

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).

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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

Europe⁵: 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

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