

Ipsen delivers strong sales growth in the first nine months of 2022 and confirms its full-year guidance

Paris (France), 27 October 2022

Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical company, today presents its sales performance for the year to date and the third quarter of 2022.

Sales summary¹

	YTD 2022	YTD 2021	% change		Q3 2022	Q3 2021	% change	
	€m	€m	Actual	CER ²	€m	€m	Actual	CER ²
Oncology	1,767.2	1,565.4	12.9%	6.9%	603.1	552.3	9.2%	1.2%
Neuroscience	407.7	309.6	31.7%	25.1%	160.7	103.8	54.8%	43.4%
Rare Disease	33.6	37.3	-9.8%	-12.5%	11.0	11.7	-5.4%	-9.3%
Total Sales	2,208.5	1,912.3	15.5%	9.5%	774.8	667.8	16.0%	7.6%

Highlights

- Total-sales growth in the year to date of 9.5% at CER², or 15.5% as reported, driven by the growth platforms of Dysport® (*botulinum toxin type A*), Decapeptyl® (*triptorelin*), Cabometyx® (*cabozantinib*) and Onivyde® (*irinotecan*) increasing by 20.8%²; Somatuline® (*lanreotide*) sales down by 2.8%²
- In the third quarter, total-sales growth of 7.6% at CER², or 16.0% as reported, boosted by an increase in Dysport sales of 43.3%², partly offset by a decline in Somatuline sales of 9.8%²
- Completion of the definitive merger agreement under which Ipsen acquired Epizyme, expanding Ipsen's presence in Oncology
- Postponement of the U.S. FDA's advisory-committee meeting for investigational palovarotene
- Full-year 2022 guidance confirmed, with total-sales growth greater than 7.0% at CER² and a core operating margin greater than 36.0% of total sales

David Loew, Chief Executive Officer, commented:

"I am proud of Ipsen's performance so far this year as we continue to drive strong sales results. Our growth platforms have delivered a double-digit sales performance, reflecting improving commercial execution and the strength of our portfolio. These results have outweighed the adverse impact from competitive activity on Somatuline in the U.S. and Europe. Based on the strong sales momentum, we are confirming our guidance for the full year.

I was also delighted by the enhancement of our pipeline, portfolio and organization as a result of the recent acquisition of Epizyme. In the near term, we look forward to a number of milestones for our pipeline, including Phase III data readouts in Oncology. I am pleased with the sustained progress we are making as we continue to maximize our brands, strengthen our pipeline, drive efficiencies and focus on our culture."

¹ Unaudited IFRS consolidated sales.

² 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.

Full-year 2022 guidance

Ipsen has confirmed its financial guidance for FY 2022³:

- Total-sales growth greater than 7.0%, at constant exchange rates. Based on the average level of exchange rates in September 2022, an additional favorable impact on total sales of around 6% from currencies is expected
- Core operating margin greater than 36.0% of total sales

Business development

In August 2022, Ipsen and Epizyme, Inc. (Epizyme) announced that they had completed a definitive merger agreement under which Ipsen acquired Epizyme, a fully integrated, commercial-stage biopharmaceutical company developing and delivering transformative therapies against novel epigenetic targets for cancer patients. Sales by Ipsen of Tazverik® (*tazemetostat*), consolidated from 1 September 2022, have been reflected in this announcement.

Ipsen and Marengo Therapeutics, Inc. (Marengo) also announced in August 2022 a strategic partnership to advance two of Marengo's preclinical STAR platform-generated candidates into the clinic. The collaboration will leverage Marengo's proprietary R&D expertise of a novel mechanism of T-cell activation with Ipsen's global Oncology footprint for clinical development and commercialization.

Palovarotene

In October 2022, the U.S. FDA announced its decision to postpone the planned Endocrinologic and Metabolic Drugs Advisory Committee meeting for investigational palovarotene until a later date to be confirmed; the original advisory-committee meeting was scheduled for 31 October 2022. The FDA informed Ipsen that the postponement related to an FDA request for new information on palovarotene clinical-trial data and did not relate to the safety profile of palovarotene. The Company is currently working to fulfil the request.

Conference call

A conference call and webcast for investors and analysts will begin today at 1.30pm, Paris time. Participants can access the call and its details by registering [here](#); webcast details can be found [here](#). A recording will be available on [ipсен.com](https://www.ipсен.com).

Calendar

Ipsen intends to publish its full-year results on 9 February 2023.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the nine-month period to 30 September 2022 (the year to date or YTD 2022) and the three-month period to 30 September 2022 (the third quarter or Q3 2022), compared to nine-month period to 30 September 2021 (YTD 2021) and the three-month period to 30 September 2021 (Q3 2021) respectively, unless stated otherwise. Commentary is based on the performance in YTD 2022, unless stated otherwise. The performance of Consumer HealthCare, divested in July 2022, has been excluded from all commentary and comparisons to prior performance.

³ Excludes any contribution from the Consumer HealthCare business, divested in July 2022.

Ipsen

Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience. With Specialty Care sales of €2.6bn in FY 2021, Ipsen sells medicines in over 100 countries. Alongside its external-innovation strategy, 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 around 5,000 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 [ipsen.com](https://www.ipsen.com).

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Total sales by therapy area and medicine

	YTD 2022	YTD 2021	% change		Q3 2022	Q3 2021	% change	
	€m	€m	Actual	CER ⁴	€m	€m	Actual	CER ⁴
Oncology	1,767.2	1,565.4	12.9%	6.9%	603.1	552.3	9.2%	1.2%
Somatuline	911.9	874.4	4.3%	-2.8%	311.9	313.0	-0.3%	-9.8%
Decapeptyl	396.0	332.6	19.1%	15.6%	131.4	110.1	19.3%	14.9%
Cabometyx	327.7	258.6	26.7%	24.1%	115.5	91.8	25.9%	21.8%
Onivyde	122.0	93.0	31.1%	17.1%	38.8	35.2	10.1%	-5.3%
Tazverik	2.8	0.0	n/a ⁵	n/a ⁵	2.8	0.0	n/a ⁵	n/a ⁵
Other Oncology	6.9	6.7	2.0%	1.6%	2.6	2.2	18.1%	18.2%
Neuroscience	407.7	309.6	31.7%	25.1%	160.7	103.8	54.8%	43.4%
Dysport	400.3	305.3	31.1%	24.8%	158.0	102.5	54.1%	43.3%
Other Neuroscience	7.3	4.3	70.5%	49.1%	2.7	1.3	n/a ⁵	54.1%
Rare Disease	33.6	37.3	-9.8%	-12.5%	11.0	11.7	-5.4%	-9.3%
NutropinAq®	20.8	24.5	-15.3%	-15.5%	6.3	7.5	-16.1%	-16.4%
Increlex®	12.8	12.8	-0.2%	-7.4%	4.8	4.2	13.5%	3.3%
Total Sales	2,208.5	1,912.3	15.5%	9.5%	774.8	667.8	16.0%	7.6%

Commentary is based on the performance in YTD 2022, unless stated otherwise.

- **Somatuline:** in North America, sales fell by 3.6%⁴, despite continued demand growth, impacted by increased competition and adverse U.S. pricing, driven by an increased level of commercial rebates and unfavorable movements in channel mix, as well as lower wholesaler inventories. In Europe, sales declined by 9.3%⁴, reflecting the larger effects of the launches of generic lanreotide in more markets, including Germany, France, Spain and the Nordics. Sales in the Rest of the World grew by 34.5%⁴, a result of strong performances in several geographies, including Japan and Brazil
- **Decapeptyl:** the performance was mainly driven by continued volume growth across all countries, higher volumes in China and Korea and favorable shipment phasing in Algeria. In the third quarter, sales were supported by a strong performance in China, partly reflecting the impact of a loosening of COVID-19 lockdown restrictions
- **Cabometyx:** the performance reflected strong volume uptakes in renal cell carcinoma across most geographies, mainly as a second-line monotherapy and, more recently, as a first-line therapy in combination with nivolumab

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 Not applicable.

- **Onivyde:** sales growth was primarily driven by a solid performance in the U.S., as well as sales to Ipsen’s ex-U.S. partner. The decline in sales in the third quarter reflected the impact of the phasing of 2022 sales to the partner
- **Dysport:** the performance in the year to date was driven by strong demand in most therapeutics markets, and similar growth in the aesthetics market, including increased sales to Ipsen’s partner, Galderma, especially in North America and Australia. The stronger growth in the third quarter was boosted by the catch-up from the recent manufacturing-capacity increase that benefitted supply to support aesthetics-market demand
- **Tazverik:** sales, which are in the U.S., were consolidated from 1 September 2022

Total sales by geographical area

	YTD 2022	YTD 2021	% change		Q3 2022	Q3 2021	% change	
	€m	€m	Actual	CER ⁶	€m	€m	Actual	CER ⁶
North America	759.2	649.8	16.8%	4.0%	279.9	246.8	13.4%	-2.6%
Europe ⁷	924.7	887.3	4.2%	3.7%	301.1	297.5	1.2%	1.1%
Rest of the World	524.6	375.2	39.8%	32.5%	193.9	123.5	57.0%	43.7%
Total Sales	2,208.5	1,912.3	15.5%	9.5%	774.8	667.8	16.0%	7.6%

Commentary is based on the performance in YTD 2022.

- **North America:** sales grew by 4.0%⁶, driven by a continued strong performance from Dysport in the therapeutics market and, in the aesthetics market, through Galderma, and from Onivyde, partly offset by a Somatuline sales decline of 3.6%⁶
- **Europe:** sales growth of 3.7%⁶, mainly reflecting strong Cabometyx performances in France, Spain and Germany, and Decapeptyl’s continued market-share uptakes. Following the launch of generic lanreotide in some European markets, Somatuline sales declined by 9.3%⁶. Dysport sales grew by 7.6%⁶, driven by volume uptakes in the therapeutics market
- **Rest of the World:** sales growth of 32.5%⁶, driven by solid volume growth in both Oncology and Neuroscience. In Oncology, the increase in Decapeptyl sales reflected the strong performance in China, share gains in several markets, and favorable shipment phasing in Algeria. The strong growth of Cabometyx was also a result of market-share gains across a number of geographies. The performance also reflected good Somatuline sales, including in Japan and Brazil. In Neuroscience, the strong growth of Dysport sales was a result of volume uptakes in both therapeutics and aesthetics markets, primarily in Latin America and Australia

⁶ 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.

⁷ Defined in this announcement as the E.U., the U.K., Iceland, Liechtenstein, Norway and Switzerland.

Appendix: geographic breakdown of total sales by medicine

YTD	Total				North America				Europe				Rest of the World			
	2022	2021	% change		2022	2021	% change		2022	2021	% change		2022	2021	% change	
	€m	€m	Actual	CER ⁸	€m	€m	Actual	CER ⁸	€m	€m	Actual	CER ⁸	€m	€m	Actual	CER ⁸
Oncology	1,767.2	1,565.4	12.9%	6.9%	634.5	570.8	11.2%	-1.0%	789.3	756.2	4.4%	3.8%	343.4	238.4	44.1%	35.6%
Somatuline	911.9	874.4	4.3%	-2.8%	525.5	485.3	8.3%	-3.6%	292.7	322.1	-9.1%	-9.3%	93.7	67.0	39.8%	34.5%
Decapeptyl	396.0	332.6	19.1%	15.6%	0.0	0.0	-	-	221.2	200.4	10.4%	10.3%	174.7	132.2	32.2%	23.5%
Cabometyx	327.7	258.6	26.7%	24.1%	12.9	9.9	30.4%	18.8%	242.4	210.0	15.4%	15.1%	72.4	38.7	87.0%	74.2%
Onivyde	122.0	93.0	31.1%	17.1%	93.1	75.1	23.8%	10.1%	26.5	17.5	51.8%	36.5%	2.4	0.4	n/a ⁹	n/a ⁹
Tazverik	2.8	0.0	n/a ⁹	n/a ⁹	2.8	0.0	n/a ⁹	n/a ⁹	0.0	0.0	-	-	0.0	0.0	-	-
Other Oncology	6.9	6.7	2.0%	1.6%	0.3	0.5	-45.1%	-50.0%	6.4	6.3	3.1%	3.2%	0.2	0.0	n/a ⁹	n/a ⁹
Neuroscience	407.7	309.6	31.7%	25.1%	116.7	70.8	64.8%	46.3%	110.9	103.0	7.7%	7.6%	180.1	135.8	32.6%	27.3%
Dysport	400.3	305.3	31.1%	24.8%	116.7	70.8	64.8%	46.3%	110.9	103.0	7.7%	7.6%	172.8	131.5	31.4%	26.5%
Other Neuroscience	7.3	4.3	70.5%	49.1%	0.0	0.0	-	-	0.0	0.0	-	-	7.3	4.3	70.5%	49.1%
Rare Disease	33.6	37.3	-9.8%	-12.5%	8.1	8.2	-1.5%	-12.3%	24.5	28.2	-13.0%	-13.1%	1.1	1.0	13.0%	4.6%
NutropinAq	20.8	24.5	-15.3%	-15.5%	0.0	0.0	-	-	19.9	23.7	-15.9%	-16.1%	0.8	0.8	3.6%	0.5%
Increlex	12.8	12.8	-0.2%	-7.4%	8.0	8.2	-2.8%	-13.4%	4.6	4.5	2.3%	2.5%	0.2	0.1	70.3%	25.6%
Total Sales	2,208.5	1,912.3	15.5%	9.5%	759.2	649.8	16.8%	4.0%	924.7	887.3	4.2%	3.7%	524.6	375.2	39.8%	32.5%

⁸ 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.

⁹ Not applicable.

Q3	Total				North America				Europe				Rest of the World			
	2022	2021	% change		2022	2021	% change		2022	2021	% change		2022	2021	% change	
	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰	€m	€m	Actual	CER ¹⁰
Oncology	603.1	552.3	9.2%	1.2%	234.1	217.4	7.7%	-7.4%	248.8	254.1	-2.1%	-2.3%	120.2	80.8	48.8%	35.3%
Somatuline	311.9	313.0	-0.3%	-9.8%	193.6	183.7	5.4%	-9.4%	86.0	107.6	-20.1%	-19.9%	32.4	21.8	48.7%	36.1%
Decapeptyl	131.4	110.1	19.3%	14.9%	0.0	0.0	-	-	70.1	65.9	6.4%	6.6%	61.3	44.2	38.6%	27.2%
Cabometyx	115.5	91.8	25.9%	21.8%	4.2	3.3	28.4%	13.5%	84.7	73.9	14.6%	14.4%	26.6	14.6	82.6%	61.1%
Onivyde	38.8	35.2	10.1%	-5.3%	33.4	30.3	10.3%	-5.7%	5.4	4.7	14.6%	1.6%	0.0	0.2	n/a ¹¹	n/a ¹¹
Tazverik	2.8	0.0	n/a ¹¹	n/a ¹¹	2.8	0.0	n/a ¹¹	n/a ¹¹	0.0	0.0	-	-	0.0	0.0	-	-
Other Oncology	2.6	2.2	18.1%	18.2%	0.1	0.1	-36.3%	-43.6%	2.6	2.1	24.3%	24.9%	0.0	0.0	-	-
Neuroscience	160.7	103.8	54.8%	43.4%	42.6	26.7	59.7%	36.0%	44.9	34.7	29.3%	29.3%	73.3	42.4	72.7%	59.8%
Dysport	158.0	102.5	54.1%	43.3%	42.6	26.7	59.7%	36.0%	44.9	34.7	29.3%	29.3%	70.5	41.1	71.5%	60.0%
Other Neuroscience	2.7	1.3	n/a ¹¹	54.1%	0.0	0.0	-	-	0.0	0.0	-	-	2.7	1.3	n/a ¹¹	54.1%
Rare Disease	11.0	11.7	-5.4%	-9.3%	3.2	2.7	18.5%	2.7%	7.4	8.7	-14.6%	-14.6%	0.5	0.3	44.6%	33.3%
NutropinAq	6.3	7.5	-16.1%	-16.4%	0.0	0.0	-	-	5.9	7.2	-17.1%	-17.2%	0.3	0.3	9.1%	3.7%
Increlex	4.8	4.2	13.5%	3.3%	3.2	2.7	18.4%	2.7%	1.5	1.5	-2.7%	-2.1%	0.1	0.0	n/a ¹¹	n/a ¹¹
Total Sales	774.8	667.8	16.0%	7.6%	279.9	246.8	13.4%	-2.6%	301.1	297.5	1.2%	1.1%	193.9	123.5	57.0%	43.7%

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.

¹¹ Not applicable.

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 2021 Universal Registration Document, available on [ipsen.com](https://www.ipsen.com).