

SANOFI SYNTHELABO SA  
Form 6-K  
April 25, 2003

---

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

---

## FORM 6-K

---

### REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 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.

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

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 by furnishing the information contained in this Form the registrant, 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- .

---





## RECENT EVENTS

The ANDROMEDA study was stopped on **January 16, 2003** on the advice of the independent committee monitoring the tolerability data. This study evaluated the tolerability of dronedarone in high-risk patients suffering from serious heart failure. As of **February 12, 2003**, on the favorable recommendation of the independent tolerability data monitoring committees, the two pivotal efficacy studies EURIDIS and ADONIS are continuing their evaluation of dronedarone in patients with atrial fibrillation.

In accordance with the authorization granted by the Annual General Meeting and the Board of Directors on **May 22, 2002** to purchase and sell the company's shares in the light of market conditions, Sanofi-Synthélabo has continued the share purchase plan initiated in 2002. As of **February 28, 2003**, this figure rose to 38.6 million shares, 5.26% of the capital, of which 24.7 million shares were acquired under the share purchasing plan.

Marketing approval granted by the U.S. health authorities for Eligard 30 mg (four month formulation of leuproreline acetate in subcutaneous injection) in the treatment of advanced prostate cancer in **February 2003**.

Subsequent to filing in **December 2002**, the U.S. health authorities granted priority review to Arixtra® in **March 2003** for a new indication: the prolonged prophylaxis of deep-vein thrombosis in patients who have undergone hip fracture surgery.

Following publication by Bristol Myers Squibb of its restated consolidated financial statements for the years 1999 - 2002, Sanofi-Synthélabo confirmed on **March 12, 2003** there were no changes in the Group accounts, established in accordance with French accounting principles, nor in the growth prospects communicated on **February 18, 2003**.

**30**

YEARS IN THE SERVICE  
OF HEALTH,  
YEARS OF PERFORMANCE

**HISTORY IN THE MAKING****SOME KEY DATES**

1973	<p><b>The story began</b></p> <p>Creation of Sanofi by Elf Aquitaine, through the takeover of the Labaz pharmaceutical company.</p> <p>L Oréal took over Synthélabo, created in 1970 by the merger of two French pharmaceutical companies, Dausse (founded in 1834) and Robert &amp; Carrière (founded in 1899).</p>
1978	<p><b>Sanofi launched its first major product on the market:</b></p> <p>Ticlid®.</p>
1988	<p><b>Synthélabo launched two major products on the French market:</b> Stilnox® and Xatral®.</p>
1993	<p><b>Synthélabo launched Stilnox® in the United States</b></p> <p>under the trade name Ambien®. As of 1994, Stilnox®/Ambien® became the leading medicine in the treatment of insomnia (IMS data).</p>
1994	<p><b>Sanofi made a significant entrance into the U.S.</b></p> <p>market through the acquisition of Sterling Winthrop, the pharmaceutical unit of Eastman Kodak.</p>
1997/1998	<p><b>In 1997, Sanofi launched its first major product in the U.S.</b></p> <p>market, Avapro®, followed by Plavix® in 1998.</p>
1998	<p><b>Two leaders of the French pharmaceutical industry</b></p> <p>At that time, Sanofi was the 2nd pharmaceutical group in France, Synthélabo the 3rd. Sanofi was majority-held by Elf Aquitaine, currently a subsidiary of TotalFinaElf and Synthélabo was majority-held by L Oréal. The merger was decided at the end of 1998.</p>
1999	<p><b>The year of the merger</b></p> <p>Following the merger, which took place on May 18, 1999, the new Group refocused on its core business, pharmaceuticals. Sanofi divested its non-strategic activities in the Beauty, Veterinary and Diagnostics businesses. TotalFinaElf and L Oréal are the reference shareholders of the new group.</p>
1999/2002	<p><b>Strength through unity</b></p> <p>Sanofi and Synthélabo combined their resources to expand the presence of the new Group worldwide, notably in the U.S., and to concentrate R&amp;D efforts on high-potential products.</p> <p>Over three years, the sales of the three flagship products, Stilnox®/Ambien®/Myslee®, Plavix®/Iscover® and Aprovel®/Avapro®/Karvea® progressed strongly. This strategy paid off, and today Sanofi-Synthélabo is the 2nd</p>

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

pharmaceutical group in France, 7th in Europe, and among the top 20 worldwide.

2001/2002

### **The American years**

The expansion of the affiliate Sanofi-Synthélabo Inc., the doubling of the sales force, the contribution of the U.S. market to Group sales and earnings all these factors justified the decision to list company shares on the New York Stock Exchange on July 1, 2002.

The U.S. health authorities granted six marketing approvals in 2002, confirming our strong presence in the world's leading pharmaceutical market.

2003

### **Sanofi-Synthélabo celebrates its 30th anniversary**





## CHAIRMAN S MESSAGE

**ALL the CONDITIONS  
for our CONTINUED  
GROWTH are met**

Jean-François Dehecq

### **n 2002 was a very good year. Which aspects of this year were particularly important for you?**

Without wishing to appear overly optimistic, I cannot deny that we are satisfied with our performance in 2002. For several years now, we have posted sales growth well into double-digits and this performance is reflected in our profits. In 2002, our consolidated earnings per share rose by 28.7% before exceptional items and goodwill amortization, one of the highest growth rates within the pharmaceutical industry, and we exceeded our objectives. If we look back, we can see that our net profit has steadily increased, practically tripling over the last three years.

This achievement is all the more remarkable in that the economic environment was far from favorable during the entire year.

In contrast to previous years, we were penalized by fluctuations in foreign exchange rates. This cost us 2.5 points with regard to our consolidated sales growth. In addition, we had to absorb the impact of the stock-reducing measures taken by our U.S. partner Bristol-Myers Squibb who distribute two of our flagship products, Plavix<sup>®</sup> and Avapro<sup>®</sup>, and which limited our sales in the U.S. despite a substantial increase in prescriptions. Finally, in common with the entire pharmaceutical industry, we continued to be affected by measures taken to curb healthcare expenditure in Europe, and by the economic crisis in Latin America.

Despite all these unfavorable factors, our sales progressed by 14.8% on a reported basis, thanks to the performance of our flagship products and also the taking back of rights to Ambien<sup>®</sup> in the U.S.

This shows that, even in challenging times, our company is capable of achieving its objectives and meeting its commitments to shareholders.

### **n Apart from the flagship products, how is the portfolio performing?**

The growth rates of our flagship products, in terms of developed sales on a comparable basis, are indeed spectacular: +32% for Plavix<sup>®</sup>, +19% for Aprovel<sup>®</sup>/Avapro<sup>®</sup>, +26% for Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup>; but the wealth of our portfolio does not rest solely on their performance.

The year 2002 saw the launch of two new medicines which are likely to become new flagship products within the next few years. Arixtra<sup>®</sup> took off slowly due to its restricted initial indication for the prophylaxis of deep-vein thromboses following major orthopedic surgery, but its potential is considerable. Apart from its remarkable efficacy, Arixtra<sup>®</sup> has the merit of being a 100% synthetic product, a characteristic ensuring a high degree of purity and safety. Its vocation is to replace current products of animal origin, as that is the long-term trend observed in the pharmaceutical industry.

As for Eloxatin<sup>®</sup>, its clear therapeutic benefits led to its approval in the U.S. within an exceptionally short time. Four months after its launch, Eloxatin<sup>®</sup> had already attained sales of 116 million euros on the U.S. market and promises to become the reference treatment for colorectal cancer worldwide.

**n 2001 was an American year. Did this effort pay off?**

We were determined to succeed in penetrating the U.S. market and we have achieved our objective. In 2002, sales of our products increased by 32% in the U.S. according to the IMS, outperforming the market more than three-fold. We doubled our sales force in 2002, following the taking back of full rights to Ambien<sup>®</sup> in April, and launched four medicines during the year. In other words, we are now firmly established in the U.S., the world's leading pharmaceutical market.

**WE were determined to  
SUCCEED in penetrating  
the U.S. MARKET,  
and we have ACHIEVED  
our objective**

We took advantage of this economic visibility to apply for a listing of Sanofi-Synthélabo shares on the New York Stock Exchange in July.

**n What about the Group's global market presence?**

Our international expansion has been rapid and, above all, well balanced: our growth exceeds that of the market in practically all countries worldwide.

In Europe, we gained market share in all countries except Italy, where severe measures taken by the health authorities affected us considerably.

---

## CHAIRMAN S MESSAGE

In other countries, our growth remained buoyant. In Japan, our performance was bolstered by the launch of our hypnotic Myslee® (zolpidem), ranking second in its market within two years.

Today we enjoy direct presence in all markets worldwide, with the exception of Japan, where we market our products through joint ventures with major partners. We will continue to optimize these cooperative agreements, while at the same time setting up our own marketing systems during the coming years.

This rapid international development justifies the priority given to our R&D: our patented products and new compounds provide the momentum driving our expansion.

**n Certain observers have criticized Sanofi-Synthélabo for its lack of visibility in the medium term. How strong is the R&D pipeline?**

With 52 compounds in development in our research portfolio, including 23 in an advanced phase and 9 new compounds entering development in 2002, we possess quite a remarkable pipeline, particularly for a company of our size. Of course, not all these products will reach the market, but if we simply apply the statistics of the pharmaceutical industry, we have a very good chance of being able to submit new filings for innovative medicines in the medium term.

Our R&D is our strength, and our earnings enable us to pursue our efforts. In 2002, our R&D expenditure once again increased by almost 20% at comparable exchange rates. Relative to our size, our R&D portfolio is one of the most fertile in the pharmaceutical industry. All our major compounds, Plavix®, Aprovel®, Arixtra®, Eloxatin®, Xatral® and Ambien®, benefit from an intense Life Cycle Management program designed to extend their clinical indications and boost sales. We also ensure the development of a backup compound as a potential successor for each major product.

These efforts have paid off. In 2002, we experienced an exceptional year with six new marketing approvals in the U.S., representing a remarkable performance in an environment where as all pharmaceutical companies agree it is more and more difficult to obtain marketing approval for new products.

**OUR R&D portfolio  
is one of the  
MOST FERTILE**

**n How do you view the current environment of the pharmaceutical industry, the rise of generics and, in particular, the generic challenges to Plavix®?**

In 2002, the pharmaceutical industry was affected by an uncertain economic environment worldwide. It also suffered, for the first time in its history, from the impact of loss of patent protection for medicines with sales amounting to several billion dollars, and the

increasing number of attacks on the patents of medicines marketed

4

Chairman s message

in the U.S. In addition, the efforts of various countries to curb their healthcare expenditure show no sign of diminishing and this policy naturally favors generics.

As regards Plavix<sup>®</sup>, which has been challenged by two generic manufacturers, legal action is still continuing. We have full confidence in the strength of Plavix<sup>®</sup> patents.

With respect to generics, it is clear that we cannot hope for profitable prices for new innovative products without the development of low-cost generics for products which are no longer protected by patents. Our portfolio of new products certainly shows that we are less affected by this situation than some of our competitors.

**n What are your prospects for 2003?**

Barring major adverse events, our prospects remain excellent for 2003. We expect to see continued double-digit growth of the same order of magnitude as that registered in 2002 and, assuming one-to-one parity between the euro and the dollar, a growth in consolidated earnings close to 20% per share before exceptional items and goodwill amortization.

In the longer term, all the conditions for our continued growth are met and our strategic products will sustain their progression.

**The INDUSTRY  
will continue to experience  
STRONG GROWTH  
in the LONG TERM**

The pharmaceutical industry will remain a sector where innovation takes precedence over all other factors. The industry will continue to experience strong growth in the long term, in view of the currently unmet therapeutic needs, the progressive aging of the world's population, the increasing demand in industrial countries and the necessity to find ways of facilitating access to medicines in the countries of the southern hemisphere. These are the challenges that the worldwide pharmaceutical industry must face. As far as we are concerned, at this start of 2003, the year in which we celebrate our 30th anniversary, all the Group's employees are ready and determined to meet them.

**Jean-François Dehecq**

**Chairman and Chief Executive Officer**





## SANOFI-SYNTHELABO IN 2002

### KEY FIGURES

**2002 Consolidated sales: 7,448 million euros**

+12.8% on a comparable basis<sup>(1)</sup> and +14.8% on a reported basis

**2002 Developed sales: 9,585 million euros**

+14.5% on a comparable basis<sup>(1)</sup>

### Our business activity

**Consolidated sales<sup>(2)</sup>**

*(in millions of euros)*

**Developed sales\*<sup>(2)</sup>**

*(in millions of euros)*

**Consolidated sales<sup>(2)</sup> of the three flagship products**

*(in millions of euros)*



**Developed sales<sup>\*(2)</sup> of the three flagship products**

*(in millions of euros)*

**Consolidated sales<sup>(1)</sup> by geographic area**

**Developed sales<sup>\*(1)</sup> by geographic area**

**Consolidated sales by therapeutic area**

*(in millions of euros)*

Another year of strong growth for Sanofi-Synthélabo, with sales up throughout the world, continued growth of major strategic products and net earnings which have almost tripled in three years.

## Our earnings

### Operating profit

*(in millions of euros)*

### Operating profit by geographic area

*(excluding non-allocated costs: 1,322 million euros)*

### Net profit attributable to the Group before exceptional items and goodwill amortization

*(in millions of euros)*

## Our resources

### Research & Development expenditure

*(in millions of euros)*

### Global workforce: 32,436 people by geographic area

at December 31, 2002

**Employees by activity**

at December 31, 2002

---

\* Developed sales include sales consolidated by Sanofi-Synthélabo, plus sales generated under the agreements with Bristol-Myers Squibb on Plavix<sup>®</sup>/Iscover<sup>®</sup> (clopidogrel) and Aprove<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup> (irbesartan), with Fujisawa on Myslee<sup>®</sup> (zolpidem), with Pharmacia on Ambien<sup>®</sup> (zolpidem) for 2000 and 2001 figures, with Organon on Arixtra<sup>®</sup> (fondaparinux sodium), as they have been communicated to us by our partners.

(1) Change on a comparable basis, at constant group structure and exchange rates

(2) On a reported basis

## SANOFI-SYNTHELABO

### STOCK EXCHANGE INFORMATION

**Providing a return on investment to shareholders through strong and steady growth in profits and in the dividend, and raising the share profile in the world's great financial markets: in 2002 Sanofi-Synthélabo achieved these two essential strategic objectives.**

#### Highlights of 2002

- **2002 unfolded in a difficult stock market climate**, marked by geopolitical uncertainties and a strong downtrend across all equity markets. At the start of the year, Sanofi-Synthélabo shares were affected by the announcement of the U.S. filing of two abbreviated new drug applications (aNDA) for generic versions of Plavix®.
- **Sanofi-Synthélabo made its entrance on the New York Stock Exchange (NYSE) on July 1, 2002.**

Dictated by the growth of the Group in the United States, where 45% of its operating profit is now generated, this decision raises the Group's financial profile in America to the height of its commercial reputation. It facilitates access to the share for many more investors in the world's leading financial market.

Sanofi-Synthélabo shares are listed on the NYSE in the form of American Depositary Receipts (ADRs), each representing half a share. Because no new shares were issued at the time of the listing, the listing had no impact on earnings per share.

## Trends in the share price

### Sanofi-Synthélabo in Paris on the Euronext Premier Marché

Base 100 at December 30, 1999

### Sanofi-Synthélabo on the New York Stock Exchange

Base 100 at June 28, 2002

Sanofi-Synthélabo shares are included in the main benchmark indices:

- <sup>1</sup> The **CAC 40** French pan-sector index
- <sup>1</sup> The **Dow Jones Euro Stoxx 50** European pan-sector index
- <sup>1</sup> The **Dow Jones Stoxx Pharma** European sector index
- <sup>1</sup> The **NYSE International 100** American pan-sector index
- <sup>1</sup> The **NYSE World Leaders** American pan-sector index

## Share particulars

Par value of the share: **2 euros**

Trading: continuous, eligible for the SRD deferred settlement service in Paris and for PEA share savings schemes

Euroclear France code: **12057**

ISIN code: [FR0000120578](#)

NYSE listing code: [SNY](#)

Euronext Paris listing code: [SAN](#)

Reuters code: [SASY.PA](#)

Bloomberg code: [SNYNF](#)

---

## SANOFI-SYNTHELABO

### STOCK EXCHANGE INFORMATION

#### Share ownership

**As of December 31, 2002**, the share capital of Sanofi-Synthélabo amounted to 1,464,735,014 euros, divided into 732,367,507 shares with a par value of 2 euros.

**As of December 31, 2002**, Sanofi-Synthélabo held 30.4 million of its own shares, representing 4.15% of the capital, of which 16.4 million shares (2.24% of the capital) were acquired in the light of market conditions in accordance with the authorization granted by the Annual General Meeting and the Board of Directors on May 22, 2002, and 14 million shares (1.91% of the capital) intended for stock option purchase plans. As of February 28, 2003, the total number of shares held by the company rose to 38.6 million shares (5.26% of the capital). (see Financial Report, page 106)

#### Ownership of Sanofi-Synthélabo shares as of December 31, 2002

##### Shares

##### Voting rights\*

---

\* Based on the total number of voting rights published following the Annual General Meeting of May 22, 2002, i.e. 1,064,540,103

\*\* Shares held through Sanofi-Synthélabo's company share savings plan mutual fund.

TotalFinaElf and L'Oréal have entered into a shareholders' agreement for an initial term of six years commencing December 2, 1998 (see Financial Report, page 105)

#### Shareholder information at a glance

Sanofi-Synthélabo provides a return for shareholders through the steady growth in its consolidated net income, coupled with a payout ratio of about 35%.

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>
<b>Number of shares as of December 31</b>	731,143,218	731,441,746	732,005,084	<b>732,367,507</b>
Share price (in euros)				
High	46.35*	71.00	86.50	<b>84.30</b>
Low	34.72*	34.70	52.60	<b>49.78</b>
Last	41.34	71.00	83.80	<b>58.25</b>
<b>Market capitalization as of December 31</b>				
(in millions of euros)	30,225	51,932	61,342	<b>42,660</b>
Ranking in CAC 40 by market capitalization	15	8	4	<b>3</b>

\* From May 25, 1999



**Consolidated earnings<sup>(1)</sup> per share (in euros)**

**Net income payout ratio<sup>(1)</sup> (%)**

**Net dividend per share<sup>(6)</sup> (in euros)**

**Total rate of return<sup>(7)</sup>**

---

(1) Before exceptional items and goodwill amortization

(2) Pro-forma data

(3) To be proposed at the Annual General Meeting on May 19, 2003

(4) In accordance with ordinary law, coupons detached from the company's shares become time-barred five years from the date they fall due for payment. Dividends invalidated by the five-year rule are forfeited to the State.

(5) In the case of individual shareholders, 50% of the net dividend. For corporate shareholders, the tax credit rate has been progressively reduced in the last three years. It was 40% in 1999, 25% in 2000, 15% in 2001, and 10% in 2002.

(6) Means the sum of the net dividend and the tax credit in the case of individual shareholders.

(7) Based on a tax credit of 50% and on the most recent share price (Euronext Paris).

**Outlook for 2003**

Barring major adverse events and assuming an exchange rate of 1 euro to the dollar, Sanofi-Synthelabo's 2003 sales figures point to continuing strong growth in earnings per share of around 20% (before exceptional items and goodwill amortization).

**The factors supporting this growth will be:**

n growth in consolidated net sales comparable with the 2002 figure;

n anticipated good performance of the three flagship products: Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Stilnox<sup>®</sup>;

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

n development of Eloxatin® sales in the U.S. after launch in August 2002

n continued good performance of the rest of the portfolio, in particular Depakine®, Solian® and Xatral®.

Research and Development efforts will continue at a high level, notably through the Phase III clinical trials on rimonabant, dronedarone, idraparinux and zolpidem MR. The strong R&D portfolio, along with sound positions for all products, give the Group confidence in its ability to develop its business activities and its earnings.

Information on the company's prospects is based on estimates regarded as realistic by the company as of the date of publication. Fulfillment of such estimates is subject to the risks and uncertainties of the markets, and may be considerably affected by a number of factors, including the success of research and development programs, the company's ability to defend its intellectual property rights, the intensity of competition, governmental constraints or the occurrence of litigation. Investors and holders of securities issued by the company may obtain free copies of documents filed by Sanofi-Synthélabo with the Commission des Opérations de Bourse in France at [www.cob.fr](http://www.cob.fr) and with the Securities and Exchange Commission in the U.S. at [www.sec.gov](http://www.sec.gov), or directly from Sanofi-Synthélabo at [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com).

## SHAREHOLDER INFORMATION

Sanofi-Synthélabo believes in the need for transparent communication, and regularly provides comprehensive and easily-accessible information to individual and institutional shareholders, analysts and journalists. Corporate Communications, based in Paris, has a network of communication managers in more than 40 countries. The Investor Relations department, based in Paris and now with a branch in New York, doubled its staff in 2002.

On the corporate website, you can e-mail directly to the Investor Relations Department and order all the Group's financial publications.

### Group publications

Sanofi-Synthélabo has the following documents available on request. They are also posted on its website:

- n All press releases,
- n The Annual Report, given out to shareholders attending the Annual General Meeting, which has reference document status with the COB (Commission des Opérations de Bourse) for 2002, and the interim report,
- n The U.S. Form 20-F, filed with the SEC (Securities and Exchange Commission),
- n Presentations to financial analysts, institutional investors and journalists on publication of earnings,
- n The Letter to Shareholders, sent to all registered shareholders at least every six months,
- n The Shareholder's Guide, available from mid-2003,
- n The financial calendar.

### Our website

[www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com)

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

Set up in 1999, the Sanofi-Synthélabo website at [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com) contains all the information required to find out about and monitor the activities of the Group: a description of the main research areas, progress reports on clinical trials, sales trends, etc.

Go to the [Finance](#) section to consult the full range of financial and stock market data needed by investors (share prices, capital, reports, etc). Items are regularly updated. The Group's various publications are available on-line, as are audio webcasts concerning financial information. From the [Finance](#) section it is also possible to:

- n [communicate directly with the Investor Relations department by e-mail](#),

- n [order the Group's financial publications](#).

## Contacting the Group

If you are	individual shareholders	institutional investors or analysts	journalists
By telephone	toll-free: +33 800 07 58 76	Paris: +33 1 53 77 45 45 New York: +1 212 551 42 93	Paris: +33 1 53 77 40 76
By fax	+33 1 53 77 42 96	Paris: +33 1 53 77 42 96 New York: +1 212 551 49 10	Paris: +33 1 53 77 41 74
By mail	Sanofi-Synthélabo  <b>Investor Relations</b>  <b>Department</b>  174 Avenue de France  75013 Paris	Sanofi-Synthélabo  <b>Investor Relations</b>  <b>Department</b>  174 Avenue de France  75013 Paris <hr/> 90 Park Avenue  New York, NY 10016	Sanofi-Synthélabo  <b>Media Relations</b>  <b>Department</b>  174 Avenue de France  75013 Paris
By e-mail	relations-actionnaires@sanofi-synthelabo.com	investor-relations@sanofi-synthelabo.com	media-relations@sanofi-synthelabo.com

### Finding out more about the Group

For individual shareholders, the Annual General Meeting is an opportunity to find out about the Group's strategy. Once a year, before the Annual General Meeting, Sanofi-Synthélabo sends shareholders a questionnaire so that they can give their opinions on issues that are of concern to them and suggest subjects for inclusion on the agenda of the Annual General Meeting. This regular procedure enables shareholders to play an active role in the life of the Company if they wish to.

Information meetings for institutional investors, financial analysts and journalists take place twice a year in Paris and London when full-year and interim results are published.

Sanofi-Synthélabo meets institutional investors throughout the year by organizing road shows, notably in the United States and Europe.

### Financial calendar for 2003:

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Wednesday, January 22	è	Press release: 2002 sales
Tuesday, February 18	è	Press release: 2002 earnings
Thursday, April 24	è	Press release: 2003 first-quarter sales
Monday, May 19	è	Annual General Meeting
Wednesday, July 23	è	Press release: 2003 first-half sales
Tuesday, September 2	è	Press release: 2003 first-half earnings
Wednesday, October 22	è	Press release: 2003 9-month sales

## CORPORATE GOVERNANCE

Since the merger in May 1999, the Board of Directors of Sanofi-Synthélabo has set up three specialist committees entrusted with advising and assisting the Board in its decisions. It has adopted a charter defining the rights and duties of Board members, along with committee composition and functioning.

### Key events in 2002

- n In accordance with the law of May 15, 2001 on the new economic regulations, the statutes of the company were modified at the Annual General Meeting on May 22, 2002, so that the Board of Directors could decide whether or not the functions of Chairman of the Board and Chief Executive Officer should be separated.

At its meeting on May 22, 2002, the Board of Directors decided that these two functions should not be separated and Jean-François Dehecq was appointed Chairman and Chief Executive Officer.

- n As proposed by the Chairman and Chief Executive Officer, the Board of Directors appointed Gérard Le Fur Senior Executive Vice President at its meeting on December 11, 2002.

### The Board of Directors

As of December 31, 2002, the Board of Directors is composed of 12 members:

- n the Chairman and Chief Executive Officer,
- n four directors proposed by TotalFinaElf and four directors proposed by L. Oréal (reference shareholders),
- n three independent directors.

The appointment of a new independent director, Mr Gérard Van Kemmel, President for Europe, Middle East and Africa at Novell will be submitted for ratification at the Annual General Meeting of shareholders on May 19, 2003.

Directors are appointed for a period of five years. Appointments are renewed by rotation. The number of directors over 70 years old cannot exceed a third of the directors in office.

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

According to the bylaws, each director must be the legal owner, in his/her own right, of at least one share throughout his/her term of office. As of December 31, 2002, individual Board members held a total of 273,756 shares.

16

Sanofi-Synthélabo and its shareholders



**Board of Directors:**

**Directors:**

n **René Barbier de la Serre**, aged 62

Director<sup>1</sup> from May 1999 to 2004

**Director** of Crédit Lyonnais and Schneider Electric

**Member of the Supervisory Board** of Compagnie Financière Saint Honoré and Pinault-Printemps-Redoute

n **Robert Castaigne**, aged 56

Director from February 2000 to 2004

**Chief Financial Officer**, TotalFinaElf SA

**Chairman and Chief Executive Officer**, Total Chimie and Total Nucléaire

**Director** of Atofina, Compagnie Générale de Géophysique and Elf Aquitaine

n **Pierre Castres Saint Martin**, aged 67

Director from May 1999 to 2004

**Chairman of the Supervisory Board** of Groupe Marc de Lacharrière

**Director** of Fimalac and SEB

n **Jean-François Dehecq**, aged 63

*Director from May 1999 to 2004*

**Chairman and Chief Executive Officer**, Sanofi-Synthélabo

**Director** of Air France and Péciney

n **Thierry Desmarest**, aged 57

*Director from February 2000 to 2004*

**Chairman and Chief Executive Officer**,

TotalFinaElf SA and Elf Aquitaine

**Member of the Supervisory Board** of AREVA and L Air Liquide

n **Lord Douro**, aged 57

*Director<sup>1</sup> from May 2002 to 2007*

**Chairman**, Richemont Holdings UK (United Kingdom)

**Chairman**, Framlington Group (United Kingdom)

n **Elf Aquitaine**

*Director from May 1999 to 2004*

Represented by **Jean-Paul Léon**, aged 65

<sup>n</sup> **Pierre-Gilles de Gennes**, aged 70

Nobel Prize for Physics (1991)

*Director<sup>1</sup> from May 1999 to 2004*

**Director** of the Ecole Supérieure de Physique et de Chimie Industrielles de Paris

**Director** of Rhodia

<sup>n</sup> **Hervé Guérin**, aged 61

*Director from May 1999 to 2004*

**Chairman of the Supervisory Board** of Human Health Investments (H2i)

<sup>n</sup> **L Oréal**

*Director from May 1999 to 2004*

Represented by **Michel Somnolet**, aged 63

**Vice-President**, General Management, Administration and Finance, L Oréal

**Director** of L Oréal

<sup>n</sup> **Lindsay Owen-Jones**, aged 57

*Director from May 1999 to 2004*

**Chairman and Chief Executive Officer**, L Oréal

**Director** of BNP Paribas and Gesparal

**Vice President and member of the Supervisory Board** of L Air Liquide

n **Bruno Weymuller**, aged 54

*Director from May 1999 to 2004*

**Executive Vice President**, Strategy and Risk Assessment, Total Fina Elf SA

**Director** of Elf Aquitaine

**Observers:**

participating in the meetings of the Board with a consultative role

n **Régis Dufour**

n **René Sautier**

*All the appointments and functions of the members of the Board of Directors and of the Senior Executive Vice President in companies in France and elsewhere, during the financial year 2002, are detailed in the Management Report.*

---

Independent director

## Corporate Governance

### Activity of the Board of Directors in 2002

In 2002, the Board of Directors met four times, with an overall attendance rate of directors above 80%.

#### The meeting agendas principally focused on the following points:

##### n **February 18, 2002:**

- review of consolidated and parent company financial statements,
- allocation of profits,
- management report,
- notice to the Annual General Meeting,
- planned 100% incorporation of affiliates,
- planned listing on the New York Stock Exchange (NYSE).

##### n **May 22, 2002:**

- Management organization,
- appointment of Lord Douro (independent director) to the audit committee,
- delegations to the Chairman and Chief Executive Officer,
- stock option plan,
- decision to apply for listing of the Company on the NYSE.

**n August 30, 2002:**

- review of financial statements for the first half of 2002,
- review of progress in Research and Development programs,

**n December 11, 2002:**

- appointment of a Senior Executive Vice President,
- forecast for the financial year 2002,
- review of the budget for 2003,
- compensation of corporate officers,
- pensions plan.

### **Compensation of directors**

The compensation paid to Board members in 2002 consisted exclusively of attendance fees <sup>(1)</sup>: the attendance fees paid to each Board member in 2002, which were allocated to them in the financial year 2001, amounted to 365,500 euros. The attendance fees paid to each Board member in 2002 are detailed in the Management Report. (Financial Report 2002, page 14)

Attendance fees allocated to Board members for the financial year 2002 amounted to 456,250 euros.

### **Specialist committees**

Since 1999, the Board of Sanofi-Synthelabo has set up specialist committees entrusted with assisting the Board in its deliberations and decisions. Their members are chosen from among the directors and appointed by the Board.

### **Audit committee**

**The audit committee currently comprises:**

n René Barbier de la Serre

n Lord Douro

n Michel Somnolet

n Bruno Weymuller

**The audit committee, entrusted with continuously evaluating the application and efficacy of the company's financial control and risk assessment procedures, is specifically responsible for examining:**

- annual financial statements and interim financial statements for the first half of the year,
- control procedures,
- the appropriateness of accounting policies,
- internal audit programs and actions,
- the annual report of major litigations,
- any issue likely to have a material financial or accounting impact,
- proposed appointments of statutory auditors.

The committee can undertake any visits and interviews relevant to the accomplishment of its assignments. It may ask to interview those involved in the preparation and control of financial statements, in particular the statutory auditors.

The audit committee met five times during 2002.

**The meeting agendas principally focused on the following points:**

n **February 18, 2002:**

- review of consolidated and parent company financial statements,

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

- proposed dividend,
- planned listing on the New York Stock Exchange

n **March 11-12, 2002:**

- presentation of the note of reconciliation of the financial statements with US GAAP in preparation for listing on the New York Stock Exchange,
- first draft of the Form 20F required by the Securities and Exchange Commission.

(1) 

---

 apart from the compensation of the Chairman and Chief Executive Officer detailed below, page 21.



**n May 16-17, 2002:**

- presentation of the final version of the Form 20F,
- timetable for listing operations

**n August 29, 2002:**

- review of interim financial statements for the first half of 2002,
- update on exchange risk management and examination of off balance sheet commitments.

**n December 5, 2002:**

- organization and functioning of internal audit,
- presentation of the procedure for preparing the Group's financial statements for 2002,
- statutory auditors' fees and duties.

**Compensation and appointments committee**

**As of December 31, 2002, this committee comprises:**

**n René Barbier de la Serre**

**n Thierry Desmarest**

**n Lindsay Owen-Jones**

**The role of the compensation and appointments committee is to:**

- formulate recommendations and proposals concerning the compensation of corporate officers and the granting of options to purchase or to subscribe for shares,

- examine the allocation of attendance fees between the directors and, where appropriate, observers,
- assist the Board in selecting new directors,
- advise the Chairman on the selection of key senior executives and their compensation.

The compensation and appointments committee met three times during 2002.

**The meeting agendas principally focused on the following points:**

**n February 18, 2002:**

- establishment of attendance fees,
- special report on stock options.

**n May 22, 2002:**

- proposed stock option plan and granting of stock options.

**n December 11, 2002 :**

- the issues of independent directors, appointment of a Senior Executive Vice President and company organization,
- compensation of the Chief Executive Officer, the Senior Executive Vice President and the principal senior executives,
- pensions plan.

**Scientific committee**

**As of December 31, 2002, the Scientific committee comprises:**

- n Pierre-Gilles de Gennes

n Jean-François Dehecq.

**The role of the Scientific committee is to:**

- inform the Board of technological advances likely to have an impact on the Company's activities,
- provide advice on Research and Development orientations,
- contribute to solving any technical problem confronting the Company.

The Scientific committee met on October 28, 2002 and reviewed all the Group's Research and Development programs.

---

Independent director

**Directors Code**

Sanofi-Synthelabo has drawn up a code for directors specifying the rights and duties of the members of the Board and its committees.

- n The Board requires that, over and above the obligations contained in the bylaws, each director must hold at least five hundred Company shares.
- n When a director attends and votes at Board meetings, he/she represents all the shareholders and must act in the Company's corporate interests.
- n Each Director must make every effort to attend meetings of the Board and of any committees of which he/she is a member. He/she must devote the necessary time to examining the matters submitted to him/her.
- n Each Director must inform the Board of any conflict of interest, even potential, and may not become involved personally in undertakings competing with Sanofi-Synthelabo without first informing the Board and obtaining its authorization.
- n Each Director must abstain from trading in the Company's shares if he/she possesses insider information.

Considering the listing of Sanofi-Synthelabo on both the Paris and New York stock exchanges, the charter governing the Board and its committees is being revised to take into account changes in corporate governance regulations in France and in the U.S. (Bouton report, Sarbanes Oxley Act).



## Compensation of Executive Committee members and attribution of stock options

The compensation of the Chairman and Chief Executive Officer, the Senior Executive Vice President, and the other members of the Executive Committee is set after taking into consideration the practices of the leading French and European industrial companies and the opinion of the compensation and appointments committee.

In addition to base compensation, Executive Committee members receive variable compensation, which is determined by the actual performance and growth of the business areas for which the manager concerned has responsibility. This variable compensation may reach over half the base compensation. Stock options may be granted in addition to compensation. The total compensation paid to the twelve members of the Sanofi-Synthelabo Executive Committee during the financial year 2002 was 7.5 million euros, including 1.9 million euros for the Chairman and Chief Executive Officer (base compensation: 0.9 million, variable compensation: 1 million) and 1.3 million euros for the Senior Executive Vice President (base compensation: 0.64 million, variable compensation: 0.68 million).

On May 22, 2002, the Board of Directors of Sanofi-Synthelabo granted 3,111,850 share purchase options to 1,162 beneficiaries at a price of 69.94 euros per share. These beneficiaries included the twelve members of the Executive Committee of Sanofi-Synthelabo who received a total of 423,000 options of which 145,000 were granted to the Chairman and Chief Executive Officer and 70,000 to the Senior Executive Vice President. Each option entitles the holder to purchase one share. These options can be exercised on or after May 23, 2006.

As of December 31, 2002, the members of the Executive Committee held 1,848,000 options to purchase or to subscribe for shares, of which 530,000 were held by the Chairman and Chief Executive Officer and 287,000 by the Senior Executive Vice President (see summary table below).

Additional information concerning the option plans to purchase or to subscribe for shares, in accordance with the Commission des Opérations de Bourse regulations, is provided in the 2002 Financial Report, under financial, administrative and legal additional information administration and management bodies stock options page 109.

### Current options to purchase or to subscribe for shares\*

#### Options granted

Date of plan(s)	1993	1994	1995 <sup>(1)</sup>	1996 <sup>(1)</sup>	1997	1998	1999	2000	2001	2002	TOTAL
<b>Total number of options granted</b>	364,000	379,600	1,498,000	1,492,800	1,382,080	1,496,400	716,040	4,292,000	2,936,500	3,111,850	17,669,270
- Executive Committee	0		268,560	158,000	236,000	247,200	36,400	472,000	431,000	423,000	2,272,160
- of which J.-F. Dehecq			44,000	44,000	60,000	80,000		160,000	145,000	145,000	678,000
- of which G. Le Fur			26,400	26,400	32,000	40,000		75,000	70,000	70,000	339,800

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Expiry date	10/2014	09/2002	09/2003	09/2004	12/2005						
Purchase/subscription price (in )	12/2013 to 12/2014	to 12/2015	to 04/2016	to 10/2017	to 06/2018	03/2019	05/2010	05/2011	05/2012		
	6.36	5.86 to 6.1	to 10.26	to 14.56	to 21.46	to 34.95	38.08	43.25	64.5	69.94	

Options exercised in 2002

Date of plan(s)	1993	1994	1995 <sup>(1)</sup>	1996 <sup>(1)</sup>	1997	1998	1999	2000	2001	2002	TOTAL
<b>Number of options exercised in 2002</b>	3,000	45,000	399,316	180,802	205,380	13,520	NA	NA	NA	NA	847,018
- Executive Committee	0	0	31,500	24,400	60,000	0	NA	NA	NA	NA	115,900
- of which J.-F. Dehecq			0	0	60,000	0	NA	NA	NA	NA	60,000
- of which G. Le Fur								NA	NA	NA	0
<b>Number of options outstanding</b>	10,400	25,000	63,600	704,055	1,133,100	1,468,880	710,320	4,225,600	2,907,900	3,102,650	14,351,505 <sup>(2)</sup>
- Executive Committee	0	0	22,000	46,400	170,000	247,200	36,400	472,000	431,000	423,000	1,848,000
- of which J.-F. Dehecq			0	0	0	80,000		160,000	145,000	145,000	530,000
- of which G. Le Fur					32,000	40,000		75,000	70,000	70,000	287,000

(1) In 1995 and 1996, there were option plans both to purchase shares and to subscribe for shares.

(2) Including 514,925 subscription options and 13,836,580 purchase options.

\* Plans for which options were exercised during 2002, including those closed during the year







---

## RESEARCH & DEVELOPMENT

### sustained momentum

The discovery of innovative medicines has been the source of the Group's expansion during the past 30 years, backed by more than 6,700 Sanofi-Synthelabo R&D staff and a budget of over 1 billion euros. Cardiovascular Disease/Thrombosis, disorders of the Central Nervous System, Oncology and Internal Medicine: the Group's areas of expertise represent major public health challenges. The Group's R&D efforts also encompass certain rare but severe diseases.

### Key events in 2002

4 products in the field of Oncology registered in the United States

2 major extensions of indications in the U.S. and in Europe for two flagship products, Plavix® and Aprovel®

9 new compounds in clinical development

*52 products in development,  
including 23 at an advanced stage*

In 2002, Sanofi-Synthelabo saw a significant increase in the number of new clinical trials intended to support marketing approval submissions for its compounds at an advanced stage of development (Phase III), and to obtain extensions in the indications of its marketed products

Research and Development portfolio in 2002

As of January 31, 2003

25

Research & Development

## RESEARCH & DEVELOPMENT

### sustained momentum

#### New submissions and marketing approvals in 2002

In 2002, Sanofi-Synthélabo's Research and Development efforts in its four areas of expertise culminated in the filing of four new marketing approval submissions in the United States, Europe and Japan, the granting of four marketing approvals in the U.S. and one in Europe, and two major extensions of indication in the U.S. and Europe.

#### CARDIOVASCULAR / THROMBOSIS

##### Arixtra®

*fondaparinux sodium*

Following the United States in December 2001 and Europe in March 2002, over 30 countries, including Australia, Canada, Brazil, South Korea and Switzerland have authorized the marketing of Arixtra® for the prevention of deep-vein thrombosis and pulmonary embolism following major orthopedic surgery.

An application for extension of the indication to prolonged prophylaxis of deep-vein thrombosis and pulmonary embolism after hip fracture was filed in December 2002 in the U.S. and Europe.

##### Plavix®

*clopidogrel*

An extension of the indication to include acute coronary syndrome was granted in the U.S. in February and in Europe in June.

##### Aprovel®

*irbesartan*

An extension of the indication to nephropathy induced by type 2 diabetes was granted in Europe in June and in the U.S. in September.

A marketing approval application for the treatment of hypertension was filed in Japan in October.

Cardiovascular/Thrombosis department: angiogenesis program.

## **CENTRAL NERVOUS SYSTEM**

**Depakine chrono<sup>®</sup>**

*sodium valproate*

A marketing approval application was filed in Europe for the treatment of bipolar disorders.

**Depakine chronospheres<sup>®</sup>**

*sodium valproate*

Marketing approval for the treatment of epilepsy was obtained in France, Portugal and Finland.

## **INTERNAL MEDICINE**

**Xatral<sup>®</sup> O.D.**

*alfuzosin*

Following the approvable letter received at the end of 2001, the results of additional studies requested by the Food and Drug Administration (FDA) to obtain the indication of symptomatic treatment of benign prostatic hyperplasia were submitted in December 2002.

26

Research & Development

## ONCOLOGY

### Fasturtec®/Elitek®

*rasburicase*

Marketing approval for the treatment of hyperuricemia related to chemotherapy in children was granted by the FDA in July.

After receiving marketing approval in Europe in 2001, Fasturtec® was granted marketing approval in 16 other countries, including Australia, New Zealand and Switzerland, in 2002.

### Eloxatin®

*oxaliplatin*

Marketing approval for the second-line treatment of colorectal cancer was granted in the U.S. in August 2002, 46 days after the application was filed.

Submission of a marketing approval application for the first-line treatment of metastatic colorectal cancer is planned in 2003. Eloxatin® is under license from Debiopharm.

### Eligard®

*leuprolide acetate*

Marketing approval for the treatment of prostate cancer was granted by the FDA in January for the one-month formulation and in July for the three-month formulation. Eligard® is under license from Atrix.

27

Research & Development

## RESEARCH & DEVELOPMENT

### sustained momentum

#### Four major therapeutic areas

#### CARDIOVASCULAR / THROMBOSIS

##### Idraparinax sodium

*Treatment and secondary prevention of thromboembolic events, and prevention of thromboembolic events associated with atrial fibrillation*

#### Initiation of Phase III studies

Like Arixtra®, idraparinax sodium belongs to the synthetic oligosaccharide family. Idraparinax sodium is an injectable synthetic pentasaccharide, selectively inhibiting coagulation factor Xa. Its potency and long duration of action permit a therapeutic regimen comprising only one injection per week in humans.

The Phase IIb study PERSIST, comparing idraparinax with anti-vitamin K in the treatment of venous thrombosis was completed in 2002 and results were published in September. These permitted selection of a dose of 2.5 mg and justified the initiation of two Phase III trials:

- in the treatment and secondary prevention of venous thromboembolic events in patients suffering from deep-vein thrombosis or pulmonary embolism (the VAN GOGH program);
- in the prevention of thromboembolic events associated with atrial fibrillation (the AMADEUS program).

These programs will start in early 2003 and will include over 10,000 patients.

##### Dronedarone



*Atrial fibrillation*

**Continuation of Phase III studies**

The prevention of cardiac arrhythmia is one of Sanofi-Synthélabo's areas of excellence, with Cordaron® (amiodarone) remaining the reference treatment to this day. With dronedarone, a potential successor to Cordaron® the Group's objective is to propose a new treatment presenting at least equivalent efficacy with improved tolerability.

The first indication developed for dronedarone is the prevention of recurrence of the most common cardiac rhythm disorder: atrial fibrillation. The usual treatment for acute atrial fibrillation is an external electric shock to the heart. To avoid recurrences, which are extremely common, this is generally followed by medicinal anti-arrhythmic treatment.

Phase III studies for this highly promising compound were initiated in 2002. The program comprises:

- two efficacy studies on the prevention of recurrences in patients who have already experienced atrial fibrillation: EURIDIS (Europe) and ADONIS (North and South America, Australia, South Africa).
- a tolerability study in high-risk patients suffering from heart failure and impaired ventricular function: ANDROMEDA.

The ANDROMEDA study was stopped in January 2003 after the enrollment of 627 patients out of the 1,000 planned. This was decided on the advice of the committee monitoring the tolerability data, following an interim tolerability analysis indicating a higher potential risk of death in the group treated with dronedarone. A new protocol will be envisaged after detailed analysis of all the data collected.

This interruption does not mean that development of dronedarone has been stopped. On the favorable recommendation of the steering committees and tolerability data monitoring committees concerned, the efficacy studies EURIDIS and ADONIS are continuing in accordance with the planned protocol. Enrollment totaling 1,245 patients was completed in August 2002.

## CENTRAL NERVOUS SYSTEM

### Xaliproden

#### *Alzheimer s disease*

#### **Completion of Phase IIb**

Alzheimer s disease is a neurodegenerative disorder leading to progressive cognitive deterioration, behavioral problems and functional decline, culminating in dementia. Alzheimer s disease, the prevalence of which increases with age, is the most common cause of dementia in elderly subjects. Worldwide, approximately 22 million patients suffer from various forms of dementia, two-thirds of which correspond to the Alzheimer type. The prevalence of this disease could double within the next 25 years. Alzheimer s disease is a major public health problem.

Current treatments are purely symptomatic.

Due to its neurotrophic and neuroprotective properties, xaliproden could be the first treatment capable of slowing the progression of the disease. This non-peptide compound activates the synthesis of endogenous neurotrophins. Its efficacy has been demonstrated *in vitro* and *in vivo* in numerous models of central or peripheral neurodegeneration, as a curative or prophylactic treatment. It is orally active as a single daily dose.

Phase IIb studies, completed in 2002, confirmed the tolerability of xaliproden in elderly subjects with Alzheimer s disease. A Phase III international development program focused on this disease will be initiated in 2003.

### Xaliproden

#### *Amyotrophic lateral sclerosis*

#### **Marketing approval application withdrawn**

In 2002, Sanofi-Synthélabo decided to withdraw its European marketing approval application for xaliproden in the treatment of amyotrophic lateral sclerosis. This rare neurological disease is caused by degeneration of the motor neurons responsible for muscle function. It results in progressive paralysis, leading to invariably fatal respiratory failure.

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

The marketing approval application, based on two Phase III trials versus placebo, was filed in 2001.

The results of these two pivotal clinical trials evaluating xaliproden at a dose of 1 or 2 mg, either alone or in combination with riluzole, in patients suffering from amyotrophic lateral sclerosis, showed that the compound was well tolerated, and that it had a beneficial effect on respiratory function and the conditions of survival. However, the interpretation of the positive effect on respiratory function was complicated by the extent of the survival benefit which was smaller than the studies were powered to detect. These results were not considered sufficiently robust to meet the regulatory requirements for marketing approval.

Sanofi-Synthelabo will continue to supply xaliproden to patients suffering from amyotrophic lateral sclerosis currently treated in Europe and elsewhere in the world in the context of ongoing long-term studies, as envisaged in the protocol and in conformity with the procedures defined by the national regulatory authorities.

Aqueous coatings for capsules have replaced organic mixtures.

29

Research & Development

## RESEARCH & DEVELOPMENT

### sustained momentum

#### Osanetant

*Schizophrenia*

#### Continuation of Phase IIb

Sanofi-Synthelabo designed an original study protocol, known as a Metatrial, to evaluate the therapeutic activity of four compounds possessing novel mechanisms of action in patients with schizophrenia. Osanetant, an NK<sub>3</sub> receptor antagonist, showed an activity and an efficacy profile close to those of haloperidol, combined with very good tolerability. Clinical investigation was continued in 2002.

In contrast, the Phase IIb study evaluating the potential of osanetant in severe depression proved non-conclusive. After six weeks of treatment, no significant difference was observed between the active treatments tested, including paroxetine, and placebo.

#### SR58611

*Depression*

#### Phase IIb

SR58611 is a beta<sub>3</sub> adrenergic receptor agonist. These substances stimulate neuronal activity in a specific region of the prefrontal cortex and could give rise to a new class of antidepressants.

In a Phase IIa trial in patients suffering from severe, recurrent depression, SR58611 was observed to be superior to fluoxetine and was very well tolerated. In a Phase IIb study comparing SR58611 to paroxetine, the efficacy of SR58611 and its tolerability profile were sufficiently encouraging to warrant the initiation of a Phase III program in depression. Two trials designed to support a marketing approval application for SR58611 in the treatment of depression will start in 2003.

**Rimonabant**

*Smoking cessation*

**Continuation of Phase III**

Rimonabant, a CB1 endocannabinoid receptor antagonist, is in development for the treatment of obesity (see Internal Medicine). In 2002, the results of a 10-week Phase IIa trial in smoking cessation showed that rimonabant resulted in smoking cessation rates superior to those achieved with placebo. Patients receiving rimonabant also lost weight, an appreciable advantage, in contrast to placebo-treated patients ceasing to smoke, who gained weight.

In view of these results, and after agreement of the FDA, a large-scale Phase III program including almost 6,000 patients was initiated in 2002 in Europe and the United States, with the aim of obtaining a marketing approval for rimonabant as a smoking cessation aid and for long-term maintenance of abstinence from smoking.

Central Nervous System department: research into eating disorders.

## INTERNAL MEDICINE

### Rimonabant

#### *Obesity*

#### **Continuation of Phase III**

Obesity is defined by elevation of the body mass index (BMI), calculated by comparing the weight and the height of patients (in kilograms/m<sup>2</sup>). Obesity is currently recognized to be a major risk factor, particularly for cardiovascular diseases and diabetes. The prevalence of this disease has reached alarming proportions in the United States and Europe. In the U.S., in 1999-2000, 30% of the adult population were obese (BMI > 30) and more than 60% were overweight (BMI > 25). Recent studies have demonstrated that obesity leads to a significant reduction in life expectancy, the risk appearing as soon as subjects were overweight and worsening with increase in BMI. This disquieting epidemiological situation makes obesity a major public health problem, affecting the young adult population and even, to an increasing extent, adolescents.

The research and development studies conducted by Sanofi-Synthelabo on rimonabant open up completely new and extremely encouraging prospects with regard to elucidation of the mechanisms regulating appetite and metabolism, likely to lead to an effective and safe treatment of obesity with long-term activity.

Rimonabant, the only selective CB1 endocannabinoid receptor antagonist currently in clinical trials in humans, has an original pharmacological profile demonstrated in animals and confirmed in humans by the positive results obtained in Phase IIa and IIb clinical studies. Rimonabant appears to intervene at the heart of central appetite-regulating systems by counteracting endogenous cannabinoids (endocannabinoids), such as anandamide. The crucial aspect of this mode of action is that it induces not only a quantitative regulation of calorie consumption, but also a qualitative regulation of nutrition by specifically diminishing appetite for fatty foods or foods with an excessive sugar content. Weight reduction is significant and the tolerability profile is very good.

Phase III trials on rimonabant in the long-term treatment of obesity, initiated in 2002, have enrolled over 6,000 patients. Two large two-year trials are ongoing in the U.S. and Europe. Patient enrollment is complete. Two other clinical trials, each including close to 1,000 patients, are designed to demonstrate the efficacy of rimonabant in obese patients suffering from diabetes or dyslipidemia, disorders aggravating the cardiovascular risk factors associated with obesity. Patient enrollment for these trials is progressing according to plan.

## ONCOLOGY

### Tirapazamine

*Non-small cell lung cancer, in combination with cisplatin and vinorelbin*

**Continuation of Phase III**

Tirapazamine is an anticancer agent which is not directly cytolytic, but promotes the destruction of resistant hypoxic cells. This innovative mechanism of action is likely to reduce the risk of relapse. Phase III trials on tirapazamine in non-small cell lung cancer will be completed by the end of 2003. Clinical studies in other indications such as head and neck cancers, in particular pharyngolaryngeal cancers, are ongoing.

## RESEARCH & DEVELOPMENT

### sustained momentum

#### R&D organization at Sanofi-Synthélabo

##### *Multiple research approaches*

To identify promising compounds that will be proposed for development, Sanofi-Synthelabo teams employ a wide range of approaches differing in both nature and objectives.

### A project-based organization

The constraints of speed, cost and quality have led to an overall project-based organization within the Development Department, extending throughout compound development from the Preclinical phase to the granting of new indications for medicines already marketed. This organization ensures the consistency and continuity of development, promotes optimal use of resources and shortening of timelines, and permits the transmission of expertise encompassing all activities from research to marketing, which are necessary to obtain marketing approval.

Aqueous film coating of pills helps protect the environment by eliminating volatile organic compounds escaping into the atmosphere.

#### Partnerships

Joint projects with biotechnology companies and other pharmaceutical companies permit Sanofi-Synthélabo Research to gain access to new technologies and methodologies and to expand or strengthen existing areas of research.

### In functional genomics

-



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

The joint project initiated in 1999 with Genfit (Lille, France) was confirmed in 2002. The objective of this project is to study inflammatory phenomena affecting the arterial wall, which could lead to the discovery of new and original biological targets for the treatment of atherosclerosis.

- The joint project with Genoway (Lyon, France) provides access to specific know-how concerning the study of mouse embryonic stem cells which should permit the construction of screening tools by genetic modifications, either in a cellular environment, or in entire organisms. This program forms part of a larger partnership, with the French Ministry of Industry, the Institut National de la Recherche Agronomique (INRA French National Agronomic Research Institute) and the Institut National de Recherche en Informatique et en Automatique (INRIA French National Institute for Research in Computer Science and Control).
- The joint project with Lifespan (Seattle, U.S.) provides access to a data base permitting the localization and validation of the function of 300 receptors coupled with G proteins that have already been identified in the human genome.

### In molecular screening

- The joint project with CEREP (Rueil-Malmaison, France), initiated in 1997, has been extended. This contract envisages the synthesis of chemical libraries expanding the Group's chemical potential and the screening of these libraries on new biological targets of interest. The discovery of novel lead compounds active on the selected targets has permitted the implementation of a program of chemical optimization.

**In the search for new development candidates**

- n The research and development agreement concluded with Mitsubishi-Pharma Corp. (Tokyo, Japan) in 1998, with the aim of identifying new neuroprotective agents for the treatment of neurodegenerative diseases, has been renewed up to the end of 2003.
- n A research and development agreement was concluded in December 2001 with Cephalon (West Chester, United States), providing access to a new compound, CEP 7055, an angiogenesis inhibitor with the potential to become an anti-cancer agent, and also to a research program designed to identify new compounds acting by this mechanism. Sanofi-Synthélabo has accepted to co-promote with Cephalon all compounds successfully developed by Cephalon, in accordance with the agreement in the U.S., Canada and Mexico. Sanofi-Synthélabo has exclusive marketing rights for these medicines in Europe and other countries, except Japan. Sanofi-Synthélabo shares development costs with Cephalon and will pay royalties on sales of developed medicines.
- n The collaboration with Organon (Oss, The Netherlands), in the area of oligosaccharides with antithrombotic activity, is continuing. This collaboration has already led to the development of Arixtra® and idraparinux.
- n In January 2002, Sanofi-Synthélabo and IDM (Paris, France) signed a cooperation agreement in cell immunotherapy for the development and marketing of immunological treatments for cancers. A first product, Uvidem®, targeting melanoma, is currently in Phase II clinical development. Under the terms of this agreement, Sanofi-Synthélabo has priority in choosing up to 20 cellular therapy programs from the range of products developed by IDM. IDM is responsible for preclinical development. Where an option is exercised, Sanofi-Synthélabo will finance the clinical development and will possess the worldwide marketing rights for the compounds selected if the clinical trials are successful, in return for paying royalties to IDM on the sales of these medicines.
- n Impact Malaria: in the context of this initiative, three cooperative R&D programs were begun in 2002.

## MEDICINES

### our portfolio gets stronger and stronger

For the third consecutive year, sales showed strong growth in 2002, exceeding that of the market. This performance was due to the success of our flagship products, the launch of new medicines and the overall strength of our portfolio.

#### Key events in 2002

New indications for Plavix<sup>®</sup> and Aprovel<sup>®</sup>/Avapro<sup>®</sup>

Launch of Arixtra<sup>®</sup> in the United States and Europe,

Launch of Eloxatin<sup>®</sup>, Eligard<sup>®</sup> and Elitek<sup>®</sup> in the United States

Rapid granting of a product license for Eloxatin<sup>®</sup> in the U.S. on the basis of clinical trial results

Commercial success of Plavix<sup>®</sup> with a 40%\* increase in consolidated sales in 2002

Plavix<sup>®</sup> patents challenged by two generic manufacturers in the U.S.

Success of Myslee<sup>®</sup> (zolpidem) in Japan

no. 2 on the market within two years.

\* on a reported basis

## The 15 leading products

## Cardiovascular/Thrombosis

Principal products	Compounds	Indications	Consolidated sales		
			(in millions of euros)		
			2000	2001	2002
Plavix®/Iscover®	clopidogrel	Atherothrombosis	437	705	987
Aprovel®/Avapro®/Karvea®	irbesartan	Hypertension	300	423	562
Fraxiparine®	nadroparin calcium	Thrombosis	255	297	324
Cordarone®/Ancaron®	amiodarone	Arrhythmia	156	162	162
Tildiem®	diltiazem	Angina, hypertension	154	152	141
Ticlid®	ticlopidine	Thrombosis	235	205	137
Corotrope®/Primacor®/Milrila®	milrinone	Heart failure	180	237	127
Kerlone®/Kerlong®	betaxolol	Hypertension, angina	77	82	77

## Central Nervous System

Principal products	Compounds	Indications	Consolidated sales		
			(in millions of euros)		
			2000	2001	2002
Stilnox®/Ambien®/Myslee®	zolpidem	Insomnia	582	786	1424
Depakine®	sodium valproate	Epilepsy	211	243	267
Solian®	amisulpride	Schizophrenia	93	116	135
Aspégic® and derivatives*	lysine acetylsalicylate	Fever, pain	100	100	108
Dogmatil®/Dogmatyl®	sulpiride	Psychosomatic disorders	134	124	78

## Internal Medicine

Principal product	Compound	Indication	Consolidated sales		
			(in millions of euros)		
			2000	2001	2002
Xatral®	alfuzosin	Benign prostatic hyperplasia	120	148	182

## Oncology

Principal product	Compound	Indication	Consolidated sales		
			(in millions of euros)		
			2000	2001	2002

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

			<u>2000</u>	<u>2001</u>	<u>2002</u>
Eloxatin®	oxaliplatin	Colorectal cancer	141	196	389

\* Including sales for Kardegic®, a product classed by the IMS in the cardiovascular therapeutic sector.

35

Medicines

## MEDICINES

### our portfolio gets stronger and stronger

#### Cardiovascular/Thrombosis

##### ***hypertension***

*Hypertension is one of the most common diseases, affecting approximately 20% of the adult population worldwide.*

*Generally asymptomatic, it induces severe damage of target organs and, for this reason, is known as the **silent killer** . It is manifested by elevation of one or both arterial pressure values beyond the thresholds associated with the onset of complications. These concern the heart, with damage to coronary arteries leading to myocardial infarction and the brain, where there is a risk of stroke, but also affect the entire vascular system, the kidneys and the eyes.*

*On the basis of large epidemiological studies, normal blood pressure is defined as 140/90 mmHg for the majority of people. However, this threshold is lowered when the risk of complications is increased by the presence of other diseases, such as diabetes, which doubles the risk, or proteinuria, an abnormal amount of protein in the urine, leading to renal impairment.*

*The guidelines published by the World Health Organization and professional bodies recommend a complete assessment of the risk profile of each hypertensive patient to enable an individually adapted treatment.*

*Certain concomitant diseases or impairments of **target organs** are sometimes silent and therefore necessitate specific research investigations. For this reason, the American Diabetes Association (ADA) recommends an annual evaluation of incipient renal impairment in diabetics. This is characterized by microscopic proteinuria, known as microalbuminuria. If renal impairment is confirmed, the ADA recommends initiating treatment with an angiotensin receptor antagonist, particularly in patients with type 2 diabetes.*

#### **Aprovel®/Avapro®**

*irbesartan*

##### **Hypertension**

2002: new indication in Europe and the United States for the treatment of kidney disease in patients with hypertension and type 2 diabetes

Launched in 1997, Aprovel® belongs to the most recent class of anti-hypertensive medications: angiotensin II receptor antagonists (AIIRAs), which are poised to become the leading treatment for this disorder in terms of market share. Highly potent and very well-tolerated, AIIRAs act by blocking the effect of the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. Aprovel®/Avapro® alone or combined with a diuretic, hydrochlorothiazide, under the name Co-Aprovel®/Avalide® achieves blood pressure control in close to 90% of patients with optimized therapeutic tolerability.

Aprovel® is currently available in more than 80 countries, including the U.S. under the name Avapro® according to agreements with Bristol-Myers Squibb. The product has also been submitted for approval in Japan.

In 2002, Aprovel® was granted a new indication in Europe and the U.S. for the treatment of diabetic nephropathy, on the basis of the PRIME program. This clinical program demonstrated that irbesartan protected diabetic hypertensive patients from the progression of renal impairment, at both early and more advanced stages of the disease. The importance of these results, demonstrated for the first time in this population, led the American Diabetes Association (ADA) to recommend the use of angiotensin receptor antagonists as first-line treatment for renal disease in patients with type 2 diabetes.

Two new, large-scale trials have now been initiated to demonstrate the ability of irbesartan to protect the cardiovascular system against a frequent complication of hypertension, ventricular hypertrophy, and to prevent recurrences of atrial fibrillation episodes:

- The I-PRESERVE trial evaluates the benefit of irbesartan in the treatment of a specific but frequent form of heart failure, known as heart failure with preserved systolic function or diastolic heart failure. In this case, the contractile capacity of the ventricles is preserved, but ventricular filling is disturbed. I-PRESERVE is the largest study conducted to date in this disease. Started in 2002, it is currently in an active stage of patient enrollment.
- The ACTIVE trial, due to start in 2003, will evaluate the efficacy of irbesartan, combined with clopidogrel, in preventing cardiovascular complications in patients suffering from atrial fibrillation.

These two trials will enroll a total of 15,000 patients and should be completed in 2006.

### **Cardiac rhythm disorders**

*Cardiac rhythm disorders can arise both in the atria, with supraventricular rhythm disorders, and in the ventricles, with ventricular rhythm disorders. Both kinds of rhythm disorder generally have an organic cause and therefore tend to recur.*

*Patients concerned may present various symptoms palpitations, malaise, loss of consciousness, etc. and even heart failure. Certain types of cardiac rhythm disorder may lead to death, sometimes sudden death.*

*The prevalence of atrial fibrillation the most common supraventricular rhythm disorder is 1% in the general population, but this increases with age. Over the age of 65, prevalence is more than 8%.*

### **Cordarone®/Ancaron®**

*amiodarone*

### **Cardiac rhythm disorders**

2002: publication of the CAT study in the medical journal *Circulation*, 03.26.02, pages 1453-58

Thirty-six years after receiving its first product license, Cordarone® remains the reference anti-arrhythmic agent for the treatment and prevention of cardiac rhythm disorders. Cordarone® is effective against potentially life-threatening supraventricular rhythm disorders.



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

Two studies, AMIOVIRT and CAT, published in 2002, showed that Cordarone® is as effective as the implantation of a defibrillator in preventing sudden cardiac death in patients with idiopathic dilated cardiomyopathy. Cordarone® has a good cardiac safety profile and only exceptionally induces the complications potentially associated with the use of anti-arrhythmics, such as torsades de pointes, a potentially fatal cardiac rhythm disorder, or ventricular insufficiency.

However, its effects on thyroid function restrict its use.

Cordarone® is available in more than 126 countries, including the U.S, where it is licensed to American Home Products, and Japan, where it is marketed under the trade name Ancaron® through a joint venture with Taisho.

The identification of tablets

and capsules make them

unique worldwide.

37

Medicines

## MEDICINES

### our portfolio gets stronger and stronger

#### Angina

*Angina results from an imbalance between myocardial oxygen demand and supply due to the narrowing of one or more of the coronary arteries, the arteries nourishing the heart. Angina is an incapacitating and life-threatening disease.*

*The usual treatment comprises control of cardiovascular risk factors and prescription of one or more anti-anginal agents, such as nitrate derivatives, beta-blockers and calcium antagonists, as well as platelet anti-aggregants. Sanofi-Synthélabo has medicines in each of these therapeutic classes.*

#### Tildiem®

#### diltiazem

#### Angina, hypertension

Among calcium antagonists, Tildiem® is considered a reference treatment for angina. It increases oxygen supply to the myocardium through coronary vasodilatation while simultaneously reducing oxygen needs by decreasing heart rate and lowering peripheral arterial resistance. Tildiem® therefore exhibits good anti-anginal efficacy, combined with a good safety profile.

The prolonged release formulations of Tildiem® LP 200/300 mg provide 24-hour protection against ischemia with a single daily dose. This convenience of use improves both compliance, and tolerability. Furthermore, a meta-analysis showed that these formulations permit consistent regulation of heart rate: the faster the heart rate initially, the more this is slowed by Tildiem®. A study conducted in 1999 showed that the profile of release of Tildiem® LP 200/300 mg is unique in its therapeutic class.

The NORDIL study of morbidity and mortality associated with hypertension showed that diltiazem was as effective as diuretics and beta-blockers the reference treatment in reducing cardiovascular complications. These results emphasize the value of treating hypertension with Tildiem® LP 200/300 mg.

Tildiem® LP 200/300 mg is marketed in most European countries.

### **Kerlone®/Kerlong®**

*betaxolol*

#### **Hypertension, angina**

A cardioselective beta-blocker, Kerlone® is marketed not only in Europe but also in the U.S., through a joint venture with Pharmacia, and in Japan under the name Kerlong®, through a joint venture with Mitsubishi. A recent clinical trial, BETACAR, showed the ease of administration of Kerlone® in the treatment of patients with an altered cardiac function.

*Heart failure*

*Related to a defect in the pumping function of the left ventricle, heart failure passes through various stages of seriousness. Accompanied by breathlessness, edemas and various types of effusion, the most severe forms may render everyday activities practically impossible. The prevalence of heart failure is between 0.3% and 2%, increasing almost exponentially with age.*

### **Corotrope®/Primacor®/Milrila®**

*milrinone*

#### **Heart failure**

Corotrope® combines positive inotropic properties, increasing the contractile force of the heart, with a vasodilatory action. It constitutes an effective treatment for advanced forms of heart failure. It is also a treatment for certain less advanced forms that have been abruptly decompensated by a dietary change or intercurrent disease. Corotrope® is marketed in several European countries, in the U.S. under the name Primacor®, where the patent came into the public domain in May 2002, and in Japan under the name Milrila® through a joint venture with Yamanouchi.

*Atherothrombosis*

*Atherothrombotic events constitute the major cause of morbidity and premature death in industrial countries. Every year, in Europe and the U.S., 3.4 million people experience an acute coronary event and 1.2 million experience an ischemic stroke, both of which*

*are related to impaired or blocked blood circulation. In addition, 16.8 million people present signs of peripheral arterial disease, an arterial disorder of inflammatory origin.*

38

Medicines

*All these symptoms are manifestations of the same underlying disease atherothrombosis.*

*Atherothrombosis is the formation of a coagulated mass of blood, known as a thrombus, in a vessel affected by atherosclerosis. Atherosclerosis is common to numerous cardiovascular diseases and gives rise to lesions on the internal wall of the artery in the form of plaques. These are likely to be disseminated in the vascular system. A thrombus is formed when an atheromatous plaque becomes unstable and breaks up, exposing components such as collagen to the circulating blood and thereby leading to platelet adhesion at the site of the lesion. The thrombus may spread and eventually obstruct the vessel to the extent that it impairs or blocks blood circulation, leading to acute ischemia and causing tissue damage. The final consequence may be a fatal or non-fatal cardiovascular event, such as stroke, acute coronary syndrome (unstable angina, myocardial infarction with or without Q-wave, vascular death) or peripheral arterial disease.*

**Plavix®**

*clopidogrel*

### **Atherothrombosis**

2002: extension of the indication to acute coronary syndrome, based on the results of the CURE trial

Plavix®, a platelet adenosine diphosphate receptor antagonist, is indicated for the prevention of atherothrombotic events in patients presenting a history of recent myocardial infarction, recent ischemic stroke or documented peripheral arterial disease. Plavix® is the only medicine indicated for the secondary prevention of atherothrombosis, irrespective of the location of the arteries initially affected, whether heart, brain or lower limbs.

The results of the CAPRIE study, the largest phase III study ever conducted with close to 20,000 patients enrolled, support the broad indication for Plavix®. CAPRIE demonstrated the superior efficacy of Plavix® relative to acetylsalicylic acid (ASA), with at least equally good safety.

Pharmaceutical forms depend on the composition of the medicine.

Launched in 1998, Plavix® is marketed in over 75 countries. In the U.S., the product is commercialized through the alliance with Bristol-Myers Squibb (see page 36 of the Financial Report for details of the alliance). In Japan, where it is being developed in partnership with Daiichi, the file submission is planned for the end of 2003.

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

The year 2002 was marked by three major events:

- on the basis of the results obtained in the CURE trial, completed in 2001, the U.S. and European health authorities approved an extension of the Plavix® indications to acute coronary syndrome. This new indication was incorporated in the guidelines of the American Heart Association and the American College of Cardiology in March 2002 and in those of the European Society of Cardiology in September 2002.

The CURE trial demonstrated that clopidogrel, on top of standard therapy including acetylsalicylic acid (ASA), reduced the risk of atherothrombotic events (myocardial infarction, stroke, death from cardiovascular cause) by 20% with only a 1% increase in the rate of major hemorrhages and provided significant short- and long-term benefit in patients presenting with an acute coronary syndrome. With more than 12,000 patients enrolled, CURE is the largest trial ever conducted in patients presenting with unstable angina or non-Q-wave myocardial infarction.

- the results of the CREDO trial, announced in November 2002, confirmed the therapeutic value of Plavix® in the short- and long-term prevention of atherothrombotic events in patients having undergone coronary angioplasty, with or without stenting. CREDO, conducted in more than 2,000 patients, demonstrated the benefit of prolonged use of clopidogrel: the risk of atherothrombotic events (myocardial infarction, stroke and cardiovascular death) was reduced by 27% after one year.
- the CHARISMA trial started in September 2002 with the enrollment of the first patients. The objective of this study is to demonstrate the value of using Plavix® on top of existing treatments in the primary prevention of cardiovascular events in patients at risk. CHARISMA will include 15,000 patients.

## MEDICINES

### our portfolio gets stronger and stronger

Other major studies are designed to support the long-term use of Plavix<sup>®</sup>, by providing complementary data

- MATCH in the treatment of high-risk patients having recently experienced a stroke or transient ischemic attack. Enrollment of the planned 7,600 patients is complete.
- CLARITY and COMMIT in patients with acute myocardial infarction.
- CAMPER in patients with peripheral arterial disease, who have undergone angioplasty or bypass surgery.
- ACTIVE in the prophylactic treatment of patients with atrial fibrillation.

In total, this major clinical program on clopidogrel will include more than 100,000 patients.

### Ticlid<sup>®</sup>

*ticlopidine*

### Thrombosis

Ticlid<sup>®</sup> is indicated for the prevention of coronary or cerebrovascular ischemic events in patients at risk (following an initial ischemic stroke or transient ischemic attack, or symptomatic peripheral arterial disease). In combination with ASA, Ticlid<sup>®</sup> is the standard prophylactic treatment against the risk of thrombosis (reocclusion of the dilated artery) in patients who have undergone coronary angioplasty with insertion of a stent. Ticlid<sup>®</sup> is marketed in over 75 countries. In the U.S., it is licensed to Roche. In Japan, where it is marketed under the brand name Panaldine<sup>®</sup>, it is licensed to Daiichi.

Arixtra<sup>®</sup> is administered using a safety syringe which protects the person giving the injection.

*Venous thrombosis*

*Deep-vein thrombosis is triggered by coagulation factor abnormalities, lesions of the vascular wall and venous stasis, which are most likely to occur during prolonged immobilization.*

*The risk of thrombosis is particularly high after surgical operations, notably major orthopedic surgery such as hip or knee replacement, and especially hip fracture. In the absence of treatment, it occurs in 40% to 50% of patients undergoing hip replacement, and in 70% to 80% of patients undergoing total knee replacement. Venous thrombosis may be manifested locally by pain or edema affecting the leg. However, venous thromboembolism often occurs without any apparent clinical sign and the patient remains ignorant of the disease. This may also have more dramatic consequences, such as pulmonary embolism, with fatal outcome.*

*Current standard prophylaxis for thrombosis is low molecular weight heparin which reduces frequency by a factor of 2 to 3.*

**Fraxiparine®**

*nadroparin calcium*

**Venous and arterial thrombosis**

Fraxiparine® is an injectable low molecular weight heparin. Launched in 1986, it is marketed in more than 100 countries, excluding the U.S. and Japan.

The indications of Fraxiparine® have expanded over the years. Initially indicated for the prevention of venous thromboembolic disease, this antithrombotic is currently indicated for the treatment of venous thromboembolism and the treatment of acute coronary syndromes.

Fraxodi®, a curative treatment for venous thromboembolic disease administered as a once-a-day injection, was launched in France in 1998. It is now marketed in most countries in Europe and Latin America. This regimen permits shorter hospital stays, facilitates outpatient treatment and enhances patient recovery.

The indication of Fraxiparine® for the treatment of the acute phase of unstable angina in association with ASA has also been granted in the majority of countries.





**Arixtra®**

*fondaparinux sodium*

**Venous thrombosis**

Arixtra® was launched in the U.S. and in Europe in 2002 in its first clinical indication, the prevention of venous thromboembolism (VTE) including deep vein thrombosis and pulmonary embolism in patients who have undergone major orthopedic surgery of the lower limbs, a high-risk situation. Arixtra®, a totally synthetic compound, has entered the market of low molecular weight heparins, which are animal sourced. Co-developed by Sanofi-Synthélabo and Organon (Akzo Nobel), Arixtra® represents a major advance in the prevention of venous thromboembolism. It is the first agent in a new class of antithrombotics: selective inhibitors of coagulation factor Xa. Arixtra® interrupts a key step in the coagulation cascade, preventing the formation of blood clots. A product of sugar chemistry, Arixtra® is a totally synthetic compound, a characteristic conferring a high degree of purity. For both these reasons, this product constitutes a major technological and therapeutic advance.

Its development potential promises to be substantial.

In this indication, Phase III trials including over 7,000 patients demonstrated a major clinical benefit relative to the reference low molecular weight heparin. Arixtra® diminishes the risk of a thromboembolic event by 55%, irrespective of the type of orthopedic surgery performed and the characteristics of the patient, without increasing the risk of clinically important bleeding. For patients undergoing surgery for hip fracture, the risk of deep-vein thrombosis is reduced from 20% to 8%. The safety profile of the two treatments is similar. Granted product license approval in the U.S. in December 2001 for the prevention of venous thromboembolic events after orthopedic surgery, after an expedited review, Arixtra® was launched in February 2002. In Europe, Arixtra® received marketing approval for this same indication in March 2002 and was launched on the first European markets in April. In Japan, the product is under development in Phase IIb/III. From launch to the end of 2002, Arixtra® was included in more than 750 formularies in some of the most prestigious U.S. and European centers. The process of inclusion in formularies is slow, but is an essential prerequisite for use of the product in hospital centers. In December 2002, the Food and Drug Administration modified the summary of product characteristics for Arixtra®. This new version provides an improved description of its profile. Sanofi-Synthélabo rapidly initiated a life cycle management program for Arixtra® which will cover all segments of the market:

- the value of prolonged prophylaxis of 30 days versus five to nine days: the result of the Penthifra Plus study established that Arixtra® administered for 28 days could significantly reduce the rate of venous thromboembolic events after surgery for hip fracture, the orthopedic surgery operation carrying the highest risk.

At the end of 2002, an application was submitted to the United States Food and Drug Administration (FDA) and to the European Agency for the Evaluation of Medicinal Products (EMA). The FDA granted expedited review status to this application on the basis that Arixtra® is the only product indicated for hip fracture patients, and in view of the results of the Penthifra Plus trial,

- treatment of venous thromboembolism: completed in 2002, the MATISSE program on 4,400 patients demonstrated that Arixtra® is as well tolerated and at least as effective as existing standard therapies low molecular weight heparins and unfractionated heparin for the treatment of deep vein thrombosis and pulmonary embolism respectively,

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

- prevention of venous thrombosis in other types of surgery, such as abdominal surgery (PEGASUS and APOLLO programs),
- prevention of venous thromboses in medical patients at high risk of venous thromboembolic events who have not undergone surgery (ARTEMIS program),
- acute coronary disease (unstable angina, coronary angioplasty, myocardial infarction): the initial efficacy results were confirmed by the Phase IIb PENTUA trial. These were presented at the Scientific Sessions of the American Heart Association in November 2001, and provide grounds for expecting a good benefit/risk ratio compared to existing therapies.

Arixtra<sup>®</sup> is marketed jointly by Sanofi-Synthélabo and Organon in the U.S., Canada and Mexico, and by Sanofi-Synthélabo alone in Europe and the rest of the world, excluding Japan.

41

Medicines

## MEDICINES

### our portfolio gets stronger and stronger

#### Central Nervous System

##### *Insomnia*

*Insomnia is usually defined as a complex of generally unsatisfactory sleep difficulty in falling asleep, waking up during the night, waking up too early in the morning, impression of non-restorative sleep and daytime consequences such as mood changes, problems of attention, alertness and memory, and difficulties in concentrating. Depending on the definition used and the method employed for collecting epidemiological data, an average of 20% to 30% of the general population report having suffered from insomnia at some time. If left untreated, insomnia may become chronic, a condition demonstrated to favor the onset of depressive states. In addition, recent epidemiological surveys have shown that the social costs of insomnia, with absenteeism and reduced professional productivity as well as the public health costs of hospitalization and more frequent use of medications, justify its early treatment.*

*Surveys have also shown that both patients and physicians tend to considerably underestimate both the existence of this disorder and the need to treat it.*

#### Stilnox®/Ambien®/Myslee®

*zolpidem*

##### **Insomnia**

2002: Myslee® no. 2 in Japan

Launched in almost 100 countries, Stilnox®/Ambien®/Myslee® is the world's leading hypnotic. Chemically and pharmacologically distinct from benzodiazepines, Stilnox®/Ambien®/Myslee® is distinguished by its selective binding exclusively to receptors mediating hypnotic activity. As a result, it induces sleep that is qualitatively close to natural sleep and devoid of certain side effects which are characteristic of the benzodiazepine class as a whole.

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

Stilnox®/Ambien®/Myslee® induces sleep rapidly and its action persists for 6 to 8 hours. It is well tolerated and allows the patient to awake with a reduced risk of impaired attention, alertness or memory lapses throughout the day.

The risk of dependence is minimal when the product is used at the recommended dosage and duration of use. Thanks to an extensive program of eight clinical trials on 6,000 patients, Stilnox®/Ambien®/Myslee® is the only product demonstrated to be suitable for use as needed, according to the requirements of each individual. This mode of administration avoids systematic intake of a hypnotic for patients who do not suffer from insomnia every night. It is consequently an effective and safe option, reassuring for both patients and their physicians.

Stilnox®/Ambien®/Myslee® is also probably the best studied hypnotic in the world: data on its efficacy and safety have been generated from 140 clinical trials including over 80,000 patients from all continents, and on an experience of 15 years, representing to date more than 8 billion nights of treatment since the product was launched.

Two key events marked the year 2002:

- in the U.S., Sanofi-Synthélabo successfully took back all rights to Stilnox®/Ambien®/Myslee® as of April. Thanks to the efforts of its sales force, the U.S. affiliate succeeded in achieving sales of 1.2 billion euros (+26.6%) by the end of 2002.
- Myslee® has achieved high market penetration in Japan. Marketed since December 2000 through a joint venture with Fujisawa, the product has already become the second leading hypnotic on the market. With an 18.5% market share in terms of sales, Japan is the country with the second-highest sales of zolpidem.

## *Epilepsy*

*Epilepsy is a frequent, chronic neurological disorder, affecting approximately 1% of the population worldwide. Children under 10 years old and the elderly are those most frequently affected.*

*Epilepsy is characterized by repeated spontaneous seizures resulting from an excessive discharge of cerebral neurons. The characteristics of these seizures and their repercussions, which include physical injury, loss of self-confidence and even decreased autonomy, their origin, the presence or absence of associated symptoms and the quality of response to treatments make this a heterogeneous disorder.*

*Our understanding of epilepsy is improving with recent progress in genetics and cerebral electrophysiology, and also thanks to new techniques of functional cerebral imaging. It is crucial to facilitate access to care, including diagnosis, treatment and counseling. With adequate treatment, the great majority of epileptic patients can continue to live normal, productive and fulfilling lives.*

Chemical library: identifying compounds from  
our chemical resources.

## **Depakine®**

*sodium valproate*

## **Epilepsy**

2002: new pharmaceutical formulation approved

Depakine® is a broad-spectrum antiepileptic which has been successfully prescribed for over 30 years.

Numerous clinical trials, as well as long years of experience have abundantly shown that Depakine® is effective in all types of epileptic seizure and epileptic syndrome, and is generally well tolerated. Depakine® consequently remains a reference treatment for epilepsy worldwide. Furthermore, in contrast to findings sometimes reported with other anti-epileptic agents, Depakine® does not induce paradoxical aggravation of seizures.

The Chrono® form (prolonged release formulation) permits once-daily administration in most cases, a criteria favoring improved compliance with treatment and overall care of the patient. Depakine® is available in a wide range of formulations, permitting its adaptation to all types of patients. A new pharmaceutical form, facilitating the use of Depakine® particularly in children and the elderly, has already been authorized for marketing in several European countries and will be launched within the next few years.

Depakine® is marketed in over 100 countries, including the U.S., where it is licensed to Abbott.

43

Medicines

## MEDICINES

### our portfolio gets stronger and stronger

#### *Neurotic and psychosomatic disorders*

*Patients suffering from these disorders present a variety of somatic complaints, associated with psychological distress. It is estimated that these somatic complaints are the main reason prompting 30% to 40% of patients to consult a physician.*

*Clinical investigations generally fail to reveal any organic cause. The management of these patients is problematic, with a frequent risk of self-medication, as well as a high rate of prescription of complementary tests.*

#### **Dogmatil®/Dogmatyl®**

#### *sulpiride*

#### **Neurotic and psychosomatic disorders**

At low doses, Dogmatil® 50 mg is used in numerous countries for the symptomatic treatment of neurotic and/or psychosomatic disorders. Its specific mechanism of action on central and peripheral dopaminergic receptors permits rapid improvement of the psychic state of the patient as well as relief of functional symptoms in patients who are difficult to treat.

At higher doses, Dogmatil® 200/400 mg is also proposed for the treatment of psychotic states. Its good cardiovascular and neurological safety profile makes it particularly suitable for the treatment of elderly patients. Dogmatil® is available in over 90 countries, including Japan, where it is marketed under the name Dogmatyl® through a joint venture with Fujisawa.

#### *Schizophrenia*

*A particularly severe and incapacitating disorder, schizophrenia affects approximately 1% of the population. It generally first appears during adolescence or early adulthood. In the majority of cases, the disease follows a chronic course, necessitating long-term treatment and often recourse to hospitalization.*



*Two principal types of symptoms are distinguished, which may coexist or appear at different stages of this progressive disease, acute or chronic:*

- *positive symptoms, notably delusions and hallucinations, most often occur during the acute phases,*
- *negative symptoms, characterized by introversion and an incapacity for action, appear very early on or during the chronic phase of the disease and lead to the progressive social isolation of the patient.*

## **Solian®**

*amisulpride*

### **Schizophrenia**

2002: launches in 12 countries worldwide, including Australia, Belgium and Spain

This antipsychotic agent has an atypical pharmacological profile. Its originality consists in its capacity to act selectively on D3/D2 dopaminergic receptors and its dual pre- and post-synaptic activity. Furthermore, its preferential action on the limbic system confers excellent neurological safety.

Solian® is effective for all symptoms of schizophrenia, both positive and negative, irrespective of the phase of the disease, whether acute or chronic. At doses of 400 mg to 800 mg per day in patients with positive symptoms and associated depressive symptoms, and at the optimal daily dose of 100 mg in patients with dominant negative symptoms, Solian® demonstrates both efficacy and very good safety.

Solian® is available in the principal European markets and worldwide in a total of 51 countries.

## Aspégic®

*lysine acetylsalicylate*

### **Fever, pain**

Aspégic® is a salicylate with the original property of total and immediate solubility. This characteristic confers both very rapid efficacy as an analgesic, antipyretic and anti-inflammatory agent.

Aspégic® is marketed in certain countries in Europe, Africa and the Middle East.

### **Internal Medicine**

*Benign prostatic hyperplasia*

*Benign prostatic hyperplasia (BPH) is the most common benign tumor in men. Both the frequency of this condition and the problems it engenders increase with age.*

*The resulting urinary symptoms consequently affect 22% of men aged 50-59 years, but up to 45% of men aged 70-80 years.*

*By 2004, the aging of the population will result in an increase in the number of patients affected by this condition to over 55 million men. This number will continue to rise to reach 60 million men in 2009. In addition, the rising expectations of this senior population in terms of quality of life will lead to a 50% increase in the number of patients treated between now and the end of the decade.*

*The need is great, as both the diagnosis and the treatment of this condition could be still further improved. A recent survey, MSAM-7 (Multinational Survey of the Aging Male), was conducted in seven countries: (United States, France, Italy, United Kingdom, Spain, Germany and the Netherlands) in 14,000 men over 50 years old. This revealed that only 20% of men suffering from moderate symptoms, and 43% of those with severe symptoms, were receiving treatment.*

*The urinary problems associated with benign prostatic hyperplasia, not correlated with prostate volume, may have a considerable effect on the patients' quality of life. They result, for example, in urgent and frequent needs to urinate, causing substantial inconvenience particularly when experienced during the night.*

*Although benign in the majority of cases, untreated BPH may in the long term trigger serious complications such as acute urinary retention, and necessitate an emergency surgical operation. This complication arises in 10% of men aged 70 years within a period of five years.*

*The same survey, MSAM-7, also demonstrated the link between urinary problems resulting from benign prostatic hyperplasia and sexual dysfunction. Irrespective of age or other concomitant pathological conditions, men over 50 years old presenting severe urinary symptoms due to BPH have a four-fold higher risk of developing sexual problems.*

**Xatral®**

*alfuzosin*

### **Benign prostatic hyperplasia**

2002: launch of Xatral® OD

Alfuzosin was discovered by Sanofi-Synthélabo research and marketed for the first time in France in 1988 under the trade name Xatral®, administered at 2.5 mg three times daily. Constantly improved since then, its optimal pharmaceutical form, Xatral® OD (10 mg once daily) has now been granted a product license in 70 countries and is marketed in 14 European countries and in more than 35 other countries.

In the U.S., the product filing for alfuzosin entered the final phase of review in 2002 and the product should be available during the course of 2003. This launch will provide a substantial opportunity for growth: the U.S. market alone represents 36% of worldwide sales of medications for BPH, with sales of close to a billion euros and a 19% annual growth rate.

Xatral® belongs to the alpha1-blocker class. It was the first product of this class to be indicated uniquely and

## MEDICINES

### our portfolio gets stronger and stronger

specifically for the treatment of symptoms of benign prostatic hyperplasia, and the first product capable of acting selectively on the urinary system. Due to this clinical uroselectivity it is immediately effective, with no need for dose titration, and shows good tolerability, particularly cardiovascular. Active from the first dose, it provides rapid and lasting symptom relief and significantly improves patients' quality of life.

Besides relieving symptoms, the results of major clinical trials completed in 2002 have demonstrated the original contribution of Xatral® to the treatment of this condition and the prevention of its complications.

- The results of the first phase of the ALFAUR trial notably showed that Xatral® doubles the probability of a restored capacity to urinate normally after an episode of acute urine retention in conjunction with catheter insertion. These are the first published results of an original development program to demonstrate the capacities of Xatral® to prevent the principal complication of benign prostatic hyperplasia: acute urinary retention. Filings for extension in this indication have been submitted in the principal European countries.
- The preliminary results of another large international trial on more than 800 patients have provided evidence that Xatral® preserves sexual function in patients suffering from BPH.

Ampoule for injectable drug preparation.

### Oncology

#### *Colorectal cancer*

*Colorectal cancer is the third most frequent cancer worldwide, with one million new cases diagnosed and close to 500,000 deaths per year, and represents a major public health problem. This disease is particularly common in western countries. Colorectal cancers are hereditary in 5% to 10% of cases, but otherwise their etiology is generally explained in terms of behavioral factors such as nutrition, excessive calorie intake and sedentary lifestyle. For localized forms of the disease, curative treatment is based on surgery. However, the risk of relapse often justifies the use of adjuvant chemotherapy.*

*For metastatic forms, chemotherapy has demonstrated its efficacy in halting or slowing tumor progression and prolonging patient survival.*

**Eloxatin®**

*oxaliplatin*

**Colorectal cancer**

2002: marketing approval in the U.S.

Eloxatin® is a new-generation platinum agent, the only one with demonstrated activity in colorectal cancer. Its recent introduction in the treatment of metastatic colorectal cancer has led to major progress:

- prolonging median survival to 20 months when used as first-line treatment;
- enabling a significant proportion of patients with isolated hepatic metastases to undergo surgical resection, due to the rapid and substantial reduction in the size of these metastases with treatment. Eloxatin® consequently gives these patients the hope of substantially prolonged survival.

Eloxatin® was granted marketing approval in the U.S. in 2002 after a particularly rapid review by the Food and Drug Administration. This was achieved on the basis of the results of a large U.S. trial conducted on patients in relapse after an initial treatment. Treatment with the combination oxaliplatin + 5-fluorouracil (5-FU) succeeded in delaying disease progression and demonstrated a clinical benefit in terms of pain reduction, weight gain, and improvement of general status.

Survival benefit with first-line treatment was also demonstrated by one of the largest randomized trials ever conducted in metastatic colorectal cancer. These data were presented at the annual congress of the American Society of Clinical Oncology (ASCO) in May. In this study, conducted with the support of the U.S. National Cancer Institute, oxaliplatin + 5-FU (Folfox regimen) was shown to be more effective and better tolerated than irinotecan + 5-FU (IFL regimen). The prolongation of median survival of patients receiving oxaliplatin led to premature discontinuation of the trial and the proposal to treat all patients still enrolled in the trial with the oxaliplatin-based regimen. A product filing for first-line treatment will be submitted in the U.S. in 2003.

Already marketed in 60 countries, Eloxatin® plays a major role in the development of new therapeutic strategies in metastatic colorectal cancer. In view of its tolerability, Eloxatin® is also being developed as an adjuvant treatment for non-metastatic colorectal cancer, to prevent relapse in patients whose recovery has not been achieved by surgery alone.

Its activity in colorectal cancer has also encouraged specialists to explore the value of Eloxatin® in the treatment of other tumors, particularly tumors of the digestive system such as pancreatic cancer, but also ovarian and breast cancers, as well as certain hematological cancers.

#### *Tumor lysis syndrome*

*While modern chemotherapies cure more and more leukemias and lymphomas, particularly in children, the need to prevent and manage their side effects is a major preoccupation of the medical community.*

*These side effects may be serious, and even potentially fatal. In certain types of cancer, the very rapid destruction of the tumor by chemotherapy leads to a massive release of uric acid that may overwhelm the kidneys' capacity for elimination. Uric acid is poorly soluble and may crystallize in the kidneys. Tumor lysis syndrome may therefore lead to acute renal failure, sometimes necessitating dialysis and inducing substantial morbidity. At the very least, it imposes a delay in chemotherapy administration, adversely affecting its efficacy.*

#### **Fasturtec®/Elitek®**

*rasburicase*

#### **Tumor lysis syndrome**

2002: market launch in Europe and the U.S.

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

Fasturtec®/Elitek® is a recombinant enzyme produced by genetic engineering. Within less than four hours, it converts uric acid into highly soluble allantoin, easily eliminated in the urine, thereby avoiding tumor lysis syndrome. Administered before or at the same time as chemotherapy, Fasturtec®/Elitek® allows clinicians to administer anticancer treatment in optimal conditions without delays or dose reductions.

Fasturtec®/Elitek® is the first biotechnology product entirely discovered and developed by Sanofi-Synthélabo and manufactured in its state-of-the-art manufacturing unit in Labège, France. Authorized for marketing in Europe in February 2001 (1.5 mg form), it was launched in the first European countries in May 2001.

2002 saw:

- in Europe, marketing authorization of the 7.5 mg form in April and launch of the product in all countries,
- in the U.S., granting of a product license in July and market launch in the following month.

The results of three clinical trials including 490 adult patients, presented at the congress of the American Society of Hematology in December, provided additional evidence of the reliability and efficacy of Fasturtec®/Elitek® in adults and in children.

Fasturtec®/Elitek® is also in clinical development in Japan.

## MEDICINES

### our portfolio gets stronger and stronger

#### Life Cycle Management of pharmaceuticals

A pharmaceutical product goes through several growth phases before reaching its full potential.

The rate of progression depends on the drive for innovation and the resources allocated to this end.

Life Cycle Management consists in exploring new properties and new indications of a medicine already on the market. An original Life Cycle Management program can meet new medical needs which are unmet or insufficiently satisfied.

It provides opportunities for innovation and progress which are at least as great as the launch of a new product.

The following examples provide graphic illustrations of this.

#### Plavix®

##### *clopidogrel*

On the basis of the landmark trials CAPRIE and CURE, Plavix® has become the worldwide reference treatment for secondary prevention in patients suffering from atherothrombosis, including acute coronary syndrome. Sanofi-Synthelabo has implemented a vast program of clinical trials designed to better define the therapeutic benefit of Plavix®, in various patient populations at risk of atherothrombosis and its most severe complications.

- The CREDO trial, presented at the annual scientific sessions of the American Heart Association in November 2002, showed the importance of a prolonged treatment of one year after stent placement in subjects presenting with acute coronary artery disease.
- The COMMIT trial, in acute myocardial infarction, currently includes almost 30,000 patients. Completion of the trial is scheduled in 2004 with over 40,000 patients.



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

- The MATCH trial in patients experiencing a transient ischemic attack or ischemic stroke completed patient enrollment in April 2002, with 7,600 patients.
- The CHARISMA trial will evaluate the benefit of the combination clopidogrel + ASA in the prevention of serious vascular events in more than 15,000 at-risk patients. The trial started in September 2002.
- The ACTIVE trial in patients with atrial fibrillation, will start in April 2003, with a planned enrollment of 15,000 patients.

A pediatric indication is in development following a written request from the FDA, and will permit a six-month extension of patent protection in the U.S. for all indications of Plavix®.

Finally, a product filing for clopidogrel, developed in partnership with Daiichi, is scheduled to be submitted in Japan at the end of 2003.

## Aprovel®

### *irbesartan*

In addition to its development in hypertension, the post-launch clinical development of irbesartan has been focused on demonstrating its protective effect on target organs: the kidneys, the heart, the blood vessels and the brain. This strategy's originality rests on designing and implementing innovative studies for diseases which are either insufficiently explored or for which there exists an unsatisfied medical need.

- The PRIME program has shown the renal protective effect of irbesartan in early and late stages of diabetic renal disease.
- The I-PRESERVE study explores the benefits of irbesartan treatment in heart failure patients with preserved systolic function.
- The ACTIVE-i study will explore the potentially beneficial effects of irbesartan in atrial fibrillation as well as the overall protection of the cardiovascular system.

## Arixtra®

### *fondaparinux sodium*

### **Prevention of deep-vein thrombosis and pulmonary embolism**

Marketed in Europe and the U.S

Deep-vein thrombosis (DVT) results from three types of risk: coagulation factor abnormalities, vascular injuries and increase in venous stasis, notably during prolonged immobilization. They most frequently occur in the lower limbs. The risk is highest after major orthopedic surgery: in 40% to 50% of patients undergoing elective hip replacement, and in 70% to 80% of those undergoing total knee replacement. The chief complication of DVT is the migration of blood clots located in the lower limbs to the lungs, where they trigger pulmonary embolism (PE), a potential cause of sudden death.

DVT and PE are therefore two expressions of a single disease, venous thromboembolism (VTE). The third most frequent cardiovascular disease after myocardial infarction and stroke, VTE has an annual incidence of between 2 and 3 per 1,000 inhabitants of western countries. Every year, VTE affects approximately two million Americans, of whom at least 60,000 die as a result of pulmonary embolism. VTE represents an annual cost of at least 2.9 billion dollars in the U.S. alone.

An original compound co-developed by Sanofi-Synthélabo and Organon (Akzo Nobel), Arixtra<sup>®</sup> (fondaparinux sodium) is the first entirely synthetic agent selectively inhibiting a key enzyme in the coagulation process, factor Xa. In contrast, other available treatments, low molecular weight heparins (LMWH) and unfractionated heparin (UFH), are of animal origin as they are obtained from the intestinal mucosa of pigs, and act on multiple targets in the cascade of reactions involved in coagulation.

The synthetic origin of Arixtra<sup>®</sup> and its selectivity of action ensure a high degree of purity and safety of use. In view of these two characteristics, it constitutes a real technological and therapeutic advance.

#### **Arixtra<sup>®</sup> in the prophylaxis of venous thromboembolism**

Arixtra<sup>®</sup> has been extensively investigated in the prophylaxis of VTE following major orthopedic surgery on the lower limbs. In the four phase III trials conducted in patients undergoing reconstructive surgery after hip fracture or surgery for hip or knee replacement, Arixtra<sup>®</sup> achieved a significant overall reduction of more than 55% ( $p < 0.001$ ) in the rate of venous thromboembolic events, with a safety profile similar to that the reference low molecular weight heparin.

A double-blind trial versus placebo conducted recently in prolonged prophylaxis in patients undergoing hip fracture showed that Arixtra<sup>®</sup>, administered for four weeks, resulted in a reduction of 96% in the incidence of thromboembolic complications ( $p < 0.001$ ), combined with very good tolerability. These results formed the basis for an extension of indication filing in Europe and in U.S. in December 2002.

#### **Arixtra<sup>®</sup> in the curative treatment of venous thromboembolism**

Currently, the initial treatment of patients presenting a documented DVT consists in the subcutaneous administration of LMWH at a dose adapted to body weight, usually as two daily injections for approximately two weeks. In patients with PE, the initial treatment remains the intravenous administration of unfractionated heparin at an adjusted dose for the same duration. In both these conditions, it is essential to administer a potent and rapidly acting antithrombotic during the acute phase, followed by a treatment with vitamin K antagonist for 3 to 6 months as secondary prophylaxis.

## MEDICINES

### our portfolio gets stronger and stronger

For methodological reasons, DVT and PE are studied separately in clinical trials, but certain patients can suffer from both disorders simultaneously. No currently available product is capable of effectively and safely treating both conditions with the same dosage regimen.

The MATISSE clinical trial program conducted by Sanofi-Synthélabo and Organon on 4,400 patients with DVT or PE was completed in 2002. The results of the MATISSE trials represent a new advance in the demonstration of the efficacy and safety of Arixtra<sup>®</sup>. Administered subcutaneously once daily at a fixed dose (7.5 mg), Arixtra<sup>®</sup> is at least as effective and well tolerated as treatments usually employed in the initial therapy of DVT and PE, besides being easier to use. A filing for these new indications will be submitted to health authorities in 2003 on the basis of the results of the MATISSE trials.

#### Arixtra<sup>®</sup>: other ongoing developments

The clinical development program for Arixtra<sup>®</sup> is continuing in the prophylaxis of VTE in general surgery (PEGASUS and APOLLO trials) and in medical patients (ARTEMIS trial). The results of these studies are expected in 2003.

A large-scale clinical program in arterial thrombosis is in preparation, with over 25,000 patients planned. It will be focused on the prevention of cardio-ischemic complications in patients presenting an acute coronary syndrome. These clinical trials will be initiated in 2003.

#### zolpidem MR

#### Sleep disorders

##### Phase III

Although numerous effective hypnotic treatments are currently available on the market, led by Sanofi-Synthélabo's Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup> (zolpidem), they do not meet the expectations of all insomniac patients. The problems of falling asleep and the quality of awakening are satisfactorily addressed, but providing the patient taking zolpidem with an even more restorative sleep for the second half of the night is still an issue. With this in mind, Sanofi-Synthélabo has developed a formulation allowing the progressive release of zolpidem in the organism - zolpidem MR - which diminishes the duration and number of awakenings during the second half of the night without increasing residual sedative effects when the patient awakes, a major advantage of zolpidem.

Two Phase III trials are ongoing, one in adults under 65 years for which enrollment is completed and one in elderly subjects. These trials are evaluating the hypnotic properties of zolpidem MR, particularly with regard to sleep maintenance. This Phase III program is completed, among other trials, by two studies designed to demonstrate the absence of residual effects on awakening. The patent protecting the specific dissolution profile of zolpidem MR was obtained on February 4, 2003 in the U.S. Sanofi-Synthélabo's objective is to submit the product filing for zolpidem MR in the second quarter of 2004, in the U.S. and then in Europe, i.e. 18 months before the patent protecting the active ingredient of Ambien® falls into the public domain in the U.S.

50

Medicines

**Xatral®**

*alfuzosin*

**Benign prostatic hyperplasia (BPH) and acute urinary retention (AUR)**

Marketed in Europe; product filing submitted in the U.S. for BPH

**Benign prostatic hyperplasia**

Xatral®, is marketed in this indication in Europe, and a new drug application (NDA) has been submitted in the U.S. Clinical development in benign prostatic hyperplasia will be started in Japan in March 2003.

**Acute urinary retention**

Acute urinary retention is a frequent and severe complication of benign prostatic hyperplasia, generally culminating in surgery, the complications of which are all the more frequent in that the operation is often performed as an emergency. A clinical development program has been implemented in Europe and the U.S. to assess the therapeutic value of Xatral®, in the long-term prevention of an initial episode of acute urinary retention in patients with benign prostatic hyperplasia of an acute episode in conjunction with urinary drainage.

**Eloxatin®**

*oxaliplatin*

**Metastatic colorectal cancer**

Marketed

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

In 2002, Eloxatin® was granted a product license in the U.S. for the second-line treatment of patients with metastatic colorectal cancer.

The results of a clinical trial studying the efficacy of oxaliplatin in association with 5-FU in the first-line treatment of colorectal cancer were presented at the congress of the American Society of Clinical Oncology (ASCO) in 2002. This trial demonstrated a survival advantage ( $p < 0.002$ ) in patients treated with oxaliplatin + 5-FU, in comparison to those receiving the reference treatment, irinotecan + 5-FU.

These results will be submitted to the FDA in 2003 in support of a supplementary new drug application (SNDA) for Eloxatin® in the U.S.

The Arixtra® syringe was awarded the User safety prize in 2003.

51

Medicines

## GLOBAL DEVELOPMENT

### strong international presence

Spurred by the quality of medicines coming from its research, Sanofi-Synthélabo continues to strengthen its international presence and gain market share throughout the world.

This performance is represented by double-digit growth in both consolidated and developed sales, up by 12.8%<sup>(1)</sup> and 14.5%<sup>(1)</sup> respectively, confirming the trend established in recent years.

Key events in 2002

+17.5%<sup>(1)</sup> in the United States

+11.8%<sup>(1)</sup> in Europe

+10.3%<sup>(1)</sup> in other countries

Growth in consolidated sales reached double digits in all major areas.

All regions grew more rapidly than their respective markets.

The United States, the world's leading pharmaceutical market worldwide, generated 37% of developed sales and 45% of the Group's profits

Sanofi-Synthélabo is intensifying its efforts in Japan, the second leading pharmaceutical market worldwide, to derive full benefit from its partnerships and to strengthen its direct presence.

---

(1) Growth based on comparable group structure and at constant exchange rates.



## Sales figures by geographic area in 2002

Consolidated sales				
	(in millions of euros)	Variation <sup>(1)</sup>	Market share <sup>(2)</sup>	Main product launches
				in 2002
<b>Europe including:</b>	<b>4 297</b>	<b>+11.8%</b>	<b>3.9%</b> <sup>(3)</sup>	
France	1 546	+8.0%	7.9%	Fasturtec <sup>®</sup> , Arixtra <sup>®</sup>
Germany	634	+7.0%	2.9%	Arixtra <sup>®</sup>
Italy	444	+3.6%	2.9%	Fasturtec <sup>®</sup> , Plavix <sup>®</sup>
Spain	358	+21.7%	2.9%	Solian <sup>®</sup> , Fasturtec <sup>®</sup>
United Kingdom	287	+7.9%	2.9%	Arixtra <sup>®</sup> , Fasturtec <sup>®</sup>
Belgium	163	+21.9%	5.1%	Fasturtec <sup>®</sup> , Solian <sup>®</sup> , Fraxodi <sup>®</sup>
Hungary	101	+23.7%	6.4%	
Greece	100	+37.8%	3.9%	Arixtra <sup>®</sup> , Solian <sup>®</sup>
Turkey	98	+41.5%	2.5%	Xatral OD <sup>®</sup>
Switzerland	92	+18.8%	3.8%	Arixtra <sup>®</sup> , Fasturtec <sup>®</sup>
Scandinavia	91	+24.3%	1.5%	Arixtra <sup>®</sup> (Sweden, Finland, Norway and Denmark) Solian <sup>®</sup> (Denmark)
Portugal	88	+12.6%	3.7%	Arixtra <sup>®</sup>
Poland	82	+15.7%	2.7%	
Netherlands	69	+26.6%	2.2%	Arixtra <sup>®</sup>
Czech Republic	41	+15.8%	3.8%	Fasturtec <sup>®</sup>
Austria	35	+19.9%	1.8%	Arixtra <sup>®</sup>
<b>United States</b>	<b>1 689</b>	<b>+17.5%</b>	<b>1.8%</b> <sup>(6)</sup>	Arixtra <sup>®</sup> , Eloxatin <sup>®</sup> , Eligard <sup>®</sup> , Elitek <sup>®</sup>
<b>Other countries including:</b>	<b>1462</b>	<b>+10.3%</b>		
Asia/Middle East	423	+27.0%		Solian <sup>®</sup> , Arixtra <sup>®</sup> (Australia)
Latin America	327	+3.6%	1.9%	Solian <sup>®</sup> , Xatral <sup>®</sup> OD (South Korea) Arixtra <sup>®</sup> (Mexico and Colombia)
Japan	312	-0.7%		
Africa	200	+6.5%		
Eastern and Central Europe	116	+7.3%		

(1) Growth based on comparable group structure and at constant exchange rates

(2) Sources IMS/GERS, 12-month Moving Annual Total December 2002

(3) 18 countries, retail market (excluding Czech Republic, Denmark, Sweden and Finland)

(4) IMS data adjusted to reallocate parallel imports to the company of origin

(5) Excluding Finland

(6) Determined on a basis of sales consolidated by Sanofi-Synthelabo and those generated through alliances in the U.S.

(7) Argentina, Brazil, Chile, Colombia, Mexico, Peru, Venezuela

Sales, market shares and growth in IMS/GERS data mentioned in the text of this Report on pages 53 to 63, correspond to annual figures at end December 2002 at constant exchange rates, valued at direct from manufacturer prices

## GLOBAL DEVELOPMENT

### strong international presence

#### EUROPE

Consolidated sales: 4,297 million euros

#### Growth in sales

Source: IMS/GERS 12-month Moving Annual Total December 2002

#### Consolidated sales and growth in millions of euros

Source: Sanofi-Synthélabo 2001 sales figures and growth on a comparable basis

All European countries, with varying degrees of intensity and resources, are committed to a policy of curbing healthcare expenditure. In 2002, the regulatory environment was strengthened noticeably in two principal markets. In Italy, cost-containment measures introduced in September 2001 exerted their full effect in 2002 and were accompanied in April by a 5% cut in all medicine prices. In Germany, retail pharmacists were authorized to substitute up to 5.5% of their sales with products imported from countries with lower prices. The net result of these measures was a decrease in prices.

Driven by the 15 leading products in the portfolio, which showed growth of 17%, consolidated sales by Sanofi-Synthélabo progressed by 12% to reach 4,297 million euros. The Group gained market share in all countries except Italy. A sustained effort with regard to patented products enabled most affiliates to achieve a growth rate exceeding that of their respective markets. Affiliates in the United Kingdom, Denmark, Finland, Turkey, Austria and Slovakia progressed twice as fast as their markets, while those in Belgium, Poland, Switzerland, Sweden, Norway, and the Netherlands outpaced the market by a factor of three or more.

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

Recently introduced products showed strong growth. Sales of Plavix<sup>®</sup> rose by 50%<sup>(1)</sup> without any increase in price. Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup> (irbesartan) became the second ranking product in its class and the leading antihypertensive in France.

The ongoing launches of Fasturtec<sup>®</sup> and Arixtra<sup>®</sup>, both high technology products, herald promising results in the coming months, though they did not significantly affect performance in 2002.

(1) Source IMS 12-month Moving Annual Total December 2002: 16 European countries, hospital and retail

### France

**Consolidated sales: 1,546 million euros**

*Growth: +8.0%*

**Market share: 7.9%**

Product launches in 2002: Fasturtec<sup>®</sup>, Arixtra<sup>®</sup>

The second half of the year was marked by a sharp acceleration in the prescription of generics by physicians or their substitution by pharmacists. In addition, the law on social security system financing, passed in autumn 2002 for the year 2003, represents a break with the previous legal framework. It schedules the introduction of a system of reference prices for medicines likely to be subject to generic competition, and envisages the progressive cessation of reimbursement of medicines which have insufficient medical benefit. The positive aspect of these measures is that they include mechanisms to facilitate market access for innovative products, which are currently being implemented. The law banks on a provisional increase in health insurance expenditure of 5.3% in 2003, compared to 3% in 2002.

Sanofi-Synthelabo sales growth in France (source: GERS) exceeded that of the market, with contrasting progression by activity:

- sales of ethical products, representing over 80% of total sales, progressed slightly faster than those of the affiliate's other activities, notably boosted by sales of the flagship products Plavix<sup>®</sup>, Aprovel<sup>®</sup>/Co-Aprovel<sup>®</sup> and Eloxatine<sup>®</sup>,

- retail sales of generics progressed at the same rate as those of the affiliate as a whole, whereas hospital generic sales progressed twice as fast. These performances were in line with the overall market development,
- consumer health (OTC) sales stagnated in the context of a national market in regression.

Within the ethical sector, the following points are noteworthy:

- extremely rapid progression of the Cardiovascular portfolio, driven by Plavix® and Aprovel®, counterbalanced by a regression of older products subjected to generic pressure. Plavix® and Aprovel®, are promoted jointly with Bristol-Myers Squibb but all sales are registered by Sanofi-Synthélabo. Plavix® is continuing to progress very rapidly. Aprovel® became leader of the angiotensin II receptor antagonist class in the summer and is also the leading medicine in the antihypertensive market as a whole in terms of market share,
- vigorous growth of the Oncology portfolio, stimulated by the progression of Eloxatine®. The initial results of the launch of Fasturtec® were positive. In contrast, the regression of Maxomat® was disappointing,
- limited progression of the Central Nervous System portfolio due to loss of momentum in much of the product range, despite the significant increase in sales of its leading products: Solian®, Stilnox® and Depakine®/Depakote®.
- similar slowdown in the Internal Medicine portfolio, despite the performances of Xatral® and Inipomp, which achieved remarkable progression,
- finally, regression of the Thrombosis portfolio, pending the expected renewal of growth from Arixtra® (launched in December 2002).

## Germany

**Consolidated sales: 634 million euros**

*Growth: +7.0%*

**Market share: 2.9%**

Product launch in 2002: Arixtra®

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

Major decisions designed to curb healthcare expenditure were taken in Germany in 2002: it was recommended that pharmacists make up to 5.5% of total pharmaceutical sales from parallel imported products and they were authorized to substitute generics for medicinal products which are no longer under patent protection. The latter measure affected important products such as Depakine® and Cordarone®, as well as Stilnox®, for which patent protection expired in 2001 in Germany. In this challenging context, the affiliate nevertheless posted growth slightly exceeding that of its market, if parallel imports are included. This result was due to the success of strategic products such as Plavix®, Eloxatin®, Aprovel® and Uroxatral®, which progressed very strongly.

### Italy

**Consolidated sales: 444 million euros**

*Growth: +3.6%*

**Market share: 2.9%**

Product launches in 2002: Fasturtec®, Plavix®

The Italian market was greatly penalized by a series of decisions taken by the health authorities to reduce healthcare expenditure:

- right of generic substitution of non-patented products. Enacted in September 2001, this measure affected the sales of Ticlid®, Tildiem®, Deursil® and Sucralfin®,
- overall 5% price cut in April 2002,
- implementation of a decentralized policy giving regions a discretionary role with regard to the reimbursement and distribution of medicinal products,
- withdrawal of reimbursable status for Deniban® (amisulpride),
- hospital resale to the public of certain products purchased by hospital pharmacies.

## GLOBAL DEVELOPMENT

### strong international presence

Plavix<sup>®</sup>, launched in 2002, is not yet reimbursed. Negotiations have been resumed with the health authorities on the basis of the new indication of Plavix<sup>®</sup> for acute coronary syndrome, obtained at the European level. A final decision is expected in 2003.

The very good performance of the leading medicines Aprovel<sup>®</sup>, Eloxatin<sup>®</sup>, Fraxiparine<sup>®</sup>, Xatral<sup>®</sup> and Stilnox<sup>®</sup> nevertheless enabled the affiliate to maintain its positions.

Information systems user support team.

### Spain

**Consolidated sales: 358 million euros**

*Growth: +21.7%*

**Market share: 2.9%**

Product launches in 2002: Solian<sup>®</sup>, Fasturtec<sup>®</sup>

Due to parallel exports, the growth in consolidated sales does not fully reflect the performance achieved nationally. Domestic sales progressed by 12% (source: IMS), in an internal market expanding by 10%. Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Eloxatin<sup>®</sup> achieved excellent performances. In contrast, the loss of patent protection of Stilnox<sup>®</sup> adversely affected the performance of this product.

Solian<sup>®</sup>, launched in May 2002, and Arixtra<sup>®</sup>, launched in February 2003, were both granted the status of reimbursable products. Seven months after its launch, Solian<sup>®</sup> achieved 5% market share.

## United Kingdom

**Consolidated sales: 287 million euros**

*Growth: +7.9%*

**Market share: 2.9%**

Product launches in 2002: Arixtra<sup>®</sup>, Fasturtec<sup>®</sup>

The dramatic development of parallel imports in the United Kingdom necessitates differentiation between the affiliate's own sales and those of Sanofi-Synthelabo products within the country. For example, an estimated 85% of Aprovel<sup>®</sup> sales and 60% of Plavix<sup>®</sup> sales came from parallel imports in 2002.

On the basis of IMS data, sales in the U.K. continued to grow considerably faster than the market: 22% versus 10%. This progress was driven by four major products, Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Eloxatin<sup>®</sup> and Xatral<sup>®</sup>.

The highly favorable opinions issued by the National Institute for Clinical Excellence (NICE) on Eloxatin<sup>®</sup> and Solian<sup>®</sup> are noteworthy. This official recommendation from one of the national authorities should benefit prescriptions in 2003.

## Belgium

**Consolidated sales: 163 million euros**

*Growth: +21.9%*

**Market share: 5.1%**

Product launches in 2002: Fasturtec<sup>®</sup>, Solian<sup>®</sup>, Fraxodi<sup>®</sup>

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

After implementing a reference price system in June 2001, the Belgian health authorities once again penalized products no longer protected by patents by diminishing their reimbursement rate. Tildiem® 60 mg (the non-delayed release form), Ticlid®, Dogmatil® and Cordarone® were among the products affected.

The Belgian affiliate nevertheless achieved an excellent performance, driven by the success of Plavix® and Aprovel®. Aprovel® is now the leading AIIRA with a 26% market share. In contrast, sales of Stilnox® were slowed by the introduction of generics.

Recent launches provided further growth. Fraxodi® effectively strengthened sales of Fraxiparine®. Eloxatin® got off to a very good start in its first year of reimbursement and Solian® captured a 7% market share in the fourth quarter of 2002.



## Hungary

**Consolidated sales: 101 million euros**

*Growth: +23.7%*

**Market share: 6.4%**

The change in government postponed until 2003 the second stage of price increases for products with high sales volumes and low prices, which was initially scheduled for mid-2002.

The portfolio as a whole generated sales growth slightly exceeding that of the market. The key event this year was the acquisition of a new manufacturing facility in Veres, with a capacity of 40 million units. This site increased the Group's industrial capacity in Hungary to 100 million units. This expansion will enable the production of Aprovel<sup>®</sup>, Fraxiparine<sup>®</sup> and the first batches of Arixtra<sup>®</sup>.

A team in the Impact Malaria project.

## Greece

**Consolidated sales: 100 million euros**

*Growth: +37.8%*

**Market share: 3.9%**

Product launches in 2002: Arixtra<sup>®</sup>, Solian<sup>®</sup>

In Greece, the introduction of new compounds remains challenging. Concerned with reducing healthcare expenditure, the health authorities continue to align prices with the lowest found within the European Union, and the time taken to grant reimbursable status to new compounds is particularly long.

The affiliate overcame these obstacles, thanks to the therapeutic advantages of the products launched over the last three years, and to highly focused marketing efforts. Sales progressed faster than the market.

Aprovel<sup>®</sup> has become the leading product in its category and has the second highest market share of all anti-hypertensives. Plavix<sup>®</sup> sales have doubled. Eloxatin<sup>®</sup> is already used by half of the patients suffering from colorectal cancer, even though it is not yet reimbursed. Fasturtec<sup>®</sup>, in the year of its launch, attained a high rate of penetration in pediatric cancer treatment centers. Stilnox<sup>®</sup> has a 60% market share and Xatral<sup>®</sup> has 19%.

## Turkey

**Consolidated sales: 98 million euros**

*Growth: +41.5%*

**Market share: 2.5%**

Product launch in 2002: Xatral<sup>®</sup> OD

The Turkish market was affected in 2002 by 30% inflation in retail prices and substantial delays in payments by the Social Security system. Despite these challenges, the affiliate flourished during this year, with sales growing more than twice as fast as the market. This result was principally due to Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Fraxiparine<sup>®</sup>.

## GLOBAL DEVELOPMENT

### strong international presence

#### Switzerland

**Consolidated sales: 92 million euros**

*Growth: +18.8%*

**Market share: 3.8%**

Product launches in 2002: Arixtra<sup>®</sup>, Fasturtec<sup>®</sup>

A new law considerably modified conditions for the distribution of medicines in 2002, with regard to both hospital and retail sectors. Products with high added value such as Arixtra<sup>®</sup> should benefit from the new system. On the other hand, retail pharmacists are now authorized to substitute generics for branded products.

The success of Aprovel<sup>®</sup>, leader in the AIIRA market, and of Plavix<sup>®</sup> substantially enhanced the results of the Swiss affiliate. Eloxatin<sup>®</sup> and Stilnox<sup>®</sup>, leaders in their respective markets in terms of market share, as well as Xatral Uno<sup>®</sup>, also contributed.

For the second year running, the affiliate achieved the strongest growth among the top ten pharmaceutical companies, achieving a growth 3.5 times greater than that of the market.

#### Scandinavia

**Consolidated sales: 91 million euros**

*Growth: +24.3%*

**Market share: 1.5% (excluding Finland)**

Product launches in 2002: Arixtra® in Sweden, Finland,  
Norway and Denmark,  
Solian® in Denmark

2002 was a good year in all Scandinavian countries, with rapid progression of sales, exceeding market growth by a factor of two to three.

- **in Sweden**, a new system implemented in October 2002 separated pricing policy from the reimbursement process. This system also makes generic substitution compulsory. The affiliate's performance was driven by the major medicines Plavix®, Aprovel®, Xatral® and Stilnoct®, despite their already high market shares.
- **in Finland**, there was a trend towards increased use of recently introduced medicines. Xatral® once daily, launched in 2001, benefited from this trend, its sales doubling within a year. Sales of Plavix® remained modest, pending approval of reimbursement in its new indications.
- **in Norway**, where the use of new medicines continues to progress, sales posted a sharp increase thanks to Aprovel®, second in its market, Plavix®, despite limited reimbursement, and Eloxatin®.
- **in Denmark**, recovery of the affiliate was confirmed. Aprovel®, Plavix®, Xatral® and Stilnoct® all showed substantial growth rates.

**Portugal**

**Consolidated sales: 88 million euros**

*Growth: +12.6%*

**Market share: 3.7%**

Product launch in 2002: Arixtra®

In February 2002, the price of Aprovel® was reduced by 7%. Portugal is preparing to adopt a reference price system in 2003.

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

The year 2002 was nevertheless satisfactory, with sales growth exceeding market expansion by three points (IMS). Sales of Aprovel<sup>®</sup>, Eloxatin<sup>®</sup> and Xatral<sup>®</sup> progressed steadily. With almost 23% of the AIIRA market, Aprovel<sup>®</sup> was the second-ranking product in its category in December, and in third position among antihypertensive treatments as a whole.

The granting of the acute coronary syndrome indication for Plavix<sup>®</sup> at European level permitted resumption of negotiations for its reimbursement, with hope of success in 2003.

58

Global Development

## Poland

**Consolidated sales: 82 million euros**

*Growth: +15.7%*

**Market share: 2.7%**

With the prospect of entry into the European Union, Poland implemented a new law in October 2002 concerning marketing approval, pricing, reimbursement and the promotion of medicines.

However, the reimbursement of innovative medicines, blocked since 1998, has still not been included in these new regulations.

As a result, the affiliate was still without the most recent compounds and concentrated its efforts on the other products in the portfolio. Fraxiparine<sup>®</sup>, boosted by the launch of Fraxodi<sup>®</sup>, Depakine<sup>®</sup>, Xatral<sup>®</sup> and Stilnox<sup>®</sup> all progressed strongly.

Medical marketing team, Latin America.

## Netherlands

**Consolidated sales: 69 million euros**

*Growth: +26.6%*

**Market share: 2.2%**

Product launch in 2002: Arixtra<sup>®</sup>

Aprovel<sup>®</sup> continued to lead the portfolio, attaining a market share of 20.5% by December 2002. Partially reimbursable since 2001, Plavix<sup>®</sup> achieved rapidly accelerating sales. Eloxatin<sup>®</sup> tripled its sales and Xatral<sup>®</sup> OD was also a success.

## Czech Republic

**Consolidated sales: 41 million euros**

*Growth: +15.8%*

**Market share: 3.8%**

Product launch in 2002: Fasturtec<sup>®</sup>

The Czech Republic faced a difficult and competitive environment, including pressure on reimbursement levels for Solian<sup>®</sup> and Deniban<sup>®</sup>, which will take effect in 2003. Despite these challenges, the affiliate succeeded in maintaining an overall growth rate slightly higher than that of its market. Fraxiparine<sup>®</sup>, Eloxatin<sup>®</sup>, Depakine<sup>®</sup> and Stilnox<sup>®</sup> progressed strongly.

## Austria

**Consolidated sales: 35 million euros**

*Growth: +19.9%*

**Market share: 1.8%**

Product launch in 2002: Arixtra<sup>®</sup>

Since October 1st, 2002, medicine reimbursement has been determined on the basis of pharmacological, medical and economic criteria. If necessary, pharmaceutical companies can appeal against decisions to a special independent commission.

Plavix<sup>®</sup>, Eloxatin<sup>®</sup> and Fraxiparine<sup>®</sup> boosted the affiliate s sales growth to twice that of the market.



---

## GLOBAL DEVELOPMENT

### strong international presence

#### UNITED STATES

**Consolidated sales: 1,689 million euros**

*Developed sales: 3,505 million euros*

**Product launches in 2002: Arixtra<sup>®</sup>, Eloxatin<sup>®</sup>, Eligard<sup>®</sup>, Elitek<sup>®</sup>**

#### Sales growth

- 
- (1) Sales generated directly by Sanofi-Synthélabo in the U.S.  
(Source: IMS, 12-month Moving Annual Total December 2002)
  - (2) Sales generated directly by Sanofi-Synthélabo and through alliances in the U.S.  
(Source: IMS, 12-month Moving Annual Total December 2002)

#### Sales in millions of euros

(Source: Sanofi-Synthélabo, 2001 sales and variations on a comparable basis)

Despite slowing growth relative to 2001, the U.S. market continued its expansion in 2002 (+12%). Sanofi-Synthelabo continued to outperform the market, with growth of 32% in developed sales (IMS November 2001, calculated on the basis of four weeks sales).

In 2002, the budgetary repercussions of the slowing U.S. economy led to a major debate on health care expenditure in the U.S. in 2002. The different states, partially responsible for managing the Medicaid and Medicare programs, all strengthened their pressure on medicine prices, with requests for rebates, higher co-payments and the creation of a preferred medicines status. Private insurance organizations also continued to exert pressure on prices. Also in 2002, increasing promotional restrictions have come

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

into effect through recommendations from the Pharmaceutical Research and Manufacturers of America (PhRMA).

The Group's products are marketed in various ways:

- by the affiliate, Sanofi-Synthelabo Inc.,
- through an alliance with Bristol-Myers Squibb for Plavix® and Avapro®
- these sales are not consolidated by Sanofi-Synthelabo,
- through a 50-50 alliance with Organon for Arixtra®,
- through licensing agreements, for Cordarone®, Depakine® and Ticlid®, among others.

In 2002, both consolidated and developed sales showed a progression of 18%. This performance was achieved despite the decision of our partner Bristol-Myers Squibb to reduce wholesalers' stocks of Plavix® and Avapro®, and the arrival of generics due to the expiry of Primacor® patent protection. It also reflects the initial effects of the 100% reacquisition of rights to Ambien® in April 2002 and the subsequent marketing efforts. Developed sales of Ambien® progressed by 27% to 1,208 million euros. In total, the U.S. currently accounts for almost a quarter of the Group's worldwide consolidated sales and over a third of its developed sales.

Flagship products were clearly the principal driving force for growth. Despite the stock-reducing operation mentioned above, developed sales of Plavix® increased by 23% to 1,565 million euros, while those of Avapro® remained at the same level as last year at 373 million euros. Prescriptions of these two products increased by 33% and 13% respectively\*. Plavix® benefited from the extension of its indication to acute coronary syndrome, on the basis of the CURE trial, and Avapro® from the approval of its supplementary new drug application (SNDA) for the renal protection of hypertensive patients suffering from diabetes, on the basis of the PRIME program. The attack on the patent protecting Plavix® by two generic companies was met by a vigorous counterattack launched jointly by Sanofi-Synthelabo and Bristol-Myers Squibb.

---

\* IMS NPA plus, 12-month Moving Annual Total December 2002.

Arixtra<sup>®</sup> was launched in February through a 50/50 alliance with Organon. Despite an extremely complex and challenging environment, this product was successfully introduced into a significant number of hospital formularies.

The year 2002 ended on a very positive note, with sales of 116 million euros attained by Eloxatin<sup>®</sup> only four months after its launch for the second-line treatment of colorectal cancer. Sanofi-Synthelabo was also granted a product license for two presentations of Eligard<sup>®</sup> for the treatment of advanced prostate cancer (under license from Arix) as well as a marketing approval for Elitek<sup>®</sup> in the treatment of chemotherapy-related hyperuricemia in children. Both these products were launched in 2002.

## OTHER COUNTRIES

**Consolidated sales: 1,462 million euros**

### Asia/Middle East

**Consolidated sales: 423 million euros**

*Growth: +27.0%*

Product launches in 2002: Solian<sup>®</sup> and Arixtra<sup>®</sup>  
in Australia,

Solian<sup>®</sup> and Xatral<sup>®</sup>

in South Korea,

Supported by Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Stilnox<sup>®</sup>, Eloxatin<sup>®</sup> and Xatral<sup>®</sup>, sales growth in the Asia-Pacific region continued at a rapid rate, significantly higher than that of the different markets, particularly in Australia and South Korea. This result is all the more impressive in that it was achieved in a context of healthcare cost containment, notably in Hong Kong.

Sanofi-Synthelabo increased its presence in the region. An affiliate was created in Indonesia in partnership with Combiphar, and the Group took a 100% stake in its affiliate in India.

- **In Australia**, sales reached 97 million euros (+29%). The affiliate registered the strongest growth in the market.

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

- **In Taiwan**, sales totaled 44 million euros. The growth of Plavix® and Aprovel®, now on the formularies of almost all medical centers, was very strong. Growth of Stilnox® and Eloxatin® was curbed by generic competition. Marketing and medical teams were strengthened..
- **In South Korea**, a strategic market, sales increased by 61.9% to 72 million euros, despite the policy of restricting healthcare expenditure. The market share of the affiliate more than doubled. The Group is examining opportunities for external growth.
- **In the Philippines**, sales reached 41 million euros (+18%). Lactacyd®, a consumer health (OTC) product, remained the affiliate's leading product.
- **In China**, the policy of healthcare cost restriction is continuing, strengthened by a fall in the price of generics. With sales of 39 million euros (+18%), the Group is now established in this country.
- **In the Middle East**, the Group's activity is progressing strongly, principally in Saudi Arabia. Total sales reached 65 million euros (+31%). A scientific unit was set up in Egypt to strengthen the Group's presence in this major market.

### Latin America

**Consolidated sales: 327 million euros**

*Growth: +3.6%*

Product launches in 2002: Arixtra® in Mexico and Colombia

This region of the world experienced a series of major crises in 2002, affecting Argentina, Brazil and Venezuela successively. All currencies lost value relative to the euro. Foreseeing the consequences of this unfavorable economic situation and concerned with protecting its profitability, the Group chose to reduce the stocks of its products held by wholesalers in Mexico and Brazil.

In the region as a whole, the growth in sales according to IMS data increased by 16%, exceeding market growth (+13%) by three points.

## GLOBAL DEVELOPMENT

### strong international presence

The following four countries accounted for more than 80% of the total sales of the region.

- **In Mexico**, after a very strong progression in 2001, sales of the affiliate were stable at 111 million euros, due to the reduction in stocks, and did not reflect the increased market growth of our products (+17% IMS). Arixtra<sup>®</sup> was launched in the second half of 2002, in partnership with Organon.
- **In Brazil**, the affiliate's sales were stable for the same reason, remaining at 88 million euros, whereas the market progression of our products was +11% (IMS), a performance in line with overall market growth.
- **In Colombia**, the affiliate strengthened its presence in an expanding market. Sales reached 44 million euros (+11%) and the year 2002 saw the launch of Arixtra<sup>®</sup>.
- **In Venezuela**, the very strong progression in sales to 22 million euros permitted gains in market share.

### Japan

#### Consolidated growth: 312 million euros

*Growth: -0.7%*

In a challenging operating environment, characterized by a sluggish market, the affiliate posted growth of 9%, not counting the licensing-out of Panaldine<sup>®</sup> (ticlopidine) to Daiichi.

This performance was attained thanks to a range of initiatives that are already bearing fruit. Launched at the end of 2000, the hypnotic Myslee<sup>®</sup> (zolpidem), marketed in partnership with Fujisawa, achieved sales of 62 million euros in 2002 (IMS) and held an 18.5% market share by the end of the year. Myslee<sup>®</sup> has already become the second leading treatment in its category and should become the market leader in 2003 or early 2004.

At the same time, Sanofi-Synthelabo is actively pursuing its strategy of development in Japan, the world's second largest pharmaceutical market. This goal is being met in several ways: the Group is strongly reinforcing existing joint ventures and optimizing their management, while preparing for a direct presence and continuing to closely examine all opportunities for external growth.

Product license applications are being submitted in rapid succession: the submission of an application for irbesartan in the fourth quarter of 2002 will be followed by those for clopidogrel in 2003 and fondaparinux sodium in early 2004. To enhance the Group's profile and to draw the attention of prescribers to its products, the development of local clinical trials is being intensified: patient enrollment for a Phase III trial on clopidogrel in stroke is now complete; patient enrollment for two Phase IIb trials on fondaparinux sodium is progressing on schedule; Phase I trials on rasburicase have been completed, and Phase II trials on rimonabant and dronedarone have started.

Consumer health customer service.

62

Global Development

## Africa

**Consolidated sales: 200 million euros**

*Growth: +6.5%*

Overall growth in Africa masked contrasting situations among the different countries.

- **In Algeria**, consolidated sales reached 52 million euros, up by 14%.
- **In Morocco**, overall sales amounted to 80 million euros, a growth rate of 2%.
- **In Tunisia**, business activity progressed appreciably in parallel with market growth to attain sales of 15 million euros.
- **South Africa** maintained its impetus with a 20% increase in sales, still driven by the very good performances of Stilnox<sup>®</sup>, Plavix<sup>®</sup> and Depakine<sup>®</sup>. Taking into account the negative impact of the devaluation of the rand, net sales were slightly down at 20 million euros.
- **In other African countries**, business activity was slowed by political instability and economic disruptions affecting several countries within this zone. Sales amounted to 33 million euros, representing very slight growth, notably due to opening of new markets in East Africa.

## Central and Eastern Europe

**Consolidated sales: 116 million euros**

*Growth: +7.3%*

In contrast to other Eastern European countries, sales in **Russia** were flat. The Russian market was disrupted by the imposition of VAT on pharmaceutical products and the introduction of a new certification system. Despite sustained growth of the flagship products, overall development of activity was curbed by the stabilization of sales of No-Spa<sup>®</sup>, which remains the leading product both for the affiliate and in the Russian market.

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

The overall situation in **Romania** remains precarious in view of the size of the national debt and the chronic delays in payments to hospitals by social security systems, affecting distribution. The affiliate experienced strong growth, notably due to Plavix<sup>®</sup>, recommended in the context of a national program to combat stroke.

In the **Baltic countries**, growth slowed as a result of economic difficulties affecting social security systems. In **Lithuania**, the development of Plavix<sup>®</sup> sales suffered from the introduction of prescription quotas affecting the medical community. In **Latvia**, the bankruptcy of the Health Insurance Fund had severe repercussions on the entire distribution system during the first half of the year.

63

Global Development



## GLOBAL DEVELOPMENT

### strong international presence

#### How Sanofi-Synthélabo's global business functions

The pharmaceutical industry is controlled by extremely exacting national and international rules and regulations. These directly affect both development and strategy. The main objective of Sanofi-Synthélabo, along with other pharmaceutical companies, is to launch innovative products worldwide as quickly as possible, within the framework of the constraints imposed by the administrative authorities to obtain regulatory approval.

#### A strictly controlled industry

Because the pharmaceutical industry directly affects human health and lives, it is strictly controlled at every stage of its operations on both national and international levels. Numerous regulations cover the implementation of preclinical and clinical trials, establishing the modes of evaluation for tolerability and efficacy which are needed for the approval of a New Chemical Entity and determining the modes of manufacture, packaging, labeling and marketing of medicines. These regulatory constraints are intended to evaluate whether an active ingredient can eventually become a medicine, as well as the amount of time and the investment necessary for such a development.

Each regulatory authority can impose its own conditions, refusing to grant authorization or requiring complementary studies, even if the product concerned has been registered in another country.

The time required to obtain marketing approval varies from country to country and can be lengthy. In many cases, notably in Japan and in several member states of the European Union, negotiations on price or on reimbursement rates with the regulatory authorities can extend the procedure significantly.

The United States and the European Union have worked hard with Japan to harmonize the registration document to be submitted, entitled a Common Technical Document (CTD). Within the European Union, requests made to the European Agency for the Evaluation of Medicinal Products in accordance with the centralized procedure, make it possible to obtain marketing approval which is valid for all E.U. member states. This procedure is obligatory for all biotechnology products and is optional for other active ingredients.

Under another procedure, the mutual recognition procedure, once an initial authorization is granted by a member state, approval can be requested in other E.U. countries. Requests for authorization on a national level are reserved for products which are intended to be marketed only in the country concerned, or for extensions to existing national product licenses. In the U.S., New Drug Applications (NDA) are filed with the Food and Drug Administration (FDA).

Generally speaking, files submitted for marketing approval are supported by clinical trial results which show the quality, tolerability and efficacy of the medicine. All indication extensions are the subject of a new filing, in both the U.S. and Europe. Once marketing approval is obtained, the proprietor of the medicine must indicate cases of undesirable side effects and must submit periodic reports. For certain medicines, the regulatory authorities can demand complementary post-approval trials to evaluate long-term effects or certain specific conditions of use. The manufacturing facilities must be approved and are periodically inspected by the regulatory authorities. In addition, manufacturing facilities which are located outside the U.S. and export products to the U.S. market must be approved by the FDA and are subject to periodic inspections. In most countries, manufacturers of pharmaceutical products must respect Good Manufacturing Practice (GMP) in order to be approved.

### **Direct marketing and partnerships: strategies adapted to the countries concerned**

Sanofi-Synthélabo markets and promotes its pharmaceutical products through its affiliates and representative offices. Global marketing strategy is adapted by the various Group affiliates to the needs of their local markets. The Group's worldwide sales force now counts more than 10,000 people, including 4,900 in Europe and more than 2,000 in the U.S. where the number of medical sales representatives has doubled in two years.

Certain Sanofi-Synthélabo products are marketed through alliances. Sanofi-Synthélabo has formed two major alliances for the marketing of three of its products.

- The first with Bristol-Myers Squibb (BMS) for the marketing of Aprovel<sup>®</sup>/Avapro<sup>®</sup> and Plavix<sup>®</sup>.
- The second with Organon, a subsidiary of Akzo Nobel, for the marketing of Arixtra<sup>®</sup>.

The nature of these agreements, whether co-marketing, exclusive marketing or co-promotion, vary according to the territories concerned. The alliances are detailed in note C-1 of the consolidated financial statements presented on pages 36 and 37 of the financial report. Counterbalancing this, Sanofi-Synthélabo has built its presence in the U.S. in April 2002 through the acquisition from its partner Pharmacia of its interest in the Lorex joint venture. This joint venture marketed zolpidem under the name Ambien<sup>®</sup> on the U.S. market.

In Japan, Sanofi-Synthélabo markets its products mainly through alliances or licensing agreements with other companies. The most important of these have been concluded with Fujisawa for Myslee<sup>®</sup>, Dogmatil<sup>®</sup> and Pimperan<sup>®</sup>; with Daiichi for Ticlid<sup>®</sup>; with Taisho for Cardarone<sup>®</sup>; with Mitsubishi for Kerlone<sup>®</sup> and with Yamanouchi for Corotrope<sup>®</sup>.

Other agreements strengthen the presence of Sanofi-Synthélabo, e.g. via alliances in certain countries such as Slovenia, China and Vietnam.

### **A crucial issue: industrial property**

The protection of patents and trademarks is of utmost importance. Sanofi-Synthélabo's policy is to protect them throughout the whole world.

Patents on individual products last for twenty years as from the date of patent submission: this protection can be extended in certain countries. The degree of protection varies in accordance with the existing legislation in each country.

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

In some countries, including E.U. member states, the U.S. and Japan, many Sanofi-Synthélabo products can also benefit from five to ten years of marketing exclusivity. This period of exclusivity can protect a product from generic competition even if there is no more patent protection. In all cases, Sanofi-Synthélabo is vigilant regarding the activities of its competitors and systematically attacks infringements of patents and trademarks.

Sanofi-Synthélabo possesses more than 9,000 patents throughout the world, and has obtained licenses for around 30 patents. These patents cover active ingredients, pharmaceutical formulations, product manufacturing processes, intermediate chemical compounds used in manufacturing or therapeutic indications.

Product patent expiry can lead to significant competition from generic products, along with a considerable drop in sales figures. If some products like Cordarone<sup>®</sup> and Dogmatil<sup>®</sup> no longer benefit from patent protection, others such as Tildiem<sup>®</sup> and Depakine<sup>®</sup> continue to be protected through their formulation. The principal patents for milrinone expired in the U.S. in May 2002, where it was sold under the name Primacor<sup>®</sup>. Plavix<sup>®</sup> is protected in the U.S. by five patents listed in the Orange Book, expiring respectively in 2003, 2011, 2014 and 2019; in Europe, the patents expire in 2003, 2013 and

---

## GLOBAL DEVELOPMENT

### strong international presence

2019. Aprovel® is protected in the U.S. until 2011 and in Europe until 2012. The principal patents for Stilnox® expire between 2002 and 2006, in 2006 for the U.S. and Japan. Arixtra® benefits from marketing exclusivity in the U.S. until 2006 and in Europe until March 2012.

In the U.S. and Canada, generic drug manufacturers have filed Abbreviated New Drug Applications for generic versions of Plavix®, challenging the validity of certain Sanofi-Synthélabo patents for clopidogrel.

Sanofi-Synthélabo considers that its patents are valid and intends to defend them vigorously. Despite the fact that the situation is gradually improving, thanks to international agreements, the absence of recognition for industrial property rights poses difficulties in certain countries.

### Competition and pricing pressure

Sanofi-Synthélabo is currently the second pharmaceutical group in France, the seventh in Europe and among the top twenty worldwide. Market shares by geographic zone are detailed in the Global Development section, pages 53 to 63 of this Report; the description of different medicines is on pages 34 to 51.

The pharmaceutical industry is highly competitive.

This competition exists between pharmaceutical companies in the development of new patented medicines, between compounds patented by different pharmaceutical companies for identical therapeutic indications and between original products and considerably cheaper bio-equivalent generics once patent protection expires.

Patented products which are launched on the market enter into direct competition with other products developed for the same therapeutic indications. This is particularly the case with Aprovel®, Eloxatin® and Arixtra®, which have to face competition from other products which have recently appeared on the market or are currently in last phases of development by other companies. Aprovel® is in direct competition with Cozaar® from Merck and Diovan® from Novartis, Eloxatin® with Campto®/Camptosar® from Aventis/Pharmacia. Arixtra® competes with the low molecular weight heparins, notably Lovenox® from Aventis.

When a pharmaceutical product loses its patent protection, it generally has to face competition from generic products. For example, since Primacor®'s U.S. patent protection expired in May 2002, it has faced direct competition from generics which has led, as forecast, to a significant drop in sales for this product. This competition from generic products is constantly growing, due to

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

increasingly stringent national policies to limit healthcare expenditure, and there are more and more attempts by generic manufacturers to challenge patent protection. (see page 89 of the Financial Report)

The normal effect of competition is to influence prices. In addition, the aim of controlling healthcare expenditure at a national level leads to a hardening of market conditions in most countries where Sanofi-Synthélabo is present. Agreed or mandatory price reductions, ceilings on promotional expenditure and/or profits, difficulties of access to medicine reimbursements or rate reductions, seeking the best price/efficacy ratio, etc. the mechanisms implemented vary from one country to another but the spirit is the same. These measures can entail considerable price differences between markets. Accentuated by currency fluctuations, these variations can be exploited by parallel importers who obtain branded products on the markets with the lowest prices to sell them on the markets with the highest prices.

**Investments Principal sites**

Investments are detailed in note D6 of the consolidated financial statements, presented on page 41 of the Financial Report.

The main administrative centers are located in Paris. Sanofi-Synthélabo owns or rents offices, R&D centers and manufacturing facilities throughout the world. In 2002, Sanofi-Synthélabo spent 423 million euros, mainly to increase its manufacturing capacity for new products.

Sanofi-Synthélabo considers that its manufacturing facilities and R&D centers are sufficient for the Group's needs in the near future.

The table below lists the main manufacturing, distribution, R&D and administrative sites. Sanofi-Synthélabo also has other sites throughout the world which serve local and regional markets.

---

**Principal sites**


---

**Chemical and pharmaceutical manufacturing**

Aramon, **France**  
 Sisteron, **France**  
 Ambarès, **France**  
 Tours, **France**  
 Notre-Dame de Bondeville, **France**  
 Quetigny, **France**  
 Riells, **Spain**  
 Fawdon, **U.K.**  
 Ujpest, **Hungary**  
 Csanyikvolgy, **Hungary**  
 Verès, **Hungary**

**R&D**

Montpellier, **France**  
 Toulouse, **France**  
 Great Valley, PA, **U.S.**  
 Bagneux, **France**<sup>(1)</sup>  
 Chilly-Mazarin, **France**<sup>(1)</sup>  
 Porcheville, **France**  
 Alnwick, **U.K.**

**Distribution**

Chilly-Mazarin, **France**  
 Amilly, **France**  
 St. Loubès, **France**

**Administration**

Sanofi-Synthélabo  
 174 Avenue de **France**,  
 Paris, **France**

Sanofi-Synthélabo  
 74-82 Avenue de Raspail  
 Gentilly, **France**

Sanofi-Synthélabo Inc.  
 90 Park Avenue  
 New York, NY, **U.S.**

---

(1) These buildings were constructed under leasing agreements, under the terms of which Sanofi-Synthélabo pays the rental fees and can exercise an option to purchase when the leasing agreements expire. Sanofi-Synthélabo finances the cost of repairs, taxes and other costs for the duration of the leasing agreement. The leasing agreements are listed as debit in the consolidated accounts.





## GLOBAL DEVELOPMENT

### strong international presence

#### How Sanofi-Synthélabo produces its medicines

We can distinguish three key steps in pharmaceutical production: active ingredient synthesis (chemical manufacturing), product formulation (pharmaceutical manufacturing), and distribution. Each stage of the process is conducted under strictly controlled conditions defined by specific regulations.

Sanofi-Synthélabo's industrial strategy is based on an absolute requirement for safety, ensuring market supply by investing in manufacturing capacity, and constantly striving for quality in medicine production.

This requirement has led the Group to develop and manufacture most the active ingredients used in its products. Equally in the interests of safety, the objective of Sanofi-Synthélabo is to obtain official authorization for two production units in the manufacture of each key active ingredient and each finished product. The Group similarly has the policy of ensuring several sources of supply for its raw materials.

#### Chemical manufacturing

The three chemical manufacturing units located in Aramon and Sisteron in France, and in Ujpest in Hungary, produce most the active ingredients used by Sanofi-Synthélabo. All three sites have been approved by the U.S. Food and Drug Administration (FDA), testifying to their high level of manufacturing quality. The investments made during recent years have enabled the Group to respond to strong growth in demand and to introduce increasingly efficient modes of synthesis. Gains in productivity and organizational rationalization have led to an appreciable reduction in costs.

In 2002, the Andromeda building on the Sisteron site was inaugurated, assuring, in liaison with Scientific Affairs, the chemical development of new compounds under optimal conditions. In parallel, the Aramon site has completed the necessary preparations for ISO 14001 certification.

Safer Medicines thanks to constant efforts to improve quality



### Pharmaceutical manufacturing

Pharmaceutical manufacturing in Europe is currently ensured by a complex of six manufacturing facilities in France, two in Spain, one in Italy, one in the U.K., one in Poland and three in Hungary. These sites are both specialized and complementary. This organization ensures the necessary capacity to meet to demand while providing several alternative manufacturing sources for each of the major products.

The acquisition in July 2002 of a new factory in Hungary, located a few kilometers from Ujpest, will strengthen manufacturing potential. An ambitious investment program has already been initiated.

Our manufacturing facilities conform to international quality norms required by the pharmaceutical industry. In 2002, our efforts to optimize quality enabled us to successfully pass the various tests necessary for certification by the FDA and the European Agency for the Evaluation of Medicinal Products (EMA). Through our manufacturing facilities located outside Europe (in Latin America with factories in Brazil, Mexico and Colombia, in Asia with factories in China, Korea and Vietnam, or in Africa with factories in Morocco) local markets also benefit from our industrial expertise.

### Pharmaceutical Distribution

Safety in terms of market supply also necessitates optimization of the distribution process. The year 2002 saw improvement of the supply chain organization, through joint efforts with European affiliates.

Major investments, implementation of computerized systems, and the introduction of standard indices, have made it possible to manage this chain more effectively at a worldwide level, improving supply flows and reducing costs, while respecting quality standards.

### Conclusion

Safety, quality, cost control, productivity and social dialogue on the basis of shared managerial principles: such were the strategic goals set by Industrial Affairs in 2002.

Pursuit of these goals resulted in a significant improvement in our performance in 2002, which will continue into 2003.





## OUR RESPONSIBILITY AS

### a pharmaceutical group

For thirty years, Sanofi-Synthélabo has been meeting a crucial need: safeguarding health through the development of safe and effective medicines consistent with ethical principles. The Group now intends to expand this goal by responding to two of the major challenges of our time: the combat against rare but severe diseases and access to medicines in the most impoverished countries.

#### Key events in 2002

The first products developed in the Impact Malaria project, designed to combat this disease which is endemic in developing countries, should be made available in 2003.

Fumagillin, in development for the treatment of intestinal diarrhea of parasitic origin, was included in the European Union list of orphan drugs in February 2002.

#### Facilitating access to medicines

The difficulty encountered by the most vulnerable countries in gaining access to medicines constitutes an unacceptable situation. The pharmaceutical industry is conscious of the critical human and social importance of this issue, and is cooperating in the search for solutions.

In this context, it must reconcile two imperatives: to reduce the price of medicines to reach a cost level accessible to patients in impoverished countries, while at the same time ensuring respect of intellectual property rights.

If this latter objective is not achieved, the pharmaceutical industry will no longer be able to support the financial cost of an ambitious research policy, the basis of its existence. The Impact Malaria project initiated by Sanofi-Synthélabo two years ago is consistent with this view. Its aim is to provide the populations most affected with the means of combatting a major disease: malaria. Approximately 300 million cases of infection per year worldwide lead to 2.7 million deaths annually.

90% of those contracting the disease live in Africa. The great majority of them are children.

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

Thanks to the efforts of the Group's scientists and a dedicated team, the first products will be available in 2003. (They will be distributed according to a specific program in order to guarantee that they are actually used by the targeted populations). Local production of these drugs within Africa is currently under review.

72

[Our Responsibility](#)

### **Integrating ethical concerns into clinical studies**

All clinical studies are performed in accordance with Good Clinical Practices, and in close cooperation with health authorities, to ensure scrupulous respect of ethical principles: evaluation of the benefit/risk ratio, complete patient information and patient's consent to participate in the study.

### **Limiting animal experimentation**

For ethical, scientific and legal reasons, animal experimentation constitutes an essential step in research prior to clinical studies in humans. These experiments are subject to strict regulations, both national and international.

Going beyond the compulsory norms, Sanofi-Synthélabo has developed an International code for the use of laboratory animals. Its objectives include: reducing to a minimum the number of animals used in studies, taking care to prevent any suffering, and developing alternative methods.

### **Targeting rare diseases**

The Group considers that it has a moral obligation to focus not only on widespread diseases, but also on severe diseases that are rare and either untreated or poorly treated, even though the sales potential of drugs indicated for these diseases is low.

A specific R&D effort has already culminated in the launch of Fasturtec® (rasburicase) in 2001, for prevention of the increase in blood uric acid levels during chemotherapy of acute leukemia. This complication may develop in children.

Other compounds are also in development, including fumagillin, designed to combat intestinal diarrhea of parasitic origin in patients with immune deficiency. Fumagillin was included on the European Union list of orphan drugs on February 4, 2002.

### **Defining and applying clear bioethical rules**

Discoveries in genetics and molecular biology have already led to major therapeutic advances and will continue to do so. They have also obliged society as a whole, and particularly the medical community and the pharmaceutical industry, to draw up clear and transparent rules with regard to gene therapy, genetic modification and the use of human tissues and embryos. In particular, it is indispensable to control the origin and use of stem cells.



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

With the aim of developing innovative medicinal products, Sanofi-Synthélabo is studying the mechanisms of differentiation of adult stem cells. However, the Group has no program on embryonic stem cells.

### **Ensuring the quality and safety of medicines**

This is the most crucial imperative for a pharmaceutical group. At Sanofi-Synthélabo, 1,600 employees, corresponding to 5% of the workforce, are dedicated to the continuous monitoring of drug quality. They intervene in all areas of activity and in all affiliates worldwide.

### **Selecting suppliers**

Whether purchasing raw materials or active ingredients, marketing its medicinal products, or contracting out clinical trials, Sanofi-Synthélabo requires its partners to respect rules ensuring quality, safety, environmental protection and ethics identical to those the Group imposes on itself. This criterion is crucial in the selection of its suppliers and external contractors.

**The Group also publishes  
a Sustainable Development Report,  
detailing the actions described above.**

73

Our Responsibility

## THE DYNAMICS OF CONTINUOUS PROGRESS:

### a methodology for our HSE policy

In the service of life and health, Sanofi-Synthélabo has adopted an ambitious program to protect the safety and health of its employees, to guarantee the safety of its industrial sites, and to respect the environment.

The Group sees this constant effort to respond to these major challenges as a driving force for internal progress and a key advantage in its relationships with partners and clients.

#### Identifying the hazards

#### Scientific expertise in the service of health

The prevention of chemical and biological risks necessitates a thorough and constantly updated knowledge of the intrinsic hazards of the materials handled on our sites.

Our scientists place their expertise at the service of the Group's employees, assessing the risks of exposure to biological or toxicological hazards from the stage of research and development of new compounds.

#### COVALIS:

#### committee for the prevention of chemical risks

Created in 1993, Covalis, Sanofi-Synthélabo's internal exposure limits committee, comprises a multidisciplinary team of experts in industrial toxicology, industrial hygiene and toxicovigilance, physicians, legal experts, representatives of research facilities and delegates from chemical synthesis and pharmaceutical manufacturing units.

This committee evaluates physical, chemical and toxicological properties and the consequent hazards of all chemical and pharmaceutical substances handled on the Group's various sites.

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

The Covalis committee also draws up the toxicological study program and interprets the results. Finally, it classes the substances in five categories according to their potential hazard by inhalation and through contact with the skin, and defines the limits of occupational exposure that should be respected in the workplace.

All these data are communicated to all facility directors and HSE coordinators, enabling them to assess the risks at each workstation and to determine the appropriate means for their prevention: standard operating procedures, collective or personal protective equipment. This system is implemented by all employees in all research, chemical and pharmaceutical activities.

Covalis experts also analyze the data of toxicovigilance collected by the Occupational Physicians. All clinical events occurring after exposure of an employee to a substance are taken into account in revising, if necessary, the defined hazard level of the substance.

### TRIBIO:

#### committee for the prevention of biological risks

Exposure to pathogenic biological agents demands a different type of expertise, as scientific issues are complicated by bioethical questions. The objective of the Tribio expert committee is to anticipate biological risks in order to better prevent them.

Equally multidisciplinary, the Tribio committee evaluates and classifies biological agents (micro-organisms, cell cultures, tissues or blood of animal or human origin) used in R&D. It unites physicians, biologists, veterinary surgeons, HSE coordinators and a legal expert. Its activity has three facets:

- n **Biosafety** to define a strategy for assessing and preventing biological risks,
- n **Biovigilance** to assure feedback on the effects of any contamination,
- n **Bioethics** to verify that research projects conform with legal requirements.

The Tribio committee lists all the biological agents to which the Group's employees may be exposed and classifies these according to various criteria: pathogenicity, biological stability, mode of propagation, route of contamination, and existence of an effective prophylactic or curative treatment. It informs employees about the nature of the risks, preventive measures, personal protective equipment, and personal hygiene measures and participates in training courses organized in this area.

#### **Process safety: a laboratory dedicated to risk evaluation**

At the service of all Sanofi-Synthélabo facilities, the PCP (Physicochemical Process unit) is a laboratory created to respond to the Group's need for expertise in evaluating the inherent hazards of processes. In this laboratory, 15 scientists analyze and quantify the intrinsic hazards of processes and products, and conduct studies on the explosive potential of powders and the stability of products and other materials. All projects concerning process development must be submitted to the PCP.

The experimental data generated by its studies are used to define the scale of safety structures in industrial facilities. They also form the basis for information documents supplied to external contractors. The PCP networks with other organizations, in particular European authorities, with which it is currently investigating runaway reactions, and universities.

#### **Assessing occupational and environmental risks**

Once all the potential hazards associated with products, procedures, processes and equipment have been evaluated, the risks are assessed in the context of normal and impaired functioning. Particular attention is paid to the road safety risks to which medical sales representatives are exposed.

#### **Assessing work stations**

All work stations or projects related to research, development or industrial production are assessed with regard to:

- n Occupational exposure to the substances used (in relation to their physicochemical, toxicological, thermal characteristics, etc),
- n Safety of the procedures and processes employed in laboratories, pilot plants of chemical development units and manufacturing areas,
- n Environmental impact.

From R&D to industrial manufacturing, each phase in the life cycle of the medicine is this way subjected to Health, Safety and Environment appraisal. Every project has an HSE file compiled on the basis of the Covalis and Tribio committee assessments and the studies of the Physicochemical Process laboratory.

### Managing change

This assessment of work stations and products is complemented by a procedure known as Hazard Vetting which re-assesses risks prior to any change in a product, procedure, installation or item of equipment. Conducted by the unit manager, the scientist responsible for the R&D study and the HSE coordinator, its aim is to evaluate all the repercussions of this change: requirements not only for technical adaptations, but also for new risk prevention and protection procedures, as well as changes in the operating procedure and further training.

### Assessing major risks

The danger of major accidents, and the risks associated with exposure to these, is subjected to a specific analysis to identify the possible scenarios, define the Safety Important factors and verify that the appropriate equipment is available to deal with these.

Seveso classified chemical sites apply this methodology through the implementation of a safety management system (SMS). This major risk assessment methodology, applicable to chemical sites, is currently being extended to the Group's other industrial activities.

## THE DYNAMICS OF CONTINUOUS PROGRESS:

### a methodology for our HSE policy

#### Controlling risks

Once the dangers have been identified and the risks assessed, it is possible to develop preventive measures, secure the necessary specific capital investments and install collective and personal protection equipment. These actions are accompanied by training programs designed to incorporate the safety reflex into all professional activities. This approach is implemented systematically in all our facilities worldwide. The HSE Department, within the Group's Strategy & Risk Assessment Department, is supported by a worldwide network of HSE coordinators and occupational physicians who assist the line managers, provide expertise, and monitor the application of HSE policy through the continuous progress management system.

Throughout the world, the Group applies a set of internal directives (rules to be applied immediately) and standards (results to be achieved, measured by performance indices). Guidelines are available to help line managers apply the directives and achieve the objectives defined by the standards.

#### Training to integrate safety into work practices

All Group employees on industrial and R&D sites benefit from compulsory general training courses run by the HSE coordinator. These are complemented by specific job-related training courses assured by the line management.

In all facilities, managers and operators must participate in training courses focused on the prevention of exposure to chemical risks. These are based on the multimedia module prepared by the Group entitled "Health at Work - Hazardous Substances".

Managers also receive training in HSE management and risk prevention. These courses are based on 18 standards of application concerning the topics of HSE organization and management, the risk prevention system, safety in the workplace, industrial hygiene and workstation organization.

#### Capital investments

Specific capital investments are allocated to risk prevention and employee protection, as well as to environmental protection, reduction of natural resource use, development of clean manufacturing processes and waste reduction and recovery.

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

These permit, for example, the provision of personal or collective protection equipment, containment techniques, and installation of fail-safe systems on machines. They also permit the installation of incinerators reducing gaseous emissions and new water treatment technologies, as well as the development of closed circuit cooling systems.

Because its aims are improvement and constant progress, the HSE management system is not a rigid one.

76

Our Responsibility

## THE HSE ANNUAL PROGRESS ACTION PLAN: PASS

Every year, all facility directors are expected to define the overall goals of an action plan designed to achieve progress in Health-Safety-Environment practices: PASS. This plan takes into account both Group policy and the specific activity of each facility. Each sector manager then draws up his own specific action plan consistent with these overall goals of the facility. Finally, the various departmental PASS plans are consolidated into the PASS plan for the facility. PASS covers four areas:

- n Workplace accident prevention
- n Industrial hygiene practice
- n Improvement of working conditions
- n Environmental protection

The objectives are clearly identified and quantified so that they can be measured. The actions are planned on a department by department basis and the necessary means and resources defined. Once finalized, the PASS is presented to the facility's Health and Safety Committee, and communicated to all employees and then to the Group's HSE Department.

Throughout the year, PASS objectives are regularly assessed: progress is checked monthly by the sector line managers and every three months by the facility director.

## Monitoring performances and organizing feedback on experience

### Indices and balance sheets

A set of indices permits the consolidation of safety and environmental protection indices for all the Group's facilities worldwide. For each individual facility, these indices constitute a balance sheet serving as the basis for orientating HSE initiatives and permitting the implementation of corrective actions to remedy any discrepancies noted between current status and the objective to be achieved.

### Audits

The HSE Department conducts internal audits to verify the application of HSE policy, directives and internal standards, as well as conformity with regulations. Audits performed by external bodies complete this internal check.



The recommendations resulting from the audits form the basis of action plans which are then monitored by tracking the appropriate indices.

### Feedback of experience

The Groupe systematically elicits feedback on experience to draw the lessons from all discrepancies, incidents or accidents occurring at a local level.

This information regularly leads to revision of internal standards and is taken into account in the annual progress action plans (PASS).

### Relations with partners

Sanofi-Synthélabo does not limit itself solely to an internal perception of its health, safety and environmental responsibilities. The Group also implements a chain of vigilance involving its suppliers and contractors, such as contract manufacturers and transporters of hazardous materials, extending throughout the manufacturing process.

We request these partners to take into account our HSE requirements and provide them with all useful information available on our products and procedures. Assessment visits are regularly conducted on their sites.

### Health Safety and Environment Policy

**The Health Safety Environment policy is based on eight guiding principles H.S.E. which define a framework of actions with respect to both our Group employees and external partners. It is applied to all of our activities.**

1. The Health, Safety and Environment policy is an integral part of the general policy of the Group.
2. The management and the employees of the group apply this policy at all levels. Each person is aware of their role and their personal responsibilities with regard to the prevention of accidents, risks to health or damage to the environment.
3. In all places in which the group operates it respects the applicable laws and the regulations, applies expert recommendations and uses the best industrial practices.
- 4.

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

Sanofi-Synthélabo operates management systems relating to safety, health at work and protection of the environment adapted to each of its activities. These systems are assessed periodically, by measurement of the results obtained, by defining objectives for progress and by implementing action plans called PASS with associated control systems. This process depends on basic understanding, learning from experience, working together and training.

5. Every development project and every product launch will be subjected to a safety, health and environmental risk assessment integrating all the scientific and technical knowledge of the Group. Such projects will be developed using the best available technology to take stewardship of the product or project throughout its life cycle.
6. Sanofi-Synthélabo takes care to economise on natural resources, to minimise the residual impact of atmospheric emissions, of effluents or of waste in all its industrial activities in order to preserve the natural environment.
7. With regard to its suppliers, contractors or sub-contractors, Sanofi-Synthélabo aims to promote the application of the rules of safety and protection of the environment, and considers the adoption of these rules as a criterion to be applied to suppliers, contractors or sub-contractors.
8. Sanofi-Synthélabo has a constructive attitude of transparency and dialogue with regard to third parties with respect to its safety, health and environmental protection policy, its achievements and its commitment.

## OUR SOCIAL RESPONSIBILITY

Sanofi-Synthelabo believes that its economic performance and its corporate social policy should be mutually enriching. All affiliates apply this principle and adapt it to their specific culture, history, activities and markets.

### Key events in 2002

Employment expanded worldwide, resulting in a 6.1% growth in the total workforce,

The Group set out the fundamental principles of its social policy and facilitated adaptation of this policy by affiliates worldwide whilst respecting the specific local context.

### Employee numbers and changes by geographic area in 2002

78

Our Responsibility

## Creating employment throughout the world

During 2002, Sanofi-Synthélabo continued its expansion in all the zones where it is present.

As a result of the growth in its sales, the Group was able to achieve one of its priority objectives: to expand its workforce throughout the world . The workforce accordingly increased by 6.1%, from 30,571 employees in 2001 to 32,436. This growth in the workforce reflected both the strengthening of sales forces in all countries and the development of our activities in four countries: Indonesia, Egypt, Algeria and Hungary.

A total of 5,297 employees were recruited, including both permanent contracts and fixed-term

## Employees by activity

**Total: 32,439 people**

## Workforce changes in 2002

contracts, of whom 1,939 joined the sales force.

For all positions, including management, priority is given to candidates from the particular country concerned, whenever the local labor market permits.

A total of 4,089 employees departed in 2002, due to retirement, internal mobility between the various affiliates of the Group, resignation, etc., including 762 redundancies. In 2002, the Group emphasized the need for decentralized recruitment, as this is key to understanding the local situation.

Gender equity is respected: 1,759 women and 1,705 men were recruited on permanent contracts in 2002.

The Group's employees currently comprise equal numbers of men and women. This balance applies to all socio-professional categories, including management positions.

### **Promoting international mobility**

Sanofi-Synthélabo is committed to respecting local identities and cultures and to privileging internal mobility. This policy means that the Group recruits employees from the country concerned whenever possible. However, it is also important to provide opportunities for professional development, exchange of expertise between countries, and the cultural intermingling indispensable to the force and cohesion of a multinational Group. In this spirit, Sanofi-Synthélabo has implemented a policy coordinating mobility of its managers between its various affiliates worldwide. A total of 73 employees benefited from this policy in 2002.

## OUR SOCIAL RESPONSIBILITY

### Fostering career development

Sanofi-Synthelabo takes care to recruit employees according to their skills, their adaptability to change and their commitment to the Group's fundamental values, notably concern for performance, audacity, creativity and respect for others. For new employees, this approach is one of the keys building a dynamic career and real professional satisfaction. Annual career development interviews give each employee the opportunity to discuss future career plans with line managers. Already implemented in Europe and North America, systematic interviews are being progressively extended to the rest of the world.

In the second half of 2002, a project was initiated to strengthen the Group's guiding principles of career development. The focus of this project brings together two distinct philosophies.

One philosophy aims to help each employee become your own career manager by facilitating progression and mobility: the publication of job offers in each country is already moving in this direction, but the Group's ambition goes beyond this.

The other philosophy is based on the need to create a pro-active system for managing exceptional human resources and hopes for the future, corresponding respectively to experts and promising young employees. Experts clearly need a mode of career management different to that of line managers, to acknowledge their contribution to the Group's performance and maintain their motivation intact.

This project is scheduled to culminate, by the end of 2003, in an improvement in information systems and a strengthening of the career development process. It will contribute significantly to increasing the Group's competitive advantage.

### Building skills to ensure continued employment

#### 1,149,814 hours of training in 2002

In 2002, the total number of training courses provided by the Group reached 1,149,814 hours worldwide, corresponding to an average of five days for each employee concerned.

Over 80% of the Group's employees were able to increase their skills, develop new know-how, prepare for career changes and build employability by learning to adapt rapidly to change.

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

The worldwide implementation of career development interviews will continue to permit optimal adjustment of the proposed training courses both to the Group's needs and to each employee's personal plans for the future.

In addition, the Group has created a module to welcome new managers recruited worldwide and to facilitate their integration.

The first session provided an opportunity for more than 60 managers, from all the countries in which the Group is present, to meet in Paris for three days. This module has also been adapted to suit each individual job and country so every newly recruited employee can gain a better insight into the Group, its history, its activities, and the fundamental values guiding its actions.

80

Our Responsibility

### Compensating performance

Sanofi-Synthélabo makes a point of compensating performance while preserving internal equity and respecting our need to be competitive. Each country adapts this principle according to local practices and realities, with the objective of setting the average salary levels above the market median for its activity.

Apart from the base salary, the Group has implemented individual and collective compensation systems which recognize the successes of each employee or work team, and everyone's contribution to the Company's performance. These systems are adapted according to the country and the local legislation.

### Ensuring the social protection of employees worldwide

In 2002, the Group carried out an inventory and an evaluation of the employee benefits policies of each of its affiliates.

Wishing to put economic performance at the service of social performance, the Group adopted the principle of a Sanofi-Synthélabo minimum with regard to the reimbursement of costs related to health care, pensions, death and invalidity. This will be defined according to the care available and the regulations applicable in each country and will complement the local coverage systems. It will be applied irrespective of age, sex, state of health or the nature of the post.

This policy, all the more ambitious in that it must respect economic constraints, will be implemented progressively worldwide within the next five years.

### Encouraging dialogue

Sanofi-Synthélabo gives priority to social dialogue in all countries, both with employee representatives and with the entire workforce. All employees need to be aware of the Company's challenges and objectives, and should also have the possibility of discussing with their managers. This approach enables all employees to focus their efforts on a common goal and will give meaning to their daily professional activities.

Exploratory chemistry: creation and synthesis of new compounds.

Designed as a forum for information and discussion concerning the Group's strategic orientations, the European Industrial Relations Committee was created in December 2001. It represents over 20,000 employees in all the European countries in which the Group is present. The Committee comprises 29 representatives and 5 observers, originating from the fifteen European Union member



countries and the first six candidate member countries, and meets twice a year.

In March 2002, the Committee elected a seven-member office team, comprising five nationalities: German, British, Spanish, Italian and French. This first meeting involved an exchange of information on the budget, results and future of the Group.

At its second meeting, in September 2002, the Committee's agenda was focused principally on the Group's research objectives and organization.

### **Contributing to the insertion of disabled employees**

In all sites or facilities, particular attention is paid to any work situations likely to lead to health problems, and these risks are addressed by specific studies and ergonomic measures. Employees who have accidents outside work are supported in their efforts to pursue their professional activity whenever possible.

Disabled persons are also incorporated within the Group as trainees or employees, under agreements with various organizations, to facilitate their professional integration. In France, the Group played a major role for the second year running in the National Handicap Week organized in November 2002. It has also assumed the presidency of the Trampoline association, comprising 25 major French companies of international dimensions. The objective of this organization is to develop training programs for handicapped students to aid their future professional integration, and also to help them ensure that the job they envisage is consistent with their abilities and to encourage them in their choice. In this way, Trampoline has enabled approximately 450 trainees to be employed by various companies, including Sanofi-Synthelabo.

## OUR CORPORATE RESPONSIBILITY

### to inform and communicate

A commitment to growth and a policy of transparency require active external and internal communication. Sanofi-Synthélabo's relationship with all its partners is based on respect for cultural diversity and provision of frank and thorough information, and the Group communicates on all its major pharmaceuticals throughout their development.

#### Key events in 2002

- n information campaign focused on the listing on the **New York Stock Exchange in July 2002**,
- n preparation of Sanofi-Synthélabo's 30th anniversary in January 2003,
- n development of the Group's web site, now accessible in three languages,
- n international media communications **on the Group's major pharmaceuticals**.

Listing on the NYSE: corporate campaign.

With the constant aim of increasing the Group's visibility and accessibility, Sanofi-Synthélabo's communication policy targets four key audiences:

- the medical community, principally interested in the major medicines emerging from its R&D,
- the financial community, comprising shareholders, institutional investors and financial analysts,
- the general public, through regular risk prevention campaigns focused on major diseases,
- and the Group's 32,436 employees, who are interested in having an overall view of company strategy and keeping up to date with the progress of its Research and Development on the different continents.

#### **Increasing Sanofi-Synthélabo's visibility worldwide**

Building the Group's image across the world implies providing comprehensive information within the shortest possible time. The Group has dedicated considerable resources to reaching its various audiences rapidly. Besides Corporate Communications, located in the head office, a network of communication managers in the different sites and countries enables the Group to disseminate information worldwide in real time in more than 20 languages and, whenever appropriate, to adapt this information to specific local contexts.

The web site, which was revised in 2002, can now be consulted in three languages: English, French and Spanish, and its content has been considerably developed. Providing information on the Group's international presence, R&D approaches, descriptions of targeted diseases, stock exchange information and financial reports, key events, human resources, health and safety, environmental protection, humanitarian commitment, etc., the new web site design emphasizes the major challenges facing the Group, providing a full picture of its activity, and includes career opportunities. Content is continuously updated. The affiliates have designated areas to develop their own communication, coordinated with that of the Group.

Major events in the life of the Group were also communicated in more than 30 press releases in 2002. The listing of the company shares on the New York Stock Exchange provided the occasion for a major corporate identity campaign, principally in New York, which received the Top Com d'Or award from France's communication professionals.

#### **Creating a link between employees**

The same concern for facilitating access to information applies to internal communication.

A bimonthly magazine, The Blue Dolphin, is published in 20 languages and has a circulation of 20,000. It is distributed to all the Group's employees worldwide. This magazine covers events and challenges, with content that includes financial results, progress

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

of clinical trials, new product launches, marketing efforts, industrial investments, environmental protection and humanitarian actions. Besides providing information, it contributes to creating a genuine Group spirit based on shared values. The affiliates have pages for local news in their national editions of the magazine.

Some affiliates also have intranets accessible to all employees and designed to facilitate rapid and reliable communication. The Group's listing on the New York Stock Exchange on July 1, 2002 was marked by a particular internal communication effort, with the publication of a special issue of The Blue Dolphin with a print run of 25,000 copies. All the Group's employees were able to witness this event as it happened, via a worldwide satellite transmission.

83

Our Responsibility

## OUR CORPORATE RESPONSIBILITY

### to inform and communicate

#### Informing the medical community

The Group regularly reports the results of clinical trials conducted on compounds originating from its R&D or on medicines which are already marketed. This information is targeted at the international medical community and the media.

In 2002, the principal communications concerned:

#### Plavix® (clopidogrel)

- n Updated recommendations of the American Heart Association/American College of Cardiology and the European Cardiology Society concerning acute coronary syndrome.
- n Results of the CREDO (Clopidogrel for Reduction of Events During Observation) trial demonstrating the long-term (one-year) efficacy of Plavix® combined with acetylsalicylic acid versus placebo combined with acetylsalicylic acid in patients having undergone percutaneous coronary intervention.
- n Present and future role of Plavix® in the long-term prophylaxis of ischemic stroke: implementation of the MATCH trial, for which the last patient was enrolled in April 2002.

Supporting the Federation for Brain Research.

#### Eloxatin® (oxaliplatin)

- n The N9741 trial, coordinated by the North Central Cancer Treatment Group (NCCTG), the results of which were announced at the American Society of Clinical Oncology (ASCO) congress in May 2002.

#### Arixtra® (fondaparinux sodium)

n

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

Results of the Penthifra Plus trial: prolonged prophylaxis of deep-vein thrombosis liable to lead to pulmonary embolism in patients operated for hip fracture.

- n Results of the Matisse PE and Matisse DVT trials in the treatment of pulmonary embolism and deep-vein thrombosis respectively.

### **Aprovel®/Avapro® (irbesartan)**

- n Role of irbesartan in renal and cardiovascular protection.
- n Presentation of the I-PRESERVE trial: evaluation of the potential effect of irbesartan in reducing mortality and cardiovascular morbidity in patients with heart failure.
- n Partnership with the International Diabetes Federation.

### **Stilnox®/Ambien®/Myslee® (zolpidem)**

- n The Per-Sleep trial performance and sleep:  
role of sleep in athletic performance: study conducted during the Tour de France Yacht Race in 2002.
- n The Sle-ep trial on sleep and epidemiology:  
35,000 questionnaires collected in 11 countries, one of the largest surveys ever undertaken in this area.
- n The Holidays and Sleep survey:  
results of a Gallup poll in the U.S. conducted on 1,000 members of the general public.
- n As needed administration: new data.

### Informing the general public about risk prevention with regard to major diseases

Sanofi-Synthélabo is committed to helping safeguard public health within its areas of expertise. This is achieved through information campaigns focused on risk prevention, conducted in partnership with health care professionals and patient associations. Numerous initiatives were organized in 2002:

- n the OPAL program, conducted with the French Stroke Association, to inform and support stroke victims and their families, and provide further training to physicians and healthcare personnel;
- n the Out of the Shadows Overcoming the stigma project under the aegis of the International Bureau for Epilepsy, the International League against Epilepsy and the World Health Organization and supported by an unrestricted educational grant from Sanofi-Synthélabo, to reduce the social prejudices associated with this disease in African countries;
- n the SOLEDUC program, to better inform patients and their families about schizophrenia, to improve understanding of treatment, to increase the degree of compliance, and to illustrate the complexity of mental illnesses;
- n the Meeting and Information Center program, implemented in cooperation with the National Anti-Cancer League and the Institut Gustave Roussy, to respond to the need of patients and their families to talk to others. Complementing the relationship established between patients and physicians, this provides the psychological and moral support which is often essential to continue fighting against this disease;
- n the International Sleep Day program, designed to raise public awareness of sleep disorders, their impact on quality of life and their treatment. Sleep Days are an integral part of the worldwide program focusing on sleep and health, initiated by the World Health Organization.

The Impact Malaria project.

### Conveying the Group's social commitment

Humanitarian actions and social commitment have been core elements of the Group's philosophy since it was founded. The values of respect for others and social commitment to which Sanofi-Synthélabo subscribes are embodied in this policy of striving to help those in need. This sense of responsibility is strongly supported by the Group's employees and contributes to reinforcing team spirit.

In the interests of efficacy and legitimacy, Sanofi-Synthélabo focuses these initiatives on its areas of expertise. Priority is given to actions promoting access to treatment, and improvement in health and quality of life. Conducted throughout the world, these initiatives involve partnerships with associations or bodies devoted to those most disadvantaged, and children in particular. The Group's expertise and voluntary work naturally complement its financial support to charitable associations and humanitarian organizations.

Sanofi-Synthélabo's actions are pursued over the long term. Some of the main associations supported by the Group over the years:

Fédération pour la Recherche sur le Cerveau, Culture à l'Hôpital, L'Envol pour les Enfants Européens, UNICEF, Mécénat Chirurgie Cardiaque, PlaNet Finance, Fraternité Universelle, Ligue Nationale contre le Cancer and the Fondation de la 2<sup>ème</sup> Chance.

85

Our Responsibility



---

## OUR CORPORATE RESPONSIBILITY

### to inform and communicate

The year 2002 also saw the inauguration of the Impact Malaria program. The objective of this program is to provide the most impoverished populations in Africa with the means of obtaining effective antimalarial treatment in locations often devoid of any primary care structure. Malaria is still a major disease today: some 300 million cases of infection are recorded each year worldwide, leading to 2.7 million deaths annually, for the most part children.

The Group's actions to improve health and quality of life are strongly supported by its affiliates, as illustrated by the following examples:

- the U.S. supports The Dream Factory association, helping to make the dreams of chronically ill children come true,
- Germany aids the association Die Kleinen Patienten, providing entertainment for hospitalized children.
- Brazil, in partnership with UNICEF, has contributed to helping 46,000 children living among refuse dumps to attain better living conditions, enabling them to return to school, providing food grants, medical and psychological care.
- Greece supports the Will to overcome association, restoring a smile to the faces of children hospitalized in pediatric oncology units by organizing a painting competition,
- Egypt also helps children suffering from cancer through the Association of the Friends of the National Cancer Institute,
- South Korea supports the Korean Foundation for Aid to Children with Leukemia,
- South Africa helps the Farranani association, educating poor children,
- India aids the Italian association CESVI, combating child poverty and malnutrition,
- and finally, Hungary supports the association Polgari védelemert alapítvány, which provides assistance in catastrophes by conveying medical supplies and transporting victims.



## SANOFI SYNTHELABO

### SIMPLIFIED ACCOUNTS

#### Sanofi-Synthelabo consolidated statements of income

	2001	% of sales	2002	% of sales	Change
<b>In millions of euros</b>					
Net Sales	6,488	100	7,448	100	+14.8%
Cost of goods sold	(1,253)	(19)	(1,378)	(19)	+9.9%
<b>Gross profit</b>	<b>5,235</b>	<b>81</b>	<b>6,070</b>	<b>81</b>	<b>+16.0%</b>
Research and Development expenses	(1,031)	(16)	(1,218)	(16)	+18.1%
Selling and general expenses	(2,306)	(36)	(2,428)	(33)	+5.3%
Other operating income and charges	208	3	190	3	-8.7%
<b>Operating profit</b>	<b>2,106</b>	<b>32</b>	<b>2,614</b>	<b>35</b>	<b>+24.1%</b>
Intangibles (amortization and impairment)	(68)		(129)		
Financial income	102		85		-16.7%
<b>Income before tax and exceptional items</b>	<b>2,140</b>	<b>33</b>	<b>2,570</b>	<b>35</b>	<b>+20.1%</b>
Exceptional items	281	4	10		
Income taxes	(842)	(13)	(746)	(10)	-11.4%
Income from equity investees net	14		20		
Goodwill amortization	(7)		(8)		
Minority interests	(1)		(87)	(1)	
<b>Net income</b>	<b>1,585</b>	<b>24</b>	<b>1,759</b>	<b>24</b>	<b>+11.0%</b>
Exceptional items and goodwill amortization	(209)	(3)	(1)		
<b>Net income before exceptional items and goodwill amortization</b>	<b>1,376</b>	<b>21</b>	<b>1,758</b>	<b>24</b>	<b>+27.8%</b>
Weighted average shares outstanding	731,711,225		727,686,372		
<b>Earnings per share before exceptional items and goodwill amortization basic and diluted in euros</b>	<b>1,88</b>		<b>2,42</b>		<b>+28.7%</b>

#### Sanofi-Synthelabo simplified consolidated balance sheets

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

<b>ASSETS</b>	<b>12/31/01</b>	<b>12/31/02</b>	<b>LIABILITIES</b>	<b>12/31/01</b>	<b>12/31/02</b>
<b>In millions of euros</b>					
Fixed assets	2,296	2,899	Shareholders equity	5,768	6,035
Deferred income taxes	471	484	Minority interests	21	17
Inventories, accounts receivable & other current assets	2,911	2,988	Other long-term liabilities	1,063	796
Cash, short term investments & deposit	4,289	3,088	Account payable & other current liabilities	2,711	2,195
			Financial debt	404	416
<b>Total assets</b>	<b>9,967</b>	<b>9,459</b>	<b>Total liabilities and equity</b>	<b>9,967</b>	<b>9,459</b>

88

Simplified Accounts

**This Business Report was designed and published by:**

Sanofi-Synthélabo Corporate Communications, Finance and Legal Departments and the DraftWorldwide agency. With the assistance of Claude Bunodière.

**Photographs:**

**Front cover page:** Rose Deren • **Back cover page:** Publicis Dialog/Daniel Therasse •

**Section cover page:** *Group profile:* Michel Fainsilber Background Photo Collection

**Section cover page:** *Sanofi-Synthélabo and its shareholders:* PhotoAlto/P.Sheandell • **Section cover page:** *Innovating and acting:* Photodisc/Javier Pierini • **Section cover page:** *Our responsibility:* Michel Fainsilber • **Section cover page:** *Simplified accounts:* Michel Fainsilber • **Pages 26 ; 27 ; 30 ; 43 ; 56 ; 57 ; 59 ; 62 ; 81: Côté Cour/Karim Daher • **Pages 29 ; 32 ; 33 ; 37 ; 39 ; 40 ; 46 ; 48 ; 49 ; 50 ; 51 ; 64 ; 65 ; 66 ; 67 ; 68 ; 69: Rose Deren • **Pages 2 and 20 :******

Jean-Christian Meyer • **Page 14 :** Spencer Rowell / Getty Images • **Page 20 :** Jean-Pierre Elie / Vincent Godeau / Brice Laval / Gilles Leimdorfer • **Page 77 :** Pixart • **Page 82 :** Andrei Jackamets • **Page 84 :** Patrice Maurein • **Page 85 :** Marie Simonnot.

*The photographs which illustrate this document feature Sanofi-Synthélabo employees: we would like to thank them for their contribution.*

**Our story began 30 years ago**

**174, avenue de France 75013 Paris France**

**Tel: +33 1 53 77 40 00**

**[www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com)**



**Contents**

<b>Management report for the year 2002</b>	<b>1</b>
<b>Consolidated Financial Statements</b>	<b>24</b>
<b>Parent Company Financial Statements</b>	<b>63</b>
<b>Financial, administrative and legal additional information</b>	<b>88</b>



## MANAGEMENT REPORT FOR THE YEAR 2002

<b>Business review</b>	<b>3</b>
<b>Consolidated financial statements</b>	<b>4</b>
<b>Sanofi-Synthelabo parent company</b>	<b>11</b>
<b>Additional information</b>	<b>12</b>
<b>Employee data</b>	<b>14</b>
<b>Environmental data</b>	<b>18</b>
<b>Directorships and other positions</b>	<b>21</b>
<b>Fees charged to the Group for services provided by the statutory auditors</b>	<b>23</b>

In 2002, Sanofi-Synthelabo significantly outperformed the pharmaceuticals market in terms of growth. Consolidated net sales for the year were 7,448 million euros, an increase of 14.8% on a reported basis and 12.8% on a comparable basis (before the impact of changes in Group structure and movements in exchange rates). Growth was driven by a fine performance from the three flagship products, Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Stilnox<sup>®</sup>, which between them generated consolidated net sales of 2,973 million euros, up 32.1% on a comparable basis. Operating profit was 2,614 million euros, 24.1% higher than in 2001, giving operating margin of 35.1% compared with 32.5% in the previous year.

This rise in operating profit was achieved:

- n despite the negative impact of euro exchange rates. At 2001 exchange rates, operating profit would have been 30.1% higher than in 2001;
- n thanks to strong growth in sales of the Group's top 15 products (up 20.1% on a comparable basis) and to an improvement in production costs;
- n and thanks to improved sales force productivity;
- n without affecting the high level of R&D spend, which at 1,218 million euros was 18.1% higher than in the previous year and represented 16.4% of net sales;
- n and despite the impact of the reduction in American wholesaler inventories of Plavix<sup>®</sup> and Avapro<sup>®</sup> by Bristol-Myers Squibb from March 2002.

Net income was 11.0% higher than in 2001 at 1,759 million euros. Exceptional items were minimal in 2002 at 10 million euros, against 281 million euros in 2001. Net income before exceptional items and goodwill amortization was 1,758 million euros. This was 27.8% higher than in 2001, and represented 23.6% of net sales, compared with 21.2% in the previous year. Earnings per share before exceptional items and goodwill amortization was 2.42 euros, 28.7% higher than the 2001 figure of 1.88 euros.

Other highlights of 2002 included the following:

- n On April 16, 2002, Sanofi-Synthelabo acquired the 51% interest in Lorex Pharmaceuticals held by Pharmacia, enabling the Group to recognize all the profits generated by Ambien<sup>®</sup> in the United States.
- n A new indication was obtained in the United States and Europe for Plavix<sup>®</sup>/Iscover<sup>®</sup> in the treatment of patients suffering from acute coronary syndrome (unstable angina or non Q-wave myocardial infarction).
- n An extension of indication was obtained in the United States and Europe for Aprovel<sup>®</sup>/Avapro<sup>®</sup> in the treatment of diabetic nephropathy in patients with high blood pressure and type 2 diabetes.

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

- 11 Arixtra<sup>®</sup> was registered in Europe, and launched in the United States and some European countries, in the prevention of venous thrombo-embolic events in patients undergoing major orthopedic surgery to the lower limbs, such as surgery of hip fracture and hip or knee replacement.
- 11 In the United States, Eloxatine<sup>®</sup> was launched in the second-line treatment of colorectal cancer, Elitek<sup>®</sup> (rasburicase) in the management of plasma uric level associated with chemotherapy in pediatric patients, and Eligard<sup>®</sup> (1-month and 3-month formulations) in the treatment of advanced prostate cancer.
- 11 Sanofi-Synthélabo defended the industrial property rights of Plavix<sup>®</sup> in the United States, working closely with Bristol-Myers Squibb to bring patent infringement proceedings against Apotex and Dr Reddy Laboratories, after these companies filed abbreviated new drug applications with the FDA for generics of Plavix<sup>®</sup>.
- 11 A new patent was registered in Europe and the United States protecting the crystalline polymorphic form 2 of clopidogrel (Plavix<sup>®</sup>/Iscover<sup>®</sup>). This new patent protects the form currently marketed worldwide, and runs until 2019.
- 11 Sanofi-Synthélabo was admitted to listing on the New York Stock Exchange (NYSE), where since July 1, 2002 the Group's shares have been listed in the form of American Depositary Receipts (ADRs), with each ADR representing one-half of an ordinary share.

n Under the authority granted by the General Meeting of May 22, 2002 to buy the company's shares in the light of market conditions, the Group initiated a share repurchase program. Under this program, the Group held 16.4 million of its own shares as of December 31, 2002, equivalent to 2.24% of the share capital.

## Business review

### DEVELOPED SALES

Developed sales include Sanofi-Synthelabo consolidated sales and sales generated under the agreements with Bristol-Myers Squibb for Plavix<sup>®</sup>/Iscover<sup>®</sup> (clopidogrel) and Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup> (irbesartan), with Fujisawa for Stilnox<sup>®</sup>/Myslee<sup>®</sup> (zolpidem), and with Organon for Arixtra<sup>®</sup> (fondaparinux). Our partners provide us with details of invoiced sales. These are used to determine developed sales, which are an indicator of the worldwide market presence of the products.

Based on data provided to us as of the date of the meeting of the Board of Directors, **developed sales for 2002 were 9,585 million euros, an increase of 14.5% on a comparable basis.**

The 3 flagship products, Plavix<sup>®</sup>, Stilnox<sup>®</sup> and Aprovel<sup>®</sup>, posted total developed sales of 5,110 million euros in 2002, up 27.3% on a comparable basis. These products now account for 53.3% of developed sales, compared with 48.0% in 2001.

**A significant feature of 2002 was the policy initiated by Bristol-Myers Squibb, starting in March 2002, of reducing inventories of Plavix<sup>®</sup> and Avapro<sup>®</sup> held by American wholesalers.**

### Developed sales of the 3 flagship products

	2001 sales	2001 sales	2002 sales	Change (%)	
	reported	comparable	reported	comparable	reported
(in millions of euros)					
<b>Plavix<sup>®</sup>/Iscover<sup>®</sup></b>					
Europe	520	531	754	+42.0%	+45.0%
United States	1,333	1,270	1,565	+23.2%	+17.4%
Other countries	180	156	268	+71.8%	+48.9%
<b>Sub-total</b>	<b>2,033</b>	<b>1,957</b>	<b>2,587</b>	<b>+32.2%</b>	<b>+27.3%</b>
<b>Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup></b>					
Europe	388	397	512	+29.0%	+32.0%
United States	392	374	373	0.3%	4.8%
Other countries	144	127	183	+44.1%	+27.1%

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

<b>Sub-total</b>	<b>924</b>	<b>898</b>	<b>1,068</b>	<b>+18.9%</b>	<b>+15.6%</b>
<b>Stilnox®/Ambien®/Myslee®</b>					
Europe	143	146	139	4.8%	2.8%
United States	1,004	954	1,208	+26.6%	+20.3%
Other countries	68	60	108	+80.0%	+58.8%
<b>Sub-total</b>	<b>1,215</b>	<b>1,160</b>	<b>1,455</b>	<b>+25.4%</b>	<b>+19.8%</b>
<b>Total: 3 flagship products</b>	<b>4,172</b>	<b>4,015</b>	<b>5,110</b>	<b>+27.3%</b>	<b>+22.5%</b>
<b>Total developed sales</b>	<b>8,746</b>	<b>8,368</b>	<b>9,585</b>	<b>+14.5%</b>	<b>+9.6%</b>

**Over the full year, developed sales of Plavix®/Iscover® came to 2,587 million euros, a rise of 32.2% on a comparable basis.**

In the United States, invoiced sales reached 1,565 million euros, up 23.2% on a comparable basis. Demand continued to grow at a fast pace, with cumulative prescription volumes to end December up 35% (IMS retail+mail order). There was also a favorable price effect. In Europe and the other countries, sales rose by 48.8% on a comparable basis in 2002.

**Developed sales of Aprovel®/Avapro®/Karvea® came to 1,068 million euros in 2002, a rise of 18.9% on a comparable basis.**

In the United States, invoiced sales amounted to 373 million euros, a decline of 0.3% on a comparable basis. Demand rose, with cumulative rolling prescription volumes to end December up 13% (IMS retail+mail order). There was also a favorable price effect. In Europe and the other countries, sales rose by 32.6% on a comparable basis in 2002.

**Worldwide developed sales of Stilnox®/Ambien®/Myslee® reached 1,455 million euros over the full year, an increase of 25.4% on a comparable basis.**

In the United States, the product registered annual sales of 1,208 million euros, an increase of 26.6% on a comparable basis. Demand remained very strong throughout the year, with cumulative prescription volumes to end December up 19% (IMS retail+mail order). There was also a favorable price effect. In Europe and the other countries, sales rose by 19.9% in 2002 on a comparable basis, thanks to the product's success in Japan, where it had market share of 16% at end November 2002.

## Consolidated financial statements

The consolidated financial statements of Sanofi-Synthélabo and its subsidiaries (the Group) have been prepared in accordance with Rule 99-02 of the Comité de la Réglementation Comptable (CRC) issued April 29, 1999, applicable with effect from January 1, 2000.

The accounting policies and methods used are identical to those applied in the preparation of the financial statements for the year ended December 31, 2001, except for the new CRC Rule 2000.06 on liabilities, implemented by Sanofi-Synthélabo with effect from January 1, 2002.

### CONSOLIDATED NET SALES

Consolidated net sales amounted to 7,448 million euros in 2002, 14.8% higher than the 2001 figure of 6,488 million euros on a reported basis. On a comparable basis, the increase was 12.8%. Changes in Group structure, which had a net favorable impact of 4.5 percentage points on consolidated net sales growth, mainly comprised the change from 49% to 100% consolidation of the sales

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

of Lorex Pharmaceuticals in the United States, the change from full consolidation to 51% proportionate consolidation of the Sanofi-Synthelabo-Fujisawa joint venture in Japan in 2002, and the deconsolidation of Ela Medical with effect from May 1, 2001. Currency fluctuations had a net unfavorable impact of 2.5 percentage points on sales growth in 2002. This included 0.8 of a point due to the fall in the US dollar against the euro, 0.5 of a point due to the fall in the Japanese yen against the euro, and 1 point due to the depreciation of Latin American currencies.

### Consolidated sales by geographical region

	2001	2001	2002	Change (%)	
	consolidated net sales reported	consolidated net sales comparable	consolidated net sales reported	comparable	reported
<b>(in millions of euros)</b>					
Europe	3,877	3,843	4,297	+11.8%	+10.8%
United States	1,098	1,437	1,689	+17.5%	+53.8%
Other countries	1,513	1,325	1,462	+10.3%	3.4%
<b>Total</b>	<b>6,488</b>	<b>6,605</b>	<b>7,448</b>	<b>+12.8%</b>	<b>+14.8%</b>

- n In Europe, net sales amounted to 4,297 million euros, an increase of 11.8% on a comparable basis and 10.8% on a reported basis. This strong level of growth in Europe during 2002 was achieved in spite of measures taken to contain healthcare costs in Italy and Germany. Europe accounted for just under 58% of total consolidated net sales in 2002, compared with 60% in 2001.
- n Net sales reached 1,689 million euros in the United States, a rise of 17.5% on a comparable basis and 53.8% on a reported basis. Eloxatine<sup>®</sup>, launched on August 30, 2002, had registered sales of 116 million euros by end December, offsetting the impact of the arrival on the market of generics of Primacor<sup>®</sup> (Corotrope<sup>®</sup>). The very marked growth in reported sales, achieved in spite of the falling dollar, was due to the fact that 100% of Ambien<sup>®</sup> sales have been consolidated with effect from January 1, 2002, compared with 49% in 2001. The United States accounted for 23% of total consolidated net sales in 2002, compared with 17% in 2001.
- n In the other countries, net sales totaled 1,462 million euros, up 10.3% on a comparable basis but 3.4% lower on a reported basis. Very good growth in Asia canceled out the negative effect of the economic and monetary crisis in Latin America. The decline in reported sales reflected the change from 100% to 51% consolidation of Sanofi-Synthelabo-Fujisawa in Japan, and the weakness of the yen and some Latin American currencies. The other countries accounted for 19% of consolidated net sales in 2002, compared with 23% in 2001.

### Consolidated net sales by product

Consolidated net sales generated by the Group's top 15 products rose by 20.1% on a comparable basis to 5,100 million euros, and accounted for 68.5% of total consolidated net sales, against 64.3% in 2001.

This strong growth was driven by a very fine performance from the 3 flagship products, Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Stilnox<sup>®</sup>, combined sales of which were 32.1% higher on comparable basis than in the previous year at 2,973 million euros. They now account for 39.9% of total net sales, against 34.1% in 2001, on a comparable basis.

(in millions of euros)	Product	Indication	2001	2001	2002	Change (%)	
			reported	comparable	reported	comparable*	reported*
	Stilnox <sup>®</sup>	Insomnia	786	1,135	1,424	+25.5%	+81.3%
	Plavix <sup>®</sup>	Atherothrombosis	705	697	987	+41.5%	+39.8%
	Aprovel <sup>®</sup>	Hypertension	423	419	562	+34.0%	+32.8%
	Eloxatine <sup>®</sup>	Colorectal cancer	196	194	389	+101.3%	+99.2%
	Fraxiparine <sup>®</sup>	Thrombosis	297	294	324	+10.1%	+8.9%
	Depakine <sup>®</sup>	Epilepsy	243	240	267	+11.0%	+9.8%
	Xatral <sup>®</sup>	Benign prostatic hyperplasia	148	147	182	+24.3%	+23.1%
	Cordarone <sup>®</sup>	Arrhythmia	162	157	162	+3.1%	0.1%
	Tildiem <sup>®</sup>	Angina, hypertension	152	151	141	6.9%	7.4%
	Ticlid <sup>®</sup>	Thrombosis	205	205	137	33.2%	33.2%
	Solian <sup>®</sup>	Schizophrenia	116	115	135	+17.2%	+16.7%
	Corotrope <sup>®</sup> / Primacor <sup>®</sup>	Heart failure	237	226	127	43.5%	46.1%
	Aspégic <sup>®</sup> and related products	Fever, pain	100	101	108	+6.7%	+7.6%
	Dogmatil <sup>®</sup>	Psychosomatic disorders	124	86	78	9.0%	37.2%
	Kerlone <sup>®</sup>	Hypertension, angina	82	81	77	5.0%	6.9%



Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

<b>Total for the top 15 products</b>	<b>3,976</b>	<b>4,248</b>	<b>5,100</b>	<b>+20.1%</b>	<b>+28.3%</b>
Other products	2,512	2,357	2,348	0.4%	6.5%
<b>Total</b>	<b>6,488</b>	<b>6,605</b>	<b>7,448</b>	<b>+12.8%</b>	<b>+14.8%</b>

\* These percentages are calculated on the basis of figures that have not been rounded.

- <sup>n</sup> Stilnox<sup>®</sup>/Ambien<sup>®</sup> is the Group's no.1 product in terms of consolidated net sales, and no.4 in terms of comparable-basis growth. The difference between the growth achieved by Stilnox<sup>®</sup>/Ambien<sup>®</sup> on a comparable basis (25.5%) and on a reported basis (81.3%) was mainly due to the fact that Lorex Pharmaceuticals was 100% consolidated in 2002, as opposed to 49% previously.
- <sup>n</sup> Consolidated net sales of Plavix<sup>®</sup> rose by 41.5% on a comparable basis to 987 million euros. Growth was maintained at a very high level thanks to the new indication obtained in 2002 and to the inclusion of the product in recommended cardiology therapy lists.
- <sup>n</sup> Consolidated net sales of Aprovel<sup>®</sup> came to 562 million euros, a rise of 34.0% on a comparable basis. This underlines the success of the product, especially in Europe where it has become no.2 in its class.
- <sup>n</sup> Consolidated net sales of Eloxatine<sup>®</sup> were 389 million euros, a rise of 101.3% on a comparable basis. This very high figure reflects the successful launch of Eloxatine<sup>®</sup> on the American market on August 30, 2002, coupled with strong growth for the product in Europe and the other countries.
- <sup>n</sup> Consolidated net sales of Arixtra<sup>®</sup> totaled 9.1 million euros. Penetration was slower than expected, in a narrow indication. The program to extend indications is proceeding as planned, with the filing at end 2002 of an extension of indication in long-term prophylaxis of venous thrombo-embolic events after orthopedic surgery.
- <sup>n</sup> Net sales of the other products in the portfolio were virtually unchanged in 2002 at 2,348 million euros, a fall of just 0.4% on a comparable basis.

#### Consolidated net sales by therapeutic area

Cardiovascular/Thrombosis sales reached 2,904 million euros (39% of Group net sales) in 2002, an increase of 10.6% on a reported basis and 12.4% on a comparable basis. The main growth driver was the boom in sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup>, offsetting lower sales of Ticlid<sup>®</sup> and Primacor<sup>®</sup> (a product now exposed to competition from generics in the United States).

Central Nervous System sales came to 2,409 million euros (32.3% of Group net sales) in 2002, a rise of 33.1% on a reported basis and 15.4% on a comparable basis. The 100% consolidation of Stilnox<sup>®</sup> in the United States had a very favorable impact on reported sales growth.

Internal Medicine sales were 1,427 million euros (19.2% of Group net sales), down 2.6% on a reported basis but up 2.0% on a comparable basis.

Oncology sales totaled 404 million euros (5.4% of Group net sales), an increase of 94.2% on a reported basis and 96.1% on a comparable basis. This strong growth was due to a doubling of Eloxatine<sup>®</sup> sales in 2002.

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

Sales of other products fell by 7.9% on a comparable basis and 20% on a reported basis to 304 million euros. The difference between reported and comparable figures was mainly due to the divestiture of Ela Medical in 2001.

The table below shows a split of consolidated net sales by therapeutic area:

(in millions of euros)	2001	2001	2002	Change (%)	
	reported	comparable	reported	comparable	reported
Cardiovascular/thrombosis	2,625	2,583	2,904	+12.4%	+10.6%
Central Nervous System	1,810	2,087	2,409	+15.4%	+33.1%
Internal Medicine	1,465	1,399	1,427	+2.0%	2.6%
Oncology	208	206	404	+96.1%	+94.2%
Other	380	330	304	7.9%	20.0%
<b>Total</b>	<b>6,488</b>	<b>6,605</b>	<b>7,448</b>	<b>+12.8%</b>	<b>+14.8%</b>

## GROSS PROFIT

Gross profit rose by 16% to 6,070 million euros. Gross margin was 81.5% in 2002, an improvement of 0.8 of a percentage point relative to the previous year.

This improvement reflects a number of positive factors, including:

- n productivity gains in the industrial cost of goods sold, giving an improvement of 0.6 of a point;
- n strong growth in sales of the top 15 products (28.3% on a reported basis) and an improved product mix, representing a further gain of 0.6 of a point.

These factors were partially canceled out by:

- n slower growth in royalty income, due to the inventory reduction program implemented in the United States by Bristol-Myers Squibb for Plavix<sup>®</sup> and Avapro<sup>®</sup>, which had a negative impact of 0.4 of a point on gross margin.

The 100% consolidation of the Lorex Pharmaceuticals joint venture had no impact on the change in the gross margin rate between 2001 and 2002.

At 2001 exchange rates, gross margin would have been 82.1%.

## RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses totaled 1,218 million euros (16.4% of consolidated net sales), an increase of 18.1% relative to 2001. At 2001 exchange rates, the increase would have been 20.4%.

The increase in research and development expenses reflects the substantial investment being made by the Group in its four areas of expertise (Cardiovascular/Thrombosis, Central Nervous System, Immuno-Oncology and Internal Medicine).

The marked acceleration in R&D spend during 2002 was due in particular to:

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

n ongoing major clinical trials programs aimed at obtaining new indications for products already on the market (Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Arixtra<sup>®</sup>, Eloxatine<sup>®</sup> and Xatral<sup>®</sup>), or covering new molecules: rimonabant (obesity, nicotine withdrawal), dronedarone (atrial fibrillation), tirapazamine (non-small-cell lung cancer) and zolpidem MR, the new formulation of Stilnox<sup>®</sup>/Ambien<sup>®</sup>.

n collaboration agreements signed in 2001 and 2002:

- with IDM in cellular immunotherapy, for the development and marketing of immunological treatments in oncology, with exclusive marketing rights;
- with Cephalon, for the development and marketing of angiogenesis inhibitors.

### SELLING AND GENERAL EXPENSES

Selling and general expenses totaled 2,428 million euros, 5.3% higher than in 2001. At 2001 exchange rates, the increase would have been 8%. In the United States, the full effect was felt during 2002 of the reinforcement of the sales force at end 2001 in anticipation of the takeover by the Group of all promotion of Ambien<sup>®</sup> with effect from January 1, 2002, and of the launch of Arixtra<sup>®</sup>. The cost of deploying these extra sales resources was recognized in the final quarter of 2001.

The Group responded to the economic and monetary crisis in Latin America by adjusting its sales resources in the region. In Europe, the Group's strong presence helped stimulate sales growth.

Overall, 2002 saw an improvement in the productivity of medical sales representatives in all regions. Marketing spend continued to rise, in support of the main products in the Group's portfolio.

### OTHER OPERATING INCOME/EXPENSE

Other operating income and expense mainly comprise transfers of profits in respect of joint operations with partners under collaboration agreements relating to product marketing and development, recorded as adjustments to operating profit. This line showed net income of 190 million euros for the year ended December 31, 2002, compared with 208 million euros for the previous year.

The three main factors underlying this change were:

- n rapid growth in European sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup>, which led to a significant increase in the profits generated in this region and hence in the amount of profit passed on by Sanofi-Synthélabo to Bristol-Myers Squibb;
- n reductions in Plavix<sup>®</sup> and Aprovel<sup>®</sup> inventories by Bristol-Myers Squibb in the United States, which slowed growth in profits in the United States, and hence reduced the amount of profit passed on by Bristol-Myers Squibb to Sanofi-Synthélabo;
- n the elimination in 2002 of the share of Lorex profits passed on to Pharmacia, following the buyout by Sanofi-Synthélabo of the rights in the joint venture. In 2001, the amount of profit passed on to Pharmacia was 14 million euros.

#### OPERATING PROFIT

Operating profit amounted to 2,614 million euros, 24.1% higher than the 2001 figure of 2,106 million euros. At 2001 exchange rates, the increase would have been 30.1%.

Operating margin was 35.1% in 2002, against 32.5% in 2001.

The table below shows the main components of operating profit for 2001 and 2002:

	2001		2002		2001/2002
		As % of sales		As % of sales	Change (%)
(in millions of euros)					
<b>Net sales</b>	<b>6,488</b>	<b>100%</b>	<b>7,448</b>	<b>100%</b>	<b>+14.8%</b>
Cost of goods sold	(1,253)	(19.3%)	(1,378)	(18.5%)	+10.0%
<b>Gross profit</b>	<b>5,235</b>	<b>80.7%</b>	<b>6,070</b>	<b>81.5%</b>	<b>+16.0%</b>
Research and development expenses	(1,031)	(15.9%)	(1,218)	16.4%	+18.1%
Selling and general expenses	(2,306)	(35.5%)	(2,428)	32.6%	+5.3%
Other operating income/expense	208	3.2%	190	2.6%	-8.7%
<b>Operating profit</b>	<b>2,106</b>	<b>32.5%</b>	<b>2,614</b>	<b>35.1%</b>	<b>+24.1%</b>

**In geographical terms**, operating profit advanced strongly in all regions.

The table below shows a split by region for 2001 and 2002:

(in millions of euros)	2001	2002	Change (%)
Europe	1,427	1,633	+14.4%
United States	1,311	1,781	+35.9%
Other countries	456	522	+14.5%
Unallocated costs	(1,088)	(1,322)	+21.5%
<b>Total operating profit</b>	<b>2,106</b>	<b>2,614</b>	<b>+24.1%</b>

The United States reported a 35.9% increase in operating profit before unallocated costs, accounting for 45.2% of the Group total in 2002, against 41.0% in 2001.

The main factors underlying this increase were:

- The recognition of 100% of the profits of the Lorex joint venture with effect from January 1, 2002, and the fine performance of Ambien<sup>®</sup> in the American market.
- The launch of Eloxatine<sup>®</sup>, which offset the fall in sales of Primacor<sup>®</sup> following the launch of generics in May 2002.

In the two other regions ( Europe and Other countries ) operating profit growth substantially outpaced sales growth year on year. Unallocated costs, which advanced by 21.5%, mainly comprise fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions. The main reason for the rise in these costs in 2002 was a substantial increase in Research and Development expenses during the year.

## INTANGIBLES AMORTIZATION AND IMPAIRMENT

Amortization and impairment of intangibles rose from 68 million euros in 2001 to 129 million euros in 2002. This increase was mainly due to the amortization of the United States rights to Avapro<sup>®</sup> (acquired from Bristol-Myers Squibb in October 2001) and to Ambien<sup>®</sup> (acquired from Pharmacia on April 16, 2002 when Sanofi-Synthélabo increased its interest in the Lorex Pharmaceuticals joint venture to 100%).

## FINANCIAL INCOME/EXPENSE

Net financial income fell from 102 million euros in 2001 to 85 million euros in 2002.

This reflects three factors:

- n a provision for impairment of 46 million euros taken against treasury shares held in connection with stock option plans, solely to cover the shortfall between the average acquisition price of the shares and the average listed stock market price of the shares during December 2002 (57.10 euros);
- n a reduction in net income on the investment of surplus cash caused by a fall in interest rates (1.1 percentage point lower on average), similar average amounts of surplus cash having been invested in both years;
- n net gains arising on hedging transactions, which were boosted by the fall in the dollar relative to the euro (net gain of 47 million euros, compared with a net gain of 5 million euros in 2001).

## INCOME BEFORE TAX AND EXCEPTIONAL ITEMS

Income before tax and exceptional items amounted to 2,570 million euros, an increase of 20.1% relative to 2001. At 2001 exchange rates, the increase would have been 23.3%.

## EXCEPTIONAL ITEMS

Exceptional items for the period showed a net gain of 10 million euros, compared with a net gain of 281 million euros in 2001. The 2002 net gain mainly comprised gains on disposals of short-term investment securities in the United States. The 2001 figure included the capital gain of 158 million euros arising on the sale of Sanofi-Synthelabo's interest in Laboratoires de Biologie Végétale Yves Rocher, plus the disposal of a number of activities and products.

## INCOME TAXES

Income taxes fell by 96 million euros, from 842 million euros in 2001 to 746 million euros in 2002. The effective tax rate (income taxes as a percentage of net income before tax) was 34.8% for the year ended December 31, 2001 and 28.9% for the year ended December 31, 2002.



Changes in the effective tax rate were due to:

- n in France, the impact of reduced-rate taxation (mainly on royalties) and of a cut in the corporate income tax rate;
- n the impact of the revaluation of the Group's contingent tax positions, resulting in a net reversal of 53 million euros of provisions following finalization of the main tax audits in the first half of 2002;
- n the impact of the full consolidation of the Lorex joint venture, a tax-transparent entity for which the Income taxes line includes only the charge attributable to the Group.

The effective tax rate for the first half of 2002, which included the impact of the second and third factors mentioned above, was 26%. The rate for the second half of the year was 32%.

#### INCOME FROM EQUITY INVESTEEES

The share of net income from equity investees for the year ended December 31, 2002 amounted to 20 million euros, mainly comprising the share of 2001 profits to which Sanofi-Synthelabo is entitled via its interest in the Yves Rocher group.

#### MINORITY INTERESTS

Minority interests totaled 87 million euros in the year ended December 31, 2002. These mainly comprise the share of profits from the Lorex Pharmaceuticals joint venture reverting to Pharmacia in respect of the period from January 1, 2002 through April 16, 2002. Because Lorex Pharmaceuticals is a tax-transparent entity, the Minority interests line does not include the related tax.

## NET INCOME

Consolidated net income was 1,759 million euros, 11% higher than the 2001 figure of 1,585 million euros.

Consolidated net income before exceptional items and goodwill amortization was 1,758 million euros, an increase of 27.8% compared with the previous year. At 2001 exchange rates, the increase would have been 31.2%. Earnings per share was 2.42 euros, compared with 1.88 euros for 2001, a rise of 28.7%.

## CONSOLIDATED STATEMENT OF CASH FLOWS

Operating cash flow before changes in working capital reached 2,260 million euros in 2002, 30.5% up on the 2001 figure (1,732 million euros).

Working capital needs rose by 584 million euros, compared with a decrease of 86 million euros in the year ended December 31, 2001. This change was due mainly to an increase in income taxes paid, both for 2001 and on account for 2002, and to payment arrangements relating to joint operations with the Group's partners. Working capital needs directly related to operations rose in line with sales, by a total of 173 million euros.

Total investments were 1,435 million euros, compared with 619 million euros in 2001. The 2002 figure includes the purchase of Pharmacia's interest in the Lorex joint venture, payment of the balance of the consideration for additional rights to Avapro<sup>®</sup> in the United States, and capital expenditure.

Proceeds from disposals of assets, net of income taxes, came to 22 million euros, compared with 492 million euros in 2001. Dividends paid to Sanofi-Synthelabo shareholders totaled 473 million euros, an increase of 49.2% on the 2001 figure of 317 million euros.

The movement in other financial investments comprised:

- share repurchases totaling 207 million euros in connection with stock option plans (these shares are included under short-term investments in the balance sheet);
- the implementation of the share repurchase program authorized by the General Meeting and the Board of Directors on May 22, 2002, which resulted in the net purchase of 16,411,795 shares for a total amount of 963 million euros (these shares are netted off consolidated shareholders' equity in the balance sheet).

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

After all these cash flows, the amount of cash and cash equivalents (defined as liquid assets, excluding treasury shares classified as short-term investments) shown in the statement of cash flows fell by 1,340 million euros during the year ended December 31, 2002.

### CONSOLIDATED BALANCE SHEET

The balance sheet total was 9,459 million euros as of December 31, 2002, 508 million euros lower than as of December 31, 2001. The consolidated balance sheet showed shareholders' equity of 6,035 million euros as of December 31, 2002, an increase of 267 million euros relative to December 31, 2001.

Balance sheet items showing material movements relative to December 31, 2001 were as follows:

#### **Assets:**

Intangible assets increased by 486 million euros, mainly due to the purchase of the rights to Ambien<sup>®</sup> arising from the acquisition of the remaining 51% of the Lorex Pharmaceuticals joint venture from Pharmacia on April 16, 2002.

#### **Liabilities:**

Provisions and other long-term liabilities fell by 267 million euros due to the reclassification as short-term items of liabilities relating to operations with joint venture and alliance partners; the application of new French accounting rules on liabilities; the reversal of provisions recorded in the opening balance sheet but no longer required; and the reassessment and utilization of provisions shown in the balance sheet at the end of the previous financial year.

Other current liabilities fell by 395 million euros, due mainly to payment during 2002 of the balance of the income tax liability for the previous year and to a reduction in taxes payable in respect of the 2002 financial year as a result of payments on account linked to the tax charge for the year.

The Group had a net year-end cash position of 2,672 million euros, compared with 3,885 million euros as of December 31, 2001, after taking account of 623 million euros of treasury shares held in connection with stock option plans.

#### OFF BALANCE SHEET COMMITMENTS

The Group does not use off balance sheet vehicles. All the Group's operations are reflected in the consolidated financial statements. All the Group's material off balance sheet commitments are identified and disclosed in the consolidated financial statements.

#### OUTLOOK

In 2003, sales and profits should show further strong growth, driven by:

- n the fine performance expected from the three blockbusters Plavix<sup>®</sup>, Stilnox<sup>®</sup> and Aprovel<sup>®</sup>;
- n growth in sales of Eloxatine<sup>®</sup> in the United States, following the launch on August 30, 2002;
- n continuing strong performances from the rest of the portfolio, especially Depakine<sup>®</sup>, Solian<sup>®</sup> and Xatral<sup>®</sup>.

Investment in Research and Development will be maintained at a high level, in particular via phase III clinical trials of rimonabant, dronedarone, idraparinux and zolpidem MR.

An impressive research pipeline, plus the solid positions of all our products, give the Group confidence in its capacity to expand its business and deliver earnings growth.

### Sanofi-Synthelabo parent company

The main features of the Sanofi-Synthelabo parent company financial statements for the year ended December 31, 2002 are as follows:

#### BALANCE SHEET

The balance sheet total as of December 31, 2002 was 8,980 million euros, compared with 7,967 million euros at end December 2001. On the assets side, the balance sheet included long-term investments (investments in and advances to subsidiaries and affiliates) of 3,976 million euros, representing 89% of total fixed assets (4,530 million euros). Current assets (4,429 million euros) mainly comprised amounts receivable from Group companies (1,182 million euros as of December 31, 2002) and short-term investments and deposits (2,856 million euros as of December 31, 2002, against 4,083 million euros at end December 2001).

On the liabilities and equity side, shareholders' equity amounted to 7,055 million euros, or 78% of the balance sheet total. The movement in current liabilities reflects the payment in 2002 of the balance of tax payable in respect of the 2001 financial year (281 million euros), and the recognition of an accrued liability relating to a license agreement (392 million euros).

## STATEMENT OF INCOME

Operating profit for the year ended December 31, 2002, was 396 million euros, compared with 521 million euros in 2001. This reduction was mainly due to an increase in research services carried out for Sanofi-Synthélabo (802 million euros in 2002, against 657 million euros in 2001). The *société en participation* (silent partnership) involved in chemicals activities was wound up on December 31, 2001, and consequently the line 'Share in profits/losses of joint venture partnerships' showed no income in 2002.

Net financial income came to 793 million euros, compared with 561 million euros in 2001, and mainly comprised dividends received from subsidiaries (674 million euros).

Exceptional items showed a net gain of 327 million euros, against a net gain of 581 million euros in 2001. In 2002, the main exceptional items were reversals of provisions relating to vendors' guarantees of liabilities and to developments in tax litigation.

After an income tax charge of 193 million euros, net income for the year ended December 31, 2002 was 1,323 million euros, compared with 1,442 million euros for the previous year.

## ACQUISITION OF PARTICIPATING INTERESTS

During the year, Sanofi-Synthélabo acquired 1,811,940 shares in Sanofi-Synthélabo A.E. (Greece) and 1,500,000 shares in Sanofi Torrent (India), in both cases taking its interest to 100%.

## Additional information

## SHARE CAPITAL

The share capital as of December 31, 2002 amounted to 1,464,735,014 euros, divided into 732,367,507 shares all entitled to dividend in respect of the 2002 financial year except the own shares and including the issuance of 362,423 new shares as a result of the exercising of stock options.

## SANOFI-SYNTHÉLABO VOTING RIGHTS AND SHARE OWNERSHIP

## Share ownership of Sanofi-Synthélabo as of December 31, 2002

	Shares		Voting rights	
	Number	%	Number	%*
TotalFinaElf	179,586,513	24.52	359,173,026	33.74
L Oréal	143,041,202	19.53	286,082,404	26.87
Treasury shares	30,376,375	4.15		
Employees	7,659,036	1.05	14,460,072	1.36
Public	371,704,381	50.75	404,824,601	38.03
<b>Total</b>	<b>732,367,507</b>	<b>100.00</b>	<b>1,064,540,103</b>	<b>100.00</b>

\* Based on the total number of voting rights published subsequent to the Ordinary General Meeting of May 22, 2002, i.e. 1,064,540,103

During the year, the interest held by TotalFinaElf, both directly and indirectly via Elf Aquitaine and its subsidiary Valorisation et Gestion Financière, fell from 26.07% of the capital and 34.90% of voting rights as of December 31, 2001 to 24.52% of the capital and 33.74% of voting rights as of December 31, 2002.

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

As required by article L.233-7 of the Commercial code, State Street Bank and Trust declared on several occasions between November 22 and December 16, 2002 that it had alternately passed above then below the legal threshold of 5% of the company's capital, on behalf of its clients. On December 16, 2002, State Street Bank and Trust declared that as of that date it held 36,638,351 of the company's shares, representing 5.00% of the capital.

No company controlled by Sanofi-Synthélabo owns any Sanofi-Synthélabo shares.

### DIVIDENDS IN RESPECT OF THE LAST THREE FINANCIAL YEARS

<b>Year</b>	<b>Net dividend paid (euros)</b>	<b>Tax already paid to the French Treasury (tax credit: 50% rate) (euros)</b>		<b>Total income (euros)</b>	<b>Tax already paid to the French Treasury (tax credit)(1) (euros)</b>		<b>Total income (euros)</b>
1999	0.32	0.16	0.48	0.13	0.45		
2000	0.44	0.22	0.66	0.11	0.55		
2001	0.66	0.33	0.99	0.10	0.76		

(1) Rate: 15% in 2001, 25% in 2000 and 40% in 1999.

#### PROPOSED DIVIDEND IN RESPECT OF THE 2002 FINANCIAL YEAR

The Board of Directors will propose to the General Meeting of May 19, 2003 that a net dividend of 0.84 euro per share be declared in respect of the year ended December 31, 2002, representing a rise of 27.3% relative to the 2001 dividend of 0.66 euro.

#### TRANSACTIONS RELATING TO STOCK OPTION PLANS

On May 22, 2002, the Board of Directors of Sanofi-Synthélabo granted 3,111,850 options to purchase shares to 1,162 grantees at a price of 69.94 euros per share.

The tables provided in note D12.6 to the consolidated financial statements show for each outstanding plan the date of grant, the total number of options granted, the exercise date and the exercise price.

During 2002, 362,423 new Sanofi-Synthélabo shares were subscribed for by grantees of stock options, at prices of between 10.26 and 14.56 euros, increasing shareholders' equity by 4.2 million euros.

As of December 31, 2002, 514,925 options to subscribe for shares were outstanding, representing a potential increase of 7.5 million euros in shareholders' equity.

During 2002, a total of 847,018 shares were subscribed for or purchased by grantees of stock options.

The information required by article L.225-184 of the Commercial code is contained in a special report of the Board of Directors.

#### EMPLOYEE SHARE OWNERSHIP

As required by article L.225-102 of the Commercial code, it is disclosed that as of December 31, 2002, employees of the company and of related companies owned 7,659,036 Sanofi-Synthélabo shares, representing 1.05% of the share capital, via the Actions Sanofi-Synthélabo mutual fund set up in connection with the Group employee savings plan.

#### AUTHORIZATION TO BUY AND SELL THE COMPANY'S SHARES ON THE STOCK MARKET



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

During the year ended December 31, 2002, the Company used the authorizations given on May 22, 2001 and May 22, 2002 to buy the company's shares on the stock market, in order to allocate shares to the stock option plan of May 22, 2002 and in the light of market conditions.

A total of 19,550,679 shares were bought at an average price of 60.57 euros per share. Trading costs on these purchases amounted to 3,320,064 euros excluding taxes, or 0.17 euros per share.

During the same period, 484,595 shares were sold to grantees of stock options at an average price of 14.49 euros per share, and 109,000 shares were sold on the market at an average price of 59.29 euros.

At end December 2002, the company held 13,964,580 treasury shares classified under Short-term investments and 16,411,795 treasury shares classified under Long-term investments at a total gross value of 1,666,642,026 euros, representing 4.15% of the share capital. Of these shares, 13,836,580 were allocated to pre-existing stock option plans.

### AUTHORIZATIONS TO ISSUE SECURITIES WITH OR WITHOUT PREEMPTIVE RIGHTS

No use has been made since the General Meeting of May 22, 2002 of the authorizations allowing the Board of Directors to issue, at its sole discretion, securities leading to an increase in the company's share capital with or without preemptive rights.

### REMUNERATION OF CORPORATE OFFICERS

Total remuneration paid to Mr Jean-François Dehecq, Chairman and Chief Executive Officer, by Sanofi-Synthélabo: 1,902,885 euros comprising a fixed component of 902,885 euros and a variable component of 1,000,000 euros.

Total remuneration paid to Mr Gérard Le Fur, Senior Executive Vice-President, by Sanofi-Synthélabo: 1,326,312 euros comprising a fixed component of 643,373 euros and a variable component of 682,939 euros (including 182,939 euros in respect of 2001).

## Remuneration of other members of the Board of Directors

The table below shows attendance fees for each member of the Board of Directors in respect of the year ended December 31, 2001, as paid in 2002 either to the Board member in question or to the main company in which he holds office.

Names	Total in thousands of euros
Mr Robert Castaigne	29.24
Mr Pierre Castres St Martin	29.24
Mr Pierre-Gilles de Gennes	30.28
Mr René Barbier de la Serre	55.35
Mr Thierry Desmarest	30.28
Elf Aquitaine	29.24
Mr Hervé Guérin	29.24
L Oréal	33.42
Mr Lindsay Owen-Jones	38.64
Mr Bruno Weymuller	33.42
Mr Régis Dufour (Observer)	14.62
Mr René Sautier (Observer)	12.53

## Employee data

Employee data are consolidated at group level on the basis of data for subsidiaries included in the scope of consolidation.

### EMPLOYEE HEADCOUNT

#### Registered employees

	Total	Europe	incl. France	USA	Other countries
<b>Registered employees: Dec 31, 2002</b>	<b>32,436</b>	<b>21,478</b>	<b>12,204</b>	<b>3,595</b>	<b>7,363</b>
<b>Split by type of contract</b>					
permanent	30,621	20,536	11,591	3,595	6,490
fixed-term	1,815	942	613	0	873
<b>Split by gender</b>					
Female	16,339	11,112	6,434	1,861	3,366
Male	16,097	10,366	5,770	1,734	3,997
<b>Split by category</b>					

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

managers	<b>7,772</b>	5,526	4,003	1,032	1,214
other	<b>14,189</b>	11,107	6,830	307	2,775
sales force	<b>10,475</b>	4,845	1,371	2,256	3,374

The total number of registered employees as of December 31, 2002 was 6.1% higher than at the previous year-end (30,571), an increase of 1,865 employees.

Of these 1,865 new employees, around 680 came from additions to the scope of consolidation (Indonesia, Egypt, Algeria, and the acquisition of a site in Hungary).

Other increases in employee headcount related mainly to the sales force (China, Europe excluding France, and the United States).

The activities with the highest number of employees are the sales force (34% of the total) and research (21% of the total).

Most of the Group's employees (66% of the total) are located in Europe.

The gender split is 50/50 male/female.

## Changes in employee headcount

Registered employees: Dec 31, 2002	Total	Europe	incl. France	USA	Other countries
<b>Total number of new recruits</b>	<b>5,297</b>	<b>2,958</b>	<b>1,647</b>	<b>733</b>	<b>1,606</b>
permanent contracts	3,464	1,689	775	733	1,042
of which female	1,759	826	368	423	510
of which male	1,705	863	407	310	532
fixed-term contracts	1,833	1,269	872	0	564
<b>Total number of leavers</b>	<b>4,089</b>	<b>2,244</b>	<b>1,326</b>	<b>361</b>	<b>1,484</b>
permanent contracts	2,609	1,063	371	361	1,185
fixed-term contracts	1,480	1,181	955	0	299
<b>Total number of dismissals</b>	<b>762</b>	<b>338</b>	<b>144</b>	<b>41</b>	<b>383</b>
for personal reasons	640	255	110	40	345
redundancies	122	83	34	1	38

The recruitment ratio (permanent and fixed-term contracts combined) was 16% in 2002, the same as in 2001. By zone, the ratio was 22% in the Other countries zone, 14% in the Europe zone (13% in France) and 20% in the United States, where there was a major campaign to recruit over 2,000 medical representatives in 2001.

Of the permanent contract employees recruited in 2002, 51% were female and 49% male.

## WORKING TIME ORGANIZATION

## Working time

	Total	Europe	incl. France	USA	Other countries
<b>Theoretical average annual working hours</b>	<b>1,703</b>	<b>1,629</b>	<b>1,547</b>	<b>1,856</b>	<b>1,865</b>
<b>Part-time</b>					
Number of registered employees at Dec 31, 2002	1,516	1,476	1,278	0	40
Full time equivalent*	1,192	1,169	1,041	0	23
<b>Temporary agency staff</b>					
Number of hours	2,547,265	1,638,340	891,234	23,433	885,492
Full time equivalent*	1,497	1,001	576	13	483

\* Full time equivalent = hours paid / theoretical hours.

Part-time staff account for 5% of registered employee headcount worldwide.

Total overtime worked in France, paid at uplifted rates and recorded in the payroll in the year ended December 31, 2002, amounted to 3,989 hours.

### Absenteeism

	<u>Total</u>	<u>Europe</u>	<u>incl. France</u>	<u>USA</u>	<u>Other countries</u>
<b>Total number of days absence</b>	<b>343,928</b>	<b>271,574</b>	<b>155,004</b>	<b>15,500</b>	<b>56,854</b>
<b>Split by reason</b>					
Sick leave	203,970	168,332	107,746	8,889	26,749
Accidents (industrial or while travelling)	8,034	6,665	3,657	103	1,266
Maternity leave	75,455	55,071	24,572	3,956	16,428
Other*	56,469	41,506	19,029	2,552	12,411
<b>Rate of industrial accidents**</b>	<b>4,1</b>	<b>4,6</b>	<b>4,5</b>	<b>2,4</b>	<b>3,7</b>

\* Other includes family events, unpaid leave, parental leave, sabbatical leave, etc.

\*\* Rate of industrial accidents (based on Health, Safety & Environment data): number of industrial accidents requiring more than one day's absence from work occurring in a 12-month period, per million hours worked. These data are consolidated across virtually all Group companies (97% of total employee headcount).

## Training

	Total	Europe	incl. France	USA	Other countries
<b>Number of employees receiving training</b>	<b>26,288</b>	<b>17,699</b>	<b>10,021</b>	<b>3,170</b>	<b>5,419</b>
Total number of training hours	<b>1,149,814</b>	718,796	341,719	129,253	301,765
Total number of health, safety and environment training hours*	<b>303,896</b>	285,634	51,289	1,897	16,365

\* Health, safety and environment training hours relate solely to industrial Sites (chemicals, pharmaceuticals, distribution) and research sites.

Training concerned 83% of the average workforce in 2002. The total number of training hours is equivalent to 5 days of training per employee during the year 2002.

## Subcontracting

Sanofi-Synthelabo aims to handle the bulk of its core business in-house. However, like all industrial groups, it outsources some of its functions, and consequently makes use of subcontractors to provide specialist services or additional capacity. In order to minimize stockout, quality, safety, environmental, ethical and citizenship risks, procurement of subcontracted services is handled by a network of trained buyers, and in-house risk management teams are involved in the supplier selection process.

## HUMANITARIAN ACTIVITIES

### Not-for-profit organizations founded or supported by Sanofi-Synthelabo

Sanofi-Synthelabo has been investing in humanitarian activities since 1986, with a particular emphasis on children in need. In more than 100 countries, we express our commitment and solidarity in areas that reflect our core business in health. We provide humanitarian organizations with financial, technical and human resources to help them solve problems relating to health, social deprivation, disease prevention, social exclusion and childhood trauma, through effective and sustainable international programs.

### EMPLOYEE INFORMATION: FRANCE, 2002

## Remuneration

**Individual remuneration**

(in euros)

Average annual basic gross salary*	<b>38,322</b>
Minimum annual gross salary after 1 year's service	18,000

\* Average annual basic gross salary: average of December 2002 basic salaries multiplied by the number of months pay for full-time, permanent staff employed from January 1 through December 31, 2002.

Effective January 1, 2002, there was a collective pay rise of 2%, supplemented in some cases by individual pay rises.

**Collective remuneration**

(in millions of euros)

**Statutory profit-sharing scheme**

2001 entitlement paid in 2002	<b>50.6</b>
% of total payroll	10.3%

**Group voluntary profit-sharing scheme\***

2001 entitlement paid in 2002	<b>23.7</b>
% of total payroll	4.8%

\* In addition, specific individual company profit shares were paid in 2002.

**Industrial relations**

The five trades unions with nationwide representation in France (CFTC, CFDT, CFE-CGC, CGT, CGT-FO) are all present within the Sanofi-Synthelabo Group in France.

31 collective agreements signed or amended since the merger of Sanofi and Synthelabo in 1999 remained in force within the Group in 2002. The main areas covered are welfare and healthcare costs; top-up pensions; trade union rights; the Group employee savings scheme; training; mobility; and health/safety/working conditions/environment

In 2002, an agreement was signed on the implementation of a mediation procedure relating to moral or sexual harassment within the Sanofi-Synthelabo Group.

Following the agreement reached in 2001 on the establishment of a European Works Council, the Council met twice in 2002. It is made up of 34 representatives from European Union countries and from six EU candidate countries.

**Disabled employees**

**Number of disabled employees:** 289 (excluding those indirectly employed via subcontracting)

Sanofi-Synthelabo has a Disabled Persons Program, helping Group companies implement an employment policy for employees whose health has been impaired. There are two objectives: to allow disabled employees to continue working through preventive measures and by adapting their jobs and organizational structures, and to recruit new disabled employees.



Pre-recruitment initiatives have been developed, including intern programs and work experience under apprenticeship or qualification contracts for both young people and adults.

### Redundancy programs

There was no restructuring within the Group's French operations during 2002. In the event of a site closure or relocation, the Group provides a range of support packages intended to minimize the impact on the employees affected. These support packages reflect the Group's continuing commitment to uphold the principles and values that have always underpinned its human resources policy, by keeping redundancies to a minimum and ensuring that everyone has help in finding new employment.

The Group's concern for the safety and the physical and moral welfare of children is reflected by its application of ILO conventions no. 138 (1973) and no. 182 (1999).

Sanofi-Synthelabo participates in regional employment initiatives via specially-formed not-for-profit and other organizations. In the same spirit, the Group has for more than 15 years operated a spin-off unit for employees who wish to set up their own business.

In all the countries in which it operates, Sanofi-Synthelabo operates integration policies which strive to preserve local identities and cultures. For example, nationals of the host country are favored for recruitment and promotion, including for management posts, subject to the constraints of the local labor market.

## Environmental data

Environmental data are consolidated at Group level from data for industrial units and research centers. No figures are given for changes or comparatives because 2002 is the first year that this report has been produced, as a result of the enactment of the NRE law.

### CONSUMPTION, WASTE AND POLLUTION

Water used for production and thermal purposes is supplied mainly from available groundwater, mostly in France. Consumption is reduced by installing closed loop cooling systems and by accurate monitoring of usage.

<u>m<sup>3</sup></u>	<u>2002</u>
Water	6,430,892

Energy is used for processes, air conditioning of buildings in line with pharmaceutical good manufacturing practices (GMP), and the operation of environmental protection installations. Compared with other industries, the pharmaceutical industry generally does not require large amounts of energy.

<u>mWh (megawatt hours)</u>	<u>2002</u>
Gas	408,156
Electricity	374,005
Liquid hydrocarbons	20,218
Other (steam)	115,201

These data do not include energy used for work-related travel by our medical reps or for transporting goods to and from our sites.

### RAW MATERIALS

Of our raw materials, solvents used mainly for synthesizing our active ingredients are the resource with the greatest potential secondary effects for the environment. Reprocessing (where possible) and thermal utilization are promoted in order to cut consumption of non-renewable raw materials. The criteria for selection or replacement include the reduction of any adverse effects on safety, health and the environment.

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

<u>Tonnes used*</u>	<u>2002</u>
Solvents	48,444

\* Tonnes used includes solvents reprocessed at Group factories. This means that the amount bought in from outside is a smaller figure.

### EMISSIONS, EFFLUENTS AND DEPOSITS

Emissions of Volatile Organic Compounds (VOC) from our synthesis and manufacturing of pharmaceuticals have been declining for several years. In particular, our research and development staff are developing solvent-free processes, while our technical staff are installing solvent vapor recovery or thermal oxidation systems at Aramon, Ambarès, Budapest and Sisteron.

<u>Tonnes</u>	<u>2002</u>
VOC	1,736

The combustion of natural gas and small quantities of liquid hydrocarbons releases carbon dioxide into the air (direct emissions). Electricity consumption involves emissions at the premises of our electricity suppliers (indirect emissions), which are calculated using Greenhouse Gas Protocol Initiative data.

Not included in this total are emissions due to steam purchased externally, our medical rep vehicle fleet and the transport of our goods. The effect of other greenhouse gases is not significant.

<u>Equivalent tonnes(1) of CO2</u>	<u>2002</u>
Fuel	79,485
Power generation	72,032

Industrial effluent discharge is processed either by our water treatment units or by municipal treatment works under agreements with their operators. The main environmental impact of our effluents is COD (Chemical Oxygen Demand). Use was made of innovative technologies (membrane bioreactors) or more traditional technologies (biological and physico-chemical stations).

<u>Tonnes</u>	<u>2002</u>
COD	481

The nitrogen contained in industrial effluents also has an environmental impact.

<u>Tonnes</u>	<u>2002</u>
N <sub>2</sub>	31.6

The Group has no landfill sites or slurry spreading areas at its units. One of our units regularly reinjects its aqueous liquid effluents under license at great depth, the corresponding tonnage has not being accounted for in this report.

## WASTE

We would highlight the very high level of utilization of hazardous wastes, either by recycling or reprocessing, or in the form of energy.

Two exceptional events this year have led to an increase in tonnage. The main one involves the incineration of liquid effluents from one of our factories during a period when the water treatment unit was malfunctioning, a decision taken in order to minimize the impact on the natural environment.

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

Where incineration treatment infrastructures are not available, a very small and constantly-declining proportion of wastes continues to be disposed of at agreed landfills.

<b>Hazardous, tonnes(1)</b>	<b>2002</b>
Recycled (utilized)	57,939
Incinerated (not utilized)	1,754
<b>Total</b>	<b>59,693</b>

Three-quarters of non-hazardous wastes are now reused, recycled or thermally utilized.

<b>Non-hazardous, tonnes(1)</b>	<b>2002</b>
Utilized	21,342
Processed (not utilized)	6,254
<b>Total</b>	<b>27,596</b>

(1) figures are provided in metric tons

### SOIL

We have instituted a long-term program of preventive monitoring and study of topsoils and sub-soils at our sites, with ten sites involved this year.

### SPECIFIC PROTECTION OF NATURAL ENVIRONMENTS

Only one of our sites is located in an area where there is specific protection of the natural environment: Csanyikvölgy in Hungary. Its activities are slightly polluting to the environment and it is specifically monitored in this connection.

## ENVIRONMENTAL EVALUATION AND CERTIFICATION

Two sites the Alnwick research center in the UK and the Veresezyhaz pharmaceutical factory have been granted ISO 14001 environmental certification.

Three other sites in France have just obtained a favorable recommendation in their certification audits: Aramon (chemicals), Amilly (pharmaceuticals) and Labège (research).

## REGULATORY COMPLIANCE

An environment law watch is organized and carried out for all industrial and scientific activities in France. Subsidiaries in other countries which carry out industrial or scientific activities also organize and carry out their own environment law watch.

An audit program is used to evaluate the effectiveness of this watch and to assess compliance with applicable administrative and regulatory provisions.

Over the 2000-2002 period, all sites were subjected to an audit, either a general health safety and environment audit or a specific environmental, health & safety or fire protection audit, except for two sites with fewer than 100 staff.

## EXPENDITURE INCURRED IN MONITORING AND CONTROLLING THE IMPACT OF THE COMPANY'S ACTIVITIES ON THE ENVIRONMENT

Investment with an industrial health, safety, working conditions, process safety or environmental dimension amounted to 23 million euros in 2002. In addition, new developments are designed with built-in preventive mechanisms, the associated investment being impossible to quantify specifically.

Expenditure on health, safety and environment, comprising HS&E personnel costs, consumables, energy, labor, waste processing and recycling, environmental taxes, studies and audit services, totaled 40 million euros in 2002.

## GROUP HSE DEPARTMENT

The HSE (Health-Safety-Environment) department comprises 14 experts in environmental technologies, industrial safety, industrial toxicology, safety at work, fire safety, industrial risks, life sciences and work-related medicine. The department is active at all the

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

Group's sites. It is responsible for formulating HSE policy and general objectives, managing and coordinating implementation, maintaining and developing competencies and reporting overall performances to divisional heads using reports and audits. It is supported by:

- n 59 HSE officers on site, implementing central guidance and directives.
- n 57 other officers at the largest sites, completing our Group HSE management services.
- n 9 full-time or part-time company doctors employed by the Group, and interprofessional doctors providing medical services on site. They are assisted in their work by company nurses.
- n 3 European sites classified as SEVESO II, which also have their own first-aid personnel and equipment.

Finally, each site has instituted and maintains its own emergency plan setting out the risks incurred and the internal and external resources to be mobilized or called upon as a result.

### AMOUNT OF PROVISIONS AND GUARANTEES RELATING TO ENVIRONMENTAL RISKS

Detailed assessments of topsoil and subsoil pollution risks were carried out at 3 sites or former sites which are to be cleaned up. In association with other corporate site-users, we also participated in an in-depth investigation and preliminary works at a former hazardous waste dump. In all, 21 million euros were provided for cleanup costs.

### AMOUNT OF COMPENSATION

We were not ordered to pay any compensation of an environmental nature through the enforcement of any judicial decision in 2002.

### OBJECTIVES SET FOR FOREIGN SUBSIDIARIES

The programs, resources and results of foreign subsidiaries are included in the above report.

## Directorships and other positions held by members of the Board of Directors and the Senior Executive Vice-President in all companies in France and abroad during the year ended December 31, 2002

René Barbier de la Serre

### **in France :**

- n Director of Crédit Lyonnais, Sanofi-Synthélabo and Schneider Electric
- n Member of the Supervisory Board of Compagnie Financière Edmond de Rothschild Banque (subsidiary of Compagnie Financière Saint Honoré), Compagnie Financière Saint-Honoré and Pinault-Printemps-Redoute
- n Observer of Fimalac and Nord-Est

### **abroad:**

- n Chairman of Tawa UK Ltd (United Kingdom)
- n Delegated Director of Harwanne Compagnie de Participations Industrielles et Financières SA (Switzerland)
- n Member of the Supervisory Board of Euronext NV (Netherlands)

Robert Castaigne

### **in France :**

- n Chief Financial Officer of TotalFinaElf SA
- n Chairman and Chief Executive Officer of Total Chimie and Total Nucléaire (subsidiary of Total Chimie)
- n



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

Director of Atofina (subsidiary of Elf Aquitaine), Compagnie Générale de Géophysique, Elf Aquitaine, Eramet, Hutchinson (subsidiary of Total Chimie) and Sanofi-Synthélabo

### abroad:

- n Director of Omnium Insurance & Reinsurance Company Ltd (Bermuda), Petrofina (Belgium), Total Nigeria Ltd (Nigeria), TotalFinaElf, Exploration Norge AS (Norway), TotalFinaElf, Exploration Holdings UK (United Kingdom) and TotalFinaElf Exploration UK (United Kingdom)

Pierre Castres Saint Martin

### in France :

- n Chairman of the Supervisory Board of Groupe Marc de Lacharrière
- n Director of Fimalac (subsidiary of Groupe Marc de Lacharrière), SEB and Sanofi-Synthélabo
- n Member of the Supervisory Board of Arc International

Jean-François Dehecq

### in France :

- n Chairman and Chief Executive Officer of Sanofi-Synthélabo
- n Director of Air France, Finance et Management, Société Financière des Laboratoires de Cosmétologie Yves Rocher and Péchiney
- n Permanent representative of Sanofi-Synthélabo as Director of Sanofi-Synthélabo Recherche (subsidiary of Sanofi- Synthélabo)

### abroad:

- n Chairman and Director of Sanofi-Synthelabo Daichi Pharmaceuticals Co Ltd (Japan)
- n Director of Sanofi-Synthelabo Inc. (United States) and Fujisawa Sanofi-Synthelabo (Japan)

Thierry Desmarest

**in France :**

- n Chairman and Chief Executive Officer of TotalFinaElf SA and Elf Aquitaine (subsidiary of TotalFinaElf SA)
- n Director of Sanofi-Synthélabo
- n Member of the Supervisory Board of Areva and L Air Liquide

Lord Douro

**in France:**

- n Director of Sanofi-Synthélabo

**abroad:**

- n Chairman of Richemont Holdings UK (United Kingdom)
- n Chairman of Framlington Group (United Kingdom)
- n Director of Compagnie Financière Richemont AG (Switzerland) and GAM Worldwide (United Kingdom)

ELF AQUITAINE

**in France:**

- n Director of Elf Aquitaine Exploration Production France, Elf Exploration Production, Elf Hydrocarbures Chine, Elf Neftegaz, Elf Petroleum Irak, Elf Petroleum Iran, Elf Union Océane, Eurotadia International, Safrep, Sanofi-Synthélabo, Sofrea, TotalFinaElf E & P Syrie and TotalFinaElf Lubrifiants

**abroad:**

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

n Director of Elf Aquitaine Algérie (Algeria), TotalFinaElf E & P Congo (Congo), Elf Gabon (Gabon), GPL (Gabon), Reachim SA (Luxembourg), SAR (Senegal), SIR (Côte d Ivoire), Sogara (Gabon), Sonara (Cameroon) and TotalFinaElf E & P (Cameroon)

21

Management Report

represented by **Jean-Paul Léon**

**in France:**

n Director of Société Financière des Laboratoires de Cosmétologie Yves Rocher

n Permanent representative of Elf Aquitaine as Director of Sanofi-Synthélabo

**Pierre-Gilles de Gennes**

Nobel Prize for Physics (1991)

**in France:**

n Professor at the Collège de France

n Director of the Ecole Supérieure de Physique et Chimie Industrielles de Paris

n Director of Rhodia and Sanofi-Synthélabo

n Member of the Supervisory Board of L'Air Liquide

**Hervé Guérin**

**in France:**

n Chairman of the Supervisory Board of Human Health Investments (H2i)

n Director of Ethypharm SA and Sanofi-Synthélabo

**Gérard Le Fur**

**in France:**

n Executive Vice-President Scientific Affairs

n Senior Executive Vice-President of Sanofi-Synthélabo

n Chairman and Chief Executive Officer of Sanofi-Synthélabo Recherche (subsidiary of Sanofi-Synthélabo)

**abroad:**

n Director of Sanofi-Synthélabo Inc. (United States)

**L ORÉAL**

**in France:**

n Director of Cospar, Ecompar, Genfa, Laboratoires Galderma, Parfums Guy Laroche, Regefi, Sanofi-Synthélabo and Semercli

**abroad:**

n Director of Biotherm (Monaco), L Oréal Hong Kong (Hong Kong) and Sofamo (Monaco)

**represented by Michel Somnolet**

**in France:**

n Vice-President of L Oréal in charge of General Management, Administration and Finance

n Chairman of Regefi

n Director of L Oréal

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

n Permanent representative of L Oréal as Director of Sanofi- Synthélabo

### **abroad:**

n Chairman and Director of Geral Inc. (United States)

n Director of L Oreal USA Inc. (United States)

n Member of the Supervisory Board of L Oréal Maroc (Morocco)

### **Lindsay Owen-Jones**

### **in France:**

n Chairman and Chief Executive Officer of L Oréal

n Director of BNP Paribas, Gesparal and Sanofi-Synthélabo

n Vice-Chairman and Member of the Supervisory Board of L Air Liquide

### **abroad:**

n Chairman and Director of L Oreal USA Inc. (United States) and L Oreal UK Ltd (United Kingdom)

n Director of Galderma-Pharma (Switzerland)

### **Bruno Weymuller**

### **in France:**

n Executive Vice-President, Strategy and Risk Assessment of TotalFinaElf SA

n Director of Elf Aquitaine and Sanofi-Synthélabo

n Member of the Supervisory Board of Technip-Coflexip

## Observers

### Régis Dufour

#### in France:

n Chairman of Mercure Pharmacie (mutual fund)

n Member of the Supervisory Board of Chevrillon Associés

n Observer of Sanofi-Synthélabo

### René Sautier

#### in France:

n Observer of Sanofi-Synthélabo

## Fees charged to the Group for services provided by the statutory auditors and by member firms of their networks (year 2002)

	PricewaterhouseCoopers		Ernst & Young	
	000	%	000	%
<b>Audit</b>				
Statutory audit, certification, examination of				
individual company financial statements and				
consolidated financial statements	2,757		2,527	
<i>France</i>	1,602		1,273	
<i>Other countries</i>	1,155		1,254	
Related engagements	164		659	
<b>Sub-total</b>	<b>2,921</b>	<b>83%</b>	<b>3,186</b>	<b>84%</b>
<b>Other services</b>				
Legal, tax, employee-related	548		527	
<i>France</i>			69	
<i>Other countries</i>	548		458	
Information technology				
Internal audit				
Other	43		92	
<b>Sub-total</b>	<b>591</b>	<b>17%</b>	<b>619</b>	<b>16%</b>
<b>TOTAL</b>	<b>3,512</b>	<b>100%</b>	<b>3,805</b>	<b>100%</b>



## CONSOLIDATED FINANCIAL STATEMENTS

Report of the statutory Auditors on the consolidated financial statements	25
Consolidated balance sheets	26
Consolidated statements of income	28
Consolidated statements of cash flows	29
Consolidated statements of shareholders' equity	30
Notes to the consolidated statements	31
Consolidated financial summary	61
Reconciliation of US GAAP financial statements	61

## Report of the statutory auditors on the consolidated financial statements

Year ended December 31, 2002

In compliance with the assignment entrusted to us by your shareholders' meeting, we have audited the accompanying consolidated financial statements of Sanofi-Synthelabo presented in euros for the year ended December 31, 2002.

These consolidated financial statements are the responsibility of the Board of Directors. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with French auditing standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statements presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Sanofi-Synthelabo and its subsidiaries as of December 31, 2002, and the results of their operations for the year then ended, in accordance with principles generally accepted in France.

Without qualifying our opinion, we draw attention to note B2 to the consolidated financial statements, which present the impact on the consolidated financial statements of the change in accounting method resulting from the application, with effect from January 1, 2002, of the new CRC rule 2000-06 on liabilities.

We have also reviewed the information contained in the Directors' report. We have nothing to report with respect to the fairness of such information or its consistency with the consolidated financial statements.

Paris, February 18, 2003

The Statutory Auditors

PricewaterhouseCoopers Audit

Ernst & Young Audit

Jacques Denizeau

Jean-Christophe Georghiou    Dominique Thouvenin

Valérie Quint



## Consolidated balance sheets

Before appropriation of profit

### ASSETS

	Note	December 31, 2002	December 31, 2001	December 31, 2000
<b>(in millions of euros)</b>				
<b>Intangible assets, net</b>	D.2			
Goodwill		134	141	82
Other intangible assets		1,161	668	319
		1,295	809	401
<b>Property, plant and equipment</b>	D.3			
Gross		1,989	1,630	1,417
Accumulated depreciation		(594)	(401)	(200)
Net		1,395	1,229	1,217
<b>Long-term investments</b>				
Investments in/advances to equity investees	D.4	109	100	86
Investments in/advances to non-consolidated companies	D.5	27	110	274
Other long-term investments		73	48	67
<b>Total fixed assets</b>		<b>2,899</b>	<b>2,296</b>	<b>2,045</b>
Deferred income taxes	D.11	484	471	397
Inventories	D.7	823	805	737
Accounts receivable	D.8	1,311	1,566	1,234
Other current assets	D.9	854	540	553
Short-term investments and deposits	D.10	2,944	4,166	2,672
Cash		144	123	207
<b>Total assets</b>		<b>9,459</b>	<b>9,967</b>	<b>7,845</b>

The accompanying notes on pages 31 to 60 are an integral part of the consolidated financial statements.

## Consolidated balance sheets

Before appropriation of profit

### LIABILITIES AND SHAREHOLDERS EQUITY

(in millions of euros)	Note	December 31, 2002	December 31, 2001	December 31, 2000
<b>Shareholders equity</b>	D.12			
Share capital		1,465	1,464	1,463
<p>(December 31, 2002: 732,367,507 shares; December 31, 2001: 732,005,084 shares; December 31, 2000: 731,441,746 shares)</p>				
Additional paid in capital and reserves		2,971	2,736	1,886
Net income for the period		1,759	1,585	985
Cumulative translation adjustment		(160)	(17)	(30)
<b>Total shareholders equity</b>		<b>6,035</b>	<b>5,768</b>	<b>4,304</b>
<b>Minority interests</b>		<b>17</b>	<b>21</b>	<b>28</b>
Long-term debt	D.13	65	119	121
Provisions and other long-term liabilities	D.14	786	1,053	1,130
Deferred income taxes	D.11	10	10	4
Accounts payable		596	717	667
Other current liabilities	D.15	1,599	1,994	1,300
Short-term debt	D.16	351	285	291
<b>Total liabilities and shareholders equity</b>		<b>9,459</b>	<b>9,967</b>	<b>7,845</b>

The accompanying notes on pages 31 to 60 are an integral part of the consolidated financial statements.

## Consolidated statements of income

(in millions of euros)	Note	Year ended Dec. 31, 2002	Year ended Dec. 31, 2001	Year ended Dec. 31, 2000
Net sales	D.28	7,448	6,488	5,963
Cost of goods sold		(1,378)	(1,253)	(1,442)
<b>Gross profit</b>		<b>6,070</b>	<b>5,235</b>	<b>4,521</b>
Research and development expenses		(1,218)	(1,031)	(945)
Selling and general expenses		(2,428)	(2,306)	(2,016)
Other operating income/(expense), net		190	208	17
<b>Operating profit</b>	<b>D.28</b>	<b>2,614</b>	<b>2,106</b>	<b>1,577</b>
Intangibles amortization and impairment		(129)	(68)	(35)
Financial income/(expense), net		85	102	18
<b>Income before tax and exceptional items</b>		<b>2,570</b>	<b>2,140</b>	<b>1,560</b>
Exceptional items	D.22	10	281	46
Income taxes	D.23	(746)	(842)	(611)
<b>Net income before income from equity investees, goodwill amortization and minority interests</b>		<b>1,834</b>	<b>1,579</b>	<b>995</b>
Income from equity investees, net		20	14	8
Goodwill amortization		(8)	(7)	(4)
<b>Net income before minority interests</b>		<b>1,846</b>	<b>1,586</b>	<b>999</b>
Minority interests	D.24	(87)	(1)	(14)
<b>Net income</b>		<b>1,759</b>	<b>1,585</b>	<b>985</b>
Weighted average shares outstanding		727,686,372	731,711,225	731,232,525
<b>Earnings per share, basic and diluted (in euros)</b>		<b>2.42</b>	<b>2.17</b>	<b>1.35</b>
<b>Net income</b>		<b>1,759</b>	<b>1,585</b>	<b>985</b>
Exceptional items and goodwill amortization, net of income taxes and minority interests		(1)	(209)	(24)
<b>Income before exceptional items and goodwill amortization, net of income taxes and minority interests</b>		<b>1,758</b>	<b>1,376</b>	<b>961</b>
<b>Earnings per share before exceptional items and goodwill amortization, basic and diluted (in euros)</b>		<b>2.42</b>	<b>1.88</b>	<b>1.31</b>

The accompanying notes on pages 31 to 60 are an integral part of the consolidated financial statements.

## Consolidated statements of cash flows

	Note	Year ended	Year ended	Year ended
		Dec. 31, 2002	Dec. 31, 2001	Dec. 31, 2000
(in millions of euros)				
Net income		1,759	1,585	985
Minority interests		87	1	14
Share in undistributed earnings of equity investees		(20)	(14)	(8)
Depreciation and amortization		379	301	241
Gains on disposals of fixed assets, net of income taxes		(9)	(216)	(28)
Provisions, long-term deferred taxes and other		64	75	91
<b>Operating cash flow before changes in working capital</b>		<b>2,260</b>	<b>1,732</b>	<b>1,295</b>
Dividends received from equity investees		11		
(Increase)/decrease in inventories		(78)	(105)	31
(Increase)/decrease in accounts receivable		(18)	(235)	(125)
Increase/(decrease) in accounts payable		(77)	70	10
Change in other operating assets and liabilities (net)		(422)	356	(12)
<b>Net cash provided by operating activities(A)</b>		<b>1,676</b>	<b>1,818</b>	<b>1,199</b>
Acquisitions of property, plant & equipment and intangibles	D.6	(1,403)	(565)	(372)
Acquisitions of investments		(32)	(54)	(93)
<b>Total investments</b>		<b>(1,435)</b>	<b>(619)</b>	<b>(465)</b>
Proceeds from disposals of fixed assets, net of income taxes		22	492	81
Net change in loans, long-term advances and other investing cash flows		4	14	(5)
<b>Net cash used in investing activities(B)</b>		<b>(1,409)</b>	<b>(113)</b>	<b>(389)</b>
Issuance of Sanofi-Synthelabo shares	D.12	4	7	3
Capital contribution from minority shareholders		5		
Dividends paid:				
to Sanofi-Synthelabo shareholders		(473)	(317)	(231)
to minority shareholders of subsidiaries		(3)	(6)	(10)
Additional long-term borrowings		1	9	
Repayments of long-term borrowings		(9)	(12)	(29)
Net change in short-term borrowings		54	(1)	(21)
Acquisitions of treasury shares		(1,170)	(163)	(183)
<b>Net cash used in financing activities(C)</b>		<b>(1,591)</b>	<b>(483)</b>	<b>(471)</b>
Impact of exchange rates on cash and cash equivalents(D)		(16)	3	1
<b>Net change in cash and cash equivalents(A) + (B) + (C) + (D)</b>		<b>(1,340)</b>	<b>1,225</b>	<b>340</b>
<b>Cash and cash equivalents, beginning of period</b>	B.10	<b>3,805</b>	<b>2,580</b>	<b>2,240</b>
<b>Cash and cash equivalents, end of period</b>	B.10	<b>2,465</b>	<b>3,805</b>	<b>2,580</b>

The accompanying notes on pages 31 to 60 are an integral part of the consolidated financial statements.





## Consolidated statements of shareholders equity

(in millions of euros)	Number of shares	Share capital	Additional paid in capital and reserves	Cumulative translation adjustment	Total
<b>Balance December 31, 1999</b>	<b>731,143,218</b>	<b>1,462</b>	<b>2,131</b>	<b>(15)</b>	<b>3,578</b>
Dividend paid out of 1999 earnings (0.32 per share)			(231)		(231)
Issuance of shares on exercise of share options	298,528	1	2		3
Net income for year ended December 31, 2000			985		985
Adjustments relating to the merger (note D.12.4.)			(16)		(16)
Movement in cumulative translation adjustment				(15)	(15)
<b>Balance, December 31, 2000</b>	<b>731,441,746</b>	<b>1,463</b>	<b>2,871</b>	<b>(30)</b>	<b>4,304</b>
Dividends paid out of 2000 earnings (0.44 per share)			(317)		(317)
Issuance of shares on exercise of stock options	563,338	1	6		7
Net income for year ended December 31, 2001			1,585		1,585
Adjustments related to the Sanofi-Synthelabo merger (note D.12.4.)			176		176
Movement in cumulative translation adjustment				13	13
<b>Balance, December 31, 2001</b>	<b>732,005,084</b>	<b>1,464</b>	<b>4,321</b>	<b>(17)</b>	<b>5,768</b>
Dividends paid out of 2001 earnings (0.66 per share)			(473)		(473)
Issuance of shares on exercise of stock options	362,423	1	3		4
Net income for year ended December 31, 2002			1,759		1,759
Adjustments related to the Sanofi-Synthelabo merger (note D.12.4.)			59		59
Change in accounting method (note D.12.3.)			24		24
Repurchase of shares (note D.12.5.)			(963)		(963)
Movement in cumulative translation adjustment				(143)	(143)
<b>Balance, December 31, 2002</b>	<b>732,367,507</b>	<b>1,465</b>	<b>4,730</b>	<b>(160)</b>	<b>6,035</b>

The accompanying notes on pages 31 to 60 are an integral part of the consolidated financial statements.

## Notes to the consolidated financial statements

### Year ended December 31, 2002

#### A. BASIS OF PREPARATION

The consolidated financial statements of Sanofi-Synthélabo and its subsidiaries (the Group) have been prepared in accordance with Rule 99-02 of the Comité de la Réglementation Comptable (CRC) issued April 29, 1999. Under the option allowed by this rule, acquisitions of companies occurring prior to 2000 have not been restated.

The accounting policies and methods used are identical to those applied in the preparation of the financial statements for the year ended December 31, 2001, except for the new CRC Rule 2000-06 on liabilities, implemented by Sanofi-Synthélabo with effect from January 1, 2002.

#### Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and the disclosures of contingent assets and liabilities as of the balance sheet date. Examples include provisions for returns, bad debts, product claims reserves, inventory obsolescence and length of product life cycles, provisions associated with restructuring activities, income tax exposures, environmental liabilities, estimated useful lives of goodwill and intangible assets and fair values of derivative financial instruments. Actual results could vary from these estimates.

#### Accounting for the May 18, 1999 merger

In 1999, Sanofi and Synthélabo merged by absorption into Sanofi-Synthélabo, a separate legal entity. The effective date of the merger for accounting purposes was July 1, 1999.

The excess of the acquisition cost of the shares (including transaction-related expenses) over the book value of net assets acquired, calculated using the Group's accounting policies, was accounted for as follows:

- n In consolidation, revaluations were recorded in the balance sheets of the companies to adjust the book value of their separately identifiable assets and liabilities to their value to the Group based on a valuation carried out as of June 30, 1999, which took into account restructuring costs and was subsequently adjusted as of December 31, 1999 and finalized as of December 31, 2000.

- n The remaining excess of cost over the adjusted book value of net assets acquired was deducted from consolidated shareholders equity, in accordance with Bulletin 210 issued by the Commission des Opérations de Bourse ( COB ). In compliance with CRC Rule 99-02, this accounting treatment was not adjusted for the new rules that became effective as of January 1, 2000.

## B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### B.1. Basis of consolidation

The consolidated financial statements include the accounts of Sanofi-Synthélabo and subsidiaries which it controls, using the full consolidation method. The existence of effectively exercisable or convertible potential voting rights is taken into account in determining whether control exists.

Companies in which Sanofi-Synthélabo and outside shareholders exercise joint control over significant financial and operational policies are accounted for using the proportionate consolidation method. For such companies, the Group recognizes in its financial statements its share of assets and liabilities, revenues and expenses, and cash flows on the same lines as used for fully-consolidated subsidiaries, in proportion to the percentage interest held by the Group.

The Group defers recognition of its share of the margin generated by the purchase of products from within the Group until such products are resold to independent third parties. However, if it is probable that the loss on a transaction will result in a reduction in the net realizable value of such products or in other-than-temporary impairment, the loss is recognized immediately in the Group's financial statements.

Companies over which Sanofi-Synthelabo exercises significant influence are accounted for under the equity method. All material intercompany balances and transactions have been eliminated in the consolidated financial statements.

The Group's share of post-acquisition profits or losses is taken to the statement of income, and post-acquisition movements in the acquired company's reserves are taken to consolidated reserves. Profits or losses arising on transactions with consolidated companies or equity investees are eliminated in proportion to the percentage interest held by the Group in the company, until the assets are resold to an independent third party.

A list of companies included in the consolidation is presented in section E. of the notes to the consolidated financial statements.

Companies are consolidated from the date on which control (exclusive or joint) or significant influence is transferred to the Group, and are excluded from consolidation from the date on which the Group transfers control or significant influence.

## **B.2. Change in accounting method**

Pursuant to the new CRC Rule 2000-06, which became effective as of January 1, 2002, the Group reviewed all its liabilities as of that date for compliance with the new rule.

The impact of applying this new rule was an adjustment to shareholders' equity of 24 million euros net of income taxes.

Adoption of CRC Rule 2000-06 had no material impact on net income for the years presented.

## **B.3. Foreign currency translation**

Each foreign subsidiary measures its results in the currency that is most representative of its economic environment (the functional currency).

### *a) Accounting for transactions in foreign currencies in individual company accounts*

Fixed assets and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the date of acquisition.

All amounts receivable or payable in foreign currencies are translated using the exchange rate prevailing at the balance sheet date or, where hedging instruments have been contracted in the market, at the hedged rate. The resulting gains and losses are recorded in the statement of income. However, foreign exchange gains and losses arising from the translation of capitalizable advances made to consolidated subsidiaries are reflected directly in the Cumulative translation adjustment line in shareholders' equity.

*b) Foreign currency translation of the financial statements of foreign subsidiaries*

All assets and liabilities are translated into euros using the exchange rate of the subsidiary's functional currency prevailing at the balance sheet date. The statements of income are translated using a weighted-average exchange rate for the period. The resulting translation difference is shown as a separate component of shareholders' equity and is recognized in the statement of income when the subsidiary is sold. By exception to this general rule, when a subsidiary operates in a hyper-inflationary environment with inflation exceeding 100% over a three-year period, fixed assets and inventories are translated using the exchange rate prevailing at the date of acquisition. Related statement of income items, such as depreciation expense, are translated using the same exchange rate as for the corresponding asset, and the resulting translation adjustment is recorded in the statement of income under Financial income/(expense), net.

**B.4. Goodwill**

When the Group acquires control of a company, the separately identifiable assets and liabilities of the acquired company are included in the consolidated balance sheet at their fair value to the Group at the date of first consolidation. The excess of the purchase price, including transaction-related expenses, over the fair value of the Group's share of the identifiable assets and liabilities as of the acquisition date is recorded as goodwill.

Goodwill is amortized over periods which do not exceed 40 years. Individual amortization periods are determined after considering the nature of the acquired business and the geographical location in which the acquired company operates. Goodwill is subject to an impairment review when events or circumstances indicate that an impairment might exist. Such events or circumstances include significant changes liable to have an other-than-temporary impact on the substance of the original investment.

#### **B.5. Other intangible assets**

Patents are amortized over the shorter of the period of legal protection or their estimated useful life.

Licenses are amortized over the shorter of the duration of the agreement or their estimated useful life.

Trademarks, leasehold rights and other intangible assets are recorded at their acquisition cost and are amortized on a straight-line basis over their estimated useful lives, net of any provision for impairment if deemed necessary. Provisions for impairment are measured on the basis of the same objective criteria that were used for the initial valuation.

Rights to pharmaceutical products that are acquired from third parties prior to receipt of regulatory approval to market the products are expensed immediately as research and development expenses. However, amounts attributable to patents or other intellectual property rights relating to molecules are capitalized if they have a market value. In such cases, they are amortized on a straight-line basis over their estimated useful lives, net of any provision for impairment if their value in use is less than net book value.

#### **B.6. Impairment of intangible assets**

The value of intangible assets is reviewed regularly once a risk of impairment has been identified. The impairment review involves a comparison of the net book value of the asset with the future cash flows from the asset.

Future cash flows are estimated by Group management on the basis of the medium-term plans for each business activity.

If net book value exceeds the value of the undiscounted cash flows, a provision for impairment is recorded equal to the difference between the discounted cash flows and net book value. The discounting rate used is determined with reference to the risks inherent in the business activities in question and to the economic situation in the country in which they operate.

#### **B.7. Property, plant and equipment**

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

Property, plant and equipment are recorded at acquisition cost to the Group or estimated value on the date of first consolidation and are depreciated on a straight-line basis over their estimated useful lives.

Interest charges incurred on the financing of property, plant and equipment during the construction period are capitalized.

Leased assets are recorded as a fixed asset with a related liability when the terms of the lease effectively transfer the risks and rewards of ownership of the asset to the Group.

Property, plant and equipment are depreciated over the following estimated useful lives:

Buildings	20 years
Plant and equipment	8 to 10 years
Other tangible fixed assets	4 to 10 years

### **B.8. Investments in/advances to non-consolidated companies**

Investments in and advances to non-consolidated companies are recorded at acquisition cost. A provision for impairment is recorded when the value in use to the Group as of the balance sheet date is less than acquisition cost, after taking account of various factors including the share held in the company's net assets, its future earnings prospects, its position in the market, and, if listed, the current market price.

### **B.9. Inventories**

Inventories are valued at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method. Returned goods are recorded at the standard cost of the accounting period in which the return occurs. Expected returns are provided for at the end of the accounting period based on the Group's past experience.

#### **B.10. Short-term investments and deposits**

Short-term investments are valued at the lower of cost or market value. They include treasury shares held in connection with stock option plans. Treasury shares held in connection with stock option plans are allocated to these plans over the term of the plan, and are valued at the lower of acquisition cost or exercise price of the related option. Provisions recorded to reduce the carrying amount of treasury shares to the expected proceeds to be received on exercise of the options are charged to the statement of income. A provision for impairment is recorded if their stock market value, taken as the average of the last 20 listed market prices preceding the balance sheet date, is less than acquisition cost. This calculation is performed separately for each plan.

Cash and cash equivalents in the statement of cash flows comprise all liquid assets, including petty cash, bank accounts, short-term deposits with an original maturity of three months or less and short-term investment securities other than treasury shares.

#### **B.11. Revenue recognition**

The Group derives the majority of its revenues from the sale of pharmaceutical products. Revenue is recognized when all of the following criteria are met: persuasive evidence exists of agreement between the parties; delivery has occurred or services have been rendered; and the price is fixed or determinable. Revenue from product sales is recognized when the risk and rewards of ownership pass to the customer. Licensing income is reflected in gross profit over the period during which it is earned. Sales of pharmaceutical product rights are recorded as exceptional income upon disposal of the rights, when no further obligation exists and there is no continuing commitment on the part of the Group. Non-refundable up-front payments received in respect of research and development and/or marketing agreements are recognized immediately in the statement of income.

Provisions for discounts, rebates to customers and product returns are recorded at the time the related sales are recognized, and are classified as adjustments to consolidated net sales.

#### **B.12. Cost of goods sold**

Cost of goods sold consists primarily of the industrial cost of goods sold, licensing income and charges, distribution costs, and specific government levies related to the pharmaceuticals sector paid in certain countries.

#### **B.13. Research and Development**

Research and development costs are expensed as incurred.



**B.14. Other operating income/(expense), net**

Other operating income/(expense), net relates primarily to profit sharing arrangements with partners under joint venture and alliance agreements. The effects of these profit sharing arrangements are reflected in operating profit (note C.).

**B.15. Intangibles amortization and impairment**

Intangibles amortization and impairment includes all amortization and impairment relating to intangible assets other than software and goodwill. Amortization of software is reflected in operating profit.

**B.16. Financial income/(expense), net**

Financial income/(expense), net comprises interest received and paid and foreign exchange gains and losses. It excludes commercial discounts, which are recorded as a reduction of consolidated net sales.

### B.17. Exceptional items

Exceptional items consist of gains and losses on disposals of tangible and intangible fixed assets and of long-term investments, costs associated with strategic restructuring programs, and significant costs or provisions relating to litigation.

### B.18. Income taxes

Income taxes include current and deferred taxation of consolidated companies.

Withholding taxes on intra-group and third-party royalties are recorded as current taxes.

Provision is also made for unrecoverable taxes payable on distributions of reserves by subsidiaries, unless such distributions are not probable.

The Group accounts for deferred taxes using the liability method, whereby deferred income taxes are recognized on:

- n differences between the tax and carrying amounts of assets and liabilities; and
- n tax loss carryforwards.

Deferred tax assets and liabilities are calculated using enacted tax rates applicable for the years during which the temporary differences are expected to reverse. A provision is recorded when it is more likely than not that the realization of the deferred tax assets will not occur.

In accordance with CRC Rule 99-02, deferred taxes are presented using a net position for each fiscal entity, aggregated as an asset or a liability in the consolidated balance sheet.

### B.19. Employee benefits

Sanofi-Synthélabo's pension and retirement benefit commitments are recognized as liabilities on the basis of an actuarial estimate of the potential rights vested in employees and retirees as of the balance sheet date, net of the valuation of funds available to meet these obligations.

This estimate is prepared annually, and takes into account assumptions regarding life expectancy, staff turnover, salary inflation, and discounting of the amounts payable.

Other post-employment benefits (healthcare and life insurance) granted by Group companies to their employees are also recognized as liabilities on the basis of an actuarial estimate of the potential rights vested in employees as of the balance sheet date.

Actuarial gains and losses less than 10% of the higher of the future obligation or the market value of invested funds are not recognized.

## **B.20. Financial instruments**

The Group applies a hedging policy based on the use of diversified, liquid financial instruments to reduce its exposure to risks arising from fluctuations in exchange rates and interest rates and to protect operating margins. Derivative financial instruments are entered into only with counterparties having a high credit rating. The Group does not require collateral with respect to these transactions.

Derivative instruments used to meet the Group's hedging objectives may include forward foreign currency exchange contracts, foreign currency options and interest rate swaps. These instruments relate to assets and liabilities existing at the balance sheet date and, in some cases, to commitments related to future transactions as determined from the Group's annual forecasting process.

Gains and losses arising on hedging transactions are calculated and recognized symmetrically with the recognition of gains and losses on the hedged item. Gains and losses arising from the mark-to-market at the balance sheet date of instruments not qualifying as hedges are recognized in the statement of income.

## B.21. Earnings per share

Basic earnings per share and basic earnings per share before exceptional items and goodwill amortization are calculated using the weighted average number of shares outstanding during the accounting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of Sanofi-Synthelabo shares held by the Group and acquired in order to stabilize the share price. In the event of a stock split or bonus issue of shares, earnings per share and earnings per share before exceptional items and goodwill amortization for prior periods are adjusted accordingly.

Diluted earnings per share and diluted earnings per share before exceptional items and goodwill amortization are calculated assuming (i) the exercise of all outstanding options and warrants and (ii) the conversion of any financial instruments giving access to the capital, after taking account of the theoretical impact of these transactions on the Group's net income.

## C. ALLIANCES

### C.1. Alliance agreements with Bristol-Myers Squibb ( BMS )

Two of the Group's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>) and the atherothrombosis treatment clopidogrel (Plavix<sup>®</sup>/Iscover<sup>®</sup>).

Sanofi-Synthelabo is paid, as inventor of the two molecules, a royalty on all sales generated by these products. This royalty is recorded as a reduction in cost of goods sold.

As co-developers of the products, Sanofi-Synthelabo and BMS each receive equal development royalties from their two licensees, which have been responsible, since 1997, for marketing the products using their local distribution network, composed of the affiliates of both groups. These licensees operate in two separate territories: (i) Europe, Africa and Asia, under the operational management of Sanofi-Synthelabo; and (ii) the rest of the world (excluding Japan), under the operational management of BMS. In Japan, Sanofi-Synthelabo has granted a license to BMS and Shionogi, a Japanese pharmaceutical company.

The products are marketed in different ways in different countries.

Co-promotion consists of a pooling of sales resources under a single brand name. Co-promotion is preferably achieved through contracts or through appropriate tax-transparent legal entities. Each partner records directly its share of taxable income.

Co-marketing consists of separate marketing of the products by each local affiliate using its own name and resources under different brand names for the product.

In certain countries of Eastern Europe, Africa, Asia, Latin America and the Middle East, the products are marketed on an exclusive basis, either by Sanofi-Synthélabo or by BMS.

In the territory managed by Sanofi-Synthélabo, operations are recognized by the Group as follows:

- (i) Co-promotion is used in most of the countries of Western Europe and Asia (excluding Japan) for both products, and in Portugal for irbesartan (Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>). The legal entities used are partnerships ( sociétés en participation ) or other tax-transparent entities, which are majority-owned by and under the operational management of the Group. Sanofi-Synthélabo recognizes all the revenue associated with the sale of the drugs, as well as the corresponding expenses. The share of net income reverting to BMS subsidiaries is recorded in Other operating income/(expense), net .
- (ii) Co-marketing is used in Germany, Italy, Spain and Greece for both products, and in Portugal for clopidogrel (Plavix<sup>®</sup>/Iscover<sup>®</sup>). Sanofi-Synthélabo recognizes revenues and expenses generated by its own operations.
- (iii) In Eastern Europe, Africa, Asia and the Middle East, where products are marketed exclusively by Sanofi-Synthélabo, the Group recognizes revenues and expenses generated by its own operations.

In the territory managed by BMS, operations are recognized by the Group as follows:

- (i) Co-promotion is used in the United States and Canada through entities which are majority-owned by and under the operational leadership of BMS. Sanofi-Synthélabo does not recognize revenues; rather, it invoices the entity for its promotion expenses, accounts for royalties in gross profit and records its share of net income in Other operating income/(expense), net .
- (ii) Co-marketing is used in Brazil, Mexico, Argentina, Colombia and Australia. Sanofi-Synthélabo recognizes revenues and expenses generated by its own operations.
- (iii) In certain other countries of Latin America, where products are marketed exclusively by Sanofi-Synthélabo, the Group recognizes revenues and expenses generated by its own operations.

The presentation of these transactions in the Sanofi-Synthélabo financial statements, in accordance with the legal nature of the agreements, results in the inclusion of Sanofi-Synthélabo's share of the results of operations in its consolidated operating profit and consolidated income before tax and exceptional items.

## C.2. Alliance agreements with Pharmacia-Searle

### Through December 29, 2001:

The hypnotic drug zolpidem (Ambien®) was sold in the US through the Lorex Pharmaceuticals joint venture ( Lorex ), owned 49% by Sanofi-Synthélabo and 51% by Pharmacia-Searle. This joint venture was accounted for under the proportionate consolidation method, as the two groups had signed an agreement under which they exercised joint control over financial and operational policy. Sanofi-Synthélabo also received royalties from Lorex, the non-Group portion of which was accounted for as an addition to gross profit.

Under the profit-sharing agreement, Sanofi-Synthélabo was entitled to 40% of the profits in 2000 (against 60% for Pharmacia-Searle). The percentage rose to 47% in 2001 and to 49% from January 1 through April 15, 2002. The difference between the net income of Lorex and the share to which Sanofi-Synthélabo was contractually entitled was recorded in the statement of income on the line Other operating income/(expense), net .

The profit-sharing agreement also provided for the acquisition by the Group of the 51% interest owned by Pharmacia-Searle on April 16, 2002.

### As from December 30, 2001:

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

On December 30, 2001, the partners signed an amendment to the profit-sharing agreement pursuant to which Pharmacia-Searle transferred control of Lorex Pharmaceuticals to Sanofi-Synthélabo as of that date. Consequently, the Lorex Pharmaceuticals balance sheet was fully consolidated as of December 31, 2001. In 2002, the Group fully consolidated the Lorex Pharmaceuticals statement of income with effect from January 1. Pharmacia-Searle retained its 51% interest in Lorex Pharmaceuticals net income until April 16, 2002, on which date Sanofi-Synthélabo exercised its rights to acquire Pharmacia-Searle's interest. These rights are shown as intangible assets in the balance sheet at a value of 697 million dollars.

### C.3. Alliance agreements with Organon

The alliance with Organon, a subsidiary of Akzo Nobel, covers the worldwide marketing of Arixtra<sup>®</sup>, which was launched in America and Europe in 2002. The marketing arrangements vary depending on the region involved:

- (i) North America: In the United States, Mexico and Canada, Arixtra<sup>®</sup> is sold by companies controlled jointly with Organon. Sales and expenses relating to Arixtra<sup>®</sup> are recorded using the proportionate consolidation method based on the 50% interest held by Sanofi-Synthélabo in the joint venture.
- (ii) Europe and the rest of the world (excluding Japan): Sanofi-Synthélabo markets and sells Arixtra<sup>®</sup> in the same way as its other products, and includes all sales in these countries in consolidated net sales. Sanofi-Synthélabo has an exclusive license to market Arixtra<sup>®</sup> in these territories. The royalty paid to Organon on the basis of these sales is accounted for in cost of goods sold.

## D. DETAILED NOTES TO THE FINANCIAL STATEMENTS

### D.1. Changes in the scope of consolidation

#### *Significant changes in 2002*

#### **Acquisitions**

The three main acquisitions during the period were:

- n Acquisition on April 16, 2002 of the 51% interest held by Pharmacia-Searle in the Lorex Pharmaceuticals joint venture (note C.2). With effect from this date, Sanofi-Synthélabo has been entitled to 100% of this entity's profits.
- n Acquisition on January 1, 2002 of 100% of Institut Médical Algérien.
- n The Group also acquired the minority interests held by third parties in two companies in India and Greece.

The acquisitions made during the period resulted in the recognition of goodwill with a gross value of 13 million euros as of December 31, 2002.

#### **Divestitures**

There were no significant divestitures in the year ended December 31, 2002.

#### **Change in method of consolidation**

The Fujisawa Sanofi-Synthélabo (Japan) joint venture is proportionately consolidated at a rate of 51%, in order to reflect new agreements that took effect in 2002. This entity was accounted for using the full consolidation method at a rate of 51% in the year ended December 31, 2001.

#### *Significant changes in 2001*



**Acquisitions**

Further to an agreement signed by Sanofi-Synthelabo and Pharmacia-Searle on December 30, 2001 (note C.2), the Lorex Pharmaceuticals balance sheet was fully consolidated as of December 31, 2001.

The table below presents the impact on the Group's balance sheet had Lorex Pharmaceuticals been fully consolidated as of December 31, 2000.

(in millions of euros)	December 31, 2000
Inventories	11
Accounts receivable	118
Other current assets	(44)
<b>Total assets</b>	<b>85</b>
Shareholders' equity	1
Accounts payable	16
Other current liabilities	68
<b>Total liabilities and shareholders' equity</b>	<b>85</b>

The negative impact on other current assets results from the elimination of 100% of the transactions between Lorex Pharmaceuticals and other Group companies.

On a 100% basis, Lorex Pharmaceuticals generated net sales of 905 million dollars in 2001 and 709 million dollars in 2000, and net income before taxes of 576 million dollars in 2001 and 420 million dollars in 2000.

In 2001, the Group also acquired the minority interests held by third parties in four companies in Sweden, Turkey, Chile and Algeria, as well as a majority interest in a company in Colombia. These acquisitions resulted in the recognition of goodwill with a gross value of 59 million euros as of December 31, 2001.

## Divestitures

The three principal divestitures during the period were as follows:

- n On February 8, 2001, the Group signed an agreement to sell its Sylachim fine chemicals subsidiary to Dynamit Nobel, a subsidiary of the German group MG Technologies. The sale was priced at 99 million euros on an enterprise value basis (selling price excluding the debt of the divested company).
- n On February 9, 2001, the Group signed an agreement to sell the urological bio-medical devices company Porgès and its subsidiaries to Mentor Corporation. The sale was priced at 35 million euros on an enterprise value basis (selling price excluding the debt of the divested sub-group).
- n On March 15, 2001, the Group signed an agreement to sell the cardiological medical devices company Ela Medical and its subsidiaries to the Snia Group. The sale was priced at 138 million euros on an enterprise value basis (selling price excluding the debt of the divested sub-group).

Amounts related to these divested businesses reflected in the consolidated balance sheet as of December 31, 2000 are shown below:

(in millions of euros)	December 31, 2000
Property, plant & equipment and intangible assets	83
Deferred income taxes	3
Inventories	67
Accounts receivable	65
Other current assets	88
Cash and cash equivalents	6
<b>Total assets</b>	<b>312</b>
Shareholders' equity	48
Long-term debt & other long-term liabilities	14
Accounts payable	35
Other current liabilities	103
Short-term debt	112
<b>Total liabilities and shareholders' equity</b>	<b>312</b>

Amounts related to these divested businesses reflected in the consolidated statements of income are summarized below

(in millions of euros)	Year ended	Year ended
------------------------	------------	------------

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

	<u>December 31, 2001</u>	<u>December 31, 2000</u>
Net sales	39	243
Operating profit/(loss)	(8)	20
Net income/(loss)	(10)	8
Net income/(loss) before exceptional items and goodwill amortization	(10)	8

The interest in Laboratoires de Biologie Végétale Yves Rocher was sold at end December 2001 for 316 million euros. The sale generated a consolidated net gain for Sanofi-Synthélabo of 125 million euros, recognized in the year ended December 31, 2001.

After this sale, and based on available information, the Group owns 39.1% of Financière des Laboratoires de Cosmétologie Yves Rocher, a holding company which in turn holds 51.3% of Laboratoires de Biologie Végétale Yves Rocher. Consequently, the Group had an indirect financial interest of 20.1% in the Yves Rocher group as of December 31, 2001.

*Significant changes in 2000***Acquisitions**

In 2000, the Group acquired the minority interests held by third parties in two companies in Poland and Finland. These acquisitions resulted in the recognition of goodwill with a gross value of 83 million euros as of December 31, 2000.

**Divestitures**

There were no significant divestitures in the year ended December 31, 2000.

**D.2. Intangible assets**

Intangible assets as of December 31, 2002, 2001 and 2000 comprise:

(in millions of euros)	December 31, 2002	December 31, 2001	December 31, 2000
<b>Goodwill</b>	153	153	86
Trademarks	53	51	40
Patents, concessions, licenses and other	1,282	697	282
Software	135	103	77
<b>Sub-total other intangible assets</b>	<b>1,470</b>	<b>851</b>	<b>399</b>
<b>Gross</b>	<b>1,623</b>	<b>1,004</b>	<b>485</b>
Amortization and impairment	(328)	(195)	(84)
<b>Net</b>	<b>1,295</b>	<b>809</b>	<b>401</b>

The increase in the line Patents, concessions, licenses and other was principally due to the purchase of the rights to Ambien in the United States.

Exceptional impairment of an immaterial amount was recognized on the basis of impairment tests carried out as of December 31, 2002 using the method described in note B.6.

**D.3. Property, plant & equipment**

Property, plant and equipment as of December 31, 2002, 2001 and 2000 comprise:

(in millions of euros)	December 31, 2002	December 31, 2001	December 31, 2000
Land	52	50	54
Buildings	611	507	445
Plant and equipment	797	679	578
Fixtures, fittings and other	311	249	205
Fixed assets in progress	218	145	135
<b>Gross</b>	<b>1,989</b>	<b>1,630</b>	<b>1,417</b>
Depreciation and impairment	(594)	(401)	(200)
<b>Net</b>	<b>1,395</b>	<b>1,229</b>	<b>1,217</b>

Depreciation expense for the years ended December 31, 2002, 2001 and 2000 amounted to 217 million euros, 194 million euros and 181 million euros respectively.

Included in property, plant and equipment are the following balances relating to capitalized leases as of December 31, 2002, 2001 and 2000:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Land	9	9	9
Buildings	105	107	120
Plant and equipment			8
<b>Gross</b>	<b>114</b>	<b>116</b>	<b>137</b>
Depreciation and impairment	(56)	(51)	(52)
<b>Net</b>	<b>58</b>	<b>65</b>	<b>85</b>

#### D.4. Investments in/advances to equity investees

Investments in/advances to equity investees as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Yves Rocher group	92	84	73
Other investments and advances	17	16	13
<b>Total</b>	<b>109</b>	<b>100</b>	<b>86</b>

As of December 31, 2002, investments in and advances to equity investees mainly comprised the 39.1% interest in Financière des Laboratoires de Cosmétologie Yves Rocher, the parent company of the Yves Rocher cosmetics group.

#### D.5. Investments in/advances to non-consolidated companies

As of December 31, 2001 and December 31, 2000, investments in/advances to non-consolidated companies included receivables relating to operations with joint venture and alliance partners. These items were included in Other current assets as of December 31, 2002.

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

As of December 31, 2000, other investments in/advances to non-consolidated companies related mainly to a direct interest in Laboratoires de Biologie Végétale Yves Rocher valued at 159 million euros. As described in note D.19, this interest was sold in December 2001 following the exercise by Yves Rocher of its purchase option.

### D.6. Acquisitions of property, plant and equipment and intangible assets

Acquisitions of property, plant and equipment and intangible assets as shown in the consolidated statement of cash flows comprise:

	Year ended Dec. 31, 2002	Year ended Dec. 31, 2001	Year ended Dec. 31, 2000
(in millions of euros)			
Acquisitions of intangible assets	980	282	119
Acquisitions of property, plant & equipment	423	283	253
<b>Total</b>	<b>1,403</b>	<b>565</b>	<b>372</b>

In 2002, acquisitions of intangible assets mainly comprised the purchase of the rights to Ambien in the United States resulting from the acquisition of Pharmacia-Searle's 51% interest in Lorex Pharmaceuticals (see note C.2), and payment of the balance for the rights to Avapro in the United States.

In 2001, they included the payment made in connection with the increase in the Group's share in profits arising from the marketing of Avapro in the United States.

In 2000, they comprised acquisitions of pharmaceutical products and buyouts of marketing rights.

Acquisitions of property, plant and equipment relate mainly to industrial facilities (chemicals and drugs manufacturing) and to research sites.

The accelerated level of investment in property, plant and equipment in 2002 is related to increases in production capacity for new products.

**D.7. Inventories**

Inventories as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Raw materials	288	305	196
Work in process	144	113	178
Finished goods	474	442	396
<b>Gross</b>	<b>906</b>	<b>860</b>	<b>770</b>
Provision	(83)	(55)	(33)
<b>Net</b>	<b>823</b>	<b>805</b>	<b>737</b>

Given the diversity of the activities carried on by the Group, some products sold within the Group and to third parties may be classified alternatively as raw materials, work in process or finished goods, depending on the circumstances. The inventory split shown above uses the classifications adopted by the subsidiary holding the inventory.

The table below shows the movement in inventory provisions for the years ended December 31, 2002, 2001 and 2000:

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
(in millions of euros)			
<b>Balance, beginning of period</b>	<b>(55)</b>	<b>(33)</b>	<b>(4)</b>
Movement in provisions recognized in net income for the period	(85)	(66)	(42)
Provisions utilized	53	37	14
Change in scope of consolidation	(2)	8	
Effect of exchange rates	6	(1)	(1)
<b>Balance, end of period</b>	<b>(83)</b>	<b>(55)</b>	<b>(33)</b>

**D.8. Accounts receivable**



Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Accounts receivable as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Gross	1,348	1,585	1,246
Provision	(37)	(19)	(12)
<b>Net</b>	<b>1,311</b>	<b>1,566</b>	<b>1,234</b>

Balances of and movements in provisions for accounts receivable for the years ended December 31, 2002, 2001 and 2000 were not material.

#### D.9. Other current assets

Other current assets as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Taxes recoverable	335	215	240
Other receivables	462	282	265
Prepaid expenses	57	43	48
<b>Total (net)</b>	<b>854</b>	<b>540</b>	<b>553</b>

Other current assets as of December 31, 2002 include receivables relating to operations with joint venture and alliance partners, shown in Investments in/advances to non-consolidated companies in 2000 and 2001 (see note D.5). The reclassification of these balances as of January 1, 2002 amounted to 83 million euros.

The balance of receivables relating to operations with joint venture and alliance partners as of January 1, 2001 was 60 million euros.

**D.10. Short-term investments and deposits**

Surplus cash is invested in money-market mutual funds and term deposits with counterparties having high credit ratings.

As of December 31, 2002, Sanofi-Synthelabo held treasury shares, mainly allocated to employee stock option plans, with a net value of 623 million euros. The value of treasury shares held as of December 31, 2001 and 2000 was 462 million euros and 299 million euros respectively. The market value of treasury shares was 813 million euros as of December 31, 2002, compared with 957 million euros as of December 31, 2001 and 635 million euros as of December 31, 2000. These shares are included in Short-term investments and deposits .

In the light of the listed market price of the shares in the 20 days preceding the balance sheet date, this line includes a provision for impairment of 46 million euros as of December 31, 2002.

**D.11. Deferred income taxes**

Net deferred tax assets as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Deferred income taxes on:			
Consolidation adjustments	237	207	133
Provision for pensions & other employee benefits	35	55	43
Other non-deductible provisions & other items	202	199	217
<b>Total net deferred tax assets</b>	<b>474</b>	<b>461</b>	<b>393</b>

Deferred tax assets not recognized because of uncertainty as to their future recovery amounted to 243 million euros as of December 31, 2002, compared with 313 million euros as of December 31, 2001 and 361 million euros as of December 31, 2000.

As of December 31, 2002, the Group had total tax loss carryforwards of 97 million euros, which are due to expire as follows:

(in millions of euros)	Loss
2003	9

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

2004	6
2005	3
2006	13
2007	19
2008 and thereafter	47
<b>Total</b>	<b>97</b>

Use of these tax loss carryforwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are applied, carryforwards are able to be netted against taxable income generated by other entities in the consolidated tax group.

In certain countries, withholding taxes are paid by the Group when dividends are distributed. Due to local investment needs, distribution of a portion of these earnings is considered unlikely. No provision has been made for deferred income taxes on this portion of earnings, which amounted to 1,001 million euros, 652 million euros and 649 million euros as of December 31, 2002, 2001 and 2000 respectively.

## D.12. Shareholders' equity

### *D.12.1. Share capital*

The share capital comprises 732,367,507 shares with a par value of 2 euros per share.

The Group held 30,376,375 treasury shares as of December 31, 2002, 11,419,291 treasury shares as of December 31, 2001 and 8,946,924 treasury shares as of December 31, 2000 respectively.

### *D.12.2. Reserves subject to restrictions on distribution*

As of December 31, 2002, 591 million euros of the Group's consolidated reserves were non-distributable. Of this amount, 193 million euros constitutes a legal reserve which is restricted as to distribution. The remaining 398 million euros principally represents a portion of net long-term gains on disposals whose distribution would be subject to supplementary taxation.

### *D.12.3. Changes in accounting method*

In application of the new CRC Rule 2000.06, non-compliant provisions amounting to 24 million euros net of taxes were reversed by crediting shareholders' equity.

### *D.12.4. Adjustments to shareholders' equity related to the merger between Sanofi and Synthélabo*

As a result of the merger between Sanofi and Synthélabo, positive adjustments of 59 million euros and 176 million euros were made to shareholders' equity in 2002 and 2001 respectively. A negative adjustment of 16 million euros was made in 2000.

These adjustments include the portion of provisions recorded in the opening balance sheet no longer required due to favorable changes in the relevant risks during the period. The 2001 adjustment also included the offset of a portion of the goodwill related to the merger (initially recorded as a reduction of equity) against the capital gain on the main businesses divested in that year.

The adjustments are summarized as follows:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
<b>(in millions of euros)</b>			
Revaluation of assets			88
Change in provisions for risks and deferred income taxes recorded in the opening balance sheet	59	90	(64)
Allocation of goodwill to divestitures		34	
Revaluation of commitments to employees		52	(40)
<b>Total</b>	<b><u>59</u></b>	<b><u>176</u></b>	<b><u>(16)</u></b>

In 2002 and 2001, the change in provisions for risks and deferred income taxes related mainly to the settlement of tax litigation, primarily in France and the United States. In 2000, this related mainly to the revaluation of contingent tax positions existing as of the date of the merger.

#### *D.12.5. Repurchase of shares*

The Annual General Meeting of May 22, 2002 authorized the implementation of a share purchase program amounting to 10% of Sanofi-Synthelabo shares. Under this authorization, the Group proceeded in 2002 with a policy of purchasing its own shares with a view to holding, selling, transferring or canceling them. Shares purchased are netted off shareholders' equity at purchase price. Gains and losses on transactions in these shares, net of taxes, are also taken to shareholders' equity. Under this plan, the Group repurchased 16,520,795 shares in 2002 for 970 million euros.

As at December 31, 2002, the Group held 16,411,795 treasury shares, amounting to 963 million euros.

*D.12.6. Stock-based compensation***Options to subscribe to Group shares**

The Sanofi shareholders' meeting of May 21, 1992 authorized a stock option plan, which allows grantees to subscribe to a fixed number of shares at a pre-determined price over a specified period. Options granted under this plan cliff vested one year from the date of grant and expired seven years from the date of grant.

Details of the options granted under this plan are presented below (in Sanofi-Synthélabo equivalent shares):

Origin	Date of Grant	Options granted	Start date	Expiration date	Exercise price (in euros)	Options
			of vesting period			exercised as of 12/31/02
Sanofi	09/20/1995	1,056,000	09/21/1996	09/20/2002	10.26	1,025,640
Sanofi	09/18/1996	1,056,000	09/19/1997	09/18/2003	14.56	539,675

The exercise of all of the stock options outstanding at December 31, 2002 would result in an increase of approximately 7 million euros in shareholders' equity.

Exercise of options under this plan resulted in the creation of 362,423 shares in 2002 (each with a par value of 2 euros per share) and aggregate proceeds of 4 million euros.

**Options to purchase Group shares**

The Group has several stock option plans which allow grantees to purchase a fixed number of shares at a pre-determined price over a specified period. Options generally cliff vest over two to five years from the date of grant and expire seven to twenty years from the date of grant. Shares acquired under these plans generally may not be disposed of prior to the fifth anniversary of the date of grant, or prior to the fourth anniversary of the date of grant with effect from the Sanofi-Synthélabo plan of May 24, 2000.

As authorized by the Sanofi-Synthélabo shareholders' meeting of May 18, 1999, the Group may grant options to its employees to acquire up to 14,611,740 shares.

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Details of the stock purchase options granted under the Group's various plans are presented below (in Sanofi-Synthélabo equivalent shares):

Origin	Date of grant	Options granted	Start date	Expiration date	Exercise price	Options exercised
			of vesting period		(in euros)	as of 12/31/02
Synthélabo	12/15/93	364,000	12/15/98	12/15/13	6.36	348,400
Synthélabo	10/18/94	330,200	10/18/99	10/18/14	6.01	305,200
Synthélabo	12/15/94	49,400	12/15/99	12/15/14	5.86	49,400
Synthélabo	12/15/95	442,000	12/15/00	12/15/15	8.50	378,400
Synthélabo	01/12/96	208,000	01/12/01	01/12/16	8.56	133,630
Synthélabo	04/05/96	228,800	04/05/01	04/05/16	10.85	114,040
Sanofi	09/22/97	1,120,000	09/23/99	09/22/04	21.46	194,020
Synthélabo	10/14/97	262,080	10/14/02	10/14/17	19.73	49,760
Synthélabo	06/25/98	296,400	06/26/03	06/25/18	28.38	
Sanofi	12/10/98	1,200,000	12/11/00	12/10/05	34.95	24,720
Synthélabo	03/30/99	716,040	03/31/04	03/30/19	38.08	
Sanofi-Synthélabo	05/24/00	4,292,000	05/25/04	05/24/10	43.25	
Sanofi-Synthélabo	05/10/01	2,936,500	05/11/05	05/10/11	64.50	
Sanofi-Synthélabo	05/22/02	3,111,850	05/23/06	05/22/12	69.94	

Shares offered under these plans are acquired in the stock market. Consequently, these plans have no impact on shareholders equity as of December 31, 2002.

In 2002, the Group repurchased 3,029,884 shares for 214 million euros for allocation under stock option plans.

**Summary of stock-based compensation plans**

A summary of the Group stock options outstanding at December 31, 2002, 2001 and 2000, and of changes during those years, is presented below:

		Exercise price (in euros)		
		Weighted		
		Number of options	average per share	Aggregate (in millions of euros)
<b>Outstanding</b>	<b>January 1, 2000</b>	<b>6,392,174</b>	<b>21.45</b>	<b>137</b>
Granted		4,292,000	43.25	186
Exercised		(499,928)	9.76	(5)
Expired/Forfeited		(5,200)	19.73	
<b>Outstanding</b>	<b>December 31, 2000</b>	<b>10,179,046</b>	<b>31.21</b>	<b>318</b>
Granted		2,936,500	64.50	189
Exercised		(881,313)	10.98	(10)
Expired/Forfeited		(76,260)	43.71	(3)
<b>Outstanding</b>	<b>December 31, 2001</b>	<b>12,157,973</b>	<b>40.64</b>	<b>494</b>
Granted		3,111,850	69.94	218
Exercised		(847,018)	13.27	(11)
Expired/Forfeited		(71,300)	36.87	(3)
<b>Outstanding</b>	<b>December 31, 2002</b>	<b>14,351,505</b>	<b>48.63</b>	<b>698</b>

As of December 31, 2002, there were 3,108,635 exercisable options outstanding, with a weighted average exercise price of 24.15 euros per share. As of December 31, 2002, there remained 4,271,390 options available for grant. The following table summarizes information concerning outstanding and exercisable options as of December 31, 2002:

Range of exercise prices per share	Outstanding			Exercisable	
	Number of options	Weighted average remaining life (years)	Weighted average exercise price per share	Number of options	Weighted average exercise price per share



Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

			(in euros)		(in euros)
From 5.86 to 10.85 euros per share	288,130	12.93	9.16	288,130	9.16
From 14.56 to 28.38 euros per share	1,944,425	4.95	20.50	1,648,025	19.09
From 34.95 to 69.94 euros per share	12,118,950	8.23	54.08	1,172,480	34.95
<b>Total</b>	<b>14,351,505</b>	<b>7.88</b>	<b>48.63</b>	<b>3,108,635</b>	<b>24.15</b>

**D.13. Long-term debt (portion due after more than one year)**

The Group's long-term debt as of December 31, 2002, 2001 and 2000 comprises:

	December 31,	December 31,	December 31,
(in millions of euros)	2002	2001	2000
Capital lease obligations	51	57	65
Other long-term debt	14	62	56
<b>Total</b>	<b>65</b>	<b>119</b>	<b>121</b>

The Group's long-term debt agreements do not contain any covenants which impose significant restrictions on the Group's activities, including its ability to pay dividends, acquire or divest other businesses or incur additional borrowings. There are no specific contractual provisions associated with this debt liable to modify the repayment terms or interest charge.

The table below presents the maturity of long-term debt as of December 31, 2002, 2001 and 2000:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
2002			8
2003		55	55
2004	11	11	9
2005	8	9	8
2006	7	8	6
2007	4	4	5
Thereafter	35	32	30
<b>Total</b>	<b>65</b>	<b>119</b>	<b>121</b>

The table below presents an analysis of long-term debt by interest rate as of December 31, 2002, 2001 and 2000, after taking into account hedging instruments. The split is based on interest rates at year-end.

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Less than 5%	8	54	54
From 5% to 7.5%	51	53	52
From 7.5% to 10%	6	12	15
<b>Total</b>	<b>65</b>	<b>119</b>	<b>121</b>
<i>Of which:</i>			
fixed rate	15	21	22
variable rate	50	98	99

The table below presents an analysis of long-term debt by currency as of December 31, 2002, 2001 and 2000, after taking into account hedging instruments:

	December 31, 2002	December 31, 2001	December 31, 2000
(in millions of euros)			
Euro	58	110	118
US dollar	2	2	3
Other currencies	5	7	

<b>Total</b>	<b>65</b>	<b>119</b>	<b>121</b>
--------------	-----------	------------	------------

The table below summarizes interest paid on the short-term and long-term portion of debt and on credit lines during each accounting period:

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
(in millions of euros)			
Interest paid	22	18	19

47

Consolidated Financial Statements

**D.14. Provisions and other long-term liabilities**

Provisions and other long-term liabilities as of December 31, 2002, 2001 and 2000 comprise:

(in millions of euros)	December 31, 2002	December 31, 2001	December 31, 2000
Provisions for pensions and other benefits (D.14.1)	427	474	474
Restructuring provisions (D.14.2)	8	46	61
Other provisions for risks (1) (D.14.3)	347	431	469
Other long-term liabilities (D.14.4)	4	102	126
<b>Total</b>	<b>786</b>	<b>1,053</b>	<b>1,130</b>
<i>(1) ) Of which:</i>			
Environmental remediation risks	21	30	23
Product risk liabilities	20	25	21

**D.14.1. Provisions for pensions and other benefits**

The Group and its subsidiaries have a significant number of benefit pension plans covering the majority of their employees. The specific features (benefit formulas, funding policies and types of assets held) of the plans vary depending on regulations and laws in the particular country in which the employees are located. Several benefit plans are defined benefit plans and cover besides employees, certain members of the Board of Directors.

Actuarial valuations of the Group's benefit obligations were computed as of December 31, 2002, 2001 and 2000. The calculations incorporate:

- n assumptions on staff turnover, life expectancy and salary inflation;
- n a retirement age of 60 to 65 for a total working life allowing for full rate retirement rights for French employees, and retirement assumptions reflecting local economic and demographic factors specific to foreign employees;
- n discounting rates used to determine the actuarial present value of the projected benefit obligations as follows:
  - Euro zone plans: 5.25% as of December 31, 2002 and 2001; 5.5% as of December 31, 2000
  - US plans: 6.75% as of December 31, 2002; 7% as of December 31, 2001 and 2000

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

- UK plans: 5.50% as of December 31, 2002; 5.75% as of December 31, 2001; 6% as of December 31, 2000
- other plans: 2%-12% as of December 31, 2002; 2.5%-14.5% as of December 31, 2001; 2.5%-15% as of December 31, 2000

n Expected long-term rates of return for plan assets ranging from 5% to 10% as of December 31, 2002; 4% to 15% as of December 31, 2001; and 5.15% to 15% as of December 31, 2000.

The majority of the fund assets are invested in the United States and the United Kingdom. The long-term rates of return used are as follows:

- for American pension plans: 8.5% as of December 31, 2002; 8.75% as of December 31, 2001 and 2000;
- for UK pension plans: 6.50% as of December 31, 2002 and 2001; 7% as of December 31, 2000.

48

Consolidated Financial Statements

*D.14.2. Restructuring provisions*

The following table summarizes movements in restructuring provisions, classified under Other long-term liabilities and Other current liabilities (note D.15), for each of the years ended December 31, 2002, 2001 and 2000:

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
<b>(in millions of euros)</b>			
<b>Balance, beginning of period</b>	<b>82</b>	<b>149</b>	<b>323</b>
<i>Of which</i>			
classified under Other long-term liabilities	46	61	135
classified under Other current liabilities	36	88	188
Charges to provisions recognized in net income for the period	1	6	
Reversals of provisions in application of CRC Rule 2000-06	(20)		
Reversals of provisions recorded in the opening balance sheet	(4)	(16)	(14)
Provisions utilized	(30)	(57)	(159)
Effect of exchange rates	(2)		(1)
<b>Balance, end of period</b>	<b>27</b>	<b>82</b>	<b>149</b>
<i>Of which:</i>			
classified under Other long-term liabilities	8	46	61
classified under Other current liabilities	19	36	88

Following the merger of Sanofi and Synthelabo in 1999, the Group developed a restructuring plan, which consisted of a combination of actions designed to integrate head offices worldwide, reorganize the sales forces and close or re-size industrial sites throughout the world. Implementation of these restructuring plans commenced in 1999 and was substantially completed in 2000 and 2001. In France, the restructuring program related to a reduction in workforce was carried out principally through a program of voluntary early retirement for people aged 55 as of December 31, 1999.

In 2000, the Group revised certain of its previous estimates for restructuring-related activities related to the merger between Sanofi and Synthelabo. The adjustment consisted of a 14 million euro decrease, comprising an 18 million euro increase for revisions to initial plans linked with industrial capacities (in particular employee termination costs) and a 32 million euro decrease for final assessments of costs to be incurred in connection with other restructuring activities, in particular the retirement or impairment of tangible assets. Expenses incurred in 2002, 2001 and 2000 and charged against the provision, shown on the line Provisions utilized, relate principally to employee termination costs (11, 56 and 145 million euros respectively), mainly in western Europe.

*D.14.3. Other provisions for risks*

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

The table below shows movements in other provisions for risks, including environmental risks and litigation, tax exposures, commercial risks, product liability risks and intellectual property risks, for each of the years ended December 31, 2002, 2001 and 2000:

	Year ended	Year ended	Year ended
	<u>December 31, 2002</u>	<u>December 31, 2001</u>	<u>December 31, 2000</u>
<b>(in millions of euros)</b>			
<b>Balance, beginning of period</b>	<b>431</b>	<b>469</b>	<b>302</b>
Charges to provisions recognized in net income for the period	88	77	70
Reversals of provisions in application of CRC Rule 2000-06	(11)		
Reversals of provisions recorded in the opening balance sheet	(32)	(96)	63
Provisions utilized	(14)	(35)	(13)
Reclassifications between accounts	(92)	12	44
Effect of exchange rates	(23)	4	3
<b>Balance, end of period</b>	<b>347</b>	<b>431</b>	<b>469</b>

The Group is involved in a number of legal proceedings and claims. These include commercial and intellectual property litigation, tax audits and other matters relating to the normal conduct of its business.

Provisions for tax exposures are recorded if the Group considers that the tax authorities might challenge a tax position taken by the Group or a subsidiary.

An assessment of these risks has been performed with the assistance of the Group's legal advisers, and provisions have been recorded where circumstances required.

In 2002, reclassifications mainly comprised the transfer of existing provisions in respect of which payments are due to be made in 2003, now shown as short-term items under Other liabilities.

#### *D.14.4. Other long-term liabilities*

As of December 31, 2001 and 2000, other long-term liabilities included liabilities on operations with joint venture and alliance partners, which were included in Other current liabilities as of December 31, 2002 (see note D.15).

#### **D.15. Other current liabilities**

Other current liabilities as of December 31, 2002, 2001 and 2000 comprise:

	December 31, 2002	December 31, 2001	December 31, 2000
<b>(in millions of euros)</b>			
Taxes payable	472	597	317
Employee-related liabilities	384	418	352
Restructuring provisions (D.14.2.)	19	36	88
Other liabilities	724	943	543
<b>Total</b>	<b>1,599</b>	<b>1,994</b>	<b>1,300</b>

In 2001, Other liabilities included the unpaid portion of the purchase price of acquisitions made in the period, and the impact of the full consolidation of the Lorex Pharmaceuticals balance sheet.



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

In 2002, Other liabilities also included the reclassification of the balance as of January 1, 2002 of liabilities on operations with joint venture and alliance partners, amounting to 85 million euros. The balance of such liabilities as of January 1, 2001 was 89 million euros.

The unpaid portion of the purchase price of acquisitions made in the period, which is included in other liabilities, amounted to 24 million euros as of December 31, 2002 and 170 million euros as of December 31, 2001, and was immaterial as of December 31, 2000.

### D.16. Short-term debt

Short-term debt as of December 31, 2002, 2001 and 2000 comprises:

(in millions of euros)	<u>December 31, 2002</u>	<u>December 31, 2001</u>	<u>December 31, 2000</u>
Current portion of long-term debt	55	9	12
Other short-term debt	146	156	145
Bank overdrafts	150	120	134
<b>Total</b>	<b><u>351</u></b>	<b><u>285</u></b>	<b><u>291</u></b>

### D.17. Derivative financial instruments

The table below presents the notional amounts of the Group's outstanding derivative financial instruments as of December 31, 2002, 2001 and 2000:

(in millions of euros)	December 31, 2002	December 31, 2001	December 31, 2000
Interest rate swaps	46	46	46
Currency options - sales of puts(1)	51	24	12
Currency options - sales of calls(2)	758	705	314
Currency options - purchases of puts(3)	448	413	164
Currency options - purchases of calls(4)	90	40	39
Forward foreign currency exchange contracts written - financial(5)	1,033	1,016	741
Forward foreign currency exchange contracts purchased - financial(6)	131	254	248

- (1) including 51 million euros on the Norwegian krone as of December 31, 2002; 18 million euros on the US dollar as of December 31, 2001; 6 million euros on the Swiss franc and 6 million euros on the US dollar as of December 31, 2000.
- (2) including 568 million euros on the US dollar and 163 million euros on the yen as of December 31, 2002; 527 million euros on the US dollar and 157 million euros on the yen as of December 31, 2001; 220 million euros on the US dollar and 74 million euros on the yen as of December 31, 2000.
- (3) including 321 million euros on the US dollar and 96 million euros on the yen as of December 31, 2002; 326 million euros on the US dollar and 77 million euros on the yen as of December 31, 2001; 113 million euros on the US dollar and 43 million euros on the yen as of December 31, 2000.
- (4) including 45 million euros on the US dollar, 19 million euros on the yen and 26 million euros on the Norwegian krone as of December 31, 2002; 16 million euros on the yen, 10 million euros on the US dollar and 9 million euros on the Norwegian krone as of December 31, 2001; 31 million euros on the US dollar and 6 million euros on the yen as of December 31, 2000.
- (5) including 798 million euros on the US dollar, 79 million euros on the yen, 60 million euros on the British pound, 26 million euros on the Canadian dollar, 16 million euros on the Czech koruna and 10 million euros on the Norwegian krone as of December 31, 2002; 812 million euros on the US dollar, 87 million euros on the yen, 45 million euros on the British pound and 29 million euros on the Canadian dollar as of December 31, 2001; 593 million euros on the US dollar, 83 million euros on the yen, 29 million euros on the British pound and 20 million euros on the Canadian dollar as of December 31, 2000.
- (6) including 68 million euros on the Swiss franc, 33 million euros on the Norwegian krone and 10 million euros on the British pound as of December 31, 2002; 118 million euros on the US dollar, 88 million euros on the Swiss franc, 30 million euros on the Norwegian krone as of December 31, 2001; 103 million euros on the US dollar, 83 million euros on the Swiss franc, 36 million euros on the British pound and 14 million euros on the yen as of December 31, 2000.

#### Fair value of financial instruments

The carrying values and estimated fair values of certain of the Group's financial instruments outstanding as of December 31, 2002, 2001 and 2000 are presented below:

(in millions of euros)	2002		2001		2000	
	Carrying value	Fair value	Carrying value	Fair value	Carrying value	Fair value

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Long-term debt (excluding capital lease obligations)	14	14	62	62	56	56
Forward foreign currency exchange Contracts written	23	48	2	23	21	49
Forward foreign currency exchange contracts purchased	1	4	2	3		(3)
Currency options sales of puts	1					
Currency options sales of calls	19	3	17	10	8	3
Currency options purchases of puts	21	36	17	20	8	14
Currency options purchases of calls	1	2		2		

51

Consolidated Financial Statements

The Group considers that for cash and cash equivalents, accounts receivable, bank overdrafts, accounts payable and other short-term debt, carrying value is a reasonable estimate of fair value due to their short-term maturities and the readily available market for these types of instruments.

The following methods and assumptions were used by the Group in estimating the fair values of financial instruments:

- n Long-term debt (excluding capital lease obligations) The carrying value of the Group's variable-rate long-term debt approximates to fair value. The fair value of long-term fixed rate debt has been estimated based on current interest rates available for debt instruments with similar terms, degrees of risk and maturities. Substantially all of the Group's long-term debt is variable rate.
- n Forward foreign currency exchange contracts (written and purchased) The fair value of forward foreign currency exchange contracts is based on the estimated amount at which they could be settled based on forward market exchange rates.
- n Foreign currency option contracts (written and purchased) The fair value of foreign currency option contracts is obtained from dealer quotes. These values represent the estimated net amount the Group would receive or pay to terminate the agreements.

#### D.18. Contractual obligations and other commercial commitments

##### Contractual obligations given

	Total	Payments due by period		
		Under 1 year	1-5 years	Over 5 years
(in millions of euros)				
Long-term debt, excluding capital lease obligations (Notes D.13-D.16)	63	49	8	6
Capital lease obligations (including interest)	72	9	29	34
Operating leases	425	70	191	164
Irrevocable purchase obligations	65	60	5	
Other long-term obligations	202	33	128	41
<b>Total</b>	<b>827</b>	<b>221</b>	<b>361</b>	<b>245</b>

##### Other commercial commitments given

	Total	Commitments by period		
		Under 1 year	1-5 years	Over 5 years
(in millions of euros)				
Credit lines				

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Letters of credit				
Guarantees:				
given	66	37	9	20
received	(60)	(60)		
Repurchase commitments				
Other commercial commitments				
<b>Total</b>	<b>6</b>	<b>(23)</b>	<b>9</b>	<b>20</b>

*Leases***Capital leases**

Future minimum payments related to capital leases as of December 31, 2002 totaling 72 million euros and including interest payments of 15 million euros are scheduled to be made as follows:

(in millions of euros)	Interest portion	Principal portion	Total
2003	3	6	9
2004	3	7	10
2005	2	6	8
2006	1	5	6
2007	1	4	5
2008 and thereafter	5	29	34
<b>Total</b>	<b>15</b>	<b>57</b>	<b>72</b>

**Operating leases**

The Group leases certain of its properties and equipment used in the ordinary course of business. Future minimum payments under non-cancelable operating leases as of December 31, 2002 amount to 425 million euros, and are scheduled to be made as follows:

(in millions of euros)	December 31, 2002
2003	70
2004	63
2005	47
2006	41
2007	40
2008 and thereafter	164
<b>Total</b>	<b>425</b>

Rental expense recognized by the Group for each of the years ended December 31, 2002, 2001 and 2000 amounted to 87 million euros, 79 million euros and 87 million euros respectively.

*Irrevocable purchase obligations*

These mainly comprise irrevocable commitments to suppliers of fixed assets.

*Other long-term obligations*

As of December 31, 2002, these included royalties payable on the marketing of Arixtra under the alliance agreements with NV Organon in countries other than the United States, Canada, Japan and Mexico. In return for taking over the rights, Sanofi-Synthélabo agreed to make phased payments to Organon up to a maximum of 100 million dollars contingent on approval of additional indications. Sanofi-Synthélabo also agreed to pay minimum royalties of 75 million dollars.

In addition, Sanofi-Synthélabo is required to pay minimum royalties of 17 million euros under three pharmaceutical license agreements.

In 2002, Sanofi-Synthélabo subscribed 20 million euros to a reserved share issue made by IDM. Sanofi-Synthélabo is also committed to making an additional investment of 10 million euros in a further share issue. As of December 31, 2002, Sanofi-Synthélabo owned 1,700,145 IDM shares, representing 12.7% of the capital. This percentage may change in the future as a result of this commitment and of the conversion of existing financial instruments giving access to the capital of IDM.

*Guarantees given*

These comprise 50 million euros of surety bonds and 16 million euros of real collateral.

*Guarantees received*

These mainly comprise surety bonds.

*Scope of consolidation*

The Group does not use off balance sheet vehicles. All the Group's operations are reflected in the accounts of the companies included in the consolidation for each of the periods presented.

There are no commitments other than those disclosed above (notes D.17 and D.18) which are or may become material, except for those arising under collaboration agreements and contingent additional payments relating to Avapro in the United States as described in note D.19.

**D.19. Other commitments and contingencies**

*Additional payments*

In connection with the increase of the Group's share in the net income derived from the marketing of Avapro in the United States (note D.6), the Group may be required to make an additional payment contingent upon the net sales of Avapro in the United States in 2003. This payment would be made in 2004 based on a percentage applied to the portion of sales over a contractually-defined threshold.

*Research and development collaborations*

The Group may be required to make payments to research and development partners under collaboration agreements. These agreements typically cover multiple products and give the Group the option to participate in development on a product-by-product basis. When the Group exercises an option with respect to a product, it pays its collaboration partner a fee and receives intellectual property rights to that product in exchange. The Group is also generally required to fund some or all of the development costs for products that it selects and to make payments to its partners when those products reach development milestones.

The Group's principal collaboration agreements are:



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

- n a collaboration agreement with Organon to develop anti-thrombotic oligosaccharides (in continuation of the work that resulted in the development of Arixtra®);
- n a collaboration agreement with Cephalon for the development of angiogenesis inhibitors, in respect of which the payment for the first product could reach 32 million dollars;
- n an agreement with Immuno-Designed Molecules to develop cellular immunology therapies for cancer, under which IDM granted Sanofi-Synthélabo 20 development options on current and future research and development programs. For each option that leads to a commercially marketed product, IDM could receive a total of between 17 and 32 million euros, depending on the potential of the market, plus reimbursement of the development costs. Contractually, Sanofi-Synthélabo may suspend the development program for each option exercised at any time and without penalty. In 2002, Sanofi-Synthélabo exercised only one option, relating to a program for the treatment of melanoma.
- n There are two further contracts relating to research work which could give rise to deferred payments of between 1 and 4 million euros per molecule.

Because of the uncertain nature of the development work, it is impossible to predict if the Group will exercise an option for a product or if the expected milestones will be achieved, or to predict the number of molecules that will reach the relevant milestones. For this reason, it is impossible to estimate the maximum aggregate amount that Sanofi-Synthélabo will actually pay in the future under outstanding collaboration agreements. Given the nature of its business, it is highly unlikely that Sanofi-Synthélabo will exercise all options for all products or that all milestones will be achieved.

### *Litigation and claims*

Following the merger of Sanofi and Synthélabo, the Group was in dispute with its co-shareholders in the Yves Rocher Group, who rejected the registration in the name of the merged entity Sanofi-Synthélabo of the Group's shares in Financière des Laboratoires de Cosmétologie Yves Rocher and Laboratoires de Biologie Végétale Yves Rocher. They had previously been held by Sanofi. Following the expert's conclusions in November 2001, and in accordance with the judgment, Laboratoires de Biologie Végétale Yves Rocher arranged for the acquisition of the Group's interest in its capital.

Pursuant to a judgment from the Rennes Appeal Court dated January 10, 2001, Sanofi-Synthélabo remains a shareholder of Financière des Laboratoires de Cosmétologie Yves Rocher, with an interest of 39.1%. This holding company in turn holds 51.3% of Laboratoires de Biologie Végétale Yves Rocher. Consequently, the Group had an indirect financial interest of 20.1% in the Yves Rocher group as of December 31, 2001.

During the first six months of 2001, both Sanofi-Synthélabo and Financière des Laboratoires de Cosmétologie Yves Rocher appealed separately to the highest procedural court in France ( Cour de Cassation ) on the appeal judgments.

In addition to the litigation described above, the Group is involved in a number of other legal proceedings and claims (note D.14.3).

#### *Environmental matters*

The Group is involved in various stages of investigation and cleanup relating to environmental matters at certain locations. Whenever identified, the Group's practice is to determine the nature and scope of contingencies related to environmental remediation activity and obtain and accrue estimates of the cost of remediation. For each period presented, the estimates of cleanup costs have been accrued. As the Group continues its efforts to ensure compliance with environmental laws and regulations, additional contingencies may be identified. The Group does not believe that additional costs that could arise from environmental remediation activities will have a significant adverse effect on its financial position or results.

#### **D.20. Personnel costs**

Personnel costs, which include compensation and other benefits paid to employees leaving the Group during the period, totaled 1,937 million euros in the year ended December 31, 2002, against 1,708 million euros in the year ended December 31, 2001 and 1,541 million euros in the year ended December 31, 2000.

Employee numbers as of December 31, 2002, 2001 and 2000 were 32,436, 30,514 and 29,200 respectively.

Employee numbers by function as of December 31, 2002, 2001 and 2000 were as follows:

	<b>December 31, 2002</b>	<b>December 31, 2001</b>	<b>December 31, 2000</b>
Research and development	6,718	6,273	6,203
Sales force	11,015	10,336	8,636
Production	8,043	7,651	8,288
Other	6,660	6,254	6,073

<b>Total</b>	<b>32,436</b>	<b>30,514</b>	<b>29,200</b>
--------------	---------------	---------------	---------------

Remuneration paid to key executive managers of the Group during the year ended December 31, 2002 totaled 7.5 million euros, compared with 6.2 million euros in the year ended December 31, 2001 for 12 executives and 5.6 million euros in the year ended December 31, 2000 for 13 executives.

#### D.21. Foreign exchange gains and losses

The Group recorded a net foreign exchange gain of 48 million euros in 2002, compared with a net gain of 5 million euros in 2001 and a net loss of 25 million euros in 2000.

#### D.22. Exceptional items

Exceptional items for the years ended December 31, 2002, 2001 and 2000 comprise:

(in millions of euros)	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
Net gains on disposals	10	281	46
Other exceptional items			
<b>Total</b>	<b>10</b>	<b>281</b>	<b>46</b>

There were no material disposals in 2002.

In 2001, net gains on disposals related principally to the four major divestitures during the period: Sylachim, Porgès, Ela Medical and the direct holding in Laboratoires de Biologie Végétale Yves Rocher (notes D.1 and D.5). The gain on these four major divestitures included an allocation of part of the goodwill arising on the merger between Sanofi and Synthélabo, which was initially offset against consolidated shareholders' equity.

Net gains on disposals in 2000 relate to the sale of minority interests in two listed companies.

### D.23. Income taxes

The Group has opted for tax consolidations in a number of countries, principally France, Germany and the United States.

Pre-tax net income and the corresponding tax charge for the years ended December 31, 2002, 2001 and 2000 break down as follows:

(in millions of euros)	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
<b>Pre-tax net income:</b>			
France	1,357	1,317	806
Rest of the world	1,215	1,097	796
<b>Total</b>	<b>2,572</b>	<b>2,414</b>	<b>1,602</b>
<b>Income tax:</b>			
France	(335)	(473)	(296)
Rest of the world	(411)	(369)	(315)
<b>Total</b>	<b>(746)</b>	<b>(842)</b>	<b>(611)</b>

The income tax charge for the years ended December 31, 2002, 2001 and 2000 comprises:

(in millions of euros)	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
Current taxation	(794)	(906)	(491)
Deferred taxation	48	64	(120)

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

	(746)	(842)	(611)
	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
(in millions of euros)			
Tax on income before goodwill amortization and exceptional items	(745)	(778)	(593)
Tax on goodwill amortization and exceptional items	(1)	(64)	(18)
<b>Total</b>	<b>(746)</b>	<b>(842)</b>	<b>(611)</b>

The difference between the effective tax rate and the standard corporate income tax rate applicable in France for each of the years ended December 31, 2002, 2001 and 2000 is explained as follows:

	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000
	(as %)		
Tax rate applicable in France	35	36	38
Impact of income tax at reduced rate in France	(4)	(3)	(4)
Loxex Pharmaceuticals	(1)		
Other	(1)	3	4
<b>Effective tax rate before exceptional items and goodwill amortization</b>	<b>29</b>	<b>36</b>	<b>38</b>
Impact of exceptional items		(1)	
<b>Effective tax rate</b>	<b>29</b>	<b>35</b>	<b>38</b>

As indicated in note C.2, Lorex Pharmaceuticals has been fully consolidated by the Group as from January 1, 2002. Net income before exceptional items and goodwill amortization therefore includes all the profits and losses of Lorex Pharmaceuticals, including the share of net income reverting to Pharmacia-Searle for the period from January 1, 2002 through April 15, 2002. Because Lorex Pharmaceuticals is a tax transparent entity, the Income taxes line includes only the charge attributable to the Group. This has the effect of reducing the effective tax rate by 1.2 points.

The Other line includes the difference between the French tax rate and the tax rate applicable in other countries and, for all three years, the impact of the revaluation of certain of the Group's tax exposures.

Income tax payments made by the Group totaled 1,120 million euros in 2002, 449 million euros in 2001 and 378 million euros in 2000.

#### **D.24. Minority interests**

As of December 31, 2002, minority interests mainly comprise the share in the net income of Lorex Pharmaceuticals reverting to Pharmacia-Searle for the period from January 1, 2002 through April 15, 2002 (see note C.2).

#### **D.25. Related party transactions**

Financial relations with the TotalFinaElf and L'Oréal groups existing prior to the merger had mainly ceased by December 31, 1999. The residual relations had no significant impact in the years ended December 31, 2002, 2001 and 2000.

#### **D.26. Post balance sheet events**

As at the date of preparation of its financial statements, the Group is not aware of any post balance sheet events that would significantly affect the financial statements as of December 31, 2002.

**D.27. Split of net sales**

The Group is not dependent on any single customer or group of customers for its sales. Products are sold throughout the world to a wide range of customers including pharmacies, hospitals, chain warehouses, governments, physicians, wholesalers and other distributors.

Sales of selected products for each of the years ended December 31, 2002, 2001 and 2000 are as follows:

(in millions of euros)	Year ended Dec. 31, 2002	Year ended Dec. 31, 2001	Year ended Dec. 31, 2000
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	1,424	786	582
Plavix <sup>®</sup>	987	705	437
Aprovel <sup>®</sup> /Avapro <sup>®</sup>	562	423	300
Eloxatine <sup>®</sup>	389	196	141
Fraxiparine <sup>®</sup>	324	297	255
Dépakine <sup>®</sup>	267	243	211
Xatral <sup>®</sup>	182	148	120
Cordarone <sup>®</sup>	162	162	156
Tildiem <sup>®</sup>	141	152	154
Ticlid <sup>®</sup>	137	205	235
Solian <sup>®</sup>	135	116	93
Corotrope <sup>®</sup> /Primacor <sup>®</sup>	127	237	180
Aspégic <sup>®</sup> and related products	108	100	100
Dogmatil <sup>®</sup>	78	124	134
Kerlone <sup>®</sup>	77	82	77

**D.28. Segment information**

The Group operates in one significant business segment: the research and development, production and sale of pharmaceutical products.

The Group has aggregated all its ethical product lines because they have close similarities in terms of regulatory environment, production process, distribution methods and customer profile. The Group's generics and OTC activities are not material, and have been aggregated with its ethical activities.

The Group mainly operates in three geographical segments: Europe, the United States and other countries.

The table below gives net sales, operating profit, total assets and long-lived assets by geographical segment. Net sales and operating profit are allocated based on the location of the end customer. Total assets and long-lived assets are allocated based on the location of the subsidiary.

## Year ended December 31, 2002

(in millions of euros)	<u>Total</u>	<u>Europe</u>	<u>USA</u>	<u>Other countries</u>	<u>Unallocated costs(1)</u>
Net sales	7,448	4,297	1,689	1,462	
Operating profit	2,614	1,633	1,781	522	(1,322)
Total assets	9,459	6,968	1,814	677	
Including long-lived assets	2,899	1,715	1,052	132	

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,584 million euros and 1,182 million euros respectively as of December 31, 2002.



**Year ended December 31, 2001**

(in millions of euros)	<u>Total</u>	<u>Europe</u>	<u>USA</u>	<u>Other countries</u>	<u>Unallocated costs(1)</u>
Net sales	6,488	3,877	1,098	1,513	
Operating profit	2,106	1,427	1,311	456	(1,088)
Total assets	9,967	7,924	1,321	722	
Including long-lived assets	2,296	1,558	602	136	

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,487 million euros and 1,096 million euros respectively as of December 31, 2001.

**Year ended December 31, 2000**

(in millions of euros)	<u>Total</u>	<u>Europe</u>	<u>USA</u>	<u>Other countries</u>	<u>Unallocated costs(1)</u>
Net sales	5,963	3,597	888	1,478	
Operating profit	1,577	1,190	835	440	(888)
Total assets	7,845	6,558	603	684	
Including long-lived assets	2,045	1,756	177	112	

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,507 million euros and 1,335 million euros respectively as of December 31, 2000.

- (1) Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.

**E. LIST OF COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2002****E.1. Fully consolidated**

**Financial  
interest %**

---

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

JV Omnipharma (Pty) Limited	South Africa	100
Sanofi-Synthélabo (Pty) Ltd	South Africa	100
Synthélabo (South Africa) (Pty) Ltd(2)	South Africa	100
Institut Médical Algérien (IMA)	Algeria	100
Lichtenstein GmbH	Germany	100
Lichtenstein Verwaltungs GmbH	Germany	100
Sanofi-Synthélabo GmbH	Germany	100
Sanofi-Synthélabo Holding GmbH	Germany	100
Sanofi-Synthélabo de Argentina SA	Argentina	100
Sanofi-Synthélabo Australia Pty Ltd	Australia	100
Sanofi-Synthélabo GmbH / Bristol-Myers Squibb GesmbH OHG(1)	Austria	51
Sanofi-Synthélabo GmbH	Austria	100
Sanofi-Synthélabo SA/ NV	Belgium	100
Sanofi-Synthélabo do Brasil Ltda	Brazil	100
Sanofi-Synthélabo Ltda	Brazil	100
Sanofi-Synthélabo Canada Inc	Canada	100
Sanofi-Synthélabo de Chile	Chile	100
Hangzhou Sanofi-Synthélabo Minsheng Pharma Co Ltd	China	55
Lakor Farmaceutica SA	Colombia	85
Pacífico Pharma	Colombia	100
Sanofi-Synthélabo de Colombie SA	Colombia	100
Sanofi-Synthélabo Korea Co Ltd	Korea	100
Sanofi-Synthélabo A/S	Denmark	100
Sanofi Winthrop BMS partnership(1)	Denmark	51
Sanofi-Synthélabo del Ecuador SA	Ecuador	100
Sanofi-Synthélabo SA	Spain	100
Synthélabo SA	Spain	100
Sanofi Winthrop BMS partnership(1)	Finland	51
Sanofi-Synthélabo OY	Finland	100
Sanofi Chimie (Ex SaSy 1)	France	100
Dakota Pharm	France	100
Europar(2)	France	100
Francopia	France	100
Groupement Fabrication Pharmaceutique	France	100
Institut d'édition Sanofi-Synthélabo	France	100
Laboratoires Irex	France	100
Sanofi Développement Pharma	France	100
Sanofi Participation	France	100

- (1) joint-venture with Bristol-Myers Squibb consolidated using the method described in note C1  
(2) deconsolidated during the year

		Financial interest %
Pharma Bristol-Myers Squibb(1)	France	51
Sanofi-Synthelabo	France	100
Sanofi-Synthelabo France	France	100
Sanofi-Synthelabo Groupe	France	100
Sanofi-Synthelabo OTC	France	100
Sanofi-Synthelabo Recherche	France	100
Sanofi Winthrop Industries	France	100
Secipe	France	100
SPI	France	100
Synthelabo Biomédical	France	100
Sanofi-Synthelabo A.E	Greece	100
Sanofi-Synthelabo HK Ltd	Hong Kong	100
Sanofi BMS Hong-Kong(1)	Hong Kong	51
Chinoïn	Hungary	99
Sanofi-Synthelabo RT	Hungary	100
Sanofi-Synthelabo India Ltd	India	100
PT Sanofi-Synthelabo Combiphar	Indonesia	70
Sanofi-Synthelabo Ireland Ltd	Ireland	100
Inverni Della Beffa Spa	Italy	100
Sanofi-Synthelabo OTC Spa	Italy	100
Sanofi-Synthelabo Spa	Italy	100
Sanofi-Synthelabo Meiji Pharmaceuticals Co Ltd	Japan	51
Sanofi-Synthelabo Taisho Pharmaceuticals Co Ltd	Japan	51
Sanofi-Synthelabo Yamanouchi Pharmaceuticals KK	Japan	51
Sanofi-Synthelabo KK	Japan	100
Sanofi-Synthelabo (Malaysia) SDN-BHD	Malaysia	100
Sanofi-Synthelabo BMS		
Malaysia partnership(1)	Malaysia	51
Laboratoires Maphar	Morocco	81
Sanofi-Synthelabo Maroc	Morocco	100
Rudefsa	Mexico	100
Sanofi-Synthelabo de Mexico SA	Mexico	100
Sanofi-Synthelabo AS	Norway	100
Sanofi Winthrop BMS partnership ANS(1)	Norway	51
Sanofi-Synthelabo (NZ) Ltd	New Zealand	100
Sanofi-Synthelabo Panama	Panama	100
Sanofi-Synthelabo BV	Netherlands	100
Sanofi-Synthelabo Polholding BV	Netherlands	100
Sanofi-Synthelabo Row BV	Netherlands	100
Sanofi Winthrop BMS VOF(1)	Netherlands	51
Synthelabo Netherlands BV	Netherlands	100
Sanofi-Synthelabo del Peru SA	Peru	51
Synthelabo Delagrange del Peru	Peru	100
Sanofi-Synthelabo Philippines Inc	Philippines	100
Sanofi-Synthelabo Sp Zoo	Poland	100
Irex Promocao e Comercializacao de produtos farmaceuticos Lda	Portugal	100
Sanofi-Synthelabo Produtos Farmaceuticos SA	Portugal	100
Sanofi Winthrop BMS AEIE(1)	Portugal	51
Sanofi-Synthelabo	Dominican	
de la Republica Dominicana	Republic	100
Sanofi-Synthelabo sro	Czech Republic	100
Laboratoires Irex Sro	Czech Republic	100
Sanofi-Synthelabo Ltd	United Kingdom	100
Sanofi-Synthelabo UK Ltd	United Kingdom	100
Sterwin Medicines Ltd	United Kingdom	100
Sanofi BMS(1)	Singapore	51
Sanofi-Synthelabo (Singapore) Pte Ltd	Singapore	100
Sanofi-Synthelabo Slovakia s.r.o.	Slovakia	100
Sanofi Winthrop BMS partnership(1)	Sweden	51

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

Sanofi-Synthelabo AB	Sweden	100
Sanofi SA-AG (Genève)	Switzerland	100
Sanofi-Synthelabo (Suisse) SA	Switzerland	100
Synthelabo Pharma Suisse	Switzerland	100
Sanofi-Synthelabo CIS & Eastern countries SA	Switzerland	100
Fujisawa Sanofi-Synthelabo Pharmaceuticals Co Ltd(2)	Taiwan	51
Sanofi-Synthelabo Taiwan Limited	Taiwan	100
Sanofi-Synthelabo (Thailand) Ltd	Thailand	100
Synthelabo (Thailand) Ltd	Thailand	100
Sanofi-Synthelabo Adwya SA	Tunisia	51
Sanofi-Synthelabo Tunisie	Tunisia	70
Sanofi-Synthelabo Ilac.	Turkey	100
Sanofi-Dogu BMS ADI Ortakligi partnership(1)	Turkey	51
Sanofi-Synthelabo Uruguay SA	Uruguay	100
Loxex Pharmaceuticals Inc.(3)	USA	100
Sanofi-Synthelabo Inc	USA	100
Loxex Inc	USA	100
Sanocore de Venezuela S.A	Venezuela	100
Sanofi-Synthelabo de Venezuela SA	Venezuela	100
Sanofi-Synthelabo Vietnam	Vietnam	70

### E.2. Equity-accounted

CKW Pharma-Extrakt	Germany	50
Belgopia SA NV	Belgium	49
Alcaliber SA	Spain	40
Groupe Yves Rocher	France	20
Mediline Ltd(2)	Israel	27
Sofarimex	Portugal	40

### E.3. Proportionately consolidated

Organon Sanofi-Synthelabo Canada Partnership	Canada	50
Synthelabo Tanabe Chimie	France	50
Fujisawa Sanofi-Synthelabo	Japan	51
Organon Sanofi-Synthelabo Mexico SA de CV	Mexico	50
Fonda BV	Netherlands	50
Fujisawa Sanofi-Synthelabo Pharmaceuticals company Limited	Taiwan	51
Organon Sanofi-Synthelabo LLC	USA	50

(1) joint-venture with Bristol-Myers Squibb consolidated using the method described in note C1

(2) deconsolidated during the year

(3) consolidated during the method described in C2 and D1

## Consolidated financial summary

(in millions of euros)	Year ended December 31, 2002	Year ended December 31, 2001	Year ended December 31, 2000	6 months ended December 31, 1999
<b>Financial position at period-end</b>				
Share capital	1,465	1,464	1,463	1,462
Number of shares in issue	732,367,507	732,005,084	731,441,746	731,143,218
Net sales	7,448	6,488	5,963	2,658
Operating profit	2,614	2,106	1,577	531
Operating cash flow before changes in working capital	2,260	1,732	1,295	466
Net income before income from equity investees, goodwill amortization & minority interests	1,834	1,579	995	344
Net income	1,759	1,585	985	342
Net income before exceptional items and goodwill amortization	1,758	1,376	961	340
Dividends		473	317	
<b>Per share data (in euros)</b>				
Net income before income from equity investees, goodwill amortization & minority interests	2.52	2.16	1.36	0.47
Net income	2.42	2.17	1.35	0.47
Net income before exceptional items and goodwill amortization	2.42	1.88	1.31	0.47
Dividends (net)		0.66	0.44	

## Reconciliation of US GAAP financial statements

Condensed financial statements prepared under accounting principles generally accepted in the United States (US GAAP), and a reconciliation of the financial statements prepared under French GAAP and under US GAAP, will be available on our website [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com) when we publish our 20-F document, filed annually with the Securities and Exchange Commission (SEC).



## PARENT COMPANY FINANCIAL STATEMENTS

<b>Report of the statutory auditors on the parent company financial statements</b>	<b>64</b>
<b>Special report of the statutory auditors on certain related-party transactions</b>	<b>65</b>
<b>Balance sheet</b>	<b>66</b>
<b>Statement of income</b>	<b>68</b>
<b>Statement of cash flows</b>	<b>69</b>
<b>Notes to the financial statements</b>	<b>70</b>
<b>Five-year financial summary</b>	<b>86</b>
<b>Parent company/subsidiary relations</b>	<b>87</b>

## Report of the statutory auditors on the parent company financial statements

**Year ended December 31, 2002**

In our capacity as statutory auditors, we present below our report on:

the accompanying annual financial statements of Sanofi-Synthélabo's management, and for the year ended December 31, 2002.

the specific procedures and disclosures prescribed by law,

The annual financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

### **I. Opinion on the financial statements**

We conducted our audit in accordance with French professional standards. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement's presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2002, and the results of its operations for the year then ended, in accordance with French accounting principles. Without qualifying our opinion, we draw attention to notes 1 and 6 to the financial statements, which present the impact on the financial statements of the change in accounting method resulting from the application with effect from January 1, 2002 of the new CRC rule 2000-06 on liabilities.

### **II. Specific procedures and disclosures**

We have also carried out the specific procedures prescribed by French law, in accordance with French professional standards. We have nothing to report with respect to the fairness of information contained in the Directors' report and its consistency with the financial statements and other information presented to shareholders concerning the financial position.



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

In accordance with French law we have ensured that the required information concerning the purchase of investments and controlling interests and the names and voting rights of the principal shareholders have been properly disclosed to you in the Director s report.

Paris, February 18, 2003

### The Statutory Auditors

PricewaterhouseCoopers Audit

Ernst & Young Audit

Jacques DenizEAU

Jean-Christophe Georghiou

Dominique Thouvenin

Valérie Quint

**64**

[Parent Company Financial Statements](#)

## Special report of the statutory auditors on certain related-party transactions

**Year ended December 31, 2002**

In our capacity as Statutory Auditors of Sanofi-Synthélabo, we are required to report on certain contractual agreements with certain related parties.

We are not required to ascertain whether any contractual agreements exist but to inform you on the basis of the information provided to us, of the terms and conditions of agreements indicated to us. It is not our role to comment whether they are beneficial or appropriate. It is your responsibility, under the terms of article 92 of March 23, 1967 of the Decree, to evaluate the benefits resulting from these agreements prior to their approval.

We hereby inform you that we have not been advised of any agreement concluded during the year ended December 31, 2002 which would be covered by article L.225-38 of French Company Law (Code de commerce).

In accordance with the March 23, 1967 Decree, we have been provided that the following agreements, approved in prior years by Synthélabo, merged into Sanofi-Synthélabo on May 18, 1999, remained effective in the year ended December 31, 2002.

A loan and a current account advance which do not bear interest have been made to AO Synthélabo Russia. The balance on these accounts as of December 31, 2002 was as follows:

	<u>Euros</u>
Loan	25,709.15
Current account	574,738.89

We conducted our work in accordance with French professional standards. These standards require that we perform procedures to verify that the information provided to us is consistent with the necessary documentation from which it has been extracted.

Paris, February 18, 2003

The Statutory Auditors

PricewaterhouseCoopers Audit

Ernst & Young Audit

Jacques Denizeau

Jean-Christophe Georghiou

Dominique Thouvenin

Valérie Quint



## Balance sheet

### ASSETS

(in millions of euros)	2002	2001	2000
Intangible assets	453	65	126
Tangible fixed assets	101	74	63
Long-term investments	3,976	2,611	2,149
<b>Fixed assets (note 3)</b>	<b>4,530</b>	<b>2,750</b>	<b>2,338</b>
<b>Receivables (notes 4, 15 et 16)</b>			
Advance payments to suppliers	1	2	1
Accounts receivable	614	365	306
Other current assets	928	753	1,431
Short-term investments and deposits (note 5)	2,856	4,083	2,619
Cash	30	3	3
<b>Current assets</b>	<b>4,429</b>	<b>5,206</b>	<b>4,360</b>
<b>Deferred charges</b>	<b>19</b>	<b>2</b>	<b>7</b>
<b>Unrealized foreign exchange losses</b>	<b>2</b>	<b>8</b>	<b>5</b>
<b>Total assets</b>	<b>8,980</b>	<b>7,967</b>	<b>6,710</b>

The accompanying notes on pages 70 to 85 are an integral part of the financial statements.

**LIABILITIES AND SHAREHOLDERS EQUITY**

	<b>2002</b>	<b>2001</b>	<b>2000</b>
(in millions of euros)			
Share capital	1,465	1,464	1,463
Additional paid-in capital	1,578	1,485	1,479
Reserves and retained earnings	2,688	1,717	1,404
Net income for the period	1,323	1,442	630
Special tax-allowable provisions	1	1	3
<b>Shareholders equity</b> (note 6)	<b>7,055</b>	<b>6,109</b>	<b>4,979</b>
<b>Provisions for risks and charges</b> (note 7)	<b>239</b>	<b>496</b>	<b>492</b>
<b>Liabilities</b> (notes 4, 15 and 16)			
Bank and other debt	777	735	804
Accounts payable	254	207	225
Other current liabilities	624	388	191
Bank overdrafts	15	1	8
<b>Other liabilities</b>	<b>1,670</b>	<b>1,331</b>	<b>1,228</b>
<b>Deferred income</b>	<b>13</b>	<b>20</b>	<b>1</b>
<b>Unrealized foreign exchange gains</b>	<b>3</b>	<b>11</b>	<b>10</b>
<b>Total liabilities and shareholders equity</b>	<b>8,980</b>	<b>7,967</b>	<b>6,710</b>

The accompanying notes on pages 70 to 85 are an integral part of the financial statements.

## Statement of income

	<u>2002</u>	<u>2001</u>	<u>2000</u>
(In millions of euros)			
<b>Operating income</b> (note 8)	<b>1,574</b>	<b>1,180</b>	<b>876</b>
Net sales	273	176	194
Other income	1,301	1,004	682
<b>Operating expenses</b> (note 9)	<b>(1,178)</b>	<b>(962)</b>	<b>(908)</b>
Other purchases and external charges	(947)	(742)	(690)
Taxes other than income taxes	(47)	(33)	(29)
Salaries and social security charges	(14)	(15)	(17)
Depreciations, amortizations and provisions	(111)	(82)	(80)
Other expenses	(59)	(90)	(92)
<b>Share in profits/losses of joint venture partnerships</b> (note 10)		<b>303</b>	<b>183</b>
<b>Operating profit</b>	<b>396</b>	<b>521</b>	<b>151</b>
Net investment income	796	415	746
Changes in provisions, cost transfers	(88)	128	(31)
Net foreign exchange gains (losses) (note 11)	85	18	(40)
<b>Net financial income</b> (note 12)	<b>793</b>	<b>561</b>	<b>675</b>
<b>Net income before tax and exceptional items</b>	<b>1,189</b>	<b>1,082</b>	<b>826</b>
<b>Exceptional items</b> (notes 2 and 13)	<b>327</b>	<b>581</b>	<b>(140)</b>
Statutory employee profit-sharing		1	(6)
Income taxes (notes 2 and 14)	(193)	(222)	(50)
<b>Net income</b>	<b>1,323</b>	<b>1,442</b>	<b>630</b>

The accompanying notes on pages 70 to 85 are an integral part of the financial statements.

## Statement of cash flows

(in millions of euros)	2002	2001	2000
<b>OPERATING ACTIVITIES</b>			
Net income	1,323	1,442	630
Depreciation and amortization	53	21	25
Net charge to (write-back of) provisions (*)	(140)	(65)	289
Gains on disposals of fixed assets (**)	2	(647)	(24)
Other items	4	(13)	1
<b>Operating cash flow before changes in working capital</b>	<b>1,242</b>	<b>738</b>	<b>921</b>
(Increase) decrease in working capital	(417)	41	(124)
<b>Net cash provided by operating activities</b>	<b>825</b>	<b>779</b>	<b>797</b>
<b>INVESTING ACTIVITIES</b>			
Acquisitions of intangible assets and tangible fixed assets	(86)	(25)	(29)
Acquisitions of investments	(36)	(34)	(75)
Long-term loans and advances granted	(6)	(1)	
Disposals of intangible assets and tangible fixed assets	9	53	24
Disposals of investments	5	382	11
Repayments of long-term loans & advances and other investing cash flows			4
<b>Net cash provided by/(used in) investing activities</b>	<b>(114)</b>	<b>375</b>	<b>(65)</b>
<b>FINANCING ACTIVITIES</b>			
Issuance of shares	4	7	3
Dividends paid	(473)	(317)	(231)
Change in debt due within less than one year (***)	(55)	(70)	134
Net change in investments maturing within less than one year (***)	(378)	690	(119)
Net acquisitions of treasury shares (note 3)	(1,170)	(****)	(****)
<b>Net cash provided by/(used in) financing activities</b>	<b>(2,072)</b>	<b>310</b>	<b>(213)</b>
<b>Change in cash and cash equivalents</b>	<b>(1,361)</b>	<b>1,464</b>	<b>519</b>
Opening cash and cash equivalents	3,624(2)	2,622	2,103
<b>Closing cash and cash equivalents(1)</b>	<b>2,263</b>	<b>4,086</b>	<b>2,622</b>

(\*) excluding write-backs of provisions relating to asset disposals

(\*\*) including write-backs of provisions relating to asset disposals

(\*\*\*) including current accounts with subsidiaries

(\*\*\*\*) net acquisitions of treasury shares: 163 million euros in 2001 and 183 million euros in 2000

(1) As of December 31, 2002, cash and cash equivalents include cash plus short-term investments other than treasury shares. As of December 31, 2001 and 2000, cash and cash equivalents included treasury shares of 462 million euros and 299 million euros respectively. Bank overdrafts and bank accounts in credit are included in debt due within less than one year.

(2) The difference of 462 million euros between closing cash and cash equivalents related to 2001 and opening cash and cash related to 2002 corresponds to treasury shares, previously included in cash and cash equivalents.





## Notes to the financial statements

### INTRODUCTION

- n The Extraordinary General Meeting of Sanofi-Synthélabo held on May 22, 2001 approved the merger of the subsidiary Laboratoires Synthélabo into Sanofi-Synthélabo. Because Sanofi-Synthélabo owned 100% of the shares of this company, these shares were cancelled and the merger did not result in the issuance of any new shares.
- n On June 30, 2001, Sanofi-Synthélabo transferred the real estate assets of two industrial sites (Amilly and Tours) to its subsidiary Sanofi-Winthrop Industrie at a fair value of 27 million euros.
- n The Extraordinary General Meeting of Sanofi-Synthélabo held on May 22, 2002 approved the merger of the three companies Sasy3, Laboratoires Cèdre and Sanofi Concept into Sanofi-Synthélabo. Because Sanofi-Synthélabo owned 100% of the shares of these companies, these shares were cancelled and the merger did not result in the issuance of any new shares.

### CONSOLIDATION

The Sanofi-Synthélabo Group is consolidated using the equity method in the consolidated financial statements of TotalFinaElf and L'Oréal.

### Note 1: Accounting policies

The financial statements for the year ended December 31, 2002 are presented in accordance with the law and regulations in force and with the following basic conventions:

- n going concern,
- n consistency of method,
- n matching of costs and revenues.

The accounting policies and methods used are identical to those applied in the preparation of the financial statements for the year ended December 31, 2001, except for the new CRC Rule 2000.06 on liabilities, implemented by Sanofi-Synthélabo with effect from January 1, 2002.

*a) Intangible assets*

Concessions, patents, licenses, trademarks, processes, rights and similar assets:

Intangible assets are amortized or written down over their period of legal protection, or over their estimated useful life where there is no such protection.

*b) Tangibles fixed assets*

Property, plant and equipment are valued at acquisition cost, comprising purchase price plus incidental costs required to bring the asset into usable condition.

Depreciation is charged on a straight-line basis. The company makes use of accelerated and exceptional depreciation where allowed by the tax authorities. The difference between accounting depreciation and tax depreciation is recorded as a reserve in the balance sheet on the Tax depreciation line under the heading Special tax-allowable provisions .

Depreciation periods and methods are as follows:

	<u>Period</u>	<u>Method</u>
Buildings and improvements to land	15-20 years	Straight-line
Fixtures, fittings & installations	10-20 years	Straight-line

*c) Participating interests, other long-term investments, short-term investments*

Initial recognition is at acquisition cost, excluding incidental purchase costs. If the fair value as defined under French accounting rules is less than the book value at the balance sheet date, a provision for impairment is recorded to cover the difference.

### **Unlisted participating interests and other long-term investments**

Various factors are used to estimate the value of such investments, including current and future earnings prospects, usefulness to the Group, shareholder's equity, the prospects for future sale, business conditions, and the criteria used in assessing the original investment.

In practice, this rule leads to a distinction being drawn between:

- interests in companies whose activities are carried on almost exclusively within the Group (facilities and service companies). In such cases, the net book value may under no circumstances exceed the share of shareholder's equity held;
- interests in companies whose industrial and commercial know-how give them a significant share of a sufficiently profitable market. In such cases, the company's market position, customer base and intangible assets may justify the investment being shown at a net book value in excess of the share of shareholder's equity held.

### **Other listed long-term investments and short-term investments**

Fair value is calculated by reference to the average quoted price for the last month of the period.

#### *d) Foreign-currency transactions*

Foreign-currency income and expenses are recorded at the exchange rate prevailing on the transaction date. Foreign-currency liabilities, receivables and cash are recorded at the exchange rate prevailing at the balance sheet date. The difference arising from the restatement of foreign-currency liabilities and receivables at this rate is taken to the balance sheet as an unrealized foreign exchange gain or loss. A provision for foreign exchange risk is recorded to cover the unrealized foreign exchange losses arising from the calculation of an overall foreign exchange position on all assets, liabilities and off balance sheet commitments existing at the balance sheet date.

Capitalizable advances to subsidiaries made in foreign currencies remain in the balance sheet at face value, converted at the historical exchange rate.

Forward purchases and sales of foreign currencies are recorded off balance sheet at the historical exchange rate.

#### *e) Retirement benefit commitments*

Sanofi-Synthélabo's pension and retirement benefit commitments are recognized as liabilities on the basis of an actuarial estimate of the potential rights vested in employees as of the balance sheet date, net of the valuation of funds available to meet these obligations.

Commitments to former employees are also recognized as liabilities.

The actuarial estimate of these commitments takes account of:

- the probability that current employees will remain with the Group until retirement, mortality rates, and assumptions on salary inflation;
- an assumption that retirement will take place at age 60 to 65 after a working life giving entitlement to full pension rights;
- discounting rates used to determine the present value of the commitments. The discounting rate used as of December 31, 2002 was 5.25%.

#### **Note 2: Taxation**

Sanofi-Synthélabo has opted for a group tax election as allowed under articles 223 A-Q of the French General Tax Code.

As of December 31, 2002, 25 French subsidiaries more than 95% owned by Sanofi-Synthélabo were included in the group tax election. The election is effective from 1999 through 2003.

Each company in the group tax election records its own income tax charge. The ultimate tax saving generated by the group tax election is recorded by the Sanofi-Synthélabo parent company as an exceptional item, including the impact of tax audits on the group tax election (see note 13).

## Note 3: Fixed assets

## MOVEMENTS IN FIXED ASSETS IN THE YEAR ENDED DECEMBER 31, 2002

(in millions of euros)	Gross values						Net book value
	Opening Balance	Mergers (1)	Acquisitions and other increases	Disposals and other decreases	Closing balance	Depreciation, amortization & impairment	
<b>Intangible assets</b>	<b>229</b>	<b>14</b>	<b>443</b>	<b>(21)</b>	<b>665</b>	<b>(212)</b>	<b>453</b>
Trading goodwill	19	14			33	(18)	15
Patents	59		46		105	(63)	42
Trademarks	65		1	(1)	65	(39)	26
Other intangible assets	86		396*	(20)	462	(92)	370
<b>Tangible fixed assets</b>	<b>163</b>		<b>59</b>	<b>(29)</b>	<b>193</b>	<b>(92)</b>	<b>101</b>
Lands	13		1	(0)	14		14
Buildings	135		26	(4)	157	(88)	69
Other tangible fixed assets	5				5	(4)	1
Fixed assets in progress	10		32	(25)	17		17
<b>Long-term investments</b>	<b>2,727</b>	<b>366</b>	<b>1,055</b>	<b>(25)</b>	<b>4,123</b>	<b>(147)</b>	<b>3,976</b>
Participating interests(2)	2,694	366	53	(15)	3,098	(94)	3,004
Loans/advances to participating interests	5		12	(2)	15	(8)	7
Other long-term investments(3)	25		20	(1)	44	(19)	25
Treasury shares(4)			970	(7)	963	(26)	937
Loans	3				3		3

\* In accordance with the Tax Instruction of November 26, 1996, Sanofi-Synthelabo has capitalized 392 million euros in respect of royalties payable over the estimated life of a product, with a matching liability recognized in the balance sheet (see Note 4).

(in millions of euros)	Depreciation, amortization and impairment				
	Opening balance	Mergers (1)	Acquisitions and other increases	Disposals and write-backs	Closing balance
<b>Intangible assets</b>	<b>164</b>	<b>10</b>	<b>76</b>	<b>(38)</b>	<b>212</b>
Trading goodwill	5	10	3		18
Patents	55		9	(1)	63
Trademarks	36		3		39
Other intangible assets	68		61	(37)	92
<b>Tangible fixed assets</b>	<b>89</b>		<b>7</b>	<b>(4)</b>	<b>92</b>
Buildings	84		7	(3)	88
Other tangible fixed assets	5			(1)	4
<b>Long-term investments</b>	<b>116</b>		<b>68</b>	<b>(37)</b>	<b>147</b>

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Participating interests(2)	114	17	(37)	94
Loans/advances to participating interests		8		8
Other long-term investments(3)	2	17		19
Treasury shares(4)		26		26

(1) See Introduction.

(2) Details of the movement in participating interests and provisions for impairment are given below.

(3) See notes on Viropharma Inc and IDM below.

(4) Sanofi-Synthélabo shares held by the company itself.

**Viropharma Inc:**

As of December 31, 2002, Sanofi-Synthélabo owned 750,000 shares in Viropharma Inc, a company listed on the Nasdaq. These shares were received in 2001 in connection with the renegotiation of the Pleconaril license agreement, and valued at 19 million euros. In the light of the average listed stock market price for December 2002, a provision for impairment of 18 million euros has been taken against these shares.

**Immuno-Designed Molecules (IDM):**

In 1999, Sanofi-Synthélabo signed a partnership agreement with IDM on the use by IDM of Interleukine 13, a product developed by Sanofi-Synthélabo's research teams. In return, Sanofi-Synthélabo received 145,660 shares together with share warrants. This operation was valued at 0.8 million euros.

In 2001, Sanofi-Synthélabo and IDM extended this partnership, signing a strategic collaboration agreement whereby IDM granted Sanofi-Synthélabo 20 development options on its current and future research and development programs. For each option that leads to a commercially marketed product, IDM could receive a total of between 17 and 32 million euros, depending on the potential of the market, plus reimbursement of the development costs. Contractually, Sanofi-Synthélabo may suspend the development program for each option exercised at any time and without penalty. As of December 31, 2002, Sanofi-Synthélabo had exercised only one option, relating to a program for the treatment of melanoma.

In 2002, Sanofi-Synthélabo subscribed 20 million euros to a reserved share issue made by IDM. Sanofi-Synthélabo is also committed to making an additional investment of 10 million euros in a further share issue. As of December 31, 2002, Sanofi-Synthélabo owned 1,700,145 IDM shares, representing 12.7% of the capital. This percentage may change in the future as a result of this commitment and of the conversion of existing financial instruments giving access to the capital of IDM.

**Sanofi-Synthélabo shares:**

During the year ended December 31, 2002, the company used the authorizations to buy its own shares in the market in order to allocate shares to stock option plans and in the light of market conditions.

A total of 19,550,679 shares were bought at an average price of 60.57 euros per share.

At end December 2002, the company owned:

-

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

13,964,580 shares classified as short-term investments at a net book value of 623 million euros. In the light of the average stock market price for December 2002, a provision for impairment of 45.6 million euros was charged to the income statement during the year. These shares represent 1.91% of the share capital, and include 13,836,580 shares allocated to employee stock option plans.

- 16,411,795 shares classified as long-term investments at a gross value of 963 million euros, and representing 2.24% of the share capital. In the light of the average stock market price for December 2002, a provision for impairment of 25.8 million euros was charged to the income statement during the year.

73

Parent Company Financial Statements



## Movements in participating interests in 2002

	(in millions of euros)
<b>Balance as of January 1, 2002</b>	<b>2,694</b>
<b>Investments during the year</b>	<b>16</b>
Sanofi-Synthelabo A.E. (Greece)	10
Sanofi-Synthelabo (India) Ltd	6
<b>Capital increases by offset of loans/advances</b>	<b>37</b>
Sanofi-Synthelabo (India) Ltd	5
Sanofi Concept	6
Laboratoires Irex	9
Sanofi Développement Pharma	8
Sanofi-Synthelabo Yamanouchi Pharma KK	5
Others	4
<b>Disposals and other decreases</b>	<b>(15)</b>
Europar	(7)
Synthelabo South Africa	(4)
Sanofi-Synthelabo Philippines inc	(4)
<b>Mergers</b>	<b>366</b>
Impact of the merger of the subsidiaries Laboratoires Cèdre, Sasy3 and Sanofi Concept into Sanofi-Synthelabo(1)	
<b>Balance as of December 31, 2002 (gross)</b>	<b>3,098</b>

(1) See Introduction.

## Movement in provisions for impairment of participating interests in 2002

	(in millions of euros)
<b>Balance as of January 1, 2002</b>	<b>114</b>
<b>1. Net write-backs during the year</b>	<b>(11)</b>
<b>Charges</b>	<b>17</b>
Sanofi-Synthelabo Panama	1
Sanofi-Synthelabo Ecuador	5
Synthelabo Biomédical	3
Sanofi Développement Pharma	4
Sanofi-Synthelabo Yamanouchi	4
<b>Write-backs</b>	<b>(28)</b>
Synthelabo Pharma Suisse	(1)
Sanofi-Synthelabo Koréa Co Ltd	(25)
Others	(2)
<b>2. Write-backs of provisions relating to liquidations, mergers or disposals</b>	<b>(9)</b>
Synthelabo South-Africa	(2)
Europar	(5)
Sanofi-Synthelabo Ilac (Turkey)	(2)
<b>Balance as of December 31, 2002 (impairment)</b>	<b>94</b>



**Note 4: Receivables and liabilities by maturity**

(in millions of euros)	Gross	Impairment	Net	≤ 1 year	> 1 year
<b>Receivables</b>					
<i>Fixed assets</i>					
Loans/advances to participating interests	15	(8)	7		7
Other long-term investments	43	(18)	25		25
Loans	3		3		3
<i>Current assets</i>					
Advance payments to suppliers	1		1	1	
Accounts receivable	616	(2)	614	609	5
Other receivables	929	(1)	928	916	12
<b>Total</b>	<b>1,607</b>	<b>(29)</b>	<b>1,578</b>	<b>1,526</b>	<b>52</b>
<b>Liabilities</b>					
Debt (see note 15)			777	775	2
Accounts payable			254	254	
<i>Other current liabilities:</i>					
<i>Tax and employee-related liabilities</i>					
Amounts payable to suppliers of fixed assets			3	3	
Other liabilities *			434	112	322
<b>Total</b>			<b>1,655</b>	<b>1,331</b>	<b>324</b>

\* In accordance with the Tax Instruction of November 26, 1996, Sanofi-Synthélabo has capitalized 392 million euros in respect of royalties payable over the estimated life of a product, with a matching liability recognized in the balance sheet (see note 3).

**Note 5: Short-term investments**

As of December 31, 2002, Sanofi-Synthélabo owned:

money-market mutual funds totaling 1,579 million euros;

certificates of deposit totaling 650 million euros;

short-term bank deposits totaling 3 million euros;

treasury bills totaling 1 million euros;

13,964,580 treasury shares with a net book value of 623 million euros (see note 3).



## Note 6: Movements in shareholders equity

	Number of shares	Share capital	Additional paid-in capital	Reserves and retained earnings	Net income for the period	Special tax- allowable provisions & investment subsidies	Total
<b>(in millions of euros)</b>							
<b>Balance as of December 31, 1999 before appropriation of profits</b>	<b>731,143,218</b>	<b>1,462</b>	<b>1,477</b>	<b>1,147</b>	<b>488</b>	<b>5</b>	<b>4,579</b>
Appropriation of 1999 profits to reserves and retained earnings				257	(257)		
Dividends distributed for the period ended December 31, 1999 (0.32 euro per share)					(231)		(231)
Issuance of shares on exercise of stock options	298,528	1	2				3
Net income for the year ended December 31, 2000					630		630
Change in special tax-allowable provisions						(2)	(2)
<b>Balance as of December 31, 2000 before appropriation of profits</b>	<b>731,441,746</b>	<b>1,463</b>	<b>1,479</b>	<b>1,404</b>	<b>630</b>	<b>3</b>	<b>4,979</b>
Appropriation of 2000 profits to reserves and retained earnings				313	(313)		
Dividends distributed for the year ended December 31, 2000 (0.44 euro per share)					(317)		(317)
Issuance of shares on exercise of stock options	563,338	1	6				7
Net income for the year ended December 31, 2001					1 442		1 442
Change in special tax-allowable provisions						(2)	(2)
<b>Balance as of December 31, 2001 before appropriation of profits</b>	<b>732,005,084</b>	<b>1,464</b>	<b>1,485</b>	<b>1 717</b>	<b>1 442</b>	<b>1</b>	<b>6109</b>
Appropriation of 2001 profits to reserves and retained earnings				969	(969)		
Dividends distributed for the year ended December 31, 2001 (0,66 euro per share)					(473)		(473)
Sasy3 merger (surplus arising on merger)			90				90

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Issuance of shares on exercise of stock options	362.423	1	3				4
Change of accounting method <sup>(1)</sup>				2			2
Net income for the year ended December 31, 2002					1,323		1,323
<b>Balance as of December 31, 2002 before appropriation of profits</b>	<b>732,367,507</b>	<b>1,465</b>	<b>1,578</b>	<b>2,688</b>	<b>1,323</b>	<b>1</b>	<b>7,055</b>

(1) In application of the new CRC Rule 2000.06 on liabilities, non-compliant provisions were reversed by crediting retained earnings.

The share capital comprises 732,367,507 shares with a par value of 2 euros.

The exercise of options relates to plans granted to employees prior to the merger.

The increase in shareholders' equity that would result from the exercise of options still outstanding as of December 31, 2002 would be approximately 7 million euros.

**Note 7: Provisions recorded in the balance sheet**

(in millions of euros)	Opening balance	Sasy3 merger	Charge for the year	Write-backs provision utilized	Write-backs provisions not utilized	Change of accounting method(1)	Closing balance
<b>Provisions for risks and charges</b>							
Provisions for miscellaneous risks(2)	425	3	25	(103)	(148)	(1)	201
Provisions for charges	23		7	(19)	(1)		10
Provisions for retirement and early retirement benefit commitments	48		15	(34)		(1)	28
<b>Total</b>	<b>496</b>	<b>3</b>	<b>47</b>	<b>(156)</b>	<b>(149)</b>	<b>(2)</b>	<b>239</b>
Charges and write-backs taken to the statement of income:							
							Total
Operating items			40	(1)			39
Financial items			4	(1)			3
Exceptional items			3	(154)	(149)		(300)
<b>Total</b>			<b>47</b>	<b>(156)</b>	<b>(149)</b>		<b>(258)</b>

(1) Written back to retained earnings in application of the new CRC Rule 2000-06 on liabilities (see note 6).

(2) This line mainly comprises provisions relating to patent rights litigation, tax audits and vendors guarantees of liabilities.

**Note 8: Operating income****Net sales**

This line mainly comprises:

*Supply of chemical active ingredients:*

During the year, Sanofi-Synthelabo invoiced a total of 123 million euros.

*Recharged research and development expenses:*

Under agreements with the principal French operating subsidiaries on the sharing of the costs and benefits of research and development expenses relating to future pharmaceutical products, Sanofi-Synthélabo recharges a share of such expenses to its subsidiaries. For the year ended December 31, 2002, the income generated by such recharges was 77 million euros, compared with 118 million euros for the year ended December 31, 2001. The reduction in income is due to the ending of an agreement between Sanofi-Synthélabo and two of its subsidiaries on December 31, 2001.

*Rent:*

Sanofi-Synthélabo owns real estate in France which is let to its subsidiaries, on which it collects rent (29 million euros).

**Other income**

This mainly comprises royalties collected by Sanofi-Synthelabo from:

its French and foreign pharmaceutical subsidiaries, to which it has licensed patents, manufacturing know-how and trademarks owned by Sanofi-Synthélabo;

third party companies, to which it has licensed a number of major pharmaceutical products.



**Note 9: Operating expenses**

**Other purchases and external charges**

This line mainly comprises:

*Manufacturing of active ingredients:*

Sanofi-Synthelabo subcontracts the manufacturing of active ingredients to a subsidiary. Costs incurred as a result amounted to 62 million euros for the year ended December 31, 2002.

*Research expenses:*

Sanofi-Synthelabo, in association with its main operating subsidiaries, assumes responsibility within the Group for research and development. It defines strategic priorities, co-ordinates the work, makes investment decisions, and takes out in its own name and at its own expense all industrial property protection covering products derived from research.

In order to fulfil this role, Sanofi-Synthelabo subcontracts research and development work to those of its subsidiaries that have the necessary resources, and if necessary to third parties.

Research expenses amounted to 802 million euros in 2002, compared with 657 million euros in 2001 and 589 million euros in 2000.

**Salaries and social security charges**

	<u>2002</u>	<u>2001</u>	<u>2000</u>
Average number of employees	22	22	26

Remuneration paid to corporate officers holding office as of December 31, 2002 amounted to 3.6 million euros, including attendance fees of 0.4 million euros.

**Note 10: Share in profits/losses of joint-venture partnerships**

Until 2001, this represented Sanofi-Synthélabo's share of the profits from the partnership entity involved in chemicals activities. This entity was wound up on December 31, 2001.

**Note 11: Management of market risk**

Sanofi-Synthélabo operates a centralized foreign exchange risk management system which provides protection from such risk for its main subsidiaries at all times.

Gains and losses arising on hedging transactions are calculated and recognized symmetrically with the recognition of gains and losses on the hedged item.

Outstanding hedging positions at year end are shown in Sanofi-Synthélabo's off balance sheet commitments.

**Note 12: Net financial income**

	2002	2001	2000
<b>(in millions of euros)</b>			
<b>Net investment income</b>	<b>796</b>	<b>415</b>	<b>746</b>
Dividends received	674	277	649
Other portfolio income	19	4	9
Net proceeds from disposals of short-term investments	49	48	9
Other interest and similar income <sup>(1)</sup>	54	86	79
<b>Net change in provisions for impairment of</b>	<b>(88)</b>	<b>128</b>	<b>(31)</b>
participating interests (see note 3)	11	115	(39)
treasury shares (see note 3)	(71)		
other long-term investments <sup>(2)</sup>	(17)	(2)	1
loans to subsidiaries	(8)	3	
other items	(3)	12	7
<b>Net foreign exchange gain/(loss)</b>	<b>85</b>	<b>18</b>	<b>(40)</b>
<b>Total</b>	<b>793</b>	<b>561</b>	<b>675</b>

(1) This line mainly comprises interest received and paid on short-term bank deposits, current accounts and loans arising under the cash pooling agreements between Sanofi-Synthelabo and its subsidiaries.

(2) See note 3 on Viropharma Inc.

**Note 13: Exceptional items**

Exceptional charges amounted to 169 million euros and exceptional income to 496 million euros. The net balance of exceptional items comprises:

	2002	2001	2000
<b>(in millions of euros)</b>			
net change in provisions for risks and charges	300	(77)	(155)
net gain/(loss) realized on mergers of Group companies	(9)	258 <sup>(1)</sup>	
net gain/(loss) realized on disposals of long-term investments		333 <sup>(2)</sup>	24
other fixed asset disposals	7	58	
net gain on group tax election (including impact of tax audits relating to the group tax election)	73	17	34
exceptional restructuring costs			(78)
payment received on a license disposal compensation			35
others items	(44) <sup>(3)</sup>	(8)	
<b>Total</b>	<b>327</b>	<b>581</b>	<b>(140)</b>

(1) including 237 million euros realized on the merger of Synthelabo Groupe into Sanofi Winthrop Industrie.

(2) including 308 million euros on the disposal of Laboratoires de Biologie Végétale Yves Rocher (see note 18)

<sup>(3)</sup> including 34 million euros relating to retirement benefit commitments.

**Note 14: Income taxes**

As stated in note 2, the annual income tax charge corresponds to the corporate income tax charge specific to Sanofi-Synthélabo. It breaks down as follows:

	<u>2002</u>	<u>2001</u>	<u>2000</u>
<b>(in millions of euros)</b>			
Tax on profit before exceptional items	(152)	(151)	(48)
Tax on exceptional items, plus the impact of tax reassessment notices accepted by the company	(41)	(71)	(2)
	<u>(193)</u>	<u>(222)</u>	<u>(50)</u>

The tax on profit before exceptional items takes into account tax credits and changes in provisions for impairment of investments included in net financial income.

Charges regarded as excessive under article 39.4 of the French General Tax Code and not deductible from taxable profits amounted to 0.1 million euros in 2002.

**Increases and reductions in future tax liabilities**

The amount of deferred tax assets not recognized in the parent company financial statements in respect of temporarily nondeductible provisions was 53 million euros as of December 31, 2002, compared with 55 million euros as of December 31, 2001. The amount of the deferred tax liability not recognized in the parent company financial statements in respect of deferred charges was 6 million euros as of December 31, 2002.

**Note 15: Transactions with related undertakings**

In the table below, a company is treated as related if it is consolidated by the Group using the full consolidation method.

	<u>2002</u>	<u>2001</u>	<u>2000</u>
<b>(in millions of euros)</b>			
<b>Long-term investments (gross):</b>			
Participating interests	3,088	2,678	2,341
Loans/advances to participating interests	15	5	57
<b>Receivables (gross):</b>			
Accounts receivable	587	342	287
Other receivables	598	473	1,201

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

<b>Liabilities:</b>			
Debt	773	730	800
Accounts payable	246	187	192
Other liabilities	2	4	10
Deferred income	12		
<b>Operating expenses:</b>			
Other purchases and external charges	(829)	(677)	(615)
Other charges	(19)	(57)	(50)
<b>Financial expenses:</b>			
Interest and similar expense	(22)	(31)	(28)
Exceptional charges on non-capital transactions	(2)		
<b>Net sales</b>	<b>253</b>	<b>163</b>	<b>172</b>
<b>Other operating income</b>	<b>736</b>	<b>421</b>	<b>496</b>
<b>Share in net income of joint venture partnerships</b>		<b>303</b>	<b>183</b>
<b>Financial income</b>	<b>689</b>	<b>318</b>	<b>710</b>

**Note 16: Accrued income and expenses**

(in millions of euros)	Accrued incomes	Accrued expenses
Accounts receivable	297	
Other receivables	117	
Accounts payable		50
Amounts payable to suppliers of fixed assets		1
Tax and employee-related liabilities		14
Other liabilities		12

**Note 17: Off balance sheet commitments**

(in millions of euros)	< 1 year	1-5 years	> 5 years	Total
<b>Commitments given:</b>				
Surety bonds given to the tax authorities in respect of contested tax liabilities relating to Sanofi-Synthélabo	6			6
Guarantees in favor of Group subsidiaries	395			395
Other surety bonds and guarantees	2		19	21
Lease		56	112	168
Currency options including	809			809
Others(1)	26	127	40	193
<b>Total</b>	<b>1,238</b>	<b>183</b>	<b>171</b>	<b>1,592</b>

- (1) Under the agreements with NV Organon on the marketing of the drug Arixtra in countries other than the United States, Canada, Japan and Mexico, Sanofi-Synthélabo agreed, in return for taking over the rights, to make phased payments to NV Organon up to a maximum of 100 million dollars contingent on the approval of additional indications. Sanofi-Synthélabo also agreed to pay minimum royalties of 75 million dollars.

Sanofi-Synthélabo is required to pay minimum royalties of 17 million euros under three pharmaceutical license agreements.

In addition, there are two contracts relating to research work which could give rise to deferred payments between 1 and 4 million euros per molecule. Because of the uncertain nature of the research work, it is impossible to predict the number of molecules that will reach the relevant milestones. For this reason, it is impossible to estimate the maximum aggregate amount that Sanofi-Synthélabo will actually pay.

Sanofi-Synthélabo is committed to making an additional investment of 10 million euros in IDM in a further share issue (see note 3).

			<u>&lt; 1 year</u>	<u>1-5 years</u>	<u>&gt; 5 years</u>	<u>Total</u>
<b>(in millions of euros)</b>						
<b>Commitments received:</b>						
In return for contract warranty retentions			4			4
Miscellaneous guarantees			1			1
Currency options including	USD:	366	539			539
	JPY:	115				
	NOK:	50				
<b>Total</b>			<b>544</b>			<b>544</b>
<b>Reciprocal commitments:</b>						
Forward currency exchange contracts:						
forward purchases,	including	CHF:	68	125		125
		NOK:	33			
		GBP:	10			
forward sales,	including	USD:	798	1 033		1 033
		JPY:	79			
		GBP:	60			
		CAD:	26			
		CZK:	16			
Commitments involving Group subsidiaries:						
export rate guarantees,	including	USD:	147	309		309
		CHF:	34			
		GBP:	28			
		JPY:	24			
		KRW:	17			
		CZK:	11			
import rate guarantees	including	CHF:	111	191		191
		GBP:	36			
		USD:	28			
		HUF:	10			

Apart from the commitments disclosed above, there are no commitments which are or may become material with the exception of those arising under the following collaboration agreements:

In 2001, Sanofi-Synthelabo signed a collaboration agreement with IDM. This agreement is described in note 3. Because of the uncertain nature of the development work, it is impossible to predict if Sanofi-Synthelabo will exercise an option for a product or if the expected milestones will be achieved. For this reason, it is impossible to estimate the maximum aggregate amount that Sanofi-Synthelabo will actually pay in the future under outstanding collaboration agreements. Given the nature of its business, it is highly unlikely that Sanofi-Synthelabo will exercise all options for all products or that all milestones will be achieved.

Sanofi-Synthelabo has signed a collaboration agreement with NV Organon to develop anti-thrombotic oligosaccharides (in continuation of the work that resulted in the development of Arixtra).



Real estate capital leases relate to administrative and research premises:

	<u>2002</u>
(in millions of euros)	
Value of assets on signature of lease	
Breakdown by balance sheet line:	
land	4
buildings	91
Lease payments:	
during the period	9
cumulative	127
Depreciation that would have been charged if the assets had been acquired outright:	
during the period	5
cumulative	56
Value of outstanding lease payments as of December 31, 2002:	
until one year	9
more than one year until five years	26
more than five years	32

The residual purchase price of the assets will be less than one euro.

#### Note 18: Note on agreements relating to the Yves Rocher Group

Following the merger of Sanofi and Synthélabo, a dispute arose between Sanofi-Synthélabo and the other shareholders of the Yves Rocher Group, who challenged the registration in the name of Sanofi-Synthélabo of the shares in the companies Financière des Laboratoires de Cosmétologie Yves Rocher and Laboratoires de Biologie Végétale Yves Rocher held prior to that date by Sanofi. The dispute relates to an alleged breach of a pact between the shareholders.

Legal action was brought. An appeal court ruling of January 10, 2001, ordered:

- the reinstatement of Sanofi-Synthélabo's rights in Financière des Laboratoires de Cosmétologie Yves Rocher;
- the appointment of an expert to value the direct interest of Sanofi in Laboratoires de Biologie Végétale Yves Rocher as of the date of the merger. On completion of this expert valuation, Yves Rocher may exercise its option to buy out the shares held by Sanofi-Synthélabo at the price set by the expert or, if it does not exercise the option, must register the shares in the name of Sanofi-Synthélabo.

Following the delivery of the expert's findings in November 2001 and in line with the court ruling, Laboratoires de Biologie Végétale Yves Rocher arranged for the acquisition of Sanofi-Synthélabo's interest in its capital.

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

This acquisition took place at end December 2001, at a price of 316 million euros. The pre-tax capital gain in the Sanofi-Synthélabo parent company financial statements was 308 million euros.

In line with the Rennes Appeal Court ruling of January 10, 2001, Sanofi-Synthélabo remains a shareholder of Financière des Laboratoires de Cosmétologie Yves Rocher.

During the first half of 2001, Sanofi-Synthélabo and Financière des Laboratoires de Cosmétologie Yves Rocher both entered appeals against the aforementioned orders in the French Supreme Court.

After this sale, Sanofi-Synthélabo, based on available information, owns 39.1% of Financière des Laboratoires de Cosmétologie Yves Rocher. This holding company owns a 51.3% interest in Laboratoires de Biologie Végétale Yves Rocher. Consequently, Sanofi-Synthélabo held an indirect interest of 20.1% in the Yves Rocher Group as of December 31, 2002.

**Note 19: List of subsidiaries and participating interests****Summary information on all subsidiaries and participating interests held by Sanofi-Synthélabo**

(in millions of euros)	Subsidiaries		Participating interests	
	French	Foreign	French	Foreign
Gross book value of shares held	1,306	1,764	4	24
Net book value of shares held	1,297	1,679	4	24
Loans and advances made	40	455		
Guarantees given	57	244	1	14
Dividends received	396	267	10	1

**Subsidiaries and participating interests of which the net book value of the shares held exceeds 1% of the share capital of Sanofi-Synthélabo**

(in millions of euros)	Capital	Equity other than capital
	<b>Subsidiaries more than 10% held</b>	
<b>French subsidiaries</b>		
Laboratoires IREX		6
S.A. N°SIREN 380663914 22, Avenue Galilée 92350 Le Plessis-Robinson Sanofi-Chimie (ex.Sasy.1)	271	198
S.A. N°SIREN 428706204 9, rue du Président Allende 94250 Gentilly Sanofi-Synthélabo France (ex. Sanofi Winthrop)	13	(10)
S.A. N°SIREN 403335904 174, Avenue de France 75013 Paris Sanofi Winthrop Industrie	159	136
S.A. N°SIREN 775662257 82, Avenue de France 94250 Gentilly Secipe	39	202
S.A. N°SIREN 722019965 174, Avenue de France 75013 Paris Synthélabo Biomédical	27	5
S.A. N°SIREN 319740726 22, Avenue Galilée 92350 Le Plessis Robinson Sanofi-Synthélabo Recherche	2	30
S.A. N°SIREN 713002269 1, Avenue P.Brossolette 91380 Chilly-Mazarin Sanofi-Synthélabo Groupe	26	38
S.A. N°SIREN 403335938 174, Avenue de France 75013 Paris		
<b>Foreign subsidiaries</b>		

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Chinoin Pharmaceutical and Chemical Works Co Ltd Budapest, Hungary	17	180
Sanofi-Synthelabo do Brasil Ltda Rio de Janeiro, Brazil	16	3
Sanofi-Synthelabo Holding GmbH Berlin, Germany	61	31
Sanofi-Synthelabo Inc New York, United States		259
Sanofi-Synthelabo SA Barcelona, Spain	1	82
Sanofi-Synthelabo SpA Milan, Italy	85	23
Sanofi-Synthelabo UK Ltd Guildford, UK		169
Sanofi-Synthelabo de Colombia S.A. Cali, Colombia	3	15
Sanofi-Synthelabo Polholding BV Maassluis, Netherlands		28
Sanofi-Synthelabo Produtos Farmaceuticos SA Alcabideche, Portugal	18	
Sanofi-Synthelao AE Peania, Greece	18	(7)
Sanofi-Synthelabo AB Bromma, Sweden		9
Sanofi-Synthelabo Koréa Co. Ltd Seoul, South Korea	27	(15)

Share of capital held (%)	Book value of shares held		Outstanding loans and advances receivable	Guarantees given by the company	Net sales for last financial year	Net income/loss for last financial year	Dividends received by the company during the year
	Gross	Net					
100	18	18	15		41	(6)	
100	430	430	17		370	22	
100	73	73			1 383	74	126
100	400	400		55	2 722	326	218
100	235	235				2	21
100	36	33				1	25
95	26	26		2	810	8	6
93	47	47			397	3	
99	157	157		35	239	45	
100	65	65				(5)	
100	80	80		2		32	30
100	608	608	432	38	363	419	139
100	104	104		8	344	39	7
100	116	116			314	20	12
100	161	161		12			10
90	16	16		17	26	2	
100	88	88	7				4
86	22	22			66	5	
100	38	38			85	8	
100	36	36		2	52	1	1
100	38	38		5	66	4	

## Five-year financial summary: Sanofi-Synthélabo parent company

(In millions of euros)	2002	2001	2000	1999 <sup>(2)</sup>	1998 <sup>(2)</sup>
<b>Capital at period-end</b>					
Share capital	1,465	1,464	1,463	1,462	
Number of shares in issue	732,367,507	732,005,084	731,441,746	731,143,218	5,000
<b>Income statement data</b>					
Net sales	273	176	194	301	
Net income before tax, depreciation, amortization and provisions	1,391	1,525	908	538	
Income taxes	193	222	50	29	
Employee profit-sharing charge for the period <sup>(1)</sup>		(1)	6	7	
Net income after tax, depreciation, amortization and provisions	1,323	1,442	630	488	
Dividend paid		473	317	231	
<b>Per share data (in euros)</b>					
Net income after tax but before depreciation, amortization and provisions					
based on actual number of shares	1.64	1.78	1.17	0.70	3.87
based on adjusted number of shares*	1.64	1.78	1.17	0.70	15.48
Net income after tax, depreciation, amortization and provisions					
based on actual number of shares	1.81	1.97	0.86	0.67	3.87
based on adjusted number of shares*	1.81	1.97	0.86	0.67	15.48
Dividend per share (net)					
based on actual number of shares		0.66	0.44	0.32	
<b>Employees</b>					
Average number of employees during the period	22	22	26	1,160	
Wages and salaries for the period	9	10	12	69	
Social security and other benefits paid	5	5	5	30	

\* Adjusted to take account of the 4-for-1 stock split that took place on May 18, 1999.

(1) Provision for statutory and voluntary employee profit-sharing schemes

(2) On May 18, 1999, Sanofi and Synthélabo were merged into a shell company, which took the name Sanofi-Synthélabo. On January 25, 2000, Sanofi-Synthélabo transferred its support activities to the 100% directly and indirectly owned subsidiary Sanofi-Synthélabo Groupe, with retrospective effect from January 1, 2000.

## Parent company/subsidiary relations

The group comprising Sanofi-Synthélabo and its subsidiaries is focused on a single business: pharmaceuticals. The Sanofi-Synthélabo parent company directly owns most of its subsidiaries and the main industrial property rights.

Sanofi-Synthélabo assumes responsibility for research and development within the Group. It defines strategic priorities, co-ordinates the work, and takes out industrial property rights in its own name and at its own expense. In order to fulfil this role, Sanofi-Synthélabo subcontracts research and development work to those of its subsidiaries that have the necessary resources.

Sanofi-Synthélabo licenses its patents, manufacturing know-how and trademarks to certain French and foreign subsidiaries. The licensee subsidiaries manufacture and distribute the Group's products, either directly or indirectly via local distribution subsidiaries.

In certain countries, in particular Japan, the Sanofi-Synthélabo Group carries on some of its activities through joint ventures with local partners. In addition, the company has signed worldwide agreements whereby some of its strategic products are marketed through alliances with Bristol Myers Squibb and Organon (cf pages 36-37 of the 2002 Financial report).

Sanofi-Synthélabo meets the financing needs of most of its subsidiaries and manages their cash surpluses. The company also operates a centralized foreign exchange risk management system, which takes out the necessary hedges to protect its main subsidiaries from such risks.

Note 15 Transactions with related undertakings provides summary financial data concerning relations between the Sanofi-Synthélabo parent company and other Group companies.

---

## FINANCIAL, ADMINISTRATIVE AND LEGAL ADDITIONAL INFORMATION

<b>Risk factors for the issuer</b>	<b>89</b>
<b>General information concerning the company and the capital</b>	<b>97</b>
<b>Administrative and management bodies</b>	<b>109</b>
<b>Combined General Meeting of May 19, 2003</b>	<b>112</b>
<b>Persons responsible and declarations</b>	<b>118</b>
<b>Registration document ( <i>document de référence</i> ) checklist</b>	<b>120</b>



## Risk factors for the issuer

### LEGAL RISKS

#### Product approval

Sanofi-Synthélabo must obtain and maintain regulatory approval for its pharmaceutical products in the European Union, the United States and other countries before a product may be sold in these markets. Filing an application with the regulatory authority in a particular country or in the European Union does not guarantee that a license to market the product will be granted. Each authority may impose its own requirements, including requiring clinical studies in its own country, and may delay or refuse approval, even though a product has already been approved in another country.

In Sanofi-Synthélabo's main markets, the approval process for one or more indications of a new product is complex and lengthy (six months to two years from the date of application). Approvals may be limited to certain indications. A product which is already marketed is also subject to continual review after regulatory approval. Problems may result in marketing restrictions or withdrawal of the product, as well as possible legal penalties.

In addition, Sanofi-Synthélabo is subject to strict government controls on the manufacture, labeling, distribution and marketing of its products.

All these factors affect the probability of a product being launched or remaining on the market, and also affect the cost of developing new products.

#### Industrial property rights

The success of Sanofi-Synthélabo's operations depends on our ability to protect our industrial property rights effectively by obtaining, maintaining and enforcing patents and other rights. Patent law in the pharmaceutical field is continually evolving, and hence is a source of uncertainty. It is never certain that:

- a new invention will be patentable;
- patents applied for will be granted;
- the scope of patent protection will be sufficient to exclude competitors.

In addition, third parties may claim ownership of patents or other industrial property rights owned by or licensed to Sanofi-Synthélabo, which could result in the cancellation or unenforceability of these rights.

Sanofi-Synthélabo currently has over 9,000 patents and patent applications worldwide, and licenses for more than 30 additional patents. We cannot be certain how much protection these will provide. Early in 2002, two pharmaceutical companies, Apotex and Dr. Reddy's Laboratories, each filed an abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration (FDA), seeking to market a generic form of Plavix<sup>®</sup> in the United States, and challenging certain American patents relating to Plavix<sup>®</sup> (see Legal Proceedings, page 90 of this report). The Plavix<sup>®</sup> patents are material to Sanofi-Synthélabo's business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction in the United States of a generic version of Plavix<sup>®</sup> would reduce the price that we receive for this product and the volume of the product that we would be able to sell.

Certain national governments have recently responded to healthcare crises by taking measures which have the effect of eroding the patent protection enjoyed by pharmaceutical companies. These measures include the threat of imposing compulsory licenses for products they view as essential.

Sanofi-Synthélabo supports the efforts of national governments to combat major healthcare crises. However, if such efforts are at the expense of effective patent protection, they will impair the ability of Sanofi-Synthélabo and other pharmaceutical companies to recover research and development expenditure, thereby inducing them to curtail such expenditure and develop fewer new products.

### *Risk of patent infringement*

There is a risk that competitors may infringe Sanofi-Synthélabo's patents or attempt to circumvent them by making innovations. To prevent infringement, Sanofi-Synthélabo may file infringement claims, which are lengthy and expensive. It is difficult to monitor the illegal use of industrial property rights, and Sanofi-Synthélabo may not always be able to prevent the fraudulent use of its industrial property rights. This risk is increased by the rapid growth in patents filed and granted in the pharmaceuticals industry.

### **Legal proceedings**

Refer also to the notes to the consolidated financial statements D.14 and D.19, pages 48 and 54 of this report.

In February 2002, Sanofi-Synthélabo was informed that Apotex, a generic drug manufacturer, had filed an Abbreviated New Drug Application (ANDA) with the FDA challenging two American patents relating to Plavix<sup>®</sup> listed in the Orange Book. In April 2002, Sanofi-Synthélabo was informed that another generic drug manufacturer, Dr. Reddy's Laboratories, had also filed an ANDA with the FDA challenging the three American patents relating to Plavix<sup>®</sup> listed in the Orange Book as of that date. An ANDA is an application made by a drug manufacturer for authorization to market a generic version of an approved product, by demonstrating that it has the same properties as the original product. Generally, an ANDA may not be filed until the expiration of the five-year market exclusivity period that applies to the original product following its initial market authorization. However, if the product is protected by a patent owned by or licensed to the manufacturer of the original version, the ANDA cannot be approved until the patent expires unless the ANDA applicant challenges the validity of the patent. In that case, the ANDA may be filed four years following the initial market authorization of the original product.

One of the patents challenged by Apotex and by Dr. Reddy's Laboratories expires in 2011, and the other in 2014. The third patent, challenged by Dr. Reddy's Laboratories, expires in 2003.

Two additional American patents expiring in 2019 were listed in the Orange Book by Sanofi-Synthélabo in September 2002 and January 2003. These patents are not included in the proceedings.

On March 21, 2002, Sanofi-Synthélabo filed suit in the U.S. District Court for the Southern District of New York against Apotex for infringement of our patents. On May 14, 2002, Sanofi-Synthélabo filed suit against Dr. Reddy's Laboratories in the same court for infringement of our patents. If either of these challenges is successful, the prevailing party would have the right to produce a generic version of Plavix<sup>®</sup> and market it in the United States in competition with Sanofi-Synthélabo and our alliance partner, BMS. Under American law, the FDA will not be able to approve the ANDAs filed by Apotex or Dr. Reddy's Laboratories until the earlier of May 17, 2005 or the issuance of a court decision that is adverse to the Plavix<sup>®</sup> patents. However, Sanofi-Synthélabo believes its patents to be valid. If the courts support this view, Plavix<sup>®</sup> will continue to enjoy patent protection. Sanofi-Synthélabo intends to defend its interests vigorously in this matter.

In March 2003, Sanofi-Synthélabo was informed that Apotex (as referred to above) had filed an application for marketing authorization with the Canadian authorities for a generic version of Plavix<sup>®</sup>, challenging the Canadian patent for clopidogrel.

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

Sanofi-Synthélabo believes that this patent is valid, and that it protects Plavix<sup>®</sup> in Canada until August 2012. Sanofi-Synthélabo intends to defend its interests vigorously in this matter.

As far as Sanofi-Synthélabo is aware, there are no exceptional facts or legal proceedings, other than the cases described above, that have not been provided for and that could have a material effect on the Group's financial position, net income, assets and liabilities or prospects.

### Pricing of products

The performance of Sanofi-Synthélabo depends in part on the price at which drugs are reimbursed to patients. There is strong pressure on prices, due in particular to:

- the current tendency of government and private healthcare providers to favor generic drugs;
- the price controls imposed by governments in many countries; and
- parallel imports, a practice whereby intermediaries exploit price differentials between markets by purchasing products in lower-priced markets for resale in higher-priced markets.

Price pressure is very strong in Europe and the United States, which in 2002 accounted for 57.7% and 22.7% respectively of consolidated net sales. Changes in pricing policies in these two markets are liable to have a material effect on Sanofi-Synthelabo's net sales and net income.

### Dependency on third parties

Sanofi-Synthelabo markets some of its products in collaboration with other pharmaceutical companies. We have signed major collaboration agreements with Bristol-Myers Squibb for the marketing of Plavix® and Aprovel®, and with Organon, a subsidiary of Akzo Nobel, for the marketing of Arixtra®. Sanofi-Synthelabo has also entered into alliances with several Japanese companies for the marketing of its products in Japan. When Sanofi-Synthelabo markets its products under collaboration agreements, certain decisions, such as the preparation of budgets and promotional strategies, are under the control of our partners. Deadlock may arise and adversely affect the activities conducted through these collaboration agreements. For example, our alliances with Bristol-Myers Squibb are subject to the operational management of Bristol-Myers Squibb in some countries, including the United States, where from March 2002 Bristol-Myers Squibb implemented a policy of reducing the level of Plavix® and Avapro® inventories towards American wholesalers.

We cannot be certain that Sanofi-Synthelabo's partners will perform their obligations as expected. Our partners may favor their own existing or alternative technologies, or pursue other products than those developed or marketed in collaboration with Sanofi-Synthelabo.

Sanofi-Synthelabo's general policy is to manufacture the active ingredients for its products itself. However, Sanofi-Synthelabo subcontracts the manufacture of the active ingredients for some of its products to third parties, and consequently is exposed to a risk of interruptions to supply in the event that its suppliers experience financial difficulties or are unable to meet demand. At present, Sanofi-Synthelabo subcontracts part of the manufacture of the active ingredients for Stilnox® and Xatral®, two of its six strategic\* products, to Dynamit Nobel, which bought the factory that manufactures these ingredients from Sanofi-Synthelabo in February 2001. Although Sanofi-Synthelabo has not experienced any problems in the past, any interruption in the supply of raw materials as a result of difficulties with subcontractors may adversely affect the ability of Sanofi-Synthelabo to supply the market, and damage its reputation and customer relations. Although we make efforts to secure alternative sources of supply wherever possible, including by manufacturing active ingredients at two or even three production sites (double/triple sourcing policy), there can be no certainty that this would prove adequate if the main source of supply were to be temporarily unavailable.

Collaborations with third parties expose Sanofi-Synthelabo to the risk that these third parties may assert intellectual or industrial property rights to our inventions or fail to keep our unpatented technology confidential.

Sanofi-Synthelabo may provide information and materials to research collaborators in universities or to other public or private entities, and may commission them to conduct tests to investigate these materials. In all cases, Sanofi-Synthelabo enters into adequate confidentiality agreements with the entities. However, these entities may assert industrial property rights over the results of the tests conducted by their staff, and may refuse to license these rights to Sanofi-Synthelabo on acceptable terms.

Our business also relies on unpatented technology, manufacturing processes, know-how and data which we regard as trade secrets, and which we protect in part by entering into confidentiality agreements with our employees and consultants and with certain joint contractors. We cannot be certain that these agreements or any other available form of protection of trade secrets will

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

afford sufficient protection, or that we will have adequate remedies if they are breached (see section A crucial issue: industrial property page 65 of the 2002 Business report).

---

\* Plavix®/Iscover®, Stilnox®/Ambien®/Myslee®, Aprovel®/Avapro®/Karvéa®, Eloxatine®, Xatral®, Arixtra®.

91

[Financial, administrative and legal additional information](#)

## RISKS RELATING TO SANOFI-SYNTHÉLABO'S ACTIVITIES

### **Sanofi-Synthélabo must invest heavily in research and development to remain competitive.**

To be successful in the highly competitive pharmaceutical industry, Sanofi-Synthélabo must commit substantial resources to research and development every year in order to develop new products. Our efforts may be undermined if our competitors gain an advantage. In 2002, Sanofi-Synthélabo spent 1,218 million euros, or around 16% of consolidated net sales, on research and development. The increase in expenditure associated with current investment in the launch of new products and the research and development of future products may not necessarily result in an increase in Sanofi-Synthélabo's net sales.

The research and development process is lengthy and carries a significant risk of failure.

The research and development process generally takes 10-15 years from discovery of the compound to commercial product launch. The process involves various phases, and at each phase there is a significant risk that the objectives will not be met and that Sanofi-Synthélabo will abandon a product in which substantial amounts have been invested. For example, in order to develop a commercially viable product Sanofi-Synthélabo must demonstrate via large-scale pre-clinical and clinical trials on humans that the compound is safe and effective for use in humans. There can be no assurance that successful pre-clinical trials will be confirmed by subsequent clinical trials, or that clinical trials will provide sufficient efficacy and product safety data to secure approval from regulatory authorities. As of December 31, 2002, Sanofi-Synthélabo had 52 compounds in pre-clinical and clinical development in its four main therapeutic fields, including 23 in phase II or phase III of clinical trials. For further information on clinical trials and the definition of clinical trial phases, refer to page 33 of the 2002 Business report. There can be no guarantee that these compounds will prove effective or safe, or that they will result in successfully marketable products.

### **Expansion in the United States**

To meet its growth targets, Sanofi-Synthélabo must profitably expand its business in the United States, the world's largest pharmaceuticals market. The United States, which accounted for 22.7% of 2002 consolidated net sales, is a major potential source of future growth for Sanofi-Synthélabo, and we plan to expand significantly our direct presence in the United States in the coming years. For example, in April 2002 Sanofi-Synthélabo acquired Pharmacia's interest in the joint venture which markets Stilno® (under the name Ambien®) and Kerlone® in the United States. A number of obstacles need to be overcome to secure profitable expansion in the United States, in particular:

- the implementation of organizational structures compatible with the size of this vast market;
- the targeting of new markets;
- the domination of the U.S. market by the major American pharmaceutical companies;

- the risks associated with pricing and healthcare reimbursement policies, which are constantly under discussion as a result of the high level of healthcare spending in the United States.

## INDUSTRIAL AND ENVIRONMENTAL RISKS

See also section [The dynamics of continuous progress: a methodology for our HSE policy](#) , pages 74-77 of the 2002 Business report.

### General overview

#### *Use of hazardous substances*

The manufacture of pharmaceutical products, and in particular of active ingredients (including storage and transportation of raw materials, products and waste), gives rise to the risk of:

- fires from inflammable substances;
- leaks from storage tanks;
- emission or disposal of toxic substances.



These operating risks may, if they crystallize, cause personal injury, property damage or environmental pollution. Consequences may include:

- the closure of the sites involved;
- the imposition of civil or criminal penalties on Sanofi-Synthélabo.

The occurrence of any such event could therefore have an adverse effect on the operating profits of Sanofi-Synthélabo.

#### *Site remediation*

Sanofi-Synthélabo is obliged to remediate contaminated sites. These may include sites that we currently own or operate, or sites that we owned or operated in the past. They may also include sites where waste generated by Sanofi-Synthélabo's activities has been discharged. As for any company involved in the pharmaceutical industry, soil or groundwater contamination has occurred at certain sites in the past, and may also recur or be discovered at other sites.

In addition:

- Sanofi-Synthélabo is currently involved in claims, lawsuits and administrative proceedings relating to environmental matters, and others may arise;
- environmental regulations are constantly changing, and the introduction of stricter health, safety and environmental rules is liable to increase the costs and liabilities incurred by the company.

#### **Significant factors liable to impact the company's assets and liabilities or results**

Sanofi-Synthélabo's manufacturing and research activities are subject to increasingly stringent laws and regulations on health, safety and the environment. These laws and regulations are complex and rapidly evolving. Sanofi-Synthélabo has incurred and will continue to incur the necessary expenditure to ensure compliance. Our investment in health, safety and the environment varies from year to year: the total amount invested was 11 millions euros in 2001 and 23 millions euros in 2002. It is not possible to predict with certainty future expenditure in this area.

Provisions booked for environmental risks are adequate, based on information available as of the date they were booked. Given the uncertainties inherent in anticipating industrial and environmental liabilities, the company cannot warrant that it will not need to incur additional expense beyond the amounts provided. Any shortfall in provisions to meet such risks could have a material impact on operating profits.

In addition, although Sanofi-Synthélabo has taken out property, liability and business interruption insurance cover in line with industry practice, there can be no guarantee that such insurance will fully cover all the consequences of potential dangers affecting its business. For more information, see the [Insurance and risk coverage](#) section, page 96 of this report.

Subject to these reservations, the company is not currently aware of any industrial or environmental risk that might significantly affect the assets and liabilities or results of the company.

### [Policy of prevention in the environmental field and risk assessment](#)

Sanofi-Synthélabo's health, safety and environment policy is designed to promote the health and well-being of its employees and respect for the environment. Sanofi-Synthélabo regards this policy as an integral part of its commitment to social responsibility. The key points of the policy are summarized below.

**Environment.** The core objectives of Sanofi-Synthélabo's environment policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our business. In order to optimize and improve our environmental performance, Sanofi-Synthélabo has undertaken to obtain ISO 14001 certification.

Two sites are certified in 2002 and three others are expected to be certified in 2003. This move is part of the rolling improvement strategy practiced at all Sanofi-Synthélabo establishments through annual implementation of progress plans in health, safety and the environment, known as PASS. Sanofi-Synthélabo believes that this strategy reflects the genuine involvement of management and individuals in health, safety and the environment.

**Health.** From the development of compounds to the launch of new drugs, Sanofi-Synthélabo's research scientists are constantly assessing the impact of products on human health. Their expertise is made available to Sanofi-Synthélabo employees via two committees responsible for chemical and biological risk assessment. The COVALIS committee classifies all chemical and pharmaceutical substances handled within Sanofi-Synthélabo and sets workplace exposure limits for each of them. To date, 659 active pharmaceutical ingredients and 435 synthesis intermediates have been assessed. The TRIBIO committee classifies all biological agents according to their degree of pathogenicity and makes decisions on confinement rules and preventive measures to be implemented within Sanofi-Synthélabo.

**Safety.** Sanofi-Synthélabo has a rigorous policy designed to identify and assess risks, and to develop preventive measures and methods to monitor the effectiveness of these measures. Sanofi-Synthélabo also invests in training programs designed to ensure that a safety culture is built into all workplace activities. Such policies are implemented worldwide in order to ensure the safety of all employees and protect their health. All projects, whether in research, development or manufacturing, are subject to evaluation procedures incorporating data on substances and chemical processes obtained from the COVALIS and TRIBIO committees described above. The preventive measures primarily aim to reduce the number and seriousness of workplace accidents for permanent and temporary staff, and for employees of outside contractors. We believe that our efforts are succeeding, given the significant improvements in safety performance since the merger.

The Sisteron site mentioned above is one of the sites that has been subject to an upgraded inspection regime, given the safety issues inherent in its manufacturing processes, which include the use of toxic and inflammable substances.

## MARKET RISKS

### Liquidity

Sanofi-Synthélabo expects that its current operating cash flows will be sufficient to finance its ongoing activities and investments for the coming years. Sanofi-Synthélabo does not expect to increase its level of investment significantly in 2003 relative to recent years, and has no current plan that would lead to a substantial rise in the next few years.

Sanofi-Synthélabo does not expect any significant change in its sources of liquidity in the future; our operating cash flows are likely to remain substantial as long as consolidated profits continue to grow. Sanofi-Synthélabo does not expect to need to increase debt significantly, unless it makes a major acquisition requiring a change to its financing strategy. Sanofi-Synthélabo cannot be sure that its profits will continue to rise as in the past. However, there is currently no reason to anticipate a fall in consolidated profits in the near future. Moreover, a substantial drop in profits or a very sizeable increase in expenditure would be required before cash flows became insufficient to finance ongoing liquidity requirements. Even then, the low level of debt would provide a major source of potential liquidity.

**Impact of interest rates**

Sanofi-Synthelabo's operations generate substantial cash flows. Investment is financed mainly out of operating cash flow, and Sanofi-Synthelabo pays regular dividends. Debt is limited and there was a positive net cash position as of December 31, 2002. At that date, the net cash position was not hedged against interest rate risk. However, a deterioration in yields following any fall in interest rates could impact the Group's net income.

## Impact of exchange rates

The financial statements are denominated in euros. Given that a substantial proportion of net sales is generated in non euro-zone countries, operating profits may be significantly impacted by exchange rate fluctuations between the euro and other currencies, mainly the US dollar and, to a lesser extent, the Japanese yen. Sanofi-Synthelabo's policy is not to set up specific hedges of net investments in foreign currencies, but to carry out a variety of foreign currency hedging transactions designed to reduce our foreign currency risk exposure and protect operating margins. Hedging instruments relate to assets and liabilities existing as of the balance sheet date and, in some cases, to commitments in respect of future transactions, determined when annual forecasts are made. As of December 31, 2002, virtually all such assets and liabilities were hedged against foreign currency risk. As a result, such transactions will have no impact on the 2003 accounts. In 2002, 22.7% of net sales were from the United States and 4.2% from Japan. As it was the case in 2002, a fall in the dollar relative to the euro in 2003 would have a negative impact on Sanofi-Synthelabo's net sales which would be unlikely to be offset by a parallel reduction in expense, and would therefore negatively impact operating profits.

## Stock market risk

Sanofi-Synthelabo has a policy of not trading in the markets for speculative purposes. Surplus cash is invested in money-market mutual funds and term deposits with bank counterparties having high credit ratings.

Sanofi-Synthelabo does not own material equity interests in listed companies.

As of December 31, 2002, the Sanofi-Synthelabo Group owned:

- 16,411,795 treasury shares, representing 2.24% of the share capital. These shares, bought under a share repurchase program, were recorded in the consolidated financial statements as a deduction from shareholders' equity (see note D12.5 to the consolidated financial statements, page 44 of this report). Movements in the Sanofi-Synthelabo share price will have no impact on consolidated net income.
- 13,964,580 treasury shares, classified under "Short-term investments" at a net value of 623 million euros (see note D10 to the consolidated financial statements, page 43 of this report). Of these shares, which represent 1.91% of the share capital, a total of 13,836,580 are allocated to stock option plans granted to employees. A provision for impairment of 46 million euros was taken against these shares in 2002. This provision equates to the shortfall, valued on a plan by plan basis, between the average acquisition price of the shares and their average listed stock market price during December 2002 (57.10 euros).

In the case of this second group of treasury shares, movements in the Sanofi-Synthelabo share price will have an impact on consolidated net income in the future. The table below shows the impact for a range of movements in the share price:

Movement relative to the listed price of 57.10 euros	Net impact in millions of euros
---	------------------------------------

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

+20%	+27
+10%	+15
-10%	-23
-20%	-45
-30%	-69

95

Financial, administrative and legal additional information

## OTHER RISKS

As of December 31, 2002, the two main shareholders, L Oréal and TotalFinaElf, held 19.5% and 24.5% of the share capital respectively, representing 26.9% and 33.7% of the voting rights respectively. They are party to a shareholders' agreement which runs to December 2004 and may be renewed; this agreement enables them to exercise significant influence over the choice of board members and officers and over other company decisions requiring the approval of shareholders. While the agreement continues in force, these factors may discourage bids for the shares of Sanofi-Synthélabo and deter a change in control.

## INSURANCE AND RISK COVERAGE

The Group has set up two worldwide insurance programs covering general and product liability, property damage and business interruption, plus damage to goods in transit. Virtually all subsidiaries have subscribed to these insurance programs, which have been taken out with top international insurance firms. Other insurance policies have been taken out for specific risks or to take account of local constraints.

Despite a tougher market, we managed to maintain the limit of liability insurance at a sufficient level in 2002; however, the cover was reduced by insurers' forced introduction of numerous new exclusions aimed specifically at certain products. This trend, which began in 2002 and affected the industry as a whole, has continued in 2003 with the exclusion of other products and the raising of the level of deductibles.

Property cover and business interruption cover were less affected by market trends, though they were subject to reductions and even some significant exclusions, particularly in relation to terrorism and natural events. In addition to insurance cover, the Group is implementing a double sourcing and storage policy for strategic products, designed to reduce our risks and ultimately our dependence on the insurance market.

Product liability is a major commercial risk which could grow, given the expansion of the business in the United States, where compensation claims for defective products can be very high. In some countries, pharmaceutical companies have been ordered to pay substantial damages following claims alleging injury caused by using their products. Some pharmaceutical companies have even withdrawn products from the market recently after major product liability claims. Sanofi-Synthélabo is not currently involved in significant litigation alleging liability for injury caused by our products, but such litigation could arise in the future.

The insurance policies taken out are of the highest standard, the best available on the market and in line with industry practice; however, they cannot totally rule out the possibility that a major event with unforeseeable or uninsurable consequences might materially affect Sanofi-Synthélabo's assets and liabilities, financial condition or results.

## General information concerning the company and the capital

### GENERAL INFORMATION CONCERNING THE COMPANY

Sanofi-Synthélabo (the Company) was formed as a result of the 1999 merger of two companies, Sanofi and Synthélabo, into a shell company (previously named DGFP Delta) which took the name of Sanofi-Synthélabo. This company was a 100%-owned subsidiary of Elf-Aquitaine, itself subsequently merged into TotalFinaElf, which had sold 50% of the capital of DGFP Delta to L'Oréal on December 15, 1998. The mergers of Sanofi and of Synthélabo into Sanofi-Synthélabo were approved by the General Meetings of Sanofi, Synthélabo and Sanofi-Synthélabo shareholders on May 18, 1999, with retrospective effect from January 1, 1999.

### Corporate name and registered office

Sanofi-Synthélabo 174, avenue de France 75013 Paris, France. Telephone number: +33 (0)1.53.77.40.00

The name Sanofi-Synthélabo was adopted by the Combined General Meeting of December 18, 1998, replacing the name DGFP Delta.

### Legal form

The Company is a French limited liability company (société anonyme), administered by a Board of Directors and governed by the French Commercial Code and decree no. 67-236 of March 23, 1967.

### Legislation

The Company is governed by French legislation.

### Date of incorporation and duration of the Company

The Company was incorporated on April 28, 1994 and first registered in the Nanterre Register of Commerce and Companies on May 18, 1994. The Company will expire on May 18, 2093 unless it is dissolved or extended prior to that date.



## Corporate objects

Under article 3 of the bylaws, the Company's corporate objects, in France and abroad, are:

- acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemicals, human and animal therapeutics, nutrition or bio-industries sectors;

in the above areas:

- purchase and sale of all raw materials and products necessary for these activities;
- research, study, and development of new products, techniques and processes;
- manufacture and sale of all chemical, biological, dietary and sanitary products;
- obtaining or acquiring all industrial property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;
- operating directly or indirectly, purchasing, and transferring for free or for consideration, pledging or securing all industrial property rights, particularly all patents, trademarks and models, processes or inventions;
- obtaining, operating, holding and granting all licenses;
- participating, as part of a Group-wide policy, in treasury management transactions in compliance with applicable legal provisions, whether as lead company or not, in the form of cash pooling, centralized exchange risk management, netting of intra-Group balances, or in any form authorized by applicable legislation;

and, more generally:

- all commercial, industrial, real or personal property, financial or other transactions connected directly or indirectly, totally or partially, with the activities described above and with all similar or related objects or with any other objects likely to promote or develop the Company's activities.

### Registration

The Company is registered in the Paris Register of Commerce and Companies as number 395 030 844. Its APE activity code is 741 J.

### Consultation of corporate documents

Corporate documents and information concerning the Company may be consulted at the registered office.

### Financial year

The financial year starts on January 1 and ends on December 31 of each year.

### Allocation of profits under the bylaws

Under articles 24 and 25 of the bylaws, the profit or loss for the financial year is the difference between the income and expenses for the financial year, after deducting depreciation, amortization and provisions, as shown in the statement of income. From the profit of the financial year, less any losses brought forward, at least 5% is transferred to a reserve fund known as the legal reserve. This deduction ceases to be compulsory when the amount of the legal reserve reaches one-tenth of the share capital, but resumes if the legal reserve falls below the said fraction for any reason.

The balance, plus any retained earnings carried forward, constitutes the distributable profit.

On the Board's proposal, the ordinary general shareholders' meeting may decide that some or all of the distributable profit will be carried forward or appropriated to one or more general or special reserve funds.

Dividends are distributed to the shareholders in proportion to the share in the capital held by each.

The general shareholders' meeting voting on the accounts for the financial year may give each shareholder the option of receiving some or all of the dividend in cash or shares.

Subject to prevailing legal or regulatory provisions, the Board of Directors may pay interim dividends in cash or shares, even during the course of the financial year.

## **General meetings**

### *Notice of meetings*

Meetings are convened by the Board of Directors under the conditions and within the time limits prescribed by law. They are held at the registered office or at any other place indicated in the notice of the meeting.

Decisions are taken by shareholders at ordinary, general or extraordinary meetings, depending on the nature of the resolution on which they are asked to vote.

### *Participation in meetings*

Under articles 9, 19 and 20 of the bylaws, all shareholders are entitled to attend meetings personally or by proxy, on presentation of proof of identity and share ownership, in the form and at the places indicated in the notice of the meeting, no less than 5 days before the date of the General Meeting. The Board of Directors shall always have the option of reducing this period, but only if it does so for all shareholders.

All shareholders may be represented by their spouse or by another shareholder at all meetings. They may also vote by mail on the conditions stipulated by law.

The Company's bylaws state that all shareholders may also, if the Board of Directors so decides at the time the meeting is called, participate in and vote at meetings by video-conference link or by any means of telecommunication that enables shareholders to be identified on the conditions and using the methods stipulated by the legal provisions in force.

#### *Voting rights*

Each shareholder has as many votes as the number of shares he owns subject to the provisions below.

Under article 9 of the bylaws, double voting rights are assigned to each registered share that is fully paid and that has been registered in the name of the same shareholder for at least two years.

Double voting rights cease automatically for any share converted into a bearer share or transferred from one owner to another, subject to exceptions laid down by law.

Bonus shares arising from an increase of share capital by incorporation of reserves, profits or share premium are entitled to double voting rights as from the time of their issue if they are allotted on the basis of shares already benefiting from this entitlement.

#### **Form and transfer of shares**

Under articles 7 and 8 of the bylaws, the shares are registered or bearer shares, at the shareholder's discretion, under the conditions established by applicable legal provisions.

The shares are freely negotiable.

Transfer of shares occurs by transfer from one account to another in accordance with the conditions laid down by law and regulations.

#### **Identification of shareholders**

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

The Company may at any time, in accordance with the law and regulations in force, request information from the securities clearing body (name, date of birth or incorporation, nationality and address) that will identify holders of securities giving immediate or future access to the right to vote at shareholders' meetings, together with the quantity of securities held by each and any restrictions attached to such securities.

### Share ownership thresholds

Under article 7 of the bylaws, any individual or entity, acting alone or in concert, who acquires a number of shares representing a proportion of the capital or of voting rights equal to or exceeding 1% of the share capital, or any multiple of this percentage, in addition to the declaration thresholds laid down by legal and regulatory provisions, must inform the Company of the total number of shares and voting rights held by such individual or entity and of any securities giving future access to the capital or voting rights potentially attached to those shares. Notification is to be made by registered mail with advice of delivery within five stock exchange days of the date on which the threshold was reached. The obligation to notify the Company also applies when the shareholder's interest in the capital or voting rights falls to a level below each of the above thresholds.

## GENERAL INFORMATION CONCERNING THE CAPITAL

### Changes to the capital and to shareholders' rights

Changes to the share capital and to voting rights attached to the securities comprising the share capital are subject only to legal provisions, the bylaws containing no specific provisions in this respect.

### Share capital

As of December 31, 2002, the share capital was 1,464,735,014 euros, divided into 732,367,507 shares with a par value of 2 euros each, fully paid and entitled to the same rights. Of these shares, 30,376,375 (i.e. 4.15% of the capital) were held by the Company itself as treasury shares.

### Capital authorized but not issued

#### *Authorizations to increase the capital*

The Combined General Meeting of Sanofi-Synthélabo shareholders held on May 22, 2002 authorized the Company, for a period of 26 months, to increase its share capital by issuance of shares or other securities giving immediate or future access, at any time or on a fixed date, to new shares in the Company by subscription, conversion, exchange, redemption, presentation of a warrant or any other means, up to a maximum aggregate par value of 750 million euros.

Such issues may be made with shareholders' preemptive rights either maintained or canceled.

The General Meeting of May 22, 2002 authorized the Board of Directors to use these authorizations to increase the share capital in the event of one or more public tender offers or public exchange offers for securities issued by the Company, during the period of said offer. This authorization was granted for a period expiring at the end of the General Meeting held to approve the financial statements for the year ended December 31, 2002. The shareholders will be asked to approve renewal of this authorization at the Combined General Meeting to be held on May 19, 2003.

The General Meeting of May 22, 2002 also authorized the Board of Directors to increase the share capital on one or more occasions by the incorporation of share premium, reserves, profits or other items, in the form of a bonus issue or an increase in the par value of the existing shares or by a combination of these two methods. This authorization is valid for a period of 26 months and for a maximum aggregate par value of 500 million euros.

The General Meeting of May 22, 2002 also authorized the Board of Directors to increase the Company's share capital on one or more occasions by issuance of new shares or allotment of bonus shares or other securities giving access to the Company's capital to the employees, early retirees or retirees of Sanofi-Synthélabo or of those French or foreign companies that are related to the Company under the law, where such employees, early retirees or retirees are members of a company or Group employee savings plan or a long-term employee savings plan set up under article L.443-1-2 of the Labor Code, up to a limit of 2% of the share capital as of the date of the said meeting, and for a period of 26 months with effect from the date of said meeting. The preemptive rights of shareholders have been waived in favor of the aforementioned beneficiaries and the shareholders have also waived any rights to bonus shares or other securities giving access to the capital issued under the terms of this authorization.

100

[Financial, administrative and legal additional information](#)

The table below summarizes the current authorizations granted by the General Meeting of Sanofi-Synthelabo shareholders of May 22, 2002 to issue securities giving access to the Company's capital.

Nature of authorization	Maximum aggregate par value of immediate or future capital increases potentially resulting from the issue (euros)	Maximum aggregate par value of issues of debt securities giving access to the capital (euros)	Shareholders preemptive rights	Priority subscription rights	Period of validity
Issuance of shares and/or any other securities, including stand-alone warrants, giving immediate or future access to the Company's capital by subscription, conversion, exchange, redemption, presentation of a warrant or any other means <sup>(3)</sup>	(a) 750,000,000 <sup>(1)</sup>	(c) 7,000,000,000 <sup>(2)</sup>	yes		26 months
Issuance of shares and/or any other securities, including stand-alone warrants, giving immediate or future access to the Company's capital by subscription, conversion, exchange, redemption, presentation of a warrant or any other means <sup>(3)</sup> / Issuance of shares or securities representing a proportion of the Company's capital subsequent to the issuance by certain Group subsidiaries of bonds with attached warrants to subscribe for shares in the Company or of other composite securities giving immediate or future access to shares in the Company	(b) 750,000,000 <sup>(1)</sup>	(d) 7,000,000,000 <sup>(2)</sup>	No	As decided by the Board of Directors	26 months
Capital increase by incorporation of reserves, profits or share premium, by allotment of bonus shares and/or an increase in par value	(e) 500,000,000 <sup>(4)</sup>				26 months
Issuance of new shares reserved for employees belonging to a company or Group employee savings plan or to a long-term employee savings plan	(f) 29,284,259 <sup>(5)</sup>		No		26 months

(1) (a) and (b) are not cumulative: the maximum aggregate par value of immediate or future capital increases potentially arising from issues that may be made with or without preemptive rights is 750,000,000 euros or the equivalent value of this sum in any other currency or currency unit



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

established by reference to more than one currency.

- (2) (c) and (d) are not cumulative: the maximum aggregate par value of debt securities giving immediate or future access to shares in the Company that may be made with or without preemptive rights is 7,000,000,000 euros or the equivalent value of this sum in any other currency or currency unit established by reference to more than one currency. However, this sum is cumulative with the maximum aggregate par value of 7,000,000,000 euros of ordinary bonds that may be issued under the authorization granted by the General Meeting of May 22, 2001.
- (3) The Board of Directors may make full or partial use, within the scope of the law, of this authorization in the event of one or more public tender offers or public exchange offers for securities issued by the Company. Renewal of this authorization in the event of one or more public tender offers or public exchange offers for securities issued by the Company will be put to the Combined General Meeting to be held on May 19, 2003.
- (4) (e) is cumulative with (a) and (b).
- (5) (f) is cumulative with (a), (b) and (e).

101

[Financial, administrative and legal additional information](#)

## Other securities giving access to the capital

### *Stock options*

The Combined General Meeting of Sanofi-Synthélabo shareholders held on May 18, 1999 authorized the Board of Directors for a 5-year period, to grant to members of the salaried staff and corporate officers of Sanofi-Synthélabo and of French or foreign companies or groupings related to Sanofi-Synthélabo according to the definition contained in article 208-4 of the law of July 24, 1966 (now codified under article L.225-180 of the Commercial Code), as such members are designated by the Board of Directors, options to subscribe for new Sanofi-Synthélabo shares to be issued by way of capital increases or options to buy existing shares acquired by Sanofi-Synthélabo as permitted by law.

The total number of options granted may not result in the subscription or purchase of a quantity of shares exceeding 2% of the share capital as of May 18, 1999, i.e. 14,611,740 shares.

The authorization entails express waiver, in favor of grantees of options to subscribe for shares, of the preemptive rights of shareholders in respect of shares issued as and when options are exercised.

The Board of Directors sets the terms on which options are granted and the arrangements as regards the dividend entitlement of the shares and (where appropriate) payment for the shares.

The same meeting also approved the assumption of the undertakings made by Sanofi and Synthélabo respectively to grantees of options to subscribe for or purchase shares granted by these companies prior to the May 1999 merger.

This substitution automatically entails the unconditional waiver, in favor of the grantees of options to subscribe for shares, of the preemptive rights of shareholders in respect of shares issued as and when options are exercised.

As of December 31, 2002, the potential number of shares liable to be issued as a result of the exercise of options to subscribe for shares was 514,925.

The number of options still to be granted by the Board of Directors under the twenty-ninth resolution of the Combined General Meeting of May 18, 1999 authorizing the Company to grant stock options is 4,271,390.

Full disclosures concerning the granting and exercise of stock options are provided on page 21 of the 2002 Business report, pages 109-111 of this report and in note D.12.6 to the consolidated financial statements on page 45 of this report.



## Changes in share capital through February 28, 2003

Date	Capital	Additional Paid-in capital	Number of shares	Transaction
As of Dec 31, 94	FRF 250,000		2,500	Incorporation
As of Dec 18, 98	250,000 F		5,000	2-for-1 stock split (FRF 50 shares)
As of Dec 31, 98	250,000 F		5,000	
As of May 18, 99	FRF 5,993,275,950			
	FRF 3,138,811,650	FRF 16,055,191,046	119,865,519	Sanofi capital contribution
		FRF 1,906,786,645	62,776,233	Synthelabo capital contribution
		FRF (7,853,487,116 )		Deduction from share premium on merger
	FRF 9,132,337,600	FRF 10,108,490,575	182,646,752	Sub-total post merger
			730,587,008	4-for-1 stock split
	FRF 452,335,640	FRF (452,335,640 )	730,587,008	Conversion into euros
	FRF 9,584,673,240	FRF 9,656,154,935		Sub-total in French francs
	EUR 1,461,174,016	EUR 1,472,071,330		Sub-total in euros
	EUR 1,112,420	EUR 4,700,035	556,210	Capital increase by exercise of options to subscribe for shares
As of Dec 31, 99	EUR 1,462,286,436	EUR 1,476,771,365	731,143,218	
	EUR 597,056	EUR 2,439,128	298,528	Capital increase by exercise of options to subscribe for shares
As of Dec 31, 00	EUR 1,462,883,492	EUR 1,479,210,493	731,441,746	
	EUR 1,126,676	EUR 5,342,269	563,338	Capital increase by exercise of options to subscribe for shares
		EUR (1,838)		Deduction from merger premium (Laboratoires Synthelabo merger)
As of Dec 31, 01	EUR 1,464,010,168	EUR 1,484,550,924	732,005,084	
	EUR 724,846	EUR 3,495,454	362,423	Capital increase by exercise of options to subscribe for shares
		EUR 90,104,605		Merger surplus (SaSy 3 merger)
As of Dec 31,02	EUR 1,464,735,014	EUR 1,578,150,983	732,367,507	
	EUR 77,182	EUR 484,703	38,591	Capital increase by exercise of options to subscribe for shares
As of Feb 28,03	EUR 1,464,812,196	EUR 1,578,635,686	732,406,098	



## OWNERSHIP OF SHARE CAPITAL AND VOTING RIGHTS

## Changes in share ownership over the last three years

## Situation as of Dec 31, 2002

Shareholder	Number of shares	% of capital	% of voting rights*
TotalFinaElf	179,586,513	24.52	33.74
L Oréal	143,041,202	19.53	26.87
Treasury shares	30,376,375	4.15	0
Employees	7,659,036	1.05	1.36
Public	371,704,381	50.75	38.03
<b>Total</b>	<b>732,367,507</b>	<b>100</b>	<b>100</b>

## Situation as of Dec 31, 2001

Shareholder	Number of shares	% of capital	% of voting rights**
TotalFinaElf	190,800,756	26.07	34.90
L Oréal	143,041,202	19.54	26.17
Treasury shares	11,419,291	1.56	0
Employees	7,004,436	0.96	1.28
Public	379,739,399	51.87	37.65
<b>Total</b>	<b>732,005,084</b>	<b>100</b>	<b>100</b>

## Situation as of Dec 31, 2000

Shareholder	Number of shares	% of capital	% of voting rights***
TotalFinaElf	239,400,756	32.73	41.60
L Oréal	143,041,202	19.55	26.35
Treasury shares	8,946,924	1.22	0

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

Employees	7,340,673	1.00	0.68
Public	332,712,191	45.50	31.37
<b>Total</b>	<b>731,441,746</b>	<b>100</b>	<b>100</b>

\* Based on the total number of voting rights published subsequent to the Ordinary General Meeting of May 22, 2002, i.e. 1,064,540,103.

\*\* Based on the total number of voting rights published subsequent to the Ordinary General Meeting of May 22, 2001, i.e. 1,093,320,462.

\*\*\* Based on the total number of voting rights published subsequent to the Ordinary General Meeting of May 24, 2000, i.e. 1,082,361,505.

The difference between the percentage of capital held and the percentage of voting rights held is due firstly to the existence of double voting rights and secondly to the existence of treasury shares which do not have voting rights.

During the year ended December 31, 2002, Sanofi-Synthelabo was informed by shareholders that the following share ownership declaration thresholds had been passed:

Between November 22 and December 16, 2002 State Street Bank and Trust declared on several occasions that it had alternately passed above and then below the legal threshold of 5% of the Company's capital on behalf of its clients. On December 16, 2002, State Street Bank and Trust declared that as of that date it held 36,638,351 of the Company's shares, representing 5.00% of the capital.

After a number of declarations that it had passed below and above the thresholds of 2% and 1% of the share capital, Caisse des Dépôts et Consignations (CDC) finally informed Sanofi-Synthelabo on December 10, 2002, that it had passed above the threshold of 1% of voting rights, disclosure of which is required under the Company's bylaws. CDC declared that as of that date it held 11,184,536 of the Company's shares and voting rights, i.e. 1.52% of the capital and 1.05% of the voting rights issued.

On June 7, 2002, Citigroup Inc. declared that companies belonging to its group had passed above the threshold of 1% of the capital, disclosure of which is required under the Company's bylaws. As of that date, these companies held a combined total of 8,019,296 shares, i.e. 1.09% of the capital.

On February 13, 2003, Capital Group International, Inc., the American-registered parent company of a group of investment management companies, filed a 13G declaration as required by the Securities and Exchange Commission (SEC) stating that it held 6.7% of the Company's capital on behalf of clients.

The Company itself passed above the threshold of 5% of its own capital on February 20, 2003. As of February 28, 2003, it held 38,560,314 of its own shares, i.e. 5.26% of the capital.

As far as the Company is aware, no other shareholder owns 5% or more of the capital or voting rights. The identifiable bearer shares inquiry ( Titres au porteur identifiable ) carried out on December 31, 2002 revealed approximately 28,000 shareholders. As far as we are aware, no Sanofi-Synthelabo shares have been pledged.

### Shareholders agreement

L Oréal and TotalFinaElf (the latter indirectly via Elf-Aquitaine) owned in concert 44.05% of the Company's capital and 60.61% of its voting rights as of December 31, 2002.

A shareholders agreement between L Oréal and Elf-Aquitaine was signed on April 9, 1999 for an initial term of six years with effect from December 2, 1998. This agreement is described in the prospectus approved by the Commission des Opérations de Bourse on April 15, 1999 as number 99-399. The Conseil des Marchés Financiers, in decisions dated November 27, 1998 (SBF opinion no.98-4707 of December 7, 1998) and March 16, 1999 (SBF opinion no. 99-1083 of March 18, 1999) exempted Elf-Aquitaine and L Oréal from the requirement to file a draft public tender offer for Sanofi-Synthelabo shares.

The main terms of this agreement are as follows:

Elf-Aquitaine and L Oréal agreed not to sell during the entire term of the agreement any of the shares covered (19.4% of the current share capital for each of the two companies). However, in the event of a public offer for the capital of Sanofi-Synthelabo, Elf-Aquitaine and L Oréal may together contribute all their shares covered by the agreement to such offer, or to any competing or higher offer. If they fail to agree to contribute their shares together, either company may contribute the shares it owns which are covered by the agreement subject to the prior written consent of the other, which will have preemptive rights over some or all of the shares involved.

Disposals of shares covered by the agreement are exempted from the agreement not to sell provided such disposals do not exceed 0.5% of the capital or voting rights of Sanofi-Synthelabo over a rolling 12-month period. Elf-Aquitaine and L Oréal also agreed to mutual preemptive rights applicable to all disposals to third parties of shares covered by the agreement during the entire term of the agreement.



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

Elf-Aquitaine and L. Oréal agreed to ensure that the Board of Directors of Sanofi-Synthélabo be composed of twelve or eleven members, split as follows:

four or three members chosen from among candidates proposed by Elf-Aquitaine, depending on whether or not the Elf Aquitaine group's interest in the capital remains more than 3% greater than that of L. Oréal;

three members chosen from among candidates proposed by L. Oréal;

two executive directors;

three independent members.

In practice, there has been a slight change in the composition of the Board of Directors with the full consent between Elf-Aquitaine and L. Oréal. (see page 16 of the 2002 Business report).

Elf-Aquitaine and L. Oréal agreed to consult one another in advance of any meeting of the Board of Directors and any General Meeting of the shareholders of Sanofi-Synthélabo, and in advance of any important decision affecting the future prospects of Sanofi-Synthélabo, with a view to establishing a common position or policy.

Elf-Aquitaine and L. Oréal have declared that they are acting in concert within Sanofi-Synthélabo. The two companies have agreed not to increase their interest, either alone or acting in concert, in such a proportion that would require them to make a public offer for the capital of Sanofi-Synthélabo (currently 2% per rolling 12-month period).

Elf-Aquitaine and L. Oréal agreed not to put themselves in a position where they were acting in concert with a third party. Shares held by the Elf-Aquitaine group which are unrestricted (i.e. they are not covered by the agreement) may be freely disposed of subject to certain conditions.

The agreement is for an initial term of six years expiring December 2, 2004, and is automatically renewable.

The Conseil des Marchés Financiers has taken the view that in the event that the interest in the capital or voting rights held by L. Oréal is likely to become greater than that held by Elf-Aquitaine due to the acquisition of shares by L. Oréal, including by the use of its preemptive rights, it would be necessary to examine the consequences of such change in the balance of the concert-party as regards the requirement to file a draft public offer.

For a description of the L Oréal and TotalFinaElf groups, refer to the registration documents ( *documents de référence* ) issued by each of the two groups.

During the financial year, the interest held by the TotalFinaElf group, both directly and indirectly via Elf Aquitaine and its subsidiary Valorisation et Gestion Financière, fell from 26.07% of the capital and 34.90% of the voting rights as of December 31, 2001 to 24.52% of the capital and 33.74% of the voting rights as of December 31, 2002.

Since the merger of Sanofi and Synthélabo into Sanofi-Synthélabo on May 18, 1999, TotalFinaElf, via Elf Aquitaine, has disposed of 10.8% of its holdings not covered by the agreement: 2.5% in September 2000, 2.3% in April 2001, and 6% between April 2001 and December 2002.

### Share repurchase program

During the year ended December 31, 2002, the Board of Directors used the authorization granted by the Combined General Meetings of Sanofi-Synthélabo shareholders held on May 22, 2001 and May 22, 2002, in conformity with articles L.225-209 et seq of the Commercial Code, to buy shares in the Company (prospectuses approved by the Commission des Opérations de Bourse on April 19, 2001 as no. 01-402 and on April 19, 2002 as no. 02-421) in order to allocate shares to the stock purchase options of the plan date May 22, 2002 and in the light of market conditions.

A total of 19,550,679 shares were bought at an average price of 60.57 euros per share. Of these, 16,520,795 were bought in the light of market conditions and 3,029,884 to allocate shares to the stock purchase options plan dated May 22, 2002. During the same period, 484,595 shares were sold to grantees of stock purchase options at an average price of 14.49 euros per share, and 109,000 shares were sold on the market at an average price of 59.29 euros.

At end December 2002, the Company held 30,376,375 of its own shares, representing 4.15% of the share capital. Of these, 13,836,580 shares were allocated to pre-existing stock purchase options plans.

Since the start of the 2003 financial year, Sanofi-Synthélabo has continued its share repurchase program in the light of market conditions. Under this program, the Company acquired 8,269,109 shares between January 1, 2003 and February 28, 2003, at an average price of 49.56 euros. At the same time, it sold 85,170 shares to grantees of stock purchase option, at an average price of 21.36 euros. This took the number of treasury shares as of February 28, 2003 to 38,560,314 (5.26% of the capital), of which 13,711,760 are allocated to existing stock purchase options plans.

The Combined General Meeting of May 19, 2003 will be asked to renew the authorization to purchase, hold or transfer the Company's shares for a period of eighteen months. Under this authorization, the quantity of shares purchased by the Company may not exceed 10% of the shares comprising the capital of the Company, up to a maximum amount of 5,858,940,080 euros. The quantity of shares held by the company at any time may not exceed 10% of the shares comprising the share capital of the company. The maximum purchase price would be 80 euros per share, and the minimum selling price of treasury shares would be 20 euros, with the exception of shares resold to beneficiaries of certain stock purchase options plans, which may be sold at prices between 6.01 euros and 69.94 euros.

The objectives of this repurchase program would be the implementation of any stock purchase options plan, the purchase or sale of the Company's shares in the light of market conditions, the regulation of the share price by systematic intervention in the market to counter price movements, the implementation of any employee share purchase plan, the delivery of shares in connection with mergers or acquisitions, the delivery of shares on the exercise of rights attached to securities, the implementation of a capital and financial management policy (see pages 116-117 of this report).

### Employee share ownership

The sums derived from voluntary and statutory employee profit-sharing schemes and from voluntary payments made by Sanofi-Synthelabo Group employees are invested in mutual funds established under the Sanofi-Synthelabo Group employee savings scheme agreement signed on December 2, 1999 (see also schemes for involving staff in the capital below, page 112 of this report). This plan is open to all employees. The profit-sharing entitlement of employees under voluntary and statutory schemes can be paid into this plan. Employees may also make voluntary contributions to the plan. Of the five mutual funds set up under the plan, one is wholly invested in Sanofi-Synthelabo shares in order to give all employees a greater stake in the Group's growth. As of December 31, 2002, this fund owned 7,659,036 shares, i.e. 1.05% of Sanofi-Synthelabo's share capital.

Options to subscribe for shares and options to purchase shares have been granted to certain employees and corporate officers of the Group (see page 21 of the 2002 Business report, pages 109-111 of this report and note D.12.6 to the consolidated financial statements on page 45 of this report).

### Shareholder s structure by geographic origin

According to the identifiable bearer shares inquiry ( Titres au porteur identifiable ) and share ownership inquiry as of December 31, 2002, and after taking account of the 3% of unidentified bearers, French shareholders, excluding the reference shareholders TotalFinaElf and L Oréal, Group employees and treasury shares represent about 14% of Sanofi-Synthélabo s share capital ; mainly formed by institutional investors. Foreign shareholders represents about 32% of the capital; mainly formed by American institutional investors (16% of the capital) and English (6% of the capital).

### MARKET IN SANOFI-SYNTHÉLABO SHARES

#### *Places of listing*

Sanofi-Synthélabo shares have been listed on the Premier Marché of Euronext Paris since May 25, 1999.

Sanofi-Synthélabo shares are included in the CAC 40 index. As of December 31, 2002, Sanofi-Synthélabo had a weighting of 3.72% in this index, and a market capitalization of 42,660 million euros, the third largest on the Paris Bourse.

Since March 2, 2001, only 50% of the market capitalization of Sanofi-Synthélabo has been included in the calculation of the CAC 40 index, as opposed to 100% previously. This change was made in order to limit the weighting of Sanofi-Synthélabo to the portion of the capital not held by the Sanofi-Synthélabo s reference shareholders also included in the CAC 40 index. Starting from October 2003, only the free float will be taken into account when calculating the share s weighting in the CAC 40 index.

The Company s ordinary shares are traded under Sicovam code 12057.

Shares identified under Sicovam code 18197 are those arising from options to subscribe for shares exercised between January 1 of any one year and the payment date of the previous year s dividend. These shares are not entitled to the previous year s dividend. After the payment date of the previous year s dividend (for example, June 2, 2003 for the 2002 dividend), shares with Sicovam code 18197 are assimilated with those which have Sicovam code 12057.

Sanofi-Synthélabo shares have been included in the Dow Jones Euro Stoxx 50 index since September 20, 1999.

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

With effect from September 18, 2000, only the free float of Sanofi-Synthélabo's capital has been taken into account when calculating the share's weighting in the Dow Jones Euro Stoxx 50 index, against 100% of the capital previously.

Sanofi-Synthélabo shares are an underlying asset for options traded on the Monep, the negotiable options market of the Paris Bourse.

With effect from July 1, 2002, Sanofi-Synthélabo shares have been listed on the New York Stock Exchange (NYSE) in the form of American Depositary Receipts (ADRs). Sanofi-Synthélabo ADRs are listed under the "SNY" symbol and each represents one-half of an ordinary share. No new shares were issued as a result of this listing. The Bank of New York acts as depository of the ADRs.

107

[Financial, administrative and legal additional information](#)

## Stock market data Euronext Paris

Dates	Transactions		Price		
	Number of shares traded	Average	Share price in euros		Closing share price of month in euros
		capital traded daily (thousands of euros)	High	Low	
<b>2001</b>					
July	43,967,660	143,176.9	78.10	66.50	71.80
August	44,189,006	138,108.2	75.80	65.80	72.05
September	52,353,808	188,083.8	77.40	65.15	71.50
October	45,259,025	145,944.3	80.40	69.25	73.25
November	41,610,991	143,711.8	79.20	71.10	77.40
December	31,172,347	135,461.0	86.50	73.80	83.80
<b>2002</b>					
January	42,625,956	155,128.3	84.30	76.30	77.80
February	72,126,236	263,929.9	78.30	69.15	75.90
March	39,651,646	144,367.6	76.00	70.15	73.60
April	44,971,872	150,296.5	73.95	66.90	71.05
May	46,416,891	143,435.7	72.30	64.20	64.95
June	78,698,782	230,726.1	65.00	53.00	61.60
July	66,095,812	164,412.8	64.00	49.78	60.20
August	52,931,515	150,179.5	65.85	57.10	61.15
September	53,760,985	145,481.8	62.75	50.50	57.05
October	59,213,345	155,563.8	65.90	56.30	61.75
November	43,294,167	121,778.7	63.10	55.05	59.40
December	39,434,063	112,412.0	59.70	54.25	58.25
<b>2003</b>					
January	62,195,736	145,467.6	59.50	44.60	48.65
February	57,305,226	134,036.4	49.90	41.60	49.62

## Stock market data New York Stock Exchange (ADRs\*)

Dates	Transactions		Price		
	Number of ADRs traded	Average	ADR price in US dollars		Closing ADR price of month in US dollars
		capital traded daily (US dollars)	High	Low	
<b>2002</b>					
July	2,430,590	3,164,656	31.55	24.90	29.30
August	1,795,689	2,521,329	32.80	28.50	30.40

Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

September	2,187,991	3,103,498	30.55	25.35	28.50
October	1,707,892	2,225,523	31.58	28.05	30.40
November	991,091	1,469,447	31.65	27.94	29.30
December	1,079,091	1,507,484	30.70	27.72	30.40
<hr/>					
<b>2003</b>					
January	2,544,200	3,216,648	32.00	24.38	26.54
February	1,521,100	2,138,670	27.00	22.53	26.70
<hr/>					

\* Each ADR represents one-half of one ordinary share

## Administrative and management bodies

### SHARES OWNED BY MEMBERS OF THE BOARD OF DIRECTORS AND OF THE EXECUTIVE COMMITTEE

As of December 31, 2002, members of the Board of Directors<sup>(1)</sup> (other than corporate members) and members of the Sanofi-Synthelabo Executive Committee between them owned 329,464 shares, i.e. 0.04% of the capital, and 178,820 voting rights for an ordinary general meeting (0.02%)<sup>(2)</sup> and 378,820 voting rights for an extraordinary general meeting (0.03%).

### STOCK OPTIONS

#### Stock options granted to and exercised by corporate officers<sup>(3)</sup>

Stock options granted to and exercised by each corporate officer	Number of options granted/shares subscribed for or bought	Price (in euros)	Expires
Options granted to each corporate officer during the year by the issuer and any other Group company:			
Mr Jean-François Dehecq	145,000	69.94	May 22, 2012
Mr Gérard Le Fur	70,000	69.94	May 22, 2012
Options exercised during the year by each corporate officer:			
Mr Jean-François Dehecq	60,000	21.46	Sept 22, 2004
Mr Hervé Guérin	90,000	8.50	Dec 15, 2015

#### Stock options granted to the ten employees (other than corporate officers<sup>(3)</sup>) receiving the highest number of stock options, and stock options exercised by the ten employees (other than corporate officers) exercising the highest number of options

Stock options granted to the 10 employees (other than corporate officers) receiving the highest number of stock options, and stock options exercised by the 10 employees (other than corporate officers) exercising the highest number of options	Total number of options granted/shares subscribed for or bought	Weighted average price (in euros)	Expires
Options granted during the year by the issuer (no options were granted by any other Group company), to the ten* employees of the issuer or of any other company included in the scope of the stock option plans receiving the highest number of stock options	273,000	69.94	May 22, 2012
	101,580	11.44	



Options relating to the shares of the issuer  
or of the aforementioned companies exercised  
during the period by the ten employees of the issuer  
or of the aforementioned companies who bought  
or subscribed for the highest number of shares

---

\* 14 employees (due to some employees ranking equally)

- (1) Includes permanent representatives and observers
- (2) Takes account of shares subject to usufruct
- (3) Corporate officers comprises members of the Board of Directors, the Chairman and Chief Executive Officer and the Senior Executive Vice President.

## History of stock options granted outstanding plans

The table below shows all plans under which options were exercised in 2002, including those which ended during the year either because the plan expiration date was reached or because all the options granted under the plan had been exercised. However, plans which ended prior to 2002 are not shown.

Source	Date of	Date of	Options granted	of which	of which
	General	Board		corporate	10 employees
	Meeting	Meeting		officers*	granted most options**
Synthelabo	06/28/90	12/15/93	364,000	130,000	104,000
Synthelabo	06/28/90	10/18/94	330,200	0	200,200
Synthelabo	06/28/90	12/15/94	49,400	0	49,400
Sanofi	05/21/92	09/20/95	1,056,000	44,000	167,640
Synthelabo	06/28/90	12/15/95	442,000	130,000	312,000
Synthelabo	06/28/90	01/12/96	208,000	0	52,000
Synthelabo	06/28/90	04/05/96	228,800	0	67,600
Sanofi	05/21/92	09/18/96	1,056,000	44,000	194,720
Sanofi	07/04/97	09/22/97	1,120,000	60,000	204,000
Synthelabo	06/28/90	10/14/97	262,080	0	165,360
Synthelabo	06/28/90	06/25/98	296,400	148,200	117,000
Sanofi	06/04/97	12/10/98	1,200,000	80,000	220,800
Synthelabo	06/23/98	03/30/99	716,040	0	176,800
Sanofi-Synthelabo	05/18/99	05/24/00	4,292,000	310,000	325,000
Sanofi-Synthelabo	05/18/99	05/10/01	2,936,500	145,000	286,000
Sanofi-Synthelabo	05/18/99	05/22/02	3,111,850	145,000	268,000

\* Holding office as of the date of grant. Corporate officers comprises members of the Board of Directors, the Chairman and Chief Executive Officer, and the Senior Executive Vice President

\*\* Calculated as of the date of grant

<u>Start date of vesting period</u>	<u>Expiration date</u>	<u>Exercise price (in euros)</u>	<u>Options exercised as of Dec. 31, 2002</u>	<u>Options canceled in 2002</u>	<u>Options outstanding</u>
12/15/98	12/15/13	6.36	348,400	0	10,400
10/18/99	10/18/14	6.01	305,200	0	25,000
12/15/99	12/15/14	5.86	49,400	0	0
09/21/96	09/20/02	10.26	1,025,640	29,040	0
12/15/00	12/15/15	8.5	378,400	0	63,600
01/12/01	01/12/16	8.56	133,630	0	74,370
04/05/01	04/05/16	10.85	114,040	0	114,760
09/19/97	09/18/03	14.56	539,675	0	514,925
09/23/99	09/22/04	21.46	194,020	0	925,980
10/14/02	10/14/17	19.73	49,760	0	207,120
06/26/03	06/25/18	28.38		0	296,400
12/11/00	12/10/05	34.95	24,720	800	1,172,480
03/31/04	03/30/19	38.08		1,560	710,320
04/25/04	05/24/10	43.25		17,900	4,225,600
05/11/05	05/10/11	64.5		12,800	2,907,900
05/23/06	05/22/12	69.94		9,200	3,102,650

## RELATED-PARTY AGREEMENTS

Refer to the Special Report of the Statutory Auditors on page 65 of this report.

No new agreements relating to the current financial year have been entered into since January 1st, 2003.

## SCHEMES FOR INVOLVING STAFF IN THE CAPITAL

### *Statutory and voluntary profit-sharing agreements*

All employees of the French companies within the Sanofi-Synthélabo Group belong to voluntary and statutory profit-sharing schemes.

### *Voluntary scheme ( Intéressement des salariés ):*

These schemes are optional for the employer. The aim is to give employees an interest in the growth of the business and improvements in its performance. It must be a collective scheme and must be contingent upon performance.

On March 18, 2000, Sanofi-Synthélabo signed a 3-year Group-wide agreement covering the years 2000, 2001 and 2002, and based on growth in the Group's consolidated net income. This Group-based component may be supplemented by a component linked to the performance or activities of individual subsidiaries.

In 2002, the Group-based component amounted to 14,054,538 euros, compared with 23,687,288.30 euros for 2001 and 24,853,024 euros for 2000.

### *Statutory scheme ( Participation des salariés aux résultats de l'Entreprise ):*

This scheme is a French legal obligation for businesses with more than 50 employees which made a profit during the previous year. Employees are entitled to a share of the profit for the year based on the relevant provisions of the Labor Code.

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

On June 28, 2001, Sanofi-Synthélabo signed a 2-year Group-wide agreement covering the years 2001 and 2002. For 2002, the gross amount of the special statutory profit-sharing reserve was 49,376,009 euros, compared with 50,615,617 euros in 2001 and 33,673,804 euros in 2000.

### Combined General Meeting of May 19, 2003

#### AGENDA

##### Ordinary business

- n Approval of the individual company financial statements for the year ended December 31, 2002.
- n Approval of the consolidated financial statements for the year ended December 31, 2002.
- n Appropriation of profits; declaration of dividend.
- n Approval of transactions covered by the Statutory Auditors' Special Report prepared in accordance with article L.225-40 of the Commercial Code.
- n Appointment of member of Board of Directors.
- n Authorization to the Board of Directors to purchase, hold and transfer the company's own shares.

##### Extraordinary business

- n Delegation to the Board of Directors to increase the share capital by issuance of shares and/or other securities giving immediate or future access to the company's shares in the event of public offers for the company's securities.
- n Amendments to the bylaws.
- n Powers for the accomplishment of formalities.

REPORT OF THE BOARD OF DIRECTORS

**Resolutions submitted to the General Meeting of May 19, 2003**

(This text is a free translation from the French language and is supplied solely for information purposes. Only the original version in the French language has legal force.)

*A. Ordinary business*

**Approval of financial statements**

*(1st and 2nd resolutions)*

The 1st resolution requests your approval of the individual company financial statements.

In accordance with law 2001-420 of May 15, 2001 (article L.225-100 paragraph 3 of the Commercial Code), we are requesting in the 2nd resolution that you approve the consolidated financial statements for the year ended December 31, 2002.

**Appropriation of profits; declaration of dividend** *(3rd resolution)*

The profit for the year amounts to 1,322,602,139.11 euros.

We propose deducting from this profit the sum of 72,484.60 euros, corresponding to a portion of the long-term capital gains arising in the year, and transferring it to the legal reserve.

The distributable profit for the year of 1,322,529,654.51 euros, plus retained earnings brought forward of 369,262,618.92 euros, gives total distributable profits of 1,691,792,273.43 euros, which it is proposed to appropriate as follows:

to the long-term capital gains reserve	878,169,310.13 euros
to the payment of dividend	615,188,705.88 euros
to be carried forward as retained earnings	198,434,257.42 euros

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

If you accept these proposals, each of the 732,367,507 shares comprising the share capital as at December 31, 2002 will receive a net dividend of 0.84 euros accompanied by a tax credit of 0.42 euros (50% rate) taking the total income per share to 1.26 euros, or of 0.08 euros (10% rate) taking the total income per share to 0.92 euros.

This dividend will be paid on June 2, 2003.

The per share amount of dividend, tax already paid to the French Treasury (tax credit) and total income for the previous three financial years is as follows:

<b>Year</b>	<b>Net dividend paid (euros)</b>	<b>Tax already paid (tax credit) (Rate: 50%) (euros)</b>	<b>income total (euros)</b>	<b>Tax already paid (tax credit) (Rate: 40% in 1999, 25% in 2000, 15% in 2001) (euros)</b>	<b>Total income (euros)</b>
1999	0.32	0.16	0.48	0.13	0.45
2000	0.44	0.22	0.66	0.11	0.55
2001	0.66	0.33	0.99	0.10	0.76

The Meeting is also requested to authorize the company to transfer to retained earnings the amount of 2002 dividend relating to shares owned by the company itself as of the payment date of the dividend.

### **Appointment of a member of the Board of Directors**

*(5th resolution)*

We propose that you appoint Mr Gérard Van Kemmel as a member of the Board of Directors to serve for a period of five years in accordance with article 11 of the bylaws.

### **Authorization to the Board of Directors to purchase, hold and transfer the company's own shares**

*(6th resolution)*

You are also requested to authorize the company to purchase, hold and transfer its own shares in accordance with articles L.225-209 et seq of the Commercial Code.

The conditions under which such purchases and transfers may be made are described in the prospectus submitted to the Commission des Opérations de Bourse for approval, a copy of which has been available to the shareholders at the registered office for the period required by law.





*B. Extraordinary business*

**Delegation to the Board of Directors of powers to increase the share capital by the issuance of shares and/or other securities giving immediate or future access to shares in the company in the event of a public offer for the company's shares (7th resolution)**

This resolution proposes that you allow the Board of Directors, as permitted by law, to continue making use of the powers to issue securities with or without preemptive rights as granted by the 8th and 9th resolutions of the Combined General Meeting of May 22, 2002 in the event that one or more public tender offers or public exchange offers for securities issued by the company occurs between the date of the present Meeting and the Meeting held to approve the financial statements for the year ending December 31, 2003. The Board is resubmitting this resolution to you this year because the similar resolution passed at the General Meeting of May 22, 2002 lapses by law at the present Meeting (article L.225-129 of the Commercial Code).

In accordance with the regulations governing capital increases, the Board of Directors has reported to you on the company's affairs since the start of the current accounting period in its management report covered in the ordinary business of this Meeting.

If the Board of Directors were to use the delegation to be granted by the 7th resolution, it would prepare as required and in accordance with the law, at the time of its decision, a supplementary report describing the final terms of the issue and indicating the impact of the issue on the position of the shareholder, and in particular on the shareholder's interest in the company's net assets. This report, together with that of the Statutory Auditors, would be made available to shareholders immediately, and then brought to their attention at the next General Meeting.

**Amendments to the bylaws (8th resolution)**

You are asked, as regards the offices of Chairman or Chairman and Chief Executive Officer, to approve the raising of the age limit to 68 and the consequent amendment of article 12 paragraph 1 and article 16 paragraph 3 of the bylaws.

## PROPOSED RESOLUTIONS

(This text is a free translation from the French language and is supplied solely for information purposes. Only the original version in the French language has legal force.)

### Ordinary business

#### *First resolution*

*Approval of the individual company financial statements for the year ended December 31, 2002.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, having reviewed the Directors' Report and the Statutory Auditors' report, approves all parts of these reports and the individual company financial statements for the year ended December 31, 2002 as presented and closed, showing a profit of 1,322,602,139.11 euros.

#### *Second resolution*

*Approval of the consolidated financial statements for the year ended December 31, 2002.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, having reviewed the Directors' Report and the Statutory Auditors' report, approves all parts of these reports and the consolidated financial statements for the year ended December 31, 2002 as presented and closed.

#### *Third resolution*

*Appropriation of profits; declaration of dividend.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, resolves to deduct from the profit for the year of 1,322,602,139.11 euros the sum of 72,484.60 euros corresponding to a fraction of the long-term capital gains arising in the year and to transfer this sum to the legal reserve.

The Meeting notes that:

n distributable profits for the year of	1,322,529,654.51
n plus retained earnings of	369,262,618.92
gives total distributable profits of	1,691,792,273.43

and resolves to appropriate this sum as follows:

n to the long-term capital gains reserve	878,169,310.13
n to the payment of dividend	615,188,705.88
n to be carried forward as retained earnings	198,434,257.42

Consequently, each of the 732,367,507 shares comprising the share capital as at December 31, 2002 will receive a net dividend of 0.84 euros. To this will be attached, under the conditions stipulated by the legislation in force, a right to reimbursement of the tax already paid to the French Treasury (tax credit) of 0.42 euros (50% rate), taking the total income per share to 1.26 euros, or of 0.08 euros (10% rate) taking the total income per share to 0.92 euros.

This dividend will be paid on June 2, 2003.

If the company holds any of its own shares as of the payment date of the dividend, the proportion of distributable profits not distributed as a result of the company holding its own shares will be appropriated to retained earnings.

The per share amount of dividend, tax already paid to the French Treasury (tax credit) and total income for the previous three financial years is as follows:

Year	Net dividend paid (euros)	Tax already paid (tax credit) (Rate: 50%) (euros)	Total income (euros)	Tax already paid (tax credit) (Rate: 40% in 1999, 25% in 2000, 15% in 2001) (euros)	Total income (euros)
1999	0.32	0.16	0.48	0.13	0.45
2000	0.44	0.22	0.66	0.11	0.55
2001	0.66	0.33	0.99	0.10	0.76

*Fourth resolution*

*Approval of transactions covered by the Statutory Auditors' Special Report prepared in accordance with article L.225-40 of the Commercial Code.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, having reviewed the Statutory Auditors' Special Report on agreements covered by articles L.225-38 et seq of the Commercial Code entered into and performed during the year, approves all parts of this report and the agreements described therein.

*Fifth resolution*

*Appointment of member of Board of Directors.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, and in accordance with article 11 of the bylaws, appoints Mr Gérard Van Kemmel as a member of the Board of Directors to serve for a period of five years, in other words until the General Meeting held to approve the financial statements for the year ending December 31, 2007.

*Sixth resolution*

*Authorization to the Board of Directors to purchase, hold, and transfer the company's own shares.*

The General Meeting, voting on the quorum and majority conditions for Ordinary Meetings, having reviewed the Directors' Report and the prospectus approved by the Commission des Opérations de Bourse, authorizes the Board of Directors, in accordance with articles L.225-209 et seq of the Commercial Code, to buy and sell the company's shares; the objectives of this program would be, in the following order of priority:

- n the implementation of any stock option plan under the terms of the twenty-ninth resolution of the Combined General Meeting of May 18, 1999, which set the number of shares that could be bought as a result of employees exercising options to purchase shares at 2% of the capital as of May 18, 1999, i.e. 14,611,740 shares, of which 10,340,350 have already been utilized;
- n the purchase or sale of the company's shares in the light of market conditions;
- n the regulation of the share price by systematic intervention in the market to counter price movements;

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

- n the implementation of any employee share purchase plan under the conditions stipulated by law, in particular articles L.443-1 et seq of the Labor Code;
- n the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers or acquisitions;
- n the delivery of shares on the exercise of rights attached to securities giving entitlement to the allotment of shares in the company, whether by redemption, conversion, exchange, presentation of a warrant or any other means;
- n the implementation of a capital and financial management policy to include the holding, sale and more generally transfer of such shares, together with the possibility of canceling some or all of the shares repurchased in this way, on the terms set by the thirteenth resolution of the Combined General Meeting of May 22, 2002.

The quantity of its own shares purchased by the company will be subject to the following restrictions:

- n the quantity of shares acquired by the company during the repurchase program may not exceed 10% of the shares comprising the share capital, which, as an indication, represents 73,236,751 shares as at December 31, 2002;
- n the quantity of shares held by the company at any time may not exceed 10% of the shares comprising the share capital of the company.

Acquisitions, sales and transfers of shares may be accomplished at any time (including during a public offer period) by any means, on the stock market or over the counter, including by block purchases or sales (with no limit on the portion of the share repurchase program that can be carried out by this means), the use of options or other derivatives traded on a regulated or over the counter market, or the implementation of options strategies. The Board of Directors shall ensure that mechanisms are not used that increase significantly the volatility of the share.

The maximum purchase price would be 80 euros per share (or the equivalent value of this amount as at the same date in any other currency), such maximum price being applicable only to acquisitions on which a decision is taken on or after the date of the present Meeting and not to forward deals concluded by virtue of an authorization given by a previous General Meeting in anticipation of share acquisitions subsequent to the date of the present Meeting.

In the event of a resale on the market, the minimum selling price of treasury shares acquired in connection with share repurchase programs authorized by the present or previous General Meetings would be 20 euros per share (or the equivalent value of this amount as at the same date in any other currency), with the exception of shares resold to beneficiaries of certain stock option plans, which may be sold at prices between 6.01 and 69.94 euros, such price being applicable both to transfers on which a decision is taken on or after the date of the present Meeting and to forward deals concluded previously in anticipation of share transfers subsequent to the present Meeting.

The maximum amount that the company is authorized to pay for the purchase of its own shares is 5,858,940,080 euros. This authorization voids with effect from this day any unused portion of any previous delegation to the Board of Directors by virtue of the seventh resolution of the General Meeting of May 22, 2002 of authority to purchase, hold and transfer the shares of the company. It is granted for a period of eighteen months from this day.

The General Meeting delegates to the Board of Directors powers to adjust the aforementioned purchase and selling prices in the event of a change in the par value of the shares, increase in share capital by incorporation of reserves, bonus issue of shares, consolidation of shares, distribution of reserves or of any other assets, redemption of capital, or any other transaction affecting shareholders' equity, so as to take account of the impact on the value of the shares. The General Meeting confers full powers on the Board of Directors, with authority to sub-delegate within the law, to decide on and implement the present authorization and if necessary to specify the conditions and determine the terms thereof, with authority to delegate, within the law, the execution of the share repurchase program, and in particular to place stock market orders, enter into agreements, arrange for the keeping of registers of purchases and sales of shares, make declarations to the Commission des Opérations de Bourse, the Conseil des Marchés Financiers or any other authority that may substitute for them, accomplish all formalities and generally do all that is necessary.

#### Extraordinary business

##### *Seventh resolution*

*Delegation to the Board of Directors to increase the share capital by issuance of shares and/or other securities giving immediate or future access to the company's shares in the event of public offers for the company's securities.*

The General Meeting, voting on the quorum and majority conditions for Extraordinary Meetings, having reviewed the Directors Report, authorizes the Board of Directors to make full or partial use, within the scope of the law, of the authorizations given to the Board of Directors by the eighth and ninth resolutions of the Combined General Meeting of May 22, 2002 to increase the share capital by issuance of the shares or other securities mentioned in said resolutions in the event of one or more public tender offers, public exchange offers, or any other form of public offer in compliance with the applicable law and regulations, for securities issued by the company, during the period of said offer.

The present authorization is given for a period expiring at the end of the Meeting held to approve the financial statements for the year ending December 31, 2003.

##### *Eighth resolution*

*Amendments to the bylaws.*

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

The General Meeting, voting on the quorum and majority conditions for Extraordinary Meetings, having reviewed the Directors Report, resolves that as regards the offices of Chairman or Chairman and Chief Executive Officer, the age limit should be raised to 68, and that article 12 paragraph 1 and article 16 paragraph 3 of the bylaws should be amended accordingly.

### **Article 12 Chairman and Vice-Chairman of the Board of Directors**

#### **Paragraph 1**

The Board of Directors shall elect from among its members a Chairman, who must be a natural person less than 68 years of age.

### **Article 16 Management**

#### **Paragraph 3**

If the executive management of the company is conducted by the Chairman, the provisions contained in the law and regulations and in the bylaws relating to the Chief Executive Officer shall apply to him except for those concerning the age limit. He shall take the title of Chairman and Chief Executive Officer and shall hold office until the age of 68.

#### *Ninth resolution*

*Powers for the accomplishment of formalities.*

The General Meeting, voting on the quorum and majority conditions for Extraordinary Meetings, confers full powers on the bearer of an original, copy or extract of the minutes of its deliberations to carry out any filings or formalities required by law.

## Persons responsible and declarations

### Persons responsible for the registration document ( *document de référence* )

Jean-François Dehecq, Chairman and Chief Executive Officer of Sanofi-Synthélabo.

### Declaration

To the best of my knowledge, the data contained in the present registration document are accurate and include all the information necessary for investors to form a judgement on the net assets, operations, financial position, results and prospects of Sanofi-Synthélabo; they do not contain any omission liable to alter the import of the document .

Paris, April 22, 2003

Jean-François Dehecq

Chairman and Chief Executive Officer of Sanofi-Synthélabo

### Persons responsible for the audit of the financial statements

#### *Statutory auditors*

1) Ernst & Young Audit, represented by Mr Dominique Thouvenin and Mrs Valérie Quint

4, rue Auber 75009 Paris

appointed April 28, 1994

reappointed at the General Meeting of May 24, 2000

term of office expires at the end of the General Meeting held to approve the financial statements for the year ended December 31, 2005



Edgar Filing: SANOFI SYNTHELABO SA - Form 6-K

2) PricewaterhouseCoopers Audit, represented by Mr Jacques Denizeau and Mr Jean-Christophe Georghiou 32, rue Guersant 75017 Paris

appointed March 12, 1999

term of office expires at the end of the General Meeting held to approve the financial statements for the year ended December 31, 2004

*Deputy statutory auditors*

1) Mr Bruno Perrin

100 rue Raymond Losserand 75014 Paris

appointed March 12, 1999(1)

reappointed at the General Meeting of May 24, 2000

term of office expires at the end of the General Meeting held to approve the financial statements for the year ended December 31, 2005

2) Mr Pierre Coll

11 rue Marguerite 75017 Paris

appointed May 22, 2001(2)

term of office expires at the end of the General Meeting held to approve the financial statements for the year ended December 31, 2004

- 
- (1) Mr Bruno Perrin was appointed to replace the previous deputy statutory auditor to Ernst & Young Audit for the previous deputy statutory auditor's remaining term of office.
- (2) Mr Pierre Coll was appointed to replace the previous deputy statutory auditor to PricewaterhouseCoopers Audit for the previous deputy statutory auditor's remaining term of office.

**Opinion of the statutory auditors on the registration document ( document de référence ).**

In our capacity as statutory auditors of Sanofi-Synthelabo and in compliance with the COB Regulation n° 98-01, we have verified, in accordance with French professional standards, the information in respect of the financial position and historic financial statements included in the accompanying registration document ( *document de référence* ).

This registration document is the responsibility of the Chairman-Chief Executive Officer. Our responsibility is to issue an opinion on the fairness of the information contained therein with respect to the financial position and financial statements.

We conducted our review in accordance with French professional standards. This review consisted in assessing the fairness of the information on the financial position and financial statements and to verify their consistency with the audited accounts. We also reviewed other financial information contained in the registration document in order to identify any significant inconsistency with information in respect of the financial position and financial statements and to bring to your attention any obvious misstatements we noted based on our general understanding of the company gained through our audit. As the prospective information has been properly prepared, our review took into account Management's assumptions on which the prospective information is based.

We conducted an audit in accordance with French professional standards on the annual and consolidated accounts for the years ended December 31, 2002, 2001 and 2000, drawn up by the Board of Directors.

We issued an unqualified opinion on the annual and consolidated accounts for the years ended December 31, 2001 and 2000. Without qualifying our opinion on the annual and consolidated accounts for the year ended December 31, 2002, we draw the attention to note B2 to the consolidated financial statements, which present the impact on the consolidated financial statements of the change in accounting method resulting from the application, with effect from January 1, 2002, of the new CRC rule 2000-06 on liabilities.

We have nothing to report with respect to the fairness of the information on the financial position and financial statements contained in the registration document ( *document de référence* ).

Paris, April 22, 2003

The Statutory Auditors

Ernst & Young Audit

PricewaterhouseCoopers Audit

Dominique Thouvenin

Valérie Quint

Jacques Denizeau

Jean-Christophe Georghiou

**Person responsible for financial information**

Individual and institutional shareholders, and financial analysts, are welcome to contact the Investor Relations Department with any questions.

Contact: Mr Philippe Goupit  
Investor Relations Department

Tel.: +33 (0)1.53.77.45.45

Toll-free (France): 0800.07.58.76

e-mail: [investor-relations@sanofi-synthelabo.com](mailto:investor-relations@sanofi-synthelabo.com)

Address: 174, avenue de France 75013 Paris, France

119

[Financial, administrative and legal additional information](#)

## Registration document ( *document de référence* ) checklist

The registration document checklist below sets out the main headings specified in the Instruction of December 2001, issued in application of regulation 98-01 of the Commission des Opérations de Bourse, and refers users to the corresponding pages of the Business report 2002 and Financial report 2002 brochures, together constituting the Annual Report, which has registration document status.

Items required under COB regulation 98-01	Relevant page of annual report with registration document status	
	2002 Business report	2002 Financial report
<b>Chapter I</b>		
Person responsible for the registration document and persons responsible for the audit of the financial statements		
1.1 Name and position of the person responsible for the registration document		118
1.2 Declaration by the person responsible for the registration document		118
1.3 Persons responsible for the audit of the financial statements		118
1.4 Opinion of the statutory auditors on the registration document		119
1.5 Information policy	14-15	119
<b>Chapter III</b>		
General information concerning the Company and its capital		
3.1 General information concerning the Company		97-99
3.2 General information concerning the capital		100-103
3.3 Current ownership of capital and voting rights		104-107
3.4 Market in the Company's securities	10-13	107-108
3.5 Dividends	13	12
<b>Chapter IV</b>		
Information concerning the Company's activities		
4.1 Presentation of the Company and the Group	22-88	87
4.2 Dependency of the Company		16,91
4.3 Employees	79	14-15
4.4 Investment policy	67	41
4.5 Risk factors for the issuer and Insurance		89-96
<b>Chapter V</b>		
Assets and liabilities Financial position Profits and losses		
5.1 Financial statements of the issuer		1-86
5.2 Fees charged to the Group for services provided by the statutory auditors		25-86
		23
<b>Chapter VI</b>		
Administrative and management bodies		
6.1 Composition and operation of administrative and management bodies, corporate governance	16-20	
6.2 Interest of members of administrative and management bodies in the issuer's capital, compensation of corporate officers and stock options plans	16,21	13, 14, 109-111
6.3 Description of schemes for involving staff in the capital		102,106,109
<b>Chapter VII</b>		
Recent developments and prospects		
7.1 Recent developments	*	
7.2 Prospects	5,13	11

The present registration document was filed with the Commission des Opérations de Bourse on 04/23/2003, in accordance with regulation 98-01. It may be used to support a financial operation if supplemented by a prospectus registered with the Commission des Opérations de Bourse.

---

\* Interleaf at the start of the 2002 Business report.

**120**

[Financial, administrative and legal additional information](#)

**This Financial Report was designed and published by:**

Sanofi-Synthelabo Corporate Communications, Finance and Legal Departments and the DraftWorldwide agency

**Photographs:**

**Front Cover:** Rose Deren   **Back cover:** Publicis Dialog/Daniel Therasse

**Our story began 30 years ago**

**174, avenue de France 75013 Paris France**

**Tel: +33 1 53 77 40 00**

**[www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com)**

## 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 25, 2003

SANOFI-SYNTHELABO

By: /s/ Marie-Hélène Laimay

**Name: Marie-Hélène Laimay**

**Title: Senior Vice President and**

**Chief Financial Officer**