

Paris, October 25, 2012

## Q3 2012 Business EPS<sup>1</sup> reflects patent expirations Growth Platforms<sup>2</sup> reached over 70% of sales

	<u>Q3 2012</u>	Change on a reported basis	Change at constant exchange rates <sup>1</sup>	<u>9-month</u> 2012	Change on a reported basis	Change at constant exchange rates
Net sales	<b>€9,040</b> m	+3.3%	-3.1%	€26,421m	+6.2%	+1.2%
Business net income <sup>1</sup>	€2,221m	-7.4%	-15.9%	€6,607m	-1.7%	-8.6%
Business EPS <sup>1</sup>	€1.68	-6.1%	-14.5%	€5.01	-1.6%	-8.4%

In order to facilitate an understanding of our operational performance, we comment on our business net income statement. Business net income<sup>1</sup> is a non-GAAP financial measure. The consolidated income statement for the 9 months of 2012 is provided in Appendix 7. A reconciliation of business net income to consolidated net income is provided in Appendix 6. Consolidated net income for the first 9 months of 2012 was  $\leq$ 4,557 million, compared to  $\leq$ 4,254 million for the first 9 months of 2011. Consolidated EPS for the first 9 months of 2012 was  $\leq$ 3.45 versus  $\leq$ 3.23 for the first 9 months of 2011.

Commenting on the Group's performance in Q3 2012, Sanofi Chief Executive Officer, Christopher A. Viehbacher said, "The loss of exclusivity for Eloxatin<sup>®</sup> in August in the U.S. marks the final step in the genericization of our legacy blockbusters. The solid performance of our growth platforms<sup>2</sup> which account for over 70% of sales, coupled with tight cost control, allowed us to limit the impact of the patent cliff on business EPS<sup>1</sup> this quarter. Furthermore, we continue to make progress with our pipeline with the launch of Zaltrap<sup>®</sup> and Aubagio<sup>®</sup> in the U.S. and the FDA approval for Auvi-Q<sup>TM</sup>".

## Q3 2012 Performance

- Total sales<sup>3</sup> reached €9,040 million, a decrease of 3.1%. Net sales lost to generic competition were €448 million in the quarter, primarily due to generic competition to Eloxatin in the U.S.
- Sales from growth platforms<sup>2</sup> grew by 6.4% to  $\in$ 6,412 million and accounted for 70.9% of total sales.
- Diabetes recorded its seventh consecutive quarter of double-digit sales growth (+17.5% to €1,486 million). Lantus<sup>®</sup> recorded strong growth (+20.7% to €1,279 million) driven by the performance in the U.S. (+22.1%) and Emerging Markets<sup>4</sup> (+31.5%).
- "New Genzyme"<sup>5</sup> achieved strong double-digit sales growth (+22.5%) driven by the Fabrazyme<sup>®</sup> recovery.
- Emerging Markets<sup>4</sup> sales were €2,821 million, an increase of 6.8% with double-digit growth recorded for Diabetes, CHC, new Genzyme and Animal Health.
- Vaccines sales reached €1,481 million (+0.7%), reflecting solid underlying performance impacted by temporary U.S. supply limitations for Pentacel<sup>®</sup> and the delivery of Flu vaccines extending into Q4 2012 unlike last year.
- The impact of the Plavix<sup>®</sup> and Avapro<sup>®</sup> loss of exclusivity in the U.S. was €469 million<sup>6</sup> at CER on Business Net Income.
- Business EPS<sup>1</sup> of €1.68 was down 14.5% at CER.

## **R&D and Guidance**

- The FDA approved Zaltrap<sup>®</sup> for previously treated metastatic colorectal cancer, Aubagio<sup>®</sup> for relapsing multiple sclerosis and Auvi-Q<sup>TM</sup> for patients with life-threatening allergies. Plavix<sup>®</sup> was approved for two new indications in Japan. Fluzone<sup>®</sup> QIV IM and a new hexavalent vaccine were filed in the U.S. and EU, respectively.
- A second set of Phase III studies for the new glargine formulation was recently initiated. Eliglustat, an oral compound for Gaucher disease, met its primary endpoint in the Phase III ENGAGE study.
- Given the Group's performance in the first nine months of this year, 2012 business EPS<sup>1</sup> is now expected to be around 12% lower at CER than 2011<sup>7</sup>, barring unforeseen adverse events.

<sup>(1)</sup> See Appendix 8 for definitions of financial indicators; (2) See Appendix 4; (3) Growth in net sales is expressed at constant exchange rates (CER) unless otherwise indicated (see Appendix 8 for a definition); (4) See definition on page 8; (5) "New Genzyme" consists of rare diseases products and Multiple Sclerosis products; (6) Including a one-time payment of \$80 million by BMS; (7)  $\in$  6.65

# 2012 third-quarter and 9-month sales

Unless otherwise indicated, all sales growth figures in this press release are stated at constant exchange rates<sup>1</sup>.

Net sales in the third quarter of 2012 reached of €9,040 million, an increase of 3.3% on a reported basis. Exchange rate movements had a positive effect of 6.4 percentage points reflecting mainly the appreciation of the U.S. dollar and, to a lesser extent, the appreciation of the Japanese Yen and Chinese Yuan against the Euro. At constant exchange rates, and adjusting for changes in the scope of consolidation (primarily the return of Copaxone<sup>®</sup> to Teva and the disposal of Dermik), net sales decreased by 1.2%.

In the first nine months of 2012, Sanofi generated net sales of €26,421 million, an increase of 6.2% on a reported basis. Exchange rate movements had a favorable effect of 5.0 percentage points driven by the appreciation of the U.S. dollar, Japanese Yen and Chinese Yuan against the Euro. At constant exchange rates, and after taking into account changes in structure (primarily the consolidation of Genzyme from the second quarter of 2011), net sales increased by 0.2%.

## **Growth Platforms**

Third quarter sales of the Group's growth platforms were €6,412 million, an increase of 6.4%, with double-digit sales growth achieved by Diabetes and "new Genzyme". The Group's growth platforms accounted for 70.9% of total consolidated sales in the third quarter of 2012, up from 64.5% in the third quarter of 2011. Year-to-date sales of growth platforms (including "new Genzyme") reached €17,546 million, up 9.3% or 6.6% with Genzyme proforma (sales of Genzyme were not consolidated in the first quarter of 2011). Growth platforms sales comprised 66.4% of total consolidated sales compared with 61.6% in the first nine months of 2011.

(€million)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change at constant exchange rates
Emerging Markets <sup>*/**</sup>	2,821	+6.8%	8,268	+8.8%
Emerging Markets excluding Diabetes, Vaccines, CHC, animal health, new Genzyme and Innovative Products	1,569	+0.3%	4,734	+2.4%
Diabetes	1,486	+17.5%	4,233	+15.2%
Vaccines	1,481	+0.7%	2,881	+1.1%
Consumer Health Care (CHC)	733	+5.9%	2,276	+9.5%
Animal Health	519	+3.8%	1,673	+2.0%
New Genzyme	470	+22.5%	1,304	+15.0%***
Innovative products****	154	+7.6%	445	+6.1%
Total Growth Platforms	6,412	+6.4%	17,546	+9.3%
Total Growth Platforms with Genzyme pro forma	6,412	+6.4%	17,546	+6.6%

#### **Net sales of Growth Platforms**

World excluding the U.S. and Canada, Western Europe, Japan, Australia and New Zealand.

Includes Diabetes, Vaccines, Consumer Health Care, new Genzyme, Animal Health and new products sales generated in Emerging Markets;

"" "new Genzyme" on a constant structure basis and at constant exchange rates;

"" Includes recent product launches which do not belong to the other Growth Platforms listed above: Multaq<sup>®</sup> and Jevtana<sup>®</sup>, Zaltrap<sup>®</sup>, and Mozobil<sup>®</sup> pro forma

## **Pharmaceuticals**

Pharmaceuticals net sales decreased 4.3% (to  $\in$ 7,040 million) in the third quarter of 2012, impacted by the loss of sales of Copaxone<sup>®</sup> (impact of  $\in$ 117 million), disposal of Dermik (impact of  $\in$ 33 million), EU austerity measures and generic competition. In the third quarter, net sales lost to generic competition were  $\in$ 448 million, due mainly to Eloxatin<sup>®</sup> and Lovenox<sup>®</sup> in the U.S. and, to a lesser extent, Aprovel<sup>®</sup>, Plavix<sup>®</sup>, Taxotere<sup>®</sup> in the EU. Year-to-date sales for the Pharmaceuticals business were  $\in$ 21,867 million, an increase of 1.2%, which includes the positive contribution from Genzyme (consolidated from April 2011).

## **Flagship Products<sup>8</sup>**

(millions of euros)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change at constant exchange rates
Lantus®	1,279	+20.7%	3,625	+18.1%
Plavix <sup>®</sup>	505	-10.4%	1,563	-4.0%
Lovenox®	437	-14.0%	1,452	-11.7%
Aprovel®	298	-8.3%	939	-6.7%
Renvela <sup>®</sup> /Renagel <sup>®</sup>	164	+12.6%	476	+10.7%*
Cerezyme®	163	+9.9%	462	-0.2%*
Eloxatin <sup>®</sup>	129	-62.9%	888	+10.1%
Taxotere®	129	-36.0%	438	-46.6%
Myozyme <sup>®</sup> /Lumizyme <sup>®</sup>	116	+8.9%	341	+11.6%*
Synvisc <sup>®</sup> /Synvisc One <sup>®</sup>	89	+0.0%	273	+5.9%*
Fabrazyme <sup>®</sup>	87	+146.9%	208	+107.6%*
Multaq <sup>®</sup>	65	-9.1%	192	-9.1%
Jevtana®	56	+17.8%	175	+18.4%
Apidra <sup>®</sup>	57	+1.9%	165	+1.9%

\* On a constant structure basis and at constant exchange rates

<sup>1</sup> See Appendix 8 for definitions of financial indicators

<sup>8</sup> See Appendix 2 for a geographical split of consolidated net sales by product

## **Diabetes**

In the third quarter, the Diabetes business reached sales of  $\leq 1,486$  million, an increase of 17.5%. The performance of Lantus<sup>®</sup> was particularly strong this quarter with sales up 20.7% (to  $\leq 1,279$  million) driven by the U.S. (+ 22.1% to  $\leq 800$  million), Emerging Markets (+31.5% to  $\leq 204$  million) and Japan (+22.5% to  $\leq 39$  million). In the U.S., Lantus<sup>®</sup> SoloSTAR<sup>®</sup> represented 51.5% of total Lantus<sup>®</sup> sales in the quarter, versus 47.2% in the third quarter of 2011. In the Emerging Markets, Lantus<sup>®</sup> sales growth was particularly strong in China (+27.9%), Brazil (+31.2%), Mexico (+24.2%) and Russia (+41.3%). Year-to-date sales of Lantus<sup>®</sup> reached  $\leq 3,625$  million, up 18.1%.

Our Diabetes portfolio was further enlarged in the Emerging Markets with the launch of **Insuman<sup>®</sup> SoloSTAR<sup>®</sup>** in Russia in July and the launch in October in India of **AllStar**<sup>™</sup>, the first Indian-manufactured, re-usable insulin pen, manufactured by a global company in India. AllStar<sup>™</sup> has been developed specifically for patients in Emerging Markets. The launch of AllStar<sup>™</sup> is a significant milestone emblematic of Sanofi's leadership in addressing the needs of people with diabetes in India. It highlights Sanofi's commitment to Diabetes and Emerging Markets and its regionalized approach to finding solutions that are adapted to local market needs. Going forward, Sanofi intends to make AllStar<sup>™</sup> accessible to other Emerging Markets.

Third-quarter and year-to-date sales of **Apidra<sup>®</sup>** reached €57 million (+1.9%) and €165 million (+1.9%), respectively.

Despite a good performance in Emerging Markets (+14.3% to €68 million), worldwide sales for **Amaryl**<sup>®</sup> were down 7.5% to €106 million, impacted by generic competition in Japan (where sales decreased 34.1% to €30 million). Year-to-date sales of Amaryl<sup>®</sup> decreased to €319 million (-6.8%), of which 62% were generated in Emerging Markets (€198 million) and increased 11.8%.

The Diabetes business recorded year-to-date sales of €4,233 million, an increase of 15.2%.

## Oncology

The third quarter was marked by the approval in the U.S. of **Zaltrap**<sup>®</sup> (ziv-aflibercept, collaboration with Regeneron). Zaltrap<sup>®</sup> is indicated for combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), for patients with metastatic colorectal cancer that is resistant to, or has progressed, following an oxaliplatin-containing regimen. Zaltrap<sup>®</sup> was launched at the end of August in the U.S. and reached sales of  $\in$ 7 million. This quarter was also marked by the expected loss of market exclusivity of **Eloxatin**<sup>®</sup> in the U.S. on August 9, 2012, resulting in a 74.7% decrease in Eloxatin<sup>®</sup> sales to  $\in$ 72 million.

Third-quarter sales of **Taxotere**<sup>®</sup> were down 36.0% to €129 million, reflecting generic erosion in the U.S. (€10 million, -70.4%) and Western Europe (€12 million, -70.7%). Year-to-date sales of Taxotere<sup>®</sup> were €438 million (down 46.6%), of which €347 million was generated outside the U.S. and Western Europe.

Sales of **Jevtana**<sup>®</sup> increased 17.8% to €56 million in the third quarter, reflecting the recent launches in Western Europe. Year-to-date Jevtana<sup>®</sup> sales totaled €175 million, an increase of 18.4%.

Sales of **Mozobil**<sup>®</sup> reached €26 million and €71 million (+9.5%) in the third quarter and (+20.0%\*) in the first 9 months, respectively.

Third-quarter sales of the **Oncology** business decreased 35.7% to €485 million. Year-to-date sales of this business decreased 6.0% to €1,977 million.

## Worldwide presence<sup>1</sup> of Plavix<sup>®</sup>/Iscover<sup>®</sup> and Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>/Avalide<sup>®</sup>

On October 3, Sanofi and Bristol-Myers Squibb (BMS) announced a restructuring of their successful long-term alliance following the loss of exclusivity of Plavix<sup>®</sup> and Avapro<sup>®</sup>/Avalide<sup>®</sup> in many major markets (Japan remains excluded from the Alliance). Under the terms of the revised agreement, which will go into effect January 1, 2013, BMS will return to Sanofi its rights to Plavix<sup>®</sup> and Avapro<sup>®</sup>/Avalide<sup>®</sup> 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, BMS will receive royalty payments on Sanofi's sales of branded and unbranded Plavix<sup>®</sup> worldwide, excluding the U.S. and Puerto Rico, and on sales of branded and unbranded Avapro<sup>®</sup>/Avalide<sup>®</sup> worldwide, in each case through 2018, and will receive a terminal payment of U.S. \$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.

The Worldwide presence of **Plavix**<sup>®</sup> decreased 70.1% to €568 million in the third quarter, impacted by generic competition in the U.S., following the loss of exclusivity on May 17, 2012 (U.S. sales, consolidated by BMS, declined by 97.5% to €33 million). In Europe, sales were down 29.6% to €102 million, also impacted by generic competition. In Emerging Markets, third-quarter consolidated sales increased 8.0% to €210 million, of which €104 million was generated in China (+28.2 %). In Japan, sales of Plavix<sup>®</sup> grew 18.1% to €214 million. Year-to-date, the worldwide presence of Plavix<sup>®</sup> was €3,430 million, a decrease of 38.7%.

(millions of euros)		Change at constant	9-month	Change at constant
	Q3 2012	exchange rates	2012	exchange rates
Europe	102	-29.6%	347	-22.1%
United States	33	-97.5%	1,813	-52.5%
Other Countries	433	-5.1%	1,270	-3.3%
TOTAL	568	-70.1%	3,430	-38.7%

## Worldwide presence of Plavix<sup>®</sup>/Iscover<sup>®</sup>: geographic split

The worldwide presence of **Aprovel**<sup>®</sup>/**Avalide**<sup>®</sup> was down 26.2% to  $\in$ 334 million in the third quarter, reflecting generic competition in the U.S. and in Europe. In the U.S., where the product lost its exclusivity on March 30, 2012, sales declined 83.7%. Sanofi launched an authorized generic version in the U.S. (sales are booked in the Generics business). In Europe, where Aprovel<sup>®</sup> faced generic competition in most countries during the third quarter, sales were down 25.2% to  $\in$ 155 million. Consolidated sales of the product in Emerging Markets were  $\in$ 95 million, down 1.1%. The year-to-date worldwide presence of Aprovel<sup>®</sup> was  $\in$ 1,120 million, a decrease of 22.0%.

## Worldwide presence of Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup>: geographic split

(millions of euros)	Q3 2012	Change at constant exchange rates	9-month 2012	Change at constant exchange rates
Europe	155	-25.2%	525	-16.5%
United States	16	-83.7%	124	-60.8%
Other Countries	163	+7.3%	471	-4.8%
TOTAL	334	-26.2%	1,120	-22.0%

<sup>1</sup>See Appendix 8 for definitions of financial indicators

\* On a constant structure basis and at constant exchange rates, Genzyme sales were not consolidated in Q1 2011

## **Other Pharmaceutical Products**

Third-quarter sales of **Lovenox**<sup>®</sup> decreased 14.0% to €437 million, due to generic pressure in the U.S. where sales declined 63.2% to €55 million. Sanofi commercializes an authorized generic of Lovenox<sup>®</sup> in the U.S. (sales are booked in the Generics business). Outside the U.S., Lovenox<sup>®</sup> recorded another quarter of growth with sales of €382 million (+4.2%). In Emerging Markets, sales increased 10.9% to €154 million. In Western Europe, sales of the product were stable at €201 million. Year-to-date sales of Lovenox<sup>®</sup> totaled €1,452 million (-11.7%), of which 81.8% (€1,188 million) was generated outside the U.S. (+7.6%).

**Renvela<sup>®</sup>/Renagel<sup>®</sup>** recorded sales of €164 million (+12.6%) in the third quarter, driven by the performance in the U.S. (sales were up 17.2% to €115 million). Year-to-date sales of Renvela<sup>®</sup>/Renagel<sup>®</sup> were €476 million, up 10.7%\*. Genzyme and generic manufacturers settled pending U.S. litigation in the District of Maryland with regard to the production and sale of generic formulations of Renvela<sup>®</sup> tablets, Renvela<sup>®</sup> for oral suspension and Renagel<sup>®</sup>. These settlements are subject to review by the U.S. Federal and Trade Commission. According to the terms of the settlements, the first-filer for each product can enter the U.S. market on March 16, 2014 and second-filers can enter the market on September 16, 2014, or earlier under certain circumstances, pending approval of their generic application.

The **Ambien**<sup>®</sup> family of products recorded sales of €126 million, (-5.0%). In Japan, given the entry of generics, sales modestly decreased 5.6% to €72 million. Year-to-date sales of the Ambien<sup>®</sup> family totaled €380 million, down 0.6%. In Japan, year-to-date sales of Myslee<sup>®</sup> reached €224 million, up 1.7%.

Third-quarter sales of **Allegra**<sup>®</sup> as a prescription drug were €110 million (-1.9%). Japan sales were €77 million and declined 8.3% reflecting the recent price decrease. Year-to-date sales of Allegra<sup>®</sup> as a prescription drug were €418 million (down 11.2%), of which 76.1% (€318 million, down 17.2%) was generated in Japan. On August 15, 2012, the Japan regulatory agency approved the first three Allegra<sup>®</sup> generics of Esai, Taisho, and Koybashi although the validity of the patents covering the product had been reinstated. On October 5, 2012, Sanofi brought a patent infringement suit against Elmed-Eisai, Taisho (Teva) and Kobayashi at the Tokyo District Court.

Sales of **Synvisc**<sup>®</sup>/**Synvisc One**<sup>®</sup> reached €89 million and €273 million (+5.9%\*) in the third quarter and the first 9 months, respectively.

Third-quarter sales of **Multaq<sup>®</sup>** were €65 million, down 9.1%, reflecting the impact of updated labeling in the second half of 2011. Sales of the product in the U.S. reached €51 million, down 2.2%. Year-to-date sales of Multaq<sup>®</sup> decreased 9.1% to €192 million.

The transfer of **Copaxone**<sup>®</sup> sales to Teva was finalized in the first quarter of 2012. As a consequence, Sanofi did not book any sales of the product in the third quarter of 2012 compared to €117 million consolidated in the third quarter of 2011. Sanofi will receive a payment of 6% on sales from Teva for a period of two years, on a country-by-country basis. Year-to-date consolidated sales of Copaxone<sup>®</sup> were €24 million compared to €350 million for the same period in 2011.

## **New Genzyme**

"New Genzyme" currently consists of Rare Disease products and Multiple Sclerosis products (Aubagio<sup>®</sup> and the investigational agent Lemtrada<sup>TM</sup>).

(€million)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change on a constant structure basis and at constant exchange rates
Cerezyme®	163	+9.9%	462	-0.2%*
Myozyme <sup>®</sup> /Lumizyme <sup>®</sup>	116	+8.9%	341	+11.6%*
Fabrazyme <sup>®</sup>	87	+146.9%	208	+107.6%*
Other Rare Disease products	104	+12.8%	293	+12.2%*
Total "new Genzyme"	470	+22.5%	1,304	+15.0%*

Third-quarter sales of "**new Genzyme**" reached €470 million, an increase of 22.5%, driven by the recovery of Fabrazyme<sup>®</sup>. Year-to-date sales of "new Genzyme" totaled €1,304 million, an increase of 15.0%\*.

\* On a constant structure basis and at constant exchange rates, Genzyme sales were not consolidated in Q1 2011

Third quarter sales of **Cerezyme**<sup>®</sup> increased 9.9% to €163 million, driven by the performance in Western Europe (+20.5%). Year-to-date sales of Cerezyme<sup>®</sup> reached €462 million (-0.2%\*). Genzyme manufacturing recovery for Cerezyme<sup>®</sup> remains on track. Significant progress in recent months has been made as all existing patients in major markets have been returned to normal dosing. This includes U.S., Japan and the majority of the EU. Cerezyme<sup>®</sup> is expected to maintain market share and deliver modest growth throughout the year.

Sales of **Myozyme<sup>®</sup>/Lumizyme<sup>®</sup>** grew 8.9% to €116 million supported by the performance in Western Europe (+12.5%) in the third quarter. Year-to-date sales of Myozyme<sup>®</sup>/Lumizyme<sup>®</sup> were €341 million, an increase of 11.6%\*.

The strong recovery of **Fabrazyme**<sup>®</sup> continued in the third quarter with sales up 146.9% to €87 million. The approval of the new Framingham plant in January, stable production runs and the return of all existing patients in all markets to full dose strengthened Fabrazyme sales. In the U.S., third-quarter sales (€44 million, up 290.0%) also benefited from Shire's withdrawal of Replagal<sup>®</sup> BLA in the U.S. earlier this year. Year-to-date sales of Fabrazyme<sup>®</sup> reached €208 million, an increase of 107.6%\*. Genzyme anticipates approval of Fabrazyme<sup>®</sup> manufactured in our Framingham facility for the majority of remaining markets by the end of 2013.

A key milestone was achieved in the third quarter towards building a leading franchise in multiple sclerosis (MS) with the FDA approval of **Aubagio**<sup>®</sup> (teriflunomide) in September as a new once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis. Aubagio<sup>®</sup> was launched in the U.S. in October through the new MS sales team recently hired by Genzyme.

## **Consumer Health Care**

Consumer Health Care (CHC) sales reached €733 million in the third quarter, an increase of 5.9%. Sales in Emerging Markets increased 16.1% to €374 million with Lactacyd<sup>®</sup>, Dorflex<sup>®</sup>, Enterogermina<sup>®</sup>, NoSpa<sup>®</sup>, and Maalox<sup>®</sup> recording double digit growth. U.S. sales of Allegra<sup>®</sup> OTC were €44 million (down 11.6%). Year-to-date sales of Consumer Health Care were €2,276 million, an increase of 9.5%.

## Generics

Third-quarter sales of generics were €479 million, up 14.9%, driven by the authorized generics of Lovenox<sup>®</sup> and Aprovel<sup>®</sup> in the U.S. (U.S. sales of generic products increased 110.3% to €70 million). In Emerging Markets, sales of generics were €262 million, up 0.8%. Year-to-date sales of generics totaled €1,386 million, an increase of 9.7%.

## **Human Vaccines**

Consolidated sales of Sanofi Pasteur were €1,481 million (+0.7%) in the third quarter, impacted by temporary supply limitations for Pentacel<sup>®</sup> in the U.S. and the timing of Flu vaccines supply. Year-to-date consolidated sales of the Human Vaccines business totaled €2,881 million, an increase of 1.1%.

Sales of **Polio/Pertussis/Hib vaccines** recorded a 16.0% increase to €320 million in the third quarter, boosted by the sales of Imovax<sup>®</sup> Polio (against acute flaccid poliomyelitis; sales of €65 million) in Japan which was added to the country's public immunization program on September 1st, 2012. Third-quarter Emerging Markets sales of Polio/Pertussis/Hib vaccines increased 32.7% to €139 million, driven by Pentaxim<sup>®</sup> sales which grew 27.0% (to €83 million) reflecting good performance in Latin America and in China. Sales of U.S. Polio/Pertussis/Hib franchise were down 45.0% to €69 million reflecting supply limitations for Pentacel<sup>®</sup>. As previously announced, Sanofi Pasteur temporarily implemented supply limitations for Pentacel<sup>®</sup> and Daptacel<sup>®</sup> vaccines in April 2012 in the U.S. This is a necessary step due to a manufacturing delay that will temporarily reduce supply below the level needed to fully satisfy market demand in the U.S. These supply limitations are likely to remain in effect until the beginning of 2013. Year-to-date sales of Polio/Pertussis/Hib vaccines totaled €838 million, up 5.2%.

<sup>\*</sup> On a constant structure basis and at constant exchange rates, Genzyme sales were not consolidated in Q1 2011

Sales of **seasonal influenza vaccines** were €608 million in the third quarter, down 8.0%, reflecting a tough comparison from the high level of supply in the U.S. in the third quarter of 2011. In the U.S., third-quarter sales of influenza vaccines decreased 8.3% to €428 million. Sanofi Pasteur expects to deliver around 60 million doses of seasonal influenza vaccine in the U.S. this season. The full commercial launch of Fluzone<sup>®</sup> Intradermal (the first influenza vaccine licensed in the U.S. that uses a novel microinjection system for intradermal delivery) occurred in the third quarter 2012 in the U.S. Year-to-date sales of seasonal influenza vaccines totaled €777million, down 5.1%.

Sales of **Menactra**<sup>®</sup> were €208 million, down 4.9% in the third quarter, reflecting a tough comparison from the high level of sales in the Middle-East in the third quarter of 2011. In the U.S., sales reached €195 million (+0.6%) despite continued competition. Year-to-date sales of Menactra<sup>®</sup> totaled €375 million, up 1.5%.

Third-quarter sales of **Adult booster** vaccines were €140 million, up 4.9%. Sales of Adacel<sup>®</sup> increased 4.5% to €108 million. Year-to-date sales of Adult boosters totaled €373 million, an increase of 5.2%.

Third-quarter **travel and other endemic vaccines** were €83 million (-20.4%) impacted by the temporary suspension of production of Theracys<sup>®</sup>/Immucyst<sup>®</sup> and BCG vaccines. Year-to-date sales of travel and other endemic vaccines totaled €260 million (-7.4%).

Following a Warning Letter received on July 12, Sanofi Pasteur continues to work diligently with the FDA to implement steps to address the issues identified in the Warning Letter.

#### **Consolidated vaccines sales**

(millions of euros)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change at constant exchange rates
Influenza Vaccines (incl. Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	608	-8.0%	777	-5.1%
of which seasonal vaccines	608	-8.0%	775	-5.4%
of which pandemic vaccines	0	-	2	Ns
Polio/Pertussis/Hib Vaccines (incl. Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	320	+16.0%	838	+5.2%
Meningitis/Pneumonia Vaccines <i>(incl. Menactra<sup>®</sup>)</i>	230	-3.3%	432	-0.5%
Adult Booster Vaccines <i>(incl. Adacel</i> ®)	140	+4.9%	373	+5.2%
Travel and Other Endemics Vaccines	83	-20.4%	260	-7.4%
Other Vaccines	100	+69.8%	201	+22.8%
TOTAL	1,481	+0.7%	2,881	+1.1%

Third-quarter sales of **Sanofi Pasteur MSD** (not consolidated), the joint venture with Merck & Co. in Europe, increased 3.8% to €270 million, driven by Gardasil<sup>®</sup> (+61.6% to €66 million) and pediatric vaccines. Year-to-date sales of Sanofi Pasteur MSD grew 5.9% to €602 million.

Sanofi Pasteur MSD announced plans to license and commercialize an innovative 6-in-1 pediatric vaccine in its European territories. The new hexavalent vaccine, developed by Sanofi Pasteur, is the only fully liquid, ready to use 6-in-1 vaccine to protect infants against diphtheria, tetanus, pertussis, Hepatitis B, poliomyelitis and Haemophilus influenzae type b. The vaccine has been submitted by Sanofi Pasteur MSD to the European Medicines Agency for license within the European Union and upon approval the company will commercialize it in its European territories under its own brand name.

## Animal Health

Third-quarter sales of **Merial** recorded a 3.8% increase to €519 million, driven by Emerging Markets (+21.1% to €140 million). Year-to-date sales of Merial reached €1,673 million, an increase of 2.0%.

Sales of the **Companion Animals** segment increased 3.1% to €330 million in the third quarter, supported by double-digit-sales increase of Heartgard<sup>®</sup> in the U.S. Despite good performance in Western Europe (+7.9% to €42 million) and Emerging Markets (+23.8% to €26 million), sales of the Frontline<sup>®</sup>/fipronil family of products were down 3.5% to €178 million, impacted by competitive pressure in the U.S. (-13.0% to €96 million). The launch of a new combination parasiticide by Merial, Frontline<sup>®</sup> TRITAK, at the beginning of September 2012 partially

compensated the increased fipronil generic competition in the U.S. Year-to-date sales of the companion animals segment totaled €1,112 million, up 1.6%.

Merial has settled all its outstanding litigation with Velcera during the third quarter. The infringement action filed by Merial has been withdrawn as have the appeals filed by Velcera. The injunction against sales of PetArmor<sup>®</sup> Plus remains in effect and the generic product is not on the market.

Third-quarter sales of the **Production Animals** segment were €189 million, up 5.1%, driven by the Veterinary Public Health segment (+46.2%) and the Swine segment (+22.2%) which includes the acquisition of Newport Laboratories in the U.S. completed in March. The Veterinary Public Health segment benefited from sales of Foot-and-Mouth vaccines following outbreaks of the disease in some Emerging Markets. Year-to-date sales of the Production Animals segment were €561 million, up 2.8%.

# Net sales by geographic region

(millions of euros)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change at constant exchange rates
United States	2,998	-8.5%	8,393	+2.1%
Emerging Markets*	2,821	+6.8%	8,268	+8.8%
of which Eastern Europe and Turkey	667	+1.1%	1,994	+1.0%
of which Asia	751	+9.4%	2,132	+11.2%
of which Latin America	892	+11.3%	2,567	+13.2%
of which Africa	247	+2.9%	754	+7.2%
of which Middle East	231	+2.8%	725	+11.2%
Western Europe**	2,045	-11.6%	6,406	-8.1%
Rest of the world***	1,176	+6.5%	3,354	+1.7%
of which Japan	832	+14.2%	2,361	+5.2%
TOTAL	9,040	-3.1%	26,421	+1.2%

\* World less the U.S., Canada, Western Europe, Japan, Australia and New Zealand

\*\* France, Germany, UK, Italy, Spain, Greece, Cyprus, Malta, Belgium, Luxembourg, Portugal, Netherlands, Austria, Switzerland, Sweden, Ireland, Finland,

Norway, Iceland, Denmark

\*\*\* Japan, Canada, Australia and New Zealand

**Emerging Markets** sales reached €2,821 million, an increase of 6.8% in the third quarter with double digit growth recorded for Diabetes (+26.5%), Animal Health (+21.1%) and CHC (+16.1%). BRIC (Brazil, Russia, India and China) sales totaled €1,000 million, an increase of 10.4%. Sales in China reached €341 million, up 11.9%, which includes strong double digit growth of Plavix<sup>®</sup>, Lantus<sup>®</sup> and vaccines and weaker sales for the CHC business. Despite strong growth of Lantus<sup>®</sup>, Lovenox<sup>®</sup> and Animal Health, Brazil sales increased 2.9% to €385 million, reflecting lower sales of Generics and vaccines. Sales in Russia increased 20.6% to €204 million, particularly driven by Lantus<sup>®</sup>, Lovenox<sup>®</sup> and vaccines. Year-to-date sales in Emerging Markets totaled €8,268 million, up 8.8% (or 7.4% with Genzyme proforma).

In October Sanofi announced that it has signed an agreement to acquire Genfar S.A., a leading pharmaceuticals manufacturer headquartered in Bogota, Colombia. In 2011, Genfar's total sales were USD 133 million, with 30% of sales generated outside of Colombia. With this acquisition, Sanofi will become a market leader in Colombia and expand its portfolio of affordable pharmaceuticals in Latin America. The closing of the transaction is subject to certain conditions precedent and is expected to occur in the first quarter of 2013.

Third quarter sales in the **U.S.** were €2,998 million, down 8.5% mainly reflecting the loss of exclusivity of Eloxatin<sup>®</sup> (sales declined 74.7%) on August 9, 2012, and further generic competition on Lovenox<sup>®</sup> (-63.2%). Sanofi delivered strong growth of Lantus<sup>®</sup>, "new Genzyme" and Generics this quarter. Year-to-date sales in the U.S. increased 2.1% to €8,393 million (or down 2.5% with Genzyme pro forma).

Third-quarter sales in **Western Europe** decreased 11.6% to €2,045 million accounting for 22.6% of Group sales compared to 26.2% in the third quarter of 2011. Sales were impacted by the transfer of the Copaxone<sup>®</sup> business

to Teva, generic competition to Taxotere<sup>®</sup>, Aprovel<sup>®</sup> and Plavix<sup>®</sup>, as well as the impact of austerity measures. Excluding the impact of Copaxone<sup>®</sup>, sales in Western Europe declined 7.1%. Year-to-date sales in Western Europe decreased 8.1% (or 6.7% with Genzyme pro forma and excluding Copaxone<sup>®</sup>) to €6,406 million.

**Japan** reported third-quarter sales of €832 million, an increase of 14.2%, driven by good performance from Plavix<sup>®</sup> and Lantus<sup>®</sup>, and the inclusion of Imovax<sup>®</sup> Polio vaccine in the country's public immunization program on September 1<sup>st</sup>. Year-to-date sales in Japan increased 5.2% to €2,361 million (or 2.7% with Genzyme pro forma).

# R&D update

Since the last R&D update on July 26, 2012, Sanofi has had favorable regulatory newsflow including the approvals of Zaltrap<sup>®</sup>, Aubagio<sup>®</sup> and Auvi-Q<sup>TM</sup> in the U.S.; new indications obtained in Japan for Plavix<sup>®</sup>; the registration filing for a new hexavalent vaccine in Europe, and the Fluzone<sup>®</sup> QIV IM filing in the U.S. In parallel, four new Phase III studies evaluating the new formulation of insulin glargine started, and the first positive Phase III trial results of the oral therapy for Gaucher disease, eliglustat, were announced. Several compounds also entered Phase I and Phase II.

At the end of October, the R&D portfolio comprises 65 NMEs (New Molecular Entities) projects and vaccines in clinical development of which 17 are in Phase III or have been submitted to the health authorities for approval.

## **Regulatory update**

Several regulatory milestones were achieved during the period:

In August:

- The FDA approved **Zaltrap**<sup>®</sup> (ziv-aflibercept, collaboration with Regeneron) for intravenous infusion, in combination with 5-fluorouracil leucovorin irinotecan (FOLFIRI), for patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.
- The FDA approved **Auvi-Q**<sup>™</sup> (epinephrine injection, USP) for the emergency treatment of lifethreatening allergic reactions in people who are at risk for or have a history of anaphylaxis.
- The Japanese Ministry of Health, Labor and Welfare granted approval for a Supplemental New Drug Application for **Plavix**<sup>®</sup> for patient with ST-elevation myocardial infarction. In September, the Japanese authorities granted approval, for a Supplemental New Drug Application for Plavix<sup>®</sup> for patients with Peripheral Arterial Disease;
- A new hexavalent vaccine (the only fully liquid, ready to use 6-in-1 vaccine to protect infants against diphtheria, tetanus, pertussis, Hepatitis B, poliomyelitis and invasive infections caused by Haemophilus influenzae type b), developed by Sanofi Pasteur, has been submitted by Sanofi Pasteur MSD to the European Medicines Agency for license within the European Union.

In September:

- The FDA approved **Aubagio**<sup>®</sup> (teriflunomide) a new once-daily, oral treatment indicated for patients with relapsing forms of multiple sclerosis.
- Fluzone<sup>®</sup> QIV IM, a quadrivalent intramuscular flu Vaccine, was filed in the U.S.

In October:

• The Endocrinologic and Metabolic Drugs Advisory Committee of the FDA recommended **Kynamro**<sup>™</sup> (mipomersen sodium, partnership with Isis Pharmaceuticals) for the treatment of patients with Homozygous Familial Hypercholesterolemia.

In August, Genzyme received a Refuse to File letter from the FDA in response to the supplemental Biologics License Application (sBLA) for the approval of Lemtrada<sup>™</sup> (alemtuzumab) as a treatment for relapsing multiple sclerosis. After collaborative consultations with the FDA, the agency requested that the company modify the presentation of the data sets to enable the agency to better navigate the application. The FDA has not requested additional data or further studies. The refilling of Lemtrada<sup>™</sup> is on track and we will make an announcement when the FDA makes a decision concerning the acceptance of the file.

## Late stage portfolio

In October, top line data for ENGAGE, the first Phase III trial of the oral therapy, **eliglustat**, was announced. This trial which evaluated eliglustat, in previously untreated patients with Gaucher disease type 1, met its primary endpoint. Patients treated with eliglustat had a statistically significant reduction in spleen size of 30% at nine months, compared with placebo. The initial safety analysis from ENGAGE suggests that eliglustat was well tolerated. Full results from the ENGAGE study are planned for presentation at the Lysosomal Disease Network WORLD meeting in February 2013. Top-line data from the second Phase III registration trial, ENCORE, are expected in early 2013.

Four new Phase III trials evaluating the **new formulation of insulin glargine** started in during quarter.

- The EDITION III trial, compares the new formulation of insulin glargine with Lantus<sup>®</sup> in patients with Type 2 diabetes on non-insulin antidiabetic therapy. The targeted number of patients to enroll in this study is 800.
- The EDITION IV trial compares the new formulation of insulin glargine with Lantus<sup>®</sup> in patients with Type 1 diabetes. The targeted number of patients to enroll in this study is 500.
- The EDITION JPI & JPII trials compare the new formulation of insulin glargine with Lantus<sup>®</sup> in Japanese patients with Type 1 and Type 2 diabetes.

The implementation of these four new studies, in addition to EDITION I and II trials, which started recruitment at the end of 2011, demonstrated full engagement of Sanofi in a large Phase III program to evaluate the new glargine formulation.

The results of the international study of insulin and cancer, ISICA, were presented at the EASD (European Association for the Study of Diabetes) Congress on October 3, 2012. ISICA assessed the relative risk for breast cancer in women with diabetes. No change in the background risk for breast cancer was demonstrated for the users of **insulin glargine**. Furthermore neither dose, nor duration of treatment altered such neutral effect of insulin glargine.

Detailed results from the pivotal Phase III VELOUR study evaluating **Zaltrap**<sup>®</sup> injection for intravenous infusion for the treatment of patients with previously treated metastatic colorectal cancer were published in the October 2012 edition of the Journal of Clinical Oncology. In this trial evaluating metastatic, patients previously treated with an oxaliplatin-containing regimen, Zaltrap<sup>®</sup> in combination with the FOLFIRI chemotherapy regimen (5-fluorouracil, leucovorin, irinotecan) showed a statistically significant improvement in overall survival, progression-free survival, and the overall tumor response rate versus placebo plus FOLFIRI.

The global phase III program of **sarilumab** (collaboration with Regeneron, the first fully-human subcutaneously administered monoclonal antibody targeting the interleukin-6 receptor with high affinity) in rheumatoid arthritis (RA) is moving forward with two pivotal efficacy and safety trials, Saril-RA-Mobility and Saril-RA-Target. The Saril-RA-Mobility is now fully enrolled (N=1197) and will evaluate sarilumab in combination with methotrexate in adult moderate-to-severe active RA patients with an inadequate response to methotrexate. The SARIL-RA-Mobility results are anticipated in 2014. The Saril-RA-Target trial will evaluate sarilumab in combination with non-biologic, disease-modifying anti-rheumatic drugs in adult moderate-to-severe active RA patients with inadequate response to, or intolerant of, one or more TNF-alpha (tumor necrosis factor alpha) inhibitors. In addition, a long-term safety study of sarilumab, Saril-RA Extend, is open for patients who complete the ongoing studies. Additional phase III studies will be announced in 2013.

In September, the JAKARTA Phase III study of **SAR302503**, an investigational JAK2 inhibitor for the treatment of myelofibrosis, completed patient enrollment.

Recruitment of the Phase III evaluating **Synvisc-One<sup>™</sup>** for the treatment of pain in osteoarthritis of the hip has started.

In September, the detailed results of the Phase IIb study conducted in Thailand evaluating the **Dengue vaccine** candidate were published in the online publication in *The Lancet*. The results show the ability of the vaccine candidate to protect against dengue fever caused by three dengue virus types. The full analysis of vaccine efficacy against each serotype, reflecting real-life conditions showed vaccine efficacy to be 61.2% against dengue virus type 1, 81.9% against type 3 and 90.0% against type 4. One of the dengue virus types (serotype 2) eluded the vaccine. Analyses are ongoing to understand the lack of protection for serotype 2 in the particular epidemiological context of Thailand. The results of the world's first efficacy study confirm the excellent safety

profile of Sanofi Pasteur's dengue vaccine candidate. Large-scale phase III clinical studies of Sanofi Pasteur's dengue vaccine candidate are underway with 31,000 children and adolescents in 10 countries in Asia and Latin America. These studies will generate important additional data in a broader population and in a variety of epidemiological settings to define the best conditions to set up vaccination programs in order to protect people at risk of dengue.

One project in Phase II (FOV2304 –a bradykinin B1 antagonist evaluated in diabetic macular edema) has been discontinued. Based on the review of Phase IIb results for FOV-1101 (a FDC prednisolone/cyclosporine), which led to a reassessment of the commercial perspectives for this compound, Sanofi has made the decision to continue the development of FOV1101 under a sublicense agreement to be entered into with an outside party still to be identified. It has also been decided not to pursue the development of SAR245409 (oral dual inhibitor of PI3K & mTOR) in breast cancer, but to focus its development in Non-Hodgkin Lymphoma (Phase II).

## Early stage portfolio

## Two project entered Phase II

- SAR156597, an interleukin-4/interleukin13 bi-specific monoclonal antibody for Idiopathic Pulmonary Fibrosis;
- SAR339658, a monoclonal antibody anti-VLA2 for the treatment of Ulcerative Colitis.

## Three compounds entered Phase I:

- SAR260301, a PI3K beta selective inhibitor, in oncology;
- SAR113244, a monoclonal antibody anti-CXCR5, in Systemic Lupus Erythematosus (SLE);
- GZ402671, a GCS inhibitor for the treatment of Fabry disease.

# Third-quarter and first nine months 2012 financial results

## Business Net Income<sup>1</sup>

Sanofi generated third-quarter **net sales** of €9,040 million, up 3.3% on a reported basis (-3.1% at constant exchange rates), reflecting the performance of growth platforms, impact from EU austerity measures, loss of €448 million of sales (at constant exchange rates) due to generic competition and a favorable currency effect. Year-to-date sales were €26,421 million, an increase of 6.2% on a reported basis (+1.2% at constant exchange rates), also reflecting the consolidation of Genzyme from April 2011 and the loss of €846 million of sales due to generic competition.

**Other revenues** decreased 52.3% (or down 55.1% at constant exchange rates) to €200 million in the third quarter due to the loss of exclusivity of Plavix<sup>®</sup> and Avapro<sup>®</sup> in the U.S. on May 17 and March 30, respectively. In the third quarter, other revenues included €45 million representing most of the one-time payment of \$80 million paid by Bristol-Myers Squibb in relation to the Avalide<sup>®</sup> supply disruption in the U.S. in 2011. In the first nine months of 2012, other revenues were down 30.4% (or down 34.0% at constant exchange rates) to €873 million.

Third-quarter **Gross profit** was €6,359 million, a decrease of 0.9% (or a decrease of 8.1% at constant exchange rates). The ratio of cost of sales to net sales was 31.9%, an increase of 0.4 percentage points versus the third quarter of 2011 mainly reflecting the negative evolution of the product mix partially offset by industrial productivity and currency effect. Year-to-date gross profit totaled €19,070 million, up 3.5% (or down 2.3% at constant exchange rates). In the first nine months of 2012, the ratio of cost of sales to net sales was 31.1%, 0.2 percentage points higher than in the same period of 2011.

Third-quarter **Research and Development expenses** decreased 5.9% to €1,149 million. Despite the investment in late-stage portfolio, R&D expenses decreased 10.7% at constant exchange rates reflecting good internal cost management, ongoing transforming initiatives and a reimbursement from the SPMSD joint-venture related to a new hexavalent vaccine. The ratio of R&D expenses to net sales reached 12.7%, versus 13.9% in the third quarter of 2011. Year-to-date R&D expenses were €3,564 million, up 1.3% (or down 6.0% with Genzyme proforma and at constant exchange rates). Year-to-date ratio of R&D expenses to net sales was 13.5%, down 0.6 percentage points versus the same period of 2012

Selling and general expenses reached €2,183 million in the third quarter, an increase of 3.3%. At constant exchange rates, SG&A decreased 2.7% driven by a 4.1% reduction in general expenses reflecting tight cost control and synergies derived from the Genzyme integration. Despite continued investment in growth platforms and launch costs for Zaltrap<sup>®</sup> and Aubagio<sup>®</sup>, marketing expenses also decreased at constant exchange rate. The ratio of selling and general expenses to net sales was 24.1%, 0.1 percentage points lower than the third quarter of 2011. Year-to-date SG&A expenses were €6,593 million, up 4.4% (or -4.0% with Genzyme proforma and at constant exchange rates). The year-to-date ratio of selling and general expenses to net sales was 25.0%, versus 25.4% in the same period of 2011.

**Other current operating income net of expenses** was an income of €67 million in the third quarter versus an income of €40 million in the third quarter of 2011. In the first nine months of 2012, other current operating income net of expenses was an income of €62 million compared to an income of €63 million in the same period of 2011. This line included a settlement of a license litigation booked in the first quarter, and an additional pre-tax reserve of €118 million linked to Ramipril litigation in Canada in the second quarter.

The **share of profits from associates** dropped 97.8% to  $\in$  million in the third quarter due to the loss of exclusivity of Plavix<sup>®</sup> and Avapro<sup>®</sup> in the U.S. The share of after-tax profits from the territories managed by BMS under the Plavix<sup>®</sup> and Avapro<sup>®</sup> alliance was  $\in$  million versus  $\in$ 264 million in the third quarter of 2011. Year-to-date profits from associates were  $\in$ 425 million, down 49.8% (or down 52.1% at constant exchange rates), and were attributed to BMS alliance.

**Non-controlling interests** were €39 million in the third quarter, down 27.8%, reflecting lower profits paid to BMS from territories managed by Sanofi (€34 million versus €51 million in Q3 2011) as a result of generic competition in Europe. Year-to-date, non-controlling interests were €143 million, down 24.7%.

<sup>&</sup>lt;sup>1</sup> See Appendix 8 for definitions of financial indicators, and Appendix 6 for reconciliation of business net income to consolidated net income attributable to equity holders of Sanofi

**Business operating income** was €3,061 million in the third quarter, down 8.5% (or down 16.7% at constant exchange rates). The ratio of business operating income to net sales was 33.9%, 4.3 percentage points lower than the same period of 2011.Year-to-date business operating income decreased 0.6% (or decreased 7.4% at constant exchange rates) to €9,257 million. The ratio of business operating income to net sales was 35.0%, down 2.4 percentage points compared to the same period of 2011.

Net financial expenses reached €84 million, compared to €121 million in the third quarter of 2011. This line included a capital gain linked to the divestment of the stake in the Yves Rocher Group. Year-to-date net financial expenses were €311 million versus €299 million in the same period of 2011 which included the financing of the Genzyme acquisition only for two quarters.

The **effective tax rate** was 25.1% compared to 27.5% in the third quarter of 2011. Following agreement with Japanese tax authorities, the Group has revised its forecast effective tax rate for 2012 from 28% to 27%. Year-to-date effective tax rate was 27.0% compared to 27.5% in the same period of 2011.

**Business net income**<sup>1</sup> reached €2,221 million in the third quarter, down 7.4% (or down 15.9% at constant exchange rates). Year-to-date business net income<sup>1</sup> was €6,607 million, down 1.7% (or down 8.6% at constant exchange rates).

In the third quarter of 2012, **Business earnings per share**<sup>1</sup> (EPS) was €1.68, down 6.1% and 14.5% on a reported basis and at constant exchange rates, respectively. The average number of shares outstanding was 1,318.4 million this quarter versus 1,339.4 million in the third quarter of 2011.

Year-to-date **Business earnings per share**<sup>1</sup> (EPS) was €5.01, down 1.6% and 8.4% on a reported basis and at constant exchange rates, respectively. The average number of shares outstanding was 1,319.0 million in the first nine months of 2012 versus 1,318.9 million in the first nine months of 2011.

## From business net income to consolidated net income (see Appendix 6)

In the first nine months of 2012, the main reconciling items between business net income and consolidated net income attributable to equity holders of Sanofi were:

- A €2,491 million amortization charge related to fair value remeasurement on intangible asset of acquired companies (primarily Aventis: €1,131 million, Genzyme: €735 million and Merial €297 million) and to acquired intangible assets (licenses/products: €102 million). The third quarter amortization charge related to fair value remeasurement on intangible asset was €816 million (primarily Aventis: €361 million, Genzyme €248 million and Merial €101 million, €29 million of which related to acquired intangible assets (licenses/products)). This item has no cash impact on the Group.
- An impairment loss (net of reversals related to intangible assets) against intangible assets of €28 million (of which a reversal of €12 million in Q3 2012 related to a product in launching phase). This item has no cash impact on the Group.
- A charge of €192 million mainly reflecting an increase in the fair value of contingent considerations related to the CVRs (€121 million, of which €65 million in Q3 2012) and Bayer contingent considerations (€51 million, of which €12 million in Q3 2012).
- A charge of €20 million arising from the workdown of inventories of acquired companies remeasured at fair value due to the application of purchase accounting to acquisitions. This item has no cash impact on the Group.
- €307 million of restructuring costs (including €57 million in the third quarter related Industrial Affairs in Europe and commercial operations).
- A €1,008 million tax effect arising from the items listed above, comprising €892 million generated by amortization charged against intangible assets and €94 million associated with restructuring costs. The third quarter tax effect was €294 million, including €277 million of deferred taxes generated by amortization charged against intangible assets and €17 million linked to restructuring costs (see Appendix 6).

<sup>1</sup> See Appendix 8 for definitions of financial indicators, and Appendix 6 for reconciliation of business net income to consolidated net income attributable to equity holders of Sanofi

 In "Share of profits/losses from associates", a charge of €22 million, net of tax, mainly relating to the share of amortization of intangible assets (of which €7 million in Q3 2012). This item has no cash impact on the Group.

## **Net Debt**

Year-to-date net cash generated by operating activities after changes in working capital, after capital expenditures (€991 million), and before restructuring costs was €5,812 million, a decrease of 10.7% compared to the same period of 2011. This amount covered dividend paid by Sanofi (€3,487 million), repurchasing of shares (€825 million), acquisitions and partnerships (€348 million) and restructuring costs (€635 million). Over the period, disposals accounted for €286 million (especially the stake in Yves Rocher). As a consequence, net debt decreased from €10,859 million at December 31, 2011 to €9,304 million at the end of the third quarter 2012 (debt of €14,164 million, net of €4,860 million cash and cash equivalents).

## **Forward-Looking Statements**

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

# **Appendices**

## List of appendices

- Appendix 1: 2012 third-quarter and 2012 9-month consolidated net sales by product
- Appendix 2: 2012 third-quarter and 2012 9-month consolidated net sales by geographic region and product
- Appendix 3: Consolidated net sales by business segment
- Appendix 4: Net sales of Growth Platforms
- Appendix 5: 2012 third-quarter and 2012 9-month business net income statement
- Appendix 6: Reconciliation of business net income to net income attributable to equity holders of Sanofi
- Appendix 7: 2012 third-quarter and 2012 9-month consolidated income statement
- Appendix 8: Definitions of non-GAAP financial indicators

## Appendix 1: 2012 third-quarter and 9-month consolidated net sales by product

(€million)	Q3 2012 net sales	Change at constant exchange rates	Change on a reported basis
Lantus®	1,279	20.7%	32.19
Apidra®	57	1.9%	7.5%
Amaryl®	106	-7.5%	0.0%
Insuman®	34	6.3%	6.3%
Total Diabetes	1,486	17.5%	28.0%
Taxotere®	129	-36.0%	-30.69
Eloxatin®	129	-62.9%	-58.49
Jevtana®	56	17.8%	24.49
Other Oncology	171	7.0%	20.49
Total Oncology	485	-35.7%	-29.0%
Lovenox®	437	-14.0%	-11.59
Plavix®	505	-10.4%	-2.39
Aprovel®	298	-8.3%	-5.1
Allegra®	110	-1.9%	6.8
Stilnox®/Ambien®/Ambien CR®/Myslee®	126	-5.0%	4.1
Copaxone®	0	-100.0%	-100.0
Depakine®	105	9.9%	15.4
Tritace®	83	-11.8%	-10.8
Multaq®	65	-9.1%	-1.5
Xatral®	32	-8.8%	-5.9
Actonel®	32	-17.9%	-17.9
Nasacort®	15	0.0%	7.1
Renagel®/ Renvela®	164	12.6%	21.5
Synvisc®/ Synvisc-one <sup>™</sup>	89	0.0%	12.7
Cerezyme®	163	9.9%	15.6
Myozyme®	116	8.9%	14.9
Fabrazyme®	87	146.9%	171.9
Other Rare Diseases products	104	12;8%	20.9
New Genzyme	470	22.5%	30.69
Other Rx Drugs	1,326	-11.5%	-8.29
Consumer Health Care	733	5.9%	10.29
Generics	479	14.9%	16.89
Total Pharmaceuticals	7,040	-4.3%	1.49
Vaccines	1,481	0.7%	10.39
Animal Health	519	3.8%	10.49
Total	9,040	-3.1%	3.39

#### Vaccines

(€million)	Q3 2012 net sales	Change at constant exchange rates	Change on a reported basis
Polio/Pertussis/Hib Vaccines	320	16.0%	25,0%
Influenza Vaccines	608	-8.0%	1.0%
Meningitis/Pneumonia Vaccines	230	-3.3%	8.5%
Adult Booster Vaccines	140	4.9%	14.8%
Travel and Other Endemics Vaccines	83	-20.4%	-15.3%
Other Vaccines	100	69.8%	88.7%
Total	1,481	0.7%	10.3%

## Animal Health

(€million)	Q3 2012 net sales	Change at constant exchange rates	Change on a reported basis
Frontline® and other fipronil products	178	-3.5%	2.9%
Vaccines	172	12.2%	17.0%
Avermectin	109	14.8%	23.9%
Others	60	-11.3%	-3.2%
Total	519	3.8%	10.4%

(€million)	9-month 2012 net sales	Change at constant exchange rates	Change on a reported basis
Lantus®	3,625	18.1%	26.7%
Apidra®	165	1.9%	6.5%
Amaryl®	319	-6.8%	-1.2%
Insuman®	99	4.2%	3.1%
Total Diabetes	4,233	15.2%	23.0%
Taxotere®	438	-46.6%	-43.3%
Eloxatin®	888	10.1%	19.0%
Jevtana®	175	18.4%	24.1%
Other Oncology	476	46.8%	58.1%
Total Oncology	1,977	<b>-6.0%</b>	0.9%
Lovenox®	1,452	-11.7%	-10.0%
Plavix®	1,563	-4.0%	3.4%
Aprovel®	939	-6.7%	-3.9%
Allegra®	418	-11.2%	-4.6%
Stilnox®/Ambien®/Ambien CR®/Myslee®	380	-0.6%	7.6%
Copaxone®	24	-93.4%	-93.1%
Depakine®	307	4.2%	7.0%
Tritace®	263	-8.4%	-8.4%
Multaq®	192	-9.1%	-2.5%
Xatral®	101	-39.9%	-38.0%
Actonel®	104	-21.5%	-20.0%
Nasacort®	53	-42.0%	-39.8%
Renagel®/ Renvela®	476	-	
Synvisc®/ Synvisc-one <sup>™</sup>	273	-	
Cerezyme®	462	-	
Myozyme®	341	-	
Fabrazyme®	208	-	
Other Rare Diseases products	293	-	
New Genzyme	1,304	-	
Other Rx Drugs	4,146	-8.7%	-6.2%
Consumer Health Care	2,276	9.5%	12.6%
Generics	1,386	9.7%	10.2%
Total Pharmaceuticals	21,867	1.2%	5.8%
Vaccines	2,881	1.1%	8.7%
Animal Health	1,673	2.0%	7.2%
Total	26,421	1.2%	6.2%

#### Vaccines

(€million)	9-month 2012 net sales	Change at constant exchange rates	Change on a reported basis
Polio/Pertussis/Hib Vaccines	838	5.2%	11.7%
Influenza Vaccines	777	-5.1%	2.2%
Meningitis/Pneumonia Vaccines	432	-0.5%	9.4%
Adult Booster Vaccines	373	5.2%	13.7%
Travel and Other Endemics Vaccines	260	-7.4%	-3.3%
Other Vaccines	201	22.8%	34.9%
Total	2,881	1.1%	8.7%

#### Animal Health

(€million)	9-month 2012 net sales	Change at constant exchange rates	Change on a reported basis
Frontline® and other fipronil products	646	-3.5%	2.2%
Vaccines	517	6.1%	9.5%
Avermectin	330	8.0%	15.4%
Others	180	0.6%	5.9%
Total	1,673	2.0%	7.2%

# Appendix 2: 2012 third-quarter and 9-month consolidated net sales by geographic region and product

## Third-quarter 2012

Pharmaceuticals

Q3 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Lantus®	197	6.6%	800	22.1%	204	31.5%	78	22.8%
Apidra®	19	11.8%	17	-25.0%	13	18.2%	8	40.0%
Amaryl®	6	-25.0%	1	-100.0%	68	14.3%	31	-31.7%
Insuman®	25	-3.8%	1	-	9	28.6%	-1	-100.0%
Total Diabetes	255	7.2%	820	20.6%	294	26.5%	117	2.9%
Taxotere®	12	-70.7%	10	-70.4%	61	-23.0%	46	-4.5%
Eloxatin®	2	-71.4%	72	-74.7%	37	-16.7%	18	0.0%
Jevtana®	21	46.7%	26	-7.7%	8	100.0%	1	-
Other Oncology	32	0.0%	99	10.3%	28	30.0%	12	-33.3%
Total Oncology	67	-28.4%	207	-52.1%	134	-10.0%	77	-9.7%
Lovenox®	201	0.0%	55	-63.2%	154	10.9%	27	0.0%
Plavix®	65	-37.1%	4*	-93.0%	210	8.0%	226	13.4%
Aprovel®	143	-20.6%	11*	-26.7%	95	-1.1%	49	51.6%
Allegra®	3	-33.3%	0	-100.0%	30	15.4%	77	-8.0%
Stilnox®/Ambien®/Ambien CR®/Myslee®	12	-15.4%	24	0.0%	17	-5.9%	73	-4.3%
Copaxone®	0	-100.0%	0	-	0	-	0	-100.0%
Depakine®	36	-2.8%	0	-	65	17.0%	4	50.0%
Tritace®	35	-16.7%	0	-	44	-2.3%	4	-42.9%
Multaq®	12	-29.4%	51	-2.2%	2	-50.0%	0	100.0%
Xatral®	10	-28.6%	5	25.0%	17	7.1%	0	-50.0%
Actonel®	8	-38.5%	0	-	16	-15.8%	8	14.3%
Nasacort®	4	0.0%	4	-25.0%	6	0.0%	1	100.0%
Renagel®/ and Renvela®	29	-6.5%	115	17.2%	16	33.3%	4	0.0%
Synvisc®/ Synvisc-one <sup>TM</sup>	4	0.0%	74	0.0%	6	25.0%	5	-20.0%
Cerezyme®	54	20.5%	45	-2.4%	46	7.0%	18	23.1%
Myozyme®	64	12.5%	30	0.0%	14	8.3%	8	14.3%
Fabrazyme®	14	100.0%	44	290.0%	15	180.0%	14	20.0%
Other Rare Diseases products	23	21.1%	33	3.6%	21	16.7%	27	14.3%
New Genzyme	155	21.4%	152	27.6%	96	20.5%	67	<b>17.6%</b>
Other Rx Drugs	490	-14.6%	139	-24.7%	507	-4.0%	190	<b>-10.9%</b>
Consumer Health Care	151	-0.7%	140	-3.1%	374	<b>16.1%</b>	68	-10.3%
Generics	138	23.6%	70	110.3%	262	0.8%	9	14.3%
Total Pharma	1,818	-12.4%	1,871	<b>-9.9</b> %	2,345	6.3%	1,006	0.4%

\*Sales of active ingredient to the American entity managed by BMS

#### Vaccines

Q3 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Polio/Pertussis/Hib Vaccines	14	18.2%	69	-45.0%	139	32.7%	98	169.7%
Influenza Vaccines	74	-5.1%	428	-8.3%	102	-8.3%	4	-20.0%
Meningitis/Pneumonia Vaccines	2	100.0%	197	0.6%	27	-20.6%	4	-50.0%
Adult Booster Vaccines	14	7.7%	111	2.0%	10	28.6%	5	25.0%
Travel and Other Endemics Vaccines	3	-57.1%	15	-53.6%	54	-3.6%	11	12.5%
Other Vaccines	2	-60.0%	88	92.5%	4	-25.0%	6	100.0%
Total vaccines	109	<b>-6.1%</b>	908	-6.9%	336	5.2%	128	101.7%

#### Animal Health

Q3 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Frontline® and other fipronil products	42	7.9%	96	-13.0%	26	23.8%	14	-7.1%
Vaccines	42	-2.4%	40	6.1%	85	23.9%	5	20.0%
Avermectin	12	-23.5%	60	32.5%	19	18.8%	18	6.7%
Others	22	-4.8%	23	-25.0%	10	0.0%	5	33.3%
Total	118	-2.5%	219	-2.5%	140	21.1%	42	5.4%

## 9-month 2012

Pharmaceuticals

9-month 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Lantus®	580	5.3%	2,244	19.4%	583	27.9%	218	21.3%
Apidra®	59	5.4%	49	-17.0%	37	15.6%	20	28.6%
Amaryl®	22	-12.0%	3	-33.3%	198	11.8%	96	-30.4%
Insuman®	73	-3.9%	1	-	26	23.8%	-1	-200.0%
Total Diabetes	755	5.8%	2,300	1 <b>8.4</b> %	844	23.1%	334	1.3%
Taxotere®	44	-73.5%	47	-81.7%	208	-12.6%	139	-15.0%
Eloxatin®	11	-64.5%	706	18.9%	118	-7.4%	53	2.1%
Jevtana®	65	150.0%	86	-26.2%	23	187.5%	1	-
Other Oncology	105	38.7%	268	49.4%	71	58.1%	32	33.3%
Total Oncology	225	-24.8%	1,107	-3.1%	420	0.5%	225	-6.5%
Lovenox®	645	3.7%	264	-52.8%	466	13.9%	77	4.3%
Plavix®	245	-24.4%	76*	-54.0%	603	6.7%	639	14.1%
Aprovel®	482	-16.5%	37*	-2.6%	299	1.4%	121	30.7%
Allegra®	10	-18.2%	-1	-125.0%	91	23.0%	318	-16.9%
Stilnox®/Ambien®/Ambien CR®/Myslee®	36	-12.5%	64	-9.4%	53	10.4%	227	2.0%
Copaxone®	19	-94.3%	0	-	0	-	5	-75.0%
Depakine®	107	-2.8%	0	-	188	8.9%	12	-0.0%
Tritace®	115	-11.5%	0	-	137	-0.7%	11	-44.4%
Multaq®	35	-31.4%	150	0.0%	6	0.0%	1	-50.0%
Xatral®	35	-22.2%	17	-76.8%	47	-2.2%	2	-33.3%
Actonel®	26	-39.5%	0	-	52	-14.8%	26	-7.7%
Nasacort®	15	-21.1%	15	-73.5%	20	11.8%	3	33.3%
Renagel®/ and Renvela®	95		28	-	37	-	16	-
Synvisc®/ Synvisc-one <sup>TM</sup>	14	-	227	-	17	-	15	-
Cerezyme®	160	-	124	-	130	-	48	-
Myozyme®	189		88	-	40	-	24	-
Fabrazyme®	35		106	-	33	-	34	-
Other Rare Diseases products	69	-	94	-	59	-	71	-
New Genzyme	453	-	412		262	-	177	-
Other Rx Drugs	1,622	-11.5%	424	-16.2%	1,541	<b>-1.8%</b>	559	-12.6%
Consumer Health Care	506	2.0%	480	-0.7%	1,098	21.4%	192	-3.8%
Generics	362	6.2%	211	102.1%	791	1.1%	22	-20.0%
Total Pharma	5,802	-8.6%	6,111	4.0%	6,972	9.2%	2,982	-0.3%

\*Sales of active ingredient to the American entity managed by BMS

#### Vaccines

9-month 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Polio/Pertussis/Hib Vaccines	40	39.3%	279	-20.3%	359	10.8%	160	68.6%
Influenza Vaccines	74	-5.1%	434	-6.8%	252	-2.7%	17	0.0%
Meningitis/Pneumonia Vaccines	4	100.0%	333	-2.0%	89	7.4%	6	-44.4%
Adult Booster Vaccines	48	-12.7%	277	4.6%	32	63.2%	16	7.1%
Travel and Other Endemics Vaccines	15	-16.7%	68	-11.6%	144	-6.5%	33	3.4%
Other Vaccines	7	-36.4%	167	30.2%	13	0.0%	14	30.0%
Total	188	-2.6%	1,558	-4.2%	889	4.2%	246	36.6%

#### Animal Health

9-month 2012 net sales (€million)	Western Europe	Change at CER	United States	Change at CER	Emerging Markets	Change at CER	Rest of the World	Change at CER
Frontline® and other fipronil products	180	1.1%	358	-7.6%	69	11.3%	39	-10.3%
Vaccines	130	-8.5%	111	8.6%	261	13.2%	15	27.3%
Avermectin	42	-10.6%	185	15.8%	47	9.3%	56	2.0%
Others	64	-3.1%	70	0.0%	30	14.8%	16	-6.3%
Total	416	-4.0%	724	0.6%	407	12.5%	126	-0.9%

## Appendix 3: Consolidated net sales by business segment

Millions of euros	Q3 2012	Q3 2011	9-month 2012	9-month 2011
Pharmaceuticals	7,040	6,940	21,867	20,670
Vaccines	1,481	1,343	2,881	2,651
Merial	519	470	1,673	1,560
Total	9,040	8,753	26,421	24,881

## **Appendix 4: Net sales of Growth Platforms**

#### **Net sales of Growth Platforms**

(€million)	Q3 2012 net sales	Change at constant exchange rates	9-month 2012 net sales	Change at constant exchange rates
Emerging Markets <sup>1/2</sup>	2,821	+6.8%	8,268	+8.8%
Emerging Markets excluding Diabetes, Vaccines, CHC, animal health, new Genzyme and Innovative Products	1,569	+0.3%	4,734	+2.4%
Diabetes	1,486	+17.5%	4,233	+15.2%
Vaccines	1,481	+0.7%	2,881	+1.1%
Consumer Health Care (CHC)	733	+5.9%	2,276	+9.5%
Animal Health	519	+3.8%	1,673	+2.0%
New Genzyme	470	+22.5%	1,304	15.0% <sup>3</sup>
Innovative products <sup>4</sup>	154	+7.6%	445	+6.1%
Total Growth Platforms	6,412	+6.4%	17,546	+9.3%
Total Growth Platforms with Genzyme pro forma	6,412	+6.4%	17,546	+6.6%

<sup>1</sup> World excluding the U.S. and Canada, Western Europe, Japan, Australia and New Zealand.

<sup>2</sup> Includes Diabetes, Vaccines, Consumer Health Care, new Genzyme, Animal Health and new products sales generated in Emerging Markets;
<sup>3</sup> "new Genzyme" on a constant structure basis and at constant exchange rates;

<sup>4</sup> Includes recent product launches which do not belong to the other Growth Platforms listed above: Multaq<sup>®</sup> and Jevtana<sup>®</sup>, Zaltrap<sup>®</sup>, and Mozobil<sup>®</sup> pro forma

## Appendix 5: Business net income statement

Third quarter 2012	Pha	rmaceutica	als		Vaccines			Animal he	alth	Oth	ner	G	roup Total	
Millions of euros	Q3 2012	Q3 2011	% change	Q3 2012	Q3 2011	% change	Q3 2012	Q3 2011	% change	Q3 2012	Q3 2011	Q3 2012	Q3 2011	% change
Net sales	7,040	6,940	1.4%	1,481	1,343	10.3%	519	470	10.4%			9,040	8,753	3.3%
Other revenues	184	406	(54.7%)	7	8	(12.5%)	9	5	80.0%			200	419	(52.3%)
Cost of sales	(2,133)	(2,094)	1.9%	(578)	(502)	15.1%	(170)	(159)	6.9%			(2,881)	(2,755)	4.6%
As % of net sales	(30.3%)	(30.2%)		(39.1%)	(37.4%)		(32.7%)	(33.9%)				(31.9%)	(31.5%)	
Gross profit	5,091	5,252	(3.1%)	910	849	7.2%	358	316	13.3%			6,359	6,417	(0.9%)
As % of net sales	72.3%	75.7%		<b>61.4%</b>	63.2%		<b>69.0%</b>	67.2%				70.3%	73.3%	
Research and development expenses	(1,016)	(1,031)	(1.5%)	(97)	(154)	(37.0%)	(36)	(36)	0.0%			(1,149)	(1,221)	(5.9%)
As % of net sales	(14.4%)	(14.9%)		(6.5%)	(11.5%)		(6.9%)	(7.7%)				(12.7%)	(13.9%)	
Selling and general expenses	(1,874)	(1,827)	2.6%	(153)	(140)	9.3%	(156)	(147)	6.1%			(2,183)	(2,114)	3.3%
As % of net sales	(26.6%)	(26.3%)		(10.3%)	(10.4%)		(30.1%)	(31.2%)				(24.1%)	(24.2%)	
Other current operating income/expenses	58	(1)		(2)	2		7	(4)		4	43	67	40	
Share of profit/loss of associates*	10	269		(4)	7							6	276	
Net income attributable to _non-controlling interests	(39)	(55)						1				(39)	(54)	
Business operating income	2,230	2,607	(14.5%)	654	564	16.0%	173	130	33.1%	4	43	3,061	3,344	(8.5%)
As % of net sales	31.7%	37.6%		44.2%	42.0%		33.3%	27.7%				33.9%	38.2%	
Financial income and expenses												(84)	(121)	
Income tax expense												(756)	(825)	
Tax rate**												25.1%	27.5%	
<b>Business net income</b>												2,221	2,398	(7.4%)
As % of net sales												24.6%	27.4%	x
Business earnings per share*** (in euros)												1.68	1.79	(6.1%)

\* Net of tax

\*\*\* Determined on the basis of Business income before tax, associates, and non-controlling interests
\*\*\* Based on an average number of shares outstanding of 1,318.4 million in the third quarter of 2012 and 1,339.4 million in the third quarter of 2011

Nine months 2012	Pha	rmaceutica	als		Vaccines			Animal he	alth	Ot	ner	G	roup Total	I
Millions of euros	9M 2012	9M 2011	% change	9M 2012	9M 2011	% change	9M 2012	9M 2011	% change	9M 2012	9M 2011	9M 2012	9M 2011	% change
Net sales	21,867	20,670	5.8%	2,881	2,651	8.7%	1,673	1,560	7.2%			26,421	24,881	6.2%
Other revenues	829	1,222	(32.2%)	17	18	(5.6%)	27	14	92.9%			873	1,254	(30.4%)
Cost of sales	(6,564)	(6,167)	6.4%	(1,144)	(1,052)	8.7%	(516)	(486)	6.2%			(8,224)	(7,705)	6.7%
As % of net sales	(30.0%)	(29.8%)		(39.7%)	(39.7%)		(30.8%)	(31.2%)				(31.1%)	(30.9%)	
Gross profit	16,132	15,725	2.6%	1,754	1,617	8.5%	1,184	1,088	8.8%			19,070	18,430	3.5%
As % of net sales	73.8%	<b>76.1%</b>		<b>60.9</b> %	61.0%		70.8%	<b>69.7</b> %				72.2%	74.1%	
Research and development expenses	(3,067)	(2,994)	2.4%	(381)	(418)	(8.9%)	(116)	(106)	9.4%			(3,564)	(3,518)	1.3%
As % of net sales	(14.0%)	(14.5%)		(13.2%)	(15.8%)		(6.9%)	(6.8%)				(13.5%)	(14.1%)	
Selling and general expenses	(5,637)	(5,441)	3.6%	(441)	(404)	9.2%	(514)	(469)	9.6%	(1)	(1)	(6,593)	(6,315)	4.4%
As % of net sales	(25.8%)	(26.3%)		(15.3%)	(15.2%)		(30.7%)	(30.1%)				(25.0%)	(25.4%)	
Other current operating income/expenses	37	41		(3)	1		8	(11)		20	32	62	63	
Share of profit/loss of associates*	435	828		(10)	5						13	425	846	
Net income attributable to non-controlling interests	(143)	(191)						1				(143)	(190)	
Business operating income	7,757	7,968	(2.6%)	919	801	14.7%	562	503	11.7%	19	44	9,257	9,316	(0.6%)
As % of net sales	35.5%	38.5%		31.9%	30.2%		33.6%	32.2%				35.0%	37.4%	
Financial income and expenses												(311)	(299)	
Income tax expense												(2,339)	(2,299)	
Tax rate**												27.0%	27.5%	
Business net income												6,607	6,718	(1.7%)
As % of net sales												25.0%	27.0%	. /
Business earnings per share*** (in euros)												5.01	5.09	(1.6%)

\* Net of tax
\*\* Determined on the basis of Business income before tax, associates, and non-controlling interests
\*\*\* Based on an average number of shares outstanding of 1,319 million in the first nine months of 2012 and 1,318.9 million in the first nine months of 2011

## Appendix 6: Reconciliation of Business net income to Net income attributable to equity holders of sanofi

Millions of euros	Q3 2012	Q3 2011	% change
Business net income	2,221	2,398	(7.4%)
Amortization of intangible assets <sup>(1)</sup>	(816)	(804)	
Impairment of intangible assets	12	(7)	
Fair value remeasurement of contingent consideration liabilities	(86)	233	
Expenses arising from the impact of acquisitions on inventories	(3)	(140)	
Restructuring costs	(57)	(70)	
Other gains and losses, and litigation			
Tax effect of items listed above:	294	427	
Amortization of intangible assets	277	354	
Impairment of intangible assets	(4)	2	
Fair value remeasurement of contingent consideration liabilities	3	5	
Expenses arising on the workdown of acquired inventories	1	42	
Restructuring costs	17	24	
Other gains and losses, and litigation			
Share of items listed above attributable to non-controlling interests	1		
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(7)	(7)	
Net income attributable to equity holders of sanofi	1,559	2,030	(23.2%)
Consolidated earnings per share <sup>(2)</sup> (in euros)	1.18	1.52	(22.4%)

<sup>(1)</sup> Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: € 787 million in the third quarter of 2012 and € 760 million in the third quarter of 2011.

<sup>(2)</sup> Based on an average number of shares outstanding of 1,318.4 million in the third quarter of 2012 and 1,339.4 million in the third quarter of 2011.

See page 13 for comments on the reconciliation of business net income to consolidated net income

Millions of euros	9M 2012	9M 2011	% change
Business net income	6,607	6,718	(1.7%)
Amortization of intangible assets <sup>(1)</sup>	(2,491)	(2,505)	
Impairment of intangible assets	(28)	(76)	
Fair value remeasurement of contingent consideration liabilities	(192)	167	
Expenses arising from the impact of acquisitions on inventories	(20)	(404)	
Restructuring costs	(307)	(537)	
Other gains and losses, and litigation		(517)	
Tax effect of items listed above:	1,008	1,429	
Amortization of intangible assets	892	913	
Impairment of intangible assets	10	22	
Fair value remeasurement of contingent consideration liabilities	6	10	
Expenses arising on the workdown of acquired inventories	6	120	
Restructuring costs	94	174	
Other gains and losses, and litigation		190	
Share of items listed above attributable to non-controlling interests	2		
Restructuring costs of associates and joint ventures, and expenses arising from the impact of acquisitions on associates and joint ventures	(22)	(21)	
Net income attributable to equity holders of sanofi	4,557	4,254	7.1%
Consolidated earnings per share <sup>(2)</sup> (in euros)	3.45	3.23	6.8%

<sup>(1)</sup> Of which related to amortization expense generated by the remeasurement of intangible assets as part of business combinations: €2,389 million in the first nine months of 2012 and €2,367 million in the first nine months of 2011.
<sup>(2)</sup> Based on an average number of shares outstanding of 1,319 million in the first nine months of 2012 and 1,318.9 million in the first nine months of 2011.

## Appendix 7: Consolidated income statements

Millions of euros	Q3 2012	Q3 2011	9M 2012	9M 2011
Net sales	9,040	8,753	26,421	24,881
Other revenues	200	419	873	1,254
Cost of sales	(2,884)	(2,895)	(8,244)	(8,109)
Gross profit	6,356	6,277	19,050	18,026
Research and development expenses	(1,149)	(1,221)	(3,564)	(3,518)
Selling and general expenses	(2,183)	(2,114)	(6,593)	(6,315)
Other operating income	117	90	436	281
Other operating expenses	(50)	(50)	(374)	(218)
Amortization of intangible assets	(816)	(804)	(2,491)	(2,505)
Impairment of intangible assets	12	(7)	(28)	(76)
Fair value remeasurement of contingent consideration liabilities	(86)	233	(192)	167
Restructuring costs	(57)	(70)	(307)	(537)
Other gains and losses, and litigation				(517)
Operating income	2,144	2,334	5,937	4,788
Financial expenses	(135)	(153)	(407)	(387)
Financial income	51	32	96	88
Income before tax and associates and joint ventures	2,060	2,213	5,626	4,489
Income tax expenses	(462)	(398)	(1,331)	(870)
Share of profit/loss of associates and joint ventures	(1)	269	403	825
Net income	1,597	2,084	4,698	4,444
Net income attributable to non- controlling interests	38	54	141	190
Net income attributable to equity holders of sanofi	1,559	2,030	4,557	4,254
Average number of shares outstanding (million)	1,318.4	1,339.4	1,319.0	1,318.9
Earnings per share (in euros)	1.18	1.52	3.45	3.23

## Appendix 8: Definitions of non-GAAP financial indicators

#### Net sales at constant exchange rates

When we refer to changes in our net sales "at constant exchange rates", this means that we exclude the effect of changes in exchange rates.

We eliminate the effect of exchange rates by recalculating net sales for the relevant period at the exchange rates used for the previous period.

Reconciliation of reported net sales to net sales at constant exchange rates for the third quarter and the first half of 2011

(millions of euros)	Q3 2012	9-month 2012
Net sales	9,040	26,421
Effect of exchange rates	(561)	(1,234)
Net sales at constant exchange	8,479	25,187

#### Net sales on a constant structure basis

We eliminate the effect of changes in structure by restating prior-period net sales as follows:

- by including sales from the acquired entity or product rights for a portion of the prior 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 make the acquisition;
- similarly, by excluding sales in the relevant portion of the prior period when we have sold an entity or rights to a product;
- for a change in consolidation method, by recalculating the prior period on the basis of the method used for the current period.

## Worldwide presence of Plavix<sup>®</sup>/Iscover<sup>®</sup>, Avapro<sup>®</sup>/Aprovel<sup>®</sup>

When we refer to the "worldwide presence" of a product, we mean our consolidated net sales of that product, minus sales of the product to our alliance partners plus non-consolidated sales made through our alliances with Bristol-Myers Squibb on Plavix<sup>®</sup>/Iscover<sup>®</sup> (clopidogrel bisulfate) and Aprovel<sup>®</sup>/Avapro<sup>®</sup>/Karvea<sup>®</sup> (irbesartan), based on information provided to us by our alliance partner.

## **Business net income**

Sanofi publishes a key non-GAAP indicator. This indicator "Business net income", replaced "adjusted net income excluding selected items".

Business net income is defined as net income attributable to equity holders of Sanofi excluding:

- amortization of intangible assets,
- impairment of intangible assets,
- fair value remeasurement of contingent consideration liabilities related to business combinations,
- other impacts associated with acquisitions (including impacts of acquisitions on associates),
- restructuring costs \*,
- other gains and losses (including gains and losses on disposals of non-current assets\*),
- costs or provisions associated with litigation\*,
- tax effects related to the items listed above as well as effects of major tax disputes,

\*Reported in the line items **Restructuring costs** and **Gains and losses on disposals, and litigation**, which are defined in Note B.20. to our consolidated financial statements.