

Press release

## Ipsen's third quarter and first nine months 2012 sales

- Third quarter specialty care sales up 14.9%
- French primary cares sales negatively impacted by the step-up in the implementation of « tiers-payant » regulation in July
  - First nine months Group sales up 5.0%<sup>1</sup>, driven by specialty care sales, up 12.8%<sup>1</sup>
    - All specialty care franchises up double digit
- 2012 financial objectives raised

Paris (France), 29 October 2012 - Ipsen (Euronext: IPN; ADR: IPSEY) reported today its sales for the third quarter and the first nine months of 2012.

### Third quarter and first nine months 2012 consolidated sales<sup>2</sup>

(in million euros)	Third Quarter			First nine months				
	2012	2011	% Variation	2012	2011	% Variation	% Variation at constant currency	
<b>SALES BY REGION</b>								
Major Western European countries	120.9	132.0	(8.4%)	393.3	405.7	(3.0%)	(3.6%)	
Other European countries	69.6	66.8	4.2%	229.4	211.2	8.6%	7.8%	
North America	18.2	14.2	28.0%	54.6	47.3	15.3%	5.3%	
Rest of the world	86.2	67.9	26.9%	247.5	199.8	23.9%	18.9%	
<b>Group Sales</b>	<b>294.9</b>	<b>280.9</b>	<b>5.0%</b>	<b>924.7</b>	<b>864.0</b>	<b>7.0%</b>	<b>5.0%</b>	
<b>SALES BY THERAPEUTIC AREA</b>								
Specialty care	212.4	184.9	14.9%	652.2	565.9	15.3%	12.8%	
Primary care	74.4	88.5	(16.0%)	246.6	274.2	(10.1%)	(11.5%)	
<b>Total Drug Sales</b>	<b>286.8</b>	<b>273.4</b>	<b>4.9%</b>	<b>898.8</b>	<b>840.0</b>	<b>7.0%</b>	<b>4.9%</b>	
Drug-related sales <sup>3</sup>	8.1	7.5	7.9%	25.9	24.0	7.8%	6.4%	
<b>Group Sales</b>	<b>294.9</b>	<b>280.9</b>	<b>5.0%</b>	<b>924.7</b>	<b>864.0</b>	<b>7.0%</b>	<b>5.0%</b>	

Commenting on the Group's performance, **Marc de Garidel, Chairman and Chief Executive Officer of Ipsen** said: "Over the first 9 months of this year, Ipsen's strategy of focus continued to deliver solid sales, up 5% year-on-year driven by specialty care. The Group benefits from a balanced growth with its

<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

<sup>2</sup> Unaudited consolidated sales in compliance with IFRS

<sup>3</sup> Drug related sales correspond to sales of active substances and raw materials

*three core franchises up double digit. On a geographic standpoint, our footprint in emerging countries continued to grow at a solid pace, up close to 20% year-on-year." Marc de Garidel added: "We believe our specialty care activity shows robustness and resilience in the current macroeconomic environment and challenging market conditions."*

### **Highlights of the third quarter and first nine months 2012 sales**

In the third quarter 2012, **drug sales** increased by 4.9% year-on-year. Excluding foreign exchange impacts<sup>1</sup>, sales in the first nine months 2012 grew by 4.9%, driven by the solid performance of specialty care up 12.8%. Over the period, all three specialty care franchises, uro-oncology, endocrinology and neurology displayed a double digit growth with a respective growth of 11.5%, 11.5% and 16.5%.

In the third quarter 2012, primary care sales were penalized by the step-up in the implementation of the "tiers-payant" in July in France. Under this regulation the patient now pays upfront for a genericized branded drug at the pharmacy and is later reimbursed. This resulted in an unprecedented and sudden increase in generic penetration in the French market place. Consequently, sales of Nisis<sup>®</sup>/Nisisco<sup>®</sup> and Forlax<sup>®</sup> in France were significantly impacted. In the first nine months of 2012, primary care sales continued to decrease, down 11.5% excluding foreign exchange impacts<sup>1</sup>.

In the first nine months 2012, sales were positively impacted by non-recurring stocking effects, notably in Algeria where sales were anticipated to better manage risk of delays resulting from local letter of credit process and in Vietnam, where orders of some Primary care products were anticipated ahead of import license expiration. In Latin America, orders were also anticipated to secure in-market product availability for year end. In addition, Dysport<sup>®</sup> sales were strong in Australia where the Group signed an agreement in April 2012 with Galderma. Restated to exclude these technical effects, drug sales in the first nine months 2012 were up 4.0% excluding foreign exchange impacts<sup>1</sup>.

In the third quarter 2012, sales of **Specialty Care** products reached €212.4 million, up 14.9% year-on-year. In the first nine months of 2012, sales amounted to €652.2, up 15.3% year-on-year or up 12.8% excluding foreign exchange impacts<sup>1</sup>, benefiting namely from positive non-recurring stocking effect in Algeria and Latin America mentioned above. Restated to exclude these impacts sales were up 12.2% excluding foreign exchange impacts<sup>1</sup>. At the end of the first nine months of 2012, the relative weight of Specialty Care products continued to increase to 70.5% of total Group sales, compared to 65.5% a year earlier.

In the third quarter 2012, sales generated in the **Major Western European countries** amounted to €120.9 million, down 8.4% year-on-year, negatively impacted by the acceleration of primary care decrease in France due to the step-up in the implementation of the "tiers-payant", mentioned above. In the first nine months of 2012, sales generated in the major Western European countries amounted to €393.3 million, down 3.6% year-on-year excluding foreign exchange impacts<sup>1</sup>. Dynamic volume sales growth of specialty care products were more than offset by the consequences of a tougher competitive environment in the French primary care landscape and administrative measures in Spain, outlined below. As a result, sales in the Major Western European countries represented 42.5% of total Group sales at the end of the first nine months of 2012, compared to 47.0% a year earlier.

In the third quarter 2012, sales generated in the **Other European countries** reached €69.6 million, up 4.2% year-on-year. In the first nine months of 2012, sales amounted to €229.4 million, up 7.8% excluding foreign exchange impacts<sup>1</sup>. Sales were mainly driven by the good performance of specialty

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<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

care products and Tanakan<sup>®</sup> in Russia, partially offset by destocking on Smecta<sup>®</sup> following its re-submission in 2011. Over the period, Poland, the Netherlands and Ukraine also contributed to the volume growth. In the first nine months of 2012, sales in this region represented 24.8% of total consolidated Group sales, compared to 24.4% a year earlier.

In the third quarter 2012, sales generated in **North America** reached €18.2 million, up 28.0% year-on-year. In the first nine months of 2012, sales amounted to €54.6 million, up 5.3% excluding foreign exchange impacts<sup>1</sup>. In November 2011, Ipsen sold its North American development and marketing rights for Apokyn<sup>®</sup>. As a consequence, Ipsen stopped recording Apokyn<sup>®</sup> sales in its accounts as of 30 November 2011. Restated to exclude Apokyn<sup>®</sup> sales, North American sales were up 14.8% year-on-year, driven by strong supply of Dysport<sup>®</sup> for aesthetic use to Medicis, by the continuous penetration of Somatuline<sup>®</sup> in acromegaly and by the value growth of Dysport<sup>®</sup> in the treatment of cervical dystonia. In the first nine months of 2012, sales in North America represented 5.9% of total consolidated Group sales, compared to 5.5% a year earlier.

In the third quarter, sales generated in the **Rest of the World** reached €86.2 million, up 26.9% year-on-year. In the first nine months of 2012, sales amounted to €247.5 million, up 23.9% year-on-year or up 18.9% excluding foreign exchange impacts<sup>1</sup>. This performance was partially driven by non-recurring effects, notably in Algeria where sales were anticipated to better manage risk of delays resulting from local letters of credit process and in Vietnam, where orders of some Primary care products were anticipated ahead of import license expiration. In Latin America, orders were also anticipated to secure in-market product availability for year end. Restated to exclude these non-recurring stocking effects, sales were up 14.8% excluding foreign exchange impacts<sup>1</sup>. In the first nine months of 2012, sales in the Rest of the World continued to increase, representing 26.8% of total consolidated Group sales, up from 23.1% a year earlier.

### **2012 financial targets**

Based on information currently available and given its solid performance in the first nine months of 2012, the Group believes it should be able to deliver on:

- **Specialty Care** drug sales growth year-on-year **around 10.0%**
- **Primary Care** drug sales decrease year-on-year **of approximately 15.0%**
- **Recurring adjusted<sup>2</sup> operating margin of approximately 15.0% of its sales**

The above objectives are set excluding foreign exchange impacts.

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<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

<sup>2</sup> Before non-recurring elements

## About Ipsen

Ipsen is a global specialty-driven pharmaceutical company with total sales exceeding €1.1 billion in 2011. Ipsen's ambition is to become a leader in specialty healthcare solutions for targeted debilitating diseases. Its development strategy is supported by four franchises: neurology / Dysport<sup>®</sup>, endocrinology / Somatuline<sup>®</sup>, uro-oncology / Decapeptyl<sup>®</sup> and hemophilia. Moreover, the Group has an active policy of partnerships. Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins. In 2011, R&D expenditure totaled more than €250 million, above 21% of Group sales. The Group has total worldwide staff of close to 4,500 employees. Ipsen's shares are traded on segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150) and eligible to the "Service de Règlement Différé" ("SRD"). The Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit [www.ipсен.com](http://www.ipсен.com).

## Forward Looking Statement

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.

Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from Generics that might translate into a loss of market share.

Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfill their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. More specifically the inability thus far of Inspiration Biopharmaceuticals Inc. to raise independent third party financing could result in the depreciation of all hemophilia-related assets for a total net amount of approximately 100 million euros after tax (unaudited figure) as of 30 September 2012.

The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law.

The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

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## APPENDICES

### Risk factors

The Group operates in an environment which is undergoing rapid change and exposes its operations to a number of risks, some of which are outside its control. The risks and uncertainties set out below are not exhaustive and the reader is advised to refer to the Group's 2011 Registration Document available on its website [www.ipsen.com](http://www.ipsen.com)

- The Group is dependent on the setting of prices for medicines and is vulnerable to the possible reduction of prices of certain of its products by public or private payers or to their possible withdrawal from the list of reimbursable products by the relevant regulatory authorities in the countries where it does business. In general terms, the Group is faced with uncertainty in relation to the prices set for all its products, in so far as medication prices have come under severe pressure over the last few years as a result of various factors, including the tendency for governments and payers to reduce prices or reimbursement rates for certain drugs marketed by the Group in the countries in which it operates, or even to remove those drugs from lists of reimbursable drugs.
- The Group depends on third parties to develop and market some of its products which generate or may generate substantial royalties for the Group, but these third parties could behave in ways which cause damage to the Group's business. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. More specifically and on the basis of currently available information, the inability for Inspiration Biopharmaceuticals Inc. to raise independent third party financing could result in the depreciation of all hemophilia-related assets for a total net amount of approximately 100 million euros after tax (unaudited figure) as of 30 September 2012.
- Actual results may depart significantly from the objectives given that a new product can appear to be promising at a development stage or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons.
- The Research and Development process typically lasts between eight and twelve years from the date of a discovery to a product being brought to market. This process involves several stages; at each stage, there is a substantial risk that the Group could fail to achieve its objectives and be forced to abandon its efforts in respect of products in which it has invested significant amounts. Thus, in order to develop viable products from a commercial point of view, the Group must demonstrate, by means of pre-clinical and clinical trials, that the molecules in question are effective and are not harmful to humans. The Group cannot be certain that favorable results obtained during pre-clinical trials will subsequently be confirmed during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safety and efficacy of the product in question such that the required marketing approvals can be obtained.
- The Group must deal with or may have to deal with competition (i) from generic products, particularly in relation to Group products which are not protected by patents, for example, Forlax<sup>®</sup> or Smecta<sup>®</sup> (ii), products which, although they are not strictly identical to the Group's products or which have not demonstrated their bioequivalence, have obtained or may obtain a marketing authorization for indications similar to those of the Group's products pursuant to the bibliographic reference regulatory procedure (well established medicinal use) before the patents protecting its products expire. Such a situation could result to the Group losing market share which could affect its current level of growth in sales or profitability.
- Third parties might claim the benefit of intellectual property rights in respect to the Group's inventions. The Group provides the third parties with which it collaborates (including universities and other public or private entities) with information and data in various forms relating to the



research, development, manufacturing and marketing of its products. Despite the precautions taken by the Group with regard to these entities, in particular of a contractual nature, they (or certain of their members or affiliates) could claim ownership of intellectual property rights arising from the trials carried out by their employees or any other intellectual property right relating to the Group's products or molecules in development.

- The Group's strategy includes acquiring companies or assets which may enable or facilitate access to new markets, research projects or geographical regions or enable it to realize synergies with its existing businesses. Should the growth prospects or earnings potential of such assets as well as valuation assumptions change materially from initial assumptions, the Group might be under the obligation to adjust the values of these assets in its balance sheet, thereby negatively impacting its results and financial situation.
- The marketing of certain products by the Group has been and could be affected by supply shortages and other disruptions. Such difficulties may be of both a regulatory nature (the need to correct certain technical problems in order to bring production sites into compliance with applicable regulations) and a technical nature (difficulties in obtaining supplies of satisfactory quality or difficulties in manufacturing active ingredients or drugs complying with their technical specifications on a sufficiently reliable and uniform basis). This situation may result in inventory shortages and/or in a significant reduction in the sales of one or more products. More specifically, in their US Hopkinton facility, Lonza, supplier of IGF-1 (Increlex<sup>®</sup> active ingredient), is facing a regulatory challenge by the Food and Drug Administration. Products manufactured for the US in this plant are currently on hold.
- In certain countries exposed to significant public deficits, and where the Group sells its drugs directly to public hospitals, it could face discount or lengthened payment terms or difficulties in recovering its receivables in full. In Greece notably, which represented in 2011 approximately 1.3% of consolidated sales, and where payment terms from public hospitals are particularly long, the Group is closely monitoring the current situation. More generally, the Group may also be unable to purchase sufficient credit insurance to protect itself adequately against the risk of payment default from certain customers worldwide. Such situations could negatively impact the Group's activities, financial situation and results.
- In the normal course of business, the Group is or may be involved in legal or administrative proceedings. Financial claims are or may be brought against the Group in connection with some of these proceedings. Ipsen Pharmaceuticals, Inc. has received an administrative demand from the United States Attorney's Office for the Northern District of Georgia seeking documents relating to its sales and marketing of Dysport<sup>®</sup> (abobotulinumtoxinA) for therapeutic use. Ipsen's policy is to fully comply with all applicable laws, rules and regulations. Ipsen is cooperating with the U.S. Attorney's Office in responding to the government's administrative demand. Additionally, In February 2012, Allergan has commenced legal proceedings against Ipsen in Italy and in the United Kingdom concerning an alleged patent infringement. The patents claim certain therapeutic uses of botulinum toxin products in the field of urology. Ipsen will vigorously defend its rights in these legal proceedings, which are based on patents that are being challenged by Ipsen in opposition proceedings before the European Patent Office.

## Major developments in the first nine months of 2012

During the first nine months of 2012, major developments included:

- On January 5, 2012 – Oncodesign, a Drug Discovery company and Oncology pharmacology service provider, and Ipsen announced that the two companies have entered into a research collaboration to discover and develop innovative LRRK2 kinase inhibitors as potential therapeutic agents against Parkinson's disease and for potential additional uses in other therapeutic areas.
- On January 24, 2012 – Santhera Pharmaceuticals and Ipsen announced that they had renegotiated their fipamezole licensing agreement. Santhera regains the worldwide rights to the development and commercialization of fipamezole, its first-in-class selective adrenergic alpha-2 receptor antagonist for the management of levodopa-induced Dyskinesia in Parkinson's disease. Under the renegotiated terms, Ipsen returns its rights for territories outside of North America and Japan in exchange for milestone payments and royalties based on future partnering and commercial success of fipamezole. Ipsen retains a call option for worldwide license to the program under certain conditions.
- On January 27, 2012 – Ipsen acknowledged the French government's decision to no longer reimburse Tanakan<sup>®</sup>, Tramisal<sup>®</sup> and Ginkogink<sup>®</sup>. This decision is linked to the French policy to reassess the reimbursement of a certain number of drugs by the French Social Security. Although Tanakan<sup>®</sup>, Tramisal<sup>®</sup> and Ginkogink<sup>®</sup> have been delisted from 1st March 2012 onwards, they can continue to be prescribed and delivered by healthcare professionals to patients in France. The Group plans a decrease of Tanakan<sup>®</sup> sales of around 35% in France in 2012. This estimate is based on decreases of sales following the delisting of veintonic in 2008.
- On February 24, 2012 – Active Biotech's and Ipsen's castrate resistant prostate cancer project, TASQ, announced the presentation of the up to three years safety data from the TASQ Phase II study in chemotherapy-naïve metastatic castrate resistant prostate cancer (CRPC) at the 27th Annual EAU Congress.
- On April 17, 2012 – Ipsen announced that its partner, Inspiration Biopharmaceuticals, Inc. (Inspiration), has submitted a Biologics License Application to the U.S. Food and Drug Administration (FDA) for the approval of IB1001, an intravenous recombinant factor IX (rFIX) for the treatment and prevention of bleeding in individuals with hemophilia B. Under the terms of this partnership and following the filing, Ipsen decided to pay Inspiration a \$35 million milestone payment. In return, Inspiration has issued a convertible note to Ipsen, bringing Ipsen's fully diluted equity ownership position in Inspiration to approximately 43.5%.
- On April 25, 2012 – Ipsen announced the official opening of its new US commercial headquarters in Basking Ridge, New Jersey. This is an important step forward for Ipsen in the United States. This announcement confirms Ipsen's commitment to growth for its uniquely targeted neurology and endocrinology therapeutics in the United States and to provide innovative specialty medicines to US patients in need.
- On May 3, 2012 – Ipsen disclosed that it had sold, under a share purchase agreement, all of its shares in Spirogen Limited (19.31% of Spirogen's equity) on February 24, 2012, and is no longer represented on the board of Spirogen. Ipsen received an upfront cash payment and may receive deferred consideration.
- On May 3, 2012 – Ipsen disclosed that it had terminated its agreement with Novartis for the co-promotion of Exforge<sup>®</sup> in France effective April 30, 2012. Ipsen will receive a contractual cash exit fee payment of €4 million from Novartis.
- On May 18, 2012 – Active Biotech and Ipsen announced the presentation of overall survival (OS) data from the Phase II study on tasquinimod (TASQ), their prostate cancer drug candidate (CRPC), at the scientific conference "2012 ASCO Annual Meeting" held in Chicago (USA) on 1-5 June 2012.



- On May 21, 2012 – Active Biotech and Ipsen announced that recruitment to the global, pivotal, randomized, double-blind, placebo-controlled phase III study of tasquinimod in patients with metastatic castrate-resistant prostate cancer (CRPC) had reached an inclusion of 600 patients, half of the planned accrual. This triggered a €10 million milestone payment from Ipsen to Active Biotech.
- On June 4, 2012 – Active Biotech and Ipsen presented overall survival (OS) data from the tasquinimod Phase II study in chemotherapy-naïve metastatic castrate resistant prostate cancer (CRPC) at the scientific conference “2012 ASCO Annual Meeting” held in Chicago (USA).
- On June 29, 2012 – Ipsen announced that its partner Teijin received manufacturing and marketing approval from the Japan’s Ministry of Health, Labour and Welfare (MHLW) for Somatuline<sup>®</sup> 60/90/120 mg for s.c. injection (lanreotide acetate). In Japan, Somatuline<sup>®</sup> is indicated for the treatment of growth hormone and IGF-I (somatomedin-C) hypersecretion and related symptoms in acromegaly and pituitary gigantism (when response to surgical therapies is not satisfactory or surgical therapies are difficult to perform). Somatuline<sup>®</sup> will be available in a new enhanced presentation with a pre-filled syringe that does not need reconstitution and with a retractable needle that enhances safety for caregivers.
- On July 10, 2012 – Ipsen announced that its partner Inspiration Biopharmaceuticals Inc. (Inspiration) was notified by the Food and Drug Administration (FDA) that the two clinical trials evaluating the safety and efficacy of IB1001 were placed on clinical hold. During the course of routine laboratory evaluations conducted as part of the ongoing phase III clinical trials, Inspiration observed, and reported to the FDA, a trend towards a higher proportion of IB1001 treated individuals developing a positive response to testing of antibodies to Chinese Hamster Ovary (CHO) protein, the product's host cell protein (HCP). A total of 86 people with hemophilia B have received IB1001 in clinical studies and, to date, no adverse events (anaphylaxis or other serious allergic type reaction and nephrotic syndrome) related to the development of antibodies to CHO protein have been reported. Furthermore, no relationship has been demonstrated between the development of antibodies to CHO protein and the development of any antibodies to factor IX. Inspiration continues to follow subjects enrolled in clinical trials of IB1001 to collect safety-related information and will share this information with regulators.
- On July 11, 2012 – Ipsen announced its decision to retain the Dreux (France)-based industrial facility within the scope of its activity. Considering the perspectives of Ipsen's primary care activity internationally and as a result the higher than-expected production volumes at this site since the beginning of this year, the Group has decided to keep its Dreux industrial site.
- On August 21, 2012 – Ipsen announced the renegotiation of its 2010 strategic partnership agreement with Inspiration Biopharmaceuticals, Inc. (Inspiration) for the development and commercialization of Inspiration's recombinant product portfolio: OBI-1, a recombinant porcine factor VIII (rpFVIII) being developed for the treatment of patients with acquired hemophilia A and congenital hemophilia A with inhibitors, and IB1001, a recombinant factor IX (rFIX) for the treatment and prevention of bleeding in patients with hemophilia B. The new agreement aims to establish an effective structure whereby Ipsen gains commercial rights in key territories. Inspiration remains responsible for the world-wide development of OBI-1 and IB1001. As part of the renegotiation, Ipsen paid Inspiration \$30.0 million (approximately €24.0 million, based on current exchange rates) upfront. Including this upfront payment, Ipsen is entitled to pay Inspiration milestones for a total amount of up to \$200m, of which \$27.5m are regulatory milestones and the remaining are commercial milestones.
- On September 10, 2012 – Ipsen announced that it has avoided an interruption in US supply of Increlex<sup>®</sup> (IGF-1) for the treatment of Severe Primary IGF-1 Deficiency due to delays in manufacturing site approval. Increlex<sup>®</sup> is an important drug used to treat patients with Severe Primary IGF-1 Deficiency (Primary IGF1D) and is considered to be a drug of medical necessity. As a result, Ipsen has worked closely with the US Food and Drug Administration to maintain product supply.

After 30 September 2012, major developments included:

- On October 1, 2012 – Active Biotech and Ipsen have presented a new set of data on biomarkers from the previously concluded tasquinimod Phase II study in chemotherapy-naïve metastatic castrate resistant prostate cancer (CRPC) at the scientific congress ESMO (European Society for Medical Oncology) held in Vienna from 28 September to 02 October 2012.
- On October 3, 2012 – Ipsen and Active Biotech announced the initiation of a new phase II proof of concept clinical trial, evaluating the activity of tasquinimod in advanced metastatic castrate resistant prostate cancer patients. The study aims at establishing the clinical efficacy of tasquinimod used as maintenance therapy in patients with metastatic castrate-resistant prostate cancer (mCRPC) who have not progressed after a first line docetaxel based chemotherapy.
- On October 3, 2012 – Ipsen announced that Inspiration Biopharmaceuticals Inc. (Inspiration) had not raised third party financing by the contractual deadline of 30 September 2012. Consequently, Ipsen no longer had the obligation to pay the additional \$12.5 million in exchange for Inspiration equity. The parties have explored various options since that date. Ipsen will report as soon as Inspiration's board of directors has made a decision as to the most appropriate route to follow.
- On October 19, 2012 – Ipsen announced that it will shortly initiate a new phase II, proof-of-concept clinical trial with tasquinimod in a so-called umbrella study evaluating the compound in four different tumour types. The study will evaluate the safety and efficacy of tasquinimod in advanced or metastatic hepato-cellular, ovarian, renal cell and gastric carcinomas in patients who have progressed after standard anti-tumor therapies.

## GOVERNMENT MEASURES

In a context of financial and economic crisis, the governments of many countries in which the Group operates continue to introduce new measures to reduce public health expenses, some of which are affecting the Group sales and profitability in 2012. In addition, certain measures introduced in 2011 have continued to affect the Group's accounts year-on-year.

### In the Major Western European countries:

- In France, the price of Forlax<sup>®</sup> was reduced by 3.5% on October 1, 2011 and the prices of Nisis<sup>®</sup>/Nisisco<sup>®</sup> by 15.0% on November 14, 2011. On January 1, 2012, the price of Decapeptyl<sup>®</sup> was reduced by 3.0% for both 3 and 6-month formulations while the price of Adrovan<sup>®</sup> was reduced by 33.0%. On 1 March 2012, Tanakan<sup>®</sup> was delisted in France. An additional tax on promotional expenses of 0.6% has also been introduced; additionally, sales of Nisis<sup>®</sup>/Nisisco<sup>®</sup> and Forlax<sup>®</sup> were negatively impacted by a step-up in July in the regulation known as « tiers-payant », whereby the patient now pays upfront for a branded drug (when genericized) at the pharmacy and is later reimbursed.
- As of 1 November, 2011, Spain raised its tax on drug sales from 7.5% (introduced in June 2010) to 15.0% for products that have been on the market for more than 10 years and have no generic or biosimilar on the Spanish market. In addition, Tanakan<sup>®</sup> was dereimbursed on 01/09/2012.

### In the Other European countries:

- In Belgium, as from 1 April 2012, as soon as a generic or a hybrid is launched on the market, drugs are regrouped per active ingredient regardless of their galenic form and prices are cut by up to 31.0%;
- In Poland, a new Reimbursement Law Reform was enforced on 1 January 2012, introducing a sales tax in case of budget excess and a tax on manufacturers' income to fund clinical trials. Regulated margins have been decreased as well. As a result, prices of Decapeptyl<sup>®</sup> and Somatuline<sup>®</sup> were both reduced by 3.0% on 1 January 2012;
- Greece voted new measures designed to decrease pharmaceutical expenditure. Key measures include higher rebates to wholesalers and retail pharmacies (9% instead of 4% - retroactive effect as of 1 January 2012), an obligation to prescribe drugs labelled International Non-proprietary Name (INN) and introduction of a payback contribution in case of Health public budget overrun;
- In 2011, Portugal introduced an electronic system encouraging prescription of the cheapest product (including generics). New countries have been included in the reference basket for the International Pricing System such as Spain, Italy and Slovenia. New measures for 2013 have already been published: 6.0% price cut on all drugs and contribution of the pharmaceutical industry to the decrease of healthcare spending through the set up by every pharma company of a provision fund equal to 2.0% of sales.
- In Hungary, a 10.0% additional tax on sales, on top of the 20.0% tax already in force, was introduced as of 1 August 2012 for all Somatuline<sup>®</sup> formulations.

### In the Rest of the World:

- China is finalizing its international reference pricing system including ten countries as the USA, France, Germany, South Korea and Japan;

- In January 2011, Algeria initiated the implementation of a new healthcare reform setting reference pricing per therapeutic class; a price alignment of Decapeptyl<sup>®</sup> on the cheapest GnRH seems imminent.
- In Korea, under the volume-control regulation in force since November 2011, the price of the 11.25 mg formulation of Diphereline<sup>®</sup> has been cut again by 4,5% on Sept. 1<sup>st</sup>, 2012.

Furthermore, and in the context of financial and economic crisis, governments of many countries in which the Group operates continue to introduce new measures to reduce public health expenses, some of them will affect the Group sales and profitability beyond 2012.

#### **In the Major Western European countries:**

- The Spanish Health Minister confirmed a 14.0% reduction of healthcare budget in 2012. The new Royal Decree published in April stated that molecules that have been introduced in Europe for more than ten years will be regrouped per active ingredient and prices will be aligned on the cheapest daily dosage.
- In Italy, new rebate measures have been approved by Parliament for the second semester of 2012.

#### **In the Other European countries:**

- Within the frame of the Healthcare Reform, Russian Health Authorities are considering a possible change in the price-setting methodology for the Vital and Essential Drug list (EDL). Future registered prices for drugs on EDL should be set as the average weighted price of all drugs with the same International Non-proprietary Name (INN);
- Ukrainian Health Authorities are implementing an International Price Referencing System. The system aims at reducing prices of drugs by 25% to 30% by aligning prices on a basket of twelve Central Europe countries including Serbia, Hungary, Moldavia and Poland.

#### **In the Rest of the World:**

- In Colombia, a new International Reference pricing system is expected during the second semester 2012, as well as maximum reimbursement prices on expensive drugs. Somatuline<sup>®</sup> could face a price cut in the range of 40-50%;
- In South Korea, price-volume agreements negotiated in 2011 that have led to a 7.0% price decrease of Decapeptyl<sup>®</sup> and Dysport<sup>®</sup> will continue to negatively impact prices in the years to come.

## Comparison of consolidated sales in the third quarters and first nine months of 2012 and 2011:

### Sales by geographical area

Group sales by geographical area in the third quarters and first nine months of 2012 and 2011 were as follows:

(in million euros)	3rd Quarter			9 Months			
	2012	2011	% Variation	2012	2011	% Variation	% variation at constant currency
France	54.5	71.1	(23.2%)	187.7	220.5	(14.9%)	(14.9%)
United Kingdom	14.3	12.4	15.6%	42.0	33.8	24.2%	15.8%
Spain	12.5	13.8	(9.5%)	42.8	44.7	(4.3%)	(4.3%)
Germany	19.3	15.9	21.8%	57.5	45.5	26.4%	26.4%
Italy	20.2	18.9	6.9%	63.4	61.1	3.7%	3.7%
<b>Major Western European countries</b>	<b>120.9</b>	<b>132.0</b>	<b>(8.4%)</b>	<b>393.3</b>	<b>405.7</b>	<b>(3.0%)</b>	<b>(3.6%)</b>
Eastern Europe	35.5	35.9	(1.1%)	125.5	112.9	11.2%	11.0%
Others Europe	34.1	30.9	10.4%	103.8	98.3	5.6%	4.2%
<b>Other European Countries</b>	<b>69.6</b>	<b>66.8</b>	<b>4.2%</b>	<b>229.4</b>	<b>211.2</b>	<b>8.6%</b>	<b>7.8%</b>
<b>North America</b>	<b>18.2</b>	<b>14.2</b>	<b>28.0%</b>	<b>54.6</b>	<b>47.3</b>	<b>15.3%</b>	<b>5.3%</b>
Asia	45.8	35.4	29.4%	124.2	101.0	23.0%	13.4%
Other countries in the rest of the world	40.4	32.5	24.2%	123.3	98.8	24.8%	25.0%
<b>Rest of the World</b>	<b>86.2</b>	<b>67.9</b>	<b>26.9%</b>	<b>247.5</b>	<b>199.8</b>	<b>23.9%</b>	<b>18.9%</b>
<b>Group Sales</b>	<b>294.9</b>	<b>280.9</b>	<b>5.0%</b>	<b>924.7</b>	<b>864.0</b>	<b>7.0%</b>	<b>5.0%</b>
<b>Of which: Total Drug Sales</b>	<b>286.8</b>	<b>273.4</b>	<b>4.9%</b>	<b>898.8</b>	<b>840.0</b>	<b>7.0%</b>	<b>4.9%</b>
<b>Drug-related Sales<sup>1</sup></b>	<b>8.1</b>	<b>7.5</b>	<b>7.9%</b>	<b>25.9</b>	<b>24.0</b>	<b>7.8%</b>	<b>6.4%</b>

In the third quarter 2012, sales generated in the **Major Western European countries** amounted to €120.9 million, down 8.4% year-on-year. In the first nine months of 2012, sales generated in the major Western European countries amounted to €393.3 million, down 3.6% year-on-year excluding foreign exchange impacts<sup>2</sup>. Dynamic volume sales growth of specialty care products were more than offset by the consequences of a tougher competitive and administrative environment in the French primary care landscape and administrative measures in Spain, outlined below. As a result, sales in the Major Western European countries represented 42.5% of total Group sales at the end of the first nine months of 2012, compared to 47.0% a year earlier.

**France** – In the third quarter 2012, sales reached €54.5 million, down 23.2% year-on-year. In the first nine months of 2012, sales totalled €187.7 million, down 14.9% year-on-year, penalized by the acceleration of the decline of primary care sales. Despite the strong volume growth of specialty care (mainly Somatuline<sup>®</sup>, NutropinAq<sup>®</sup> and launch of Hexvix<sup>®</sup>), sales were negatively impacted by declining sales of Nisis<sup>®</sup>/Nisisco<sup>®</sup> following a 15% price reduction and the arrival of several generics in November 2011 and by decreasing sales of Tanakan<sup>®</sup> after the delisting of the product as of 1<sup>st</sup> March 2012. Additionally, sales of Nisis<sup>®</sup>/Nisisco<sup>®</sup> and Forlax<sup>®</sup> were negatively impacted by a step-up in July in the regulation known as « Tiers-Payant », whereby the patient now pays upfront for a branded drug at the pharmacy if a generic is available, and obtains reimbursement later on. This has generated an unprecedented and sudden increase in generic penetration. Consequently, the relative weight of France in the Group's consolidated

<sup>1</sup> Active ingredients and raw materials

<sup>2</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

sales continued to decrease, representing 20.3% of total Group sales compared to 25.5% a year earlier.

**United Kingdom** – In the third quarter 2012, sales reached €14.3 million, up 15.6% year-on-year. In the first nine months of 2012, sales totalled €42.0 million, up 15.8% excluding foreign exchange impacts<sup>1</sup>, fuelled by a very strong double digit growth of Decapeptyl<sup>®</sup> and a double digit growth of Dysport<sup>®</sup> and Somatuline<sup>®</sup>. Sales also benefited from a technical comparison basis related to accruals booked in 2011 in accordance with the Pharmaceutical Price Regulation Scheme (PPRS). Restated to exclude this PPRS effect, sales in the first nine months of 2012 were up 11.5% year-on-year. Over the period, the United Kingdom represented 4.5% of total Group sales compared to 3.9% in 2011.

**Spain** – In the third quarter 2012, sales reached €12.5 million, down 9.5% year-on-year. In the first nine months of 2012, sales totalled €42.8 million, down 4.3% year-on-year, penalized by the tax on sales increase to 15.0% from 7.5% implemented on 1 November 2011. Additionally, the Spanish pharmaceutical market significantly slowed down during the summer, with a double digit year-on-year decrease. At the end of the first nine months of 2012, sales in Spain represented 4.6% of total group sales, compared to 5.2% a year earlier.

**Germany** – In the third quarter 2012, sales reached €19.3 million, up 21.8% year-on-year. In the first nine months of 2012, sales amounted to €57.5 million, up 26.4% year-on-year, driven by strong volume growth of Somatuline<sup>®</sup>, Hexvix<sup>®</sup> and drug-related sales<sup>2</sup>. In the first nine months of 2012, sales in Germany represented 6.2% of total Group sales compared to 5.3% a year earlier.

**Italy** – In the third quarter 2012, sales reached €20.2 million, up 6.9% year-on-year. In the first nine months of 2012, sales reached €63.4 million, up 3.7% year-on-year, driven by the good performance of Somatuline<sup>®</sup> but partially offset by the performance of Dysport<sup>®</sup> affected by strong competitive pressure and by the decline of Forlax<sup>®</sup> following a change in distribution model. Italy represented 6.9% of the Group's consolidated sales at the end of the first nine months of 2012 compared to 7.1% a year earlier.

In the third quarter 2012, sales generated in the **Other European countries** reached €69.6 million, up 4.2% year-on-year. In the first nine months of 2012, sales amounted to €229.4 million, up 7.8% excluding foreign exchange impacts<sup>1</sup>. Sales were mainly driven by the good performance of specialty care products and Tanakan<sup>®</sup> in Russia, partially offset by destocking on Smecta<sup>®</sup> following its re-submission in 2011. Over the period, Poland, the Netherlands and Ukraine also contributed to the volume growth. In the first nine months of 2012, sales in this region represented 24.8% of total consolidated Group sales, compared to 24.4% a year earlier.

In the third quarter 2012, sales generated in **North America** reached €18.2 million, up 28.0% year-on-year. In the first nine months of 2012, sales amounted to €54.6 million, up 5.3% excluding foreign exchange impacts<sup>1</sup>. In November 2011, Ipsen sold its North American development and marketing rights for Apokyn<sup>®</sup>. As a consequence, Ipsen stopped recording Apokyn<sup>®</sup> sales in its accounts as of 30 November 2011. Restated to exclude Apokyn<sup>®</sup> sales, North American sales were up 14.8% year-on-year, driven by strong supply of Dysport<sup>®</sup> for aesthetic use to Medicis, by the continuous penetration of Somatuline<sup>®</sup> in acromegaly and by the value growth of Dysport<sup>®</sup> in the treatment of cervical dystonia. Sales in North America represented 5.9% of total consolidated Group sales, compared to 5.5% a year earlier.

In the third quarter, sales generated in the **Rest of the World** reached €86.2 million, up 26.9% year-on-year. In the first nine months of 2012, sales amounted to €247.5 million, up 23.9% year-on-year or up 18.9% excluding foreign exchange impacts<sup>1</sup>. This performance was partially driven by non-recurring effects, notably in Algeria where sales were anticipated to better manage risk of delays resulting from local letter of credit process and in Vietnam, where orders of some Primary care products were anticipated ahead of import license expiration. In Latin America, orders were also anticipated to secure in-market product availability for year end. Restated to exclude these non-recurring stocking effects, sales were up 14.8% excluding foreign exchange impacts<sup>1</sup>. In the first nine months of 2012, sales in the

<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

<sup>2</sup> Active ingredients and raw materials



Rest of the World continued to increase, representing 26.8% of total consolidated Group sales, up from 23.1% a year earlier.

### Sales by therapeutic area and by product

The following table shows sales by therapeutic area and by product for the third quarters and first nine months of 2012 and 2011:

(in million euros)	3rd Quarter			9 Months			
	2012	2011	% Variation	2012	2011	% Variation	% variation at constant currency
<b>Uro-oncology</b>	<b>78.7</b>	<b>72.3</b>	<b>8.8%</b>	<b>240.8</b>	<b>211.5</b>	<b>13.8%</b>	<b>11.5%</b>
of which Hexvix®	2.9	-	N/A	9.0	-	N/A	N/A
of which Decapeptyl®	75.7	72.3	4.7%	231.8	211.5	9.6%	7.3%
<b>Endocrinology</b>	<b>75.5</b>	<b>67.0</b>	<b>12.6%</b>	<b>229.9</b>	<b>200.9</b>	<b>14.4%</b>	<b>11.5%</b>
of which Somatuline®	55.1	48.0	14.9%	168.4	142.9	17.8%	15.1%
of which NutropinAq®	13.2	12.5	5.5%	39.7	38.6	2.9%	2.0%
of which Increlex®	7.2	6.5	9.8%	21.7	19.4	12.0%	3.8%
<b>Neurology</b>	<b>58.3</b>	<b>45.6</b>	<b>27.9%</b>	<b>181.5</b>	<b>153.4</b>	<b>18.3%</b>	<b>16.5%</b>
of which Dysport®	58.3	44.5	31.0%	181.4	149.4	21.4%	19.9%
of which Apokyn®	-	1.1	(99.9%)	0.1	4.0	(97.1%)	(97.3%)
<b>Specialty Care</b>	<b>212.4</b>	<b>184.9</b>	<b>14.9%</b>	<b>652.2</b>	<b>565.9</b>	<b>15.3%</b>	<b>12.8%</b>
<b>Gastroenterology</b>	<b>48.9</b>	<b>43.7</b>	<b>11.9%</b>	<b>147.2</b>	<b>142.9</b>	<b>3.0%</b>	<b>0.2%</b>
of which Smecta®	29.0	24.5	18.1%	83.5	76.5	9.1%	4.1%
of which Forlax®	8.7	8.9	(2.7%)	29.4	30.6	(4.0%)	(5.0%)
<b>Cognitive Disorders</b>	<b>16.9</b>	<b>25.4</b>	<b>(33.7%)</b>	<b>61.8</b>	<b>70.6</b>	<b>(12.5%)</b>	<b>(12.9%)</b>
of which Tanakan®	16.9	25.4	(33.7%)	61.8	70.6	(12.5%)	(12.9%)
<b>Cardiovascular</b>	<b>5.8</b>	<b>15.7</b>	<b>(63.2%)</b>	<b>28.2</b>	<b>49.6</b>	<b>(43.1%)</b>	<b>(43.1%)</b>
of which Nisis® & Nisisco®	2.9	11.7	(75.1%)	16.7	36.3	(54.2%)	(54.2%)
of which Ginkor Fort®	2.5	3.3	(24.8%)	9.6	10.4	(7.8%)	(7.8%)
<b>Other Primary Care</b>	<b>2.9</b>	<b>3.7</b>	<b>(22.9%)</b>	<b>9.4</b>	<b>11.1</b>	<b>(15.0%)</b>	<b>(15.0%)</b>
of which Adroavance®	2.6	3.1	(15.8%)	8.6	8.9	(3.1%)	(3.1%)
<b>Primary Care</b>	<b>74.4</b>	<b>88.5</b>	<b>(16.0%)</b>	<b>246.6</b>	<b>274.2</b>	<b>(10.1%)</b>	<b>(11.5%)</b>
<b>Total Drug Sales</b>	<b>286.8</b>	<b>273.4</b>	<b>4.9%</b>	<b>898.8</b>	<b>840.0</b>	<b>7.0%</b>	<b>4.9%</b>
<b>Drug-related Sales<sup>1</sup></b>	<b>8.1</b>	<b>7.5</b>	<b>7.9%</b>	<b>25.9</b>	<b>24.0</b>	<b>7.8%</b>	<b>6.4%</b>
<b>Group Sales</b>	<b>294.9</b>	<b>280.9</b>	<b>5.0%</b>	<b>924.7</b>	<b>864.0</b>	<b>7.0%</b>	<b>5.0%</b>

In the third quarter 2012, sales of **Specialty Care products** reached €212.4 million, up 14.9% year-on-year. In the first nine months of 2012, sales amounted to €652.2, up 15.3% year-on-year or up 12.8% excluding foreign exchange impacts<sup>2</sup>, benefiting namely from positive non-recurring stocking effect in Algeria and anticipated orders in Latin America mentioned above. Restated to exclude these impacts sales were up 12.2% excluding foreign exchange impacts<sup>2</sup>. At the end of the first nine months of 2012, the relative weight of Specialty Care products continued to increase to 70.5% of total Group sales, compared to 65.5% a year earlier.

In **Uro-Oncology**, sales of **Decapeptyl®** reached €75.7 million in the third quarter 2012, up 4.7% year-on-year. In the first nine months of 2012, sales amounted to €231.8 million, up 7.3% excluding foreign exchange impacts<sup>2</sup>, mainly driven by a good performance in China, United Kingdom, Algeria, Russia, and Poland. In September 2011, Ipsen in-licensed Hexvix®, the first approved and marketed drug for

<sup>1</sup> Active ingredients and raw materials

<sup>2</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

improved detection of bladder cancer. In the first nine months of 2012, sales of Hexvix<sup>®</sup> amounted to €9.0 million, mostly generated in Germany. Sales in uro-oncology represented 26.0% of total Group sales compared to 24.5% a year earlier.

In **endocrinology** sales continued to grow, reaching €75.5 million in the third quarter 2012, up 12.6% year-on-year. In the first nine months of 2012, sales amounted to €229.9 million, up 11.5% excluding foreign exchange impacts<sup>1</sup>, representing 24.9% of total Group sales, compared to 23.3% a year earlier.

**Somatuline<sup>®</sup>** – In the third quarter 2012, sales reached €55.1 million, up 14.9%. In the first nine months of 2012, Somatuline<sup>®</sup> sales reached €168.4 million, up 15.1% year-on-year excluding foreign exchange impacts<sup>1</sup>, fuelled by strong growth in France, Germany, North America, Italy, Poland, United Kingdom, Latin America and the Netherlands.

**NutropinAq<sup>®</sup>** – In the third quarter 2012, sales reached €13.2 million, up 5.5% year-on-year. In the first nine months of 2012, sales of NutropinAq<sup>®</sup> reached €39.7 million, up 2.0% excluding foreign exchange impacts<sup>1</sup>, driven notably by a good performance in Major Western European countries.

**Increlex<sup>®</sup>** – In the third quarter 2012, sales reached €7.2 million, up 9.8% year-on-year, mainly due to the recognition in the US of the paediatric use of Increlex<sup>®</sup> by the Centre for Medicare and Medicaid Services (CMS), allowing for a reduced rebate (17% rebate instead of 23%). Sales of Increlex<sup>®</sup> in the first nine months of 2012 amounted to €21.7million, up 3.8% excluding foreign exchange impacts<sup>1</sup>.

In **neurology**, sales reached €58.3 million in the third quarter 2012, up 27.9% year-on-year. In the first nine months of 2012, sales amounted to €181.5 million, up 16.5% excluding foreign exchange impacts<sup>1</sup>. Sales in neurology represented 19.6% of total Group sales, compared to 17.8% a year earlier.

**Dysport<sup>®</sup>** – In the third quarter 2012, sales reached €58.3 million, up 31.0% year-on-year. In the first nine months of 2012, sales reached €181.4 million, up 19.9% year-on-year excluding foreign exchange impacts<sup>1</sup>, fuelled by strong sales growth in Russia, Brazil and Australia where the Group signed an agreement in April 2012 with Galderma. Sales were also driven by supply sales to the Group's aesthetics' partners Medicis and Galderma.

**Apokyn<sup>®</sup>** – In November 2011, Ipsen sold its North American development and marketing rights for Apokyn<sup>®</sup> to Britannia Pharmaceuticals. As a result, Ipsen stopped recording Apokyn<sup>®</sup> sales in its accounts as of 30 November 2011.

In the third quarter 2012, sales of **Primary Care products** amounted to €74.4 million, down 16.0% year-on-year, negatively impacted by the destocking effect on Smecta<sup>®</sup> in Russia and the consequences of a tougher competitive environment in France, reinforced by the implementation of the "tiers-payant" regulation, both mentioned above. In the first nine months of 2012, sales amounted to €246.6 million, down 10.1% year-on-year or down 11.5% excluding foreign exchange impacts<sup>1</sup> despite positive non-recurring effects described above (mainly the renewal of import licences in Vietnam and stocking in Algeria). Restated to exclude these impacts, sales were down 13.2% excluding foreign exchange impacts<sup>1</sup>. Primary Care sales in France represented 39.1% of total Group Primary Care sales in 2012, against 48.6% a year earlier.

In **gastroenterology**, sales reached €48.9 million in the third quarter 2012, up 11.9% year-on-year. In the first nine months of 2012, sales amounted to €147.2 million, flat year-on-year excluding foreign exchange impacts<sup>1</sup>.

**Smecta<sup>®</sup>** – In the third quarter 2012, sales reached €29.0 million, up 18.1% year-on-year. Sales of Smecta<sup>®</sup> in the first nine months of 2012 reached €83.5 million, up 4.1% year-on-year excluding foreign exchange impacts<sup>1</sup>, fuelled notably by a good performance in China. Sales of

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<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates

Smecta<sup>®</sup> represented 9.0% of total Group sales during the period compared with 8.9% a year earlier.

**Forlax<sup>®</sup>** – In the third quarter 2012, sales reached €8.7 million, down 2.7% year-on-year. In the first nine months of 2012, sales amounted to €29.4 million, down 5.0% year-on-year, mainly due to the sales decrease in Italy (related to the change in distribution model described above), in Algeria and Belgium. In France, Forlax<sup>®</sup> sales were impacted by the “Tiers-payant” regulation mentioned above, however partially offset by supply to generic partner. In the first nine months of 2012, France represented 58.2% of the total sales of the product, up from 56.6% a year earlier.

**In the cognitive disorders area**, sales of **Tanakan<sup>®</sup>** in the third quarter 2012 reached €16.9 million, down 33.7% year-on-year. Sales in the first nine months of 2012 reached €61.8 million, down 12.9% year-on-year excluding foreign exchange impacts<sup>1</sup>, penalized by the delisting of the product in France as of 1 March 2012, in Romania in May 2012 and in Spain in September, despite solid sales in Russia and anticipated orders in Vietnam before import licences renewal. In the first nine months of 2012, 35.5% of Tanakan<sup>®</sup> sales were made in France compared with 50.0% a year earlier.

**In the cardiovascular area**, sales in the third quarter 2012 amounted to €5.8 million, down 63.2% year-on-year. In the first nine months 2012, sales amounted to €28.2 million, down 43.1% year-on-year, impacted mainly by the 15% price decrease of Nisis<sup>®</sup>/Nisisco<sup>®</sup>, the arrival of several generics in November 2011 and the implementation of the “tiers-payant” regulation described above.

**Other primary care products** sales reached €2.9 million in the third quarter 2012, down 22.9% year-on-year. Sales in the first nine months of 2012 amounted to €9.4 million, down 15.0% year-on-year, with sales of **Adavance<sup>®</sup>** contributing to €8.6 million, down 3.1% year-on-year, following a 33.0% price cut enforced in January 2012 in France.

In the third quarter 2012, **drug-related sales (active ingredients and raw materials)** reached €8.1 million, up 7.9% year-on-year. In the first nine months of 2012, sales amounted to €25.9 million, up 6.4% excluding foreign exchange impacts<sup>1</sup>.

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<sup>1</sup> Variations excluding foreign exchange impacts are computed by restating the first nine months 2011 with the first nine months 2012 average exchange rates