

# Ipsen FY 2018 Results

February 14, 2019



# **Disclaimer & Safe Harbor**

This presentation includes only summary information and does not purport to be comprehensive. Forward-looking statements, targets and estimates contained herein are for illustrative purposes only and are based on management's 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 in the summary information. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably given that a new product can appear to be promising at a preparatory stage of development or after clinical trials but never be launched on the market or be launched on the market but fail to sell notably for regulatory or competitive reasons. The Group must deal with or may have to deal with competition from generic that may result in market share losses, which could affect its current level of growth in sales or profitability. The Company expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this presentation to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based unless so required by applicable law.

All product names listed in this document are either licensed to the Ipsen Group or are registered trademarks of the Ipsen Group or its partners.

The implementation of the strategy has to be submitted to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation.

The Group operates in certain geographical regions whose governmental finances, local currencies or inflation rates could be affected by the current crisis, which could in turn erode the local competitiveness of the Group's products relative to competitors operating in local currency, and/or could be detrimental to the Group's margins in those regions where the Group's drugs are billed in local currencies.

In a number of countries, the Group markets its drugs via distributors or agents: some of these partners' financial strength could be impacted by the crisis, potentially subjecting the Group to difficulties in recovering its receivables. Furthermore, in certain countries whose financial equilibrium is threatened by the crisis and where the Group sells its drugs directly to hospitals, the Group could be forced to lengthen its payment terms or could experience difficulties in recovering its receivables in full.

Finally, in those countries in which public or private health cover is provided, the impact of the financial crisis could cause medical insurance agencies to place added pressure on drug prices, increase financial contributions by patients or adopt a more selective approach to reimbursement criteria.

All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today.





01	FY 2018 Overview	David Meek Chief Executive Officer
02	FY 2018 Financial Performance/ 2019 Financial Guidance	Aymeric Le Chatelier Chief Financial Officer
03	Conclusion	David Meek Chief Executive Officer
04	Q&A	David Meek Aymeric Le Chatelier



# 01 FY 2018 Overview

David Meek Chief Executive Officer





# 01 Excellent execution in FY 2018 to deliver growth strategy

✓ Top line

- Group sales growth of +20.1%<sup>1</sup> driven by Specialty Care growth of +24.7%<sup>1</sup>
  - Somatuline<sup>®</sup> achieved blockbuster status with continuing momentum
  - Strong performance across all major products and geographies

✓ Bottom line

- Core Operating Income growth of 31.0% and margin expansion
  - Cabometyx<sup>®</sup> launch leveraging European Oncology infrastructure
  - Significant synergies in U.S. Oncology commercial team with Onivyde<sup>®</sup>

Pipeline

- Cabometyx<sup>®</sup> approvals in 1L RCC and 2L HCC
  - Program advancements for new chemical entities and LCM programs
  - Active business development efforts including global licensing and joint development agreement with MD Anderson



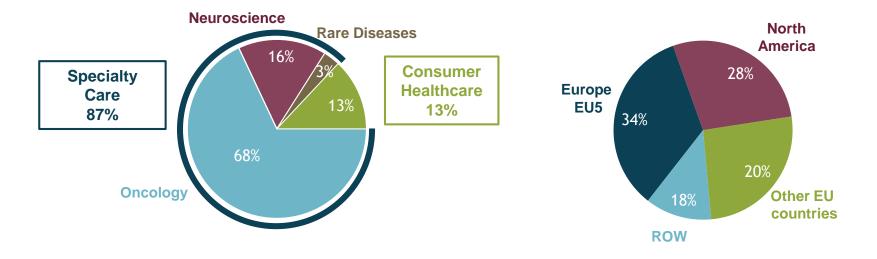
01 Being a leading global biopharmaceutical company focused on innovation and Specialty Care

Specialty Care representing 87% of sales

FY 2018 sales by therapeutic area

North America sales growing by +38% and representing 28% of sales

FY 2018 sales by geographical area





01 Oncology representing 68% of sales, growing by +29.9%<sup>1</sup> with Somatuline<sup>®</sup>, new launches and expanding pipeline

## Commercial highlights

#### **Somatuline**®

- Achieved blockbuster status in 2018
- Strong global momentum and continued market share gains in the U.S. and Europe

## Cabometyx®

- Positioned as TKI of choice in 2L RCC with growing market share in 2L+
- 1L RCC 7 countries reimbursed incl. Germany, UK
  Onivyde<sup>®</sup>
- Strong synergies with the U.S. Oncology team
- Inclusion in key U.S. formularies





Onivyde<sup>™</sup> (irinotecan liposome injection)

# Pipeline highlights

#### **Recent approvals:**

- Cabometyx<sup>®</sup> EMA approval for treatment of 2L HCC
- Somatuline<sup>®</sup>: approval for new delivery system (EU)

### Key mid-stage programs:

- Cabometyx<sup>®</sup>: CheckMate 9ER Phase 3 combination trial with nivolumab in 1L RCC
- Cabometyx<sup>®</sup>: COSMIC-312 Phase 3 combination trial with atezolizumab in 1L HCC
- Onivyde<sup>®</sup>: Phase 2 trial for 1L PDAC
- Onivyde<sup>®</sup>: Phase 2 trial for 2L SCLC



01 Neuroscience leadership position with strong pipeline and Dysport<sup>®</sup> double-digit growth at +12.6%<sup>1</sup>

## Commercial highlights

- Double-digit growth for Therapeutics and Aesthetics
- Total in-market sales under Dysport<sup>®</sup> brand >€500 million

#### Therapeutics

- Strong momentum in the U.S. with more targeted approach and commercial partnership
- Robust performance in Rest of World, including Brazil resupply

#### Aesthetics

- Continued market share gains by partner Galderma
- Strong growth in Ipsen-led aesthetics territories

## Pipeline highlights

#### Mid-stage programs

 Two Phase 2 trials for new indications with significant unmet need and no currently approved therapeutic treatments - hallux valgus (bunions) and vulvodynia

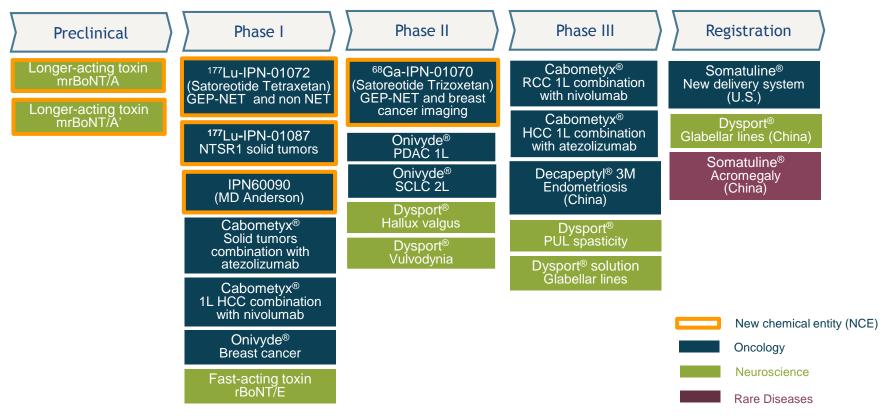
#### Earlier-stage recombinant toxin programs

- Fast-acting neurotoxin completed Phase 1 trial
- Long-acting neurotoxin currently in preclinical development





# 01 Building sustainable R&D pipeline in Oncology, Neuroscience and Rare Diseases with promising NCEs





GEP-NET: Gastroenteropancreatic Neuroendocrine Tumors; HCC: Hepatocellular Carcinoma; PDAC: Pancreatic ductal adenocarcinoma; PUL: Pediatric Upper Limb; rBoNT/A: recombinant Botulinum Toxin Type A; rBoNT/E: recombinant Botulinum Toxin Type E; RCC: Renal Cell Carcinoma; SCLC: Small Cell Lung Cancer; 1L: First line; 2L: Second line; 3M: 3-month formulation

# 01 Developing leading systemic radiation therapy program

## Systemic Radiation Therapy (SRT)

Site-directed targeted therapeutic strategy using radiolabeled peptides or other molecules to deliver radiation to cancer cells which overexpress specific receptors

#### Ipsen's commitment to SRT

- Developing radiolabeled diagnostics and therapeutics for enhanced care through precision medicine and a theranostic strategy
- Strengthened team with new talent and expertise



## Early-stage theranostic programs

#### Satoreotide (SRT for NET) – Phase 1/2 development

- Potential best-in-class theranostic radiopharmaceutical for NET
- SSA antagonist with potential superior efficacy and benefit/ risk vs. SSA agonist
- Platform technology to target multiple indications

#### IPN1087 (SRT for PDAC) – Phase 1 development

- Radiopharmaceutical theranostic targeting tumors expressing NTSR1
- Lead indication: PDAC with other potential indications to follow
- Established a formal partnership with the Pancreatic Cancer Action Network (PanCAN) to leverage its scientific and medical expertise



# 01 Accelerating internal and external innovation model



## Ambition

- Build an innovative and sustainable pipeline in all phases of clinical development
- Deliver at least one new molecular entity/meaningful indication every year
  - Optimize portfolio management and accelerate priority programs
- Focus on Specialty Oncology, Neuroscience, Rare Diseases



# Strategy

Focused internal business development efforts + collaborations with venture capital funds and incubators
 ARIXO Ubiolabs Imobio MDAnderson



Significant firepower for Business Development >€1bn supported by strong balance sheet and cash flow generation



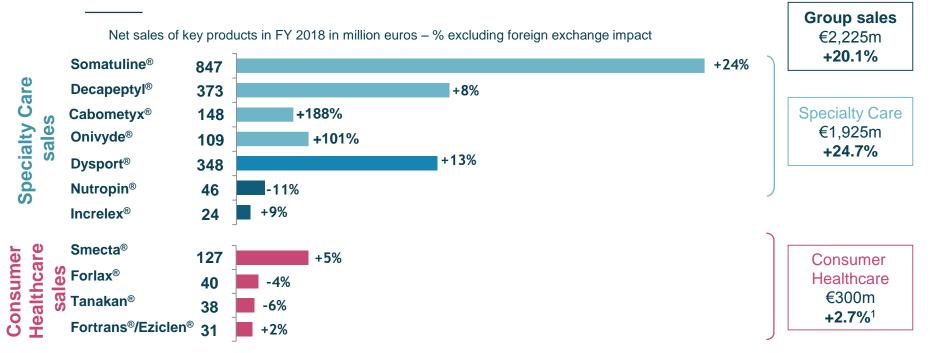
# 02 Financials

Aymeric Le Chatelier Chief Financial Officer





# 02 FY 2018 sales growth driven by Specialty Care business



Specialty Care growth driven by Somatuline<sup>®</sup> and contribution of Cabometyx<sup>®</sup> and Onivyde<sup>®</sup>



# **02** FY 2018 performance highlights for key products

## Established Specialty Care

#### Somatuline®

- Significant volume growth and market share expansion in the U.S. (+38%)
- Double-digit growth in EU5 countries

#### **Dysport**®

- Good growth in most therapeutics markets
- Strong performance in Aesthetic especially with Galderma including Brazil (benefit from product resupply)

#### Decapeptyl®

- Volume growth in Europe and China
- · Continued pricing pressure in China

## Specialty Care launches

#### Cabometyx<sup>®</sup>

- Growing sales and market share in Europe in 2L RCC and launches in new geographies
- Majority of sales in 2L RCC, good uptake for 1L RCC in already-approved countries

#### Onivyde®

- Continued steady growth in the U.S.
- Growing contribution from sales to ex-U.S. partner

## **Consumer Healthcare**

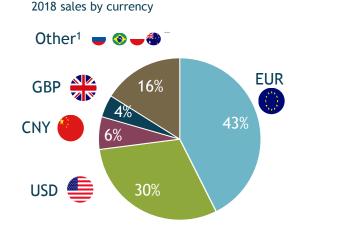
#### Smecta<sup>®</sup> growth driven by the good performance in France including new formulations and in China

- Positive contribution from 2017 acquisitions (Prontalgine<sup>®</sup>, Buscopan<sup>®</sup>)
- New Etiasa<sup>®</sup> contractual set up in China negatively impacting sales (without any impact on profit)



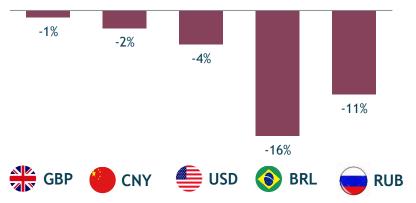
# **02** Significant impact of foreign exchange in 2018

## 57% of sales in non-EUR currencies USD representing more than 30% of sales



## Currency evolution in 2018

Average rates change (2018 vs. 2017)



Negative impact on Sales of -3.5% from lower USD and Emerging Market currencies

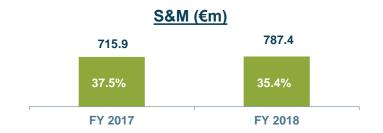
Limited bottom-line impact thanks to hedging of key currencies and cost base in local currencies



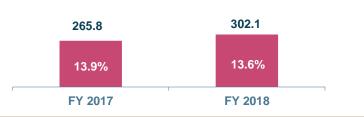
# 02 Investments focused on pipeline strategy and commercial launch support



Positive mix effect from growing Specialty Care business offset by higher Cabometyx® royalties



Investments to support Cabometyx<sup>®</sup> and Onivyde<sup>®</sup> launches, and growth of Somatuline<sup>®</sup> and Dysport<sup>®</sup>



**R&D** (€m)

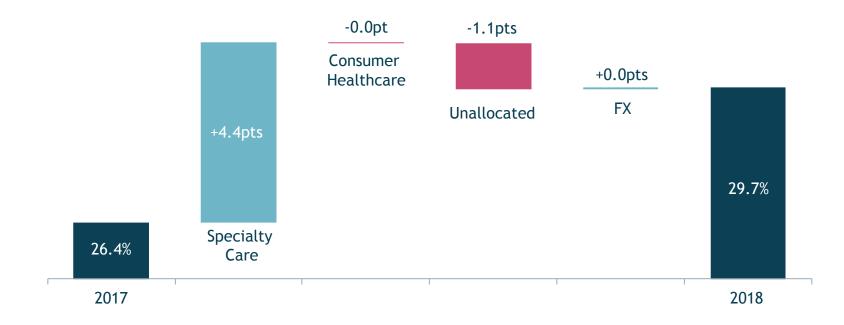
Advancement of pipeline programs and growing medical affairs and oncology capabilities



Impact of increased corporate structure to support group transformation, including relocation of U.S. headquarters



# **02** Operating leverage driving significant margin expansion



Group margin expansion driven by Specialty Care sales growth and operating leverage <u>No impact of currencies after</u> hedging strategy on margins



# 02 Core Operating Income to EPS

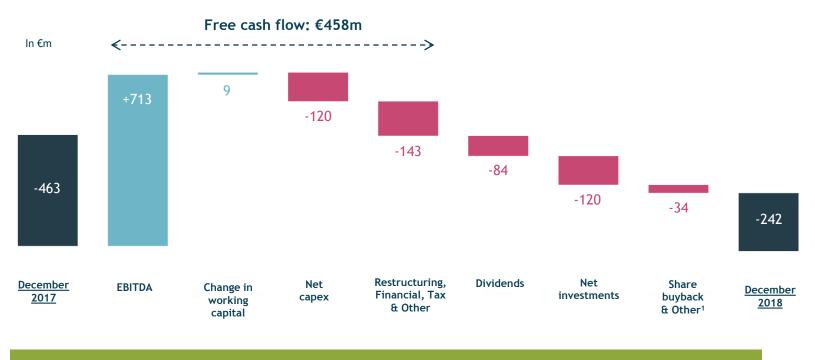
In €m	FY 2018	FY 2017	Change	% Change
Net sales	2,224.8	1,908.7	+316.1	+16.6%
Core Operating Income	659.9	503.6	+156.3	+31.0%
Core operating margin	<b>29.7%</b>	26.4%	+3.3 pts	
Amortization of intangible assets	(73.1)	(53.3)	-19.8	
Other operating income/expense	(30.4)	(48.9)	+18.5	
Restructuring costs	(21.9)	(18.8)	-3.1	
Impairment gain / (losses)	(15.0)	14.8	-29.8	
Operating Income	519.4	397.2	+122.2	+30.8%
Net financing costs	(5.3)	(8.1)	+2.8	
Other financial income / expense	(20.1)	(18.4)	-1.7	
Income taxes and other	(105.0)	(97.7)	-7.3	
Consolidated net profit	389.1	272.9	+116.2	+42.6%
EPS – fully diluted (€)	4.68	3.28	+1.40	+42,7%
Core EPS – fully diluted (€)	5.91	4.36	+1.55	+35.5%

Sales growth at +16.6% (+20.1% excluding negative impact of currencies) Core Operating Income +31.0% Operating Income +30.8% Higher amortization of intangible assets from Cabometyx<sup>®</sup> and Onivyde<sup>®</sup> • Other Operating expenses and Restructuring costs mainly related to the relocation of the U.S. commercial HQ and the termination of R&D studies • Higher impairment losses Consolidated net profit +42.6% Lower financing costs Lower effective tax rate due to U.S. tax reform

• Core EPS growth of +35.5%



# O2 Growing Free Cash Flow greater than €450m and strong balance sheet



Strong free cash flow of €458 million, up +48% compared to 2017

Net closing debt at €242 million and strong balance sheet with leverage ratio < 0.3x



# O2 FY 2019 guidance

## Sales growth at constant currency

## Core Operating margin as % of sales

## > +13.0%

- Driven by the continued growth of Specialty Care
- Limited impact from currencies of approximately +1.0% based on the current level of exchange rates

## ~31.0%

• Excluding incremental investments in pipeline expansion initiatives

On track to deliver 2020 financial targets\* one year earlier

\*Sales >€2.5 billion and COI margin >30%



# **02** Key FY 2018 financial takeaways

- Group sales growth at +20.1%<sup>1</sup> driven by the strong performance of the Specialty Care business
- Core Operating Income growing by +31.0% and Core Operating Margin reaching 29.7% of sales, up +3.3 pts
- EPS growing by +42.7% and proposed dividend at 1.00€/share<sup>2</sup>
- Solid cash flow conversion with free cash flow growing by +48.3%
  Strong balance sheet to support future Business Development



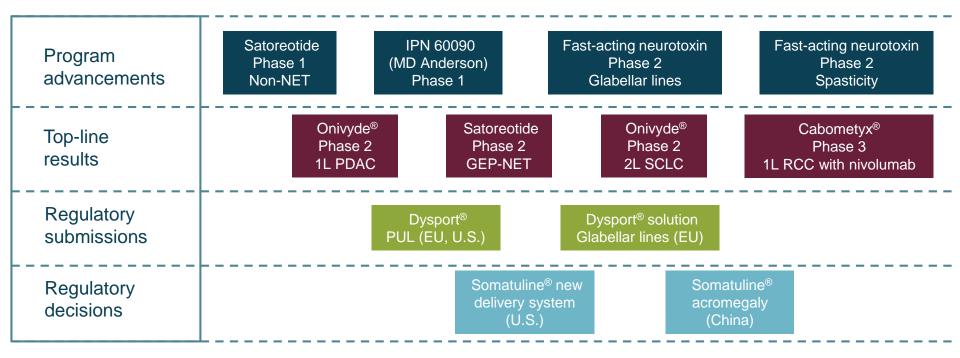
# 03 Conclusion

David Meek Chief Executive Officer





# 03 2019 R&D Milestones





# 03 2019 Objectives

