

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.

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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>The story began</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 & Carrière (founded in 1899).</p> |
| 1978 | <p>Sanofi launched its first major product on the market:</p> <p>Ticlid®.</p> |
| 1988 | <p>Synthélabo launched two major products on the French market: Stilnox® and Xatral®.</p> |
| 1993 | <p>Synthélabo launched Stilnox® in the United States</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>Sanofi made a significant entrance into the U.S.</p> <p>market through the acquisition of Sterling Winthrop, the pharmaceutical unit of Eastman Kodak.</p> |
| 1997/1998 | <p>In 1997, Sanofi launched its first major product in the U.S.</p> <p>market, Avapro®, followed by Plavix® in 1998.</p> |
| 1998 | <p>Two leaders of the French pharmaceutical industry</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>The year of the merger</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>Strength through unity</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&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> |

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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[®] and Avapro[®], 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[®] 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[®], +19% for Aprovel[®]/Avapro[®], +26% for Stilnox[®]/Ambien[®]/Myslee[®]; 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[®] 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[®] 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[®], its clear therapeutic benefits led to its approval in the U.S. within an exceptionally short time. Four months after its launch, Eloxatin[®] 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[®] 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

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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[®], which has been challenged by two generic manufacturers, legal action is still continuing. We have full confidence in the strength of Plavix[®] 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⁽¹⁾ and +14.8% on a reported basis

2002 Developed sales: 9,585 million euros

+14.5% on a comparable basis⁽¹⁾

Our business activity

Consolidated sales⁽²⁾

(in millions of euros)

Developed sales*⁽²⁾

(in millions of euros)

Consolidated sales⁽²⁾ of the three flagship products

(in millions of euros)

Developed sales^{*(2)} of the three flagship products

(in millions of euros)

Consolidated sales⁽¹⁾ by geographic area

Developed sales^{*(1)} 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®/Iscover® (clopidogrel) and Aprove®/Avapro®/Karvea® (irbesartan), with Fujisawa on Myslee® (zolpidem), with Pharmacia on Ambien® (zolpidem) for 2000 and 2001 figures, with Organon on Arixtra® (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:

- ¹ The **CAC 40** French pan-sector index
- ¹ The **Dow Jones Euro Stoxx 50** European pan-sector index
- ¹ The **Dow Jones Stoxx Pharma** European sector index
- ¹ The **NYSE International 100** American pan-sector index
- ¹ 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

ⁿ **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.

ⁿ **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%.

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

* From May 25, 1999

Consolidated earnings⁽¹⁾ per share (in euros)

Net income payout ratio⁽¹⁾ (%)

Net dividend per share⁽⁶⁾ (in euros)

Total rate of return⁽⁷⁾

(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[®], Aprovel[®], Stilnox[®];

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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 and with the Securities and Exchange Commission in the U.S. at www.sec.gov, or directly from Sanofi-Synthélabo at 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

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Set up in 1999, the Sanofi-Synthélabo website at 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 Investor Relations Department 174 Avenue de France 75013 Paris | Sanofi-Synthélabo Investor Relations Department 174 Avenue de France 75013 Paris <hr/> 90 Park Avenue New York, NY 10016 | Sanofi-Synthélabo Media Relations Department 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:

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| | | |
|-----------------------|---|--|
| 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-Synthelabo 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.

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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.

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Sanofi-Synthélabo and its shareholders

Board of Directors:

Directors:

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

Director¹ 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

Director¹ 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

ⁿ **Pierre-Gilles de Gennes**, aged 70

Nobel Prize for Physics (1991)

Director¹ from May 1999 to 2004

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

Director of Rhodia

ⁿ **Hervé Guérin**, aged 61

Director from May 1999 to 2004

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

ⁿ **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

ⁿ **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 ⁽¹⁾: 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,

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- 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 ⁽¹⁾ | 1996 ⁽¹⁾ | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | TOTAL |
|--|---------|---------|---------------------|---------------------|-----------|-----------|---------|-----------|-----------|-----------|------------|
| Total number of options granted | 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 |

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| Expiry date | 10/2014 | 09/2002 | 09/2003 | 09/2004 | 12/2005 | | | | | | |
|-----------------------------------|--------------------|-------------|------------|------------|------------|----------|---------|---------|---------|-------|--|
| | 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 | | |
| Purchase/subscription price (in) | 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 ⁽¹⁾ | 1996 ⁽¹⁾ | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | TOTAL |
|--|--------|--------|---------------------|---------------------|-----------|-----------|---------|-----------|-----------|-----------|---------------------------|
| Number of options exercised in 2002 | 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 |
| Number of options outstanding | 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 ⁽²⁾ |
| - 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-Synthélabo 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-Synthélabo 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

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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[®]

sodium valproate

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

Depakine chronospheres[®]

sodium valproate

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

INTERNAL MEDICINE

Xatral[®] 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.

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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.

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Research & Development

RESEARCH & DEVELOPMENT

sustained momentum

Four major therapeutic areas

CARDIOVASCULAR / THROMBOSIS

Idraparinix sodium

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

Initiation of Phase III studies

Like Arixtra®, idraparinix sodium belongs to the synthetic oligosaccharide family. Idraparinix 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 idraparinix 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-Synthelabo 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.

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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-Synthélabo 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.

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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 NK₃ 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 beta₃ 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/m²). 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

-

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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[®] and Aprovel[®]/Avapro[®]

Launch of Arixtra[®] in the United States and Europe,

Launch of Eloxatin[®], Eligard[®] and Elitek[®] in the United States

Rapid granting of a product license for Eloxatin[®] in the U.S. on the basis of clinical trial results

Commercial success of Plavix[®] with a 40%* increase in consolidated sales in 2002

Plavix[®] patents challenged by two generic manufacturers in the U.S.

Success of Myslee[®] (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) | | |

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| | | | <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.

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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.

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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.

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Medicines

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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.

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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.

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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.

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Other major studies are designed to support the long-term use of Plavix[®], 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[®]

ticlopidine

Thrombosis

Ticlid[®] 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[®] 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[®] 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[®], it is licensed to Daiichi.

Arixtra[®] 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,

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- 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[®] 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.

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Medicines

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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.

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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.

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Medicines

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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

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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.

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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.

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- 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[®] (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[®] 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[®] in the prophylaxis of venous thromboembolism

Arixtra[®] 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[®] 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[®], 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[®] 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[®]. Administered subcutaneously once daily at a fixed dose (7.5 mg), Arixtra[®] 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[®]: other ongoing developments

The clinical development program for Arixtra[®] 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[®]/Ambien[®]/Myslee[®] (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-Synthelabo'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.

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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

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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.

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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%⁽¹⁾ and 14.5%⁽¹⁾ respectively, confirming the trend established in recent years.

Key events in 2002

+17.5%⁽¹⁾ in the United States

+11.8%⁽¹⁾ in Europe

+10.3%⁽¹⁾ 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 ⁽¹⁾ | Market share ⁽²⁾ | Main product launches |
| | | | | in 2002 |
| Europe including: | 4 297 | +11.8% | 3.9%⁽³⁾ | |
| France | 1 546 | +8.0% | 7.9% | Fasturtec [®] , Arixtra [®] |
| Germany | 634 | +7.0% | 2.9% ⁽⁴⁾ | Arixtra [®] |
| Italy | 444 | +3.6% | 2.9% | Fasturtec [®] , Plavix [®] |
| Spain | 358 | +21.7% | 2.9% | Solian [®] , Fasturtec [®] |
| United Kingdom | 287 | +7.9% | 2.9% | Arixtra [®] , Fasturtec [®] |
| Belgium | 163 | +21.9% | 5.1% | Fasturtec [®] , Solian [®] , Fraxodi [®] |
| Hungary | 101 | +23.7% | 6.4% | |
| Greece | 100 | +37.8% | 3.9% | Arixtra [®] , Solian [®] |
| Turkey | 98 | +41.5% | 2.5% | Xatral OD [®] |
| Switzerland | 92 | +18.8% | 3.8% | Arixtra [®] , Fasturtec [®] |
| Scandinavia | 91 | +24.3% | 1.5% ⁽⁵⁾ | Arixtra [®] (Sweden, Finland, Norway and Denmark) Solian [®] (Denmark) |
| Portugal | 88 | +12.6% | 3.7% | Arixtra [®] |
| Poland | 82 | +15.7% | 2.7% | |
| Netherlands | 69 | +26.6% | 2.2% ⁽⁴⁾ | Arixtra [®] |
| Czech Republic | 41 | +15.8% | 3.8% | Fasturtec [®] |
| Austria | 35 | +19.9% | 1.8% | Arixtra [®] |
| United States | 1 689 | +17.5% | 1.8%⁽⁶⁾ | Arixtra [®] , Eloxatin [®] , Eligard [®] , Elitek [®] |
| Other countries including: | 1462 | +10.3% | | |
| Asia/Middle East | 423 | +27.0% | | Solian [®] , Arixtra [®] (Australia) |
| Latin America | 327 | +3.6% | 1.9% ⁽⁷⁾ | Solian [®] , Xatral [®] OD (South Korea) Arixtra [®] (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.

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

The ongoing launches of Fasturtec[®] and Arixtra[®], 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[®], Arixtra[®]

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[®], Aprovel[®]/Co-Aprovel[®] and Eloxatine[®],

- 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[®]

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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[®], launched in 2002, is not yet reimbursed. Negotiations have been resumed with the health authorities on the basis of the new indication of Plavix[®] 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[®], Eloxatin[®], Fraxiparine[®], Xatral[®] and Stilnox[®] 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[®], Fasturtec[®]

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[®], Aprovel[®] and Eloxatin[®] achieved excellent performances. In contrast, the loss of patent protection of Stilnox[®] adversely affected the performance of this product.

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

United Kingdom

Consolidated sales: 287 million euros

Growth: +7.9%

Market share: 2.9%

Product launches in 2002: Arixtra[®], Fasturtec[®]

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[®] sales and 60% of Plavix[®] 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[®], Aprovel[®], Eloxatin[®] and Xatral[®].

The highly favorable opinions issued by the National Institute for Clinical Excellence (NICE) on Eloxatin[®] and Solian[®] 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[®], Solian[®], Fraxodi[®]

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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[®], Fraxiparine[®] and the first batches of Arixtra[®].

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[®], Solian[®]

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

Turkey

Consolidated sales: 98 million euros

Growth: +41.5%

Market share: 2.5%

Product launch in 2002: Xatral[®] 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[®], Aprovel[®] and Fraxiparine[®].

GLOBAL DEVELOPMENT

strong international presence

Switzerland

Consolidated sales: 92 million euros

Growth: +18.8%

Market share: 3.8%

Product launches in 2002: Arixtra[®], Fasturtec[®]

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[®] 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[®], leader in the AIIRA market, and of Plavix[®] substantially enhanced the results of the Swiss affiliate. Eloxatin[®] and Stilnox[®], leaders in their respective markets in terms of market share, as well as Xatral Uno[®], 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.

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The year 2002 was nevertheless satisfactory, with sales growth exceeding market expansion by three points (IMS). Sales of Aprovel[®], Eloxatin[®] and Xatral[®] progressed steadily. With almost 23% of the AIIRA market, Aprovel[®] 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[®] at European level permitted resumption of negotiations for its reimbursement, with hope of success in 2003.

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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[®], boosted by the launch of Fraxodi[®], Depakine[®], Xatral[®] and Stilnox[®] 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[®]

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

Czech Republic

Consolidated sales: 41 million euros

Growth: +15.8%

Market share: 3.8%

Product launch in 2002: Fasturtec[®]

The Czech Republic faced a difficult and competitive environment, including pressure on reimbursement levels for Solian[®] and Deniban[®], 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[®], Eloxatin[®], Depakine[®] and Stilnox[®] progressed strongly.

Austria

Consolidated sales: 35 million euros

Growth: +19.9%

Market share: 1.8%

Product launch in 2002: Arixtra[®]

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®, Eloxatin® and Fraxiparine® 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[®], Eloxatin[®], Eligard[®], Elitek[®]

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

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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[®] 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[®] only four months after its launch for the second-line treatment of colorectal cancer. Sanofi-Synthélabo was also granted a product license for two presentations of Eligard[®] for the treatment of advanced prostate cancer (under license from Arix) as well as a marketing approval for Elitek[®] 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[®] and Arixtra[®]
in Australia,

Solian[®] and Xatral[®]

in South Korea,

Supported by Plavix[®], Aprovel[®], Stilnox[®], Eloxatin[®] and Xatral[®], 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-Synthélabo 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.

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- **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[®] 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[®].
- **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[®] (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[®] (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[®] 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.

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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[®], Plavix[®] and Depakine[®]. 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[®], which remains the leading product both for the affiliate and in the Russian market.

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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[®], 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[®] 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.

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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[®]/Avapro[®] and Plavix[®].
- The second with Organon, a subsidiary of Akzo Nobel, for the marketing of Arixtra[®].

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[®] 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[®], Dogmatil[®] and Pimperan[®]; with Daiichi for Ticlid[®]; with Taisho for Cardarone[®]; with Mitsubishi for Kerlone[®] and with Yamanouchi for Corotrope[®].

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.

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In some countries, including E.U. member states, the U.S. and Japan, many Sanofi-Synthelabo 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-Synthelabo is vigilant regarding the activities of its competitors and systematically attacks infringements of patents and trademarks.

Sanofi-Synthelabo 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[®] and Dogmatil[®] no longer benefit from patent protection, others such as Tildiem[®] and Depakine[®] 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[®]. Plavix[®] 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

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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**⁽¹⁾
 Chilly-Mazarin, **France**⁽¹⁾
 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.

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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.

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[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.

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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.**

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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.

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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.

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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.

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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-Synthelabo 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.

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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

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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.

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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.

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Our Responsibility

Compensating performance

Sanofi-Synthelabo 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-Synthelabo 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-Synthelabo 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-Synthélabo.

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

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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.

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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)

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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^{ème} Chance.

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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 |
|---|--------------|------------|--------------|------------|---------------|
| In millions of euros | | | | | |
| Net Sales | 6,488 | 100 | 7,448 | 100 | +14.8% |
| Cost of goods sold | (1,253) | (19) | (1,378) | (19) | +9.9% |
| Gross profit | 5,235 | 81 | 6,070 | 81 | +16.0% |
| 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% |
| Operating profit | 2,106 | 32 | 2,614 | 35 | +24.1% |
| Intangibles (amortization and impairment) | (68) | | (129) | | |
| Financial income | 102 | | 85 | | -16.7% |
| Income before tax and exceptional items | 2,140 | 33 | 2,570 | 35 | +20.1% |
| 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) | |
| Net income | 1,585 | 24 | 1,759 | 24 | +11.0% |
| Exceptional items and goodwill amortization | (209) | (3) | (1) | | |
| Net income before exceptional items and goodwill amortization | 1,376 | 21 | 1,758 | 24 | +27.8% |
| Weighted average shares outstanding | 731,711,225 | | 727,686,372 | | |
| Earnings per share before exceptional items and goodwill amortization basic and diluted in euros | 1,88 | | 2,42 | | +28.7% |

Sanofi-Synthelabo simplified consolidated balance sheets

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| ASSETS | 12/31/01 | 12/31/02 | LIABILITIES | 12/31/01 | 12/31/02 |
|---|-----------------|-----------------|---|-----------------|-----------------|
| In millions of euros | | | | | |
| 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 |
| Total assets | 9,967 | 9,459 | Total liabilities and equity | 9,967 | 9,459 |

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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.

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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

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MANAGEMENT REPORT FOR THE YEAR 2002

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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[®], Aprovel[®] and Stilnox[®], 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[®] and Avapro[®] 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[®] in the United States.
- n A new indication was obtained in the United States and Europe for Plavix[®]/Iscover[®] 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[®]/Avapro[®] in the treatment of diabetic nephropathy in patients with high blood pressure and type 2 diabetes.

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- 11 Arixtra[®] 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[®] was launched in the second-line treatment of colorectal cancer, Elitek[®] (rasburicase) in the management of plasma uric level associated with chemotherapy in pediatric patients, and Eligard[®] (1-month and 3-month formulations) in the treatment of advanced prostate cancer.
- 11 Sanofi-Synthélabo defended the industrial property rights of Plavix[®] 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[®].
- 11 A new patent was registered in Europe and the United States protecting the crystalline polymorphic form 2 of clopidogrel (Plavix[®]/Iscover[®]). 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[®]/Iscover[®] (clopidogrel) and Aprovel[®]/Avapro[®]/Karvea[®] (irbesartan), with Fujisawa for Stilnox[®]/Myslee[®] (zolpidem), and with Organon for Arixtra[®] (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[®], Stilnox[®] and Aprovel[®], 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[®] and Avapro[®] 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) | | | | | |
| Plavix[®]/Iscover[®] | | | | | |
| 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% |
| Sub-total | 2,033 | 1,957 | 2,587 | +32.2% | +27.3% |
| Aprovel[®]/Avapro[®]/Karvea[®] | | | | | |
| 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% |

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| | | | | | |
|-----------------------------------|--------------|--------------|--------------|---------------|---------------|
| Sub-total | 924 | 898 | 1,068 | +18.9% | +15.6% |
| Stilnox®/Ambien®/Myslee® | | | | | |
| 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% |
| Sub-total | 1,215 | 1,160 | 1,455 | +25.4% | +19.8% |
| Total: 3 flagship products | 4,172 | 4,015 | 5,110 | +27.3% | +22.5% |
| Total developed sales | 8,746 | 8,368 | 9,585 | +14.5% | +9.6% |

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-Synthelabo 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-Synthelabo 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

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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 |
| (in millions of euros) | | | | | |
| 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% |
| Total | 6,488 | 6,605 | 7,448 | +12.8% | +14.8% |

- 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[®], 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[®] (Corotrope[®]). The very marked growth in reported sales, achieved in spite of the falling dollar, was due to the fact that 100% of Ambien[®] 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[®], Aprovel[®] and Stilnox[®], 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 [®] | Insomnia | 786 | 1,135 | 1,424 | +25.5% | +81.3% |
| | Plavix [®] | Atherothrombosis | 705 | 697 | 987 | +41.5% | +39.8% |
| | Aprovel [®] | Hypertension | 423 | 419 | 562 | +34.0% | +32.8% |
| | Eloxatine [®] | Colorectal cancer | 196 | 194 | 389 | +101.3% | +99.2% |
| | Fraxiparine [®] | Thrombosis | 297 | 294 | 324 | +10.1% | +8.9% |
| | Depakine [®] | Epilepsy | 243 | 240 | 267 | +11.0% | +9.8% |
| | Xatral [®] | Benign prostatic hyperplasia | 148 | 147 | 182 | +24.3% | +23.1% |
| | Cordarone [®] | Arrhythmia | 162 | 157 | 162 | +3.1% | 0.1% |
| | Tildiem [®] | Angina, hypertension | 152 | 151 | 141 | 6.9% | 7.4% |
| | Ticlid [®] | Thrombosis | 205 | 205 | 137 | 33.2% | 33.2% |
| | Solian [®] | Schizophrenia | 116 | 115 | 135 | +17.2% | +16.7% |
| | Corotrope [®] / Primacor [®] | Heart failure | 237 | 226 | 127 | 43.5% | 46.1% |
| | Aspégic [®] and related products | Fever, pain | 100 | 101 | 108 | +6.7% | +7.6% |
| | Dogmatil [®] | Psychosomatic disorders | 124 | 86 | 78 | 9.0% | 37.2% |
| | Kerlone [®] | Hypertension, angina | 82 | 81 | 77 | 5.0% | 6.9% |

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

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

- ¹¹ Stilnox[®]/Ambien[®] 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[®]/Ambien[®] 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.
- ¹¹ Consolidated net sales of Plavix[®] 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.
- ¹¹ Consolidated net sales of Aprovel[®] 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.
- ¹¹ Consolidated net sales of Eloxatine[®] were 389 million euros, a rise of 101.3% on a comparable basis. This very high figure reflects the successful launch of Eloxatine[®] on the American market on August 30, 2002, coupled with strong growth for the product in Europe and the other countries.
- ¹¹ Consolidated net sales of Arixtra[®] 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.
- ¹¹ 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[®] and Aprovel[®], offsetting lower sales of Ticlid[®] and Primacor[®] (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[®] 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[®] sales in 2002.

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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% |
| Total | 6,488 | 6,605 | 7,448 | +12.8% | +14.8% |

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[®] and Avapro[®], 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:

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n ongoing major clinical trials programs aimed at obtaining new indications for products already on the market (Plavix[®], Aprovel[®], Arixtra[®], Eloxatine[®] and Xatral[®]), 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[®]/Ambien[®].

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[®] with effect from January 1, 2002, and of the launch of Arixtra[®]. 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® and Aprovel®, which led to a significant increase in the profits generated in this region and hence in the amount of profit passed on by Sanofi-Synthelabo to Bristol-Myers Squibb;
- n reductions in Plavix® and Aprovel® 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-Synthelabo;
- n the elimination in 2002 of the share of Lorex profits passed on to Pharmacia, following the buyout by Sanofi-Synthelabo 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) | | | | | |
| Net sales | 6,488 | 100% | 7,448 | 100% | +14.8% |
| Cost of goods sold | (1,253) | (19.3%) | (1,378) | (18.5%) | +10.0% |
| Gross profit | 5,235 | 80.7% | 6,070 | 81.5% | +16.0% |
| 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% |
| Operating profit | 2,106 | 32.5% | 2,614 | 35.1% | +24.1% |

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% |
| Total operating profit | 2,106 | 2,614 | +24.1% |

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[®] in the American market.
- The launch of Eloxatine[®], which offset the fall in sales of Primacor[®] 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[®] (acquired from Bristol-Myers Squibb in October 2001) and to Ambien[®] (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-Synthélabo 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[®] 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).

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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[®] 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[®], Stilnox[®] and Aprovel[®];
- n growth in sales of Eloxatine[®] in the United States, following the launch on August 30, 2002;
- n continuing strong performances from the rest of the portfolio, especially Depakine[®], Solian[®] and Xatral[®].

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 |
| Total | 732,367,507 | 100.00 | 1,064,540,103 | 100.00 |

* 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.

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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-Synthelabo owns any Sanofi-Synthelabo shares.

DIVIDENDS IN RESPECT OF THE LAST THREE FINANCIAL YEARS

| Year | Net dividend paid (euros) | Tax already paid to the French Treasury (tax credit: 50% rate) (euros) | | Total income (euros) | Tax already paid to the French Treasury (tax credit)(1) (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 | | |

(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

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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 |
|---|---------------|---------------|---------------|--------------|-----------------|
| Registered employees: Dec 31, 2002 | 32,436 | 21,478 | 12,204 | 3,595 | 7,363 |
| Split by type of contract | | | | | |
| permanent | 30,621 | 20,536 | 11,591 | 3,595 | 6,490 |
| fixed-term | 1,815 | 942 | 613 | 0 | 873 |
| Split by gender | | | | | |
| Female | 16,339 | 11,112 | 6,434 | 1,861 | 3,366 |
| Male | 16,097 | 10,366 | 5,770 | 1,734 | 3,997 |
| Split by category | | | | | |

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| | | | | | |
|-------------|---------------|--------|-------|-------|-------|
| managers | 7,772 | 5,526 | 4,003 | 1,032 | 1,214 |
| other | 14,189 | 11,107 | 6,830 | 307 | 2,775 |
| sales force | 10,475 | 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 |
|-------------------------------------|--------------|--------------|--------------|------------|-----------------|
| Total number of new recruits | 5,297 | 2,958 | 1,647 | 733 | 1,606 |
| 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 |
| Total number of leavers | 4,089 | 2,244 | 1,326 | 361 | 1,484 |
| permanent contracts | 2,609 | 1,063 | 371 | 361 | 1,185 |
| fixed-term contracts | 1,480 | 1,181 | 955 | 0 | 299 |
| Total number of dismissals | 762 | 338 | 144 | 41 | 383 |
| 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 |
|---|--------------|--------------|--------------|--------------|-----------------|
| Theoretical average annual working hours | 1,703 | 1,629 | 1,547 | 1,856 | 1,865 |
| Part-time | | | | | |
| 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 |
| Temporary agency staff | | | | | |
| 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

| | Total | Europe | incl. France | USA | Other countries |
|--|----------------|----------------|----------------|---------------|-----------------|
| Total number of days absence | 343,928 | 271,574 | 155,004 | 15,500 | 56,854 |
| Split by reason | | | | | |
| 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 |
| Rate of industrial accidents** | 4,1 | 4,6 | 4,5 | 2,4 | 3,7 |

* 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 |
|--|------------------|---------------|---------------|--------------|-----------------|
| Number of employees receiving training | 26,288 | 17,699 | 10,021 | 3,170 | 5,419 |
| Total number of training hours | 1,149,814 | 718,796 | 341,719 | 129,253 | 301,765 |
| Total number of health, safety and environment training hours* | 303,896 | 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* | 38,322 |
| Minimum annual gross salary after 1 year's service | <u>18,000</u> |

* 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 | 50.6 |
| % of total payroll | 10.3% |

Group voluntary profit-sharing scheme*

| | |
|-------------------------------|-------------|
| 2001 entitlement paid in 2002 | 23.7 |
| % 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>m³</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.

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| <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.

| Equivalent tonnes(1) of CO2 | 2002 |
|------------------------------------|-------------|
| 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).

| Tonnes | 2002 |
|---------------|-------------|
| COD | 481 |

The nitrogen contained in industrial effluents also has an environmental impact.

| Tonnes | 2002 |
|----------------|-------------|
| N ₂ | 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.

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Where incineration treatment infrastructures are not available, a very small and constantly-declining proportion of wastes continues to be disposed of at agreed landfills.

| Hazardous, tonnes(1) | 2002 |
|-----------------------------|---------------|
| Recycled (utilized) | 57,939 |
| Incinerated (not utilized) | 1,754 |
| Total | 59,693 |

Three-quarters of non-hazardous wastes are now reused, recycled or thermally utilized.

| Non-hazardous, tonnes(1) | 2002 |
|---------------------------------|---------------|
| Utilized | 21,342 |
| Processed (not utilized) | 6,254 |
| Total | 27,596 |

(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

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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-Synthelabo 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

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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:

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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)

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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

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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 | % |
| Audit | | | | |
| 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 | |
| Sub-total | 2,921 | 83% | 3,186 | 84% |
| Other services | | | | |
| Legal, tax, employee-related | 548 | | 527 | |
| <i>France</i> | | | 69 | |
| <i>Other countries</i> | 548 | | 458 | |
| Information technology | | | | |
| Internal audit | | | | |
| Other | 43 | | 92 | |
| Sub-total | 591 | 17% | 619 | 16% |
| TOTAL | 3,512 | 100% | 3,805 | 100% |

CONSOLIDATED FINANCIAL STATEMENTS

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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 |
|---|-------------------|----------------------|----------------------|----------------------|
| | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| (in millions of euros) | | | | |
| Intangible assets, net | D.2 | | | |
| Goodwill | | 134 | 141 | 82 |
| Other intangible assets | | 1,161 | 668 | 319 |
| | | <u>1,295</u> | <u>809</u> | <u>401</u> |
| Property, plant and equipment | D.3 | | | |
| Gross | | 1,989 | 1,630 | 1,417 |
| Accumulated depreciation | | (594) | (401) | (200) |
| Net | | <u>1,395</u> | <u>1,229</u> | <u>1,217</u> |
| Long-term investments | | | | |
| 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 |
| | | <u> </u> | <u> </u> | <u> </u> |
| Total fixed assets | | <u>2,899</u> | <u>2,296</u> | <u>2,045</u> |
| 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 |
| | | <u> </u> | <u> </u> | <u> </u> |
| Total assets | | <u>9,459</u> | <u>9,967</u> | <u>7,845</u> |

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 |
|--|------|----------------------|----------------------|----------------------|
| Shareholders equity | 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) |
| Total shareholders equity | | 6,035 | 5,768 | 4,304 |
| Minority interests | | 17 | 21 | 28 |
| 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 |
| Total liabilities and shareholders equity | | 9,459 | 9,967 | 7,845 |

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) |
| Gross profit | | 6,070 | 5,235 | 4,521 |
| 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 |
| Operating profit | D.28 | 2,614 | 2,106 | 1,577 |
| Intangibles amortization and impairment | | (129) | (68) | (35) |
| Financial income/(expense), net | | 85 | 102 | 18 |
| Income before tax and exceptional items | | 2,570 | 2,140 | 1,560 |
| Exceptional items | D.22 | 10 | 281 | 46 |
| Income taxes | D.23 | (746) | (842) | (611) |
| Net income before income from equity investees, goodwill amortization and minority interests | | 1,834 | 1,579 | 995 |
| Income from equity investees, net | | 20 | 14 | 8 |
| Goodwill amortization | | (8) | (7) | (4) |
| Net income before minority interests | | 1,846 | 1,586 | 999 |
| Minority interests | D.24 | (87) | (1) | (14) |
| Net income | | 1,759 | 1,585 | 985 |
| Weighted average shares outstanding | | 727,686,372 | 731,711,225 | 731,232,525 |
| Earnings per share, basic and diluted (in euros) | | 2.42 | 2.17 | 1.35 |
| Net income | | 1,759 | 1,585 | 985 |
| Exceptional items and goodwill amortization, net of income taxes and minority interests | | (1) | (209) | (24) |
| Income before exceptional items and goodwill amortization, net of income taxes and minority interests | | 1,758 | 1,376 | 961 |
| Earnings per share before exceptional items and goodwill amortization, basic and diluted (in euros) | | 2.42 | 1.88 | 1.31 |

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 |
| Operating cash flow before changes in working capital | | 2,260 | 1,732 | 1,295 |
| 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) |
| Net cash provided by operating activities(A) | | 1,676 | 1,818 | 1,199 |
| Acquisitions of property, plant & equipment and intangibles | D.6 | (1,403) | (565) | (372) |
| Acquisitions of investments | | (32) | (54) | (93) |
| Total investments | | (1,435) | (619) | (465) |
| 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) |
| Net cash used in investing activities(B) | | (1,409) | (113) | (389) |
| 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) |
| Net cash used in financing activities(C) | | (1,591) | (483) | (471) |
| Impact of exchange rates on cash and cash equivalents(D) | | (16) | 3 | 1 |
| Net change in cash and cash equivalents(A) + (B) + (C) + (D) | | (1,340) | 1,225 | 340 |
| Cash and cash equivalents, beginning of period | B.10 | 3,805 | 2,580 | 2,240 |
| Cash and cash equivalents, end of period | B.10 | 2,465 | 3,805 | 2,580 |

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 |
|---|---------------------|------------------|---|---|--------------|
| Balance December 31, 1999 | 731,143,218 | 1,462 | 2,131 | (15) | 3,578 |
| 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) |
| Balance, December 31, 2000 | 731,441,746 | 1,463 | 2,871 | (30) | 4,304 |
| 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 |
| Balance, December 31, 2001 | 732,005,084 | 1,464 | 4,321 | (17) | 5,768 |
| 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) |
| Balance, December 31, 2002 | 732,367,507 | 1,465 | 4,730 | (160) | 6,035 |

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-Synthélabo 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

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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-Synthélabo 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[®]/Avapro[®]/Karvea[®]) and the atherothrombosis treatment clopidogrel (Plavix[®]/Iscover[®]).

Sanofi-Synthélabo 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-Synthélabo 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-Synthélabo; and (ii) the rest of the world (excluding Japan), under the operational management of BMS. In Japan, Sanofi-Synthélabo 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[®]/Avapro[®]/Karvea[®]). 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[®]/Iscover[®]). 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:

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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[®], 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[®] is sold by companies controlled jointly with Organon. Sales and expenses relating to Arixtra[®] 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[®] 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[®] 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-Synthélabo 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 |
|---|-----------------------------|
| | <u> </u> |
| Inventories | 11 |
| Accounts receivable | 118 |
| Other current assets | (44) |
| | <u> </u> |
| Total assets | 85 |
| | <u> </u> |
| Shareholders' equity | 1 |
| Accounts payable | 16 |
| Other current liabilities | 68 |
| | <u> </u> |
| Total liabilities and shareholders' equity | 85 |
| | <u> </u> |

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 |
| Total assets | 312 |
| Shareholders' equity | 48 |
| Long-term debt & other long-term liabilities | 14 |
| Accounts payable | 35 |
| Other current liabilities | 103 |
| Short-term debt | 112 |
| Total liabilities and shareholders' equity | 312 |

Amounts related to these divested businesses reflected in the consolidated statements of income are summarized below

| (in millions of euros) | Year ended | Year ended |
|------------------------|------------|------------|
|------------------------|------------|------------|

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| | <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 |
|--|----------------------|----------------------|----------------------|
| Goodwill | 153 | 153 | 86 |
| Trademarks | 53 | 51 | 40 |
| Patents, concessions, licenses and other | 1,282 | 697 | 282 |
| Software | 135 | 103 | 77 |
| Sub-total other intangible assets | 1,470 | 851 | 399 |
| Gross | 1,623 | 1,004 | 485 |
| Amortization and impairment | (328) | (195) | (84) |
| Net | 1,295 | 809 | 401 |

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 |
| Gross | 1,989 | 1,630 | 1,417 |
| Depreciation and impairment | (594) | (401) | (200) |
| Net | 1,395 | 1,229 | 1,217 |

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 |
| Gross | 114 | 116 | 137 |
| Depreciation and impairment | (56) | (51) | (52) |
| Net | 58 | 65 | 85 |

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 |
| Total | 109 | 100 | 86 |

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.

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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 |
| Total | 1,403 | 565 | 372 |

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 |
| Gross | 906 | 860 | 770 |
| Provision | (83) | (55) | (33) |
| Net | 823 | 805 | 737 |

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) | | | |
| Balance, beginning of period | (55) | (33) | (4) |
| 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) |
| Balance, end of period | (83) | (55) | (33) |

D.8. Accounts receivable

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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) |
| Net | 1,311 | 1,566 | 1,234 |

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 |
| Total (net) | 854 | 540 | 553 |

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 |
| Total net deferred tax assets | 474 | 461 | 393 |

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 |

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| | |
|---------------------|-----------|
| 2004 | 6 |
| 2005 | 3 |
| 2006 | 13 |
| 2007 | 19 |
| 2008 and thereafter | 47 |
| Total | 97 |

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> |
|--|------------------|-------------------|--------------------|
| (in millions of euros) | | | |
| 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) |
| Total | <u>59</u> | <u>176</u> | <u>(16)</u> |

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.

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Details of the stock purchase options granted under the Group's various plans are presented below (in Sanofi-Synthelabo 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 |
| Synthelabo | 12/15/93 | 364,000 | 12/15/98 | 12/15/13 | 6.36 | 348,400 |
| Synthelabo | 10/18/94 | 330,200 | 10/18/99 | 10/18/14 | 6.01 | 305,200 |
| Synthelabo | 12/15/94 | 49,400 | 12/15/99 | 12/15/14 | 5.86 | 49,400 |
| Synthelabo | 12/15/95 | 442,000 | 12/15/00 | 12/15/15 | 8.50 | 378,400 |
| Synthelabo | 01/12/96 | 208,000 | 01/12/01 | 01/12/16 | 8.56 | 133,630 |
| Synthelabo | 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 |
| Synthelabo | 10/14/97 | 262,080 | 10/14/02 | 10/14/17 | 19.73 | 49,760 |
| Synthelabo | 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 |
| Synthelabo | 03/30/99 | 716,040 | 03/31/04 | 03/30/19 | 38.08 | |
| Sanofi-Synthelabo | 05/24/00 | 4,292,000 | 05/25/04 | 05/24/10 | 43.25 | |
| Sanofi-Synthelabo | 05/10/01 | 2,936,500 | 05/11/05 | 05/10/11 | 64.50 | |
| Sanofi-Synthelabo | 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 | | |
| | | average per | Aggregate | |
| | | share | (in millions of euros) | |
| | | Number of options | | |
| Outstanding | January 1, 2000 | 6,392,174 | 21.45 | 137 |
| Granted | | 4,292,000 | 43.25 | 186 |
| Exercised | | (499,928) | 9.76 | (5) |
| Expired/Forfeited | | (5,200) | 19.73 | |
| Outstanding | December 31, 2000 | 10,179,046 | 31.21 | 318 |
| Granted | | 2,936,500 | 64.50 | 189 |
| Exercised | | (881,313) | 10.98 | (10) |
| Expired/Forfeited | | (76,260) | 43.71 | (3) |
| Outstanding | December 31, 2001 | 12,157,973 | 40.64 | 494 |
| Granted | | 3,111,850 | 69.94 | 218 |
| Exercised | | (847,018) | 13.27 | (11) |
| Expired/Forfeited | | (71,300) | 36.87 | (3) |
| Outstanding | December 31, 2002 | 14,351,505 | 48.63 | 698 |

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 |
| | | | | | |

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| | | | (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 | |
| Total | 14,351,505 | 7.88 | 48.63 | 3,108,635 | 24.15 | |

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, |
|---------------------------|--------------|--------------|--------------|
| | 2002 | 2001 | 2000 |
| (in millions of euros) | | | |
| Capital lease obligations | 51 | 57 | 65 |
| Other long-term debt | 14 | 62 | 56 |
| Total | 65 | 119 | 121 |

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 |
| Total | 65 | 119 | 121 |

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 |
| Total | 65 | 119 | 121 |
| <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 | |

| | | | |
|--------------|-----------|------------|------------|
| Total | 65 | 119 | 121 |
|--------------|-----------|------------|------------|

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 |

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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 |
| Total | 786 | 1,053 | 1,130 |
| <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

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- 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.

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 |
|---|---------------------------------|---------------------------------|---------------------------------|
| <i>(in millions of euros)</i> | | | |
| Balance, beginning of period | 82 | 149 | 323 |
| Of which | | | |
| 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) |
| Balance, end of period | 27 | 82 | 149 |
| <i>Of which:</i> | | | |