

# Ipsen

## 2014 First Half Financial Results

Morgan Stanley Global Healthcare Conference - New York, September 8, 2014



# Disclaimer

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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.

# Safe Harbor

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.

# Business update

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# Ipsen well positioned to deliver strong results in 2014 and beyond

Strong sales and operating performance driven by double-digit growth of Somatuline<sup>®</sup> & Decapeptyl<sup>®</sup> and appropriate cost control

Sales and Core EBIT margin guidance revised upward to reflect good business momentum

Somatuline<sup>®</sup> NET launch preparation well under way

Long-term agreement with Galderma to maximize neurotoxins potential in aesthetics & therapeutics

# Business update

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Somatuline<sup>®</sup>: NET market opportunity and launch preparation

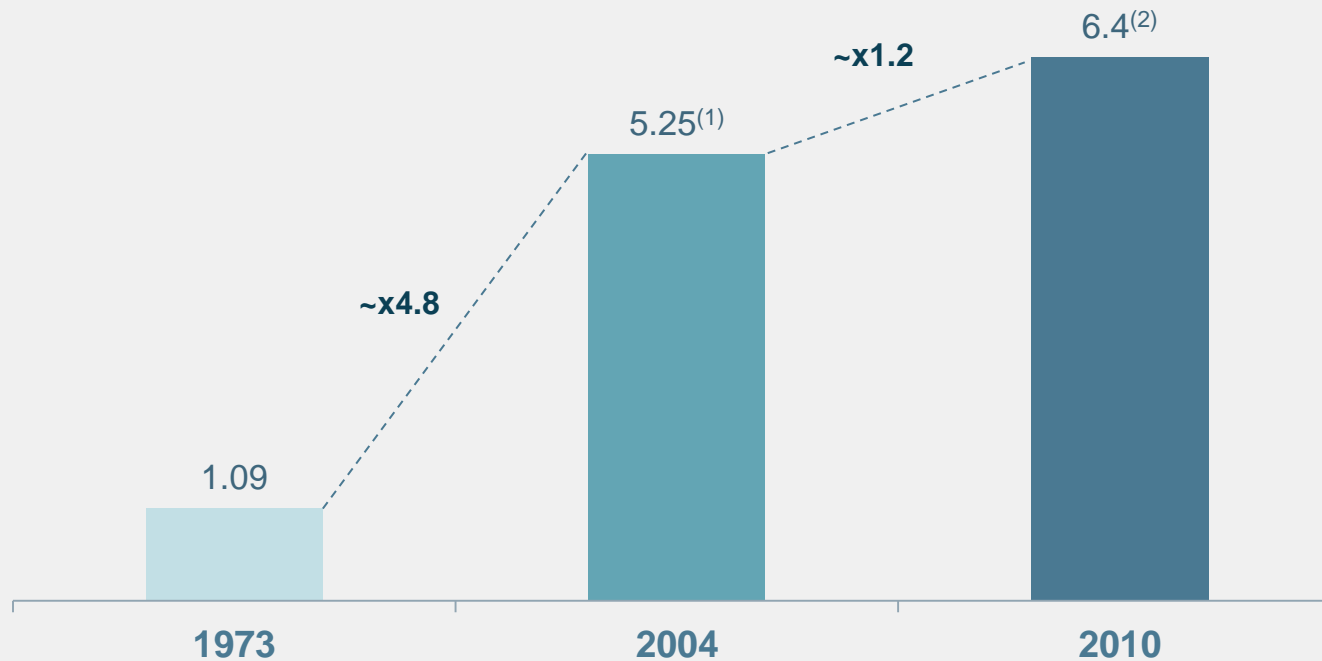
2

Dysport<sup>®</sup>: Several growth levers including new Galderma deal

# Significant increase in neuroendocrine tumors (NET) incidence in the US...

## Evolution of annual NET incidence in the US

Per 100 000 Americans



**US incidence increased ~6x in 40 years, driven by improved diagnosis and disease awareness**

# ... but still high unmet needs in today's US GEP-NET market



Patients with GEP-NETs whose disease has metastasized at diagnosis



Asymptomatic patients who receive nothing, or something other than an SSA



5-year survival rate for patients with distant metastases



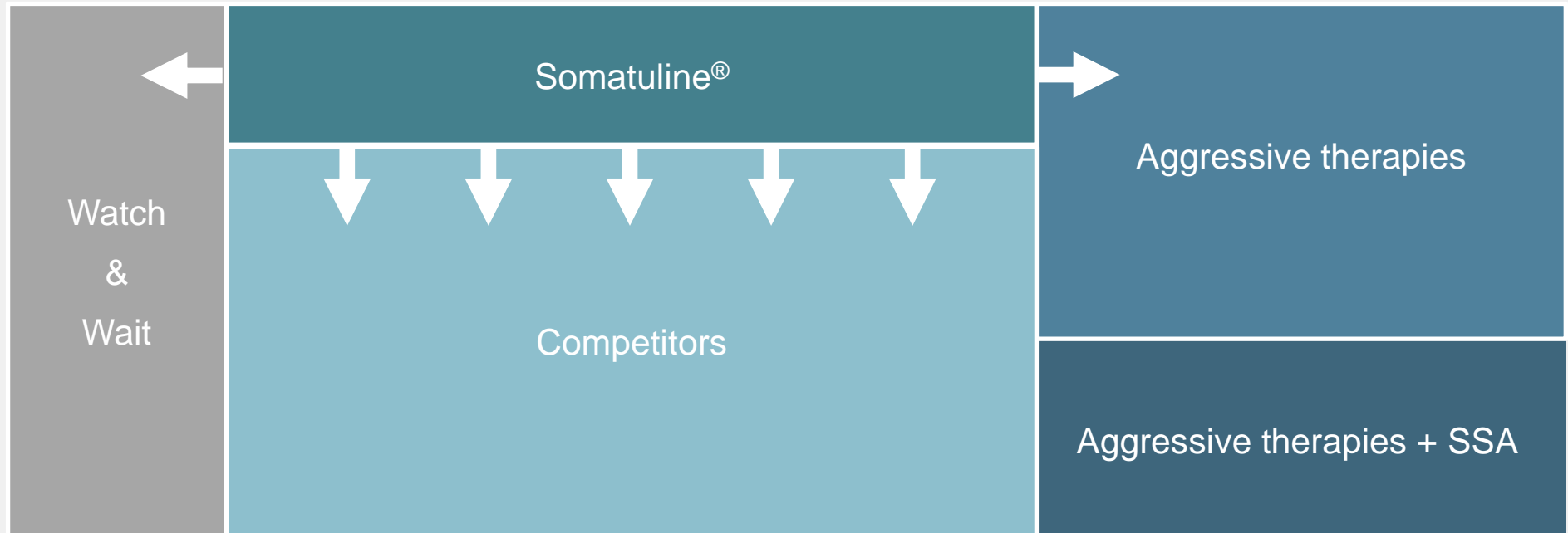
Number of FDA-approved treatments for GEP-NETs

*Note: GEP-NETs = Gastroenteropancreatic neuroendocrine tumors – (1) Schimmack S, et al. Langenbecks Arch Surg. 2011;396(3):273-98 – (2) Source: IMS 2013-14 Somatuline® Depot: Quantitative Survey and Forecast Model Results – US – Jan. 2014; n= 112 Oncology physician online responses; – (3) Yao JC, et al. J Clin Oncol 2008;26:3063-3072 [5-year survival rates for Pancreas (27%), Gastric (25%), Duodenum (46%) and Jejunum (54%) tumor sites].– (4) Some agents are approved for pNETs*



# Somatuline<sup>®</sup> could potentially be used along the entire treatment paradigm

## Expansion potential for Somatuline<sup>®</sup>



**Somatuline<sup>®</sup>, potentially the first and only antitumoral SSA for the treatment of GEP-NETs**

*Note: GEP-NETs = Gastroenteropancreatic neuroendocrine tumors – SSA = Somatostatin analogs*

# Primary paper in the prestigious New England Journal of Medicine echoed by other major publications

## New England Journal of Medicine

*Lanreotide in Metastatic Enteropancreatic Neuroendocrine Tumors*<sup>(1)</sup>  
17 July 2014

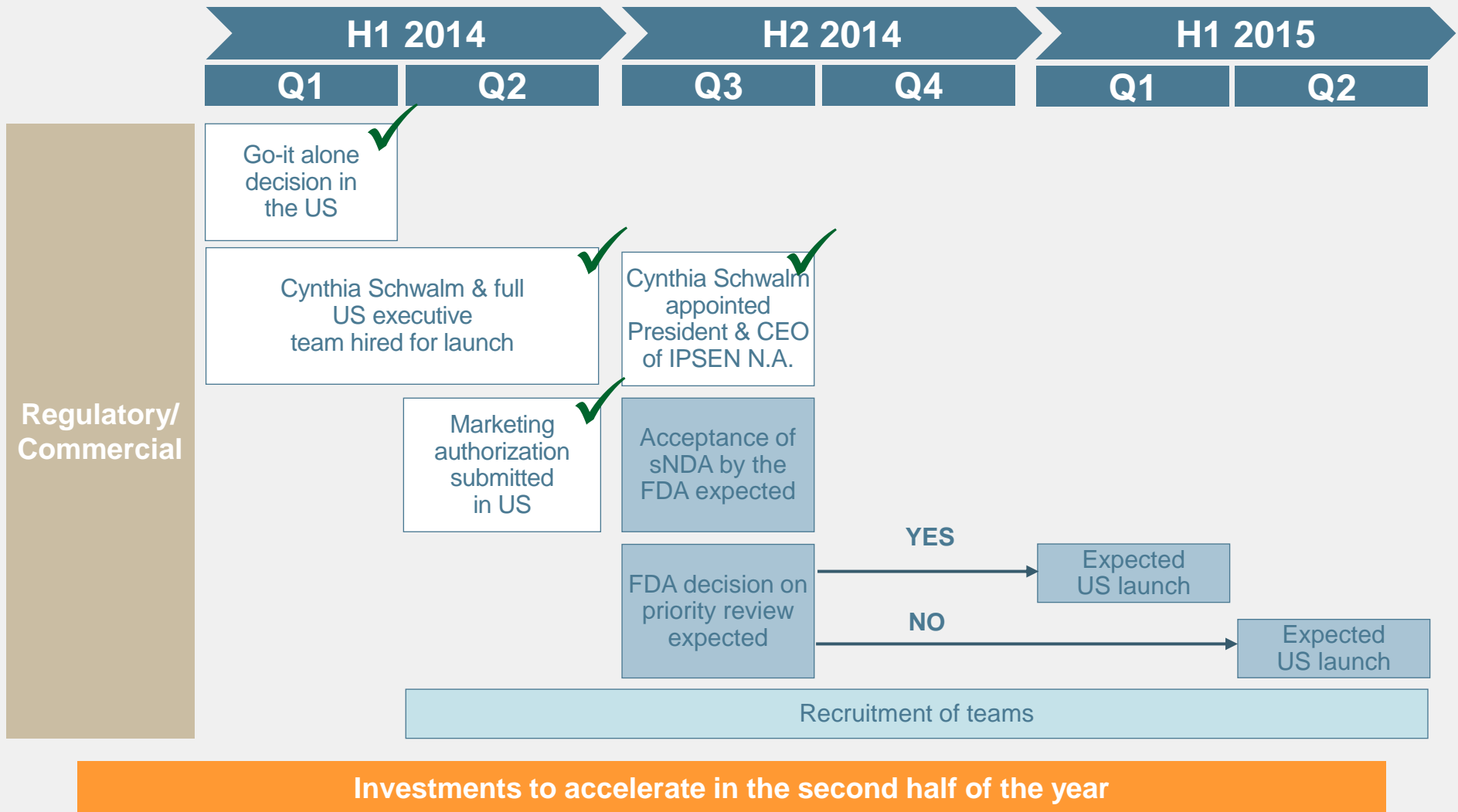
## The Lancet

*Neuroendocrine cancer Clarinet: new option for Nets*<sup>(2)</sup>  
25 July 2014

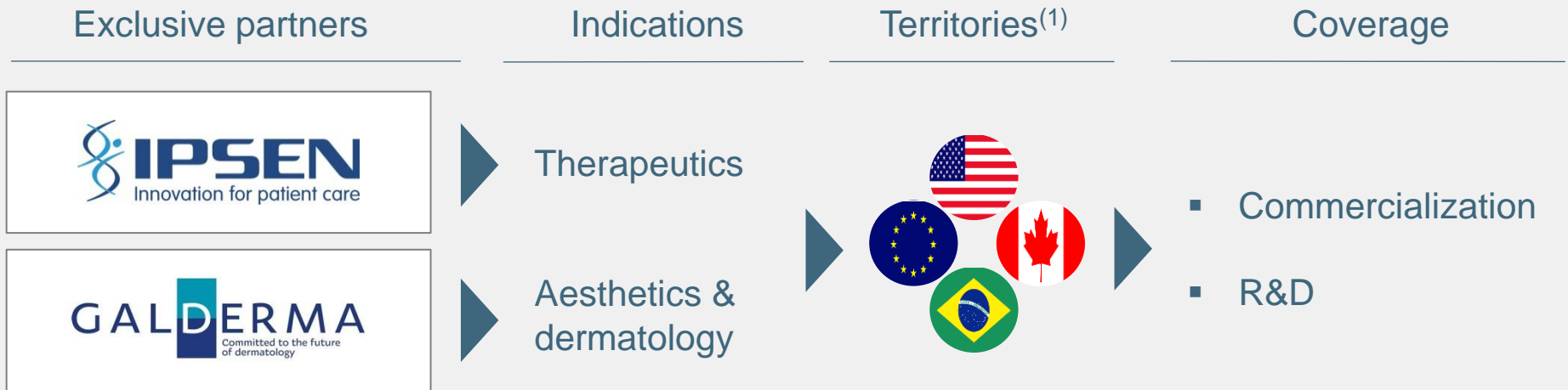
## Nature Reviews Clinical Oncology

*Lanreotide delays progression of Neuroendocrine Tumours*<sup>(3)</sup>  
29 July 2014

# US launch plan for Somatuline® in GEP-NETs on track



# Ipsen and Galderma expand their partnership to become a world leader in neurotoxins



- **Commercialization:** Galderma paid €25 million to Ipsen as part of this renegotiated agreement<sup>(2)</sup>
- **R&D collaboration:** Ipsen paid €10 million to gain control of the IP for Galderma's liquid toxin<sup>(3)</sup>

**Territories covered by the partnership represent ~75% of the world aesthetics market**

<sup>(1)</sup> US, Canada, Brazil and Europe excluding Russia – <sup>(2)</sup> As part of this renegotiated agreement, Galderma will benefit from improved margins in those territories – <sup>(3)</sup> Ipsen will gain control of the IP for Galderma's liquid toxin in those territories, while Galderma retains commercialization rights

# Short and long term Dysport® growth drivers

## Dysport® AUL

- Positive Phase III data presented at major neurology congresses
- US filing expected in H2 2014
- Global spasticity market opportunity of [€200m - €300m]<sup>(1)</sup>

## Dysport® other indications

- PLL<sup>(2)</sup> and ALL<sup>(3)</sup> spasticity Phase III topline results expected in H2 2014
- Positive Phase II results in NDO<sup>(4)</sup>

## Dysport® Next Generation

- EMA feedback expected in H2 2014
- Potentially first liquid toxin A “ready to use” on the market
- Phase III completed in Cervical Dystonia
- Phase III to start in glabellar lines

## Galderma's liquid toxin

- New option to potentially penetrate the US market
- Reinforced IP in the liquid toxin arena

## Syntaxin

- Integration completed
- Access to rich toxin IP portfolio
- Several toxin programs with a potential for breakthrough innovation

*Note: AUL = Adult Upper Limb  
(1) Ipsen analysis – (2) Pediatric Lower Limb – (3) Adult Lower Limb – (4) Neurogenic Detrusor Overactivity*

# H1 2014 – Operational overview

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# H1 2014: Strong sales and operating performance

Encouraging performance for Somatuline<sup>®</sup>, up 14.6%<sup>(1)</sup>,  
growing double-digit across all geographies<sup>(2)</sup>

Strong performance of Decapeptyl<sup>®</sup>, up 10.3%<sup>(1)</sup>,  
benefitting from favorable comparison base in China and Middle East

Stable<sup>(1)</sup> Primary care sales, driven by international performance

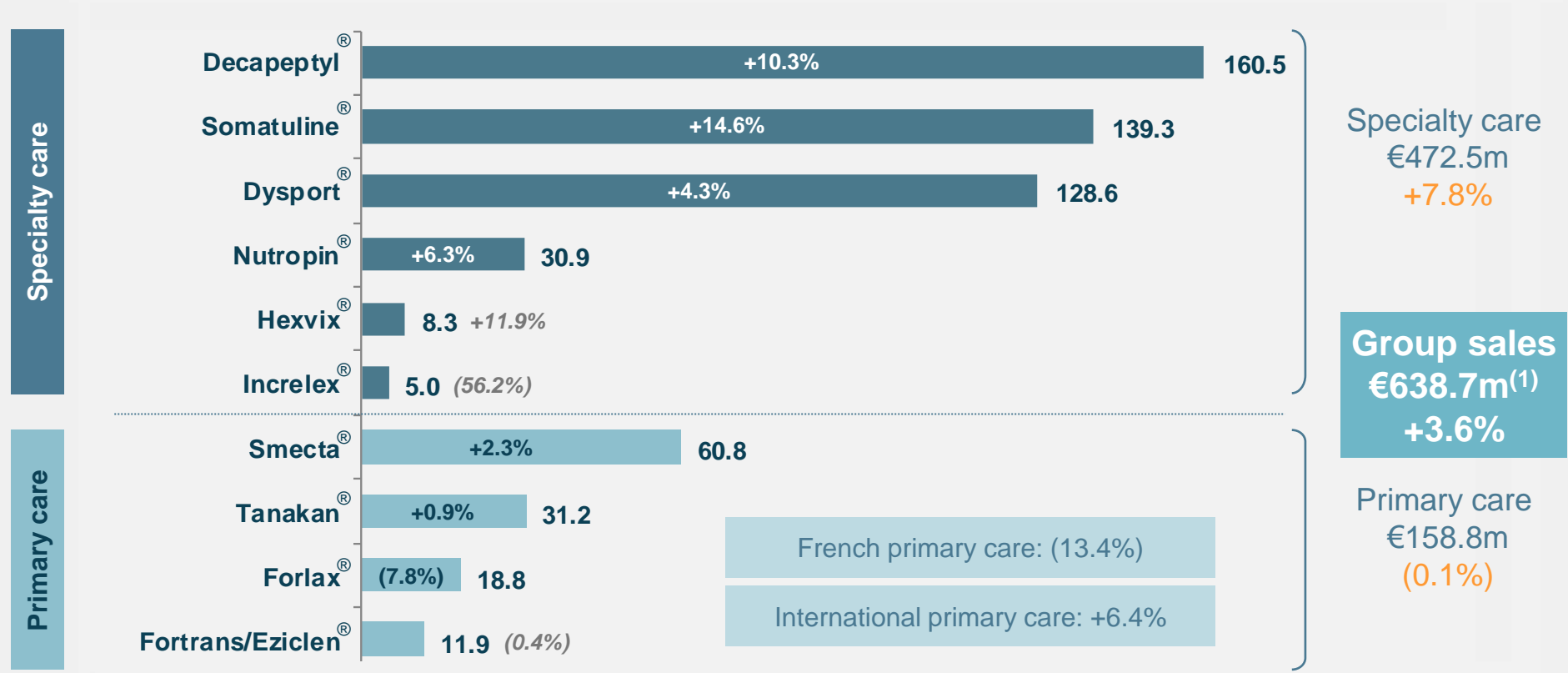
Core Operating Income up 12.5%, supported by continuous cost control  
Core EPS of €1.40<sup>(3)</sup>, up 18.6% year-on-year

Operating cash flow<sup>(4)</sup> up 12.6% and closing cash balance of €129.0m

<sup>(1)</sup> Excluding foreign exchange impacts – <sup>(2)</sup> Europe G5, Other European countries, North America, Rest of the world  
<sup>(3)</sup> Fully diluted Core EPS – <sup>(4)</sup> From continuing operations

# Strong specialty care fueled by Somatuline<sup>®</sup> and Decapeptyl<sup>®</sup>, resilient primary care supported by international growth

Drug sales – H1 2014 in million euros – % excluding foreign exchange impact



**Increlex<sup>®</sup> resupplied in Europe in January 2014 and in the US in June 2014**

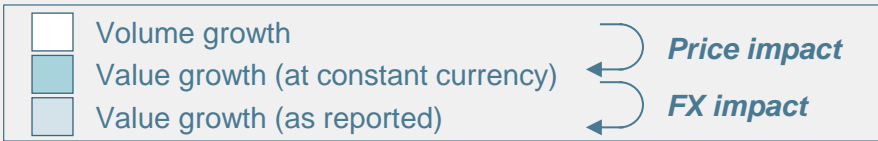
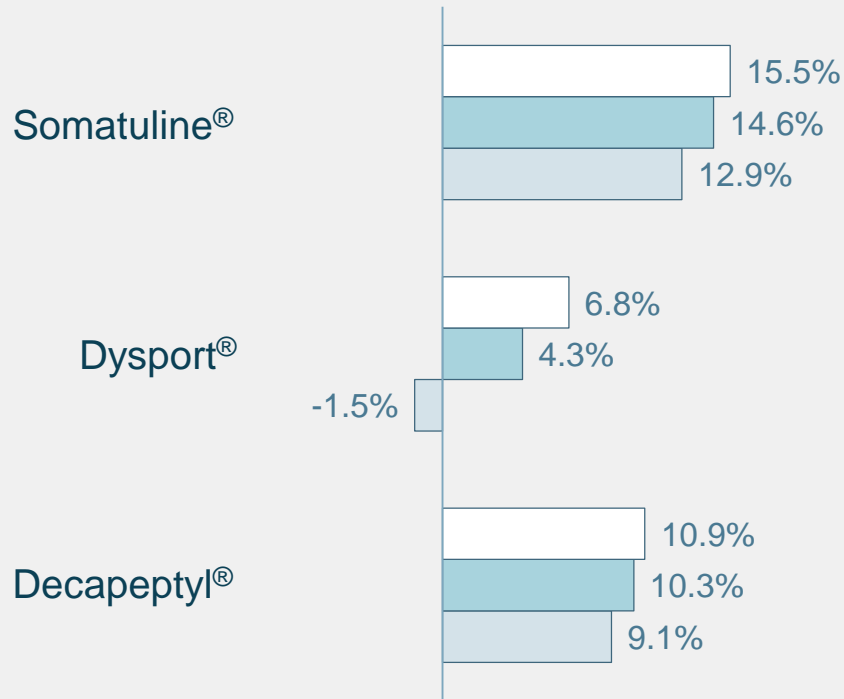
<sup>(1)</sup> Includes €7.4m drug-related sales



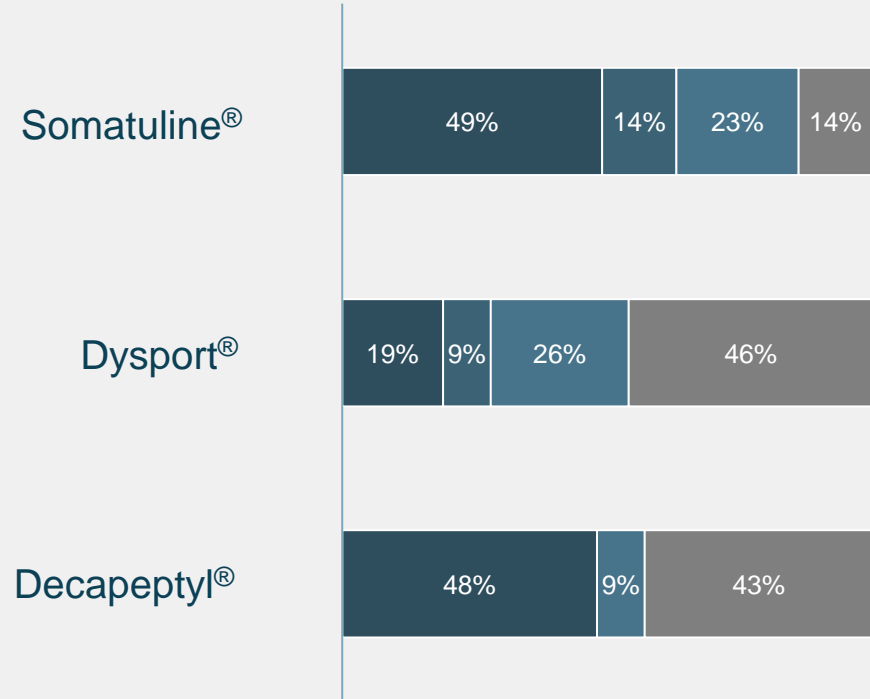


# Price pressure and FX have uneven impacts on specialty care product growth

## H1 2014 volume and value growth



## H1 2014 sales geographic distribution

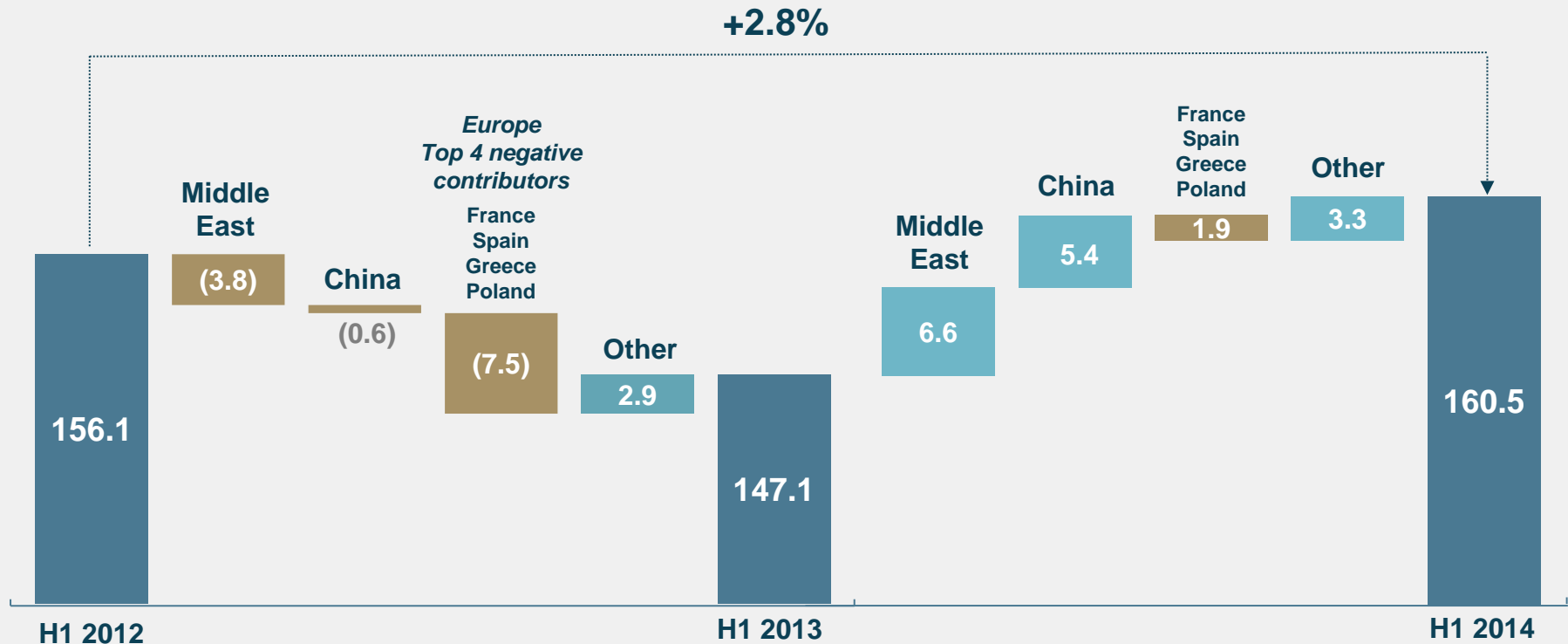


<sup>(1)</sup> France, Germany, UK, Italy, Spain – <sup>(2)</sup> Notably includes China, Russia and Brazil



# Strong rebound of Decapeptyl® after a particularly difficult year 2013 in China and the Middle East

Decapeptyl® sales  
in million euros at current currency

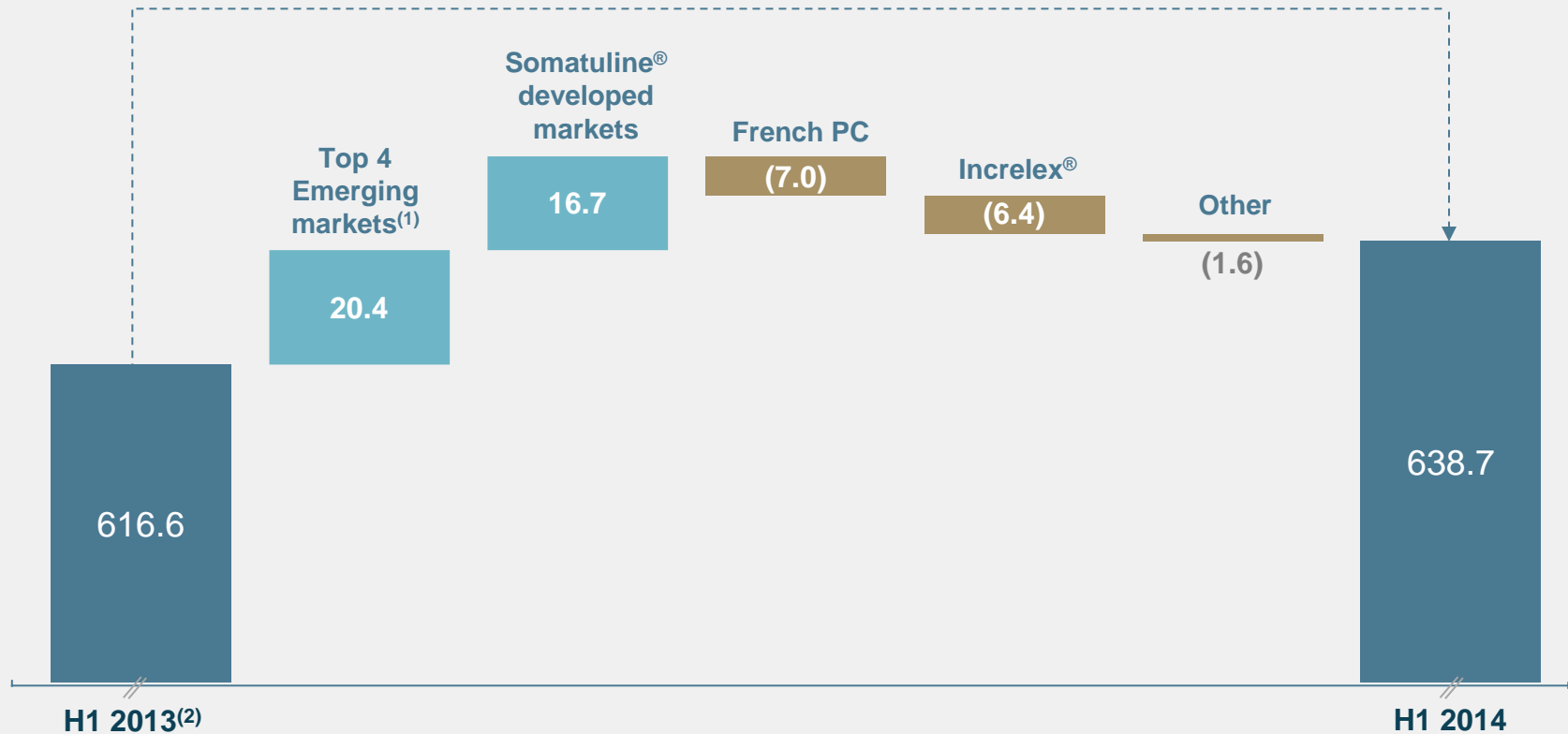


Decapeptyl® performance largely due to favorable comparison base

# Group sales growth driven by emerging markets and Somatuline<sup>®</sup> performance in developed markets

H1 sales  
in million euros

**GROUP SALES growth: +3.6% at constant currency**



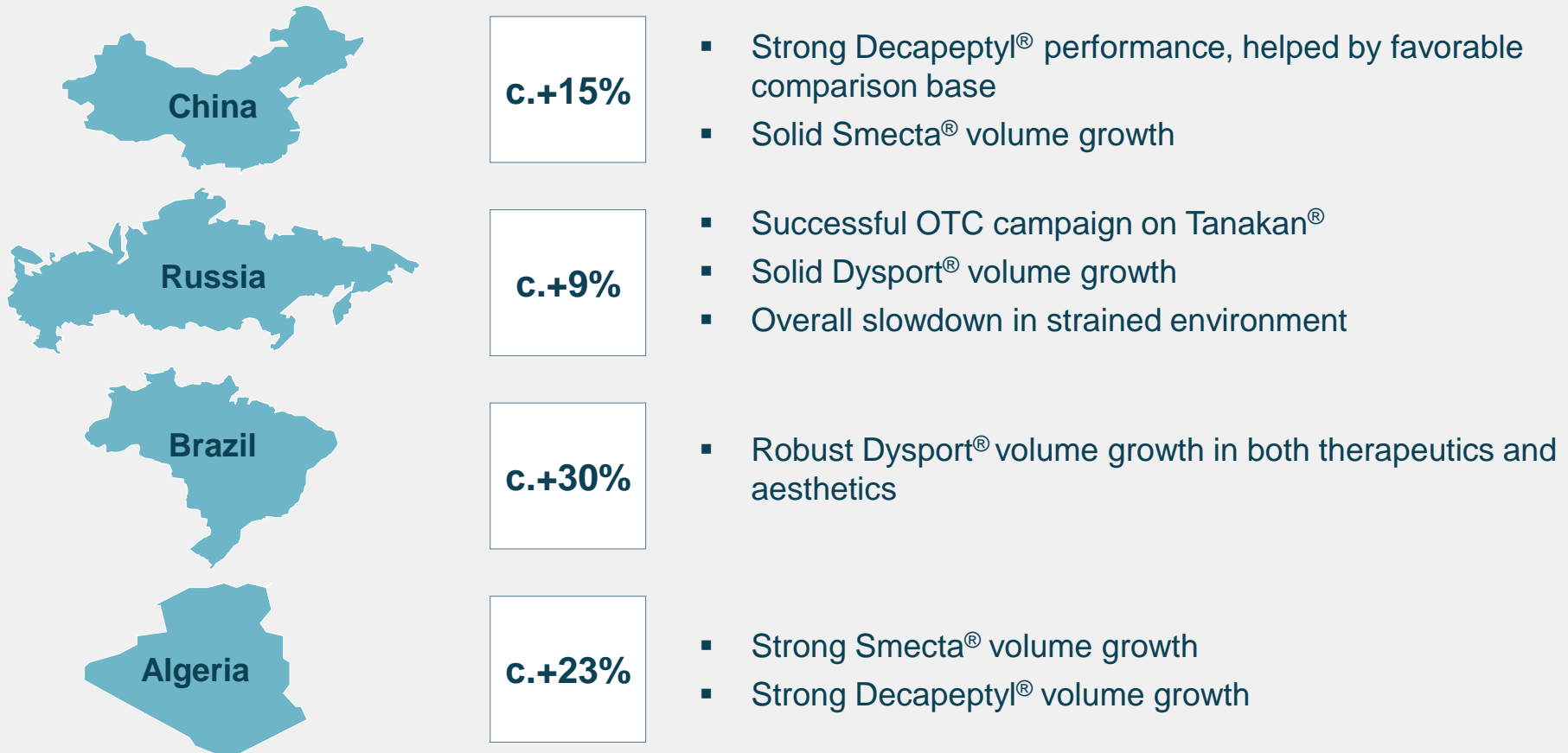
**Continued strategic focus on growth drivers**

Note: H1 2013 figures have been restated to provide comparative information between H1 2013 and H1 2014

<sup>(1)</sup> China, Russia, Brazil, Algeria – <sup>(2)</sup> H1 2013 at H1 2014 exchange rate

# Growth continuously driven by emerging markets

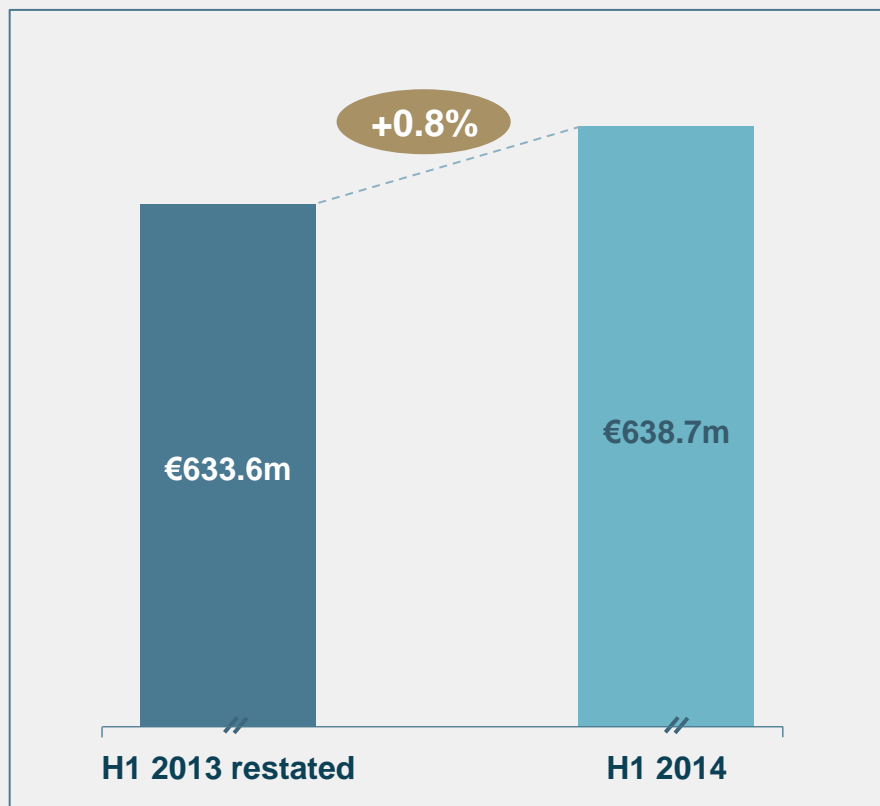
H1 2014 yoy growth



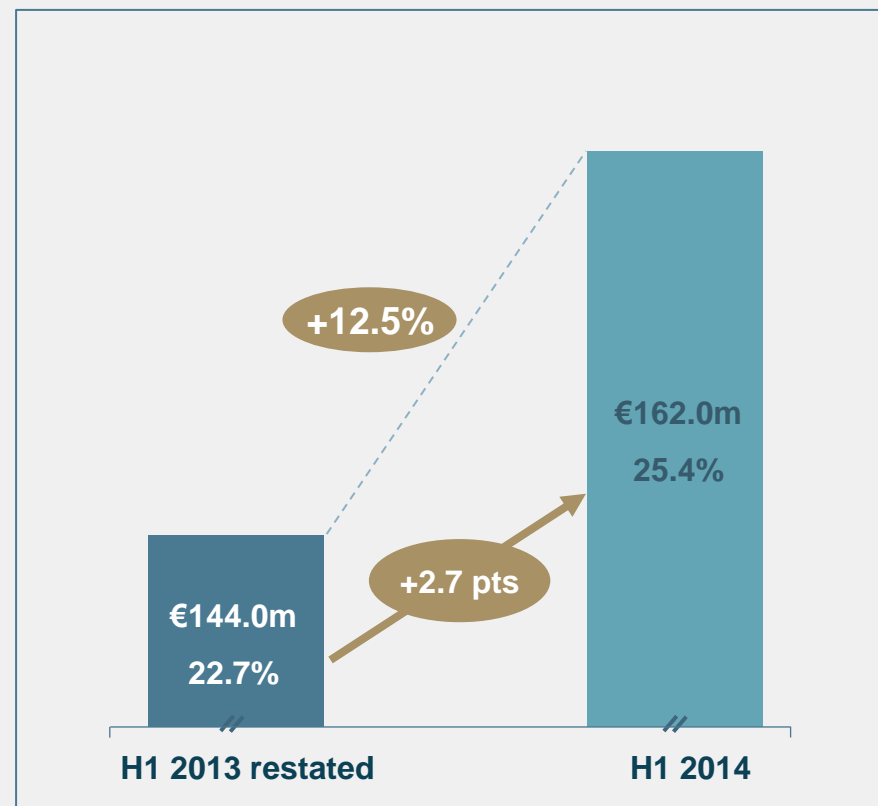
**These 4 emerging countries account for >50% of Group sales growth at constant currency<sup>(1)</sup>**

# Core Operating Income growing much faster than sales...

Group sales evolution (current FX)



Core Operating Income evolution (current FX)

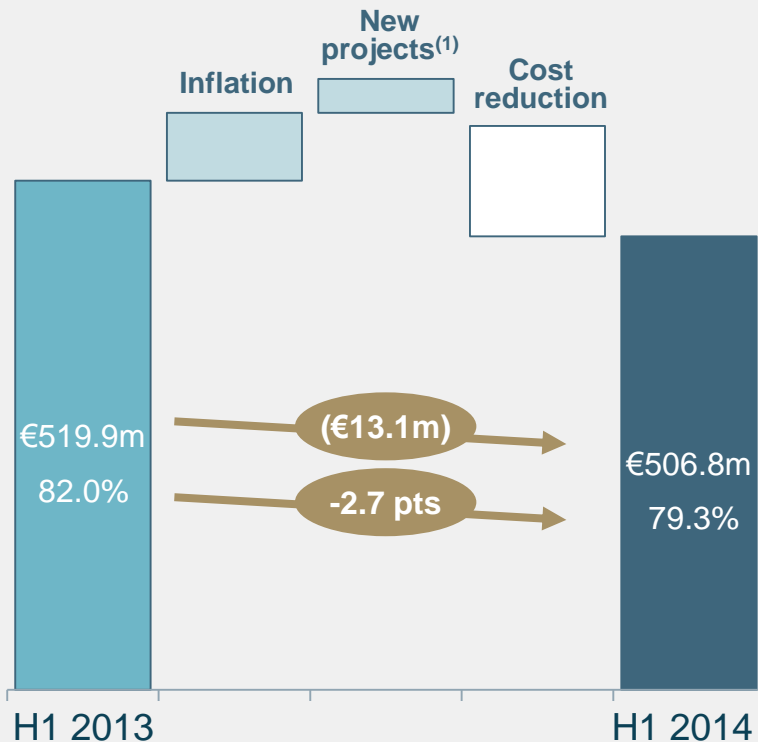


**Sales growth hit by FX, Core Operating Income growth driven by restructuring savings**

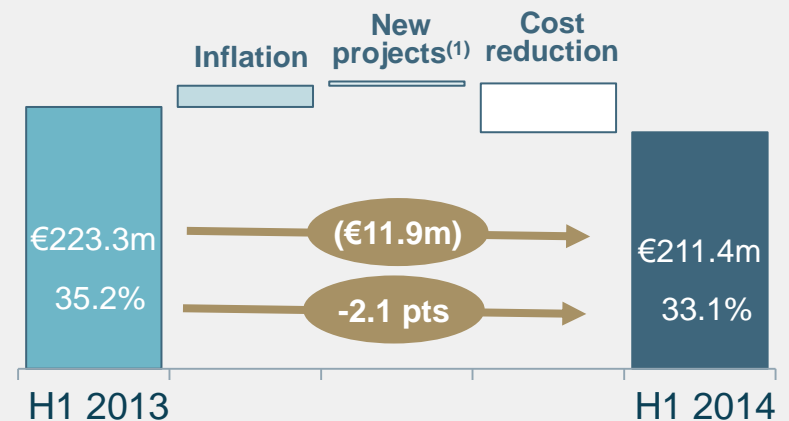
*Note: H1 2013 figures have been restated to provide comparative information between H1 2014 and H1 2013  
Ratios in % of Group sales*

# ... boosted by significant reduction in SMM expenses, more than offsetting inflation and new projects

## Total Opex



## SMM



# H1 2014 – Financial overview

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# Rationale for the accounting changes

Use the opportunity of the new reporting of Specialty Care vs. Primary Care activities to align the P&L so as to:

1

Comply with IASB and AMF recommendations

2

Better reflect industry standards

3

Provide transparent and pertinent information to investors



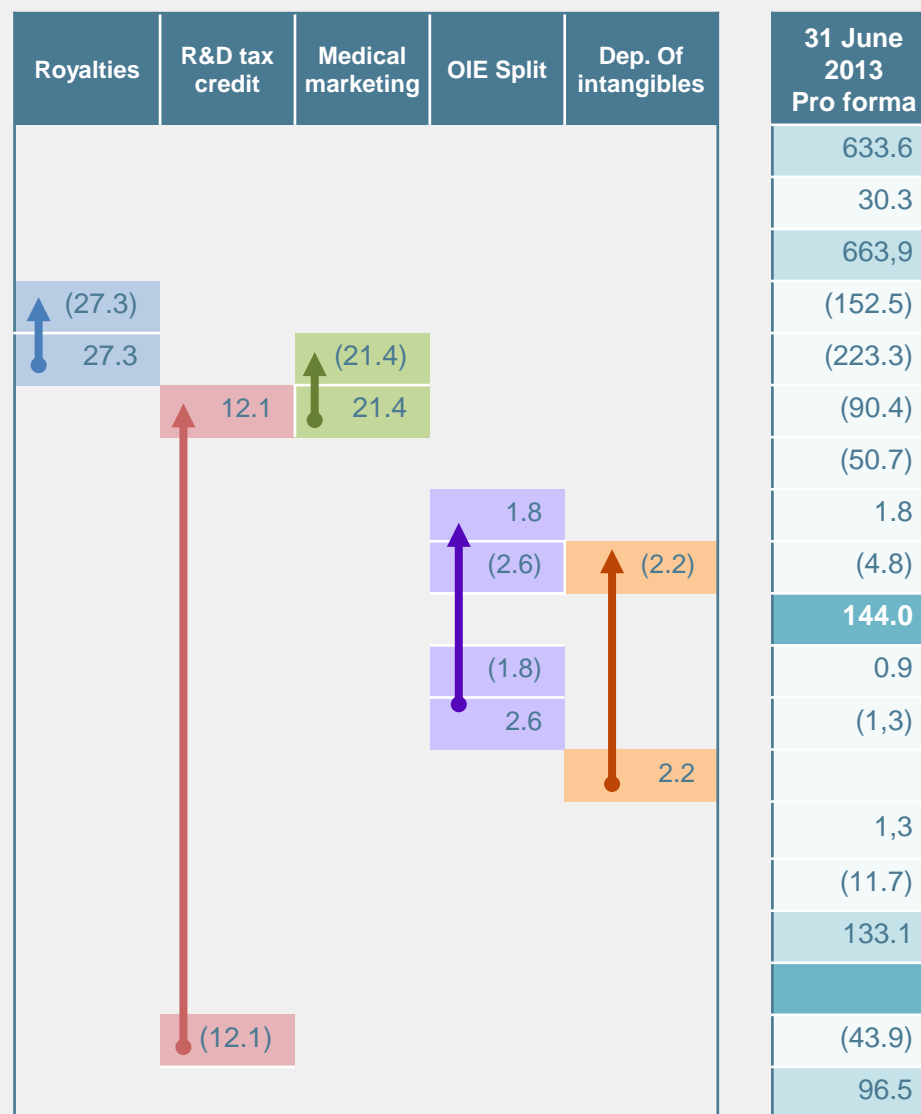
# Key changes to have in mind...

- 1** Royalties paid
  - From selling expenses to COGS
- 2** R&D Tax Credit
  - From income taxes to R&D expenses
- 3** Medical marketing
  - From R&D expenses to selling expenses
- 4** Creation of a “Core Operating Income” aggregate
  - To replace Recurring Adj. Operating Income

**Reclassifications have no impact on net income**

# H1 2013 P&L reconciliation

<i>in million euros</i>	Impact	31 June 2013
Net sales	=	633.6
Other revenues	=	30,3
Revenue	=	663,9
Cost of goods sold	↑	(125.2)
Selling expenses	↓	(229.2)
Research and development expenses	↓	(124.0)
General and administrative expenses	=	(50.7)
<i>Other Core operating income</i>	NEW	
<i>Other Core operating expenses</i>	NEW	
<b>Core Operating income</b>	NEW	
Other operating income	↓	2.7
Other operating expenses	↓	(3.9)
Depreciation of intangible assets	MOVED	(2.2)
Restructuring costs	=	1.3
Impairment gain/(losses)	=	(11.7)
Operating income	↑	121.0
Recurring adjusted operating profit	REMOVED	132.2
Income taxes	↑	(31.8)
Consolidated profit	=	96.5



# Condensed P&L

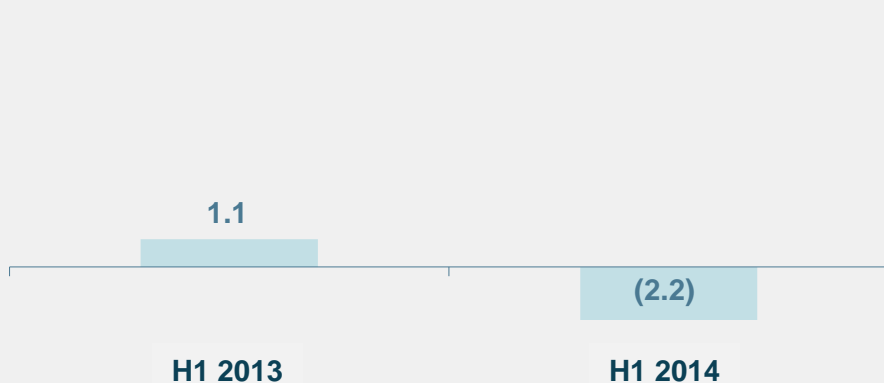
<i>in million euros</i>	H1 2013 restated	H1 2014	% change
Sales	633.6	638.7	+0.8%
Other revenues	30.3	30.1	(0.7)%
<b>Revenues</b>	<b>663.9</b>	<b>668.8</b>	<b>+0.7%</b>
Cost of goods sold	(152.5)	(155.8)	+2.2%
Selling and marketing expenses	(223.3)	(211.4)	(5.3)%
Research and development expenses	(90.4)	(87.6)	(3.1)% <sup>(1)</sup>
General and administrative expenses	(50.7)	(51.3)	+1.2%
Other core operating income /expenses	(3.0)	(0.6)	(78.6)%
<b>Core Operating Income</b>	<b>144.0</b>	<b>162.0</b>	<b>+12.5%</b>
Operating Income	133.1	146.3	+9.9%
Income taxes	(43.9)	(40.7)	(7.4)%
<b>Consolidated net profit</b>	<b>96.5</b>	<b>104.5</b>	<b>+8.2%</b>

Note: H1 2013 figures have been restated to provide comparative information between H1 2014 and H1 2013

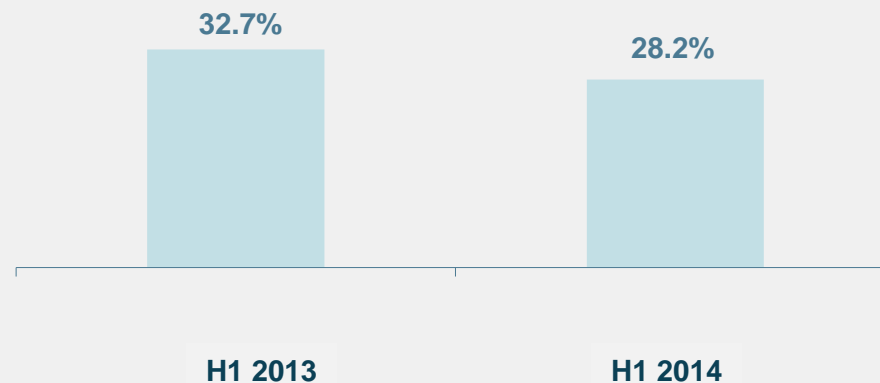
<sup>(1)</sup> Excluding the research tax credit, research and development expenses grew 1.6%.

# Main P&L items: Below operating income

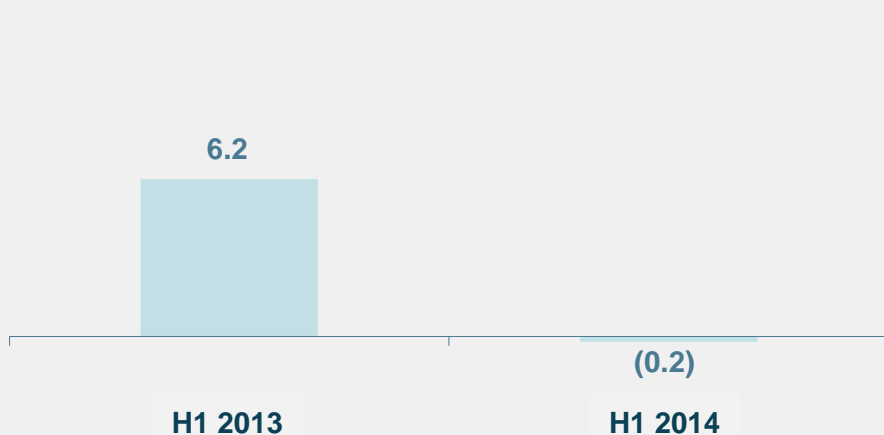
Financial Result (€m)



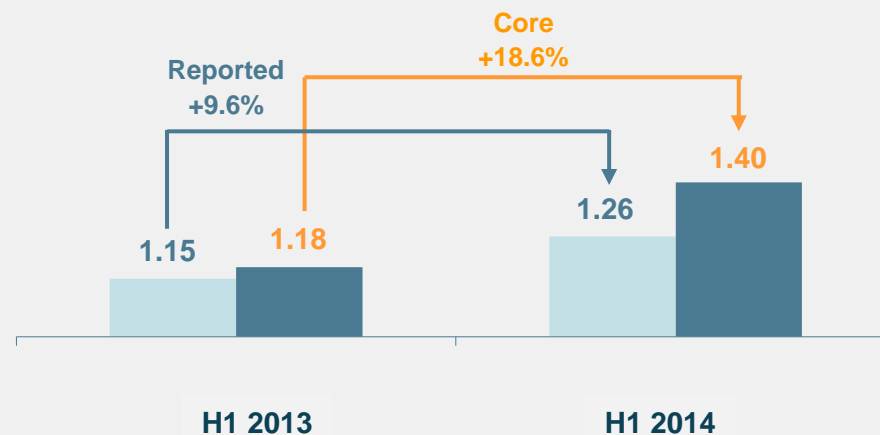
Effective tax rate



Net income from discontinued operations (€m)



EPS (€)



Note: H1 2013 figures have been restated to provide comparative information between H1 2014 and H1 2013

# Balance sheet evolution

ASSETS			LIABILITIES		
<i>in million euros</i>	FY 2013 Restated	H1 2014	<i>in million euros</i>	FY 2013 Restated	H1 2014
Goodwill	310.7	312.3	Capital and reserves	971.5	980.3
Investments in associates	0.0	12.9	Minority interest	2.2	2.5
Property, plant and equipment	287.5	296.0	<b>Total equity</b>	<b>973.7</b>	<b>982.8</b>
Other intangible assets	144.8	142.4	Provisions	90.7	98.8
Other non current assets	220.5	214.8	Bank loans	0.0	80.0
<b>Non-current assets</b>	<b>963.5</b>	<b>978.4</b>	Other non current liabilities	124.7	117.7
<b>Current assets</b>	<b>601.8</b>	<b>651.4</b>	<b>Non-current liabilities</b>	<b>215.4</b>	<b>296.4</b>
<i>Incl. Cash and cash equivalents</i>	131.0	131.9	<b>Current liabilities</b>	<b>376.2</b>	<b>350.6</b>
<b>Total Assets</b>	<b>1,565.3</b>	<b>1,629.8</b>	<b>Total Liabilities</b>	<b>1,565.3</b>	<b>1,629.8</b>

Note: FY 2013 figures have been restated to provide comparative information between H1 2014 and H1 2013

# Solid cash flow generation

*in million euros*

	H1 2013 Restated	H1 2014
<b>Consolidated net profit</b>	<b>96.5</b>	<b>104.5</b>
Share of profit (loss) from associated companies before impairment gain/(losses)	0.0	0.4
<b>Non cash and non operating items</b>	<b>43.4</b>	<b>23.1</b>
<i>of which Depreciation, amortization, provisions</i>	18.5	15.7
<i>of which Impairment losses</i>	11.7	0.4
<i>of which Change in deferred taxes</i>	7.1	7.1
<b>Cash flow from operating activities before changes in working capital</b>	<b>139.9</b>	<b>128.0</b>
Changes in working capital requirement related to operating activities	(85.3)	(73.3)
<b>Net cash flow generated by operating activities</b>	<b>54.6</b>	<b>54.7</b>
Purchase of tangible and intangible assets	(12.0)	(24.2)
Other	(16.7)	(7.8)
<b>Net cash flow used in investing activities</b>	<b>(28.7)</b>	<b>(32.0)</b>
Dividends paid	(66.6)	(65.5)
Treasury shares	0.1	(33.4)
Other (incl. borrowings)	45.7	78.4
<b>Net cash used in financing activities</b>	<b>(20.8)</b>	<b>(20.5)</b>
<b>Opening cash position</b>	<b>113.3</b>	<b>125.4</b>
Change in cash and cash equivalents	5.1	2.2
Change in cash and FX	(0.8)	1.4
<b>Closing cash position</b>	<b>117.6</b>	<b>129.0</b>

**Solid operating cash flow generation in H1 2014**

*Note: H1 2013 figures have been restated to provide comparative information between H1 2014 and H1 2013*

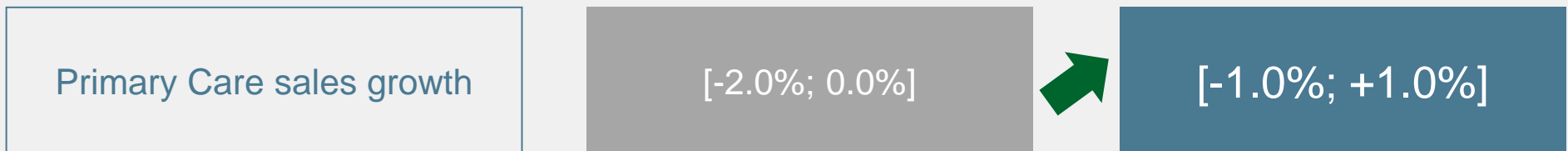
# Closing remarks and 2014 outlook

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# Sales objectives raised for 2014



- driven by strong growth of Somatuline<sup>®</sup>, solid Decapeptyl<sup>®</sup> performance notably due to normalization of the situation in China and the Middle East, and resumption of Increlex<sup>®</sup> supply in the United States in June 2014



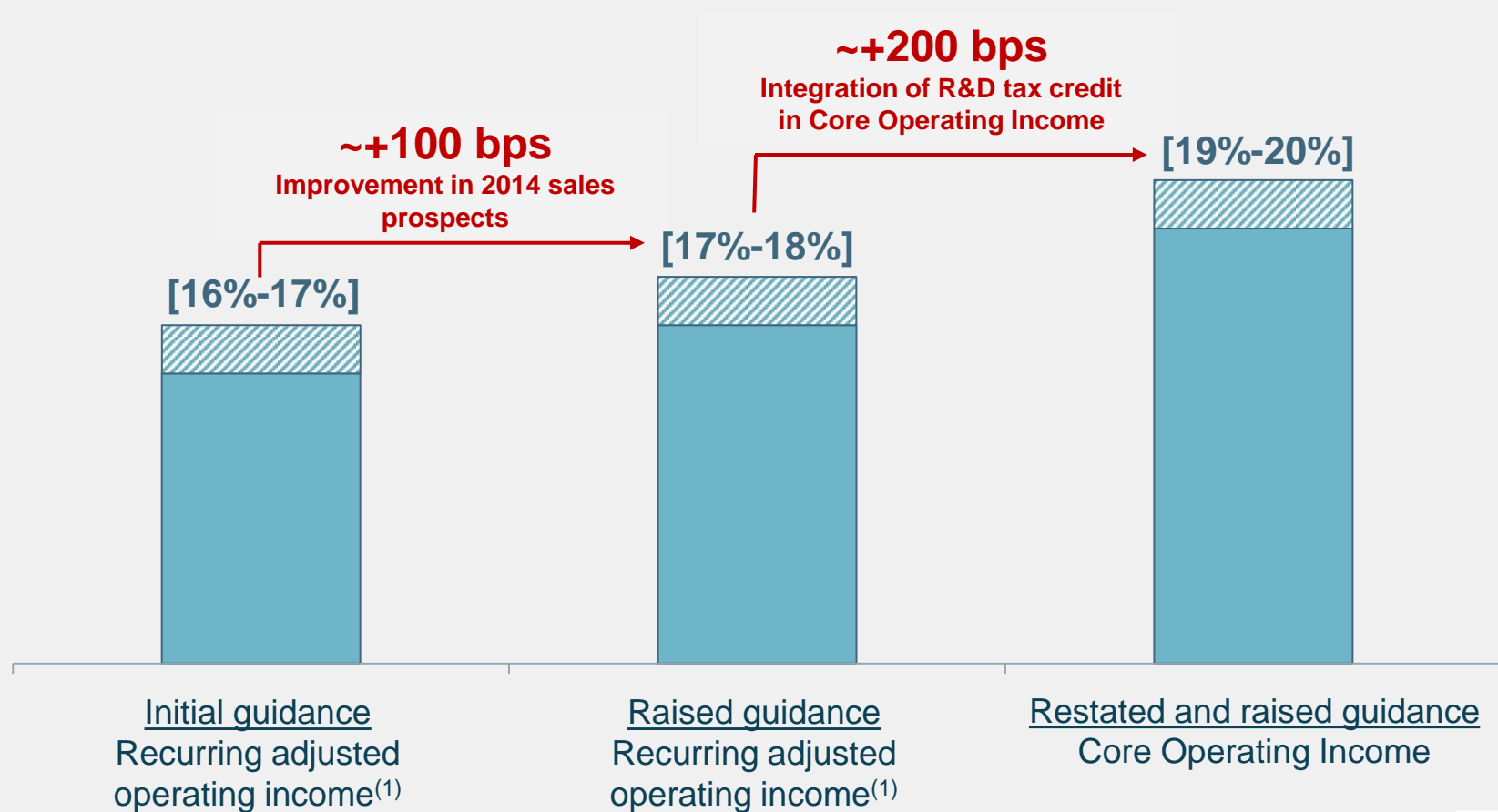
- excluding the reimbursement of Smecta<sup>®</sup>'s generic in France

*Note: The above objectives are set at constant exchange rates, in the context of a tense and uncertain geopolitical environment in Russia, Ukraine and the Middle East*



# 2014 profitability objective raised, due to a mix of underlying and technical effects

## 2014 profitability guidance upgrade



# In 2014, continued business development efforts to complement organic growth

## Areas of focus

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### Commercial deals

- In-licensing or acquisition of marketed drugs (including orphan drugs)
- Acquisition of small companies
- Various geographies targeted, notably the US

### R&D deals

- Late stage compounds (Phase III) in various therapeutic areas (oncology, endocrinology, neurology, etc.)
- Early stage compounds (Phase I and II) with a potential for breakthrough innovation

# Tasquinimod, potentially a new first-in-class oral therapy for chemo naïve patients with metastatic CRPC

A unique mechanism of action...

- Immune activation
- Anti-angiogenic effects
- Anti-metastatic effects

... which could fill gaps in the current treatment paradigm

- Some patients do not respond to/escape current hormonal treatments

Significant market potential

- Addressable market: [€1.3bn - €1.5bn]<sup>(1)</sup> in Ipsen territories
- Important growth anticipated in the coming years

**Phase III top-line results to be disclosed by Q1 2015**

# You will hear from us in the months to come...

**Regulatory authorities decision on whether to accept Somatuline® NET filing**  
**FDA decision on whether to grant priority review**

**TasQ Phase III clinical results**

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Somatuline<sup>®</sup> NET launch preparation well under way

Long-term agreement with Galderma to maximize neurotoxins potential in aesthetics & therapeutics

