	Change on a comparable basis
Europe	634	+23.6%	169	+19.9%
United States	407	+30.0%	121	+80.6%
Rest of the world	214	+35.4%	61	+27.1%
	1,255	+27.5%	351	+37.1%

2003 developed sales of Aprovel(R)/Avapro(R)/Karvea(R) reached 1,255 million euros. In the United States, demand for Avapro(R) again grew at a robust pace in 2003, with prescriptions up 14.9%(11), coupled with a favorable price effect. Invoiced sales of Avapro(R) increased 30.0% on a comparable basis.

(11) prescriptions IMS NPA+ 12/2003 retail + mail order + long term care

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

-----  
 2003 Fourth Quarter Detailed figures  
 -----

Fourth-Quarter Consolidated Sales by Geographical Region

In millions of euros	Q4 2003	Q4 2002 Comparable	Q4 2002 Reported	Change on a comparable basis	Change on a reported basis
Europe	1,220	1,078	1,099	+13.2%	+11.0%
United States	499	389	450	+28.3%	+10.9%
Rest of the world	389	335	353	+16.1%	+10.2%
<b>Total</b>	<b>2,108</b>	<b>1,802</b>	<b>1,902</b>	<b>+17.0%</b>	<b>+10.8%</b>

Fourth-Quarter Consolidated Sales of the Top 10 Products

In millions of euros	Q4 2003	Q4 2002 Comparable	Q4 2002 Reported	Change on a comparable basis	Change on a reported basis
Stilnox (R) /Ambien (R)	350	316	361	+10.8%	-3.0%
Plavix (R)	361	255	259	+41.6%	+39.4%
Eloxatine (R)	224	146	159	+53.4%	+40.9%
Aprovel (R)	177	150	153	+18.0%	+15.7%
Fraxiparine (R)	80	81	83	-1.2%	-3.6%
Depakine (R)	71	66	68	+7.6%	+4.4%
Xatral (R)	66	49	49	+34.7%	+34.7%
Solian (R)	40	32	33	+25.0%	+21.2%
Cordarone (R)	36	39	40	-7.7%	-10.0%
Tildiem (R)	32	33	34	-3.0%	-5.9%
<b>Total</b>	<b>1,436</b>	<b>1,167</b>	<b>1,239</b>	<b>+23.1%</b>	<b>+15.9%</b>

Growth in Prescriptions of Plavix(R), Avapro(R) Ambien(R) in the United States in the Fourth Quarter (Prescriptions IMS NPA+ fourth quarter retail + mail order + long term care) (excluding favorable price effect)

=====	
Q4 growth in prescriptions	
-----	
Plavix (R)	+27.6%
Ambien (R)	+12.8%

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

Avapro (R) +16.9%  
-----

-----  
2003 Detailed Sales Figures  
-----

2003 Consolidated Sales by Geographical Region

In millions of euros	2003	2002 Comparable	2002 Reported	Change on a comparable basis	Change on a reported basis
Europe	4,693	4,249	4,304	+10.4%	+9.0%
United States	1,912	1,439	1,689	+32.9%	+13.2%
Rest of the world	1,443	1,276	1,455	+13.1%	-0.8%
Total	8,048	6,964	7,448	+15.6%	+8.1%

2003 Consolidated Sales of the Top 10 Products

In millions of euros	2003	2002 Comparable	2002 Reported	Change on a comparable basis	Change on a reported basis
Stilnox (R) /Ambien (R)	1,345	1,218	1,424	+10.4%	-5.5%
Plavix (R)	1,325	964	987	+37.4%	+34.2%
Eloxatine (R)	824	365	389	+125.8%	+111.8%
Aprovel (R)	683	549	562	+24.4%	+21.5%
Fraxiparine (R)	319	314	324	+1.6%	-1.5%
Depakine (R)	277	258	267	+7.4%	+3.7%
Xatral (R)	222	178	182	+24.7%	+22.0%
Solian (R)	148	133	135	+11.3%	+9.6%
Cordarone (R)	146	154	162	-5.2%	-9.9%
Tildiem (R)	131	138	141	-5.1%	-7.1%
Total	5,420	4,271	4,572	+26.9%	+18.5%

Growth in Prescriptions of Plavix(R), Avapro(R) Ambien(R) in the United States in 2003 (Prescriptions IMS NPA+ 12/2003 retail + mail order + long term care) (excluding favorable price effect)

-----  
2003 growth in  
prescriptions  
-----

Plavix(R) +26.8%

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

Ambien(R)	+13.4%
Avapro(R)	+14.9%

-----

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.

### Reconciliation of 2002 reported-basis sales to 2002 comparable-basis sales

	In millions of euros
2002 reported-basis sales	7,448
Impact of changes in Group structure	-24
Impact of exchange rates	-460
2002 comparable-basis sales	6,964

**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.

### Reconciliation of 2003 consolidated sales to 2003 developed sales



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

	In millions of euros
2003 consolidated sales	8,048
Non-consolidated sales of Plavix(R)/Iscover(R) net of sales of product to Bristol-Myers Squibb	+1,900
Non-consolidated sales of Aprovel (R)/Avapro (R)/Karvea (R)	+572
Non-consolidated sales of Stilnox(R)/Myslee(R)	+36
Non-consolidated sales of Arixtra(R)	+5
2003 developed sales	10,560

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 that are described in our Form 20-F as filed with the US Securities and Exchange Commission on June 25, 2003 and in the Reference Document filed with the French Commission des Operations de Bourse (now the Autorite des Marches Financiers) on April 23, 2003, 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. Sanofi-Synthelabo does not undertake any obligation to provide updates or to revise any forward-looking statements.

Investors and security holders may obtain a free copy of the Form 20-F and any other documents filed by Sanofi-Synthelabo with the US Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov) as well as of the Reference Document filed with the French Autorite des Marches Financiers at [www.amf-france.org](http://www.amf-france.org) or directly from Sanofi-Synthelabo on the web site [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com).

Investor Relations Department:

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

Contacts:

E-mail: <a href="mailto:investor-relations@sanofi-synthelabo.com">investor-relations@sanofi-synthelabo.com</a>	
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

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

### REMINDER

On the occasion of the 2003 Full Year sales publication, a conference call for financial analysts, institutional investors and journalists will be held on Thursday, January 22nd, 2004 at 3.00 p.m. (Paris time). This conference call will be in English.

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: 459621
United Kingdom:	00 44 (0) 207 984 75 82	code: 459621
USA:	00 1 718 354 11 58	code: 459621

A recorded version of the conference will be made available through Wednesday February 11th, 2004 by dialing:

France:	00 33 (0) 1 70 70 82 10	code: 459621#
United Kingdom:	00 44 (0) 207 784 10 24	code: 459621#
USA:	00 1 718 354 11 12	code: 459621#

A live audio webcast of this conference will be made available at our internet site ([www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com)) and a recorded version will be archived through Wednesday, February 11th, 2004.

### 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: January 22, 2004

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay

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