

## Ipsen delivers strong sales growth of 20.2%<sup>1</sup> for the third quarter of 2018 and confirms full year guidance

Paris (France), 25 October 2018 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, today announced sales for the third quarter of 2018.

### Financial highlights

- Q3 2018 Group sales growth of 20.2%<sup>1</sup> driven by Specialty Care sales growth of 24.2%<sup>1</sup> reflecting strong momentum for Somatuline<sup>®</sup> and Dysport<sup>®</sup>, continued sequential sales growth for Cabometyx<sup>®</sup> and Onivyde<sup>®</sup>, and sustained growth of Consumer Healthcare sales at 5.0%<sup>2</sup>
- YTD Group sales growth of 21.1%<sup>1</sup> fueled by strong Specialty Care sales growth of 25.8%<sup>1</sup> and Consumer Healthcare sales growth of 2.9%<sup>2</sup>
- Full Year 2018 guidance confirmed with Group sales growth of greater than 19.0%<sup>1</sup> and core operating margin of around 29.0% of sales

### Pipeline highlights

- Positive CHMP (Committee for Medicinal Products for Human Use) opinion for Cabometyx<sup>®</sup> for the treatment of second-line patients with hepatocellular carcinoma (HCC)
- European approval for improved device for Somatuline<sup>®</sup>

### Key figures

Third quarter and nine months 2018 unaudited IFRS consolidated sales

(in million euros)	Third Quarter				Nine Months			
	2018	2017	% Variation	% Variation at constant currency	2018	2017	% Variation	% Variation at constant currency
Specialty Care	484.1	396.2	22.2%	24.2%	1,404.2	1,160.8	21.0%	25.8%
Consumer Healthcare	71.9	73.9	-	5.0% <sup>2</sup>	216.2	228.8	-	2.9% <sup>2</sup>
Group sales	555.9	470.1	18.3%	20.2%	1,620.4	1,389.6	16.6%	21.1%

**David Meek, Chief Executive Officer of Ipsen** stated: “In the third quarter, we continued to execute against our 2018 objectives with industry-leading top-line growth of over 20%, driven by the powerful momentum of our Specialty Care business. During the quarter, we received a positive CHMP opinion for Cabometyx for the treatment of second-line advanced hepatocellular carcinoma (HCC) and also received European approval for our improved Somatuline device. On our pipeline, we are prioritizing and rapidly advancing key programs. Looking forward, building a sustainable pipeline through externally sourcing innovation, including additional successful business development transactions, remains a top priority to sustain strong top-line growth and to deliver additional value to patients and shareholders.”

<sup>1</sup> Year-on-year growth excluding foreign exchange impacts

<sup>2</sup> Consumer Healthcare reported sales down 1.1% in Q3 and down 3.0% in YTD, non-restated from the new contractual set-up of Etiasa<sup>®</sup>

## Third quarter 2018 sales highlights

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts (currency effects established by recalculating net sales for the relevant period at the exchange rates from the previous period)

(in million euros)	2018	2017	% Variation	% Variation at constant currency
<b>Specialty Care</b>	<b>484.1</b>	<b>396.2</b>	<b>22.2%</b>	<b>24.2%</b>
Somatuline®	217.0	173.0	25.4%	26.2%
Decapeptyl®	89.2	88.2	1.2%	1.9%
Cabometyx®	38.8	14.3	171.8%	173.0%
Onivyde®	26.9	17.9	49.9%	52.1%
Dysport®	87.7	77.4	13.3%	20.6%
<b>Consumer Healthcare</b>	<b>71.9</b>	<b>73.9</b>	<b>-2.8%</b>	<b>-1.1%</b>
Smecta®*	32.8	25.0	31.0%	32.5%
Forlax®	9.5	10.4	-9.2%	-8.4%
Tanakan®	9.6	11.2	-14.2%	-10.7%
<b>Group sales</b>	<b>555.9</b>	<b>470.1</b>	<b>18.3%</b>	<b>20.2%</b>

\*including Smectite sales previously recorded in Other Consumer Healthcare

**Consolidated Group sales** grew 20.2% to €555.9 million.

Sales of **Specialty Care** products reached €484.1 million, up 24.2% year-on-year.

**Somatuline®** sales reached €217.0 million, up 26.2%, year-on-year, driven by the continued excellent growth in North America of 37.2%, and by the strong performance in key European countries and Japan.

**Decapeptyl®** sales reached €89.2 million, up 1.9% year-on-year, due to the good performance in Europe, partly offset by the negative impact of inventory in China, Algeria and the Middle East.

**Cabometyx®** sales reached €38.8 million, driven primarily by the performance in Germany, Italy, France and in other European countries with continued double-digit quarter-on-quarter growth.

**Onivyde®** sales reached €26.9 million, growing 52.1% year-on-year, and increased by 4.4% over the second quarter of 2018, reflecting the steady launch in the U.S. despite some impact from seasonality and inventories.

**Dysport®** sales reached €87.7 million, up 20.6% year-on-year, led by a solid performance in the U.S. both in Therapeutics and Aesthetics through the Galderma partnership, Galderma sales in Europe and the resupply and strong performance in Brazil.

**Consumer Healthcare** product sales totaled €71.9 million, up +5.0% re-stated from the new Etiasa® contractual set-up (or down 1.1% as reported).

**Smecta®** sales reached €32.8 million, up 32.5% year-on-year, mainly driven by the good performance in China (and a negative inventory impact in 2017) and the good performance in France, Italy and several emerging markets.

**Forlax®** sales reached €9.5 million, down 8.4% year-on-year, due to competitive pressure.

**Tanakan®** sales reached €9.6 million, down 10.7% year-on-year, due to competitive pressure in emerging countries and a market slow-down in France.

## Conference call

Ipsen will hold a conference call Thursday, 25 October 2018 at 2:30 p.m. (Paris time, GMT+2). Participants should dial in to the call approximately five to ten minutes prior to its start. No reservation is required to participate in the conference call.

Standard International: +44 (0) 2071-928-000  
France and continental Europe: + 33 (0) 1 76 70 07 94  
UK: 08-444-5718-892  
U.S.: 1-6315-107-495  
Conference ID: 5459297

A recording will be available for seven days on Ipsen's website.

## About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and specialty care. The group develops and commercializes innovative medicines in three key therapeutic areas - Oncology, Neuroscience and Rare Diseases. Its commitment to Oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €1.9 billion in 2017, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,400 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information on Ipsen, visit [www.ipsen.com](http://www.ipsen.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. Use of the words "believes", "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. 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 generic products 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. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. 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 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. 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. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2017 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

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## Comparison of Consolidated Sales for the Third Quarter and First Nine Months of 2018 and 2017:

### Sales by therapeutic area and by product

Note: Unless stated otherwise, all variations in sales are stated excluding foreign exchange impacts (currency effects established by recalculating net sales for the relevant period at the exchange rates from the previous period)

The following table shows sales by therapeutic area and by product for the third quarter and first nine months of 2018 and 2017:

(in million euros)	3rd Quarter				9 Months			
	2018	2017	% Variation	% Variation at constant currency	2018	2017	% Variation	% Variation at constant currency
<b>Oncology</b>	<b>378.7</b>	<b>299.2</b>	<b>26.6%</b>	<b>27.3%</b>	<b>1,088.4</b>	<b>860.0</b>	<b>26.5%</b>	<b>30.9%</b>
Somatuline®	217.0	173.0	25.4%	26.2%	619.5	513.3	20.7%	26.1%
Decapeptyl®	89.2	88.2	1.2%	1.9%	272.5	259.1	5.2%	6.5%
Cabometyx®	38.8	14.3	171.8%	173.0%	100.8	31.1	223.8%	224.9%
Onivyde®	26.9	17.9	49.9%	52.1%	75.8	37.2	103.5%	118.5%
Other Oncology	6.8	5.9	15.4%	15.7%	19.8	19.2	3.0%	3.3%
<b>Neuroscience</b>	<b>88.3</b>	<b>78.0</b>	<b>13.2%</b>	<b>20.4%</b>	<b>262.8</b>	<b>243.3</b>	<b>8.0%</b>	<b>15.4%</b>
Dysport®	87.7	77.4	13.3%	20.6%	260.5	241.0	8.1%	15.4%
<b>Rare diseases</b>	<b>17.1</b>	<b>19.0</b>	<b>-9.8%</b>	<b>-9.7%</b>	<b>53.1</b>	<b>57.4</b>	<b>-7.5%</b>	<b>-5.7%</b>
NutropinAq®	11.3	12.4	-9.4%	-9.2%	35.4	39.5	-10.4%	-10.2%
Increlex®	5.9	6.5	-10.4%	-10.7%	17.7	17.9	-1.1%	4.3%
<b>Specialty Care</b>	<b>484.1</b>	<b>396.2</b>	<b>22.2%</b>	<b>24.2%</b>	<b>1,404.2</b>	<b>1,160.8</b>	<b>21.0%</b>	<b>25.8%</b>
Smecta®*	32.8	25.0*	31.0%	32.5%	95.2	87.7	8.6%	12.1%
Forlax®	9.5	10.4	-9.2%	-8.4%	28.6	31.7	-9.8%	-8.6%
Tanakan®	9.6	11.2	-14.2%	-10.7%	25.5	26.7	-4.3%	-0.7%
Fortrans/Eziclen®	8.1	7.6	6.3%	9.3%	22.1	23.4	-5.8%	-2.0%
Etiasa®	0.0	5.3	-99.7%	-99.7%	0.2	14.7	-99.0%	-98.9%
Other Consumer Healthcare	11.9	14.4	-17.3%	-16.8%	44.6	44.6	0.0%	0.8%
<b>Consumer Healthcare</b>	<b>71.9</b>	<b>73.9</b>	<b>-2.8%</b>	<b>-1.1%</b>	<b>216.2</b>	<b>228.8</b>	<b>-5.5%</b>	<b>-3.0%</b>
<b>Group Sales</b>	<b>555.9</b>	<b>470.1</b>	<b>18.3%</b>	<b>20.2%</b>	<b>1,620.4</b>	<b>1,389.6</b>	<b>16.6%</b>	<b>21.1%</b>

\*including Smectite sales previously recorded in Other Consumer Healthcare

### Nine months 2018 sales highlights

Group sales reached €1,620.4 million, up 21.1%, driven by Specialty Care sales growth of 25.8% and Consumer Healthcare sales growth of 2.9% re-stated from the new Etiasa® contractual set-up (or down 3.0% as reported).

**Specialty Care** sales amounted to €1,404.2 million, up 25.8%. Oncology and Neuroscience sales grew by 30.9% and 15.4%, respectively and Rare Diseases sales decreased by 5.7%. Over the period, the relative weight of Specialty Care continued to increase to reach 86.7% of total Group sales compared to 83.5% in 2017.

In **Oncology**, sales reached €1,088.4 million up 30.9% year-on-year, driven by the continued strong performance of Somatuline® as well as the launches of Cabometyx® and Onivyde®. Over the period, Oncology sales represented 67.2% of total Group sales compared to 61.9% in 2017.

**Somatuline®** – Sales reached €619.5 million, up 26.1% year-on-year, driven by strong growth in North America of 39.4% and strong performance in most European countries, notably France, Germany, Sweden and the UK, as well as the contribution from Japan following the launch of the neuroendocrine tumor indication in 2017.

**Decapeptyl®** – Sales reached €272.5 million, up 6.5% year-on-year, positively impacted by good volume

growth, notably in France, Spain, the UK and Algeria.

**Cabometyx**<sup>®</sup> – Sales reached €100.8 million, driven by good performance in all European countries including Germany, France and the UK, as well as new launches in other countries including Australia. In the third quarter of 2018, sales increased by 14.9% over the second quarter of 2018.

**Onivyde**<sup>®</sup> – Sales amounted to €75.8 million. In the third quarter of 2018, sales were up 52.1% year-on-year and increased by 4.4% over the second quarter of 2018 with continued growth in the U.S. despite some impact from seasonality and inventories.

In **Neuroscience**, sales of **Dysport**<sup>®</sup> reached €260.5 million, up 15.4%, driven by the resupply and strong performance in Brazil, strong volume growth in the U.S. in the therapeutics market as well as the good performance of Galderma in the aesthetics market in Europe. In the first nine months of 2018, Neuroscience sales represented 16.2% of total Group sales compared to 17.5% in 2017.

In **Rare Diseases**, sales of **NutropinAq**<sup>®</sup> reached €35.4 million, down 10.2% year-on-year, impacted by lower volumes across Europe. Sales of **Increlex**<sup>®</sup> reached €17.7 million, growing by 4.3% year-on-year, driven by the performance in the U.S. Over the period, Rare Diseases sales represented 3.3% of total Group sales compared to 4.1% in 2017.

**Consumer Healthcare** sales reached €216.2 million, up 2.9% year-on-year re-stated from the new Etiasa contractual set-up (or down 3.0% as reported). Sales were positively impacted by the good performance of the Smecta<sup>®</sup> brand and the contribution from the products acquired in 2017. Over the period, Consumer Healthcare sales represented 13.3% of total Group sales, compared to 16.5% in 2017.

**Smecta**<sup>®</sup> – Sales reached €95.2 million, up 12.1% year-on-year, driven by the good growth in China (boosted by a negative inventory impact in 2017) and in France as well in Algeria, Korea and Central Asia.

**Forlax**<sup>®</sup> – Sales reached €28.6 million, down 8.6% year-on-year, impacted by lower volumes due to the importation delay in Algeria.

**Tanakan**<sup>®</sup> – Sales reached €25.5 million, down 0.7% year-on-year, impacted by a continuous market slow-down in France and importation constraints in Algeria, offset by a rebound in Russia due to a negative inventory impact in 2017.

**Fortrans/Eziclen**<sup>®</sup> – Sales reached €22.1 million, down 2.0% year-on-year, impacted by the negative inventory impact and competitive pressure in Eastern European Countries, partly offset by the good performance in China, Vietnam and Ukraine.

**Etiasa**<sup>®</sup> – Sales reached €0.2 million, down 98.9% year-on-year due to the new contractual set-up in China.

**Other Consumer Healthcare** – Sales reached €44.6 million, up 0.8% year-on-year, supported by the contribution of products acquired in 2017 and of other drug-related products, offsetting the Adavance<sup>®</sup> erosion in France.

## Sales by geographical area

Group sales by geographical area in the third quarter and first nine months of 2018 and 2017:

(in million euros)	3rd Quarter				9 Months			
	2018	2017	% Variation	% Variation at constant currency	2018	2017	% Variation	% Variation at constant currency
France	67.5	58.6	15.2%	15.3%	201.2	182.8	10.1%	10.1%
Germany	42.0	38.5	9.1%	9.1%	133.0	108.8	22.3%	22.3%
Italy	25.5	19.3	32.1%	32.1%	78.6	68.2	15.2%	15.2%
United Kingdom	24.0	19.5	23.0%	22.1%	70.5	57.9	21.8%	23.3%
Spain	22.3	17.8	25.6%	25.6%	66.3	53.1	24.8%	24.8%
<b>Major Western European countries</b>	<b>181.3</b>	<b>153.7</b>	<b>18.0%</b>	<b>17.9%</b>	<b>549.7</b>	<b>470.9</b>	<b>16.7%</b>	<b>16.9%</b>
Eastern Europe	48.4	44.4	9.0%	13.7%	141.0	142.5	-1.1%	4.0%
Others Europe	57.6	48.0	20.1%	26.3%	185.5	144.3	28.5%	32.1%
<b>Other European Countries</b>	<b>106.0</b>	<b>92.4</b>	<b>14.8%</b>	<b>20.2%</b>	<b>326.5</b>	<b>286.8</b>	<b>13.8%</b>	<b>18.2%</b>
<b>North America</b>	<b>161.3</b>	<b>119.0</b>	<b>35.5%</b>	<b>34.9%</b>	<b>439.3</b>	<b>339.4</b>	<b>29.5%</b>	<b>38.8%</b>
Asia	56.5	50.2	12.6%	13.0%	150.8	150.2	0.4%	3.8%
Other countries in the Rest of the world	50.8	54.9	-7.4%	0.4%	154.1	142.3	8.3%	16.8%
<b>Rest of the World</b>	<b>107.3</b>	<b>105.0</b>	<b>2.2%</b>	<b>6.5%</b>	<b>304.9</b>	<b>292.5</b>	<b>4.2%</b>	<b>10.1%</b>
<b>Group Sales</b>	<b>555.9</b>	<b>470.1</b>	<b>18.3%</b>	<b>20.2%</b>	<b>1,620.4</b>	<b>1,389.6</b>	<b>16.6%</b>	<b>21.1%</b>

Sales in **Major Western European countries** reached €549.7 million, up 16.9% year-on-year. Over the period, sales in Major Western European countries represented 33.9% of total Group sales, stable compared to 2017.

**France** – Sales reached €201.2 million, up 10.1% year-on-year, mainly driven by the Cabometyx® ramp-up, the strong sales of Decapeptyl® and the sustained growth of Somatuline®.

**Germany** – Sales reached €133.0 million, up 22.3% year-on-year, driven by the Cabometyx® ramp-up and the strong growth of Somatuline®.

**Italy** – Sales reached €78.6 million, up 15.2% year-on-year, mainly driven by the launch of Cabometyx®, as well as the volume growth of Decapeptyl® and Somatuline®.

**United Kingdom** – Sales reached €70.5 million, up 23.3% year-on-year, driven by the strong performance of Cabometyx®, Somatuline® and Decapeptyl®.

**Spain** – Sales reached €66.3 million, up 24.8% year-on-year, driven by the contribution of Cabometyx® and the good performance of Somatuline® and Decapeptyl®.

Sales in **Other European countries** reached €326.5 million, up 18.2% year-on-year, supported by the launch of Cabometyx® in certain countries, Onivyde® sales to Ipsen's partner, the strong growth of Dysport® as well as the solid performance of Somatuline® and Decapeptyl®. Over the period, sales in the region represented 20.1% of total Group sales compared to 20.6% in 2017.

Sales in **North America** reached €439.3 million, up 38.8% year-on-year, driven by the continued strong growth of Somatuline® as well as the Onivyde® launch contribution and the good performance of Dysport® in the therapeutics market. Over the period, sales in North America represented 27.1% of total Group sales compared to 24.4% in 2017.

Sales in the **Rest of the World** reached €304.9 million, up 10.1% year-on-year, driven by the resupply and strong performance of Dysport® in Brazil, the growth of Somatuline® in Japan as well as in other countries, partly offset by the negative impact of the new Etiasa® contractual set-up in China. Over the period, sales in the Rest of the World represented 18.8% of total Group sales compared to 21.1% in 2017.

## 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 2017 Registration Document available on its website ([www.ipsen.com](http://www.ipsen.com)).

- 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 generates or may generate substantial royalties for the Group, but these third parties could behave in ways that cause damage to the Group's business. 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.
- 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 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 (ii), products which, although they are not strictly identical to the Group's products or which have not demonstrated their bioequivalence, 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 in 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 with 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 the Group 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.

- The Group's activities are largely dependent on information systems. Despite the procedures and security measures in place internally and at the providers with which the Group operates, the Group may have to deal with incidents, notably connected to malicious acts against such information systems, such as cyber-attacks that could lead to activity disruptions, the loss or alteration of critical data, or the theft or corruption of data.
- In certain countries exposed to significant public deficits, and where the Group sells its drugs directly to public hospitals, the Group could face discount or lengthened payment terms or difficulties in recovering its receivables in full. The Group closely monitors the evolution of the situation in Southern Europe where hospital payment terms are especially long. 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.
- The cash pooling arrangements for foreign subsidiaries outside the euro zone expose the Group to financial foreign exchange risk. The variation of these exchange rates may impact significantly the Group's results.