SANOFI SYNTHELABO SA
Form 6-K
September 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 September 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 ---

(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 ---

(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, September 2nd, 2003

>> 2003 FIRST-HALF EPS* UP 18.6% ON A REPORTED BASIS
AND 31.9% AT 2002 EXCHANGE RATES

>> 2003 FULL-YEAR FORECASTS UPGRADED:
AT A RATE OF 1.10 DOLLARS TO ONE EURO, EPS* GROWTH
CLOSE TO 20%

*Earnings per share before exceptional items and goodwill amortization

FIRST HALF 2003:

- Acceleration in consolidated sales growth in the second quarter to 15.4%(1), against 13.4%(1) in the first quarter.
  - Very strong growth in first-half consolidated sales of Plavix(R)(27%(1)), Aprovel(R)(29.5%(1)) and Ambien(R)(20.8%(1)).
  - Confirmation of blockbuster status for Eloxatin(R)
- Continued investment in R&D, with expenditure up by 12.9% at 2002 exchange rates and by 5.8% on a reported basis.
  - Progress to phase III of xaliprodene in Alzheimer's disease and SR 58611 in depression
  - Progress to phase II b of SR 57667 in Alzheimer's disease
- Strong growth in operating profit, up by 30.3% at 2002 exchange rates and by 12.8% on a reported basis.
- First-half net income(2) 27.5% higher at 2002 exchange rates and 14.4% higher on a reported basis.
- 2003 first-half EPS(2) up 18.6% at 1.34 euros, ahead of the Group's forecasts.

OUTLOOK FOR 2003:

- Upgrade to our forecast for 2003 full-year sales growth, which we now expect to be in the region of 15% on a comparable basis, as opposed to our initial forecast of close to 12.8%.
- Growth of close to 20% in full-year 2003 EPS(2) expected at an average annual rate of 1.10 dollars to one euro (as opposed to the 1 dollar per euro rate previously assumed), giving an upgrade of 20% to our original forecast for 2003 full-year EPS(2) growth. The sensitivity of this growth rate to fluctuations in the dollar is unchanged at 1% for a 3-cent movement.
- These revised expectations are, after taking account of a sustained effort during the second half of the year designed to build for the future, involving:
  - an acceleration in R&D spend, associated with clinical trials;
  - a reinforcement of marketing resources, especially in the United States for the launch of Uroxatral(R).

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(1) on a comparable basis
(2) before exceptional items and goodwill amortization

SHARE BUY-BACK PROGRAM 2003/2004:

- New authorization(3) for 1 billion euros, without any significant impact on 2003 EPS(2)

On September 1st, 2003, the Sanofi-Synthelabo Board of Directors examined the Group's consolidated financial statements for the six months to June 30, 2003.

- 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(4) and 6.1% 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, and the rest was due to the weakness of some Latin American and Asian currencies. Changes in Group structure(5) had an unfavorable impact of 0.5 of a percentage point over the half-year.

- Gross profit was 3,153 million euros, a rise of 6.0%. At 2002 exchange rates, gross profit would have risen by 16.9%.
  The gross margin rate was unchanged relative to the first half of 2002 at 80.8%. This reflects a favorable product mix/industrial cost effect, offset by a negative currency effect. At 2002 exchange rates, the gross margin rate would have been 81.9%, an improvement of 1.1 percentage points.

- Research and development expenses increased by 5.8% during the first half of 2003 to 621 million euros, representing 15.9% of sales, in line with the 2002 first-half figure. At 2002 exchange rates, research and development expenses would have risen by 12.9%. This increase was mainly due to major clinical trials programs covering products already on the market (Plavix(R), Aprovel(R)/Avapro(R)), products in phase III (rimonabant, idraparinux, zolpidem MR, tirapazamine), and phase I and II projects. During the second half of the year, the rate of growth in research and development expenditure is likely to accelerate, due in particular to the progress of two new compounds into phase III.

- Selling and general expenses amounted to 1,204 million euros, 2.8% lower than in the first half of 2002. At 2002 exchange rates, rigorous cost management kept general expenses stable, restricting the rise in selling and general expenses to 5.1%. Marketing spend rose by 6.6% at 2002 exchange rates. Growth in marketing spend should accelerate in the second half of 2003, especially in the United States in anticipation of the launch of Uroxatral(R).

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(3) decided by the Board of Directors further to being authorized by the Shareholders'Meeting of May, 19th 2003 (Prospectus visa COB n. 03-299 dated April 22nd 2003).

(4) Comparable basis means constant Group structure and constant 2003 exchange rates

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

- Other operating income and expenses, mainly comprising transfers in respect of joint operations with our partners (primarily Bristol-Myers Squibb), represented a net gain of 63 million euros, against 85 million euros for the first half of 2002. At 2002 exchange rates, this item would have shown an increase of about 12.9%. The reported-basis decline in this item was due mainly to the following factors:
  - Negative currency effect on the share of profits generated by Plavix(R)and Avapro(R)in the United States transferred by Bristol-Myers Squibb.
  - An increase in profits transferred to Bristol-Myers Squibb as a result of the strong growth of Plavix(R)and Aprovel(R)in Europe.

- Operating profit rose to 1,391 million euros in the first half of 2003, up by 12.8% over the first half of 2002. The operating margin rate advanced by more than 2 percentage points to 35.6%, against 33.5% in the first half of 2002. If the net gains arising from the Group's currency hedging policy had been recognized at operating level, operating profit would have risen by approximately 16%. At 2002 exchange rates, growth in operating profit would have been 30.3%.

- During the first half of 2003, net financial income totaled 63 million euros, compared with 28 million euros in the first half of 2002. The reduction in the Group's net cash position as a result of the share buy-back program initiated in 2002 and a fall in the rate of interest on the investment of surplus cash led to a decline in investment income. However, two other factors resulted in an overall increase in net financial income:
  - A net foreign exchange gain generated by the Group's hedging policy of 53 million euros in the first half of 2003, against 13 million euros in the first half of 2002.
  - A further charge of 20 million euros in the first half of 2003 to the provision for treasury shares allocated to stock option plans, against the 38 million euros charged in the first half of 2002.

- Income taxes amounted to 458 million euros, against 313 million euros in the first half of 2002, bringing the Group's effective tax rate to 33% (versus 26% in the first half of 2002). The effective tax rate was abnormally low in the first half of 2002, due to the write-back of provisions for taxes and to the non-taxation of the share of Lorex profits transferred to Pharmacia.

- Minority interests came to 2 million euros, compared with 83 million euros in the first half of 2002. The 2002 first-half figure mainly comprised the entitlement of Pharmacia to a share in the profits of the Lorex joint venture for the period from January 1st, 2002 through April 16th, 2002, the date on which Sanofi-Synthelabo bought out Pharmacia's 51% interest in Lorex.

- Net income came to 944 million euros, an increase of 13.7%. At 2002 exchange rates, the increase would have been 26.7%.

- Net income before exceptional items and goodwill amortization totaled 947 million euros, a rise of 14.4%. At 2002 exchange rates, the rise would have been 27.5%.

- Earnings per share before exceptional items and goodwill amortization was 1.34 euros, compared with 1.13 euros for the first half of 2002, an increase of 18.6%. At 2002 exchange rates, the increase would have been 31.9%. The difference between growth in net income and growth in earnings per share was mainly due to the share buy-back initiated in 2002. The average number of shares used to calculate earnings per share for the first half of 2003 was 706.5 million, against 731.8 million for the first half of 2002.

Implementation of the share buy-back programs authorized by the General Meetings of May 22nd, 2002 and May 19th, 2003 led to the repurchase of 13.9 million shares, acquired during the first half of 2003 in the light of market conditions for a total of 688 million euros. As of August 31st, 2003, the Group owned 32.3 million shares acquired under the share buy-back programs implemented since 2002. These shares, acquired in the light of market conditions for a total of 1,749 million euros, represented 4.41% of the capital.

The net cash position in the balance sheet as of June 30th, 2003 stood at 1,967 million euros (versus 2,672 million euros as of December 31st, 2002), including treasury shares amounting to 599 million euros held in connection with stock option plans.

Recent events

- Announcement in June 2003 at the 39th annual conference of the ASCO (American Society of Clinical Oncology) of major results with oxaliplatine (Eloxatin(R)), clearly demonstrating consistent superiority in the treatment of colorectal cancer at all settings of the disease (early stage, 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, and favorable opinion in July 2003 from the Committee for Proprietary Medicinal Products on approval for marketing in Europe, for 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).

- In connection with the Plavix litigation in the United States, and as announced on June 20th, 2003, patent "328" expiring 2014 has been withdrawn from the patent infringement action and will be delisted from the Food and Drug Administration "Orange Book". This withdrawal has no effect on product patent "265" expiring 2011, which protects clopidogrel, the active ingredient of Plavix, which we are confidently defending. As regards the action itself, fact discovery is scheduled to end on October 15th, 2003, with the pre-trial order expected towards mid-2004. The trial itself will follow, on a date to be fixed by the Court.

Sanofi-Synthelabo consolidated statements of income

In millions of euros	H1 2002	H1 2
Net sales	3,680	3,9
Gross profit	2,974	3,1
Research and development expenses	(587)	(62
Selling and general expenses	(1,239)	(1,2
Other operating income/(expense), net	85	6

Operating profit	1,233	1,3
Intangibles - amortization and impairment	(55)	(6
Financial income/(expense), net	28	6
Exceptional items	6	1
Income taxes	(313)	(45
Income from equity investees, net	18	1
Goodwill amortization	(4)	(4
Minority interests	(83)	(2
Net income	830	94
Exceptional items and goodwill amortization, net of income taxes	(2)	3
Net income before exceptional items and goodwill amortization	828	94
Average number of shares outstanding	731,762,997	706,51
Earnings per share before exceptional items and goodwill amortization, in euros	1.13	1.

Sanofi-Synthelabo simplified balance sheet

In millions of euros

ASSETS	June 30, 2002	June 30, 2003	LIABILITIES & SHAREHOLDERS' EQUITY	June 30, 2002
Total fixed assets	2,879	2,819	Shareholders' equity	5,905
Deferred income taxes	487	471	Minority interests	10
Inventories, accounts receivable and other current assets	3,022	3,273	Other long-term liabilities	813
Short-term investments and deposits, cash	3,045	2,274	Accounts payable and other short-term liabilities	2,252
			Debt	453

Total assets	9,433	8,837	Total liabilities & shareholders' equity	9,433

Sanofi-Synthelabo simplified statement of cash flows

In millions of euros	H1 2002
Operating cash flow before changes in working capital	1,087
Changes in working capital	(697)
Net cash provided by operating activities	390
Total investments	(1,026)
Asset disposals and other items	17
Net cash used in investing activities	(1,009)
Change in borrowings and other items	68
Dividends paid	(476)
Repurchase of own shares	(386)
Net cash used in financing activities	(794)
Net change in cash and cash equivalents	(1,413)

First-half consolidated sales by geographical region

Millions of euros	H1 2003	H1 2002 (comparable)	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 of the top 10 products

Millions of euros	H1 2003	H1 2002 (comparable)	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%

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. 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 documents filed by Sanofi-Synthelabo with the French Commission des Operations de Bourse at www.cob.fr and with the US Securities and Exchange Commission at www.sec.gov, or directly from Sanofi-Synthelabo on the web 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: September 2, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Helene Laimay

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