

SANOFI SYNTHELABO SA

Form 6-K

April 22, 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 April 2004

Commission File Number: 001-31368

SANOFI-SYNTHÉLABO
(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 O

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 O

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 declared effective on April 9, 2004 by the United States Securities Exchange Commission, and the related prospectus filed on April 12, 2004 pursuant to Rule 424(b) under the United States Securities Exchange Act of 1933, as amended, and shall be part thereof from the date on which this Report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Investor Relations

Paris, April 22, 2004

SUSTAINED AND VERY STRONG SALES GROWTH

IN THE FIRST QUARTER OF 2004:

CONSOLIDATED SALES: 2,193 MILLION EUROS

UP 18.4% ON A COMPARABLE BASIS

UP 11.9% ON A REPORTED BASIS

DEVELOPED SALES¹:

UP 27.1% ON A COMPARABLE BASIS

Unless otherwise indicated, growth rates are on a comparable basis

Excellent first quarter 2004:

Ø Increase of **26.5%** in consolidated sales of the top 10 products (representing **69.5%** of consolidated sales)

Ø Growth of **3.4%** in consolidated sales of the rest of the portfolio

Ø Strong growth of **Plavix[®]**, **Aprovel[®]**, **Ambien[®]** and **Eloxatin[®]** sales:

Plavix[®]: growth of **39.2%** in consolidated sales and an increase of **63.4%** in developed sales.

Aprovel[®]/Avapro[®]: growth of **16.8%** in consolidated sales and an increase of **20.4%** in developed sales.

Stilnox[®]/Ambien[®]: growth of **16.6%** in consolidated sales.

Eloxatin[®]: growth of **53.3%** in consolidated sales.

Ø Inventory levels² in the United States of **Plavix[®]**, **Aprovel[®]**, **Ambien[®]** and **Eloxatin[®]** in line with those at end December 2003

2004 forecasts³ clearly confirmed

High quality of the fundamentals:

*Once again, Sanofi-Synthelabo delivers an excellent quarterly performance that is **among the best in the sector** and that further highlights **its ability to deliver a strong, sustainable and profitable organic growth** and the **relevance of its strategy** stated the Chairman, Jean-François Dehecq*

¹ Developed sales include Sanofi-Synthelabo consolidated sales and sales generated under the agreements with Bristol-Myers Squibb on **Plavix[®]/Iscover[®]** (clopidogrel) and **Aprovel[®]/Avapro[®]/Karvea[®]** (irbesartan), with Fujisawa on **Stilnox[®]/Myslee[®]** (zolpidem) (see explanatory note)

² Inventories expressed in months sales

³ Barring major adverse events and based on the current Group structure: 1) a similar level of consolidated sales growth, on a comparable basis, to that achieved in 2003; 2) at an exchange rate of 1 euro per 1.25 dollar, an increase in earnings per share of around 15%, before exceptional items and goodwill amortization.

Consolidated sales in the first quarter of 2004: up 18.4% on a comparable basis

Sanofi-Synthelabo generated consolidated sales in the first quarter of 2004 of 2,193 million euros, up 18.4% on a comparable basis (11.9% on a reported basis). There was a negative currency effect of 6.4 points, more than two-thirds of which was due to the US dollar.

Consolidated sales in the first quarter of 2004 by geographical region: double-digit growth in all three regions on a comparable basis

Millions of euros	Consolidated sales Q1 2004	Change on a comparable basis	Change on a reported basis
Europe	1,269	+10.9%	+9.6%
United States	538	+34.2%	+14.2%
Rest of the world	386	+25.7%	+17.0%
Total	2,193	+18.4%	+11.9%

- **In Europe, consolidated sales in the first quarter of 2004 reached 1,269 million euros, up 10.9% on a comparable basis (9.6% on a reported basis).**
- **In the United States, consolidated sales in the first quarter of 2004 (which do not include Plavix® and Avapro® sales consolidated by Bristol Myers Squibb) were 538 million euros, up 34.2% on a comparable basis. On a reported basis, growth was 14.2%, due to fluctuations in the dollar/euro exchange rate.**
- **In the Rest of the world, consolidated sales in the first quarter of 2004 amounted to 386 million euros, up 25.7% on a comparable basis (17.0% on a reported basis).**

Consolidated sales in the first quarter of 2004 by product: 26.5% growth for the top 10 products on a comparable basis

Consolidated sales in the first quarter of 2004 of the Group's top 10 products were 1,525 million euros, up 26.5% on a comparable basis (18.5% on a reported basis) and represented 69.5% of consolidated sales, compared to 65.1% in the first quarter of 2003 (on a comparable basis).

Millions of euros	Q1 2004 consolidated sales	Change on a comparable basis	Change on a reported basis
Plavix®	394	+39.2%	+36.3%
Stilnox®/Ambien®	345	+16.6%	+0.9%
Eloxatin®	256	+53.3%	+38.4%
Aprovel®	188	+16.8%	+14.6%
Fraxiparine®	84	+1.2%	-1.2%
Depakine®	74	+12.1%	+8.8%
Xatral®	72	+50.0%	+46.9%
Solian®	44	+29.4%	+25.7%
Cordarone®	35	0.0%	-5.4%
Tildiem®	33	0.0%	0.0%
Total	1,525	+26.5%	+18.5%

In the first quarter of 2004:

- **Consolidated sales of Plavix®** (which do not include Plavix® sales consolidated by Bristol Myers Squibb) **totaled 394 million euros** (up 39.2% on a comparable basis). Excluding deliveries of finished product to Bristol-Myers Squibb, sales of Plavix® would have been up 37.5%.
- **Consolidated sales of Stilnox®/Ambien®/Myslee® were 345 million euros, up 16.6%** on a comparable basis. **In the United States**, sales of Ambien® reached 289 million euros (up 19.9% on a comparable basis) and were in line with demand. In Japan, consolidated sales (at 51%) of Myslee®, the market leader in this market, were 9 million euros.
- **Consolidated sales of Eloxatin® reached 256 million euros, up 53.3%** on a comparable basis. Sales of Eloxatin® were 147 million euros in the United States (up 75.0% on a comparable basis) and 109 million euros outside the United States (up 31.3% on a comparable basis).
- **Consolidated sales of Aprovel® totaled 188 million euros, up 16.8%** on a comparable basis. Excluding deliveries of finished product to Bristol-Myers Squibb, sales of Aprovel® would have been up 21.4%.
- Consolidated sales of Xatral®/Uroxatral® reached 72 million euros, up 50.0% on a comparable basis. The launch of Uroxatral® in the United States with general practitioners took place in February, and progressed as planned. Apart from the top 10 drugs, **the rest of the portfolio** recorded consolidated sales of 668 million euros in the first quarter of 2004, up **3.4%** on a comparable basis.

Developed sales⁵ in the first quarter of 2004: up 27.1% on a comparable basis

In the first quarter of 2004, developed sales, which reflect the worldwide market presence of Sanofi-Synthélabo products in the market, **totaled 2,826 million euros, up 27.1% on a comparable basis.**

Developed sales of Plavix[®]/Iscover[®] in the first quarter of 2004: up 63.4% on a comparable basis

Millions of euros	Q1 2004	Change on a comparable basis
Europe	310	+33.6%
United States	472	+94.2%
Rest of the world	102	+54.5%
Total	884	+63.4%

Developed sales of Plavix[®]/Iscover[®] amounted to 884 million euros in the first quarter of 2004 of which **412 million euros were outside the United States (up 38.3% on a comparable basis). In the United States, demand for Plavix[®] in the first quarter of 2004 continued to grow at a very fast rate, with an increase in prescriptions of 29.8%⁶ and a favorable price effect.** Plavix[®] growth corresponds to invoiced sales in line with demand, but benefit from a favorable comparative base. In the first quarter of 2003, sales were affected by the sharp reduction in wholesaler inventories.

Developed sales of Aprovel[®]/Avapro[®]/Karvea[®]: up 20.4% on a comparable basis

Millions of euros	Q1 2004	Change on a comparable basis
Europe	174	+20.0%
United States	93	+13.4%
Rest of the world	57	+35.7%
Total	324	+20.4%

Developed sales of Aprovel[®]/Avapro[®]/Karvea[®] in the first quarter of 2004 were 324 million euros. **In the United States, demand for Avapro[®] in the first quarter of 2004 continued to show strong growth, with prescriptions up 17.5%⁷ and a favorable price effect. Invoiced sales of Avapro[®] rose by 13.4% on a comparable basis and were slightly below demand for the quarter.**

⁵ Developed sales include Sanofi-Synthélabo consolidated sales and sales generated under the agreements with Bristol-Myers Squibb on Plavix[®]/Iscover[®] (clopidogrel) and Aprovel[®]/Avapro[®]/Karvea[®] (irbesartan), with Fujisawa on Stilnox[®]/Myslee[®] (zolpidem) (see explanatory note)

⁶ Prescriptions IMS NPA + 03/2004 retail + mail order + long term care

⁷ *Prescriptions IMS NPA + 03/2004 retail + mail order + long term care*

Recent events :

- **In Japan:** The Group has set up the basis of its future operating presence:
 - Agreement with Taisho in order to purchase the full rights of Ancaron® (amiodarone) in 2006;
 - Creation of our own sales force in order to promote the existing marketed products and to prepare for future launches of products under development.

Plavix® has been submitted to the Japanese health authorities on February 24th 2004.

- **Eloxatin®:**
 - January 7, 2004 announcement of successful completion of a Mutual Recognition Procedure in Europe, which will allow Eloxatin® to receive the full indication: treatment of Metastatic Colorectal Cancer in combination with 5-fluorouracil and folinic acid (i.e. 1st line and 2nd line treatment).

 - January 12, 2004 announcement of the approval of Eloxatin® in combination with 5FU/LV by the U.S. Food and Drug Administration (FDA) for the first line treatment of advanced colorectal cancer.

 - January 19, 2004 announcement of a submission of a supplemental New Drug Application in the United States and an extension of indication in Europe for Eloxatin® in the adjuvant treatment of patients with colon cancer.

- **Dronedarone:**

February 16, 2004 presentation of the positive results of two pivotal phase III studies, EURIDIS and ADONIS: dronedarone is effective in the prevention of recurrences of atrial fibrillation with an incidence of side effects similar to that observed with placebo.

- **Acomplia™ (Rimonabant):**

March 9, 2004 announcement of the results of two studies RIO-LIPIDS and STRATUS US at the American College of Cardiology which indicate that Acomplia™ offers a novel approach to cardiovascular risk management in overweight/obese people and smokers.

- **Xatral®/Uroxatral®:**

March 25, 2004 announcement at the XIXth European Association of Urology Congress, of the results of the ALFAUR (ALFuzosin in Acute Urinary Retention) study.

Recent events relating to the bid for Aventis shares:

March 9 th , 2004	Filing of the notification of the offer for Aventis with the European anti-trust authority.
March 15 th , 2004	Opening of the offer for Aventis in Germany.
March 19 th , 2004	Successful completion of the first round of syndication of the 12 billion euro credit facility put in place in connection with the offer for Aventis.
April 5 th , 2004	Filing of the notification of the offer for Aventis with the U.S. anti-trust authority (Federal Trade Commission).
April 9 th , 2004	The U.S. registration statement relating to the shares of Sanofi-Synthélabo to be issued in the U.S. offer declared effective by the Securities and Exchange Commission (SEC)
April 12 th , 2004	The opening of the U.S offer for Aventis.
April 13 th , 2004	Signature of an agreement with GlaxoSmithKline Group, conditioned to the successful completion of the offer for Aventis, regarding the divestment of Arixtra [®] and Fraxiparine [®] and related assets (including the manufacturing facility located in Notre-Dame de Bondeville). The consideration for this transaction is 453 millions euros.
April 15 th , 2004	Announcement of the payment on May 5, 2004, of an interim dividend of 0.97 euro toward the total annual dividend in respect of 2003 results (the total dividend proposed for approval by the annual general meeting of Sanofi-Synthelabo shareholders being 1.02 euros), with the balance to be paid on the settlement date of the offers.

Detailed figures for the first quarter of 2004

First-quarter consolidated sales by geographical region

Millions of euros	Q1 2004	Q1 2003 Comparable	Q1 2003 reported	Change on a comparable basis	Change on a reported basis
Europe	1,269	1,144	1,158	+10.9%	+9.6%
United States	538	401	471	+34.2%	+14.2%
Rest of the world	386	307	330	+25.7%	+17.0%
Total	2,193	1,852	1,959	+18.4%	+11.9%

First-quarter consolidated sales of the top 10 products

Millions of euros	Q1 2004	Q1 2003 Comparable	Q1 2003 reported	Change on a comparable basis	Change on a reported basis
Plavix®	394	283	289	+39.2%	+36.3%
Stilnox®/Ambien®	345	296	342	+16.6%	+0.9%
Eloxatin®	256	167	185	+53.3%	+38.4%
Aprovel®	188	161	164	+16.8%	+14.6%
Fraxiparine®	84	83	85	+1.2%	-1.2%
Depakine®	74	66	68	+12.1%	+8.8%
Xatral®	72	48	49	+50.0%	+46.9%
Solian®	44	34	35	+29.4%	+25.7%
Cordarone®	35	35	37	0.0%	-5.4%
Tildiem®	33	33	33	0.0%	0.0%
Total	1,525	1,206	1,287	+26.5%	+18.5%

Growth in prescriptions of Plavix®, Avapro® and Ambien® in the United States in the first quarter (Prescriptions IMS NPA first quarter 2004 retail + mail order + long term care) (excluding favorable price effect)

*Q1 2004
growth in
prescriptions*

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Plavix®	+29.8%
Ambien®	+15.3%
Avapro®	+17.5%

Explanatory notes:

Except as otherwise noted, 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 Q1 2003 reported-basis sales to Q1 2003 comparable-basis sales

	In millions of euros
Q1 2003 reported-basis sales	1,959
Impact of changes in Group structure	-2
Impact of exchange rates	-105
Q1 2003 comparable-basis sales	1,852

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[®] /Iscover[®] (clopidogrel) and Aprovel[®]/Avapro[®] /Karvea[®] (irbesartan), with Fujisawa on Stilnox[®] /Myslee[®] (zolpidem). 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 a useful measurement tool because they demonstrate trends in the overall presence of our products in the market.

Reconciliation of Q1 2004 consolidated sales to Q1 2004 developed sales

In millions of
euros

Q1 2004 consolidated sales	2,193
Non-consolidated sales of Plavix® /Iscover® net of sales of product to Bristol-Myers Squibb	+490
Non-consolidated sales of Aprovel® /Avapro® /Karvea®	+136
Non-consolidated sales of Stilnox®/ Myslee®	+7
Q1 2004 developed sales	2,826

The present press release has been sent to the *Autorité des Marchés Financiers* (French Financial Markets Authority) before publication, pursuant to article 7 of COB Regulation 2002.04.

Important Information

In connection with the proposed acquisition of Aventis, Sanofi-Synthélabo has filed with the United States Securities and Exchange Commission (SEC), a registration statement on Form F-4 (File no: 333-112314), which includes a final prospectus/offer to exchange and related exchange offer materials, to register the Sanofi-Synthélabo ordinary shares (including Sanofi-Synthélabo ordinary shares represented by Sanofi-Synthélabo ADSs) to be issued in exchange for Aventis ordinary shares held by holders located in the United States and for Aventis ADSs held by holders wherever located and Sanofi-Synthélabo has also filed a Statement on Schedule TO with the SEC. **Investors and holders of Aventis securities are strongly advised to read the registration statement and the final prospectus/offer to exchange, the related exchange offer materials and the Statement on Schedule TO, and any other relevant documents filed with the SEC, as well as any amendments and supplements to those documents, because they contain important information.** Investors and holders of Aventis securities may obtain free copies of the registration statement, the final prospectus/ offer to exchange and related exchange offer materials, and the Statement on Schedule TO, as well as other relevant documents filed with the SEC, at the SEC's web site at www.sec.gov. The final prospectus/offer to exchange and other transaction-related documents are being mailed to Aventis securityholders eligible to participate in the U.S. offer and additional copies may be obtained for free from MacKenzie Partners, Inc., the information agent for the U.S. offer, at the following address: 105, Madison Avenue, New York, New York 10016; telephone 1-(212) 929-5500 (call collect) or 1-(800) 322-2885 (toll-free call); e-mail proxy@mackenziepartners.com.

In France, holders of Aventis securities are requested, with respect to the offer, to refer to the prospectus (*note d information*), which has been granted *visa* number 04-0090 by the *Autorité des marchés financiers* (AMF) and which is available on the website of the AMF (www.amf-france.org) and without cost from: BNP Paribas Securities Services, GIS-Emetteurs, Service Logistique, Les Collines de l Arche, 75450 Paris Cedex 9.

The public offer to holders of Aventis ordinary shares located in Germany (the German Offer) is being made in accordance with applicable German law and pursuant to an offer document/sales prospectus, which is available free of charge at BNP Paribas Securities Services, Grüneburgweg 14, D-60322 Frankfurt am Main (Fax: 069 - 152 05 277) and on the website of the Company (www.sanofi-synthelabo.com). Any decision to tender Aventis ordinary shares in exchange for Sanofi-Synthélabo ordinary shares under the German Offer must be taken exclusively with regard to the terms and conditions of the German Offer, as well as with regard to the information included in the offer document/sales prospectus, including any amendments and supplements thereto, issued in Germany.

The French Offer, the U.S. Offer and the German Offer are being made on substantially the same terms and completion of these offers is subject to the same conditions. It is intended that the three offers will expire at the same time.

This press release does not constitute an offer to purchase or exchange or the solicitation of an offer to sell or exchange any securities of Aventis or an offer to sell or exchange or the solicitation of an offer to buy or exchange any securities of Sanofi-Synthélabo, nor shall there be any sale or exchange of securities in any jurisdiction (including the United States, Germany, Italy and Japan) in which such offer, solicitation or sale or exchange would be unlawful prior to the registration or qualification under the laws of such jurisdiction. The distribution of this communication may, in some countries, be restricted by law or regulation. Accordingly, persons who come into possession of this document should inform themselves of and observe these restrictions. The solicitation of offers to buy Sanofi-Synthélabo ordinary shares (including Sanofi-Synthélabo ordinary shares represented by Sanofi-Synthélabo ADSs) in the United States will only be made pursuant to a prospectus and related offer materials that Sanofi-Synthélabo expects to send to holders of Aventis securities. The Sanofi-Synthélabo ordinary shares (including Sanofi-Synthélabo ordinary shares represented by Sanofi-Synthélabo ADSs) may not be sold, nor may offers to buy be accepted, in the United States prior to the time the registration statement becomes effective. No offering of securities shall be made in the United States except by means of a prospectus meeting the requirements of Section 10 of the United States Securities Act of 1933, as amended.

Forward-Looking Statements

This press release contains statements that constitute forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Forward-Looking statements are statements that are not historical facts. These statements include financial projections and estimates and their underlying assumptions, statements regarding plans, objectives and expectations with respect to future operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words expect, anticipates, believes, intends, estimates and similar expressions. Although Sanofi-Synthélabo's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi-Synthélabo, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. The following factors, among other risks and uncertainties that are described in our Form 20-F as filed with the SEC on April 2, 2004 and in the Reference Document filed with the French Autorité des Marchés Financiers on April 2, 2004, could cause actual results to differ materially from those described in the forward-looking statements: the ability of Sanofi-Synthélabo to expand its presence profitably in the United States; the success of Sanofi-Synthélabo's research and development programs; the ability of Sanofi-Synthélabo 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 Europe. Sanofi-Synthélabo 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 filed with the SEC on April 2, 2004 and any other documents filed by Sanofi-Synthélabo with the SEC at www.sec.gov as well as of the Reference Document filed

with the AMF on April 2, 2004 N° 04-0391 with the French Autorité des Marchés Financiers at www.amf-france.org or directly from Sanofi-Synthelabo on our web site at: www.sanofi-synthelabo.com.

Investor Relations Department:

<i>Philippe Goupit</i>	<i>Director of Investor Relations</i>
<i>Arnaud Delépine</i>	<i>Investor Relations Europe</i>
<i>Sanjay Gupta</i>	<i>Investor Relations US</i>
<i>Anne d Halluin-Sulzer</i>	<i>Investor Relations</i>

Contacts:

E-mail:

investor-relations@sanofi-synthelabo.com

Europe

Tel: +33 1 53 77 45 45

Fax: +33 1 53 77 42 96

United States

Tel: 00 1 212 551 42 93

Fax: 00 1 212 551 49 92

REMINDER: A conference call will be organized today at 3:00 p.m. (Paris time). The following numbers are to be dialed 10 minutes before it starts:

France:	00 33 (0) 1 70 70 81 98	code: 579164
United Kingdom:	00 44 (0) 207 984 75 82	code: 579164
USA:	00 1 718 354 11 58	code: 579164

A live audio webcast of this conference will be made available at our internet site (www.sanofi-synthelabo.com).

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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: April 22, 2004

SANOFI-SYNTHÉLABO

By: /s/ Marie-Hélène Laimay
Name: Marie-Hélène Laimay
Title: Senior Vice President and Chief
Financial Officer