

Press release

Intended for international media and investor audiences only

Ipsen delivers strong sales momentum in the first nine months of 2024 and increases its full-year guidance

PARIS, FRANCE, 23 October 2024 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-care biopharmaceutical company, today presents its performance for the year to date and the third quarter of 2024.

	YTD 2024	YTD 2023	% change		Q3 2024	Q3 2023	% change	
	€m	€m	Actual	CER ¹	€m	€m	Actual	CER ¹
Oncology	1,829.8	1,744.1	4.9%	5.8%	604.0	574.5	5.1%	5.6%
Neuroscience	536.4	489.0	9.7%	11.8%	181.9	164.8	10.4%	10.1%
Rare Disease	129.7	76.0	70.7%	71.3%	50.8	33.2	53.1%	54.4%
Total Sales	2,495.9	2,309.1	8.1%	9.2%	836.6	772.4	8.3%	8.6%

Highlights

- » Total-sales growth in the year to date of 9.2% at CER¹, or 8.1% as reported, with notable performances from Dysport[®] (abobotulinumtoxinA), Cabometyx[®] (cabozantinib) and Bylvay[®] (odevixibat), with robust Somatuline[®] (lanreotide) sales, as well as the increasing contribution from the launches of Iqirvo[®] (elafibranor) in 2L PBC² and Onivyde[®] (irinotecan) in 1L mPDAC³
- » Regulatory approvals in the E.U. of Iqirvo and Kayfanda[®] (odevixibat)
- » Increased 2024 financial guidance: total-sales growth greater than 8.0% at CER¹ (prior guidance: greater than 7.0% at CER¹); core operating margin greater than 31.0% of total sales (prior guidance: greater than 30.0%)

“Since the launch of our strategy in 2020, we have enjoyed uninterrupted growth. This quarter was no exception and was accompanied by further progress in the pipeline”, commented David Loew, Chief Executive Officer. “We have also continued to launch across several indications and lines of therapy, including the recent rollouts of Iqirvo and Onivyde, which are progressing well. Supported by the performance so far this year, we are further increasing our 2024 sales and margin guidance.”

“We have built a track record of delivery, grounded in a strong foundation of external innovation, commercial excellence and our ongoing mission to offer more choices for patients.”

¹ At constant exchange rates (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.

² Second-line primary biliary cholangitis.

³ First-line metastatic pancreatic ductal adenocarcinoma.

Full-year 2024 guidance

Based on the strong performance in the third quarter, Ipsen has further increased its financial guidance for 2024:

- » Total-sales growth greater than 8.0%, at constant currency (prior guidance of greater than 7.0%). Based on the average level of exchange rates in September 2024, an adverse impact on total sales of around 1.5% from currencies is expected
- » Core operating margin greater than 31.0% of total sales (prior guidance of greater than 30.0%)

Pipeline update

In September 2024, the European Commission conditionally approved Iqirvo 80mg tablets for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as a monotherapy in patients unable to tolerate UDCA. Iqirvo was approved in the same setting by the U.S. FDA in June 2024.

In September 2024, the European Commission also approved Kayfanda as a treatment for pruritus in children from as young as six months of age who have Alagille syndrome (ALGS). Odevixibat, under the brand name Bylvay, is already marketed in the E.U. for the treatment of progressive familial intrahepatic cholestasis (PFIC), and in the U.S. and E.U. for PFIC, and in the U.S. for ALGS.

In the same month, final results from the CABINET Phase III trial were presented at the 2024 European Society for Medical Oncology Congress and were published in the New England Journal of Medicine, reinforcing the efficacy benefits of Cabometyx in advanced neuroendocrine tumors. It was announced at that time that Ipsen had submitted an extension of indication Marketing Authorization to the European Medicines Agency.

Business development

In August 2024, Ipsen entered into an agreement to sell its rare pediatric disease Priority Review Voucher. As part of the agreement, Ipsen received a cash payment of \$158m in the third quarter.

In October 2024, Eton Pharmaceuticals entered into an agreement with Ipsen to acquire Increlex[®] (mecasermin injection). The transaction is expected to close before the end of 2024.

Arbitration proceedings with Galderma

As of 30 September 2024, two arbitration proceedings initiated by Galderma against Ipsen at the International Chamber of Commerce (ICC) were ongoing. The first dispute, initiated by Galderma in 2021, pertains to the territorial scope of the commercial partnership related to Azzalure[®] (abobotulinumtoxinA) and Dysport under an agreement signed in 2007 in the E.U., in certain Eastern European countries, and in Central Asia. The Tribunal of the ICC Internal Court of Arbitration issued a final award, in October 2024, dismissing most, if not all, of Galderma's claims in this first arbitration and ordered that Galderma bear the majority of the legal fees and arbitration costs incurred by Ipsen.

A second dispute was initiated by Galderma in November 2023, related to the validity of Ipsen's 2023 termination of a joint R&D collaboration agreement entered into in 2014 under the parties' respective early-stage neurotoxin programs, including the development of IPN10200. At this stage, Ipsen cannot reasonably predict any potential financial impact from this final remaining arbitration process, for which it intends to fully defend and vindicate its rights.

Conference call

A conference call and webcast for investors and analysts will begin today at 2pm CET. Participants can access the call and its details by registering [here](#); webcast details can be found [here](#).

Calendar

Ipsen intends to publish its full-year and fourth-quarter results on 13 February 2025.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the nine-month period to 30 September 2024 (YTD 2024) and the three-month period to 30 September 2024 (Q3 2024), compared to the nine-month period to 30 September 2023 (YTD 2023) and the three-month period to 30 September 2023 (Q3 2023), respectively. Commentary is based on the performance in YTD 2024, unless stated otherwise.

About Ipsen

Ipsen is a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Our pipeline is fuelled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen 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).

Ipsen contacts

Investors

- » Craig Marks +44 (0)7584 349 193
- » Nicolas Bogler +33 6 52 19 98 92

Media

- » Jennifer Smith-Parker +44 (0) 7843 137 764
- » Anne Liontas +33 7 67 34 72 96

Total sales by therapy area and medicine

	YTD 2024	YTD 2023	% change		Q3 2024	Q3 2023	% change	
	€m	€m	Actual	CER ⁴	€m	€m	Actual	CER ⁴
Oncology	1,829.8	1,744.1	4.9%	5.8%	604.0	574.5	5.1%	5.6%
Somatuline [®]	793.8	787.9	0.7%	1.1%	271.5	259.2	4.7%	5.5%
Cabometyx [®]	449.5	397.7	13.0%	15.0%	145.3	131.9	10.1%	10.7%
Decapeptyl [®]	401.3	407.1	-1.4%	-0.6%	124.4	130.3	-4.5%	-4.9%
Onivyde [®]	147.9	120.2	23.0%	23.3%	50.7	42.6	18.9%	19.7%
Tazverik [®]	34.6	28.1	23.0%	23.4%	11.2	9.4	18.1%	19.1%
Other Oncology	2.8	3.1	-10.6%	-10.7%	0.9	1.0	-9.6%	-9.9%
Neuroscience	536.4	489.0	9.7%	11.8%	181.9	164.8	10.4%	10.1%
Dysport [®]	528.8	482.0	9.7%	11.7%	180.1	162.6	10.8%	10.6%
<i>Dysport Aesthetics</i>	314.2	279.7	12.3%	15.0%	119.5	100.0	19.5%	17.8%
<i>Dysport Therapeutics</i>	214.6	202.2	6.1%	7.2%	60.6	62.6	-3.2%	-1.2%
Other Neuroscience	7.6	7.0	7.9%	17.8%	1.8	2.2	-18.9%	-24.1%
Rare Disease	129.7	76.0	70.7%	71.3%	50.8	33.2	53.1%	54.4%
Bylvay [®]	93.8	45.7 ⁵	n/a	n/a	37.1	22.5	64.5%	66.0%
Sohonos [®]	13.3	2.8	n/a	n/a	2.9	2.3	26.9%	29.3%
Increlex [®]	12.0	12.7	-6.1%	-6.0%	4.5	4.3	4.2%	4.7%
Iqirvo [®]	7.6	-	n/a	n/a	6.3	-	n/a	n/a
NutropinAq [®]	3.0	14.8	-79.4%	-79.4%	-0.1	4.0	n/a	n/a
Total Sales	2,495.9	2,309.1	8.1%	9.2%	836.6	772.4	8.3%	8.6%

⁴ 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.

⁵ Sales in year to date 2023 consolidated for seven months, following the acquisition of Albireo that was completed in March 2023.

- » **Somatuline:** sales growth, reflecting the continued benefit of generic-lanreotide shortages in several countries in Europe, and a solid performance in Rest of World. In North America, sales declined, primarily reflecting adverse U.S. pricing, despite stable demand
- » **Decapeptyl:** performance mainly impacted by increased competition and pricing pressure in Europe and in China
- » **Cabometyx:** growth supported by increased volumes in the first-line combination with nivolumab and second-line monotherapy renal cell carcinoma indications across all geographies, as well as a favorable impact from shipment-phasing in the first half of the year
- » **Onivyde:** accelerated growth in the U.S., driven by the recent launch in the first-line indication and from higher sales to Ipsen's ex-U.S. partner
- » **Tazverik:** growth driven by higher demand in the follicular-lymphoma and epithelioid-sarcoma indications
- » **Dysport:** good performance, driven by continued growth in most aesthetics markets, including those operated by Ipsen's partner, as well as in therapeutics markets in North America and Latin America. Solid performance in Europe, with volume growth in aesthetics. In the third quarter, therapeutics sales were adversely impacted by unfavourable phasing and inventory movements
- » **Bylvay**⁶: growth driven by increased global sales in the PFIC indication, and in the Alagille syndrome indication in the U.S.
- » **Sohonos:** sales mainly in the U.S., following its launch in the fourth quarter of 2023
- » **Iqirvo:** first full quarter of sales, following U.S. FDA approval in June 2024
- » **NutropinAq:** declining sales, reflecting the end of commercialization in April 2024

⁶ Sales consolidated only for seven months in the year-to-date 2023, following the completion of the acquisition of Albireo in March 2023.

Total sales by geographical area

	YTD 2024	YTD 2023	% change		Q3 2024	Q3 2023	% change	
	€m	€m	Actual	CER ⁷	€m	€m	Actual	CER ⁷
North America	841.5	760.8	10.6%	10.7%	299.6	269.2	11.3%	11.3%
Europe ⁸	975.7	923.2	5.7%	5.3%	328.1	304.5	7.8%	7.3%
Rest of World	678.7	625.1	8.6%	13.1%	208.9	198.8	5.1%	7.0%
Total Sales	2,495.9	2,309.1	8.1%	9.2%	836.6	772.4	8.3%	8.6%

North America: sales growth driven by the solid performances of Dysport, in both therapeutics and aesthetics markets and Onivyde, and the increased contribution from the new medicines (including Bylvay, Sohonos, and Iqirvo), partly offset by lower sales of Somatuline

Europe: solid performances of Cabometyx, contribution from Bylvay and growth of Somatuline benefiting from generic-lanreotide shortages, offset by lower sales of Decapeptyl reflecting increased competition and pricing pressure

Rest of World: sales driven by the strong performance of Cabometyx, the growth of Somatuline, Decapeptyl and Dysport across both aesthetics and therapeutics markets

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.

⁸ Defined in this announcement as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

Appendix: September YTD geographic breakdown of total sales by medicine

	Total				North America				Europe				Rest of World			
	YTD 2024	YTD 2023	% change		YTD 2024	YTD 2023	% change		YTD 2024	YTD 2023	% change		YTD 2024	YTD 2023	% change	
	€m	€m	Actual	CER ⁹	€m	€m	Actual	CER ⁹	€m	€m	Actual	CER ⁹	€m	€m	Actual	CER ⁹
Oncology	1,829.8	1,744.1	4.9%	5.8%	603.3	600.0	0.6%	0.9%	788.2	742.1	6.2%	5.7%	438.3	402.1	9.0%	13.1%
Somatuline®	793.8	787.9	0.7%	1.1%	423.4	450.2	-6.0%	-5.6%	262.1	238.7	9.8%	9.0%	108.3	99.1	9.3%	12.8%
Cabometyx®	449.5	397.7	13.0%	15.0%	15.8	13.5	17.2%	18.9%	295.0	266.8	10.6%	10.2%	138.7	117.4	18.1%	25.7%
Decapeptyl®	401.3	407.1	-1.4%	-0.6%	–	–	–	–	211.0	222.5	-5.2%	-5.5%	190.3	184.6	3.1%	5.3%
Onivyde®	147.9	120.2	23.0%	23.3%	129.6	108.1	19.9%	20.2%	17.5	11.3	55.3%	55.6%	0.9	0.9	-4.9%	-6.4%
Tazverik®	34.6	28.1	23.0%	23.4%	34.6	28.1	23.0%	23.4%	–	–	–	–	–	–	–	–
Other Oncology	2.8	3.1	-10.6%	-10.7%	–	0.2	n/a	n/a	2.7	2.9	-9.2%	-9.4%	0.1	–	n/a	n/a
Neuroscience	536.4	489.0	9.7%	11.8%	153.2	125.4	22.2%	20.6%	147.9	144.6	2.3%	2.4%	235.3	219.1	7.4%	12.9%
Dysport®	528.8	482.0	9.7%	11.7%	153.2	125.4	22.2%	20.6%	147.9	144.6	2.3%	2.4%	227.7	212.0	7.4%	12.8%
Dysport Aesthetics	314.2	279.7	12.3%	15.0%	113.5	90.7	25.2%	22.8%	39.6	33.9	16.9%	17.1%	161.1	155.2	3.8%	9.9%
Dysport Therapeutics	214.6	202.2	6.1%	7.2%	39.7	34.7	14.4%	14.8%	108.3	110.7	-2.2%	-2.0%	66.7	56.8	17.3%	20.5%
Other Neuroscience	7.6	7.0	7.9%	17.8%	–	–	–	–	–	–	–	–	7.6	7.0	7.9%	17.8%
Rare Disease	129.7	76.0	70.7%	71.3%	85.0	35.4	n/a	n/a	39.6	36.6	8.2%	8.4%	5.2	4.0	28.7%	30.0%
Bylvay®	93.8	45.7	n/a	n/a	59.4	27.6	n/a	n/a	32.1	17.7	81.4%	82.4%	2.2	0.3	n/a	n/a
Sohonos®	13.3	2.8	n/a	n/a	10.9	–	n/a	n/a	0.6	0.6	-3.0%	-3.0%	1.8	2.2	-18.1%	-18.1%
Increlex®	12.0	12.7	-6.1%	-6.0%	7.0	7.8	-10.4%	-10.1%	4.0	4.2	-4.6%	-5.5%	1.0	0.8	27.1%	29.8%
Iqirvo®	7.6	–	n/a	n/a	7.6	–	n/a	n/a	–	–	n/a	n/a	–	–	–	–
NutropinAq®	3.0	14.8	-79.4%	-79.4%	–	–	–	–	2.9	14.1	-79.2%	-79.2%	0.1	0.7	-84.1%	-84.1%
Total Sales	2,495.9	2,309.1	8.1%	9.2%	841.5	760.8	10.6%	10.7%	975.7	923.2	5.7%	5.3%	678.7	625.1	8.6%	13.1%

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.

Appendix: Q3 geographic breakdown of total sales by medicine

	Total				North America				Europe				Rest of World			
	Q3 2024	Q3 2023	% change		Q3 2024	Q3 2023	% change		Q3 2024	Q3 2023	% change		Q3 2024	Q3 2023	% change	
	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰
Oncology	604.0	574.5	5.1%	5.6%	201.8	197.7	2.1%	3.0%	267.6	250.3	6.9%	6.4%	134.6	126.4	6.5%	7.9%
Somatuline®	271.5	259.2	4.7%	5.5%	139.9	147.3	-5.0%	-4.1%	95.1	78.4	21.4%	20.7%	36.5	33.6	8.7%	12.3%
Cabometyx®	145.3	131.9	10.1%	10.7%	5.7	5.0	14.6%	17.5%	101.7	94.1	8.1%	7.7%	37.9	32.8	15.4%	17.8%
Decapeptyl®	124.4	130.3	-4.5%	-4.9%	—	—	—	—	64.3	70.3	-8.5%	-8.8%	60.1	60.0	0.1%	-0.4%
Onivyde®	50.7	42.6	18.9%	19.7%	45.1	36.1	25.1%	26.0%	5.6	6.6	-14.7%	-14.8%	—	—	-46.3%	—
Tazverik®	11.2	9.4	18.1%	19.1%	11.2	9.4	18.1%	19.1%	—	—	—	—	—	—	—	—
Other Oncology	0.9	1.0	-9.6%	-9.9%	—	—	n/a	n/a	0.8	1.0	-19.5%	-19.8%	0.1	—	n/a	n/a
Neuroscience	181.9	164.8	10.4%	10.1%	62.9	55.6	13.1%	9.4%	47.9	39.4	21.4%	20.8%	71.1	69.7	2.0%	4.9%
Dysport®	180.1	162.6	10.8%	10.6%	62.9	55.6	13.1%	9.4%	47.9	39.4	21.4%	20.8%	69.4	67.6	2.7%	5.9%
Dysport Aesthetics	119.5	100.0	19.5%	17.8%	48.6	43.0	13.2%	8.2%	13.2	4.2	n/a	n/a	57.7	52.9	9.2%	11.0%
Dysport Therapeutics	60.6	62.6	-3.2%	-1.2%	14.2	12.6	12.7%	13.6%	34.7	35.3	-1.6%	-1.6%	11.7	14.7	-20.6%	-13.1%
Other Neuroscience	1.8	2.2	-18.9%	-24.1%	—	—	—%	—%	—	—	—%	—%	1.8	2.2	—	—
Rare Disease	50.8	33.2	53.1%	54.4%	34.9	15.8	n/a	n/a	12.7	14.7	-14.0%	-13.6%	3.2	2.6	21.6%	22.6%
Bylvay®	37.1	22.5	64.5%	66.0%	23.5	13.2	77.4%	78.8%	11.8	9.1	29.7%	30.8%	1.8	0.2	n/a	n/a
Sohonos®	2.9	2.3	26.9%	29.3%	2.6	—	n/a	n/a	-0.3	0.5	n/a	n/a	0.6	1.8	-67.8%	-67.8%
Increlex®	4.5	4.3	4.2%	4.7%	2.5	2.6	—	—	1.2	1.4	-10.8%	-11.4%	0.8	0.4	n/a	n/a
Iqirvo®	6.3	—	n/a	n/a	6.3	—	n/a	n/a	—	—	n/a	n/a	—	—	—	—
NutropinAq®	-0.1	4.0	n/a	n/a	—	—	—	—	-0.1	3.8	n/a	n/a	—	0.2	n/a	n/a
Total Sales	836.6	772.4	8.3%	8.6%	299.6	269.2	11.3%	11.3%	328.1	304.5	7.8%	7.3%	208.9	198.8	5.1%	7.0%

¹⁰ 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.

Disclaimers and/or 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; possible failure of products launches; and the exposure to litigation, including patent litigation, and/or regulatory actions; and risks of tax adjustments given the regular audits from tax authorities considering Ipsen's M&A activities and its presence in multiple geographies. 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 latest Universal Registration Document, available on ipсен.com.