DWS MUNICIPAL INCOME TRUST
Form N-Q
October 26, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM N-Q
QUARTERLY SCHEDULE OF PORTFOLIO HOLDINGS OF REGISTERED
MANAGEMENT INVESTMENT COMPANY

Investment Company Act file number: 811-05655

DWS Municipal Income Trust
(Exact name of registrant as specified in charter)

345 Park Avenue
New York, NY 10154
(Address of principal executive offices) (Zip code)

Paul Schubert
60 Wall Street
New York, NY 10005
(Name and address of agent for service)

Registrant's telephone number, including area code: (212) 250-3220

Date of fiscal year end: 11/30

Date of reporting period: 8/31/2012

ITEM 1. SCHEDULE OF INVESTMENTS

Investment Portfolio as of August 31, 2012 (Unaudited)

DWS Municipal Income Trust

	Principal Amount ($)	Value ($)
Municipal Bonds and Notes 115.9%		
Alabama 0.2%		
Camden, AL, Industrial Development Board Revenue, Series B, AMT, Prerefunded, 6.375%, 12/1/2024	1,000,000	1,076,940
Arizona 1.1%		
Arizona, Salt Verde Financial Corp., Gas Revenue:		
5.0%, 12/1/2037	1,050,000	1,121,999
5.5%, 12/1/2029	1,400,000	1,577,716

Phoenix, AZ, Civic Improvement Corp., Airport Revenue, Series A, 5.0%, 7/1/2040	3,000,000	3,315,570
		6,015,285
California 21.7%		
California, Bay Area Toll Authority, Toll Bridge Revenue, San Francisco Bay Area, Series F-1, 5.125%, 4/1/2039	5,000,000	5,604,950
California, Health Facilities Financing Authority Revenue, Catholic Healthcare West, Series A, 6.0%, 7/1/2039	3,500,000	4,133,535
California, M-S-R Energy Authority, Series A, 7.0%, 11/1/2034	3,180,000	4,232,834
California, San Gorgonio Memorial Healthcare, Election of 2006, Series C, 7.2%, 8/1/2039	5,000,000	5,881,900
California, South Bayside Waste Management Authority, Solid Waste Enterprise Revenue, Shoreway Environmental Center, Series A, 6.25%, 9/1/2029	5,345,000	6,106,235
California, Special Assessment Revenue, Golden State Tobacco Securitization Corp., Series 2003-A-1, Prerefunded, 6.75%, 6/1/2039	11,730,000	12,305,943
California, State General Obligation:		
5.0%, 2/1/2033	5,000,000	5,637,750
5.25%, 4/1/2035	4,295,000	4,904,246
5.5%, 3/1/2040	1,370,000	1,572,239
6.0%, 4/1/2038	10,000,000	11,796,200
California, State Public Works Board, Lease Revenue, Capital Projects, Series I-1, 6.375%, 11/1/2034	2,000,000	2,428,680
California, State Public Works Board, Lease Revenue, Department of Corrections, Series C, Prerefunded, 5.5%, 6/1/2021	2,500,000	2,663,425
California, State Public Works Board, Lease Revenue, Department of General Services, Buildings 8 & 9, Series A, 6.25%, 4/1/2034	6,640,000	7,896,288
California, Statewide Communities Development Authority Revenue, American Baptist Homes of the West, 6.25%, 10/1/2039, GTY: American Baptist Homes of the Midwest	1,250,000	1,359,650
Corona-Norco, CA, Unified School District, Election of 2006, Series A, 5.0%, 8/1/2031, INS: AGMC	5,130,000	5,611,604
Kern, CA, High School District, Election of 2004, Series B, 5.0%, 8/1/2030, INS: AGMC	13,270,000	14,007,281
Los Angeles, CA, Community College District, Election of 2008, Series C, 5.25%, 8/1/2039	3,000,000	3,491,970
Los Angeles, CA, Department of Airports Revenue, Los Angeles International Airport, Series B, 5.0%, 5/15/2035	8,500,000	9,503,255
Port Oakland, CA, Series A, AMT, 5.0%, 11/1/2027, INS: NATL	5,850,000	6,175,670
San Diego, CA, Community College District, Election of 2006, 5.0%, 8/1/2036	2,850,000	3,282,146
		118,595,801
Colorado 1.0%		

Colorado, E-470 Public Highway Authority Revenue, Series A-1, 5.5%, 9/1/2024, INS: NATL	2,500,000	2,733,525
Colorado, Health Facilities Authority Revenue, Covenant Retirement Communities, Inc., 5.0%, 12/1/2035	2,500,000	2,578,800
		5,312,325
Florida 10.5%		
Miami-Dade County, FL, Aviation Revenue, Series A, 5.5%, 10/1/2041	10,000,000	11,409,700
Miami-Dade County, FL, Aviation Revenue, Miami International Airport:		
Series A, AMT, 5.25%, 10/1/2033, INS: AGC	8,500,000	9,175,495
Series A-1, 5.375%, 10/1/2035	2,000,000	2,288,460
Miami-Dade County, FL, Educational Facilities Authority Revenue, University of Miami, Series A, 5.75%, 4/1/2028	3,000,000	3,389,880
Miami-Dade County, FL, Expressway Authority, Toll Systems Revenue, Series A, 5.0%, 7/1/2035, INS: AGMC	3,000,000	3,337,350
North Brevard County, FL, Hospital District Revenue, Parrish Medical Center Project:		
5.5%, 10/1/2028	5,290,000	5,811,805
5.75%, 10/1/2038	5,000,000	5,534,950
Orlando & Orange County, FL, Expressway Authority Revenue:		
Series C, 5.0%, 7/1/2035	2,705,000	3,023,000
Series A, 5.0%, 7/1/2040	11,895,000	13,163,483
		57,134,123
Georgia 7.5%		
Atlanta, GA, Airport Revenue:		
Series A, 5.0%, 1/1/2035	1,030,000	1,139,994
Series C, AMT, 5.0%, 1/1/2037	1,690,000	1,850,111
Atlanta, GA, Water & Wastewater Revenue, Series A, 6.25%, 11/1/2039	5,815,000	6,996,201
Gainesville & Hall County, GA, Hospital Authority Revenue, Anticipation Certificates, Northeast Georgia Healthcare, Series A, 5.5%, 2/15/2045	2,135,000	2,381,144
Georgia, Main Street Natural Gas, Inc., Gas Project Revenue:		
Series A, 5.0%, 3/15/2020	7,250,000	8,243,612
Series A, 5.5%, 9/15/2024	5,000,000	5,553,100
Series A, 5.5%, 9/15/2028	10,000,000	11,019,900
Georgia, Medical Center Hospital Authority Revenue, Anticipation Certificates, Columbus Regional Healthcare Systems, 6.5%, 8/1/2038, INS: AGC	3,300,000	3,841,101
		41,025,163
Hawaii 2.2%		
Hawaii, State Airports Systems Revenue, Series A, 5.0%, 7/1/2039	4,200,000	4,623,654
	1,000,000	1,172,250

Hawaii, State Department of Budget & Finance, Special Purpose Revenue, Hawaiian Electric Co., Inc., 6.5%, 7/1/2039, GTY: Hawaiian Electric Co., Inc.		
Honolulu City & County, HI, Wastewater Systems Revenue, Series A, 5.25%, 7/1/2036	5,215,000	6,166,007
		11,961,911
Idaho 1.0%		
Idaho, Health Facilities Authority Revenue, St. Luke's Regional Medical Center:		
5.0%, 7/1/2035, INS: AGMC	2,500,000	2,764,800
6.75%, 11/1/2037	2,135,000	2,533,007
		5,297,807
Illinois 10.5%		
Chicago, IL, Airport Revenue, O'Hare International Airport:		
AMT, 5.5%, 1/1/2014, INS: AMBAC	10,000,000	10,013,900
Series A, 5.75%, 1/1/2039	5,000,000	5,895,900
Series B, 6.0%, 1/1/2041	9,000,000	10,782,720
Chicago, IL, General Obligation, Series A, 5.25%, 1/1/2035	2,025,000	2,279,907
Chicago, IL, Water Revenue, 5.0%, 11/1/2032	3,000,000	3,495,120
Illinois, Finance Authority Revenue, Advocate Health Care Network:		
Series B, 5.375%, 4/1/2044	2,500,000	2,754,125
Series D, 6.5%, 11/1/2038	1,000,000	1,177,480
Illinois, Finance Authority Revenue, Elmhurst Memorial Healthcare, Series A, 5.625%, 1/1/2037	3,000,000	3,228,150
Illinois, Finance Authority Revenue, Memorial Health Systems, 5.5%, 4/1/2039	4,200,000	4,572,750
Illinois, Finance Authority Revenue, Northwest Community Hospital, Series A, 5.5%, 7/1/2038	5,750,000	6,277,217
Illinois, Metropolitan Pier & Exposition Authority, Dedicated State Tax Revenue, McCormick Place, Series B, 5.0%, 6/15/2050, INS: AGMC	3,000,000	3,270,150
Illinois, Railsplitter Tobacco Settlement Authority, 6.0%, 6/1/2028	915,000	1,074,393
Illinois, State Finance Authority Revenue, Ascension Health Credit Group:		
Series A, 5.0%, 11/15/2032	730,000	829,966
Series A, 5.0%, 11/15/2037	520,000	579,389
University of Illinois, Auxiliary Facilities Systems, Series A, 5.25%, 4/1/2041	1,250,000	1,402,563
		57,633,730
Indiana 0.4%		
Indiana, Finance Authority Hospital Revenue, Deaconess Hospital Obligation, Series A, 6.75%, 3/1/2039	1,745,000	2,063,812
Kentucky 1.8%		
	4,000,000	4,399,480

Kentucky, Economic Development Finance Authority, Louisville Arena Project Revenue, Series A-1, 6.0%, 12/1/2042, INS: AGC		
Louisville & Jefferson County, KY, Metropolitan Government Health Systems Revenue, Norton Healthcare, Inc., 5.0%, 10/1/2030	5,000,000	5,200,800
		9,600,280
Louisiana 1.0%		
Louisiana, Public Facilities Authority, Hospital Revenue, Lafayette General Medical Center, 5.5%, 11/1/2040	3,000,000	3,299,610
Louisiana, St. John Baptist Parish Revenue, Marathon Oil Corp., Series A, 5.125%, 6/1/2037	2,315,000	2,456,007
		5,755,617
Maryland 0.5%		
Maryland, State Health & Higher Educational Facilities Authority Revenue, Anne Arundel Health Systems, Series A, 6.75%, 7/1/2039	1,100,000	1,332,276
Maryland, State Health & Higher Educational Facilities Authority Revenue, Washington County Hospital, 5.75%, 1/1/2033	1,500,000	1,611,075
		2,943,351
Massachusetts 1.8%		
Massachusetts, Airport Revenue, U.S. Airways, Inc. Project, Series A, AMT, 5.875%, 9/1/2023, INS: NATL	5,000,000	5,005,450
Massachusetts, State Development Finance Agency Revenue, Babson College, Series A, 0.16% *, 10/1/2032, LOC: Citizens Bank	600,000	600,000
Massachusetts, State Health & Educational Facilities Authority Revenue, Suffolk University, Series A, 5.75%, 7/1/2039	3,570,000	3,979,622
		9,585,072
Michigan 5.0%		
Detroit, MI, Water & Sewerage Department Disposal System Revenue, Series A, 5.25%, 7/1/2039	1,120,000	1,194,805
Michigan, State Building Authority Revenue, Series I-A, 5.375%, 10/15/2041	7,500,000	8,637,225
Michigan, State Building Authority Revenue, Facilities Program:		
Series H, 5.125%, 10/15/2033	2,495,000	2,787,688
Series I, 6.0%, 10/15/2038	1,000,000	1,156,620
Michigan, State Hospital Finance Authority Revenue, Henry Ford Health Hospital, 5.75%, 11/15/2039	5,000,000	5,739,900
Michigan, State Hospital Finance Authority, Trinity Health Credit Group, Series C, 5.0%, 12/1/2034	4,950,000	5,543,406
Royal Oak, MI, Hospital Finance Authority Revenue, William Beaumont Hospital, 8.25%, 9/1/2039	1,800,000	2,319,390

		27,379,034
Minnesota 0.2%		
Minneapolis, MN, Health Care Systems Revenue, Fairview Health Services, Series A, 6.75%, 11/15/2032	1,140,000	1,362,175
Mississippi 0.4%		
Mississippi, State Business Finance Commission, Gulf Opportunity Zone, Chevron U.S.A., Inc. Project:		
Series G, 0.16% *, 12/1/2030, GTY: Chevron Corp.	400,000	400,000
Series E, 0.17% *, 12/1/2030, GTY: Chevron Corp.	300,000	300,000
Warren County, MS, Gulf Opportunity Zone, International Paper Co., Series A, 6.5%, 9/1/2032	1,525,000	1,727,901
		2,427,901
Nevada 3.2%		
Clark County, NV, Airport Revenue, Series B, 5.125%, 7/1/2036	4,305,000	4,746,478
Henderson, NV, Health Care Facility Revenue, Catholic Healthcare West, Series B, 5.25%, 7/1/2031	10,000,000	10,645,600
Las Vegas Valley, NV, Water District, Series B, 5.0%, 6/1/2037	1,830,000	2,076,848
		17,468,926
New Jersey 4.6%		
New Jersey, Economic Development Authority Revenue, Cigarette Tax, Prerefunded, 5.75%, 6/15/2034	1,090,000	1,196,090
New Jersey, Hospital & Healthcare Revenue, General Hospital Center at Passaic, ETM, 6.75%, 7/1/2019, INS: AGMC	5,000,000	6,263,100
New Jersey, Industrial Development Revenue, Economic Development Authority, Harrogate, Inc., Series A, 5.875%, 12/1/2026	1,400,000	1,400,784
New Jersey, State Transportation Trust Fund Authority, Transportation Systems:		
Series B, 5.5%, 6/15/2031	1,200,000	1,428,672
Series A, 5.5%, 6/15/2041	5,460,000	6,390,111
Series A, 6.0%, 12/15/2038	1,955,000	2,295,502
Series A, Prerefunded, 6.0%, 12/15/2038	1,045,000	1,367,895
New Jersey, State Turnpike Authority Revenue:		
Series A, 5.0%, 1/1/2035	1,065,000	1,230,192
Series E, 5.25%, 1/1/2040	1,750,000	1,969,590
New Jersey, Tobacco Settlement Financing Corp., Series 1-A, 5.0%, 6/1/2041	1,700,000	1,417,783
		24,959,719
New York 9.5%		
New York, Metropolitan Transportation Authority Revenue:		
Series D, 5.0%, 11/15/2032	2,565,000	2,962,960
Series E, 5.0%, 11/15/2042	765,000	856,800

New York, State Agency General Obligation Lease, Higher Education Revenue, Dormitory Authority, City University, Series A, 5.625%, 7/1/2016	1,490,000	1,689,198
New York, State Environmental Facilities Corp., State Clean Water & Drinking Revolving Funds, New York City Municipal Water Finance Authority Projects, 5.0%, 6/15/2036	2,000,000	2,316,140
New York, State Liberty Development Corp. Revenue, World Trade Center Port Authority Construction:		
5.0%, 12/15/2041	4,255,000	4,748,282
5.25%, 12/15/2043	5,000,000	5,737,650
New York, State Thruway Authority, General Revenue, Series I, 5.0%, 1/1/2037	1,340,000	1,514,186
New York, Tobacco Settlement Financing Corp., Series B-1C, 5.5%, 6/1/2019	15,500,000	16,091,790
New York City, NY, Municipal Water Finance Authority, Water & Sewer Revenue, Second General Resolution, Series EE, 5.375%, 6/15/2043	3,750,000	4,400,625
New York City, NY, Municipal Water Finance Authority, Water & Sewer Systems Revenue, Second General Resolution:		
Series A-1, 0.17% *, 6/15/2044, SPA: Mizuho Corporate Bank	1,950,000	1,950,000
Series AA-1, 0.18% *, 6/15/2032	1,460,000	1,460,000
Niagara Falls, NY, School District General Obligation, 5.6%, 6/15/2014, INS: AGMC	1,180,000	1,292,584
Port Authority of New York & New Jersey, AMT, 5.0%, 10/1/2034	6,000,000	6,776,760
		51,796,975
North Carolina 0.8%		
North Carolina, Electric Revenue, Municipal Power Agency, Series C, 5.375%, 1/1/2017	1,000,000	1,016,120
North Carolina, Medical Care Commission, Health Care Facilities Revenue, University Health System, Series D, 6.25%, 12/1/2033	3,000,000	3,520,920
		4,537,040
North Dakota 0.7%		
Fargo, ND, Sanford Health Systems Revenue, 6.25%, 11/1/2031	3,240,000	3,957,563
Ohio 2.7%		
Kent, OH, State University Revenues, General Receipts, Series A, 5.0%, 5/1/2037	1,500,000	1,700,880
Lucas County, OH, Hospital Revenue, Promedica Healthcare, Series A, 6.5%, 11/15/2037	1,500,000	1,873,560
Ohio, American Municipal Power, Inc. Revenue, Fremont Energy Center Project, Series B, 5.0%, 2/15/2037	1,445,000	1,622,518
Ohio, State Hospital Facility Revenue, Cleveland Clinic Health:		
Series A, 5.5%, 1/1/2039	5,000,000	5,610,150

Series B, 5.5%, 1/1/2039	3,500,000	3,927,105
		14,734,213
Oregon 0.2%		
Port of Portland, OR, Special Obligation Revenue, Horizon Air Industries, Inc. Project, AMT, 0.2% *, 6/15/2027, LOC: Bank of America NA	1,000,000	1,000,000
Pennsylvania 2.3%		
Allegheny County, PA, Hospital Development Authority Revenue, University of Pittsburgh Medical, 5.625%, 8/15/2039	1,700,000	1,917,362
Franklin County, PA, Industrial Development Authority Revenue, Chambersburg Hospital Project, 5.375%, 7/1/2042	7,000,000	7,580,230
Philadelphia, PA, Airport Revenue, Series A, 5.0%, 6/15/2035	2,835,000	3,079,264
		12,576,856
Puerto Rico 3.9%		
Puerto Rico, Sales Tax Financing Corp., Sales Tax Revenue:		
Series A, 5.375%, 8/1/2039	3,200,000	3,425,792
Series A, 6.5%, 8/1/2044	15,000,000	17,910,450
		21,336,242
Rhode Island 0.4%		
Rhode Island, Health & Educational Building Corp., Higher Education Facility Revenue, University of Rhode Island, Series A, 6.25%, 9/15/2034	2,000,000	2,343,780
South Carolina 1.8%		
Greenwood County, SC, Hospital Revenue, Self Regional Healthcare, Series B, 5.0%, 10/1/2031	1,000,000	1,109,600
South Carolina, Jobs Economic Development Authority, Hospital Facilities Revenue, Palmetto Health Alliance, Series C, Prerefunded, 7.0%, 8/1/2030	5,420,000	5,755,173
South Carolina, State Ports Authority Revenue, 5.25%, 7/1/2040	2,550,000	2,872,855
		9,737,628
Tennessee 2.9%		
Clarksville, TN, Natural Gas Acquisition Corp., Gas Revenue, 5.0%, 12/15/2021	2,000,000	2,140,340
Jackson, TN, Hospital Revenue, Jackson-Madison Project, 5.625%, 4/1/2038	4,000,000	4,506,400
Shelby County, TN, Health, Educational & Housing Facility Board, Hospital Revenue, Methodist Health Care, Prerefunded, 6.5%, 9/1/2026	7,000,000	7,000,000
Sullivan County, TN, Health, Educational & Housing Facilities Board, Hospital Revenue, Wellmont Health Systems Project, Series C, 5.25%, 9/1/2036	2,050,000	2,141,163

		15,787,903
Texas 12.7%		
Harris County, TX, Health Facilities Development Corp., Hospital Revenue, Memorial Hermann Healthcare System, Series B, 7.25%, 12/1/2035	1,000,000	1,251,190
Harris County, TX, Houston Port Authority, Series A, AMT, 6.25%, 10/1/2029	3,000,000	3,723,900
Houston, TX, Airport Revenue, People Mover Project, Series A, AMT, 5.5%, 7/15/2017, INS: AGMC	3,300,000	3,310,296
North Texas, Tollway Authority Revenue:		
First Tier, Series A, 5.625%, 1/1/2033	3,500,000	3,912,055
Second Tier, Series F, 5.75%, 1/1/2038	6,500,000	7,134,270
First Tier, 6.0%, 1/1/2043	5,000,000	5,855,100
North Texas, Tollway Authority Revenue, Special Project Systems, Series D, 5.0%, 9/1/2032	2,000,000	2,324,580
Texas, Dallas/Fort Worth International Airport Revenue:		
Series A, 5.25%, 11/1/2038	4,000,000	4,522,120
Series A, AMT, 5.875%, 11/1/2016, INS: FGIC, NATL	1,955,000	1,962,820
Texas, Industrial Development Revenue, Waste Disposal Authority, Series A, AMT, 6.1%, 8/1/2024	2,000,000	2,006,960
Texas, Municipal Gas Acquisition & Supply Corp. I, Gas Supply Revenue:		
Series B, 0.863% **, 12/15/2017	7,970,000	7,465,021
Series B, 1.013% **, 12/15/2026	1,500,000	1,134,300
Series D, 6.25%, 12/15/2026	5,000,000	5,951,450
Texas, SA Energy Acquisition Public Facility Corp., Gas Supply Revenue:		
5.5%, 8/1/2021	1,155,000	1,310,902
5.5%, 8/1/2025	7,250,000	8,208,450
Texas, Southwest Higher Education Authority, Inc., Southern Methodist University Project, 5.0%, 10/1/2035	1,600,000	1,831,232
West Harris County, TX, Regional Water Authority, Water Systems Revenue, 5.0%, 12/15/2035	6,500,000	7,415,980
		69,320,626
Virginia 0.3%		
Washington County, VA, Industrial Development Authority, Hospital Facility Revenue, Mountain States Health Alliance, Series C, 7.75%, 7/1/2038	1,370,000	1,704,691
Washington 2.8%		
Washington, State Health Care Facilities Authority Revenue, Virginia Mason Medical Center, Series A, 6.125%, 8/15/2037	6,000,000	6,620,340
Washington, State Health Care Facilities Authority, Swedish Health Services, Series A, Prerefunded, 6.75%, 11/15/2041	1,825,000	2,595,917
Washington, State Motor Vehicle Tax-Senior 520 Corridor Program, Series C, 5.0%, 6/1/2031	5,000,000	5,909,900
		15,126,157

Wisconsin 0.3%		
Wisconsin, State Health & Educational Facilities Authority Revenue, Prohealth Care, Inc. Obligation Group, 6.625%, 2/15/2039	1,555,000	1,817,437
Total Municipal Bonds and Notes (Cost $547,538,524)		633,376,083
Municipal Inverse Floating Rate Notes (a) 41.8%		
California 2.1%		
California, San Francisco Bay Area Toll Authority, Toll Bridge Revenue, Series F, 5.0%, 4/1/2031 (b)	10,000,000	11,388,894
Trust: California, San Francisco Bay Area Toll Authority, Toll Bridge Revenue, Series 1962-5, 144A, 13.574%, 4/1/2014, Leverage Factor at purchase date: 3 to 1		
Florida 6.7%		
Miami-Dade County, FL, Transit Sales Surtax Revenue, 5.0%, 7/1/2023, INS: AGMC (b)	3,740,000	4,170,744
Miami-Dade County, FL, Transit Sales Surtax Revenue, 5.0%, 7/1/2024, INS: AGMC (b)	3,915,000	4,365,900
Miami-Dade County, FL, Transit Sales Surtax Revenue, 5.0%, 7/1/2025, INS: AGMC (b)	4,122,500	4,597,298
Miami-Dade County, FL, Transit Sales Surtax Revenue, 5.0%, 7/1/2026, INS: AGMC (b)	4,317,500	4,814,756
Miami-Dade County, FL, Transit Sales Surtax Revenue, 5.0%, 7/1/2032, INS: AGMC (b)	16,470,000	18,366,888
Trust: Miami-Dade County, FL, Transit Improvements, Series 2008-1160, 144A, 9.241%, 7/1/2016, Leverage Factor at purchase date: 2 to 1		
		36,315,586
Massachusetts 4.9%		
Massachusetts, State Water Pollution Abatement Trust, Series 13, 5.0%, 8/1/2032 (b)	18,250,000	20,874,278
Massachusetts, State Water Pollution Abatement Trust, Series 13, 5.0%, 8/1/2037 (b)	5,000,000	5,718,980
Trust: Massachusetts, State Pollution Control, Water Utility Improvements, Series 3159, 144A, 13.512%, 8/1/2015, Leverage Factor at purchase date: 3 to 1		
		26,593,258
Nevada 6.0%		
Clark County, NV, General Obligation, Limited Tax-Bond Bank, 5.0%, 6/1/2028 (b)	9,447,355	10,716,415
Clark County, NV, General Obligation, Limited Tax-Bond Bank, 5.0%, 6/1/2029 (b)	9,919,723	11,252,236
Clark County, NV, General Obligation, Limited Tax-Bond Bank, 5.0%, 6/1/2030 (b)	9,627,878	10,921,188

Trust: Clark County, NV, General Obligation, Series 3158, 144A, 13.513%, 6/1/2016, Leverage Factor at purchase date: 3 to 1		
		32,889,839
New York 12.0%		
New York, State Dormitory Authority, State Personal Income Tax Revenue, Series A, 5.0%, 3/15/2026 (b)	10,000,000	11,581,891
Trust: New York, State Dormitory Authority Revenue, Series 3160, 144A, 13.514%, 3/15/2015, Leverage Factor at purchase date: 3 to 1		
New York, State Dormitory Authority, State Personal Income Tax Revenue, Series A, 5.0%, 3/15/2024 (b)	10,000,000	11,641,000
Trust: New York, State Dormitory Authority Revenue, Secondary Issues, Series 1955-3, 144A, 17.87%, 3/15/2015, Leverage Factor at purchase date: 4 to 1		
New York, State Dormitory Authority Revenues, State Supported Debt, University Dormitory Facilities, 5.0%, 7/1/2025 (b)	5,425,000	6,184,375
New York, State Dormitory Authority Revenues, State Supported Debt, University Dormitory Facilities, 5.0%, 7/1/2027 (b)	8,080,000	9,211,013
Trust: New York, State Dormitory Authority Revenues, Series 3169, 144A, 13.511%, 7/1/2025, Leverage Factor at purchase date: 3 to 1		
New York, Triborough Bridge & Tunnel Authority Revenues, Series C, 5.0%, 11/15/2033 (b)	6,000,000	6,851,520
Trust: New York, Triborough Bridge & Tunnel Authority Revenues, Series 2008-1188, 144A, 9.2%, 11/15/2033, Leverage Factor at purchase date: 2 to 1		
New York City, NY, Transitional Finance Authority Revenue, Series C-1, 5.0%, 11/1/2027 (b)	17,560,000	20,567,852
Trust: New York City, NY, Series 2008-1190, 144A, 9.2%, 11/1/2027, Leverage Factor at purchase date: 2 to 1		
		66,037,651
Tennessee 6.7%		
Nashville & Davidson County, TN, Metropolitan Government, 5.0%, 1/1/2027 (b)	10,756,695	12,604,510
Trust: Nashville & Davidson County, TN, Metropolitan Government, Series 2631-3, 144A, 17.865%, 1/1/2016, Leverage Factor at purchase date: 4 to 1		
Nashville & Davidson County, TN, Metropolitan Government, 5.0%, 1/1/2026 (b)	10,200,000	11,951,646

Trust: Nashville & Davidson County, TN, Metropolitan Government, Series 2631-2, 144A, 17.87%, 1/1/2016, Leverage Factor at purchase date: 4 to 1		
Nashville & Davidson County, TN, Metropolitan Government, 5.0%, 1/1/2028 (b)	10,564,925	11,996,544
Trust: Nashville & Davidson County, TN, Metropolitan Government, Series 2631-4, 144A, 17.878%, 1/1/2016, Leverage Factor at purchase date: 4 to 1		
		36,552,700
Virginia 3.4%		
Virginia, State Resource Authority, Clean Water Revenue, 5.0%, 10/1/2027 (b)	8,190,000	9,646,053
Virginia, State Resource Authority, Clean Water Revenue, 5.0%, 3/25/2028 (b)	7,630,000	8,986,493
Trust: Virginia, State Resource Authority, Clean Water Revenue, Series 2917, 144A, 11.162%, 10/1/2028, Leverage Factor at purchase date: 2.5 to 1		
		18,632,546
Total Municipal Inverse Floating Rate Notes (Cost $200,822,875)		228,410,474

	% of Net Assets	Value ($)
Total Investment Portfolio (Cost $748,361,399) †	157.7	861,786,557
Other Assets and Liabilities, Net	(21.3)	(116,569,688)
Preferred Shares, at Redemption Value	(36.4)	(198,750,000)
Net Assets Applicable to Common Shareholders	100.0	546,466,869

For information on the Fund's policies regarding the valuation of investments and other significant accounting policies, please refer to the Fund's most recent semi-annual or annual financial statements.

* Variable rate demand notes are securities whose interest rates are reset periodically at market levels. These securities are payable on demand and are shown at their current rates as of August 31, 2012.

** Floating rate securities' yields vary with a designated market index or market rate, such as the coupon-equivalent of the U.S. Treasury Bill rate. These securities are shown at their current rate as of August 31, 2012.

† The cost for federal income tax purposes was $748,361,399. At August 31, 2012, net unrealized appreciation for all securities based on tax cost was $113,425,158. This consisted of aggregate gross unrealized appreciation for all securities in which there was an excess of value over tax cost of $113,425,158 and aggregate gross unrealized depreciation for all securities in which there was an excess of tax cost over value of $0.

(a) Securities represent the underlying municipal obligations of inverse floating rate obligations held by the Fund.

(b)

Security forms part of the below tender option bond trust. Principal Amount and Value shown take into account the leverage factor.

144A: Security exempt from registration under Rule 144A of the Securities Act of 1933. These securities may be resold in transactions exempt from registration, normally to qualified institutional buyers.
AGC: Assured Guaranty Corp.
AGMC: Assured Guaranty Municipal Corp.
AMBAC: Ambac Financial Group, Inc.
AMT: Subject to alternative minimum tax.
ETM: Bonds bearing the description ETM (escrow to maturity) are collateralized usually by U.S. Treasury securities which are held in escrow and used to pay principal and interest on bonds so designated.
FGIC: Financial Guaranty Insurance Co.
GTY: Guaranty Agreement
INS: Insured
LOC: Letter of Credit
NATL: National Public Finance Guarantee Corp.
Prerefunded: Bonds which are prerefunded are collateralized usually by U.S. Treasury securities which are held in escrow and used to pay principal and interest on tax-exempt issues and to retire the bonds in full at the earliest refunding date.
SPA: Standby Bond Purchase Agreement

Fair Value Measurements

Various inputs are used in determining the value of the Fund's investments. These inputs are summarized in three broad levels. Level 1 includes quoted prices in active markets for identical securities. Level 2 includes other significant observable inputs (including quoted prices for similar securities, interest rates, prepayment speeds, and credit risk). Level 3 includes significant unobservable inputs (including the Fund's own assumptions in determining the fair value of investments). The inputs or methodology used for valuing securities are not necessarily an indication of the risk associated with investing in those securities.

The following is a summary of the inputs used as of August 31, 2012 in valuing the Fund's investments.

	Level 1	Level 2	Level 3	Total
Assets				
Municipal Investments(c)	$—	$861,786,557	$—	$861,786,557
Total	$—	$861,786,557	$—	$861,786,557

There have been no transfers between Level 1 and Level 2 fair value measurements during the year ended August 31, 2012.

(c) See Investment Portfolio for additional detailed categorizations.

ITEM 2. CONTROLS AND PROCEDURES

(a) The Chief Executive and Financial Officers concluded that the Registrant’s Disclosure Controls and Procedures are effective based on the evaluation of the Disclosure Controls and Procedures as of a date within 90 days of the filing date of this report.

(b) There have been no changes in the registrant's internal control over financial reporting that occurred during the registrant's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal controls over financial reporting.

ITEM 3. EXHIBITS

Certification pursuant to Rule 30a-2(a) under the Investment Company Act of 1940 (17 CFR 270.30a-2(a)) is filed and attached hereto as Exhibit 99.CERT.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Registrant: DWS Municipal Income Trust

By: /s/W. Douglas Beck
W. Douglas Beck
President

Date: October 24, 2012

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By: /s/W. Douglas Beck
W. Douglas Beck
President

Date: October 24, 2012

By: /s/Paul Schubert
Paul Schubert
Chief Financial Officer and Treasurer

Date: October 24, 2012

eatment for the prevention of VTE, mainly in acutely ill patients not undergoing surgery.

Table of Contents

Two generics of enoxaparin and our authorized generic of Lovenox® are available in the U.S. No biosimilar has been approved in the European Union. See "Item 5. Operating and Financial Review and Prospects Impacts from generic competition".

In 2013, Lovenox® was the leading anti-thrombotic in Germany, France, Italy, Spain, and the United Kingdom.

Aprovel® / Avapro® / Karvea®

Aprovel® (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel® / Avapro® / Karvea®, we also market CoAprovel® / Avalide® / Karvezide®, a fixed dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect. These products achieve control of blood pressure in over 80% of patients, with a very good safety profile.

Aprovel® and CoAprovel® tablets are available in a wide range of dosages to fit the needs of patients with different levels of hypertension severity.

Aprovel® is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. CoAprovel® is indicated in patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals (in the United States only).

Aprovel® and CoAprovel® are marketed in more than 80 countries. The marketing of Aprovel® and CoAprovel® is organized through an alliance with BMS which was restructured in 2012 (see "Item 5 Alliance Arrangements with Bristol-Myers Squibb" below). In Japan, the product is licensed to Shionogi Co. Ltd and sub-licensed Dainippon Sumitomo Pharma Co. Ltd.

Renagel® and Renvela®

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis as well as late-stage CKD patients in Europe to treat a condition called hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second generation, buffered phosphate binder.

In the United States, there are an estimated 395,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are an estimated 350,000 dialysis patients in the E.U. and 65,000 in Brazil. In the E.U., Renvela® is also approved to treat CKD patients not on dialysis.

We market Renagel® and Renvela® directly to nephrologists through Sanofi's employee sales force and distribute these products through wholesalers and distributors. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

In the United States, as part of an amendment to the ANDA settlement, Sanofi has agreed to grant Impax a license to sell a specific allotment of bottles of an authorized generic version of Renvela® tablets on April 16, 2014. The specific allotment corresponds to 7-10% of the total 2013 sevelamer sales in the United States. This amendment does not change Sanofi's prior settlement agreement with Impax to sell generic versions of two other sevelamer products, Renvela® for oral suspension and Renagel®, starting on September 16, 2014, which is conditioned on their receiving FDA ANDA approval.

The top five countries contributing to the sales of Renagel® and Renvela® in 2013 were the U.S., France, Italy, Brazil, and UK.

Allegra® / Telfast®

Allegra® (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and for the treatment of uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

Table of Contents

We also market Allegra-D® 12 Hour and Allegra-D® 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. Generics of most forms of Allegra® / Tefast® have been approved in our major markets.

In the United States, the Allegra® family moved to over-the-counter (OTC) use in adults and children two years of age and older in 2011. Allegra® was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription (see " Consumer Health Care" below).

Allegra® / Telfast® is marketed in approximately 80 countries. The largest market for prescriptions of Allegra® is Japan, where competing generics entered the market in early 2013 (for more information see "Item 8 Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings").

Depakine®

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years. Numerous clinical trials and long years of experience have shown that it is effective for most forms of epilepsy, and that it is generally well tolerated. Consequently, Depakine® remains a reference treatment for epilepsy worldwide.

Depakine® is also a mood stabilizer, registered in numerous countries in the treatment of manic episodes associated with bipolar disorder and in the prevention of mood episodes.

We provide a wide range of formulations of Depakine® enabling it to be adapted to most types of patients: syrup, oral solution, injection, enteric-coated tablets, Depakine® Chrono (a sustained release formulation in tablets), and Depakine® Chronosphere (sustained release formulation of Depakine® packaged in sachets, facilitating its use by children, the elderly and adults with difficulties swallowing).

Depakine® is marketed in over 100 countries, and is generally subject to generic competition.

Stilnox® / Ambien® / Myslee®

Stilnox® (zolpidem tartrate) is indicated in the short-term treatment of insomnia. Stilnox® 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 a minimum of six hours, and it is generally well tolerated, allowing the patient to awaken with a reduced risk of impaired attention, decreased alertness or memory lapses throughout the day.

Stilnox® is marketed in over 100 countries. It is available under the brand name Ambien® / Ambien®CR in the United States and Myslee® in Japan, where it is co-promoted jointly with Astellas. Stilnox® and Ambien CR® are subject to generic competition in most markets, including the United States and Europe. In Japan, generics of Myslee® entered the market in June 2012.

Synvisc® / Synvisc-One®

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc is indicated for the treatment of pain associated with osteoarthritis (OA) of the knee, hip, ankle, and shoulder joint in countries that have adopted CE marking, and for pain due to knee osteoarthritis in the United States. Synvisc-One® is approved for use in patients with OA of the knee in United States and countries that require CE marking. Currently the main viscosupplementation market is for the treatment of pain associated with osteoarthritis of the knee.

Synvisc® is a triple-injection product and Synvisc-One® a single-injection product. Both are administered directly into the intra-articular space of the joint to temporarily restore osteoarthritis synovial fluid.

In 2013, the top countries contributing to Synvisc® and Synvisc-One® sales were the U.S., France, Mexico, Canada, Japan, and Brazil.

Multaq®

Multaq® (dronedarone) is the most extensively studied anti-arrhythmic drug (AAD) in AF and has demonstrated a unique cardiovascular (CV) outcome benefit in the ATHENA study in addition to effective rhythm control in the EURIDIS and ADONIS studies.

31

Table of Contents

Multaq® is a multichannel blocker with both rhythm (prevention of AF recurrences) and rate (decrease of ventricular rate) controlling properties and additional effects (anti-hypertensive, vasodilatory). It is the first and only anti-arrhythmic drug to have shown a significant reduction in CV hospitalization and death in patients with paroxysmal and persistent AF/Atrial Flutter.

The main countries contributing to Multaq® sales in 2013 were the U.S., Germany and Spain.

Actonel®

Actonel® (risedronate sodium) is a biphosphonate used for the treatment of osteoporosis and Paget's disease. The product is marketed through an alliance with Warner Chilcott (see note C-3 to our consolidated financial statements).

Auvi-Q

At the end of January 2013, Sanofi launched Auvi-Q (epinephrine injection, USP), in the U.S. Auvi-Q is the first-and-only epinephrine auto-injector with audio and visual cues for the emergency treatment of life-threatening allergic reactions in people who are at risk for or have a history of anaphylaxis. Up to six million Americans may be at risk for anaphylaxis, although the precise incidence is unknown and likely underreported.

Sanofi US licensed the North American commercialization rights to Auvi-Q from Intellijet, Inc.

f) Consumer Health Care (CHC)

Consumer Health Care is a growth platform in our global strategy. In 2013, we set up a Global Consumer Health Care Division, to identify development priorities more proactively and co-ordinate international delivery on these priorities. The division is focused on 6 key categories: Anti-Allergics, Analgesics, Cough and Cold Remedies, Digestive System Products, Feminine Hygiene Products, and Vitamins, Minerals & Supplements (VMS). This new global division, which is being rolled out from the start of 2014, will direct the growth of our CHC activities over the coming years.

In 2013, our CHC sales reached €3,004 million, up 5.2% year-on-year; nearly half of these sales were generated in Emerging Markets, 22% in Western Europe, and 21% in the United States.

In the U.S., mid-September 2013 saw the relaunch of the Rolaids® brand, that we had acquired at the start of the year from McNeil Consumer Healthcare®. An antacid sold over-the-counter through all American distribution channels, Rolaids® is now once again available to the people who suffer from heartburn and acid reflux. Still in the U.S., we have obtained approval from the FDA in October 2013 for the over-the-counter sale of Nasacort® Allergy 24H, a nasal spray indicated for seasonal and perennial allergies of the upper respiratory tract (allergic rhinitis) in adults and in children aged two and over. Launched in February 2014 in the U.S., Nasacort® (triamcinolone) is the first and to date only treatment in its category to be available over-the-counter.

Growth during 2013 was also supported by our full range of CHC products, which give us a well-established presence in analgesics and the digestive system.

Doliprane® offers a range of paracetamol-based products for pain and fever. Thanks to a broad range of dosage options (from suspensions containing 2.4% paracetamol to 1-gram formulations) and pharmaceutical forms (suspensions, pills, powders, suppositories), Doliprane® meets the needs of patients of all ages. Doliprane® is sold mainly in France and various African countries.

No Spa® (drotaverine hydrochloride) is an abdominal anti-spasmodic indicated for intestinal spasm, period pains and bladder spasm; it is sold mainly in Russia and Eastern Europe.

Enterogermina® is a probiotic, which is available as a drinkable suspension in 5-ml mini-bottles or in capsules containing two billion *Bacillus clausii* spores. Enterogermina® is indicated for the prevention and restoration of gut flora in the treatment of acute or chronic intestinal disorders (in babies and adults). Enterogermina® has historically been sold in Europe, and is now enjoying strong growth in Latin America, India, Ukraine and Belarus.

Essentiale® is a plant-based product used in the treatment of liver problems. Composed of essential phospholipids extracted from highly purified soya, it is rich in phosphatidylcholine, a major component of cell membrane. Essentiale® is used to alleviate symptoms such as loss of appetite, oppression of the right

Table of Contents

epigastrium, food-related liver lesions and hepatitis. Essentiale® is sold mainly in Russia, Eastern Europe, various countries in South-East Asia and China.

Maalox® is a well-established brand that contains two antacids: aluminium hydroxide and magnesium hydroxide. Maalox® is available in various forms (pills, drinkable suspension, sachets), giving consumers a choice of suitable solutions. Initially launched in France in 1972, Maalox® is now available in 55 countries in Europe, Latin America and Asia.

Magne B6® is a food supplement containing magnesium and vitamin B6. Magne B6® has a wide range of therapeutic indications: irritability, anxiety, sleep disorders, and women's health issues (pre-menstrual stress and menopausal problems). Magne B6® is available in Europe and Russia.

The Lactacyd® range covers a number of intimate feminine hygiene products. Lactacyd® is sold primarily in Brazil and in Asia, where the range is enjoying growth driven by a number of new presentations.

In addition to these historical brands:

The principal products marketed by Chattem in the U.S. (apart from Allegra® OTC) are ACT®, Gold Bond®, Icy Hot®, Cortizone-10®, Selsun Blue® and Unisom®.

Oenobiol® products are food supplements with applications in beauty (sunscreen, slimming, haircare and skincare), wellbeing (digestive aids, anti-stress) and menopause, and are sold mainly in France.

In China, BMP Sunstone markets Haowawa® (which means "Good Baby" in Chinese), a leading brand of children's cough and cold remedies, alongside a portfolio of over-the-counter Western medicines and traditional Chinese remedies.

Also in China, Minsheng Pharmaceuticals Co. Ltd markets 21 Super Vita, one of the leading vitamin and mineral supplements in the local market.

Universal Medicare, a leading player in India, sells nutraceuticals and other products including vitamins, antioxidants, mineral supplements, and anti-arthritis products such as Seacod®, CoQ®10, Collaflex® and Multivit®. At the end of 2013, the marketing of Universal Medicare products was extended to Pakistan.

We are also continuing to expand into the Vitamins, Minerals and Supplements (VMS) market, with the Omnivit® range in various emerging market countries and with the Cenovis® and Nature's Own® brands in Australia.

g) Generics

To reinforce its generics business, Sanofi created a global "Generics" division in October 2013. The main missions of this division are to:

pursue the alignment of the Generics Portfolio strategy and the coordination of the different Generics platforms;

drive Generics business performance through specific performance management indicators;

establish centers of reference in Generics-specific expertise and skills.

In 2013, sales of the Generics business reached €1,625 million, a decrease of 11.9% from 2012 (8.2% at constant exchange rates). Performance was impacted by temporary difficulties with inventory levels in Brazil as well as by lower sales of Lovenox®, Aprovel® and Taxotere® authorized generics in the U.S.

During the second quarter of 2013, Sanofi became aware that distribution channels in Brazil were holding inventory in excess of the volumes needed to meet demand (see "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012." for further explanations). The re-order point was reached in August and sales have been improving progressively since that date.

In Latin America, Sanofi completed the acquisition of Genfar S.A., a leading Columbian pharmaceuticals manufacturer, headquartered in Bogota, Colombia, and expanded its leading presence in affordable quality pharmaceuticals.

In Europe, despite significant price pressure, sales of generics grew 4.7%, driven by strong volume performance overall, led by Western European countries such as France and Italy. However, increased volume did not totally compensate price pressure in Central and East European countries (such as the Czech Republic).

Table of Contents

Emerging Markets significantly contributed to the 2013 performance with remarkable growth in Russia and Africa, the expansion of Medreich products in Nigeria and increased antiretroviral business in South Africa.

B.3. Vaccine Products

Sanofi Pasteur, the vaccine division of Sanofi, offers a broad range of vaccines. In 2013, Sanofi Pasteur provided more than one billion doses of vaccines, making it possible to immunize more than 500 million people across the globe against 20 serious diseases, and generated net sales of €3,716 million. Sales were favorably impacted by record sales of influenza vaccines, especially in the United States, and strong growth in Emerging Markets. Nevertheless, 2013 sales were negatively impacted by Pentacel® and Adacel® supply delays due to manufacturing issues.

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the U.S., Sanofi Pasteur is the leading producer of influenza and meningitis vaccines.

In Europe, Sanofi Pasteur vaccine products are developed and marketed by Sanofi Pasteur MSD, a joint venture that serves 19 countries. Created in 1994 and held equally by Sanofi Pasteur and Merck, Sanofi Pasteur MSD also distributes Merck vaccines, such as Gardasil® and Zostavax®. In 2013, Sanofi Pasteur MSD net sales amounted to €876 million.

Sanofi Pasteur is expanding in Asia, Latin America, Africa, the Middle East and Eastern Europe. In addition, Sanofi Pasteur is a key supplier to publicly funded international markets such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

See " Vaccines Research and Development" below for a presentation of the Sanofi Pasteur R&D portfolio.

The table below lists net vaccine sales by product range:

(€ million)	**2013 Net Sales**
Polio/Pertussis/Hib Vaccines	1,148
Influenza Vaccines	929
Meningitis/Pneumonia Vaccines	496
Adult Booster Vaccines	391
Travel and Other Endemic Vaccines	382
Other Vaccines	370
Total Human Vaccines	**3,716**

a) Pediatric, Combination and Poliomyelitis (Polio) Vaccines

Sanofi Pasteur is one of the key players in pediatric vaccines in both mature and emerging markets with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection. Due to the diversity of immunization schedules throughout the world, vaccines vary in composition according to regional preferences.

Pentaxim®, a combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib), was first marketed in 1997. To date, more than 180 million doses of Pentaxim® have been distributed in over 100 countries, and the vaccine has been included in the national immunization programs of more than 23 countries.

Hexaxim® is the only fully liquid, ready to use, 6-in-1 (hexavalent) pediatric vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. In February 2013, the EMA recommended market approval for this hexavalent pediatric vaccine in the

E.U., commercialized under the brand name Hexyon in Western Europe by Sanofi Pasteur MSD and under the brand name Hexacima in Eastern Europe by Sanofi Pasteur. The roll-out of this new hexavalent vaccine began in July 2013 in Germany and 10 countries have already included Hexaxim® in their public or private immunization programs.

Table of Contents

Pentacel®, a vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib) was launched in the U.S. in 2008. In 2013, supply issues were responsible for a delay in U.S. market delivery. These issues have now been resolved and supplies of Pentacel® have improved progressively from mid-October 2013.

Pediacel®, a fully liquid pentavalent vaccine, has been the standard of care in the United Kingdom since 2004 for protecting against diphtheria, tetanus, pertussis, polio and Hib.

Act-HIB®, for the prevention of Hib, is also an important growth driver within the pediatric product line. In 2008, Act-HIB® became the first Hib vaccine to be approved in Japan.

Quadracel® is a combination vaccine against diphtheria, tetanus, pertussis and polio. It is proposed as a booster to be administered as the fifth dose in the primary series of vaccines, allowing children to complete the entire childhood schedule with as few injections as possible. Quadracel® is already available in Canada and Australia. A Phase III clinical study is currently underway in order to submit an application for the licensure of Quadracel® in the U.S..

Sanofi Pasteur is co-developing, with Merck, a combination vaccine (6-in-1 vaccine PR5i) designed to help protect against six diseases. This new vaccine will protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. Phase III clinical studies conducted in the U.S. and in Europe were concluded in 2013.

Sanofi Pasteur is one of the world's leading developers and manufacturers of polio vaccines, with both oral polio vaccines (OPV) and injectable polio vaccines (IPV) in its portfolio. Sanofi Pasteur is a preferred partner for the supply of OPV and IPV for the Global Polio Eradication Initiative led by the WHO and UNICEF. In November 2013, GAVI announced its support for the introduction of IPV in the national immunization programs of the world's 73 poorest countries. The combined use of OPV and IPV is expected to improve the level of protection in countries threatened by the resurgence of polio. GAVI Alliance support paves the way for the implementation of the recommendation made by the WHO expert group on immunization (SAGE) that all countries introduce at least one dose of IPV in their routine polio immunization programs before the end of 2015. Consequently, Sanofi Pasteur expects the use of IPV to increase considerably in the coming five years. As a result, Sanofi Pasteur is expanding its production capacity to meet the growing demand.

Shantha Biotechnics (Shantha), in India, is currently pursuing requalification of Shan5 , a combination vaccine protecting against diphtheria, tetanus, pertussis, Hib and hepatitis B, with the WHO. Shantha has worked closely with Sanofi Pasteur to improve key manufacturing steps in the production of the antigen components of the vaccine. The path to obtaining prequalification status has been discussed extensively with the WHO and local Indian regulators. If ongoing clinical studies results are positive, Shan5® should regain WHO prequalification in 2014.

b) Influenza Vaccines

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines with over 200 million doses delivered in 2013. In recent years, influenza vaccine demand has experienced strong growth in many countries, particularly the U.S., Brazil and Mexico. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in Emerging Markets and wider government immunization recommendations.

Sanofi Pasteur remains focused on meeting the increasing demand for both pandemic and seasonal influenza vaccines through the launch of innovative vaccines. The differentiated product strategy is strengthening Sanofi Pasteur's leadership in the influenza market with the following new product launches:

Fluzone® High-Dose vaccine, launched in the U.S. in 2010, was specifically designed to generate a more robust immune response against influenza in people 65 or older. In August, 2013, top line results of a large scale study in people 65 or older showed a superior clinical benefit for Fluzone® High-Dose vaccine, compared to Fluzone® vaccine, in preventing influenza (Fluzone® High-Dose vaccine was 24% more effective than Fluzone vaccine). The strong sales growth registered by this new vaccine since its launch was confirmed in 2013.

Fluzone® ID (intradermal) continues its growth following its launch in the U.S. in 2012. The advantages of this vaccine are, in particular, its convenience and ease of administration. Fluzone ID® and Intanza®/IDflu® vaccines are now approved in Australia, Canada, the E.U., the U.S. and several other countries.

Fluzone® QIV vaccine is a quadrivalent inactivated influenza vaccine containing two type A antigens and two type B antigens. Compared to the trivalent influenza vaccine, the addition of a second B strain to the vaccine

Table of Contents

will provide increased protection against the most prevalent strains. In June 2013, Sanofi Pasteur obtained FDA authorization for Fluzone® QIV to be commercialized in the U.S. for children over 6 months, adolescents and adults.

Sanofi Pasteur recently made the decision to withdraw the QIV marketing authorization application submitted in Europe through a decentralized procedure, in order to update the pharmaceutical section at the request of the regulatory authorities. Sanofi Pasteur will take the opportunity of this update to extend the target group to children aged 36 months. A Phase III study will start in 2014 with the objective of providing the necessary data.

c) Adult and Adolescent Boosters

Many countries now recommend pertussis immunization for adolescents and adults. These recommendations, combined with immunization awareness initiatives, have led to higher sales for this product group in recent years.

Adacel®, the first trivalent adolescent and adult booster against diphtheria, tetanus and pertussis, was licensed and launched in the U.S. in 2005. Since its launch in the U.S., more than 100 millions doses of Adacel® have been sold. This vaccine plays an important role in efforts to better control pertussis, by preventing the disease in adolescents and adults, and by breaking the cycle of transmission to infants too young to be immunized or only partially vaccinated. Adacel® is now registered in more than 60 countries.

Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides all the benefits of Adacel® along with polio vaccine. This product is useful in those markets that recommend adolescent/adult immunizations to protect against both pertussis and polio. This vaccine is licensed in more than 30 countries.

d) Meningitis and Pneumonia Vaccines

Sanofi Pasteur is at the forefront in the development of vaccines to prevent bacterial meningitis. In 2005, Sanofi Pasteur introduced Menactra®, the first quadrivalent conjugate vaccine against meningococcal meningitis, considered by many as the deadliest form of meningitis in the world. In April, 2011, the FDA granted Sanofi Pasteur a license to expand the indication of Menactra® to children as young as nine months of age. Menactra® is now indicated for people aged nine months through 55 years in the U.S., Canada, Saudi Arabia and numerous other countries in Latin America, the Middle East and Asia Pacific regions.

Sanofi Pasteur is developing a second-generation conjugated meningococcal vaccine. This second-generation meningococcal vaccine uses an alternative conjugation technology. Phase II clinical trial results have demonstrated its safety and immunogenicity. Sanofi Pasteur is continuing the development of this vaccine to suit a wider range of age groups and a flexible range of vaccination schedules.

e) Travel and Endemic Vaccines

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever, and Japanese encephalitis, as well as rabies vaccines and immunoglobulins. These vaccines and serums are used in endemic settings in the developing world and are the basis of important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military in endemic areas. Sanofi Pasteur is the leader in most of the world's travel and endemic vaccine markets.

In December, 2009, Shantha launched Shanchol , the first oral cholera vaccine for children and adults made in India. Shanchol received WHO prequalification in 2011, and in 2013 the WHO approved the creation of a stockpile of over 2 million doses.

IMOJEV®, a Japanese encephalitis vaccine, the most recent travel and endemic vaccines portfolio addition, was successfully launched in Australia and Thailand in December 2012, for use in individuals aged 12 months and over, and was then launched in 2013 in Malaysia and the Philippines. An extension of the indication to include children aged nine months and older has been submitted and is currently under approval in the Asia Pacific region.

f) Other Products

Growth in other products is mainly driven by VaxServe, a leading specialty distributor in the U.S. market. VaxServe, a Sanofi Pasteur company, is a strategic asset that enables us to be closer to our customers and better understand their needs, and to offer a broad product portfolio of both Sanofi Pasteur and non-group products.

Table of Contents

B.4. Animal Health: Merial

Our Animal Health activity is carried out through Merial, one of the world's leading animal healthcare companies (source: Vetnosis), dedicated to the research, development, manufacture and delivery of innovative pharmaceuticals and vaccines used by veterinarians, farmers, and pet owners. Merial provides a comprehensive range of products to enhance the health, well-being and performance of a wide range of production and companion animals. Its net sales for 2013 amounted to €1,985 million.

Merial became Sanofi's dedicated Animal Health division following the end of Sanofi and Merck's agreement to create a new animal health joint venture by combining their respective animal health segments in March 2011. See Note D.2. to our consolidated financial statements included at Item 18 of this annual report.

The Animal Health product range comprises four major segments: parasiticides, anti-infectious drugs, other pharmaceutical products (such as anti-inflammatory agents, anti-ulcerous agents, etc.), and vaccines. Merial's top-selling products include Frontline®, a topical anti-parasitic flea and tick brand for dogs and cats, the highest selling veterinary product in the world (source: Vetnosis); Heartgard®, a parasiticide for control of heartworm in companion animals; Ivomec®, a parasiticide for the control of internal and external parasites in livestock; Vaxxitek®, a high-technology vector vaccine, protecting chickens against infectious bursal disease (IBD) and Marek's disease; Previcox®, a highly selective anti-inflammatory/COX-2 inhibitor for relief of pain and control of inflammation in dogs; Eprinex®, a parasiticide for use in cattle; and Circovac®, a PCV2 (porcine circovirus type 2) vaccine for swine. Merial plays a key role in the veterinary public health activities of governments around the world. It is the world leader in vaccines for Foot-and-Mouth disease (FMD), rabies, and bluetongue (BTV) (source: Vetnosis).

In 2013, Merial's antiparasiticide product range for companion animals was extended to include:

NexGard (afoxolaner), monthly beef flavored soft chewables for treatment and prevention of flea and tick infestations in dogs and puppies. The product was approved by the FDA in September 2013, by the EMA in February 2014, and launched in the U.S. in January 2014.

Broadline , a broad spectrum parasite treatment and prevention for cats sold throughout the European Union. Broadline is a combination of four active ingredients and helps protect cats for one month. The product was approved by the EMA in December 2013.

The compound patent protecting fipronil, the active ingredient of Frontline®, expired in 2009 in Japan and in some European countries, including France, Germany, Italy, and the United Kingdom, and in August 2010 in the United States. In those markets where the fipronil compound patent has expired, Frontline® products are generally still protected through formulation patents (directed to combinations) which expire in 2017 in Europe (August 2016 in the United States). Frontline® is also protected by a method of use patent in the United States and the European Patent area (Germany, France, Italy, and the United Kingdom), which expires in March 2018.

As with human pharmaceutical products, patent protection for animal pharmaceutical products extends in most cases for 20 years from the filing date of the priority application.

From a regulatory standpoint, in Europe veterinary products (pharmaceutical products and vaccines) enjoy eight-year regulatory exclusivity for data and a ten-year exclusivity period for commercialization.

In the United States, there is no exclusivity for animal vaccines. For animal pharmaceutical products, those approved by the Environmental Agency (EPA) enjoy ten-year regulatory exclusivity, with the possibility of obtaining an additional five-year period of exclusivity during which any generics products that cite the innovator's data must indemnify the innovator. For pharmaceutical products approved by the FDA, a five-year regulatory exclusivity period is granted for a new chemical entity, and a three-year period for a previously-approved active ingredient.

In June 2013, Merial finalized the acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, creating a market entry for Merial in that country's strategically important and growing animal health sector. Dosch Pharmaceuticals commercializes 86 products under 50 brands for ruminants, poultry and companion animals.

The 2013 performance of Merial was mainly affected by the decrease in Frontline® sales in the U.S. and in Europe, impacted by the cold weather conditions and increased competition. Sales from the rest of Merial's portfolio are increasing, mainly driven by the performance of avian products (notably Vaxxitek®) and the pet vaccine range.

37

Table of Contents

Merial's major markets are the United States, France, Brazil, Italy, the United Kingdom, Australia, Germany, Japan, Spain, China, and Canada. Emerging Markets now account for 30% of total Merial sales, with particularly strong growth in China (18% in 2013).

B.5. Global Research & Development

The mission of Sanofi's Global R&D organization is to discover and develop therapies that prevent, treat or cure diseases. Our day-to-day commitment is to respond to patients' needs and to provide them with adapted therapeutic solutions in order to improve their well-being and extend their lives.

To meet these challenges, R&D has evolved towards an integrated organization, encompassing a wide range of therapeutic areas that represent a large and growing burden on populations and healthcare systems, in line with global trends and the most pressing health needs.

These include:

Pharma activities (see Section 5.2. below)

Diabetes. Diabetes is a rapidly growing health problem in all parts of the world. The current global prevalence of diabetes is approximately 366 million and this number is expected to exceed half a billion people by 2030 (source: www.idf.org). Despite numerous therapeutic offerings, people with diabetes are at considerably higher risk of premature death and debilitating complications, impairing their quality of life and imposing massive costs on health care systems around the world.

Cardiovascular diseases. Despite medical advances, cardiovascular diseases account for the largest number of deaths worldwide. Today over 17 million annual deaths are attributable to cardiovascular diseases and because of an aging population and a global epidemic of metabolic disease these numbers are expected to double over the next 25 years (source: WHO 2008).

Oncology. Cancer remains a leading cause of death worldwide accounting for over 7 million deaths per year. Deaths from cancer are projected to continue to rise with over 13 million deaths projected in 2030 (source: WHO 2008). While progress has been made in some cancers, development of new therapies is desperately needed.

Immune mediated diseases (including MS). Immune disorders correspond to a dysfunction of the immune system leading to an over or an under activation of the system and can be characterized by whether the condition is congenital or acquired. More than 150 primary immunodeficiency congenital diseases have been identified and figures for the acquired diseases are even greater (source: International Union of Immunological Societies 2007).

Age-related degenerative diseases. The increasing proportion of older people in the global population is contributing to a rise in age-related degenerative diseases and has serious implications for health care systems. Care-givers, health systems and societies need to be ready to manage the growing needs of the elderly in every part of the world.

Infectious diseases. These create significant and critical unmet medical needs both in the developed and developing worlds. Hospital-acquired infections are a major concern for public health in industrialized countries. Every year in the United States, 1.7 million people fall victim to hospital-acquired bacterial infections. In low-income countries, mortality is predominantly due to infectious diseases such as lung infections, tuberculosis and malaria.

Rare diseases. Approximately 7,000 rare disorders are known to exist and new ones are discovered each year. Rare diseases affect between 25-30 million people in the United States, and about 30 million people in the European Union (source: European Organization for Rares Diseases).

Vaccines (see Section B.5.3. below).

Animal Health.

To carry out our mission, meet these challenges and maximize our impact we are striving to bring innovation to patients and to build a pipeline of high value projects.

Table of Contents

Medical value, scientific quality and operational effectiveness are the three drivers that underpin our strategy. We focus on projects that have the potential to provide the best medical value differential to patients and payers and to reduce healthcare costs for society.

By using a translational medicine approach, ensuring that research hypotheses are validated in humans as early as possible, we can translate basic research findings into medical practice more quickly and efficiently and improve the scientific quality of our projects. The open innovation and large collaboration processes applied worldwide helped us to deliver the best and most innovative solutions for patients. By implementing new operating models to ensure optimal progress on our projects, especially during clinical development phases, we will improve our operational effectiveness and deliver the right therapeutic solutions to patients more quickly.

B.5.1. Research & Development Organization

Over recent years, we have moved from a pure pharmaceutical R&D organization to a global and integrated R&D organization where forces are combined to meet a diversity of health needs.

- Sanofi Pharma R&D, which is dedicated to the discovery and development of human medicines. This is a project-driven organization, consisting of two divisions (Diabetes and Oncology, a launch unit (PCSK9) and Therapeutic Strategic Units (TSUs), supported by Scientific Platforms, responsible for the operational aspects of R&D.

- Genzyme R&D, which has strong expertise in rare diseases, is now fully integrated into Sanofi Pharma R&D.

- Sanofi Pasteur R&D, which closely monitors all new approaches and technological discoveries in vaccines against infectious diseases. Its research priorities include new vaccines, the improvement of existing vaccines, combination vaccines, administration systems and innovative technologies.

- Merial R&D, which aims to deliver and support effective, innovative, safe and cost-effective animal health products. Although the specifics of animal health are different from human health, there are many potential synergies opening up a wide range of new research avenues.

We have developed geographically-focused integrated research innovation hubs in four areas: North America, Germany, France and Asia.

Our R&D is now organized to promote the best use of our resources within the local ecosystem. Our network-based organization is open to external opportunities, and enables us to more effectively capitalize on innovation from a wide range of sources.

B.5.2. Pharmaceuticals

In 2013, R&D again conducted a rigorous and comprehensive portfolio review. Projects were assessed using two key criteria which allow management to rapidly understand how the portfolio performs in terms of innovation, unmet medical needs, risk and value. The two key criteria are:

- relative medical value: which encompasses the extent of the unmet need, the market dynamics and the likelihood of getting satisfactory market conditions.

- science translation: which includes the level of innovation and translatability of the science including likelihood of development success.

The clinical portfolio as of the date of filing of this annual report is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties via acquisition, collaboration or alliances.

As described at "Item 3. Key Information D. Risk Factors Risks Relating to Our Business We may fail to adequately renew our product portfolio whether through our own R&D or through acquisitions and strategic alliances." our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

39

Table of Contents

The clinical portfolio for new products can be summarized as follows:

	Phase I	Phase II	Phase III / registration
Diabetes Solutions	Insulin biosimilar program		Lyxumia® (lixisenatide) Lixilan® (lixisenatide / insulin glargine) U300
Oncology	SAR125844 SAR153192 SAR245408 SAR260301 SAR307746 SAR405838 SAR566658 SAR650984	SAR245409 SAR256212 SAR3419	
Cardiovascular diseases		fresolumimab	alirocumab
Immune Mediated diseases (including Multiple Sclerosis)	SAR113244 SAR252067	SAR100842 SAR156597 SAR339658 dupilumab	Lemtrada (alemtuzumab) sarilumab Aubagio® (teriflunomide)
Age Related Degenerative Diseases	SAR228810	SAR391786	
Infectious diseases		ferroquine (combo OZ439) SAR279356	
Rare diseases	GZ402665 GZ402666 GZ402671		Cerdelga (eliglustat) patisiran (SAR438027)
Ophthalmology	GZ402663 StarGen UhsStat RetinoStat®	sarilumab (uveitis)	

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where possible the pharmacodynamic profiles of the new drug (i.e. how the product may react on some receptors).

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug, in the intended indication and population. They are designed to provide an adequate basis for registration.

a) Diabetes Solutions

Lyxumia® (Lixisenatide) is already registered in the E.U. and many other countries outside the U.S. and is presented in the section " Pharmaceutical Products Main Pharmaceutical Products" above.)

The main compounds currently in Phase III clinical development in the Diabetes field are

Investigational New Insulin U300:

A new formulation of insulin glargine has been shown in Phase I studies to have an improved pharmacodynamic profile with even longer, more stable and flatter activity than Lantus®, with the potential to translate into good glycemic outcomes with less hypoglycemia.

The completed Phase III program includes four studies (EDITION I, II, III and IV) and two studies in Japanese patients (EDITION JPI and JPII). The Phase III program is assessing the efficacy and safety of U300 compared with Lantus® in various populations. The results of Edition I and II have demonstrated similar level of glycemic control

Table of Contents

between U300 and Lantus®, while U300 was consistently associated with a reduction in risk of hypoglycemia. Topline results of EDITION III, IV and JPI showed a similar level of glycemic control in both groups. In EDITION III, fewer patients were affected by the nocturnal severe or confirmed hypoglycemic events in the U300 group but the difference was not statistically significant. The analysis of this criterion was not planned as main secondary endpoint in EDITION IV and JPI.

Lixilan® Fixed-Ratio: Lixilan® Fixed-Ratio, a combination of insulin glargine and lixisenatide, is also under clinical development. A proof-of-concept study to examine the glycemic control of Lixilan® versus insulin glargine alone over 24 weeks has been completed. The Lixilan® Phase III program started recently in the first quarter of 2014 with two clinical studies:

LixiLan-O study in patients insufficiently controlled on oral antidiabetics drugs;

LixiLan-L study in patients not at goal on basal insulin.

Lixilan® has the potential to be the first combination of Basal Insulin/GLP-1 in a single daily injection marketed in the U.S.

Sanofi Diabetes maintains a significant network of R&D collaborations with world leading academic institutions, including partnerships with the Joslin Diabetes Center (an affiliate of Harvard Medical School), the Charite in Berlin and the Helmholtz Zentrum in Munich. Collaborations with Gentofte Hospital (Copenhagen), and Gubra (a Danish biotech company specialized in gut hormone R&D) were recently established, and collaboration on innovative implantable glucose sensors was extended. Sanofi and JDRF continue to jointly fund selected innovation projects in the field of type I diabetes research.

b) Oncology

The main compounds currently in Phase II clinical development are:

SAR256212 (MM-121). Under an exclusive global collaboration and licensing agreement, Merrimack Pharmaceuticals, Inc. and Sanofi are co-developing SAR256212, a fully human monoclonal antibody targeting ErbB3. ErbB3 has been identified as a key node in tumor growth and survival. SAR256212 is in Phase II stage of development in Breast, Lung and Ovarian cancers.

SAR245409 (XL765) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral agent is an inhibitor of phosphoinositide-3-kinase (PI3K) and also acts against the mammalian target of rapamycin (mTOR). A Phase II trial of monotherapy in mantle cell lymphoma, follicular lymphoma, chronic lymphocytic leukemia and diffuse large B cell lymphoma is ongoing.

Coltuximab ravtansine (**SAR3419)** is an Antibody Drug Conjugate (ADC) maytansin-loaded anti-CD19 mAb that has been in-licensed from Immunogen Inc and is being developed in Phase II in B-cell malignancies: refractory/relapse Diffuse Large B Cell Lymphoma (DLBCL, aggressive lymphoma type) with the aim of confirming clinical activity both as a single agent and in combination with rituximab (Rituxan®, anti CD20 mAb).

Early stage products:

SAR245408 (XL147) was in-licensed from Exelixis, Inc. and is being developed by Sanofi. This oral phosphoinositide-3-kinase (PI3K) inhibitor is currently under evaluation in a Phase I study of the new formulation (Polymorphic Form E Tablet).

SAR650984 is a naked humanized immunoglobulin (IgG1) monoclonal antibody (mAb) that has been in-licensed from Immunogen Inc. SAR650984 selectively binds to CD38, a cell surface antigen widely expressed in multiple myeloma cancer cells, and other hematological malignancies. The program is in Phase I with 2 ongoing studies: as a single agent and in

combination with lenalidomide/dexamethasone in heavily pretreated relapsed multiple myeloma patients.

Two compounds, **SAR260301** (PI3Kβ selective inhibitor) and **SAR405838** (P53/HDM2 antagonist) were added to the Sanofi Phase I pipeline.

A Phase I trial of a novel combination with **SAR405838/**pimasertib in solid tumors has been initiated.

Projects discontinued in 2013:

Iniparib (**SAR240550**; BSI-201) The project, whose initial Phase III trial in triple-negative breast cancer was negative in 2011, was discontinued following an additional negative Phase III trial in advanced squamous non-small cell lung cancer, as well as inconclusive results of the two Phase II trials in ovarian cancer.

Table of Contents

Fedratinib (SAR302503; TG101348) was acquired when we purchased TargeGen, Inc. in 2010 and has been developed exclusively by Sanofi. Fedratinib is a selective oral, small molecule inhibitor of the JAK2 kinase. Sanofi recently announced its decision to halt all clinical trials and cancel plans for regulatory filings with fedratinib following reports of cases consistent with Wernicke's encephalopathy in patients participating in fedratinib clinical trials and a thorough risk-benefit analysis which determined that the risk to patient safety outweighed the benefit that fedratinib would bring to patients.

c) Cardiovascular diseases

Alirocumab (SAR236553), developed in collaboration with Regeneron: positive results from a Phase III study (ODYSSEY mono) with alirocumab, an investigational monoclonal antibody targeting PCSK9 (proprotein convertase subtilisin/kexin type 9), were obtained in 2013.

The mean low-density lipoprotein-cholesterol (LDL-C) reduction from baseline to week 24, the primary efficacy endpoint of the study, was significantly greater in patients randomized to alirocumab, as compared to patients randomized to ezetimibe. In the trial, which employed a dose increase (up-titration) for patients who did not achieve an LDL-C level of 70 milligrams/deciliter (mg/dL), the majority of patients remained on the initial low dose of alirocumab of 75 milligrams (mg).

A large Phase III clinical program (ODYSSEY 14 studies) is ongoing to assess the product efficacy in different populations, and new results are expected during the second and third quarters of 2014.

Sanofi and Regeneron have been advised by the FDA that it has become aware of neurocognitive adverse events in the PCSK9 inhibitor class. Neurocognitive adverse events have also been associated with the use of statins for lowering LDL cholesterol. Neither company knows the circumstances under which the FDA became aware of these adverse events or whether these adverse events were observed with a drug candidate tested as monotherapy or in combination with a statin or other cholesterol-lowering agent. The FDA has requested that Sanofi and Regeneron make an assessment of potential neurocognitive adverse events across the global development program for alirocumab, especially in the longer-term studies. Additionally, the FDA requested to be informed about the feasibility of incorporating neurocognitive testing into at least a subset of patients in the ODYSSEY OUTCOMES trial or other long-term Phase III trial(s). While neither company is aware of any neurocognitive adverse event signal relating to alirocumab, if this or another adverse event signal is detected, the further development of alirocumab may be delayed or fail, or its commercial value diminished, which could severely harm future prospects.

Fresolumimab (GZ402669 Genzyme) TGF-ß antagonist in Phase II in the treatment of Focal Segmental Glomerulosclerosis (FSGS).

d) Immune Mediated diseases and Multiple Sclerosis

Lemtrada (Alemtuzumab), a humanized monoclonal antibody targeting CD52 antigen, has been developed and is registered in Europe (dossier under discussion in the U.S.) to treat patients with relapsing forms of MS. The current development activities are described in the section " Pharmaceutical Products Main Pharmaceutical Products" above.

Aubagio® (Teriflunomide), a once daily, oral immunomodulator approved in the United States and Europe in the treatment of MS. The current development activities are described in the section " Pharmaceutical Products Main Pharmaceutical Products" above.

Sarilumab (SAR153191), a monoclonal antibody against the Interleukin-6 Receptor (anti IL-6R mAb) derived from our alliance with Regeneron, is in Phase III in adult patients with moderate to severe rheumatoid arthritis (RA). The SARIL-RA Phase III program evaluating two doses of sarilumab is underway with one completed and four ongoing clinical studies:

The SARIL-RA-TARGET study is investigating the effects of Sarilumab when added to DMARD (Disease-Modifying Anti-Rheumatic Drug) therapy in patients with active RA who are inadequate responders or intolerant to tumor necrosis factor alpha (TNF-α) antagonists on reduction of signs and symptoms at week 24 and

improvement of physical function over 24 weeks in patients;

The SARIL-RA-ASCERTAIN study is a safety calibrator study evaluating sarilumab and tocilizumab in combination with DMARD therapy in patients with RA who are inadequate responders to, or intolerant of, TNF-alpha inhibitors over 24 weeks;

Table of Contents

The SARIL-RA-EXTEND study, which enrolled patients from MOBILITY and is enrolling participants by invitation from the TARGET and ASCERTAIN studies, aims to evaluate in this uncontrolled extension the long term safety and efficacy of Sarilumab on top of DMARDs in patients with active RA;

The SARIL-RA-COMPARE study is evaluating the strategy of using IL-6 inhibition with sarilumab in combination with MTX in patients who have had an inadequate response to open-label adalimumab + MTX after 16 weeks of therapy. Those patients identified as inadequate responders are then randomized to a second TNF-alpha inhibitor (etanercept) + MTX or sarilumab + MTX.

Additional studies in the SARIL-RA clinical program are to be implemented in 2014.

Dupilumab (SAR231893), a monoclonal antibody against the Interleukin-4 alpha Receptor (anti IL-4R alpha) derived from our alliance with Regeneron, is currently being developed in two indications. Dupilumab modulates signaling of both IL 4 and IL 13 pathways. Atopic dermatitis will enter Phase III in the fourth quarter of 2014. Asthma will enter Phase III in the second quarter of 2015.

SAR339658 (GBR500), a monoclonal antibody directed at the VLA-2 (Very Late Antigen 2) integrin receptor, was in-licensed from Glenmark Pharmaceuticals in May 2011. The primary target indication is inflammatory bowel disease such as Ulcerative Colitis or Crohn's disease. The compound successfully completed Phase I in 2010 and entered Phase IIA in 2012. Enrollment continued in 2013.

SAR100842 (Genzyme, LPA1 receptor antagonist): a Phase IIA study in the treatment of systemic sclerosis has started in 2013 and is currently ongoing.

SAR156597 (Genzyme, humanized bi-specific monoclonal antibody targeting the IL-4 and IL-13 cytokines) is currently in Phase IIA in the treatment of Idiopathic Pulmonary Fibrosis.

e) Age Related Degenerative Diseases

One compound has progressed into phase II clinical development:

SAR391786 REGN1033 (Anti GDF8 mAb in sarcopenia) in collaboration with Regeneron

One compound has completed Phase I single rising dose in with Alzheimer's disease (AD) patients and started multiple ascending dosing:

SAR228810 (anti-protofibrillar AB mAb for the treatment of patients with mild cognitive impairment due to AD)

Three compounds have been terminated:

SAR110894 (H3 receptor antagonist for the treatment of Alzheimer's disease)

SAR113945 (IKK-ß kinase inhibitor for the treatment of osteoarthritis by intra-articular administration)

SAR292833 (TRPV3 antagonist for the oral treatment of chronic pain)

f) Infectious Diseases

Ferroquine/OZ439, a combination for malaria (Partnership with Medicines for Malaria Venture (MMV)). Ferroquine is a new 4-amino-quinoline being developed for the treatment of acute uncomplicated malaria, and is active against chloroquine-sensitive and chloroquine-resistant *Plasmodium* strains. Due to its long half-life it has the potential to be part of single dose cure regimens for the treatment of both *P. vivax* and *P. falciparum* malaria. OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans.

A Phase I study of combination of the two compounds was conducted in 2013. A Phase IIB clinical study of the combination will commence in the second half of 2014.

SAR279356 (a first-in-class human monoclonal antibody for the prevention and possible treatment of *S. aureus, S. epidermidis, E. coli, Y. pestis* and other serious infections) Following the successful completion of a Phase I study in early 2011, further extensive preclinical credentialing experiments have been successfully completed to further validate the potential for application of the product in the prevention of nosocomial infections and support a future Phase II clinical proof of concept study.

Table of Contents

g) Rare Diseases (Genzyme)

Cerdelga (Eliglustat) a substrate reduction therapy targeted for the treatment of Gaucher disease type 1. This product candidate is administered orally in capsule form and has the potential to transform the treatment experience of patients by providing an alternative to bi-weekly infusions. Eliglustat was submitted for licensure in both Europe and the U.S. in September 2013. In November 2013 the FDA gave the eliglustat submission Fast Track status. The approval is expected for the second half of 2014.

Patisiran (SAR438027) (mRNA inhibition Alnylam ALN-TTR02). In October 2012, Genzyme entered into an exclusive license agreement with Alnylam, covering ALN-TTR programs in the Asia-Pacific-Japan region. ALN-TTR01 and ALN-TTR02 Phase I results were published in the New England Journal of Medicine in August 2013. Results showed that RNAi therapeutics targeting transthyretin (TTR) achieved rapid, dose-dependent, durable, and specific knockdown of TTR, the disease-causing protein in TTR-mediated amyloidosis (ATTR). The Phase III program has just started. It is proposed that a Japanese Phase I trial begin in early 2014. Genzyme's exclusive territory rights for the ALN-TTR programs were extended to the rest of world excluding North America and Western Europe on January 14, 2014.

GZ402665 (rhASM) an enzyme replacement therapy targeting the treatment of Niemann-Pick B disease. A Phase Ib study was fully enrolled in July 2013.

GZ402666 (Neo GAA) in Phase I in the treatment of Pompe disease.

GZ402671 (CGS inhibitor) in Phase I in the treatment of Fabry's disease.

GZ404477 (AAV-AADC) Gene therapy based on AAV vector targeting the treatment of moderate to severe Parkinson's disease. Phase I was completed in 2013. Genzyme discontinued development on this program due to strategic considerations.

h) Ophthalmology portfolio (Sanofi-fovea)

A proof-of-concept study is being conducted for **SAR153191 sarilumab** (Phase II) in an ophthalmology indication: this anti-IL-6-receptor mAb could be a safe and efficient option to treat non-infectious uveitis affecting the posterior segment of the eye at risk of vision loss.

GZ402663 (sFlt01 Phase I): a gene therapy to deliver an anti-angiogenic gene (anti-sFlt01) to stop the progression of neovascularization and edema related to wet Age-related Macular Degeneration (AMD) and to improve patients' vision;

Retino Stat® (**SAR421868** Phase I): a gene therapy to treat wet Age-related Macular Degeneration (AMD); Retino Stat® is being developed with Oxford BioMedica and is still under opt-in conditions.

StarGen (**SAR422459** Phase I): a gene therapy to treat (by replacing the missing ABCR gene) Stargardt disease, an orphan inherited condition that leads to progressive sight loss from age seven;

UshStat® (**SAR421869** Phase I): a gene therapy to deliver a functional MY07A gene to the photoreceptor in Usher type 1B disease, an orphan inherited condition that results in progressive visual field constriction and vision loss.

Table of Contents

B.5.3 Vaccines

Our Human Vaccines R&D is focused on improving existing vaccines and on developing new prophylactic vaccines.

Portfolio

The Sanofi Pasteur R&D portfolio includes 13 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with six vaccines/antibody products for novel targets and seven vaccines which are enhancements of existing vaccine products.

Phase I	Phase II	Phase III	Submitted
Streptococcus pneumonia* Pneumonia and meningitis vaccine	**Meningitis A,C,Y,W conj. 2nd generation** Meningococcal conjugate vaccine	**Dengue*** Mild-to-severe dengue fever vaccine	
Tuberculosis* Recombinant subunit vaccine	**Rabies VRVg** Purified vero rabies vaccine	**C. difficile toxoid vaccine*** Toxoid vaccine against *clostridium difficile*	
Pseudomonas aeruginosa* Antibody fragment product for prevention of ventilator-associated pneumonia	**Rotavirus** Live attenuated tetravalent oral rotavirus vaccine	**DTP-HepB-Polio-Hib**(1) Pediatric hexavalent vaccine	
Herpes Simplex* Live attenuated viral vaccine		**Fluzone® QIV ID** Quadrivalent inactivated intradermal influenza vaccine	
		Vaxigrip® QIV IM Quadrivalent inactivated influenza vaccine	
		Quadracel® DTP(1) IPV vaccine 4-6 years U.S.	

(1) *D=Diphtheria, T=Tetanus, P=Pertussis, Hib=Haemophilus influenzae b, HepB=Hepatitis B.*

* *New targets*

Table of Contents

Project highlights

This section focuses on Phase I and Phase II compounds and novel targets in Phase III. Other vaccines in Phase III (excluding novel targets) are described in the "B.3. Vaccine Products" section above.

Influenza

To sustain our global leadership in the development of influenza vaccines, our R&D efforts are focused on innovative approaches. Following up on the development of quadrivalent flu vaccines (see " Vaccine Products"), Sanofi Pasteur will continue to assess new formulations and alternative delivery systems, as well as "universal" vaccine approaches in order to address specific patient needs and to continue to offer innovative solutions in the future.

Pediatric Combination & Adolescent/Adult Boosters

Several pediatric vaccines are under development. Tailored for specific markets, they are aimed at protecting against five or all six of the following diseases: diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (see " Vaccine Products").

Meningitis

Neisseria meningitidis bacteria are a leading cause of meningococcal disease in the U.S., Europe, the African meningitis belt and other endemic regions such as Brazil and Australia. Ongoing projects around a new generation of meningococcal conjugate vaccine are aimed at lowering the age at which this vaccine can first be administered. (see " Vaccine Products").

Pneumococcal Vaccine

Streptococcus pneumoniae bacteria are the leading etiological agent causing severe infections (over three million deaths per year worldwide, including one million children). The anti-microbial resistance in *Streptococcus pneumoniae* has complicated the treatment of pneumococcal disease and further emphasized the need for vaccination to prevent large-scale morbidity and mortality.

Sanofi Pasteur is focused on the development of a multi-protein-based pneumococcal vaccine. This approach should result in a vaccine with superior serotype coverage, compared to current polysaccharide or conjugate based vaccines, and should not induce nor be sensitive to serotype replacement. A Phase I clinical trial in Bangladesh of a vaccine with three protein-based antigens ended in 2013; the results are expected in 2014.

Rabies Vaccine

A new generation serum-free Vero cell human rabies vaccine (VerorabVax) is under development to allow both of our currently available rabies vaccines to be replaced by a single vaccine. The results of a Phase II clinical trial, carried out in 2009, demonstrated the non-inferiority of VRVg versus Verorab® in pre-exposure prophylaxis. VRVg was approved in France as a line extension of Verorab® in January, 2011. In China, the completion of the clinical development confirmed its non-inferiority against Verorab® in the Chinese population, enabling a registration file to be submitted in 2013. The clinical development plan for licensure in the U.S. is currently ongoing.

New Vaccine Targets

Dengue Dengue fever constitutes a major medical and economic burden in the endemic areas of Asia-Pacific, Latin America and Africa; more than 100 countries, representing nearly half of the world's population, are at risk. Over the last 50 years, the incidence of the disease has increased 30-fold. In 2013, dengue once again proved how unpredictable it can be with record breaking epidemics in Brazil, French overseas territories and Singapore. In response to this global threat, the WHO has set ambitious objectives to reduce the burden of the disease. The first objective is to have an evaluation of the real burden of the disease by 2015. The second one is to reduce morbidity by 25% and mortality by 50% by 2020.

In 2012, the results of the world's first efficacy study conducted in Thailand confirmed the excellent safety profile of the Sanofi Pasteur dengue vaccine candidate which targets four viral serotypes. Nevertheless, this study showed vaccine efficacy against 3 types of dengue virus out of four (61.2% against dengue virus type 1, 81.9% against type 3 and 90% against type 4). Thorough investigations have been launched to interpret this lack of efficacy against

Table of Contents

serotype 2 in the specific epidemiological context of Thailand. Furthermore, large scale phase III efficacy studies with 31,000 volunteers are ongoing in several Latin American and Southeast Asian countries. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to demonstrate vaccine efficacy against the four circulating dengue virus serotypes. Results are expected in the second half of2014. Transmission and vaccination models have already demonstrated the significant impact vaccination with a dengue vaccine having the efficacy levels observed in the Phase IIb study could have on morbidity.

C.diff Toxoid *Clostridium difficile* is a major public health concern in North America and Europe. In hospitals, it is the leading cause of infectious diarrhea in adults, particularly the elderly. The epidemiology of *Clostridium difficile* associated disease has been increasing at a worrying rate since 2003, driven primarily by the emergence of a treatment-resistant, highly virulent strain: CD027. There is currently no vaccine available and our C.diff vaccine is the only candidate in Phase III. C.diff is a toxoid-based vaccine. Toxoids have been used as the basis of a number of highly successful licensed vaccines. Sanofi Pasteur received a positive response from the FDA's Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. A multinational, large scale, Phase III study, named Cdiffense , began in August 2013. This trial is focused on evaluating the vaccine's efficacy in preventing the first episode of *Clostridium difficile* infection in at-risk individuals, including adults with imminent hospitalization or current or impending residence in a long-term care or rehabilitation facility.

Rotavirus Rotavirus is the world's leading cause of severe, dehydrating diarrhea in children under age five. Shantha has a non-exclusive license for rotavirus strains from the NIH and is developing a live-attenuated human-bovine reassortant vaccine. The license excludes Europe, Canada, the U.S., China and Brazil. The Shantha rotavirus vaccine candidate completed Phase II in 2013. Results from the Phase I/II dose ranging study demonstrated the safety and immunogenicity of the vaccine candidate, and one dose has been selected for Phase III studies starting in 2014.

HIV A follow-up study to the phase III clinical trial in Thailand provided new clues, in 2011, about the types of immune responses that may have played a role in the protection seen in 2009 with our ALVAC®-HIV vaccine. In 2011, Sanofi Pasteur entered into a public-private partnership to substantiate and extend the vector prime/protein subunit boost regimen used in Thailand. This collaboration is expected to further the field of HIV vaccine development by sharing resources and by providing the manufacturing component of a partnership of funding agencies, research organizations, governments, and experts in the field of HIV vaccine development. Sanofi Pasteur is also looking at its NYVAC-HIV vaccine replicating vectors and a flavivirus-based viral vector, by participating in an international consortium under the Collaboration for AIDS Vaccine Discovery (CAVD).

Tuberculosis Statens Serum Institute of Denmark (SSI) has granted Sanofi Pasteur a license to its technology with regard to the use of certain fusion proteins in the development of a tuberculosis vaccine. The candidate vaccine is made up of recombinant protein units. Results from the 2008 phase I trial found that the candidate vaccine was safe when administered to healthy adults living in a region of high endemic tuberculosis. A phase I/II study was initiated in July, 2013, in South Africa in infants.

Pseudomonas aeruginosa In February 2010, Sanofi Pasteur entered an agreement with KaloBios Pharmaceuticals, for the development of a Humaneered® antibody fragment to both treat and prevent *Pseudomonas aeruginosa (Pa)* infections. Most serious *Pa* infections occur in hospitalized and critically or chronically ill patients. Sanofi Pasteur acquired worldwide rights for all disease indications related to *Pa* infections except cystic fibrosis and bronchiectasis, which Sanofi Pasteur has the option to obtain at a later date. KaloBios has already completed phase I clinical trials and a small proof of concept phase II clinical trial. Sanofi Pasteur is developing a new formulation of antibody fragments. Completion of the Phase I study in healthy adult volunteers is expected in 2014.

Herpes Simplex Virus Herpes simplex virus 2 is a member of the herpes virus family and, as such, establishes life-long infections, with latent virus established in neural ganglia. Although antivirals currently exist to treat infections, no vaccine exists, greatly limiting options in disease management. The vaccine candidate is a live, attenuated virus and is being assessed as a therapeutic and, possibly, prophylactic vaccine to reduce recurrence and transmission. An NIH-sponsored phase I trial was initiated in October 2013.

B.5.4 R&D expenditures for late stage development

Expenditures on research and development amounted to €4,770 million in 2013, comprising €4,087 million in the Pharmaceuticals segment, €518 million in Human Vaccines and €165 million in Animal Health. Research and development expenditures were the equivalent of about 14.5% of net sales in 2013, compared to about 14.1% in 2012, 14.4% in 2011 and 14.1% in 2010. The stability in R&D expenditure as a percentage of sales over the past three years is attributable to active management of the portfolio and close cost control, and has been achieved

Table of Contents

despite a greater proportion of products being in late stage development. Preclinical research in the pharmaceutical segment amounted to €951 million in 2013 compared to €1,037 million in 2012, €1,113 million in 2011 and €1,037 million in 2010. Of the remaining €3,136 million relating to clinical development in the Pharmaceuticals segment (€3,181 million in 2012, €2,989 million in 2011 and €2,848 million in 2010), the largest portion was generated by Phase III or post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

For each of our current late stage (Phase III) compounds in the Pharmaceuticals segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the United States, European Union and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols and recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also "Item 3. Key Information D. Risk Factors Risks Relating to Our Business".

Phase III	**Entry into Phase III(1)**	**Compound Patent Term(2)**			**Comments**
	(month/year)	**U.S.**	**E.U.**	**Japan**	
Lyxumia® (lixisenatide)[3][4] (AVE0010)	May 2008[5]	2020	2020	2020	Dossier approved in Europe in February 2013 submitted and withdrawn in the U.S. in December 2013. Complementary Phase III study to be added to the U.S. dossier before re-submission (expected in 2015)
Lixilan®	January 2014	2020	2020	2020	Phase III program ongoing
Alirocumab (SAR236553) (REGN727)	July 2012	2029	2029	2029	Phase III program ongoing in hypercholesterolemia
Lemtrada[4] (alemtuzumab) (GZ402673)	September 2007	2015 Regulatory exclusivity: N/A	expired	expired	Dossier approved in Europe in September 2013 for the treatment of relapsing forms of Multiple Sclerosis. In the U.S. Complete Response Letter received from the FDA in December 2013. Sanofi is preparing its appeal.
U300	December 2011	2014 Protection extended to 2015, by pediatric extension.	2014 Protection extended to 2015, by pediatric extension.	2014	Phase III program ongoing; submission expected in the second quarter of 2014
Cerdelga (eliglustat) (GZ385600)	September 2009	2022	2022	2022	Dossier submitted in U.S. and Europe in September 2013 for the treatment of Gaucher Disease type 1
sarilumab (SAR153191)	August 2011	2028	2027	2027	Phase III program in the treatment of Rheumatoid Arthritis ongoing

(1)

First entry into Phase III in any indication.

(2)

Subject to any future supplementary protection certificates and patent term extensions.

(3)

Application pending in some countries.

(4)

See also table in section " Patents, Intellectual Property and Other Rights" for more information.

(5)

Development of lixisenatide as stand alone entity. A program evaluating the benefit of a combination of lixisenatide / Lantus® is in development.

Table of Contents

With respect to the compound patent information set out above, investors should bear the following additional factors in mind.

The listed compound patent expiration dates do not reflect possible extensions of up to five years available in the United States, the European Union, and Japan for pharmaceutical products. See " Patents, Intellectual Property and Other Rights Patent Protection" for a description of supplementary protection certificates and patent term extensions.

Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.

Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection, and in many cases may provide more efficacious or longer lasting marketing exclusivity than a compound's patent estate. See " Patents, Intellectual Property and Other Rights Regulatory Exclusivity" for additional information. In the United States the data protection generally runs five years from first marketing approval of a new chemical entity extended to seven years for an orphan drug indication and twelve years from first marketing approval of a biological product (e.g., aflibercept). In the European Union and Japan the corresponding data protection periods are generally ten years and eight years, respectively.

B.6. Markets

A breakdown of revenues by business segment and by geographic region for 2013, 2012, and 2011 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information is based on sales data from IMS Health MIDAS, retail and hospital for full year 2013, in constant euros (unless otherwise indicated). For more information on market shares and ranking, see "Presentation of Financial and Other Information" at the beginning of this document.

Genzyme's sales are included from the acquisition date (April 1, 2011).

B.6.1. Marketing and Distribution

Sanofi has a commercial presence in approximately 100 countries, and our products are available in more than 170. Our main markets in terms of net sales are, respectively:

Emerging Markets (see definition in "Item 4. Information on the Company Introduction" above) represent 33.3% of our 2013 net sales, the largest contribution to net sales of any region. We are the leading healthcare company in emerging markets. In 2013, sales in emerging markets grew by 4.4% at constant exchange rates. Asia and Middle East recorded double-digit sales growth in 2013. Sales in BRIC (Brazil, Russia, India and China) countries account for 34% of Emerging Markets sales. Sales in China and Russia were up 18.6% and 12.0% respectively. In 2013, sales in Africa and the Middle East each exceeded €1 billion.

The United States represents 31.7% of our net sales; we rank twelfth with a market share of 3.3% (3.7% in 2012). Sales in the U.S. were down 0.7% at constant exchange rates in 2013.

Western Europe represents 23.8% of our net sales; we are the leading pharmaceutical company in France where our market share is 8.7% (9.3% in 2012), and we rank fourth in Germany with a 4.5% market share. In 2013, sales in Western Europe were down 5.6% at constant exchange rates.

Other countries represent 11.3% of our net sales; our market share in Japan is 3.3% (3.5% in 2012). Full-year 2013 sales in Japan were down 4.3% at constant exchange rates.

A breakdown of our sales by geographic market is presented in "Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012."

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed care organizations and government institutions. Rare disease, renal, and biosurgery products are also sold directly to physicians. With the

Table of Contents

exception of CHC products, these drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

We use a selection of channels to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our mature products, as they provide the foundation for satisfying major therapeutic needs. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and we sometimes use new media channels (such as the internet) to market our products. National education and prevention campaigns can be used to improve patients' knowledge of conditions.

Our medical representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics. As of December 31, 2013, we had a global sales force of 33,509 representatives: 8,281 in Europe (including 3,691 in Eastern Europe), 4,771 in the United States, and 20,457 in the rest of the world.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographic areas. Our major alliances are detailed at "Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances." See also "Item 3. Key Information D. Risk Factors We rely on third parties for the marketing of some of our products."

Our vaccines are sold and distributed through multiple channels, including physicians, pharmacies, hospitals, private companies and distributors in the private sector, and governmental entities and non-governmental organizations in the public and international donor markets, respectively.

Our Animal Health products are sold and distributed through various channels, depending on each country's legislation for veterinary products. Merial takes into account each country's specific characteristics and sells either to veterinaries, chemists, or via wholesalers. In the case of epizootics, Merial delivers directly to governments.

B.6.2. Competition

The pharmaceutical industry continues to experience significant changes in its competitive environment. Innovative drugs, a broad product range, and a presence in all geographical markets are key factors in maintaining a strong competitive position.

There are four types of competition in the prescription pharmaceutical market:

- competition between pharmaceutical companies to research and develop new patented products or new therapeutic indications;
- competition between different patented pharmaceutical products marketed for the same therapeutic indication;
- competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and
- competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included at Item 18 of this annual report.

Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies such as: Novo Nordisk and Merck in diabetes; Eli Lilly in diabetes and oncology; Bristol-Myers Squibb in oncology; GlaxoSmithKline in thrombosis and oncology; Novartis in diabetes, multiple sclerosis, thrombosis and oncology; Shire in rare diseases and renal; Pfizer in rare diseases and oncology; Biogen Idec, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and thrombosis prevention; Roche in oncology; Johnson & Johnson in oncology and thrombosis prevention; AstraZeneca in cardiovascular diseases and oncology; Boehringer-Ingelheim in diabetes and

thrombosis; and Fresenius Medical Care in renal diseases.

Our CHC business competes with multinational corporations such as Johnson & Johnson, Bayer, Pfizer, Novartis, and GlaxoSmithKline as well as local players, especially in emerging markets.

Table of Contents

Our generics business competes with multinational corporations such as Teva, Sandoz (a division of Novartis), Mylan and Actavis and local players, especially in emerging markets.

In our Human Vaccines business, we compete primarily with multinational players backed by large healthcare groups, including Merck (outside Europe), GlaxoSmithKline, Pfizer (Wyeth), Novartis and Johnson & Johnson (Crucell). In specific market segments, Sanofi Pasteur competes with mid-size international players (such as CSL of Australia in the influenza market for the Southern Hemisphere). Sanofi Pasteur also competes with an increasing number of manufacturers entrenched in densely populated and economically emerging regions that are leveraging their cost/volume advantage and raising their level of technical capability and quality standards to compete with more sophisticated antigens in their domestic markets and increasingly in international donor markets. Multinational players are increasingly seeking alliances with manufacturers from emerging economies to secure positions in their markets of origin. Finally, there are emerging vaccine manufacturers in middle income countries, where privately owned companies in various industry sectors are investing in me-too vaccine production. Overall, there is increasingly intense competition for existing vaccines across the middle to low income segments.

In our Animal Health business, we compete primarily with international companies like Zoetis, Merck and Elanco in both production and companion animals; with Boehringer Ingelheim in production animals; with Boehringer Ingelheim mainly in the vaccines segment; with Novartis and Bayer for pets, particularly for parasiticides; and with Virbac, Ceva and Vetoquinol, French companies with global presence, for pharmaceuticals and/or vaccines.

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see " Patents, Intellectual Property and Other Rights" above). Similarly, when a competing patented drug from another pharmaceutical company faces generic competition, these generic products can also affect the competitive environment of our own patented product. See "Item 3. Key Information D. Risk factors Risks related to our business".

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents or regulatory exclusivity have expired.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date. Such launch may occur notwithstanding the fact that the owner of the original product may already have commenced patent infringement litigation against the generics manufacturer. Such launches are said to be "at risk" for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, these launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the Internet. This situation is of particular relevance to the European Union, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising up to 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value.

B.6.3. Regulatory Framework

B.6.3.1 Overview

The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval commitments that may include pediatric development.

Table of Contents

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the product development and application review. It may refuse to grant approval and require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and penalties for violations of regulations based on data that are made available to them.

Product approval can vary from six months or less to several years from the date of application depending upon the country. Factors such as the quality of data, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

In recent years, efforts have been made by members of the ICH (International Conference on Harmonization) on harmonization of product development and regulatory submission requirements. The ICH consists of the regulatory agencies of the three founding members (the European Union, Japan, and the United States), plus Health Canada and Swissmedic as observers. An example of these efforts is the Common Technical Document (CTD), which is a format used for product applications in ICH, with only local or regional adaptation.

In 2013, the ICH Steering Committee continued its discussions on its reform on increased engagement and implementation of guidelines globally, increased transparency, and reviewed future ICH topics. Organizational reform measures are planned to foster international cooperation.

Emerging markets countries are starting to participate in ICH standardization discussions, and will be more involved in the near future. ICH has expanded beyond its initial members and observers with the 1999 formation of the Global Cooperation Group (GCG), which was formed as a subcommittee of the ICH Steering Committee in response to a growing interest in ICH Guidelines beyond the three ICH regions. Recognising the need to engage actively with other harmonisation initiatives, representatives from five Regional Harmonisation's Initiatives (RHIs) were invited to participate in GCG discussions: APEC, ASEAN, EAC, GCC, PANDRH and SADC. A further expansion of the GCG was agreed in 2007 and regulators were invited from countries with a history of ICH Guideline implementation and/or where major production and clinical research are carried out (Australia, Brazil, China, Chinese Taipei, India, Czech Republic, Russia and Singapore).

International collaboration between regulatory authorities continues to develop with the implementation of confidentiality arrangements and memoranda of understanding between both ICH and non-ICH regulatory authorities. Examples include work-sharing on Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections and regular interactions in the form of "clusters" (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphans, biosimilars, and blood products) between the United States and the European Union.

In addition to the joint efforts listed above, Free Trade Agreements (FTAs) have proved to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries.

The requirement of many countries, including Japan and several member states of the European Union, to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extends the time for market entry beyond the initial marketing approval. While marketing approvals for new pharmaceutical products in the European Union have been largely centralized with the EMA, pricing and reimbursement remain a matter of national competence.

In the European Union, there are three main procedures by which to apply for marketing authorization:

The centralized procedure is mandatory for drugs derived from biotechnologies, new active substances designed for human use to treat HIV, viral diseases, cancers, neurodegenerative diseases, diabetes and auto-immune diseases, orphan drugs and innovative products for veterinary use. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants an E.U. marketing authorization. Such a marketing authorization is valid throughout the E.U. and the drug may be marketed within all E.U. member states.

If a company is seeking a national marketing authorization in more than one member state, the mutual recognition or decentralized procedure is available to facilitate the granting of harmonized national

52

Table of Contents

authorizations across member states. Both the decentralized and the mutual recognition procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one member state.

National authorizations are still possible, but are only for products intended for commercialization in a single E.U. member state or for line extensions to existing national product licenses.

Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the E.U. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is "bioequivalent" to the originator product (i.e., works in the same way in the patient's body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product's dossier. Generic product applications can be filed and approved in the European Union only after the originator product eight-year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period has elapsed from the date of approval of the originator product.

Another relevant aspect in the E.U. regulatory framework is the "sunset clause": a provision leading to the cessation of the validity of any marketing authorization if it is not followed by marketing within three years or, if marketing is interrupted for a period of three consecutive years.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. The E.U. pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder and of the regulatory authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions.

It is possible for the regulatory authorities to withdraw products from the market for safety reasons. Responsibilities for pharmacovigilance rest with the regulatory authorities of all the E.U. member states in which the marketing authorizations are held. In accordance with applicable legislation, each E.U. member state has a pharmacovigilance system for the collection and evaluation of information relevant to the benefit to risk balance of medicinal products. The regulatory authority regularly monitors the safety profile of the products available in its territory, takes appropriate action where necessary, and monitors the compliance of marketing authorization holders (MAHs) with their pharmacovigilance obligations. All relevant information is shared between the regulatory authorities and the MAH, in order to allow all parties involved in pharmacovigilance activities to fulfill their obligations and responsibilities. In 2010, new legislation aimed at improving patient protection by strengthening the E.U. system for the safety monitoring of medicines was approved. In July 2012, pharmacovigilance legislation came into force, with significant impacts on the regulatory environment. Changes include the creation of a new scientific advisory committee, the Pharmacovigilance Risk Assessment Committee (PRAC) at EMA level, with a key role in the assessment of all aspects of the risk management of the use of medicinal products for human use approved in the European Economic Area (EEA). This includes measures relating to the detection, assessment, minimisation and communication of the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product. This committee is also responsible for the design and evaluation of post-authorisation safety studies (PASS) and pharmacovigilance audits.

Since its introduction in the second quarter of 2012 the PRAC has initiated reviews of marketed products (by class or on *ad hoc* basis) through various procedures. 38 Sanofi products underwent PRAC review from July 2012 to October 2013, generating 10 labeling variations (up to November 2013; two additional variations are ongoing). In only one case for Sanofi (Myolastan®) did the review lead to the product being withdrawn from the E.U. market.

The pharmacovigilance legislation was amended in October 2012 by Regulation (EU) No 1027/2012 (applicable since June 5, 2013 to centrally authorized medicines) and Directive 2012/26/EU (applicable since October 28, 2013 to nationally authorized medicines). The amendments aim to further strengthen of the protection of patient health by promoting prompt and appropriate regulatory action on European medicines. The amendments include major changes to notification requirements: MAHs of human medicines have to notify E.U. regulators of any action to withdraw a product from the market, together with the reason for this action.These amendments also include other aspects: clarification of the scope and strengthened safety-referral procedures in the E.U.; improved coordination and facilitation of swift action and extension of assessment, for the benefit of public health; the scope of translation exemptions to include cases of severe issues of availability, including shortages of medicines, in order to facilitate the availability of medicines across the E.U.; and extension of the mandatory scope of the medicines subject to additional monitoring.

Table of Contents

The Pharmacovigilance legislation also strengthens the legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of a medicinal product, with regulatory supervision of protocols and results. Such studies are aimed at collecting data to enable the safety or efficacy of medicinal products to be assessed in everyday medical practice. The granting of marketing authorization will be conditional on such studies being performed. Consequently, the pharmaceutical industry will have to build the need for post-authorization safety studies (PASS) and post-authorization efficacy studies (PAES) into development and life cycle management plans. Sanofi has put in place robust processes to ensure that required PASS and PAES can be properly implemented as required, either in the frame of a RMP (Risk Management Plan) or following a Health Authority request.

The Pharmacovigilance legislation also introduces a new periodic safety report to be prepared by the pharmaceutical companies. This is no longer limited to safety data, but instead presents a critical analysis of the risk-benefit balance of the medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits. Sanofi has fully implemented the new report since January 2013.

In the **United States**, applications for approval are submitted for review to the FDA, which has broad regulatory powers over all pharmaceutical and biological products that are intended for sale and marketing in the U.S. To commercialize a product in the U.S., a New Drug Application (NDA) under the Food, Drug and Cosmetic (FD&C) Act or Biological License Application (BLA) under the Public Health Service (PHS) Act is submitted to the FDA with data for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use, if the benefits of the drug's use outweigh its risks, whether the drug's labeling is adequate, and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments and requirements. Approval for a new indication of a previously approved product requires the submission of a supplemental NDA (sNDA) for a drug or supplemental BLA (sBLA) for a biological product.

The FD&C Act provides another abbreviated option for NDA approved products, called the 505(b)(2) pathway. This pre-market application may rely on the FDA finding that the reference product has been found to be safe and effective by the FDA based upon the innovator's preclinical and clinical data.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are "abbreviated" because they are generally not required to include data to establish safety and effectiveness, but need only demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product). Consequently, the length of time and cost required for development of generics can be considerably less than for the originator's drug. With effect from October 1, 2012, under the Food and Drug Administration Safety and Innovation Act (FDASIA) and the Generic Drug User Fee Amendments (GDUFA), an application for a generic drug product requires a user fee payment. The current review time for an ANDA exceeds 30 months. The ANDA pathway in the United States can only be used for generics of drugs approved under the FD&C Act.

The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amends the Public Health Service Act to create an abbreviated licensure pathway (351k) for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product. As of January 1, 2014, no sponsor has submitted a 351k application to the FDA for review.

The FDASIA, signed into law on July 9, 2012, expands the FDA's authority and strengthens its ability to safeguard and advance public health by giving the FDA the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products; promoting innovation to speed patient access to safe and effective products; increasing stakeholder involvement in FDA processes; and enhancing the safety of the drug supply chain. The FDA has established a three-year implementation plan, which is planned to be updated on a monthly basis.

In Japan, regulatory authorities can require local development studies, though they also accept multi-national studies. They can also request bridging studies to verify that foreign clinical data are applicable to Japanese patients and require data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a significant delay in the registration of some innovative products in Japan compared to the European Union and the United States. In order to solve this drug-lag problem, the MHLW (Ministry of Health, Labor and Welfare) introduced the new NHI (National Health Insurance) pricing system on a trial basis in April 2010. Reductions in NHI prices of new drugs every two years are compensated by a "Premium" for a maximum of 15 years. A "Premium" is granted in exchange for the development of off-label indications with high medical needs. The pharmaceutical companies concerned are required to conduct submission based on available documentation within six months or start a clinical trial for registration within one year after the official development request of the off label

Table of Contents

indications. For unproven drugs with high medical needs, clinical trials in Japanese patients are generally required. Otherwise, NHI prices of all products of the company would be reduced dramatically.

Based on the reform of the NHI price system finalized on December 25, 2013, the "Premium" classification will be restricted to new products from companies which conduct R&D on "pharmaceuticals truly conducive to the improvement of healthcare quality," namely (a) pediatric/orphan drugs, (b) drugs to treat diseases which cannot be adequately controlled with existing drugs. The "Premium" policy will continue its trial stage.

The PMDA plans to achieve its targets for a total review time of 12 months for products with standard review status and 9 months for products with priority review status for 80% (currently 50%) of all applications by the end of 2018.

The PMDA also plans to eliminate the "review lag" between the application filing and approval of drugs and medical devices compared to the FDA by the end of 2020.

The revised Pharmaceutical Affairs Law was enacted on November 27, 2013. There are three major objectives. The first objective is to strengthen safety measures for drugs and medical devices. In particular, MAHs must prepare a package insert based on the latest knowledge and notify the J-MHLW before placing products on the market or when revisions are made. The second objective is to accelerate the development of medical devices. The third-party accreditation system will be expanded to specially controlled generic medical devices (i.e. Class III devices). Consequently, the PMDA can accelerate the review of innovative medical devices. The third objective is accelerated commercialization of regenerative medicinal products.

The term "Regenerative Medicinal Products" used in the law includes cellular and tissue-based products and gene therapies. This concept is similar to "Advanced Therapy Medicinal Products (ATMPs)" in the E.U. This law enables conditional regulatory approval based on confirmation of probable efficacy and safety in small-scale clinical trials, followed up by comprehensive studies to confirm safety and efficacy in a wider population that would then lead to a regular (full) approval.

For new drugs and biosimilar products with approval applications submitted on or after April 2013 Japan will begin implementing an RMP, similar to the E.U. Pharmacogivilance system.

For generic products, the data necessary for filing are similar to E.U. and U.S. requirements. Pharmaceutical companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is administered intravenously.

B.6.3.2 Biosimilars

Products can be referred to as "biologics" when they are derived from plant or animal tissues, including blood products or products manufactured within living cells (e.g., antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of "generics" is not scientifically appropriate for biologics due to their high level of complexity and therefore the concept of "biosimilar" products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical/chemical, biological, non-clinical and clinical similarity.

In the European Union, a regulatory framework for developing and evaluating biosimilar products has been in place since November 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products including guidance on preclinical and clinical development of biosimilars of low molecular weight heparins (LMWH). However, starting in 2011 and continuing in 2013, the EMA initiated a revision of the majority of the existing biosimilar guidelines (general over-arching guidelines, quality, non-clinical and clinical guidelines, comments on which had to be submitted to the EMA by end of 2013, as well as immunogenicity and product-related guidelines for recombinant insulin and LMWH).

The major update in the revised over-arching biosimilar guideline is the opportunity to use a version of the reference product sourced outside the EEA provided bridging data are generated by the applicant. This important change will help facilitate the global development of biosimilars and will come into force via the revision of the over-arching biosimilar guideline, expected in 2014.

Table of Contents

While the EMA has adopted a balanced approach for all biosimilars, allowing evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, the EMA has expressed some willingness to simplify the pathway in very specific circumstances. For a very simple biological fully characterized on the quality level, a biosimilar could be authorized based on a bioequivalence study combined only with an extensive quality package. With respect to vaccines, the CHMP position is that it is at present unlikely that these products may be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

In 2013, the European Commission granted marketing authorisations for the first monoclonal-antibody biosimilar. This approval was considered a landmark decision by the EMA, proving that the biosimilar concept can be successfully applied to complex molecules such as monoclonal antibodies and that extrapolation of multiple indications is possible.

Since February 2012, the FDA has published for consultation four draft scientific guidance documents for biosimilar development. All four of these guidance documents remain in draft format.

At the December 2013 FDA-CMS meeting, the FDA acknowledged that the agency has had the equivalent of pre-NDA "meetings" in the biosimilar space.

In Japan, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical and clinical CMC (Chemistry, Manufacturing and Control) data to be considered for the development of the new application category of biosimilars. Unlike the CHMP guidelines, the main scope of the Japanese guidelines includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

Many regulatory authorities worldwide have in place, or are in the process of developing, a regulatory framework for biosimilar development and approval. It should be noted that although many emerging markets are basing their regulations and guidance on WHO or EMA documentation, some markets have approved biosimilars under an existing regulatory framework that is not specific to biosimilars.

B.6.3.3 Medical Devices

Currently in the E.U., there is no pre-market authorisation by a regulatory authority. Instead there is a Conformity Assessment Procedure (for medium and high risk devices), involving an independent third party "Notified Body" (NB). Once certified, medical devices bear the CE-mark, allowing them to circulate freely in the EU/EFTA countries and Turkey. Medical Devices are currently regulated by three core Directives.

On September 26, 2012 the European Commission adopted proposals to introduce two Regulations that will overhaul and tighten the current E.U. rules governing medical devices (EU Medical Device Directive 93/42/EC amended in 2007, 2007/47/EC).

The proposed texts are currently being discussed in the European Parliament and in the Council.

The position of the European Parliament Committee on the Environment, Public Health and Food Safety (ENVI) passed a vote on September 25, 2013, and ratified by the full European Parliament on October 22, 2013. With these votes, members of the European Parliament endorsed essential measures that will strengthen patient safety and which are supported by the industry, such as improving the competence and control of Notified Bodies, introducing unannounced site visits by Notified Bodies, increasing the transparency and traceability of medical devices, introducing a stricter post-market follow-up, and improved stakeholder engagement. A "scrutiny procedure" would be used at least for high-risk Class III devices (novel technologies or specific public health threats). The recycling of single use medical devices is still under discussion.

The new revised framework also formally introduces the concept of "companion diagnostic", which is expected to deliver a more accurate definition of the patient population that will benefit from a given product.

B.6.3.4 Generic drugs

In the E.U., the number of positive opinions by centralized procedure for generics is unchanged year-on-year (16 in 2013). Most of the generics applications for chemical entities use mutual recognition and decentralized procedures, with about 8% of the procedures relating to non-prescription products. Pricing systems for generics remain at national level in the E.U.

Table of Contents

In the U.S., to help the FDA ensure that participants in the U.S. generic drug system comply with U.S. quality standards and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, the FDA and the industry have jointly agreed to a comprehensive user fee program (GDUFA) to supplement traditional appropriated funding, focused on safety, access, and transparency.

In December 2013 the FDA and EMA announced the launch of a joint initiative to share information on inspections of bioequivalence studies submitted in support of generic drug approvals. This collaborative effort provides a mechanism to conduct joint facility inspections for generic drug applications submitted to both agencies. Taking part in this initiative are the EMA and the E.U. member states France, Germany, Italy, the Netherlands and the United Kingdom

The NHI price system will be reformed in Japan in fiscal year 2014, including a new special price reduction rule for long-listed drugs. The new rule would reduce the NHI prices of long-listed drugs whose generic replacement rates are less than 20% five years after their first generics join the NHI price list by 2.0% in the first NHI price revision, by 1.75% if the substitution rate is 20% or higher but less than 40%, and by 1.5% if the rate is 40% or higher but less than 60%. The rule would be introduced in April 2014.

Under the new price system, NHI prices of first generics (currently set at 70%) would be set at 60% of the price of the originator product, while a 50% rule would be applied to oral first generics when more than 10, with the same ingredients, obtain listing.

In addition, a 10% "precursor premium" would be introduced for new drugs with new mechanisms of action that obtain approval in Japan ahead of the rest of the world if they receive either the premium for innovativeness or the premium for usefulness.

B.6.3.5 OTC drugs

In the E.U., one product has had a prescription-to-OTC switch approved through Centralized Procedure since May, 2009.

In the United States, FDA approved two first-in-class prescription-to-OTC switches in 2013, one of which was Sanofi's Nasacort® Allergy 24HR.

The FDA's Nonprescription Drug Safe Use Regulatory Expansion (NSURE) Initiative was launched to explore regulatory approaches to expanding the nonprescription drug market but the timeline for implementation may be longer than some anticipated.

In Japan, the J-MHLW drug safety committee meeting held on December 20, 2013 decided on the details of safety evaluations for drugs newly switched from prescription to OTC, following the passage of a bill to revise the Pharmaceutical Affairs Law (PAL). The J-MHLW will give the green light for online sales of such OTC drugs if no safety concerns arise during their three-year safety evaluation period (the safety evaluation period is currently four years). During the three-year evaluation period, drugs that moved from prescription to OTC will have to be categorized as products that require pharmacist consultations when purchasing.

Under the new plan, the J-MHLW will require marketing authorization holders to submit interim reports upon the completion of their post-marketing surveillance (PMS). Based on these interim reports and other reports on adverse events, the J-MHLW will evaluate serious adverse events two years after the launch of OTC drugs or later.

B.6.3.6 Transparency and public access to documents

Transparency regarding clinical trials

Over the last two to three years the pharmaceutical industry has been subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pushed for more openness and transparency, for example by making more comprehensive disclosures about the rationale and basis of regulatory decisions on medicinal products, so as to enhance the credibility of the regulatory process. This is a significant driver of the transparency initiatives undertaken in several countries.

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

Table of Contents

From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities.

E.U. pharmaceutical legislation for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorization and supervision of medicinal products. The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as improving the format of the European Public Assessment Report and web-published product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative efficacy and effectiveness. The new E.U. pharmacovigilance legislation aims at giving greater transparency, especially with regard to communication of safety issues (e.g. public hearings, specific European web-portals with information on medicinal products). Finally, patients and consumers are increasingly involved in the work of the EMA's scientific committees.

In June 2013, the EMA released a draft policy on publication and access to clinical-trial data.

In the U.S., the FDA launched a Transparency Initiative in June 2009. The objective of the initiative was to render the FDA much more transparent and open to the American public by providing the public with useful, user-friendly information about agency activities and decision-making.

The FDA Transparency Initiative has three phases: Phase I Improving the understanding of the FDA basics (completed with ongoing updates); Phase II Improving the FDA's disclosure of information to the public (ongoing); and Phase III Improving the FDA's transparency to regulated industry (ongoing). Proposals to improve transparency and access to information were released for consultation for both Phase II and Phase III. Some of the less controversial proposals have been implemented; others, such as proactive release of information that the Agency has in its possession, may require revisions to U.S. federal regulations.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have strengthened their long-standing commitment to enhancing public health by endorsing joint "Principles for Responsible Clinical Trial Data Sharing". Under the new commitments, biopharmaceutical companies will dramatically increase the amount of information available to researchers, patients, and members of the public. On January 2, 2014 Sanofi announced its commitment to expanding access to its clinical trial data.

In Japan, the J-MHLW/PMDA actively publishes information concerning approvals of medicinal products (ethical drugs, non-prescription drugs, and quasi-drugs) and medical devices. For ethical drugs discussed at the J-MHLW's Pharmaceutical Affairs and Food Sanitation Council, the redacted clinical trials data module 1&2 (except for commercial confidential information and personal data) have been made publicly available on the PMDA website.

Transparency regarding Health Care Professionals

Regarding transparency regarding Health Care Professionals (HCP), there is no common harmonized approach in the E.U. For transparency purpose, there is an increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level with legal provisions or with Healthcare Industry voluntary undertakings (Pharma Code) in some countries (such as United Kingdom, Denmark, France, Portugal or Slovakia).

The EFPIA released mid-2013 a new Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare Organizations (HCOs) the "EFPIA HCP/HCO Disclosure Code". The compliance with this new Disclosure Code has become an obligation for EFPIA's memberships, who are required to transpose this Code into their national codes in full by 31 December 2013.

This new Code includes stricter rules on hospitality and gifts, with the requirement for member associations to include a threshold on hospitality in their national codes and the prohibition of gifts.

B.6.3.7 Other new legislation proposed or pending implementation

Clinical trials regulation: a proposal for a regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC, was first released in July 2012.

On December 20, 2013, the Council of the E.U. endorsed a compromise agreement, reached by the Council, the European Parliament and the European Commission. The move opens the way to the regulation's final approval before the parliamentary elections in May 2014.

One of the main objectives behind a new proposal for clinical trials regulation by the European Commission was the impact on the competitiveness of the European life sciences industry caused by changes to the conditions of the

Table of Contents

clinical trial approval process. The new legislation was drafted as a more stringent form of regulation instead of a directive in order to reach better harmonization between countries, without interfering with Member States' competences in terms of ethical aspects.

While the final text has not been released yet, the following major points are known:

The timeline for approving a clinical trial proposal was set at 60 days without questions (and a maximum of 99 with questions and clock stops). This can be seen as a setback for the industry, as the Commission's proposal was based on 41 days without questions and a maximum of 74 days including all possible delays. In the case of advanced therapy medicinal products, the timeline can be extended by another 50 days, making 110 days in total.

To make both the reference state and the relevant Member States comply with the timelines, the legislation includes the concept of tacit approval. The fact that this feature was accepted by all parties can be seen as a positive outcome for the industry.

As regards transparency requirements for clinical trial data submitted through a single E.U. submission portal and stored in a Union-level database, the new clinical trial regulation allows for protection of personal data of patients and commercially confidential information, which is in line with the industry data sharing laid out in Policy 70 (see previous section).

Selection of reference Member State by the sponsor was maintained.

During the three-year transition period, both sets of rules will apply in parallel.

Falsified medicines: implementation of Directive 2011/62/EU: The European Union has reformed the rules for importing active substances for medicinal products for human use into the E.U. As of January 2, 2013, all imported active substances must have been manufactured in compliance with good manufacturing practice (GMP) standards or standards at least equivalent to GMP. The manufacturing standards in the E.U. for active substances are those of the "International Conference for Harmonisation" ICH Q7. As of July 2, 2013, such compliance must be confirmed in writing by the competent authority of the exporting country, except for countries with waivers. Written confirmation must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of GMP at least equivalent to that in the E.U.

Implementation of Directive 2011/62/EU was expected by July 2, 2013. To date 17 of the 27 Member States have yet to transpose the directive in to national law.

A major uncertainty was expected regarding potential temporary drug shortages in the E.U. in cases where manufacturers were unable to supply the required documentation. At end 2013, no shortages of medicines from innovator or generic companies associated with the Falsified Medicines Directive had been identified, largely due to measures taken by companies to avoid importation problems.

In the U.S., on November 28, 2013, President Obama signed into law H.R. 3204, the Drug Quality and Security Act (DQSA). The legislation introduces a federal track-and-trace system for medicines with serial numbers added to individual packs and (non-mixed) cases within four years of the legislation being adopted, and electronic tracing of production through the supply chain mandated within 10 years.

It also strengthens licensure requirements for wholesale distributors and third-party logistics providers, and requires the FDA to maintain a database of wholesalers that will be available to the public through its website.

The law also boosts oversight of compounding pharmacies that make drugs to order, with the FDA getting greater powers to oversee large-volume or 'outsourcing' compounders without individual prescriptions.

NDA electronic clinical trial data submission: In Japan, the PMDA intends to require pharmaceutical companies to submit clinical trial data for their NDAs in electronic formats, beginning in fiscal year 2016 a move that would allow the authority to efficiently store and analyze the data to improve its efficacy and safety predictions.

Under its plan, the PMDA would launch a pilot program this fiscal year, which would run through to the end of fiscal year 2015, to verify its capabilities for storing, managing, and analyzing submitted electronic data with its current setup. Although the agency aims to require such

electronic data filings from fiscal year 2016, it will also consider transitional measures to smooth the way for the full changeover.

Table of Contents

Such mandatory electronic submissions are expected to be limited to clinical trial data for new drugs newly filed for regulatory approval. The necessity of the electronic submission for Phase I trial data will likely be decided on a case-by-case basis, while makers will be required to file nonclinical toxicity study data in one of the SEND (Standard for the Exchange on Non-clinical Data) formats in due course.

In the E.U., electronic submission for marketing authorization and variation applications has already been in place for many years. To allow secure submission over the internet for all types of eCTD applications for human medicines, the EMA launched the eSubmission Gateway; this was followed by the eSubmission web client, launched in January, 2013. From March, 2014, the use of the eSubmission Gateway or web client will become mandatory for all eCTD submissions through the centralized procedure, order to improve efficiency and decrease costs for applicants.

The EMA will extend the use of eSubmission Gateway and web client to paediatric submissions, veterinary medicines and referral procedures in the near future.

B.6.4. Pricing & Reimbursement

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which Sanofi operates. Increasingly, these efforts result in pricing and market access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third party payers are increasingly demanding comparative / relative effectiveness data to support their decision making process. They are also increasing their utilization of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

Significant recent pricing events and trends include:

In the United States, mandatory health insurance has begun (January 1, 2014). The positive effects of this on the size of the market should begin to appear over the coming years, while increased mandated rebates will have a deleterious effect on the net value of products in these segments of the market.

In Europe, the financial crisis of recent years seems to have stabilised. The long-anticipated Value-Based Pricing system in the UK has not led to considerable changes from previous framework agreements. Instead, a new edition of the Pharmaceutical Price Regulation Scheme has been approved, while certain evaluation criteria used by the National Institute for Health and Clinical Excellence (NICE) are to be revised in 2014. In Germany, the price freeze implemented under the law on the restructuring of the pharmaceutical market (AMNOG) and scheduled to finish at the end of 2013 has been temporarily extended so that debates can take place to renew the measure for the medium term. However, the mandatory rebate has been reduced from 16% to 6% as scheduled.

The global theme of universal healthcare, with implementation underway in several regions, has led to many issues in funding. Price controls for all products and all sectors of the market have been at issue and are anticipated to be a subject for scrutiny in the future. Among the large emerging markets, India has finally implemented price control. Also, instances of positions taken against innovative product patents have multiplied and compulsory licensing has again been considered with a wider therapeutic scope. Russia continues to widen its programme of pilot insurance schemes and reforms to its Essential Drugs List price controls are expected in 2014, while legislation favours national production. National production is also a theme of policy in Brazil.

We believe that third party payers will continue to act to curb the cost of pharmaceutical products. While the impact of these measures cannot be predicted with certainty, we are taking the necessary steps to defend the accessibility and price of our products in order to reflect the value of our innovative product offerings:

We actively engage with our key stakeholders on the value of our products to them. These stakeholders including physicians, patient groups, pharmacists, government authorities and third party payers can have a significant impact on market access for our products.

We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets.

Table of Contents

Conscious of the importance of recognizing the value of our products and the high cost of R&D, we continue to analyze innovative pricing and access strategies that balance patient access with appropriate rewards for innovation. Specifically, we are involved in risk sharing agreements with payers, whereby part of the financial risk related to a treatment's success is carried by the marketing company. Those agreements provide that clinical efficacy be monitored after launch, for a specified period of time and patient population. The price and reimbursement level of the drug is then either confirmed or revised based on these post-marketing results.

We are also actively looking at tiered pricing options where this is possible, allowing wider access to populations that would otherwise be denied this for new, innovative therapies.

B.7. Patents, Intellectual Property and Other Rights

Patent Protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover:

active ingredients;

pharmaceutical formulations;

product manufacturing processes;

intermediate chemical compounds;

therapeutic indications/methods of use;

delivery systems; and

enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new molecule (small molecule or biologic) has generally already passed by the time the related product obtains marketing approval. As a result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate regulatory delay in Europe (a Supplementary Protection Certificate or SPC), the United States (a Patent Term Extension or PTE) and Japan (also a PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing approval. The protection a patent affords the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2013, an EPO patent application may cover the 38 European Patent Convention member states, including all 27 member states of the European Union. The granted "European Patent" establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European Patent Convention member states, resulting in different treatment in those countries.

In 2013, E.U. regulations were signed to create a European patent (Unitary Patent) and a Unified Patent Court. However, they will only enter into force once the agreement on the Unified Patent Court is ratified by at least 13 Member States including France, Germany, and the United Kingdom. As of the date of this document only Austria has ratified.

The Unitary Patent will provide a unitary protection within the participating states of the European Union (when ratified by the member states with the exception of Italy and Spain). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary patents. The Court will be composed of a central division (with seat in Paris and the pharmaceutical section in London) and by several local and regional divisions in the contracting Member States to the agreement. The Court of Appeal will be located in Luxembourg.

Table of Contents

We monitor our competitors and vigorously seek to challenge patent infringement when such challenges would negatively impact our business objectives. See "Item 8 A. Consolidated Financial Statements and Other Financial Information Patents" of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product. See "Item 3. Key Information D. Risk Factors We may lose market share to competing remedies or generic brands if they are perceived to be equivalent or superior products". In some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. See " Focus on Biologics" below. Patent protection is also an important factor in our animal health business, but is of comparatively lesser importance to our Consumer Health Care and generics businesses, which rely principally on trademark protection.

Regulatory Exclusivity

In some markets, including the European Union and the United States, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators the exclusive use for a limited time of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the United States, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. The FDA will accept the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in " Product Overview Challenges to Patented Products" below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired U.S. regulatory and patent-related exclusivities by a pediatric extension. See " Pediatric Extension", below.

Further, in the United States, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), was enacted on March 23, 2010 as part of the much larger health care reform legislation known as the Patient Protection and Affordable Care Act ("PPACA"). The BPCIA introduced an approval pathway for biosimilar products. A biosimilar product is a biologic product that is highly similar to the reference (or innovator) product notwithstanding minor differences in clinically inactive components, and which has no clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product. The BPCIA provides that an application for a biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed.

In the European Union, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the "8+2+1" rule.

In Japan, the regulatory exclusivity period varies from four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions, to six years for new drugs containing a medicinal composition, or requiring a new route of administration, to eight years for drugs containing a new chemical entity, to ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

Emerging Markets

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-

Table of Contents

Related Aspects of Intellectual Property Rights (TRIP) has required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005, although it provides a limited number of developing countries an extension to 2016. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See "Item 3. Key Information D. Risk Factors Risks Relating to the Group Structure and Strategy The globalization of the Group's business exposes us to increased risks"

Pediatric Extension

In the United States and Europe, under certain conditions, it is possible to extend a product's regulatory exclusivities for an additional period of time by providing data regarding pediatric studies.

In the United States, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called "pediatric exclusivity"), for example, Lantus® received FDA grant of pediatric exclusivity.

In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

In Japan, for pediatric research there is no extension of patent protection (for patented medicinal products), however, it may result in an extension of marketing exclusivity from 8 to 10 years.

Orphan Drug Exclusivity

Orphan drug exclusivity may be granted in the United States to drugs intended to treat rare diseases or conditions (affecting fewer than 200,000 patients in the U.S. or in some cases more than 200,000 with no expectation of recovering costs).

Obtaining orphan drug exclusivity is a two-step process. An applicant must first seek and obtain orphan drug designation from the FDA for its drug. If the FDA approves the drug for the designated indication, the drug will receive orphan drug exclusivity.

Orphan drug exclusivity runs from the time of approval and bars approval of another application (ANDA, 505(b)(2), New Drug Application (NDA) or Biologic License Application (BLA)) from a different sponsor for the same drug in the same indication for a seven-year period. Whether a subsequent application is for the "same" drug depends upon the chemical and clinical characteristics. The FDA may approve applications for the "same" drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the European Union and Japan.

Product Overview

We summarize below the intellectual property coverage in our major markets of the marketed products described above at " Pharmaceutical Products Main Pharmaceutical Products". Concerning animal health products, Merial's intellectual property coverage is described above (see " Animal Health: Merial"). In the discussion of patents below, we focus on active ingredient patents (compound patents) and any later filed patents listed, as applicable, in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") or on their foreign equivalents. These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic version of one of our products (see " Challenges to Patented Products" below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (*e.g.*, patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. U.S. patent expirations presented below reflect U.S. Patent and Trademark Office dates, and also reflect six-month pediatric extensions to the FDA's Orange Book dates for Lantus®. Where patent terms have expired we indicate such information and mention if generics are on the market.

Table of Contents

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the European Union. Specific situations may vary by country, most notably with respect to older patents and to countries having only recently joined the European Union.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the United States, European Union or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While E.U. regulatory exclusivity is intended to be applied throughout the European Union, in some cases member states have taken positions prejudicial to our exclusivity rights.

Lantus® (insulin glargine)

U.S.	**E.U.**	**Japan**
Compound: August 2014, protection extended to February 2015 by Pediatric Extension[(1)]	Compound: November 2014 in most of Western Europe extended until May 2015 by Pediatric Extensions	Compound: November 2014

(1)

A patent infringement suit was filed by Sanofi against Eli Lilly on January 30, 2014 in the United States. The suit was triggered by Eli Lilly's submission to FDA of an NDA (505(b)(2) New Drug Application) seeking approval to sell an insulin glargine drug product. The suit resulted in a stay during which the FDA cannot approve Eli Lilly's NDA. The stay is expected to expire the earlier of (i) a court decision favorable to Eli Lilly or (ii) June 2016.

Apidra® (insulin glulisine)

U.S.	**E.U.**	**Japan**
Compound: June 2018	Compound: September 2019 in most of the EU	Compound: May 2022
Later filed patent: ranging through January 2023	Later filed patent: March 2022	Later filed patent: July 2022
	Regulatory exclusivity: September 2014	Regulatory exclusivity: April 2017

Jevtana® (cabazitaxel)

U.S.	**E.U.**	**Japan**
Compound: March 2021	Compound: March 2016	Compound: March 2016 (patent term extension to be determined once product is approved in Japan)
Later filed patents: coverage ranging through December 2025	Later filed patents: coverage ranging through September 2024 to March 2025 with SPC granted in some EU countries	Later filed patents: coverage ranging through September 2024
Regulatory exclusivity: June 2015	Regulatory exclusivity: March 2021	Regulatory exclusivity: to be determined upon approval of a product in Japan

Lovenox® (enoxaparin sodium)

U.S.	**E.U.**	**Japan**
Compound: no compound patent coverage Generics on the market	Compound: expired	Compound: expired Regulatory exclusivity: January 2016

Table of Contents

Plavix® (clopidogrel bisulfate)

U.S.	**E.U.**	**Japan**
Compound: expired Generics on the market	Generics on the market	Compound: expired Regulatory exclusivity: expired

Aprovel® (irbesartan)

U.S.	**E.U.**	**Japan**
Compound: expired Generics on the market	Compound: expired Generics on the market	Compound: March 2016 Regulatory exclusivity: April 2016

Multaq® (dronedarone hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: July 2016 with PTE Later filed patent: formulation (June 2018) Regulatory exclusivity: July 2014	Compound: expired Later filed patent: formulation June 2018 extended with SPC up to June 2023 in most of the countries Regulatory exclusivity: November 2019	Compound: expired

Stilnox® (zolpidem tartrate)

U.S.	**E.U.**	**Japan**
Compound patent: expired Generics on the market	Compound patent: expired Generics on the market	Compound patent: expired Regulatory exclusivity: expired Later filed patent: Ambien® CR formulation (December 2019); not commercialized

Depakine® (sodium valproate)

U.S.	**E.U.**	**Japan**
Compound: N/A[(1)]	Compound: N/A[(1)] Later filed patent: Depakine® Chronosphere formulation (October 2017)	Compound: N/A[(1)] Later filed patent: Depakine® Chronosphere formulation (October 2017)

(1)

No rights to compounds in the U.S., E.U. and Japan.

Allegra® (fexofenadine hydrochloride)

U.S.	**E.U.**	**Japan[(1)]**
Compound: expired Generics on the market Converted to Over-the-Counter	Compound: expired Generics on the market	Compound: expired Generics on the market Converted to over-the counter Later filed patents: coverage ranging through January 2016

(1)

See "Item 8 A. Consolidated Financial Statements and Other Financial Information Patents Allegra® Patent Litigation" of this annual report for further information.

Table of Contents

Actonel® (risedronate sodium)[(1)]

U.S.	**E.U.**	**Japan**
Compound: protection extended to June 2014 by Pediatric extension	Compound: expired	Compound: expired
Later filed patents: coverage ranging through June 2018	Later filed patents: coverage ranging through June 2018	

(1)

On October 30, 2009, Procter & Gamble Pharmaceuticals (P&G) sold its pharmaceutical business to Warner Chilcott (WCRX) which became the successor to P&G in rights and interests for the Actonel® alliance and now holds the NDA and the patents for this product in the United States. We commercialize Actonel® with WCRX. See "Item 5 Financial Presentation of Alliances".

Amaryl® (glimepiride)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: expired	Compound: expired

Insuman® (human insulin)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A

Fabrazyme® (agalsidase beta)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through September 2015		Later filed patents: expired
Biologics Regulatory Exclusivity: April 2015		Orphan regulatory exclusivity: expired

Cerezyme® (imiglucerase)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: N/A	Compound: N/A

Lumizyme® / Myozyme® (alglucosidase alpha)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through February 2023	Later filed patents: coverage ranging from March 2021 to May 2023	Later filed patents: July 2021
Orphan Drug Exclusivity: expired	Orphan Regulatory Exclusivity: March 2016	Orphan Regulatory Exclusivity: April 2017
Biologics Regulatory Exclusivity: April 2018	Biologics Regulatory Exclusivity: March 2016	

Renagel® (sevelamer hydrochloride)

U.S.	**E.U.**	**Japan**
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patent: coverage ranging through September 2014	Later filed patent: August 2014	Later filed patent: August 2014
	SPC coverage to January 2015 in certain EU countries	PTE protection to December 2016

Table of Contents

Renvela® (sevelamer carbonate)

U.S.	**E.U.**	**Japan**
Compound: N/A Later filed patent: coverage ranging through September 2014	Compound: N/A Later filed patent: August 2014 SPC coverage to January 2015 in certain EU countries SPC coverage to August 2019 in certain countries (Austria, Greece, Itay and Luxembourg)	Compound: N/A Later filed patent: August 2014

Synvisc® (hyaline G-F 20)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: N/A	Compound: expired

Synvisc-One® (hyaline G-F 20)

U.S.	**E.U.**	**Japan**
Compound: expired	Compound: N/A	Compound: expired

Lyxumia® (lixisenatide)

U.S.	**E.U.**	**Japan**
Compound: July 2020	Compound: July 2020 SPC coverage to July 2025 in most of Western Europe Regulatory Exclusivity: February 2023	Compound: July 2020 PTE pending for compound patent and two device patents Regulatory Exclusivity: June 2021

Zaltrap® (aflibercept)

U.S.	**E.U.**	**Japan**
Compound: May 2020 (July 2022 if PTE is granted) Biologics Regulatory Exclusivity: November 2023	Compound: May 2020 (May 2025 if SPC granted) Regulatory Exclusivity: November 2022	Compound: May 2020

Aubagio® (teriflunomide)

U.S.	**E.U.**	**Japan**
Compound: October 2014 (May 2019 if PTE is granted) Regulatory Exclusivity: September 2017	Compound: expired	Compound: expired

Aldurazyme® (laronidase)

U.S.	**E.U.**	**Japan**
Compound: November 2019 Later filed patents: June 2020 Regulatory Exclusivity: April 2015	Compound: November 2020 in some EU countries only	Compound:November 2020 Orphan Regulatory exclusivity: October 2016

Table of Contents

Mozobil® (plerixafor)

U.S.	**E.U.**	**Japan**
Compound: N/A Later filed patents: ranging through July 2023 Orphan Regulatory Exclusivity: December 2015	Compound: N/A Later filed patents: ranging through July 2022 Regulatory Exclusivity: July 2019	Compound: N/A Later filed patents: ranging through July 2022

Lemtrada (alemtuzumab)

U.S.	**E.U.**	**Japan**
Compound: December 2015 Regulatory Exclusivity: N/A Later filed patents: coverage ranging through September 2027 (pending)	Compound: expired Later filed patent: September 2027 (pending)	Compound: expired Later filed patent: September 2027

Patents held or licensed by the Group do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors launched generic versions of Eloxatin® in Europe, Allegra® in the United States (prior to the product being switched to over-the-counter status) and Plavix® in Europe.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which the Group determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See "Item 3. Key Information D. Risk Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

As disclosed in Item 8 of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

Challenges to Patented Products

In the United States, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See " Focus on Biologics" below. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name "abbreviated" new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years following the initial U.S. marketing authorization of the original product. See " Regulatory Exclusivity" above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar is referred to in our industry as a "30-month stay"), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

In the European Union, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe

Table of Contents

comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched and in some jurisdictions, even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8 of this annual report.

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See " Focus on Biologics" and " Regulation" below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against another competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See "Item 3. Key Information D. Risk Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected".

Trademarks

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. Trademarks are particularly important to the commercial success of our CHC, generics and retail animal health business.

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on their countries of commercialization: i.e., on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

The process and degree of trademark protection vary country by country, as each country applies its own trademark laws and regulations. In most countries, trademark rights may only be obtained through formal trademark application and registration. In some countries, trademark protection can be based primarily on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, except in some countries where maintenance of the trademarks is subject to their effective use.

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 certificate. 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.

Our trademarks are monitored and defended based on this policy and in order to prevent counterfeit, infringement and/or unfair competition.

B.8. Production and Raw Materials

For many years, we have chosen to keep the manufacture of our products in-house in order to have better control of quality and distribution. Our production process consists of three principal stages: the manufacture of active pharmaceutical ingredients, the transformation of these ingredients into products, and packaging.

Our general policy is to produce our main active ingredients and principal products at our own plants in order to minimize our dependence on external manufacturers and to maintain strict and precise control over the product throughout the production cycle. In some cases, however, we rely on third parties for the manufacture and supply of certain active ingredients and medical devices. We have outsourced some of our production, under supply contracts associated with plant divestitures or to establish a local presence to capitalize on growth in emerging markets. In particular, we outsource part of the production of the active ingredients used in Stilnox® and Xatral®, and certain pharmaceutical product formulations. Our main pharmaceutical subcontractors are Famar, MSD, Unither, Valeant and Alza. These subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See "Item 3. Key Information D. Risk Factors Risks Relating to Our Business".

Table of Contents

We also obtain active ingredients from third parties under partnership agreements. This applies to the monoclonal antibodies developed with Regeneron.

Our pharmaceutical production sites are divided into three categories:

- Global sites, which serve all markets. Situated principally in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectables, and a number of our principal products in solid form;

- Regional sites, which serve markets at continental level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets;

- Local sites, which serve their domestic market only.

Sanofi Pasteur produces vaccines at sites located in North America, France, Mexico, China, Thailand, Argentina and India. The pharmaceutical sites at Le Trait (France) and Anagni (Italy) also contribute to Sanofi Pasteur's industrial operations by making available their aseptic filling and freeze-drying facilities. In 2013, the new influenza vaccine production plant at Shenzhen was approved by the Chinese authorities (CFDA).

In 2011, we diversified our industrial operations into rare diseases (with the acquisition of Genzyme) and via the integration of Merial, Sanofi's dedicated animal health division.

Merial markets pharmaceutical products (Frontline®, Heartgard®, Zactran®, Previcox®) and a broad range of vaccines for different animal species (dogs, cats, horses, ruminants, pigs and fowl). A number of pharmaceutical products are subcontracted (Heartgard®, Eprinex®) but almost all veterinary vaccines are manufactured at its own plants. Merial's dedicated animal health industrial operations cover all activities, from the purchase of raw materials through to the delivery of the finished product, meeting customer needs through a reliable and flexible offering that meets quality expectations. There are 18 production sites spread across nine countries.

All of our pharmaceutical and vaccine facilities are GMP compliant, in line with international guidelines. Our principal sites are approved by the FDA.

This applies to our pharmaceutical facilities in France (Ambarès, Tours, Le Trait, Maisons-Alfort, Compiègne and Lyon); in the United Kingdom (Haverhill, Holmes Chapel, and Fawdon, the latter due to close in 2015); in Ireland (Waterford); in Germany (Frankfurt); in Hungary (Veresegyhaz); in Italy (Anagni); and in the United States (Saint Louis and Chattanooga). Our Vaccines sites with FDA approval are Marcy l'Étoile and Le Trait (Fluzone® ID USA) in France; Swiftwater, Canton and Rockville in the United States; and Toronto in Canada.

The Genzyme facilities in the United States (Allston, Framingham, Ridgefield, Cambridge, Northpointe-Lynnwood, Woburn and Northborough) and in Europe (Geel, Belgium) are all FDA approved.

Our Animal Health facilities in Athens, Worthington, Gainesville, Berlin and Raleigh in the United States are managed by the U.S. Department of Agriculture (USDA), while the sites at Paulinia (Brazil) and Toulouse (France) have FDA approval for some of their operations.

Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products. This is the case with Lovenox®, for example.

On May 24, 2010, Genzyme entered into a consent decree with the FDA relating to the facility at Allston in the United States, following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies. A consent decree is a court order entered by agreement between a company and the government (in this case the FDA) that requires the company to take certain actions as set out in the decree. Under the terms of Genzyme's consent decree, Genzyme is permitted to continue manufacturing at the site during the remediation process, subject to compliance with the terms of the consent decree.

The consent decree requires Genzyme to implement a plan to bring the Allston facility operations into compliance with applicable laws and regulations. The plan must address any deficiencies reported to Genzyme or identified as part of an inspection completed by a third-party expert in February 2011. Genzyme has itself retained an expert to monitor and oversee the implementation of the remediation workplan. This workplan

was submitted to the FDA in April 2011 and accepted by the FDA in January 2012, and is expected to be completed in 2016. It includes a timetable of specified milestones. If the milestones are not met in accordance with the timetable, the FDA can require

Table of Contents

us to pay $15,000 per day, per affected drug, until these compliance milestones are met. Upon satisfying all compliance requirements in accordance with the terms of the consent decree, Genzyme will be required to retain an auditor to monitor and oversee ongoing compliance at the Allston facility for an additional five years. To date, all requirements of the consent decree, including all requirements of the workplan, have been met by Genzyme.

In March 2012, modifications to the workplan were submitted to the FDA to take account of planned changes in manufacturing operations for Fabrazyme® and Cerezyme® at the Allston facility. These modifications were accepted by the FDA. In addition, the U.S. facility at Framingham was approved by the FDA and the EMA in January 2012 for the production of Fabrazyme® (agalsidase beta). Production of the Fabrazyme® active substance at the Allston factory ended in 2012.

In July 2012, Sanofi Pasteur received a warning letter from the FDA following routine inspections conducted at its facilities in Toronto (Canada) and Marcy l'Étoile (France). Sanofi Pasteur is working actively with the FDA to implement a series of immediate and ongoing measures to address the issues raised in the warning letter and to further strengthen its production tools and quality systems.

In June and September 2013, follow-up inspections took place at the Marcy l'Etoile and Toronto facilities respectively. Though significant progress in quality systems was reported by the U.S. authorities at the time of the inspections, Sanofi Pasteur decided to strengthen and accelerate its improvement plan in the third quarter of 2013.

More details about our manufacturing sites are found below at section "D. Property, Plant and Equipment".

B.9. Insurance and Risk Coverage

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our captive insurance company, Carraig Insurance Ltd (Carraig).

These four key programs cover Property & Business Interruption, General & Product Liability, Stock and Transit, and Directors & Officers Liability.

Our captive insurance company, Carraig, participates in our coverage for various lines of insurance mainly including Property & Business Interruption, Stock and Transit, and General & Product Liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly-owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover. It sets premiums for Group entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all Group entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between Group entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects goods of all kinds owned by the Group that are in transit nationally or internationally, whatever the means of transport, and all our inventories wherever they are located. Sharing risk between Group entities means that we can set deductibles at appropriate levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General & Product Liability program has been renewed for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at

Table of Contents

Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at the country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by the Group including our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third-party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions, including generics coverage in the U.S. Coverage is adjusted every year in order to take into account the relative weight of new product liability risks, such as those relating to rare diseases with very low exposure or to healthcare products which do not require marketing approval.

Our cover for risks that are not specific to the pharmaceutical industry (general liability) is designed to address the potential impacts of our operations.

For all lines of business of Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient data history from the company or from the market for claims made and settled, management with assistance from independent actuaries prepares an actuarial estimate of the company's exposure to unreported claims for the risks covered. The actuaries perform an actuarial valuation of the company's IBNR (incurred but not reported) and ALAE (allocated loss adjustment expense) liabilities at year end. Two ultimate loss projections (based upon reported losses and paid losses respectively) are computed each year using the Bornhuetter-Ferguson method; these projections form the basis for the provisions set.

The Directors & Officers Liability program protects the legal entities under our control, and their directors and officers. Our captive insurance company is not involved in this program.

The Group also operates other insurance programs, but these are of much lesser importance than those described above.

All the insurance programs are backed by best-in-class insurers and reinsurers and are designed in such a way that we can integrate most newly-acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, not only do we reduce costs, but we also provide world-class coverage for the entire Group.

B.10. Health, Safety and Environment (HSE)

The manufacturing and research operations of Sanofi are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year and totaled approximately €86 million in 2013.

The applicable environmental laws and regulations may require Sanofi to eradicate or reduce the effects of chemical substance usage and release at its various sites. The sites in question may belong to the Group, be currently operational, or they may have been owned or operational in the past. 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 under certain circumstances caused the presence of the contaminants, or at the time site operations occurred, the discharge of those substances was authorized.

Table of Contents

Moreover, as is the case for a number of companies involved in the pharmaceutical, chemical and agrochemical industries, soil and groundwater contamination has occurred at some Group sites in the past, and may still occur or be discovered at others. In the Group's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic,, Brazil, Italy and the United Kingdom. As part of a program of environmental audits conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Group sites. In cooperation with national and local authorities, the Group regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planed in Rochester, Cincinnati, Mount-Pleasant, East Palo Alto, and Portland in the United States; Frankfurt in Germany; Beaucaire, Valernes, Limay, Rousset, Romainville, Neuville, Vitry, Tours and Toulouse in France; Dagenham in the United Kingdom; Brindisi and Garessio in Italy; Ujpest in Hungary; Prague in the Czech Republic; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi. Sanofi may also have potential liability for investigation and cleanup at several other sites.

Provisions have been established for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. For example, the Group is currently participating in an assessment process for natural resource damage liability (NRD) and in the allocation process for future remediation costs that are related to the past operations of a former Rhone-Poulenc site in Portland Harbor, Oregon. The Group retains the ultimate liability for these costs under contractual environmental guarantees granted at the time of Bayer's acquisition of the CropScience business. Rehabilitation studies and an NRD assessment are underway in a similar project in Portland, Oregon. Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report. In 2013, Sanofi spent € 52 million on rehabilitating sites previously contaminated by soil or groundwater pollution. During the year ended December 31, 2013, a comprehensive review was carried out relating to the legacy of environmental pollution. In light of data collected during this review, the Group adjusted the provisions to approximately €698 million as at December 31, 2013;

Due to changes in environmental regulations governing site remediation, the Group's provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques considered, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations of Aventis arising from its past involvement in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See "Item 3.D. Risk Factors Environmental Risks of Our Industrial Activities".

To our knowledge, the Group has not been subject in 2013 to liabilities for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained. Regular HSE audits (43 in 2013) are carried out by the Group in order to assess compliance with our standards (which implies compliance with regulations) and to initiate corrective measures. Additionally, 81 specialized audits covering contractors (72) or biosafety (9) and 164 loss prevention technical visits were carried out by our teams in 2013.

Sanofi has implemented a worldwide master policy on health, safety and the environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, 78 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, industrial hygiene, health in the workplace and protection of the environment.

Health

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. The Group's COVALIS committee classifies all chemical and pharmaceutical products handled within the Group and establishes workplace exposure limits for each of them. The Group's TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout the Group. See "Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations".

Table of Contents

Appropriate industrial hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate initial and routine medical program, focused on the potential occupational health risks linked to their duties.

In addition, a committee has been set up to prepare and support the implementation of the new European Union REACH regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. To fully comply with the new European regulation on the labeling of chemicals (Classification Labeling Packaging), the Group has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

Safety

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso II (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state-of-the-art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes: process or installation changes, as well as changes in production scale and transfers between industrial or research units.

Our laboratories that specialize in process safety testing, which are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure that our risk assessments are relevant.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

Environment

The main objectives of our environmental policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our activities. In order to optimize and improve our environmental performance, we have a strategy of continuous improvement practiced at all our sites through the annual implementation of HSE progress plans. In addition, 54 sites are currently ISO 14001 certified and 15 buildings are LEED certified either in U.S. and Europe. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2013, eight of our European sites were included in the scope of the European CO_2 Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. In 2013, we reduced carbon dioxide emissions caused by our sales representation car fleet by 10% versus 2012 due to the policy of using energy efficient cars as well as a reduction in

Table of Contents

the number of cars. Measured against the benchmark year for our new targets (2010), direct and indirect emissions from our production and research facilities (excluding vehicle fleets) have fallen by 11.0% overall. We are targeting a 20% reduction in CO_2 emissions in 2020 vs. 2010 on a constant structure basis.

An internal committee of experts called ECOVAL assesses the environmental impact of the pharmaceutical agents found in products marketed by Sanofi. It has developed an environmental risk assessment methodology and runs programs to collect the necessary data for such assessments. Additional ecotoxicity assessments are being performed on certain substances which predate current regulations, in order to obtain information that was not gathered when they were launched (as regulatory requirements were different at that time) and evaluate environmental risks resulting from their use by patients.

C. Organizational Structure

Significant subsidiaries

Sanofi is the holding company of a consolidated group of subsidiaries. The table below sets forth our significant subsidiaries and affiliates as of December 31, 2013. For a list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary or Affiliate	Date of Incorporation	Country of Incorporation	Principal Activity	Financial and Voting Interest
Aventis Inc.	07/01/1998	United States	Pharmaceuticals	100%
Aventis Pharma S.A.	09/24/1974	France	Pharmaceuticals	100%
Genzyme Corporation	11/21/1991	United States	Pharmaceuticals	100%
Hoechst GmbH	07/08/1974	Germany	Pharmaceuticals	100%
Merial Ltd	08/01/1997	United Kingdom	Animal Health	100%
Merial S.A.S.	02/25/1941	France	Animal Health	100%
Sanofi-Aventis Amérique du Nord S.A.S.	09/20/1985	France	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	06/30/1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Europe S.A.S.	07/15/1996	France	Pharmaceuticals	100%
Sanofi-Aventis U.S. LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi Pasteur	02/08/1989	France	Vaccines	100%
Sanofi Pasteur Inc.	01/18/1977	United States	Vaccines	100%
Sanofi Winthrop Industrie	12/11/1972	France	Pharmaceuticals	100%

Since 2009, we have transformed our Group through numerous acquisitions (see Item 4A "History and Development of the Company"), in particular those of Genzyme in April 2011 and Merial in September 2009. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements, included in this annual report at Item 18. The financial effects of the Merial acquisition are

presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2010, included in our annual report on Form 20-F for that year.

In certain countries, we carry on some of our business operations through joint ventures with local partners. We have also entered into worldwide marketing arrangements. Two of our major products (Plavix® and Aprovel®) are marketed through an alliance with BMS, Actonel® is marketed through an alliance with Warner Chilcott (acquired by Actavis), and Zaltrap® is marketed through an alliance with Regeneron. See "Item 5 Financial Presentation of Alliances".

Internal organization of activities

Sanofi and its subsidiaries form a group, organized around three activities: Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health.

Within the Group, responsibility for research and development (R&D) in their respective fields rests with Sanofi and Genzyme Corporation (Pharmaceuticals), Sanofi Pasteur and Sanofi Pasteur, Inc. (Vaccines), and Merial Ltd

Table of Contents

and Merial S.A.S. (Animal Health); these entities define strategic priorities and coordinate R&D efforts. To fulfill this role, these entities subcontract R&D work to subsidiaries that have the necessary resources. They also license patents, manufacturing know-how and trademarks to certain French and foreign subsidiaries. In these cases, the licensee subsidiaries manufacture and distribute the Group's products, either directly or via local distribution entities.

Our industrial property rights, patents and trademarks are mainly held by the following companies:

Pharmaceuticals: Sanofi, Aventis Pharma S.A. (France), Sanofi-Aventis Deutschland GmbH (Germany), Sanofi-Aventis U.S. LLC and Genzyme Corporation (United States);

Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (United States);

Animal Health: Merial Ltd (United Kingdom) and Merial S.A.S. (France).

For a description of our principal items of property, plant and equipment, see Item 4.D. "Property, Plant and Equipment". These assets are mainly held by Sanofi Pasteur, Genzyme Corporation, Sanofi Chimie, Sanofi-Aventis Deutschland GmbH, Sanofi Pasteur Inc. and Sanofi Winthrop Industrie.

D. Property, Plant and Equipment

D.1. Overview

Our headquarters are located in Paris, France. See " Office Space" below.

We operate our business through office premises and research, production and logistics facilities in approximately 100 countries around the world. Our office premises house of all our support functions, plus operational representatives from our subsidiaries and the Group.

A breakdown of these sites by use and by ownership status (owned versus leasehold) is provided below. Breakdowns are based on surface area. All surface area figures are unaudited.

Breakdown of sites by use*

Industrial	60%
Research	13%
Offices	12%
Logistics	10%
Other	5%

* *Our Vaccines and Animal Health activities occupy offices and research, production and warehouse facilities. These sites are allocated between the first four categories in the table above as appropriate.*

Breakdown of sites by ownership status

Leasehold	31%
Owned	69%

We own most of our research and development and production facilities, either freehold or under finance leases with a purchase option exercisable at expiration of the lease.

D.2. Description of our sites

Sanofi industrial sites

The profound transformation of Sanofi and the increased importance of our growth platforms are driving the continuing evolution of our Industrial Affairs department in support of our new business model. As a result, since June 2013 the Industrial Affairs department has been responsible for all production and quality operations within the Group. The department focuses on the needs of customers and the quality of service, the sharing of lean manufacturing practices, the development of a common culture committed to quality, and the sharing of expertise within technology platforms, particularly in biologics and injectables.

Table of Contents

We carry out our industrial production at 112 sites in 41 countries (including 37 sites in emerging markets):

- 82 sites for our Pharmaceuticals activity, including Genzyme;
- 12 sites for the industrial operations of Sanofi Pasteur in vaccines; and
- 18 sites for the Animal Health activities of Merial.

In 2013, we produced the following quantities:

- Pharmaceuticals: 3,153 million boxes produced and packaged (3,758 including outsourced production);
- Vaccines: 476 million containers prepared (including outsourced production); and
- Animal Health: 550 million doses of vaccines for all species other than avian, 90 billion doses of avian vaccines, and 68 million units of pharmaceutical products.

We believe that our production facilities are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. Nonetheless, we regularly inspect and evaluate these facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3 to our consolidated financial statements, included at Item 18 of this annual report and "B.8 Production and Raw Materials."

Industrial Sites: Pharmaceuticals

Production of chemical and pharmaceutical products is the responsibility of our Industrial Affairs department, which is also in charge of most of our logistics facilities (distribution and storage centers).

The sites where our major drugs, active ingredients, specialties and medical devices are manufactured are:

- France: Ambarès (Aprovel®, Depakine®, Multaq®), Aramon (irbesartan), Compiègne (Arava®, Orelox®, Magne B6®), Le Trait (Lovenox®), Lyon Gerland (Thymoglobulin®, Celsior®), Maisons-Alfort (Lovenox®), Neuville-sur-Saône (which discontinued its traditional chemicals activities at end 2013 with the transfer of dronedarone production to the Sisteron site), Quetigny (Stilnox®, Plavix®), Sisteron (clopidogrel bisulfate, dronedarone, zolpidem tartrate), Tours (Stilnox®, Aprovel®, Xatral®), Vitry-sur Seine (docetaxel/ aflibercept);
- Germany: Frankfurt (insulins, Ramipril, Lantus®, Tritace®, oncology, Taxotere®, Eloxatine®, medical devices, Apidra®);
- Ireland: Waterford (Myozyme®, Lumizyme®, Cholestagel®, Thymoglobulin®, Renagel®, Renvela®, and Cerezyme®);
- Italy: Scoppito (Tritace®, Amaryl®) and Anagni (Depakine®, Fasturtec®, Rifa antibiotic family);
- United Kingdom: Dagenham (Taxotere® and Eloxatine®, production of which was transferred to Frankfurt in Germany after closure of the site in June 2013), Fawdon (Plavix®, Aprovel®), Haverhill (sevelamer hydrochloride API (Renagel®), sevelamer carbonate API (Renvela®), Cerezyme®, Fabrazyme®, Thyrogen®, Myozyme®, etc), and Holmes Chapel (Nasacort®, Flutiform);

Hungary: Ujpest (irbesartan), Csanyikvölgy (Lovenox®);

Japan: Kawagoe (Plavix®);

United States: Kansas City (Allegra®, currently being transferred to Tours and Compiègne in France), and Chattanooga (Consumer Health Care products);

Brazil: Suzano (Amaryl® and Novalgine®) and Campinas (generics);

Mexico: Ocoyoacac (Flagyl®); and

Singapore: Jurong (enoxaparin).

Genzyme manages 11 production sites and works with more than 20 subcontractors to manufacture 22 commercial products over a broad range of technological platforms.

Genzyme's sites are as follows:

Belgium: Geel (A1 alpha glucosidase: Myozyme®/Lumizyme®);

Table of Contents

United States: Allston (Cerezyme®), Framingham (Fabrazyme®, Myozyme®, Thyrogen®, Seprafilm®, hyaluronic acid), Cambridge (Carticel®, Epicel®, MACI® (Matrix-induced Autologous Chondrocyte Implantation), Ridgefield (Synvisc®, Hectorol®, Mozobil®, Jonexa®, Prevelle®), Woburn (LeGoo®), and Lynnwood, Washington (Leukine®); and

Denmark: Copenhagen (MACI®).

Industrial Sites: Vaccines (Sanofi Pasteur)

The headquarters of our Vaccines division, Sanofi Pasteur, are located in Lyon, France. Sanofi Pasteur has production and/or R&D sites at Swiftwater, Cambridge, Rockville, Canton and Orlando (United States); Toronto, (Canada); Marcy l'Étoile, Neuville and Val de Reuil (France); Shenzhen (China); Pilar (Argentina); Chachoengsao (Thailand); Hyderabad (India); and Ocoyoacac (Mexico).

In May 2009, we began construction of a new vaccine manufacturing center at our Neuville-sur-Saône site in France. This €300 million investment over the 2009-2011 period, the largest ever made by Sanofi, is intended to gradually replace the chemicals activity on the site, which was discontinued at the end of 2013, by vaccine production from 2014 onwards.

Sanofi Pasteur owns its R&D and production sites, either freehold or under finance leases with a purchase option exercisable at expiration of the lease.

Industrial Sites: Animal Health (Merial)

Merial has 18 industrial sites in nine different countries, 15 R&D sites, and numerous administrative offices including its headquarters at Lyon, France.

Merial industrial sites are as follows:

Brazil: Paulinia (avermectin-based pharmaceutical products, and vaccines against foot-and-mouth disease and rabies), and a production unit approved by the FDA and EMA for NexGard ;

China: Nanchang (live avian vaccines) and Nanjing (inactivated avian vaccines);

France: Toulouse (Frontline® and clostridial vaccines), St-Priest LPA (vaccines), Lyon Gerland, Saint-Herblon (Coophavet), Lentilly (packaging);

Italy: Noventa (inactivated avian vaccines);

Netherlands: Lelystad (antigen against foot-and-mouth disease);

Uruguay: Montevideo (primarily anti-clostridium antigens);

United Kingdom: Pirbright (antigens and vaccines against foot-and-mouth disease);

United States: dedicated facilities for Merial's avian vaccines at Berlin (Maryland), Gainesville (Georgia) and Raleigh (North Carolina), dedicated facility for mammal viral and bacterial vaccines at Athens (Georgia), and dedicated facility for autogenous bovine and swine vaccines at Worthington (Minnesota); and

New Zealand: Ancare facility, Auckland (pharmaceutical products, mainly for the bovine market).

Research & Development sites

In Pharmaceuticals, research and development activities are conducted at 15 sites:

6 operational sites in France: Chilly/Longjumeau, Montpellier, Paris, Strasbourg, Toulouse and Vitry/Alfortville;

2 sites in the rest of Europe (Germany and the Netherlands), the larger of which is in Frankfurt (Germany);

5 sites in the United States, the largest being the Bridgewater, Cambridge and Framingham sites; and

2 sites in Asia (1 clinical research unit in Beijing, China and 1 unit in Japan).

Vaccines research and development sites are presented above.

In Animal Health, research and development activities are conducted at 15 sites.

Table of Contents

D.3. Acquisitions, Capital Expenditures and Divestitures

The carrying amount of our property, plant and equipment at December 31, 2013 was €10,182 million. During 2013, we invested €1,082 million (see Note D.3. to our consolidated financial statements, included at Item 18 of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal capital expenditures and divestitures in 2011, 2012 and 2013 are described in Notes D.1. ("Impact of changes in the scope of consolidation"), D.2. ("Merial"), D.3. ("Property, plant and equipment") and D.4. ("Goodwill and other intangible assets") to our consolidated financial statements, included at Item 18 of this annual report.

As of December 31, 2013, our firm commitments in respect of future capital expenditures amounted to €324 million. The principal sites involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Vertolaye (France), and in Hungary; and for the Vaccines segment, the facility at Swiftwater (United States).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average €1.3 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.

Our principal ongoing investments are described below. During 2013, our industrial network actively contributed to the development of our seven growth platforms: Emerging Markets, Diabetes Solutions, Consumer Health Care, Genzyme and Other Innovative Products (all of which are part of our Pharmaceuticals segment), Vaccines, and Animal Health.

Pharmaceuticals

In our **Diabetes Solutions** growth platform, the Frankfurt site the principal manufacturing center for Sanofi Diabetes products is being equipped with a new aseptic processing area that uses isolator technology to significantly improve the aseptic filling process and improve productivity. This investment will be operational in 2016. The Frankfurt site also celebrated the production of its billionth SoloSTAR® insulin pen on World Diabetes Day in November 2013. In February 2013, Sanofi announced it was investing €44 million in Genzyme's biotechnology campus in Waterford, Ireland. In particular, Sanofi will be investing in filling facilities for Lantus®. Subject to regulatory approval, Lantus® should go into commercial production in Waterford in 2017.

The Sanofi Diabetes industrial network is also expanding its footprint in emerging markets, both in Russia with the Orel site, which is now Sanofi's second largest insulin pen production site after Frankfurt, and in China (Beijing), where a new facility inaugurated in 2012 has begun assembly and packaging of **SoloSTAR®**, the pre-filled injection system for **Lantus®**. Finally in order to incorporate Shantha (India) into Sanofi's injectables platform, a certain number of technologies for manufacturing Insuman® insulin are currently being transferred from the Frankfurt site to the Indian site so that it can handle filling and packaging for the local market.

Our industrial pharmaceutical operations for the **Consumer Health Care** platform are based on a network of 10 production sites spread over four growth hubs: in Europe, with the Lisieux (France) factories producing Doliprane®, Origgio (Italy), Cologne (Germany) and Rzeszow (Poland); in Asia, where the new consumer products facility at Hangzhou in China (production capacity: 3 billion pills) has been operational since the beginning of 2013, as well as the Tangshan (China) and Virginia (Australia) sites; in South America, with the Suzano (Brazil) site; and in the United States, with the Chattem site, which in September 2013 launched the over-the-counter antacid Rolaids® product from its Chattanooga (Tennessee) production facility (which in 2012 led preparations for the U.S. launch of the pediatric oral suspension formulation of Allegra®). In 2013, the industrial development teams also continued making an active contribution to consumer health care product launches, expanding our presence in this highly competitive market.

In the **Other Innovative Products** platform, our industrial teams are pooling their expertise to develop ever more sophisticated processes. Three dedicated biotech hubs are being developed in Europe at Frankfurt (Germany); Vitry-sur-Seine (France), our biggest integrated cell culture facility, which in 2013 completed a production campaign of **aflibercept** (the active ingredient of **Zaltrap®**) as well as launching production of a new product; and Lyon Gerland (France), a new world center dedicated to production of **thymoglobulin®** for the prevention and treatment of transplant

rejection.

In March 2013, a bioproduction platform was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Genzyme, Merial and the Biotherapeutics businesses. This platform will enable Sanofi to build its

Table of Contents

presence in biotechnologies by taking advantage of transversal opportunities, in particular in the use of production capacity, development, technologies of the future in biotechnology, and skills management.

The development of our **Emerging Markets** platform is built on a network of over 30 regional and local industrial sites in 20 countries, supporting growth in these markets. In addition to our recent investments in China in Diabetes Solutions and CHC, a number of other projects are under way. In the Middle East, 2012 saw Sanofi lay the foundation stone for a facility in Saudi Arabia that will produce solid pharmaceutical formulations, which will be marketed from 2015. In Latin America, where we already have a large industrial footprint, the Brasilia plant has been operational since 2013, producing oral antibiotics and generic contraceptives, with potential capacity of 66 million units. In addition, after the acquisition of Genfar at end 2012, Sanofi is now the leading player in the Colombian pharmaceuticals market and in the generics market, with the Villa-Rica factory supporting the Sanofi production site at Cali.

In India since 2012, the Ankleshwar Pharma site in Gujarat State (India) has handled packaging and quality control through to release of the first commercial batches of **AllStar** , the first high-quality affordable insulin pen. The Goa site (India) invested to extend its solid formulation production capacity to around 2.5 billion pills a year. In Vietnam, Sanofi announced in March 2013 that it was investing $75 million in the construction of a new factory to produce specialty pharmaceuticals and CHC products from 2015.

In Algeria, where Sanofi has been operating for over 20 years, the foundation stone of the new Sidi Abdellah factory was laid in September 2013. This site, which will be the largest Sanofi industrial complex in the Africa/Middle East territory, will mainly produce dry and liquid formulations, and will also host a distribution center. It will have production and distribution capacity of 100 million units per annum, or around 80% of the volumes distributed by Sanofi in Algeria.

During 2013, our Pharmaceuticals segment continued to roll out the economic performance improvement plan launched in 2011. Based on its Sanofi Manufacturing System, the plan is intended to deliver performance standards commensurate with the diversity of our pharmaceuticals businesses and markets, and to meet the industrial challenges ahead to 2020. Our Industrial Affairs department is constantly adapting the network of industrial sites to market needs, as a result of which a number of sites are in the process of sale or closure, such as Kansas City in 2015 (United States), Dagenham in 2013 and Fawdon in 2015 (United Kingdom), Romainville in 2013, and the traditional chemicals business in Neuville-sur-Saône in 2013 (France).

The industrial network of the **Genzyme** growth platform is predominantly located in the United States where major investments are under way. The site at Allston (Massachusetts) has initiated a major investment program in connection with the implementation of its compliance remediation workplan, approved by the FDA in January 2012. In addition, the Framlington Biologics site, based at 74 New York Avenue, has started construction of a new factory to increase purification capacity for production of Fabrazyme® representing an investment of $83 million.

Vaccines (Sanofi Pasteur)

Sanofi Pasteur is undergoing a major investment phase, particularly the new dedicated dengue fever vaccine facility at Neuville (France), which produced its first batches in 2014. Two new dedicated influenza vaccine facilities are in the start-up phase: Shenzhen (China), approved by the Chinese authorities (CFDA) at end 2013, and Ocoyoacac (Mexico). Ocoyoacac was approved by the Mexican authorities at the start of 2012, had a successful first influenza vaccination season in Mexico in 2013, and is currently doubling its capacity for 2014. In response to observations made by the FDA during routine inspections conducted in 2012 in Toronto (Canada) and Marcy l'Etoile (France), Sanofi Pasteur initiated and stepped up a compliance program to address the quality issues identified.

Animal Health (Merial)

Merial is adapting its industrial capacity to keep pace with the growing animal health market. In 2012, Merial acquired Newport Laboratories, which has an autogenous vaccine production facility at Worthington, Minnesota (United States). In order to support the future growth of avian and other vaccines in the Chinese market, Merial has invested $70 million in a new site in the Nanchang high-tech development zone, which was inaugurated in October 2013. In Brazil at the Paulinia site, Merial is adapting its industrial facilities for the production of the new product **NexGard** (to be governed by European Union Good Manufacturing Practices and approved by the FDA).

Table of Contents

Innovation and culture of industrial excellence

In 2013 Sanofi highlighted industrial innovation by organizing its fifth annual round of innovation trophies, centered on patient needs, industrial performance and citizen entrepreneurship.

In addition, the investment in an innovative biosynthesis process at the Saint-Aubin-Lès-Elbeuf and Vertolaye sites in France is entering the final phase before start-up and production, with the certification/approval of the numerous items of fermentation and extraction plant which will improve Sanofi's international competitiveness in the production of corticosteroids.

The Chemistry and Biotechnology teams were awarded the 2013 industry prize by the Chemistry Society of France for developing an innovative industrial process for manufacturing artemisinin, used as the basis for anti-malarial drugs. Finally, the development teams won the Good Design Award, one of the most important industrial design prizes, giving worldwide recognition for Lyxumia® and its AllStar and JuniorSTAR® insulin pens.

The ambition of our Industrial Affairs department is to continue to raise quality standards in the Group's production activities, and to remain a world leader and a benchmark in the global pharmaceutical industry. To achieve this goal, all our activities share a common culture of industrial excellence, enshrined in the Sanofi Manufacturing System. This sets out a series of priorities (such as customer service, constant improvement, site network optimization and transverse optimization) that constitute our industrial vision and will be crucial to our mutual success.

D.4. Office Space

As part of the rationalization of our office sites in the Paris region of France, we have been carrying out a review of our office space master plan for the Greater Paris area since 2009.

This review will result in all our Group support functions and operating divisions being housed on a smaller number of sites (five in 2012 on completion of phase 1, and three by 2015). All of these sites will meet environmental certification standards, and offer cost-effective space solutions.

In this context, the new "Campus Sanofi Val de Bièvre" (CSVB) is currently under construction on the old site (Gentilly Val De Bièvre). The foundation stone was laid at end 2012, with completion expected in early 2015.

Group support functions and operational divisions were brought together under one roof at the new world headquarters in the business district of Paris (54 rue La Boétie, 8th arrondissement) in February 2012. The headquarters, in which new work spaces have been developed, marks the Group's transformation symbolically.

A new Master Plan, initiated at end 2011, which defines the Group's medium-term office space requirements in the Lyon agglomeration, is in the implementation phase. A first off-plan lease was signed in early 2013 covering some of the "Pooled Services" functions, due to be delivered in March 2015 by its owner, Plastic Omnium. A second lease will be signed in early October 2014 for 2016, covering the corporate functions of Merial and Sanofi Pasteur via the sale of an existing freehold site and the off-plan reconstruction of the Group's first energy-positive building in France. The Master Plan aims to align the new sites on the Paris Master Plan, involving buildings with environmental certification, accompanied by a reduction in overall occupancy costs and work space in line with the new Corporate Charter.

An office space integration project covering the real estate portfolio of Genzyme and Merial, begun in 2011, is operative in 50 countries covering 540,000m^2. At end 2013, 44 sites had been integrated.

Other Master Plans were initiated at end 2012 to define office space real estate strategy, the first in the Cambridge (Massachussetts, USA) agglomeration, the second in Frankfurt (Germany). Operational implementation had not begun at end 2013. Integration of Genzyme's activities in the United States will enable office space use to be redefiined in that city.

Item 4A. Unresolved Staff Comments

N/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 at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2013.

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 "Cautionary Statement Regarding Forward-Looking Statements" at the beginning of this document.

Unless otherwise stated, all change figures in this item are given on a reported basis.

2013 Overview

During 2013, we continued to follow the strategic direction that we established in 2008, and to pursue our four key objectives: continuing to build a global healthcare leader with synergistic platforms, bringing innovative products to market, exploring value-enhancing external growth opportunities, and adapting our structures to meet the opportunities and challenges of the future.

Our full-year results for 2013 were, until August, negatively impacted by the residual effects of the loss of exclusivity in the United States of a number of our historical flagship products in the previous year: Avapro® in March 2012, Plavix® in May 2012, and Eloxatin® in August 2012. Despite temporary difficulties for our Generics business in Brazil, a slowdown in the Chinese pharmaceutical market, temporary supply limitations for our Pentacel® and Adacel® vaccines in the United States and strong competition for our Frontline® product in Animal Health, our net sales growth has nevertheless moved back into positive territory since September 2013, which marked the end of the patent cliff related to some of our major products. In a tough economic climate and against a backdrop of pressure by governments to cut healthcare costs, we have been able to limit the drop in our net sales and profitability thanks to the performance of our growth platforms and rigorous cost control.

Our net sales for the year were €32,951 million, 5.7% lower than in 2012 (0.5% at constant exchange rates, see definition at " Presentation of Net Sales" below), reflecting the €1.3 billion of net sales lost through competition from generics (see " Impacts from generic competition" below) but also good performances from our Diabetes Solutions, Genzyme and Emerging Markets growth platforms. The year also saw a number of new product launches stemming from our research efforts including Zaltrap® (metastatic colorectal cancer), Lyxumia® (type 2 diabetes), and Aubagio® and Lemtrada (multiple sclerosis) in Europe, and Kynamro (homozygous familial hypercholesterolemia) in the United States.

Our other revenues fell by €655 million (64.9%) year-on-year, mainly as a result of the loss of license revenues under the worldwide alliance with Bristol-Myers Squibb (BMS) on Plavix® and Aprovel®. The restructuring of the alliance between Sanofi and BMS, announced in October 2012 following the loss of exclusivity for Plavix® and Avapro®/Avalide® in many major markets, took effect on January 1, 2013. Under the new agreement, BMS returned to us our rights to Plavix® and Avapro®/ Avalide® worldwide, with the exception of the United States and Puerto Rico for Plavix®, thereby giving us exclusive control over these products and their commercialization.

The ongoing realignment of our resources, combined with favorable exchange rate effects, helped reduce further our research and development expenses by 2.8% and our selling and general expenses by 3.7%. Our business net income was €6,687 million, down 17.5% from 2012, while our business earnings per share were €5.05, down 17.8% from 2012. This year-on-year fall includes the effect of exchange rates, which was negative overall. Business net income and business earnings per share are non-GAAP financial measures which our management uses to monitor our operational performance, and which are defined under " Business Net Income" below.

Net income attributable to equity holders of Sanofi amounted to €3,717 million, down 24.0% from 2012. Basic earnings per share were €2.81, down 24.3% from 2012; diluted earnings per share for 2013 were €2.78 (24.5% lower).

During 2013, we continued our policy of targeted acquisitions and of alliances in research and development. In Consumer Health Care, we acquired the worldwide rights to the Rolaids® brand via our Chattem subsidiary in January 2013. In Generics, we completed the acquisition of Colombian pharmaceutical company Genfar S.A., a

Table of Contents

significant player in its home country and throughout Latin America generally, in March 2013. In Animal Health, Merial acquired the animal health division of Dosch Pharmaceuticals Pvt Ltd in India in June 2013. We also entered into various alliances and licensing deals to extend or strengthen our existing research fields.

As of December 31, 2013, we had reduced our debt, net of cash and cash equivalents to €6.0 billion (compared with €7.7 billion as of December 31, 2012). A dividend of €2.80 per share in respect of the 2013 financial year, representing a payout equivalent to 55% of our business net income, will be submitted for approval by the shareholders at the Annual General Meeting of May 5, 2014.

Our operations generate significant cash flow. We recorded €6,954 million of net cash provided by operating activities in 2013 compared to €8,171 million in 2012. During 2013, we paid out €3.6 billion in dividends. With respect to our financial position, we ended 2013 with our debt, net of cash and cash equivalents (see definition at " Liquidity and Capital Resources" below) at €6,043 million (2012: €7,719 million). Debt, net of cash and cash equivalents, is a financial indicator that is used by management to measure our overall net indebtedness and to manage our equity capital. In order to assess our financing risk, we also use a "gearing ratio", a non-GAAP financial measure that we define as the ratio of debt, net of cash and cash equivalents, to total equity. Our gearing ratio was 10.6% at the end of 2013 compared to 13.4% at the end of 2012. See " Liquidity and Capital Resources" below.

Impacts from generic competition

Some of our flagship products continued to experience sales erosion in 2013 due to generic competition. While we do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition, we are able to estimate the impact of generic competition for each product.

A comparison of our consolidated net sales for the years ended December 31, 2013 and 2012 (see " Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012") shows that in 2013, generic competition led to a loss of €1.3 billion of net sales on a reported basis (or €1.3 billion at constant exchange rates). The table below sets forth the impact by product.

(€ million) **Product**	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change on a reported basis (%)**
Plavix® Western Europe	257	307	(50)	-16.3%
Aprovel® Western Europe	338	557	(219)	-39.3%
Taxotere® Western Europe	22	53	(31)	-58.5%
Eloxatin® U.S.	19	718	(699)	-97.4%
Lovenox® U.S.	187	319	(132)	-41.4%
Plavix® U.S.[(1)]	5	76	(71)	-93.4%
Aprovel® U.S.[(1)]	17	45	(28)	-62.2%
Taxotere® U.S.	42	53	(11)	-20.8%
Ambien® U.S.	88	85	+3	+3.5%
Xatral® U.S.	3	20	(17)	-85.0%
Nasacort® U.S.	7	21	(14)	-66.7%

Xyzal® U.S.	6	6		
Allegra® U.S.	(3)	(1)	(2)	
Total	**988**	**2,259**	**(1,271)**	**-56.3%**

(1)

Sales of active ingredient to the BMS majority-owned entity in the United States.

We expect the erosion caused by generic competition to continue in 2014, with a negative impact on net income. Products susceptible to the effects of such competition in 2014 include:

those for which new generic competition can reasonably be expected in 2014 based on expiration dates, patents or other regulatory or commercial exclusivity: Renagel®/Renvela® in the United States and Europe;

Table of Contents

those which already faced generic competition as of January 1, 2013, but whose sales can reasonably be expected to be subject to further sales erosion in 2014: Plavix® and Aprovel® in Europe; Lovenox®, Ambien® and Taxotere® in the United States; and Allegra®, Amaryl®, Myslee® and Taxotere® in Japan.

In 2013, the aggregate consolidated net sales of these products in countries where generic competition currently exists or is expected in 2014 were €2,260 million (€848 million in the United States, €728 million in Europe and €684 million in Japan). This 2013 figure includes Renagel®/Renvela® sales of €531 million in the U.S. and €133 million in Western Europe. The negative impact on our 2014 net sales is liable to represent a substantial portion of this amount, but the actual impact will depend on a number of factors such as the actual launch dates of generic products in 2014, the prices at which they are sold, and potential litigation outcomes.

Purchase Accounting Effects

Our results of operations and financial condition for the years ended December 31, 2013, December 31, 2012 and December 31, 2011 have been significantly affected by our August 2004 acquisition of Aventis and certain subsequent transactions, mainly our acquisition of Genzyme on April 4, 2011. See " Critical accounting and reporting policies Business combinations" below for an explanation of the impact of business combinations on our results of operations.

The Aventis business combination has given rise to significant amortization expenses (€1,199 million in 2013, €1,489 million in 2012, and €1,788 million in 2011). The Genzyme business combination has given rise to significant amortization of intangible assets (€930 million in 2013, €976 million in 2012 and €705 million in 2011) and impairment of intangible assets (€665 million in 2013, €25 million in 2012 and €119 million in 2011).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as "business net income". For a further discussion and definition of "business net income", and business net income for the years ended December 31, 2013, 2012 and 2011, see " Business Net Income" below.

Sources of Revenues and Expenses

Revenue. Revenue arising from the sale of goods is presented in the income statement under "Net sales". Net sales comprise revenue from sales of pharmaceutical products, human vaccines, animal health products and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates described above are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.14. to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products, vaccines and animal health products directly, through alliances, and through licensees throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. 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. For more information about our alliances, see " Financial Presentation of Alliances" below. When we sell products through licensees, we receive royalty income that we record in "Other revenues". See Note C. to the consolidated financial statements included at Item 18 of this annual report.

Cost of Sales. Our cost of sales consists primarily of the cost of purchasing raw materials and active ingredients, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we manufacture, sell and 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 sales, and when we receive royalties, we record them in "Other revenues" as discussed above.

Operating Income. Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our business segments, we also measure our results of operations through an indicator referred to as "Business Operating Income," which we describe below under " Segment Information Business Operating Income of Segments."

Table of Contents

Segment Information

Operating Segments

In accordance with IFRS 8 "Operating Segments," we have defined our segments as "Pharmaceuticals", "Human Vaccines" (Vaccines) and "Animal Health". Our other identified segments are categorized as "Other".

The Pharmaceuticals segment covers research, development, production and marketing of medicines, including activities acquired with Genzyme. Sanofi's pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health products. This segment also includes all associates and joint ventures whose activities are related to pharmaceuticals, in particular the entities majority owned by BMS. See " Financial Presentation of Alliances" below.

The Vaccines segment is wholly dedicated to vaccines, including research, development, production and marketing. This segment includes our Sanofi Pasteur MSD joint venture with Merck & Co., Inc. in Europe.

The Animal Health segment comprises the research, development, production and marketing activities of Merial, which offers a complete range of medicines and vaccines for a wide variety of animal species.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8 "Operating Segments"; it also includes the effects of retained commitments in respect of divested businesses. In particular, this segment included our interest in the Yves Rocher group (see note D.6. to our consolidated financial statements included at Item 18 of this annual report).

Inter-segment transactions are not material.

Business Operating Income of Segments

We report segment results on the basis of "Business Operating Income". This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources.

"Business Operating Income" is derived from "Operating income", adjusted as follows:

- the amounts reported in the line items "Fair value remeasurement of contingent consideration liabilities", "Restructuring costs" and "Other gains and losses, and litigation" are eliminated;
- amortization and impairment losses charged against intangible assets (other than software) are eliminated;
- the share of profits/losses of associates and joint ventures is added;
- the share attributable to non-controlling interests is deducted;
- other acquisition-related effects (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated; and
- restructuring costs relating to associates and joint ventures are eliminated.

Table of Contents

The following table presents our Business Operating Income for the year ended December 31, 2013.

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**27,250**	**3,716**	**1,985**		**32,951**
Other revenues	295	30	30		355
Cost of sales	(8,517)	(1,776)	(689)		(10,982)
Research and development expenses	(4,087)	(518)	(165)		(4,770)
Selling and general expenses	(7,361)	(588)	(653)		(8,602)
Other operating income and expenses	421	3	(1)	26	449
Share of profit/(loss) of associates and joint ventures	48	41	(4)		85
Net income attributable to non-controlling interests	(162)	1	(1)		(162)
Business operating income	**7,887**	**909**	**502**	**26**	**9,324**

The following table presents our Business Operating Income for the year ended December 31, 2012[(1)].

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**28,871**	**3,897**	**2,179**		**34,947**
Other revenues	933	44	33		1,010
Cost of sales	(8,745)	(1,629)	(701)		(11,075)
Research and development expenses	(4,203)	(538)	(164)		(4,905)
Selling and general expenses	(7,650)	(609)	(669)	(1)	(8,929)
Other operating income and expenses	134	(7)	3	18	148
Share of profit/(loss) of associates and joint ventures	432	(1)	(7)		424
Net income attributable to non-controlling interests	(171)		(1)		(172)
Business operating income	**9,601**	**1,157**	**673**	**17**	**11,448**

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

The following table presents our Business Operating Income for the year ended December 31, 2011[(1)].

(€ million)	**Pharmaceuticals**	**Vaccines**	**Animal Health**	**Other**	**Total**
Net sales	**27,890**	**3,469**	**2,030**		**33,389**
Other revenues	1,622	25	22		1,669
Cost of sales	(8,340)	(1,400)	(649)		(10,389)
Research and development expenses	(4,082)	(562)	(144)		(4,788)
Selling and general expenses	(7,351)	(541)	(615)	(1)	(8,508)
Other operating income and expenses	29		(7)	24	46
Share of profit/(loss) of associates and joint ventures	1,088	1		13	1,102
Net income attributable to non-controlling interests	(246)		(1)		(247)
Business operating income	**10,610**	**992**	**636**	**36**	**12,274**

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Table of Contents

The following table (in accordance with paragraph 28 of IFRS 8) reconciles our Business Operating Income to our Income before tax and associates and joint ventures for the years ended December 31, 2013, 2012 and 2011:

(€ million)	**2013**	**2012(1)**	**2011(1)**
Business Operating Income	**9,324**	**11,448**	**12,274**
Share of profit/(loss) of associates and joint ventures[(2)]	(85)	(424)	(1,102)
Net income attributable to non-controlling interests[(3)]	162	172	247
Amortization of intangible assets	(2,914)	(3,291)	(3,314)
Impairment of intangible assets	(1,387)	(117)	(142)
Fair value remeasurement of contingent consideration liabilities	314	(192)	15
Expenses arising from the impact of acquisitions on inventories[(4)]	(8)	(23)	(476)
Restructuring costs	(300)	(1,141)	(1,314)
Other gains and losses and litigation[(5)]			(327)
Operating Income	**5,106**	**6,432**	**5,861**
Financial expense	(612)	(751)	(744)
Financial income	109	93	140
Income before tax and associates and joint ventures	**4,603**	**5,774**	**5,257**

(1) *Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).*

(2) *Excluding restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures.*

(3) *Excluding the portion attributable to non-controlling interests of the adjustments shown in the table above.*

(4) *This line comprises the workdown of inventories remeasured at fair value at the acquisition date.*

(5) *See Note D.28. to our consolidated financial statements included at Item 18 of this annual report.*

Business Net Income

In addition to net income, we use a non-GAAP financial measure that we refer to as "business net income" to evaluate our Group's performance. Business net income, which is defined below, represents the aggregate business operating income of all of our operating segments, less net financial expenses and the relevant income tax effects. We believe that this non-GAAP financial measure allows investors to understand the performance of our Group because it segregates the results of operations of our current business activities, as opposed to reflecting the impact of past transactions such as acquisitions.

Our management uses business net income to manage and to evaluate our performance, and we believe it is appropriate to disclose this non-GAAP financial measure, as a supplement to our IFRS reporting, in order to assist investors in analyzing the factors and trends affecting our business performance. Our management also intends to use business net income as the basis for proposing the dividend policy for the Group. Accordingly, management believes that an investor's understanding of trends in our dividend policy is enhanced by disclosing business net income.

We have also decided to report "business earnings per share". Business earnings per share is a specific non-GAAP financial measure, which we define as business net income divided by the weighted average number of shares outstanding. Our management intends to give earnings guidance based on business earnings per share. We also present business earnings per share on a diluted basis.

Business net income is defined as "Net income attributable to equity holders of Sanofi", determined under IFRS, excluding (i) amortization of intangible assets; (ii) impairment of intangible assets; (iii) fair value remeasurement of contingent consideration liabilities; (iv) other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures); (v) restructuring costs (including restructuring costs relating to associates and joint ventures); (vi) other gains and losses, and litigation; (vii) the tax effect related to the items listed in (i) through (vi); as well as (viii) the effects of major tax disputes, the tax on dividends distributed to Sanofi shareholders starting in 2013, and as an exception for 2011, the retroactive effect (2006-2010) on the tax liability resulting from the agreement signed on December 22, 2011 by France and the United States on transfer prices (APA-Advance Pricing Agreement), for which the amount is deemed to be significant; and (ix) the share of non-controlling interests in items (i) through (viii). Items (i), (ii), (iii), (v) and (vi) correspond to those reported in the income statement line items

Table of Contents

"Amortization of intangible assets", "Impairment of intangible assets", "Fair value remeasurement of contingent consideration liabilities", "Restructuring costs" and "Other gains and losses, and litigation", as defined in Notes B.19. and B.20. to our consolidated financial statements.

The following table reconciles our business net income to our Net income attributable to equity holders of Sanofi for the years ended December 31, 2013, 2012 and 2011:

(€ million)		**2013**	**2012(1)**	**2011(1)**
Business net income		**6,687**	**8,101**	**8,748**
(i)	Amortization of intangible assets	(2,914)	(3,291)	(3,314)
(ii)	Impairment of intangible assets	(1,387)	(117)	(142)
(iii)	Fair value remeasurement of contingent consideration liabilities	314	(192)	15
(iv)	Expenses arising from the impact of acquisitions on inventories[2]	(8)	(23)	(476)
(v)	Restructuring costs	(300)	(1,141)	(1,314)
(vi)	Other gains and losses, and litigation[3]			(327)
(vii)	Tax effects on the items listed above, comprising:	1,480	1,580	1,905
	amortization of intangible assets	*939*	*1,159*	*1,178*
	impairment of intangible assets	*527*	*42*	*37*
	fair value remeasurement of contingent consideration liabilities	*(85)*	*2*	*34*
	expenses arising from the impact of acquisitions on inventories	*2*	*7*	*143*
	restructuring costs	*97*	*370*	*399*
	other gains and losses, and litigation			*114*
(iv)/(ix)	Other tax items[4]	*(109)*		577
(x)	Share of items listed above attributable to non-controlling interests	4	3	6
(iv)/(v)	Restructuring costs and expenses arising from the impact of acquisitions on associates and joint ventures[5]	(50)	(31)	(32)
Net income attributable to equity holders of Sanofi		**3,717**	**4,889**	**5,646**

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

(2)

This line comprises the workdown of inventories remeasured at fair value at the acquisition date.

(3)

See Note D.28. to our consolidated financial statements included at Item 18 of this annual report.

(4)

In 2013, this line item corresponds to the tax on dividends distributed to Sanofi shareholders. In 2011, this line item includes €349 million relating to the effect of the Franco-American Advance Pricing Agreement (APA), and a €228 million reduction in deferred tax liabilities on remeasurements of intangible assets of Merial as a result of changes in tax legislation in the United Kingdom.

(5)

This line shows the portion of major restructuring costs incurred by associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures (workdown of acquired inventories, amortization and impairment of intangible assets, and impairment of goodwill).

The following table sets forth the calculation of our business net income for the years ended December 31, 2013, 2012 and 2011:

(€ million)	**2012**	**2012(1)**	**2011(1)**
Business operating income	**9,324**	**11,448**	**12,274**
Financial income and expenses	(503)	(658)	(604)
Income tax expense	(2,134)	(2,689)	(2,922)
Business net income	**6,687**	**8,101**	**8,748**

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

The most significant reconciliation items in the table above (reconciling our business net income to our Net income attributable to equity holders of Sanofi) relate to the purchase accounting effect of our acquisitions, particularly the amortization and impairment of intangible assets. We believe that excluding these non-cash charges

Table of Contents

enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

The purchase-accounting effects on net income primarily relate to:

- charges related to the amortization and impairment of intangible assets, net of tax and non-controlling interests;
- charges to cost of sales resulting from the workdown of acquired inventories remeasured at fair value, net of tax; and
- charges related to the impairment of goodwill.

We believe (subject to the limitations described below) that disclosing business net income enhances the comparability of our operating performance, for the following reasons:

- the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;
- the elimination of selected items, such as the increase in cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets and costs and provisions associated with major litigation, improves comparability from one period to the next; and
- the elimination of restructuring costs relating to the implementation of our transformation strategy enhances comparability because these costs are directly, and only, incurred in connection with transformation processes such as the rationalization of our research and development structures.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, net income attributable to equity holders of Sanofi reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

There are material limitations associated with the use of business net income as compared to the use of IFRS net income attributable to equity holders of Sanofi in evaluating our performance, as described below:

The results presented by business net income cannot be achieved without incurring the following costs that the measure excludes:

? *Amortization of intangible assets.* Business net income excludes the amortization charges related to intangible assets. Most of these amortization charges relate to intangible assets that we have acquired. Although amortization is a non-cash charge, it is important for investors to consider it because it represents an allocation in each reporting period of a portion of the purchase price that we paid for certain intangible assets that we have acquired through acquisitions. For example, in connection with our acquisition of Aventis in 2004, we paid an aggregate of €31,279 million for these amortizable intangible assets (which, in general, were to be amortized over their useful lives, representing an average amortization period of eight years) and €5,007 million for in-progress research & development. More recently, in connection with our acquisition of Genzyme in April 2011, we paid an aggregate of €7,873 million for amortizable intangible assets (average amortization period of eight and a half years) and €2,148 million for in-progress research & development. A large part of our revenues

could not be generated without owning acquired intangible assets.

?

Restructuring costs. Business net income does not reflect restructuring costs even though it does reflect the benefits of the optimization of our activities, such as our research and development activities, much of which we could not achieve in the absence of restructuring costs.

In addition, the results presented by business net income are intended to represent the Group's underlying performance, but items such as gains and losses on disposals and provisions associated with major litigation may recur in future years.

Table of Contents

We compensate for the above-described material limitations by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in business net income.

In determining the level of future dividend payments, and in analyzing dividend policy on the basis of business net income, our management intends to take into account the fact that many of the adjustments reflected in business net income have no effect on the underlying amount of cash available to pay dividends. However, although the adjustments relating to the elimination of the effect of the purchase accounting treatment of the Aventis acquisition and other acquisitions represent non-cash charges, the adjustments relating to restructuring costs represent significant cash charges in the periods following the closing of the acquisition.

This Item 5 contains a discussion and analysis of business net income on the basis of consolidated financial data. Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

Presentation of Net Sales

In the discussion below, we present our consolidated net sales for 2013, 2012 and 2011. We break down our net sales among various categories, including by business segment, product and geographic region. We refer to our consolidated net sales as "reported" sales.

In addition to reported sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in group structure.

When we refer to changes in our net sales "at constant exchange rates", we exclude the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period. See Note B.2 to our consolidated financial statements for further information relating to the manner in which we translate into euros transactions recorded in other currencies.

When we refer to our net sales on a "constant structure basis", we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales from an entity or with respect to product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we made the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

A reconciliation of our reported net sales to our net sales at constant exchange rates is provided at " Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012 Net Sales" and at " Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31, 2011 Net Sales" below.

Financial Presentation of Alliances

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on the Company's income statement is described in " Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012" and " Year Ended December 31, 2012 Compared with Year Ended December 31, 2011", in particular in " Net sales", " Other Revenues", " Share of Profit/Loss of Associates and Joint Ventures" and " Net Income Attributable to Non-Controlling Interests".

Table of Contents

Alliance Arrangements with Bristol-Myers Squibb (BMS)

Our revenues, expenses and operating income are affected significantly by the presentation of our alliance with BMS in our consolidated financial statements.

Initial Alliance Agreement

Under the terms of the initial alliance agreement, 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 agreement depends upon who has majority ownership and operational management in that territory, as discussed below.

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

Discovery Royalty. As inventor of the two molecules, we earn an adjustable discovery royalty on part of Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® sold in alliance countries regardless of the marketing system. The discovery royalty earned in territories under operational management of BMS is reflected in our consolidated income statement in "Other revenues."

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®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover®.

We record development royalties paid to BMS in our consolidated income statement as an increase to our cost of sales in countries where we consolidate sales of the products. We record development royalties that we receive as "other revenues" in countries where BMS consolidates sales of the products.

Under the initial 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® has been marketed jointly by Shionogi Pharmaceuticals and Dainippon Sumitomo Pharma Co. Ltd since June 2008. Our alliance with BMS does not cover distribution rights to Plavix® in Japan, which is marketed by Sanofi.

Territory under our operational management. In the territory under our operational management, the marketing arrangements and recognition of operations by the Group are as follows:

we use the co-promotion system for most of the countries in Western Europe for Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® and for certain Asian countries for Plavix®/Iscover®. 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 income of the alliances is recorded as "non-controlling interests";

we use the co-marketing system in Germany, Spain and Greece for both Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® and in Italy for Aprovel®/Avapro®/Karvea®/Karvezide®; and

we have the exclusive right to market Aprovel®/Avapro®/Karvea®/Karvezide® and Plavix®/Iscover® in Eastern Europe, Africa, the Middle East, and certain Asian countries (excluding Japan); we have the exclusive right to market Aprovel® in Scandinavia and Ireland, and Plavix® in Malaysia.

Table of Contents

Territory under BMS operational management. In the territory under BMS operational management, the marketing arrangements and recognition of operations by the Group are as follows:

- we use the co-promotion system in the United States, Canada and Puerto Rico, where the products are sold through the alliances under the operational management of BMS. With respect to Avapro® (the brand name used in the United States for Aprovel®) and Plavix®, we record our share of the alliance's operating income under "Share of profit/loss of associates and joint ventures". 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®/Iscover® and Aprovel®/Avapro®/Karvea®/Karvezide® and in Colombia for Plavix®/Iscover®; and

- 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 to BMS or such entities, which we record as "Net sales" in our consolidated income statement.

Revised Agreement effective January 1, 2013

On September 27, 2012 Sanofi and BMS restructured their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets. Under the terms of the revised agreement, which came into effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the U.S. and Puerto Rico, giving Sanofi sole control and freedom to operate commercially. In exchange, starting January 1, 2013 BMS receives royalty payments on Sanofi's sales of branded and unbranded Plavix® worldwide, excluding the U.S. and Puerto Rico, and on sales of branded and unbranded Avapro®/Avalide® worldwide, in each case through 2018; BMS will also receive a terminal payment of $200 million from Sanofi in December 2018. Plavix® rights in the U.S. and Puerto Rico will continue unchanged under the terms of the existing agreement through December 2019.

In addition, under the terms of this new agreement ongoing disputes between the companies related to the alliance have been resolved. The resolution of these disputes includes various commitments by both companies, including a one-time payment of $80 million by BMS to Sanofi in relation to the Avalide® supply disruption in the U.S. in 2011.

In the territory managed by BMS (the United States and Puerto Rico for Plavix®), the accounting policies applied by Sanofi remain unchanged and in accordance with the terms of the initial agreement. Marketing is handled through co-promotion entities majority owned by and under the operational management of BMS. Sanofi does not recognize the sales, but invoices these entities for its promotional expenses, recognizes its royalty income in "*Other revenues*", and recognizes its share of profits (net of tax) in "*Share of profit/(loss) of associates and joint ventures*".

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the new agreement, the Group recognizes in its financial statements the revenue and expenses generated by its own operations. Payments due to BMS are recognized in "*Cost of sales*".

Alliance Arrangements with Regeneron

Our relationship with Regeneron began in 2003 with an agreement for the co-development of the anti-angiogenic agent Zaltrap®. We expanded our relationship in 2007 and created a strategic R&D collaboration on fully human monoclonal antibodies.

Collaboration agreement on Zaltrap® (aflibercept)

Zaltrap® (aflibercept) is a solution administered by intravenous perfusion, used in association with 5-fluorouracil, leucovorin and irinotecan (FOLFIRI) as a treatment for metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.

In September 2003, Sanofi and Regeneron signed an agreement to collaborate on the development and commercialization of Zaltrap®. Under the terms of this agreement (as amended in 2005), Sanofi is responsible for funding 100% of the development costs, co-promotion rights are shared between Sanofi and Regeneron, and the profits generated from sales of Zaltrap® worldwide (except Japan) are shared equally. Sales of Zaltrap® made by subsidiaries under the control of Sanofi are recognized in consolidated net sales, and the associated costs incurred by those subsidiaries are recognized as operating expenses in the consolidated income statement. Regeneron's share of the profits is recognized in the line item "Other operating expenses", a component of operating income.

Table of Contents

Under the terms of the same agreement, Regeneron agreed to repay 50% of the development costs initially funded by Sanofi. Contractually, this amount represents 5% of the residual repayment obligation per quarter, but may not exceed Regeneron's profit share for the quarter unless Regeneron voluntarily decides to make a larger payment in a given quarter.

The agreement also stipulates milestone payments to be made by Sanofi on receipt of specified marketing approvals for Zaltrap® in the United States, within the European Union and in Japan.

In the United States, Zaltrap® is a registered trademark of Regeneron Pharmaceuticals, Inc. The product was approved by the U.S. Food and Drug Administration ("FDA") in August 2012, and has been marketed in the United States since that date. On February 5, 2013, the European Commission granted marketing authorization in the European Union for Zaltrap®. Regeneron has not elected to co-promote Zaltrap® at launch in the major market countries defined as United States, France, Italy, Spain, United Kingdom, Germany and Canada.

In Japan, Sanofi will develop and commercialize Zaltrap®, with Regeneron entitled to receive a royalty.

Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies

In November 2007, Sanofi and Regeneron signed additional agreements for the discovery, development and commercialization of fully human therapeutic antibodies. In November 2009, the agreements were broadened and the term extended. Under the 2009 agreements Sanofi committed to funding Regeneron's discovery and pre-clinical development of fully human therapeutic antibodies, up to $160 million per year through 2017 (see Note D.21. to our consolidated financial statements included at Item 18 of this annual report). Sanofi has an option to license for further development any antibodies discovered by Regeneron that attain Investigational New Drug (IND) status.

If such an option is exercised, Sanofi would be primarily responsible for funding, and would co-develop the antibody with Regeneron. Sanofi and Regeneron would share co-promotion rights and profits on sales of the co-developed antibodies. Development costs for the drug candidate would be shared between the companies, with Sanofi generally funding these costs up front, except that following receipt of the first positive Phase III trial results for a co-developed drug candidate, subsequent Phase III trial-related costs for that drug candidate would be shared 80% by Sanofi and 20% by Regeneron. Once a product begins to be marketed, Regeneron would progressively repay out of its profits 50% of the development costs borne by Sanofi for all antibodies licensed by Sanofi. However, Regeneron would not be required to apply more than 10% of its share of the profits from collaboration products in any calendar quarter towards reimbursing Sanofi for these development costs. Under the terms of the collaboration agreement, Sanofi may also be required to make milestone payments based on aggregate sales of antibodies. In 2013, seven antibodies were in clinical development, two of which were in Phase III.

If Sanofi does not exercise its licensing option for an antibody under development, Sanofi would be entitled to receive a royalty once the antibody begins to be marketed.

Investor Agreement

On January 11, 2014, Regeneron, Sanofi and some of its subsidiaries (collectively "Sanofi") agreed to amend and restate the original investor agreement, dated as of December 20, 2007, as amended in its entirety and entered into the Amended and Restated Investor Agreement (the "Amended Investor Agreement"). The Amended Investor Agreement was amended to, among other things, provide Sanofi with the right to nominate a single independent director to the Regeneron's Board of Directors upon reaching 20% ownership of the Company's then outstanding shares of Class A Stock, par value $0.001 per share and Common Stock (together the "Capital Stock") and to extend the term of the lock-up obligations. Sanofi retains its right to acquire up to 30% of the Capital Stock. The Amended Investor Agreement also provides Sanofi with the right to receive certain information as may be reasonably agreed upon by the parties that will facilitate Sanofi 's ability to account for their investment in the Company using the equity method of accounting under International Financial Reporting Standards.

Subsequently Sanofi has determined to purchase, directly or through its subsidiaries, additional shares of Common Stock to increase its beneficial ownership to approximately 20.5% of the Common Stock outstanding. Sanofi made no commitment in terms of the timing of such transactions, which will depend on market conditions including the price and availability of shares of Common Stock, and on such other factors considered relevant to Sanofi.

Table of Contents

Alliance arrangements with Warner Chilcott (previously with Procter & Gamble Pharmaceuticals)

Our agreement with Warner Chilcott ("the Alliance Partner") covers the worldwide development and marketing arrangements of Actonel®, except Japan for which we hold no rights. Until October 30, 2009, this agreement was between Sanofi and Procter & Gamble Pharmaceuticals (P&G). Since the sale by P&G of its pharmaceutical business to Warner Chilcott on October 30, 2009, Actonel® has been marketed in collaboration with Warner Chilcott. The local marketing arrangements may take various forms.

Co-promotion, whereby sales resources are pooled but only one of the two parties to the alliance agreement (Sanofi or the Alliance Partner) invoices product sales. Co-promotion is carried out under contractual agreements and is not based on any specific legal entity. The Alliance Partner sells the product and incurs all of the related costs in France and Canada. This co-promotion scheme formerly included Germany, Belgium and Luxembourg until December 31, 2007, the Netherlands until March 31, 2008, and the United States and Puerto Rico until March 31, 2010. We recognize our share of revenues under the agreement in our income statement as a component of operating income in the line item "Other operating income". Since April 1, 2010, we have received royalties from the Alliance Partner on sales made by the Alliance Partner in the United States and Puerto Rico. In the secondary co-promotion territories (the United Kingdom until December 31, 2008, Ireland, Sweden, Finland, Greece, Switzerland, Austria, Portugal and Australia), we sell the product and recognize all the revenues from sales of the product along with the corresponding expenses. The share due to the Alliance Partner is recognized in "Cost of sales";

Co-marketing, which applies in Italy, whereby each party to the alliance agreement sells the product in the country under its own brand name, and recognizes all revenues and expenses from its own operations in its respective income statement. Each company also markets the product independently under its own brand name in Spain, although Spain is not included in the co-marketing territory;

Warner Chilcott only territories: the product has been marketed by the Alliance Partner independently in Germany, Belgium and Luxembourg since January 1, 2008, in the Netherlands since April 1, 2008, in the United Kingdom since January 1, 2009 and in the United States and Puerto Rico since April 1, 2010. We recognize our share of revenues under the alliance agreement in "Other operating income"; and

Sanofi only territories: we have exclusive rights to sell the product in all other territories. We recognize all revenues and expenses from our own operations in our income statement, but in return for these exclusive rights we pay the Alliance Partner a royalty based on actual sales. This royalty is recognized in "Cost of sales".

In 2010, Sanofi and Warner Chilcott began negotiations on the future of their alliance arrangements. In an arbitration proceeding, an arbitration panel decided on July 14, 2011 that the termination by Warner Chilcott of an ancillary agreement did not lead to the termination of the Actonel® Alliance. Pursuant to this decision, the alliance will remain in effect until January 1, 2015.

In October 2013, Warner Chilcott and Sanofi have agreed on an early buy-back of Sanofi's interest in the product in the United States and Puerto Rico. As a consequence, the parties have amended the U.S. amendment (arising from a 2010 restructuring for the U.S. and Puerto Rico) with a view to restructure the parties' economic rights and obligations for the contract year 2014. As such, Warner Chilcott has paid to Sanofi a definitive lump-sum of $125 million.

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 affected by exchange rate movements between the euro and other currencies, primarily the U.S. dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2013, we earned 31.7% of our net sales in the United States. A decrease in the value of the U.S. dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A decrease in the value of the U.S. dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our alliance with BMS in the United States, which is under the operational management of BMS, as described at " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above.

For a description of positions entered into to manage operational foreign exchange risks as well as our hedging policy, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk", and "Item 3. Key Information D. Risk Factors Risks Related to Financial Markets Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition".

Table of Contents

Divestments

In 2013, Sanofi sold its U.S. commercial rights to five pharmaceutical products to Covis Pharma. The gain on this sale amounted to €165 million.

In August 2012, Sanofi sold its 39.1% interest in Société Financière des Laboratoires de Cosmétologie Yves Rocher, in line with the Group's desire to focus on strategic activities.

In December 2011 Sanofi sold the Dermik dermatology business to Valeant Pharmaceuticals International Inc., for €321 million (see Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report).

Acquisitions

The principal acquisitions during 2013 are described below:

In January 2013, Sanofi (via Chattem) completed the acquisition of the worldwide rights to the Rolaids® brand from the McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. Rolaids® is an over-the-counter antacid that helps relieve heartburn and acid reflux.

In March 2013, Sanofi acquired Genfar S.A. (Genfar), a Colombian pharmaceutical company that is a significant player in Colombia and other countries in Latin America. Genfar is the second-largest generics manufacturer in Colombia by sales, with annual sales around €100 million. See Note D.1.1. to our consolidated financial statements included at Item 18 of this annual report.

In June 2013, Merial announced the completion of its acquisition of the animal health division of the Indian company Dosch Pharmaceuticals Private Limited, which markets 86 animal health products and 50 specialities for ruminants, poultry and companion animals.

Other than Genfar, the impact of these acquisitions on our consolidated financial statements is not material.

The principal acquisitions during 2012 are described below:

In April 2012, Sanofi strengthened its presence in biosurgery by acquiring a 100% equity interest in Pluromed, Inc. (Pluromed), an American medical devices company. Pluromed has developed a proprietary polymer technology Rapid Transition Polymers (RTP) pioneering the use of plugs that can be injected into blood vessels to improve the safety, efficacy and economics of medical interventions.

In March 2012, Merial completed the acquisition of Newport Laboratories, a privately held company based in Worthington, Minnesota (United States), which is a leader in autogenous vaccines for the bovine and swine markets.

The impact of these two acquisitions on our consolidated financial statements is not material.

The principal acquisitions during 2011 are described below:

In February 2011, Sanofi completed the acquisition of 100% of the share capital of BMP Sunstone Corporation (BMP Sunstone), a pharmaceutical company that is developing a portfolio of branded pharmaceutical and healthcare products in China. See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In April 2011, Sanofi acquired Genzyme Corporation (Genzyme), a major biotechnology company headquartered in Cambridge, Massachussets (United States), with primary areas of focus in rare diseases, renal endocrinology, oncology and biosurgery. The transaction was completed in accordance with the terms of the public exchange offer at a price of $74 in cash plus the issuance to Genzyme shareholders of one contingent value right (CVR) per share. The total purchase price amounted to €14.8 billion. The purchase price allocation is disclosed in Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In October 2011, Sanofi acquired Topaz Pharmaceuticals Inc. (Topaz), a U.S. pharmaceutical research company that developed an innovative anti-parasitic product for treating head lice. An upfront payment of $35 million was made on completion of the transaction. According to the agreement, future milestone payments may be made upon market approval and depending on the achievement of sales targets.

See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

In November 2011, Sanofi acquired the business of Universal Medicare Private Limited (Universal), a major producer of nutraceuticals in India. The acquisition price amounted to €83 million. See Note D.1.3. to our consolidated financial statements included at Item 18 of this annual report.

Table of Contents

In December 2011, Sanofi co-invested in Warp Drive Bio, an innovative start-up biotechnology company, along with two venture capital firms, Third Rock Ventures (TRV) and Greylock Partners. Warp Drive Bio is an innovative biotechnology company, focusing on proprietary genomic technology to discover drugs of natural origin. Sanofi and TRV / Greylock have invested in Warp Drive Bio at parity.

Results of Operations

Year Ended December 31, 2013 Compared with Year Ended December 31, 2012

The consolidated income statements for the years ended December 31, 2013 and December 31, 2012 break down as follows:

(under IFRS) *(€ million)*	**2013**	**as % of net sales**	**2012 (1)**	**as % of net sales**
Net sales	**32,951**	**100.0%**	**34,947**	**100.0%**
Other revenues	355	1.1%	1,010	2.9%
Cost of sales	(10,990)	(33.4%)	(11,098)	(31.8%)
Gross profit	**22,316**	**67.7%**	**24,859**	**71.1%**
Research & development expenses	(4,770)	(14.5%)	(4,905)	(14.0%)
Selling & general expenses	(8,602)	(26.1%)	(8,929)	(25.6%)
Other operating income	691		562	
Other operating expenses	(242)		(414)	
Amortization of intangible assets	(2,914)		(3,291)	
Impairment of intangible assets	(1,387)		(117)	
Fair value remeasurement of contingent consideration liabilities	314		(192)	
Restructuring costs	(300)		(1,141)	
Other gains and losses, and litigation				
Operating income	**5,106**	**15.5%**	**6,432**	**18.4%**
Financial expenses	(612)		(751)	
Financial income	109		93	
Income before tax and associates and joint ventures	**4,603**	**14.0%**	**5,774**	**16.5%**
Income tax expense	(763)		(1,109)	
Share of profit/(loss) of associates and joint ventures	35		393	

Net income	**3,875**	**11.8%**	**5,058**	**14.5%**
Net income attributable to non-controlling interests	158		169	
Net income attributable to equity holders of Sanofi	**3,717**	**11.3%**	**4,889**	**14.0%**
Average number of shares outstanding (million)	1,323.1		1,319.5	
Average number of shares outstanding after dilution (million)	1,339.1		1,329.6	
Basic earnings per share (in euros)	2.81		3.71	
Diluted earnings per share (in euros)	2.78		3.68	

(1)

Includes the impact of applying the revised IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Table of Contents

Net Sales

Consolidated net sales for the year ended December 31, 2013 amounted to €32,951 million, 5.7% lower than in 2012. Exchange rate movements had an unfavorable effect of 5.2 points, mainly reflecting the depreciation of the yen, the U.S. dollar, the Brazilian real, the Venezuelan bolivar, the Australian dollar and the South African rand against the euro. At constant exchange rates, net sales fell by 0.5% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2013 and December 31, 2012 to our net sales at constant exchange rates:

(€ million)	**2013**	**2012**	**Change**
Net sales	**32,951**	**34,947**	**-5.7%**
Effect of exchange rates	1,806		
Net sales at constant exchange rates	**34,757**	**34,947**	**-0.5%**

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health segments.

The following table breaks down our 2013 and 2012 net sales by business segment:

(€ million)	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Pharmaceuticals	27,250	28,871	-5.6%	-0.2%
Vaccines	3,716	3,897	-4.6%	-0.1%
Animal Health	1,985	2,179	-8.9%	-5.3%
Total	**32,951**	**34,947**	**-5.7%**	**-0.5%**

Net Sales by Product Pharmaceuticals segment

In 2013, net sales for the Pharmaceuticals segment were €27,250 million, down 5.6% on a reported basis and 0.2% at constant exchange rates.

The year-on-year change (decrease of €1,621 million) reflects the negative effect of exchange rates (€1,551 million) on the one hand, and the following impacts at constant exchange rates on the other hand:

- the positive performance of growth platforms (€1,684 million), mainly our Diabetes and Genzyme businesses;
- the negative effects of generic competition (mainly on sales of Eloxatin® and Lovenox® in the United States, and of Aprovel® and Plavix® in Western Europe), totaling €1,253 million of net sales lost; and
- other impacts (negative evolution of €501 million), including the negative impact of austerity measures in the European Union and temporary difficulties in distribution channels for our Generics business in Brazil.

Our flagship products (Lantus® and Apidra®, Cerezyme®, Myozyme®/Lumizyme®, Fabrazyme®, Aubagio® and Lemtrada , Multaq®, Jevtana®, Auvi-Q®, Mozobil®, Zaltrap®, Plavix®, Lovenox®, Aprovel®/CoAprovel®, Renagel®/Renvela®, Allegra®, Stilnox® / Ambien® / Myslee®, Synvisc® / Synvisc-One®, Taxotere® and Eloxatin®) are discussed below.

Table of Contents

The following table breaks down our 2013 and 2012 net sales for the Pharmaceuticals segment by product:

(€ million) **Product**	**Indication**	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Lantus®	Diabetes	5,715	4,960	+15.2%	+20.0%
Apidra®	Diabetes	288	230	+25.2%	+31.7%
Amaryl®	Diabetes	375	421	-10.9%	-1.0%
Insuman®	Diabetes	132	135	-2.2%	0.0%
Lyxumia®	Diabetes	9			
Other products		49	36	+36.1%	+38.9%
Total: Diabetes	**Diabetes**	**6,568**	**5,782**	**+13.6%**	**+18.7%**
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	409	563	-27.4%	-19.5%
Jevtana®	Prostate cancer	231	235	-1.7%	+1.3%
Eloxatin®	Colorectal cancer	221	956	-76.9%	-76.0%
Thymoglobulin®	Organ rejection	198	193	+2.6%	+7.3%
Mozobil®	Hematologic malignancies	101	96	+5.2%	+8.3%
Zaltrap®	Colorectal cancer	53	25	+112.0%	+116.0%
Other products		252	326	-22.7%	-18.7%
Total: Oncology		**1,465**	**2,394**	**-38.8%**	**-35.3%**
Cerezyme®	Gaucher disease	688	633	+8.7%	+13.9%
Myozyme®/Lumizyme®	Pompe disease	500	462	+8.2%	+11.9%
Fabrazyme®	Fabry disease	383	292	+31.2%	+39.0%
Aldurazyme®	Mucopolysaccharidosis	159	150	+6.0%	+11.3%

Other products		244	241	+1.2%	+8.7%
Sub-total: Rare diseases		**1,974**	**1,778**	**+11.0%**	**+16.6%**
Aubagio®	Multiple sclerosis	166	7		
Lemtrada	Multiple sclerosis	2			
Sub-total: Multiple sclerosis		**168**	**7**		
Total: Genzyme		**2,142**	**1,785**	**+20.0%**	**+25.9%**
Plavix®	Atherothrombosis	1,857	2,066	-10.1%	+1.1%
Lovenox®	Thrombosis	1,703	1,893	-10.0%	-7.2%
Aprovel®/CoAprovel®	Hypertension	882	1,151	-23.4%	-20.9%
Renagel®/Renvela®	Hyperphosphatemia	750	653	+14.9%	+19.0%
Allegra®	Allergic rhinitis, urticaria	406	553	-26.6%	-12.1%
Depakine®	Epilepsy	405	410	-1.2%	+2.7%
Stilnox®/Ambien®/Myslee®	Sleep disorders	391	497	-21.3%	-9.5%
Synvisc®/Synvisc-One®	Arthritis	371	363	+2.2%	+6.1%
Tritace®	Hypertension	307	345	-11.0%	-7.2%
Multaq®	Atrial fibrillation	269	255	+5.5%	+8.2%
Lasix®	Edema, hypertension	172	210	-18.1%	-9.5%
Targocid®	Bacterial infections	166	198	-16.2%	-11.1%
Orudis®	Rheumatoid arthritis, osteoarthritis	144	184	-21.7%	-9.8%
Cordarone®	Arrhythmia	141	163	-13.5%	-4.3%
Xatral®	Benign prostatic hypertrophy	101	130	-22.3%	-20.0%
Actonel®	Osteoporosis, Paget's disease	100	134	-25.4%	-20.1%
Auvi-Q	Severe allergies, anaphylaxis	51			
Other prescription products		4,230	4,853	-12.8%	-8.1%
Total: Other prescription products		**12,446**	**14,058**	**-11.5%**	**-5.5%**

Consumer Health Care	**3,004**	**3,008**	**-0.1%**	**+5.2%**
Generics	**1,625**	**1,844**	**-11.9%**	**-8.2%**
Total Pharmaceuticals	**27,250**	**28,871**	**-5.6%**	**-0.2%**

Table of Contents

Diabetes division

Net sales for the Diabetes division were €6,568 million, up 18.7% at constant exchange rates, driven by double-digit growth for Lantus® and Apidra®.

Lantus® increased its net sales by 20.0% (at constant exchange rates) to €5,715 million in 2013 due to robust growth in the United States (up 25.6% at constant exchange rates, at €3,747 million) driven by Lantus® SoloSTAR®, which accounted for 57% of full-year sales, and to a solid performance in Emerging Markets (up 16.8% at constant exchange rates), especially in the Africa/Middle East region (up 34.6% at constant exchange rates) and in Eastern Europe (up 14.5% at constant exchange rates). In Western Europe, growth was once again modest (up 4.1% at constant exchange rates).

The product's sales growth reflected both an increase in volumes and a generally favorable price effect. Volumes advanced in all geographic segments during 2013 (+9.8% overall), especially in Emerging Markets but also in the United States, reflecting continued strength in prescription rates. We expect continued strength in prescription rates in all geographic segments in the medium term. In the longer term, volume growth will be dependent on a number of factors such as new competing products entering the markets and prevalence of type 2 diabetes. We expect the Emerging Markets zone to continue to be a robust contributor to volume growth going forward, reflecting increased diagnosis of Diabetes and better access to drugs.

Price effects were overall favorable (+10.2% at constant exchange rates), with price rises in the United States and other key markets more than offsetting price pressure in some countries, such as China. We cannot foresee what the long-term price effects will be, as these will depend on the impact of new competing products on the pricing of diabetes treatments across all geographic treatments. However, favorable price effects are expected in the United States in the short term.

Net sales of **Apidra®** totaled €288 million in 2013, up 31.7% at constant exchange rates, due to a strong performance in the United States (up 58.9% at constant exchange rates, at €112 million).

Amaryl® posted a 1.0% fall in net sales at constant exchange rates to €375 million, reflecting the effect of generic competition in Japan (down 18.4% at constant exchange rates, at €81 million), but also a good performance in Emerging Markets (up 9.9% at constant exchange rates, at €269 million).

Lyxumia® (lixisenatide, in-licensed from Zealand Pharma) was launched in various Western European countries, in Japan and in Mexico in 2013, and generated net sales of €9 million.

Oncology business

The Oncology business posted net sales of €1,465 million, down 35.3% at constant exchange rates, due mainly to the effects of the expected expiration of exclusivity for Eloxatin® in the United States.

Eloxatin® saw net sales fall sharply in 2013, by 76.0% at constant exchange rates to €221 million, triggered by increased competition from generics in the United States beginning in August 2012.

Net sales of **Taxotere®** fell by 19.5% at constant exchange rates to €409 million. The product is facing competition from generics in Western Europe (down 56.6% at constant exchange rates, at €22 million), in the United States (down 18.9% at constant exchange rates, at €42 million) and in Emerging Markets (down 18.5% at constant exchange rates, at €211 million).

Jevtana® reported net sales of €231 million in 2013, up 1.3% at constant exchange rates, reflecting competitive pressure in the United States, where sales slipped by 19.3% at constant exchange rates to €86 million, counteracted by a strong performance in Western Europe (up 22.0% at constant exchange rates, at €110 million).

Sales of **Mozobil®** rose by 8.3% at constant exchange rates to €101 million.

Net sales of **Zaltrap®** reached €53 million, up 116.0% at constant exchange rates. The product generated sales of €36 million in the United States, where it was launched in the third quarter of 2012 (up 54.2% at constant exchange rates), and sales of €15 million in Western Europe, where launches began during the first half of 2013.

Net sales of other Oncology products fell by 18.7% at constant exchange rates to €252 million, due mainly to the withdrawal of Campath® from the market in the second half of 2012.

Table of Contents

Jevtana®, Zaltrap® and Mozobil®, along with the other pharmaceutical products Multaq® and Auvi-Q ™ (1) (see " Other pharmaceutical products" below), constitute the "Other Innovative Products" growth platform, which in 2013 generated €705 million of net sales, up 18.8% at constant exchange rates.

Genzyme business

The Genzyme business consists of treatments for rare diseases, and treatments for multiple sclerosis (Aubagio® and Lemtrada). The business generated net sales of €2,142 million, up 25.9% at constant exchange rates, reflecting the return to full supply capacity for Cerezyme® and Fabrazyme®, an increased number of patients in rare diseases, and the launch of Aubagio® in the United States.

In rare diseases, **Cerezyme®** increased its net sales by 13.9% at constant exchange rates to €688 million, driven by Emerging Markets (up 36.3% at constant exchange rates, at €241 million) and the United States (up 10.8% at constant exchange rates, at €178 million).

Net sales of **Myozyme® / Lumizyme®** rose by 11.9% at constant exchange rates to €500 million, due to an increase in sales in Emerging Markets (up 43.6% at constant exchange rates, at €74 million) and in Western Europe (up 7.4% at constant exchange rates, at €274 million).

Fabrazyme® reported strong net sales growth of 39.0% at constant exchange rates, to €383 million. The product was boosted by a rebound in the United States (up 33.6% at constant exchange rates, at €196 million) and Western Europe (up 69.2% at constant exchange rates at €87 million), mainly due to an increase in the number of new patients.

For more information regarding the manufacturing issues related to Cerezyme® and Fabrazyme® see "Item 4 Information on the Company Production and Raw Materials."

In multiple sclerosis, **Aubagio®**, which was launched in the United States in October 2012, and in some Western European countries in the fourth quarter of 2013, generated net sales of €166 million in 2013 (of which €152 million came from the United States). **Lemtrada** , launched in Germany in October 2013, posted sales of €2 million.

Other pharmaceutical products

Net sales of **Plavix®** were up 1.1% at constant exchange rates at €1,857 million. Growth was limited by the effect of a fall in sales of the active ingredient to the entity majority owned by BMS in the United States (down 93.4% at constant exchange rates, at €5 million), where the product lost its exclusivity on May 17, 2012. Sales of Plavix® in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see " Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb" above). In Emerging Markets, Plavix® reported net sales growth of 4.6% at constant exchange rates to €807 million, driven by sales in China (up 14.3% at constant exchange rates, at €422 million). In Japan, sales advanced by 13.3% at constant exchange rates to €748 million. In Western Europe, sales fell year-on-year (down 16.3% at constant exchange rates, at €257 million) as a result of competition from generics.

Lovenox® saw net sales fall in 2013 by 7.2% at constant exchange rates to €1,703 million due to competition from generics in the United States, where sales of the branded product were down 39.5% at constant exchange rates at €187 million (sales of the generic version of Lovenox® launched by Sanofi in 2012 are recorded by our Generics business). Sales rose by 0.9% at constant exchange rates in Western Europe to €858 million, while in Emerging Markets sales were down 2.6% at €563 million.

Aprovel® / CoAprovel® reported a drop in net sales of 20.9% at constant exchange rates to €882 million, mainly as a result of competition from generics in Western Europe, where sales were 39.1% lower at €338 million. Emerging Markets net sales increased by 9.1% at constant exchange rates to €410 million.

Net sales of **Renagel® / Renvela®** rose by 19.0% at constant exchange rates to €750 million, driven by a strong performance in the United States (up 22.0% at constant exchange rates, at €531 million) and in Emerging Markets (up 35.8% at constant exchange rates, at €67 million).

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(1)

Sanofi U.S. has in-licensed the North American commercialization rights for Auvi-Q from Intellijet, Inc.

Table of Contents

Allegra® posted a fall in prescription net sales (down 12.1% at constant exchange rates, at €406 million), affected by competition from generics in Japan (down 18.4% at constant exchange rates, at €280 million). Net sales of Allegra® OTC in the United States and in Japan are recorded by the Consumer Health Care business.

Net sales of **Stilnox® / Ambien® / Myslee®** fell by 9.5% at constant exchange rates to €391 million, reflecting competition from generics of Myslee® in Japan (down 17.1% at constant exchange rates at €192 million).

Synvisc® / Synvisc-One® achieved net sales of €371 million, up 6.1% at constant exchange rates. Sales held fairly steady in the United States (up 1.0% at constant exchange rates, at €295 million).

Net sales of **Multaq®** increased by 8.2% at constant exchange rates to €269 million, of which €216 million was generated in the United States (up 11.5% at constant exchange rates).

Auvi-Q recorded net sales of €51 million in the United States, where it was launched in January 2013.

No comments are called for in respect of our other prescription medicines.

Consumer Health Care business

During 2013, the **Consumer Health Care** business increased its net sales by 5.2% at constant exchange rates to €3,004 million, driven by growth in Emerging Markets (up 7.9% at constant exchange rates, at €1,482 million) and the United States (up 4.8% at constant exchange rates, at €616 million).

Net sales of Allegra® OTC rose by 7.4% at constant exchange rates, reflecting the product's launch in Japan at the end of 2012. Essentiale®, Enterogermina® and No Spa® all achieved double-digit net sales growth (at constant exchange rates).

The following table breaks down our 2013 and 2012 net sales for the Consumer Health Care business by product:

(€ million) **Product**	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Doliprane®	290	268	+8.2%	+9.0%
Allegra®	264	256	+3.1%	+7.4%
Essentiale®	207	178	+16.3%	+21.9%
Enterogermina®	130	119	+9.2%	+21.8%
No Spa®	117	110	+6.4%	+10.0%
Lactacyd®	105	110	-4.5%	+3.6%
Dorflex®	93	101	-7.9%	+5.0%
Other products	1,798	1,866	-3.6%	+1.4%
Total Consumer Healh Care	**3,004**	**3,008**	**-0.1%**	**+5.2%**

Generics business

The **Generics** business reported net sales of €1,625 million in 2013, down 8.2% at constant exchange rates, with the performance adversely affected by temporary difficulties in distribution channels in Brazil.

During the second quarter of 2013, Sanofi became aware that distribution channels in Brazil were holding inventory levels substantially and inappropriately in excess of the volumes needed to meet demand. Consequently, an adjustment was booked for product returns, discounts and chargebacks, the net impact of which was to reduce net sales by €122 million. An additional provision of €79 million was also booked to cover inventory write-downs and other associated costs.

However, the business was boosted by organic sales growth in Western Europe (up 11.4% at constant exchange rates, at €552 million), principally in the French market, where the penetration of generics increased. In Emerging Markets, the business generated sales of €858 million (down 12.8% at constant exchange rates), hampered by the adjustment to net sales in Brazil. In the United States, net sales fell by 32.4% at constant exchange rates to €179 million, reflecting a decline in sales of authorized generics of Lovenox®, Aprovel® and Taxotere®, due partly to unfavorable price effects.

Table of Contents

The following table breaks down net sales of our Pharmaceutical segment products by geographical region in 2013:

(€ million) **Product**	**Western Europe (1)**	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets (2)**	**Change at constant exchange rates**	**Rest of the world (3)**	**Change at constant exchange rates**
Lantus®	804	+4.1%	3,747	+25.6%	874	+16.8%	290	+12.3%
Apidra®	84	+7.7%	112	+58.9%	63	+31.4%	29	+28.6%
Amaryl®	22	-21.4%	2	-33.3%	269	+9.9%	82	-18.1%
Insuman®	90	-8.2%	1	0.0%	42	+18.9%	(1)	-100.0%
Lyxumia®	6						3	
Other products	45	+50.0%		-100.0%	2		2	
Total: Diabetes	**1,051**	**+4.4%**	**3,862**	**+26.1%**	**1,250**	**+16.1%**	**405**	**+5.7%**
Taxotere®	22	-56.6%	42	-18.9%	211	-18.5%	134	-10.7%
Jevtana®	110	+22.0%	86	-19.3%	31	+3.0%	4	+150.0%
Eloxatin®	6	-53.8%	19	-97.4%	127	-14.4%	69	+1.4%
Thymoglobulin®	31	+6.9%	102	+8.2%	53	+10.0%	12	-6.3%
Mozobil®	32	+6.7%	56	+3.6%	10	+42.9%	3	+33.3%
Zaltrap®	15		36	+54.2%	2			-100.0%
Other products	54	-26.7%	149	-15.8%	30	-28.9%	19	+4.3%
Total: Oncology	**270**	**-6.2%**	**490**	**-59.3%**	**464**	**-13.3%**	**241**	**-5.3%**
Cerezyme®	225	+5.1%	178	+10.8%	241	+36.3%	44	-16.1%
Myozyme®/Lumizyme®	274	+7.4%	123	+9.4%	74	+43.6%	29	+3.0%
Fabrazyme®	87	+69.2%	196	+33.6%	51	+31.7%	49	+29.8%
Aldurazyme®	60	+5.2%	29	+15.4%	54	+21.3%	16	0.0%
Other products	39	+14.7%	99	+5.2%	39	+13.9%	67	+8.0%

Sub-total Rare diseases	**685**	**+12.0%**	**625**	**+16.0%**	**459**	**+32.8%**	**205**	**+4.7%**
Aubagio®	12		152		2			
Lemtrada	2							
Sub-total Multiple sclerosis	**14**		**152**		**2**			
Total: Genzyme(4)	**699**	**+14.3%**	**777**	**+42.6%**	**461**	**+33.3%**	**205**	**+5.1%**
Plavix®	257	-16.3%	5*	-93.4%	807	+4.6%	788	+12.1%
Lovenox®	858	+0.9%	187	-39.5%	563	-2.6%	95	-1.9%
Aprovel®/CoAprovel®	338	-39.1%	17*	-60.0%	410	+9.1%	117	-20.8%
Renagel®/Renvela®	133	+4.7%	531	+22.0%	67	+35.8%	19	0.0%
Allegra®	10	-9.1%	(3)		120	+12.5%	279	-18.7%
Depakine®	138	-2.1%			252	+5.6%	15	0.0%
Stilnox®/Ambien®/Myslee®	42	-8.7%	88	-7.1%	65	0.0%	196	-16.6%
Synvisc®/Synvisc-One®	25	+25.0%	295	+1.0%	33	+45.8%	18	+17.6%
Tritace®	136	-9.3%			160	-4.4%	11	-20.0%
Multaq®	43	-6.5%	216	+11.5%	8	+12.5%	2	0.0%
Lasix®	75	-5.1%	3	0.0%	50	-11.3%	44	-13.6%
Targocid®	79	-8.1%			75	-10.0%	12	-27.3%
Orudis®	24	-52.9%			117	+7.8%	3	-25.0%
Cordarone®	25	-10.7%			74	+2.6%	42	-10.2%
Xatral®	39	-13.3%	3	-85.0%	58	-3.2%	1	-33.3%
Actonel®	22	-33.3%			48	-22.7%	30	-2.9%
Auvi-Q			51					
Other prescription products	1,645	-13.1%	497	-12.0%	1,607	-0.3%	481	-11.1%
Total: Other prescription products	**3,889**	**-13.0%**	**1,890**	**-6.1%**	**4,514**	**+1.8%**	**2,153**	**-5.4%**
Consumer Health Care	**664**	**-0.2%**	**616**	**+4.8%**	**1,482**	**+7.9%**	**242**	**+3.9%**

Generics	**552**	**+11.4%**	**179**	**-32.4%**	**858**	**-12.8%**	**36**	**+51.9%**
Total pharmaceuticals	**7,125**	**-5.4%**	**7,814**	**+1.8%**	**9,029**	**+3.2%**	**3,282**	**-2.6%**

(1)
France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)
World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(3)
Japan, Canada, Australia and New Zealand.

*
Sales of active ingredient to the entity majority-owned by BMS in the United States.

Table of Contents

Net Sales Human Vaccines (Vaccines) segment

In 2013, the Vaccines segment posted net sales of €3,716 million, down 4.6% on a reported basis and 0.1% at constant exchange rates.

The following table presents the 2013 and 2012 sales of our Vaccines segment by range of products:

(€ million)	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,148	1,184	-3.0%	+3.2%
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	929	884	+5.1%	+9.3%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	496	650	-23.7%	-20.8%
Adult Booster Vaccines (*including Adacel®*)	391	496	-21.2%	-18.5%
Travel and Other Endemics Vaccines	382	364	+4.9%	+9.9%
Other Vaccines	370	319	+16.0%	+21.0%
Total Vaccines	**3,716**	**3,897**	**-4.6%**	**-0.1%**

Polio / Pertussis / Hib vaccines reported net sales up 3.2% at constant exchange rates, to €1,148 million. This reflected a good performance in Emerging Markets (€644 million, up 33.9% at constant exchange rates), driven by the success of Pentaxim®, especially in China, but also a decline in net sales of 23.8% at constant exchange rates in the United States (to €275 million) triggered by supply limitations for of Pentacel® and Adacel® lasting from April 2012 until October 2013.

Net sales of **Influenza** vaccines were up 9.3% at constant exchange rates at €929 million, helped by a strong performance in the United States (up 20.4% at €533 million) with the Fluzone® range; in Emerging Markets, net sales were down 5.7% at constant exchange rates at €291 million.

Meningitis / Pneumonia vaccines posted net sales of €496 million, down 20.8% at constant exchange rates, affected by a contraction in sales of Menactra® (down 21.5% at constant exchange rates, at €424 million), largely in the United States where the timing of public procurement tenders was less favorable than in 2012. In Emerging Markets, sales for the franchise fell by 17.6% at constant exchange rates to €132 million.

Net sales of **Adult Booster** vaccines were 18.5% lower at constant exchange rates at €391 million, mainly due to reduced sales of Adacel® in the United States (down 25.3% at constant exchange rates, at €234 million) following the temporary restrictions on shipments.

Net sales of **Travel and Other Endemics** vaccines were up 9.9% at constant exchange rates at €382 million, driven by vaccines against rabies and hepatitis A.

Other Vaccines saw net sales rise by 21.0% at constant exchange rates to €370 million, reflecting the expansion of VaxServe, a Sanofi Pasteur company that supplies vaccines in the United States.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, reached €876 million in 2013, up 3.7% (on a reported basis), boosted by sales of the Zostavax® vaccine launched at the end of 2012. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

Table of Contents

The following table presents the 2013 sales of our Vaccines segment by range of products and by region:

(€ million)	**Western Europe (1) Reported**	**Change at constant exchange rates**	**United States Reported**	**Change at constant exchange rates**	**Emerging Markets (2) Reported**	**Change at constant exchange rates**	**Rest of the world (3) Reported**	**Change at constant exchange rates**
Polio/Pertussis/Hib Vaccines (*inc. Pentacel® and Pentaxim®*)	35	-34.5%	275	-23.8%	644	+33.9%	194	-8.5%
Influenza Vaccines (*inc. Vaxigrip® and Fluzone®*)	83	+5.1%	533	+20.4%	291	-5.7%	22	+4.5%
Meningitis/Pneumonia Vaccines (*inc. Menactra®*)	5	+25.0%	352	-22.4%	132	-17.6%	7	-12.5%
Adult Booster Vaccines (*inc. Adacel®*)	60	+3.4%	268	-25.3%	48	+11.1%	15	-25.0%
Travel and Other Endemics Vaccines	18	-14.3%	97	+5.2%	215	+11.4%	52	+23.9%
Other Vaccines	3	-88.9%	347	+30.0%	11	-33.3%	9	-13.3%
Total Vaccines	**204**	**-10.1%**	**1,872**	**-5.2%**	**1,341**	**11.5%**	**299**	**-4.9%**

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.*

(2) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(3) *Japan, Canada, Australia and New Zealand.*

In the United States, sales of vaccines were down 5.2% at constant exchange rates at €1,872 million, reflecting the supply limitations for Pentacel® and Adacel® coupled with weaker sales of Menactra®. In Emerging Markets, sales growth (up 11.5% at constant exchange rates) was driven by the success of Pentaxim®, especially in China. In the Rest of the World, the fall of 4.9% at constant exchange rates was due largely to lower sales of Imovax® in Japan, reflecting the end of the catch-up vaccinations that followed the launch of this product in September 2012.

Net Sales Animal Health segment

Net sales for the Animal Health segment in 2013 amounted to €1,985 million, down 5.3% at constant exchange rates or 8.9% on a reported basis.

The following table presents the 2013 and 2012 sales of our Animal Health segment by range of products:

(€ million)	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Companion animals	1,195	1,372	-12.9%	-9.8%
Production animals	790	807	-2.1%	+2.1%
Total Animal Health	**1,985**	**2,179**	**-8.9%**	**-5.3%**
Of which Frontline® and other fipronil-based products	*611*	*775*	*-21.2%*	*-17.8%*
Of which Vaccines	*727*	*730*	*-0.4%*	*+3.0%*
Of which Avermectin	*413*	*423*	*-2.4%*	*+1.7%*
Of which Other products	*234*	*251*	*-6.8%*	*-2.8%*

Net sales for the **Companion Animals** franchise were 9.8% lower at constant exchange rates, at €1,195 million. Sales of products in the **Frontline® / fipronil** range (down 17.8% at constant exchange rates, at €611 million) were affected by increased competition from prescription products and branded generics, and by unfavorable weather conditions in the United States and Western Europe; however, they performed well in Emerging Markets (up 16.1% at constant exchange rates, at €99 million).

Table of Contents

Sales of **Production Animals** franchise products rose by 2.1% at constant exchange rates to €790 million, driven by growth for avermectin products in the United States (up 3.6% at constant exchange rates, at €225 million).

The following table breaks down net sales of our Animal Health segment by product and by geographical region in 2013:

(€ million) **Product**	**Western Europe(1)**	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets(2)**	**Change at constant exchange rates**	**Rest of The World(3)**	**Change at constant exchange rates**
Frontline® and other fipronil-based products	177	-13.9%	289	-28.0%	99	+16.1%	46	-14.3%
Vaccines	182	+1.1%	152	+3.3%	374	+4.3%	19	-4.5%
Avermectin	58	-6.5%	225	+3.6%	59	-1.5%	71	+5.5%
Other products	85	-2.3%	81	-11.7%	55	+28.3%	13	-30.4%
Total Animal Health	**502**	**-6.1%**	**747**	**-12.8%**	**587**	**+7.4%**	**149**	**-7.2%**

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.*

(2) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(3) *Japan, Canada, Australia and New Zealand.*

Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table breaks down our 2013 and 2012 net sales by region:

(€ million)	**2013 Reported**	**2012 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
United States	10,433	10,873	-4.0%	-0.7%
Emerging Markets[(1)]	10,957	11,145	-1.7%	+4.4%

Of which Eastern Europe and Turkey	*2,673*	*2,721*	*-1.8%*	*+2.2%*
Of which Asia (excl. Pacific region)	*3,040*	*2,841*	*+7.0%*	*+10.1%*
Of which Latin America	*3,013*	*3,435*	*-12.3%*	*-1.5%*
Of which Africa	*1,028*	*1,018*	*+1.0%*	*+7.7%*
Of which Middle East	*1,071*	*1,001*	*+7.0%*	*+10.6%*
Western Europe[2]	7,831	8,335	-6.0%	-5.6%
Rest of the World[3]	3,730	4,594	-18.8%	-2.9%
Of which Japan	*2,507*	*3,274*	*-23.4%*	*-4.3%*
Total	**32,951**	**34,947**	**-5.7%**	**-0.5%**

(1)

World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(2)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3)

Japan, Canada, Australia and New Zealand.

In the United States, net sales fell by 0.7% at constant exchange rates to €10,433 million. Negative factors included the loss of exclusivity of Eloxatin® in August 2012 (down 97.4% at constant exchange rates), competition from generics of Lovenox® (down 39.5% at constant exchange rates), and supply limitations for Pentacel® and Adacel® in the Polio/Pertussis/Hib vaccines franchise (down 23.8% at constant exchange rates). Positive factors included strong performances by the Genzyme business (up 42.6% at constant exchange rates, at €777 million) and the Diabetes division (up 26.1% at constant exchange rates, at €3,862 million).

In Emerging Markets, net sales were €10,957 million, an increase of 4.4% at constant exchange rates. Growth was slowed by temporary difficulties in the Generics business in Brazil, but was mainly driven by the Diabetes division (up 16.1% at constant exchange rates, at €1,250 million), by the Vaccines segment (up 11.5% at constant exchange rates, at €1,341 million) and by Genzyme (up 33.3% at constant exchange rates, at €461 million). In China, net sales

Table of Contents

totaled €1,471 million, up 18.6% at constant exchange rates, reflecting strong performances by Plavix®, Aprovel®, Lantus® and the Vaccines segment. Russia posted sales of €901 million, up 12.0% at constant exchange rates, with Consumer Health Care and Generics having the most impact. Net sales in Brazil slipped by 18.2% at constant exchange rates to €1,111 million, affected by temporary difficulties in distribution channels for the Generics business.

Western Europe saw net sales fall by 5.6% at constant exchange rates to €7,831 million, hit by competition from generics of Aprovel® (down 39.1% at constant exchange rates) and Plavix® (down 16.3% at constant exchange rates) and by the impact of austerity measures.

In the Rest of the World, net sales were €3,730 million, down 2.9% at constant exchange rates. In Japan, net sales came to €2,507 million (down 4.3% at constant exchange rates), reflecting on the one hand the impact of generic competition on sales of Allegra® (down 18.4% at constant exchange rates, at €280 million) and Myslee® (down 17.1% at constant exchange rates, at €192 million) combined with lower sales of the Imovax® vaccine, but on the other hand a fine performance by Plavix® (up 13.3% at constant exchange rates, at €748 million).

Other Revenues

Other revenues, which mainly comprise royalties under licensing agreements contracted in connection with ongoing operations, fell by 64.9% to €355 million (compared with €1,010 million in 2012).

The decrease was largely due to lower licensing revenue under the worldwide alliance with BMS on Plavix® and Aprovel®, which represented €4 million in 2013 versus €532 million in 2012 (down 99.2% on a reported basis), due to the loss of exclusivity in the United States for Aprovel® (from March 30, 2012) and Plavix® (from May 17, 2012).

A further factor was a drop in royalties received from Amgen under a worldwide license for Enbrel®, reflecting the contractual termination of royalty payments on U.S. sales of the product in February 2013.

Gross Profit

Gross profit amounted to €22,316 million in 2013 (67.7% of net sales), versus €24,859 million in 2012 (71.1% of net sales). This represents a year-on-year fall of 10.2%, equivalent to a 3.4-point drop in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment was 3.1 points lower at 69.8%, reflecting not only the drop in royalty revenue (2.1 points) but also a deterioration in the ratio of cost of sales to net sales (1.0 point), due in particular to the adverse impact of generic competition and exchange rates, coupled with temporary difficulties in distribution channels for our generics in Brazil.

The gross margin ratio for the Vaccines segment was 6.3 points lower at 53.0%, as a result of an unfavorable product mix that was due partly to the temporary supply limitations for Pentacel® and Adacel®.

The gross margin ratio for the Animal Health segment fell by 2.5 points to 66.8%, reflecting lower sales of fipronil products.

Research and Development Expenses

Research and development (R&D) expenses amounted to €4,770 million in 2013 (versus €4,905 million in 2012) and represented 14.5% of net sales (versus 14.0% in 2012). The year-on-year reduction was €135 million, or 2.8%.

In the Pharmaceuticals segment, R&D expenses decreased by €116 million (2.8%), the principal factors being favorable exchange rate effects and ongoing transformation and project portfolio rationalization initiatives.

R&D expenses for the Vaccines segment fell by €20 million (3.7%), largely due to the end of enrollment of patients for clinical trials of the dengue fever vaccine.

In the Animal Health segment, R&D expenses were €1 million (0.6%) higher than in 2012.

Table of Contents

Selling and General Expenses

Selling and general expenses totaled €8,602 million, versus €8,929 million in 2012, a reduction of €327 million or 3.7%. These expenses represented 26.1% of net sales, versus 25.6% in 2012.

The Pharmaceuticals segment recorded a reduction of €289 million (3.8%), reflecting favorable exchange rate effects, despite increased spend on the Diabetes Solutions and Genzyme growth platforms in North America.

In the Vaccines segment, selling and general expenses were €21 million (3.4%) lower, again helped by favorable exchange rate effects and despite an increase in promotional spending, especially in China and Japan.

In the Animal Health segment, selling and general expenses were down €16 million (2.4%), due to a reduction in promotional spending and favorable exchange rate effects.

Other Operating Income and Expenses

In 2013, other operating income totaled €691 million (versus €562 million in 2012), and other operating expenses €242 million (versus €414 million in 2012).

Overall, other operating income and expenses represented net income of €449 million in 2013, versus net income of €148 million in 2012. This €301 million rise was mainly due to receipt of a payment of €92 million ($125 million) arising from a change to the contractual terms of the alliance with Warner Chilcott on Actonel® (see Note C.3. to our consolidated financial statements), a €93 million gain arising on the settlement of a dispute between Hoechst and Genentech relating to Rituxan®, and a €165 million gain on the sale to Covis Pharma of commercial rights to some pharmaceutical products in the United States.

This line item also includes a net operational foreign exchange loss of €64 million, versus €41 million in 2012.

Amortization of Intangible Assets

Amortization charged against intangible assets totaled €2,914 million in 2013, versus €3,291 million in 2012. the year-on-year decrease of €377 million was mainly due to a reduction in amortization charged against intangible assets recognized on the acquisition of Aventis (€1,199 million in 2013, versus €1,489 million in 2012) as some pharmaceutical products reached the end of their life cycles in the face of competition from generics, plus (to a lesser extent) favorable exchange rate effects.

Impairment of Intangible Assets

In 2013, this line showed impairment losses of €1,387 million against intangible assets, versus €117 million in 2012. The impairment losses recognized in 2013 related primarily to (i) Lemtrada (alemtuzumab) in the United States, following the refusal by the FDA to approve the U.S. marketing application for this product as it stands (€612 million); (ii) the discontinuation of the iniparib R&D project in non-small cell lung cancer and ovarian cancer (€384 million); and (iii) the discontinuation of the project on fedratinib, a selective JAK2 inhibitor in the treatment of polycythemia vera (€170 million).

In 2012, impairment losses related mainly to the discontinuation of R&D projects in the Pharmaceuticals segment, in particular development programs in oncology.

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net gain of €314 million in 2013, versus a net expense of €192 million in 2012. This item mainly relates to changes in the fair value of (i) the CVRs issued in connection with the Genzyme acquisition, (ii) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi, and (iii) the contingent consideration arising from the acquisition of TargeGen (see Note D.18. to our consolidated financial statements).

Table of Contents

Restructuring Costs

Restructuring costs amounted to €300 million in 2013, versus €1,141 million in 2012, and relate primarily to measures associated with the major transformation program that we initiated in 2009 to adapt our structures to the challenges of the future.

In 2013, these costs related mainly to employee-related expenses arising from headcount adjustment plans in France and the rest of Europe.

In 2012, these costs mainly related to measures taken to adapt our resources in France, transform our industrial facilities in Europe and make adjustments to our sales forces worldwide, along with the integration of Genzyme and impairment losses against property, plant and equipment in France.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in either 2013 or 2012.

Operating Income

Operating income totaled €5,106 million for 2013, versus €6,432 million for 2012, a fall of 20.6%. This year-on-year change reflected the drop in gross profit, but also the reduction in selling and general expenses, research and development expenses and restructuring costs.

Financial Income and Expenses

Net financial expense for 2013 was €503 million, versus €658 million for 2012, a decrease of €155 million.

Financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in section "3. Consolidated Balance sheet" below) amounted to €317 million in 2013, compared with €349 million in 2012. This decrease mainly reflects a reduction in both the average level of our total debt, and the average financing rate.

The reduction in net financial expense was mainly attributable to a decrease in the net interest cost on defined-benefit pension plans (€159 million, versus €198 million in 2012); a lower level of impairment losses on investments and financial assets (€8 million, versus €30 million in 2012), which related mainly to available-for-sale financial assets; and a net financial foreign exchange gain of €5 million (versus a net loss of €17 million in 2012).

Gains on disposals of non-current financial assets totaled €50 million (versus €37 million in 2012), and mainly related to divestments by Genzyme.

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures amounted to €4,603 million in 2013, versus €5,774 million in 2012, a fall of 20.3%.

Income Tax Expense

Income tax expense represented €763 million in 2013, versus €1,109 million in 2012, giving an effective tax rate (based on consolidated net income) of 16.6% in 2013 compared with 19.2% in 2012 (see Note D.30. to our consolidated financial statements).

The level of income tax expense was significantly impacted by the positive tax effect relating to the amortization and impairment of intangible assets (€1,466 million in 2013, versus €1,201 million in 2012) and to restructuring costs (€97 million in 2013, versus €370 million in 2012).

In 2013, this line also includes the "contribution on distributed income", a new French tax levied on the dividend payout to Sanofi shareholders (3%, equivalent to €109 million).

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 24.0% in 2013, versus 25.5% in 2012. This

Table of Contents

decrease was mainly due to the geographical mix of the results from Group entities, and to recent proceedings involving the tax authorities of various countries that had a positive net effect in 2013.

Share of Profit/Loss of Associates and Joint Ventures

The share of profits from associates and joint ventures was €35 million in 2013, versus €393 million in 2012. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which fell by 94.0% to €25 million (versus €420 million in 2012). The decline in our share was mainly attributable to the drop in sales of Plavix® in the United States due to the loss of exclusivity and competition from generics.

Net Income

Net income amounted to €3,875 million in 2013, versus €5,058 million in 2012.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests was €158 million in 2013, versus €169 million in 2012. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (€141 million, versus €149 million in 2012).

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi amounted to €3,717 million, versus €4,889 million in 2012.

Basic earnings per share for 2013 was €2.81, 24.3% lower than the 2012 figure of €3.71, based on an average number of shares outstanding of 1,323.1 million in 2013 (1,319.5 million in 2012). Diluted earnings per share for 2013 was €2.78 in 2013 (versus €3.68 in 2012), based on an average number of shares outstanding after dilution of 1,339.1 million in 2013 and 1,329.6 million in 2012.

Business Operating Income

Sanofi reports segment results on the basis of "Business Operating Income". This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See "Item 5. Operating and Financial Review and Prospects Segment information" above for the definition of business operating income and reconciliation to our Income before tax and associates and joint ventures.

Business operating income amounted to €9,324 million in 2013, 18.6% lower than in 2012 (€11,448 million) and represented 28.3% of net sales, versus 32.8% in 2012.

Business operating income for 2013 and 2012 is set forth below:

(€ million)	**2013**	**2012**	**Change**
Pharmaceuticals	7,887	9,601	-17.9%
Vaccines	909	1,157	-21.4%
Animal Health	502	673	-25.4%
Other	26	17	+52.9%
Business operating income	**9,324**	**11,448**	**-18.6%**

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance. See "Item 5. Operating and Financial Review and Prospects Business Net Income" above for the definition of business net income and reconciliation to our Net income

attributable to equity holders of Sanofi.

Business net income totaled €6,687 million in 2013, versus €8,101 million in 2012, a fall of 17.5%; it represented 20.3% of net sales, against 23.2% in 2012.

Table of Contents

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see " Business Net Income" above).

Business earnings per share were €5.05 in 2013, 17.8% lower than the 2012 figure of €6.14, based on an average number of shares outstanding of 1,323.1 million in 2013 and 1,319.5 million in 2012.

Year Ended December 31, 2012 Compared with Year Ended December 31, 2011

The consolidated income statements for the years ended December 31, 2012 and December 31, 2011 break down as follows:

(under IFRS) *(€ million)*	**2012(1)**	**as % of net sales**	**2011(1)**	**as % of net sales**
Net sales	**34,947**	**100.0%**	**33,389**	**100.0%**
Other revenues	1,010	2.9%	1,669	5.0%
Cost of sales	(11,098)	(31.8%)	(10,865)	(32.5%)
Gross profit	**24,859**	**71.1%**	**24,193**	**72.5%**
Research & development expenses	(4,905)	(14.0%)	(4,788)	(14.3%)
Selling & general expenses	(8,929)	(25.6%)	(8,508)	(25.5%)
Other operating income	562		319	
Other operating expenses	(414)		(273)	
Amortization of intangible assets	(3,291)		(3,314)	
Impairment of intangible assets	(117)		(142)	
Fair value remeasurement of contingent consideration liabilities	(192)		15	
Restructuring costs	(1,141)		(1,314)	
Other gains and losses, and litigation			(327)	
Operating income	**6,432**	**18.4%**	**5,861**	**17.6%**
Financial expenses	(751)		(744)	
Financial income	93		140	
Income before tax and associates and joint ventures	**5,774**	**16.5%**	**5,257**	**15.7%**
Income tax expense	(1,109)		(440)	

Share of profit/(loss) of associates and joint ventures	393		1,070	
Net income	**5,058**	**14.5%**	**5,887**	**17.6%**
Net income attributable to non-controlling interests	169		241	
Net income attributable to equity holders of Sanofi	**4,889**	**14.0%**	**5,646**	**16.9%**
Average number of shares outstanding (million)	1,319.5		1,321.7	
Average number of shares outstanding after dilution (million)	1,329.6		1,326.7	
Basic earnings per share (in euros)	3.71		4.27	
Diluted earnings per share (in euros)	3.68		4.26	

(1)

Includes the impact of applying the amended IAS 19 (see Note A.2.2. to our consolidated financial statements included at Item 18 of this annual report).

Our consolidated income statements include the results of the operations of Genzyme from April 2011. In order to help investors gain a better understanding of our performances, in the narrative discussion of certain income statement line items ("net sales", "research & development expenses", and "selling & general expenses"), we include non-consolidated 2011 first-quarter data for Genzyme in additional analyses.

Table of Contents

Net Sales

Net sales for the year ended December 31, 2012 amounted to €34,947 million, up 4.7% on 2011. Exchange rate movements had a favorable effect of 4.2 points, mainly reflecting the appreciation of the U.S. dollar against the euro, and to a lesser extent the appreciation of the yen and the yuan. At constant exchange rates and after taking account of changes in structure (mainly the consolidation of Genzyme from April 2011), net sales rose by 0.5% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2012 and December 31, 2011 to our net sales at constant exchange rates:

(€ million)	**2012**	**2011**	**Change**
Net sales	**34,947**	**33,389**	**+4.7%**
Effect of exchange rates	(1,400)		
Net sales at constant exchange rates	**33,547**	**33,389**	**+0.5%**

Our net sales comprise the net sales generated by our Pharmaceuticals, Human Vaccines (Vaccines) and Animal Health segments.

The following table breaks down our 2012 and 2011 net sales by business segment:

(€ million)	**2012 Reported**	**2011 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Pharmaceuticals	28,871	27,890	+3.5%	-0.4%
Vaccines	3,897	3,469	+12.3%	+5.7%
Animal Health	2,179	2,030	+7.3%	+3.1%
Total	**34,947**	**33,389**	**+4.7%**	**+0.5%**

Net Sales by Product Pharmaceuticals segment

Net sales generated by our Pharmaceuticals segment were €28,871 million in 2012, up 3.5% on a reported basis but down 0.4% at constant exchange rates. The year-on-year change (increase of €981 million) reflects the positive effect of exchange rates (€1,082 million) on the one hand, and the following impacts at constant exchange rates on the other hand:

the positive impact of consolidating Genzyme from April 2011 (non-consolidated sales of €733 million were generated by Genzyme in the first quarter of 2011);

the performance of growth platforms (€1,381 million);

the negative effects of generic competition (mainly on sales of Lovenox®, Taxotere® and Eloxatin® in the United States, and of Taxotere®, Plavix® and Aprovel® in Western Europe), totaling €1,345 million;

the ending of the co-promotion agreement with Teva on Copaxone® and the divestiture of the Dermik business in 2011 (negative effects of €559 million); and

other impacts (negative effects of €311 million), including the negative impact of austerity measures in the European Union.

On a constant structure basis and at constant exchange rates (which primarily means including the non-consolidated sales of Genzyme for the first quarter of 2011 and excluding sales of Copaxone® for the whole of 2011), net sales for the Pharmaceuticals segment fell by 0.6% in 2012.

Our flagship products (Lantus® and Apidra®, Cerezyme®, Myozyme® / Lumizyme®, Fabrazyme®, Aubagio®, Multaq®, Jevtana®, Mozobil®, Zaltrap®, Lovenox®, Renagel® / Renvela®, Allegra®, Stilnox® / Ambien® / Myslee®, Synvisc® / Synvisc-One®, Taxotere® and Eloxatin®) are discussed below. Sales of Plavix® and Aprovel® are discussed further below under " Worldwide Presence of Plavix® and Aprovel®".

Table of Contents

The following table breaks down our 2012 and 2011 net sales for the Pharmaceuticals segment by product:

(€ million)				Change on a reported basis	Change at constant exchange rates
Product	**Indication**	**2012 Reported**	**2011 Reported**		
Lantus®	Diabetes	4,960	3,916	+26.7%	+19.3%
Apidra®	Diabetes	230	190	+21.1%	+16.8%
Amaryl®	Diabetes	421	436	-3.4%	-8.0%
Insuman®	Diabetes	135	132	+2.3%	+3.0%
Other products		36	10	+260.0%	+250.0%
Total: Diabetes	**Diabetes**	**5,782**	**4,684**	**+23.4%**	**+16.7%**
Eloxatin®	Colorectal cancer	956	1,071	-10.7%	-17.3%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	563	922	-38.9%	-41.9%
Jevtana®	Prostate cancer	235	188	+25.0%	+20.2%
Thymoglobulin®(1)	Organ rejection	193	128		
Zaltrap®	Colorectal cancer	25			
Mozobil®(1)	Hematologic malignancies	96	59		
Other products(1)		326	261		
Total: Oncology(1)		**2,394**	**2,629**	**-8.9%**	**-14.3%**
Cerezyme®(1)	Gaucher disease	633	441		
Myozyme®/Lumizyme®(1)	Pompe disease	462	308		
Fabrazyme®(1)	Fabry disease	292	109		
Aldurazyme®(1)	Mucopolysaccharidosis	150	100		
Other products(1)		241	164		
Sub-total: Rare diseases(1)		**1,778**	**1,122**		

Aubagio®	Multiple sclerosis	7			
Sub-total: Multiple sclerosis		**7**			
Total: Genzyme(1)		**1,785**	**1,122**		
Plavix®	Atherothrombosis	2,066	2,040	+1.3%	-4.6%
Lovenox®	Thrombosis	1,893	2,111	-10.3%	-12.0%
Aprovel®/CoAprovel®	Hypertension	1,151	1,291	-10.8%	-13.3%
Renagel®/Renvela®(1)	Hyperphosphatemia	653	415		
Allegra®	Allergic rhinitis, urticaria	553	580	-4.7%	-9.5%
Stilnox®/Ambien®/Myslee®	Sleep disorders	497	490	+1.4%	-4.5%
Depakine®	Epilepsy	410	388	+5.7%	+3.1%
Synvisc®/Synvisc-One®(1)	Arthritis	363	256		
Tritace®	Hypertension	345	375	-8.0%	-8.3%
Multaq®	Atrial fibrillation	255	261	-2.3%	-8.0%
Lasix®	Edema, hypertension	210	213	-1.4%	-3.8%
Targocid®	Bacterial infections	198	200	-1.0%	-2.5%
Orudis®	Rheumatoid arthritis, osteoarthritis	184	158	+16,5%	+15.8%
Cordarone®	Arrhythmia	163	160	+1.9%	-2.5%
Xatral®	Benign prostatic hypertrophy	130	200	-35.0%	-37.0%
Actonel®	Osteoporosis, Paget's disease	134	167	-19.8%	-21.6%
Other prescription products		4,853	5,738	-15.4%	-17.4%
Total: Other prescription products(1)		**14,058**	**15,043**	**-6.5%**	**-9.6%**
Consumer Health Care		**3,008**	**2,666**	**+12.8%**	**+9.9%**
Generics		**1,844**	**1,746**	**+5.6%**	**+5.0%**
Total Pharmaceuticals		**28,871**	**27,890**	**+3.5%**	**-0.4%**

(1)

In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).

Table of Contents

Diabetes division

Net sales for the Diabetes division amounted to €5,782 million, up 16.7% at constant exchange rates, driven by strong growth for Lantus®.

Lantus® posted a 19.3% increase in net sales at constant exchange rates in 2012 to €4,960 million, driven by very strong growth in the United States (up 22.0% at €3,087 million); in Emerging Markets (up 25.4% at €793 million), especially in China (up 35.9%) and Latin America (up 32.3%); and in Japan (up 22.0%). In Western Europe, growth was a more modest 5.3% at constant exchange rates.

Net sales of the rapid-acting insulin analog **Apidra®** advanced by 16.8% (at constant exchange rates) to €230 million in 2012, buoyed by the product's performance in Emerging Markets (up 37.8%).

Amaryl® saw net sales fall by 8.0% at constant exchange rates to €421 million, mainly as a result of competition from generics in Japan (down 31.7%, at €125 million), and in spite of 11.4% growth in Emerging Markets to €263 million.

Oncology business

Net sales for the Oncology business were €2,394 million, down 14.3% at constant exchange rates.

Net sales of **Eloxatin®** fell by 17.3% at constant exchange rates to 956 million in 2012, reflecting the loss of exclusivity in the United States on August 9, 2012, which had been expected.

Taxotere® reported a fall in net sales of 41.9% at constant exchange rates, to €563 million. The product faced competition from generics in Western Europe (down 72.5%) and the United States (down 80.2%). Emerging Markets sales amounted to €270 million, down 11.2% at constant exchange rates.

Jevtana® posted net sales of €235 million in 2012, up 20.2% at constant exchange rates, boosted by product launches in various countries in Western Europe (€91 million, up 104.5% at constant exchange rates) and in Emerging Markets.

Zaltrap®, launched in the United States and Puerto Rico at the end of August 2012, generated net sales of €25 million for the year.

Mozobil® reported net sales of €96 million, up 19.7% on a constant structure basis and at constant exchange rates (i.e., including non-consolidated sales generated by Genzyme in the first quarter of 2011).

Jevtana®, Zaltrap® and Mozobil®, along with Multaq® (see " Other pharmaceutical products" below), form the "Other Innovative Products" growth platform. This platform generated net sales of €611 million in 2012.

Genzyme business

The Genzyme business consists of products used to treat rare diseases, and products for the treatment of multiple sclerosis (Aubagio® and the experimental agent Lemtrada). Because Genzyme's net sales have been consolidated from the acquisition date (i.e. the start of April 2011), the 2011 consolidated net sales of the Genzyme business do not include sales for the first quarter of 2011. On a constant structure basis and at constant exchange rates, i.e. after including non-consolidated net sales for the first quarter of 2011, the net sales of the Genzyme business rose by 16.9% in 2012 to € 1,785 million.

Table of Contents

The following table breaks down our 2012 and 2011 net sales for the Genzyme business by product:

(€ million) **Product**	**Indication**	**2012 Reported**	**2011 Reported**	**Change on a constant structure basis and at constant exchange rates**
Aubagio®	Multiple sclerosis	7		
Sub-total: Multiple sclerosis		**7**		
Cerezyme®[(1)]	Gaucher disease	633	441	+6.0%
Myozyme®/Lumizyme®[(1)]	Pompe disease	462	308	+11.4%
Fabrazyme®[(1)]	Fabry disease	292	109	+96.4%
Aldurazyme®[(1)]	Mucopolysaccharidosis	150	100	+9.8%
Other rare disease products[(1)]		241	164	+6.1%
Sub-total: Rare diseases[(1)]		**1,778**	**1,122**	**+16.4%**
Total: Genzyme[(1)]		**1,785**	**1,122**	**+16.9%**

(1) *In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).*

Cerezyme® recorded net sales growth of 6.0% on a constant structure basis and at constant exchange rates, to €633 million (+0.9% in Western Europe, at €215 million; +6.3% in the United States, at €166 million). Production continued to improve during the year, enabling normal doses to be delivered to patients in the product's principal markets.

Net sales of **Myozyme®/Lumizyme®** were up 11.4% on a constant structure basis and at constant exchange rates at €462 million (+10,4% in Western Europe, at €257 million; +6.9% in the United States, at €117 million).

Fabrazyme® reported a 96.4% surge in net sales on a constant structure basis and at constant exchange rates, to €292 million. This increase was due mainly to the resumption of production at the new facility at Framingham (United States) in March 2012, enabling full doses to be supplied in all markets where the product is approved for sale.

For more information regarding the manufacturing issues related to Cerezyme® and Fabrazyme® see "Item 4. Information on the Company Production and Raw Materials."

In multiple sclerosis, **Aubagio®** was launched in the United States in October 2012, and recorded fourth-quarter net sales of €7 million.

Other pharmaceutical products

Lovenox® recorded a fall in net sales of 12.0% at constant exchange rates to €1,893 million in 2012, as a result of competition from generics in the United States, where sales slipped by 53.1% (at constant exchange rates) to €319 million. Sales generated outside the United States

accounted for 83.1% of worldwide net sales and rose by 5.5% at constant exchange rates to €1,574 million, driven by Emerging Markets (up 11.6% at constant exchange rates at €615 million). Sanofi also launched its own generic version of Lovenox® in the United States, sales of which are recognized in the Generics business.

Net sales of **Renagel®/Renvela®** rose by 13.0% on a constant structure basis and at constant exchange rates (i.e. including non-consolidated sales generated by Genzyme in the first quarter of 2011) to €653 million, on a fine performance in the United States (up 19.2% on a constant structure basis and at constant exchange rates).

Synvisc®/Synvisc-One® reported sales growth of 4.0% on a constant structure basis and at constant exchange rates (including non-consolidated sales generated by Genzyme in the first quarter of 2011) to €363 million, driven mainly by the Synvisc-One® franchise in the United Sates (€302 million, up 5.7% on a constant structure basis and at constant exchange rates).

Net sales of the **Ambien®** range fell by 4.5% at constant exchange rates to €497 million, reflecting competition from generics of Ambien® CR in the United States and Western Europe and the introduction of generic versions of Myslee® in Japan during the second half of 2012.

Table of Contents

Allegra® reported a decline in net sales as a prescription medicine (down 9.5% at constant exchange rates) to €553 million, reflecting lower prices in Japan (down 15.2% at constant exchange rates, at € 423 million). This product is sold over the counter in the United States, and has also been available over the counter in Japan since November 2012. Sales over the counter are recognized in the Consumer Health Care business. In August 2012 three generic versions of Allegra® were approved by the regulatory authorities in Japan; since February 2013, Allegra® as a prescription medicine has been subject to generic competition in this country.

Net sales of **Multaq®** fell by 8.0% at constant exchange rates to €255 million, due to the effect of restrictions placed on the product's indication during the second half of 2011.

Net sales of **Copaxone®** (reported under the line item "Other prescription products") amounted to €24 million, versus €436 million in 2011, down 94.7% (at constant exchange rates), reflecting the ending of the co-promotion agreement with Teva in all territories in the first quarter of 2012. Since the transfer of Copaxone® to Teva, we no longer recognize net sales of the product. Instead, for the two years following the transfer we are entitled to receive a payment representing 6% of net sales, which we recognize under the income statement line item "Other revenues".

Consumer Health Care business

Net sales for the **Consumer Health Care** business rose by 9.9% at constant exchange rates in 2012, to €3,008 million. This figure includes revenues generated from the acquisitions made in 2011 (primarily BMP Sunstone in China, and the nutraceuticals business of Universal Medicare in India).

In Emerging Markets, net sales advanced by 19.9% at constant exchange rates to €1,478 million. In the United States, sales growth was modest (up 2.2% at constant exchange rates, at €606 million) compared with 2011; this reflects the fact that in the early part of 2011, distributors were building up inventories of the over-the-counter (OTC) version of Allegra®, launched in March 2011. Excluding Allegra® OTC, growth in the United States reached 6.2% at constant exchange rates. Allegra® OTC was also launched in Japan in November 2012.

Generics business

The **Generics** business reported net sales of €1,844 million in 2012, a rise of 5.0% at constant exchange rates. The business was boosted by sales growth in the United States (up 42.4% at constant exchange rates, at €272 million), where we launched our own authorized generic versions of Lovenox® and Aprovel®. In Emerging Markets, net sales fell slightly (down 2.7% at constant exchange rates) to €1,045 million, due to the impact of tougher competition and disruptions in the Brazilian market.

Table of Contents

The following table breaks down net sales of our Pharmaceutical segment products by geographical region in 2012:

(€ million)								
Product	**Western Europe(1)**	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets(2)**	**Change at constant exchange rates**	**Rest of the world(3)**	**Change at constant exchange rates**
Lantus®	778	+5.3%	3,087	+22.0%	793	+25.4%	302	+20.6%
Apidra®	78	+14.7%	73	+3.1%	51	+37.8%	28	+30.0%
Amaryl®	28	-12.5%	3	-25.0%	263	+11.4%	127	-32.6%
Insuman®	98	-4.9%	1		37	+27.6%	(1)	
Other products	30	+190.0%	3				3	
Total: Diabetes	**1,012**	**+4.3%**	**3,167**	**+21.5%**	**1,144**	**+22.5%**	**459**	**+0.2%**
Eloxatin®	13	-65.8%	718	-18.0%	153	-10.5%	72	+3.1%
Taxotere®	53	-72.5%	53	-80.2%	270	-11.2%	187	-10.7%
Jevtana®	91	+104.5%	109	-23.7%	33	+153.8%	2	
Thymoglobulin®(4)	29		98		50		16	
Zaltrap®			24				1	
Mozobil®(4)	30		56		7		3	
Other products(4)	75		183		45		23	
Total: Oncology	**291**	**-23.7%**	**1,241**	**-19.8%**	**558**	**0.0%**	**304**	**-1.7%**
Cerezyme®(4)	215		166		190		62	
Myozyme®/Lumizyme®(4)	257		117		55		33	
Fabrazyme®(4)	52		152		41		47	
Aldurazyme®(4)	58		26		47		19	
Other products(4)	34		96		36		75	
Sub-total Rare diseases(4)	**616**		**557**		**369**		**236**	

Aubagio®			7					
Sub-total Multiple sclerosis			**7**					
Total: Genzyme(4)	**616**		**564**		**369**		**236**	
Plavix®	307	-25.8%	76*	-62.2%	799	+5.5%	884	+13.4%
Lovenox®	854	+1.9%	319	-53.1%	615	+11.6%	105	+2.1%
Aprovel®/CoAprovel®	557	-26.4%	45*	-8.2%	395	+2.5%	154	+17.5%
Renagel®/Renvela®(4)	128		451		53		21	
Allegra®	11	-15.4%	(1)	-133.3%	120	+21.2%	423	-15.1%
Stilnox®/Ambien®/Myslee®	46	-13.2%	85	-4.9%	70	+7.7%	296	-5.5%
Depakine®	143	-3.4%			251	+7.9%	16	-6.3%
Synvisc®/Synvisc-One®(4)	20		302		24		17	
Tritace®	150	-11.8%			180	-1.1%	15	-37.5%
Multaq®	46	-31.8%	200	+0.5%	8	0.0%	1	-25.0%
Lasix®	79	-3.7%	3	0.0%	62	+7.0%	66	-12.7%
Targocid®	86	-9.5%			90	-3.3%	22	+53.8%
Orudis®	51	+6.3%			129	+20.8%	4	
Cordarone®	28	-9.7%			76	+7.4%	59	-9.8%
Xatral®	45	-24.1%	20	-74.7%	62	-6.3%	3	0.0%
Actonel®	33	-38.9%			66	-16.7%	35	-5.7%
Other prescription products	1,900	-27.0%	585	-20.5%	1,731	-4.6%	637	-11.4%
Total: Other prescription products(4)	**4,484**	**-19.2%**	**2,085**	**-18.7%**	**4,731**	**+2.6%**	**2,758**	**-2.5%**
Consumer Health Care	**666**	**+2.2%**	**606**	**+2.2%**	**1,478**	**+19.9%**	**258**	**-2.1%**
Generics	**500**	**+11.5%**	**272**	**+42.4%**	**1,045**	**-2.7%**	**27**	**-29.4%**
Total pharmaceuticals	**7,569**	**-9.9%**	**7,935**	**+0.9%**	**9,325**	**+7.8%**	**4,042**	**-0.3%**

(1)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)

World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(3)

Japan, Canada, Australia and New Zealand.

(4)

In 2011, net sales of Genzyme products were recognized from the acquisition date (April 2011).

*

Sales of active ingredient to the entity majority-owned by BMS in the United States.

Table of Contents

Net Sales Human Vaccines (Vaccines) segment

Net sales for the Vaccines segment amounted to €3,897 million in 2012, up 12.3% on a reported basis and 5.7% at constant exchange rates.

The following table presents the 2012 and 2011 sales of our Vaccines segment by range of products:

(€ million)	**2012 Reported**	**2011 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Polio/Pertussis/Hib Vaccines (*including Pentacel® and Pentaxim®*)	1,184	1,075	+10.1%	+5.0%
Influenza Vaccines (*including Vaxigrip® and Fluzone®*)	884	826	+7.0%	-0.2%
Meningitis/Pneumonia Vaccines (*including Menactra®*)	650	510	+27.5%	+18.0%
Adult Booster Vaccines (*including Adacel®*)	496	465	+6.7%	0.0%
Travel and Other Endemics Vaccines	364	370	-1.6%	-4.9%
Other Vaccines	319	223	+43.0%	+31.8%
Total Vaccines	**3,897**	**3,469**	**+12.3%**	**+5.7%**

Polio/Pertussis/Hib vaccines saw net sales increase by 5.0% at constant exchange rates to €1,184 million. This rise reflects a strong performance in Japan (€239 million, up 140.9% at constant exchange rates, mainly due to the successful launch of Imovax® in September 2012) and a good performance in Emerging Markets (€495 million, up 5.7% at constant exchange rates), but also a drop in net sales in the United States (down 25.1% at constant exchange rates, at €374 million) due to supply limitations for Pentacel® and Adacel® following a temporary shutdown in production at Sanofi Pasteur.

Net sales of **Influenza** vaccines were flat (down 0.2% at constant exchange rates), at €884 million. In the United States, net sales fell by 5.5% at constant exchange rates, to €466 million; in Emerging Markets, net sales rose by 5.1% at constant exchange rates, to €317 million.

Meningitis/Pneumonia vaccines posted net sales of €650 million, up 18.0% at constant exchange rates, driven by a strong performance from Menactra® (€564 million, up 21.8% at constant exchange rates). Growth was especially strong in Emerging Markets (up 52.9% at constant exchange rates, at €165 million) and in the United States (up 10.5% at constant exchange rates, at €473 million).

Net sales of **Adult Booster** vaccines were unchanged year-on-year (at constant exchange rates), at €496 million.

Net sales of **Travel and Other Endemics** vaccines fell by 4.9% (at constant exchange rates) to €364 million, hit by a temporary shutdown in production of the Theracys®/Immucyst® and BCG vaccines.

In addition to the Vaccines activity reflected in our consolidated net sales, sales of Sanofi Pasteur MSD, our joint venture with Merck & Co., Inc. in Europe, amounted to €845 million in 2012, up 6.8% on a reported basis. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales. The main growth drivers were the performance of Gardasil® (up 13.6% on a reported basis, at €206 million) and sales of the travel and endemics vaccines franchise.

Table of Contents

The following table presents the 2012 sales of our Vaccines segment by range of products and by region:

(€ million)	**Western Europe(1) Reported**	**Change at constant exchange rates**	**United States Reported**	**Change at constant exchange rates**	**Emerging Markets(2) Reported**	**Change at constant exchange rates**	**Rest of the world(3) Reported**	**Change at constant exchange rates**
Polio/Pertussis/Hib Vaccines (*inc. Pentacel® and Pentaxim®*)	55	+52.8%	374	-25.1%	495	+5.7%	260	+105.0%
Influenza Vaccines (*inc. Vaxigrip® and Fluzone®*)	79	+2.6%	466	-5.1%	317	+5.1%	22	+16.7%
Meningitis/Pneumonia Vaccines (*inc. Menactra®*)	4	+33.3%	473	+10.5%	165	+52.9%	8	-38.5%
Adult Booster Vaccines (*inc. Adacel®*)	59	-22.4%	372	+0.9%	45	+50.0%	20	-5.0%
Travel and Other Endemics Vaccines	21	-12.5%	96	-1.1%	201	-4.8%	46	-8.5%
Other Vaccines	9	-46.7%	277	+46.6%	18	0.0%	15	-25.0%
Total Vaccines	**227**	**-2.2%**	**2,058**	**-0.7%**	**1,241**	**+9.1%**	**371**	**+48.9%**

(1) *France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark. Net sales in Europe generated by Sanofi Pasteur MSD (the joint venture between Sanofi and Merck & Co., Inc.) are not consolidated.*

(2) *World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.*

(3) *Japan, Canada, Australia and New Zealand.*

In Western Europe and the United States, net sales fell slightly (by 2.2% and 0.7% at constant exchange rates, respectively). In Emerging Markets, most of the rise in sales (9.1% at constant exchange rates) was generated in Latin America and China. The Rest of the World region reported strong growth (48.9% at constant exchange rates), due mainly to the performance of Imovax® in Japan.

Net Sales Animal Health segment

The Animal Health segment achieved net sales of €2,179 million in 2012, up 3.1% at constant exchange rates (7.3% on a reported basis), driven by the performance in Emerging Markets and the first-time consolidation of the net sales of Newport Laboratories ("Newport").

The following table presents the 2012 and 2011 sales of our Animal Health segment by range of products:

(€ million)	**2012 Reported**	**2011 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
Companion animals	1,372	1,277	+7.4%	+1.9%
Production animals	807	753	+7.2%	+5.1%
Total Animal Health	**2,179**	**2,030**	**+7.3%**	**+3.1%**
Of which Frontline® and other fipronil-based products	*775*	*764*	*+1.4%*	*-3.4%*
Of which Vaccines	*730*	*662*	*+10.3%*	*+7.6%*
Of which Avermectin	*423*	*372*	*+13.7%*	*+7.8%*
Of which Other products	*251*	*232*	*+8.2%*	*+3.9%*

Net sales for the **companion animals** franchise rose by 1.8% at constant exchange rates to €1,372 million. Erosion in sales of the **Frontline®/fipronil** range of products was limited to 3.4% at constant exchange rates (€775 million) despite competitive pressure in the United States (down 7.8% at constant exchange rates, at €411 million), thanks to good performances in Emerging Markets (up 10.5%, at €93 million).

Net sales for the **production animals** franchise were 5.1% higher at constant exchange rates, at €807 million. These figures include the contribution from Newport from April 2012 onwards.

Table of Contents

The following table breaks down net sales of our Animal Health segment by product and by geographical region in 2012:

(€ million) **Product**	**Western Europe(1)**	**Change at constant exchange rates**	**United States**	**Change at constant exchange rates**	**Emerging Markets(2)**	**Change at constant exchange rates**	**Rest of The World(3)**	**Change at constant exchange rates**
Frontline® and other fipronil-based products	208	-0.5%	411	-7.8%	93	+10.5%	63	-3.3%
Vaccines	181	-7.7%	152	+11.1%	375	+14.2%	22	+31.3%
Avermectin	62	-4.7%	223	+15.8%	65	+10.0%	73	-2.8%
Other products	88	-2.2%	94	+1.1%	46	+27.8%	23	0.0%
Total Animal Health	**539**	**-3.8%**	**880**	**+1.4%**	**579**	**+14.0%**	**181**	**+0.6%**

(1)
France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(2)
World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(3)
Japan, Canada, Australia and New Zealand.

Net Sales by Geographical Region

We divide our sales geographically into four regions: the United States, Emerging Markets, Western Europe and the Rest of the World. The following table breaks down our 2012 and 2011 net sales by region:

(€ million)	**2012 Reported**	**2011 Reported**	**Change on a reported basis**	**Change at constant exchange rates**
United States	10,873	9,957	+9.2%	+0.7%
Emerging Markets[(1)]	11,145	10,133	+10.0%	+8.3%
Of which Eastern Europe and Turkey	*2,721*	*2,666*	*+2.1%*	*+2.1%*
Of which Asia (excl. Pacific region)	*2,841*	*2,416*	*+17.6%*	*+10.1%*

Of which Latin America	*3,435*	*3,111*	*+10.4%*	*+11.3%*
Of which Africa	*1,018*	*949*	*+7.3%*	*+8.3%*
Of which Middle East	*1,001*	*872*	*+14.8%*	*+12.2%*
Western Europe[(2)]	8,335	9,130	-8.7%	-9.3%
Rest of the World[(3)]	4,594	4,169	+10.2%	+2.5%
Of which Japan	*3,274*	*2,865*	*+14.3%*	*+6.6%*
Total	**34,947**	**33,389**	**+4.7%**	**+0.5%**

(1)

World excluding United States, Canada, Western Europe, Japan, Australia and New Zealand.

(2)

France, Germany, United Kingdom, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland, Norway, Iceland, Denmark.

(3)

Japan, Canada, Australia and New Zealand.

In the United States, net sales were up 0.7% at constant exchange rates (but fell by 2.8% after including Genzyme in the first quarter of 2011) to €10,873 million. The year-on-year change reflected strong performances from Lantus® and from the Genzyme and Generics businesses (including our own generic version of Lovenox®), but also the impact of generics of Taxotere®, Lovenox® and Eloxatin®.

In Emerging Markets, net sales reached €11,145 million, up 8.3% at constant exchange rates (or 7.2% after including Genzyme for the first quarter of 2011). In China, net sales were €1,249 million, up 15.0% at constant exchange rates, on a strong performance from Plavix® and Lantus®. In Brazil, net sales increased by 7.7% at constant exchange rates to €1,530 million, boosted by the Consumer Health Care business and the contribution from Genzyme, although growth was hampered by a slowdown in sales of generics. The Africa and Middle East zones topped the billion-euro mark for the first time (€1,018 million and €1,001 million, respectively). Sales in Russia reached €851 million, up 13.6% at constant exchange rates, driven by the Consumer Health Care and Generics businesses and also by Lantus®, Plavix® and Lovenox®.

Table of Contents

Net sales in Western Europe fell by 9.3% at constant exchange rates to €8,335 million, hampered by the transfer of the Copaxone® business to Teva; by competition from generics of Taxotere® (down 72.5% at constant exchange rates), Aprovel® (down 26.4% at constant exchange rates) and Plavix® (down 25.8% at constant exchange rates); and by the impact of austerity measures implemented by European governments. After including Genzyme for the first quarter of 2011 and excluding Copaxone®, net sales fell by 7.5% at constant exchange rates.

In the Rest of the World region, net sales totaled €4,594 million, up 2.5% at constant exchange rates (or 0.8% after including Genzyme sales for the first quarter of 2011). In Japan, net sales were €3,274 million (up 6.6% at constant exchange rates, or 4.7% after including Genzyme sales for the first quarter of 2011); positive factors included strong performances from Plavix® (up 16.0% at constant exchange rates, at €837 million) and from the Polio/Pertussis/Hib vaccines franchise (up 140.9% at constant exchange rates at €239 million, driven by the successful launch of Imovax®), while negative factors included erosion in sales of Allegra® (down 15.2% at constant exchange rates, at €423 million) and the impact of bi-annual price cuts.

Worldwide Presence of Plavix® and Aprovel®

Two of our leading products Plavix® and Aprovel® were discovered by Sanofi and jointly developed with BMS under an alliance agreement. In all territories except Japan, these products are sold either by Sanofi or by BMS in accordance with the terms of this alliance agreement applicable in 2012 and 2011 (see " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above). Plavix® and Aprovel® lost exclusivity in the U.S. on May 17, 2012 and March 30, 2012, respectively.

Worldwide sales of these two products in 2012 and 2011 are an important indicator because they facilitate a financial statement user's understanding and analysis of our consolidated income statement, particularly in terms of understanding our overall profitability in relation to consolidated revenues, and also facilitate a user's ability to understand and assess the effectiveness of our research and development efforts.

Also, disclosing sales made by BMS of these two products in 2012 and 2011 enables the users to have a clearer understanding of trends in different lines of our income statement, in particular the lines "*Other revenues"*, where we record royalties received on those sales (see " Other Revenues"); "*Share of profit/loss of associates and joint ventures"* (see " Share of Profit/Loss of Associates and Joint Ventures"), where we record our share of the profit/loss of entities included in the BMS Alliance and under BMS operational management; and "*Net income attributable to non-controlling interests"* (see " Net Income Attributable to Non-Controlling Interests"), where we record the BMS share of the profit/loss of entities included in the BMS Alliance and under our operational management.

On September 27, 2012, Sanofi and BMS restructured their alliance with effect from January 1, 2013 (see " Financial Presentation of Alliances Alliance arrangements with Bristol-Myers Squibb" above).

Table of Contents

The table below sets forth the worldwide sales of Plavix® and Aprovel® in 2012 and 2011, by geographic region:

	2012			2011				
(€ million)	**Sanofi(2)**	**BMS(3)**	**Total**	**Sanofi(2)**	**BMS(3)**	**Total**	**Change on a reported basis**	**Change at constant exchange rates**
Plavix®/Iscover®(1)								
Europe	424	29	**453**	530	44	**574**	-21.1%	-21.2%
United States		1,829	**1,829**		4,759	**4,759**	-61.6%	-63.7%
Other countries	1,613	89	**1,702**	1,370	286	**1,656**	+2.8%	-4.6%
Total	**2,037**	**1,947**	**3,984**	**1,900**	**5,089**	**6,989**	**-43.0%**	**-46.2%**
Aprovel®/Avapro® /Karvea®/Avalide®(4)								
Europe	527	99	**626**	694	130	**824**	-24.0%	-24.3%
United States	24	110	**134**		374	**374**	-64.2%	-66.5%
Other countries	521	91	**612**	451	156	**607**	+0.8%	-5.1%
Total	**1,072**	**300**	**1,372**	**1,145**	**660**	**1,805**	**-24.0%**	**-26.6%**

(1) *Plavix® is marketed under the trademarks Plavix® and Iscover®.*

(2) *Net sales of Plavix® consolidated by Sanofi, excluding sales to BMS (€86 million in 2012 and €208 million in 2011). Net sales of Aprovel® consolidated by Sanofi, excluding sales to BMS (€111 million in 2012 and €150 million in 2011).*

(3) *Translated into euros by Sanofi using the method described in Note B.2. "Foreign currency translation" to our consolidated financial statements included at Item 18 in this annual report.*

(4) *Aprovel® is marketed under the trademarks Aprovel®, Avapro®, Karvea® and Avalide®.*

Worldwide sales of Plavix®/Iscover® fell by 46.2% at constant exchange rates in 2012 to €3,984 million, under the impact of competition from generics in the United States and Europe. In the United Sates, where the product lost exclusivity on May 17, 2012, sales (consolidated by BMS) were down 63.7% at constant exchange rates, at €1,829 million. In Europe, net sales of Plavix® fell by 21.2% at constant exchange rates, to €453 million. In the Other Countries region, net sales were down 4.6% at constant exchange rates; this reflected the entry of generics into the Canadian market (where sales, consolidated by BMS, dipped by 76.1% at constant exchange rates to €50 million), but also the continuing success of the product in Japan and China where net sales (consolidated by Sanofi) reached €837 million (up 16.0% at constant exchange rates) and

€371 million (up 20.6% at constant exchange rates), respectively.

Worldwide sales of Aprovel®/Avapro®/Karvea®/Avalide® in 2012 amounted to €1,372 million, a decline of 26.6% at constant exchange rates, reflecting loss of exclusivity in the United States on March 30, 2012 and competition from generics in most Western European countries. In Japan and China, net sales (consolidated by Sanofi) came to €101 million (up 47.0% at constant exchange rates) and €138 million (up 17.3% at constant exchange rates), respectively.

Other Revenues

Other revenues, which mainly comprise royalty income under licensing agreements contracted in connection with ongoing operations, fell by 39.5% to €1,010 million (versus €1,669 million in 2011).

The decrease was mainly due to lower licensing revenue under the worldwide alliance with BMS on Plavix® and Aprovel®, which totaled €532 million in 2012 versus €1,275 million in 2011 (down 58.1% on a reported basis), due largely to the loss of exclusivity in the United States for Aprovel® (on March 30, 2012) and Plavix® (on May 17, 2012). However, the appreciation of the U.S. dollar against the euro had a favorable impact on other revenues, as did the recognition in 2012 of a €45 million payment from BMS relating to the Avalide® supply disruption in the United States during 2011.

This line also includes royalty income of €171 million from Amgen relating to a worldwide license contracted on the product Enbrel®. Royalties received on U.S. sales represented a significant portion of this income in 2012 and will contractually end in February 2013.

Table of Contents

Gross Profit

Gross profit amounted to €24,859 million in 2012 (71.1% of net sales), versus €24,193 million in 2011 (72.5% of net sales). This represents an increase of 2.8% in gross profit, but a fall of 1.4 points in the gross margin ratio.

The gross margin ratio for the Pharmaceuticals segment slipped by 3.0 points to 72.9%, reflecting a lower level of royalty income (-2.6 points) and a deterioration in the ratio of cost of sales to net sales (-0.4 of a point); this latter trend was mainly attributable to the adverse impact of generics (mainly of Taxotere® in the United States), partially offset by productivity gains and lower raw materials prices for heparins.

The gross margin ratio for the Vaccines segment fell by 1.1 point to 59.3%.

The gross margin ratio for the Animal Health segment improved by 0.2 of a point to 69.3%.

In addition, consolidated gross profit for 2012 was adversely affected by a €23 million expense (0.1 of a point) arising from the workdown of acquired inventories remeasured at fair value in connection with the acquisition of Genzyme. In 2011, this expense was €476 million (1.4 points), out of which €473 million were related to the acquisition of Genzyme.

Research and Development Expenses

Research and development (R&D) expenses totaled €4,905 million (versus €4,788 million in 2011), representing 14.0% of net sales (versus 14.3% in 2011). Overall, R&D expenses rose by €117 million, or 2.4% on a reported basis. After including Genzyme's costs for the first quarter of 2011, R&D expenses were virtually stable year-on-year. In addition, the amount of R&D expenses reported for 2012 was adversely affected by the appreciation of the U.S. dollar against the euro.

R&D expenses for the Pharmaceuticals segment increased by €121 million, up 3.0% on a reported basis. After including Genzyme's costs for the first quarter of 2011, R&D expenses were virtually stable year-on-year, reflecting our ongoing transformation initiatives and the rationalization of the project portfolio.

R&D expenses for the Vaccines segment fell by €24 million to €538 million (down 4.3% on a reported basis), due mainly to trends in the cost of clinical trials on the dengue fever vaccine and various influenza-related projects.

In the Animal Health segment, R&D expenses rose by €20 million (up 13.9% on a reported basis) versus 2011.

Selling and General Expenses

Selling and general expenses amounted to €8,929 million, compared with €8,508 million in 2011, an increase of €421 million or 4.9% on a reported basis. The ratio of selling and general expenses to net sales was virtually unchanged year-on-year at 25.6% (25.5% in 2011). After including Genzyme's costs for the first quarter of 2011, selling and general expenses were up around 1.8% year-on-year. In addition, the amount reported for 2012 was adversely affected by the appreciation of the U.S. dollar against the euro.

In the Pharmaceuticals segment, selling and general expenses increased by €299 million, or 4.1% on a reported basis. After including Genzyme's costs for the first quarter of 2011, selling and general expenses for the segment were virtually stable year-on-year. This trend reflects tight cost control (especially in mature regions) and the effect of synergies unlocked by the integration of Genzyme, and was achieved in spite of ongoing investment in our growth platforms and the launch costs incurred on Zaltrap® and Aubagio®.

Selling and general expenses for the Vaccines segment rose by €68 million (up 12.6% on a reported basis), due partly to adverse trends in the U.S. dollar/euro exchange rate and partly to increased promotional investments.

In the Animal Health segment, selling and general expenses increased by €54 million (up 8.8% on a reported basis), reflecting adverse trends in the U.S. dollar/euro exchange rate and higher promotional costs on the companion animals franchise.

Other Operating Income and Expenses

In 2012, other operating income amounted to €562 million (versus €319 million in 2011), and other operating expenses to €414 million (versus €273 million in 2011).

122

Table of Contents

Overall, other operating income and expenses represented net income of €148 million in 2012, compared with €46 million in 2011. This increase was mainly due to the favorable outcome of litigation relating to a license.

This line item also includes a net operational foreign exchange loss of €41 million, against €5 million in 2011.

Amortization of Intangible Assets

Amortization charged against intangible assets amounted to €3,291 million in 2012, versus €3,314 million in 2011. The year-on-year reduction of €23 million was mainly due to:

- reductions: a fall in amortization charged against intangible assets recognized on the acquisition of Aventis (€1,489 million in 2012, versus €1,788 million in 2011), as some products reached the end of their life cycles in the face of competition from generics;
- increases: amortization charges generated by intangible assets recognized on the acquisition of Genzyme in the second quarter of 2011 (€981 million over 12 months in 2012, versus €709 million over 9 months in 2011).

Impairment of Intangible Assets

This line showed impairment losses of €117 million against intangible assets in 2012, compared with €142 million in 2011. The impairment losses recognized in 2012 relate mainly to the discontinuation of R&D projects in the Pharmaceuticals segment, in particular some development programs in oncology.

In 2011, the impairment losses related mainly to (i) the discontinuation of a Genzyme research project; (ii) certain Zentiva generics, following a downward revision of sales projections; and (iii) the discontinuation of a joint project with Metabolex in diabetes. This line also included a reversal of impairment losses on Actonel®, recognized following confirmation of the terms of the collaboration agreement with Warner Chilcott (see Note C.3. to our consolidated financial statements included at Item 18 of this annual report).

Fair Value Remeasurement of Contingent Consideration Liabilities

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented an expense of €192 million in 2012, compared with a net gain of €15 million in 2011. This item mainly relates to the contingent value rights (CVRs) issued in connection with the Genzyme acquisition, and to contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report).

Restructuring Costs

Restructuring costs amounted to €1,141 million in 2012, versus €1,314 million in 2011, and relate primarily to measures announced in connection with the major transformation program that we initiated in 2009 to adapt our structures to the challenges of the future.

In 2012, these costs mainly related to measures taken to adapt our resources in France, transform our industrial facilities in Europe and make adjustments to our sales forces worldwide, along with the integration of Genzyme and impairment losses against property, plant and equipment in France.

In 2011, these costs reflected the transformation and reorganization of our R&D operations, measures taken to adapt our industrial facilities in Europe, adjustments to our sales forces in the United States and Europe, the implementation of multi-country organizations in Europe, and the integration of Genzyme entities worldwide.

Other Gains and Losses, and Litigation

Nothing was recognized on this line in 2012.

In 2011, this line item included a net expense of €327 million, mainly comprising (i) a €519 million backlog of depreciation and amortization expense that was not charged against the property, plant and equipment and intangible assets of Merial from September 18, 2009 through December 31, 2010 because these assets were classified as held for sale or exchange during that period in accordance with IFRS 5 (see Note D.8.2. to the consolidated financial statements included at Item 18 of this annual report); (ii) a gain of €210 million arising from damages received in connection with a Plavix® patent; and (iii) the impact of the divestiture of the Dermik dermatology business (see Note D.28. to our consolidated financial statements).

Table of Contents

Operating Income

Operating income totaled €6,432 million for 2012, versus €5,861 million for 2011, an increase of 9.7%.

Financial Income and Expenses

Net financial expense for 2012 was €658 million, compared with €604 million for 2011, an increase of €54 million.

Financial expenses directly related to our debt, net of cash and cash equivalents (see definition at " Liquidity and Capital Resources" below) were €349 million in 2012 compared to €325 million in 2011. This increase was due to a reduction in financial income resulting from a lower average rate of return on cash.

Because the average level of debt and the average rate of interest on debt were relatively stable year-on-year, financial expenses were virtually unchanged in 2012.

Impairment losses on investments and financial assets amounted to €30 million in 2012 (versus €58 million in 2011). In 2012, these losses related primarily to available-for-sale financial assets; in 2011, they related mainly to Greek government bonds (€49 million, versus €6 million in 2012).

Gains on disposals of non-current financial assets amounted to €37 million in 2012, compared with €25 million in 2011. The 2011 figure included the effect of the change in consolidation method for the investment in Société Financière des Laboratoires de Cosmétologie Yves Rocher following loss of significant influence (see Note D.6. to our consolidated financial statements). In August 2012, Sanofi sold this investment.

The effect of the unwinding of discount on provisions was €87 million in 2012 (versus €83 million in 2011), and the net financial foreign exchange loss was €17 million in 2012 (versus a net gain of €10 million in 2011).

Income before Tax and Associates and Joint Ventures

Income before tax and associates and joint ventures for 2012 was €5,774 million in 2011, versus €5,257 million in 2011, an increase of 9.8%.

Income Tax Expense

Income tax expense amounted to €1,109 million in 2012, versus €440 million in 2011.

Income tax expense in 2011 included a significant reduction in the deferred tax liability relating to the remeasurement of the intangible assets of Merial in response to changes in tax rates and legislation (primarily in the United Kingdom) and the effect of the Franco-American Advance Pricing Agreement (APA) for the period from 2006 through 2011 (see Note D.30. to our consolidated financial statements).

These effects did not impact income tax expense for 2012. However, the rise in income tax expense during the year was limited by the favorable effects of differential income tax rates applicable to our foreign subsidiaries (including the impact of an Advance Pricing Agreement (APA) with the Japanese authorities covering the period from 2012 through 2014), and also by the settlement of tax audits and the effects of some items becoming time-barred.

This item includes positive tax effects arising from (i) the amortization of intangible assets, totaling €1,159 million in 2012 (versus €1,178 million in 2011, including the impact of the Merial backlog, see " Other Gains and Losses, and Litigation" above) and (ii) restructuring costs (€370 million in 2012, versus €399 million in 2011).

The effective tax rate based on our business net income is calculated on the basis of business operating income minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. The effective tax rate was 25.5% in 2012, versus 27.0% in 2011. The difference relative to the standard corporate income tax rate applicable in France (34.4%) was mainly due to royalty income being taxed at a reduced rate in France, and to the differential in tax rates applied to profits of our foreign subsidiaries.

Share of Profit/Loss of Associates and Joint Ventures

The share of profit/loss of associates and joint ventures in 2012 was €393 million, versus €1,070 million in 2011. This line mainly includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance, which fell by 60.7% to €420 million (versus €1,070 million in 2011). The decline in our share was

Table of Contents

mainly attributable to a 61.6% drop in sales of Plavix® in the United States due to the loss of exclusivity and competition from generics.

Net Income

Net income amounted to €5,058 million in 2012, compared with €5,887 million in 2011.

Net Income Attributable to Non-Controlling Interests

Net income attributable to non-controlling interests totaled €169 million in 2012, against €241 million in 2011. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi (€149 million, versus €225 million in 2011); this year-on-year fall was directly related to increased competition from generics of clopidogrel (Plavix®) in Europe.

Net Income Attributable to Equity Holders of Sanofi

Net income attributable to equity holders of Sanofi was €4,889 million in 2012, versus €5,646 million in 2011.

Basic earnings per share for 2012 was €3.71, 13.1% lower than the 2011 figure of €4.27, based on an average number of shares outstanding of 1,319.5 million in 2012 (1,321.7 million in 2011). Diluted earnings per share for 2012 was €3.68, compared to €4.26 for 2011, based on an average number of shares outstanding after dilution of 1,329.6 million in 2012 and 1,326.7 million in 2011.

Business Operating Income

Sanofi reports segment results on the basis of "Business Operating Income". This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See "Item 5. Operating and Financial Review and Prospects Segment information" above for the definition of business operating income and reconciliation to our Income before tax and associates and joint ventures.

Business operating income for 2012 was €11,448 million, compared to €12,274 million in 2011 (down 6.7%). The table below shows trends in business operating income by business segment for 2012 and 2011:

(€ million)	**2012**	**2011**	**Change**
Pharmaceuticals	9,601	10,610	-9.5%
Vaccines	1,157	992	+16,6%
Animal Health	673	636	+5.8%
Other	17	36	-52.8%
Business operating income	**11,448**	**12,274**	**-6.7%**

Business Net Income

Business net income is a non-GAAP financial measure that we use to evaluate our Group's performance. See "Item 5. Operating and Financial Review and Prospects Business Net Income" above for the definition of business net income and reconciliation to our Net income attributable to equity holders of Sanofi.

Business net income totaled €8,101 million in 2012 versus €8,748 million in 2011 (down 7.4%), and represented 23.2% of net sales compared with 26.2% in 2011.

Business Earnings Per Share

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see " Business Net Income" above).

Business earnings per share for 2012 were €6.14 versus €6.62 in 2011, down 7.3%, based on an average number of shares outstanding of 1,319.5 million in 2012 (1,321.7 million in 2011). Diluted business earnings per share for 2012 were €6.09 versus €6.59 in 2011, down 7.6%, based on an average number of shares outstanding of 1,329.6 million in 2012 and 1,326.7 million in 2011.

Table of Contents

Liquidity and Capital Resources

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow, and pay regular dividends on our shares. In addition, we reduced our net debt during 2013 and 2012, whereas in 2011 our debt increased significantly to finance the acquisition of Genzyme.

We define "debt, net of cash and cash equivalents" as (i) the sum total of short-term debt, long-term debt and interest rate and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate and currency derivatives used to hedge cash and cash equivalents. As of December 31, 2013, our debt, net of cash and cash equivalents stood at €6,043 million versus €7,719 million as of December 31, 2012 and €10,859 million as of December 31, 2011. See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

In order to assess the Company's financing risk, we also use the "gearing ratio", a non-GAAP financial measure. The gearing ratio is defined as the ratio of debt, net of cash and cash equivalents, to total equity. As of December 31, 2013, our gearing ratio stood at 10.6% of our net equity versus 13.4% as of December 31, 2012 and 19.3% as of December 31, 2011.

Consolidated Statement of Cash Flows

The table below shows our summarized cash flows for the years ended December 31, 2013, 2012 and 2011:

(€ million)	**2013**	**2012**	**2011**
Net cash provided by / (used in) operating activities	6,954	8,171	9,319
Net cash provided by / (used in) investing activities	(1,273)	(1,587)	(14,701)
Net cash provided by / (used in) financing activities	(3,726)	(4,351)	2,893
Impact of exchange rates on cash and cash equivalents	(79)	24	1
Net change in cash and cash equivalents (decrease) / increase	**1,876**	**2,257**	**(2,341)**

Generally, factors that affect our earnings for example, pricing, volume, costs and exchange rates flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

Year Ended December 31, 2013 Compared with Year Ended December 31, 2012

Net cash provided by operating activities amounted to €6,954 million in 2013, versus €8,171 million in 2012.

Operating cash flow before changes in working capital for 2013 was €6,819 million, versus €8,503 million in 2012, reflecting the fall in consolidated net income (partly attributable to the decline in revenues from the BMS alliance). Working capital requirements fell by €135 million in 2013, after increasing by €332 million in 2012; the 2013 decrease was attributable mainly to changes in short-term provisions.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect "Operating income", which is discussed in detail above under "Results of Operations Year Ended December 31, 2013 Compared with Year Ended December 31, 2012". The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Net cash used in investing activities decreased from €1,587 million in 2012 to €1,273 million in 2013.

Acquisitions of property, plant and equipment and intangible assets totaled €1,398 million (versus €1,612 million in 2012). The main items were investments in industrial and research facilities (€1,058 million, compared with €1,324 million in 2012), together with contractual payments for intangible rights under license and collaboration agreements (€310 million, versus €293 million in 2012).

Acquisitions of investments during 2013 amounted to €319 million, net of cash acquired and after including assumed liabilities and commitments. The main items were the acquisitions of Genfar and Dosch, plus contingent consideration arising from the acquisition of Genzyme. In 2012, acquisitions of investments totaled €328 million, net

Table of Contents

of cash acquired and after including assumed liabilities and commitments. The main items were a payment of contingent consideration to Bayer arising from the acquisition of Genzyme, the repurchase of some of the CVRs issued in connection with that acquisition, the acquisitions of Pluromed and Newport, and the purchase of an equity interest in Merrimack.

After-tax proceeds from disposals (€409 million) mainly comprised the sale to Covis Pharma of U.S. commercial rights to five pharmaceutical products, the receipt of a $125 million payment associated with changes to the contractual terms of the alliance on Actonel®, and disposals of property, plant and equipment in the United States and France. In 2012, proceeds from disposals amounted to €358 million, related to divestitures of financial assets (in particular, our equity interests in Financière des Laboratoires de Cosmétologie Yves Rocher and Handok) and to disposals of various items of property, plant and equipment and intangible assets.

Net cash used in financing activities came to €3,726 million in 2013, versus €4,351 million in 2012. The 2013 figure includes net external debt finance raised (net change in short-term and long-term debt) of €599 million (versus €615 million in 2012); the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to €637 million (compared to €178 million in 2012); and the dividend payout to our shareholders of €3,638 million (€3,487 million in 2012).

The net change in cash and cash equivalents during 2013 was a €1,876 million increase, compared with a €2,257 million increase in 2012.

Year Ended December 31, 2012 Compared with Year Ended December 31, 2011

Net cash provided by operating activities amounted to €8,171 million in 2012, compared with €9,319 million in 2011. Operating cash flow before changes in working capital was €8,503 million, versus €9,834 million in 2011. This decrease was largely attributable to erosion in revenues from the territories managed by BMS under the alliance on Plavix® and Avapro®, due to competition from generics in the United States. This revenue erosion was reflected in a reduced share of after-tax profits from these territories (€420 million, versus €1,070 million in 2011) and lower license revenue from the worldwide alliance with BMS on Plavix® and Aprovel®/Avapro® (€532 million in 2012, versus €1,275 million in 2011).

Our operating cash flow before changes in working capital is generally affected by the same factors that affect "Operating income", which is discussed in detail above under "Results of Operations Year Ended December 31, 2012 Compared with Year Ended December 31, 2011". The principal difference is that operating cash flow before changes in working capital reflects our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

Working capital requirements rose by €332 million in 2012, after an increase of €515 million in 2011. The increase during 2012 was mainly attributable to an increase in inventories (€445 million, including €315 million for reconstituting inventories at the Genzyme business).

Net cash used in investing activities amounted to €1,587 million in 2012, versus €14,701 million in 2011.

Acquisitions of property, plant and equipment and intangible assets totaled €1,612 million (2011: €1,782 million). The main items were investments in industrial and research facilities (€1,324 million, versus €1,394 million in 2011) and contractual payments for intangible rights under license and collaboration agreements (€293 million, versus €245 million in 2011).

Acquisitions of investments in the period amounted to €328 million, net of cash acquired and after including assumed liabilities and commitments. The main items were a payment of contingent consideration to Bayer arising from the acquisition of Genzyme, the repurchase of some of the CVRs issued in connection with that acquisition, the acquisitions of Pluromed and Newport, and the purchase of an equity interest in Merrimack. In 2011, acquisitions of investments amounted to €13,616 million; after including assumed liabilities and commitments, they totaled €14,079 million, and mainly comprised the acquisitions of Genzyme (€13,602 million) and BMP Sunstone (€374 million).

After-tax proceeds from disposals (€358 million) related to divestitures of financial assets (in particular, our equity interests in Société Financière des Laboratoires de Cosmétologie Yves Rocher and Handok), and to disposals of various items of property, plant and equipment and intangible assets. In 2011, proceeds from disposals came to €359 million, mainly generated by the divestiture of the Dermik dermatology business (€321 million).

Table of Contents

Financing activities generated a net cash outflow of €4,351 million in 2012, compared with a net cash inflow of €2,893 million in 2011. The 2012 figure includes €615 million of debt repayments (net change in short-term and long-term debt), as compared with net external debt raised of €5,283 million in 2011; it also includes the Sanofi dividend payout of €3,487 million (versus €1,372 million in 2011).

After the impact of exchange rates and of the cash and cash equivalents of Merial, the net change in cash and cash equivalents in 2012 was an increase of €2,257 million, compared with a decrease of €2,341 million in 2011.

Consolidated Balance Sheet and Debt

Total assets stood at €96,065 million as of December 31, 2013, versus €100,409 million a year earlier, a decrease of €4,344 million.

Debt, net of cash and cash equivalents (see definition above) was €6,043 million as of December 31, 2013, versus €7,719 million as of December 31, 2012. The table below shows our financial position for the years ended December 31, 2013, 2012 and 2011:

(€ million)	**2013**	**2012**	**2011**
Long-term debt	10,414	10,719	12,499
Short-term debt and current portion of long-term debt	4,176	3,812	2,940
Cash and cash equivalents	(8,257)	(6,381)	(4,124)
Related interest rate and currency derivatives	(290)	(431)	(456)
Debt, net of cash and cash equivalents	**6,043**	**7,719**	**10,859**

Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) fell from 13.4% in 2012 to 10.6% in 2013. Analyses of debt as of December 31, 2012 and December 31, 2011, by type, maturity, interest rate and currency, are provided in Note D.17. to our consolidated financial statements.

The financing arrangements in place as of December 31, 2013 at Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating.

Other key movements in the balance sheet are described below.

Total equity stood at €57,014 million as of December 31, 2013, versus €57,466 million as of December 31, 2012. The net year-on-year decrease in equity was attributable primarily to:

- increases: our net income for the year ended December 31, 2013 (€3,723 million) and the effects of share-based payment plans (€1,236 million);
- decreases: the dividend payout to our shareholders in respect of the 2012 financial year (€3,638 million) and repurchases of our own shares (€1,641 million).

As of December 31, 2013, we held 3.6 million of our own shares, recorded as a deduction from equity and representing 0.27% of our share capital.

Goodwill and Other intangible assets (€52,529 million in total) decreased by €5,736 million, mainly reflecting:

- decreases: amortization and impairment losses recognized during the period (€4,475 million), and currency translation differences on assets denominated in foreign currencies (€1,766 million, mainly relating to the U.S. dollar);

increases: the impact of the Genfar and Dosch acquisitions (€199 million), and acquisitions of other intangible assets (€310 million).

Provisions and other non-current liabilities (€8,735 million) decreased by €2,308 million, due mainly to a net decrease in provisions for pensions and other long-term employee benefits of €1,217 million (primarily as a result of actuarial gains on defined-benefit plans, contributions paid into pension funds, and plan settlements) and to transfers to other current liabilities (€682 million).

Table of Contents

Net deferred tax liabilities (€906 million) fell by €647 million year-on-year. This reflects a reduction caused by reversals of deferred tax liabilities relating to the remeasurement of acquired intangible assets (€1,459 million), but also an increase associated with provisions for pensions (€281 million) and accrued expenses (€271 million).

Current and non-current liabilities related to business combinations and to non-controlling interests were €542 million lower year-on-year at €908 million. This reduction reflects the impact of fair value remeasurements to the contingent value rights (CVRs) issued in connection with the Genzyme acquisition and to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi, plus the reversal of contingent consideration relating to the BiPar and TargeGen acquisitions (see Note D.18. to our consolidated financial statements).

Liquidity

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2013, we held cash and cash equivalents amounting to €8,257 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements). As at December 31, 2013, €573 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

Since 2010, some countries in Southern Europe have been facing severe financial difficulties (see section " 3.1.8. Risk Factors 2. Risks Relating to Our Business We are subject to the risk of non-payment by our customers"). Deteriorating credit and economic conditions and other factors in these countries have resulted in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action.

During 2012, the amount of our trade receivables in Europe decreased, primarily as a result of a reduction in the sums owed to us by public-sector customers in Spain due to payments received. The total consolidated amount of trade receivables overdue by more than 12 months which primarily consists of amounts due from public-sector customers fell from €276 million as of December 31, 2011 to €161 million as of December 31, 2012 due to payments received (see Note D.10. to our consolidated financial statements included at Item 18 of this annual report).

During 2013, the amount of our trade receivables in Europe continued to fall, primarily as a result of a reduction in the sums owed to us by public-sector customers in Italy and Greece. Over the Group as a whole, the amount of trade receivables overdue by more than 12 months which primarily consists of amounts due from public-sector bodies around the world rose from €161 million as of December 31, 2012 to €168 million as of December 31, 2013 (see Note D.10. to our consolidated financial statements).

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ("CVR") and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately $70 million). In 2013, Sanofi purchased an additional 10,928,075 CVRs (for a total consideration of approximately $9 million). As of December 31, 2013, 238,275,333 CVRs were outstanding out of 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2013, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of €10.0 billion at December 31, 2013. For a discussion of our treasury policies, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see "Item 11. Quantitative and Qualitative Disclosures about Market Risk."

Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2013 are shown in Notes D.3., D.17., D.18. and D.21. to our consolidated financial statements included at Item 18 of this annual report. Note D.21.

Table of Contents

to our consolidated financial statements included at Item 18 discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2012 consolidated financial statements.

The Group's contractual obligations and other commercial commitments are set forth in the table below:

		Payments due by period			
December 31, 2013 *(€ million)*	**Total**	**Under 1 year**	**From 1 to 3 years**	**From 3 to 5 years**	**Over 5 years**
Future contractual cash-flows relating to debt and debt hedging instruments[1]	15,688	4,372	3,681	2,611	5,024
Operating lease obligations	1,265	257	356	224	428
Finance lease obligations[2]	78	18	33	23	4
Irrevocable purchase commitments[3]					
given	3,189	1,707	800	385	297
received	(237)	(151)	(64)	(3)	(19)
Research & development license agreements					
Future service commitments[4]	569	150	253	142	24
Potential milestone payments[5]	1,589	100	174	171	1,144
Obligations relating to business combinations[6]	4,416	28	583	480	3,325
Firm commitment related to the BMS agreement[7]	75			75	
Estimated benefit payments on unfunded pensions and post employment benefits[8]	1,039	54	110	119	756
Total contractual obligations and other commitments	**27,671**	**6,535**	**5,926**	**4,227**	**10,983**
Undrawn general-purpose credit facilities	**10,021**	**3,020**		**7,001**	

(1)

See Note D.17. to our consolidated financial statements included at Item 18 of this annual report.

(2)

See Note D.3. to our consolidated financial statements included at Item 18 of this annual report.

(3)

These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and (ii) goods and services.

(4)

Future service commitments relating to research & development license agreements mainly comprise research financing commitments, but also include consideration for access to technologies.

(5)

This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase.

(6)

See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

(7)

See Note C.1. to our consolidated financial statements included at Item 18 of this annual report.

(8)

See Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report. The table above does not include the ongoing annual employer's contributions to plan assets, estimated at €268 million in 2013.

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 collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also 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.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Table of Contents

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects in the Pharmaceuticals segment are described below. Milestone payments relating to development projects under these agreements amounted to €1.4 billion in 2013. These exclude projects in the research phase (€3.8 billion in 2013, €5.0 billion in 2012) and payments contingent upon the attainment of sales targets once a product is on the market (€3.6 billion in 2013, €4.7 billion in 2012).

In May 2011, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. (Glenmark), a subsidiary of Glenmark Pharmaceuticals Limited India, for the development and commercialization of GBR500, a novel monoclonal antibody for the treatment of Crohn's disease and other chronic autoimmune diseases.

In June 2010, Sanofi signed an exclusive global collaboration and license agreement with Ascenta Therapeutics, a U.S. biopharmaceutical company, on a number of molecules that could restore apoptosis (cell death) in tumor cells.

At the end of April 2010, Sanofi signed a license agreement with Glenmark for the development and commercialization of novel agents to treat chronic pain. Those agents are vanilloid receptor (TRPV3) antagonist molecules, including a first-in-class clinical compound, GRC 15300, which is currently in Phase I clinical development.

In April 2010, Sanofi signed a global license agreement with CureDM Group Holdings, LLC for Pancreate, a novel human peptide which could restore a patient's ability to produce insulin and other pancreatic hormones in both type 1 and 2 diabetes.

In December 2009, Sanofi and the U.S. biotechnology company Alopexx Pharmaceuticals LLC simultaneously signed (i) a collaboration agreement, and (ii) an option for a license on an antibody for the prevention and treatment of infections originating in the bacterium that causes plague and other serious infections.

In May 2009, Sanofi signed a global license agreement with Exelixis, Inc. for XL147 and XL765, and simultaneously signed an exclusive research collaboration agreement for the discovery of inhibitors of Phosphoinositide-3-Kinase (PI3K) for the management of malignant tumors. On December 22, 2011, Sanofi and Exelixis, Inc. agreed to end this collaboration agreement.

May 2009, Sanofi signed a collaboration and licensing agreement with Kyowa Hakko Kirin Co., Ltd, under which Sanofi obtained the worldwide rights to the anti-LIGHT fully human monoclonal antibody. This anti-LIGHT antibody is expected to be first-in-class in the treatment of ulcerative colitis and Crohn's disease.

In November 2007, Sanofi signed a collaboration agreement with Regeneron to discover, develop and commercialize fully human therapeutic antibodies. This agreement was broadened, and its term extended, on November 10, 2009. Under the terms of the development agreement, Sanofi committed to fund the discovery and pre-clinical development costs of Regeneron's antibody research program until 2017 (see Note C.2. to our consolidated financial statements included at Item 18 of this annual report). Once a product begins to be marketed, Regeneron will repay out of its profits (provided they are sufficient) half of the development costs borne by Sanofi. As of December 31, 2013, the balance of the development costs initially funded by Sanofi amounted to €1.3 billion.

In September 2003, Sanofi signed a collaboration agreement in oncology with Regeneron Pharmaceuticals Inc. (Regeneron) to develop the Vascular Endothelial Growth Factor (VEGF) Trap program. Under the terms of the agreement, Sanofi will pay 100% of the development costs of the VEGF Trap. Once a VEGF Trap product starts to be marketed, Regeneron will repay 50% of the development costs (originally paid by Sanofi) in accordance with a formula based on Regeneron's share of the profits.

Sanofi has also entered into the following major agreements, which are currently in a less advanced research phase:

In November 2012, Sanofi and the U.S. biotechnology company Selecta Biosciences signed a collaboration agreement to identify and develop food allergy treatments using a technology based on nanoparticles.

Since acquiring Genzyme in April 2011, the Group has had a commitment to Isis Pharmaceuticals Inc. under a collaboration agreement signed in January 2008. This agreement granted an exclusive license to develop and commercialize mipomersen, a treatment in an advanced development phase for the treatment of severe familial hypercholesterolemia.

Table of Contents

In December 2010: Sanofi signed a global licensing and patent transfer agreement with Ascendis Pharma (Ascendis) on the proprietary Transcon Linker and Hydrogel Carrier technology developed by Ascendis for precise, time-controlled release of therapeutic active ingredients into the body. The agreement will enable Sanofi to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders.

Also in December 2010, Sanofi entered into an alliance with Avila Therapeutics Inc. (Avila) to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells. Under the terms of the agreement, Sanofi will have access to Avila's proprietary Avilomics® platform offering "protein silencing" for these pathogenic proteins.

In June 2010, Sanofi entered into an alliance with Regulus Therapeutics Inc. to discover, develop and commercialize novel micro-RNA therapeutics, initially in fibrosis. Sanofi also received an option which if exercised would provide access to the technology to develop and commercialize other micro-RNA based therapeutics, beyond the first four targets.

At the end of April 2010, Sanofi signed a license agreement with Glenmark Pharmaceuticals S.A. for the development and commercialization of novel agents to treat chronic pain. These are vanilloid receptor (TRPV3) antagonist molecules, including ERC 15300, a first-in-class clinical compound.

At the end of September 2009, Sanofi and Merrimack Pharmaceuticals Inc. signed an exclusive global licensing and collaboration agreement covering the MM-121 molecule for the management of solid tumors.

In July 2013, Sanofi decided to discontinue the project on novel classes of antibiotics derived from the RX-04 and Rib-X program, and to terminate its research agreement with Rib X Pharmaceuticals, Inc.

In September 2013, Sanofi decided to discontinue the project to identify novel targets in oncology for the development of new therapeutic agents directed towards these targets and their associated biomarkers, and to end its collaboration with the Belfer Institute of Applied Cancer Science at Dana-Farber Cancer Institute (DFCI).

In November 2013, Sanofi decided to discontinue the project relating to an exclusive global licensing option with Oxford BioTherapeutics for three existing antibodies, plus a research and collaboration agreement to discover and validate new targets in oncology.

In the Vaccines segment, Sanofi Pasteur has entered into a number of collaboration agreements. Milestone payments relating to development projects under those agreements amounted to €0.2 billion in 2013.

In February 2014, pursuant to the "Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits", Sanofi Pasteur and the WHO signed a "Standard Material Transfer Agreement" (SMTA 2). This bilateral agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. This agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

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:

Revenue recognition. Our policies with respect to revenue recognition are discussed in Note B.14. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement under "Net sales". Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active

ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; the Group no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to the Group.

Table of Contents

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. They are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. We also estimate the amount of product returns, on the basis of contractual sales terms and reliable historical data; the same recognition principles apply to sales returns. For additional details regarding the financial impact of discounts, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-product revenues, mainly comprising royalty income from license arrangements that constitute ongoing operations of the Group, are presented in "Other revenues".

Business combinations. As discussed in Note B.3. "Business combinations and transactions with non-controlling interests" to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets, liabilities and contingent liabilities that satisfy the recognition criteria of IFRS 3 "Business combinations" are measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, "Consolidated and individual financial statements". In particular, contingent consideration to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. Any subsequent changes in amounts recorded as a liability are recognized in the consolidated income statement (see Note D.18. "Liabilities related to business combinations and non-controlling interests" to our consolidated financial statements included at Item 18 of this annual report).

Goodwill impairment and intangible assets. As discussed in Note B.6. "Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures" and in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for impairment. We test for impairment on the basis of the same objective criteria that were 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 (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is disclosed in Note D.5. "Impairment of intangible assets and property, plant and equipment" to our consolidated financial statements included at Item 18 of this annual report.

Pensions and post-retirement benefits. As described in Note B.23. "Employee benefit obligations" to our consolidated financial statements included at Item 18 of this annual report, 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 at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through equity. A sensitivity analysis to discount rate is set forth in Note D.19.1. "Provisions for pensions and other benefits" to our consolidated financial statements included at Item 18 of this annual report.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. "Provisions for pensions and other benefits" to our consolidated financial statements included at Item 18 of this annual report.

Deferred taxes. As discussed in Note B.22. "Income tax expense" to our consolidated financial statements included at Item 18 of this annual report, we account for deferred taxes using the liability method, whereby

Table of Contents

deferred income taxes are recognized on tax loss carry-forwards, and on the difference between the tax base 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 do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The estimates of recognized deferred tax assets are based on our assumptions regarding future profits and the timing of reversal of temporary differences. These assumptions are regularly reviewed; however, final deferred income tax could differ from those estimates.

Provisions for risks. Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. "Provisions for risks" at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; when it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and when a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. "Other provisions" and D.22. "Legal and Arbitral Proceedings" to our consolidated financial statements included at Item 18 of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the balance sheet date, of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The offices of Chairman and Chief Executive Officer have been separated since January 1, 2007. The annual evaluations conducted since that date have indicated that this governance structure is appropriate to the Group's current configuration. This arrangement was therefore continued with the appointment of Serge Weinberg to the office of Chairman on May 17, 2010 and again with his reappointment on May 6, 2011. The Board of Directors considers that this governance structure is appropriate in the Group's current context.

The **Chairman** represents the Board of Directors, organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance practices. The Chairman coordinates the work of the Board of Directors with its Committees. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

When the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary Shareholders' General Meeting called to approve the financial statements held during the calendar year in which he reaches the age of 70.

The Chairman being an independent director, the Board of Directors has not deemed it necessary to appoint a lead independent director, since this role has been broadly assumed by Serge Weinberg.

The **Chief Executive Officer** is responsible for the management of the Company, and represents the Company in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer must be no more than 65 years old.

Table of Contents

Limitations on the powers of the Chief Executive Officer set by the Board

The Board of Directors Meeting of July 28, 2009 set limits on the powers of the Chief Executive Officer. The prior authorization of the Board of Directors is required to commit Sanofi to investments, acquisitions and divestments in the following cases:

- a €500 million cap for each undertaking pertaining to a previously approved strategy; and
- a €150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting parties for such undertakings includes potential installment payments contingent upon the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

Board of Directors

The Company is administered by a Board of Directors, currently comprising sixteen members.

Since May 14, 2008, the terms of office of the directors have been staggered, in order to ensure that the directors are progressively re-elected.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and the composition of its Committees. In particular, the Board seeks to ensure a balanced representation of men and women and diversity of background and country of origin, since the business of the Group is both diversified and global. The Board investigates and evaluates potential candidates whenever individual directors are up for election. Above all, the Board seeks talented directors, who show independence of mind and who are competent, dedicated and committed.

Under the terms of the AFEP-MEDEF corporate governance code (hereafter referred to as the "AFEP-MEDEF Code"), a director is deemed to be independent when the director has no relationship of any nature whatsoever with the Company, the group it belongs to or its senior management which could compromise the exercise of the director's freedom of decision. More specifically, independent directors are required:

- not to be an employee or corporate officer of the Company, or a corporate officer of a related company;
- not to be a customer, supplier, or investment banker or corporate banker of the Company;
- not to have close family ties with any corporate officer of the Company;
- not to have acted as auditor for the Company over the course of the last five years;
- not to be representative of a significant shareholder or of a controlling interest of the Company.

The influence of other factors such as length of service on the Board, the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before a director qualifies as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, a discussion as to the independence of the current directors took place during the meeting of the Board of Directors of October 29, 2013. Of the sixteen directors, eleven were deemed to be independent directors with reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Uwe Bicker, Robert Castaigne, Lord Douro, Jean-René Fourtou, Claudie Haigneré, Fabienne Lecorvaisier, Suet-Fern Lee, Carole Piwnica, Klaus Pohle, Gérard Van Kemmel and Serge Weinberg.

In particular, it was determined that the situation of Robert Castaigne had changed. Until 2012, Robert Castaigne had not been considered as an independent director due to his past links with the Total Group. Since April 2008, when the independence criteria of the AFEP-MEDEF Code were adopted, his situation has changed in two ways:

Robert Castaigne retired from the Total Group four years ago.

Total passed below the threshold of 5% of our voting rights: notification of February 16, 2012. (Since that date, Total has ceased to have any equity interest in the Group.)

Table of Contents

Consequently, the Board of Directors considered that the links with Total no longer created a presumption of non-independence.

Moreover, contrary to the independence criteria set by the AFEP-MEDEF Code, the Board of Directors does not consider that belonging to the Board for more than 12 years of itself disqualifies a director from being independent. The length of service criterion is intended to address the concern that the passage of time may deprive a director of his ability to challenge senior management. This is a legitimate concern, which Sanofi takes very seriously. Nevertheless a mechanical application of this criterion is not considered desirable as it does not take account of the diversity of situations.

Consequently, although this criterion is applied by the Board of Directors, it is not of itself a determining factor in making a decision as to a director's independence. The Board of Directors assesses the reality of each situation when making a decision. In the case of Robert Castaigne, the Board considers that this director has always demonstrated a questioning approach, which is fundamentally what the APEF-MEDEF criteria are seeking to check.

Finally, there was no other reason to determine that Robert Castaigne is not independent.

Consequently, the Board determined on this basis, at its meeting of May 4, 2012, that Robert Castaigne qualified as an independent director.

It should be noted that this decision has no detrimental effect on compliance with the independence rules of the AFEP-MEDEF Code, which is the main objective of the Code. The fact that the proportion of independent directors on the Board is over 68% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

In 2013, it was considered that the rules governing the office of the Chairman of the Board had changed, and they henceforth enabled the Board to consider the Chairman as an independent director in accordance with the continued assessment of the Board of Directors. Until 2013, Serge Weinberg had not been considered as an independent director only because of the previous version of the AFEP-MEDEF Code which in its former article 8.4 did not distinguish the case where the functions of Chairman and Chief Executive Officer are separated from the case where both functions are combined. Effective June 2013, the AFEP-MEDEF Code (in its new article 9.4) stipulates that if the offices of Chairman and Chief Executive Officer are separated, the Chairman is not automatically considered as non-independent, but his (or her) independence has to be scrutinized in the light of the criteria generally used to assess directors' independence. The Board of Directors considered that no factor other than his role as Chairman is liable to undermine his independence, especially given that prior joining the Board he had no links to Sanofi. The Board assessment concerning his situation was reflected in the previous annual reports on form 20-F. On October 29, 2013 the Board of Directors determined that Serge Weinberg was an independent director.

In its examination of the independence of each Director, the Board of Directors took into account the various relationships that could exist between Directors and the Group and concluded that no such relationships were of a nature that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the last three years, sold products and provided services to, and/or purchased products and received services from, companies in which certain of the Company's directors who are classified as independent or members of their close family were senior managers or employees during 2013. On each occasion, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the Directors in question. Similarly, the Board of Directors did not find the office of trustee held by Uwe Bicker and Klaus Pohle with the Aventis Foundation (Germany) was of such a nature as to undermine their independence as members of the Sanofi Board of Directors. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

Subject to the powers expressly attributed to the Shareholders' General Meeting and within the scope of the Company's corporate purpose, the Board of Directors' powers cover all issues relating to the proper management of the Company, and through its decisions the Board determines all matters falling within its authority.

Board evaluation

The Board Charter provides that a discussion of the operating procedures of the Board must be included on the agenda of a Board meeting once a year and that a formal evaluation must be performed every three years.

Table of Contents

The latest three-year formal evaluation of the operating procedures of the Board and its committees took place in late 2012 early 2013. The directors were heavily involved in the process, as demonstrated by the quality and the quantity of their responses. The Board indicated that it wished its contributions to be systematically acted upon and implemented.

The general appraisal of how the Board and its committees functioned was positive. The quality of the Audit Committee's work was particularly appreciated and acknowledged.

The evaluation showed that R&D performance monitoring was appreciated, and the directors expressed their wish that it should be continued and intensified. Directors would welcome a systematic *ex-post* assessment of acquisitions.

Since 2011, in response to needs expressed in the 2010 evaluation presentations from various Group activities have been given during Board meetings or Strategy Committee sessions. Directors requested more interactions with key Group managers. To satisfy this request, an annual business presentation program has been set up, systematically involving Group managers.

Presentations were given by the Executive Vice President Chief Financial Officer, Executive Vice President Legal Affairs and General Counsel, Vice President Global Compliance Officer, Executive Vice President Chief Strategy Officer, Senior Vice President Diabetes and Senior Vice President Zentiva.

Directors expressed their desire to get more information about human resources management and our main competitors' strategies. In 2013, directors were regularly kept informed of the work conducted by the Appointments and Governance Committee on the succession planning review, in particular concerning the replacement of Hanspeter Spek (President Global Operations) following his retirement. Each business activity presentation included an overview of the market and the competitive environment.

Concerning the composition of the Board, directors requested that the onboarding of more women be continued and that certain competencies be reinforced. This was achieved through the proposed appointment of Fabienne Lecorvaisier as a director.

On arrival, Fabienne Lecorvaisier received several days' training during which she acclimatized herself to the Company, its businesses, the health sector background and in particular the pharmaceutical industry.

Two strategic seminars took place in 2013: one in March on the Group research strategy in core disease areas, and a two-day seminar held in October in China which reviewed the development portfolio and the long range plan.

The annual discussion of the Board's operations during 2013 delivered an overall positive self-evaluation.

The Strategic Committee sessions centered on the R&D portfolio were perceived as having facilitated the Board's oversight of Sanofi's performance in research and development.

The directors also felt that their contacts with the Group's management had improved in both quality and frequency.

The recent changes in board composition were viewed favorably and the directors indicated a desire to see continued investment in pharmaceutical expertise.

The directors gave particularly positive feedback of their session in China, which they felt permitted them to better understand the context and the challenges of this country.

The directors highlighted the need to:

- Reduce the number of board members after the current transitory period;
- Institutionalize the Strategic Committee's review of all acquisition files before their presentation to the Board, as well as the Audit Committee's post hoc review of acquisitions; and
- Spend more time on the competitive landscape and on discussions of the Company's challenges and strategic alternatives.

Composition of the Board of Directors as of December 31, 2013

Positions held in listed companies are flagged by an asterisk. Each person's principal position is indicated in bold.

Table of Contents

Serge Weinberg
1,636 shares

Date of birth:	February 10, 1951
Nationality:	French
First elected:	December 2009
Last reappointment:	May 2011
Term expires:	2015

Directorships and appointments of Serge Weinberg

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Chairman of the Board of Sanofi*, independent director	Member of the Supervisory Board of Schneider Electric*
Chairman of the Appointments and Governance Committee of Sanofi	**Chairman of Weinberg Capital Partners**
Chairman of the Strategy Committee of Sanofi	Chairman of Financière Piasa and Piasa Holding
	Manager of Alret and Maremma
	Director of VL Holding
	Member of the Supervisory Board of Financière BFSA
	Vice Chairman and Director of Financière Poinsétia and Financière Sasa
	Weinberg Capital Partners' representative on the Board of Alliance Industrie and Sasa Industrie
In foreign companies	

None None

Past directorships since 2009

In French companies

None

Chairman of the Board of Accor* (until 2009)

Director of Rasec (until 2010), of Fnac (until 2010), of Rothschild Concordia (until 2010) and of Team Partners Group (until 2011)

Member of the Supervisory Board of Rothschild & Cie (until 2010)

Member of the Board of Pharma Omnium International (until 2010)

Vice Chairman of the Supervisory Board of Schneider Electric* (until 2010)

Member of the Supervisory Board of Amplitude Group and of Alfina (until 2011)

In foreign companies

None

Member of the Supervisory Board of Gucci Group (Netherlands, until 2010)

Chairman of Corum (Switzerland, until 2013)

Education and business experience

Graduate in law, degree from the *Institut d'Etudes Politiques*

Graduate of ENA (*Ecole Nationale d'Administration*)

Since 2005 **Chairman of Weinberg Capital Partners**

1976-1982	*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)
1982-1987	Deputy General Manager of FR3 (French Television Channel) and then Chief Executive Officer of Havas Tourisme
1987-1990	Chief Executive Officer of Pallas Finance
1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years

Table of Contents

Christopher Viehbacher
135,442 shares

Date of birth:	March 26, 1960
Nationality:	German and Canadian
First elected:	December 2008
Last reappointment:	May 2010
Term expires:	2014

Directorships and appointments of Christopher Viehbacher

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Director and Chief Executive Officer of Sanofi*	None
Chairman of the Executive Committee and Head of Global Leadership Team of Sanofi	
Member of the Strategy Committee of Sanofi	
In foreign companies	
Chairman of Genzyme (United States)	Chairman of European Federation of Pharmaceutical Industries and Associations (EFPIA, Belgium)
	Member of Visitors of Fuqua School of Business, Duke University (United States)
	Member of the Board of Business Roundtable (United States)
	Member of the International Business Council, World Economic Forum (Switzerland)

Chairman of the CEO Roundtable on Cancer (United States)

Past directorships since 2009

In French companies

None

None

In foreign companies

Chairman and Chief Executive Officer of Genzyme (United States, until 2011)

Member of Advisory Council of Center for Healthcare Transformation (United States, until 2010)

Chairman and member of the Board of Directors of Research America and Burroughs Wellcome Fund (United States, until 2011)

Chairman of the Board of Directors of PhRMA (United States, until 2012)

Vice Chairman of European Federation of Pharmaceutical Industries and Associations (EFPIA, Belgium, until June 2013)

Education and business experience

B.A. in Commerce from Queens University (Ontario-Canada); certified public accountant

Began his career at PricewaterhouseCoopers Audit

1988-2008 Various positions at the GSK group, including President Pharmaceutical Operations for North America
2004-2008 Member of the Cardinal Club (United States)

Table of Contents

Laurent Attal
1,000 shares

Date of birth: February 11, 1958
Nationality: French
First elected: May 2012
Term expires: 2016

Directorships and appointments of Laurent Attal

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Director of Sanofi*	Director of *Fondation d'Entreprise L'Oréal*
Member of the Strategy Committee of Sanofi	
In foreign companies	
None	None
Past directorships since 2009	
In French companies	
None	None
In foreign companies	
None	President and Chief Executive Officer of L'Oréal USA (United States, until 2009)

Education and business experience

Doctor in medicine, dermatologist

MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

Since 1986 Various positions within the L'Oréal* Group notably within the active cosmetics division
Since 2002 Member of L'Oréal* Executive Committee
Since 2010 **Vice President General Manager Research and Innovation at L'Oréal***

Table of Contents

Uwe Bicker
1,000 shares

Date of birth:	June 14, 1945
Nationality:	German
First elected:	May 2008
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Uwe Bicker

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	None
Member of the Strategy Committee of Sanofi	
In foreign companies	
None	Trustee of the Aventis Foundation[(1)] (not-for-profit, Germany)
	Chairman of the Board of Marburg University (Germany)
	Member of the Advisory Board of Morgan Stanley (Germany)
Past directorships since 2009	
In French companies	
None	None
In French companies	
None	Member of the Board of Trustees of Bertelsmann Stiftung (Bertelsmann Foundation, Germany, until 2011)
	Chairman of the Supervisory Board of Siemens Healthcare Diagnostics Holding GmbH (Germany, until 2012)

Vice-Chairman of the Supervisory Board of Epigenomics AG (Germany) and of Definiens AG (Germany, until 2012)

Member of the Supervisory Board of Future Capital AG (Germany, until 2013)

Education and business experience

Doctorate in chemistry and in medicine

Honorary Doctorate, Klausenburg University

Honorary Senator, Heidelberg University

Since 1983	Professor at the Medical Faculty of Heidelberg (Germany)
Since 2011	**Dean at the Medical Faculty, Heidelberg University** (Germany)
1975-1994	Various positions at Boehringer Mannheim GmbH (later Roche AG) (Germany)
1994-2004	Various positions at Hoechst group (Germany)
1997-2007	Chairman of the Supervisory Board of Dade Behring GmbH (Germany)
2011-2013	Managing Director at the University Clinic of Mannheim (Germany)

(1)

No compensation is paid for this office. Appointments to the Board of Trustees of the Foundation are made independently of Sanofi.

Table of Contents

Robert Castaigne	Date of birth:	April 27, 1946
1,000 shares	Nationality:	French
	First elected:	February 2000
	Last reappointment:	May 2010
	Term expires:	2014

Directorships and appointments of Robert Castaigne

Within the Sanofi Group	**Outside the Sanofi Group**
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	Société Générale*:
Member of the Audit Committee of Sanofi	Director
	Member of the Audit, Internal control and Risk Committee
	Vinci*:
	Director
	Member of the Audit Committee
	Member of the Remuneration Committee
In foreign companies	
None	None
Past directorships since 2009	
In French companies	
None	None

In foreign companies

None

Director and member of the Audit Committee of Compagnie Nationale à Portefeuille (Belgium, until 2011)

Education and business experience

Degree from *Ecole Centrale de Lille* and *Ecole Nationale Supérieure du Pétrole et des Moteurs*

Doctorate in economics

1972-2008 Various positions at the Total* group, including Chief Financial Officer and member of the Executive Committee (1994-2008)

Table of Contents

Thierry Desmarest
1,017 shares

Date of birth:	December 18, 1945
Nationality:	French
First elected:	February 2000
Last reappointment:	May 2011
Term expires:	2015

Directorships and appointments of Thierry Desmarest

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Director of Sanofi*	**Total SA***:
Member of the Compensation Committee of Sanofi	**Director and Honorary President**
Member of the Appointments and Governance Committee of Sanofi	Chairman of the Nominating and Governance Committee
Member of the Strategy Committee of Sanofi	Member of the Compensation Committee
	Member of the Strategy Committee
	Chairman of *Fondation Total*
	L'Air Liquide*:
	Director

Chairman of the Appointments and Governance Committee

Member of the Compensation Committee

Renault group:

Director of Renault SA*

Chairman of the International Strategy Committee of Renault SA

Member of the Remuneration Committee of Renault SA

Member of the Industrial Strategy Committee of Renault SA

Director of Renault SAS

Member of the Board of Directors of l'*Ecole Polytechnique* and Chairman of *Fondation de l'Ecole Polytechnique*

Director of *Musée du Louvre*

In foreign companies

None

Bombardier Inc.* (Canada):

Director

Past directorships since 2009

In French companies

None

Chairman of the Board of Directors of Total SA* (until 2010)

Member of the Supervisory Board of Areva* (until 2010)

In foreign companies

None

Bombardier Inc.* (Canada):

Member of the Appointments and Governance Committee (until 2013)

Member of the Human Resources and Compensation Committee (until 2013)

Education and business experience

Degree from *Ecole Polytechnique* and *Ecole Nationale Supérieure des Mines de Paris*

Since 1981 Various positions at the Total* group including Chairman and Chief Executive Officer (1995-2007)
2000-2007 CEO and Chairman of the Board of Elf Aquitaine

Table of Contents

Lord Douro
2,000 shares

Date of birth:	August 19, 1945
Nationality:	British
First elected:	May 2002
Last reappointment:	May 2010
Term expires:	2014

Directorships and appointments of Lord Douro

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Independent Director of Sanofi*	None
Member of the Appointments and Governance Committee of Sanofi	
Member of the Strategy Committee of Sanofi	
In foreign companies	
None	Chairman of Richemont Holdings UK Ltd (United Kingdom) and Kings College London (United Kingdom)
	Compagnie Financière Richemont AG* (Switzerland):
	Director
	Member of the Appointments Committee and of the Compensation Committee
	Member of the International Advisory Board of Abengoa SA* (Spain)

RIT Capital* (United Kingdom):

Director

Chairman of the Remuneration Committee and the Conflicts Committee

Member of the Nominations Committee

Past directorships since 2009

In French companies

None

Pernod Ricard*:

Director (until 2011)

Member of the Compensation Committee and of the Appointments Committee (until 2010)

In foreign companies

None

Director of Abengoa Bioenergy (Spain, until 2011)

Advisor to Crédit Agricole CIB (United Kingdom, until 2012)

Director of GAM Worldwide (United Kingdom, until 2013)

Education and business experience

Master of Arts from Oxford University

1979-1989	Member of the European Parliament
1995-2000	Chairman of Sun Life & Provincial Holdings Plc* (United Kingdom)
1993-2005	Chairman of Framlington Ltd (United Kingdom)
2003-2007	Commissioner of English Heritage (United Kingdom)

Table of Contents

Jean-René Fourtou
4,457 shares

Date of birth:	June 20, 1939
Nationality:	French
First elected:	August 2004
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Jean-René Fourtou

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	**Chairman of the Supervisory Board of Vivendi***
Member of the Compensation Committee of Sanofi	
Member of the Appointments and Governance Committee of Sanofi	
Member of the Strategy Committee of Sanofi	
In foreign companies	
None	Member of the Supervisory Board of Maroc Telecom* (Vivendi Group, Morocco)
Past directorships since 2009	
In French companies	
None	Chairman of the Supervisory Board of Canal+* Group (until 2011)
	Axa*:
	Vice President, then member of the Supervisory Board (until 2009)

Member of the Ethics and Governance Committee (until 2009)

Director of AXA Millésimes SAS (until 2011)

Director of Cap Gemini SA* (until 2010)

In foreign companies

None

Director of NBC Universal Inc. (United States, until 2010)

Director and member of the Compensation Committee of Nestlé* (Switzerland, until 2012)

Education and business experience

Degree from *École Polytechnique*

1963-1986	Various positions at the Bossard group, including Chairman and Chief Executive Officer (1977-1986)
1986-1999	Chairman and Chief Executive Officer of Rhône-Poulenc*
1999-2004	Vice Chairman of the Management Board, then Vice Chairman of the Supervisory Board and member of the Strategy Committee of Aventis*
2002-2005	Chairman and Chief Executive Officer of Vivendi*
2002-2008	Vice Chairman, Chairman then Honorary Chairman of the International Chamber of Commerce

Table of Contents

Claudie Haigneré
1,000 shares

Date of birth:	May 13, 1957
Nationality:	French
First elected:	May 2008
Last reappointment:	May 2012
Term expires:	2016

Directorships and appointments of Claudie Haigneré

Within the Sanofi Group	**Outside the Sanofi Group**
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	France Telecom*:
Member of the Appointments and Governance Committee of Sanofi	Director
Member of the Compensation Committee of Sanofi	Member of the Strategy Committee
	Chairman of the Board of Directors of *La Géode*
	Chairman of Universcience (*Cité des Sciences et de l'Industrie* and *Palais de la Découverte*)
	Director of *Fondation de France*
	Director of *Fondation CGénial*

Director of *Fondation d'Entreprise L'Oréal*

Director of *Fondation Lacoste*

Member of *Académie des Technologies*, of *Académie des Sports*, of *Académie Nationale de l'Air et de l'Espace*

Director of *Ecole Normale Supérieure* (ENS)*, Campus Condorcet,* and PRES HESAM *(Pôle de Recherche et d'Enseignement Supérieur Hautes-Etudes-Sorbonne-Arts-et-Métiers*)

In foreign companies

None None

Past directorships since 2009

In French companies

None

Counselor at the European Space Agency (until 2009)

Director and Chairman of the *Cité des Sciences et de l'Industrie* (until 2009)

Chairman of *Palais de la Découverte* (until 2009)

Director of the Aéro Club de France (until 2011)

Vice President of the IAA (International Academy of Astronautics, until 2011)

In foreign companies

None None

Education and business experience

Rheumatologist, doctorate in sciences majoring in neurosciences

Selected in 1985 by the CNES (French National Space Center) as an astronaut candidate

1984-1992	Rheumatologist, Cochin Hospital (Paris)
1996	Scientific space mission to the MIR space station (Cassiopée, Franco-Russian mission)
2001	Scientific and technical space mission to the International Space Station (Andromède mission)
2002-2004	Deputy Minister for Research and New Technologies in French government
2004-2005	Deputy Minister for European Affairs
2005-2009	Counselor at the European Space Agency (ESA)

Table of Contents

Igor Landau
1,000 shares

Date of birth: July 13, 1944
Nationality: French
First elected: August 2004
Last reappointment: May 2011
Term expires: 2015

Directorships and appointments of Igor Landau

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
	In French companies
Director of Sanofi*	Director of INSEAD (*Institut Européen d'Administration des Affaires*)
	In foreign companies
None	Chairman of the Supervisory Board of Adidas* (Germany)
	Allianz SE* (formerly Allianz AG*, Germany):
	Member of the Supervisory Board
	Member of the Audit Committee
Past directorships since 2009	
	In French companies
None	Director of HSBC France (until 2012)
	In foreign companies
None	Allianz AG* (Germany, until 2012):
	Member of the Steering Committee

Member of the General Committee

Member of the Mediation Committee

Member of the Nomination Committee

Education and business experience

Degree from HEC (*Ecole des Hautes Etudes Commerciales*)

MBA from INSEAD (*Institut Européen d'Aministration des Affaires*)

1968-1970	Chief Executive Officer of the German subsidiary of La Compagnie du Roneo (Germany)
1971-1975	Management consultant at McKinsey (France)
1975-2004	Various positions at the Rhône-Poulenc group, including member of the Management Board of Aventis (1999-2002) and Chairman of the Management Board of Aventis (2002-2004)
2001-2005	Director of Essilor*
2002-2005	Director of Thomson* (later Technicolor*)
2003-2006	Member of the Supervisory Board of Dresdner Bank (Germany)

Table of Contents

Fabienne Lecorvaisier
1,000 shares

Date of birth:	August 27, 1962
Nationality:	French
First elected:	May 2013
Term expires:	2017

Directorships and appointments of Fabienne Lecorvaisier

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	Air Liquide Group:
Member of the Audit Committee of Sanofi	Chief Executive Officer of Air Liquide Finance
	Director of Air Liquide France Industries
	Director of Air Liquide International
	Director of Air Liquide Eastern Europe
	Director of Aqualung International
In foreign companies	
None	Air Liquide Group:
	Executive Vice-President of Air Liquide International Corporation

Director of American Air Liquide Holdings, Inc.

Manager of Air Liquide US LLC

Director of SOAEO

Past directorships since 2009

In French companies

None None

In foreign companies

None

Director of Air Liquide Japon (since 2013)

Education and business experience

Civil Engineer, graduate from Ecole Nationale des Ponts et Chaussées

Since 2008	**Chief Financial Officer and Executive Committee Member of Air Liquide**
Since 2013	In charge of the diving activities of Air Liquide (Aqualung)
1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1993-2007	Various positions within Essilor including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)

Table of Contents

Suet-Fern Lee
1,000 shares

Date of birth: May 16, 1958
Nationality: Singaporean
First elected: May 2011
Term expires: 2015

Directorships and appointments of Suet-Fern Lee

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	Axa*:
	Director
	Member of the Finance Committee
In foreign companies	
None	Director of Macquarie International Infrastructure Fund Ltd* (Bermuda)
	Director of National Heritage Board (Singapore)
	Director of Rickmers Trust Management Pte Ltd* (Singapore)
	Director of Stamford Corporate Services Pte Ltd (Singapore)
	Chairman of the Board of directors of the Asian Civilizations Museum (Singapore)
	Director of the World Justice Project (USA)
Past directorships since 2009	

In French companies

None

None

In foreign companies

None

Director of Richina Pacific Limited* (Bermuda, until 2009)

Director of Transcu Group Limited* (Singapore, until 2010)

Director of Sembcorp Industries Ltd* (Singapore, until 2011)

Education and business experience

Law degree from Cambridge University (1980)

Admitted to London (1981) and Singapore (1982) Bars

Senior Partner of Stamford Law Corporation (Singapore)

Since 2006	Member of the Board of Trustees of Nanyang Technological University (Singapore)
	Member of the Accounting Advisory Board of National University of Singapore Business School (Singapore)
Since 2007	Member of the Advisory Committee of the Singapore Management University School of Law (Singapore)
Since 2014	Member of the Senate of the Singapore Academy of Law
2000-2007	Director of ECS Holdings Limited* (Singapore)
2004-2007	Director of International Capital Investment Limited (Singapore)
	Director of Media Asia Entertainment Group Limited (Hong Kong)
	Director of Transpac Industrial Holdings Limited* (Singapore)
2005-2008	Director of China Aviation Oil* (Singapore)
2006-2008	Director of Sincere Watch* (Hong Kong)
2010-2011	President of the Inter-Pacific Bar Association

Table of Contents

Christian Mulliez
1,444 shares

Date of birth:	November 10, 1960
Nationality:	French
First elected:	June 2004
Last reappointment:	May 2010
Term expires:	2014

Directorships and appointments of Christian Mulliez

Within the Sanofi Group	Outside the Sanofi Group
Current directorships and appointments	
In French companies	
Director of Sanofi*	Chairman of the Board of Directors of Regefi
Member of the Audit Committee of Sanofi	Director of DG 17 Invest
Member of the Compensation Committee of Sanofi	
In foreign companies	
None	Director of L'Oréal USA Inc. (United States)
	Director of Galderma Pharma (Switzerland)
	Director of The Body Shop International (United Kingdom)
Past directorships since 2009	
In French companies	
None	None
In foreign companies	
None	None

Education and business experience

Degree from ESSEC (*Ecole Supérieure des Sciences Economiques et Commerciales*)

Since 2003 **Vice President General Manager Administration and Finance at L'Oréal***

1984-2002 Various positions at Synthélabo and then at Sanofi-Synthélabo, including Vice President Finance

150

Table of Contents

Carole Piwnica	Date of birth:	February 12, 1958
1,000 shares	Nationality:	Belgian
	First elected:	December 2010
	Last reappointment:	May 2012
	Term expires:	2016

Directorships and appointments of Carole Piwnica

Within the Sanofi Group	**Outside the Sanofi Group**
Current directorships and appointments	
In French companies	
Independent director of Sanofi*	Eutelsat Communications*:
Member of the Audit Committee of Sanofi	Independent Director
	Chairman of the Committee of Governance, Compensation and Appointment
In foreign companies	
None	**Director of Naxos UK Ltd** (United Kingdom)
	Director of Big Red (United States)
	Director of Elevance (United States)
	Director of Amyris Inc.* (United States)
Past directorships since 2009	
In French companies	
None	None
In foreign companies	
None	

Director of Toepfer GmbH (Germany, until 2010)

Director of Dairy Crest Plc.* (United Kingdom, until 2010)

Member of the Ethical Committee of Monsanto* (United States, until 2009)

Aviva Plc.* (United Kingdom, until 2011):

Director

Chairman of the Corporate Responsibility Committee

Member of the Compensation Committee

Director of Louis Delhaize* (Belgium, until 2013)

Education and business experience

Degree in law, *Université Libre de Bruxelles*

Masters in law, New York University

Admitted to Paris and New York Bars

Since 2006	**Founder Director of Naxos UK Ltd** (United Kingdom)
1985-1991	Attorney at Proskauer, Rose (New York) and Shearman & Sterling (Paris) with practice in mergers and acquisitions
1991-1994	General Counsel of Gardini & Associés
1994-2000	Chief Executive Officer of Amylum France, then Chairman of Amylum Group
1998-2004	Director of Spadel (Belgium)
1996-2006	Director of Tate & Lyle Plc. (United Kingdom)
2000-2006	Director and Vice-Chairman of Tate & Lyle Plc. for Governmental Affairs (United Kingdom)

1996-2006