

Ipsen delivers strong sales growth for the first nine months and improves its full-year guidance

Paris (France), 21 October 2021 – Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical group, publishes its sales performance for the third quarter of 2021 and the year to date.

Sales summary

(unaudited IFRS consolidated sales)

	Third Quarter				Year To Date			
	2021	2020	% change		2021	2020	% change	
	€m	€m	Actual	CER ¹	€m	€m	Actual	CER ¹
Specialty Care	667.8	580.5	15.0%	15.1%	1,912.3	1,747.6	9.4%	12.5%
Consumer Healthcare	59.6	52.8	12.8%	12.2%	165.5	154.0	7.5%	9.8%
Total Sales	727.4	633.3	14.9%	14.9%	2,077.7	1,901.6	9.3%	12.3%

Highlights

- Total sales growth of 12.3% at CER¹ in the year to date, or 9.3% as reported, to €2,077.7m. In the third quarter, total sales of €727.4m represented growth of 14.9% at CER¹ and as reported
- An increase in Specialty Care sales in the year to date of 12.5%¹ to €1,912.3m, driven by the growth of Somatuline® (*lanreotide*), Cabometyx® (*cabozantinib*), Decapeptyl® (*triptorelin*) and Dysport® (*botulinum toxin type A*)
- Consumer Healthcare sales growth of 9.8%¹ in the year to date to €165.5m, reflecting the performance of Smecta® (*diosmectite*) and the strong COVID-19 recovery
- Strong business-development activity, with agreements in Oncology and Neuroscience
- Full-year guidance upgraded:
 - Total sales growth¹: greater than +11.0% (prior guidance: greater than +8.0%)
 - Core operating margin²: around 34% (prior guidance: around 32.0%)

David Loew, Chief Executive Officer, commented:

“We delivered a strong performance in the third quarter, reflecting the implementation of our new strategy and improving levels of commercial execution. Somatuline and Cabometyx growth was particularly encouraging, while strong sales of Dysport continue to underpin confidence in the potential of this important medicine. Despite regulatory delays for palovarotene in FOP, the replenishment of our pipeline gathered pace, with our external-innovation strategy providing an exciting platform for sustainable top-line growth.

We continue to maximize our brands, strengthen the pipeline and are driving efficiencies across our business. This strategy, built on our culture and an unrelenting focus on patients, is delivering strong results, giving us the confidence to upgrade this year’s guidance while remaining focused on the long-term Ipsen growth story.”

¹ At constant exchange rates (CER), which exclude any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

² As a ratio of core operating income to total sales.

FY 2021 guidance

Based on the strong performance in the year to date, the gradual easing of the COVID-19 pandemic and a limited impact from the launch of generic lanreotide in Europe, the Company today upgrades its financial guidance for FY 2021:

	New guidance	Prior guidance
Total sales growth ³	Greater than 11.0%	Greater than 8.0%
Core operating margin ⁴	Around 34%	Around 32.0%

Currency impact

Ipsen anticipates an unchanged adverse impact of 2% from currencies on total sales in FY 2021, based on the level of exchange rates at the end of September 2021.

Business development

Since the publication of the H1 2021 results announcement, Ipsen signed two agreements in line with its external-innovation focus on strengthening the pipeline:

METTL3 (Oncology)

In October 2021, Ipsen and Accent Therapeutics (Accent) signed an exclusive worldwide-collaboration agreement to research, develop, manufacture, and commercialize Accent's pre-clinical stage METTL3 program. This collaboration reinforces Ipsen's expansion into hematological malignancies, with a focus on acute myeloid leukemia.

Spherical Nucleic Acids (Neuroscience)

In August 2021, Ipsen entered into an exclusive collaboration agreement with Exicure to research, develop, and commercialize novel Spherical Nucleic Acids as potential investigational treatments for Huntington's disease and Angelman syndrome.

Palovarotene

In August 2021, Ipsen withdrew the New Drug Application (NDA) for palovarotene in FOP⁵, after discussions with the U.S. Food and Drug Administration (FDA). This followed ongoing dialogue with the FDA after the acceptance of the NDA for Priority Review, announced in May 2021. During the review and the ongoing dialogue, it was recognized that additional analyses and evaluation of data collected from Ipsen's Phase III MOVE and FOP program would be required to progress and complete the review process. It was agreed that it would not be possible to complete this within the NDA review cycle. Upon successful completion of the additional data analyses, Ipsen currently anticipates regulatory resubmission in the U.S. in H1 2022. A 'clock-stop' was also granted by the European Medicines Agency.

Conference call

A conference call and webcast for investors and analysts will begin at 2:30pm Paris time today. Participants should dial in to the call early and can register [here](#); a recording will be available on [ipсен.com](https://www.ipсен.com), while the webcast can be accessed [here](#). The event ID is 4312698.

³ At CER, which exclude any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

⁴ As a ratio of core operating income to total sales.

⁵ Fibrodysplasia ossificans progressiva.

Calendar

The Company intends to publish its FY 2021 results on 11 February 2022.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the nine-month period to 30 September 2021 (the year to date or YTD 2021) and the three-month period to 30 September 2021 (the third quarter or Q3 2021), compared to nine-month period to 30 September 2020 (YTD 2020) and the three-month period to 30 September 2020 (Q3 2020) respectively, unless stated otherwise. Commentary is based on the performance in YTD 2021, unless stated otherwise.

Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established Consumer Healthcare business. With total sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. The Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has c.5,700 colleagues worldwide and is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit [ipсен.com](https://www.ipсен.com).

Contacts

Investors

Craig Marks

Vice President, Investor Relations
+44 7584 349 193

Adrien Dupin de Saint-Cyr

Investor Relations Manager
+33 6 64 26 17 49

Media

Gwenan White

Executive Vice President, Communications and Public Affairs
+44 7876 391 429

Fanny Allaire

Global Communications Director
+ 33 6 08 91 92 55

Sales by therapeutic area and product

	Third Quarter				Year To Date			
	2021	2020	% change		2021	2020	% change	
	€m	€m	Actual	CER ⁶	€m	€m	Actual	CER ⁶
Total Specialty Care	667.8	580.5	15.0%	15.1%	1,912.3	1,747.6	9.4%	12.5%
Oncology	552.3	479.1	15.3%	15.2%	1,565.4	1,446.5	8.2%	11.0%
Somatuline	313.0	272.9	14.7%	15.0%	874.4	835.1	4.7%	8.5%
Decapeptyl	110.1	94.5	16.5%	15.0%	332.6	288.0	15.5%	15.9%
Cabometyx	91.8	76.8	19.5%	19.2%	258.6	213.6	21.1%	21.6%
Onivyde®	35.2	27.5	28.0%	29.2%	93.0	90.0	3.3%	10.4%
Other Oncology	2.2	7.4	-70.2%	-70.4%	6.7	19.8	-65.9%	-66.2%
Neuroscience	103.8	87.9	18.1%	19.1%	309.6	258.4	19.8%	25.1%
Dysport	102.5	87.4	17.3%	18.2%	305.3	256.9	18.8%	24.0%
Rare Diseases	11.7	13.5	-13.5%	-13.7%	37.3	42.6	-12.5%	-11.3%
NutropinAq®	7.5	8.5	-12.6%	-13.0%	24.5	27.7	-11.6%	-11.9%
Increlex®	4.2	5.0	-14.9%	-14.7%	12.8	14.9	-14.0%	-10.1%
Total Consumer Healthcare	59.6	52.8	12.8%	12.2%	165.5	154.0	7.5%	9.8%
Smecta	27.9	20.2	38.1%	36.4%	63.5	58.0	9.6%	11.9%
Tanakan®	7.3	7.2	1.8%	0.6%	27.9	26.6	5.0%	8.7%
Forlax®	8.6	10.2	-16.0%	-16.0%	25.8	30.0	-13.9%	-12.9%
Fortrans/Eziclen®	9.3	7.2	30.1%	29.4%	26.0	19.0	36.8%	40.6%
Other Consumer Healthcare	6.5	8.1	-19.4%	-18.6%	22.2	20.4	8.7%	10.7%
Total Sales	727.4	633.3	14.9%	14.9%	2,077.7	1,901.6	9.3%	12.3%

⁶ At CER, which exclude any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Specialty Care

In the year to date, Specialty Care sales amounted to €1,912.3m, an increase of 12.5%⁷. Oncology and Neuroscience sales increased by 11.0%⁷ and 25.1%⁷ to €1,565.4m and €309.6m, respectively, while Rare Disease sales declined by 11.3%⁷ to €37.3m.

Specialty Care comprised 92.0% of total sales (YTD 2020: 91.9%).

Oncology

Sales of €1,565.4m in the year to date represented growth of 11.0%⁷ reflecting good performance from Somatuline, Cabometyx and Decapeptyl, driven by continued market-share gains in most markets and a strong Decapeptyl recovery in China.

Oncology sales comprised 75.3% of total sales (YTD 2020: 76.1%).

- a) **Somatuline** sales reached €874.4m, an increase of 8.5%⁷, with growth of 9.3%⁷ in North America that reflected strong volumes, even with the residual impact of COVID-19 on patient diagnoses and treatments. The performance was also a result of continued market-share gains in most geographies. There was only a limited impact from generic octreotide and no impact of generic lanreotide sales in Europe.
- b) **Decapeptyl** sales of €332.6m reflected growth of 15.9%⁷, mainly driven by China, which significantly recovered from the impacts of COVID-19, along with market-share gains in rest of Asia, France and Spain.
- c) **Cabometyx** sales reached €258.6m, up by 21.6%⁷, driven by a strong volume uptake across most geographies in both renal cell carcinoma and hepatocellular carcinoma.
- d) **Onivyde** (*irinotecan liposome injection*) sales of €93.0m, growing by 10.4%⁷, were driven by higher sales to Ipsen's ex-U.S. partner and higher volumes in the U.S.

Neuroscience

Dysport sales in the year to date reached €305.3m, up by 24.0%⁷, driven by a strong recovery from the pandemic in most geographies for aesthetics markets, mainly in the Middle East, Turkey and Russia, along with therapeutics markets in North America and Europe. There was also a continued solid aesthetics performance from Ipsen's partner, Galderma, in most of its markets.

Neuroscience sales comprised 14.9% of total sales (YTD 2020: 13.6%).

Rare Disease

NutropinAq (*somatropin*) sales in the year to date of €24.5m, a decline of 11.9%⁷, reflected a slowdown in the market and competitive pressures across Europe. A decline in **Increlex** (*mecasermin*) sales of 10.1%⁷ to €12.8m was a result of lower demand in the U.S., reflecting the ongoing effects of COVID-19.

Rare Disease sales comprised 1.8% of total sales (YTD 2020: 2.2%).

Consumer Healthcare

Sales of €165.5m in the year to date, up by 9.8%⁷, was a result of the 11.9%⁷ growth in sales of **Smecta** to €63.5m that was driven by the COVID-19 recovery in China and Russia. **Fortrans/Eziclen** (*macrogol 4000*) sales increased by 40.6%⁷ to €26.0m, also reflecting the recovery in China. **Tanakan** (*ginkgo biloba extract*) sales increased by 8.7%⁷ to €27.9m, driven by performance and a high level of deliveries in Vietnam.

Consumer Healthcare sales comprised 8.0% of total sales (YTD 2020: 8.1%).

⁷ At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Sales by geographical area

	Third Quarter				Year To Date			
	2021	2020	% change		2021	2020	% change	
	€m	€m	Actual	CER ⁸	€m	€m	Actual	CER ⁸
Major Western European Countries	218.3	201.4	8.4%	7.5%	659.1	615.7	7.0%	6.9%
France	77.7	73.2	6.2%	6.2%	233.1	220.0	6.0%	6.5%
Germany	48.0	52.1	-7.8%	-7.8%	150.2	146.1	2.8%	2.8%
Italy	31.1	21.8	42.5%	42.5%	96.5	82.9	16.4%	16.4%
U.K.	31.3	28.2	11.2%	5.0%	90.0	85.6	5.1%	2.8%
Spain	30.1	26.1	15.4%	15.4%	89.2	81.0	10.1%	10.1%
Other European Countries	136.6	115.1	18.8%	19.6%	394.2	364.3	8.2%	11.8%
Eastern Europe	66.7	50.9	30.9%	31.2%	185.5	157.9	17.4%	23.5%
Others Europe	70.0	64.1	9.1%	10.2%	208.8	206.4	1.2%	2.9%
North America	246.8	204.5	20.7%	21.7%	649.8	623.3	4.2%	10.6%
Rest of the World	125.7	112.4	11.8%	10.6%	374.6	298.2	25.6%	27.6%
Asia	62.6	60.0	4.4%	1.8%	188.9	135.7	39.2%	38.7%
Other Rest of the World	63.1	52.4	20.4%	20.6%	185.7	162.5	14.3%	18.3%
Total Sales	727.4	633.3	14.9%	14.9%	2,077.7	1,901.6	9.3%	12.3%

Major Western European countries

In the year to date, sales reached €659.1m, an increase of 6.9%⁸. Major Western European countries comprised 31.7% of total sales (YTD 2020: 32.4%).

- a) **France:** sales of €233.1m, reflecting growth of 6.5%⁸, reflected a solid recovery from the pandemic, with continued market-share gains for Somatuline and Decapeptyl, along with additional Onivyde sales to Ipsen's ex-U.S. partner. This was offset by the effect of a low diarrhea market impacting the Consumer Healthcare performance.
- b) **Germany:** sales reached €150.2m, up by 2.8%⁸, mainly driven by continued market-share gains for Cabometyx and Somatuline, with no material impact from the launch of generic lanreotide.
- c) **Italy:** sales of €96.5m, up by 16.4%⁸, were mainly a result of a solid Cabometyx uptake and the Somatuline performance.
- d) **U.K.:** sales reached €90.0m, an increase of 2.8%⁸, mainly driven by a strong Somatuline performance, partly offset by lower volumes of Decapeptyl.
- e) **Spain:** sales of €89.2m reflected growth of 10.1%⁸, driven by market-share gains for Somatuline and Decapeptyl.

⁸ At CER, which exclude any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Other European countries

In the year to date, sales reached €394.2m, up by 11.8%⁹, mainly driven by market-share gains and successful launches for Cabometyx, strong Dysport performances in Turkey and Russia, along with good Consumer Healthcare sales in Eastern Europe.

Other European countries sales comprised 19.0% of total sales (YTD 2020: 19.2%).

North America

Sales of €649.8m in the year to date reflected growth of 10.6%⁹, driven by continued strong Somatuline and Cabometyx demand, despite an overall adverse impact from the pandemic on cancer treatment. Strong Dysport sales reflected good performance in the aesthetics and therapeutics markets after the impact of COVID-19 in 2020.

North America sales comprised 31.3% of total sales (YTD 2020: 32.8%).

Rest of the World

Sales reached €374.6m in the year to date, an increase of 27.6%⁹, driven by the China recovery that resulted in strong Decapeptyl and Consumer Healthcare sales. This was accompanied by a solid Dysport performance in Latin America and the Middle East, along with good Decapeptyl sales mainly in South Korea and Taiwan.

Rest of the World sales comprised 18.0% of total sales (YTD 2020: 15.7%).

⁹ At CER, which excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Forward-looking statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen'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 Ipsen'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 Ipsen'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 Ipsen. 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 medicine 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. Ipsen must face or might face competition from generic medicine 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 Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical 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 medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine 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 healthcare legislation; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen'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 Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen 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 Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen 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. Ipsen'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 Ipsen's 2020 Universal Registration Document, available on [ipсен.com](https://www.ipсен.com).