

SANOFI SYNTHELABO SA

Form 20-F

April 02, 2004

Table of Contents

As filed with the Securities and Exchange Commission on April 2, 2004

---

# SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

---

## FORM 20-F

---

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2003

Commission File Number: 001-31368

---

**Sanofi-Synthélabo**

(exact name of registrant as specified in its charter)

N/A

(translation of registrant's name into English)

France

(jurisdiction of incorporation)

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

174, avenue de France, 75013 Paris, France

(address of principal executive offices)

---

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of Securities:</b>	<b>Name of each exchange on which registered:</b>
American Depositary Shares, each representing one-half of one ordinary share, nominal value 2 per share	New York Stock Exchange
Ordinary shares, nominal value 2 per share	New York Stock Exchange (for listing purposes only)

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:**

None

**The number of outstanding shares of each of the issuer's classes of capital or**

**common stock as of December 31, 2003 was:**

ordinary shares: 732,848,072

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17    Item 18



**Table of Contents**


---

**TABLE OF CONTENTS**


---

<b>Part I</b>		3
Item 1.	<u>Identity of Directors, Senior Management and Advisers</u>	3
Item 2.	<u>Offer Statistics and Expected Timetable</u>	3
Item 3.	<u>Key Information</u>	4
	<u>A. Selected Financial Data</u>	4
	<u>B. Capitalization and Indebtedness</u>	9
	<u>C. Reasons for Offer and Use of Proceeds</u>	9
	<u>D. Risk Factors</u>	10
Item 4.	<u>Information on the Company</u>	21
	<u>A. History and Development of the Company</u>	21
	<u>B. Business Overview</u>	22
	<u>C. Organizational Structure</u>	52
	<u>D. Property, Plants and Equipment</u>	52
Item 5.	<u>Operating and Financial Review and Prospects</u>	56
Item 6.	<u>Directors, Senior Management and Employees</u>	85
	<u>A. Directors and Senior Management</u>	85
	<u>B. Compensation</u>	90
	<u>C. Board Practices</u>	92
	<u>D. Employees</u>	93
	<u>E. Share Ownership</u>	95
Item 7.	<u>Major Shareholders and Related Party Transactions</u>	97
	<u>A. Major Shareholders</u>	97
	<u>B. Related Party Transactions</u>	99
	<u>C. Interests of Experts and Counsel</u>	99
Item 8.	<u>Financial Information</u>	100
	<u>A. Consolidated Statements and Other Financial Information</u>	100
	<u>B. Significant Changes</u>	101
Item 9.	<u>The Offer and Listing</u>	106
	<u>A. Offer and Listing Details</u>	106
	<u>B. Plan of Distribution</u>	107
	<u>C. Markets</u>	107
	<u>D. Selling Shareholders</u>	108
	<u>E. Dilution</u>	108
	<u>F. Expenses of the Issue</u>	108
Item 10.	<u>Additional Information</u>	109
	<u>A. Share Capital</u>	109
	<u>B. Memorandum and Articles of Association</u>	111
	<u>C. Material Contracts</u>	123
	<u>D. Exchange Controls</u>	123
	<u>E. Taxation</u>	123
	<u>F. Dividends and Paying Agents</u>	129
	<u>G. Statement by Experts</u>	129
	<u>H. Documents on Display</u>	129
	<u>I. Subsidiary Information</u>	129
Item 11.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	130
Item 12.	<u>Description of Securities other than Equity Securities</u>	134

**Table of Contents**

**Part II**

Item 13.	<u>Defaults, Dividend Arrearages and Delinquencies</u>	140
Item 14.	<u>Material Modifications to the Rights of Security Holders and Use of Proceeds</u>	140
Item 15.	<u>Controls and Procedures</u>	140
Item 16.A.	<u>Audit Committee Financial Expert</u>	140
Item 16.B.	<u>Code of Ethics</u>	140
Item 16.C.	<u>Principal Accountant Fees and Services</u>	140
Item 16.D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	141

**Part III**

Item 17.	<u>Financial Statements</u>	142
Item 18.	<u>Financial Statements</u>	142
Item 19.	<u>Exhibits</u>	142

**Table of Contents**

**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

Not applicable.

**Item 2. Offer Statistics and Expected Timetable**

Not applicable.

## **Table of Contents**

### **Item 3. Key Information**

#### **A. Selected Financial Data**

##### **Introduction**

Our company is the result of the 1999 merger of two French companies, Sanofi and Synthélabo. While we have prepared consolidated financial statements for 2000, 2001, 2002 and 2003 and a consolidated balance sheet as of December 31, 1999, we did not prepare a consolidated statement of income or statement of cash flows for 1999, the year of the merger. Instead, each of Sanofi and Synthélabo prepared consolidated statements of income and cash flows for the first half of 1999, and we prepared consolidated statements of income and cash flows for the second half of 1999. We have presented those statements of income and cash flows below, but they do not provide information that is comparable to the information in our 2000, 2001, 2002 and 2003 statements of income and cash flows.

We have also prepared a pro forma income statement for the year ended December 31, 1999, based on the assumption that the merger of Sanofi and Synthélabo occurred on January 1, 1999 and that the sale of Sanofi's beauty division occurred on December 31, 1998. The pro forma income statement data was prepared under French accounting rules applicable to pro forma financial information, and not in accordance with the regulations of the Securities and Exchange Commission applicable to pro forma financial statements. We have included certain data from the pro forma information below in order to reflect trends in our business during the period from 1999 to 2003. The methodology used to calculate our pro forma financial information is described in our registration statement on Form 20-F dated June 25, 2002 (SEC File No. 001-31368).

Our consolidated financial statements and those of our predecessor companies have been prepared in accordance with French generally accepted accounting principles, or French GAAP, and applicable French laws, which differ in certain significant respects from generally accepted accounting principles in the United States, or U.S. GAAP. These differences include, among other things:

- the treatment of the merger under U.S. GAAP as a purchase of Synthélabo by Sanofi and related subsequent accounting consequences;
- the treatment of certain provisions for restructuring;
- the treatment of stock options granted to employees at fair value;
- revenue recognition of a U.S. alliance under the operational management of Bristol-Myers Squibb; and
- the deferred income tax effect of our U.S. GAAP adjustments.

We have reconciled our net income and shareholders' equity to U.S. GAAP. Note F to our consolidated financial statements sets out the details of the reconciliation.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Unless otherwise indicated, U.S. dollar amounts in this annual report are translated using the December 31, 2003 Noon Buying Rate (as defined under Exchange Rate Information below) of \$1.00 = 0.79384.



**Table of Contents**

**Selected Financial Data**

The selected financial data set forth below have been derived from:

our audited consolidated financial statements as of and for the years ended December 31, 2000, 2001, 2002 and 2003;

our audited consolidated statement of income for the second half of 1999;

our unaudited pro forma statement of income for the year ended December 31, 1999;

the audited consolidated financial statements of Sanofi for the six months ended June 30, 1999; and

the audited consolidated financial statements of Synthelabo for the six months ended June 30, 1999 (gross profit and operating profit data are unaudited as they are derived from management accounts and reflect classification differences to conform to the presentation of selected financial data for Sanofi for such periods).

The data derived from our pro forma statement of income are presented for illustration only, and do not necessarily reflect the actual results that would have been realized had Sanofi and Synthelabo operated on a combined basis for all of 1999. Due to the merger, the selected financial data for Sanofi and Synthelabo, as well as our selected financial data for the second half of 1999, are not comparable to our selected financial data for 2000, 2001, 2002 and 2003.

The first table below presents selected financial data for our company for the second half of 1999, and all of 2000, 2001, 2002 and 2003, as well as selected pro forma financial data for 1999. The second table presents selected financial data for Sanofi and Synthelabo for the first half of 1999.

**Table of Contents**

	Six months ended		As of and for the year ended December 31,				
	December 31,						
	1999	1999 (pro forma unaudited)	2000	2001	2002	2003	2003 U.S. \$
	(millions of \$, except per share data)						
<b>Income statement data:</b>							
<i>French GAAP</i>							
Net sales	2,658	5,350	5,963	6,488	7,448	8,048	10,138
Gross profit	1,889	3,744	4,521	5,235	6,070	6,620	8,339
Operating profit	531	971	1,577	2,106	2,614	3,075	3,874
Net income	342	625	985	1,585	1,759	2,076	2,615
Earnings per share (basic <sup>(a)</sup> and diluted)	0.47	0.85	1.35	2.17	2.42	2.95	3.72
<b>Balance sheet data:<sup>(b)</sup></b>							
<i>French GAAP</i>							
Property, plant and equipment, net	1,143		1,217	1,229	1,395	1,449	1,825
Total assets	6,824		7,845	9,967	9,459	9,749	12,281
Long-term debt	137		121	119	65	53	67
Total shareholders' equity	3,578		4,304	5,768	6,035	6,323	7,965
<b>U.S. GAAP Data:<sup>(c)</sup></b>							
<i>French GAAP Net income</i>			985	1,585	1,759	2,076	2,615
Purchase accounting adjustments			(606)	(445)	(311)	(269)	(339)
Provisions and other liabilities			(99)	(23)			
Stock-based compensation <sup>(d)</sup>			(5)	(8)	(8)	(50)	(63)
Revenue recognition - U.S. BMS alliance			(8)	(136)	117	33	41
Other			104	(42)	31	(16)	(20)
Income tax effects			221	167	52	91	115
<i>U.S. GAAP Net income</i>			592	1,098	1,640	1,865	2,349
<i>French GAAP Shareholders' equity</i>			4,304	5,768	6,035	6,323	7,965
Purchase accounting adjustments			9,479	8,927	8,576	8,267	10,414
Provisions and other liabilities			110	35			
Revenue recognition - U.S. BMS alliance			(21)	(160)	(35)		
Other			(168)	(456)	(695)	(635)	(800)
Income tax effects			(1,563)	(1,365)	(1,282)	(1,219)	(1,536)
<i>U.S. GAAP Shareholders' equity</i>			12,141	12,749	12,599	12,736	16,043
<b>U.S. GAAP Earnings per share</b>							
basic <sup>(d)</sup>			0.82	1.52	2.30	2.71	3.41
diluted <sup>(e)</sup>			0.82	1.51	2.28	2.70	3.40

(a) Based on the weighted average number of shares outstanding in each year, equal to 731,232,525 shares in 2000, 731,711,225 shares in 2001, 727,686,372 shares in 2002 and 702,745,208 shares in 2003. Each ADS represents one-half of one share. For 1999, the weighted average number of shares for the six months ended December 31, 1999 was 731,011,354, and for the full year (pro forma) it was equal to 730,783,868 shares.

(b) As discussed in Note B.2 to our consolidated financial statements included under Item 18, we changed our method of accounting for liabilities as of January 1, 2002. The impact of this change on shareholders' equity was \$24 million.

(c) As discussed in Note G.3.1 to our consolidated financial statements included under Item 18, we applied Statement of Financial Accounting Standard 142, Goodwill and Other Intangible Assets, as of January 1, 2002.

(d) Based on the weighted average number of shares outstanding in each year used to compute basic earnings per share, equal to 723,095,521 shares in 2000, 720,726,645 shares in 2001, 714,322,379 shares in 2002 and 689,018,905 shares in 2003.

(e) Based on the weighted average number of shares outstanding in each year used to compute diluted earnings per share, equal to 726,783,765 shares in 2000, 725,665,764 shares in 2001, 718,041,806 shares in 2002 and 691,120,198 shares in 2003.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

- (f) As discussed in Note G.1.C to our consolidated financial statements included under Item 18, we voluntarily adopted the fair value recognition provisions of Statement of Accounting Standards 123, Accounting for Stock-Based Compensation, as of January 1, 2003.

**Table of Contents**

	<u>Sanofi</u>	<u>Synthélabo</u>
	<u>Six months</u>	<u>Six months</u>
	<u>ended</u>	<u>ended</u>
	<u>June 30, 1999</u>	<u>June 30, 1999</u>
	<i>(unaudited)<sup>(b)</sup></i>	
	<i>(millions of \$, except</i>	
	<i>per share data)</i>	
<b>Income statement data:</b>		
<i>French GAAP</i>		
Net sales	1,880	995
Gross profit	1,264	734
Operating profit	272	180
Net income	146	109
Earnings per share (basic and diluted) <sup>(a)</sup>	0.30	2.26
<b>Balance sheet data:</b>		
<i>French GAAP</i>		
Property, plant and equipment, net	753	281
Total assets	6,197	2,021
Long-term debt	39	58
Total shareholders' equity	4,331	1,155

(a) Due to the merger, per share data for Sanofi and Synthélabo are not meaningful.

(b) Gross profit and operating profit data are unaudited. All other data is audited.

**Table of Contents****DIVIDENDS**

We paid annual dividends for the years ended December 31, 1999, 2000, 2001 and 2002 and our shareholders will be asked to approve the payment of dividends for the year 2003 at our next annual shareholders meeting. If approved, this dividend will be paid on June 3, 2004. However, if we have reason to believe that our offers to acquire Aventis may not close by that date, our board of directors will arrange for an interim dividend of 0.97 per share to be paid, with the balance to be paid after the offers close. We expect that we will continue to pay regular dividends based on our financial condition and results of operations.

The following table sets forth information with respect to the dividends paid by our company in respect of the years 1999, 2000, 2001 and 2002 and the dividend that will be proposed for approval by our shareholders in regards to the year ended in 2003 at our May 24, 2004 shareholders meeting.

	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003<sup>(1)</sup></u>
<b>Net Dividend per Share (in €)</b>	0.32	0.44	0.66	0.84	1.02
<b>Net Dividend per Share (in U.S. \$)</b>	0.28	0.39	0.59	0.88	1.28

(1) Proposal, subject to shareholder approval.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our board of directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting where they are approved. The shares registered hereby are eligible for all dividends (if any) declared and approved.

In France, dividends are paid out of after-tax income. French residents were formerly entitled to a tax credit, known as the *avoir fiscal*, in respect of dividends received from French companies. However, the French Finance Law for 2004 includes a reform of the French tax treatment of distributions that involves the implementation of a new mechanism to avoid double taxation of dividends and the elimination of the former *avoir fiscal* and *précompte* mechanisms as explained in Item 10 Additional Information Taxation. French resident individual shareholders will still benefit from the *avoir fiscal* with respect to dividend distributions made in 2004 but will no longer be entitled to any such tax credit with respect to dividend distributions made as from 2005, as a consequence of the implementation of a new taxation system. French resident corporate shareholders will lose the benefit of the *avoir fiscal* for tax credits that they would otherwise have been able to use as from January 1, 2005. Dividends paid to non-residents normally are subject to a 25% French withholding tax and are not eligible for the benefit of the *avoir fiscal*. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate of withholding tax and entitled to certain other benefits. See Item 10 Additional Information Taxation. The information in the table above represents the net dividend paid, without regard to the *avoir fiscal*.

**Table of Contents****EXCHANGE RATE INFORMATION****Exchange Rates**

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 1999 through March 31, 2004, expressed in U.S. dollar per euro. The information concerning the U.S. dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into U.S. dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5 Operating and Financial Review and Prospects.

	Period-end	Average		
	Rate	Rate <sup>(1)</sup>	High	Low
	<i>(U.S. dollar per euro)</i>			
1999	1.01	1.06	1.18	1.00
2000	0.94	0.92	1.03	0.83
2001	0.89	0.89	0.95	0.84
2002	1.05	0.95	1.05	0.86
2003	1.26	1.14	1.26	1.04
2004 (through March 31, 2004)	1.21	1.23	1.29	1.21
2003				
September	1.17	1.13	1.17	1.08
October	1.16	1.17	1.18	1.16
November	1.20	1.17	1.20	1.14
December	1.26	1.23	1.26	1.20
2004				
January	1.25	1.26	1.29	1.24
February	1.24	1.26	1.28	1.24
March	1.21	1.22	1.24	1.21

(1) The average of the Noon Buying Rates on the last business day of each month (or portion thereof) during the relevant period for year average; on each business day of the month (or portion thereof) for monthly average. On March 31, 2004, the Noon Buying Rate was \$1 = .81 (\$1.23 per 1).

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.



## **Table of Contents**

### **D. Risk Factors**

#### **Risks Relating to Proposed Acquisition of Aventis**

As of the date of this annual report, we have open three separate offers, on substantially similar terms, pursuant to which we are offering to acquire all the ordinary shares, nominal value 3.82 per share, of Aventis, including Aventis ordinary shares represented by American depositary shares, or ADSs. For further information on the terms and conditions of these offers, see Item 8 Financial Information Significant Changes of this annual report. As of the date of this annual report, we do not know whether the offers will be successful. There are a number of risks to our shareholders associated with the offers, the most significant of which we describe in this section. Any of these risks could have an adverse effect on our business, financial condition, results of operations or prospects, which could in turn affect the price of our shares or our ADSs.

*If the offers are not successful, the failure to complete the acquisition of Aventis could have an adverse effect on our share price, investor relations and employee morale.*

Our offers for the Aventis securities are subject to the conditions that Aventis securities representing at least 50% of the total share capital and voting rights in Aventis, calculated on a fully diluted basis, plus one Aventis ordinary share have been tendered into the offer, that the applicable waiting period under the U.S. Hart-Scott-Rodino Act of 1976, or HSR Act, shall have expired or been terminated and no order has been entered prohibiting the transaction, and that our shareholders shall have approved the issuance of the additional shares to be issued on completion of the offer. In addition, because our offers are subject to an antitrust condition, under applicable French regulations, the French offer will lapse as soon as the U.S. Federal Trade Commission issues a second request for information before the expiration of the HSR Act waiting period. If the French offer lapses for this reason, we will withdraw the U.S. offer and the German offer. There is a risk that we may not be successful in completing the offers because of the failure to satisfy these conditions. If the offers are not successful, the failure to complete the acquisition of Aventis could have an adverse effect on our share price, investor relations and employee morale. Moreover, if the offers are not successful, we will have incurred costs in connection with the offers without realizing the benefits that we expected to gain upon completion of the offers.

*The integration of the companies will present significant challenges that may result in the combined business not operating as effectively as expected or in the failure to achieve some or all of the anticipated benefits of the transaction.*

The benefits and synergies expected to result from the offers will depend in part on whether our operations and those of Aventis can be integrated in a timely and efficient manner. We will face significant challenges in consolidating our functions with those of Aventis, and integrating the organizations, procedures and operations of the two businesses. The integration of our company and Aventis will be complex and time-consuming, and the managements of both companies will have to dedicate substantial time and resources to it. These efforts could divert management's focus and resources from other strategic opportunities and from day-to-day operational matters during the integration process. Failure to successfully integrate the operations of our company and Aventis could result in the failure to achieve some or all of the anticipated benefits of the transaction, including synergies and other operating efficiencies, and could have an adverse effect on the business, results of operations, financial condition or prospects of our company after the transaction.

*Even if we consummate the offers, there may be a delay before we can obtain control of the management of Aventis.*



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In order for us to control the management of Aventis following successful completion of the offers, we will need to take control of the supervisory board (*conseil de surveillance*) and the management board (*directoire*) of

---

**Table of Contents**

Aventis. Pursuant to Article L. 225-103, II, 4 of the French Commercial Code, if we gain control of Aventis pursuant to the offers, we may request the management board (*directoire*) of Aventis to convene a meeting of shareholders with an agenda that, among other things, will provide for the election of a new supervisory board (*conseil de surveillance*) and, if necessary, the dismissal of the existing management board (*directoire*) of Aventis. Under French law, the supervisory board (*conseil de surveillance*) could then appoint a new management board (*directoire*). If the management board refuses to convene such a shareholders meeting, we are permitted, after a reasonable delay and the notice mentioned above to Aventis management board (*directoire*), to convene a meeting for the election of the supervisory board (*conseil de surveillance*). In any event, shareholders meetings may be held no sooner than 30 days after the publication of a notice announcing the meeting in the *Bulletin des Annonces Légales Obligatoires*, or BALO, the French official legal gazette.

***Compliance with conditions and obligations imposed in connection with regulatory approvals could adversely affect our business and the business of Aventis.***

Our proposed acquisition of the Aventis securities will be reviewed by and require regulatory approvals from the European Commission, any member state of the European Union that has successfully sought jurisdiction to review the offers under its national competition law and the U.S. antitrust authorities. In order to obtain these regulatory approvals, we may have to divest, or commit to divesting, to third parties certain of our businesses or products and/or the business or products of Aventis. In the alternative or in addition, in order to obtain the necessary regulatory approvals, we may have to make other commitments to the European Commission and/or the U.S. antitrust authorities. These divestitures and other commitments, if any, may have an adverse effect on our business, results of operations, financial condition or prospects after the transaction. Further, if we do not complete any required divestiture, or provide commitments satisfactory to the U.S. Federal Trade Commission, or FTC, with respect to such a divestiture, before the expiration of the initial thirty-day waiting period under the HSR Act, the FTC may issue a second request in order to extend the waiting period. Because the offers are subject to an anti-trust condition, under applicable French regulations, the French offer will lapse (*est caduque*, meaning it is null and void) as soon as the FTC issues a second request. If the French offer lapses for this reason, we will withdraw the U.S. offer and the German offer.

In addition, if the European Commission initiates a Phase II investigation and we close the offers while such investigation is ongoing (as the procedure for antitrust review by the European Commission permits), until completion of the Phase II investigation, we may not be able to exercise the voting rights of the Aventis ordinary shares that we acquire pursuant to the offers or may only be able to exercise those voting rights to maintain the full value of the Aventis ordinary shares acquired. In such case, we may be delayed from implementing the current plans that we have for Aventis after the successful completion of the offers, and we may not be able to realize some or all of the anticipated benefits from the transaction, including synergies and other operating efficiencies, on the timetable that we currently expect.

Jurisdictions throughout the world claim jurisdiction under their competition or antitrust laws in respect of acquisitions or mergers that have the potential to affect their domestic marketplace. A number of these jurisdictions may claim to have jurisdiction to review the transaction. Such investigations or proceedings may be initiated and, if initiated, may have an adverse effect on our business, results of operations, financial condition or prospects after the transaction.

***If the offers are successful, we will incur a substantial amount of debt to finance the cash portion of the consideration for the Aventis securities to be acquired, which debt could restrict our ability to engage in additional transactions or incur additional indebtedness.***

In connection with our proposed acquisition of the Aventis securities, on January 25, 2004, we entered into a credit facility agreement that permits us to borrow up to 12,000 million. We may only borrow amounts under this credit facility if our offers for the Aventis securities are successful. If the offers are successful, we expect to borrow a substantial amount under this credit facility, which we will use mainly to finance the cash portion of the consideration to be paid to holders of Aventis securities pursuant to the offers and to refinance certain debt of



## **Table of Contents**

Aventis and its subsidiaries. The credit facility includes terms and conditions customary for agreements of this type, which could restrict our ability to engage in additional transactions or incur additional indebtedness. For additional information regarding the 12,000 million credit facility, see Item 5 Operating and Financial Review and Prospects Liquidity and Capital Resources and Item 8 Financial Information Significant Changes Proposed Acquisition of Aventis The 12,000 Million Credit Facility of this annual report.

***We have not been given the opportunity to conduct a due diligence review of the non-public records of Aventis. Therefore, we may be subject to unknown liabilities of Aventis, which may have an adverse effect on our profitability and results of operations.***

In commencing the offers and determining their terms and conditions, we have relied solely and exclusively upon publicly available information relating to Aventis, including periodic and other reports for Aventis as filed with or furnished to the Securities and Exchange Commission on Form 20-F and Form 6-K, as well as Aventis' 2003 *document de référence*, as filed with the AMF. We have not conducted an independent due diligence review of, nor had access to, any non-public information about Aventis. As a result, after the consummation of our offers, we may be subject to unknown liabilities of Aventis, which may have an adverse effect on our profitability, results of operations and financial position, which we might have otherwise discovered if we had been permitted by Aventis to conduct a complete due diligence review.

***Consummation of the offers may result in adverse tax consequences to us resulting from a change of ownership of Aventis.***

We have not had access to information concerning Aventis' tax situation. It is possible that the consummation of the offers may result in adverse tax consequences arising from a change of ownership of Aventis. The tax consequences of a change of ownership of a corporation can lead to an inability to carry-over certain tax attributes, including, but not limited to, tax losses, tax credits and/or tax basis of assets. In addition, the change of ownership may result in other tax costs not normally associated with the ordinary course of business. Such other tax costs include, but are not limited to, stamp duties, land transfer taxes, franchise taxes and other levies. The fact that we are unaware of information relevant to a determination of the potential tax consequences and related costs represents an additional transaction risk.

***Change of control provisions in Aventis' agreements may be triggered upon our acquisition of control of Aventis and may lead to adverse consequences for us, including the loss of significant contractual rights and benefits, the termination of joint venture and/or licensing agreements or the need to renegotiate financing agreements.***

Aventis may be a party to joint ventures, licenses and other agreements and instruments that contain change of control provisions that may be triggered when we acquire control of Aventis upon the completion of the offers. Aventis has not provided us with copies of any of the agreements to which it is party and these types of agreement are not generally publicly available. Agreements with change of control provisions typically provide for, or permit the termination of, the agreement upon the occurrence of a change of control of one of the parties or, in the case of debt instruments, require repayment of all outstanding indebtedness. These provisions, if any, may be waived with the consent of the other party and we will consider whether we will seek these waivers. In the absence of these waivers, the operation of the change of control provisions, if any, could result in the loss of significant contractual rights and benefits, the termination of joint venture agreements and licensing agreements or require the renegotiation of financing agreements.

In addition, employment agreements with members of the Aventis senior management and other Aventis employees may contain change of control clauses providing for compensation to be paid in the event the employment of these employees is terminated, either by Aventis or by those employees, following the consummation of the offers. These payments, if triggered, could be substantial and could adversely affect our results of operations in the period they become payable.



## **Table of Contents**

*If the offers for Aventis securities are successful, but some Aventis securities remain outstanding, the existence of minority interests in Aventis following the offers may limit our ability to integrate and manage the assets and operations of the combined businesses and therefore reduce benefits that we could otherwise achieve.*

The existence of minority interests in Aventis after the completion of the offers could impede the integration of our operations with those of Aventis and thereby make it more difficult to achieve the cost savings and other operating efficiencies or to realize the revenue and earnings growth that might otherwise be possible.

## **Risks Relating to Our Company**

*We may not be able to continue to expand our presence profitably in the United States, a market that is a key to our growth strategy, and where we are investing substantial resources.*

We may not achieve our growth strategy if we do not continue to profitably expand our presence in the United States, the world's largest pharmaceuticals market. We have identified the United States, which accounted for 23.8% of our consolidated sales in 2003, as a potential major source of continued future growth and plan to continue to expand significantly our direct presence in the United States in the coming years. We face a number of challenges to profitable growth in the United States, including:

The success of the new management organization that we have established in the United States.

The targeting of new markets.

The fact that the United States market is dominated by major U.S. pharmaceutical companies.

Potential changes in health care reimbursement policies and possible cost control regulations in the United States, such as Medicare reform.

*We depend on third parties for the marketing of some of our products outside Europe. These third parties may act in ways that could harm our business.*

We commercialize some of our products outside Europe in collaboration with other pharmaceutical companies. We currently have a major collaborative arrangement with Bristol-Myers Squibb for the marketing of Plavix® and Aprovel®. We also have alliances with several Japanese companies for the marketing of our products in Japan. See Item 4 Information on the Company Business Overview Marketing and Distribution. When we commercialize our products through collaboration arrangements, we are subject to the risks that certain decisions, such as the establishment of budgets and promotion strategies, are subject to the control of our collaboration partners, and that deadlocks may adversely affect the activities conducted through the collaboration arrangements. For example, our alliances with Bristol-Myers Squibb are subject to the operational management of Bristol-Myers Squibb in some countries, including the United States. We cannot be certain that our partners will perform their obligations as expected. Further, our partners might pursue their own existing or alternative technologies or product candidates in preference to those being developed or marketed in collaboration with us.

***We depend on third parties for the manufacturing of the active ingredients for some of our products, including Stilnox<sup>®</sup>, Eloxatin<sup>®</sup> and Xatral<sup>®</sup>, three of our strategic products.***

Although our general policy is to manufacture the active ingredients for our products ourselves, we subcontract the manufacture of some of our active ingredients to third parties, which exposes us to the risk of a supply interruption in the event that our suppliers experience financial difficulties or are unable to manufacture a sufficient supply of our products. The manufacture of the active ingredients for Stilnox<sup>®</sup>, Eloxatin<sup>®</sup> and Xatral<sup>®</sup>, which are three of our strategic products, is currently done by third parties. See Item 4 Information on the Company Business Overview Production and Raw Materials for a description of these outsourcing

## **Table of Contents**

arrangements. Although we have not experienced any problems in the past, if disruptions were to arise from problems with our manufacturers, this would impact our ability to sell our products in the quantities demanded by the market, and could damage our reputation and relationships with our customers. Even though we try to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at a second or third facility when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable.

***Our collaborations with third parties expose us to risks that they will assert intellectual property rights on our inventions or fail to keep our unpatented technology confidential.***

We occasionally provide information and materials to research collaborators in academic institutions or other public or private entities, or request them to conduct tests to investigate certain materials. In all cases we enter into appropriate confidentiality agreements with such entities. However, those entities might assert intellectual property rights with regard to the results of the tests conducted by their collaborators, and might not grant licenses to us regarding their intellectual property rights on acceptable terms.

We also rely upon unpatented proprietary technology, processes, know-how and data that we regard as trade secrets and protect them in part by entering into confidentiality agreements with our employees, consultants and certain contractors. We cannot be sure that these agreements or other trade secret protection will provide meaningful protection, or if they are breached, that we will have adequate remedies. You should read Item 4 Information on the Company Business Overview Patents and Intellectual Property Rights for more information about our patents and licenses.

***We have two principal shareholders who continue to maintain a significant degree of influence and who will continue to own a significant percentage of our enlarged share capital and voting rights immediately after the offers are completed.***

Our two principal shareholders, Total and L. Oréal, owned 24.4% and 19.5% of our share capital, respectively, as of December 31, 2003. Our bylaws provide that our fully paid up shares that have been held in registered form for at least two years under the name of the same shareholder acquire double voting rights. As a result, as of December 31, 2003, Total and L. Oréal held shares representing 35.0% and 28.1%, respectively, of our voting rights, and are in a position to exert significant influence in the election of our directors and officers and other corporate actions that require shareholder approval.

Even if all of the Aventis securities are validly tendered and exchanged pursuant to the terms of the U.S. offer, the French offer and the German offer, immediately after the exchange, Total and L. Oréal will own, on a diluted basis and taking into account all in-the-money options that are exercisable as of the expected closing date, approximately 13.2% and approximately 10.6%, respectively, of the share capital (other than share capital held by us) and approximately 21.1% and approximately 16.9%, respectively, of our voting rights. Under the terms of a shareholders agreement, Total and L. Oréal have agreed to act in concert with respect to their shareholdings in our company and to certain restrictions on the transfer of their ordinary shares. On November 24, 2003, Total and L. Oréal amended the shareholders agreement so that it terminates on December 2, 2004 according to its terms, the parties having indicated that they do not intend to act in concert with respect to their shareholdings in our company as from that date. See Item 7 Major Shareholders and Related Party Transactions Major Shareholders Shareholders Agreement.

To the extent these shareholders maintain such level of shareholding, and particularly if they act in concert, after the exchange Total and L. Oréal will remain in a position to exert heightened influence in the election of our directors and officers and in other corporate actions that require shareholders approval. Continued ownership of a large percentage of our share capital and voting rights by these two principal shareholders, who are also members of our board of directors, particularly if they act in concert, may have the effect of delaying, deferring or preventing a future



change in our control and may discourage future bids for our shares other than with the support of these shareholders.

## **Table of Contents**

*Fluctuations in currency exchange rates could adversely affect our financial condition and results of operations.*

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar and, to a lesser extent, certain currencies in Latin America. In 2003, approximately 23.8% of our consolidated sales were realized in the United States (the United States also represented 45.4% of our 2003 operating profit excluding unallocated costs). While we incur expenses in those currencies, the impact of these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. For example, in 2003, our operating income grew by 17.6% compared to 2002. However, at 2002 exchange rates, our operating income would have grown by 34.4%. When deemed appropriate, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations. For more information concerning our exchange rate exposure, see Item 11 Quantitative and Qualitative Disclosures About Market Risk.

## **Risks Relating to Our Industry**

**We invest substantial sums in research and development in order to remain competitive, and we may not recover these sums if our products are unsuccessful in clinical trials or fail to receive regulatory approval.**

*We need to invest heavily in research and development to remain competitive.*

To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products. Even if our research and development efforts are fruitful, our competitors may develop more effective products or a greater number of successful new products. In 2003, we spent 1,316 million on research and development, amounting to approximately 16.4% of our consolidated net sales. Our ongoing investments in new product launches and research and development for future products could produce higher costs without a proportionate increase in revenues.

*The research and development process is lengthy and carries a substantial risk of product failure.*

The research and development process typically takes from 10 to 15 years from discovery to commercial product launch. This process is conducted in various stages, and during each stage there is a substantial risk that we will not achieve our goals and will have to abandon a product in which we have invested substantial amounts. For example, in order to develop a commercially viable product, we must demonstrate, through extensive pre-clinical and human clinical trials, that the pharmacological compounds are safe and effective for use in humans. There is also no assurance that favorable results obtained in pre-clinical trials will be confirmed by later clinical trials, or that the clinical trials will establish sufficient safety and efficacy data necessary for regulatory approval. As of February 16, 2004, we had 56 compounds in pre-clinical and clinical development in our four targeted therapeutic areas, of which 25 were in phase II or phase III clinical trials. For additional information regarding clinical trials and the definition of the phases of clinical trials, see Item 4 Information on the Company Business Overview Research and Development. There can be no guarantee that any of these compounds will be proven safe or effective, or that they will produce commercially successful products.

*After completing the research and development process, we must invest substantial additional resources seeking to obtain government approval in multiple jurisdictions, with no guarantee that approval will be obtained.*

We must obtain and maintain regulatory approval for our pharmaceutical products from the European Union, the United States and other regulatory authorities before a given product may be sold in its markets and thereafter. The submission of an application to a regulatory authority does not guarantee that it will grant a license to market the product. Each authority may impose its own requirements, including requiring local studies, and may delay or refuse to grant approval, even though a product has already been approved in another country.

## Table of Contents

In our principal markets, the approval process for one or more indications of a new product is complex and lengthy, and typically takes from six months to two years from the date of application depending on the country. Moreover, if regulatory approval of a product is granted, the approval may place limitations on the indicated uses for which it may be marketed. A marketed product is also subject to continual review even after regulatory approval. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in marketing restrictions or withdrawal of the product, as well as possible legal sanctions. In addition, we are subject to strict government controls on the manufacture, labeling, distribution and marketing of our products. Each of these factors can increase our costs of developing new products and the risk that we will not succeed in selling them successfully.

*If we are unable to protect our proprietary rights, we may not compete effectively or operate profitably.*

It is important for our success that we be able effectively to obtain, maintain and enforce our patents and other proprietary rights. Patent law relating to the scope of claims in the pharmaceutical field in which we operate is a continually evolving field of law and can be subject to some uncertainty. Accordingly, we cannot be sure that:

new, additional inventions will be patentable,

patents for which applications are now pending will be issued to us, or

the scope of any patent protection will be sufficiently broad to exclude competitors.

Additionally, third parties may challenge the validity of the patents issued or licensed to us, which may result in the invalidation of these rights. We currently have approximately 9,800 patents and patent applications worldwide, and we license-in approximately 30 additional patents. We cannot be sure how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court or in other proceedings.

In the first half of 2002, two pharmaceutical companies, Apotex and Dr. Reddy's Laboratories, each filed an Abbreviated New Drug Application, or ANDA, with the U.S. Food and Drug Administration, or FDA, seeking to market a generic form of Plavix® in the United States and challenging certain U.S. patents relating to Plavix®. In March 2003, Apotex instituted a similar challenge in Canada. For additional information regarding ANDAs, see Item 4 Information on the Company Business Overview Regulation. We have filed suit against Apotex and against Dr. Reddy's Laboratories for infringement of our patent rights. See Item 8 Financial Information Legal Proceedings. The ~~P~~atent rights are material to our company's business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of a generic prescription version of Plavix® in the U.S. would reduce the price that we receive for this product and the volume of the product that we would be able to sell.

In recent years, governments faced with national crises have used pressure to obtain substantial concessions from pharmaceutical companies, including threatening compulsory licensing of products that they consider essential. While we support the efforts of national governments to combat major health care crises, if those efforts come at the expense of effective patent protection, the ability of our company and other pharmaceutical manufacturers to recover amounts spent on research and development will be adversely affected. In such event, we and other manufacturers might curtail our research and development expenditures, and as a result might not develop as many new products.

*Our patents may be infringed, or we may infringe the patents of others.*

Our competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement, we may file infringement claims, which are expensive and time consuming. Policing unauthorized use of our intellectual property is difficult, and we may not be able to prevent misappropriation of our proprietary rights. This risk is increased by the growth in the number of patent applications filed and patents granted in the pharmaceutical industry.

## **Table of Contents**

### ***Product liability claims could adversely affect our business and results of operations.***

Product liability is a significant commercial risk for us, and could become a more significant risk as we expand in the United States (where product liability claims can be particularly costly). Substantial damage awards have been made in certain jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, some pharmaceutical companies have recently withdrawn products from the market in the wake of significant product liability claims. Although we are not currently involved in any significant product liability cases claiming damages as a result of the use of our products, it is possible that such cases will be brought in the future. Further, there is a general trend in the insurance industry to exclude certain products from coverage and to reduce insured limits for liabilities arising through joint ventures. Although we maintain insurance to cover this risk, we cannot be certain that our insurance will be sufficient to cover all potential liabilities.

### ***We face uncertainties over pricing of pharmaceutical products.***

The commercial success of our products depends in part on the extent to which the cost of our products is reimbursed. Price pressure is strong due to:

a tendency of governments and private health care providers to favor generic pharmaceuticals;

price controls imposed by governments in many countries; and

parallel imports, in particular in the European Economic Area, a practice by which traders exploit price differentials among markets by purchasing in lower-priced markets for resale in higher-priced markets.

Price pressure is considerable in our two largest markets, Europe and the United States, which represented 58.3% and 23.8%, respectively, of our consolidated sales in 2003 (the United States also accounted for 45.4% of our 2003 operating profit excluding unallocated costs). Changes in the pricing environments in the United States or Europe (on an individual country basis) could have a significant impact on our revenues and operating profits. See Item 4 Information on the Company Business Overview Pricing for a description of certain regulatory pricing systems that impact our company.

### ***Risks from the handling of hazardous materials could harm our operating results.***

Pharmaceutical manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes exposes us to various risks, including:

fires and/or explosions from inflammable substances;

storage tank leaks and ruptures; and

discharges or releases of toxic or hazardous substances.

These operating risks can cause personal injury, property damage and environmental contamination, and may result in:

the shutdown of affected facilities and

the imposition of civil or criminal penalties.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and harm our operating results.

## **Table of Contents**

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with customary industry practices, we cannot assure you that this insurance will be adequate to cover fully all potential hazards incident to our business. For more detailed information on environmental issues, see Item 4 Information on the Company Business Overview Health, Safety and Environment.

*Environmental liabilities and compliance costs may have a significant negative effect on our operating results.*

The environmental laws of various jurisdictions impose actual and potential obligations on our company to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate,

that we formerly owned or operated, or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. In particular, our accruals for these obligations may be insufficient if the assumptions underlying these accruals prove incorrect or if we are held responsible for additional, currently undiscovered contamination. Any shortfalls could have a material impact on our operating profits. See Item 4 Information on the Company Business Overview Health, Safety and Environment and Regulation for additional information regarding our environmental policies.

Furthermore, we are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. An adverse outcome in any of these might have a significant negative impact on our operating results. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby harming our business and operating results.

## **Risks Relating to an Investment in our Shares or ADSs**

*Foreign exchange fluctuations may adversely affect the U.S. dollar value of our ADSs and dividends (if any).*

As a holder of ADSs, you may face some exchange rate risk. Our ADSs will trade in U.S. dollars and our shares will trade in euro. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we do pay dividends, they would be denominated in euro. Fluctuations in the exchange rate between the euro and the U.S. dollar will affect the U.S. dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the U.S. dollar price of the ADSs on the New York Stock Exchange, whether or not we pay dividends in addition to the amounts, if any, that you would receive upon our liquidation or upon the sale of assets, merger, tender offer or similar transactions denominated in euro or any other foreign currency other than U.S. dollars.



*If you hold ADSs rather than shares it may be difficult for you to exercise some of your rights as a shareholder.*

As a holder of ADSs, it may be more difficult for you to exercise your rights as a shareholder than it would be if you directly held shares. For example, if we offer new shares and you have the right to subscribe for a portion of them, the depositary is allowed, in its own discretion, to sell for your benefit that right to subscribe for new shares instead of making it available to you. Also, to exercise your voting rights, as a holder of ADSs, you

**Table of Contents**

must instruct the depositary how to vote your shares. Because of this extra procedural step involving the depositary, the process for exercising voting rights will take longer for you, as a holder of ADSs, than for holders of shares. ADSs for which the depositary does not receive timely voting instructions will not be voted at any meeting. For a detailed description of your rights as a holder of ADSs, you should read Item 12 Description of Securities other than Equity Securities Description of American Depositary Shares.

*Sales of our shares that will be eligible for sale in the near future may cause the market price of our shares or ADSs to decline.*

At December 31, 2003, we had 732,848,072 shares outstanding, approximately 43.9% of which are held by our two largest shareholders, Total and L Oréal. On November 24, 2003, Total and L Oréal amended their shareholders agreement so that it terminates on December 2, 2004 according to its terms, as the parties have indicated that they do not intend to act in concert with respect to their shareholdings in our company as from that date. See Item 7 Major Shareholders and Related Party Transactions Major Shareholders Shareholders Agreement. Upon the termination of the existing shareholders agreement between those two shareholders, all of our shares owned by these shareholders will become available to be sold in the public market, subject to applicable laws and regulations. Sales of a substantial number of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. See Item 10 Additional Information Share Capital Shares Eligible for Future Sale for a more detailed description of the eligibility of our shares for future sale.

**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our proxy statements, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

projections of operating revenues, net income, net earnings per share, capital expenditures, dividends, capital structure or other financial items or ratios;

statements of our plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition;

statements about our future economic performance or that of France, the United States or any other countries in which we operate; and

statements of assumptions underlying such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent risks and uncertainties. We caution you that a number of important factors could cause actual results to differ materially from those contained in any forward-looking statements. Such factors, some of which are discussed under Item 3 Key Information Risk Factors beginning on page 10, include but are not limited to:

the impact of our proposed acquisition of Aventis;

our ability to continue to expand our presence profitably in the United States;

the success of our research and development programs;

our ability to protect our intellectual property rights; and

the risks associated with reimbursement of healthcare costs and pricing reforms, particularly in the United States and Europe.

We caution you that the foregoing list of factors is not exclusive and that other risks and uncertainties may cause actual results to differ materially from those in forward-looking statements.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Forward-looking statements speak only as of the date they are made. We do not undertake any obligation to update them in light of new information or future developments.

## **Table of Contents**

### **Item 4. Information on the Company**

#### **Introduction**

We are an international pharmaceutical group engaged in the research, development, manufacture and marketing of pharmaceutical products for sale principally in the prescription market. In 2003, our consolidated net sales were 8,048 million (\$10,138 million), our operating profit was 3,075 million (\$3,874 million) and our net income was 2,076 million (\$2,615 million). On the basis of 2003 sales, we are the second largest pharmaceutical group in France, the seventh largest pharmaceutical group in Europe and among the twenty largest pharmaceutical groups in the world (IMS data).

In our prescription pharmaceuticals business, we specialize in four therapeutic areas:

*Cardiovascular/Thrombosis.* Our Cardiovascular/Thrombosis products include two of the fastest-growing products on the Cardiovascular/Thrombosis market today: the blood pressure medication Aprovel® and the anti-clotting agent Plavix®.

*Central Nervous System, or CNS.* Our CNS medicines include Stilnox®, the world's leading prescription insomnia medication, and Depakine®, one of the leading treatments for epilepsy.

*Internal Medicine.* Our Internal Medicine products include Xatral®, a leading treatment for benign prostatic hypertrophy. In November 2003, we launched a once-a-day formulation in the United States under the brand name Uroxatral®.

*Oncology.* Our lead product in this strategic market is Eloxatin®, which is our fastest growing product in terms of sales. Eloxatin® is marketed in Europe and the United States as a first- and second-line treatment against colorectal cancer in combination with 5-FU/LV.

Our five strategic products are Aprovel®, Eloxatin®, Plavix®, Stilnox® and Xatral®, which together accounted for 54.7% of our total consolidated net sales, or 4,399 million, in 2003.

We have a strong commitment to research and development. We have 14 research centers and have over 6,800 employees devoted to research and development. At February 16, 2004, we had 56 compounds in development in the four therapeutic areas, 25 of which were in phase II or phase III clinical trials.

The legal and commercial name of our company is Sanofi-Synthélabo. We are a French *société anonyme*, a form of limited liability stock company, formed in 1994 pursuant to the French commercial code for a term of 99 years. Our registered office is located at 174, avenue de France, 75013 Paris, France. Our telephone number is +33 (0)1 53 77 40 00.

#### **A. History and Development of the Company**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Our company is the result of the 1999 merger of Sanofi and Synthelabo, two major French pharmaceutical companies. Since the merger, we have combined the resources of the two companies to expand our global presence, particularly in the United States, and to increase our focus on research and development for products with strong future potential. In 2003 we celebrated the thirtieth anniversary of our group worldwide.

Sanofi was founded in 1973 by Elf Aquitaine, a French oil company, when it took control of the Labaz Group (a pharmaceutical company) for diversification purposes. Sanofi launched its first major product on the market, Ticlid<sup>®</sup>, in 1978. At the time of the merger in 1999, Sanofi was the second largest pharmaceutical group in France in terms of sales. A majority of its share capital was owned by Elf Aquitaine, which was acquired by Total. Sanofi made a significant venture into the United States market in 1994, when it acquired the prescription pharmaceuticals business of Sterling Winthrop, an affiliate of Eastman Kodak. Sanofi launched its first major product on the U.S. market, Aprovel<sup>®</sup>, in 1997, followed by Plavix<sup>®</sup> in 1998.

## **Table of Contents**

Synthélabo was founded in 1970 through the merger of two French pharmaceutical laboratories, Laboratoires Dausse (founded in 1834) and Laboratoires Robert & Carrière (founded in 1899). In 1973, the French cosmetics group L'Oréal acquired the majority of its share capital and in 1988, Synthélabo launched two major products on the French market: Stilnox<sup>®</sup> and Xatral<sup>®</sup>. At the time of the merger, Synthélabo was the third largest pharmaceutical group in France in terms of sales. A majority of its share capital was still owned by L'Oréal. In 1993, Synthélabo launched Stilnox<sup>®</sup> in the United States under the brand name Ambien<sup>®</sup>. By 1994, Stilnox<sup>®</sup> had become the leading insomnia prescription medication worldwide according to IMS data.

Sanofi and Synthélabo agreed to merge at the end of 1998, and the merger became effective in the second quarter of 1999. Following the merger, Total and L'Oréal were the largest shareholders of the new group, although neither held a majority of the share capital. These two principal shareholders have entered into a shareholders' agreement that lasts until December 2004. The terms of the shareholders' agreement are described under Item 7 Major Shareholders and Related Party Transactions Major Shareholders.

Part of our strategy following the merger was to concentrate on our core prescription pharmaceuticals business. To implement this strategy, we divested non-core businesses, including:

in 1999, Sanofi's beauty business, our diagnostics business, our animal health and nutrition business and an equity affiliate in the cheese business; and

in 2001, our custom chemicals business and two medical equipment businesses, as well as our direct shareholding in Laboratoires de Biologie Végétale Yves Rocher.

In January 2004, we made a mixed cash/exchange offer to acquire Aventis, a major French pharmaceutical company. This transaction is described under Item 8 Financial Information Significant Changes.

For a description of our principal capital expenditures and divestitures since 2000, our expectations as to future capital expenditures and divestitures and the impact of the merger and these divestitures on our results of operations and financial condition, see Item 5 Operating and Financial Review and Prospects. We currently have no material capital expenditures or divestitures in progress other than divestitures that we expect to make if the Aventis transaction goes forward.

## **B. Business Overview**

### **Strategy**

We believe we have the potential to grow profitably by taking advantage of our focused portfolio of current and potential drugs centered around four targeted therapeutic areas. The key elements of our strategy to achieve these goals are to:

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

*Capitalize on our direct presence in the United States.* We intend to continue to capitalize on our potential for growth in the U.S. market. Our strategy in the United States has been based largely on organic growth, with upgrades to our sales force and local infrastructure timed to match the progress of our product portfolio and product launches. For example, we have also more than tripled our U.S. sales force in the past four years to 2,675 employees as at December 31, 2003. During this period, we increased our interest in the promotional activities and profitability of our alliance with Bristol-Myers Squibb that markets Aprovel<sup>®</sup> (under the name Avapro<sup>®</sup>) in the United States, we purchased Pharmacia's interest in the joint venture that markets Stilnox<sup>®</sup> (under the name Ambien<sup>®</sup>) in the U.S. and regained full U.S. marketing rights to Ambien<sup>®</sup>, we launched Eloxatin<sup>®</sup> in August 2002 with great success, and most recently we launched Uroxatral<sup>®</sup>, which we began marketing in November 2003.

*Capitalize on the sales potential of our five strategic products.* We believe that each of Aprovel<sup>®</sup>, Plavix<sup>®</sup>, Stilnox<sup>®</sup> and Eloxatin<sup>®</sup> will continue to have strong growth potential and that Xatral<sup>®</sup> has the



**Table of Contents**

potential to become a leading product. We intend to make the necessary investment of marketing and other resources to fully promote these strategic products, which are early in their life cycles and have significant remaining potential for sustained growth.

*Continue our strong commitment to research and development.* As at February 16, 2004, we had 56 compounds in our research and development pipeline, of which 25 were in phase II or III clinical trials. We believe that the number of compounds in later stage development in our pipeline, together with our capabilities in the high technology areas of genomics, proteomics, high throughput screening, combinatorial chemistry and bioinformatics, gives us a solid foundation for developing future products. We intend to continue to focus our efforts on developing products to meet unmet medical needs in our four targeted therapeutic areas and to maintain our current high level of research and development spending as a percentage of revenues.

*Continue to improve sales force productivity.* Over the last few years, we have successfully improved the productivity of our sales force, reorganizing affiliates in Europe to sharpen customer focus and achieving a critical mass in the United States that puts us among the leaders in productivity measured by the number of sales calls that result in a physician intending to change prescriptions. We believe that our focused structure gives us the opportunity to improve our profitability, and we intend to take advantage of this opportunity by targeting our promotional efforts on our higher margin products.

*Continue to enhance our presence worldwide.* Over time, we intend to build progressively our presence in Japan and other targeted countries. Our strategy is to establish local subsidiaries and a local sales force, when possible. In Japan, we plan to replicate the business model that has been successful in the United States, by reinforcing our local research projects, capitalizing on our strategic partnerships with Fujisawa and Daiichi, putting in place our own sales force and pursuing marketing authorization for Plavix®. As part of our strategy in Japan, in January 2004 we signed an agreement with Taisho that will permit us to market Ancaron® directly beginning in 2006.

*Seize appropriate opportunities for growth through selective mergers, acquisitions and strategic alliances.* Where appropriate, we intend to continue to seize appropriate external opportunities for growth through selective mergers, acquisitions and strategic alliances. Our principal focus in this regard is our proposed acquisition of Aventis, which is described under Item 8 Financial Information Significant Changes.

**Table of Contents****Principal Products**

Our principal products are prescription pharmaceuticals, which we group into four main therapeutic categories: Cardiovascular/Thrombosis, Central Nervous System, Internal Medicine and Oncology. The following table outlines our consolidated net sales by therapeutic area for the year ended December 31, 2003.

**Consolidated Sales by Therapeutic Area**

	Year Ended	
	December 31, 2003	
	(millions of )	% of Net Sales
<b>Prescription Pharmaceuticals*</b>		
<i>Cardiovascular/Thrombosis</i>		
Aprovel®/Avapro®/Karvea®	683	8.5%
Plavix®/Iscover®	1,325	16.5%
Other	1,161	14.4%
<b>Total</b>	<b>3,169</b>	<b>39.4%</b>
<i>Central Nervous System</i>		
Stilnox®/Ambien®/Myslee®	1,345	16.7%
Other	974	12.1%
<b>Total</b>	<b>2,319</b>	<b>28.8%</b>
<i>Internal Medicine</i>		
Xatral®/ Uroxatral®	222	2.8%
Other	1,190	14.8%
<b>Total</b>	<b>1,412</b>	<b>17.6%</b>
<i>Oncology</i>		
Eloxatin®	824	10.2%
Other	47	0.6%
<b>Total</b>	<b>871</b>	<b>10.8%</b>
<i>Other Pharmaceuticals</i>	277	3.4%
<b>Total consolidated net sales</b>	<b>8,048</b>	<b>100.0%</b>

\* Our products include over 160 Cardiovascular/Thrombosis products, over 130 Central Nervous System products, over 500 Internal Medicine products and over 15 Oncology products worldwide. Other Pharmaceuticals includes all of our other pharmaceutical products that cannot be classified in our main therapeutic areas, such as our dental hygiene products.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

A number of our products, including three of our five strategic products (Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Stilnox<sup>®</sup>), are sold in certain countries through alliances that we have entered into with other pharmaceutical companies, or through licensees. Our consolidated revenues only reflect a portion of the total revenues realized by the alliances and licensees. In some cases, our revenue shares from the alliances are based on formulas that make our consolidated revenues grow at a different rate than the overall growth in sales of the products. In this annual report, we present both our consolidated revenues from products sold through alliances, and developed sales, which represent the overall sales of these products, including sales by our alliance partners and licensees. We believe that developed sales are a useful measurement tool because they demonstrate trends in the overall sales of our products in the market, without regard to the formulas under which our revenue shares are determined.

A drug can be referred to either by its international non-proprietary name, or INN, or by its brand name, which is normally exclusive to the company that markets it. In most cases, our brand names, which may vary from country to country, are protected by trademark registrations. In the description that follows, our products are generally referred to by the brand names that we use in France.

## **Table of Contents**

### **Prescription Pharmaceuticals**

Our portfolio of prescription pharmaceuticals includes a range of innovative products with strong market positions in our four targeted therapeutic areas. In Thrombosis, we are the leader in the European and U.S. markets for anti-platelet agents based on total consolidated sales of our anti-atherothrombotic agent Plavix<sup>®</sup> (clopidogrel) and rank second in the European market for heparins with products including Fraxiparine<sup>®</sup> and Arixtra<sup>®</sup> (IMS data). In the Cardiovascular market, we rank second in the European market and third in the U.S. market for angiotensin II receptor antagonists based on annual sales of Aprovel<sup>®</sup> (IMS data). In the area of central nervous system disorders, according to IMS data, we are the leader in Europe, Japan and the U.S. based on total consolidated net sales of our product Stilnox<sup>®</sup> (zolpidem), the treatment of choice for sleep disorders.

In our prescription pharmaceuticals business, we specialize in four therapeutic areas: Cardiovascular/Thrombosis, Central Nervous System, Internal Medicine and Oncology. On an industry-wide basis, these four therapeutic areas account for more than half of worldwide pharmaceutical sales, according to IMS data. Certain of our products are sold both by us and, in selected markets, by our alliance partners and licensees, giving these products a broad, worldwide market presence. For a discussion of these arrangements, see Item 4 Information on the Company Business Overview Marketing and Distribution Alliances. The following table outlines our leading prescription pharmaceuticals based on consolidated net sales for the year ended December 31, 2003. In some countries, our products have only been approved (or approval has only been sought) for a portion of the areas of use indicated in the table.

**Table of Contents****Principal Prescription Pharmaceuticals**

<b>Therapeutic Area / Product Name</b>	<b>Year Ended December 31, 2003</b>	
	<b>Consolidated Net Sales</b>	<b>Drug Category/ Main Areas of Use</b>
	(millions of )	
<b>Cardiovascular/Thrombosis</b>		
<i>Cardiovascular Products</i>		
Aprovel® (irbesartan)	683	Angiotensin II receptor antagonist
Cordarone® (amiodarone)	146	Hypertension Anti-arrhythmic agent  Treatment / prevention of cardiac
Tildiem® (diltiazem)	131	arrhythmia (irregular heartbeat) Calcium antagonist  Angina Pectoris  Hypertension
<i>Thrombosis Products</i>		
Plavix® (clopidogrel)	1,325	ADP receptor antagonist
Fraxiparine® (nadroparin calcium)	319	Atherothrombosis Low molecular weight heparin  Venous thromboembolism (VTE)
<b>Central Nervous System</b>		
Stilnox® (zolpidem)	1,345	Hypnotic
Depakine® (sodium valproate)	277	Sleep disorders Anti-epileptic
Solian® (amisulpride)	148	Epilepsy Neuroleptic  Schizophrenia  Dysthymia
<b>Internal Medicine</b>		
Xatral® (alfuzosin)	222	Uroselective alpha1 blocker  Benign prostatic hypertrophy
<b>Oncology</b>		
Eloxatin® (oxaliplatin)	824	Cytotoxic agent  Colorectal cancer

Three of our five strategic products are sold directly by us and through alliances. The figures above reflect only sales included in our consolidated net sales. In 2003, total worldwide developed sales of Plavix<sup>®</sup>, Aprovel<sup>®</sup> and Stilnox<sup>®</sup> were 3,225 million, 1,255 million and 1,381 million respectively.

*Cardiovascular/Thrombosis*

The Cardiovascular/Thrombosis market as a whole is the largest therapeutic area in the worldwide pharmaceutical market. According to IMS data, in the cardiovascular market, we rank second in the European market and third in the U.S. market for angiotensin II receptor antagonists with Aprovel<sup>®</sup> in terms of annual sales. We are number three in the European market for calcium antagonists with Tildiem<sup>®</sup> and are number two in the European market for anti-arrhythmics with Cordarone<sup>®</sup> (IMS data). In Thrombosis, we rank first in the European and U.S. markets for anti-platelet agents with Plavix<sup>®</sup> and we are number two in the European market for heparins with Fraxiparine<sup>®</sup> and Arixtra<sup>®</sup> according to IMS data.

---

## Table of Contents

*Cardiovascular.* Our main products for the treatment of cardiovascular disease are:

*Aprovel®/Avapro®/Karvea® (irbesartan; hypertension).* Aprovel® belongs to the most recent class of anti-hypertensives, angiotensin II receptor antagonists, and is indicated as a first-line treatment for hypertension, or high blood pressure. Angiotensin II receptor antagonists, which are highly potent and generally well tolerated, act by blocking the effect of angiotensin, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel®, we market CoAprovel®/Avalide® a combination of irbesartan and hydrochlorothiazide, a diuretic that increases the excretion of water by the kidneys. These products achieve control of blood pressure in close to 90% of patients and with a very good safety profile.

Aprovel® was launched in 1997 and is now marketed in more than 80 countries, including the United States, through an alliance with Bristol-Myers Squibb, or BMS (under the brand name Avapro®). In Japan, where the product is licensed to BMS and Shionogi, an application for marketing authorization for the treatment of hypertension was submitted in October 2002.

In 2002, Aprovel® was approved for a new indication, the treatment of diabetic nephropathy, in both Europe (June 2002) and the United States (September 2002). These approvals were based on the results of the PRIME program, a clinical program that demonstrated that irbesartan protects type-2 diabetic hypertensive patients from the progression of renal impairment, at both early and more advanced stages of the disease. Following the announcement of the PRIME results, the American Diabetes Association (ADA) recommended the use of angiotensin receptor antagonists as a first-line treatment for renal disease in patients with type 2 diabetes.

In 2003, at the request of the FDA, we worked on the development of a pediatric indication for Aprovel® in the United States.

We are currently conducting two large-scale clinical programs, part of our life cycle management program for Aprovel®, that will enroll a total of 14,000 patients and that we expect to complete in 2006:

I-PRESERVE, to evaluate the benefit of irbesartan in the treatment of a specific but common form of heart failure, heart failure with preserved systolic function or diastolic heart failure. In this type of heart failure, the contractile capacity of the ventricles is preserved, but ventricular filling is disturbed. This study was initiated in 2002 and is currently in the active stage of patient enrollment.

ACTIVE-I, to evaluate the efficacy of irbesartan, combined with clopidogrel (the active ingredient in Plavix®), in preventing complications in patients suffering from atrial fibrillation. We began this clinical program in April 2003.

*Cordarone®/Ancaron® (amiodarone; cardiac rhythm disorders).* Thirty-six years after its first marketing authorization was granted, Cordarone® remains a leading anti-arrhythmic drug for the treatment and prevention of cardiac rhythm disorders such as cardiac arrhythmia, or irregular heart beat. Cordarone® is also effective against potentially life-threatening supraventricular rhythm disorders, the most common of these being atrial fibrillation. Two clinical studies, CAT, published in 2002, and AMIOVIRT, published in 2003, demonstrated that Cordarone® is as effective as the implantation of a defibrillator in preventing sudden cardiac death in patients with idiopathic dilated cardiomyopathy, a rare disease that attacks the heart muscle. Cordarone® has a good cardiac safety profile and only exceptionally induces complications potentially associated with the use of anti-arrhythmics, such as Torsades de Pointe (a serious and potentially fatal ventricular rhythm disorder) or ventricular insufficiency. However, its effects on thyroid function limit its use. Cordarone® is available in more than 126 countries, including the United States where it is licensed to Wyeth (formerly American Home Products), and Japan where it is marketed under the brand name Ancaron® through joint venture with Taisho. In January 2004 we signed an agreement with Taisho to purchase its interest in the joint venture, which will permit us to market Ancaron® directly

beginning in 2006.



---

**Table of Contents**

*Tildiem® (diltiazem; angina, hypertension).* Among calcium antagonists, Tildiem® is considered a reference treatment for angina. Tildiem® works by increasing oxygen supply to the myocardium (the muscle surrounding the heart) through coronary vasodilatation, while simultaneously reducing oxygen needs by decreasing the heart rate and lowering peripheral artery resistance. Tildiem® thereby exhibits good anti-anginal efficacy, combined with a good safety profile. Our sustained 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 (a statistical analysis) showed that these formulations permit consistent regulation of heart rate: the faster the heart rate initially, the more it is slowed by Tildiem®. Additionally, the NORDIL study of morbidity and mortality associated with hypertension showed that Tildiem® 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.

*Thrombosis.* Thrombosis occurs when a thrombus, or blood clot, forms inside a blood vessel. Left unchecked, a thrombus within a blood vessel can eventually grow large enough to block the blood vessel, preventing blood and oxygen from reaching the organ being supplied. Our principal products for the treatment of thrombosis are:

*Plavix®/Iscover® (clopidogrel; atherothrombosis).* Plavix®, a platelet adenosine diphosphate receptor antagonist, is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction, recent ischemic stroke or documented peripheral arterial disease. Plavix® is currently the only drug indicated for the secondary prevention of atherothrombosis regardless of the location of the arteries initially affected (heart, brain, lower limbs). This broad indication is supported by the results of the CAPRIE study, the largest phase III study ever conducted with almost 20,000 patients enrolled. CAPRIE demonstrated the superior efficacy of Plavix® to acetylsalicylic acid, with a safety profile at least equally good.

Plavix® was launched in 1998, and is now marketed in over 75 countries, including the United States, through our alliance with BMS. In Japan, where it is being developed in partnership with Daiichi, we submitted an application for marketing authorization in February 2004.

In 2002, U.S. and European health authorities approved an extension of indication of Plavix® for the treatment of acute coronary syndrome following the results of the CURE trial. The new indication was incorporated into the guidelines of the American Heart Association, the American College of Cardiology, and the European Society of Cardiology. The CURE trial demonstrated that clopidogrel, when added to a standard therapy including or comprising acetylsalicylic acid, reduced the risk of atherothrombotic events (myocardial infarction, stroke and 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 an acute coronary syndrome. With more than 12,000 patients enrolled, CURE is the largest clinical trial ever conducted with patients presenting unstable angina or non-Q-wave myocardial infarction.

The results of the CREDO clinical 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, either with or without stenting. The CREDO trial, conducted in more than 2,000 patients, demonstrated the benefit of prolonged use of clopidogrel and showed that the risk of atherothrombotic events was reduced by 27% after one year.

In September 2002, the CHARISMA trial began enrolling patients, and is expected to include a total of 15,000 patients. CHARISMA aims to demonstrate the value of using Plavix® when added to existing treatments in the primary prevention of cardiovascular events in patients at risk. We anticipate results from the CHARISMA study in 2006.

---

**Table of Contents**

In 2003, at the request of the FDA, we worked on the development of a pediatric indication for Plavix® in the United States.

We have other major on-going clinical studies that are designed to support the long-term use of Plavix® by providing complementary data. These include:

MATCH, assessing the benefit of clopidogrel combined with acetylsalicylic acid in the prevention of serious ischemic events in 7,600 high-risk patients who have recently experienced a stroke or transient ischemic attack, should yield results in 2004;

CLARITY and COMMIT, evaluating the benefit of clopidogrel combined with acetylsalicylic acid in acute myocardial infarction;

CAMPER, assessing the benefit of clopidogrel in patients with peripheral arterial disease who have undergone angioplasty or bypass surgery; and

ACTIVE (A & W), assessing the value of clopidogrel in patients in the prophylactic treatment of thromboembolic events in patients with atrial fibrillation, which should yield results in 2007.

The WATCH study, which is assessing the value of clopidogrel in patients suffering from heart failure, is ongoing with a smaller number of patients than initially expected due to a slow inclusion rate.

The extensive core clinical program for Plavix®, including all completed, ongoing and planned studies, will enroll more than 100,000 patients.

*Arixtra® (fondaparinux sodium; venous thrombosis).* Arixtra®, fondaparinux sodium, is a totally synthetic compound that is currently indicated for the prevention of venous thromboembolism, including deep vein thrombosis and pulmonary embolism, in patients who have undergone major orthopedic surgery of the lower limbs (a high risk situation). We co-developed Arixtra® with Organon (a subsidiary of Akzo Nobel), and believe that it represents a major advance in the prevention of venous thromboembolism. It is the first agent in a new class of injectable anti-thrombotics (anti-coagulant), selective synthetic inhibitors of coagulation factor Xa, and works by interrupting a key step in the coagulation cascade, thereby preventing the formation of blood clots. Further, Arixtra® is obtained by chemical synthesis, which leads to a high level of purity. For both of these reasons, we believe Arixtra® constitutes a major technological and therapeutic advance.

We believe its development potential is substantial. Phase III studies, which included over 7,000 patients, demonstrated a major clinical benefit relative to the reference low molecular weight heparin. Irrespective of the orthopedic surgical procedure (hip replacement, hip fracture or knee surgery) and the characteristics of the patient, Arixtra® reduced the risk of a thromboembolic event by 55% without increasing the risk of clinically important bleeding. For patients undergoing surgery for hip fracture, the risk of deep-vein thrombosis was reduced to 8% with Arixtra® compared to around 20% with the reference treatment. The safety profile of the two treatments is similar.

We launched Arixtra® in February 2002 in the United States, where it was approved for the prevention of venous thromboembolic events after orthopedic surgery in December 2001 following a priority review. In March 2002, Arixtra® received its European marketing authorization for the same indication and launch has been rolling out in various countries since that time. In December 2002, the FDA modified the summary product characteristics for Arixtra® to provide an improved description of its profile, and approved Arixtra® for a new indication, extended prophylaxis of deep vein thrombosis, in June 2003 and the new indication was approved in Europe in November 2003. Arixtra® is currently the only anti-thrombotic agent indicated in the United States for the extended prophylaxis of deep vein



**Table of Contents**

thrombosis in patients undergoing hip fracture surgery. Unlike other injectable anti-coagulants, Arixtra<sup>®</sup> is very well tolerated by patients suffering from renal insufficiency. In 2003, a new indication of a 1.5 mg dosage for patients with severe renal insufficiency was approved in Europe. In Japan, the product completed phase IIb/III clinical development, with results anticipated in 2004. We currently plan to submit an application for marketing authorization in late 2004.

Because of the development potential of Arixtra<sup>®</sup>, we have implemented a life cycle management program to cover all segments of the thrombosis market:

*Treatment of venous thromboembolism.* In 2002, the completed MATISSE study, which enrolled over 4,000 patients, demonstrated that Arixtra<sup>®</sup> is as well tolerated and at least as effective as the existing standard therapies for the treatment of deep vein thrombosis and pulmonary embolism (when compared to low weight molecular heparin and unfractionated heparin, respectively). Based on these results, in the third quarter of 2003 we submitted applications in both the United States and Europe for the approval of Arixtra<sup>®</sup> for this new indication.

*Prevention of venous thrombosis.* Our APOLLO and PEGASUS programs studied Arixtra<sup>®</sup> in the prevention of venous thrombosis in other types of surgery, such as abdominal surgery. The results of the PEGASUS study demonstrated benefits in Arixtra<sup>®</sup> that could reduce the risk of deep venous thrombosis after major abdominal surgery. We also studied Arixtra<sup>®</sup> for the prevention of venous thrombosis in medical patients at high risk of venous thromboembolic events who have not undergone surgery (our ARTEMIS program). The results of the ARTEMIS study were presented at the International Society on Thrombosis and Haemostasis conference in July 2003, and demonstrated a significant reduction of the risk of deep vein thrombosis in acutely ill medical patients treated with Arixtra<sup>®</sup>. Based on these results, we submitted applications in both the United States and Europe for the approval of Arixtra<sup>®</sup> for these new indications in the first quarter of 2004.

*Acute coronary disease.* We are studying Arixtra<sup>®</sup>'s effectiveness in acute coronary disease (unstable angina, coronary angioplasty, myocardial infarction). The initial efficacy results were confirmed by the Phase IIb Pentua trial, which were presented at the November 2001 scientific sessions of the American Heart Association. We believe that these studies provide a basis for expecting a good benefit to risk ratio when compared to existing therapies for acute coronary disease. A phase III clinical program that began in April 2003 (the Michelangelo program) will enroll 26,000 patients. From 2003 through 2005, Michelangelo/Oasis 5 will study Arixtra<sup>®</sup>'s effectiveness in the treatment of unstable angina, while Michelangelo/Oasis 6 will study Arixtra<sup>®</sup>'s effectiveness in the treatment of myocardial infarction.

In the United States, Canada and Mexico, we marketed Arixtra<sup>®</sup> through our joint venture with Organon. In January 2004, we agreed to acquire all of Organon's interests relating to Arixtra<sup>®</sup> that were the subject of this joint venture, as well as Organon's interests relating to idraparin sodium and other oligosaccharides. For additional information regarding the sale of Arixtra<sup>®</sup> see Item 4 Information on the Company Business Overview Marketing and Distribution Alliances. In the rest of the world (apart from Japan), we market Arixtra<sup>®</sup> on our own.

*Fraxiparine<sup>®</sup> (nadroparin calcium; venous and arterial thrombosis).* Fraxiparine<sup>®</sup> is an injectable low-molecular-weight heparin. Launched in 1986, it is currently marketed in over 100 countries (excluding the United States and Japan). Fraxiparine<sup>®</sup>'s approved indications have expanded over the years. Initially indicated for the prevention of venous thromboembolic disease, Fraxiparine<sup>®</sup> is currently indicated for the treatment of this disease as well, and the treatment of acute coronary syndromes. It is also indicated for the prevention of extra-corporal coagulation in patients undergoing dialysis. We launched Fraxodi<sup>®</sup>, a curative treatment for venous thromboembolic disease administered as a once-a-day injection, in France in 1998. Fraxodi<sup>®</sup> is now marketed in most countries in Europe and Latin America. The once-a-day regimen permits shorter hospital stays, facilitates outpatient treatment and

## **Table of Contents**

enhances overall patient recovery. A new indication of Fraxiparine<sup>®</sup> for the treatment of the acute phase of unstable angina in association with acetylsalicylic acid is now successfully registered in many countries, including the principal European markets, but excluding Japan and the United States.

In connection with our proposed acquisition of Aventis, on January 26, 2004, we began a sales process to divest our interests in Arixtra<sup>®</sup> and Fraxiparine<sup>®</sup> in order to be able to respond to possible demands of the competition authorities. As of the date of this annual report, confidential discussions and negotiations are ongoing with several interested parties.

Other products in the Cardiovascular/Thrombosis market include Ticlid<sup>®</sup>, Corotrope<sup>®</sup> and Kerlone<sup>®</sup>.

### ***Central Nervous System***

In the Central Nervous System market, according to IMS data, we rank first in the European and U.S. markets and in the Japanese market since December 2003, for hypnotics with Stilnox<sup>®</sup>, and are number three in Europe in the market for anti-epileptics, with drugs including Depakine<sup>®</sup>. In the market for neuroleptics, we rank third in Europe and fifth in Japan with drugs such as Solian<sup>®</sup> (IMS data). Key products in this therapeutic area include:

*Stilnox<sup>®</sup>/Ambien<sup>®</sup>/Myslee<sup>®</sup> (zolpidem; insomnia).* Stilnox<sup>®</sup> is the leading hypnotic in the United States, Europe and Japan (based on IMS data), and is sold in over 100 countries worldwide. Stilnox<sup>®</sup> is both chemically and pharmacologically distinct from benzodiazepines, and is distinguished by its selective binding exclusively to receptors that mediate hypnotic activity. Due to this characteristic, Stilnox<sup>®</sup> rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for six to eight hours, and is generally well tolerated, allowing the patient to awake with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day. The risk of dependence is minimal when Stilnox<sup>®</sup> is used at the recommended dosage and duration of use. Based on the results of an extensive program of eight clinical trials, which together enrolled over 6,000 patients, Stilnox<sup>®</sup> is currently the only hypnotic demonstrated to be suitable for use on an as needed basis depending upon each patient's individual requirements. This mode of administration avoids the systematic intake of a hypnotic for patients who suffer only occasionally from insomnia.

We believe that Stilnox<sup>®</sup> is also one of the most studied hypnotics in the world as data on its efficacy and safety have been generated from 140 clinical trials that included 80,000 patients worldwide.

Although launched only in December 2000, by October 2003, Stilnox<sup>®</sup> had achieved high market penetration in Japan, and became the leading hypnotic on the Japanese market in December 2003 (according to IMS data) where it is sold under the brand name Myslee<sup>®</sup> through our joint venture with Fujisawa. With a market share of 22.4% in December 2003 (according to IMS data), Japan is now the second-largest market for sales of Stilnox<sup>®</sup>.

We are also developing a controlled release formula of zolpidem, Ambien<sup>®</sup> CR. A three-week placebo-controlled study, ZOLADULT, conducted in sleep laboratories assessed Ambien<sup>®</sup> CR in the treatment of patients experiencing insomnia. The ZOLADULT study showed that Ambien<sup>®</sup> CR improved sleep maintenance, sleep duration, and the ability to fall asleep. Based on these results, we plan to file an application for the approval of Ambien<sup>®</sup> CR in the United States in the second quarter of 2004.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

*Depakine® (sodium valproate; epilepsy)*. Depakine® is a broad-spectrum anti-epileptic that has been prescribed for over 30 years. Numerous clinical trials, as well as long years of experience have shown that it is effective for all types of epileptic seizures and epileptic syndromes, and is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide. Furthermore, in contrast to findings sometimes reported with other anti-epileptic agents, Depakine® does not induce

**Table of Contents**

paradoxical aggravation of seizures. The Chrono<sup>®</sup> form (our prolonged release formulation) permits once-a-day administration in most cases, thereby improving compliance with treatment and overall patient care. We produce a wide range of formulations of Depakine<sup>®</sup>, permitting its adaptation to all types of patients. A new formulation of Depakine<sup>®</sup>, chronosphere, facilitating its use by children and the elderly, has been approved in several European countries, and we plan to launch it gradually over the next few years as we register the product and reach agreement on pricing in those countries. Depakine<sup>®</sup> is marketed in over 100 countries, including the United States where it is licensed to Abbott. In 2003, we received marketing approval in certain European countries for Depakine Chrono<sup>®</sup> for use in the treatment of bipolar disorders.

*Solian<sup>®</sup> (amisulpride; schizophrenia).* Solian<sup>®</sup> is an anti-psychotic with an atypical pharmacological profile. Its originality consists of 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<sup>®</sup> is effective on 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, the efficacy of Solian<sup>®</sup> is accompanied by a good safety profile. Solian<sup>®</sup> is available over 50 countries worldwide, including the principal European markets. In 2003, we launched Solian<sup>®</sup> in 6 additional countries, including Hungary, Taiwan and Hong Kong.

In addition to these products, we market Aspégic<sup>®</sup> in European, African and Asian Markets and Dogmatil<sup>®</sup> in over 90 countries worldwide. We also market products for the treatment of anxiety, and agitation and aggressiveness.

***Internal Medicine***

Our principal fields in this therapeutic area are urology, gastroenterology, respiratory disease, and the musculoskeletal system. Our leading product in this field is Xatral<sup>®</sup> (alfuzosin).

*Xatral<sup>®</sup> (alfuzosin; benign prostatic hyperplasia).* Our research efforts resulted in the discovery of alfuzosin, the active ingredient in Xatral<sup>®</sup>, which we first launched in France in 1988. Xatral<sup>®</sup> belongs to the alpha<sub>1</sub>-blocker class, and was the first product of the class to be indicated uniquely and specifically for the treatment of the symptoms of benign prostatic hyperplasia, as well as the first marketed product capable of acting selectively on the urinary system. Due to this clinical uroselectivity, Xatral<sup>®</sup> 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 improves patient quality of life.

Besides this symptomatic action, the results of major clinical trials completed in 2002 demonstrated the original contribution of Xatral<sup>®</sup> to the treatment of benign prostatic hyperplasia, and the prevention of its complications.

The results of the first phase of the ALFAUR trial showed that Xatral<sup>®</sup> doubles the probability of restored capacity to urinate normally after an episode of acute urine retention in conjunction with catheter insertion. These are the first published results that demonstrate the capacity of Xatral<sup>®</sup> to prevent acute urinary retention, the principal complication of benign prostatic hyperplasia. We obtained authorizations of this extension of indication in nine European countries in 2003.

The results of the ALFAUR trial have led to another clinical study, ALTESS, which includes over 1,400 patients in a two-year study for an extension of indication of Xatral<sup>®</sup> for the primary prevention of acute urinary retention.

---

## **Table of Contents**

The results of another large international trial with over 800 patients have shown that Xatral® preserves sexual function in patients suffering from benign prostatic hyperplasia.

Since its launch in 1988 in France, we have constantly worked on developing improvements to optimize the formulation of Xatral®. The new once-daily formulation of Xatral® has now been registered in over 90 countries and is currently marketed in 14 European countries and in more than 35 other countries worldwide. As of December 2003, we ranked third on the European market for prostatic diseases with our product Xatral® (IMS data). In June 2003, we received FDA approval for alfuzosin, and we launched Uroxatral®, the once-a-day formula of Xatral® in the United States in November 2003. We also completed phase I clinical trials for the once-a-day formulation of Xatral® for the treatment of benign prostatic hyperplasia in Japan.

Our main products in gastroenterology are Pimpéran® (metoclopramide), a leading treatment for nausea and vomiting, Ercefuryl® (nifuroxazide), an intestinal antiseptic with a broad anti-bacterial spectrum and Inipomp® (pantoprazole), a potent inhibitor of gastric acid secretion. We also market Mizollen® (mizolastine) and Virlix® (cetirizine), for the treatment of allergic reactions, and Myolastan® (tetrazepam), a muscle relaxant.

## ***Oncology***

Oncology is a new therapeutic area for our company, and one in which we expect to concentrate significant efforts in the future. Our first product in this therapeutic area is Eloxatin®.

*Eloxatin® (oxaliplatin; colorectal cancer).* Eloxatin® is an innovative platinum agent, and is currently the only one to have demonstrated activity in colorectal cancer. Its recent introduction in the treatment of metastatic colorectal cancer has led to major progress, including both the prolongation of the median survival to 20 months when used as a first-line treatment in connection with 5-fluorouracil, or 5-FU, and 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. Consequently, Eloxatin® gives these patients the hope of substantially prolonged survival.

In the United States, the FDA granted approval as a second-line treatment in August 2002 following a 46-day priority review for registration. This rapid review was on the basis of the results of a large U.S. trial conducted on patients in relapse after an initial treatment, which showed that treatment with oxaliplatin in combination with infusional 5-fluorouracil/leucovorin, or 5-FU/LV, succeeded in delaying disease progression and demonstrated a clinical benefit in terms of pain reduction, weight gain and improvement of general status.

The final results of the N-9741 study were presented at the May 2003 meeting of the American Society of Clinical Oncology, or ASCO. The N-9741 study, one of the largest randomized trials ever conducted in metastatic colorectal cancer, demonstrated survival benefit with first-line treatment with oxaliplatin. Conducted with the support of the U.S. National Cancer Institute, the study showed that the combination of oxaliplatin, the active ingredient in Eloxatin®, with 5-FU (the Folfox regimen) was more effective and better tolerated than irinotecan in combination with 5-FU (the IFL regimen, and current reference first-line treatment). Because of the prolongation of median survival of patients receiving oxaliplatin, the trial was prematurely discontinued, and all patients still enrolled in the trial were then treated with the oxaliplatin-based regimen.

In January 2004, the FDA approved Eloxatin® in combination with 5-FU as a first-line treatment in the United States. This approval indicates the use of Eloxatin® (oxaliplatin for injection) in combination with infusional 5FU/LV for the treatment of advanced carcinoma of the colon or



rectum. Also in January 2004, we announced that Eloxatin<sup>®</sup> successfully completed a Mutual Recognition Procedure in Europe, which will allow the product to be indicated for first- and second-line treatment of metastatic colorectal cancer.

## **Table of Contents**

Due to its tolerability, Eloxatin<sup>®</sup> is being developed as an adjuvant treatment for non-metastatic colorectal cancer, to prevent relapse in patients undergoing surgery. The results of the MOSAIC study, which studied the efficacy of Eloxatin<sup>®</sup> as an adjuvant treatment in over 2,200 patients, were presented at the May 2003 meeting of the ASCO. The study showed that the addition of oxaliplatin to the current post-surgery standard chemotherapy of 5-FU/LV for colon cancer reduces the risk of recurrence by 23% when compared to the standard treatment alone. We believe that this important result, coming 15 years after 5-FU/LV was established as the standard adjuvant treatment, is a major step towards curing more patients and was obtained without dramatically impacting safety.

In January 2004, we filed an application for the approval of oxaliplatin as an adjuvant, or post-surgery, treatment for colorectal cancer in the United States and in Europe.

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

We in-license Eloxatin<sup>®</sup> from Debiopharm, and market it in 60 countries in Europe, Asia and Latin America. Since September 2002, we have also marketed it in the United States.

*Fasturtec<sup>®</sup>/Elitek<sup>®</sup> (rasburicase; tumor lysis syndrome).* Fasturtec<sup>®</sup> is a recombinant enzyme produced through genetic engineering and is the first biotechnology product discovered and developed entirely by our company. Fasturtec<sup>®</sup> works by converting uric acid, which is poorly soluble and nephrotoxic, into allantoin, a highly soluble compound that is readily eliminated through urination, thereby avoiding tumor lysis syndrome. Administered at the same time as chemotherapy, Fasturtec<sup>®</sup> allows clinicians to administer anti-cancer treatment in optimal conditions without delays or dose reductions that are often required due to tumor lysis syndrome. In February 2001, we obtained a European marketing authorization for Fasturtec<sup>®</sup>, and have launched it in several European countries, including Germany and the United Kingdom, beginning in May 2001. In April 2002, we received European authorization for an additional formulation of Fasturtec<sup>®</sup>, and in July 2002, Fasturtec<sup>®</sup> received FDA approval and was made commercially available in August 2002 under the brand name Elitek<sup>®</sup>. Fasturtec<sup>®</sup> is currently in clinical development in Japan.

*Eligard<sup>®</sup> (leuprolide acetate; prostate cancer).* Eligard<sup>®</sup> is a luteinizing hormone releasing hormone (LHRH) agonist indicated in the treatment of advanced prostate cancer that we in-license from Atrix. In January 2002, the FDA granted marketing approval for the one-month formulation in the treatment of prostate cancer. In July 2002, the three-month formulation received marketing approval from the FDA, and in February 2003, the four-month formulation received marketing approval from the FDA. We market Eligard<sup>®</sup> in the United States and Canada.

## **Generics**

We also manufacture and market a variety of generics in France, Germany and the United Kingdom. These products cover various therapeutic classes, and are typically sold under their international non-proprietary names, or INNs, although in some cases they have a specific brand name. For example, we market Dialgirex<sup>®</sup>, a generic product used for aches and pains, in France and Monoflam<sup>®</sup>, an anti-inflammatory, in Germany.

## **Research and Development**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

We have a long tradition of commitment to research and development and many of our products have resulted from our own research and development activities. In 2003, we spent 1,316 million (16.4% of total consolidated net sales) on research and development.

## **Table of Contents**

We often enter into collaborative research and development arrangements with other pharmaceutical or biotechnology companies under which we fund research expenses in exchange for a right to use and market the products upon regulatory approval. Some of our collaboration agreements include those with Mitsubishi-Pharma Corp., Cephalon and IDM.

In 1998, we entered into an agreement with Mitsubishi-Pharma Corp. to identify new neuroprotective agents for use in the treatment of neurodegenerative disorders. This agreement was recently renewed up to the end of 2004.

In December 2001, we entered into an agreement with Cephalon to have access to specific angiogenesis inhibitors that are potential anti-cancer agents, as well as to a research program aimed at identifying new compounds with a similar mechanism of action. Angiogenesis inhibitors are molecules that act by preventing the development of blood vessels in tumors. We have agreed to co-promote any drugs that are successfully developed in the United States, Canada and Mexico with Cephalon, and we have exclusive marketing rights to such drugs in Europe and the rest of the world (excluding Japan). Under the agreement, we made an upfront payment to Cephalon, share in the costs of development, will make milestone payments during the development process and pay royalties on sales of drugs that are successfully developed.

In 2001, we signed a ten-year agreement with IDM to cooperate in cellular immunotherapy research for the development and marketing of immunologic treatments for cancers. Under this agreement, we have a right of first refusal to select up to twenty cell drugs from IDM's line of products. IDM will undertake the preclinical development, and if we exercise our option, we will finance the clinical development and have worldwide marketing rights for the selected drugs if the clinical trials are successful. A first product under this agreement, Uvidem<sup>®</sup>, which targets melanoma, is currently in Phase II clinical development.

We have entered into collaborative agreements for data-base sharing in the field of genomics with Human Genome Sciences and Genset as well as agreements with research centers specialized in combinatorial chemistry, high throughput screening and structural analysis and proteomics. These collaborative agreements have now terminated but provide for payments should products resulting from these collaborations experience future success. In the field of functional genomics, we have entered into joint projects with Genfit, Genoway and Lifespan. We also have a joint project with CEREP for compound screening, as well as capabilities in bioinformatics.

In 2002, we began three cooperative research and development programs for Impact Malaria. Impact Malaria is a program created by a dedicated team within our company in order to develop and design new drugs and new health strategies for the treatment of malaria that conform to WHO recommendations, such as anti-malarial combination therapies, which are at prices adapted to the population for which they are intended. In 2003, ferroquine (SR 97193) entered the pre-clinical development phase. Impact Malaria also includes a follow-up aspect both to guarantee that the new drugs are used appropriately (through educational programs), and to ensure that the drugs are used by the populations for which they are intended.

We employ over 6,800 personnel in research and development and have 14 research facilities in 6 countries. At February 16, 2004, we had 56 compounds in our research and development pipeline, of which 25 were in phase II or III clinical trials. These 56 compounds include 53 projects for new chemical entities, 2 projects for additional indications for 2 of those new chemical entities (rimonabant and saredutant), and 1 project for an additional formulation of an existing product (Stilnox<sup>®</sup>). In addition, in 2003 three new compounds entered pre-clinical development. We significantly reinforced our research and development efforts in Japan in 2003. In particular, we accelerated the development of new products for the Japanese market.

**Table of Contents**

We focus our research and development efforts on our four targeted therapeutic areas. The composition of our research and development pipeline by therapeutic area as of February 16, 2004 is outlined in the following table.

	Cardiovascular/ Thrombosis	Central Nervous System	Oncology	Internal Medicine	TOTAL
Phase III	2	4	1	2	9
Phase IIb	1	6	2	1	10
Phase IIa	2	1	1	2	6
Phase I	2	5	3	1	11
Pre-clinical	3	6	4	7	20
<b>TOTAL</b>	<b>10</b>	<b>22</b>	<b>11</b>	<b>13</b>	<b>56</b>

The research and development process historically takes from 10 to 15 years from discovery to initial product launch and is conducted in various stages. During the pre-clinical stage, research scientists perform pharmacology and toxicology studies in various animals. Before testing in humans, an application for the compound must be filed with and approved by the requisite regulatory authorities. Testing in humans is performed in different clinical phases to demonstrate the safety and efficacy of a new compound:

*Phase I.* In clinical phase I, studies are performed on healthy human volunteers to obtain information concerning safety, preliminary dose-ranging, pharmacokinetics and preliminary interaction with other medications.

*Phase IIa.* In clinical phase IIa, studies are performed to study the pharmacological activity of the dose range determined in the phase I studies and/or to assess preliminary therapeutic activity in patients.

*Phase IIb.* In clinical phase IIb, the aim is to determine the risk ratio, *i.e.*, to demonstrate the clinical activity and to determine the optimal dose in a larger and more varied population.

*Phase III.* In clinical phase III, we verify the clinical efficacy of the compound on a large population of patients (usually between 3,000 and 5,000 volunteers). These studies involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound).

Together, phases II(b) and III typically take from three to five years to complete. Thereafter, an application containing all data for the proposed drug is sent to regulatory authorities for approval, which may take an additional six months to two years or longer. There are two types of further clinical trials: one called phase IIIb, where new indications are sought; and one called phase IV trials, which are generally carried out after product launch to continue to monitor the efficacy and safety of a new drug.

**Table of Contents**

The table below sets out, in summary form, our current principal projects in phase IIb or phase III clinical trials, together with the current projected filing dates for each product if phase III trials are successful. No assurance can be given that the products discussed below will complete the development process, that they will be filed for approval on the planned timetable or that they will ultimately receive the required governmental approvals necessary for commercial launch.

**Principal Compounds in Phase IIb, III or IIIb Clinical Trials**

<b>Product</b>	<b>Indication</b>	<b>Status</b>	<b>Targeted Filing</b>
<b>Cardiovascular/Thrombosis</b>			
Arixtra® (fondaparinux sodium)	Acute coronary syndrome	Phase IIIb	2005
	Other venous thromboembolic events after surgery or in medical patients	Phase IIIb	2004
Dronedarone	Atrial fibrillation	Phase III	2006
Idraparinux sodium	Long-term treatment of deep venous thrombosis/pulmonary embolism and atrial fibrillation	Phase III	2007
SR 121463	SIADH (inappropriate secretion of anti-diuretic hormone syndrome), chronic heart failure, cirrhotic ascites	Phase IIb	2007
<b>Central Nervous System</b>			
Xaliproden	Alzheimer's disease	Phase III	2007
Rimonabant (Acomplia)	Smoking cessation	Phase III	2005
Stilnox® CR (zolpidem MR)	Insomnia	Phase III	2004
Osanetant	Schizophrenia	Phase IIb	2006/2007
Saredutant	Depression/anxiety	Phase IIb	2006/2007
SR 58611	Depression	Phase III	2006/2007
SL 65.1498	Anxiety; muscular contractions	Phase IIb	2006/2007
Eplivanserin	Sleep disorders	Phase IIb	
SL 65.0155	Alzheimer's disease; Parkinson's disease	Phase IIb	
SR 57667B	Alzheimer's disease; Parkinson's disease	Phase IIb	
<b>Oncology</b>			
Eloxatin®	Gastric-pancreas cancer	Phase IIIb	
Tirapazamine	Head and neck cancer	Phase III	
SR 31747	Prostate cancer	Phase IIb	2006/2007
SR 48692	Small cell lung cancer	Phase IIb	
<b>Internal Medicine</b>			
Fumagillin	Intestinal microsporidiosis	Phase III	2004 (Europe)

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Rimonabant (Acomplia)  
Xatral® (alfuzosin)  
Saredutant

Obesity  
Acute urinary retention  
Irritable bowel syndrome

Phase III  
Phase IIIb  
Phase IIb

2005  
2005 (U.S.)

**Table of Contents****Cardiovascular/Thrombosis**

Certain of our principal products in the field of Cardiovascular/Thrombosis currently in phase IIIb, phase III or phase IIb clinical trials are described below.

*Idraparinix sodium (thromboembolic events; Phase III).* Idraparinix sodium belongs to the synthetic oligosaccharide family and is an injectable synthetic pentasaccharide, selectively inhibiting coagulation factor Xa. Idraparinix sodium has a demonstrated potency and long duration of action that permit a therapeutic regimen consisting of only one injection per week in humans. The results of the PERSIST phase IIb study, published in September 2002, compared idraparinix sodium with anti-vitamin K in the treatment of venous thrombosis and permitted selection of the 2.5mg dose and the initiation of two Phase III trials, VAN GOGH and AMADEUS, both of which started in early 2003 and are expected to enroll over 10,000 patients. The VAN GOGH program is studying idraparinix sodium in the long-term treatment of thromboembolic events in patients suffering from deep-vein thrombosis or pulmonary embolism. The AMADEUS program is studying idraparinix sodium in the prevention of thromboembolic events associated with atrial fibrillation.

*Dronedarone (atrial fibrillation; phase III).* The current reference anti-arrhythmic is still amiodarone, which we have marketed since the late 1960s under the brand name Cordarone®. With dronedarone, a potential successor to Cordarone®, our goal is to develop a new treatment that is at least as effective as amiodarone, but with improved tolerability. The first indication being developed for dronedarone is the prevention of recurrence of atrial fibrillation, the most common cardiac rhythm disorder. The usual treatment for acute atrial fibrillation is an external electric shock to the heart, which is then generally followed by a medicinal anti-arrhythmic agent to avoid recurrences, which are extremely common. In 2002, we initiated two Phase III programs to study both the efficacy and tolerability of dronedarone. The EURIDIS (Europe) and ADONIS (North and South America, Australia and South Africa) phase III trials are studying the efficacy of dronedarone in the prevention of recurrences in patients who have already experienced atrial fibrillation. We completed the trials involving 1,245 patients in early 2003. These studies confirmed dronedarone as an anti-arrhythmic with a high benefit/risk ratio, particularly with the absence of any proarrhythmic effect. We have concluded based on these results that dronedarone is highly effective in all recurrences of atrial fibrillation, including symptomatic recurrences. The other phase III trial we began during 2002, ANDROMEDA, was studying the tolerability of dronedarone in high-risk patients suffering from heart failure and impaired ventricular function. We stopped the ANDROMEDA trial in January 2003 after enrolling 627 patients instead of the planned 1,000 when an interim tolerability analysis indicated a higher potential risk of death in the group treated with dronedarone. We plan to develop a new protocol for the tolerability study after we have completed a detailed analysis of all data gathered.

SR 121463 (*Vasopressin V2 receptor antagonist; phase IIb*). SR 121463, a pure aquaretic compound, is a Vasopressin V2 receptor antagonist developed to correct serum sodium levels. A phase IIb study of this compound on Syndrome of Inappropriate AntiDiuretic Hormone Secretion (SIADH) was completed in 2003. In a double-blind comparison study of five-day treatments, we saw a significant increase in serum sodium levels. We also saw positive outcomes in a Phase IIa study of SR 121463 on the levels of diuresis and plasma sodium in cirrhotic patients. Based on these favorable results, we plan to start phase III development of SR 121463 in the second quarter of 2004, enrolling 75 patients in a placebo-controlled study of the correction of serum sodium levels in SIADH.

**Central Nervous System**

Certain of our principal products in the field of Central Nervous System currently in phase IIIb, phase III or phase IIb clinical trials are described below.

*Xaliproden (Alzheimer's disease; phase III).* Xaliproden is a non-peptide compound that activates the synthesis of endogenous neurotrophins. It is orally active as a single daily dose. Because xaliproden has





---

**Table of Contents**

both neurotrophic and neuroprotective properties, we believe it could be the first treatment capable of slowing the progression of Alzheimer's disease, compared to current treatments for Alzheimer's disease, which are purely symptomatic. So far, xaliproden's efficacy as a curative or preventive treatment has been demonstrated in vitro and in vivo in numerous models of central or peripheral neurodegeneration. We completed phase II studies in 2002, which confirmed the tolerability of xaliproden in elderly subjects with Alzheimer's disease, and we initiated an international Phase III development program in 2003.

*SR 57677B (Alzheimer's disease, Parkinson's disease; phase IIb)*. SR 57667B, like xaliproden, is a non-peptide compound that activates the synthesis of endogenous neurotrophins. With both neurotrophic and neuroprotective properties, we believe that SR 57677B may have potential therapeutic applications in the treatment of Alzheimer's disease and Parkinson's disease. In 2003, we initiated a phase IIb research program, which we expect to enroll more than 1,200 patients in total.

*SL 65.0155 (Alzheimer's disease, Parkinson's disease; phase IIb)*. SL 65.0155 is a partial serotonin receptor agonist that has both neuroprotective and memory improving properties. We believe that these properties will enable SL 65.0155 to encourage neuron repair and to prevent memory loss. In 2003, we began phase IIb studies.

*Osanetant (schizophrenia; phase IIb)*. We designed an original study protocol, METATRIAL, to evaluate the therapeutic activity of four compounds possessing novel mechanisms of action in patients with schizophrenia. Osanetant, an NK<sub>3</sub> receptor antagonist, showed an activity and a profile close to those of haloperidol, the reference treatment, combined with very good tolerability. Based on these results, the phase II clinical investigation continued in 2003. Osanetant was also being developed for depression. However, the phase IIb trial evaluating the potential of osanetant in severe depression proved non-conclusive and was discontinued.

*SR58611 (depression; phase III)*. SR58611 is a beta<sub>3</sub> adrenergic receptor antagonist. These substances stimulate neuronal activity in a specific region of the prefrontal cortex and could give rise to a new class of anti-depressants. In a phase IIa trial in patients suffering from severe, recurrent depression, SR58611 was observed to be superior to fluoxetine, a reference treatment, and was well-tolerated. The results of a phase IIb study comparing SR58611 to paroxetine, a reference treatment, demonstrated an efficacy and tolerability profile that were sufficiently encouraging to warrant further studies. We initiated two phase III trials in 2003.

*Saredutant (depression; phase IIb)*. Saredutant is an NK<sub>2</sub> receptor antagonist developed for the treatment of Major Depressive Disorders. In 2003, we completed a phase IIb study of six-week treatment of patients with moderate to severe major depressive disorder episodes. The results of the study were positive, and we plan to progress to phase III studies in 2004. We are also studying the use of saredutant in irritable bowel syndrome.

*Rimonabant (smoking cessation; phase III)*. Rimonabant is a CB<sub>1</sub> endocannabinoid receptor antagonist that we are studying as an aid both to quit smoking and for the long-term maintenance of abstinence from smoking. The results of a 10-week phase IIa trial completed in 2002 showed that rimonabant resulted in smoking cessation rates superior to those achieved with placebo. The trial also showed the patients receiving rimonabant lost an appreciable amount of weight in contrast to placebo-treated patients ceasing to smoke, who gained weight. Based on these results, and in agreement with the FDA, we began a large-scale phase III program, to include over 6,500 patients, in the United States and Europe in 2002. Preliminary results of the STRATUS-US program on smoking cessation demonstrated elevated prolonged abstinence rates in smokers receiving dosages of 20 mg of rimonabant during the last four weeks of treatment, with a low incidence of body weight gain and a positive safety profile, with no safety issue detected through laboratory, vital signs or ECG data. We are also studying the use of rimonabant for the treatment of obesity, see Internal Medicine below.

## **Table of Contents**

### ***Internal Medicine***

Certain of our principal products in the field of Internal Medicine currently in phase III clinical trials are described below.

*Rimonabant (obesity; phase III).* Rimonabant is currently the only selective CB1 endocannabinoid receptor antagonist in clinical trials in humans for use in the treatment of obesity. Rimonabant appears to intervene at the center of central appetite, regulating systems by counteracting endogenous cannabinoids (endocannabinoids), such as anandamide. The important aspect of this mode of action is that it induces both a quantitative regulation of calorie consumption and a quantitative regulation of nutrition by diminishing the appetite for fatty foods, or foods with excessive sugar content. Studies to date so far have demonstrated that weight reduction is significant with rimonabant and that it has a good tolerability profile. We began phase III studies to assess rimonabant in the reduction of weight and in the prevention of weight regain in August 2001, enrolling over 6,600 patients. These phase III studies included two large two-year studies, in the United States and in Europe, of 4,200 patients total. The phase III studies also include two additional studies, each including close to 1,000 patients, which 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. The results of one of these phase III studies, presented at the March 2004 conference of the American College of Cardiology, demonstrated the central and peripheral roles of the CB1 receptor and the activity of rimonabant in the regulation of lipid and glucid metabolism and in body weight loss with an excellent safety profile. The other phase III studies will complete recruitment in 2004. We believe that due to its effects on obesity and glyco-lipidic profile, rimonabant is likely to become a cornerstone treatment in the management of patients with cardiovascular risk factors. We are also evaluating rimonabant as an aid to cease smoking, see Central Nervous System above.

*Fumagillin (intestinal microsporidial infection; phase III).* Fumagillin is currently in development for the treatment of intestinal diarrhea of parasitic origin (microsporidia). This kind of diarrhea is severe and can be life-threatening in patients whose immune systems have been weakened. In February 2002, fumagillin was included on the European Union's list of orphan drugs.

### ***Oncology***

One of our principal products in the field of Oncology currently in phase III clinical trials is described below.

*Tirapazamine (head and neck cancer; phase III).* Tirapazamine is an anti-cancer agent that is not directly cytolytic, but promotes the destruction of resistant hypoxic cells. This innovative mechanism of action is likely to diminish the rate of relapse. Phase III trials on tirapazamine in combination with cisplatin and vinorelbine in non-small-cell lung cancer were not conclusive, and the development of Tirapazamine for this indication was discontinued. Phase III clinical studies for indications in head and neck cancer are ongoing.

### **Production and Raw Materials**

Generally, we develop and manufacture the active ingredients that we use in our products. We have a general policy of producing the active ingredients for our principal products at our own plants rather than outsourcing production. Even though we must outsource certain production elements, we are committed to this general principle, which reduces our dependency on key suppliers.

In February 2001, we sold two manufacturing facilities to Dynamit Nobel, and we outsource to those facilities the production of the active ingredients used in Stilnox®, Kerlone®, Xatral®, Solian® and Tildiem®. Our outsourcing agreement requires us to purchase around 80% of our

manufacturing requirements of the ingredients

## **Table of Contents**

for Stilnox<sup>®</sup>, Xatral<sup>®</sup> and Solian<sup>®</sup> and all of our manufacturing requirements of the ingredients for Kerlone<sup>®</sup> and Tildiem<sup>®</sup> from these facilities through December 31, 2004, at which point we may manufacture these ingredients ourselves or negotiate a new outsourcing agreement. Either we or Dynamit Nobel may terminate the outsourcing agreement in the event of a material breach that is not cured for any one of the active ingredients. Additionally, we may terminate the agreement for any one of the active ingredients if they continuously fail to meet specifications or are used in a product that is withdrawn from the market.

In connection with our proposed acquisition of Aventis we have begun to divest our interests in Arixtra<sup>®</sup> and Fraxiparine<sup>®</sup>. Our facility at Notre-Dame de Bondeville may also be sold.

Among our other key products, we also depend on third parties in connection with the manufacture of Eloxatin<sup>®</sup>. Under the terms of our license agreement, we purchase the active ingredient from Debiopharm, and the production of the finished product is outsourced to two manufacturers.

Our principal manufacturing processes consist of three stages: the manufacture of active ingredients, the incorporation of those ingredients into products designed for use by the consumer and packaging. Each stage of the manufacturing process is carried out under carefully controlled conditions and is regulated by applicable legislation including, for facilities that produce products marketed in the United States, the U.S. Food and Drug Administration, or FDA. Wherever possible, we seek to have at least three plants approved for the production of key active ingredients and finished products. All of our facilities are Good Manufacturing Practice, or GMP, compliant in accordance with international guidelines.

We purchase a variety of raw materials for use in our manufacturing processes. When possible, we have a policy of maintaining multiple sources of supply for materials. In a few cases raw materials may be in short supply. For example, there are limited supplies of a raw material used in the manufacture of Fraxiparine<sup>®</sup>. Nonetheless, we have not experienced any difficulty in obtaining a sufficient supply of raw materials in recent years and believe that we will be able to obtain supplies in sufficient quantities in the future. We are not exposed to any material risk related to the volatility of the prices of raw materials that we outsource.

Our main production facilities are located in France, Hungary, the United Kingdom and Spain, with additional facilities located in many other countries around the world including in Northern Africa, Eastern Europe, Asia and Latin America.

## **Marketing and Distribution**

### *Overview*

We have our largest presence in Europe, which accounted for 4,693 million, or 58.3% of 2003 consolidated net sales. In Europe, France is our largest single country in terms of sales and accounted for 1,646 million, or 20.4% of our 2003 consolidated net sales. Other European countries accounted for 3,047 million, or 37.9% of our 2003 consolidated net sales, with Germany, Italy, Spain and the United Kingdom representing the largest European markets other than France. Our next largest market is the United States, which accounted for 1,912 million, or 23.8% of 2003 consolidated sales.



**Table of Contents**

The following table breaks down our consolidated net sales by geographic market for 2001, 2002 and 2003:

	<b>Year Ended December 31,</b>		
	<b>2001</b>	<b>2002</b>	<b>2003</b>
	( in millions)		
<i>Europe</i>			
France <sup>(1)</sup>	1,487	1,584	1,646
Germany	596	634	667
Italy	433	444	478
Other <sup>(2)</sup>	1,361	1,642	1,902
<i>Total Europe</i>	<u>3,877</u>	<u>4,304</u>	<u>4,693</u>
United States	1,098	1,689	1,912
Other countries	1,513	1,455	1,443
<i>Total net sales</i>	<u>6,488</u>	<u>7,448</u>	<u>8,048</u>

(1) Includes French overseas territories (Guadeloupe, Martinique, Réunion and French Guyana).

(2) From 2003, figures for Europe include sales in Slovenia. Prior to 2003, sales in Slovenia were included in other countries. 2002 figures have been modified to conform to the new presentation. The impact on 2001 figures is not significant.

Our principal marketing activities have historically focused on Europe and have been conducted through our own subsidiaries. In the United States and Japan, which together with Europe make up the most significant part of the world pharmaceutical market, we have historically marketed most of our products through partnerships with other pharmaceutical companies. We have increased our presence in the U.S. market, by acquiring the remainder of the Lorex Pharmaceuticals joint venture, which marketed Stilnox<sup>®</sup> (under the name Ambien<sup>®</sup>) and Kerlone<sup>®</sup> in the United States, from Pharmacia in April 2002, by increasing our involvement in the promotional activities and profits of the alliance with Bristol-Myers Squibb that markets Aprovel<sup>®</sup> (under the name Avapro<sup>®</sup>) in the United States from October 2001, and by marketing directly in the United States key strategic products such as Eloxatin<sup>®</sup> and Xatral<sup>®</sup> (under the name Uroxatral<sup>®</sup>). These alliances are described below under Alliances and Item 5 Operating and Financial Review and Prospects Overview Financial Presentation of Alliances. Our proprietary U.S. sales force, which numbered 2,675 as at December 31, 2003, has tripled over the last three years from 880 as at December 31, 2000.

We manage the marketing process by integrating the marketing approach developed by our central strategic marketing group at our headquarters in Paris with that of our group companies in their local markets. A major focus of our marketing strategy is to launch new products in the appropriate key world markets as rapidly as possible, subject to the constraints imposed by the extensive process of obtaining regulatory approvals. The launch of a major product is supported by participation in scientific conferences and exhibitions and by informing the medical community of the qualities, applications and limitations of the product. This process involves the presentation of information generated by clinical trials in a form tailored to each market.

**Table of Contents*****Direct Sales Force and Representative Offices***

We market and promote our products primarily through our own sales force and also have representative offices in certain countries. The following table sets forth certain information about the geographical distribution of our sales force.

**Sales Force by Region**

	<b>At December 31, 2003</b>	
	<b>Sales Force</b>	<b>% of Total</b>
Europe	5,090	43.9%
United States	2,675	23.1%
Other Countries	3,836	33.1%
<b>Total</b>	<b>11,601</b>	<b>100%</b>

***Alliances***

In 2003, we had two major alliances through which three of our leading products were marketed. The first, with Bristol-Myers Squibb, or BMS, governs the development and marketing of Aprovel<sup>®</sup> and Plavix<sup>®</sup>. The second, with Organon, a subsidiary of Akzo Nobel, governed the development and marketing of Arixtra<sup>®</sup>. In addition, until April 2002, Stilnox<sup>®</sup> was the subject of a major alliance. The alliance structures have had a significant impact on the effect that sales of these products have had on our financial condition and results of operations. The financial impact of these structures on our results of operations is described in detail under Item 5 Operating and Financial Review and Prospects Overview Financial Presentation of Alliances.

***BMS***

We market Aprovel<sup>®</sup> and Plavix<sup>®</sup> through a series of alliances with Bristol-Myers Squibb, or BMS. The alliance agreements include marketing and financial arrangements that vary depending on the country in which the products are marketed.

There are three principal marketing arrangements that are used in the BMS alliance:

*Co-marketing.* Under a co-marketing system, each company markets the products independently under its own brand names.



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

*Exclusive Marketing.* Under the exclusive marketing system, one company has the exclusive right to market the products.

*Co-promotion.* Under a co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel<sup>®</sup> is under development through agreements between BMS and the Japanese pharmaceutical company Shionogi Pharmaceuticals, and Plavix<sup>®</sup> is under development through an alliance between our company and Daiichi Pharmaceuticals Co., Ltd.

*Territory under our operational management.* In the territory under our operational management, the marketing arrangements are as follows:

We use the co-promotion system for most of the countries of Western Europe for Aprovel<sup>®</sup> and Plavix<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>.

**Table of Contents**

We use the co-marketing system in Germany, Spain and Greece for both Aprovel® and Plavix®, and in Italy for Aprovel®.

We have the exclusive right to market Aprovel® and Plavix® in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel® in Asia (excluding Japan).

*Territory under BMS operational management.* In the territory under BMS operational management, the marketing arrangements are as follows:

We use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS.

We use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix® and Aprovel® and in Colombia for Plavix®.

We have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we often sell the active ingredients for the products to BMS or such entities.

*Organon*

Through January 2004, we had an alliance with Organon, a subsidiary of Akzo Nobel, covering the worldwide development, manufacturing and commercialization of Arixtra®. Similar to our other alliances, the marketing and financial arrangements varied depending on the region in which Arixtra® was sold, as follows:

*North America.* In the United States, Mexico and Canada, Arixtra® was sold by entities that we jointly controlled on a 50/50 basis with Organon.

*Europe and Other Countries (excluding Japan).* We had the exclusive right to market and sell Arixtra®.

In January 2004, we agreed to acquire all of Organon's interests relating to Arixtra® that were the subject of this joint venture, as well as Organon's interests relating to idraparinux sodium and other oligosaccharides. We now have full rights to market Arixtra® and other products worldwide and will make royalty payments to Organon based on future sales, under a licensing arrangement.

In connection with our proposed acquisition of Aventis, on January 26, 2004, we began a sales process to divest our interests in Arixtra® in order to be able to respond to possible demands of the competition authorities. As of the date of this annual report, confidential discussions and negotiations are ongoing with several interested parties.

*Japan*

In Japan, we market our products primarily through alliances or by licensing our products to other pharmaceutical companies. Our most important alliances and licensing agreements in Japan are with Fujisawa for Stilnox<sup>®</sup> and Dogmatil<sup>®</sup>; Daiichi for the development of Plavix<sup>®</sup>; Mitsubishi for Kerlone<sup>®</sup> and Yamanouchi for Corotrope<sup>®</sup>. We also have an agreement with Taisho for Cordarone<sup>®</sup> (under the name Ancaron<sup>®</sup>), although in January 2004 we signed an agreement with Taisho that will permit us to market the product directly beginning in 2006.

## **Table of Contents**

### ***Other Countries***

In order to strengthen our worldwide presence, we have entered into other types of agreements, including alliances in Slovenia, China, Vietnam and Indonesia.

### **Patents, Intellectual Property and Other Rights**

#### ***Trademarks***

Our products are sold around the world under brand-name trademarks that we consider to be of material importance in the aggregate. It is our policy to register our trademarks worldwide, and to monitor the trademarks in our portfolio and defend them worldwide.

The degree of trademark protection varies country by country, as each state implements its own laws applicable to trademarks used in its territory. In some countries, trademark protection is primarily based on use, whereas in other countries, trademark rights may only be obtained by registration. Registrations are generally granted for a fixed term (typically ten years) and are renewable indefinitely, but in some instances may be subject to the continued use of the trademark. When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration. We usually register our trademarks so as to cover pharmaceutical products in class 5, although we sometimes are required, subject to local trademark law requirements, to further specify the type of product protected by the trademark. Additionally, in certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to better protect and defend our trademarks.

#### ***Patents***

We currently own approximately 9,800 patents and patent applications worldwide, and we license-in approximately 30 patents. These patents cover:

active ingredients,

pharmaceutical formulations,

product manufacturing processes,

intermediate chemical compounds used in manufacturing, and

therapeutic indications.

Patent protection for individual products typically extends for 20 years from the filing date in countries where we seek patent protection. This protection may be further extended in some countries, in particular in Europe, the United States and Japan. The protection afforded depends upon the type of patent and its scope of coverage and may also vary from country to country. In most industrial countries, patent protection exists for new active substances and formulations, as well as for new indications and production processes. We monitor our competitors and vigorously challenge patent and trademark infringements.

The expiration of a product patent may result in significant competition from generic products against the covered product and, particularly in the United States, can result in a dramatic reduction in sales of the pioneering product. In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets, patents on processes and intermediates for the economical manufacture of the active ingredients, patents for special formulations of the product or for delivery mechanisms, and conversion of the active ingredient to OTC products. In some countries, including Europe and the United States, many of our

---

## Table of Contents

products may also benefit from a 5- to 10-year market exclusivity period. This exclusivity period operates independently of patent protection and may protect the product from generic competition even if the basic patent for the product has expired.

Among our top ten products, Cordarone<sup>®</sup> and Solian<sup>®</sup> no longer enjoy any kind of patent protection in major markets. For certain of our other top 10 products, including Fraxiparine<sup>®</sup>, Tildiem<sup>®</sup> and Depakine<sup>®</sup>, the main patent has expired and we only have patent protection on a particular formulation of the drug or on a manufacturing process in certain countries. For Plavix<sup>®</sup> there are three U.S. patents, one expiring in 2011 and two expiring in 2019, and two European patents, expiring in 2013 and 2019, respectively. We have an additional U.S. patent expiring in 2014, although we have requested the FDA to delist this patent from its list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the FDA's Orange Book. Finally, two patents expired during 2003 (one U.S. and one European). Aprovel<sup>®</sup> protected in the United States until 2011 and in Europe until 2012. Stilnox<sup>®</sup> began to lose some of its patent protection in 2002, and its remaining main patents will expire in different countries during 2004 (France) through 2006 (United States and Japan). Arixtra<sup>®</sup> has market exclusivity in the United States until 2006, and in Europe it will have data protection until 2012. Among our strategic products, Eloxatin<sup>®</sup> is marketed under a licensing agreement, as we do not own the Eloxatin<sup>®</sup> patents but in-license them from a third party for marketing. Those patents expire in 2013.

The most recent of our major pharmaceutical products to go off patent in major markets was Corotrope<sup>®</sup>, whose main patents expired in the United States in May 2002 (where it is sold under the brand name Primacor<sup>®</sup>).

One of the main limitations on our operations in some countries outside the U.S. and Europe is the lack of effective intellectual property protection of our products. Under international agreements in recent years, global protection of intellectual property rights is improving. The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which forms part of the General Agreement on Tariffs and Trade, requires developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products by the end of a 10-year transition period that expires on January 1, 2005, and a number of countries have already enacted such amendments. Although the situation has gradually improved, the lack of protection for intellectual property rights poses difficulties in certain countries.

In the United States, two pharmaceutical companies have filed Abbreviated New Drug Applications, or ANDAs, challenging our patent related to Plavix<sup>®</sup> that expires in 2011, as well as other patents that have since expired or that we have not pursued in the litigation. See Item 8 Financial Information Legal Proceedings. An ANDA is an application by a generic manufacturer for an abbreviated approval of a generic product. See Regulation below. We believe that our patent rights are valid and we intend to defend them vigorously.

On March 5, 2004, we were informed that Teva Pharmaceuticals USA, Inc., or Teva, a generic drug manufacturer, filed an ANDA with the FDA claiming that one of our patents relating to Plavix<sup>®</sup> is invalid (the patent expiring in 2014 that we are seeking to delist from the FDA's Orange Book as discussed above) and that two others (those expiring in 2019) will not be infringed by Teva. None of these patents is involved in the pending patent infringement litigation involving Plavix<sup>®</sup> that we have filed against Apotex and Dr. Reddy's Laboratories, two generic drug manufacturers. The Teva filing does not challenge the patent at issue in the Plavix<sup>®</sup> litigation and therefore is not expected to have any impact on that litigation; nor does it appear that Teva intends to commercialize a generic form of Plavix<sup>®</sup> prior to the expiration or termination of the patent at issue in the Plavix<sup>®</sup> litigation (which does not expire until 2011), although there can be no assurance that this will continue to be the case.

Other than as described in this annual report, we are not currently involved in any material patent or trademark litigation nor, to our knowledge, is any such litigation threatened.

---

## Table of Contents

### **Competition**

The pharmaceutical industry in which we operate is highly competitive. Over the last few years, the pharmaceutical industry has experienced increased vertical and horizontal consolidation. In addition to the consolidation, significant changes in marketing conditions are occurring in the European, U.S. and Japanese pharmaceutical markets, including decreased pricing flexibility, increased cost control measures, and the impact of managed care, especially with respect to product selections and pricing concessions. As a result of these factors, the breadth of products that we offer and our distribution capabilities have become increasingly important.

The pharmaceutical market is generally defined by three types of competition:

competition among pharmaceutical companies to develop new patented products for a specific therapeutic indication;

competition among patented pharmaceutical products for a specific therapeutic indication; and

competition among original products with generic bioequivalent products following the loss of patent protection.

We compete with other pharmaceutical companies to develop new and innovative pharmaceutical products. We may develop new technologies and new patented products entirely internally, or we may enter into collaborative research and development arrangements in order to access additional new technologies. When we compete for new technologies through outside research and development collaborative arrangements, we compete directly with large pharmaceutical companies. Some of these companies have substantially greater resources than our company and may be able to offer more attractive milestone payment or other terms. Additionally, as many of these companies have larger U.S. sales forces and consequently larger presences in the U.S. market, the largest market for pharmaceuticals, they may be more attractive partners for smaller pharmaceutical companies that are typically compensated with royalty payments of sales of products developed.

Once a patented product is on the market, it competes directly with other products that have been developed for the same therapeutic indication. For example, Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Stilnox<sup>®</sup>, Eloxatin<sup>®</sup>, Xatral<sup>®</sup> and Arixtra<sup>®</sup>, among others, may face competition from existing products or other products that have recently appeared on the market or are in later-stage development by other companies. Plavix<sup>®</sup>, for example, has always faced competition from acetylsalicylic acid, and a combination of acetylsalicylic acid and dipyridamole (Asasantin<sup>®</sup>/Aggrenox<sup>®</sup> produced by Boehringer-Ingelheim GmbH). Aprovel<sup>®</sup> competes directly with Cozaar<sup>®</sup> (produced by Merck & Co., Inc.), Diovan<sup>®</sup> (produced by Novartis AG) and Benicar<sup>®</sup> (produced by Sankyo/Forest Laboratories), Stilnox<sup>®</sup> competes directly with Sonata<sup>®</sup> (produced by King Pharmaceuticals), Eloxatin<sup>®</sup> competes directly with Campto<sup>®</sup>/Camptosar<sup>®</sup> (produced by Aventis/Pfizer), Xatral<sup>®</sup> competes with Flomax<sup>®</sup> (produced by Abbott Laboratories/Boehringer-Ingelheim GmbH), Proscar<sup>®</sup> (produced by Merck & Co., Inc.) and Hytrin<sup>®</sup> (produced by Abbott Laboratories) and Arixtra<sup>®</sup> competes directly with low molecular weight heparins, notably Lovenox<sup>®</sup> (produced by Aventis).

Finally, when a pharmaceutical product loses patent protection, it typically faces competition from generic products, which generally are priced much lower than the original product. We thus compete directly on price with generic product manufacturers for sales once one of our products loses patent protection. For example, since Corotrope<sup>®</sup>'s U.S. patent protection expired in May 2002, it has faced direct competition from generics. As expected, this competition has led to a significant drop in sales in the United States of Corotrope<sup>®</sup> (where it is sold under the brand name Primacor<sup>®</sup>).

**Pricing**

In addition to the normal competitive forces that affect the level of prices, a further constraint exists in the form of price controls in most countries where we sell our products. These controls arise either by law or because



**Table of Contents**

the government or other healthcare providers in a particular jurisdiction are the principal purchasers of the product or reimburse purchasers for the cost of the product. Price control mechanisms operate differently in different jurisdictions and can result in large price differentials between markets, which may be aggravated by currency fluctuations (apart from countries of the European Monetary Union, which have had the same currency since January 1, 2002). These price differentials can also be exploited by traders (parallel importers) who purchase brand-name products in lower-priced markets for resale in higher-priced markets.

In recent years, cost-control efforts by public authorities have led to a tightening of reimbursement policies in most of the countries in which we operate, particularly in Western Europe, where state-controlled healthcare programs (with reimbursement of a percentage of health expenses by the state) are common. Direct cost control measures can take a variety of forms, including mandatory price reductions (or failure to approve price increases), increases in the percentages to be paid by patients (the co-pay), exclusion of certain products from lists of reimbursable products, benchmarking of reimbursement prices based on the lowest priced therapy available in a category, cost-benefit analysis of prescription pharmaceuticals, encouragement of the growth of generic drug markets and consideration of the price paid in other countries for the same product. For example, in 2003, Italian authorities continued cost-containment measures by implementing a 2% price decrease for reimbursed products in January 2003 and extended the reference price system to certain therapeutic classes.

German healthcare reforms published in November 2003 call for a benefit analysis of prescription drugs and drug guidelines to be conducted by a future public institute for quality and economic efficiency in the health sector, and the inclusion of patented drugs without significant therapeutic benefits in the reference price system. The inclusion of drugs in the reference price system has the effect of lowering their prices. Although the implementation of these proposed changes is not yet finalized, until such time, the obligatory manufacturers' discount to *Krankenkassen* (German public health insurance system) on non-reference priced drugs increased from 6% to 16% effective from January 1, 2004, and life-style and non-prescription drugs will no longer be reimbursed.

In certain European countries, governments also influence the price of pharmaceutical products indirectly through control of national healthcare systems that fund a significant portion of the cost of such products. In France, for example, a government authority sets the price level for reimbursable medications and, since 2002, must take into account the scientific value of the product, as well as the individual agreements signed between the governmental authority and the pharmaceutical companies. Every five years (to be reduced to three years in the near future), the reimbursement of and price levels for products on the list are reviewed. The price of a product depends on the benefits it provides in rendering medical treatment (including innovations) as well as an economic analysis of the product in comparison to existing treatments. In furtherance of these rules, the French government published an official list of 617 products judged to have weak or moderate medical benefits in April 2003, for which the reimbursement rate has been reduced from 65% to 35%. None of our major products were included on this list. An additional list of 82 products, judged to be of low medical value, was also published, and since October 25, 2003, these products are no longer reimbursed. None of our major products were included on this list. Finally, in August 2003, the French government published a list of 29 active ingredients to be affected by a reference price system. Although none of our top 10 products was on this list, certain of our other non-core products were included, so we have reduced the retail price to the reference price level. The government is expected to publish a second list of products to be affected by the reference price system during 2004.

Additionally, in June 2003, a new framework agreement regulating French pharmaceutical prices, promotions and reimbursement of sales, was entered into by the Economic Committee for Medical Products (CEPS) and the National Union for the Pharmaceutical Industry (LEEM) that will be in effect through December 31, 2006. One of the main features of this new framework agreement is faster price determination for products authorized under the EU centralized procedure and for those products that represent an improvement in medical service via a price notification system. The system requires French pharmaceutical companies to propose prices comparable to those in Germany, the United Kingdom, Spain and Italy, and imposes a 14 to 21-day deadline for the CEPS to object to the price.

## **Table of Contents**

In Japan, the National Health Ministry conducts bi-annual reviews of the prices of certain pharmaceutical products (in the past, these reviews have resulted in regular price reductions). In the United States, there are currently no price controls over private sector pharmaceutical purchases; however, federal and state legislation require drug manufacturers to pay rebates on certain drugs to state Medicaid agencies based on each state's reimbursement of pharmaceutical products under the Medicaid program. We also must give discounts or rebates in the United States on purchases or reimbursements of pharmaceutical products by certain other federal and state agencies and programs. Although Medicare reform was enacted in December 2003 in the United States, it is not effective until 2006 and we are evaluating the impact it could have on our business, although we do not expect it to be material. Further healthcare reforms continue to be considered in both the United States and other jurisdictions and, depending on their form, adoption could have a material effect on our future operations. In the absence of new government regulation, managed care has become a potent force in the market place that increases downward pressure on prices of pharmaceutical products.

## **Regulation**

The international pharmaceutical industry is highly regulated. National and supranational regulatory authorities administer numerous laws and regulations covering the testing, approval, manufacturing, importation, exportation, labeling and marketing of drugs, and also review the quality, safety and efficacy of pharmaceutical products. Of particular importance is the requirement to obtain and maintain regulatory approval for a pharmaceutical product from a country's national regulatory authority before such product may be marketed in that country and thereafter. These regulatory requirements are a major factor in determining whether a substance can be developed into a marketable product and the amount of time and expense associated with such development.

The submission of an application to a regulatory authority does not guarantee that a license to market the product will be granted. Furthermore, each regulatory authority may impose its own requirements and may refuse to grant, or may require additional data before granting, an approval, even though the relevant product has been approved in another country. Regulatory authorities also have administrative powers that determine product recalls, seizure of products and other sanctions.

Europe, the United States and Japan all have very high standards for technical appraisal. The length of time required to obtain approval varies by country, but generally takes from six months to, in some cases, several years from the date of application, depending on the quality of data produced, the degree of control exercised by the regulatory authority, the efficiency of its review procedures and the nature of the product. In recent years, intensive efforts have been made among the United States, the European Union, or EU, and Japan to harmonize registration requirements. Many pharmaceutical companies are now able to prepare a common technical document, or CTD, that can be used in each jurisdiction for a particular product with local or regional adaptation. However, the requirement of many countries (including Japan and several member-states of the EU) to negotiate selling prices or reimbursement levels with government regulators can substantially extend the time to market after initial approval is granted.

In the EU, there are two main procedures by which to apply for marketing authorization, namely the Centralized Procedure and the Mutual Recognition Procedure. In the Centralized Procedure, applications are made to the European Agency for the Evaluation of Medicinal Products for an authorization that is valid across all EU member-states. The Centralized Procedure is mandatory for all biotechnology products and optional for other new chemical compounds or innovative medicinal products. In the Mutual Recognition Procedure, a first authorization is granted by a single EU member-state. Subsequent mutual recognition of this first authorization is sought from the other EU member-states. National authorizations are still possible but are only for products intended for commercialization in a single EU member-state, or for line extensions to existing national product licenses.

In the United States, applications for drug registration are submitted to and reviewed by the FDA. The FDA has broad regulatory powers over all pharmaceutical products that are intended to be, and which are,



## **Table of Contents**

commercialized in the United States. To commercialize a product in the U.S., a new drug application ( NDA ) is filed with the FDA with data that sufficiently demonstrate the drug's quality, safety and efficacy. A supplemental new drug application ( sNDA ) must be filed for the approval of a new indication of a previously registered drug.

Generic drug manufacturers may file an abbreviated new drug application ( ANDA ). These applications are abbreviated because generic manufacturers need only demonstrate that their product is bioequivalent (*i.e.*, that it performs in the same manner as the innovator's drug). Consequently, the length of time for development of such product can be considerably shorter than for the innovator's drug.

Once marketing authorization is granted, the new pharmaceutical (or new indication) may be prescribed by physicians. Thereafter, the drug owner must submit periodic reports to regulatory authorities including any cases of adverse reactions. For some medications, regulatory authorities may require additional studies to evaluate long-term effects or to gather information on the use of the product under special conditions. In addition, manufacturing facilities must also be approved by regulatory authorities, and are subject to periodic inspections. In addition to local regulatory approvals, a non-U.S. manufacturing facility that exports products for sale in the United States must be approved by the FDA, and is also subject to periodic FDA inspection.

In addition to the regulatory approval of our products, all of our manufacturing facilities must be Good Manufacturing Practice ( GMP ) compliant. GMP is a term that is used internationally to describe a set of principles and procedures that, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality for human use. A basic tenet of GMP is that quality cannot be tested in a batch of product but must be built into all stages of the manufacturing process. These quality system regulations include requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling and storing pharmaceutical products, including guidelines relating to the installation and servicing the equipment used in drug manufacture. Compliance with specified GMP requirements is used by most countries as the basis for licensing the manufacturer of pharmaceutical products.

## **Health, Safety and Environment**

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental laws and regulations. Such laws and regulations are complex and rapidly changing. We have made, and intend to continue to make, necessary expenditures for compliance with them. Our expenditures related to health, safety and environmental compliance vary from year to year. In 2003, we invested approximately 20 million in health, safety and environmental compliance, compared to 23 million in 2002. While we cannot predict with certainty the future costs for compliance, we believe that our designated provisions are adequate based on currently available information. However, given the inherent uncertainties in projecting environmental liabilities we cannot guarantee that additional costs will not be incurred beyond the amounts accrued.

The environmental laws and regulations that we are subject to may require us to remove or mitigate the effects of the disposal or release of chemical substances at our various sites. Under some of these laws and regulations, a current or previous owner or operator of a property may be held liable for the costs of removal or remediation of hazardous substances on, under or in its property, or transported from its property to third party sites, without regard to whether the owner or operator knew of, or caused the presence of, the contaminants. The current or previous owner may also be liable regardless of whether the practices that resulted in the contamination were legal at the time they occurred.

Because certain of our manufacturing sites have an extended history of industrial use, it is impossible to predict precisely what effect these laws and regulations will have on us in the future. As is typical for companies involved in the pharmaceutical industry, soil and groundwater contamination has occurred in the past at some of our sites, and might occur or be discovered at other sites. Four of our French sites are currently

included on a list

## Table of Contents

of potentially contaminated land and sites on a database known as the BASOL, which is maintained by the *Directions Régionales de l'Industrie, de la Recherche et de l'Environnement* (or DRIRE), the French equivalent of the U.S. Environmental Protection Agency, or EPA. In connection with an audit conducted in 1999 and 2000 at the request of the DRIRE, an assessment of the groundwater contamination was conducted at our Sisteron site, and we are now in the process of rehabilitating the site in cooperation with the DRIRE. We also have been identified as having potential liability for investigation and cleanup at several other sites and we are conducting remediation projects at three other sites (current and former). We have established reserves for the currently known sites and for contractual guarantees for environmental liabilities for sites that we have sold, and do not consider these reserves to be amounts that are material to our results of operations.

We believe that we are not currently subject to liabilities for non-compliance with applicable environmental, health and safety laws and regulations that would materially and adversely affect our business, financial condition or results of operations. We also believe that we are in substantial compliance with environmental, health and safety laws and regulations and that we have obtained all material environmental permits required for the operation of our facilities. We are committed to providing safe and environmentally sound work places that will not adversely affect the health or environment of our employees or the communities in which we operate.

We have implemented a health, safety and environmental policy that promotes the health and well-being of our employees and respect for our environment. We consider this policy to be an integral element of our commitment to social responsibility. The key points of this policy are summarized below.

**Health.** From the development of compounds to the launch of new drugs, our research scientists continuously assess the effect of our products on human health. We make this expertise available to our employees through two committees responsible for chemical and biological risk assessment. Our COVALIS committee classifies all chemical and pharmaceutical products handled within the group and sets workplace exposure limits for each of them. Our TRIBIO Committee classifies all biological agents according to their degree of pathogenicity and establishes guidelines for their containment and the preventive measures to be respected throughout our operations.

**Safety.** We have a rigorous policy in place to identify and evaluate risks and to develop preventive measures and methods for checking their efficacy. Additionally, we invest in training schemes that are designed to ensure that a concern for safety is built into all professional activities. We implement these policies worldwide to ensure the safety to our employees and protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures incorporating the chemical substance and processes data from the COVALIS and TRIBIO committees discussed above. Our preventive measures are designed primarily to reduce the number and seriousness of industrial accidents involving our permanent and temporary employees or employees of outside contractors.

Under a recent French law concerning the prevention of technological risks, two of our French sites, Sisteron and Aramon, are subject to increased levels of safety inspections due to the toxic and/or inflammable materials stored on site or used in manufacturing activities. We believe that the security and safety procedures, the risk evaluation studies and the risk management controls in place at each site, as well as the insurance policies covering any possible future material harm to third parties, comply with the new French legal requirements.

**Environment.** Our environmental policy's core objectives are to implement clean manufacturing processes, minimize the use of natural resources and reduce the environmental impact of our business. In order to optimize and improve our environmental performance, we are working towards obtaining ISO 14001 certification. Currently, three of our manufacturing sites and two of our research and development sites are certified. This goal is an integral part of the strategy of continuous improvement practiced in all of our establishments through the annual implementation of health, safety and environment progress plans, known as PASS. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and environment.



**Table of Contents**

Our recent environmental protection efforts have targeted reduction in water consumption, improvement in performance of water treatment installations, in the release of volatile organic compounds, savings or recycling of raw materials and reduction or improved recycled ratios in waste materials. Even with our increased production volume, we have achieved considerable improvements in each of these areas.

**Insurance**

We have set up two worldwide insurance programs with reputable internationally recognized firms. These programs are designed to cover general and product liability, property damage and business interruption, plus damage to goods in transit. In addition to these general programs, we have also taken out other insurance policies for specifically identified risks or to comply with local requirements.

Although we were able to maintain our liability coverage at sufficient levels in 2003, the general trend of introducing new exclusions that are aimed at certain products and of raising the level of deductibles has continued in the insurance industry. This market trend did not affect property cover and business interruption policies to the same degree, although these policies were subject to reductions and some significant exclusions related to the perceived terrorism threat and natural events. In order to address this market trend, we formed a Bermuda-based mutual insurance company in May 2003 with six other major makers of medicinal products. In order to improve our coverage and reduce our costs, this company has participated in our insurance coverage since January 2004.

**C. Organizational Structure**

The table below sets forth our significant subsidiaries and affiliates as of the date of this annual report. For a complete list of our consolidated subsidiaries, see Note F to our consolidated financial statements, included under Item 18 Financial Statements.

<u>Significant Subsidiary or Affiliate</u>	<u>Country</u>	<u>Ownership Interest</u>
Sanofi-Synthelabo Inc.	United States	100%
Sanofi Winthrop Industrie	France	100%
Loxex Inc.	United States	100%

**D. Property, Plants and Equipment**

Our principal executive offices are located in Paris, France. We operate our business through a number of offices, research facilities and production sites throughout the world.

We both own and lease our facilities. We have entered into material leasing and operating leasing agreements with respect to real estate properties located in France in Paris, Gentilly, Chilly Mazarin and Bagneux. Under our operating leases, our real estate properties are composed of buildings constructed pursuant to the operating lease agreements, under which we pay periodic rent and have a purchase option exercisable at expiration. We are responsible for all repairs, taxes and other costs during the term of the operating leases. The operating leases are classified as



debt in our consolidated balance sheet.

In 2003, we spent 338 million primarily to increase capacity and improve productivity at our various manufacturing sites. We believe that our production plants and research facilities are well maintained and generally adequate to meet our needs for the foreseeable future.

**Table of Contents**

Below is a summary of our principal manufacturing, distribution, research and development and administrative facilities. In addition to these principal sites, we have 86 additional facilities throughout the world that serve their local and regional markets.

Facility	Appx. Size (m <sup>2</sup> )	Principal Use
<b>Manufacturing</b>		
Ambarès, France (near Bordeaux)	72,600	Pharmaceutical Manufacturing
Sanofi Winthrop Industrie		(primarily Plavix <sup>®</sup> , Aprovel <sup>®</sup> , Depakine <sup>®</sup> and Cordarone <sup>®</sup> )
1, rue de la Vierge		
BP 599		
33440 Ambarès, France		
Amy, France (near Orléans)	25,800	Chemical and Pharmaceutical Manufacturing and storage
Sanofi Winthrop Industrie		(primarily Aspégic <sup>®</sup> )
196, rue du Maréchal Juin		
Zone Industrielle Amy		
45208 Montargis Cedex, France		
Aramon, France (near Avignon)	47,000	Chemical Manufacturing
Sanofi Chimie		(primarily irbesartan, amiodarone and fondaparinux sodium)
Route d Avignon		
30390 Aramon, France		
Colomiers, France (near Toulouse)	16,200	Pharmaceutical Manufacturing
Sanofi Winthrop Industrie		(primarily Depakine <sup>®</sup> )
1-3 Allée de la Neste		
BP 319		
31773 Colomiers cedex, France		
Notre Dame de Bondeville, France	49,400	Chemical and Pharmaceutical Manufacturing (primarily
(near Rouen)		Fraxiparine <sup>®</sup> , Depakine <sup>®</sup> , Eloxatin <sup>®</sup> (packaging), Arixtra <sup>®</sup> and fondaparinux sodium)
Sanofi Winthrop Industrie		
1, rue de l Abbaye		

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

<p>76960 Notre Dame de Bondeville, France                  Quetigny, France (near Dijon)</p> <p>Sanofi Winthrop Industrie</p> <p>6, boulevard de l Europe</p> <p>21800 Quetigny, France</p>	<p>27,600</p>	<p>Pharmaceutical Manufacturing</p> <p>(primarily Stilnox<sup>®</sup>, Tildiem<sup>®</sup>, Plavix<sup>®</sup> and Solian<sup>®</sup>)</p>
<p>Sisteron, France (near Marseille)</p> <p>45, chemin de Meteline</p> <p>BP 15</p> <p>04201 Sisteron Cedex, France</p> <p>Tours, France</p> <p>30-36, avenue Gustave Eiffel</p> <p>37100 Tours cedex, France</p>	<p>58,000</p>	<p>Chemical Manufacturing</p> <p>(primarily clopidogrel, ticlopidine and fondaparinux sodium)</p>
<p>Alcobendas (near Madrid)</p> <p>Sanofi-Synthelabo SA</p> <p>Avda. de la Industria, 31</p> <p>Poligono Industrial</p> <p>28108 Alcobendas, Spain</p>	<p>12,600</p>	<p>Pharmaceutical Manufacturing</p> <p>(primarily Dogmatil<sup>®</sup>)</p>

**Table of Contents**

Facility	Appx. Size (m <sup>2</sup> )	Principal Use
Csanyikvolgy, Hungary Chinoin Pharmaceuticals Works Co. Ltd P.O.B. 5653510 Miskolc Csanyikvolgy Hungary	13,400	Pharmaceutical Manufacturing (primarily Fraxiparine <sup>®</sup> and Arixtra <sup>®</sup> )
Fawdon, England (near Newcastle) Sanofi Winthrop Ltd. Fawdon Manufacturing Centre Edgefield Avenue, Fawdon Newcastle Upon Tyne, NE3 3TT England	29,000	Pharmaceutical Manufacturing (primarily Plavix <sup>®</sup> , Aprovel <sup>®</sup> and Cordarone <sup>®</sup> )
Riells, Spain (near Barcelona) Sanofi-Synthelabo Carretera de la Batlloria a Hostarlich KM 1,4 17404 Riells y Viabrea (Girona), Spain	15,200	Pharmaceutical Manufacturing (primarily Ticlid <sup>®</sup> and Cordarone <sup>®</sup> )
Ujpest, Hungary (near Budapest) Chinoin Pharmaceutical and Chemical Works Co. Ltd. TO U 1-5 P.O.B. 110 1325 Budapest Hungary	101,000	Chemical and Pharmaceutical Manufacturing (primarily Ticlid <sup>®</sup> and irbesartan)
Veresegyhaz, Hungary Chinoin Levai utca 5	13,300	Pharmaceutical Manufacturing (primarily Cordarone <sup>®</sup> )

Veresgyhaz H-2112

Hungary

**Research and Development**

Alnwick, U.K. (near Newcastle) 12,600 Research

Willowburn Avenue

Alnwick

Northumberland, NE66 NQ

England

Bagneux, France (near Paris) 21,700 Research

Sanofi-Synthelabo Recherche

31, avenue Paul Vaillant Couturier

92200 Bagneux, France

Chilly-Mazarin, France (near Paris) 61,800 Research, as well as distribution

1, avenue Pierre Brossolette

(primarily for the French consumer products market)

91385 Chilly-Mazarin cedex, France

Great Valley, PA, United States 30,100 Research

Sanofi-Synthelabo Research

a division of Sanofi-Synthelabo Inc.

9, Great Valley Parkway

Malvern, PA 19355

U.S.A.

**Table of Contents**

Facility	Appx. Size (m <sup>2</sup> )	Principal Use
Porcheville, France (near Paris) 2-8, rue de Royen Zone Industrielle de Limay 78440 Porcheville, France	24,500	Research
Montpellier, France Sanofi-Synthélabo Recherche 371, rue du Professeur Joseph Blayac 34184 Montpellier cedex 04, France	52,000	Research
Strasbourg, France Sanofi-Synthélabo Recherche 18, rue d Ankara 67080 Strasbourg, France	7,300	Research
Toulouse, France Sanofi-Synthélabo Recherche 195, route d Espagne 31306 Toulouse, France	19,400	Research
<b>Distribution</b>		
Amilly, France (near Orléans) Sanofi-Winthrop Industrie 196, rue du Maréchal Juin Zone Industrielle Amilly 45208 Montargis Cedex, France	16,500	Distribution center for pharmaceutical products
St. Loubes, France (near Bordeaux) Sanofi Winthrop Industrie site No. 4 Z.I. La Lande 7, rue des Genets BP 53	15,500	Distribution center for pharmaceutical products

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

33451 Saint Loubes cedex, France

**Office Space**

Sanofi-Synthélabo

17,100

Headquarters

174, avenue de France,

Paris, France

Sanofi-Synthélabo

29,300

Administrative offices and other operational activities

74-82, avenue de Raspail

Gentilly, France (near Paris)

Sanofi-Synthelabo, Inc.

18,000

Administrative offices, U.S. headquarters

90 Park Avenue

New York, NY

U.S.A.

## **Table of Contents**

### **Item 5. Operating and Financial Review and Prospects**

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report under Item 18. Our consolidated financial statements have been prepared in accordance with French GAAP, which differ in certain significant respects from U.S. GAAP. Note G to our consolidated financial statements provides a description of the principal differences between French GAAP and U.S. GAAP as they relate to our company, and reconciles our shareholders' equity and net income to U.S. GAAP as of and for each of the years ended December 31, 2001, 2002 and 2003. Unless otherwise indicated, the following discussion relates to our French GAAP financial information.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See Item 3 Key Information Forward-Looking Statements.

#### **Introductory Note Relating to our Proposed Acquisition of Aventis**

If successful, our proposed acquisition of Aventis may have a significant impact on our results of operations and financial condition. If the offer is successful, we will issue a substantial number of new shares, and we will incur substantial indebtedness and be required to comply with financial covenants under our new credit agreement. In addition, the combination of our business with that of Aventis will impact trends in revenue growth, margins, financial expense, overall profitability and operating cash flow. As a result, trends evidenced by our historical financial statements and the discussion below may not be indicative of the future operating results or financial condition or future performance of the combined businesses of our company and Aventis.

We describe the terms of the offer, its current status and its potential impact under Item 8 Financial Information Significant Changes, and Item 3 Key Information Risk Factors Risks Relating to Our Proposed Acquisition of Aventis. As of the date of this annual report, the offer has been launched, but has not closed. As a result, we cannot be certain whether we will complete the offer, or if so whether we will modify the terms of the offer before its completion.

#### **Overview**

Over the last several years, our revenues have grown significantly. Our net sales in 2003 were 8,048 million, representing an increase of 8.1% compared to 2002, or an increase of 15.6% excluding the impact of changes in the scope of consolidation and exchange rates. Our 2002 net sales were 14.8% higher than our 2001 net sales, or 12.8% higher excluding the impact of changes in the scope of consolidation and exchange rates.

Our growth has been driven principally by strong sales of our four leading products, Plavix®, Aprovel®, Stilnox® and Eloxatin®, which together accounted for net sales of 2,110 million in 2001, 3,362 million in 2002 and 4,177 million in 2003. Between 2001 and 2002, a portion of our net sales growth was also due to our increased interest in the entity that markets Stilnox® in the United States.



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

We have also improved our operating margins over the last three years. Operating profit represented 32.5% of our net sales in 2001, 35.1% in 2002 and 38.2% in 2003. The principal reasons for our improved operating margins have been:

strong growth in our top 10 products in 2003, which represented 67.3% of our net sales in 2003, compared to 61.4% in 2002, and 49.8% in 2001;

improved productivity from our sales teams, which we adapted to meet the needs of our various markets, including a substantial reinforcement in the United States for the launch of new products in the U.S. market (Eloxatin<sup>®</sup> and Uroxatral<sup>®</sup>) as well as our assumption of the responsibility for marketing Stilnox<sup>®</sup>; and

our increased financial interest in operating profits resulting from sales of Stilnox<sup>®</sup> and Aprovel<sup>®</sup> in the United States.

## **Table of Contents**

While we have improved our operating margins over the last few years, we have also maintained a significant research and development effort. In 2003, we had research and development expenses of 1,316 million, which represented an 8.0% increase over 1,218 million in 2002 (a 14.7% increase based on 2002 exchange rates), which itself represented an 18.1% increase over 2001. The 2003 figure represented 16.4 % of our net sales.

Our activities generate significant operating cash flow, which has historically been sufficient to fund our investment needs and to allow us to pay dividends. At the end of 2003, we had a net cash position of 3,010 million, including the value of treasury shares reserved for stock option plans. We do not anticipate needing cash resources other than those generated by our operations to fund our existing activities. However, if our proposed acquisition of Aventis is successful, we will incur substantial indebtedness in order to fund the cash portion of the consideration we are offering to pay for Aventis shares. In the future, we will need to use a portion of our operating cash flow to make debt service payments. See Item 8 Financial Information Significant Changes.

### ***Sources of Revenues and Expenses***

*Revenues.* Our principal source of revenues is the sale of pharmaceutical products. We sell these products directly, through alliances and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated revenues. When we sell products through alliances, the revenues reflected in our consolidated financial statements are based on the overall level of sales of the products and on the arrangements governing those alliances. We describe our principal alliances below under Financial Presentation of Alliances. When we sell products through licensees, we receive royalty income that we record as a reduction in our cost of goods sold, as discussed further below.

*Cost of Goods Sold.* Our cost of goods sold consists primarily of the cost of purchasing active ingredients and raw materials, labor and other costs relating to our manufacturing activities, packaging materials and distribution costs, as well as government charges that we are required to pay in some countries.

Our cost of goods sold also includes our net royalties relating to license agreements for products. We have license agreements under which we distribute products that are patented by other companies and license agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in cost of goods sold, and when we receive royalties, we record them as reductions in our cost of goods sold.

*Operating Profit.* Our operating profit consists of gross profit less research and development costs, selling and general expenses and items that we record as other operating income/(expense), net. We expense all of our research and development costs as incurred. Our other operating income/(expense), net relates primarily to profit sharing arrangements with partners under joint ventures and alliance agreements for the commercialization of products. The effects of these profit sharing arrangements are reflected in operating profit. See Financial Presentation of Alliances below for a description of these arrangements. Amortization and depreciation of intangible assets is presented below operating income in our consolidated financial statements.

### ***Treatment of Milestone Payments Under Licensing Agreements***

When we enter into a licensing agreement with respect to products under development, we frequently pay the patent owner an up-front payment and/or payments for reaching certain development milestones. If the product has not yet received regulatory approval, we record these payments

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

as additions to our research and development expenses. If the product has already received regulatory approval or the payment is made upon receipt of regulatory approval, we record the payment as an addition to our intangible assets, which is amortized over the shorter of the useful life of the product and the duration of the relevant license.

## **Table of Contents**

### ***Presentation of Net Sales***

In the discussion below, we present our net sales for each period, and we break down our net sales among various categories, such as by therapeutic class, product and geographical area. We refer to our historical sales as reported sales. In addition to reported sales, we also present and discuss two other non-GAAP indicators that we believe are useful measurement tools to explain changes in our reported net sales:

*Comparable Sales.* When we refer to the change in our net sales on a comparable basis, we mean that we exclude the impact of exchange rate fluctuations and changes in our group structure (due to acquisitions and divestitures of entities, rights to products as well as changes in the consolidation percentage for consolidated entities). For any two periods, we exclude the impact of exchange rates by recalculating net sales for the earlier period on the basis of exchange rates used in the later period. We exclude the impact of acquisitions by including sales for a portion of the prior period equal to the portion of the current period during which we owned the entity or product rights based on sales information we receive from the party from whom we make the acquisition. Similarly, we exclude sales in the relevant portion of the prior period when we have sold an entity or rights to a product. For a change in the consolidation percentage of a consolidated entity, the prior period is recalculated on the basis of the consolidation method used for the current period.

A reconciliation of our reported sales to our comparable sales is provided below in the results of operations sections for each year-on-year comparison.

*Developed Sales.* When we refer to developed sales of a product, we mean consolidated sales worldwide, excluding sales of products to our alliance partners, but including those that are made through our alliances but that are not included in our consolidated net sales (as described under Financial Presentation of Alliances below). Our alliance partners provide us information regarding their sales in order to allow us to calculate developed sales. We believe that developed sales are a useful measurement tool because they demonstrate trends in the overall presence of our products in the market.

A reconciliation of our developed sales to our consolidated net sales is provided below in the results of operations sections for each year-on-year comparison.

### ***Impact of Exchange Rates***

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in countries where the euro is not the local currency, our results of operations can be significantly impacted by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, Latin American, Asian and other European currencies. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2003, we earned 23.8% of our revenues in the United States. A decrease in the value of the U.S. dollar against the euro, like that experienced during 2003, has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively impacts our operating profits. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating margins, which are higher in the United States than elsewhere due mainly to the fact that we record operating profit, but only limited consolidated net sales, from sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in the United States by alliance entities under the operational management of BMS.

As a general policy, we do not specifically hedge foreign currency net investments, but rather engage in various foreign currency transactions to reduce our exposure to the risks arising from fluctuations in exchange rates and to protect our operating margins. Hedging instruments relate to

assets and liabilities existing at the balance sheet date and, in some cases, to commitments related to future transactions as determined in our annual forecast process.

## **Table of Contents**

### ***Financial Presentation of Alliances***

Our revenues, expenses and operating profits are affected significantly by the presentation of our alliances in our consolidated financial statements. We have a major alliance with Bristol-Myers Squibb that covers two of our four leading products, Aprovel® and Plavix®. Additionally, until January 2004, we had a major alliance with Organon (a subsidiary of Akzo Nobel) for the development and marketing of Arixtra®. We also have an alliance for Stilnox®, one of our four leading products, in Japan and we had an alliance for Stilnox® in the United States until April 2002.

### ***The Bristol-Myers Squibb Alliance***

The two products that are subject to the Bristol-Myers Squibb alliance, Aprovel® and Plavix®, accounted for an aggregate of 1,128 million of consolidated net sales in 2001, 1,549 million of consolidated net sales in 2002 and 2,008 million of consolidated net sales in 2003. Total developed sales of the two products amounted to an aggregate of 2,957 million in 2001, 3,655 million in 2002 and 4,480 million in 2003.

The proportion of developed sales of these products represented by our consolidated revenues from these products varies from year to year because differences in the marketing arrangements for these products from country to country impact the presentation of sales of these products. There are three principal marketing arrangements that are used:

*Co-marketing.* Under the co-marketing system, each company markets the products independently under its own brand names. We record our own sales and related costs in our consolidated financial statements.

*Exclusive Marketing.* Under the exclusive marketing system, one company has the exclusive right to market the products. We record our own sales and related costs in our consolidated financial statements.

*Co-promotion.* Under the co-promotion system, the products are marketed through the alliance arrangements (either by contractual arrangements or by separate entities) under a single brand name. The accounting treatment of the co-promotion arrangement depends upon who has majority ownership and operational management in that territory, as discussed below.

The alliance arrangements include two royalty streams that are applied on a worldwide basis (excluding Japan), regardless of the marketing system and regardless of which company has majority ownership and operational management:

*Discovery Royalty.* We earn a discovery royalty on all sales of Aprovel® and Plavix® regardless of the marketing system. The discovery royalty is reflected in our consolidated statement of income in our gross profit, which results in an increase in our gross margin.

*Development Royalty.* In addition to the discovery royalty, we and BMS are each entitled to a development royalty related to certain know-how and other intellectual property in connection with sales of Aprovel® and Plavix®. Each legal entity that markets products pays a development royalty. We record development royalties paid to BMS in our consolidated statement of income as an increase to our cost of goods sold in countries where we consolidate sales of the products. We record development royalties that we receive as a reduction to our cost of goods sold in countries where BMS consolidates sales of the products.

In 2003, we received an aggregate of \$501 million in royalties under the alliance arrangements, and we paid BMS an aggregate of \$51 million in royalties under the alliance arrangements.

Under the alliance arrangements, there are two territories, one under our operational management and the other under the operational management of BMS. The territory under our operational management consists of

## **Table of Contents**

Europe and most of Africa and Asia, while the territory under the operational management of BMS consists of the rest of the world excluding Japan. In Japan, Aprovel<sup>®</sup> is under development through agreements between BMS and the Japanese pharmaceutical company Shionogi Pharmaceuticals, and Plavix<sup>®</sup> is under development through an alliance between our company and Daiichi Pharmaceuticals Co., Ltd.

*Territory under our operational management.* In the territory under our operational management, the marketing arrangements are as follows:

We use the co-promotion system for most of the countries of Western Europe for Aprovel<sup>®</sup> and Plavix<sup>®</sup> and for certain Asian countries for Plavix<sup>®</sup>. We record 100% of all alliance revenues and expenses in our consolidated financial statements. We also record, as selling and general expenses, payments to BMS for the cost of BMS's personnel involved in the promotion of the products. BMS's share of the operating profit of the alliances is recorded as other operating income/(expense), net and thus is deducted from our operating profit.

We use the co-marketing system in Germany, Spain and Greece for both Aprovel<sup>®</sup> and Plavix<sup>®</sup> and in Italy for Aprovel<sup>®</sup>.

We have the exclusive right to market Aprovel<sup>®</sup> and Plavix<sup>®</sup> in Eastern Europe, Africa and the Middle East, and we have the exclusive right to market Aprovel<sup>®</sup> in Asia (excluding Japan).

*Territory under BMS operational management.* In the territory under BMS operational management, the marketing arrangements are as follows:

We use the co-promotion system in the United States and Canada, where the products are sold through the alliances under the operational management of BMS. There are different arrangements applicable to each of the two products in these countries:

*Aprovel<sup>®</sup>.* With respect to Avapro<sup>®</sup> (the brand name used in the United States for Aprovel<sup>®</sup>), in October 2001, we entered into an agreement to increase our participation in the promotional activities and profitability of Aprovel<sup>®</sup> in the United States and we have made payments to BMS totalling \$350 million under this agreement. We do not expect to make any further payments to BMS. In addition to our profit share recorded under other operating income/(expense), net, we also receive payments from BMS for the cost incurred for our personnel in connection with the promotion of the product (which are deducted from our consolidated selling and general expenses).

*Plavix<sup>®</sup>.* With respect to Plavix<sup>®</sup>, we record our share of the alliance's operating profit under other operating income/(expense), net, with the result that our operating profit is increased by this amount. We also record payments from BMS for the cost of our personnel in connection with the promotion of the product as a deduction from our selling and general expenses.

We use the co-marketing system in Brazil, Mexico, Argentina and Australia for Plavix<sup>®</sup> and Aprovel<sup>®</sup> and in Colombia for Plavix<sup>®</sup>.

We have the exclusive right to market the products in certain other countries of Latin America.

In countries where the products are marketed by BMS on a co-marketing basis, or through alliances under the operational management of BMS, we also earn revenues from the sale of the active ingredients for the products, which we record as sales in our consolidated statement of income.



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In March 2002, BMS began a program to reduce excess wholesaler inventories with respect to certain of the products that it markets, including Plavix® and Aprove1®. As a result of the inventory workdown program, sales

## **Table of Contents**

of these products in the United States were adversely affected in 2002, and as a consequence the amount we report as developed sales, and our share of the operating profit of the alliance entities that market these products in the United States, were adversely affected in 2002. The impact of the inventory workdown program in 2002 is detailed under Results of Operations Year ended December 31, 2002 compared with year ended December 31, 2001. The impact of the inventory workdown program on U.S. sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> ended after the first quarter of 2003, explaining a part of the growth of our operating profits in 2003 compared to 2002.

### ***The Arixtra<sup>®</sup> Alliance with Organon***

Through January 2004, we had an alliance with Organon covering the development, manufacturing and commercialization of Arixtra<sup>®</sup> on a worldwide basis. We launched Arixtra<sup>®</sup> in the United States in February 2002 and began rolling it out in Europe in the second half of 2002. The treatment of the alliance varied by geographical region, as follows:

*North America.* In the United States, Mexico and Canada, Arixtra<sup>®</sup> was sold by entities that we jointly controlled with Organon. We consolidated the sales and related expenses of Arixtra<sup>®</sup> using the proportional consolidation method based upon our 50.0% ownership interest in the alliance.

*Europe and Other Countries (excluding Japan).* We had the exclusive right to market and sell Arixtra<sup>®</sup>, and included 100% of our sales in these countries in our consolidated net sales. We paid a royalty to Organon based on sales of Arixtra<sup>®</sup>, which is recorded as cost of goods sold.

In January 2004, we agreed to acquire all of Organon's interests relating to Arixtra<sup>®</sup> that were the subject of this joint venture, as well as Organon's interests relating to idraparinux sodium and other oligosaccharides. We now have full rights to market Arixtra<sup>®</sup> and other products worldwide and will make royalty payments to Organon based on future sales, under a licensing arrangement. We have launched the process of selling our interests in Arixtra<sup>®</sup> in order to respond to possible demands of competition authorities in connection with our proposed acquisition of Aventis.

### ***Stilnox<sup>®</sup> Marketing Arrangements***

The impact on our financial results of sales of Stilnox<sup>®</sup> has been significantly impacted by the treatment of two marketing arrangements for the product, one of which is in Japan and the other of which was in the United States until we acquired our partner's interest in the arrangement in April 2002. In 2001, 2002 and 2003, we recorded consolidated sales of Stilnox<sup>®</sup> of 786 million, 1,424 million and 1,345 million, respectively, compared to total developed sales of the product of 1,215 million, 1,455 million and 1,381 million, respectively.

In Japan, we market Stilnox<sup>®</sup> (under the brand name Myslee<sup>®</sup>) through a joint venture with Fujisawa. Until the end of 2001, we fully consolidated the joint venture. Beginning in 2002, we recorded our 51% interest in the joint venture on the basis of the proportional consolidation method, pursuant to which we included our share of the revenues and expenses of the joint venture in the appropriate line items of our consolidated financial statements. The change occurred because we modified our contract with Fujisawa, as a result of which we no longer have exclusive control of the joint venture.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In the United States, until April 16, 2002 we marketed Stilnox® (as well as Kerlone®) through Lorex Pharmaceuticals, a joint venture with Pharmacia. On April 16, 2002 we purchased Pharmacia's interest in Lorex Pharmaceuticals for 670 million. In December 2001 we signed an agreement with Pharmacia giving us exclusive control over Lorex Pharmaceuticals. As a result, we fully consolidated Lorex Pharmaceuticals beginning as of December 31, 2001, and we recorded Pharmacia's share of the net income of Lorex Pharmaceuticals from January 1, 2002 through April 15, 2002 as a minority interest.

## **Table of Contents**

In 2001, we recorded our 49% interest in Lorex Pharmaceuticals on the basis of the proportional consolidation method. However, while our ownership in Lorex Pharmaceuticals was 49%, our entitlement to the operating profit of Lorex Pharmaceuticals was 47% in 2001. We recorded the difference between our proportionately consolidated revenues and operating expenses and our actual financial interest in the operating profits of the joint venture under other operating income/(expense), net. We also recorded royalties that we received from Lorex Pharmaceuticals as a deduction from our cost of sales.

### ***Divestitures***

In 2001, we sold our custom chemicals subsidiary, Sylachim (effective for accounting purposes as of January 1, 2001), our two medical equipment businesses, Porgès (effective as of January 1, 2001) and Ela Medical (effective as of May 1, 2001), and our direct shareholding in Laboratoires de Biologies Végétale Yves Rocher (effective as of December 18, 2001). Total proceeds from these divestitures, excluding the repayment of inter-company loans, were 588 million.

In 2001, the contribution to our consolidated net sales of Ela Medical was 39 million, or less than 1% of our consolidated net sales of 6,488 million for the same period. The direct shareholding in Laboratoires de Biologie Végétale Yves Rocher was classified as an investment in a non-consolidated company.

### ***Acquisitions***

We did not make any significant acquisitions during 2003. On January 26, 2004, we announced our intention to acquire all of the outstanding shares of Aventis. This proposed acquisition is described in more detail under Item 8 Financial Information Significant Changes.

### **Recent Developments**

The most significant recent development that could impact our results of operations and financial condition is our proposed acquisition of Aventis. In addition, we have initiated the process of divesting our interests in Arixtra® and Fraxiparine®. See Item 8 Financial Information Significant Changes.

### **Results of Operations**

#### ***Year Ended December 31, 2003 Compared to Year Ended December 31, 2002***

##### ***Developed Sales***

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Developed sales of our products were 10,560 million in 2003, representing a 10.2% increase over 2002. On a comparable basis, developed sales increased by 20.4% between 2002 and 2003. Plavix® and Aprovel® had combined developed sales of 4,480 in 2003, a 22.6% increase over 2002, or 36.2% on a comparable basis. Sales of these two products accounted for 42.4% of total developed sales of our products, compared to 38.1% in 2002. Developed sales in 2002 were impacted by Bristol-Myers Squibb's program to reduce inventory levels of Plavix® and Aprovel® at wholesalers in the United States.

The following table reconciles our developed sales and our consolidated net sales for the year ended December 31, 2003:

	2003
	<i>(in millions of \$)</i>
<i>Total Consolidated Net Sales</i>	8,408
Plavix® non-consolidated sales less product sales to Bristol-Myers Squibb	1,900
Aprovel® non-consolidated sales less product sales to Bristol-Myers Squibb	572
Stilnox® non-consolidated sales less product sales to Fujisawa	36
Arixtra® non-consolidated sales	5
<i>Total Developed Sales</i>	10,560

**Table of Contents**

The following table sets forth developed sales of Plavix® and Aprovel® in 2002 and 2003, broken down into our three geographic markets:

	Year Ended December 31,			% change	
	2002	2002	2003	Reported	Comparable
	Reported	Comparable	Reported		
( in millions)					
<b>Plavix®/Iscover®</b>					
Europe <sup>(1)</sup>	770	766	1,056	37.1%	37.9%
United States	1,565	1,318	1,817	16.1%	37.9%
Other Countries <sup>(1)</sup>	252	221	352	39.7%	59.3%
	<u>2,587</u>	<u>2,305</u>	<u>3,225</u>	24.7%	39.9%
<b>Aprovel®/Avapro®/Karvea®</b>					
Europe <sup>(1)</sup>	515	513	634	23.1%	23.6%
United States	373	313	407	9.1%	30.0%
Other Countries <sup>(1)</sup>	180	158	214	18.9%	35.4%
	<u>1,068</u>	<u>984</u>	<u>1,255</u>	17.5%	27.5%
Total two products	<u>3,655</u>	<u>3,289</u>	<u>4,480</u>	22.6%	36.2%
<b>Total developed sales</b>	<u>9,585</u>	<u>8,768</u>	<u>10,560</u>	10.2%	20.4%

(1) In 2003, we included Slovenia under Europe whereas in previous years, these sales were included under Other Countries. For comparison purposes, we have restated the 2002 figures to take into account this reallocation.

Developed sales of Plavix® were 3,225 million in 2003, a 24.7% increase over developed sales of 2,587 million in 2002. In the United States, developed sales of Plavix® reached 1,817 million, an increase of 16.1%, or 37.9% on a comparable basis, adjusting for the impact of the weak dollar. Plavix® sales in the United States, which are included in the developed sales totals but are not reflected in our consolidated net sales, saw an increase in overall U.S. demand for Plavix® in 2003, with overall prescription volume increasing by 26.8% from 2002 to 2003 (based on IMS retail, mail order and long-term care data). Additionally, we estimate that Plavix® inventory levels were at approximately 1 month at the end of December 2003 following the end of the BMS wholesaler inventory workdown program. In addition, prices increased for the product in the United States. In Europe and in the Other Countries, developed sales of Plavix® increased by 37.1% and 39.7%, respectively, in 2003 compared to 2002.

Developed sales of Aprovel® were 1,255 million in 2003, a 17.5% increase over developed sales of 1,068 million in 2002. In the United States, developed sales of Aprovel® reached 407 million, an increase of 9.1%, or 30.0% on a comparable basis, adjusting for the impact of the weak dollar. As with Plavix®, U.S. sales of Aprovel® are not included in our consolidated net sales, although they are included in developed sales. During 2003, overall U.S. demand for Aprovel® was up, with a 14.9% increase in overall prescription volume from 2002 to 2003 (based on IMS retail, mail order and long-term care data). Favorable price movements in the United States also had a positive effect. Additionally, we estimate that Aprovel® inventory levels were at approximately 1 month at the end of December 2003 following the end of the BMS wholesaler inventory workdown program. In Europe and in the Other Countries, developed sales of Aprovel® increased by 23.1% and 18.9%, respectively, in 2003 compared to 2002.

*Net Sales*

We had total consolidated net sales of 8,048 million in 2003, an increase of 8.1% over net sales of 7,448 in 2002, or an increase of 15.6% on a comparable basis. Our net sales were negatively impacted by 7.2 percentage points due to currency effects, 4.0 percentage points of which was attributable to the weakness of the U.S. dollar compared to the euro, with the remainder due to the decrease in value of certain Latin American,

**Table of Contents**

Asian and other European currencies. Changes in the scope of consolidation had a negative impact of 0.3 percentage points, mostly attributable to the change in consolidation method to proportional consolidation (51%) for our joint venture with Fujisawa in Taiwan in May 2002.

The following table sets forth a reconciliation between our reported sales for the year ended December 31, 2002 and our comparable sales for that year based on 2003 exchange rates and group structure:

	<b>Year Ended December 31, 2002</b>
	<i>(in millions of )</i>
<i>Reported</i>	7,448
Impact of change of group structure	(24)
Impact of exchange rate fluctuation	(460)
<i>Comparable</i>	6,964

*Markets.* We divide our sales into three markets: Europe, the United States and Other Countries. The following table breaks down our 2002 and 2003 consolidated net sales by market.

	<b>Year Ended December 31,</b>			<b>% change</b>	
	<b>2002</b>	<b>2002</b>	<b>2003</b>	<b>Reported</b>	<b>Comparable</b>
	<b>Reported</b>	<b>Comparable</b>	<b>Reported</b>	<b>Reported</b>	<b>Comparable</b>
	<i>( in millions)</i>				
<b>Europe</b>					
France <sup>(1)</sup>	1,584	1,580	1,646	3.9%	4.2%
Germany	634	630	667	5.2%	5.9%
Italy	444	443	478	7.7%	7.9%
Other <sup>(2)</sup>	1,642	1,596	1,902	15.8%	19.2%
<b>Total Europe<sup>(2)</sup></b>	<b>4,304</b>	<b>4,249</b>	<b>4,693</b>	<b>9.0%</b>	<b>10.4%</b>
United States	1,689	1,439	1,912	13.2%	32.9%
Other Countries <sup>(2)</sup>	1,455	1,276	1,443	(0.8%)	13.1%
<b>Total net sales</b>	<b>7,448</b>	<b>6,964</b>	<b>8,048</b>	<b>8.1%</b>	<b>15.6%</b>

(1) Includes French overseas territories (Guadeloupe, Martinique, Réunion and French Guyana).

(2) In 2003, we included Slovenia under Europe whereas in previous years, these sales were included under Other Countries. For comparison purposes, we have restated the 2002 figures to take into account this reallocation.

In Europe, we had consolidated net sales of 4,693 million, representing an increase of 9.0% on a reported basis (or 10.4% on a comparable basis). This growth was achieved despite health-care cost containment measures enacted during 2003 in France and Germany, our two biggest



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

European markets. Europe represented 58.3% of our total consolidated net sales in 2003 compared to 57.8% in 2002.

In the United States, our consolidated net sales reached 1,912 million, representing an increase of 13.2% on a reported basis, or 32.9% on a comparable basis. The difference between reported and comparable sales growth is principally due to the weakness of the U.S. dollar compared to the euro. Growth in the United States was principally driven by the success of Eloxatin<sup>®</sup>, which had U.S. net sales of 460 million in 2003, more than quadruple 2002 U.S. net sales on a comparable basis and a 296.6% increase on a reported basis. In addition, U.S. sales of Stilnox<sup>®</sup> increased to 1,124 million in 2003, representing a decrease of 7.0% compared to 2002 on a reported basis (or growth of 10.6% on a comparable basis). The increase in U.S. sales of Stilnox<sup>®</sup> on a comparable basis was achieved despite a significant reduction in inventory levels compared to the end of 2002. The United States represented 23.8% of our total consolidated net sales in 2003 compared to 22.7% in 2002.

In the other countries, our consolidated net sales reached 1,443 million, representing a slight decrease of 0.8% on a reported basis, but an increase of 13.1% on a comparable basis. The principal reason for the difference

**Table of Contents**

between reported and comparable growth is due to the weakness of certain Latin American and Asian currencies compared to the euro, as well as the change from full consolidation to proportional consolidation (51%) of our joint venture with Fujisawa in Taiwan. The other countries represented 17.9% of our total consolidated net sales in 2003 compared to 19.5% in 2002.

*Products.* Our ten largest products had 5,420 million in total consolidated net sales in 2003, representing an increase of 18.5% over 2002. Sales of our top ten products represented approximately 67.3% of our total consolidated net sales in 2003, compared to 61.4% in 2002.

The main reason for this growth was the strong performance of our four leading products, Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Stilnox<sup>®</sup> and Eloxatin<sup>®</sup>, which together had total net sales of 4,177 million, an increase of 24.2% over 2002 on a reported basis, or 34.9% on a comparable basis. Sales of our four leading products represented 51.9% of our total consolidated net sales compared to 45.1% in 2002.

The following table breaks down our consolidated net sales by product.

		Year ended December 31,			% change	
		2002	2002	2003	Reported	Comparable
		Reported	Comparable	Reported		
( in millions)						
Product	Therapeutic Area					
Stilnox <sup>®</sup>	Central Nervous System	1,424	1,218	1,345	(5.5%)	10.4%
Plavix <sup>®</sup>	Cardiovascular/Thrombosis	987	964	1,325	34.2%	37.4%
Eloxatin <sup>®</sup>	Oncology	389	365	824	111.8%	125.8%
Aprovel <sup>®</sup>	Cardiovascular/Thrombosis	562	549	683	21.5%	24.4%
Fraxiparine <sup>®</sup>	Cardiovascular/Thrombosis	324	314	319	(1.5%)	1.6%
Depakine <sup>®</sup>	Central Nervous System	267	258	277	3.7%	7.4%
Xatral <sup>®</sup>	Internal Medicine	182	178	222	22.0%	24.7%
Cordarone <sup>®</sup>	Cardiovascular/Thrombosis	162	154	146	(9.9%)	(5.2%)
Solian <sup>®</sup>	Central Nervous System	135	133	148	9.6%	11.3%
Tildiem <sup>®</sup>	Cardiovascular/Thrombosis	141	138	131	(7.1%)	(5.1%)
<i>Total of top 10 Products</i>		4,572	4,271	5,420	18.5%	26.9%
Others		2,876	2,693	2,628	(8.6%)	(2.4%)
<i>Total consolidated net sales</i>		7,448	6,964	8,048	8.1%	15.6%

Stilnox<sup>®</sup> was our largest product in terms of consolidated net sales. The difference between the 10.4% increase in sales of Stilnox<sup>®</sup> on a comparable basis and the 5.5% decline on a reported basis is due to the weakness of the dollar, as we realize a majority of Stilnox<sup>®</sup> sales in the United States (marketed under the brand name Ambien<sup>®</sup>). The growth in Stilnox<sup>®</sup> sales on a comparable basis included a reduction in inventory levels in the United States equivalent to an estimated 0.8 month's sales. In Japan, consolidated sales of Stilnox<sup>®</sup> (where it is marketed under the brand name Myslee<sup>®</sup>) reached 49 million, an increase of 16.7% on a reported basis and 28.9% on a comparable basis, making it the market leader in its therapeutic class in the Japanese market just three years after its launch (IMS data).

Consolidated net sales of Plavix<sup>®</sup> were 1,325 million in 2003, an increase of 34.2% over 2002. The continued strong level of growth in Plavix<sup>®</sup> since its launch in 1998 comes from both Europe, where it was approved for health-care reimbursement in both Italy and Portugal in 2003, and the other countries. The difference between reported growth and comparable growth was relatively small, as U.S. sales are limited to sales of active ingredients to the alliance entities under the operational management of BMS.

**Table of Contents**

Consolidated net sales of Aprovel® were 683 million in 2003, an increase of 21.5% over 2002. Much of the growth was realized in Europe where Aprovel®, in terms of sales, became the second product in its class, angiotensin II receptor antagonists, in Europe and first in France, Belgium, Greece and Switzerland (according to IMS data).

Consolidated net sales of Eloxatin® were 824 million in 2003, an increase of 111.8% over 2002. This is principally a result of the strong growth in the U.S. market since its launch on August 30, 2002, with U.S. sales of 460 million in 2003. Outside the United States, Eloxatin® grew by 37.4% in Europe and 14.5% in the other countries.

Consolidated net sales of Arixtra® reached 19 million, principally due to the limited nature of its currently approved indication. Our efforts to increase its approved indications are continuing as planned, and the approval of Arixtra® in the prevention of deep vein thrombosis after orthopedic surgery was obtained in both the United States and Europe in 2003.

Consolidated net sales of Xatral® increased by 22.0%, as sales of the product were boosted by the continued success of the once-a-day formulation that was gradually launched in various countries in Europe in 2002.

Among our other top 10 products, we recorded strong growth in sales of Solian®, while sales of Tildiem® and Cordarone® declined due to generic competition. Sales of Fraxiparine® were relatively flat.

Consolidated net sales of other products in our product portfolio decreased by 8.6% to 2,628 million in 2003, although they remained essentially stable on a comparable basis, declining by only 2.4%. The main reason for the difference between reported and comparable sales is due to currency effects. Excluding sales of Corotrope®, which declined by 71.7% in 2003 due to the introduction of generics in the U.S. market in May 2002 following expiration of its patent, and Ticlid®, which declined by 37.2% as it is gradually replaced with Plavix®, the remaining products in our portfolio have slight growth of 2.2% in 2003 on a comparable basis (on a reported basis, they declined by 4.1% in 2003).

*Therapeutic Areas.*

The following table breaks down our consolidated net sales by therapeutic area:

	Year Ended December 31,			% change	
	2002	2002	2003	Reported	Comparable
	Reported	Comparable	Reported	Reported	Comparable
	( in millions)				
Therapeutic area:					
Cardiovascular/Thrombosis	2,904	2,800	3,169	9.1%	13.2%
Central Nervous System	2,409	2,162	2,319	(3.7%)	7.3%
Internal Medicine	1,427	1,341	1,412	(1.1%)	5.3%

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Oncology	404	378	871	115.6%	130.4%
<i>Total</i>	7,144	6,681	7,771		
Other	304	283	277	(8.9%)	(2.1%)
<i>Total consolidated net sales</i>	7,448	6,964	8,048	8.1%	15.6%

Cardiovascular/Thrombosis sales were 3,169 million in 2003, representing approximately 39.4% of our total consolidated net sales. The sales growth in this category reflects primarily the increase in sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup>, which offset the decline in sales of Ticlid<sup>®</sup> and Corotrope<sup>®</sup>.

Central Nervous System sales were 2,319 million in 2003, representing approximately 28.8% of our total consolidated net sales. The main reason for the difference between reported and comparable sales in this category is the impact of the weakness of the dollar compared to the euro on the sales of Stilnox<sup>®</sup> in the United States.

## **Table of Contents**

Internal Medicine sales were 1,412 million in 2003, accounting for approximately 17.5% of our total consolidated net sales. The main reason for the difference between reported and comparable sales in this category is currency effects.

Oncology sales were 871 million in 2003, representing approximately 10.8% of our total consolidated net sales. The robust growth in this category was mainly due to net sales of Eloxatin<sup>®</sup>, which more than doubled in 2003.

Other sales were 277 million in 2003, a decrease of 8.9% on a reported basis, or 2.1% on a comparable basis. The main reason for the difference is currency effects.

### *Gross Profit*

Our gross profit was 6,620 million in 2003, an increase of 9.1% compared to 2002, and represented 82.3% of our total consolidated net sales in 2003, compared to 81.5% in 2002, which itself represented an 0.8 percentage point increase over 2001. Using 2002 exchange rates, our gross margin would have been 83.5% in 2003.

This improvement in our gross margin is mainly due to improvements in our productivity and overall product mix, which we estimate accounted for a 0.9 percentage point increase, as well as increased royalty payments on sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup>, which we estimate accounted for a 0.3 percentage points increase. These gains were partially offset by the significant increase in the required contribution to be paid by pharmaceutical companies as part of healthcare reforms in Europe, notably in Germany, which we estimated accounted for a loss of 0.4 percentage points.

### *Operating Profit*

Our operating profit was 3,075 million in 2003, representing a 17.6% increase compared to our operating profit in 2002 of 2,614 million. The weak U.S. dollar exchange rate against the euro had a negative impact on our operating profit, which would have increased by 34.4% over 2002 if exchange rates had remained constant. If net income arising from our hedging activities had been recognized at the operating level (rather than as financial income), operating profit would have increased by 19.4%.

Operating profit in 2003 represented 38.2% of consolidated net sales, while in 2002 operating profit was 35.1% of consolidated net sales. This improvement in our operating margins was driven principally by:

continued strong sales of our top 10 products, including rapid growth of Eloxatin<sup>®</sup> and strong growth of Plavix<sup>®</sup> and Aprovel<sup>®</sup>; and

an overall increase in the productivity of our sales force.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The following table breaks down our operating profit for 2002 and 2003 among its principal components.

	Year ended December 31			
	2002		2003	
	Amount	% of Sales	Amount	% of Sales
	<i>( in millions)</i>			
<i>Net sales</i>	7,448	100.0%	8,048	100.0%
Cost of goods sold	(1,378)	(18.5%)	(1,428)	(17.7%)
<i>Gross profit</i>	6,070	81.5%	6,620	82.3%
Research and development expenses	(1,218)	(16.4%)	(1,316)	(16.4%)
Selling and general expenses	(2,428)	(32.6%)	(2,477)	(30.8%)
Other operating income/(expense), net	190	2.6%	248	3.1%
<i>Operating profit</i>	2,614	35.1%	3,075	38.2%

**Table of Contents**

Research and development expenses increased to 1,316 million in 2003, representing 16.4% of our total consolidated net sales, and an 8.0% increase over 2002. Using 2002 exchange rates, the increase in our research and development expenses would have been 14.7%. The increase in spending was principally due to clinical trials that are underway both for new indications for products that are already on the market, such as Plavix<sup>®</sup>, Aprovel<sup>®</sup>, Eloxatin<sup>®</sup>, Xatral<sup>®</sup> and Arixtra<sup>®</sup>, as well as for new products in development, such as rimonabant, dronedarone, idraparinix sodium, xaliprodene and tirapazamine, and the new sustained release formulation of Stilnox<sup>®</sup>, zolpidem MR, among others.

Selling and general expenses were 2,477 million in 2003, representing 30.8% of our total consolidated net sales, and a 2.0% increase over 2002. Using 2002 exchange rates, our selling and general expenses would have increased by 9.2%. The increase is principally the result of our continued efforts to improve our commercial and marketing efforts in all of our geographic markets, which included:

the incurrence of significant costs relating to establishing the U.S. in connection with the launch of Xatral<sup>®</sup> in the United States in November 2003 (where it is marketed under the name UroXatral<sup>®</sup>); and

ongoing investments in our European marketing efforts.

Our other operating income/(expense), net was 248 million (or 3.1% of our net sales) in 2003, a 30.5% increase over 190 million in 2002. Using 2002 exchange rates, our other operating income would have increased by 71.1%. As discussed above, this item reflects operating profits of our alliances to which we are entitled or to which our partners are entitled, and is tied to an alliance with BMS. In 2003, our profit share from sales of Plavix<sup>®</sup> and Aprovel<sup>®</sup> by our alliance entity under the operational management of BMS, mainly in North America, were 436 million, compared to 348 million in 2002, with the increase reflecting in part the end of the BMS inventory workdown program. We paid to BMS profit shares from sales of these products under our operational management of 173 million in 2003, compared to 142 million in 2002.

The following table breaks down our 2002 and 2003 operating profit by geographical market.

	Year Ended December 31,		
	2002	2003	% change
	( in millions)		
Europe	1,633	1,874	14.8%
United States	1,781	2,025	13.7%
Other Countries	522	561	7.5%
Unallocated costs <sup>(1)</sup>	(1,322)	(1,385)	4.8%
<b>Total operating profit</b>	<b>2,614</b>	<b>3,075</b>	<b>17.6%</b>

(1) Unallocated costs consists mainly of a portion of our research and development expenses and of our corporate expenses.

We experienced growth in our operating profit in all three of our geographical segments, although growth in the United States was negatively impacted by the weakness of the dollar compared to the euro. Despite this unfavorable currency effect, the United States still accounted for 45.4% of our operating profit excluding unallocated costs compared to 45.2% in 2002. The increase in the United States was due principally to rapid growth in sales of Eloxatin<sup>®</sup>, sales of Stilnox<sup>®</sup> and an increase in operating profit from Plavix<sup>®</sup> and Aprovel<sup>®</sup>.



Unallocated costs increased by 4.8% in 2003 over 2002 principally as a result of the increase in our research and development expenses.

*Amortization and Impairment of Intangibles*

Our amortization and impairment of intangibles remained stable at 129 million in 2003, the same amount as in 2002. The increase in amortization due to the repurchase of full rights to Lorex Pharmaceuticals joint venture from Pharmacia in April 2002 was offset by the weakness of the dollar compared to the euro.

## **Table of Contents**

### *Net Financial Income/(Expense)*

Net financial income/(expense) increased from 85 million in 2002 to 155 million in 2003. This increase is principally due to a net foreign exchange gain of 103 million (compared to only 48 million in 2002) and by the reversal of a 2 million impairment provision against treasury shares held in connection with our stock option plans (compared to an increase of 46 million in the provision in 2002). These gains were only partially offset by a reduction in our invested cash position due to the share buyback program initiated in 2002, coupled with lower interest rates (which decreased on the average by 1 percentage point).

### *Exceptional Income*

Exceptional income increased from 10 million in 2002 to 24 million in 2003. This increase is principally due to an additional payment received from the purchaser in connection with our divestiture of Sylachim in 2001.

### *Income Taxes*

Income taxes increased by 312 million, from 746 million in 2002 to 1,058 million in 2003. Our effective tax rate was 33.9% in 2003 compared to 28.9% in 2002. The increase was principally attributable to an increase in consolidated sales in the United States (due to strong sales of our leading products), as well as the establishment of provisions relating to tax audits in certain countries. The increase is also attributable to the fact that our 2002 rate was particularly low due to the release of tax provisions of 53 million and the fact that we consolidated all of the operating profit of the Lorex joint venture, while we paid tax only on our profit share through our acquisition of Pharmacia's share in April 2002.

### *Minority Interests*

Income attributable to minority interests was 3 million in 2003 compared to 87 million in 2002. In 2002, income attributable to minority interests represented primarily Pharmacia's share of the profits of the Lorex joint venture from January 1, 2002 through April 16, 2002.

### *Net Income*

As a result of the foregoing, our net income increased 18.0% from 1,759 million in 2002 to 2,076 million in 2003. Using 2002 exchange rates, the increase would have been 31.6%. Net income per share in 2003 was 2.95 per share compared to 2.42 per share in 2002, or a 21.9% increase. The difference between the rate of growth in net income and in earnings per share is principally due to the share buyback program initiated in 2002, which decreased the number of outstanding shares.

### *Year Ended December 31, 2002 Compared to Year Ended December 31, 2001*

*Developed Sales*

Developed sales of our products were 9,585 million in 2002, representing a 9.6% increase over 2001. On a comparable basis, developed sales increased by 14.5% between 2001 and 2002. Two of our four leading products, Plavix® and Aprove1®, had combined developed sales of 3,655 in 2002, a 23.6% increase over 2001, or 28.0% on a comparable basis. Sales of these two products accounted for 38.1% of total developed sales of our products, compared to 33.8% in 2001. Developed sales were impacted by Bristol-Myers Squibb's program to reduce inventory levels of Plavix® and Aprove1® at wholesalers in the United States, beginning in March 2002.

**Table of Contents**

The following table reconciles our developed sales and our consolidated net sales for the year ended December 31, 2002:

	<b>2002</b>
	<i>(in millions of \$)</i>
<i>Total Consolidated Net Sales</i>	7,448
Plavix <sup>®</sup> non-consolidated sales less product sales to Bristol-Myers Squibb	1,600
Aprovel <sup>®</sup> non-consolidated sales less product sales to Bristol-Myers Squibb	506
Stilnox <sup>®</sup> non-consolidated sales less product sales to Fujisawa	31
Arixtra <sup>®</sup> non-consolidated sales	0
<i>Total Developed Sales</i>	9,585

The following table sets forth developed sales of two of our leading products broken down into our three geographic markets:

	<b>Year Ended December 31,</b>			<b>% change</b>	
	<b>2001</b>	<b>2001</b>	<b>2002</b>		
	<b>Reported</b>	<b>Comparable</b>	<b>Reported<sup>(1)</sup></b>	<b>Reported</b>	<b>Comparable</b>
	<i>( in millions)</i>				
<b>Plavix<sup>®</sup>/Iscover<sup>®</sup></b>					
Europe	520	531	754	45.0%	42.0%
United States	1,333	1,270	1,565	17.4%	23.2%
Other Countries	180	156	268	48.9%	71.8%
	<u>2,033</u>	<u>1,957</u>	<u>2,587</u>	27.3%	32.2%
<b>Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup></b>					
Europe	388	397	512	32.0%	29.0%
United States	392	374	373	(4.8%)	(0.3%)
Other Countries	144	127	183	27.1%	44.1%
	<u>924</u>	<u>898</u>	<u>1,068</u>	15.6%	18.9%
Total Plavix <sup>®</sup> and Aprovel <sup>®</sup>	<u>2,957</u>	<u>2,855</u>	<u>3,655</u>	23.6%	28.0%
<i>Total developed sales</i>	<u>8,746</u>	<u>8,368</u>	<u>9,585</u>	9.6%	14.5%

<sup>(1)</sup> Reported sales for 2002 are based on the geographical classifications that we used in 2002. As a result, reported figures above do not correspond to the reported figures in the tables comparing sales in 2002 and 2003.

Developed sales of Plavix<sup>®</sup> were 2,587 million in 2002, a 27.3% increase over developed sales of 2,033 million in 2001. In the United States, developed sales of Plavix<sup>®</sup> were 1,565 million, a 17.4% increase over 2001, or 23.2% on a comparable basis, adjusting for the impact of the dollar. Plavix<sup>®</sup> sales in the United States, which are included in the developed sales totals but are not reflected in our consolidated net sales, were

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

impacted by the BMS inventory workdown program. In addition, sales at the end of 2002 benefited from orders from wholesalers, which anticipated a price increase in early 2003. Overall United States demand for Plavix<sup>®</sup> increased in 2002 with a 35% increase in overall prescription volume from 2001 to 2002 (based on IMS retail and mail-order data). In addition, prices increased for the product in the United States. In Europe and in Other Countries, developed sales of Plavix<sup>®</sup> increased by 45.8% in 2002 compared to 2001.

Developed sales of Aprovel<sup>®</sup> were 1,068 million in 2002, a 15.6% increase over the 2001 figure of 924 million. In the United States, developed sales were 373 million, a decrease of 4.8% compared to 2001, or 0.3% on a comparable basis, adjusting for the impact of the dollar. As with Plavix<sup>®</sup>, U.S. sales of Aprovel<sup>®</sup> are not included in our consolidated net sales, although they are included in developed sales. Notwithstanding the decrease in the United States, which was due to the BMS inventory workdown program, overall demand for Aprovel<sup>®</sup> was up, with a 13% increase in overall prescription volume from 2001 to 2002 (based on IMS retail and mail-order data). Favorable price movements in the United States also had a positive effect. In Europe and in Other Countries, developed sales of Aprovel<sup>®</sup> increased by 30.6% in 2002 compared to 2001.

**Table of Contents**

*Net Sales*

Our net sales in 2002 were 7,448 million, representing a 14.8% increase compared to net sales of 6,488 million in 2001. On a comparable basis, our net sales increased by 12.8% from 2001 to 2002, after taking into account the impact of changes in the scope of consolidation and currency exchange rate fluctuations.

The following table sets forth a reconciliation between our reported sales for the year ended December 31, 2001 and our comparable sales for that year based on 2002 exchange rates and group structure:

	<b>Year Ended December 31, 2001</b>
	<i>(in millions of \$)</i>
<i>Reported</i>	6,488
Impact of change of group structure	252
Impact of exchange rate fluctuation	(135)
<i>Comparable</i>	6,605

Changes in the scope of consolidation, which increased sales by 4.5 percentage points, are principally related to our switch from the proportional consolidation method (49%) to 100% consolidation of the Lorex Pharmaceuticals joint venture (following our acquisition of exclusive control over the joint venture), which was partially offset by the switch to the proportional consolidation method (51%) for our joint venture with Fujisawa in Japan, as well as the deconsolidation of Ela Medical beginning in May 2001.

Currency exchange rate fluctuations reduced sales by approximately 2.5 percentage points. The decline of the U.S. dollar against the euro represented 0.8 percentage point of the decrease, 0.5 percentage point was due to the decline of the Japanese yen against the euro and 1 percentage point was due to currency devaluations in Latin America.

*Markets.* We divide our sales into three markets: Europe, the United States and Other Countries. The following table breaks down our 2001 and 2002 consolidated net sales by market.

	<b>Year Ended December 31,</b>			<b>% change</b>	
	<b>2001</b>	<b>2001</b>	<b>2002</b>	<b>Reported</b>	<b>Comparable</b>
	<b>Reported</b>	<b>Comparable</b>	<b>Reported<sup>(2)</sup></b>	<b>Reported</b>	<b>Comparable</b>
	<i>( in millions)</i>				
Europe					
France <sup>(1)</sup>	1,487	1,466	1,584	6.5%	8.0%

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

<i>Germany</i>	596	592	634	6.4%	7.1%
<i>Italy</i>	433	428	444	2.5%	3.7%
<i>Other</i>	1,361	1,357	1,635	20.1%	20.5%
	<u>          </u>	<u>          </u>	<u>          </u>		
<i>Total Europe</i>	3,877	3,843	4,297	10.8%	11.8%
	<u>          </u>	<u>          </u>	<u>          </u>		
United States	1,098	1,437	1,689	53.8%	17.5%
Other Countries	1,513	1,325	1,462	(3.4%)	10.3%
	<u>          </u>	<u>          </u>	<u>          </u>		
<i>Total net sales</i>	6,488	6,605	7,448	14.8%	12.8%
	<u>          </u>	<u>          </u>	<u>          </u>		

(1) Includes French overseas territories (Guadeloupe, Martinique, Réunion and French Guyana).

(2) Reported sales for 2002 are based on the geographical classifications that we used in 2002. As a result, reported figures above do not correspond to the reported figures in the tables comparing sales in 2002 and 2003.

Our 2002 net sales in Europe were 4,297 million, an increase of 10.8% over 2001. The healthy growth in Europe in 2002 was despite the implementation of health-care cost containment measures in Germany and Italy in 2002. Europe represented approximately 57.7% of our total consolidated net sales in 2002, compared to 59.8% in 2001.

**Table of Contents**

In Europe, we recorded strong sales growth despite the impact of new cost containment measures implemented by the governments in Germany and Italy. Outside of our three largest countries, France, Germany and Italy, our sales growth was uniformly strong, with the largest growth recorded in Spain, Belgium, Hungary, Greece and Turkey, each of which experienced growth of more than 20%. In Spain, where we recorded 358 million of sales in 2002, growth in sales of Plavix®, Aprovel® and Eloxatin® offset the loss of patent protection for Stilnox®.

In the United States, we had 1,689 million of consolidated net sales in 2002, representing a 53.8% increase over 2001. The difference between reported growth and comparable growth in the United States reflects primarily the inclusion of 100% of the sales of Stilnox® in the United States beginning in 2002. The launch of Eloxatin® in the United States in August 2002 resulted in U.S. sales of the product of 116 million in 2002, helping to offset declining sales of Corotrope® (sold under the brand name Primacor®), which began to face competition from generics in 2002. Our strong reported U.S. sales growth is despite the weakening of the U.S. dollar against the euro. The United States represented approximately 22.7% of our total consolidated net sales in 2002 compared to 16.9% in 2001.

Outside the United States and Europe, we recorded 1,462 million of sales, representing a 3.4% decrease compared to 2001, but a 10.3% increase on a comparable basis. The reason for the difference between reported and comparable sales is mainly due to the switch from 100% consolidation of our joint venture with Fujisawa to 51% proportional consolidation, as well as the weakness of the Japanese yen and certain Latin American currencies. Our growing presence in Asia helped offset the effects of the continued economic crisis in Latin America. The Other Countries represented 19.6% of our total consolidated net sales in 2002, compared to 23.3% in 2001.

*Products.* Our ten largest products had 4,575 million in total consolidated net sales in 2002, representing an increase of 37.9% over 2001. Sales of our top ten products represented approximately 61.4% of our total consolidated net sales in 2002, compared to approximately 51.1% in 2001.

The main reason for this growth was the strong performance of our four leading products, Plavix®, Aprovel®, Stilnox® and Eloxatin®, which together had total net sales of 3,362 million, an increase of 59.3% over 2001 on a reported basis, or 37.5% on a comparable basis. Sales of our four leading products represented 45.1% of our total consolidated net sales compared to 32.5% in 2001 on a reported basis.

The following table breaks down our consolidated net sales by product.

Product	Therapeutic Area	Year ended December 31,			% change <sup>(1)</sup>	
		2001 Reported	2001 Comparable	2002 Reported	Reported	Comparable
( in millions)						
Stilnox®	Central Nervous System	786	1,135	1,424	81.3%	25.5%
Plavix®	Cardiovascular/Thrombosis	705	697	987	39.8%	41.5%
Aprovel®	Cardiovascular/Thrombosis	423	419	562	32.8%	34.0%
Eloxatin®	Oncology	196	194	389	99.2%	101.3%
Fraxiparine®	Cardiovascular/Thrombosis	297	294	324	8.9%	10.1%
Depakine®	Central Nervous System	243	240	267	9.8%	11.0%
Xatral®	Internal Medicine	148	147	182	23.1%	24.3%
Cordarone®	Cardiovascular/Thrombosis	162	157	162	(0.1%)	3.1%
Tildiem®	Cardiovascular/Thrombosis	152	151	141	(7.4%)	(6.9%)



Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Ticlid®	Cardiovascular/Thrombosis	205	205	137	(33.2%)	(33.2%)
<i>Total of top 10 Products</i>		3,317	3,639	4,575	37.9%	25.7%
		<hr/>	<hr/>	<hr/>		
Others		3,171	2,966	2,873	(9.4%)	(3.1%)
		<hr/>	<hr/>	<hr/>		
<i>Total consolidated net sales</i>		6,488	6,605	7,448	14.8%	12.8%
		<hr/>	<hr/>	<hr/>		

(1) These percentages are calculated on the basis of figures that have not been rounded.

## **Table of Contents**

Stilnox<sup>®</sup> was our largest product in terms of consolidated net sales and our second fastest growing product (on a comparable basis it was our fourth fastest growing product). The difference between reported growth of Stilnox<sup>®</sup> (81.3%) and comparable growth (25.5%) is principally the result of consolidation of 100% of sales of Stilnox<sup>®</sup> in the United States in connection with our repurchase of Lorex Pharmaceuticals joint venture in 2002.

Consolidated net sales of Plavix<sup>®</sup> were 987 million in 2002, an increase of 39.8% over 2001. The continued strong level of growth in Plavix<sup>®</sup> is due to the approval of a new indication in 2002, as the product was approved in Europe and the United States for the treatment of acute coronary syndrome. In addition, Plavix<sup>®</sup> was included on a list of recommended cardiologic therapies both in Europe and the United States.

Consolidated net sales of Aprovel<sup>®</sup> were 562 million in 2002, an increase of 32.8% over 2001. Much of the growth was realized in Europe where Aprovel<sup>®</sup> became the second product in its class, angiotensin II receptor antagonists, in terms of sales (according to IMS data).

Consolidated net sales of Eloxatin<sup>®</sup> were 389 million, an increase of 99.2% over 2001. This strong growth is principally a result of the launch of Eloxatin<sup>®</sup> in the U.S. market in August 30, 2002, as well as overall growth in Europe and Other Countries.

Consolidated net sales of Xatral<sup>®</sup> increased by 23.1%, as sales of the product were boosted by the early success of the once-a-day formulation that was gradually launched in various countries in Europe in 2002.

Among our other top 10 products, we recorded strong growth in sales of Fraxiparine<sup>®</sup> and Depakine<sup>®</sup>. Sales of Ticlid<sup>®</sup> declined due to migration to sales of Plavix<sup>®</sup>.

Consolidated net sales of other products in our product portfolio decreased by 9.4% to 2,873 million in 2002, although they remained essentially stable on a comparable basis, declining by only 3.1%. The main reason for the difference between reported and comparable sales is the deconsolidation of Ela Medical in May 2001, and the switch to the proportional consolidation method (51%) for our joint venture with Fujisawa in Japan.

For our other pharmaceuticals, Corotrope<sup>®</sup> sales were adversely affected by the expiration of the product's patent in the United States. The decline in sales of Dogmatil<sup>®</sup>, and the difference between recorded and comparable sales of Dogmatil<sup>®</sup>, resulted from the switch to the proportional consolidation method (51%) for our joint venture with Fujisawa in Japan, while the consolidation of sales of Kerlone<sup>®</sup> in the United States (through the Lorex Pharmaceuticals joint venture) offset the impact of the weakening of the U.S. dollar and the Japanese Yen.

Consolidated net sales of Arixtra<sup>®</sup> were 9.1 million, due to slower penetration than expected in its narrowly defined initial indication. Our program to enlarge its approved indications is progressing, with the filing at the end of 2002 of an application to approve its use in the long-term preventive treatment of venous thrombo-embolic (or VTE) events following orthopedic surgery.

**Table of Contents***Therapeutic Areas.*

The following table breaks down our consolidated net sales by therapeutic area:

	Year Ended December 31,			% change	
	2001	2001	2002	Reported	Comparable
	Reported	Comparable	Reported		
	( in millions)				
<i>Therapeutic area:</i>					
Cardiovascular/Thrombosis	2,625	2,583	2,904	10.6%	12.4%
Central Nervous System	1,810	2,087	2,409	33.1%	15.4%
Internal Medicine	1,465	1,399	1,427	(2.6%)	2.0%
Oncology	208	206	404	94.2%	96.1%
<i>Total</i>	6,108	6,275	7,144	17.0%	13.8%
Other	380	330	304	(20.0%)	(7.9%)
<i>Total consolidated net sales</i>	6,488	6,605	7,448	14.8%	12.8%

Cardiovascular/Thrombosis sales were 2,904 million in 2002, representing approximately 39.0% of our total consolidated net sales. The sales growth in this category reflects primarily the increase in sales of Plavix® and Aprovel®, which offset the decline in sales of Ticlid® and Corotrope®.

Central Nervous System sales were 2,409 million in 2002, representing approximately 32.3% of our total consolidated net sales. The main reason for the difference between reported and comparable sales in this category is the consolidation of 100% of the sales of Stilnox® in the United States in 2002.

Internal Medicine sales were 1,427 in 2002, accounting for approximately 19.2% of our total consolidated net sales in 2002. The slight decline in sales in this category was principally a result of the switch to the proportional consolidation method (51%) for our joint venture with Fujisawa in Japan.

Oncology sales were 404 million in 2002, representing approximately 5.4% of our total consolidated net sales. The robust growth in this category was mainly due to the nearly doubling in sales of Eloxatin® in 2002.

Other sales were 304 million in 2002, a decrease of 20.0% on a reported basis, or 7.9% on a comparable basis. The main reason for the difference is the deconsolidation of Ela Medical in May 2001.

*Gross Profit*

Our gross profit was 6,070 million in 2002, an increase of 15.9% compared to 2001, and represented 81.5% of our total consolidated net sales in 2002, compared to 80.7% in 2001. Using 2001 exchange rates, our gross margin would have been 82.1% in 2002.

This improvement in our gross margin is mainly due to improvements in our productivity, which we estimate accounted for a 0.6 percentage point increase, as well as strong performance from our top 10 products and overall improvements in our product mix, which also accounted for a 0.6 percentage point increase. These gains were partially offset by reductions in revenues received due to Bristol-Myers Squibb's program to reduce inventory levels of Plavix® and Aprovel® at wholesalers in the United States, which had a negative impact of 0.4 percentage points. The full consolidation of Lorex Pharmaceuticals was offset by the loss of sales of bulk active ingredients to the joint venture, such that it had a neutral effect on our gross margin.

*Operating Profit*

Our operating profit was 2,614 million in 2002, representing a 24.1% increase compared to our operating profit in 2001 of 2,106 million. The weak U.S. dollar exchange rate against the euro had a negative impact on our operating profit, which would have increased by 30.1% over 2001 if exchange rates had remained constant.

**Table of Contents**

Operating profit in 2002 represented 35.1% of consolidated net sales, while in 2001 operating profit was 32.5% of consolidated net sales. This improvement in our operating margins was driven principally by the change in consolidation method of the Lorex Pharmaceuticals joint venture, as well as improvements in our overall product mix and productivity, which was partially offset by the negative effects of Bristol-Myers Squibb's program to reduce inventory levels of Plavix® and Aprovel® at wholesalers in the United States.

The following table breaks down our operating profit for 2001 and 2002 among its principal components.

	Year ended December 31			
	2001		2002	
	Amount	% of Sales	Amount	% of Sales
	( in millions)			
<i>Net sales</i>	6,488	100.0%	7,448	100.0%
Cost of goods sold	(1,253)	(19.3%)	(1,378)	(18.5%)
<i>Gross profit</i>	5,235	80.7%	6,070	81.5%
Research and development expenses	(1,031)	(15.9%)	(1,218)	(16.4%)
Selling and general expenses	(2,306)	(35.5%)	(2,428)	(32.6%)
Other operating income/(expense), net	208	3.2%	190	2.6%
<i>Operating profit</i>	2,106	32.5%	2,614	35.1%

Research and development expenses increased to 1,218 million in 2002, representing 16.4% of our total consolidated net sales, and an 18.1% increase over 2001. Using 2001 exchange rates, the increase in our research and development expenses would have been 20.4%. The increase in spending was principally due to clinical trials that are underway both for new indications for products that are already on the market, such as Plavix®, Arixtra®, Eloxatin® and Xatral®, as well as for new products in development, such as rimonabant, dronedarone, tirapazamine, and the new sustained release formulation of Stilnox®, zolpidem MR. Some of the increase is also attributable to development agreements signed in 2001 and 2002 with IDM and Cephalon, which are described in Item 4 Information on the Company Research and Development.

Selling and general expenses were 2,428 million in 2002, a 5.3% increase from 2,306 million in 2001. Using 2001 exchange rates, our selling and general expenses would have increased by 8.0%. The relatively modest increase is the result of several factors:

the incurrence in the last quarter of 2001 of significant costs relating to putting in place in the United States the commercial teams necessary to permit us to take over fully the marketing of Stilnox® and to launch Arixtra®;

an adjustment in our sales efforts in Latin America as a result of the economic and monetary crisis;

increased sales in Europe; and

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

an overall improvement in the productivity of our medical visits in all geographic markets.

These factors more than offset an increase in marketing expenses that we incurred in order to develop the principal products in our portfolio.

Our other operating income/(expense), net, declined by 8.6% from 208 million (or 3.2% of our net sales) in 2001 to 190 million (or 2.6% of our net sales) in 2002. As discussed above, this item reflects principally operating profits of our alliances to which we are entitled or to which our partners are entitled. The decrease was primarily due to two factors: the rapid growth of Plavix<sup>®</sup> and Aprovel<sup>®</sup> in Europe, which increased the amount paid to Bristol-Myers Squibb under our alliance arrangements; and a decrease in operating profit from Plavix<sup>®</sup>.

**Table of Contents**

and Aprovel® in the United States due to Bristol-Myers Squibb's wholesaler inventory workdown program. These were both offset by the fact that we no longer had to pay Pharmacia its share of the profits from our Lorex Pharmaceuticals joint venture, which we repurchased in April 2002. The profits paid to Pharmacia equaled 14 million in 2001, and were recorded under minority interests.

Our operating profit improved in all of our markets. The following table breaks down our 2001 and 2002 operating profit by geographical market.

	Year Ended December 31,		
	2001	2002	% change
	( in millions)		
Europe	1,427	1,633	14.4%
United States	1,311	1,781	35.9%
Other Countries	456	522	14.5%
Unallocated costs <sup>(1)</sup>	(1,088)	(1,322)	21.5%
<b>Total operating profit</b>	<b>2,106</b>	<b>2,614</b>	<b>24.1%</b>

<sup>(1)</sup> Unallocated costs consists mainly of a portion of our research and development expenses and of our administrative expenses.

Among our three geographical segments, operating profit grew most rapidly in the United States, which accounted for 45.2% of our operating profit excluding unallocated costs compared to 41.0% in 2001. The increase in the United States was due principally to the change in the consolidation method of our Lorex Pharmaceuticals joint venture as well as the other factors that resulted in our sales increase in the United States discussed above.

Unallocated costs increased by 21.5% in 2002 over 2001 principally as a result of the increase in our research and development expenses.

*Amortization and Impairment of Intangibles*

Our amortization and impairment of intangibles increased from 68 million in 2001 to 129 million in 2002. This increase was principally due to amortization of the intangible assets relating to our October 2001 payment to Bristol-Myers Squibb in exchange for an increase in our participation in the promotional activities and profitability of the alliance relating to U.S. sales of Aprovel® and the amortization of the U.S. rights to Stilnox® in connection with our acquisition of the Lorex Pharmaceuticals joint venture in April 2002.

*Net Financial Income/(Expense)*

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Net financial income/(expense) decreased from 102 million in 2001 to 85 million in 2002. This decrease was due primarily to three factors: a 46 million provision for treasury shares allocated to our stock option plans, which relates entirely to the difference, evaluated on a plan by plan basis, between the market value of our shares and the average price paid to acquire the shares on the market and our average share price ( 57.10) in December 2002; a decrease in returns from investments following reductions in interest rates by an average of 1.1 percentage points, with average investments remaining constant over the past two years; and an increase in returns from exchange rate hedging transactions due to the decrease in the value of the U.S. dollar against the euro ( 47 million in 2002 compared to 5 million in 2001).

### *Exceptional Income*

Exceptional income decreased significantly from 281 million to 10 million in 2002. This significant decrease is principally due to the fact that in 2001, we sold our interest in Laboratoires de Biologie Végétale Yves Rocher, which resulted in a gain of 158 million. In 2002, exceptional income represented mainly gains from sales of stock in the United States.



## **Table of Contents**

### *Income Taxes*

Income taxes decreased by 96 million, from 842 million in 2001 to 746 million in 2002. Our effective tax rate was 28.9% in 2002, compared to 34.8% in 2001. The decrease was principally attributable to a decrease in the French tax rate and, in particular, the tax rate applied to royalty payments; the adjustment of prior tax returns resulting in the recovery of 53 million following a tax audit; and the impact of the integration of the Lorex Pharmaceuticals joint venture, a tax transparent company that we acquired in April 2002 (for which our income tax charge includes only the amount allocated to our company, even though we consolidated Lorex Pharmaceuticals fully in 2002).

Our effective tax rate for the first half of 2002, which was affected by the last two elements mentioned above, was 25.8%. Our effective tax rate increased to 31.6% for the second half of 2002.

### *Minority Interests*

Income attributable to minority interests was 87 million in 2002 and represents primarily Pharmacia's share of the profits of the Lorex Pharmaceuticals joint venture from January 1, 2002 through April 14, 2002. Because the Lorex Pharmaceuticals joint venture is tax transparent, minority interests does not include the corresponding taxes.

### *Net Income*

As a result of the foregoing, our net income increased 11.0% from 1,585 million in 2001 to 1,759 million in 2002. Net income before exceptional items and goodwill amortization was 1,758 million, an increase of 27.8% compared to 2001. Using 2001 exchange rates, the increase would have been 31.2%.

## **Liquidity and Capital Resources**

Our operations generate significant positive cash flow. We fund our investments primarily with operating cash flow and pay regular dividends on our shares. Our current financial debt is limited, and we had a net cash position as of December 31, 2003, although this position will change if our proposed acquisition of Aventis is successful.

### *Cash Flow*

For the year ended December 31, 2003, our activities generated 2,428 million of cash flow, an increase of 7.4% compared to 2,260 million recorded in 2002. The increase was smaller than the increase in our net income because the 2002 cash flow figure re-integrated the minority interest in the former Lorex joint venture, which was offset against the cash used for the acquisition in our cash flow statement. Our working capital requirements in 2003 increased by 163 million compared to 2002. This increase is generally in line with the growth of our activities and

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

principally relates to an increase in accounts receivable. However, our working capital requirements increased more significantly in 2002 due to the payment of taxes that were recorded as payables in 2001. As a result, our cash flow from operations increased from 1,676 million in 2002 to 2,265 million in 2003.

We used 350 million of cash in our investing activities during the year ended December 31, 2003, a 1,059 million decrease compared to 1,409 million in 2002. The difference is principally the inclusion in 2002 of our acquisition of the remaining 51% of the Lorex joint venture for 670 million and payments made to BMS with respect to the increase in our interest in Aprovel<sup>®</sup> in the United States. Our investments in tangible fixed assets (principally manufacturing facilities and, to a lesser extent, research sites) slightly decreased from 423 million in 2002 to 338 million in 2003. Proceeds from asset sales slightly increased from 22 million in 2002 to 27 million in 2003.

## **Table of Contents**

In 2003, we used 1,598 million in connection with our financing activities, reflecting primarily the acquisition of our shares under a share buy back program ( 1,003 million net of sales) and the payment of dividends on our shares ( 582 million). Cash used in financing activities was 1,591 million in 2002, reflecting essentially the same items. Our borrowings were essentially unchanged in 2003.

### ***Financial Debt***

Our financial debt amounted to approximately 368 million at December 31, 2003, of which 315 million was short-term debt. Most of the long-term debt consisted of capital lease obligations. As of December 31, 2003, we had 8 million of long-term debt maturing in 2005 and 7 million of long-term debt maturing in 2006.

As of December 31, 2003, our cash and cash equivalents were 3,378 million. As a result, our net cash position was 3,010 million as of that date.

In connection with our proposed acquisition of Aventis, on January 25, 2004, we entered into a credit facility agreement that permits us to borrow up to 12,000 million. We may only borrow amounts under this credit facility if our offer for the Aventis securities is successful. If the offer is successful, we expect to borrow a substantial amount under this credit facility, which we will use mainly to finance the cash portion of the consideration we are offering to pay for the Aventis securities and to refinance certain debt of Aventis and its subsidiaries. The credit facility includes terms and conditions customary for agreements of this type, including the requirement that we maintain certain financial ratios and restrictions on our ability to engage in additional transactions or incur additional indebtedness. For additional information relating to our proposed acquisition of Aventis and the credit facility, see Item 8 Financial Information Significant Changes.

### ***Liquidity***

We expect that our existing cash resources will be sufficient to finance our existing ongoing activities and investments. We do not anticipate any significant increase in our capital expenditures in 2004 compared with recent years, and we have no current plans that would result in a significant increase for the next several years. However, we expect that our overall liquidity position will change significantly if our proposed acquisition of Aventis is successful, due to the fact that we expect to incur substantial debt under our 12,000 million credit facility. See Item 8 Financial Information Significant Changes.

### ***Off-Balance Sheet Arrangements***

In 2003, we had no off-balance sheet arrangements that have or, in our opinion, are reasonably likely to have a current or future effect on our financial condition. We do not consider our off-balance sheet arrangements as of December 31, 2003 to be significant.

### ***Contractual Obligations and Other Commercial Commitments***

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

We have various contractual obligations and other commercial commitments arising from our operations. These obligations and commitments are more fully described in this annual report under Item 4 and in this Item 5. We do not consider our aggregate contractual obligations and other commercial commitments as of December 31, 2003 to be significant.

**Table of Contents**

The following table lists the aggregate maturities of our contractual obligations given as of December 31, 2003.

**Contractual obligations given**

	<b>Payments due by Period</b>				
	<b>Total</b>	<b>Under 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>Over 5 Years</b>
	<i>(in millions of \$)</i>				
Long-term debt, excluding capital lease obligations	13	3	5	1	4
Capital lease obligations (including interest)	62	10	14	10	28
Operating leases	441	91	110	76	164
Irrevocable purchase obligations <sup>(1)</sup>	150	138	11	1	
Other long-term obligations	226	88	73	25	40
<b>Total</b>	<b>892</b>	<b>330</b>	<b>213</b>	<b>113</b>	<b>236</b>

<sup>(1)</sup> Including open purchase orders.

As of December 31, 2003, we had given a total of \$892 million in commercial commitments, \$330 million of which is payable within one year, \$213 million of which is payable between one to three years, \$113 million of which is payable between three to five years and \$236 million of which is payable in more than five years from such date. Otherwise, we have no outstanding commercial commitments. For additional information regarding our commercial commitments, see Note D.18 to our consolidated financial statements included under Item 18.

In addition, we may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaborative partner a fee and receive intellectual property rights to the product in exchange. We also are generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

Our principal agreements of this nature are:

our agreement under which we purchased Organon's rights to Arixtra<sup>®</sup> and certain other products, which is described above under Financial Presentation of Alliances, and under which we have agreed to support all of the research and development costs and pay Organon an aggregate of \$74 million in minimum royalty payments;

three licensing agreements under which we have agreed to pay aggregate minimum royalties of \$7 million;

a collaboration agreement with Cephalon for the development of angiogenesis inhibitors, in respect of which the payment for the first product could reach \$32 million;

an agreement with Mitsubishi-Pharma Corp to develop neuroprotective agents for use in the treatment of neurogenerative disorders;  
and

an agreement with Immuno-Designed Molecules, or IDM, to develop cellular immunology therapies for cancer under which our payments could reach \$32 million for each of up to 20 products, at our option, over 10 years, and under which we acquired 20 million in shares of IDM in 2002. As of December 31, 2003, we had only exercised our option for one product under this agreement. We have agreed to acquire up to an additional 10 million of shares of IDM if IDM elects to list its shares on a public market or conducts a private placement prior to July 31, 2004.

## **Table of Contents**

Because of the uncertain nature of development work, it is impossible to predict if we will exercise an option for a product or if the relevant milestones will be achieved. For this reason, it is impossible to estimate the maximum aggregate amount that we will actually pay in the future under our outstanding collaborative agreements. Given the nature of our business, it is highly unlikely that we will exercise all options for all products or that all milestones will be reached.

## **International Financial Reporting Standards**

Like all European listed companies, we will be required to apply International Financial Reporting Standards (IFRS) in the preparation of our consolidated financial statements for financial years from January 1, 2005 on. In 2003, we initiated a comprehensive IFRS conversion project for our consolidated financial statements. This project includes:

workgroups assigned to perform detailed diagnostic work;

a project committee responsible for managing the conversion project; and

a technical committee responsible for validating the accounting policies adopted.

The review of our consolidated financial statements in connection with our listing on the New York Stock Exchange (and preparation of the U.S. GAAP reconciliation) enabled us to identify, anticipate and use accounting options available under existing French accounting standards to achieve convergence with IFRS. This led to our adoption of the following accounting treatments:

recognition of pension and similar obligations and other post-employment benefits (Notes B.20 and D.14.1 to the consolidated financial statements);

balance sheet recognition of finance leases (Note B.7 to the consolidated financial statements); and

recording foreign exchange gains and losses after income statement recognition of hedging operations (Note B.3 to the consolidated financial statements).

In 2003, we also took steps to comply with a new French accounting rule regarding asset depreciation, amortization and impairment, and elected component-based accounting treatment, which requires a more detailed analysis of fixed assets. This new rule is consistent with IFRS. We expect to be able to present fully quantified disclosures of the impact of the transition to IFRS in 2005.

## **U.S. GAAP Reconciliation and Presentation Differences**

We prepare our consolidated financial statements in accordance with French GAAP, which differ in certain significant respects from U.S. GAAP. As a result, our net income and shareholders' equity is different under U.S. GAAP and under French GAAP. For a detailed discussion of

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

the differences between French GAAP and U.S. GAAP as they relate to our consolidated net income and shareholders' equity, see Note G to our audited consolidated financial statements included under Item 18.



**Table of Contents****Net Income**

The following table sets forth our net income under French GAAP and U.S. GAAP for the periods indicated.

	Year Ended December 31,		
	2001	2002	2003
	(in millions of \$)		
<i>French GAAP net income</i>	1,585	1,759	2,076
Purchase accounting adjustments	(445)	(311)	(269)
Provisions and other liabilities	(23)		
Stock-based compensation	(8)	(8)	(50)
Revenue recognition U.S. BMS alliance	(136)	117	33
Other	(42)	31	(16)
Income tax effects	167	52	91
<i>U.S. GAAP net income</i>	1,098	1,640	1,865

*Purchase accounting.* The principal purchase accounting adjustment, amounting to a charge of 364 million in 2001, 265 million in 2002 and 249 million in 2003, relates to the business combination of Sanofi and Synthelabo. Under French GAAP, the transaction was accounted for as a merger. As a result, no goodwill was recorded in connection with the merger, and existing assets and liabilities of Sanofi and Synthelabo were revalued to adjust them to their value to our company. Under U.S. GAAP, the business combination is accounted for as a purchase, with Sanofi deemed the acquirer of Synthelabo. As a result, the transaction resulted in the recognition of significant goodwill and intangible assets. The difference in net income in 2001 was principally the result of amortization of goodwill and identified intangible assets. Beginning in 2002, we no longer amortize goodwill, but instead test goodwill annually for impairment, in accordance with Statement of Financial Accounting Standards No. 142. As a result, in 2002 and 2003 this item reflected primarily the amortization of intangible assets.

Our net income was also affected by the purchase accounting treatment under U.S. GAAP of Sanofi's acquisition of the human healthcare division of Eastman Kodak, Sterling Winthrop, in 1994. Under French GAAP, no goodwill or intangibles associated with the acquisition of Sterling Winthrop are reflected in our consolidated financial statements. Under U.S. GAAP, a portion of the purchase price was allocated to identified intangible assets, which are being amortized over periods ranging from 8 to 20 years. This difference amounted to 52 million in 2001, 46 million in 2002 and 20 million in 2003.

*Provisions and other liabilities.* In connection with the merger, under French GAAP we recorded certain provisions, principally in respect of anticipated restructuring costs. Under U.S. GAAP, which has more restrictive criteria, certain of these charges do not qualify for provisioning under U.S. restructuring rules and were charged to expense in 2001. This was the primary factor that led to a reduction of 23 million of net income in 2001.

*Stock-based compensation.* Under French GAAP, we do not recognize compensation expense related to stock-based compensation. Shares issued upon the exercise of stock options are reflected as an increase in share capital upon exercise of the stock option. Under U.S. GAAP, prior to 2003, if the exercise price of the stock options was less than the market price of the underlying shares on the grant date, we recognized compensation expense over the related vesting period. Beginning in 2003, we adopted the fair value recognition provisions of Statement of Accounting Standards No. 123, using the modified prospective method under Statement of

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Accounting Standards No. 148, and we now recognize compensation expense over the vesting period based on the fair value of the option on the grant date. This was the primary factor that led to a reduction of \$50 million of net income in 2003.

**Table of Contents****Presentation Differences**

In addition to the foregoing, there are differences in presentation between our French GAAP and U.S. GAAP financial statements, which have no impact on our net income or shareholders' equity, but instead impact classification and display. The principal presentation differences are the following:

Under U.S. GAAP, our Lorex Pharmaceuticals joint venture was accounted for using the equity method until December 31, 2001. Under French GAAP, until December 31, 2001, we accounted for Lorex Pharmaceuticals using the proportionate consolidation method, which means that we presented our share of the assets, liabilities, equity, revenue and expense of the joint venture in each major caption of our balance sheet and statement of income.

Under French GAAP, the alliance entities majority-owned by BMS are presented in a manner similar to the equity method, with our share of the operating profit recorded under other operating income/ (expense) in our statement of income. Alliance entities that we majority-own are consolidated, with BMS' share of the operating profit recorded as a charge under other operating income/(expense) in our statement of income. Under U.S. GAAP, the alliance entities majority-owned by BMS are presented as equity method investees, with our share of the operating profits recorded as income from equity method investees in our statement of income. Alliance entities that we majority-own are fully consolidated, with BMS' share of the operating profit presented in minority interests in our statement of income.

Restructuring charges and certain other items are treated as exceptional income or expenses under French GAAP but are treated as operating income or expenses under U.S. GAAP. As a result, these items impact our operating income under U.S. GAAP, while they do not impact our operating income under French GAAP.

Under French GAAP, we record royalties received under licenses and specific government levies related to the pharmaceuticals sector paid in certain countries in cost of goods sold. Under U.S. GAAP, license royalties are reflected as revenues, and specific government levies related to the pharmaceuticals sector are reflected in selling and general expense.

**Shareholders' Equity**

The following table sets forth our shareholders' equity under French GAAP and U.S. GAAP as of the dates indicated.

	As of December 31,		
	2001	2002	2003
	<i>(in millions of \$)</i>		
French GAAP shareholders' equity	5,768	6,035	6,323
Purchase accounting adjustments	8,927	8,576	8,267
Provisions and other liabilities	35		
Stock-based compensation			
Revenue recognition - U.S. BMS alliance	(160)	(35)	
Other	(456)	(695)	(635)
Income tax effects	(1,365)	(1,282)	(1,219)

<i>U.S. GAAP shareholders equity</i>	12,749	12,599	12,736
--------------------------------------	--------	--------	--------

## **Table of Contents**

The principal factor affecting the determination of our shareholders' equity under U.S. GAAP was the purchase accounting treatment of the merger, which resulted in shareholders' equity under U.S. GAAP being \$8,761 million more than the corresponding French GAAP figure in 2001, \$8,465 million more in 2002 and \$8,170 million more in 2003. These differences were partially offset by the impact of the income taxes, which decreased our U.S. GAAP shareholders' equity compared to the corresponding French GAAP figure by \$1,365 million in 2001, \$1,282 million in 2002 and \$1,219 million in 2003.

## ***Recent Accounting Pronouncements***

The U.S. Financial Accounting Standards Board, or FASB, issued the following recent accounting pronouncements in 2003, which are applicable to our company:

FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51, which requires consolidation of certain special purposes entities. We have identified a number of such potential variable interest entities, primarily in connection with our joint venture arrangements, and are currently determining whether or not consolidation is required. We expect to finalize the aforementioned determinations and analyses with respect to our joint venture arrangements and any other potential variable interest entities in the third quarter of 2004;

Statement of Financial Accounting Standards, or SFAS, No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities, we do not expect this statement to have a material impact on our results of operations; and

SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, we do not expect this statement to have a material impact on our results of operations.

Additionally, since June 15, 2003, we have applied the FASB's Emerging Issues Task Force, or EITF, recommendation, EITF 00-21, Revenue Arrangements with Multiple Deliverables.

For details regarding these recent accounting pronouncements and their expected impact on our future financial results, please see Note G.3.6 to our consolidated financial statements included under Item 18.

## **Critical Accounting and Reporting Policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

***Treatment of Alliances.*** Our policies with respect to alliances are discussed above under Overview Financial Presentation of Alliances and Overview Sources of Revenues and Expenses. While our treatment of alliances does not require us to make significant

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

estimates, an understanding of our income statement requires an understanding of the presentation of the results of our alliances, including the presentation of royalties paid and received in our cost of sales, and the presentation of our share of profits from our alliances under Other operating income / (expense), net.

**Impairment Testing.** We test our intangible assets periodically for impairment. The most significant intangible assets that we test for impairment are those resulting from the U.S. GAAP treatment of business combinations, as discussed above under U.S. GAAP Reconciliation and Presentation Differences Net Income. We test for impairment on the basis of the same objective criteria that are used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset

**Table of Contents**

(for its initial valuation) or the recorded value of the asset (for ongoing tests). The determination of the underlying assumptions related to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Any changes in key assumptions about our business and prospects, or changes in market conditions, could result in an impairment charge.

***Pension and Retirement Benefits.*** We recognize our pension and retirement benefit commitments 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 to meet these obligations. We prepare this estimate on an annual basis taking into account actuarial assumptions, including life expectancy, staff turnover, salary growth, long-term return on plan assets, retirement and discounting of amounts payable. Depending on the assumptions and estimates used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings.

***Deferred Taxes.*** We account for deferred taxes using the liability method, whereby deferred income taxes are recognized on tax loss carry-forwards, and the difference between the tax and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We record a provision when it is more likely than not that the realization of the deferred tax assets will not occur.

**Table of Contents****Item 6. Directors, Senior Management and Employees****A. Directors and Senior Management***Directors*

In accordance with our bylaws (*statuts*), we are managed by our Board of Directors (*conseil d'administration*), which must be composed of a minimum of 3 and a maximum of 18 members. Each member of the Board of Directors is appointed for a term of 5 years and we cannot have more than 1/3 of our Directors be older than 70 years of age. Under French law, the Board of Directors has broad authority to take actions in the name of Sanofi-Synthelabo within the scope of our corporate purpose (subject to the authority expressly reserved by law to the shareholders). In accordance with our bylaws, each director must be the direct legal owner of at least one of our shares throughout his or her term of office.

In 2003, our Board of Directors was composed of 13 members. Total, through its subsidiary Elf Aquitaine, and L. Oréal, our major shareholders, are parties to a shareholders' agreement that includes provisions relating to the composition of our Board of Directors. See Item 7 Major Shareholders and Related Party Transactions Major Shareholders' Shareholders' Agreement. This agreement provides that four of the members are chosen from among candidates proposed by Total, three are chosen from among candidates proposed by L. Oréal, two are chosen by mutual agreement between Total and L. Oréal from among our corporate officers, and three are chosen by mutual agreement between Total and L. Oréal from among candidates independent of Total, L. Oréal and our company. In practice and with the consent of Total and L. Oréal, the actual composition of our Board of Directors has varied slightly from that contemplated in the agreement.

The names and positions of the members of our Board of Directors in 2003, their ages, business experience, dates of initial appointment, the year in which their term expires and information on their principal business activities outside our company are as follows:

Jean-François Dehecq Chairman and Chief Executive Officer	Age: First elected: Term expires: Principal occupation: Other directorships and business experience:	64 May 18, 1999 2004 <sup>(1)</sup> Chairman and Chief Executive Officer of Sanofi-Synthelabo Director of Air France and Société Financière des Laboratoires de Cosmétologie Yves Rocher
René Barbier de la Serre Director	Age: First elected: Term expires: Principal occupation: Other directorships and business experience:	63 May 18, 1999 2004 <sup>(1)</sup> Retired Former Executive Vice Chairman of CCF; Former Chairman <i>Conseil des Marchés Financiers</i> (now part of the AMF); Director of Crédit Agricole Indosuez and Schneider Electric; Member of the Supervisory Boards of Pinault-Printemps-Redoute, Compagnie Financière St. Honoré and Euronext N.V.
Robert Castaigne Director	Age: First elected: Term expires: Principal occupation:	57 February 21, 2000 2004 <sup>(1)</sup> Chief Financial Officer of Total



Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Other directorships and  
business experience:

Director of Atofina, Compagnie Générale de Géophysique, Elf Aquitaine,  
Hutchinson, Société Financière d Auteuil and Omnium Insurance and  
Reinsurance Company Ltd. (Bermuda)

**Table of Contents**

Pierre Castres Saint Martin	Age:	68
Director	First elected:	May 18, 1999
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Retired
	Other directorships and business experience:	Former Deputy General Manager of L Oréal; Director of Fimalac, and SEB, Chairman of the SICAV Diversified Portfolio, Chairman of Supervisory Board of Group Marc de Lacharrière, Member of Supervisory Board of Arc International
Thierry Desmarest	Age:	58
Director	First elected:	February 21, 2000
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Chairman and Chief Executive Officer of Total SA and Elf Aquitaine
	Other directorships and business experience:	Member of Supervisory Boards of Areva and L Air Liquide
Lord Douro	Age:	58
Director	First elected:	May 22, 2002
	Term expires:	2007
	Principal occupation:	Chairman, Richemont Holdings (U.K.)
	Other directorships and business experience:	Chairman, Framlington Group (U.K.), Director of Compagnie Financière Richemont AG (Switzerland), Global Asset Management Worldwide (U.K.) and Pernod Ricard S.A. (France); Commissioner of English Heritage
Pierre-Gilles de Gennes	Age:	71
Director	First elected:	May 18, 1999
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Professor at the Collège de France
	Other directorships and business experience:	Member of Supervisory Board of L Air Liquide; Director of and Scientific Advisor to Rhodia; Scientific Advisor to Sanofi-Synthélabo Recherche; Nobel Prize in Physics (1991)
Hervé Guérin	Age:	62
Director	First elected:	May 18, 1999
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Retired
	Other directorships and business experience:	Former Chairman and Chief Executive Officer of Synthélabo prior to the merger; Former Vice Chairman and Managing Director of Sanofi-Synthélabo
Elf Aquitaine, Director permanent representative:		
Jean-Paul Léon	Age:	66
	First elected:	May 18, 1999
	Term expires:	2004 <sup>(2)</sup>
	Principal occupation:	Retired
	Other directorships and business experience:	Former Chief Financial Officer, Executive Vice President Corporate Strategy of Sanofi prior to the merger; Director of Société Financière des Laboratoires de Cosmétologie Yves Rocher

**Table of Contents**

Lindsay Owen-Jones	Age:	58
Director	First elected:	May 18, 1999
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Chairman and Chief Executive Officer of L. Oréal
	Other directorships and business experience:	Director of BNP Paribas (France) and Gesparal (France); Vice President and Member of Supervisory Board of L. Air Liquide (France); Director and Chairman of Galderma Pharma (Switzerland)
L. Oréal, Director permanent representative:		
Christian Mulliez*	Age:	43
	First elected:*	May 18, 1999
	Term expires:	2004 <sup>(2)</sup>
	Principal occupation:	Vice President, General Management, Administration and Finance of L. Oréal (France)
	Other directorships and business experience:	Former Chief Financial Officer, Sanofi-Synthélabo
Gérard Van Kimmel	Age:	64
Director	First Elected	May 19, 2003
	Term Expires:	2008
	Principal occupation:	President of Novell for Europe, the Middle East and Africa
	Other directorships and business experience:	
Bruno Weymuller	Age:	55
Director	First elected:	May 18, 1999
	Term expires:	2004 <sup>(1)</sup>
	Principal occupation:	Executive Vice President, Strategy and Risk Assessment of Total SA
	Other directorships and business experience:	Director of Elf Aquitaine and Technip-Coflexip

\* Christian Mulliez replaced Michel Somnolet as L. Oréal's permanent representative on our Board of Directors effective November 15, 2003. Mr. Somnolet had served as L. Oréal's permanent representative since the beginning of L. Oréal's current term as Director (*i.e.*, from May 18, 1999). Mr. Mulliez will represent L. Oréal on our Board for the remainder of its current term.

(1) We will ask our shareholders at the May 24, 2004 general meeting to renew the appointments of these directors, whose terms are due to expire in 2004.

(2) We will ask our shareholders at the May 24, 2004 general meeting to appoint Mr. Léon and Mr. Mulliez in their individual capacities as directors. We will not ask shareholders to re-appoint L. Oréal and Elf Aquitaine, the entities, as directors.

None of our directors has any family relationship with any of our other directors or member of our senior management. None of our directors has entered into a service contract with our company or any of our subsidiaries providing for benefits upon termination of his service as a director. Mr. de Gennes has a contract to serve as Scientific Advisor to one of our subsidiaries, Sanofi-Synthélabo Recherche. For more information about this contract, please see Item 7 Major Shareholders and Related Party Transactions Related Party Transactions.

**Senior Management**

The names, positions and business experience of our senior officers are as follows:

*Jean-Francois Dehecq* is our Chairman and Chief Executive Officer. Mr. Dehecq has a degree from the Ecole Nationale des Arts et Metiers. He began his career as a mathematics professor and then served in the Army as a research scientist at the Nuclear Propulsion Department. From 1965 until 1973, he served in a variety of



---

**Table of Contents**

positions at the Société Nationale des Pétroles d'Aquitaine (SNPA) before joining Sanofi as Managing Director (*Directeur Général*) in 1973. From 1982 to 1988, Mr. Dehecq served as Vice President and Managing Director (*Vice Président Directeur Général*) of Sanofi, before being appointed Chairman and Chief Executive Officer (*Président Directeur Général*) of Sanofi in 1988. Following the merger in 1999, he was appointed to his present position. Mr. Dehecq sits on the board of directors of Air France. From 1988 through 1999, he also served as Managing Director of Health for the Elf Aquitaine Group.

*Gérard Le Fur* is our Senior Executive Vice President and Executive Vice President, Scientific Affairs. Mr. Le Fur has degrees in both pharmacy and science. He began his career at Laboratoires Pharmuka as Chief of Laboratories and later served as Assistant Director of Research and Development before joining Laboratoires Rhône-Poulenc as Director of Biology. He began his career at Sanofi in 1986 as Assistant Director of Research and Development, and was named Director of Research and Development in 1995, prior to being named to Executive Vice President, Scientific Affairs in June 1999 following the merger. He was appointed Senior Executive Vice President (*Directeur Général Délégué*) by our Board of Directors on December 11, 2002.

*Pierre-Jean Lepienne* is our Executive Vice President, Corporate Affairs. He has a degree from the Ecole Supérieure de Commerce of Paris, a diploma in Economics and Finance from the University of São Paulo and completed graduate studies in finance at Stanford University. Mr. Lepienne began his career at Robert et Carrère Laboratory as General Secretary, and then served as Chief Financial Officer (*Directeur Financier*), a position that he continued to hold once it became the Synthélabo Group. Mr. Lepienne later served as President of Synthélabo Pharmacie and as Executive Vice President and Director of Synthélabo S.A. before being named to his present position in 1999 following the merger.

*Hanspeter Spek* is our Executive Vice President, Operations. He graduated from business school in Germany and then completed an apprenticeship. In 1974, Mr. Spek completed a management training program for Pfizer International and then joined Pfizer RFA as a junior product manager. He served in various positions at Pfizer RFA, including as manager of the marketing division. Mr. Spek joined Sanofi Pharma GmbH, Sanofi's German affiliate, in 1985 as Marketing Director, and served in various positions in Germany and then at Sanofi in France, before being named Senior Vice President Europe following the merger in 1999. He served as Executive Vice President, International Operations from October 2000 until January 2003, when he was named to his present position.

*Jean-Claude Armbruster* is our Senior Vice President, Corporate Human Resources. Mr. Armbruster has both a diploma (DES) and a bachelor's degree (*maîtrise*) in private law and a diploma (DES) in criminal science. He joined Sanofi's legal staff in 1980 and served in a variety of positions, including Director of Human Resources at Sanofi, prior to being named to his present position in October 2000.

*Laurent Cohen-Tanugi* is our Senior Vice President, Corporate Legal Affairs and General Counsel. Mr. Cohen-Tanugi is a graduate of the Ecole Normale Supérieure and the Institut d'Etudes Politiques de Paris, and received law degrees (*maîtrise* and DEA) from the University of Paris and the Harvard Law School (LLM). Prior to joining Sanofi-Synthélabo, Mr. Cohen-Tanugi was a partner in the Paris office of the law firm Cleary Gottlieb Steen & Hamilton from 1991. Mr. Cohen-Tanugi began serving in his present position at Sanofi-Synthélabo in January 2004.

*Nicole Cranois* is our Senior Vice President, Group Public Relations and Communication. Mrs. Cranois has a bachelor's degree (*maîtrise*) in literature from the Sorbonne, a degree from the Ecole Française des Attachés de Presse and has a degree from Sydney University (Australia). Mrs. Cranois previously worked for Elf France as a press executive and served as the Director of Communication for the French Ministry for Family Affairs (*Ministère de la Famille*) from 1981 to 1983. She joined Sanofi in 1985 as Director of Communication, and was named to her present position in June 1999 following the merger.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

*Jean-Pierre Kerjouan* is our Senior Vice President, Advisor to the Chairman and Chief Executive Officer. Mr. Kerjouan has a degree in business from HEC (Ecole des Hautes Etudes Commerciales) as well as a law

---

**Table of Contents**

degree. From 1968 until 1981, Mr. Kerjouan worked for Yves Rocher, first as Chief Financial Officer (*Directeur Financier*) and then as the Vice President and Managing Director of Yves Rocher (*Vice Président Directeur Général*). He joined Sanofi Pharma International in 1981 as Managing Director (*Directeur Général*) and worked in a variety of positions at Sanofi, including Managing Director of Sanofi's beauty division before being appointed Senior Vice President, Legal Affairs, of Sanofi in 1996. Mr. Kerjouan served as General Counsel and Senior Vice President, Legal Affairs, of Sanofi-Synthelabo from May 1999 until December 31, 2003 before being named to his present position in January 2004.

*Marie-Hélène Laimay* is our Senior Vice President and Chief Financial Officer. Mrs. Laimay has a degree in business from a French business school (Ecole Supérieure de Commerce et d'Administration des Entreprises) and a DECS, an accounting qualification. She worked as an auditor for Ernst and Young for three years prior to joining Sanofi in 1985. During her career at Sanofi, Mrs. Laimay has served in a variety of finance positions, including Financial Director of Sanofi's beauty division, and as our Deputy Financial Director following the merger in 1999. She served as our Vice President, Internal Audit from November 2000, until being named to her present position in May 2002.

*Christian Lajoux* is our Senior Vice President, Europe. He has a masters degree (DEUG) in psychology, a bachelor's degree (*maîtrise*) in philosophy and a master's degree (DESS) in management from the Institut d'Administration des Entreprises (Paris). Mr. Lajoux served in a variety of positions at Sandoz, including Division Director, before joining Sanofi Winthrop in 1993. He then served in various positions, including as Director of Operations and Managing Director (*Directeur Général*) of Sanofi Winthrop France, before being named Senior Vice President, France, just prior to the merger in 1999. He served in that position until being named to his present position in January 2003.

*Jean-Claude Leroy* is our Senior Vice President, Strategy. Mr. Leroy has a degree in business (DESCAF) from the Ecole Supérieure de Commerce de Reims, France. He began his career at Elf Aquitaine in 1975 as an internal auditor, and worked in a variety of financial positions prior to joining Sanofi as the Financial Director of Bio Industries in 1985. Mr. Leroy served in a variety of positions at Sanofi, including Financial Director, and was named Senior Vice President - Finance following the merger, before being appointed to his present position in October 2000.

*Gilles Lhernould* is our Senior Vice President, Industrial Affairs. Mr. Lhernould has a diploma in pharmacy, and a master's degree (DEA) in industrial pharmaceuticals. He began his career as manufacturing supervisor at Laboratories Bruneau, and joined one of Sanofi's subsidiaries in 1983 where he managed the production, and later the factory. Mr. Lhernould then served in a variety of positions within the Sanofi group, including Director of Human Resources - Pharmacy for Sanofi Pharma, and Director of Operational Human Resources at Sanofi. Following the merger, he served as our Vice President for integration, and then Vice President of Information Systems before being named to his present position in March 2001.

*Gordon Proctor* is our Senior Vice President, Intercontinental. Mr. Proctor has a degree in Economics and an M.B.A. in Business Management. He began his career in various sales and marketing positions in the pharmaceutical industry, moving into general management roles. From 1991 through 1994, Mr. Proctor was responsible for the Sanofi Pharmaceutical business in the United Kingdom, Ireland, Scandinavia, Belgium, Holland, Italy and Greece. Following Sanofi's acquisition of the pharmaceutical business of Sterling, he served as regional Vice President for Asia, Australia, the Middle East, Africa, Eastern Europe, the United Kingdom and Scandinavia. Following the merger, Mr. Proctor was appointed President and Chief Executive Officer of our North American operations until being named to his present position in 2003.

*Timothy Rothwell* is our Senior Vice President, President North America, Chief Executive Officer of Sanofi-Synthelabo Inc. Mr. Rothwell has a B.A. from Drew University (New Jersey) and a J.D. from Seton Hall University. He began his career in 1972 as a patent attorney at Sandoz Pharmaceuticals, where he worked in a variety of operational positions, including as Chief Operating Officer for U.S. Business, until he left Sandoz in 1989. From 1989 to 1991, Mr. Rothwell worked in marketing and sales both at Squibb Corporation and





**Table of Contents**

Burroughs Wellcome before returning to Sandoz in 1992 as its Chief Executive Officer, U.S. Pharmaceuticals, a position that he held through 1995. From 1995 to 1998, Mr. Rothwell served in a variety of senior management positions at Rhône-Poulenc Rorer, and then joined Pharmacia in 1998. At Pharmacia he also served in a variety of managerial positions, including as Executive Vice President, and President of Global Prescription Business until leaving Pharmacia to join our company in May 2003.

None of these individuals has any principal business activities outside of Sanofi-Synthélabo.

None of these individuals has any family relationship with any director or nominee for director or other member of our senior management.

Under French law, Mr. Dehecq and Mr. Le Fur qualify as *mandataires sociaux* (corporate officers) of our company.

**B. Compensation***Compensation*

The compensation of our Chairman and Chief Executive Officer, Senior Executive Vice President and Executive Vice President, Scientific Affairs and of other senior management is based on an analysis of the practices of major French and European industrial companies and the opinion of the compensation and appointments committee of our Board of Directors. In addition to base compensation, senior managers receive variable compensation (which may exceed one-half of base compensation), which is determined by the actual performance and growth of the business areas for which the senior manager is responsible. Senior management may also be awarded stock options.

In 2003, the aggregate amount of compensation paid to our directors and senior management (25 persons in total) for services in all capacities was 9.26 million. Because fees paid in 2003 are attributable to 2002 services, only directors who served on the board in 2002 received fees. Of the 9.26 million, 0.46 million consisted of attendance fees (*jetons de présence*) paid to members of our Board of Directors (for 2002 services) as set out in the table below, 2.1 million was paid to our Chairman and Chief Executive Officer and 1.35 million was paid to our Senior Executive Vice President and Executive Vice President, Scientific Affairs.

Name	Attendance Fees Paid in 2003
	(in thousands of )
<b>Directors</b>	
Mr. Robert Castaigne	23.00
Mr. Pierre Castres St. Martin	27.00
Mr. Pierre-Gilles de Gennes	33.00
Mr. René Barbier de la Serre	79.00
Mr. Thierry Desmarest	39.00
Lord Douro	31.25
Elf Aquitaine	31.00
Mr. Hervé Guérin	31.00

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

L. Oréal	51.00
Mr. Lindsay Owen-Jones	35.00
Mr. Bruno Weymuller	47.00
<b>Observers</b>	
Mr. Régis Dufour	15.50
Mr. René Sautier	13.50

**Table of Contents*****Bonus or Profit Sharing***

Our senior management are eligible for bonuses, as described above under Compensation. We do not have separate profit-sharing plans for senior management. As employees, they are able to participate in our yearly and long-term profit-sharing plans on the same terms as our other employees. These plans are described below under Employees.

***Stock Options***

Under French law, directors may not receive options solely as compensation for service on the board, thus only those directors who are also our employees may receive stock options. During 2003, a total of 604,000 options were granted to senior management (13 persons total), as set forth in the following table. Each option gives the right to purchase one of our shares at an exercise price of 55.74 from December 11, 2007 until December 10, 2013.

<u>Name and Title</u>	<u>Number of Options Granted</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
Jean-François Dehecq			
<i>Chairman and Chief Executive Officer</i>	150,000	55.74	December 10, 2013
Gérard Le Fur			
<i>Senior Executive Vice President and Executive Vice President, Scientific Affairs</i>	90,000	55.74	December 10, 2013
Hanspeter Spek			
<i>Executive Vice President, Operations</i>	63,000	55.74	December 10, 2013
Jean-Pierre Kerjouan			
<i>Senior Vice President, Advisor to the Chairman and Chief Executive Officer</i>	30,000	55.74	December 10, 2013
Christian Lajoux			
<i>Senior Vice President, Europe</i>	38,000	55.74	December 10, 2013
Jean-Claude Leroy			
<i>Senior Vice President, Strategy</i>	26,000	55.74	December 10, 2013
Pierre-Jean Lepienne			
<i>Executive Vice President, Corporate Affairs</i>	25,000	55.74	December 10, 2013
Jean-Claude Armbruster			
<i>Senior Vice President, Corporate Human Resources</i>	25,000	55.74	December 10, 2013

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Nicole Cranois			
<i>Senior Vice President, Public Relations and Communications</i>	22,000	55.74	December 10, 2013
Marie-Hélène Laimay			
<i>Senior Vice President and Chief Financial Officer</i>	25,000	55.74	December 10, 2013
Gilles Lhernould			
<i>Senior Vice President, Industrial Affairs</i>	26,000	55.74	December 10, 2013
Timothy Rothwell			
<i>Senior Vice President, President North America, Chief Executive Officer of Sanofi-Synthelabo Inc.</i>	60,000	55.74	December 10, 2013
Gordon Proctor			
<i>Senior Vice President, Intercontinental</i>	24,000	55.74	December 10, 2013

## **Table of Contents**

For additional information regarding our stock options, see [Share Ownership](#) below, [Item 10 Additional Information](#) [Share Capital](#) [Stock Options](#) and [Note D.12.6](#) to our consolidated financial statements included under [Item 18 Financial Statements](#).

### ***Pension or Retirement Benefits***

The aggregate amount that we set aside or accrued to provide pension, retirement or similar benefits during 2003 for members of senior management as of December 31, 2003 (13 persons total), was 6.4 million. We do not provide pension, retirement or similar benefits to directors other than to Mr. Dehecq.

### **C. Board Practices**

Pursuant to our bylaws, two other persons attend the meetings of the Board of Directors as observers (*censeurs*), without voting rights. The current *censeurs* are Régis Dufour and René Sautier.

Our Board of Directors has established an audit committee, a compensation and appointments committee, and a scientific committee. The functions of these committees are described below.

#### ***Audit Committee***

The audit committee is responsible for evaluating the existence and efficacy of our financial controls and risk management. Among other responsibilities, it is responsible for reviewing the following:

the scope of consolidation of our company;

annual and interim consolidated financial statements, and any auditors' reports;

internal control procedures;

internal audit assignments;

appropriateness of accounting policies;

significant risks and material off-balance sheet commitments;

any issue liable to have a material financial or accounting impact; and

major litigation on an annual basis.

In addition to these reviews, the committee may visit or interview individuals responsible for our operations or in the preparations of our consolidated financial statements. It may interview the statutory auditors outside of the presence of management, and it may consult with external experts. The audit committee directs the procedures for selecting the statutory auditors before each re-appointment, and monitors fees paid to them as well as compliance with the rules ensuring their independence.

In 2003, the members of the audit committee were Lord Douro and Messrs. Barbier de la Serre, Mulliez, Somnolet, Van Kemmel and Weymuller. Mr. Mulliez replaced Mr. Somnolet as L'Oréal's permanent representative on our Audit Committee effective November 15, 2003.

The audit committee met four times in 2003.

**Table of Contents**

***Compensation and Appointments Committee***

The compensation and appointments committee is responsible for the following:

formulating recommendations and proposals concerning the compensation of corporate officers, including retirement and pension benefits, and the granting of stock options; fixing rules for the variable portion of compensation for our *mandataires sociaux* (corporate officers); formulating policy for the granting and interval between grants of our stock options;

reviewing the allocation of attendance fees between directors and, where appropriate, observers (*censeurs*);

assisting our Board of Directors in selecting new directors, and in particular, independent directors;

make recommendations regarding the composition and future nominations to the board of directors and to senior management; and

advising the Chairman of our Board of Directors on the selection of key senior managers and their compensation.

In 2003, the members of the compensation and appointments committee were Messrs. Barbier de la Serre, Desmarest and Owen-Jones.

The compensation and appointments committee met twice in 2003.

***Scientific Committee***

The scientific committee is responsible for the following:

advising the Board of Directors about the development of technologies that may influence our operations;

advising the Board of Directors on the direction of our research and development; and

assisting in addressing technical issues facing our business.

In 2003, the members of the scientific committee were Messrs. de Gennes and Dehecq.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The scientific committee met once in 2003.

### D. Employees

We had 33,086 employees worldwide as of December 31, 2003. The following tables set forth the breakdown of employees by geographic area and by main category of activity as of December 31, 2001, 2002 and 2003.

	As of December 31:					
	2003	%	2002	%	2001	%
France	12,058	36.4%	12,204	37.6%	11,842	38.8%
Other Europe	9,380	28.4%	9,274	28.6%	8,674	28.4%
United States	4,162	12.6%	3,595	11.1%	3,221	10.6%
Japan	118	0.4%	95	0.3%	75	0.2%
Other Countries	7,368	22.2%	7,268	22.4%	6,702	22.0%
<b>Total</b>	33,086	100.0%	32,436	100.0%	30,514	100.0%

(1) Includes Canada and Puerto Rico.



**Table of Contents**

	As of December 31:					
	2003	%	2002	%	2001	%
Sales	11,601	35.0%	11,015	34.0%	10,336	33.9%
Research and Development	6,877	20.8%	6,718	20.7%	6,273	20.5%
Production	7,901	23.9%	8,043	24.8%	7,651	25.1%
Other	6,707	20.3%	6,660	20.5%	6,254	20.5%
<b>Total</b>	<b>33,086</b>	<b>100.0%</b>	<b>32,436</b>	<b>100.0%</b>	<b>30,514</b>	<b>100.0%</b>

Under French law, all employers of more than 20 employees in France are required to implement a 35-hour workweek. Although the workweek is shorter on average and we have not reduced salaries, we have greater flexibility than before to organize the use of employee time. For example, our employees can work more than 35 hours in some weeks, but in exchange we are required to reduce the number of hours worked in other weeks to ensure that they do not work more than 35 hours per week on an annual basis. We believe this added flexibility partly compensates for the reduction in hours and that the 35-hour week does not have a material adverse effect on our financial condition.

The five principal French labor unions, the *Confédération Générale du Travail* (CGT), the *Confédération Française Démocratique du Travail* (CFDT), the *Confédération Française de l'Encadrement-Confédération Générale des Cadres* (CFE-CGC), the *Confédération Générale du Travail-Force Ouvrière* (CGT-FO) and the *Confédération Française des Travailleurs Chrétiens* (CFTC), are represented in our group companies in France. In 2003, we concluded agreements with our French employees on a variety of issues including annual and long-term profit-sharing plans, group savings plans, and revisions to insurance and health care agreements.

In certain other countries, our employees are also represented by labor unions, with whom we enter into collective bargaining agreements. Under a 2001 agreement with employee representatives, we established a European Works Council (*Comité d'Entreprise Européen*) to foster employee consultation and the exchange of information with all of our European employees. The Council has 34 representatives from each of the European Union countries and from 6 European Union candidate countries. In 2003, the European Works Council held two meetings, one of which was a joint meeting with the French Council. These meetings were chaired by Jean-François Dehecq, our Chairman and Chief Executive Officer.

Although we have had labor movements and work stoppages from time to time, none of them had a significant impact on our activities. We believe our relations with our employees are good.

**Profit-Sharing**

We have both a yearly and a long-term profit-sharing plan for our French companies and their employees, including our senior management, the basic terms of which are described below.

*Yearly Profit-Sharing Plan.* Our yearly profit-sharing plan is designed to provide a collective return based on a formula tied to the results and performance of our business. It is not required by law, and the amount is unpredictable in nature. Our portion of the yearly profit-sharing plan agreements of our French subsidiaries varies according to our net profit. This amount is then complemented by a

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

portion that is tied to the performance or activities of our subsidiaries themselves. On May 12, 2003, we entered into a 3-year agreement that covers 2003, 2004 and 2005 and relates to our portion of the yearly profit-sharing plan for the companies of the Sanofi-Synthelabo group. For 2003, the gross amount of the incentive at the group level was 13 million. Our employees also benefit from an incentive at the company level or establishment at which they are employed.

*Long-Term Profit-Sharing Plan.* In France, salaried employees have the right to participate in the profits of the business. A long-term profit-sharing plan is obligatory for companies that have at least 50 salaried employees, and the amount of the share is calculated based on the profits of the business in accordance

**Table of Contents**

with terms set forth in French labor laws (*Code du Travail*). On April 24, 2003, we signed a long-term profit-sharing agreement covering 2003, 2004 and 2005. For 2003, the gross amount of the special profit-sharing reserve was 54 million.

**E. Share Ownership**

As of December 31, 2003, our directors (other than L Oréal and Elf Aquitaine, but including their permanent representatives) and senior management (13 persons in total as at such date) beneficially held a total of 1,494,834 shares, representing less than 1% of our total shares outstanding as of such date, excluding the beneficial ownership of 178,476,513 shares held by Total as of such date, which may be attributed to Mr. Desmarest, who disclaims beneficial ownership of such shares, and excluding the beneficial ownership of 143,041,202 shares held by L Oréal as of such date, which may be attributed to Mr. Owen-Jones, who disclaims beneficial ownership of such shares. None of the other directors or members of our senior management is the beneficial owner of more than 1% of our shares.

Under our option plans existing as of December 31, 2003 or terminated in 2003, we (or our predecessor companies) granted a total of 2,711,600 options to our senior management (13 persons total at December 31, 2003) of which 2,357,600 stock options remained to be exercised as of December 31, 2003. Of the options granted to senior management, 784,000 stock options were given to our Chairman and Chief Executive Officer, of which 680,000 remained to be exercised as of December 31, 2003, and 403,400 were given to our Senior Executive Vice President and Executive Vice President, Scientific Affairs, of which 377,000 remained to be exercised as of December 31, 2003.

Following the merger, all previously granted options for the shares of Sanofi or Synthélabo were converted into options for our shares. Each of our stock options is exercisable for one of our shares.

The main characteristics of our stock options are described in the table on the following page and in Note D.12.6 to our consolidated financial statements, included under Item 18 Financial Statements.

**Table of Contents****EXISTING OPTION PLANS AS OF DECEMBER 31, 2003<sup>(1)</sup>****OPTIONS GRANTED**

<b>Date of Plan(s)</b>	<b>1993</b>	<b>1994</b>	<b>1995<sup>(2)</sup></b>	<b>1996<sup>(2)</sup></b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>Total</b>
Total number of options Granted	364,000	330,200	442,000	1,492,800	1,382,080	1,496,400	716,040	4,292,000	2,936,500	3,111,850	4,217,700	20,781,570
of which were to												
Senior Management			104,000	158,000	236,000	247,200	36,400	472,000	431,000	423,000	604,000	2,711,600
of which were to Mr. Dehecq				44,000	60,000	80,000		160,000	145,000	145,000	150,000	784,000
of which were to Mr. LeFur				26,400	32,000	40,000		75,000	70,000	70,000	90,000	403,400
Expiration Dates	Dec 2013	Oct 2014	Dec 2015	Sept 2003- Apr 2016	Sept 2004- Oct 2017	Dec 2005- Jun 2018	Mar 2019	May 2010	May 2011	May 2012	Dec. 2013	
Exercise price (in )	6.36	6.10	8.50	8.56 to 14.56	19.73 to 21.46	28.38 to 34.95	38.08	43.25	64.50	69.94	55.74	

(1) Including plans terminated in 2003.

(2) In 1996 and 2003, we had subscription options (*options de souscription d'actions*). Subscription options means that we will issue new shares upon the exercise of these options. For additional information regarding our stock options, please see Item 10 Additional Information Share Capital Stock options and Note D.12.6 to our consolidated financial statements filed under Item 18 Financial Statements.

**Table of Contents****Item 7. Major Shareholders and Related Party Transactions****A. Major Shareholders**

The table below shows the ownership of our shares at December 31, 2003, indicating the beneficial owners of more than 5.0% or more of our shares.

	Shares		Voting Rights	
	Number	Percentage	Number	Percentage
L Oréal	143,041,202	19.52%	286,082,404	28.09%
Total	178,476,513	24.35%	356,953,026	35.04%
State Street Bank and Trust <sup>(1)</sup>	36,638,351	4.99%	36,638,351	3.60%
Capital Group International, Inc. <sup>(2)</sup>	49,143,540	6.70%	49,143,540	4.82%
Other Public	267,438,758	36.51%	274,886,529	26.99%
Treasury Shares	49,990,262	6.82%		0%
Employees <sup>(3)</sup>	8,119,446	1.11%	14,920,482	1.46%
<b>Total</b>	<b>732,848,072</b>	<b>100.0%</b>	<b>1,018,624,332<sup>(4)</sup></b>	<b>100.0%</b>

- (1) Based on a declaration filed with the French *Autorité des Marchés Financiers* on December 16, 2002. In such declaration, State Street Bank and Trust informed us that it holds on shares on behalf of third parties. To our knowledge, the shares held by State Street Bank and Trust do not carry double voting rights.
- (2) Based on information provided in a Form 13G filed with the SEC on February 13, 2003. Since the date of the information included in this table, Capital Group International, Inc. filed a Form 13G with the SEC, details of which are described below. To our knowledge, the shares held by Capital Group International, Inc. do not carry double voting rights.
- (3) Represents shares held through our employee savings plan.
- (4) Based on the total number of voting rights on December 31, 2003.

Our *statuts* (bylaws) provide for double voting rights. For more information relating to our shares, see Item 10 Additional Information Memorandum and Articles of Association.

Since the merger, Total has gradually reduced its ownership of our shares. Immediately after the merger, Total held 35.3% of our shares and 43.0% of our voting rights, and together with L Oréal, held 54.8% of our share capital and 69.1% of our voting rights. Since that time, Total, in accordance with its announced intention to reduce its ownership of our share capital, has gradually decreased its ownership interest in our company. During 2003, Total reduced its ownership interest from 24.5% of our share capital as of December 31, 2002 to 24.4% of our share capital as of December 31, 2003. Total and L Oréal together no longer hold more than 50.0% of our share capital nor more than 2/3 of our voting rights.

In accordance with our *statuts*, shareholders are required to notify our company once they have acquired more than 1% of our share capital (see Item 10 Additional Information Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages ).

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

During the year ended December 31, 2003, we were informed that the following share ownership declaration thresholds had been passed:

Between April 25 and May 23, 2003, Caisse des Dépôts et Consignations (CDC) declared that it had successively passed below and then above the threshold of 1% of our voting rights, disclosure of which is required under our bylaws.

On May 23, 2003, CDC declared that as of that date, it held 12,339,057 shares and voting rights, representing 1.68% of our capital and 1.15% of our voting rights.

On May 12, 2003, Northern Trust declared that as intermediary, it had passed below the 1% threshold of our capital, disclosure of which is required under our bylaws. As of that date, Northern Trust declared that it held 3,620,462 of our shares, representing 0.49% of our share capital.

---

## **Table of Contents**

On June 6, 2003, L Oréal declared that it passed above the threshold of 27% of the voting rights following the publication of the aggregate number of our voting rights following the general meeting of May 19, 2003. For the same reasons, Total declared on June 5, 2003 that the concert between Total and L Oréal passed above the threshold of 61% and 62% of our voting rights and that Total and their subsidiaries passed above the threshold of 34% of our voting rights. Total declared on June 6, 2003 that the concert between Total and L Oréal passed below the threshold of 44% of our share capital as a result of sales on the market.

On June 13, 2003, Boston Safe Deposit and Trust declared that as intermediary it had passed above the 1% threshold of our capital, disclosure of which is required under our bylaws. As of that date, Boston Safe Deposit and Trust declared that it held 12,987,550 of our shares, representing 1.77% of our share capital.

Having passed above the 1% threshold of our capital and voting rights on June 27, 2003, the Société Générale group then declared on July 11, 2003 that it had passed below the 1% threshold of our voting rights, and on August 1, 2003, that it had passed below the 1% threshold of our share capital.

As of August 1, 2003, the Société Générale group declared that it held 7,054,456 shares and voting rights, representing 0.963% of our capital and 0.688% of our voting rights.

On February 10, 2004, Capital Group International, Inc. filed a Schedule 13G as required by the SEC indicating that it held 8.6% of our share capital on behalf of its clients and as an intermediary. As of that date, it held 62,635,030 of our shares.

As of December 31, 2003, and after taking into account unidentified holders of bearer shares, French shareholders (excluding shares held by L Oréal, Total, our employee savings plan and treasury shares) represent approximately 16% of our share capital (which is mainly held by institutional investors). Foreign shareholders represent approximately 28% of our share capital, which is held primarily by institutional investors in the United States (approximately 14%) and the United Kingdom (approximately 6%).

### ***Shareholders Agreement***

On April 9, 1999, Elf Aquitaine (now an affiliate of Total) and L Oréal entered into a shareholders agreement (*pacte d actionnaires*) with respect to their shareholdings in our company. Under the terms of the shareholders agreement, the parties agreed not to sell any of the shares covered by the shareholders agreement except in certain limited circumstances, such as the commencement of a tender offer for our shares. The shares covered by the shareholders agreement are, at present, the 19.41% of our share capital held by L Oréal and 19.41% of our share capital held by Total. Sales to direct and indirect subsidiaries of the parties are exempted from this provision of the shareholders agreement. In addition, each of the parties granted to the other a preferential right to purchase any shares covered by the shareholders agreement in case of a sale of such shares under the terms of the shareholders agreement, and agreed to notify the other party of any sale or purchase of our shares that it makes. The shareholders agreement also contains provisions relating to the composition of our Board of Directors, cooperation among the parties respective appointees to our Board of Directors (as described above under Item 6 Directors, Senior Management and Employees Directors and Senior Management ), dilution of the parties respective shareholdings in us, and the crossing of certain percentage shareholding thresholds by the parties acting separately or in concert. Finally, the shareholders agreement contains provisions regulating the sale of the free shares not covered by the agreement s prohibition on sale. The initial term of the shareholders agreement expires on December 1, 2004. A copy of this agreement is filed as an exhibit to this annual report.

The shareholders agreement was amended on November 24, 2003. Total became a party to the shareholders agreement, and, together with L Oréal and Elf Aquitaine, formalized the decision not to renew the shareholders agreement. Elf Aquitaine, Total and L Oréal also indicated that they do not intend to act in concert





## **Table of Contents**

with respect to their shareholdings in our company from December 2, 2004, but they agreed to let each other party know of any plan to transfer securities in our company representing more than 1% of the share capital for three years following that date. A copy of this amendment is filed as an exhibit to this annual report.

On January 25, 2004, Total and L Oréal entered into an agreement to set forth their common position in favor of our offer to acquire Aventis. This agreement was filed with the AMF and a summary notice was published on February 6, 2004. A copy of this agreement is filed as an exhibit to this annual report.

## **B. Related Party Transactions**

In the ordinary course of business, we purchase materials, supplies and services from numerous companies throughout the world. Members of our Board of Directors are affiliated with some of these companies. We conduct our transactions with such companies on an arm's length basis and do not consider the amounts involved in such transactions to be material.

During 2003 and through the date of this annual report, we have not been involved in, and we do not currently anticipate becoming involved in, any transactions with related parties that are material to us or to any of our related parties and that are unusual in their nature or conditions. We have not made any outstanding loans to or for the benefit of:

enterprises that, directly or indirectly, control or are controlled by, or are under common control with us;

enterprises in which we have significant influence or that have significant influence over us other than in the ordinary course of business;

shareholders beneficially owning a 10.0% or greater interest in our voting power;

any member of our senior management; or

enterprises in which persons described above own, directly or indirectly, a substantial interest in the voting power.

Pierre-Gilles de Gennes, a member of our Board of Directors, serves as Scientific Advisor to our subsidiary, Sanofi-Synthélabo Recherche. As Scientific Advisor, he receives compensation from our company. The amount of compensation paid to Mr. de Gennes is not material to our company.

## **C. Interests of Experts and Counsel**

Not applicable.



---

**Table of Contents****Item 8. Financial Information****A. Consolidated Statements and Other Financial Information**

See Item 18 Financial Statements and pages F-1 through F-66.

***Legal Proceedings***

From time to time, we and our subsidiaries may be parties to or targets of lawsuits, claims, investigations and proceedings that are handled and defended in the ordinary course of business.

In February 2002, we learned that Apotex, a generic drug manufacturer, filed an Abbreviated New Drug Application, or ANDA, with the FDA challenging two of our U.S. patents relating to Plavix®. In April 2002, we learned that Dr. Reddy's Laboratories, a generic drug manufacturer, filed an ANDA with the FDA challenging three of our U.S. patents relating to Plavix®. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of an approved product, by demonstrating that it has the same properties as the original approved product. For more information on ANDAs, see Item 4 Information on the Company Business Overview Regulation. In general, an ANDA may not be filed until the expiration of the five-year market exclusivity period that applies to the original product following its initial market authorization. If the product is protected by a patent owned by or licensed to the manufacturer of the original version, however, the ANDA cannot be approved until the patent expires unless the ANDA applicant challenges the patent. In that case, the ANDA may be filed four years following the initial market authorization of the original product.

On March 21, 2002, we and Bristol-Myers Squibb Sanofi-Synthelabo Pharmaceuticals Holding Partnership (or Sanofi-Synthelabo BMS Holding, our joint venture with Bristol-Myers Squibb) filed suit in the United States District Court for the Southern District of New York against Apotex for the infringement of two of the U.S. patents relating to Plavix®. The lawsuit is captioned *Sanofi-Synthelabo, Sanofi-Synthelabo Inc., and Bristol-Myers Squibb Sanofi-Synthelabo Pharmaceuticals Holding Partnership v. Apotex Inc. and Apotex Corp.*, 02-CV-2255 (RWS). The first patent, U.S. Patent No. 4,847,265, which expires in 2011, discloses and claims the compound clopidogrel, the active ingredient in Plavix®. The second patent, U.S. Patent No. 5,576,328, which expires in 2014, discloses and claims, among other things, the use of clopidogrel in the treatment of patients to prevent a secondary ischemic event. On May 14, 2002, we and Sanofi-Synthelabo BMS Holding filed suit in the United States District Court for the Southern District of New York against Dr. Reddy's Laboratories for infringement of these same two patents. That lawsuit is captioned *Sanofi-Synthelabo, Sanofi-Synthelabo Inc. and Bristol-Myers Squibb Sanofi-Synthelabo Pharmaceuticals Holding Partnership v. Dr. Reddy's Laboratories, LTD, and Dr. Reddy's Laboratories, Inc.*, 02-CV-3672 (RWS).

On June 20, 2003, we announced that U.S. Patent No. 5,576,328 has been withdrawn from the patent infringement lawsuits discussed above and we are seeking to have it delisted from the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the FDA's Orange Book. The withdrawal of this method patent from the lawsuit has no effect on U.S. Patent No. 4,847,265, which we are vigorously defending (together with our alliance partner, Bristol-Myers Squibb, or BMS). As regards the proceedings, fact discovery was essentially completed on October 15, 2003. The trial may reasonably be expected to take place before year-end at a date to be fixed by the court. However, on February 25, 2004, both the patent litigation cases were reassigned to a new judge. The possible impact of this reassignment on the timetable of the litigation may only be assessed after the new judge has had an opportunity to review the case.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

If either of the challenges to U.S. Patent No. 4,847,265 were successful, the prevailing party would have the right to produce a generic version of Plavix® and market it in the United States in competition with us and our alliance partner, BMS. Under U.S. law, the FDA will not be able to approve the ANDAs filed by Apotex or Dr. Reddy's Laboratories until the earlier of May 17, 2005 (*i.e.*, five years plus 30 months after the approval date of our Plavix® NDA) or the issuance of a court decision that is adverse to our U.S. Patent No. 4,847,265. We believe that Plavix® will continue to benefit from its patent protection in the United States. We intend to defend our interests in this matter vigorously.

## **Table of Contents**

In September 2002 and in January 2003, we obtained two additional U.S. patents related to Plavix<sup>®</sup>. At the present time, we do not believe we have a basis to assert these patents against Apotex or Dr. Reddy's Laboratories.

In March 2003, we learned that Apotex filed an application with Canadian authorities for a marketing authorization for a generic version of Plavix<sup>®</sup>, challenging the Canadian patent for clopidogrel. We believe that our Canadian patent, which protects Plavix<sup>®</sup> in Canada until August 2012, is valid and are defending our interests in this matter vigorously.

The Plavix<sup>®</sup> patent rights are material to our company's business, and if we were unsuccessful in asserting them or they were deemed invalid, any resulting introduction of a generic prescription version of Plavix<sup>®</sup> in the U.S. would reduce the price that we receive for this product and the volume of the product that we would be able to sell. See Item 3. Key Information Risk Factors Risks Relating to Our Industry If we are unable to protect our proprietary rights, we may not compete effectively or operate profitably.

As a reference, the developed sales of Plavix<sup>®</sup> in 2003 in the United States amounted to 1,817 million out of total worldwide developed sales of Sanofi-Synthelabo of 10,560 million. In 2003, Sanofi-Synthelabo's share of profits generated by Plavix<sup>®</sup> and Aprovel<sup>®</sup> (under the name Avapro<sup>®</sup>) in North America, a territory managed by BMS under the alliance agreements, amounted to 436 million, versus 348 million in 2002. The alliances with BMS are further explained in Item 4 Information on the Company Business Overview Marketing and Distribution Alliances and Item 5 Operating and Financial Review and Prospects Overview Financial Presentation of Alliances.

To our knowledge, other than the matters described above, there are no currently pending or threatened legal proceedings that could have a material effect on our business, results of operations or financial condition.

## **B. Significant Changes**

Except as set forth below, there have not been any significant changes since the date of our consolidated financial statements included under Item 18 Financial Statements.

### ***Proposed Acquisition of Aventis***

On January 26, 2004, we announced our intention to make a mixed cash/exchange offer to acquire all the outstanding ordinary shares, nominal value 3.82, of Aventis. For legal reasons in order to satisfy regulatory requirements, we are making three offers: a U.S. offer, a French offer and a German offer, which we refer to collectively as the Offers.

The U.S. offer is open to all holders of Aventis ordinary shares who are located in the United States and to all holders of American depository shares, or ADSs, representing Aventis ordinary shares, wherever located. The French offer is open to all holders of Aventis ordinary shares who are located in France and to holders of Aventis ordinary shares who are located outside of France, Germany and the United States, if, pursuant to the local laws and regulations applicable to those holders, they are permitted to participate in the French offer. The German offer is open to all holders of Aventis ordinary shares who are located in Germany.

*Main Terms of the Offers*

The U.S. offer, the French offer and the German offer are being made on substantially similar terms and completion of the Offers is subject to the same conditions.

## **Table of Contents**

We are offering:

5 newly issued Sanofi-Synthelabo ordinary shares and 69.00 in cash, without interest, for 6 Aventis ordinary shares tendered (equivalent to 0.8333 of a newly issued Sanofi-Synthelabo ordinary share and 11.50 in cash, without interest, in exchange for each Aventis ordinary share tendered); and

in the U.S. offer only, 1.6667 newly issued Sanofi-Synthelabo ADSs (each Sanofi-Synthelabo ADS representing one-half of one ordinary share), and an amount in U.S. dollars equal to 11.50, in cash, without interest, in exchange for each Aventis ADS (each Aventis ADS representing one Aventis ordinary share) tendered.

The offers include a mix and match election feature that allows tendering holders of Aventis ordinary shares, including Aventis ordinary shares represented by Aventis ADSs, to elect to receive, in lieu of the mix of consideration described above:

*All Stock Election:* 35 Sanofi-Synthelabo ordinary shares for every 34 Aventis ordinary shares tendered (equivalent to 1.0294 newly issued Sanofi-Synthelabo ordinary shares in exchange for each Aventis ordinary share tendered); and, in the U.S. offer only, 2.0588 newly issued Sanofi-Synthelabo ADSs in exchange for each Aventis ADS tendered; or

*All Cash Election.* 60.43 in cash, without interest, in exchange for each Aventis ordinary share tendered; or, in the U.S. offer only, an amount in U.S. dollars equal to 60.43, in cash, without interest, in exchange for each Aventis ADS tendered.

The mix and match elections are subject to proration and allocation adjustments that will ensure that, in the aggregate (and subject to adjustment if Aventis pays any dividend or interim dividend before the settlement of the offers), 81.0% of the Aventis ordinary shares (including Aventis ordinary shares underlying the Aventis ADSs) tendered in the offers will be exchanged for our ordinary shares (including our ordinary shares represented by ADSs) and 19.0% will be exchanged for cash.

If Aventis pays any dividend or any interim dividend in respect of the Aventis ordinary shares, including Aventis ordinary shares represented by Aventis ADSs, before the settlement of the offers, the consideration offered in exchange for each Aventis ordinary share and each Aventis ADS tendered will be reduced by an amount equal to the net value of the dividend paid per Aventis ordinary share.

In respect of our ordinary shares, including our ordinary shares represented by ADSs, that a former holder of Aventis securities receives in exchange for the Aventis ordinary shares or Aventis ADSs tendered in the Offers, that holder will be entitled to receive any annual dividend with respect to our 2003 results that is declared on our ordinary shares, as well as any other dividend that is paid after the settlement of the Offers.

## ***Conditions***

We will not be obligated to purchase any tendered Aventis securities pursuant to the Offers unless:

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Aventis ordinary shares (including Aventis ordinary shares represented by Aventis ADSs) representing at least 50% of the total share capital and voting rights in Aventis, calculated on a fully diluted basis, plus one Aventis ordinary share, are validly tendered and not withdrawn in the offers, on an aggregate basis (the Minimum Tender Condition ). We may waive the Minimum Tender Condition at any time on or prior to the date that is five French trading days prior to the expiration date of the Offers;

the applicable waiting period under the U.S. Hart-Scott-Rodino Act of 1976, as amended (the HSR Act ), has expired or been terminated and no order has been entered prohibiting the transaction; in addition, because the French offer is subject to an antitrust condition, under applicable French law and



## **Table of Contents**

regulations, the French offer will lapse as soon as the U.S. Federal Trade Commission issues a second request for information before the expiration of the HSR waiting period (if the French offer lapses for this reason we will withdraw the U.S. Offer and the German Offer); and

the issuance of additional Sanofi-Synthélabo ordinary shares to be issued on completion of the Offers has been duly approved by our shareholders at an extraordinary meeting of shareholders to be held for this purpose.

### ***Expected expiration date***

The AMF has agreed that the U.S. offer, the French offer and the German offer will all expire simultaneously. Under French tender offer rules, it is the AMF that sets the expiration date for the French offer. The AMF also has the sole authority to determine whether or not to subsequently extend the French tender period.

In February 2004, Aventis filed appeals with the Court of Appeals of Paris challenging the AMF's decision clearing the terms of the French offer and the AMF's subsequent decision to grant a *visa* to our French offer prospectus. We believe that the AMF's decisions to clear the terms of the French offer and to grant its *visa* were proper and that Aventis' claims are without merit. We intend to defend our interests in these appeals vigorously. In connection with Aventis' legal appeals the AMF has undertaken to set the expiration date of the French offer to be at least eight days after the Court of Appeals of Paris announces its decision on these appeals, which the Court has indicated should occur before the end of May 2004.

In any event, under its regulations, the AMF will announce the expiration date of the French offer only after the AMF has received evidence that the FTC has approved the acquisition of the Aventis ordinary shares pursuant to the Offers.

We currently expect that the Offers will expire and, if the conditions to the Offers have been satisfied, that we will complete the acquisition of the Aventis securities by the end of the second quarter of 2004, although this timetable may be delayed if a competing bid for Aventis is made and the Offers could lapse if the legal appeals were resolved unfavorably for our company.

### ***Extraordinary meeting of shareholders.***

The issuance of our ordinary shares in connection with the Offers must be approved by an extraordinary meeting of our shareholders. As of the date of this annual report, the date of the extraordinary meeting has not been set, but it will take place before the expiration date of the Offers.

As of December 31, 2003, Total and L'Oréal, our two principal shareholders, held 178,476,513 and 143,041,202 of our ordinary shares, respectively, representing in aggregate 47.1% of our outstanding share capital (excluding shares held by us) and 63.1% of our voting rights. At the January 25, 2004 meeting of our board of directors, the representatives of Total and L'Oréal confirmed their full support of the Offers. Additionally, Total and L'Oréal have announced that they will approve the increase in share capital that will be submitted to the extraordinary meeting of shareholders.

*The 12,000 Million Credit Facility*

Assuming all of the outstanding Aventis ordinary shares (including Aventis ordinary shares represented by Aventis ADSs), on a diluted basis taking into account all in-the-money options that are exercisable as of the expected closing date, are tendered into the U.S. offer, the French offer or the German offer, pursuant to the terms of the Offers, we would be obligated to issue 661,949,024 new ordinary shares (ordinary shares represented by our ADSs) and to pay an aggregate amount of 9,168 million in cash to the holders of those Aventis securities. These aggregate amounts of ordinary shares and of cash will be lower if less than 100% of the currently outstanding Aventis securities are tendered into the Offers. The amounts may also vary depending on the number of Aventis securities outstanding at the time of the closing of the Offers.

## **Table of Contents**

In connection with the proposed acquisition of Aventis, we have entered into a credit facility agreement dated January 25, 2004 permitting borrowing in the amount of up to 12,000 million, which will be used mainly to finance the cash consideration to be paid to holders of Aventis securities pursuant to the Offers and refinance certain debt of Aventis and its subsidiaries. This facility has been, subject to certain conditions, entirely underwritten by BNP Paribas and an affiliate of Merrill Lynch & Co. The first round of syndication of the 12,000 million credit facility was completed on March 18, 2004. Alongside BNP Paribas and the affiliate of Merrill Lynch & Co., seven international banks have joined the syndicate.

We may only borrow amounts under this credit facility if the Offers are completed. However, subject to the delivery of customary certificates and other documents generally evidencing the success of the Offers, the success of the Offers is the only material condition to our ability to borrow amounts under this credit facility to finance the cash component of the offer consideration. Accordingly, we have not put in place any alternative financing arrangements.

The credit facility agreement provides that the credit facility will be divided into a 364-day 4,000 million term loan facility ( Tranche A ), a three-year 4,000 million term loan facility ( Tranche B ) and a five-year 4,000 million revolving loan facility ( Tranche C ). Each Tranche is required to be repaid in its entirety on its final maturity date except that we have an option to extend the final maturity date of Tranche A until a date falling two years following the date of the credit facility agreement.

Amounts borrowed under Tranche A and Tranche B may only be used to finance part of the cash consideration to be paid to holders of Aventis securities pursuant to the Offers. Amounts borrowed under Tranche C may be used for various purposes, including to pay fees, costs and expenses incurred in connection with the Offers and to refinance certain indebtedness of Aventis and its subsidiaries.

Upon delivery of customary certificates and other documents generally evidencing the success of the Offers, the credit facility will be made available immediately upon all of the conditions to the Offers having been satisfied and when the cash consideration is required to be paid to holders of Aventis securities who have validly tendered such securities into the Offers. Borrowings under Tranche A and Tranche B will be made available in euros only whereas borrowings under Tranche C will be made available in euros and, as the case may be, in U.S. dollars, pounds sterling and Japanese yen.

The credit facility is subject to terms and conditions customary for facilities of this type, including mandatory prepayment provisions (for example, in the event of certain asset disposals or a change of control of Sanofi-Synthelabo), events of default (for example, in the event of cross-default or insolvency), representations and warranties (such as in relation to status, power and authority and financial statements), covenants (such as information undertakings, negative pledge and financial ratio), indemnities, provisions to protect the margin due to the lenders and commitment fee arrangements. In particular, under the financial covenants our consolidated net debt (generally defined as our total financial borrowings less our total cash, cash equivalents and marketable securities) may not exceed 2.5 times our consolidated EBITDA (generally defined as our operating profit plus (1) any amortization and depreciation charges, (2) any purchase-accounting charge in respect of in-process research and development or a write-up of inventory to fair value that we would be required to take as a result of the acquisition of Aventis, and (3) any restructuring charge of up to 1 billion per year incurred in 2004 or 2005 that is incurred directly in connection with the acquisition of Aventis). Also, in general, the total financial borrowings of our subsidiaries on a consolidated basis (excluding any borrowings under the credit facility) may not exceed our consolidated EDITDA. There are also customary restrictions on our ability, in general, to create any security interest in our assets, to sell, lease, transfer or dispose of our assets (unless the net proceeds are applied to prepaying borrowings under the credit facility), to make acquisitions or investments outside the ordinary course of business in an aggregate amount in excess of 10 billion, or to enter into a merger or amalgamation (other than with a subsidiary).

The applicable margin for each Tranche under the credit facility varies according to the credit ratings that will be assigned to us at the relevant time. The margin under Tranche A will be initially 0.40% per annum and



**Table of Contents**

may range from 0.35% per annum to 0.525% per annum, the margin under Tranche B will be initially 0.45% per annum and may range from 0.40% per annum to 0.575% per annum and the margin under Tranche C will be initially 0.50% per annum and may range from 0.45% per annum to 0.625% per annum. The margins determined above will be decreased by five basis points once more than 50% of the credit facility has been repaid and cancelled. Interest on Euro-based borrowings shall accrue at the applicable margin plus EURIBOR, and interest on U.S. dollars, pounds sterling or Japanese yen shall accrue at the applicable margin plus LIBOR.

We reasonably expect that we will be able to repay the amounts borrowed under the credit facility within five years out of internal cash flow. We currently have no plans to refinance the credit facility.

The foregoing description of the credit facility is a summary and is qualified in its entirety by reference to the Facility Agreement, dated 25 January, 2004, between Sanofi Synthelabo, BNP Paribas and Merrill Lynch Credit Products, in various capacities as mandated lead arrangers, original lenders, agent and presenting bank included as an Exhibit to this annual report under Item 19 Exhibits.

***Divestiture of Arixtra® and Fraxiparine®***

In connection with our proposed acquisition of Aventis, on January 26, 2004, we began a sales process to divest our interests in Arixtra® and Fraxiparine® in order to be able to respond to possible demands of the competition authorities. As of the date of this prospectus, confidential discussions and negotiations are ongoing with several interested parties.

**Table of Contents****Item 9. The Offer and Listing****A. Offer and Listing Details**

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by The Bank of New York. For additional information regarding our shares, see Item 10

Additional Information Share Capital. For additional information regarding the ADSs, please see Item 12 Description of Securities other than Equity Securities American Depositary Shares.

Our shares trade on the *Premier Marché* of Euronext Paris S.A. and our ADSs trade on the New York Stock Exchange. There can be no assurances as to the establishment or continuity of a public market for our shares or ADSs.

**Trading History**

The table below sets forth, for the periods indicated, the reported high and low quoted prices of our shares on the *Premier Marché* of Euronext Paris S.A. and on the New York Stock Exchange.

Period	Euronext Paris		NYSE	
	High*	Low*	High**	Low**
	(in €)		(in \$)	
<b>2000</b>	71.00	34.70		
<b>2001</b>	86.50	52.60		
<b>2002</b> (NYSE beginning on July 1)	84.30	49.78	32.80	24.90
First Quarter	84.30	69.15		
Second Quarter	73.95	53.00		
Third Quarter (NYSE beginning on July 1)	65.85	49.78	32.80	24.90
Fourth Quarter	65.90	54.25	31.65	27.72
<b>2003</b>	60.00	41.50	37.92	22.53
First Quarter	59.50	41.50	32.00	22.53
Second Quarter	58.20	46.32	33.67	25.65
Third Quarter	56.75	47.61	32.00	26.02
Fourth Quarter	60.00	50.80	37.92	30.26
<b>2004</b>				
First Quarter	63.25	52.90	40.10	32.23
<b>2003</b>				
September	56.75	50.90	32.00	27.97
October	54.65	50.80	31.89	30.26
November	57.85	53.20	34.01	30.78
December	60.00	55.10	37.92	33.30
<b>2004</b>				

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

January	63.25	54.10	40.10	33.75
February	58.30	54.30	36.99	33.87
March	57.55	52.90	35.51	32.23

\* Source: Euronext Paris S.A.

\*\* Source: New York Stock Exchange

---

**Table of Contents****B. Plan of Distribution**

Not applicable.

**C. Markets**

Our shares are listed on the *Premier Marché* of Euronext Paris S.A. under the symbol *SAN* and our ADSs are listed on the New York Stock Exchange, or NYSE under the symbol *SNY*. At the date of this annual report, our shares are included in the *CAC 40 Index* (a widely followed index of 40 major French stocks), the Euronext 100 index (which includes the largest and most liquid stocks admitted to trading on Euronext), the Dow Jones EuroStoxx 50 Index (a widely followed index of major European stocks) and the Dow Jones Stoxx Healthcare Index. Since September 2002, our shares have also been included in the NYSE International 100 Index and the NYSE World Leaders Index, two U.S. pan-sector indices, and since April 2003, our shares have been included in the FTSEurofirst 80 and 100 Indices, two European pan-sector indices.

**Trading On The Premier Marché*****General***

Securities approved for listing by Euronext Paris are traded in one of two regulated markets, the *Bourse de Paris*, which in turn comprises the *Premier Marché* and the *Second Marché*, and the *Nouveau Marché*. These markets are operated and managed by Euronext Paris, a market operator (*entreprise de marché*) responsible for the admission of securities and the supervision of trading in listed securities. Euronext Paris publishes a daily official price list that includes price information on listed securities. The securities of most large public companies are listed on the *Premier Marché*, with the *Second Marché* available for small and medium-sized companies. Trading on the *Nouveau Marché* was introduced in March 1996 to allow small capitalization and start-up companies to access the stock market. In addition, the securities of certain other companies are traded on a non-regulated, over-the-counter market, the *Marché Libre OTC*.

***Premier Marché***

Securities listed on the *Premier Marché* of Euronext Paris are officially traded through authorized financial institutions that are members of Euronext Paris. Euronext Paris places securities listed on the *Premier Marché* in one of two categories, depending on their trading volume. Our shares trade in the category known as *Continu*, which includes the most actively traded securities. Securities that are traded continuously are traded on each trading day from 9:00 a.m. to 5:25 p.m. (Paris time), with a pre-opening session from 7:15 a.m. to 9:00 a.m. and a post-closing session from 5:25 p.m. to 5:30 p.m. (during which times trades are recorded but not executed until, respectively, the opening auction at 9:00 a.m. and the closing auction at 5:30 p.m.). In addition, from 5:30 p.m. to 5:40 p.m., trading can take place at the closing auction price. Trading in a security after 5:40 p.m. until the beginning of the pre-opening session of the following trading day may take place at a price that must be within the last auction price plus or minus 1%. Euronext Paris has introduced continuous electronic trading during trading hours for most listed securities.



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Euronext Paris automatically restricts trading in a security listed on the *Premier Marché* in the *Continu* category upon entry of an order in the order book likely to result in a trade being executed at a price exceeding the specific price limits defined by its regulations. In particular, trading is automatically restricted in a security whose quoted price varies by more than 10.0% from the last price determined in an auction or by more than 2.0% from the last traded price. Trading of this security resumes after a call phase of four minutes, during which orders are entered in the central order book but not executed, which ends by an auction. Euronext Paris may also suspend trading of a security listed on the *Premier Marché* in other limited circumstances (*suspension de la cotation*), in particular to prevent or halt disorderly market conditions. In addition, in exceptional cases, including, for example, in the context of a takeover bid, Euronext Paris may also suspend trading of the security concerned, upon request of the AMF.

## **Table of Contents**

Trades of securities listed on the *Premier Marché* are settled on a cash basis on the third day following the trade. Market intermediaries are also permitted to offer investors a deferred settlement service (*service à règlement différé*) for a fee. The deferred settlement service is only available for trades in securities that have both a total market capitalization of at least 1 billion and a daily average volume of trades of at least 1 million. Investors can elect on the determination date (*jour de liquidation*), which is the fifth trading day before the end of the month, either to settle by the last trading day of the month or to pay an additional fee and postpone the settlement decision to the determination date of the following month. At the date of this annual report, our shares are currently eligible for the deferred settlement service.

Equity securities traded on a deferred settlement basis are considered to have been transferred only after they have been registered in the purchaser's account. Under French securities regulations, any sale of a security traded on a deferred settlement basis during the month of a dividend payment is deemed to occur after the dividend has been paid. If the sale takes place before, but during the month of, a dividend payment date, the purchaser's account will be credited with an amount equal to the dividend paid and the seller's account will be debited by the same amount.

### ***Trading by the Company in its Shares***

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described in Item 10 under Additional Information – Memorandum and Articles of Association – Trading in Our Own Shares.

### **D. Selling Shareholders**

Not applicable.

### **E. Dilution**

Not applicable.

### **F. Expenses of the Issue**

Not applicable.

## **Table of Contents**

### **Item 10. Additional Information**

#### **A. Share Capital**

As of December 31, 2003, our share capital amounted to 1,465,696,144, divided into 732,848,072 outstanding shares with a nominal value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we held 49,990,262 shares (or 6.82% of our outstanding share capital), as treasury shares as of such date.

On May 22, 2002, our shareholders authorized our board of directors, for a period of 26 months, to increase our share capital by a maximum 750 million through the issuance of new shares or other securities giving an immediate or future right to our shares.

In connection with our proposed acquisition of Aventis, we will hold an extraordinary general shareholders meeting, at which we will seek approval from our shareholders for the issuance of the new shares to be issued in connection with the acquisition. See Item 8 Financial Information Significant Changes.

For additional information regarding our shares, see Memorandum and Articles of Association below.

#### **Shares Eligible For Future Sale**

Sales of substantial amounts of our shares and ADSs in the public market, or the perception that such sales could occur, could adversely affect prevailing market prices of our shares and ADSs and could impair our future ability to raise capital through an offering of our equity securities.

At December 31, 2003, we had 732,848,072 shares outstanding, all of which are freely tradable without restriction or further registration under the Securities Act, except that any shares or ADSs held by our affiliates, as that term is described in Rule 144 under the Securities Act, may generally only be sold in compliance with the limitations of Rule 144 described below. The shares held by Total and L Oréal are restricted securities, as that term is defined in Rule 144, in the United States. Restricted securities may be sold in the U.S. public market only if they are registered or qualify for an exemption from registration under Rule 144 of the Securities Act, described below. With certain limited exceptions, all of our shares, regardless of whether these shares are deemed to be restricted securities under the Securities Act, are freely tradable on Euronext Paris.

#### ***Shareholders Agreement***

As of December 31, 2003, Total and L Oréal owned 24.4% and 19.5% of our share capital, respectively. As of such date, Total could sell 36,241,425 of its shares on either Euronext Paris or, subject to Rule 144, in the United States, and L Oréal could sell 806,114 of its shares on either Euronext Paris or, subject to Rule 144, in the United States. Both Total and L Oréal will be able to sell the remainder of their shares when

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

the shareholders' agreement expires on December 1, 2004. Total has been gradually reducing its shareholding in our company since the merger. In November 2003, Total and L'Oréal amended the shareholders' agreement to formalize the decision not to renew the shareholders' agreement. See Item 7 Major Shareholders and Related Party Transactions Major Shareholders' Shareholders' Agreement and Item 3 Key Information Risk Factors We have two principal shareholders who continue to maintain a significant degree of influence for more information regarding Total and L'Oréal's respective shareholdings.

### ***Rule 144***

In general, under Rule 144 of the Securities Act, any of our affiliates, or a person or persons whose shares are aggregated who has beneficially owned restricted securities for at least one year (including the holding period of any prior owner except an affiliate) is entitled to sell in any three-month period a number of shares that does not exceed the greater of:

1% of the number of shares then outstanding; or

## **Table of Contents**

the average weekly trading volume of the ADSs on the NYSE during the four calendar weeks immediately preceding such sale.

Sales under Rule 144 are also subject to requirements relating the manner of sale, notice and availability of current public information about us. Under Rule 144(k), any person or persons whose shares are aggregated, who has not been one of our affiliates at any time during the 90 days immediately preceding the sale and who has beneficially owned his or her shares for at least two years is entitled to sell such shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

### ***Stock Options and Warrants***

As of December 31, 2003, 17,401,648 options were outstanding and 53,690 options were available for future option grants. Of these, 2,351,068 were fully vested and exercisable as of December 31, 2003. Each of our options is exercisable for one of our shares. We currently have no warrants outstanding.

### **Stock Options**

#### ***Types of Stock Options***

We have two types of stock options outstanding: subscription options (*options de souscription*), which were granted by Sanofi prior to the merger; and purchase options (*options d'achat d'actions*). Upon exercise of a subscription option, we issue new shares, whereas upon exercise of a purchase option, the option holder receives existing shares. We purchase our shares on the market prior to the grant of the purchase options in order to provide the option holder with shares upon exercise. Following the merger, all previously granted options for the shares of Sanofi or Synthélabo were converted into options for our shares.

As at December 31, 2003, we had 4,217,700 subscription options outstanding and 13,183,948 purchase options outstanding, for a combined total of 17,401,648 options outstanding exercisable for the same number of our shares. During 2003, the exercise of outstanding subscription options (at an exercise price of 14.56) led to the creation of 480,565 new shares, 2 par value each, and which increased shareholders' equity by 961,130. Because the exercise of purchase options will be satisfied with shares repurchased on the market, the exercise of purchase options have no impact on our equity capital.

#### ***Stock Option Plans***

Our ordinary and extraordinary shareholders' meeting of May 18, 1999 authorized our board of directors, for a five-year period, to grant subscription options and/or purchase options to members of our salaried staff and our corporate officers, as well as to related French or foreign companies or consortiums under the conditions referred to Article L.225-180 of the French Commercial Code. Under the authorization, the board of directors sets the conditions under which the options are granted, and the terms and conditions of their exercise, including the exercise price.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The authorization provides that the total number of granted options may not give rise to subscription for, or purchase of, a number of shares greater than 2% of our share capital as at May 18, 1999, *i.e.*, 14,611,740 shares, and includes, in favor of the beneficiaries of stock options, an express waiver of the preferential subscription rights of our shareholders with respect to any shares to be issued upon the exercise of subscription options.

At this meeting, our shareholders also agreed to assume the undertakings of Sanofi and Synthélabo, respectively, with respect to the beneficiaries of their respective stock options, which were granted prior to the merger. Options granted by Sanofi and Synthélabo are now exercisable for our shares. The substitution automatically entailed the suppression of the preferential subscription rights with respect to our shares to be issued upon exercise of subscription options. We plan to ask our shareholders to renew this authorization for an additional 38 month period at our next shareholders meeting, scheduled to be held May 24, 2004.

## **Table of Contents**

On December 10, 2003, our board of directors granted a total of 4,217,700 purchase options in favor of 1,349 beneficiaries, including the members of our senior management, which have an exercise price of \$55.74 per share and are exercisable between December 11, 2007 and December 10, 2013. For additional information regarding the options granted to our directors and senior management, see Item 6 Directors, Senior Management and Employees Compensation Stock Options.

## **B. Memorandum and Articles of Association**

### **General**

Our company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our *statuts*, an English translation of which has been filed as an exhibit to this annual report. For a description of the provisions of our *statuts* relating to our Board of Directors and statutory auditors, see Item 6 Directors, Senior Management and Employees. You may obtain copies of our *statuts* in French from the *greffe* (Secretary) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France). Please refer to that full document for additional details.

Our *statuts* specify that our corporate affairs are governed by:

Title II of the French Commercial Code (previously French Company Law No. 66-537 of July 24, 1966, as amended), and

the *statuts* themselves.

At an extraordinary general meeting held on May 22, 2002, our shareholders authorized our board of directors to increase our share capital, through the issuance of shares, securities with or without preferential rights or warrants, by an aggregate maximum nominal amount of \$750 million for a period ending 26 months from the date of such shareholders' meeting.

We plan to ask our shareholders to renew this authorization for an additional 26 month period up to an aggregate maximum nominal amount of \$750 million at our next general shareholders' meeting, scheduled to be held on May 24, 2004. We will also ask our shareholders to authorize our board of directors to increase our share capital by incorporation of reserves up to a maximum nominal amount of \$500 million for a period of 26 months from the date of the meeting, for an aggregate maximum nominal amount of \$1,250 million of authorized share capital increases.

### **Share Capital**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

As of December 31, 2003, our share capital amounted to 1,465,696,144, divided into 732,848,072 outstanding shares with a nominal value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Our *statuts* provide that shares may be held in registered form or in bearer form, at the option of the shareholder.

Our *statuts* provide that any fully paid-up shares acquire double voting rights if held in registered form for at least two years under the name of the same shareholder. As of December 31, 2003, there were 335,766,522 shares that were entitled to double voting rights, representing 45.8% of the total share capital, approximately 49.2% of our outstanding share capital that is held by holders other than us, and 65.9% of our total voting rights. Double voting rights are not taken into account in determining whether a quorum exists. Under the French Commercial Code, shares of a company held in treasury or by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.



## **Table of Contents**

Our *statuts* allow us to obtain from Euroclear France the name, nationality, address and number of shares held by the holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that an individual on any list provided by Euroclear France holds for the account of another person, our *statuts* allow us to request such information regarding beneficial ownership directly of any shareholder named on the list provided by Euroclear France. See Form, Holding and Transfer of Shares below.

### **Shareholders Meetings and Voting Rights**

#### ***General***

In accordance with the French Commercial Code, there are three types of shareholders meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

electing, replacing and removing directors;

appointing independent auditors;

approving the annual accounts;

declaring dividends or authorizing dividends to be paid in shares, provided the *statuts* contain a provision to that effect;

issuing non-convertible bonds; and

approval of stock repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our *statuts*, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

changing our company's name or corporate purpose;

increasing or decreasing our share capital;

creating a new class of equity securities;

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

authorizing the issuance of investment certificates, convertible or exchangeable securities;

establishing any other rights to equity securities;

selling or transferring substantially all of our assets; and

the voluntary liquidation of our company.

Special meetings of shareholders of a certain category of shares (such as, among others, shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

## **Table of Contents**

### ***Annual Ordinary Meetings***

The French Commercial Code requires our board of directors to convene an annual ordinary general meeting of shareholders for approval of the annual accounts. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The board of directors may also convene an ordinary or extraordinary meeting of shareholders upon proper notice at any time during the year. If the board of directors fails to convene a shareholders meeting, our independent auditors may call the meeting. In case of bankruptcy, our liquidator or court-appointed agent may also call a shareholders meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders meeting:

one or several shareholders holding at least 5% of our share capital,

any interested party in cases of urgency,

the workers council in cases of urgency, or

duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of the voting rights of our company.

### ***Notice of Shareholders Meetings***

We must announce general meetings at least 30 days in advance by means of a preliminary notice (*avis de reunion*), which is published in the *Bulletin des Annonces Légales Obligatoires* or BALO. The preliminary notice must first be sent to the *Autorité des Marchés Financiers*, or AMF. The AMF also recommends that prior to or simultaneously with the publication of the preliminary notice we publish a summary of the notice indicating the date of the meeting in a newspaper of national circulation in France. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders and the procedure for voting by mail.

At least 15 days prior to the date set for a first call, and at least 6 days prior to any second call, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information for the meeting. Such final notice must be sent by registered mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our company is registered as well as in the BALO, with prior notice having been given to the AMF. If no shareholder has proposed any new resolutions to be submitted to the vote of the shareholders at the meeting and provided that the board of directors has not altered the draft resolutions included in the preliminary notice, we are not required to publish the final notice; publishing a preliminary notice that stipulates that it is equivalent to a final notice will be deemed sufficient.

In general, shareholders can only take action at shareholders meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the dismissal of directors and certain other matters even though these actions have not been included on the agenda. Additional resolutions to be submitted for approval by the shareholders at the meeting may be proposed to the board of directors, for recommendation to the shareholders, within ten days of the publication of the preliminary notice in the BALO by:

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

one or several shareholders together holding a specified percentage of shares;

a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

the workers' council.

## **Table of Contents**

The board of directors must submit these resolutions to a vote of the shareholders after having made a recommendation thereon.

Following the publication of the final notice, a shareholder may submit written questions to the board of directors relating to the agenda for the meeting. The board of directors must respond to these questions during the meeting.

### **Attendance at Shareholders Meetings; Proxies and Votes by Mail**

In general, all shareholders who have properly registered their shares may participate in general meetings. Shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

In order to participate in any general meeting, a holder of registered shares must have its shares registered in its name in a shareholder account maintained by us or on our behalf by an agent appointed by us at least five days prior to the date of the meeting. Similarly, a holder of bearer shares must obtain from the accredited financial intermediary (*intermédiaire financier habilité*) with whom such holder has deposited its shares, a certificate (*certificat d immobilisation*) indicating the number of bearer shares owned by such holder and evidencing the holding of such shares in its account until the date of the meeting. Such certificate must be deposited at the place specified in the notice of the meeting at least five days before the meeting.

#### ***Attendance in Person***

Shareholders may attend ordinary general meetings and extraordinary general meetings and exercise their voting rights subject to the conditions specified in the French Commercial Code and our *statuts*. There is no requirement that a shareholder have a minimum number of shares in order to attend, to be represented or to vote at an ordinary or extraordinary general meeting.

#### ***Proxies and Votes by Mail***

Proxies will be sent to any shareholder on request. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice convening the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to the meeting). A shareholder may grant proxies only to his or her spouse or to another shareholder. A shareholder that is a corporation may grant proxies to a legal representative. Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the board of directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request. The completed form must be returned to us at least three days prior to the date of the shareholders meeting.

**Quorum**

The French Commercial Code requires that shareholders together holding at least 25% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

an ordinary general meeting; and

an extraordinary general meeting where only an increase in our share capital is proposed through incorporation of reserves, profits or share premium.

For any other extraordinary general meeting the quorum requirement is one-third of the shares entitled to vote, present in person, or voting by mail or by proxy.

## **Table of Contents**

For a special meeting of holders of a certain category of shares, the quorum requirement is half of the shares entitled to vote in that category, present in person, or voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. When an adjourned meeting is resumed, there is no quorum requirement for an ordinary meeting or for an extraordinary general meeting where only an increase in our share capital is proposed through incorporation of reserves, profits or share premium. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 25% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), present in person or voting by mail or by proxy. If a quorum is not present, the reconvened meeting may be adjourned for a maximum of two months. No deliberation or action by the shareholders may take place without a quorum.

## **Votes Required for Shareholder Action**

A simple majority of shareholders may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where only an increase in our share capital is proposed (through incorporation of reserves, profits or share premium). At any other extraordinary general meeting and at any special meeting of holders of a specific category of shares, a two-thirds majority of the shareholder votes cast is required.

A unanimous shareholder vote is required to increase liabilities of shareholders.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

## **Amendments Affecting Shareholder Rights**

Shareholder rights can be amended only after an extraordinary general meeting of the class of shareholders affected has taken place. Two-thirds of the shares of the affected class voting either in person or by mail or proxy must approve any proposal to amend shareholder rights. The voting and quorum requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general meeting, except that the quorum requirements for a special meeting are 50% of the voting shares, or 25% upon resumption of an adjourned meeting.

## **Financial Statements and Other Communications with Shareholders**

In connection with any shareholders' meeting, we must provide a set of documents including our annual report and a summary of the results of the five previous fiscal years to any shareholder who so requests.

## **Dividends**

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserve that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our *statuts*. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our *statuts*.

***Legal Reserve***

The French Commercial Code requires us to allocate 5% of our unconsolidated statutory net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate nominal value of the issued and outstanding



## **Table of Contents**

share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2003, our legal reserve was 146,473,501, representing 10% of the aggregate nominal value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may only be distributed to shareholders upon liquidation of the company.

### ***Approval of Dividends***

According to the French Commercial Code, our board of directors may propose a dividend for approval by the annual general meeting of shareholders. If we have earned distributable profits since the end of the preceding fiscal year, as reflected in an interim income statement certified by our auditors, our board of directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our board of directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

### ***Distribution of Dividends***

Dividends are distributed to shareholders pro rata according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date of our board of directors meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general meeting or by our board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders meeting so decides by ordinary resolution, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our *statuts* provide that, upon a decision of the shareholders meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

### ***Timing of Payment***

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

## **Changes in Share Capital**

### ***Increases in Share Capital***

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

As provided by the French Commercial Code, our share capital may be increased only with the shareholders' approval at an extraordinary general meeting following the recommendation of our board of directors. Increases in our share capital may be effected by:

issuing additional shares,

increasing the nominal value of existing shares, or

creating a new class of equity securities.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

in consideration for cash,

in consideration for assets contributed in kind,

## **Table of Contents**

through an exchange offer,

by conversion of debt securities previously issued,

by capitalization of profits, reserves or share premiums, or

subject to various conditions, in satisfaction of debt incurred by our company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premiums require the approval of an extraordinary general meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the nominal value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premiums. All other capital increases require the approval of an extraordinary general meeting acting under the regular quorum and majority requirements for such meetings. See **Quorum and Shareholders' Meetings and Voting Rights** above.

The shareholders may delegate the right to carry out any increase in share capital to our board of directors, provided that the increase has been previously authorized by the shareholders. Our board of directors may further delegate this right to our chairman and chief executive officer.

### ***Decreases in Share Capital***

According to the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the nominal value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

Our shareholders may delegate the right to effect a decrease in our share capital to our board of directors, provided that the decrease has been previously approved by our shareholders.

### **Preferential Subscription Rights**

According to the French Commercial Code, if we issue specific kinds of additional securities, current shareholders will have preferential subscription rights to these securities on a *pro rata* basis. These preferential rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to an issue of any securities that may increase the share capital of our company by means of a cash payment or a set-off of cash debts. Preferential subscription rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on the *Premier Marché* of Euronext Paris.

Preferential subscription rights with respect to any particular offering may be waived by a vote of shareholders holding a two-thirds majority of the shares entitled to vote at an extraordinary general meeting. Our board of directors and our independent auditors are required by French law to

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

present reports that specifically address any proposal to waive preferential subscription rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders also may notify us that they wish to waive their own preferential subscription rights with respect to any particular offering if they so choose.

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, during a limited period of time.

## **Table of Contents**

In the event of a capital increase without preferential subscription rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the average market price of the shares in any consecutive ten trading day period within the 20 trading days preceding the capital increase.

## **Form, Holding and Transfer of Shares**

### ***Form of Shares***

Our *statuts* provide that the shares may be held in either bearer form or registered form at the option of the holder.

### ***Holding of Shares***

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and issues certificates of inscription for the shares it holds. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. Under a French statute dated May 15, 2001, when shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal person (*personne morale*) who holds more than 2.5% of our shares, to disclose the name of any person who owns, directly or indirectly, more than a third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

### ***Transfer of Shares***

Our *statuts* do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the *Premier Marché* on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary. For dealings on the *Premier Marché*, a tax assessed on the price at which the securities were traded, or *impôt sur les opérations de bourse*, is payable at the rate of 0.3% on transactions of up to 153,000 and at a rate of 0.15% thereafter. This tax is subject to a rebate of 23 per transaction and a maximum assessment of 610 per transaction. However, non-residents of France are not required to pay this tax. In addition, a fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. No registration duty is normally payable in France, unless a transfer instrument has been executed in France.

## **Table of Contents**

### **Liquidation Rights**

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will be first distributed to repay in full the nominal value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the nominal value of their shareholdings.

### **Requirements for Holdings Exceeding Certain Percentages**

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 20%, 33 <sup>1</sup>/<sub>3</sub>%, 50% or 66 <sup>2</sup>/<sub>3</sub>% of the outstanding shares or voting rights of a listed company in France, such as our company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, within five trading days of the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF within five trading days of the date it crosses the threshold. The AMF makes the notice public.

French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10% or 20% of the outstanding shares or voting rights of a listed company. These persons must file a report with the company and the AMF within 10 trading days of the date they cross the threshold. In the report, the acquirer must specify if it acts alone or in concert with others and specify its intentions for the following 12-month period, including whether or not it intends to continue its purchases, to acquire control of the company in question or to seek nomination to the board of directors. The AMF makes the report public. The acquirer must also publish a press release stating its intentions in a financial newspaper of national circulation in France. The acquirer may amend its stated intentions, provided that it does so on the basis of significant changes in its own situation or shareholding. Upon any change of intention, it must file a new report.

In order to permit holders to give the required notice, we must publish in the BALO, not later than 15 calendar days after the annual ordinary general meeting of shareholders, information with respect to the total number of voting rights outstanding as of the date of such meeting. In addition, if the number of outstanding voting rights changes by 5% or more between two annual ordinary general meetings, we must publish in the BALO, within 15 calendar days of such change, the number of voting rights outstanding. In both cases, we must also provide the AMF with a written notice setting forth the number of voting rights outstanding. The AMF publishes the total number of voting rights so notified by all listed companies in a weekly notice (*avis*), mentioning the date each such number was last updated.

If any proprietary owner fails to comply with the legal notification requirement, the shares or voting rights in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

If a registered intermediary fails to comply with the legal notification requirement, the shares or voting rights registered in his name will be deprived of voting rights for all shareholders' meetings until the registered intermediary complies with the notification and payment of dividends as postponed until such date. In addition, if a registered intermediary willfully fails to comply with these requirements, the shares may be deprived of all or part of their voting rights and dividends for up to five years by the Commercial Court, at the request of the company or shareholders holding 5% or more of the company's share capital.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or persons acting in concert that crosses the ownership threshold of 33 <sup>1</sup>/<sub>3</sub>% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the share capital of such company. In addition, our *statuts* provide that any person or entity, acting alone or in concert with others, who becomes the



## **Table of Contents**

owner of 1% of our share capital or our voting rights, or any multiple of that percentage, must notify us by certified mail, return receipt requested, within five trading days of the total number of shares and voting rights that such person then owns. The same provisions of our *statuts* apply to each increase or decrease in excess of 1%. Any person or entity that fails to comply with such notification requirements, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, will be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

### **Purchase of Our Own Shares**

Under French law, our company may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. To acquire our shares for this purpose, we must file a *note d'information* that has received the approval (*visa*) of the AMF. We can elect to file such *note d'information* either prior to obtaining our shareholders' approval at an ordinary general meeting, or after our board of directors, duly authorized by our shareholders, has decided to initiate the share purchase plan.

If we repurchase our shares in the foregoing manner, we have three options. We may:

keep the shares;

sell or transfer them, including to our employees under an authorized profit-sharing plan or stock option plan; or

cancel the shares, with our shareholders' approval at an extraordinary general meeting.

We may not cancel more than 10% of our outstanding share capital over any 24-month period. Our repurchase of shares also must not result in our company holding, directly or through a person acting on our behalf, more than 10% of our outstanding share capital, or if we have different classes of shares, 10% of the shares of each class.

We must hold any shares we repurchase in registered form. These shares also must be fully paid up. Shares repurchased by us are deemed outstanding under French law but are not entitled to dividends or voting rights, and we may not exercise the preferential subscription rights attached to them.

The shareholders, at an extraordinary general meeting, may decide not to take these shares into account in determining the preferential subscription rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

The purchase and possible cancellation of 10% of our shares (up to 5.8 billion) was authorized by our shareholders on May 19, 2003. Under such authorization, the purchase price for any such share may not be greater than 80, and the selling price of any such share may not be lower

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

than 20, except for shares sold to beneficiaries of certain stock option plans (which may be sold at a price between 6.01 and 64.94). We may purchase our shares from the date of our shareholders' meeting of May 19, 2003 through the period ending 18 months from such date, which is November 19, 2004. The prospectus (*note d information*) relating to this share repurchase program was granted *visa* No. 03-299 by the COB. Shares repurchased under this program may be used to:

respond to market conditions;

regulate market prices;

## **Table of Contents**

provide shares to our employees and officers under stock option plans;

provide shares to our employees and officers under share purchase plans;

finance external growth;

grant shares following the exercise of rights attached to securities that give the right to receive shares; and

optimize our capital allocation.

During 2003, and pursuant to the May 22, 2002 and May 19, 2003 share purchase authorizations, we acquired 20,192,769 of our own shares at an average share price of \$50.43. Fees associated with such purchases were \$2,422,416 before taxes, or approximately \$0.12 per share. During 2003, we sold 550,882 of our shares in connection with the exercise of purchase options at an average price of \$23.41 per share, and sold 28,000 of our shares on the market at an average price of \$65.84 per share. As at December 31, 2003, we held 49,990,262 of our own shares, representing 6.8% of our capital.

At our next general shareholders' meeting, scheduled for May 24, 2004, we plan to ask our shareholders to renew the authorization to purchase up to 10% of our shares for an additional 18-month period. Under the proposed resolution, the purchase price for any such shares may not be greater than \$90.00 per share.

## **Trading in Our Own Shares**

Under *Règlement n° 90-04* of the AMF, as amended, we may not trade in our own shares for the purpose of manipulating the market. There are three requirements for trades by a company in its own shares to be considered valid. Specifically, in order to be valid:

trades must be executed on behalf of the company by only one intermediary in each trading session, unless the issuer executes its purchase plan partly through derivative instruments, in which case two intermediaries may be used, but only to the extent that the issuer is able to ensure adequate coordination between the intermediaries;

any block trades may not be made at a price above the current market price; and

each trade must be made at a price that falls between the lowest and the highest trading price of the trading session during which it is executed.

If a company's shares, like our shares, will be continuously quoted (*cotation en continu*), then a trade must meet three further requirements to be considered valid:

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

the trade must not influence the determination of the quoted price before the opening of trading, at the first trade of the shares, at the reopening of trading following a suspension, or, as applicable, in the last half-hour of any trading session or at the fixing of the closing price;

the trade must not account for more than 25% of the average total daily trading volume on Euronext Paris in the shares during the three trading days immediately preceding the trade; and

the trade must not be carried out in order to influence the price of a derivative instrument relating to the company's shares.

There are two periods during which we are not permitted to trade in our own securities: the 15-day period before the date on which we make our consolidated or annual accounts public, and the period beginning on the

## **Table of Contents**

date at which we become aware of information that, if disclosed, would have a significant impact on the market price of our securities and ending on the date this information is made public.

There are certain exceptions to the above requirements:

trades by a company in its own shares that are used to finance an acquisition are deemed valid, regardless of whether the six requirements listed above are met if (a) the acquisition takes place at least three months after the company's last trade in its own shares and (b) an independent advisor has been appointed in order to assess the value of the shares, the value of the assets acquired and the fairness of the exchange ratio; and

trades by a company in its own shares that are executed on behalf of the company by an intermediary pursuant to a liquidity agreement are deemed valid, regardless of whether the first two requirements listed above regarding continuous quotation and the two restrictions regarding the trading period are met if the terms of the liquidity agreement comply with the ethics guidelines (*charte de déontologie*) approved by the AMF in its *Instruction* of April 10, 2001.

After making an initial purchase of our own shares, we must file monthly reports with the AMF that contain specified information about subsequent transactions (including purchases, sales and share cancellations). The AMF makes this information publicly available.

## **Ownership of Shares by Non-French Persons**

The French Commercial Code currently does not limit the right of non-residents of France or non-French persons to own and vote shares. However, non-residents of France must file an administrative notice with French authorities in connection with the acquisition of a controlling interest in our company. Under existing administrative rulings, ownership of 20% or more of our share capital or voting rights is regarded as a controlling interest, but a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

the acquiring party's intentions,

the acquiring party's ability to elect directors, or

financial reliance by the company on the acquiring party.

## **Enforceability of Civil Liabilities**

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our directors and officers reside outside the United States. In addition, a substantial portion of our assets are located in France. As a result, it may be difficult for investors to effect service of process within the United States on such persons. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under the U.S. federal securities laws. There is doubt as to the enforceability

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on the U.S. federal securities laws. Actions for enforcement of foreign judgments against such persons would require such persons who are of French nationality to waive their right under Article 15 of the French Civil Code to be sued only in France. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law of July 26, 1968, as amended, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

## **Table of Contents**

### **C. Material Contracts**

We are not party to any contracts that we regard as material to our business or financial position.

### **D. Exchange Controls**

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary. In France, all registered banks and most credit establishments are accredited intermediaries.

### **E. Taxation**

#### **French Taxation**

The following generally summarizes the material French tax consequences of purchasing, owning and disposing of our shares or ADSs. The statements relating to French tax laws set forth below are based on the laws in force as of the date hereof, and are subject to any changes in applicable laws and tax treaties after such date.

This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our shares or ADSs.

The following summary does not address the treatment of shares or ADSs that are held by a resident of France (except for purposes of describing related tax consequences for other holders) or in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France, or by a person that owns, directly or indirectly, 5% or more of the stock of our company.

There are currently no procedures available for holders that are not U.S. residents to claim tax treaty benefits in respect of dividends received on ADSs or shares registered in the name of a nominee. Such holders should consult their own tax advisor about the consequences of owning and disposing of ADSs.

#### ***Taxation of Dividends on Shares***

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In France, dividends are paid out of after-tax income. Dividends paid to non-residents normally are subject to a 25% French withholding tax. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate (generally 15%) of French withholding tax. If a non-resident holder establishes its entitlement to treaty benefits prior to the payment of a dividend, then French tax generally will be withheld at the reduced rate provided under the treaty.

The French Finance Law of 2004 includes a reform of the French tax treatment of distributions implementing a new mechanism to avoid double taxation of dividends and the elimination of the former *avoir fiscal* and *précompte* mechanisms as explained below.

### *Avoir Fiscal Tax Credit*

Prior to enactment of the reform, French resident shareholders were entitled to a tax credit, known as the *avoir fiscal*, on dividends received from French companies. The *avoir fiscal* was equal to 50% of the dividend received for individuals and, generally, equal to 10% of the dividend received for other investors, although the 10% rate was generally increased by 80% of any *précompte* actually paid in cash by the distributing corporation.

As a result of the reform:

French resident individuals will still benefit from the *avoir fiscal* with respect to dividend distributions made during 2004 but will not be entitled to the *avoir fiscal* with respect to dividend distributions made



**Table of Contents**

from 2005 on. Instead, from 2005 on, French resident individuals will only be taxed on half of dividends received and, in addition to the annual allowance of 2,440 for couples subject to joint taxation and 1,220 for single persons, widowers or divorcees which is already applicable, will be entitled to a tax credit equal to 50% of the dividend (the Tax Credit). The Tax Credit will have a cap of 230 for married couples and members of a union agreement subject to joint taxation and 115 for single persons, widows or widowers, divorcees or married persons subject to separate taxation.

French resident shareholders other than individuals will lose the benefit of the *avoir fiscal* for tax credits that they would otherwise have been able to use as from 2005 on; thus French corporate shareholders with a fiscal year corresponding to the calendar year will not be entitled to the *avoir fiscal* with respect to dividends received in 2004.

Dividends paid to non-residents are not normally eligible for the benefit of the *avoir fiscal* and, from 2005 on, will not be eligible for the Tax Credit described above. However, France has entered into tax treaties with certain countries under which qualifying residents complying with the procedures for claiming benefits under an applicable tax treaty may be entitled to benefit from a refund of the *avoir fiscal* (net of applicable withholding tax), in addition to a reduced rate of withholding tax. Certain of these treaties impose additional conditions for the entitlement of corporate entities to the *avoir fiscal* and under certain treaties only individual residents are entitled to the *avoir fiscal*.

As a result of the French Finance Law of 2004 reform:

qualifying non-resident individuals who hold shares directly will be entitled to a refund of the *avoir fiscal* with respect to dividends received in 2004 but will not be entitled to *avoir fiscal* refunds with respect to distributions made from 2005. Instead, qualifying non-resident individuals who were previously entitled to a refund of the *avoir fiscal* may benefit, under the same conditions as for the *avoir fiscal*, from a refund of the Tax Credit (net of applicable withholding tax); the French tax authorities have not yet issued any guidance with regard to the refund of the Tax Credit to non-resident individuals, but claiming such refund may likely entail compliance with cumbersome formalities.

non-resident shareholders other than individuals are no longer entitled to a refund of the *avoir fiscal* with respect to dividend distributions made from 2004.

*Précompte 25% Equalization Tax*

Dividends paid out of profits that have not been taxed at the ordinary corporate rate, or were earned and taxed more than five years before the distribution, are subject to an equalization tax called the *précompte*, which is payable by the distributing corporation to the French tax authorities. The *précompte* generally is equal to one-half of the amount of the dividend paid to shareholders prior to deduction of withholding tax. When a tax treaty does not provide for a refund of the *avoir fiscal*, or when a non-resident shareholder is not entitled to such a refund but is otherwise entitled to the benefits of the tax treaty, then a qualifying shareholder may generally obtain from the French tax authorities a payment equal to 100% of the *précompte* actually paid in cash by the distributing corporation, net of applicable withholding tax. These rules will be applicable to distributions made through December 31, 2004.

Distributions made by French companies from 2005 on will no longer be subject to *précompte*. However, an equalization tax will apply to distributions made in 2005 out of profits that have not been taxed at the ordinary corporate tax rate, or which were earned and taxed more than five years before the distribution. This equalization tax will be equal to 25% of the amount of the dividends paid to the shareholder. Unlike *précompte*, this equalization tax will not be refundable to non-resident shareholders, as it will be refunded to the distributing corporation in three installments of one third each with respect to the three fiscal years closed after the distribution, either as a credit against its corporate tax liability or in cash, if the corporate tax liability is insufficient to offset the entire tax credit.



## **Table of Contents**

Distributions made as from 2006 will not give rise to *précompte* or equalization tax liability.

### ***Taxation on Sale or Disposition of Shares***

Subject to the more favorable provisions of a relevant tax treaty, holders that are not residents of France for tax purposes, do not hold shares or ADSs in connection with the conduct of a business or profession in France, and have not held more than 25% of our dividend rights (*droits aux bénéfices sociaux*), directly or indirectly, at any time during the preceding five years, are not subject to French income tax or capital gains tax on the sale or disposition of shares or ADSs.

A 1% *ad valorem* registration duty (subject to a maximum of 3,049 per transfer) applies to certain transfers of shares or ADSs in French companies. This duty does not apply to transfers of shares or ADSs in listed companies that are not evidenced by a written agreement, or if any such agreement is executed outside France.

### ***Estate and Gift Tax***

France imposes estate and gift tax on shares or ADSs of a French corporation that are acquired by inheritance or gift. The tax applies without regard to the tax residence of the transferor. However, France has entered into estate and gift tax treaties with a number of countries pursuant to which, assuming certain conditions are met, residents of the treaty country may be exempted from such tax or obtain a tax credit.

### ***Wealth Tax***

Individuals who are not residents of France for purposes of French taxation are not subject to a wealth tax (*impôt de solidarité sur la fortune*) in France as a result of owning an interest in the share capital of a French corporation, provided that such ownership interest is less than 10% of the corporation's share capital and does not enable the shareholder to exercise influence over the corporation. Double taxation treaties may provide for a more favorable tax treatment.

### **Taxation of U.S. Investors**

The following is a summary of the material French and U.S. federal income tax consequences of the purchase, ownership and disposition of our shares or ADSs if you are a holder that is a resident of the United States for purposes of the income tax convention between the United States and France (the Treaty) and are fully eligible for benefits under the Treaty (a U.S. holder). You generally will be entitled to Treaty benefits in respect of our shares or ADSs if you are:

the beneficial owner of the shares or ADSs (and the dividends paid with respect thereto);

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

an individual resident of the United States, a U.S. corporation, or a partnership, estate or trust to the extent its income is subject to taxation in the United States in its hands or in the hands of its partners or beneficiaries;

not also a resident of France for French tax purposes; and

not subject to an anti-treaty shopping article that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

For U.S. federal income tax purposes, a U.S. holder's ownership of the company's ADSs will be treated as ownership of the company's underlying shares.

## **Table of Contents**

This summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. In particular, the summary does not deal with shares that are not held as capital assets, and does not address the tax treatment of holders that are subject to special rules, such as banks, insurance companies, dealers in securities or currencies, regulated investment companies, persons that elect mark-to-market treatment, persons holding shares as a position in a synthetic security, straddle or conversion transaction, persons that own, directly or indirectly, 5% or more of our voting stock or 10% or more of our outstanding capital and persons whose functional currency is not the U.S. dollar. The summary is based on laws, treaties, regulatory interpretations and judicial decisions in effect on the date hereof, all of which are subject to change.

This summary does not discuss the treatment of shares or ADSs that are held in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France.

This summary does not constitute legal or tax advice. You should consult your own tax advisers regarding the tax consequences of the purchase, ownership and disposition of shares or ADSs in light of your particular circumstances, including the effect of any state, local or other national laws.

### ***Dividends***

As discussed in more detail above, the French Finance Law of 2004 includes a reform of the French tax treatment of distributions and dividends paid by French companies to non-residents of France. Generally, non-residents of France are subject to French withholding tax at a 25% rate and are not eligible for the benefit of the *avoir fiscal*. In addition, as of 2005, non-residents generally will not be eligible for the benefit of the Tax Credit available to French resident individuals, as described above.

However, under the Treaty, you can claim the benefit of a reduced dividend withholding tax rate of 15%.

If you are an individual U.S. holder, you will also be entitled to a payment from the French tax authorities equal to the *avoir fiscal* with respect to dividends distributed in 2004 at a 50% rate, less a 15% withholding tax. Because of the 2004 French tax reform you will no longer be entitled to the *avoir fiscal* refund with respect to dividend distributions made from 2005 on. Instead, under the same conditions as for the *avoir fiscal*, you may be entitled to a refund of the Tax Credit less a 15% withholding tax. You generally will be entitled to receive a refund of the *avoir fiscal* or the Tax Credit only if you are subject to U.S. federal income tax on the *avoir fiscal* payment (or the Tax Credit) and the dividend to which it relates. The refund of the *avoir fiscal* (or the Tax Credit) will not be made available before January 15 following the end of the calendar year in which the dividend is paid. The French tax authorities have not yet issued any guidance with regard to the refund of the Tax Credit to non-resident individuals, and may entail compliance with cumbersome formalities.

As a result of the 2004 French tax reform, U.S. holders that are legal entities, pension funds or other tax-exempt holders are no longer entitled to tax credit payments from the French Treasury in respect of dividends paid from 2004.

French withholding tax will be withheld at the 15% Treaty rate if you have established before the date of payment that you are a resident of the United States under the Treaty and, if you are not an individual, that you are the owner of all the rights relating to the full ownership of the shares or ADSs (including, but not limited to, dividend rights).

With respect to distributions of dividends made during 2004, U.S. holders that are not entitled to a refund of the *avoir fiscal* (e.g., corporations, pension funds and other tax-exempt U.S. holders) may generally obtain from the French tax authorities a refund of the entire *précompte* equalization tax (discussed under French Taxation, above) we actually pay in cash in respect of a dividend, less a 15% French withholding tax.

## **Table of Contents**

Thus, for example, if we pay a dividend of 100 to an individual U.S. holder in 2004, the holder initially will receive 85, but will be entitled to an additional payment of 42.50, consisting of the *avoir fiscal* of 50 less a 15% withholding tax. If we pay a dividend of 100 to a corporate U.S. holder, such U.S. holder will receive 85, and will not be entitled to any *avoir fiscal*; in the event that the dividend distribution triggers payment by us of the *précompte*, such U.S. holder generally may also obtain from the French tax authorities a refund of the *précompte* that we pay in cash, less a 15% withholding tax.

The gross amount of dividend, *avoir fiscal* (or Tax Credit) and *précompte* payments that you receive (prior to deduction of French withholding tax) generally will be subject to U.S. federal income taxation as foreign source dividend income. Subject to certain exceptions for positions that are hedged or held for less than 60 days, an individual U.S. holder generally will be subject to U.S. taxation at a maximum rate of 15% in respect of dividends received after 2002 and before 2009. Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations. French withholding tax at the 15% Treaty rate will be treated as a foreign income tax that, subject to applicable limitations under U.S. law, is eligible for credit against your U.S. federal income tax liability or, at your election, may be deducted in computing taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in securities. You should consult your own tax advisers concerning the implications of these rules in light of your particular circumstances.

Dividends paid in euro will be included in your income in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date you receive the dividend (or the date the depository receives the dividend, in the case of the ADSs), regardless of whether the payment is in fact converted into U.S. dollars. If such a dividend is converted into U.S. dollars on the date of receipt, you generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

### ***Procedures for Claiming Treaty Benefits***

In order to claim Treaty benefits, if you are an individual U.S. holder, you must complete and deliver to the French tax authorities either:

the simplified certificate described below; or

an application for refund on French Treasury Form RF 1A EU-No. 5052.

A simplified certificate must state that:

you are a U.S. resident within the meaning of the Treaty;

you do not maintain a permanent establishment or fixed base in France with which the holding giving rise to the dividend is effectively connected;

you own all the rights attached to the full ownership of the shares (including dividend rights); and

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

you meet all the requirements of the Treaty for obtaining the benefit of the reduced rate of withholding tax and the refund of the *avoir fiscal*.

Copies of the simplified certificate and the application for refund are available from the U.S. Internal Revenue Service and from the *Centre des Impôts des Non-Résidents* (9, rue d Uzès, 75094 Paris Cedex 2).

If the certificate or application is not filed prior to a dividend payment, then holders may claim withholding tax and *avoir fiscal* refunds by filing an application for refund at the latest by December 31 of the second year following the year in which the withholding tax is paid.



## **Table of Contents**

The *avoir fiscal* and any French withholding tax refund will not be paid before January 15 following the end of the calendar year in which the dividend is paid.

As noted above, the French tax authorities have not yet issued any guidance with regard to the refund of the Tax Credit to non-resident individuals, which may entail compliance with cumbersome formalities.

If you are a U.S. holder not entitled to a refund of the *avoir fiscal*, in order to claim Treaty benefits (reduced withholding tax rate and, as the case may be, refund of the *précompte*), you must file French Treasury Form RF 1B EU-No. 5053 before the end of the second year following the year in which the dividend was paid. This form, together with instructions, is available from the U.S. Internal Revenue Service or at the *Centre des Impôts des Non-Résidents* (9, rue d Uzès, 75094 Paris Cedex 2). If the form is filed prior to the dividend payment, then the French withholding tax generally will be withheld at the reduced rate.

The French tax authorities are expected to issue new guidelines setting out formalities to be complied with by U.S. holders that are not entitled to a refund of the *avoir fiscal* in order to obtain the reduced withholding tax rate.

## ***Capital Gains***

Under the Treaty, you will not be subject to French tax on any gain derived from the sale or exchange of shares or ADSs, unless the gain is effectively connected with a permanent establishment or fixed base of business maintained by you in France.

For U.S. federal income tax purposes, gain or loss you realize on the sale or other disposition of the shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the shares were held for more than one year. The net amount of long-term capital gain recognized by an individual U.S. holder generally is subject to taxation at a maximum rate of 20%; however, net long-term capital gain recognized by an individual U.S. holder after May 5, 2003 and before January 1, 2009 generally is subject to taxation at a maximum rate of 15%. Your ability to offset capital losses against ordinary income is limited.

## ***French Estate and Gift Tax***

Under the estate and gift tax convention between the United States and France, a transfer of shares or ADSs by gift or by reason of the death of a U.S. holder entitled to benefits under that convention will not be subject to French gift or inheritance tax, so long as the donor or decedent was not domiciled in France at the time of the transfer, and the shares or ADSs were not used or held for use in the conduct of a business or profession through a permanent establishment or fixed base in France.

## ***French Wealth Tax***

The French wealth tax does not generally apply to shares or ADSs of a U.S. Holder if the holder is a resident of the United States for purposes of the Treaty.

**U.S. Information Reporting and Backup Withholding Rules**

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting and may be subject to backup withholding unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary.

**Table of Contents**

**F. Dividends and Paying Agents**

Not applicable.

**G. Statement by Experts**

Not applicable.

**H. Documents on Display**

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, and, in accordance therewith, we are required to file reports, including annual reports on Form 20-F, and other information with the U.S. Securities and Exchange Commission by electronic means. Our public filings are available to the public over the Internet at the Commission's Website at <http://www.sec.gov>.

**I. Subsidiary Information**

Not applicable.

## **Table of Contents**

### **Item 11. Quantitative And Qualitative Disclosures About Market Risk**

As a result of our international operating and financing activities, we are subject to various market risks relating primarily to fluctuations in foreign currency exchange rates and interest rates. Accordingly, in order to reduce our exposure to these fluctuations and help guarantee operating margins resulting from its business, we apply a hedging policy based on the use of diversified, liquid financial instruments. We centralize all such transactions, except when, for legal or practical reasons, it is more convenient for affiliates to enter directly into these transactions.

The tables below are based on certain assumptions and expectations that, by their nature, may prove to be different, particularly due to changes in foreign exchange rates and interest rates, and changes in our exposure to these risks.

#### **Foreign Currency Exchange Risk**

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the U.S. dollar and, to a lesser extent, the Japanese yen. In 2003, approximately 23.8% of our consolidated sales were realized in the United States (the United States also represented 45.4% of our 2003 operating profit excluding unallocated costs). While we incur expenses in those currencies, the impact of these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. For example, in 2003, our operating profit was 3,075 million, representing a 15.6% increase compared to our operating profit in 2002 of 2,614 million, which would have increased by 34.4% over 2002 if exchange rates had remained constant.

When deemed appropriate, we enter into transactions to hedge our exposure to foreign exchange risks. This policy entails the periodic calculation of our global foreign currency exposure based on budgeted and forecasted operational transactions of both our parent company and of our affiliates that are denominated in foreign currencies. These transactions primarily concern purchases, sales, co-marketing and co-development expenses and royalties. In order to reduce our exposure to currency fluctuations impacting these transactions, we enter into transactions to hedge our exposure to foreign exchange risks, such as foreign exchange forwards, put and call options or combined optional derivatives such as collars. All such financial transactions are entered into with counterparts with a high credit rating and are centralized under a dedicated treasury team, except when, for legal or for regulatory reasons, it is more convenient for our affiliates to enter directly into these transactions. The hedging strategy is presented to and validated by our Audit Committee, and a regular review of the level of our commitments related to these financial transactions is conducted by senior financial management. Nevertheless, these efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations.

**Table of Contents**

The following tables provide an indication of the estimated future cash flows from the existing currency hedging instruments at December 31, 2003, shown by maturity date, and calculated based on the applicable forward rate. See Note D.17 to our consolidated financial statements for the carrying amount and fair value information of these instruments at December 31, 2003 and 2002.

	<u>2004</u>	<u>After 2004</u>
	<i>(in millions of \$)</i>	
<b>Forward purchases of:</b>		
U.S. dollar	(130)	
Swiss franc	(92)	
Norwegian krona	(23)	(12)
British pound		
Hungarian forint	(57)	
Japanese yen		
Swedish krona	(4)	
<b>Forward sales of:</b>		
U.S. dollar	981	
Japanese yen	49	21
British pound	45	
Canadian dollar	23	
Czech koruna	13	
Swiss franc		
Singapore dollar	2	
Swedish krona	10	
Australian dollar	13	
Norwegian krona	8	
Polish zloty	14	
Hungarian forint		
Slovakian koruna	5	
Korean won	10	
Mexican peso	7	
South African rand	6	
Taiwanese dollar	6	
Thai baht	5	
Other currencies	6	
<b>Foreign currency Option Purchases(*)</b>		
<b>Call purchases of:</b>		
Norwegian krona		
Swiss franc		
U.S. dollar		
Hungarian forint	(11)	
<b>Put purchases of:</b>		
U.S. dollar	234	
Japanese yen	43	
Swiss franc		
Czech koruna	2	
Polish zloty	2	
Swedish krona	3	
Australian dollar	1	
Norwegian krona	1	
Thai baht	1	
South African rand	1	



**Table of Contents**

	<u>2004</u>	<u>After 2004</u>
	<i>(in millions of )</i>	
<b>Foreign currency Option Sales(*)</b>		
<b>Call sales of:</b>		
U.S. dollar	(20)	
Australian dollar	(1)	
Czech koruna	(2)	
Norwegian krona		
Slovakian koruna	(3)	
<b>Put Sales of:</b>		
Norwegian krona	20	10

(\*) Based on in the money options

These positions cover all future material foreign currency cash flows occurring after the balance sheet date that relate to transactions that have occurred during the financial year and which are accounted for on our balance sheet at December 31, 2003. The gains and losses arising on these positions have been calculated and recognized alongside the recognition of gains and losses on the hedged items.

In addition, these positions cover anticipated foreign currency cash flows relating to transactions occurring after the balance sheet date. We are particularly sensitive to exchange movements between the euro and the U.S. dollar, which constitutes approximately 75% of these positions by notional value. Globally the total net amount of our U.S. dollar positions at December 31, 2003 was \$985 million, representing approximately 86% of the forecast transactions denominated in this currency in 2004 at an average hedged rate of \$1.11 to the euro. It is estimated that if the average exchange rate in 2004 applicable to these transactions was to be \$1.20 to the euro the impact of these positions would be to increase our income before tax in 2004 by approximately 70 million; if the average exchange rate in 2004 was to be \$1.10 to the euro the impact would be to reduce our income before taxes in 2004 by 5 million.

**Interest Rate and Liquidity Risk**

We operate a centralized treasury platform under which all surplus cash resources or financing requirements of affiliates are pooled with those of the parent company under arm's length agreements, where permitted. Where needed, we negotiate local working capital credit facilities by affiliates with banking counterparts and validated by a specialist central treasury team. This team monitors our current and forecast cash position and manages our investment portfolio, which consists entirely of money market funds and term deposits.

As at December 31, 2003, our borrowings were not significant and mostly consisted of short-term credit for our foreign subsidiaries. The total amount of these credit lines was approximately 500 million at December 31, 2003.

Because all of our short-term deposits and borrowings are subject to variable interest rates, we are exposed to movements in short-term interest rates. In 2003, we earned net financial income of 47 million on an average net short-term cash position excluding treasury shares in 2003 of 1,960 million, which represents a before tax return of 2.4%. At December 31, 2003, our short-term cash position excluding treasury shares was 2,558 million. Based on this position, a change in average short-term interest rates of 1% would result in an impact of 25 million on our before tax income in 2004.

We held no interest rate instruments at December 31, 2003.

**Stock Market Risk**

We have a general policy of not trading in the markets for speculative purposes and generally invest our surplus cash in money market mutual funds and term deposits with banks counterparties that have high credit



**Table of Contents**

ratings. We do not own any material equity interest in listed companies, although we acquire our own shares under a share repurchase plan pursuant to an authorization from our shareholders. This plan and the limitations on trading in our own shares are described in more detail in Item 10. Additional Information Share Capital. As of December 31, 2003, we held:

36,576,564 treasury shares (4.99% of our share capital), which was recorded as a deduction from shareholders equity (see Note D.12.5 to the consolidated financial statements included under Item 18 Financial Statements ). Movements in the share price will not result in an impact on consolidated net income as a result of the holding of these treasury shares.

13,413,698 treasury shares (1.83% of our share capital), which are classified under short-term investments at a net value of 613 million (see note D.10 to the consolidated financial statements included under Item 18 Financial Statements ). Of these shares, 13,183,948 were allocated to stock option plans. 2 million was provisioned in 2003 for impairment of these shares, which amount is equal to shortfall, valued on a plan-by-plan basis, between the average acquisition price of the shares and their average listed stock market price during December 2003 ( 57.34).

Movements in our share price will have an impact on our consolidated net income. The following table shows the impact for a range of movements in our share price:

Movement relative to the average December 2003 listed price of 57.34	Net impact on consolidated net income
	<i>(in millions of )</i>
+20%	+28
+10%	+23
-10%	-23
-20%	-46
-30%	-69

**Table of Contents**

**Item 12. Description of Securities other than Equity Securities**

**A. Debt Securities**

Not applicable.

**B. Warrants and Rights**

Not applicable.

**C. Other Securities**

Not applicable.

**D. American Depositary Shares**

**American Depositary Receipts**

The Bank of New York, as depositary, will execute and deliver ADRs. ADRs are American Depositary Receipts. Each ADR is a certificate evidencing a specific number of ADSs. Each ADS will represent one-half of one share (or the right to receive one-half of one share) deposited with the Paris, France office of BNP Paribas, as custodian.

Each ADS will also represent any other securities, cash or other property that may be held by the depositary under the deposit agreement. The Bank of New York's Corporate Trust Office is located at 101 Barclay Street, New York, New York 10286. The principal executive office of the depositary is located at One Wall Street, New York, New York 10286.

You may hold ADSs either directly (by having an ADR registered in your name) or indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADR holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

As an ADR holder, we will not treat you as one of our shareholders and you will not have shareholder rights. French law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a holder of ADRs, you will have ADR holder rights. A deposit agreement among Sanofi-Synthélabo, the depositary, you, as an ADR holder, and the beneficial owners of ADRs sets out ADR holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs.

The following is a summary of the deposit agreement. For more complete information, you should read the entire deposit agreement and the ADR itself. Directions on how to obtain copies of these from the Securities and Exchange Commission are provided in the section entitled Additional Information. You may also inspect a copy of the deposit agreement at the depositary's Corporate Trust Office.

### **Share Dividends and Other Distributions**

#### ***How Will You Receive Dividends and Other Distributions on the Shares?***

The depositary has agreed to pay to you the cash dividends or other distributions that it or the custodian receives on shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of ADSs you hold.

*Cash.* The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not

## **Table of Contents**

possible or if any approval from the French government is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The section entitled **Taxation of Shareholders** France explains the relevant French tax rules. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the euro, you may lose some or all of the value of the distribution.*

**Shares.** The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. The depositary will only distribute whole ADRs. It will sell shares that would require it to deliver a fractional ADR and distribute the net proceeds in the same way as it distributes cash. If the depositary does not distribute additional ADRs, the outstanding ADRs will also represent the new shares.

**Rights to Receive Additional Shares.** If we offer holders of our shares any rights to subscribe for additional shares or any other rights, the depositary may make these rights available to you. The depositary must first consult with us and we must furnish it with satisfactory evidence that is legal to do so. If we do not furnish this evidence and/or give these instructions, and the depositary decides it is practical to sell the rights, the depositary will sell the rights and distribute the proceeds, in the same way as it distributes cash. The depositary may allow rights that are not distributed or sold to lapse. *In that case, you will receive no value for them.*

If the depositary makes rights available to you, upon instruction from you, it will exercise the rights and purchase the shares on your behalf. The depositary will then deposit the shares and deliver ADRs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

U.S. securities laws may restrict the sale, deposit, cancellation and transfer of ADRs issued upon exercise of rights. For example, you may not be able to trade the ADRs freely in the United States. In this case, the depositary may deliver ADRs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to put the restrictions in place.

**Other Distributions.** The depositary will send to you anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds in the same way as it distributes cash or it may choose any method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. Other than our obligation to register the ADSs, we also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to ADR holders. *This means that you may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to you.*

## **Deposit, Withdrawal and Cancellation**

*How Does the Depositary Deliver ADRs?*

The depositary will deliver ADRs if you or your broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock

## **Table of Contents**

transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADRs at its Corporate Trust Office to the persons you request.

### ***How Do ADR Holders Cancel an ADR and Obtain Shares?***

You may turn in your ADRs at the depositary's Corporate Trust Office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by you and (2) any other deposited securities underlying the ADR at the office of a custodian or, at your request, risk and expense, the depositary will deliver the deposited securities at its Corporate Trust Office.

## **Voting rights**

### ***How Do You Vote?***

You may instruct the depositary to vote the shares underlying your ADRs, but only if we ask the depositary to ask for your instructions. *Otherwise, you will not be able to exercise your right to vote unless you withdraw the shares from the ADR program and vote as an ordinary shareholder. However, you may not know about the meeting sufficiently in advance to withdraw the shares.*

If we ask for your instructions, the depositary will notify you of the upcoming vote and arrange to deliver our voting materials to you. The materials will (1) describe the matters to be voted on and (2) explain how you may instruct the depositary to vote the shares or other deposited securities underlying your ADRs as you direct. For instructions to be valid, the depositary must receive them on or before the date specified. The depositary will try, as far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. The depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.*

Similar to our shares, ADSs evidenced by ADRs registered in the name of the same owner for at least two (2) years will be eligible for double voting rights if certain procedures are followed, as set out in the Deposit Agreement. For additional information regarding double voting rights, see Item 10 Additional Information Memorandum and Articles of Association.

The deposit agreement allows the depositary and Sanofi-Synthelabo to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate to comply with French or United States law or our *statuts*. *For example, you might be required to arrange to have your ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.*



**Table of Contents**

**Fees and Expenses**

*ADR holders must pay:*

\$5.00 (or less) per 100 ADSs (or portion thereof)

\$.02 (or less) per ADS

Registration or Transfer Fees

Expenses of The Bank of New York

Taxes and other governmental charges the depository or the Custodian have to pay on any ADR or share underlying an ADR, for example, stock transfer taxes, stamp duty or withholding taxes

A fee equal to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

*For:*

Each issuance of an ADS, including as a result of a distribution of shares or rights or other property

Each cancellation of an ADS for purposes of withdrawal, including if the agreement terminates

Any cash payment

Transfer and registration of shares on the share register of the foreign registrar from your name to the name of the depository or its agent when you deposit or withdraw shares

Conversion of foreign currency to U.S. dollars

Cable, telex and facsimile transmission expenses

Servicing of shares or deposited securities

As necessary

Distribution of securities to holders of deposited securities by the depository

**Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADRs or on the deposited securities underlying your ADSs. The depository may refuse to transfer your ADRs or allow you to withdraw the deposited securities underlying your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities underlying your ADSs to pay any taxes owed and you will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any proceeds, or send to you any property, remaining after it has paid the taxes.

**Changes affecting Deposited Securities**

*If We:*

Change the nominal or par value of our shares.

Reclassify, split up or consolidate any of the deposited securities.

Distribute securities on the deposited shares that are not distributed to you.

Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or take any similar action.

*Then either:*

The cash, shares or other securities received by the depository will become deposited securities. Each ADS will automatically represent its equal share of the new deposited securities.

*or:*

The depository may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask you to surrender your outstanding



ADRs in exchange for new ADRs identifying the new deposited securities.

## **Table of Contents**

### **Disclosure of Interests**

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to you and any other persons with an interest in the ADRs other than the depositary. The consequences for failure to comply with these provisions will be the same for you and any other persons with an interest as for a holder of our shares. For additional information regarding these obligations, see Item 10 Additional Information Memorandum and Articles of Association Share Capital.

### **Amendment and Termination**

#### ***How May the Deposit Agreement be Amended?***

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of ADR holders, it will only become effective 30 days after the depositary notifies you of the amendment. *At the time an amendment becomes effective, you will be considered, by continuing to hold your ADR, to have agreed to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

#### ***How May the Deposit Agreement be Terminated?***

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify you at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities and (2) deliver shares and other deposited securities upon cancellation of ADRs. One year or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that the depositary will hold the money it received on the sale, as well as any other cash it is holding under the agreement for the pro rata benefit of the ADR holders that have not surrendered their ADRs. It will not invest the money and will have no liability for interest. The depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

### **Limitations on Obligations and Liability to ADR Holders**

#### ***Limits on Our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADRs***

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The deposit agreement expressly limits our obligations and the obligations of the depositary and it limits our liability and the liability of the depositary. We and the depositary:

are obligated only to take the actions specifically set forth in the deposit agreement without negligence or bad faith;

are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;

are not liable if either exercises discretion permitted under the deposit agreement;

have no obligation to become involved in a lawsuit or other proceeding related to the ADRs or the deposit agreement on your behalf or on behalf of any other party; and

## **Table of Contents**

may rely upon any documents it believes in good faith to be genuine and to have been signed or presented by the proper party.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

### **Requirements for Depositary Actions**

Before the depositary will deliver or register transfer of an ADR, make a distribution on an ADR, or process a withdrawal of shares, the depositary may require:

payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADRs, register transfers of ADRs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

### ***Your Right to Receive the Shares Underlying Your ADRs***

You have the right to cancel your ADRs and withdraw the underlying shares at any time except:

when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;

when you or other ADR holders seeking to withdraw shares owe money to pay fees, taxes and similar charges; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADRs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

**Pre-release of ADRs**

Unless we tell the depositary not to, the deposit agreement permits the depositary to deliver ADRs before deposit of the underlying shares. This is called a pre-release of the ADRs. The depositary may also deliver shares upon cancellation of pre-released ADRs (even if the ADRs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADRs instead of shares to close out a pre-release. The depositary may pre-release ADRs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depositary in writing that it or its customer (i) owns the shares or ADRs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so.

**Table of Contents**

**PART II**

**Item 13. Defaults, Dividend Arrearages and Delinquencies.**

Not applicable.

**Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.**

Not applicable.

**Item 15. Controls and Procedures**

*Disclosure Controls and Procedures*

We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon our evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, the disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in the reports we file and submit under the Exchange Act is recorded, processed, summarized and reported as and when required.

*French Descriptive Report on Internal Controls*

Under French law, we are required to publish descriptions of the material elements of our internal control procedures. The French report is not the equivalent of the report we will be required to file under the Sarbanes-Oxley Act of 2002 beginning with the annual report to be filed for the year ending December 31, 2005. An English translation of our French report is filed as an exhibit to this annual report.

**Item 16. [Reserved]**

**Item 16.A. Audit Committee Financial Expert**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In 2003, our board of directors appointed Gérard Van Kemmel to be the financial expert for the Audit Committee. The board of directors determined that Mr. Van Kemmel was qualified for the position based on his experience as a partner at an international accounting firm.

### **Item 16.B. Code of Ethics**

We have adopted a code of ethics, as defined in Item 16.B. of Form 20-F under the Exchange Act. Our code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our code of ethics is available on our Website at [www.sanofi-synthelabo.com](http://www.sanofi-synthelabo.com). We will disclose any amendment to the provisions of such code of ethics or any waiver that our board of directors may grant on our Website at the same address.

### **Item 16.C. Principal Accountant Fees and Services**

Pursuant to French law, our company has engaged two independent accounting firms to audit our accounts and provide related services permissible under applicable French and U.S. laws and regulations. In respect of fiscal year 2003, our independent statutory auditors are Ernst & Young Audit and PricewaterhouseCoopers Audit. In accordance with French law, we consider each of these auditing firms as our principal accountants.

## **Table of Contents**

During 2003, we paid total fees of 4.7 million to Ernst & Young Audit and 3.6 million to PricewaterhouseCoopers Audit for the services described below.

### **Audit Fees**

We paid 2.5 million to Ernst & Young Audit and 2.4 million to PricewaterhouseCoopers Audit for professional audit services in 2003 and 2.5 million to Ernst & Young Audit and 2.8 million to PricewaterhouseCoopers Audit for professional audit services in 2002.

### **Audit-Related Fees**

We paid 0.9 million to Ernst & Young Audit and 0.7 million to PricewaterhouseCoopers Audit for audit-related services in 2003 and 0.7 million to Ernst & Young Audit and 0.2 million to PricewaterhouseCoopers Audit for audit-related services in 2002. Such audit-related services included assistance in analyzing International Financial Reporting Standards and implementation of the Sarbanes-Oxley Act of 2002 and the French Financial Security Law (*Loi de Sécurité Financière*) of 2003.

### **Tax Fees**

We paid 0.9 million to Ernst & Young Audit and 0.4 million to PricewaterhouseCoopers Audit for tax services in 2003 and 0.5 million to Ernst & Young Audit and 0.5 million to PricewaterhouseCoopers Audit for tax services in 2002. Such tax services included preparation of local tax returns, assistance in documentation of our transfer pricing policy and consulting on various tax matters.

### **All Other Fees**

We paid 0.4 million to Ernst & Young Audit and 0.1 million to PricewaterhouseCoopers Audit for other professional services in 2003 and 0.1 million to Ernst & Young Audit for other professional services in 2002. Such other services primarily included the preparation of a comparative study of different accounting principles.

### **Audit Committee Pre-Approval Policies and Procedures**

Our audit committee is responsible, among other matters, for the oversight of our independent statutory auditors subject to the requirements of French law. Our audit committee has established a list of prohibited non-audit services in order to ensure the independence of our independent statutory auditors. Our audit committee has also adopted a policy and established certain procedures for the approval of audit and permissible non-audit services and for the pre-approval of permissible non-audit services to be provided by our independent statutory auditors. During 2003, our audit committee established an annual budget, broken down and detailed as to the type of service to be provided and the authorized amount for such service, for all permissible non-audit services (including on-going non-audit engagements). Our audit committee also delegated to the



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Chairman the responsibility for pre-approving any new permissible non-audit engagements that fell within such budgeted amounts for the particular permissible non-audit service. Any engagements pre-approved by the Chairman must be reported to the full audit committee at its next succeeding meeting.

During 2003, no services were provided to our company by our independent statutory auditors pursuant to the *de minimis* exception to the pre-approval requirement provided by paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X.

### **16.D. Exemptions from the Listing Standards for Audit Committees**

Not applicable.

**Table of Contents**

**PART III**

**Item 17.**

See Item 18.

**Item 18. Financial Statements**

See pages F-1 through F-66, incorporated herein by reference.

**Item 19. Exhibits**

Documents filed as exhibits to this annual report:

- 1.1 Bylaws (*statuts*) of Sanofi-Synthélabo (English translation) (incorporated herein by reference to Exhibit 3.1 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.1 Form of Deposit Agreement between Sanofi-Synthélabo and The Bank of New York, as depositary (incorporated herein by reference to Exhibit A to the Registration Statement on Form F-6 dated June 26, 2002 relating to our American Depositary Shares, SEC File No. 333-91658)
- 2.2 Shareholders Agreement among Elf Aquitaine, Valorisation et Gestion Financière and L Oréal dated April 9, 1999 (English translation) (incorporated herein by reference to Exhibit 2.2. to our Registration Statement on Form 20-F dated June 25, 2002, SEC File No. 001-31368)
- 2.3 Amendment to Shareholders Agreement among Elf Aquitaine, Valorisation et Gestion Financière and L Oréal dated November 24, 2003 (English translation) (incorporated herein by reference to Exhibit 10.2 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.4 Protocol of Agreement, dated January 25, 2004, between Total S.A., Elf Aquitaine, Valorisation et Gestion Financière and L Oréal (English translation) (incorporated herein by reference to Exhibit 10.3 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.5 Credit Facility Agreement dated January 25, 2004 between Sanofi-Synthélabo and BNP Paribas and Merrill Lynch Credit Products (incorporated herein by reference to Exhibit 10.4 to Amendment No. 2 to our Registration Statement on Form F-4 dated March 29, 2004, SEC File No. 333-112314)
- 8.1 For a list of our significant subsidiaries, see Item 4 Information on the Company Organizational Structure
- 12.1 Certifications by Jean-François Dehecq, Chairman and Chief Executive Officer, and Marie-Hélène Laimay, Chief Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

- 13.1 Certifications by Jean-François Dehecq, Chairman and Chief Executive Officer, and Marie-Hélène Laimay, Chief Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 14.1 Consent of Ernst & Young Audit dated April 2, 2004
- 14.2 Consent of PricewaterhouseCoopers Audit dated April 2, 2004
- 99.1 Report of the Chairman of the Board of Directors for 2003 as required by Art. 117 of the French Financial Security Law (*Loi de Sécurité Financière*) (English Translation)

**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

Report of Independent Auditors	F-2
Consolidated Balance Sheets as of December 31, 2003, 2002 and 2001	F-3
Consolidated Statements of Income for the Years Ended December 31, 2003, 2002, and 2001	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2003, 2002 and 2001	F-6
Consolidated Statements of Shareholders' Equity for the Years Ended December 31, 2003, 2002 and 2001	F-7
Notes to the Consolidated Financial Statements	F-8

**Table of Contents**

<b>PricewaterhouseCoopers</b>	<b>Ernst &amp; Young Audit</b>
<b>Audit</b>	Tour Ernst & Young
32, rue Guersant	11, Allée de l' Arche
75017 Paris	92400 Courbevoie
S.A. au capital de EUR. 2 510 460	S.A. au capital de EUR.3.044.220
672 006 483 RCS Paris	344 366 315 R.C.S. Paris
Commissaire aux comptes	Commissaire aux Comptes
Membre de la Compagnie	Membre de la Compagnie
Régionale de Paris	Régionale de Paris

**REPORT OF INDEPENDENT AUDITORS**

To the Board of Directors and Shareholders of Sanofi-Synthelabo:

We have audited the accompanying consolidated balance sheets of Sanofi-Synthelabo and its subsidiaries (together, the Group) as of December 31, 2003, 2002 and 2001, and the related consolidated statements of income, cash flows and shareholders' equity for each of the three years in the period ended December 31, 2003, all expressed in millions of euro. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2003, 2002 and 2001, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003 in conformity with accounting principles generally accepted in France.

As discussed in note B2, the Group changed its method of accounting for liabilities as of January 1, 2002.

Accounting principles generally accepted in France vary in certain significant respects from accounting principles generally accepted in the United States of America. Information relating to the nature and effect of such differences is presented in Note G to the consolidated financial statements.

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Paris, France

March 22, 2004

PricewaterhouseCoopers Audit

Ernst & Young Audit

Jacques Denizeau

Jean-Christophe Georghiou

Jean-Claude Lomberget

Valérie Quint

F-2

**Table of Contents****SANOFI-SYNTHELABO****CONSOLIDATED BALANCE SHEETS****Before appropriation of profit**

		December 31,	December 31,	December 31,
	Note	2003	2002	2001
<i>in millions of euros</i>				
<b>ASSETS</b>				
<b>Intangible assets, net</b>	D.2			
Goodwill		124	134	141
Other intangible assets		897	1,161	668
		<u>1,021</u>	<u>1,295</u>	<u>809</u>
<b>Property, plant and equipment</b>	D.3			
Gross		2,230	1,989	1,630
Accumulated depreciation		(781)	(594)	(401)
<b>Net</b>		1,449	1,395	1,229
<b>Long-term investments</b>				
Investments in/advances to equity investees	D.5	126	109	100
Investments in/advances to non-consolidated companies	D.6	8	27	110
Other long-term investments	D.6	108	73	48
		<u>2,712</u>	<u>2,899</u>	<u>2,296</u>
<b>Total fixed assets</b>				
Deferred income taxes	D.11	472	484	471
Inventories	D.7	799	823	805
Accounts receivable	D.8	1,491	1,311	1,566
Other current assets	D.9	897	854	540
Short-term investments and deposits	D.10	3,226	2,944	4,166
Cash		152	144	123
		<u>9,749</u>	<u>9,459</u>	<u>9,967</u>
<b>TOTAL ASSETS</b>				

*The accompanying notes are an integral part of the consolidated financial statements.*

**Table of Contents****SANOFI-SYNTHELABO****CONSOLIDATED BALANCE SHEETS****Before appropriation of profit**

		December 31,	December 31,	December 31,
	Note	2003	2002	2001
<i>in millions of euros</i>				
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>				
<b>Shareholders equity</b>				
Share capital	D.12	1,466	1,465	1,464
(December 31, 2003: 732,848,072 shares; December 31, 2002: 732,367,507 shares; December 31, 2001: 732,005,084 shares)				
Additional paid in capital and reserves		3,185	2,971	2,736
Net income for the period		2,076	1,759	1,585
Cumulative translation adjustment		(404)	(160)	(17)
<b>Total shareholders equity</b>		<b>6,323</b>	<b>6,035</b>	<b>5,768</b>
Minority interests		18	17	21
Long-term debt	D.13	53	65	119
Provisions and other long-term liabilities	D.14	754	786	1,053
Deferred income taxes	D.11	9	10	10
Accounts payable		657	596	717
Other current liabilities	D.15	1,620	1,599	1,994
Short-term debt	D.16	315	351	285
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>		<b>9,749</b>	<b>9,459</b>	<b>9,967</b>

*The accompanying notes are an integral part of the consolidated financial statements.*



**Table of Contents****SANOFI-SYNTHELABO****CONSOLIDATED STATEMENTS OF INCOME**

	Note	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
<i>in millions of euros</i>				
Net sales	D.27-D.28	8,048	7,448	6,488
Cost of goods sold		(1,428)	(1,378)	(1,253)
<b>Gross profit</b>		<b>6,620</b>	<b>6,070</b>	<b>5,235</b>
Research and development expenses		(1,316)	(1,218)	(1,031)
Selling and general expenses		(2,477)	(2,428)	(2,306)
Other operating income/(expense), net	D.21	248	190	208
<b>Operating profit</b>	B.15-D.28	<b>3,075</b>	<b>2,614</b>	<b>2,106</b>
Intangibles amortization and impairment		(129)	(129)	(68)
Financial income/(expense), net	D.22	155	85	102
<b>Income before tax and exceptional items</b>		<b>3,101</b>	<b>2,570</b>	<b>2,140</b>
Exceptional items	D.23	24	10	281
Income taxes	D.24	(1,058)	(746)	(842)
<b>Net income before income from equity investees, goodwill amortization and minority interests</b>		<b>2,067</b>	<b>1,834</b>	<b>1,579</b>
Income from equity investees, net	D.5	20	20	14
Goodwill amortization		(8)	(8)	(7)
<b>Net income before minority interests</b>		<b>2,079</b>	<b>1,846</b>	<b>1,586</b>
Minority interests	D.25	(3)	(87)	(1)
<b>Net income</b>		<b>2,076</b>	<b>1,759</b>	<b>1,585</b>
Weighted average shares outstanding		702,745,208	727,686,372	731,711,225
<b>Earnings per share, basic and diluted (in euros)</b>		<b>2.95</b>	<b>2.42</b>	<b>2.17</b>

*The accompanying notes are an integral part of the consolidated financial statements.*

**Table of Contents****SANOFI-SYNTHELABO****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Note	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
<i>in millions of euros</i>				
<b>Net income</b>		2,076	1,759	1,585
Minority interests		3	87	1
Share in undistributed earnings of equity investees		(20)	(20)	(14)
Depreciation and amortization		390	379	301
Gains on disposals of fixed assets, net of income taxes		(15)	(9)	(216)
Provisions, long-term deferred taxes and other		(6)	64	75
<b>Operating cash flow before changes in working capital</b>		2,428	2,260	1,732
Dividends received from equity investees			11	
(Increase)/decrease in inventories		(55)	(78)	(105)
(Increase)/decrease in accounts receivable		(206)	(18)	(235)
Increase/(decrease) in accounts payable		65	(77)	70
Change in other operating assets and liabilities (net)		33	(422)	356
<b>Net cash provided by operating activities (A)</b>		2,265	1,676	1,818
Acquisitions of property, plant & equipment and intangibles	D.4	(371)	(1,403)	(565)
Acquisitions of investments		(10)	(32)	(54)
Proceeds from disposals of fixed assets, net of income taxes		27	22	492
Net change in loans, long-term advances and other investing cash flows		4	4	14
<b>Net cash used in investing activities (B)</b>		(350)	(1,409)	(113)
Issuance of Sanofi-Synthelabo shares	D.12	7	4	7
Capital contribution from minority shareholders		3	5	
Dividends paid:				
to Sanofi-Synthelabo shareholders		(579)	(473)	(317)
to minority shareholders of subsidiaries		(3)	(3)	(6)
Additional long-term borrowings		1	1	9
Repayments of long-term borrowings		(57)	(9)	(12)
Net change in short-term borrowings		33	54	(1)
Acquisitions of treasury shares net of disposals, including disposals made in connection with stock option plans		(1,003)	(1,170)	(163)
<b>Net cash used in financing activities (C)</b>		(1,598)	(1,591)	(483)
Impact of exchange rates on cash and cash equivalents (D)		(17)	(16)	3
<b>Net change in cash and cash equivalents (A) + (B) + (C) + (D)</b>		300	(1,340)	1,225
Cash and cash equivalents, beginning of period	B.10	2,465	3,805	2,580
Cash and cash equivalents, end of period	B.10	2,765	2,465	3,805

*The accompanying notes are an integral part of the consolidated financial statements.*

F-6

Table of Contents

## SANOFI-SYNTHELABO

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

	Number of	Share	Additional	Cumulative	
	Shares	Capital	Capital and	Translation	Total
	<u>Shares</u>	<u>Capital</u>	<u>Reserves</u>	<u>Adjustment</u>	<u>Total</u>
			<i>in millions of euros</i>		
<b>Balance, December 31, 2000</b>	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 the year ended December 31, 2001			1,585		1,585
Adjustments related to the Sanofi-Synthelabo merger (note D.12.4.)			176		176
Movement in cumulative translation adjustment				13	13
<b>Balance, December 31, 2001</b>	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 the year ended December 31, 2002			1,759		1,759
Adjustments related to the Sanofi-Synthelabo merger (note D.12.4.)			59		59
Change in accounting method (note D.12.3.)			24		24
Repurchase of shares (note D.12.5.)			(963)		(963)
Movement in cumulative translation adjustment				(143)	(143)
<b>Balance, December 31, 2002</b>	732,367,507	1,465	4,730	(160)	6,035
Dividends paid out of 2002 earnings ( 0.84 per share)			(579)		(579)
Issuance of shares on exercise of stock options	480,565	1	6		7
Net income for the year ended December 31, 2003			2,076		2,076
Adjustments related to the Sanofi-Synthelabo merger (note D.12.4.)			45		45
Repurchase of shares (note D.12.5.)			(1,017)		(1,017)
Movement in cumulative translation adjustment				(244)	(244)
<b>Balance, December 31, 2003</b>	732,848,072	1,466	5,261	(404)	6,323

The accompanying notes are an integral part of the consolidated financial statements.



**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**YEAR ENDED DECEMBER 31, 2003**

**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 and applicable with effect from January 1, 2000. Under the option allowed by this rule, acquisitions of companies occurring prior to January 1, 2000 have not been restated.

Pursuant to CRC Rule 2000-06, which took effect on January 1, 2002, the Group reviewed all its liabilities as of that date for compliance with the new rule (see notes B.2.b and D.12.3).

The accounting policies and methods used are identical to those applied in the preparation of the consolidated financial statements for the year ended December 31, 2002, except for the new CRC Rule 2002-10 on the depreciation, amortization and impairment of assets, which Sanofi-Synthélabo Group has applied with effect from January 1, 2003 (see note B.2.a).

**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.

**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. 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.

## **Table of Contents**

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. 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.

A list of companies included in the consolidation is presented in section F. of the notes to the consolidated financial statements.

The main non-consolidated companies are presented in note D.6.

### **B.2. Changes in accounting method**

#### **a) CRC Rule 2002-10**

Sanofi-Synthelabo has taken steps to comply with the new CRC Rule 2002-10 requiring a more detailed analysis of fixed assets. A review conducted by the Group showed that the only assets for which more detailed analysis was required were buildings and fixtures. As a result, the depreciation period for these assets has been adjusted from an average period of 20 years to periods ranging between 10 and 30 years.

Adoption of CRC Rule 2002-10 had no material impact on the Group's financial statements.

#### **b) CRC Rule 2000-06**

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 in 2002 of applying this new rule was an adjustment to shareholders' equity of 24 million euros net of income taxes (see note D.12.3).

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

## **Table of Contents**

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**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

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 the Group 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.

F-10

**Table of Contents**

**B.7. Property, plant and equipment**

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 and fixtures	10 to 30 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 acquired and held in connection with stock option plans and allocated to these plans over the term of the plan. The valuation method used depends on the probability that the option will be exercised:

where exercise is **probable**, because the exercise price is lower than the stock market price at the balance sheet date, the shares are valued plan by plan at the lower of acquisition cost or exercise price;

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

where exercise is **improbable**, because the exercise price is higher than the stock market price at the balance sheet date, and in the case of shares not yet allocated to options or allocated to plans that have lapsed, the shares are valued at the lower of the average acquisition cost of all these shares or the average stock market price for the last month of the financial year.

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

F-11

## **Table of Contents**

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 under Research and development expenses .

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. Operating profit**

Operating profit includes profits and losses from joint venture operations, in particular with Bristol-Myers Squibb, which are shown on the line Other operating income and expense (see notes B.14 and C.1). Amortization and impairment of intangible fixed assets, which are technically an operating item, are shown on a separate line below operating profit, in line with the definition used by the Group.

### **B.16. 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.17. Financial income/(expense), net**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

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.18. 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.19. 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.

## **Table of Contents**

The Group accounts for deferred taxes using the liability method, whereby deferred income taxes are recognized on:

differences between the tax and carrying amounts of assets and liabilities; and

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.20. 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.21. 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.22. Earnings per share**

Basic earnings per share is 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 the light of market conditions. In the event of a stock split or bonus issue of shares, earnings per share for prior periods is adjusted accordingly.

## **Table of Contents**

Diluted earnings per share is 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) other countries (excluding Japan), under the operational management of BMS. In Japan, Sanofi-Synthélabo has granted a license for irbesartan to BMS and Shionogi, a Japanese pharmaceutical company. The alliance agreement does not cover the distribution of Plavix in Japan.

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) In most countries of Western Europe and Asia for clopidogrel (Plavix®/Iscover®) (excluding Japan), co-promotion is used for both products. 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

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

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) In Germany, Spain and Greece, and in Italy for irbesartan only (Aprovel®/Avapro®/ Karvea®), co-marketing is used for both products, and 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 .

**Table of Contents**

- (ii) In Brazil, Mexico, Argentina, Colombia for clopidogrel (Plavix®/Iscover®) and Australia, co-marketing is used, and 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.

**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, 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 Pharmaceuticals, 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 47% of the profits in 2001 (against 53% for Pharmacia-Searle). The difference between the net income of Lorex Pharmaceuticals 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 Sanofi-Synthélabo of the 51% interest owned by Pharmacia-Searle on April 16, 2002.

**As from December 30, 2001:**

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. With effect from January 1, 2002, Sanofi-Synthélabo fully consolidated the Lorex Pharmaceuticals statement of income. 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 gross value of 697 million dollars.

**C.3. Alliance agreements with Organon**

The alliance with Organon, a subsidiary of Akzo Nobel, defined by the agreement of June 28, 2000, governs the arrangements for the marketing of Arixtra<sup>®</sup> and for the sharing of profits worldwide. Arixtra<sup>®</sup> was launched in America and Europe in 2002. Marketing arrangements vary depending on the region involved:

- (i) North America: In the United States, Mexico and Canada, Arixtra<sup>®</sup> is sold by companies controlled jointly with Organon. Sales and expenses relating to Arixtra<sup>®</sup> are recorded using the proportionate consolidation method based on the 50% interest held by Sanofi-Synthélabo in the joint venture.

F-15

**Table of Contents**

- (ii) Europe and the rest of the world (excluding Japan): Sanofi-Synthélabo markets and sells Arixtra<sup>®</sup> in the same way as its other products, and includes all sales in these countries in consolidated net sales. Sanofi-Synthélabo has an exclusive license to market Arixtra<sup>®</sup> in these territories. The royalty paid to Organon on the basis of these sales is accounted for in cost of goods sold.

As of December 31, 2003, the financial statements of the entities which market Arixtra<sup>®</sup> in the United States, Canada and Mexico are consolidated using the proportionate consolidation method.

On January 7, 2004, Sanofi-Synthélabo reached agreement with Organon to acquire all Organon's rights relating to Arixtra<sup>®</sup>, idraparinux and other oligosaccharides.

Sanofi-Synthélabo will make payments to Organon based largely on future sales, and will bear all research and development costs.

Sanofi-Synthélabo will also buy at net book value the interests held by Organon in the entities dedicated to this activity.

Consequently, the financial statements of these entities will be consolidated by Sanofi-Synthélabo using the full consolidation method with effect from January 1, 2004 (see note E).

***D. DETAILED NOTES TO THE FINANCIAL STATEMENTS***

**D.1. Changes in the scope of consolidation**

**Significant changes in 2003:**

***Acquisitions***

During 2003, the Group acquired minority interests held by third parties in companies located in Colombia and Peru, plus 20% of a joint venture in China.

The acquisitions made during the year resulted in the recognition of goodwill with a gross value of 7 million euros as of December 31, 2003.

***Divestitures***

These were no significant divestitures in the year ended December 31, 2003.

**Significant changes in 2002:**

*Acquisitions*

The three main acquisitions during the period were:

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.

Acquisition on January 1, 2002 of 100% of Institut Médical Algérien.

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.

## **Table of Contents**

### *Divestitures*

These were no significant divestitures in the year ended December 31, 2002.

### *Change in method of consolidation*

The Fujisawa Sanofi-Synthelabo (Japan) joint venture is proportionately consolidated at a rate of 51%, in order to reflect new agreements that took effect in 2002. This entity was accounted for using the full consolidation method at a rate of 51% in the year ended December 31, 2001.

### **Significant changes in 2001:**

#### *Acquisitions*

Further to an agreement signed by Sanofi-Synthelabo and Pharmacia-Searle on December 30, 2001 (note C.2), the Lorex Pharmaceuticals balance sheet was fully consolidated as of December 31, 2001.

On a 100% basis, Lorex Pharmaceuticals generated net sales of 905 million dollars and net income before taxes of 576 million dollars in 2001.

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:

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).

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





**Table of Contents**

After this sale, and based on available information as of December 31, 2002, the Group owns 39.1% of Financière des Laboratoires de Cosmétologie Yves Rocher, the parent company of the Yves Rocher cosmetics group. This holding company in turn holds a direct interest of 48.8% in Laboratoires de Biologie Végétale Yves Rocher.

**D.2. Intangible assets**

Intangible assets as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
<b>Goodwill</b>	148	153	153
Trademarks	66	53	51
Patents, concessions, licenses and other	1,091	1,282	697
Software	171	135	103
<b>Sub-total other intangible assets</b>	1,328	1,470	851
<b>GROSS</b>	1,476	1,623	1,004
Amortization and impairment	(455)	(328)	(195)
<b>NET</b>	1,021	1,295	809

The increase in Patents, concessions, licenses and other in the year ended December 31, 2002 was principally due to the purchase of the rights to Ambien in the United States.

The decrease in this line during 2003 was related to the fall in the dollar, the currency in which the US rights to Ambien are expressed.

**D.3. Property, plant and equipment**

Property, plant and equipment as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Land	50	52	50

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Buildings	692	611	507
Plant and equipment	942	797	679
Fixtures, fittings and other	341	311	249
Fixed assets in progress	205	218	145
	<u>          </u>	<u>          </u>	<u>          </u>
<b>GROSS</b>	2,230	1,989	1,630
	<u>          </u>	<u>          </u>	<u>          </u>
Depreciation and impairment	(781)	(594)	(401)
	<u>          </u>	<u>          </u>	<u>          </u>
<b>NET</b>	1,449	1,395	1,229
	<u>          </u>	<u>          </u>	<u>          </u>

Depreciation expense for the year ended December 31, 2003 amounted to 225 million euros, against 217 million euros for the year ended December 31, 2002 and 194 million euros for the year ended December 31, 2001.

**Table of Contents**

Included in property, plant and equipment are the following balances relating to capitalized leases as of December 31, 2003, 2002 and 2001:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Land	9	9	9
Buildings	105	105	107
Plant and equipment			
<b>GROSS</b>	<b>114</b>	<b>114</b>	<b>116</b>
Depreciation and impairment	(61)	(56)	(51)
<b>NET</b>	<b>53</b>	<b>58</b>	<b>65</b>

**D.4. 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, 2003	Year ended Dec. 31, 2002	Year ended Dec. 31, 2001
		<i>(in millions of euros)</i>	
Acquisitions of intangible assets	33	980	282
Acquisitions of property, plant & equipment	338	423	283
<b>TOTAL</b>	<b>371</b>	<b>1,403</b>	<b>565</b>

In 2003, acquisitions of intangible assets comprised purchases of software (24 million euros) and purchases of pharmaceutical products (9 million euros).

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.

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 was related to increases in production capacity for new products.

**D.5. Investments in/advances to equity investees**

Investments in and advances to equity investees as of December 31, 2003, 2002 and 2001 comprise:

	<b>December 31,</b>	<b>December 31,</b>	<b>December 31,</b>
	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<u>          </u>	<u>          </u>	<u>          </u>
		<i>(in millions of euros)</i>	
Financière des Laboratoires de Cosmétologie Yves Rocher	108	92	84
Other investments and advances	18	17	16
	<u>          </u>	<u>          </u>	<u>          </u>
<b>TOTAL</b>	<b>126</b>	<b>109</b>	<b>100</b>
	<u>          </u>	<u>          </u>	<u>          </u>

**Table of Contents**

As of December 31, 2003, investments in and advances to equity investees mainly comprised the 39.1% interest in Financière des Laboratoires de Cosmétologie Yves Rocher. This holding company has a direct interest of 48.8% in Laboratoires de Biologie Végétale Yves Rocher.

**D.6. Investments in/advances to non-consolidated companies and other long-term investments**

	<u>Country</u>	<u>Gross</u>	<u>Provision</u>	<u>Net</u>	<u>Financial interest %</u>	<u>Business</u>
<b>Investments in/advances to non-consolidated companies</b>						
Laboratoires Goemar	France	5	(2)	3	20%	Personal hygiene products
Tersan Insaat Ve Ticaret As	Turkey	1		1	100%	Real estate
Adwya S.A.	Tunisia	1		1	10%	Pharmaceuticals
Barberet Blanc Italia	Italy	2	(2)		100%	Dormant
Barberet Blanc Talee	Italy	1	(1)		100%	Dormant
Other investments and advances		7	(4)	3		
		<u>17</u>	<u>(9)</u>	<u>8</u>		
<b>Total investments in/advances to non-consolidated companies</b>						

Most non-consolidated companies controlled by the Group are dormant companies.

The aggregate balance sheet total of these companies is less than 15 million euros, and their aggregate sales are less than 5 million euros.

	<u>Country</u>	<u>Gross</u>	<u>Provision</u>	<u>Net</u>	<u>Financial interest %</u>	<u>Business</u>
<b>Long-term investment securities</b>						
Viropharma Inc	USA	19	(18)	1	3%	Pharmaceuticals
Atrix Inc	USA	12		12	4%	Pharmaceuticals
IDM (see note D. 18)	France	21		21	12.5%	Research & development
<b>Other items</b>						
Long-term loans <sup>(1)</sup>		5		5		
Pre-funded pension and other benefits (see note D. 14.1)		52		52		
Other <sup>(2)</sup>		32	(15)	17		
		<u>141</u>	<u>(33)</u>	<u>108</u>		
<b>Total other long-term investments</b>						

(1) Mainly loans to employees.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

(2) Including funds deposited as security under insurance policies (5 million euros) and other security deposits (10 million euros).

As of December 31, 2001, 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 and December 31, 2003 (see note D.9).

F-20

**Table of Contents****D.7. Inventories**

Inventories as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Raw materials	236	288	305
Work in process	201	144	113
Finished goods	463	474	442
<b>GROSS</b>	<b>900</b>	<b>906</b>	<b>860</b>
Provision	(101)	(83)	(55)
<b>NET</b>	<b>799</b>	<b>823</b>	<b>805</b>

Given the diversity of the activities carried on by the Group, some products sold within the Group and to third parties may be classified alternatively as raw materials, work in process or finished goods, depending on the circumstances. The inventory split shown above uses the classifications adopted by the subsidiary holding the inventory.

The table below shows the movement in inventory provisions for the years ended 2003, 2002 and 2001.

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		<i>(in millions of euros)</i>	
<b>Balance, beginning of period</b>	<b>(83)</b>	<b>(55)</b>	<b>(33)</b>
Movement in provisions recognized in net income for the period	(48)	(85)	(66)
Provisions utilized	23	53	37
Change in scope of consolidation		(2)	8
Effect of exchange rates	7	6	(1)
<b>BALANCE, END OF PERIOD</b>	<b>(101)</b>	<b>(83)</b>	<b>(55)</b>

**D.8. Accounts receivable**



Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Accounts receivable as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Gross	1,556	1,348	1,585
Provision	(65)	(37)	(19)
<b>NET</b>	<b>1,491</b>	<b>1,311</b>	<b>1,566</b>

**D.9. Other current assets**

Other current assets as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Taxes recoverable	249	335	215
Other receivables	584	462	282
Prepaid expenses	64	57	43
<b>TOTAL (NET)</b>	<b>897</b>	<b>854</b>	<b>540</b>

**Table of Contents**

Other current assets as of December 31, 2003 and December 31, 2002 include receivables relating to operations with joint venture and alliance partners, shown in 2001 under Investments in/advances to non-consolidated companies (see note D.6). The reclassification of these balances as of January 1, 2002 amounted to 83 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, 2003 Sanofi-Synthelabo held treasury shares, mainly allocated to employee stock option plans, with a net value of 613 million euros, after taking account of a reversal of provisions of 2 million euros in 2003. The value of treasury shares held was 623 million euros as of December 31, 2002, after taking account of additional provisions of 46 million euros booked in 2002, and 462 million euros as of December 31, 2001. The market value of treasury shares was 769 million euros as of December 31, 2003, against 813 million euros as of December 31, 2002, compared with 957 million euros as of December 31, 2001. These shares are included in Short-term investments and deposits. As of December 31, 2003, the 13,413,698 treasury shares held by the Group and recorded on this line represented 1.83% of the capital, and 13,183,948 of these shares were allocated to employee stock option plans.

In the light of the listed market price of the shares on the balance sheet date and during the 20 days preceding the balance sheet date, this line includes a provision for impairment of 44 million euros as of December 31, 2003.

**D.11. Deferred income taxes**

Net deferred tax assets as of December 31, 2003, 2002 and 2001 comprise:

	December 31, 2003	December 31, 2002	December 31, 2001
	<u>          </u>	<u>          </u>	<u>          </u>
	<i>(in millions of euros)</i>		
<b>Deferred income taxes on:</b>			
Consolidation adjustments	275	237	207
Provision for pensions & other employee benefits	39	35	55
Other non-deductible provisions & other items	149	202	199
	<u>          </u>	<u>          </u>	<u>          </u>
<b>TOTAL NET DEFERRED TAX ASSETS</b>	<b>463</b>	<b>474</b>	<b>461</b>
	<u>          </u>	<u>          </u>	<u>          </u>

Deferred tax assets not recognized because of uncertainty as to their future recovery amounted to 182 million euros as of December 31, 2003, against 243 million euros as of December 31, 2002 and 313 million euros as of December 31, 2001.

As of December 31, 2003, the Group had total tax loss carryforwards of 233 million euros, which are due to expire as follows:

	<b>Loss</b>
	<u>(in millions of euros)</u>
2004	5
2005	3
2006	4
2007	13
2008	3
2009 and thereafter	205
<b>TOTAL</b>	<b><u>233</u></b>

**Table of Contents**

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 the 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 294 million euros as of December 31, 2003.

**D.12. Shareholders' equity****D.12.1. Share capital**

The share capital comprises 732,848,072 shares with a par value of 2 euros per share.

Treasury shares held by Sanofi-Synthélabo are as follows:

Balance sheet date	Number of shares	%
December 31, 2003	49,990,262	6.82%
December 31, 2002	30,376,375	4.15%
December 31, 2001	11,419,291	1.56%

**D.12.2. Reserves subject to restrictions on distribution**

As of December 31, 2003, 742 million euros of the Group's consolidated reserves were non-distributable. Of this amount, 186 million euros constitutes a legal reserve which is restricted as to distribution. The remaining 556 million euros principally represents a portion of net long-term gains on disposals whose distribution would be subject to supplementary taxation.

**D.12.3. Change in accounting method**

In application of the new CRC Rule 2000-06, non-compliant provisions totaling 24 million euros net of taxes were reversed as of January 1, 2002 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, adjustments of 45 million euros, 59 million euros and 176 million euros were made to shareholders' equity in 2003, 2002 and 2001 respectively.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

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:

	2003	2002	2001
	<i>(in millions of euros)</i>		
Change in provision for risks and deferred income taxes recorded in the opening balance sheet	44	59	90
Allocation of goodwill to divestitures			34
Revaluation of commitments to employees	1		52
	45	59	176
<b>TOTAL</b>	<b>45</b>	<b>59</b>	<b>176</b>

**Table of Contents**

In 2003, 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.

**D.12.5. Repurchase of shares**

The Annual General Meetings of May 22, 2002 and May 19, 2003 authorized the implementation of share purchase programs amounting to 10% of Sanofi-Synthélabo shares. Under these authorizations, the Group continued in 2003 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 these programs, the Group repurchased 20,192,769 shares in 2003 for 1,018 million euros, and 16,520,795 shares in 2002 for 970 million euros.

As of December 31, 2003 the Group held 36,576,564 shares under these programs, amounting to 1,979 million euros.

**D.12.6. Stock-based compensation****a) Plans pre-dating the May 18, 1999 merger****Options to purchase Group shares**

Sanofi and Synthélabo operated 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.

Details of the stock purchase options granted under the Group's various plans are presented below (in Sanofi-Synthélabo equivalent shares):

Origin	Date of Grant	Options Granted	Start date of		Exercise Price (in euros)	Options
			Vesting Period	Expiration Date		Exercised as of 12/31/03
Synthélabo	12/15/1993	364,000	12/15/1998	12/15/2013	6.36	348,400
Synthélabo	10/18/1994	330,200	10/18/1999	10/18/2014	6.01	305,200
Synthélabo	12/15/1995	442,000	12/15/2000	12/15/2015	8.50	387,900
Synthélabo	01/12/1996	208,000	01/12/2001	01/12/2016	8.56	149,230
Synthélabo	04/05/1996	228,800	04/05/2001	04/05/2016	10.85	141,034
Sanofi	09/22/1997	1,120,000	09/23/1999	09/22/2004	21.46	450,280
Synthélabo	10/14/1997	262,080	10/14/2002	10/14/2017	19.73	105,868
Synthélabo	06/25/1998	296,400	06/26/2003	06/25/2018	28.38	124,880
Sanofi	12/10/1998	1,200,000	12/11/2000	12/10/2005	34.95	72,020
Synthélabo	03/30/1999	716,040	03/31/2004	03/30/2019	38.08	6,240

Shares offered under these plans are acquired in the stock market. Consequently, these plans have no impact on shareholders' equity as of December 31, 2003.

**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.

**Table of Contents**

Details of the options granted under this plan are presented below (in Sanofi-Synthélabo equivalent shares):

<u>Origin</u>	<u>Date of grant</u>	<u>Options granted</u>	<u>Start date of vesting period</u>	<u>Expiration date</u>	<u>Exercise price (in euros)</u>	<u>Options exercised as of 09/18/03</u>
Sanofi	09/18/1996	1,056,000	09/19/1997	09/18/2003	14.56	1,020,240

Exercise of options under this plan resulted in the creation of 480,565 shares in 2003 (each with a par value of 2 euros per share) and aggregate proceeds of 7 million euros.

This stock subscription option plan ended on September 18, 2003.

**b) Plans post-dating the May 18, 1999 merger**

The Sanofi-Synthélabo Annual General Meeting of May 18, 1999 authorized the Board of Directors to grant options to subscribe to new Sanofi-Synthélabo shares to be issued by way of capital increases, or to purchase existing Sanofi-Synthélabo shares bought in the market by Sanofi-Synthélabo.

The maximum number of shares that may be subscribed to or purchased under these plans is 14,611,740.

The options may not be exercised, and the corresponding shares may not be sold, prior to the fourth anniversary of the date of grant.

**Options to purchase Group shares**

The terms of the stock purchase options granted under this authorization are as follows:

<u>Origin</u>	<u>Date of grant</u>	<u>Options granted</u>	<u>Start date of vesting period</u>	<u>Expiration date</u>	<u>Exercise price (in euros)</u>	<u>Options exercised as of 12/31/03</u>
Sanofi-Synthélabo	05/24/2000	4,292,000	05/25/2004	05/24/2010	43.25	8,000
Sanofi-Synthélabo	05/10/2001	2,936,500	05/11/2005	05/10/2011	64.50	
Sanofi-Synthélabo	05/22/2002	3,111,850	05/23/2006	05/22/2012	69.94	



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Shares offered under these plans are acquired in the stock market. Consequently, these plans have no impact on shareholders' equity as of December 31, 2003.

### Options to subscribe to Group shares

The terms of the stock subscription options granted under this authorization are as follows:

<u>Origin</u>	<u>Date of grant</u>	<u>Options granted</u>	<u>Start date of vesting period</u>	<u>Expiration date</u>	<u>Exercise price (in euros)</u>	<u>Options exercised as of 12/31/03</u>
Sanofi-Synthélabo	12/10/2003	4,217,700	12/11/2007	12/10/2013	55.74	

The exercise of the stock options outstanding at December 31, 2003 would result in an increase of approximately 235 million euros in shareholders' equity.

**Table of Contents****Summary of stock-based compensation plans**

A summary of stock options outstanding at December 31, 2003, 2002 and 2001 and of changes during those years, is presented below:

	Number of options	Exercise price (in euros)	
		Weighted average per share	Aggregate (in millions of euros)
<b>Outstanding January 1, 2001</b>	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)
<b>Outstanding December 31, 2001</b>	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)
<b>Outstanding December 31, 2002</b>	14,351,505	48.63	698
Granted	4,217,700	55.74	235
Exercised	(1,031,447)	19.28	(20)
Expired/Forfeited	(136,110)	47.29	(6)
<b>OUTSTANDING DECEMBER 31, 2003</b>	17,401,648	52.10	907

As of December 31, 2003, there were 2,351,068 exercisable options outstanding, with a weighted average exercise price of 27.05 euros per share. As of December 31, 2003, there remained 53,690 options available for grant. The following table summarizes information concerning outstanding and exercisable options as of December 31, 2003:

	Outstanding			Exercisable	
	Number of options	Weighted average remaining life (years)	Weighted average exercise price per share (in euros)	Number of options	Weighted average exercise price per share (in euros)
<b>Range of exercise prices per share</b>					
From 6.01 to 10.85 euros per share	236,036	11.89	9.03	236,036	9.03
From 19.73 to 28.38 euros per share	991,252	5.10	22.39	991,252	22.39

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

From 34.95 to 69.94 euros per share	16,174,360	7.95	54.55	1,123,780	34.95
<b>TOTAL</b>	<b>17,401,648</b>	<b>7.84</b>	<b>52.10</b>	<b>2,351,068</b>	<b>27.05</b>

**D.13. Long-term debt (portion due after more than one year)**

The Group's long-term debt as of December 31, 2003, 2002 and 2001 comprises:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
Capital lease obligations	43	51	57
Other long-term debt	10	14	62
<b>TOTAL</b>	<b>53</b>	<b>65</b>	<b>119</b>

**Table of Contents**

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, 2003, 2002 and 2001:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
2003			55
2004		11	11
2005	8	8	9
2006	7	7	8
2007	4	4	4
2008	5	4	5
Thereafter	29	31	27
<b>TOTAL</b>	<b>53</b>	<b>65</b>	<b>119</b>

The table below presents an analysis of long-term debt by interest rate as of December 31, 2003, 2002 and 2001, after taking into account hedging instruments. The split is based on interest rates at year-end.

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
Less than 5%	7	8	54
From 5% to 7.5%	43	51	53
From 7.5% to 10%	3	6	12
<b>TOTAL</b>	<b>53</b>	<b>65</b>	<b>119</b>
<b>Of which:</b>			
fixed rate	11	15	21
variable rate	42	50	98

The table below presents an analysis of long-term debt by currency as of December 31, 2003, 2002 and 2001, after taking into account hedging instruments:

<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
------------------------------	------------------------------	------------------------------

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

	<u>                    </u>	<u>                    </u>	<u>                    </u>
	<i>(in millions of euros)</i>		
Euro	48	58	110
US dollar	2	2	2
Other currencies	3	5	7
<b>TOTAL</b>	<u>53</u>	<u>65</u>	<u>119</u>

The table below summarizes interest paid on the short-term and long-term portion of debt and on credit lines during each accounting period:

	<u>Year ended</u> <u>December 31, 2003</u>	<u>Year ended</u> <u>December 31, 2002</u>	<u>Year ended</u> <u>December 31, 2001</u>
		<i>(in millions of euros)</i>	
Interest paid	16	22	18

**Table of Contents****D.14. Provisions and other long-term liabilities**

Provisions and other long-term liabilities as of December 31, 2003, 2002 and 2001 comprise:

	<b>Provisions for pensions &amp; other benefits (D.14.1)</b>	<b>Restructuring provisions (D.14.2)</b>	<b>Other provisions for risks (D.14.3)</b>	<b>Other long- term liabilities (D.14.4)</b>	<b>Total</b>
	<i>(in millions of euros)</i>				
<b>December 31, 2001</b>	474	46	431	102	1,053
Charged during the period	92		126	1	219
Reversals of provisions in application of CRC Rule 2000-06		(15)	(11)		(26)
Reversals of provisions recorded in the opening balance sheet			(32)		(32)
Provisions utilized	(144)	(11)	(14)	(1)	(170)
Reversals of unutilized provisions			(38)		(38)
Transfers	29	(10)	(92)	(97)	(170)
Effect of exchange rates	(24)	(2)	(23)	(1)	(50)
<b>December 31, 2002</b>	427	8	347	4	786
Charged during the period	78		111	5	194
Reversals of provisions recorded in the opening balance sheet	(2)	(1)	(36)		(39)
Provisions utilized	(52)	(1)	(30)	(1)	(84)
Reversals of unutilized provisions	(1)		(60)		(61)
Transfers	(2)	(1)	1		(2)
Effect of exchange rates	(19)		(21)		(40)
<b>DECEMBER 31, 2003</b>	429 <sup>(1)</sup>	5	312	8	754

<sup>(1)</sup> 380 million euros in respect of long-term pension obligations and 49 million euros in respect of post-employment benefits (see note D.14.1).

**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, 2003, 2002 and 2001. The calculations incorporate:

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

assumptions on staff turnover, life expectancy and salary inflation;

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;

discounting rates used to determine the actuarial present value of the projected benefit obligations as follows:

Euro zone plans: 5.15% as of December 31, 2003; 5.25% as of December 31, 2002 and 2001

US plans: 6% as of December 31, 2003; 6.75% as of December 31, 2002; 7% as of December 31, 2001

F-28

**Table of Contents**

UK plans: 5.30% as of December 31, 2003; 5.50% as of December 31, 2002; 5.75% as of December 31, 2001

other plans: 1.5%-11.5% as of December 31, 2003; 2%-12% as of December 31, 2002; 2.5%-14.5% as of December 31, 2001

Expected long-term rates of return for plan assets ranging from 5% to 10% for the year ended December 31, 2003; 4% to 15% for the year ended December 31, 2002; and 5.15% to 15% for the year ended December 31, 2001. 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% for the year ended December 31, 2003; 8.75% for the years ended December 31, 2002 and 2001;

for UK pension plans: 6.50% for the years ended December 31, 2003 and 2002; 7% for the year ended December 31, 2001.

The main assumptions used in the actuarial valuations are summarized below:

	Pensions and			Post-employment benefits		
	similar benefits			other than pensions		
	2003	2002	2001	2003	2002	2001
<i>Assumptions (weighted averages):</i>						
<i>Discounting rate</i>	5.25%	5.34%	5.60%	6.01%	6.75%	7.00%
<i>Salary inflation rate</i>	3.86%	3.79%	3.92%			
<i>Expected long-term rate of return on plan assets</i>	7.27%	7.23%	7.56%			

In calculating the pension cost for the period, the Group recognizes actuarial gains and losses if at the beginning of the period the net unrealized actuarial gain or loss exceeds 10% of the greater of the projected obligation or the market value of plan assets.



**Table of Contents**

The table below reconciles the net obligation under Group pension plans with the amounts recognized in the consolidated financial statements as of December 31, 2003, 2002 and 2001:

	Pensions and			Post-employment		
	similar benefits			benefits		
				other than pensions		
	2003	2002	2001	2003	2002	2001
<i>(in millions of euros)</i>						
<b>Valuation of obligations:</b>						
Beginning of period	1,108	1,069	910	53	61	53
Service cost	49	51	42	2	1	1
Interest cost	61	60	56	3	4	4
Actuarial (gain)/loss	34	43	29	28	3	5
Contributions from plan members	3	2	2			
Modifications to plans		37	63			
Effect of exchange rates	(87)	(75)	26	(11)	(10)	3
Changes in Group structure			(9)			
Benefits paid	(51)	(79)	(50)	(6)	(6)	(5)
<b>Obligation at period-end</b>	<b>1,117</b>	<b>1,108</b>	<b>1,069</b>	<b>69</b>	<b>53</b>	<b>61</b>
<b>Market value of plan assets</b>						
Beginning of period	431	477	533			
Actual return on assets	62	(37)	(59)			
Effect of exchange rates	(57)	(49)	20			
Contributions from plan members	3	2	2			
Employers contributions	93	105	16			
Changes in Group structure						
Benefits paid	(29)	(67)	(35)			
<b>Market value of plan assets at period-end</b>	<b>503</b>	<b>431</b>	<b>477</b>			
<b>Net amount shown in balance sheet:</b>						
Net obligation	614	677	592	69	53	61
Transitional liability	1	9	18			
Unrecognized past service cost	(82)	(90)	(61)	2	3	4
Unrecognized actuarial gain/(loss)	(191)	(224)	(136)	(21)	8	10
Benefits/contributions, final quarter	(14)	(32)	(12)	(1)	(3)	
<b>Net provision in the balance sheet</b>	<b>328</b>	<b>340</b>	<b>401</b>	<b>49</b>	<b>61</b>	<b>75</b>
<b>Amounts recognized in the balance sheet:</b>						
Pre-funded obligations (D.6)	(52)	(27)	(8)			
Obligations provided (long-term portion)	380	366	399	49	61	75
Obligations provided (short-term portion)		1	10			
<b>Net amount recognized</b>	<b>328</b>	<b>340</b>	<b>401</b>	<b>49</b>	<b>61</b>	<b>75</b>
<b>Pension cost for the period:</b>						
Service cost	49	50	42	2	1	1

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Interest cost	61	60	56	3	4	4
Expected return on plan assets	(31)	(34)	(44)			
Recognition of transitional liability	(8)	(8)	(8)			
Amortization of past service cost	7	8	3	(1)	(1)	
Recognition of actuarial losses/(gains)	12	8				(1)
	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>
<b>Pension cost for the period</b>	90	84	49	4	4	4
	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>	<u>        </u>
<b>Gross obligation based on period-end salaries</b>	960	944	898			
	<u>        </u>	<u>        </u>	<u>        </u>			

As of December 31, 2003, 2002 and 2001, the impact on the financial statements of a 1% change in assumptions regarding future healthcare costs is not material.

**Table of Contents****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, 2003, 2002 and 2001:

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
	<i>(in millions of euros)</i>		
<b>Balance, beginning of period</b>	27	82	149
Of which			
classified under Other long-term liabilities	8	46	61
classified under Other current liabilities	19	36	88
Movement in provisions recognized in net income for the period	6	1	6
Reversals of provisions in application of CRC Rule 2000-06		(20)	
Reversals of provisions recorded in the opening balance sheet	(2)	(4)	(16)
Provisions utilized	(11)	(30)	(57)
Transfers	1		
Effect of exchange rates	(1)	(2)	
<b>BALANCE, END OF PERIOD</b>	<b>20</b>	<b>27</b>	<b>82</b>
Of which:			
classified under Other long-term liabilities	5	8	46
classified under Other current liabilities	15	19	36

Following the merger of Sanofi and Synthélabo in 1999, the Group developed a restructuring plan, which consisted of a combination of actions designed to integrate head offices worldwide, reorganize the sales forces and close or re-size industrial sites throughout the world. Implementation of these restructuring plans commenced in 1999 and was substantially completed in 2000 and 2001. In France, the restructuring program related to a reduction in workforce was carried out principally through a program of voluntary early retirement for people aged 55 as of December 31, 1999.

Expenses incurred in 2003, 2002 and 2001 and charged against the provision, shown on the line Provisions utilized, relate principally to employee termination costs (4, 11 and 56 million euros respectively), mainly in western Europe.

**Table of Contents****D.14.3. Other provisions for risks**

The table below shows movements in other provisions for risks, including environmental risks and litigation, tax exposures, commercial risks, product liability risks and intellectual property risks, for each of the years ended December 31, 2003, 2002 and 2001:

	<b>Year ended</b>		
	<b>December 31,</b>	<b>Year ended</b>	<b>Year ended</b>
	<b>2003</b>	<b>December 31,</b>	<b>December 31,</b>
	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<i>(in millions of euros)</i>		
<b>Balance, beginning of period</b>	347	431	469
Movement in provisions recognized in net income for the period	51	88	77
Reversals of provisions in application of CRC Rule 2000-06		(11)	
Reversals of provisions recorded in the opening balance sheet	(36)	(32)	(96)
Provisions utilized	(30)	(14)	(35)
Reclassifications between accounts	1	(92)	12
Effect of exchange rates	(21)	(23)	4
<b>BALANCE, END OF PERIOD</b>	<b>312</b>	<b>347</b>	<b>431</b>
Tax risks	206	217	260
Intellectual property risks	16	37	18
Environmental risks	20	21	30
Product liability risks	17	20	25
Other risks	53	52	98
<b>TOTAL</b>	<b>312</b>	<b>347</b>	<b>431</b>

The Group is involved in a number of legal proceedings and claims. These include commercial and intellectual property litigation, tax audits and other matters relating to the normal conduct of its business.

Provisions for tax exposures are recorded if the Group considers that the tax authorities might challenge a tax position taken by the Group or a subsidiary.

An assessment of these risks has been performed with the assistance of the Group's legal advisers, and provisions have been recorded where circumstances required.

In 2002, reclassifications mainly comprised the transfer of provisions to current liabilities, under Other liabilities.

**D.14.4. Other long-term liabilities**

As of December 31, 2001, other long-term liabilities included liabilities on operations with joint venture and alliance partners, which were included in Other current liabilities as of December 31, 2002 and December 31, 2003 (see note D.15).

**D.15. Other current liabilities**

Other current liabilities as of December 31, 2003, 2002 and 2001 comprise:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
Taxes payable	370	472	597
Employee-related liabilities	424	384	418
Restructuring provisions (D.14.2)	15	19	36
Other liabilities	811	724	943
<b>TOTAL</b>	<b>1,620</b>	<b>1,599</b>	<b>1,994</b>

**Table of Contents**

In 2001, Other liabilities included the unpaid portion of the purchase price of acquisitions made in the period, and the impact of the full consolidation of the Lorex Pharmaceuticals balance sheet.

In 2002, Other liabilities also included the reclassification of the balance as of January 1, 2002 of liabilities on operations with joint venture and alliance partners, totaling 85 million euros.

The unpaid portion of the purchase price of acquisitions made in the period, which is included in Other liabilities, amounted to 37 million euros as of December 31, 2003, 24 million euros as of December 31, 2002 and 170 million euros as of December 31, 2001.

**D.16. Short-term debt**

Short-term debt as of December 31, 2003, 2002 and 2001 comprises:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
Current portion of long-term debt	10	55	9
Other short-term debt	117	146	156
Bank overdrafts	188	150	120
<b>TOTAL</b>	<b>315</b>	<b>351</b>	<b>285</b>

**D.17. Derivative financial instruments**

The table below presents the notional amounts of the Group's outstanding derivative financial instruments as of December 31, 2003, 2002 and 2001:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
		<i>(in millions of euros)</i>	
Interest rate swaps		46	46
Currency swaps - puts written <sup>(1)</sup>	59	51	24
Currency swaps - calls written <sup>(2)</sup>	708	758	705
Currency swaps - puts purchased <sup>(3)</sup>	357	448	413
Currency swaps - calls purchased <sup>(4)</sup>	100	90	40
Forward foreign currency exchange contracts written - financial <sup>(5)</sup>	1,224	1,033	1,016
Forward foreign currency exchange contracts purchased - financial <sup>(6)</sup>	318	131	254

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

- (1) including 36 million euros on the Norwegian krone and 23 million euros on the Hungarian florint as of December 31, 2003; 51 million euros on the Norwegian krone as of December 31, 2002; 18 million euros on the US dollar as of December 31, 2001.
- (2) including 555 million euros on the US dollar and 101 million euros on the yen as of December 31, 2003; 568 million euros on the US dollar and 163 million euros on the yen as of December 31, 2002; 527 million euros on the US dollar and 157 million euros on the yen as of December 31, 2001.
- (3) including 284 million euros on the US dollar and 49 million euros on the yen as of December 31, 2003; 321 million euros on the US dollar and 96 million euros on the yen as of December 31, 2002; 326 million euros on the US dollar and 77 million euros on the yen as of December 31, 2001.
- (4) including 46 million euros on the US dollar, 22 million euros on the yen and 21 million euros on the Norwegian krone as of December 31, 2003; 45 million euros on the US dollar, 19 million euros on the yen and 26 million euros on the Norwegian krone as of December 31, 2002; 16 million euros on the yen, 10 million euros on the US dollar and 9 million euros on the Norwegian krone as of December 31, 2001.
- (5) including 981 million euros on the US dollar, 70 million euros on the yen, 45 million euros on the British pound, 23 million euros on the Canadian dollar, 13 million euros on the Czech koruna, 13 million euros on the Canadian dollar and 14 million euros on the Polish zloty as of December 31, 2003; 798 million euros on the US dollar, 79 million euros on the yen, 60 million euros on the British pound, 26 million euros on the Canadian dollar, 16 million euros on the Czech koruna and 10 million euros on the Norwegian krone as of December 31, 2002; 812 million euros on the US dollar, 87 million euros on the yen, 45 million euros on the British pound and 29 million euros on the Canadian dollar as of December 31, 2001.
- (6) including 130 million euros on the US dollar, 92 million euros on the Swiss franc, 35 million euros on the Norwegian krone and 57 million euros on the Hungarian florint as of December 31, 2003; 68 million euros on the Swiss franc, 33 million euros on the Norwegian krone and 10 million euros on the British pound as of December 31, 2002; 118 million euros on the US dollar, 88 million euros on the Swiss franc, 30 million euros on the Norwegian krone as of December 31, 2001.

F-33

**Table of Contents****Fair value of financial instruments**

The carrying values and estimated fair values of certain of the Group's financial instruments outstanding as of December 31, 2003, 2002 and 2001 are presented below:

	2003		2002		2001	
	Carrying value	Fair value	Carrying value	Fair value	Carrying value	Fair value
<i>(in millions of euros)</i>						
Long-term debt (excluding capital lease obligations)	10	10	14	14	62	62
Forward foreign currency exchange contracts written	30	117	23	48	2	23
Forward foreign currency exchange contracts purchased	(4)	(6)	1	4	2	3
Currency options puts written	1	2	1			
Currency options calls written	16	2	19	3	17	10
Currency options puts purchased	23	36	21	36	17	20
Currency options calls purchased	1	1	1	2		2

The Group considers that for cash and cash equivalents, accounts receivable, bank overdrafts, accounts payable and other short-term debt, carrying value is a reasonable estimate of fair value due to their short-term maturities and the readily available market for these types of instruments.

The following methods and assumptions were used by the Group in estimating the fair values of financial instruments:

**Long-term debt (excluding capital lease obligations)** The carrying value of the Group's variable-rate long-term debt approximates to fair value. The fair value of long-term fixed rate debt has been estimated based on current interest rates available for debt instruments with similar terms, degrees of risk and maturities. Substantially all of the Group's long-term debt is variable rate.

**Forward foreign currency exchange contracts (written and purchased)** The fair value of forward foreign currency exchange contracts is based on the estimated amount at which they could be settled based on forward market exchange rates.

**Foreign currency option contracts (written and purchased)** The fair value of foreign currency option contracts is obtained from dealer quotes. These values represent the estimated net amount the Group would receive or pay to terminate the agreements.



**Table of Contents****D.18. Contractual obligations and other commercial commitments**

The Group's contractual obligations and other commercial commitments as of December 31, 2003 comprise:

	<b>Payments due by period</b>			
	<b>Total</b>	<b>Under 1 year</b>	<b>1-5 years</b>	<b>Over 5 years</b>
	<i>(in millions of euros)</i>			
<b>Contractual obligations given</b>				
Long-term debt, excluding capital lease obligations (Notes D.13 and D.16)	13	3	6	4
Capital lease obligations (including interest)	62	10	24	28
Operating leases	441	91	186	164
Irrevocable purchase obligations	150	138	12	
Other long-term obligations	226	88	98	40
<b>TOTAL</b>	<b>892</b>	<b>330</b>	<b>326</b>	<b>236</b>

	<b>Commitments by period</b>			
	<b>Total</b>	<b>Under 1 year</b>	<b>1-5 years</b>	<b>Over 5 years</b>
	<i>(in millions of euros)</i>			
<b>Other commercial commitments given</b>				
Credit lines				
Letters of credit				
Guarantees:				
given	64	14	5	45
received	(75)	(59)	(1)	(15)
Repurchase commitments				
Other commercial commitments				
<b>TOTAL</b>	<b>(11)</b>	<b>(45)</b>	<b>4</b>	<b>30</b>

**Leases***Capital leases*

Future minimum payments related to capital leases as of December 31, 2003 totaling 62 million euros and including interest payments of 12 million euros are scheduled to be made as follows:

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

	<b>Interest portion</b>	<b>Principal portion</b>	<b>Total</b>
		<i>(in millions of euros)</i>	
2004	3	7	10
2005	2	6	8
2006	1	5	6
2007	1	4	5
2008	1	4	5
2009 and thereafter	4	24	28
	<hr/>	<hr/>	<hr/>
<b>TOTAL</b>	12	50	62
	<hr/>	<hr/>	<hr/>

F-35

**Table of Contents*****Operating leases***

The Group leases certain of its properties and equipment used in the ordinary course of business. Future minimum payments under non-cancelable operating leases as of December 31, 2003 amounted to 441 million euros, and are scheduled to be made as follows:

	<b>December 31, 2003</b>
	<i>(in millions of euros)</i>
2004	91
2005	63
2006	47
2007	39
2008	37
2009 and thereafter	164
<b>TOTAL</b>	<b>441</b>

Rental expense recognized by the Group for each of the years ended December 31, 2003, 2002 and 2001 totaled 93 million euros, 87 million euros and 79 million euros respectively.

**Irrevocable purchase obligations**

These mainly comprise irrevocable commitments to suppliers of fixed assets, net of payments on account, and firm commitments to buy goods and services.

**Other long-term obligations**

As of December 31, 2003, these included royalties payable on the marketing of Arixtra<sup>®</sup> under the alliance agreements with Organon in countries other than the United States, Canada, Japan and Mexico. In return for taking over the rights, Sanofi-Synthélabo agreed to make phased payments to Organon up to a maximum of 100 million dollars contingent on approval of additional indications. Sanofi-Synthélabo also agreed to pay minimum royalties of 74 million dollars. On January 7, 2004, a new agreement was signed with Organon under which Sanofi-Synthélabo will acquire all Organon's rights to Arixtra<sup>®</sup> (see note E).

In addition, Sanofi-Synthélabo is required to pay minimum royalties of 7 million euros under three pharmaceutical license agreements.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

As of December 31, 2003, Sanofi-Synthélabo owned 1,700,145 IDM shares, representing 12.54% of the capital. This percentage may change in the future due to (i) a commitment by Sanofi-Synthélabo, valid until July 31, 2004, to make an additional investment of 10 million euros in a further share issue, and (ii) the conversion of existing financial instruments giving access to the capital of IDM.

### **Guarantees given**

These comprise 53 million euros of surety bonds and 11 million euros of real collateral.

### **Guarantees received**

These mainly comprise surety bonds.

### **Scope of consolidation**

The Group does not use off balance sheet vehicles. All the Group's operations are reflected in the accounts of the companies included in the consolidation for each of the periods presented.

## **Table of Contents**

There are no commitments other than those disclosed above (notes D.17 and D.18) which are or may become material, except for those arising under collaboration agreements.

### **D.19. Other commitments, litigation and claims**

#### **Commitment to purchase shares in subsidiaries**

In August 2003, Sanofi-Synthélabo signed an agreement with its partner Hangzhou Minsheng Pharmaceuticals Group giving it the option to acquire additional shares, taking its interest to 100%, in their joint subsidiary in China.

#### **Research and development collaborations**

The Group may be required to make payments to research and development partners under collaboration agreements. These agreements typically cover multiple products and give the Group the option to participate in development on a product-by-product basis. When the Group exercises an option with respect to a product, it pays its collaboration partner a fee and receives intellectual property rights to that product in exchange. The Group is also generally required to fund some or all of the development costs for products that it selects and to make payments to its partners when those products reach development milestones.

The Group's principal collaboration agreements are:

A collaboration agreement with Cephalon for the development of angiogenesis inhibitors, in respect of which the payment for the first product could reach 32 million US dollars.

Under a strategic collaboration agreement signed in 2001, IDM granted Sanofi-Synthélabo 20 development options on current and future research and development programs. For each option that leads to a commercially marketed product, IDM could receive a total of between 17 and 32 million euros, depending on the potential of the market, plus reimbursement of the development costs. Contractually, Sanofi-Synthélabo may suspend the development program for each option exercised at any time and without penalty. As of December 31, 2003, Sanofi-Synthélabo had exercised only one option, relating to a program for the treatment of melanoma.

There are two further contracts relating to research work which could give rise to deferred payments of between 1 and 4 million euros per molecule.

Because of the uncertain nature of the development work, it is impossible to predict if the Group will exercise an option for a product or if the expected milestones will be achieved, or to predict the number of molecules that will reach the relevant milestones. For this reason, it is impossible to estimate the maximum aggregate amount that Sanofi-Synthélabo will actually pay in the future under outstanding collaboration agreements. Given the nature of its business, it is highly unlikely that Sanofi-Synthélabo will exercise all options for all products or that all milestones will be achieved.

**Litigation and claims**

Following the merger of Sanofi and Synthélabo, the Group was in dispute with its co-shareholders in the Yves Rocher Group, who rejected the registration in the name of the merged entity Sanofi-Synthélabo of the Group's shares in Financière des Laboratoires de Cosmétologie Yves Rocher and Laboratoires de Biologie Végétale Yves Rocher. They had previously been held by Sanofi.

Following the expert's conclusions in November 2001, and in accordance with the judgment, Laboratoires de Biologie Végétale Yves Rocher arranged for the acquisition of the Group's interest in its capital.

**Table of Contents**

Pursuant to a judgment from the Rennes Appeal Court dated January 10, 2001, Sanofi-Synthélabo remains a shareholder of Financière des Laboratoires de Cosmétologie Yves Rocher, with an interest of 39.1%.

During the first six months of 2001, both Sanofi-Synthélabo and Financière des Laboratoires de Cosmétologie Yves Rocher appealed separately to the highest procedural court in France ( Cour de Cassation ) on the appeal judgments. Their appeals were rejected on May 6, 2003.

**Environmental risks**

The Group is involved in various stages of investigation and cleanup relating to environmental matters at certain locations. Whenever identified, the Group's practice is to determine the nature and scope of contingencies related to environmental remediation activity and obtain and accrue estimates of the cost of remediation. For each period presented, the estimates of cleanup costs have been accrued. As the Group continues its efforts to ensure compliance with environmental laws and regulations, additional contingencies may be identified. The Group does not believe that additional costs that could arise from environmental remediation activities will have a significant adverse effect on its financial position or results.

**D.20. Personnel costs**

Personnel costs, which include compensation and other benefits paid to employees leaving the Group during the period, totaled 1,992 million euros in the year ended December 31, 2003, against 1,937 million euros in the year ended December 31, 2002 and 1,708 million euros in the year ended December 31, 2001.

Employee numbers as of December 31, 2003, 2002 and 2001 were 33,086, 32,436 and 30,514 respectively.

Employee numbers by function as of December 31, 2003, 2002 and 2001 were as follows:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
Research and development	6,877	6,718	6,273
Sales force	11,601	11,015	10,336
Production	7,901	8,043	7,651
Other	6,707	6,660	6,254
<b>TOTAL</b>	<b>33,086</b>	<b>32,436</b>	<b>30,514</b>

Remuneration paid to the 13 key executive managers of the Group during the year ended December 31, 2003 totaled 8.8 million euros, against 7.5 million euros in the year ended December 31, 2002 (12 executives) and 6.2 million euros in the year ended December 31, 2001 (12 executives).

**D.21. Other operating income/(expense), net**

In 2003, other operating income and expense, related mainly to operations with Bristol-Myers Squibb (see note C.1), represented a net gain of 248 million euros against 190 million euros in 2002, an increase of 30.5% relative to the previous year.

In 2003, Sanofi-Synthélabo's share of profits generated by Plavix® and Avapro® in North America, the territory managed by Bristol-Myers Squibb, amounted to 436 million euros, against 348 million euros in 2002. Conversely, profits passed on to Bristol-Myers Squibb in respect of the territory managed by Sanofi-Synthélabo totaled 172 million euros in 2003, compared with 142 million euros in 2002.



**Table of Contents****D.22. Financial income/(expense), net**

This line includes a net foreign exchange gain of 103 million euros in 2003, compared with 48 million euros in 2002 and 5 million euros in 2001.

**D.23. Exceptional items**

Exceptional items for the years ended December 31, 2003, 2002 and 2001 comprise:

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		<i>(in millions of euros)</i>	
Net gains on disposals	24	10	281
Other exceptional items			
<b>TOTAL</b>	<b>24</b>	<b>10</b>	<b>281</b>

There were no material disposals in 2003 or 2002.

In 2001, net gains on disposals related principally to the four major divestitures during the period: Sylachim, Porgès, Ela Medical and the direct holding in Laboratoires de Biologie Végétale Yves Rocher (see note D.1). The gain on these four major divestitures included an allocation of part of the goodwill arising on the merger between Sanofi and Synthélabo, which was initially offset against consolidated shareholders' equity.

**D.24. Income taxes**

The Group has opted for tax consolidations in a number of countries, principally France, Germany and the United States.

Pre-tax net income and the corresponding tax charge for the years ended December 31, 2003, 2002 and 2001 break down as follows:

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		<i>(in millions of euros)</i>	
<b>Pre-tax net income</b>			
France	1,473	1,357	1,317

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Rest of the world	1,644	1,215	1,097
<b>TOTAL</b>	<b>3,117</b>	<b>2,572</b>	<b>2,414</b>
<b>Income tax:</b>			
France	(426)	(335)	(473)
Rest of the world	(632)	(411)	(369)
<b>TOTAL</b>	<b>(1,058)</b>	<b>(746)</b>	<b>(842)</b>

The income tax charge for the years ended December 31, 2003, 2002 and 2001 comprises:

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		(in millions of euros)	
Current taxation	(1,076)	(794)	(906)
Deferred taxation	18	48	64
<b>TOTAL</b>	<b>(1,058)</b>	<b>(746)</b>	<b>(842)</b>

**Table of Contents**

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		<i>(in millions of euros)</i>	
Tax on income before exceptional items	(1,049)	(745)	(778)
Tax on exceptional items	(9)	(1)	(64)
<b>TOTAL</b>	<b>(1,058)</b>	<b>(746)</b>	<b>(842)</b>

The difference between the effective tax rate and the standard corporate income tax rate applicable in France for each of the years ended December 31 2003, 2002 and 2001 is explained as follows:

	Year ended December 31, 2003	Year ended December 31, 2002	Year ended December 31, 2001
		<i>(as %)</i>	
Tax rate applicable in France	35	35	36
Impact of income tax at reduced rate in France	(3)	(4)	(3)
Loxex Pharmaceuticals		(1)	
Other	2	(1)	3
<b>Effective tax rate on income before exceptional items</b>	<b>34</b>	<b>29</b>	<b>36</b>
Impact of exceptional items			(1)
<b>EFFECTIVE TAX RATE</b>	<b>34</b>	<b>29</b>	<b>35</b>

As indicated in note C.2, Loxex Pharmaceuticals has been fully consolidated by the Group since January 1, 2002. Net income before exceptional items and goodwill amortization therefore includes all the profits and losses of Loxex Pharmaceuticals, including the share of net income reverting to Pharmacia-Searle for the period from January 1, 2002 through April 15, 2002. Because Loxex Pharmaceuticals is a tax-transparent entity, the Income taxes line includes only the charge attributable to the Group. This had the effect of reducing the effective tax rate by 1.2 points during the year ended December 31, 2002.

The Other line includes the difference between the French tax rate and the tax rate applicable in other countries and the impact of the revaluation of certain of the Group's tax exposures.

Income tax payments made by the Group totaled 908 million euros in 2003, 1,120 million euros in 2002 and 449 million euros in 2001.

**D.25. Minority interests**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In 2002, minority interests mainly comprised the share in the net income of Lorex Pharmaceuticals reverting to Pharmacia-Searle for the period from January 1, 2002 through April 15, 2002 (see note C.2).

### **D.26. Related party transactions**

Financial relations with the Total and L. Oréal groups were not material as of December 31, 2003, 2002 and 2001.

### **D.27. Split of net sales**

The Group is not dependent on any single customer or group of customers for its sales. Products are sold throughout the world to a wide range of customers including pharmacies, hospitals, chain warehouses, governments, physicians, wholesalers and other distributors.

F-40

**Table of Contents**

Sales of selected products for each of the years ended December 31, 2003, 2002 and 2001 were as follows:

	<b>December 31, 2003</b>	<b>December 31, 2002</b>	<b>December 31, 2001</b>
	<i>(in millions of euros)</i>		
Stilnox®/Ambien®/Myslee®	1,345	1,424	786
Plavix®	1,325	987	705
Eloxatin®	824	389	196
Aprovel®/Avapro®	683	562	423
Fraxiparine®	319	324	297
Depakine®	277	267	243
Xatral®	222	182	148
Solian®	148	135	116
Cordarone®	146	162	162
Tildiem®	131	141	152

**D.28. Segment information**

The Group operates in one significant business segment: the research and development, production and sale of pharmaceutical products.

The Group has aggregated all its ethical product lines because they have close similarities in terms of regulatory environment, production process, distribution methods and customer profile. The Group's generics and OTC activities are not material, and have been aggregated with its ethical activities.

The Group mainly operates in three geographical segments: Europe, the United States and Other countries.

The table below gives net sales, operating profit, total assets and long-lived assets by geographical segment. Net sales and operating profit are allocated based on the location of the end customer. Total assets and long-lived assets are allocated based on the location of the subsidiary.

	<b>Year ended December 31, 2003</b>				
	<b>Total</b>	<b>Europe</b>	<b>United States</b>	<b>Other countries</b>	<b>Unallocated costs (1)</b>
	<i>(in millions of euros)</i>				
Net sales	8,048	4,693	1,912	1,443	
Operating profit	3,075	1,874	2,025	561	(1,385)
Total assets	9,749	7,381	1,728	640	
Including long-lived assets	2,712	1,756	823	133	

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,646 million euros and 1,225 million euros respectively as of December 31, 2003.

	<b>Year ended December 31, 2002</b>				
	<b>Total</b>	<b>Europe</b>	<b>United States</b>	<b>Other countries</b>	<b>Unallocated costs (1)</b>
	<i>(in millions of euros)</i>				
Net sales	7,448	4,297	1,689	1,462	
Operating profit	2,614	1,633	1,781	522	(1,322)
Total assets	9,459	6,968	1,814	677	
Including long-lived assets	2,899	1,715	1,052	132	

F-41

**Table of Contents**

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,584 million euros and 1,182 million euros respectively as of December 31, 2002.

	Year ended December 31, 2001				
	Total	Europe	United States	Other countries	Unallocated costs <sup>(1)</sup>
	<i>(in millions of euros)</i>				
Net sales	6,488	3,877	1,098	1,513	
Operating profit	2,106	1,427	1,311	456	(1,088)
Total assets	9,967	7,924	1,321	722	
Including long-lived assets	2,296	1,558	602	136	

Net sales generated in France and long-lived assets situated in France, where the Group is headquartered, totaled 1,487 million euros and 1,096 million euros respectively as of December 31, 2001.

<sup>(1)</sup> Unallocated costs consist mainly of fundamental research and worldwide development of pharmaceutical molecules, and part of the cost of support functions.

**E. POST BALANCE SHEET EVENTS**

On January 7, 2004, Sanofi-Synthélabo reached agreement with Organon to acquire all Organon's rights relating to Arixtra<sup>®</sup>, idraparinux and other oligosaccharides (see note C.3). The price of this transaction is based largely on future sales.

As well as taking over all ongoing development programs, Sanofi-Synthélabo will bear all research and development costs. In return, the phased payments described in note D.18 are canceled.

\*\*\*\*\*

On January 26, 2004, Sanofi-Synthélabo announced a share and cash offer for the shares of Aventis. The management believes that this offer, driven by a compelling strategic rationale, is expected to deliver strong, sustainable and profitable growth.

If the bid succeeds, it will create the no. 1 in Europe and no. 3 in the world in the pharmaceuticals industry.

The new group will benefit from a large portfolio of high-growth drugs and enjoy firmly established positions in key fast-growth therapeutic fields such as cardiovascular, thrombosis, cancer, diabetes, central nervous system, urology, internal medicine and human vaccines.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Annual synergies are expected by management to be 1.6 billion euros before tax, with 10% achievable in 2004, 60% in 2005 and 100% from 2006. Integration and restructuring costs are forecast by management at around 2 billion euros.

The offer was approved unanimously by the Board of Directors of Sanofi-Synthélabo on January 25, 2004 and is fully supported by Total and L'Oréal, Sanofi-Synthélabo's principal shareholders.

The principal terms of the offer are as follows:

A standard entitlement of 5 Sanofi-Synthélabo shares<sup>(1)</sup> and 69 euros in cash for 6 Aventis shares<sup>(1)</sup>;

An all stock election: 35 Sanofi-Synthélabo shares<sup>(1)</sup> for 34 Aventis shares<sup>(1)</sup>;

F-42



**Table of Contents**

An all cash election: 60.43 euros in cash for each Aventis share<sup>(1)</sup>;

Aventis shareholders can opt for any or a combination of the above, provided that, in aggregate, 81% of the Aventis shares tendered will be exchanged for Sanofi-Synthelabo shares and 19% of the Aventis shares tendered will be exchanged for cash.

The offer is conditional upon obtaining over 50% of the issued share capital and voting rights of Aventis on a fully diluted basis, as well as expiration or termination of the applicable waiting period under the US Hart-Scott Rodino Act and no order being entered prohibiting the transaction.

A General Meeting of Sanofi-Synthelabo shareholders will be convened to approve the issuance of the new shares to be exchanged for the Aventis shares tendered.

Sanofi-Synthelabo estimates that the offer should be completed during the second quarter of 2004.

In connection with this offer, Sanofi-Synthelabo announced that it had begun the process of divesting its interests in Arixtra<sup>®</sup> and Fraxiparine<sup>®</sup>.

\*\*\*\*\*

---

<sup>(1)</sup> dividend attached

**Table of Contents**

On January 30, 2004, the Sanofi-Synthelabo Group reached agreement with Taisho Pharmaceutical Co. Ltd. to acquire the latter's 49% interest in the Sanofi-Synthelabo-Taisho Pharmaceutical Co. Ltd. joint venture. This joint venture markets the anti-arrhythmic Ancaron® (amiodarone hydrochloride) in Japan.

**F. LIST OF COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2003****F.1. Fully consolidated**

	<b>Financial interest</b>
	<b>%</b>
<i>Europe</i>	
Lichtenstein GmbH	Germany 100
Lichtenstein Verwaltungs GmbH	Germany 100
Sanofi-Synthelabo GmbH	Germany 100
Sanofi-Synthelabo Holding GmbH	Germany 100
Sanofi-Synthelabo GesmbH / Bristol-Myers Squibb GesmbH OHG <sup>(1)</sup>	Austria 51
Sanofi-Synthelabo GmbH	Austria 100
Sanofi-Synthelabo SA/ NV	Belgium 100
Sanofi-Synthelabo A/S	Denmark 100
Sanofi Winthrop BMS partnership <sup>(1)</sup>	Denmark 51
Sanofi-Synthelabo SA	Spain 100
Synthelabo SA	Spain 100
Sanofi Winthrop BMS partnership <sup>(1)</sup>	Finland 51
Sanofi-Synthelabo OY	Finland 100
Dakota Pharm	France 100
Francopia	France 100
Groupement Fabrication Pharmaceutique	France 100
Institut d'édition Sanofi-Synthelab <sup>(2)</sup>	France 100
Laboratoires Irex	France 100
Sanofi Développement Pharma	France 100
Sanofi Chimie	France 100
Sanofi Participation	France 100
Sanofi Pharma Bristol-Myers Squibb <sup>(1)</sup>	France 51
Sanofi-Synthelabo	France 100
Sanofi-Synthelabo France	France 100
Sanofi-Synthelabo Groupe	France 100
Sanofi-Synthelabo OTC	France 100
Sanofi-Synthelabo Recherche	France 100
Sanofi Winthrop Industries	France 100
Secipe	France 100
SPI	France 100
Synthelabo Biomédical <sup>(2)</sup>	France 100
Sanofi-Synthelabo A.E	Greece 100
Chinoï	Hungary 99
Sanofi-Synthelabo RT	Hungary 100
Sanofi-Synthelabo Ireland Ltd	Ireland 100
Inverni Della Beffa Spa	Italy 100
Sanofi-Synthelabo OTC Spa	Italy 100
Sanofi-Synthelabo Spa	Italy 100
Sanofi-Synthelabo AS	Norway 100
Sanofi Winthrop BMS partnership ANS <sup>(1)</sup>	Norway 51

Sanofi-Synthélabo BV

Netherlands

100

- (1) Joint venture with Bristol-Myers Squibb, consolidated using the method described in note C.1.
- (2) Company liquidated during the year

F-44

**Table of Contents**

		<b>Financial interest</b>
		<b>%</b>
<b>Europe</b>		
Sanofi-Synthelabo Polholding BV	Netherlands	100
Sanofi-Synthelabo Row BV	Netherlands	100
Sanofi Winthrop BMS VOF <sup>(1)</sup>	Netherlands	51
Synthelabo Netherlands BV	Netherlands	100
Sanofi-Synthelabo Sp Zoo	Poland	100
Irex Promocao e Comercializacao de produtos farmaceuticos Lda	Portugal	100
Sanofi-Synthelabo Produtos Farmaceuticos SA	Portugal	100
Sanofi Winthrop BMS AEIE <sup>(1)</sup>	Portugal	51
Sanofi-Synthelabo sro	Czech Republic	100
Laboratoires Irex Sro	Czech Republic	100
Sanofi-Synthelabo Ltd	United Kingdom	100
Sanofi-Synthelabo UK Ltd	United Kingdom	100
Sterwin Medicines Ltd	United Kingdom	100
Sanofi-Synthelabo Slovakia s.r.o.	Slovakia	100
Sanofi Winthrop BMS partnership <sup>(1)</sup>	Sweden	51
Sanofi-Synthelabo AB	Sweden	100
Sanofi SA-AG (Genève)	Switzerland	100
Sanofi-Synthelabo (Switzerland) SA	Switzerland	100
Synthelabo Pharma Switzerland <sup>(3)</sup>	Switzerland	100
Sanofi-Synthelabo CIS & Easterncountries SA	Switzerland	100
Dogu Ilac Veteriner Urunleri SA	Turkey	100
Sanofi-Synthelabo Ilac AS.	Turkey	100
Sanofi-Dogu BMS ADI Ortakligi partnership <sup>(1)</sup>	Turkey	51
<b>United States</b>		
Lorex Pharmaceuticals Inc.	USA	100
Sanofi-Synthelabo Inc	USA	100
Lorex Inc	USA	100
<b>Other Countries</b>		
JV Omnipharm (Pty) Limited	South Africa	100
Sanofi-Synthelabo (Pty) Ltd	South Africa	100
Institut Médical Algerian (IMA)	Algeria	100
Sanofi-Synthelabo de Argentina SA	Argentina	100
Sanofi-Synthelabo Australia Pty Ltd	Australia	100
Sanofi-Synthelabo do Brasil Ltda	Brazil	100
Sanofi-Synthelabo Ltda	Brazil	100
Sanofi-Synthelabo Canada Inc	Canada	100
Sanofi-Synthelabo de Chile	Chile	100
Hangzhou Sanofi-Synthelabo Minsheng Pharma Co Ltd	China	75
Lakor Farmaceutica SA	Colombia	100
Pacifico Pharma	Colombia	100
Sanofi-Synthelabo de Colombie SA	Colombia	100
Sanofi-Synthelabo Korea Co Ltd	Korea	100
Sanofi-Synthelabo del Ecuador SA	Ecuador	100
Sanofi-Synthelabo HK Ltd	Hong Kong	100
Sanofi BMS Hong-Kong <sup>(1)</sup>	Hong Kong	51
Sanofi-Synthelabo India Ltd	India	100
PT Sanofi-Synthelabo Combiphar	Indonesia	70
Sanofi-Synthelabo Meiji Pharmaceuticals Co Ltd	Japan	51
Sanofi-Synthelabo Taisho Pharmaceuticals Co Ltd	Japan	51

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

- (1) Joint venture with Bristol-Myers Squibb, consolidated using the method described in note C.1.
- (3) Company absorbed by other consolidated companies during the year

F-45

**Table of Contents**

	<b>Financial interest</b>
	<b>%</b>
<b>Other Countries</b>	
Sanofi-Synthelabo Yamanouchi Pharmaceuticals KK	Japan 51
Sanofi-Synthelabo KK	Japan 100
Sanofi-Synthelabo (Malaysia) SDN-BHD	Malaysia 100
Sanofi-Synthelabo BMS Malaysia partnership <sup>(1)</sup>	Malaysia 51
Laboratoires Maphar	Morocco 81
Sanofi-Synthelabo Maroc	Morocco 100
Rudefsa	Mexico 100
Sanofi-Synthelabo de Mexico SA	Mexico 100
Sanofi-Synthelabo (NZ) Ltd	New Zealand 100
Sanofi-Synthelabo Panama	Panama 100
Sanofi-Synthelabo del Peru SA	Peru 100
Synthelabo Delagrangre del Peru <sup>(3)</sup>	Peru 100
Sanofi-Synthelabo Philippines Inc	Philippines 100
Sanofi-Synthelabo de la Republica Dominicana	Dominican Rep. 100
Sanofi BMS <sup>(1)</sup>	Singapore 51
Sanofi-Synthelabo (Singapore) Pte Ltd	Singapore 100
Fujisawa Sanofi-Synthelabo Pharmaceuticals Co Ltd	Taiwan 51
Sanofi-Synthelabo Taiwan Limited	Taiwan 100
Sanofi-Synthelabo (Thailand) Ltd	Thailand 100
Synthelabo (Thailand) Ltd	Thailand 100
Sanofi-Synthelabo Adwya SA	Tunisia 51
Sanofi-Synthelabo Tunisie	Tunisia 70
Sanofi-Synthelabo Uruguay SA	Uruguay 100
Sanocore de Venezuela S.A <sup>(3)</sup>	Venezuela 100
Sanofi-Synthelabo de Venezuela SA	Venezuela 100
Sanofi-Synthelabo Vietnam	Vietnam 70
<b>F.2. Equity-accounted</b>	
<b>Europe</b>	
CKW Pharma-Extrakt	Germany 50
Belgopia SA NV	Belgium 49
Alcaliber SA	Spain 40
Financière des Laboratoires de Cosmétologie Yves Rocher <sup>(4)</sup>	France 39
Sofarimex	Portugal 40
<b>F.3. Proportionately consolidated</b>	
<b>Europe</b>	
Synthelabo Tanabe Chimie	France 50
Fonda BV	Netherlands 50
<b>United States</b>	
Organon Sanofi-Synthelabo LLC	USA 50
<b>Other Countries</b>	
Organon Sanofi-Synthelabo Canada Partnership	Canada 50
Fujisawa Sanofi-Synthelabo	Japan 51
Organon Sanofi-Synthelabo Mexico SA de CV	Mexico 50
Fujisawa Sanofi-Synthelabo Pharmaceuticals company Limited	Taiwan 51

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The main non-consolidated companies are presented in note D.6.

---

- (1) Joint venture with Bristol-Myers Squibb, consolidated using the method described in note C.1.
- (3) Company absorbed by other consolidated companies during the year
- (4) Based on the consolidated financial statements of Financière des Laboratoires de Cosmétologie Yves Rocher

F-46

**Table of Contents****G. SIGNIFICANT DIFFERENCES BETWEEN FRENCH AND US GAAP****G.1. Reconciliation of net income and shareholders' equity and condensed consolidated US GAAP statements of income and balance sheets.**

The Group's consolidated financial statements have been prepared in accordance with French GAAP which, as applied by the Group, differs in certain significant respects from accounting principles generally accepted in the United States of America (US GAAP).

The effects of the application of US GAAP on net income for each of the years ended December 31, 2003, 2002 and 2001 are set out in the table below:

	Year Ended		
	December 31, 2003	December 31, 2002	December 31, 2001
	<i>(in millions of euros)</i>		
<b>Net income, as reported under French GAAP</b>	2,076	1,759	1,585
<b>US GAAP adjustments:</b>			
(a) Purchase accounting:			
Synthelabo Group	(249)	(265)	(364)
Sterling	(20)	(46)	(52)
Other			(29)
(b) Provisions and other liabilities			(23)
(c) Stock-based compensation	(50)	(8)	(8)
(d) Revenue recognition - US BMS Alliance	33	117	(136)
(e) Other	(16)	31	(42)
(f) Deferred income tax effect on above adjustments	94	54	169
(g) Deferred income tax on equity investees	(3)	(2)	(2)
<b>Total US GAAP adjustments</b>	(211)	(119)	(487)
<b>Net income, as determined under US GAAP</b>	1,865	1,640	1,098



**Table of Contents**

The effects of the application of US GAAP on shareholders' equity as of December 31, 2003, 2002 and 2001 are set out in the table below:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
<b>Shareholders' equity, as reported under French GAAP</b>	6,323	6,035	5,768
<b>US GAAP adjustments:</b>			
(a) Purchase accounting:			
Synthelabo Group	8,170	8,465	8,761
Sterling	6	1	18
Other	91	110	148
(b) Provisions and other liabilities			35
(c) Stock-based compensation			
(d) Revenue recognition - US BMS Alliance		(35)	(160)
(e) Other	(635)	(695)	(456)
(f) Deferred income tax effect on above adjustments	(1,198)	(1,264)	(1,349)
(g) Deferred income taxes on equity investees	(21)	(18)	(16)
<b>Total US GAAP adjustments</b>	6,413	6,564	6,981
<b>Shareholders' equity, as determined under US GAAP</b>	12,736	12,599	12,749

The following are the Group's condensed consolidated statements of income prepared in accordance with US GAAP for each of the years ended December 31, 2003, 2002 and 2001:

	December 31, 2003	December 31, 2002	December 31, 2001
		<i>(in millions of euros)</i>	
Revenues from sale of products	8,048	7,448	6,069
Revenues from licensing agreements	611	565	496
<b>Revenues</b>	8,659	8,013	6,565
Cost of goods sold	(1,941)	(1,850)	(1,722)
Research and development	(1,343)	(1,225)	(1,037)
Selling and general	(2,579)	(2,472)	(2,272)
Intangibles - amortization and impairment	(453)	(502)	(592)
Other income and expense, income from equity investees and minority interests	454	337	773
	2,797	2,301	1,715
Income taxes	(932)	(661)	(617)
<b>Net income</b>	1,865	1,640	1,098

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

<b>Earnings per share (in euros)</b>			
Basic earnings per share	2.71	2.30	1.52
Diluted earnings per share	2.70	2.28	1.51

F-48

**Table of Contents**

The following are the Group's condensed consolidated balance sheets prepared in accordance with US GAAP as of December 31, 2003, 2002 and 2001:

	December 31, 2003	December 31, 2002	December 31, 2001
	<i>(in millions of euros)</i>		
<b>Assets</b>			
Cash and cash equivalents	152	144	123
Short-term investments and deposits	2,614	2,321	3,710
Accounts receivable	1,576	1,341	1,587
Inventories	799	823	805
Deferred income taxes	362	364	332
Other current assets	923	868	550
<b>Total current assets</b>	<b>6,426</b>	<b>5,861</b>	<b>7,107</b>
Property, plant and equipment	1,427	1,363	1,178
Goodwill	4,788	4,784	4,587
Other intangible assets	4,533	5,140	5,178
Other non-current assets	250	214	182
<b>Total assets</b>	<b>17,424</b>	<b>17,362</b>	<b>18,232</b>
<b>Liabilities and shareholders' equity</b>			
Accounts payable	657	596	717
Current portion of long-term debt	315	351	285
Other current liabilities	1,614	1,591	2,089
<b>Total current liabilities</b>	<b>2,586</b>	<b>2,538</b>	<b>3,091</b>
Long-term debt	53	65	119
Deferred income taxes	1,118	1,184	1,280
Other non-current liabilities	913	959	972
<b>Total liabilities</b>	<b>2,084</b>	<b>4,746</b>	<b>5,462</b>
Minority interests	18	17	21
Shareholders' equity	12,736	12,599	12,749
<b>Total liabilities and shareholders' equity</b>	<b>17,424</b>	<b>17,362</b>	<b>18,232</b>

**Table of Contents**

The following are the Group's consolidated statements of comprehensive income prepared in accordance with US GAAP for each of the years ended December 31, 2003, 2002 and 2001:

	December 31, 2003	December 31, 2002	December 31, 2001
	<i>(in millions of euros)</i>		
<b>Net income, as determined under US GAAP</b>	1,865	1,640	1,098
<b>Other comprehensive income (loss):</b>			
Foreign currency translation adjustments	(233)	(112)	3
Net unrealized gain (loss) on cash flow hedges, net of related tax of 17, 8 and 11, respectively	31	14	21
Net unrealized gain (loss) on available-for-sale securities, net of related tax of (2), 2 and 15, respectively	5	(5)	(21)
Reclassification adjustment for realized gains (losses) included in income, net of related tax of zero, zero and zero, respectively			
Total change in unrealized gains on available-for-sale securities	5	(5)	(21)
Additional minimum pension liability, net of related tax of 4, 33 and 21, respectively	(7)	(67)	(39)
<b>Comprehensive income, as determined under US GAAP</b>	1,661	1,470	1,062

**(a) Purchase accounting**

Under French and US GAAP, business combinations are generally accounted for as purchases. The cost of an acquired company is assigned to the tangible and intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. Any excess of purchase price over the fair value of the tangible and intangible assets acquired is allocated to goodwill, which is amortized over its estimated useful life under French GAAP only. Information with respect to the specific differences between French GAAP and US GAAP for the Group's significant acquisitions is provided below.

**a-1 Merger of Sanofi Group and Synthelabo Group**

Sanofi-Synthelabo was formed following the merger of the Sanofi Group and the Synthelabo Group in 1999. Under French GAAP, the transaction between the Sanofi Group and the Synthelabo Group was accounted for as a merger, effective July 1, 1999, which resulted in the harmonization of accounting policies and the revaluation of assets and liabilities of both the Sanofi Group and the Synthelabo Group to adjust them to their value to the Group.

Under US GAAP, the merger is required to be accounted for as a purchase in accordance with APB Opinion No. 16, Business Combinations. The Sanofi Group is deemed to be the accounting acquirer with the assets and liabilities of the Synthelabo Group being recorded at their estimated fair values. The effective date of the acquisition for accounting purposes was July 1, 1999; accordingly, the results of operations and

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

cash flows of Synthélabo are included from July 1, 1999.

The aggregate adjustment related to the merger included in the reconciliations of net income and shareholders' equity includes adjustments related to both (i) the application of US GAAP purchase accounting to the assets and liabilities of the Synthélabo Group as well as (ii) the effects of US GAAP adjustments related to the reversal of revaluations recorded in connection with the merger related to the assets and liabilities of the Sanofi Group.

F-50

**Table of Contents**

The components of the aggregate shareholders' equity and net income adjustments included in the reconciliations as of and for each of the years ended December 31, 2003, 2002 and 2001 are summarized below:

	2003		2002		2001	
	Net Income	Equity	Net Income	Equity	Net Income	Equity
	<i>(in millions of euros)</i>					
Investment in Lorex	(67)	566	(67)	638	(67)	705
Identified intangible assets	(237)	2,928	(259)	3,160	(215)	3,438
Goodwill	8	4,690	8	4,684	(189)	4,628
Stock-based compensation			(1)		(2)	
Provisions and other	47	(14)	54	(17)	109	(10)
<b>Total adjustment</b>	<b>(249)</b>	<b>8,170</b>	<b>(265)</b>	<b>8,465</b>	<b>(364)</b>	<b>8,761</b>

The identified intangible assets are being amortized over their estimated useful lives (ranging from 10 to 40 years). Goodwill was being amortized over its estimated useful life of 30 years until December 31, 2001.

Following the issuance in June 2001 by the Financial Accounting Standards Board ( FASB ) of Statement of Financial Accounting Standards ( SFAS ) 141, Business Combinations, the Group has reclassified as goodwill an assembled workforce, previously treated as an intangible asset. This reclassification took effect from January 1, 2002.

With effect from January 1, 2002, the date on which the Group adopted SFAS 142, Goodwill and Other Intangible Assets and SFAS 144 Accounting for the Impairment or Disposal of Long-Lived Assets :

goodwill is no longer amortized;

existing goodwill and intangible assets acquired in prior business combinations have been subject to impairment tests using the specific methods required by these standards. These tests, performed as October 1, 2003, identified no impairment of goodwill.

Impairment tests performed on identified intangible assets during the year ended December 31, 2003 resulted in the recognition of an impairment loss of 67 million euros.

Impairment tests performed on identified intangible assets during the year ended December 31, 2002 resulted in an impairment loss of 80 million euros.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

The adjustments to identified intangible assets and goodwill for the year ended December 31, 2001 include losses of 24 million euros and of 11 million euros, respectively, related to the gain (loss) on disposals of certain businesses during the year.

### *Provisions and other provisions recorded in connection with a business combination*

Under US GAAP, the criteria related to recognition of restructuring provisions recorded in connection with a business combination are provided by EITF 95-3, Recognition of Liabilities in Connection with a Purchase Business Combination . EITF 95-3 requires that (i) management having the appropriate level of authority has begun to assess and formulate a restructuring plan, (ii) management having the appropriate level of authority completes the assessment and approves and commits the company to the plan as soon as possible after consummation of the acquisition and (iii) the plan is sufficiently detailed and the time period required to implement the plan is sufficiently short. In addition, costs associated with an exit plan are recognized as provisions only if the related costs are not associated with or do not benefit continuing activities of the company. Where these criteria are met, restructuring provisions are recorded directly in the purchase price allocation thereby not recognizing an expense in the statement of income.

## **Table of Contents**

Under French GAAP, until December 31, 2001 restructuring charges were recognized when management expected that the related costs would be incurred. The Group recorded restructuring liabilities, which were incurred principally in connection with the merger of the Sanofi Group and the Synthélabo Group (note D.14.2), during the period when a decision for the restructuring had been approved by management of the Group.

With the adoption and application, effective January 1, 2002, of *Comité de la Réglementation Comptable* standard CRC 2000-06, there are no longer any differences between French GAAP and US GAAP regarding the criteria for the recognition of provisions and other liabilities, with effect from the year ended December 31, 2002.

For the year ended December 31, 2001, certain of the restructuring provisions which were recorded in the fair value adjustments recognized under French GAAP in connection with the merger of the Sanofi Group and the Synthélabo Group did not qualify for recognition under US GAAP in accordance with EITF 95-3. Restructuring charges which did not qualify for recognition in purchase accounting under US GAAP were charged to expense under US GAAP when the criteria in EITF 94-3 were satisfied. For additional information on the requirements of EITF 94-3, see note G.1.(b).

### ***Provisions and other adjustments to shareholders equity related to the merger***

Under French GAAP, the Group recorded adjustments to beginning shareholders equity in the year ended December 31, 2001 as a result of the finalization of estimates in conjunction with the merger of Sanofi and Synthélabo, including provisions for restructuring, provisions for income taxes and other provisions. Depending on their nature, these French GAAP adjustments to shareholders equity were eliminated under US GAAP and were recorded either (i) as an adjustment to goodwill recorded in connection with the merger or (ii) as an adjustment to net income of the year ended December 31, 2001.

### ***a-2 Sterling***

In September 1994, Sanofi acquired the worldwide assets of the human healthcare division of Eastman Kodak ( Sterling ). Under French GAAP, no goodwill or intangibles associated with the acquisition of Sterling are reflected in the Sanofi-Synthélabo consolidated financial statements.

Under US GAAP certain intangible assets, including acquired in-process research and development, intellectual property rights and an assembled workforce, were valued and recorded, and were being amortized over their estimated useful lives ranging from 8 to 20 years. Effective January 1, 2002, following adoption of SFAS 141 and SFAS 142, the assembled workforce has been reclassified as goodwill and is no longer amortized. The aggregate cost of Sterling to the Sanofi Group was approximately 940 million euros, excluding assumed liabilities.

### ***a-3 Other***

Under French GAAP, no goodwill or intangible assets associated with certain other acquisitions made by the Sanofi Group before June 30, 1999 are reflected in the Sanofi-Synthélabo consolidated financial statements. Under US GAAP, certain intangible assets, including assembled workforce, were initially valued and recorded, and were amortized over their estimated useful lives. Effective January 1, 2002, following



adoption of SFAS 141 and SFAS 142, assembled workforces have been reclassified as goodwill and are no longer amortized.

**Table of Contents****(b) Provisions and other liabilities**

The components of the aggregate shareholders' equity and net income adjustments for provisions and other liabilities included in the reconciliations as of and for each of the years ended December 31, 2003, 2002 and 2001 are summarized below:

	2003		2002		2001	
	Net Income	Equity	Net Income	Equity	Net Income	Equity
	<i>(in millions of euros)</i>					
Restructuring provisions					(21)	20
Other provisions for risks and charges					(2)	15
<b>Total adjustment, before tax</b>					<b>(23)</b>	<b>35</b>

Until December 31, 2001:

Under French GAAP, certain provisions and reserves, excluding reserves for restructuring charges, could be provided for as of the balance sheet date when management had determined that it was more likely than not that the related costs would be incurred.

In addition, restructuring charges were recorded when management expected that the related costs would be incurred. The Group recorded restructuring liabilities, which were incurred principally in connection with the merger of the Sanofi Group and the Synthelabo Group (note D.14), during the period when a decision for the restructuring had been approved by management of the Group.

Under US GAAP, loss contingencies may only be accrued if it is considered probable that a liability has been incurred as of the balance sheet date and the amount of loss can be reasonably estimated. In addition, for certain reserves such as restructuring charges, additional criteria must be met in order to allow recognition of contingent losses as described further below.

Criteria related to recognition of restructuring provisions recorded in situations other than those involving a business combination are provided by EITF 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity* ( EITF 94-3 ). EITF 94-3 requires that certain specific conditions be satisfied prior to accruing for termination-related costs. Specifically, EITF 94-3 requires that (i) management having the appropriate level of authority has approved the restructuring plan, (ii) affected employees be notified prior to the balance sheet date and (iii) the plan is sufficiently detailed and the time period required to implement the plan is sufficiently short. In addition, costs associated with an exit plan are recognized as restructuring provisions only if the related costs are not associated with or do not benefit continuing activities of the company.

Effective January 1, 2002:

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Under French GAAP, adoption of CRC 2000-06 has led the Group to review all liabilities existing as of January 1, 2002 for compliance with the new rules. There is now no longer any difference between French GAAP and US GAAP as regards the criteria for the recognition of provisions.

### (c) **Stock-based compensation**

Under French GAAP, no compensation expense related to stock-based compensation plans is recognized in the financial statements. The shares issued upon exercise of the options are reflected as an increase in share capital upon exercise of the option.

F-53

**Table of Contents**

Under US GAAP, prior to 2003, the company accounted for stock-based employee compensation plans under the recognition and measurement provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. Under APB 25, when the exercise price of the stock options is less than the market price of the underlying shares on date of grant, compensation expense is recognized over the related vesting period, if any. Stock-based employee compensation cost determined in accordance with the provisions of APB 25 is reflected in 2002 and 2001 net income.

Effective January 1, 2003, the Group voluntarily adopted the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Under the modified prospective method of adoption selected by the Group under the provisions of FASB Statement No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, compensation cost recognized in 2003 is the same as that which would have been recognized had the recognition provisions of Statement 123 been applied from its original effective date. In accordance with the modified prospective method of adoption, results for prior years have not been restated. In accordance with FAS 123, compensation expense for options is measured by the fair value of the option at the date of grant and recognized over the vesting period. This fair value is estimated using the Black-Scholes option-pricing model.

**(d) Revenue recognition BMS Alliance**

Not all US GAAP revenue recognition criteria were met for sales made by alliance entities under the operational management of BMS to certain wholesalers made between 1999 and 2002. The related revenues have therefore been restated under US GAAP.

Certain revenues were recognized on the date of shipment, whereas under US GAAP they should have been recognized on a consignment basis. In the case of these sales, the risks and rewards of ownership are not treated as having been transferred under US GAAP, in that the wholesalers were holding inventory in excess of the requirements of their normal business cycle. Consequently, the seller had a future commitment to reduce the selling price to cover the costs incurred by the wholesalers in carrying the excess inventories.

Revenue recognition on a consignment basis involves accounting for the sale as deferred revenue on shipment, and accounting for the inventory physically held by the wholesaler as consignment inventory priced at cost. The revenue is recognized when the inventory is no longer subject to specific rebate conditions in favor of the wholesaler, or on final sale by the wholesaler at the latest.

These adjustments relate to entities treated as equity investees in the Group's US GAAP financial statements, and have an impact on these financial statements, primarily on the following three lines:

Revenues from licensing agreements

Other income and expense, income from equity investees and minority interests

Income tax

In 2003 no more sales have been made on a consignment basis and as at December 31,2003 all specific rebate conditions in favor of wholesaler have been accrued.



**Table of Contents****(e) Other**

The aggregate adjustment included as *Other* in the reconciliations of consolidated net income and shareholders' equity as of and for the years ended December 31, 2003, 2002 and 2001, consists of:

	Net Income			Shareholders' Equity		
	2003	2002	2001	2003	2002	2001
	<i>(in millions of euros)</i>					
<b>US GAAP adjustments:</b>						
Derivative financial instruments	1	8	(36)	112	63	34
Revenue recognition			14			
Marketable and investment securities	(4)	(1)		6	2	10
Pensions and post-retirement benefits	(11)	(11)	(11)	(140)	(137)	(38)
Treasury shares	(2)	35	(9)	(613)	(623)	(462)
<b>Total adjustment, before tax</b>	<b>(16)</b>	<b>31</b>	<b>(42)</b>	<b>(635)</b>	<b>(695)</b>	<b>(456)</b>

*Derivative financial instruments*

Under French GAAP, the Group uses derivative instruments to hedge its exposure to risks arising from fluctuations in exchange rates and interest rates and to protect operating margins. Generally, the Group's derivative financial instruments hedge anticipated transactions. 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 of instruments not qualifying for hedge accounting under French GAAP are recognized in the statement of income.

Under US GAAP, the Group applies SFAS 133, which establishes accounting and reporting standards for derivative instruments, including derivatives embedded in other contracts, and hedging activities. All derivatives, whether designated in a hedging relationship or not, are required to be recorded on the balance sheet at fair value. If the derivative is designated as a fair value hedge, the changes in the fair value of the derivative instrument and of the hedged item attributable to the hedged risk are recognized in earnings. If the derivative is designated as a cash flow hedge, the effective portion of changes in the fair value of the derivative instrument is recorded in other comprehensive income and recognized in earnings when the hedged item affects earnings. The ineffective portion of changes in the fair value of cash flow hedges is recognized in earnings.

Under US GAAP, the Group applies SFAS 133, and accounts for substantially all of its derivative financial instruments as cash flow hedges.

For the years ended December 31, 2003, 2002, and 2001 the Group recognized a net unrealized gain of respectively six million euros, six million euros and one million euro in net income, which is included in *Other income/(expense), net* in the statement of income related to derivative financial instruments which either did not qualify as cash flow hedges or which are designated as trading instruments.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Unrealized gains and losses included in other comprehensive income are reclassified into earnings when the forecasted transaction occurs. The Group estimates that a net unrealized gain of 102 million euros (before income taxes), which is included in accumulated other comprehensive income as of December 31, 2003, will be reclassified to earnings during the year ending December 31, 2004.

The Group's cash flow hedges of forecasted transactions as of December 31, 2003 relate to exposures to variability in future cash flows which are forecasted to occur in the future. For the year ended December 31, 2003, no gains or losses were reclassified into earnings as a result of the discontinuance of cash flow hedges because it was probable that the original forecasted transaction would not occur.

F-55

## **Table of Contents**

### *Revenue recognition other*

Under French GAAP, non-refundable up-front payments received related to research and development and/or marketing arrangements are recognized immediately in the statement of income. Also, amounts not recoverable at the time of execution of an agreement are recorded as revenue and are provided for.

Under US GAAP, Staff Accounting Bulletin ( SAB ) No. 104, Revenue Recognition in Financial Statements , precludes immediate recognition of up-front payments received related to these types of arrangements except in limited circumstances. In situations where up-front payments, even if non-refundable, are not permitted to be recognized immediately in income, they are generally recognized over the period to which they are considered to relate. Amounts not recoverable at the time of execution of an agreement are deferred and recognized if, and when, recoverability is assured.

### *Marketable and investment securities*

Under French GAAP, marketable securities are valued at the lower of cost or market value. Investment securities are stated at the lower of acquisition cost or value in use. Provisions for impairment that are recorded when value in use is lower than acquisition cost may be reversed if asset values increase. Unrealized gains on marketable and investment securities are not recognized.

Under US GAAP, marketable securities and investment securities are classified into three categories: trading, held-to-maturity and available-for-sale. The Group owns principally available-for-sale securities for which unrealized gains and losses are recorded in other comprehensive income. Unrealized losses that are other-than-temporary are charged to the statement of income. As of December 31, 2003, 2002 and 2001, the Group's available-for-sale securities had an aggregate fair value of 20 million euros, 15 million euros and 42 million euros, respectively.

### *Pensions and post-retirement benefits*

Under French GAAP, the Group's pension schemes and post-retirement benefits are reflected in the balance sheet as liabilities and in the statement of income as expense based on actuarial computations that comply with French GAAP requirements.

Under US GAAP, the Group accounts for its pension and post-retirement benefit plans in accordance with SFAS 87, Employers Accounting for Pensions and SFAS 106, Employers Accounting for Postretirement Benefits . Transition obligations for pensions were calculated as of December 31, 1999 as permitted for companies outside the United States and have been amortized from the initial implementation date of SFAS 87 in 1989 over a period equal to the higher of 15 years or the remaining expected service life of employees.

In US GAAP financial statements, an additional minimum pension liability is required when, as result of unamortized actuarial losses, prior service costs and transition obligation, the accrued liability is lower than the excess of the accumulated benefit obligation over the fair value of the plan assets. This additional minimum pension liability is recorded, according to the SFAS 87, with a counterpart in an asset account included



in intangible assets for an amount limited to the addition of unrecognized prior service costs and transition obligation. The residual amount is recorded with a counterpart in other comprehensive income.

**Table of Contents**

*Treasury shares*

Under French GAAP, treasury shares repurchased for purposes of re-allocating them to employees pursuant to a stock-based compensation plan are recorded, as an asset in the Group's balance sheet. Their valuation depends on the probability of exercise at the closing date:

purchase options whose future exercise is deemed probable, because their exercise price is less than their stock market value at the closing date, are valued separately for each plan at the lower of cost or exercise price;

purchase options whose future exercise is deemed not probable, because their exercise price is higher than their stock market value at the closing date, are valued at the lower of their average acquisition cost or average stock market value during the last month; treasury shares repurchased that were not yet allocated to specific plans or that became expired during the period are valued in accordance with the same method.

Under US GAAP, treasury shares repurchased are recorded, at cost, as a reduction of shareholders' equity. Any difference between the recorded cost and proceeds received on a subsequent issuance of the treasury shares is also reflected directly in shareholders' equity.

As of December 31, 2003, the Group held 13,183,948 of its common shares in treasury for the purposes of stock-based compensation plans.

The Group acquired in the market 20,192,769 of its common shares, equivalent to 2,76% of the share capital. As of that date, the Group held 49,990,262 of its common shares, equivalent to 6,82% of the share capital.

**(f) Deferred income tax effect on above adjustments**

This adjustment reflects the tax effects of the adjustments reflected in the reconciliations of shareholders' equity and net income.

The Group is in a net deferred tax liability position under US GAAP principally due to the deferred tax liabilities recognized related to identified intangible assets recorded under US GAAP in connection with the merger of Sanofi and Synthélabo. The reversal of these deferred tax liabilities will allow the Group to realize the benefit of certain deferred tax assets under US GAAP. Therefore, this adjustment also includes the recognition of certain deferred tax assets under US GAAP.

**(g) Deferred income taxes on equity investees**

Under French GAAP, a deferred tax liability is recorded for a taxable distribution when such distribution is considered probable.

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Under US GAAP, a deferred tax liability is recorded for the excess of the amount for financial reporting over the tax basis of investments in a 50%-or-less owned entity.

### **G.2. Differences in presentation between French GAAP and US GAAP**

Certain differences exist between the presentation of financial statements under French GAAP and US GAAP. Below is a summary of the significant presentation differences for the Group.

F-57

## **Table of Contents**

### ***Proportionate consolidation***

Under French GAAP, joint ventures are accounted for under the proportionate consolidation method. Under this method, the Group presents its proportionate share of the assets, liabilities, equity, revenues and expenses of the joint venture in each major caption of its balance sheets and statements of income.

Under US GAAP, investments in joint ventures are generally accounted for by the equity method.

The differences in accounting treatment between the proportionate consolidation method and the equity method have no impact on shareholders equity or net income. The impact is limited to presentation differences only.

These presentation differences for Lorex Pharmaceuticals, the only significant investment accounted for by the proportionate consolidation method under French GAAP until December 31, 2001, have been reflected in the statements of income for 2001. Summarized financial information relating to Lorex Pharmaceuticals is presented in note G.4 on an aggregate basis with the Group's other equity method investees.

Lorex Pharmaceuticals is fully consolidated in the balance sheet as of December 31, 2001 under French and US GAAP, with the statement of income fully consolidated as from January 1, 2002.

### ***Presentation of Alliance agreements with BMS***

Under French GAAP, the Alliance entities majority-owned by BMS are presented in a manner similar to the equity method with the Group's share of the Alliance's operating profit recorded in "Other operating income/(expense)" in the statements of income. Alliance entities majority-owned by the Group are fully consolidated, with BMS' share of the operating profit recorded in "Other operating income/(expense)" in the statements of income.

Under US GAAP, the entities majority-owned by BMS are presented as equity method investees in the condensed US GAAP financial statements with the Group's share of the operating profits of the Alliance recorded as income from equity method investees in the statements of income. Under US GAAP, Alliance entities majority-owned by the Group are fully consolidated in the condensed US GAAP financial statements with BMS' share of the operating profit presented in minority interests in the condensed US GAAP statements of income.

The difference is solely in terms of classification and display and has no impact on shareholders' equity or net income. These reclassifications have been reflected in the condensed US GAAP balance sheets and statements of income.

Summarized financial information relating to Alliance entities majority-owned by BMS is presented in note G.4 on an aggregate basis with the Group's other equity method investees.

*License income and government levies*

Under French GAAP, the Group records license income and specific government levies related to the pharmaceuticals sector paid in certain countries in Cost of goods sold .

Under US GAAP, license income is reflected as Revenues , and specific government levies related to the pharmaceuticals sector are reflected in Selling and general expenses .

These reclassifications have been reflected in the condensed US GAAP statements of income.

## **Table of Contents**

### ***Exceptional items***

Certain amounts presented as exceptional income and expense (non-operating) in the consolidated statements of income under French GAAP do not qualify as non-operating items under US GAAP.

### ***Cash flow presentation***

Under French GAAP, the share of undistributed earnings of the Alliance entities majority-owned by and under the operational management of BMS, and BMS' share of undistributed earnings of the Alliance entities majority-owned by and under the operational management of the Group, are presented in "Change in other operating assets and liabilities (net)" in the statements of cash flows.

Under US GAAP, the share of undistributed earnings of the Alliance entities majority-owned by BMS would be presented under "Share in undistributed earnings of equity investees", and BMS' share of undistributed earnings of the Alliance entities majority-owned by the Group would be presented as "Minority interests" in the statements of cash flows.

This presentation difference has no impact on cash from operations as reported under French GAAP.

## **G.3. Additional disclosures for the Group's US GAAP financial statements**

Additional financial disclosures are required under US GAAP related to the Group's financial statements measured under US GAAP. The following disclosures relate to the Group's financial statements after reconciliation to US GAAP.

### **G.3.1. Intangible assets**

Effective January 1, 2002, the Group adopted SFAS 142 "Goodwill and Other Intangible Assets". Under SFAS 142 goodwill and intangible assets with indefinite useful lives are no longer amortized, but are subject to impairment tests, initially upon adoption of SFAS 142 and subsequently on an annual basis. All other intangible assets (those with a definite useful life) must be amortized over their estimated useful lives, and are only subject to impairment tests if an impairment event occurs.

The main effects of adopting SFAS 142 on the Group's US GAAP financial disclosures for 2002 are:

assembled workforces, previously identified by the Group as intangible assets and amortized, have been reclassified as goodwill and are no longer amortized as from January 1, 2002;

goodwill, which was previously amortized, is no longer amortized as from January 1, 2002.

**Table of Contents**

The Group's intangible assets as of December 31, 2003 and 2002, as determined under US GAAP, consist of:

	<u>Estimated</u>		
	<u>Useful</u>		
	<u>Life</u>	<u>December 31, 2003</u>	<u>December 31, 2002</u>
	(years)	(millions of euros)	(millions of euros)
<b>Unamortized intangible assets</b>			
Goodwill	N/A	5,444	5,462
Less: Accumulated amortization		(656)	(678)
<b>Total goodwill</b>		<b>4,788</b>	<b>4,784</b>
<b>Amortized intangible assets</b>			
Intellectual property rights	5 10	59	56
Trademarks	5 20	23	10
Product rights and patents	3 23	6,808	7,313
		6,890	7,379
Less: Accumulated amortization		(2,375)	(2,277)
<b>Sub-total amortized intangible assets</b>		<b>4,515</b>	<b>5,102</b>
<b>Intangible asset related to pensions</b>		<b>18</b>	<b>38</b>
<b>Total: other intangible assets</b>		<b>4,533</b>	<b>5,140</b>

As of December 31, 2003 and 2002, the geographical allocation of goodwill net of accumulated amortization was as follows:

	<u>December 31,</u>	<u>December 31,</u>
	<u>2003</u>	<u>2002</u>
	(in millions of euros)	
Europe	2,605	2,606
United States	1,757	1,757
Other countries	426	421

Amortization expense and impairment losses charged against intangible assets during the year ended December 31, 2003 and 2002 amounted respectively to 453 million euros and 502 million euros.

This amount includes an impairment loss of 67 million euros related to intellectual property rights for two of the Group's products for the year ended December 31, 2003 and an impairment loss of 80 million euros related to intellectual property rights for three of the Group's products for the year ended December 31, 2002. These losses were primarily allocated to the Europe segment for the year ended December 31, 2003 and to



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

the Europe and Other countries segments for the year ended December 31, 2002, and represent the difference between fair value calculated on a discounted cash flow basis and carrying amount for the intangible assets in question.

Estimated amortization charges for the next 5 years are presented below:

	<b>Amount</b>
	<u>(in millions of euros)</u>
2004	394
2005	388
2006	388
2007	388
2008	388

F-60

**Table of Contents**

If SFAS 142 had been applied effective January 1, 2001, net income and earnings per share for the year ended December 31, 2001 would have been as follows:

	<b>December 31, 2001</b>
	<i>(in millions of euros, except for per-share amounts)</i>
<b>Net income</b>	1,098
Add back: Intangibles amortization	42
Add back: Goodwill amortization	178
Adjust: Deferred taxes	(52)
Adjusted net income	1,266
<b>Basic earnings per share:</b>	
Net income	1.52
Intangibles amortization	0.06
Goodwill amortization	0.25
Deferred taxes	(0.07)
Adjusted net income	1.76
<b>Diluted earnings per share:</b>	
Net income	1.51
Intangibles amortization	0.06
Goodwill amortization	0.24
Deferred taxes	(0.07)
Adjusted net income	1.74

**G.3.2. Stock-based compensation****Options to purchase Group shares**

In conjunction with the acquisition of Synthélabo by Sanofi in 1999, Sanofi assumed stock option plans initiated by Synthélabo. The options were adjusted by the exchange ratio specified in the transaction but otherwise retained the same terms as those contained in the original Synthélabo Group options. No additional options will be granted under any of the assumed stock option plans.

**Options to subscribe Group shares**

No further grants may be made under the ex-Sanofi or ex-Synthélabo legacy stock option plans.

**Pro forma information**

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Pro forma information regarding net income and earnings per share is required under SFAS 123, Accounting for Stock-Based Compensation. The US GAAP information provided below has been determined as if the Group had accounted for its employee stock option plans under the fair value method of SFAS 123 for each of the years ended December 31, 2003, 2002 and 2001.

	<b>December 31,</b>	<b>December 31,</b>
	<b>2002</b>	<b>2001</b>
	<i>(in millions of euros, except</i>	
	<i>per-share amounts)</i>	
Net income	1,640	1,098
Add: Stock-based compensation expense included in net income	8	8
Deduct: Stock-based compensation expense using the fair value method	(43)	(31)
Pro forma net income	1,605	1,075
Basic earnings per share	2.30	1.52
Basic earnings per share pro forma	2.25	1.49
Diluted earnings per share	2.28	1.51
Diluted earnings per share pro forma	2.24	1.48

F-61

**Table of Contents**

The fair value of each option was estimated as of the date of grant using the Black-Scholes option-pricing model. The assumptions used in this model to value stock options granted during each of the years ended December 31, 2003, 2002 and 2001 are provided below:

	December 31, 2003	December 31, 2002	December 31, 2001
<b>Weighted average assumptions</b>			
Expected dividend yield	2.80%	1.93%	1.27%
Volatility percentage	35.90%	33.80%	32.90%
Risk-free interest rate	3.00%	4.75%	4.50%
Holding period	5 years	5 years	5 years
Weighted average fair value of options granted (in euros)	15.53	19.43	24.63
Total fair value of options granted (in euros)	65,500,880	60,463,246	72,325,993

**G.3.3. Pensions and postretirement benefits**

The following table analyses the amounts recognized in the Group's US GAAP condensed consolidated balance sheet as of December 31, 2003, 2002 and 2001:

	Pensions and Retirement			Post-retirement Benefits		
	Indemnities			Other Than Pensions		
	2003	2002	2001	2003	2002	2001
<i>(in millions of euros)</i>						
<b>Amounts recognized in the balance sheet :</b>						
Prepaid benefit costs	(52)	(28)	(8)			
Accrued benefit liability	538	542	466	49	61	75
Intangible asset	(18)	(38)	(19)			
Accumulated other comprehensive income	(140)	(148)	(60)			
Net amount recognized	328	328	379	49	61	75

**G.3.4. Earnings per share**

Under US GAAP, basic earnings per share is computed using the weighted average number of common shares outstanding (excluding treasury shares). Diluted earnings per share is computed using the weighted average common and potentially dilutive common shares outstanding, determined as follows for each of the years ended December 31, 2003, 2002 and 2001:

Year ended December 31,		
2003	2002	2001

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

Weighted average shares outstanding used to compute basic earnings per share	689,018,905	714,322,379	720,726,645
Incremental shares issuable upon the assumed exercise of stock options	2,101,293	3,719,427	4,939,119
<b>Weighted average shares used to compute diluted earnings per share</b>	<b>691,120,198</b>	<b>718,041,806</b>	<b>725,665,764</b>

Incremental shares issuable upon the assumed exercise of outstanding stock options are computed using the average market price during the related period.

F-62

**Table of Contents****G.3.5. Accumulated other comprehensive income**

Accumulated other comprehensive income (determined in accordance with US GAAP) as of December 31, 2003, 2002 and 2001 comprises :

	December 31,	December 31,	December 31,
	2003	2002	2001
		<i>(in millions of euros)</i>	
Foreign currency translation adjustments	(547)	(314)	(202)
Net unrealized gain (loss) on cash flow hedges	66	35	21
Net unrealized gain (loss) on available-for-sale securities	4	(1)	4
Additional minimum pension liability	(93)	(106)	(39)
<b>TOTAL</b>	<b>(570)</b>	<b>(386)</b>	<b>(216)</b>

**G.3.6. Recent accounting pronouncements****Consolidation of Variable Interest Entities.**

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities, an interpretation of ARB No. 51, which was subsequently revised, in December 2003, through the issuance of Interpretation No. 46 (revised) ( FIN 46 ). FIN 46 requires variable interest entities ( VIE ) to be consolidated by the primary beneficiary of the VIE. Generally, entities are considered to be VIEs if the equity investors in the entity do not have the characteristics of a controlling financial interest or if the entity does not have sufficient equity at risk for it to finance its activities without additional subordinated financial support from other parties.

For VIEs created prior to February 1, 2003, the transition provisions of FIN 46 (revised) stipulate different transition provisions for application depending on whether or not a VIE constitutes a special purpose entity. For VIEs that are also considered to be special purpose entities, Sanofi-Synthelabo is required to apply the consolidation requirements of FIN 46 to that entity as of January 1, 2004. For VIEs that are not considered to be special purpose entities, Sanofi-Synthelabo is required to apply the consolidation requirements of FIN 46 to that entity as of December 31, 2004.

Sanofi-Synthelabo has begun the process of identifying potential variable interest entities and determining whether such variable interest entities should be consolidated in its financial statements. A number of potential variable interest entities, principally related to Sanofi-Synthelabo's joint venture arrangements, have been identified and Sanofi-Synthelabo is in the process of gathering and/or preparing the information and analysis necessary to determine whether it is the primary beneficiary.

Specifically, Sanofi-Synthelabo is in the process of assessing whether its potential VIEs qualify for scope exemptions from the provisions of FIN 46 (for example, pursuant to par. 4h of FIN 46 because the entities being evaluated constitute businesses, as that term is defined by FIN 46). If, as a result of this determination, it is determined that some or all of the entities being evaluated are VIEs that do not qualify for an exemption from the provisions of FIN 46, Sanofi-Synthelabo will be required to perform a more detailed analysis of the entities' expected losses and expected residual returns to determine whether it is the primary beneficiary of the entities. Sanofi-Synthelabo expects to finalize the

## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

aforementioned determinations and analyses with respect to its joint venture arrangements and any other potential variable interest entities in the third quarter of 2004.

Certain disclosure provisions of FIN 46 are effective for financial statements initially issued after January 31, 2003. In addition, the consolidation requirements of FIN 46 are effective immediately for all VIEs created after January 31, 2003. The application of FIN 46 to variable interest entities created after January 31, 2003 did not have any impact on the consolidated financial statements of Sanofi-Synthelabo as of or for the year ended December 31, 2003.

F-63

## **Table of Contents**

### **Amendment of Statement 133 on Derivative Instruments and Hedging Activities**

In April 2003, the FASB issued Statement of Financial Accounting Standards No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities ( SFAS 149 ). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133 Accounting for Derivative Instruments and Hedging Activities. In particular, SFAS 149 (1) clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative, (2) clarifies when a derivative contains a financing component, (3) amends the definition of an underlying to conform it to language used in FIN 45, and (4) amends certain other existing pronouncements. This Statement is effective for contracts entered into or modified after June 30, 2003, and for hedging relationships designated after June 30, 2003. In addition, most provisions of SFAS 149 are to be applied prospectively.

The Company does not anticipate that adoption of SFAS 149 will have a material impact on its results of operations, its financial position or its cash flows.

### **Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity**

In May 2003, the FASB issued Statement of Financial Accounting Standard No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ( SFAS 150 ). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). SFAS 150 affects the issuer's accounting for three types of freestanding financial instruments:

- (1) Mandatorily redeemable shares, which embodies an unconditional obligation requiring the issuer to redeem the instrument in exchange for cash or other assets at a specified or determinable date(s) or upon an event that is certain to occur;
- (2) Instruments that require or may require the issuer to repurchase some of its shares in exchange for cash or other assets, including written put options and forward purchase contracts;
- (3) Obligations that must or may be settled by issuing a variable number of equity shares, the monetary value of which is fixed, tied solely or predominantly to a variable such as a market index or varies inversely with the value of the issuer's shares.

SFAS 150 does not apply to features embedded in a financial instrument that is not a derivative in its entirety. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003. For instruments entered into prior to May 31, 2003, the provisions of SFAS 150 are effective at the beginning of the first interim period beginning after June 15, 2003 (for the Company, as of January 1, 2004). However, the Company does not anticipate that the adoption of SFAS 150 will have a material impact on its results of operations, financial position or cash flows when adopted.

### **Revenue Arrangements with Multiple Deliverables**



## Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

In November 2000, the EITF reached a consensus on EITF 00-21, Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). EITF 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF 00-21 applies to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company does not anticipate that the adoption of EITF 00-21 will have a material impact on its results of operations, financial position or cash flows.

F-64

## **Table of Contents**

### **International Financial Reporting Standards adoption**

The Company is to adopt International Financial Reporting Standards ( IFRS ) as primary generally accepted accounting principles ( GAAP ) by 2005 as required under European Regulation applicable to European public companies. The full set of IFRS applicable by 2005 is not yet known and still subject to endorsement by the European Commission.

Provided SEC regulations regarding the periods to be presented under a comprehensive set of GAAP is amended as proposed in March 2003 to allow foreign private issuers to include only two years of audited financial statements for their first year of reporting under IFRS, the Company is to select January 1, 2004 as its transition date to IFRS and thus to present restated 2004 and 2005 IFRS financial statements in its 2005 Form 20-F and to continue to report under French GAAP as primary GAAP in the meantime (2004).

Transition from French GAAP to IFRS will be made in compliance with IFRS 1 First Time Adoption of International Financial Reporting Standards general retrospective application guidance and related exemptions and exceptions.

The company is currently assessing the impact, which may be significant, that the application of IFRS will have on its 2004 financial statements and will disclose in any case as soon as practically possible after the full set of applicable IFRS is known and the transition date to IFRSs could be considered definitive:

in its primary GAAP financial statements, the reconciliation disclosure between French GAAP and IFRS (including narrative and net income and shareholders' equity detailed reconciliations) required with respect to 2004 financial statements and

the additional reconciliation disclosure between IFRS and US GAAP (including narrative and tabular net income and shareholders' equity reconciliations) with respect to 2004 financial statements required under SEC Rules when reporting under primary GAAP other than US GAAP.

#### ***G.4. Additional disclosures for the Group's French GAAP financial statements***

Additional financial statement disclosures are required under US GAAP related to the Group's financial statements measured under French GAAP. The following disclosures relate to the Group's financial statements as prepared under French GAAP.

### **Summarized financial information related to equity investees**

The table below presents summarized balance sheet information for Yves Rocher, Lorex Pharmaceuticals (accounted for by the equity method under US GAAP in 2001) and the significant Alliance entities majority-owned and under the operational management of BMS as of December 31, 2003, 2002 and 2001:

Edgar Filing: SANOFI SYNTHELABO SA - Form 20-F

	December 31, 2003	December 31, 2002	December 31, 2001
	<i>(in millions of euros)</i>		
<b>Assets</b>			
Current assets	1,435	1,411	1,257
Non-current assets	391	365	325
<b>TOTAL</b>	<b>1,826</b>	<b>1,776</b>	<b>1,582</b>
<b>Liabilities And Partners Capital</b>			
Current liabilities	1,297	1,238	1,051
Non-current liabilities	344	368	318
Equity	185	170	213
<b>TOTAL</b>	<b>1,826</b>	<b>1,776</b>	<b>1,582</b>

F-65

**Table of Contents**

The table below presents summarized income statement information for Yves Rocher, Lorex Pharmaceuticals (accounted for by the equity method under US GAAP in 2001) and the significant Alliance entities majority-owned and under the operational management of BMS for each of the years ended December 31, 2003, 2002 and 2001:

	<b>December 31,</b>	<b>December 31,</b>	<b>December 31,</b>
	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<u>          </u>	<u>          </u>	<u>          </u>
		<i>(in millions of euros)</i>	
Net sales	4,045	3,714	4,409
Cost of goods sold	1,192	1,121	1,392
Operating income	1,101	824	1,395
Net income	990	732	1,339

As described in notes C.2 and D.1, the balance sheet of Lorex Pharmaceuticals was fully consolidated as of December 31, 2001 following the transfer of control of Lorex Pharmaceuticals to Sanofi-Synthelabo from Pharmacia-Searle at the end of 2001. The results of operations of Lorex Pharmaceuticals have been fully consolidated as from January 1, 2002. Consequently, summarized financial information for 2001 includes balances for Lorex Pharmaceuticals for the statement of income only.

**Table of Contents**

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Dated: April 2, 2004

SANOFI-SYNTHÉLABO

By: /s/ Jean-François Dehecq

Name: Jean-François Dehecq

Title: Chairman and Chief Executive Officer

**Table of Contents**

**Exhibit Index**

Documents filed as exhibits to this annual report:

- 1.1 Bylaws (*statuts*) of Sanofi-Synthélabo (English translation) (incorporated herein by reference to Exhibit 3.1 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.1 Form of Deposit Agreement between Sanofi-Synthélabo and The Bank of New York, as depository (incorporated herein by reference to Exhibit A to the Registration Statement on Form F-6 dated June 26, 2002 relating to our American Depositary Shares, SEC File No. 333-91658)
- 2.2 Shareholders Agreement among Elf Aquitaine, Valorisation et Gestion Financière and L Oréal dated April 9, 1999 (English translation) (incorporated herein by reference to Exhibit 2.2. to our Registration Statement on Form 20-F dated June 25, 2002, SEC File No. 001-31368)
- 2.3 Amendment to Shareholders Agreement among Elf Aquitaine, Valorisation et Gestion Financière and L Oréal dated November 24, 2003 (English translation) (incorporated herein by reference to Exhibit 10.2 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.4 Protocol of Agreement, dated January 25, 2004, between Total S.A., Elf Aquitaine, Valorisation et Gestion Financière and L Oréal (English translation) (incorporated herein by reference to Exhibit 10.3 to our Registration Statement on Form F-4 dated January 29, 2004, SEC File No. 333-112314)
- 2.5 Credit Facility Agreement dated January 25, 2004 between Sanofi-Synthélabo and BNP Paribas and Merrill Lynch Credit Products (incorporated herein by reference to Exhibit 10.4 to Amendment No. 2 to our Registration Statement on Form F-4 dated March 29, 2004, SEC File No. 333-112314)
- 8.1 For a list of our significant subsidiaries, see Item 4 Information on the Company Organizational Structure
- 12.1 Certifications by Jean-François Dehecq, Chairman and Chief Executive Officer, and Marie-Hélène Laimay, Chief Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
- 13.1 Certifications by Jean-François Dehecq, Chairman and Chief Executive Officer, and Marie-Hélène Laimay, Chief Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
- 14.1 Consent of Ernst & Young Audit dated April 2, 2004
- 14.2 Consent of PricewaterhouseCoopers Audit dated April 2, 2004
- 99.1 Report of the Chairman of the Board of Directors for 2003 as required by Art. 117 of the French Financial Security Law (*Loi de Sécurité Financière*) (English Translation)