

Ipsen delivers strong H1 2021 results and upgrades full-year guidance

Paris (France), 29 July 2021 - Ipsen (Euronext: IPN; ADR: IPSEY), a global specialty-driven biopharmaceutical company, today announced its financial results for the first half of 2021:

- **Strong financial results**

- Total sales growth in H1 2021 of 11.0% at CER¹, or 6.5% as reported, to €1,350.3m
 - Q2 2021 total sales growth of 16.8% at CER¹, or 12.7% as reported, to €691.8m
- Core operating income of €479.8m (H1 2020: €410.2m); IFRS operating income of €412.2m (H1 2020: €249.8m)
- Core operating margin²: 35.5% (H1 2020: 32.3%). IFRS operating margin: 30.5% (H1 2020: 19.7%)
- Healthy balance sheet: net debt down to €336.5m, a reduction of €188.7m versus December 2020

- **Delivering against the strategy**

- Maximizing the brands:
 - Speciality Care sales growth in H1 2021 of 11.2%¹ to €1,244.5m
 - Consumer Healthcare sales growth in H1 2021 of 8.6%¹ to €105.9m
- Strengthening the pipeline:
 - Good progress in external innovation: agreements announced in early and mid-stage pipeline
 - Regulatory submission acceptance for palovarotene in FOP³ in the U.S. and E.U.
 - Regulatory approval and launch of first-line renal cell carcinoma indication for Cabometyx[®] (*cabozantinib*) in combination with nivolumab and positive Phase III results for Cabometyx[®] in differentiated thyroid cancer
- Driving efficiencies:
 - Cost savings driven by reduced face-to-face activity as a result of the pandemic, and by some efficiency gains
 - Ratio of SG&A expenses to total sales declined to 35.8% (H1 2020: 37.0%)
- Focus on culture:
 - Strong momentum with Ipsen's ambitious CSR⁴ agenda

- **Full-year guidance upgraded**

- Total sales growth: greater than +8.0%¹ (prior guidance: greater than +4.0%¹)
- Core operating margin: around 32.0% (prior guidance: greater than 30.0%)

David Loew, Chief Executive Officer, commented:

"Our strong results reflected the progress we are making with our new strategy. We continued to grow our brands, with particularly strong sales in the second quarter partly a result of the gradual lifting of pandemic confinement measures. We achieved the important regulatory approval and launch of the combination of Cabometyx[®] with nivolumab in first-line renal cell carcinoma and, while we were disappointed with the recent Phase III data readout in liver cancer, our pipeline continued to strengthen, with the positive Phase III results for Cabometyx[®] in thyroid cancer and the regulatory submission of palovarotene in FOP. This progress was coupled with recent licensing agreements in the early and mid-stage pipeline. I was also pleased with the efficiencies achieved throughout our business, with the focus on our culture also underpinning more exciting opportunities to benefit patients and society.

Our raised expectations for our full-year results reflect the strength of our business. In the near term, we await further regulatory steps for palovarotene in the U.S. and Europe, while we continue to anticipate launches of generic lanreotide in Europe this year. I expect Ipsen to continue to deliver, driven by a clear strategy, strong fundamentals and attractive growth opportunities, reinforced by an unrelenting focus on serving patients."

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 Operating margin defined as a ratio of operating income to total sales.

³ Fibrodysplasia ossificans progressiva.

⁴ Company social responsibility.

Review of results

Extract of half year condensed consolidated financial statements 2021 and 2020⁵

<i>(in million euros)</i>	H1 2021	H1 2020	Change	
			Actual	CER ⁶
Total Sales	1,350.3	1,268.3	6.5%	11.0%
Specialty Care	1,244.5	1,167.1	6.6%	11.2%
Consumer Healthcare	105.9	101.2	4.7%	8.6%
Core Operating Income	479.8	410.2	17.0%	
Core operating margin	35.5%	32.3%	3.2% points	
Core Consolidated Net Profit	359.8	297.0	21.2%	
Core EPS ⁷ (fully diluted)	€4.31	€3.55	21.3%	
IFRS Operating Income	412.2	249.8	65.0%	
IFRS operating margin	30.5%	19.7%	10.8% points	
IFRS Consolidated Net Profit	303.3	222.7	36.2%	
IFRS EPS ⁷ (fully diluted)	€3.64	€2.66	36.5%	

- Total sales growth in H1 2021 of 11.0% at CER⁶, or 6.5% as reported, to €1,350.3m. This included an increase in Specialty Care sales of 11.2%⁶ to €1,244.5m, driven by the growth of Cabometyx[®], Decapeptyl[®] (*triptorelin*), Somatuline[®] (*lanreotide*) and Dysport[®] (*botulinum toxin type A*). Consumer Healthcare sales growth of 8.6%⁶ to €105.9m was partly a result of the reducing effects of the COVID-19 pandemic, particularly in China
- Core operating income of €479.8m, up by 17.0%, partly reflected the strong growth in total sales and other revenue. The increase in SG&A costs to €483.4m was limited to 3.0%, with cost savings realized in selling expenses, a result of reduced travel, the full effect of virtual conferences and medical meetings, as well as efficiency gains from procurement savings, project prioritization, digital initiatives and manufacturing optimization
- Core operating margin of 35.5%, an increase of 3.2 percentage points versus the first half of 2020
- Core consolidated net profit of €359.8m, with growth of 21.2% reflecting the aforementioned increase in core operating income. Core EPS⁷ (fully diluted) grew by 21.3% to reach €4.31
- IFRS operating income of €412.2m after amortization of intangible assets, impairment losses and other operating expenses. An IFRS operating income margin of 30.5% represented an increase of 11 percentage points compared to H1 2020, when an impairment loss on the intangible assets of palovarotene was recognized, following termination of the MO-Ped Phase II trial
- IFRS consolidated net profit of €303.3m represented an increase of 36.2%. IFRS EPS⁷ (fully diluted) was up by 36.5% to €3.64
- Free cash flow of €291.4m represented an increase of 24.9%, mainly driven by higher operating cash flow and a reduction in current income tax
- Closing net debt came to €336.5m (H1 2020: €923.3m), with the improvement in H1 2021 primarily reflecting the generation of free cash flow.

⁵ The Company's auditors performed a limited review of the 2021 half year condensed consolidated financial statements.

⁶ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

⁷ Earnings per share.

The Board of Directors approved the condensed consolidated financial statements on 28 July 2021. The company's auditors performed a limited review of 2021 half year condensed consolidated financial statements.

The interim financial report, with regards to the regulated information, is available on the Group's website, under the Regulated Information tab in the Investor Relations section.

FY 2021 guidance

The Company today upgrades its financial guidance for FY 2021, which incorporates an assumed progressive global recovery from COVID-19 in the second half of the year. Subsequent to the July 2021 launch of generic lanreotide in Germany, further launches of generic lanreotide in Europe in the second half of the year are also assumed; Ipsen does not, however, anticipate the launch of octreotide or lanreotide generics in the U.S. in 2021.

Total sales	Growth greater than 8.0% ⁸
Core operating margin	Around 32.0% ⁹ , excluding any potential impact of incremental investments from external innovation

Currency impact

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

Research and development update

In May 2021, Ipsen announced that its New Drug Application for palovarotene had been accepted by the U.S. Food and Drug Administration (FDA). Palovarotene is an oral, investigational, selective RAR γ agonist for the prevention of heterotopic ossification (new bone formation). The target regulatory action date assigned by the FDA under Priority Review status is 30 November 2021. Similar applications were accepted by the European Medicines Agency and Swissmedic.

During the period, Ipsen announced that it would exercise its option to collaborate with Exelixis on the COSMIC-311 Phase III pivotal trial of Cabometyx[®] in patients with previously treated radioactive iodine-refractory differentiated thyroid cancer. Ipsen has an exclusive collaboration agreement with Exelixis for the commercialization of Cabometyx[®] outside the U.S. and Japan.

In June 2021, Ipsen and Exelixis announced that COSMIC-312, the ongoing pivotal Phase III trial evaluating Cabometyx[®] in combination with atezolizumab, versus sorafenib in patients with previously untreated advanced hepatocellular carcinoma, met one of the primary endpoints, demonstrating significant improvement in progression-free survival (PFS) at the planned primary analysis. A prespecified interim analysis for the second primary endpoint of overall survival (OS), conducted at the same time as the primary analysis for PFS, showed a trend favoring the combination of Cabometyx[®] and atezolizumab, but did not reach statistical significance. Based on this preliminary OS data, it is anticipated that the probability of reaching statistical significance at the time of the final analysis is low.

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.

⁹ As a ratio of core operating income to total sales.

Business development

Ipsen recently announced two agreements in line with its external-innovation focus on strengthening the pipeline:

– BKX-001 (Oncology)

In July 2021, Ipsen [announced](#) a licensing agreement with BAKX Therapeutics, providing Ipsen exclusive rights to develop, manufacture and commercialize BKX-001 as a potential treatment for leukemia, lymphoma and solid tumors.

– Mesdopetam (Neuroscience)

Earlier in July 2021, Ipsen also [announced](#) a licensing agreement with IRLAB, providing Ipsen exclusive development and commercial rights to mesdopetam, a novel dopamine D3-receptor antagonist, as a potential treatment option for people living with Parkinson's disease experiencing levodopa-induced dyskinesia.

Company Social Responsibility

Ipsen's CSR focus is on three areas: Employees, Communities and Environment. Examples of progress in the first half are shown below:

– Employees

Ipsen has established a balanced gender-target ratio for its Global Leadership Team by 2025. A similar timeframe has been established for the Executive Leadership Team at a minimum of 35% of both genders.

– Communities

The Company's revolving credit facility (RCF) includes a key ESG¹⁰ element. Favorable results versus ESG-based targets by Ipsen are rewarded with charitable donations, one of which was recently awarded to [International Health Partners](#), a charity supporting people in some of the world's most challenging places to get the medicines they need.

– Environment

Ipsen is now using 100% green electricity across its sites in U.K., Ireland and France; 88% of Ipsen's global electricity usage is now from renewable sources. The Company is also committed to the sustainable consumption of resources and will continue to increase energy efficiency within its operations.

Conference call

A conference call and webcast for investors and analysts will begin at 2:30pm Paris time today. Participants are encouraged to dial in to the call early and can register [here](#); a recording will be available on [ipsen.com](#), while the webcast can be accessed [here](#). The event ID is 8026207.

Calendar

The Company intends to publish its year-to-date and third-quarter sales update on 21 October 2021.

¹⁰ Environmental, Social, and Governance.

Notes

All financial figures are in € millions (€m). The performance shown in this announcement covers the six-month period to 30 June 2021 (the first half or H1 2021) and the three-month period to 30 June 2021 (the second quarter or Q2 2021), compared to six-month period to 30 June 2020 (H1 2020) and the three-month period to 30 June 2020 (Q2 2020) respectively, unless stated otherwise. Commentary is based on the performance in H1 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 around 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).

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Total sales by therapeutic area and product

<i>(in million euros)</i>	6 months				2 nd Quarter			
	2021	2020	Change		2021	2020	Change	
			Actual	CER ¹¹			Actual	CER ¹¹
Total Specialty Care	1,244.5	1,167.1	6.6%	11.2%	632.9	564.5	12.1%	16.2%
Oncology	1,013.1	967.5	4.7%	8.9%	517.7	474.9	9.0%	13.0%
Somatuline®	561.4	562.3	-0.1%	5.2%	284.5	276.8	2.8%	8.0%
Decapeptyl®	222.5	193.6	15.0%	16.3%	116.2	97.0	19.9%	20.6%
Cabometyx®	166.8	136.8	22.0%	22.9%	83.6	64.4	29.8%	30.2%
Onivyde®	57.8	62.5	-7.6%	1.5%	31.3	31.3	-0.1%	9.9%
Other Oncology	4.5	12.4	-63.4%	-63.6%	2.1	5.4	-60.5%	-60.9%
Neuroscience	205.8	170.5	20.7%	28.3%	102.7	77.1	33.2%	38.2%
Dysport®	202.8	169.5	19.6%	27.1%	101.0	76.6	31.8%	36.6%
Rare Disease	25.6	29.1	-12.0%	-10.1%	12.6	12.6	-	2.0%
NutropinAq®	17.0	19.2	-11.2%	-11.3%	8.6	8.1	6.5%	6.0%
Increlex®	8.6	9.9	-13.6%	-7.7%	4.0	4.5	-11.7%	-5.3%
Total Consumer Healthcare	105.9	101.2	4.7%	8.6%	58.9	49.1	19.8%	23.1%
Smecta®	35.7	37.8	-5.6%	-1.8%	19.4	19.9	-2.8%	0.9%
Tanakan®	20.6	19.4	6.2%	11.8%	12.1	9.2	31.1%	34.9%
Forlax®	17.2	19.8	-12.8%	-11.2%	8.1	9.9	-18.0%	-16.8%
Fortrans/Eziclen®	16.7	11.8	40.9%	47.6%	9.9	5.0	97.6%	102.0%
Other Consumer Healthcare	15.7	12.3	27.0%	29.8%	9.4	5.1	85.3%	87.1%
Total Sales	1,350.3	1,268.3	6.5%	11.0%	691.8	613.6	12.7%	16.8%

Specialty Care

Sales in H1 2021 amounted to €1,244.5m, an increase of 11.2%¹¹. Oncology and Neuroscience sales increased by 8.9%¹¹ and 28.3%¹¹ to €1,013.1m and €205.8m, respectively, while Rare Disease sales declined by 10.1%¹¹ to €25.6m.

Specialty Care comprised 92,2% of total sales (H1 2020: 92,0%).

Oncology

Sales of €1,013.1m in H1 2021 represented growth of 8.9%¹¹, reflecting continued market-share gains in most markets, and a market recovery in China underpinned the strong performance of Decapeptyl®, while there were also good results for Cabometyx® and Somatuline® globally.

Oncology sales in H1 2021 comprised 75.0% of total sales (H1 2020: 76.3%).

- a) **Somatuline®** sales reached €561.4m in H1 2021, an increase of 5.2%¹¹, driven by continued market-share gains in most markets and a limited impact from generic-octreotide sales in Europe. North America sales grew by 3.6%¹¹, partly a reflection of a strong Q2 2020 performance impacted by end-user buying patterns; the performance in H1 2021 in North America was driven by encouraging volumes.

¹¹ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

- b) **Decapeptyl**[®] sales in H1 2021 of €222.5m reflected growth of 16.3%¹², mainly driven by China, which significantly recovered from the initial impacts in 2020 from COVID-19. The good performance in France and rest of Asia was mirrored by market-share gains.
- c) **Cabometyx**[®] sales in H1 2021 reached €166.8m, up by 22.9%¹², driven by a strong volume uptake across most geographies in both renal cell carcinoma and hepatocellular carcinoma. Following regulatory approval, Cabometyx[®], in combination with nivolumab, was recently launched in Germany as a first-line treatment for patients with renal cell carcinoma.
- d) **Onivyde**[®] sales in H1 2021 of €57.8m reflected an increase of 1.5%¹², driven by higher sales to Ipsen's ex-U.S. partner, Servier, offset by the impact of the pandemic on cancer treatment in the U.S.

Neuroscience

Dysport[®] sales reached €202.8m in H1 2021, up by 27.1%¹², partly driven by an encouraging recovery from the pandemic in most markets, particularly in the second quarter, as well as a good performance in the North America and Europe therapeutics markets and growing aesthetics markets in Turkey, Russia and the Middle East. There was also a continued solid aesthetics performance from Ipsen's partner, Galderma, in most of its markets.

Neuroscience sales comprised 15.2% of total sales in H1 2021 (H1 2020:13.4%).

Rare Disease

NutropinAq[®] (*somatropin*) sales in H1 2021 of €17.0m, a decline of 11.3%¹², reflected competitive pressures across Europe. A decline in **Increlex**[®] (*mecasermin*) sales of 7.7%¹² to €8.6m was partly a result of lower demand in the U.S., reflecting continued COVID-19 effects.

Rare Disease sales in H1 2021 comprised 1.9% of total sales (H1 2020: 2.3%).

Consumer Healthcare

Sales of €105.9m in H1 2021 reflected growth of 8.6%¹², with a strong performance complemented by an element of phasing and by the 47.6%¹² growth of **Fortrans/Eziclen**[®] (*macrogol 4000*) to €16.7m, mainly reflecting the reduced level of sales in the comparative period, particularly in China. There was also an 11.8%¹² increase in sales of **Tanakan**[®] (*ginkgo biloba extract*) to €20.6m, driven by a good performance and a high level of deliveries in Vietnam. **Smecta**[®] (*diosmectite*) sales declined by 1.8%¹² to €35.7m, with the recovery in China offset by generic-medicine pressure in France.

Consumer Healthcare sales in H1 2021 comprised 7.8% of total sales (H1 2020: 8.0%).

¹² Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Total sales by geographical area

<i>(in million euros)</i>	6 Months				2 nd Quarter			
	2021	2020	Change		2021	2020	Change	
			Actual	CER ¹³			Actual	CER ¹³
Major Western European Countries	440.7	414.3	6.4%	6.6%	223.3	190.2	17.4%	17.4%
France	155.4	146.8	5.8%	6.7%	80.9	68.1	18.8%	20.1%
Germany	102.2	94.0	8.7%	8.7%	49.1	43.8	12.2%	12.2%
Italy	65.4	61.1	7.1%	7.1%	32.5	25.9	25.5%	25.5%
Spain	59.1	54.9	7.5%	7.5%	30.8	25.1	22.6%	22.6%
U.K.	58.6	57.4	2.2%	1.6%	30.0	27.4	9.7%	6.6%
Other European Countries	257.6	249.3	3.4%	8.0%	137.0	117.2	17.0%	20.9%
Eastern Europe	118.8	107.0	11.0%	19.6%	64.8	49.7	30.4%	37.1%
Other Europe	138.8	142.3	-2.4%	-0.5%	72.3	67.5	7.0%	9.1%
North America	403.0	418.9	-3.8%	4.9%	196.1	203.4	-3.6%	5.0%
Rest of the World	248.9	185.9	33.9%	38.3%	135.4	102.9	31.7%	33.4%
Asia	126.3	75.7	66.8%	68.6%	72.4	44.1	64.0%	65.3%
Other Rest of the World	122.6	110.1	11.4%	17.2%	63.1	58.7	7.4%	9.7%
Total Sales	1,350.3	1,268.3	6.5%	11.0%	691.8	613.6	12.7%	16.8%

Major Western European countries

Sales in H1 2021 reached €440.7m, an increase of 6.6%¹³. Major Western European countries comprised 32.6% of total sales in H1 2021 (H1 2020: 32.7%).

- a) **France:** sales of €155.4m, an increase of 6.7%¹³, reflected a solid recovery from the pandemic with continued market-share gains for most Specialty Care medicines, offset by a low diarrhea market, impacting Consumer Healthcare.
- b) **Germany:** sales reached €102.2m, up by 8.7%¹³, mainly driven by continued market-share gains for Cabometyx[®] and Somatuline[®], with a limited impact from the sale of generic octreotide.
- c) **Italy:** sales of €65.4m, up by 7.1%¹³, with a solid performance of Cabometyx[®], along with an improved Consumer Healthcare performance.
- d) **Spain:** sales of €59.1m reflected an increase of 7.5%¹³, driven by market-share gains for Somatuline[®] and Decapeptyl[®].
- e) **U.K.:** sales reached €58.6m, an increase of 1.6%¹³, driven by solid growth of Somatuline[®] due to market-share gains, partly offset by lower volumes of Decapeptyl[®].

Other European countries

Sales in H1 2021 reached €257.6m, up by 8.0%¹³, mainly driven by higher Dysport[®] volumes in Russia and Greece, along with successful launches and market-share gains for Cabometyx[®], offset by reduced Consumer Healthcare sales in Eastern Europe.

In H1 2021, sales in other European countries comprised 19.1% of total sales (H1 2020: 19.7%).

¹³ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

North America

Sales of €403.0m in H1 2021 reflected growth of 4.9%¹⁴, driven by continued growth of Somatuline®, despite an overall adverse impact from the pandemic on cancer treatment. Dysport® sales reflected a good performance in the aesthetics and therapeutics markets, after the significant impact of COVID-19 in H1 2020.

In H1 2021, sales in North America comprised 29.8% of total sales (H1 2020: 33.0%).

Rest of the World

Sales in H1 2021 reached €248.9m, an increase of 38.3%¹⁴, driven by a China recovery that resulted in strong Decapeptyl® and Consumer Healthcare sales. This was accompanied by a solid Dysport® performance in Latin America, Australia and the Middle East, as well as a good performance from Decapeptyl® in the rest of Asia.

In H1 2021, sales in the Rest of the World comprised 18.4% of total sales (H1 2020: 14.7%).

¹⁴ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Comparison of core consolidated income statement

Core financial measures are performance indicators. A reconciliation between these indicators and IFRS aggregates is presented in Appendix 4 'Bridges from IFRS consolidated net profit to core consolidated net profit'.

	H1 2021		H1 2020		Change
	€m	% of total sales	€m	% of total sales	
Total Sales	1,350.3	100%	1,268.3	100 %	6.5%
Other revenue	64.3	4.8%	38.6	3.0 %	66.3%
Total Revenue	1,414.6	104.8%	1,306.9	103.0 %	8.2%
Cost of goods sold	(250.6)	-18.6%	(241.8)	-19.1 %	3.6%
Selling expenses	(384.3)	-28.5%	(375.4)	-29.6 %	2.4%
Research and development expenses	(207.3)	-15.4%	(190.6)	-15.0 %	8.8%
General and administrative expenses	(99.1)	-7.3%	(94.0)	-7.4 %	5.4%
Other core operating income	6.6	0.5%	5.3	0.4 %	25.1%
Other core operating expenses	-	-	(0.2)	0.0 %	-92.1%
Core Operating Income	479.8	35.5%	410.2	32.3 %	17.0%
Net financing expenses	(11.4)	-0.8%	(13.6)	-1.1 %	-16.5%
Core other financial income and expenses	(2.5)	-0.2%	(11.6)	-0.9 %	-78.8%
Core income taxes	(106.3)	-7.9%	(86.6)	-6.8 %	22.7%
Share of net profit/(loss) from equity-accounted companies	0.1	-	(1.3)	-0.1 %	-106.0%
Core Consolidated Net Profit	359.8	26.6%	297.0	23.4 %	21.2%
- Attributable to attributable to Ipsen SA shareholders	360.5	26.7%	296.2	23.4 %	21.7%
- Attributable to non-controlling interests	(0.7)	-0.1%	0.8	0.1 %	n.a.
Core EPS¹⁵ (fully diluted): attributable to Ipsen SA shareholders (€)	4.31	-	3.55	-	21.3%

¹⁵ Earnings per share.

Reconciliation from core consolidated net profit to IFRS consolidated net profit

	H1 2021 €m	H1 2020 €m
Core Consolidated Net Profit	359.8	297.0
Amortization of intangible assets (excluding software)	(30.7)	(32.0)
Other operating income and expenses	(16.8)	(14.2)
Restructuring costs	(3.0)	(10.8)
Impairment losses	-	(58.9)
Others	(6.0)	41.7
IFRS Consolidated Net Profit	303.3	222.7
IFRS EPS¹⁶ (fully diluted): attributable to Ipsen SA shareholders (€)	3.64	2.66

Total sales

Total sales grew in H1 2021 by 11.0% at CER¹⁷, or 6.5% as reported, to €1,350.3m.

Other revenue

Other revenue totaled €64.3m, an increase of 66.3%, reflecting the growth in royalties paid by partners, mainly by Galderma in respect of Dysport®.

Cost of goods sold

Cost of goods sold of €250.6m represented 18.6% of total sales (H1 2020: €241.8m, 19.1%), reflecting growth of 3.6%. The favorable mix impact of Specialty Care growth continued to drive a decline in the cost of goods sold as a percentage of total sales, despite an increase of royalties paid to partners, notably for Cabometyx®.

Selling expenses

Selling expenses increased by 2.4% to €384.3m, driven by the commercial efforts deployed to support Specialty Care growth, the recovery of activities postponed or cancelled mainly due to COVID-19 as well as the impact of the Company's efficiency program. Selling expenses represented 28.5% of total sales, a decline of one percentage point.

Research and development expenses

Research and development expenses totaled €207.3m, representing growth of 8.8%. Investment in lifecycle management continued, including in Oncology for Onivyde® and Cabometyx® and in Neuroscience for Dysport®. Potential new medicines also benefited from investment, such as palovarotene in Rare Disease and next-generation neurotoxins in Neuroscience.

General and administrative expenses

General and administrative expenses increased by 5.4% to €99.1m, mainly driven by the reinforcement of the global IT strategy; the ratio to total sales was broadly stable at 7.3%.

Other core operating income and expenses

Other core operating income and expenses amounted to an income of €6.6m (H1 2020 income of €5.1m), primarily reflecting the impact of Ipsen's currency-hedging policy.

Core operating income

Core operating income amounted to €479.8m, representing growth of 17.0% and comprised 35.5% of total sales (H1 2020: 32.3%).

¹⁶ Earnings per share.

¹⁷ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Core net financing costs and other financial income and expense

Net financial costs declined by 16.5% to €11.4m. Other core financial expenses of €2.5m reflected a fall of 78.8%, mainly driven by favorable foreign-exchange differences and lower hedging costs.

Core income taxes

Core income tax expense of €106.3m, an increase of 22.7%, reflected a core effective tax rate of 22.8% (H1 2020: 22.5%).

Core consolidated net profit

Core consolidated net profit increased by 21.2% to €359.8m, with €360.5m fully attributable to Ipsen SA shareholders.

Core EPS¹⁸

Core EPS¹⁸ (fully diluted) came to €4.31, representing growth of 21.3%.

From core financial measures to IFRS reported figures

Reconciliations between IFRS June 2021 and June 2020 results and the Core financial measures are presented in Appendix 4. The main reconciling items between core consolidated net profit and IFRS consolidated net profit were:

Amortization of intangible assets (excluding software)

Amortization of intangible assets (excluding software) in the first half amounted to €41.0m before tax (H1 2020: €43.9m).

Other operating income and expenses and restructuring costs

Other non-core operating income and expenses in the first half totaled an expense of €22.7m before tax, primarily reflecting Ipsen's transformation programs, including the discontinuation of deprioritized research programs in line with the Company's strategy (H1 2020: an expense of €19.2m).

Restructuring costs

Restructuring expenses in the first half amounted to €4.0m. In H1 2020, restructuring costs before tax came to €15.4m, mainly impacted by Consumer Healthcare transformation projects and by the relocation of the Onivyde[®] manufacturing site from Cambridge, Massachusetts, U.S. to Signes, France.

Impairment losses

No impairment loss or gain was recognized in the first half. In H1 2020, Ipsen recognized an impairment loss of €81.7m before tax, mainly on the intangible assets of palovarotene following the decision to terminate the MO-Ped trial related to the multiple osteochondromas indication.

Others

Other financial income and expenses in the first half included financial income of €2.6m before tax, mainly due to the change in fair value in equity investments. In H1 2020, other financial income and expenses included financial income of €45.0m before tax related to the Contingent Value Right (CVR) and milestones' revaluation for Clementia.

IFRS financial measures

Operating income

Operating income in the first half totaled €412.2m (H1 2020: €249.8m) with an operating margin of 30.5%, up by 11 percentage points.

Consolidated net profit

Consolidated net profit of €303.3m in the first half represented an increase of 36.2%.

EPS¹⁸

EPS¹⁸ (fully diluted) in the first half increased by 36.5% to €3.64.

¹⁸ Earnings per share.

Operating segments: core operating income by therapeutic area

Segmental information is presented according to Ipsen's two operating segments, Specialty Care and Consumer Healthcare. All costs allocated to these two segments are presented in the key performance indicators. Corporate overhead expenses and the impact of the Company's currency-hedging policy are not allocated to the two operating segments.

Core operating income is the indicator used by Ipsen to measure operating performance and to allocate resources. Total sales, total revenue and core operating income are presented by therapeutic area for H1 2021 versus H1 2020 in the following table:

	H1 2021	H1 2020	Change	
	€m	€m	€m	%
Specialty Care				
Total sales	1,244.5	1,167.1	77.3	6.6%
Total revenue	1,296.3	1,194.6	101.7	8.5%
Core operating income	570.5	503.5	67.0	13.3%
Core operating margin	45.8%	43.1%		
Consumer Healthcare				
Total sales	105.9	101.2	4.7	4.7%
Total revenue	118.3	112.3	5.9	5.3%
Core operating income	15.6	5.6	10.0	179.9%
Core operating margin	14.7%	5.5%		
Total Unallocated				
Core operating income	(106.2)	(98.9)	(7.3)	7.4%
Total				
Total sales	1,350.3	1,268.3	82.0	6.5%
Total revenue	1,414.6	1,306.9	107.7	8.2%
Core operating income	479.8	410.2	69.7	17.0%
Core operating margin	35.5%	32.3%		

In H1 2021, Specialty Care sales grew to €1,244.5m, up by 6.6% (11.2% at CER¹⁹), reaching 92.2% of total sales (H1 2020: 92.0%). Core operating income for Specialty Care increased by 13.3% to €570.5m, representing 45.8% of total sales (H1 2020: 43.1%). The improvement reflected the continued growth of Somatuline[®] in the U.S. and Europe, Dysport[®] and Decapeptyl[®] from COVID-19 recovery, the contribution of Cabometyx[®], as well as an increase in research & development investment and in selling expenses.

Consumer Healthcare sales in the first half increased by 4.7% (8.6% at CER¹⁹) to €105.9m. Core operating income for Consumer Healthcare amounted to €15.6m, representing 14.7% of total sales (H1 2020: 5.5%), reflecting higher sales that were partly driven by the COVID-19 recovery in China, higher other revenue, coupled with a decline in commercial investments.

Unallocated core operating income in the first half amounted to a negative €106.2m (H1 2020: negative €98.9m), partly a result of the reinforcement of the global IT strategy, somewhat offset by the favorable impact in H1 2021 from the currency-hedging policy.

¹⁹ Excludes any foreign-exchange impact by recalculating the performance for the relevant period by applying the exchange rates used for the prior period.

Net cash flow and financing

Ipsen had a net debt decline of €188.7m in H1 2021, bringing closing net debt to €336.5m.

	H1 2021 €m	H1 2020 €m
Opening Net Cash/(Debt)	(525.3)	(1,115.6)
Core Operating Income	479.8	410.2
Non-cash items	74.3	69.4
Change in operating working-capital requirement	(67.5)	(16.8)
(Increase)/decrease in other working capital requirement	(28.7)	(37.8)
Net capex (excluding milestones paid)	(58.2)	(56.3)
Dividends received from entities accounted for using the equity method	-	-
Operating Cash Flow	399.7	368.7
Other non-core operating income and expenses and restructuring costs (cash)	(27.9)	(15.5)
Financial income (cash)	(13.5)	(24.8)
Current income tax (P&L, excluding provisions for tax contingencies)	(67.9)	(99.4)
Other operating cash flow	0.9	4.3
Free Cash Flow	291.4	233.3
Distributions paid	(83.1)	(83.5)
Net investments (business development and milestones)	7.8	(4.4)
Share buyback	(5.8)	(6.1)
FX on net indebtedness and change in earn-out	(22.4)	49.5
Other	0.8	3.5
Shareholders Return and External Growth Operations	(102.6)	(41.0)
Change in Net Cash/(Debt)	188.7	192.3
Closing Net Cash/(Debt)	(336.5)	(923.3)

Operating cash flow

Operating cash flow increased by 8.4% in the first half to €399.7m, driven by higher core operating income (up by €69.7m) and higher working-capital requirements.

Non-cash items increased by 7.1% in the first half to €74.3m (H1 2020: €69.4m) and mainly included the amortization of tangible assets and provisions.

Working-capital requirements for operating activities in the first half increased by €67.5m (H1 2020: €16.8m), mainly from higher trade receivables. Other working-capital requirements increased by €28.7m in the first half, mainly driven by variable compensation payments to colleagues in H1 2021.

Net capital expenditure amounted to €58.2m in the first half (H1 2020: €56.3m), and mainly included projects to increase efficiency at industrial sites in the U.K. and France, along with company investments in IT and digital projects.

Free cash flow

The increase in free cash flow in the first half to €291.4m (H1 2020: €233.3m) was mainly a result of higher operating cash flow combined with lower current income tax.

Shareholders' return and external growth operations

In H1 2021, the distribution payout to Ipsen SA shareholders amounted to €82.9m.

Net investments of €7.8m in the first half mainly related to Onivyde®'s commercial milestones received for €20.8m and to the proceeds from the divestiture in equity-accounted companies for €21.4m, partly offset by additional milestone payments of €33.9m to Exelixis.

Foreign exchange on net indebtedness and change in earn-out adversely impacted net debt mainly due to a higher USD versus EUR on indebtedness, compared to a favorable impact of €49.5m on net debt in the first half of 2020, which included the aforementioned CVR and milestone revaluation in respect of Clementia.

Reconciliation of cash and cash equivalents and net cash

	H1 2021 €m	H1 2020 €m
Current Financial Assets (derivative instruments on financial operations)	0.2	0.7
Closing Cash and Cash Equivalents	726.1	420.8
Non-current loans	(550.2)	(565.6)
Other financial liabilities (excluding derivative instruments) ²⁰	(221.1)	(227.0)
Non-Current Financial Liabilities	(771.3)	(792.6)
Credit lines and bank loans	(150.3)	(267.9)
Financial liabilities (excluding derivative instruments)	(141.2)	(284.3)
Current Financial Liabilities	(291.5)	(552.2)
Debt	(1,062.8)	(1,344.8)
Net Debt²¹	(336.5)	(923.3)

²⁰ Financial liabilities mainly exclude €4.5m in derivative instruments related to commercial operations (H1 2020: €5.3m).

²¹ Derivative instruments booked in financial assets and related to financial operations, cash and cash equivalents, less bank overdrafts, bank loans and other financial liabilities and excluding financial-derivative instruments on commercial operations.

Analysis of cash

- On 16 June 2016, Ipsen SA issued €300m in unsecured, seven-year public bonds
- On 24 May 2019, Ipsen SA signed an initial five-year RCF of €1.5bn, which was extended in 2020 to May 2025, and in 2021 to May 2026
- On 23 July 2019, Ipsen SA also issued \$300m through a U.S. Private Placement (USPP) in two tranches of seven and 10-year maturities
- Ipsen must comply with a net debt / EBITDA covenant to remain below 3.5 times at each financial closing in both the RCF and the USPP. The RCF also includes specific indicators linked to ESG, assessed annually
- Ipsen has fully complied with its covenant ratio for the RCF and the USPP
- On 30 June 2021, the RCF was utilized for €150.3m and the Ipsen SA issuance program of Negotiable European Commercial Paper of €600m was drawn for €100.0m

Appendix 1: consolidated income statement

	H1 2021 €m	H1 2020 €m
Total Sales	1,350.3	1,268.3
Other revenue	64.3	38.6
Total Revenue	1,414.6	1,306.9
Cost of goods sold	(250.6)	(241.8)
Selling expenses	(384.3)	(375.4)
Research and development expenses	(207.3)	(190.6)
General and administrative expenses	(99.1)	(94.0)
Other operating income	25.8	8.2
Other operating expenses	(82.9)	(66.2)
Restructuring costs	(4.0)	(15.4)
Impairment losses	—	(81.7)
Operating Income	412.2	249.8
Investment income	0.6	1.1
Financing expenses	(12.0)	(14.7)
Net financing expenses	(11.4)	(13.6)
Other financial income and expenses	0.1	33.9
Income taxes	(99.0)	(47.5)
Share of net profit/(loss) from equity-accounted companies	0.1	(1.3)
Net profit (loss) from Continuing Operations	302.1	221.3
Net profit (loss) from discontinued operations	1.2	1.4
Consolidated net profit (loss)	303.3	222.7
- Attributable to Ipsen SA shareholders	304.0	221.9
- Attributable to non-controlling interests	(0.7)	0.8
Basic EPS ²² , continuing operations (€)	3.66	2.65
Diluted EPS ²² , continuing operations (€)	3.62	2.65
Basic EPS ²² , discontinued operations (€)	0.01	0.02
Diluted EPS ²² , discontinued operations (€)	0.01	0.02
Basic EPS²² (€)	3.67	2.67
Diluted EPS²² (€)	3.64	2.66

²² Earnings per share.

Appendix 2: consolidated balance sheet before allocation of net profit

	30 June 2021	31 December 2020
	€m	€m
ASSETS		
Goodwill	604.4	592.8
Other intangible assets	1,142.4	1,121.1
Property, plant & equipment	645.7	646.6
Equity investments	90.3	84.5
Investments in equity-accounted companies	13.8	19.1
Non-current financial assets	24.7	23.1
Deferred tax assets	231.0	247.4
Other non-current assets	4.9	3.8
Total non-current assets	2,757.3	2,738.4
Inventories	232.7	213.9
Trade receivables	554.6	476.2
Current tax assets	91.7	83.6
Current financial assets	2.1	48.9
Other current assets	142.1	113.7
Cash and cash equivalents	737.5	642.5
Assets of disposal group classified as held for sale	3.6	-
Total current assets	1,764.2	1,578.8
TOTAL ASSETS	4,521.5	4,317.2
EQUITY AND LIABILITIES		
Share capital	83.8	83.8
Additional paid-in capital and consolidated reserves	2,013.4	1,546.8
Net profit (loss) for the period	304.0	548.0
Foreign exchange differences	(14.6)	(59.6)
Equity attributable to Ipsen SA shareholders	2,386.6	2,119.1
Equity attributable to non-controlling interests	1.7	2.7
Total shareholders' equity	2,388.3	2,121.7
Retirement benefit obligation	56.9	63.7
Non-current provisions	49.3	32.0
Other non-current financial liabilities	771.2	761.6
Deferred tax liabilities	92.1	79.9
Other non-current liabilities	46.6	45.1
Total non-current liabilities	1,016.1	982.3
Current provisions	42.7	45.7
Current financial liabilities	297.0	408.6
Trade payables	518.6	495.2
Current tax liabilities	5.6	10.8
Other current liabilities	241.7	250.0
Bank overdrafts	11.5	2.8
Liabilities related to assets held for sale	—	—
Total current liabilities	1,117.0	1,213.1
TOTAL EQUITY & LIABILITIES	4,521.5	4,317.2

Appendix 3.1: consolidated statement of cash flow

	30 June 2021	30 June 2020
	€m	€m
Consolidated Net Profit	303.3	222.7
Share of profit (loss) from equity-accounted companies	(0.1)	4.3
Net Profit (Loss) before Share from Equity-Accounted Companies	303.2	227.0
Non-Cash and Non-Operating Items:		
- Depreciation, amortization, provisions	110.3	116.5
- Impairment losses included in operating income and net financial income	-	81.5
- Change in fair value of financial derivatives	2.3	3.9
- Net gains or losses on disposals of non-current assets	1.5	2.6
- Unrealized foreign-exchange differences	(4.7)	4.0
- Change in deferred taxes	31.1	(51.9)
- Share-based payment expense	18.8	10.6
- Other non-cash items	(7.6)	(39.8)
Cash Flow from Operating Activities before Changes in Working-Capital Requirement	454.9	354.3
- (Increase)/decrease in inventories	(15.9)	(10.2)
- (Increase)/decrease in trade receivables	(68.4)	21.1
- Increase/(decrease) in trade payables	16.7	(27.8)
- Net change in income tax liability	(8.1)	(2.1)
- Net change in other operating assets and liabilities	(22.1)	(41.9)
Change in Working-Capital Requirement Related to Operating Activities	(97.7)	(60.7)
NET CASH PROVIDED (USED) BY OPERATING ACTIVITIES	357.2	293.6
Acquisition of property, plant & equipment	(34.1)	(33.3)
Acquisition of intangible assets	(44.5)	(18.3)
Proceeds from disposal of intangible assets and property, plant & equipment	0.1	-
Acquisition of shares in non-consolidated companies	(7.8)	(3.2)
Payments to post-employment benefit plans	(0.7)	(2.3)
Impact of changes in the consolidation scope	21.4	-
Change in working capital related to investment activities	(14.5)	(7.7)
Other cash flow related to investment activities	2.6	(1.5)
NET CASH PROVIDED (USED) BY INVESTMENT ACTIVITIES	(77.6)	(66.3)
Additional long-term borrowings	12.2	5.7
Repayment of long-term borrowings	(0.7)	(0.7)
Net change in short-term borrowings	(114.5)	(55.7)
Capital increase	-	-
Treasury shares	(5.8)	(6.0)
Distributions paid by Ipsen SA	(82.9)	(83.2)
Dividends paid by subsidiaries to non-controlling interests	(0.2)	(0.3)
Change in working capital related to financing activities	(2.8)	(4.9)
NET CASH PROVIDED (USED) BY FINANCING ACTIVITIES	(194.6)	(145.2)
CHANGE IN CASH AND CASH EQUIVALENTS	85.0	82.1
OPENING CASH AND CASH EQUIVALENTS	639.6	339.0
Impact of exchange rate fluctuations	1.4	(0.3)
CLOSING CASH AND CASH EQUIVALENTS	726.1	420.8

Appendix 3.2: consolidated net cash flow statement

	H1 2021 €m	H1 2020 €m
Opening Net Cash/(Debt)	(525.3)	(1,115.6)
CORE OPERATING INCOME	479.8	410.2
Non-Cash Items	74.3	69.4
(Increase)/decrease in inventories	(15.9)	(10.2)
(Increase)/decrease in trade receivables	(68.4)	21.1
Increase/(decrease) in trade payables	16.7	(27.8)
Change in Operating Working-Capital Requirement	(67.5)	(16.8)
Change in income tax liability	(8.2)	(2.1)
Change in other operating assets and liabilities (excluding milestones received)	(20.5)	(35.7)
Other Changes in Working-Capital Requirement	(28.7)	(37.8)
Acquisition of property, plant & equipment	(34.1)	(33.3)
Acquisition of intangible assets (excluding milestones paid)	(10.1)	(8.2)
Disposal of fixed assets	0.1	-
Change in working capital related to investment activities	(14.1)	(14.8)
Net Capex (excluding milestones paid)	(58.2)	(56.3)
Dividends Received from Entities Accounted for Using the Equity Method	-	-
Operating Cash Flow	399.7	368.7
Other non-core operating income and expenses and restructuring costs	(27.9)	(15.5)
Financial income	(13.5)	(24.8)
Current income tax	(67.9)	(99.4)
Other operating cash flow	0.9	4.3
Free Cash Flow	291.4	233.3
Distributions Paid (Including Payout to Non-Controlling Interests)	(83.1)	(83.5)
Acquisition of shares in non-consolidated companies ²³	(7.8)	(3.4)
Acquisition of other financial assets	-	-
Impact of changes in consolidation scope	21.4	-
Milestones paid ²⁴	(34.9)	(2.8)
Milestones received	25.0	1.8
Other business-development operations	4.0	-
Net Investments (Business Development and Milestones)	7.8	(4.4)
Share buyback	(5.8)	(6.1)
FX on net indebtedness and change in earn-out	(22.4)	49.5
Other	0.8	3.5
Shareholders Return and External-Growth Operations	(102.6)	(41.0)
CHANGE IN NET CASH/(DEBT)	188.7	192.3
Closing Net Cash/(Debt)	(336.5)	(923.3)

²³ Acquisition of shares in non-consolidated companies mainly reflected investments in external innovation funds.

²⁴ The milestones paid were recorded as an increase in intangible assets on the consolidation balance sheet. The transactions were included in the 'Acquisition of intangible assets' line item in the consolidated statement of cash flow (see Appendix 3.1).

Appendix 4: bridges from IFRS Consolidated Net Profit to Core Consolidated Net Profit

H1 2021	IFRS						Core H1 2021
	H1 2021 €m	Amortization of intangible assets (excl. software) €m	Other operating income or expenses €m	Restructuring €m	Impairment losses €m	Other €m	
Total Sales	1,350.3	—	—	—	—	—	1,350.3
Other revenue	64.3	—	—	—	—	—	64.3
Total Revenue	1,414.6	—	—	—	—	—	1,414.6
Cost of goods sold	(250.6)	—	—	—	—	—	(250.6)
Selling expenses	(384.3)	—	—	—	—	—	(384.3)
Research and development expenses	(207.3)	—	—	—	—	—	(207.3)
General and administrative expenses	(99.1)	—	—	—	—	—	(99.1)
Other operating income	25.8	—	(19.2)	—	—	—	6.6
Other operating expenses	(82.9)	41.0	41.9	—	—	—	—
Restructuring costs	(4.0)	—	—	4.0	—	—	—
Impairment losses	—	—	—	—	—	—	—
Operating Income	412.2	41.0	22.7	4.0	—	—	479.8
Net financing expenses	(11.4)	—	—	—	—	—	(11.4)
Other financial income and expenses	0.1	—	—	—	—	(2.6)	(2.5)
Income taxes	(99.0)	(10.3)	(5.9)	(0.9)	—	9.8	(106.3)
Share of profit/(loss) from equity-accounted companies	0.1	—	—	—	—	—	0.1
Net Profit/(Loss) from Continuing Operations	302.1	30.7	16.8	3.0	—	7.2	359.8
Net profit/(loss) from discontinued operations	1.2	—	—	—	—	(1.2)	—
Consolidated Net Profit	303.3	30.7	16.8	3.0	—	6.0	359.8
– Attributable to Ipsen SA shareholders	304.0	30.7	16.8	3.0	—	6.0	360.5
– Attributable to non-controlling interests	(0.7)	—	—	—	—	—	(0.7)
EPS²⁵ (fully diluted): attributable to Ipsen SA shareholders (€)	3.64	0.37	0.20	0.04	0.00	0.07	4.31

The reconciliation items between core consolidated net profit and IFRS consolidated net profit are described in the paragraph 'From core financial measures to IFRS reported figures'.

²⁵ Earnings per share.

H1 2020	IFRS						Core
	H1 2020 €m	Amortization of intangible assets (excl. software) €m	Other operating income or expenses €m	Restructuring €m	Impairment losses €m	Other €m	H1 2020 €m
Total Sales	1,268.3						1,268.3
Other revenue	38.6						38.6
Total Revenue	1,306.9	—	—	—	—	—	1,306.9
Cost of goods sold	(241.8)						(241.8)
Selling expenses	(375.4)						(375.4)
Research and development expenses	(190.6)						(190.6)
General and administrative expenses	(94.0)						(94.0)
Other operating income	8.2		(2.9)				5.3
Other operating expenses	(66.2)	43.9	22.2				(0.2)
Restructuring costs	(15.4)			15.4			—
Impairment losses	(81.7)				81.7		—
Operating Income	249.8	43.9	19.2	15.4	81.7	—	410.2
Net financing expenses	(13.6)						(13.6)
Other financial income and expenses	33.9					(45.5)	(11.6)
Income taxes	(47.5)	(11.9)	(5.0)	(4.6)	(22.8)	5.2	(86.6)
Share of profit/(loss) from equity-accounted companies	(1.3)						(1.3)
Net Profit/(Loss) from Continuing Operations	221.3	32.0	14.2	10.8	58.9	(40.3)	297.0
Net profit/(loss) from discontinued operations	1.4					(1.4)	—
Consolidated Net Profit	222.7	32.0	14.2	10.8	58.9	(41.7)	297.0
– Attributable to Ipsen SA shareholders	221.9	32.0	14.2	10.8	58.9	(41.7)	296.2
– Attributable to non-controlling interests	0.8						0.8
EPS²⁶ (fully diluted): attributable to Ipsen SA shareholders (€)	2.66	0.38	0.17	0.13	0.71	(0.50)	3.55

²⁶ Earnings per share.

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 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. Ipsen 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 Ipsen 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, 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 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; 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 products; 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 products 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).