# 2008, a cornerstone year in Ipsen's development

**FULL YEAR 2008 RESULTS** 

6 March 2009





### **DISCLAIMER**

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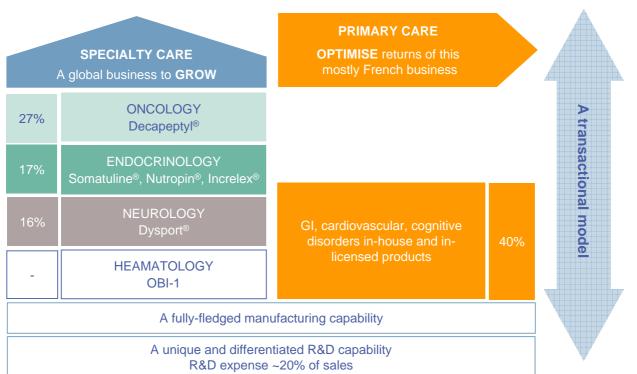
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### Introduction





### Ipsen is a Global - Innovation Driven - Specialty Pharma



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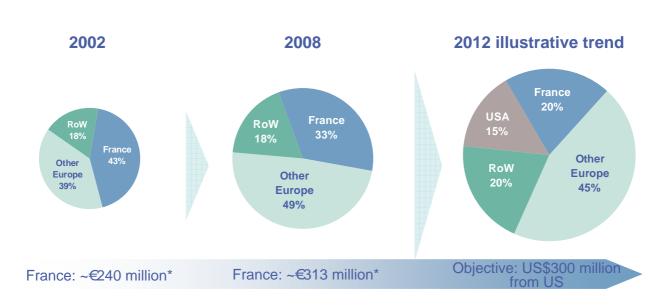
### **Ipsen strong revenue dynamics**



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### A global geographic footprint



<sup>\*</sup> Excludes sales of Ginkor Fort (€61 million in 2002, €14 million in 2008)



### A new growth engine: North America

US Endocrinology platform

2012

Sales in excess of \$250 million

US Neurology platform

Sales in excess of \$50 million

WW hematology (OBI-1)

At peak

Sales in excess of \$200 million

A US platform generating close to \$1 billion by the end of the next decade

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### An increasingly transactional model













**ONCOLOGY** 











**NEUROLOGY** 





















### **Truly Differentiated Discovery Capabilities**





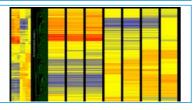
### Defining Ipsen's competitive edge in drug Discovery

Hormones provide well defined templates with matching targets both novel or validated

### Resident know how based on the integration of basic discovery technologies

Target identification, validation and drugability based on clinical observations supported by ...omics technologies

**Technologies** 



### **Medicinal chemistry**

Steroids peptides, proteins engineering aiming at enhanced efficacy, potency, selectivity and safety over the endogenous hormone



### **Delivery systems**

Emphasis on improved pharmacological properties, optimization of dosing regimen and improved patients compliance and convenience

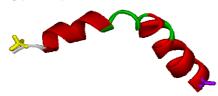




# An example of this unique technology convergence: taspoglutide

### Once-a-week or twice-a-month injection

- Equal / greater potency compared to native compound
- Extended metabolic half-life, 22x more stable in plasma
- Complete retention of incretin properties
- Strong patent positions



### Expected needle gauge

- (LAR) → 23G
- Taspoglutide Liquid SRF → 29G
   Insulin type needle for subcutaneous injection

50 to 300 µl of highly concentrated aqueous solution devoid of excipient

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# 2008 performance and 2009 outlook





### 2008: major strategic initiatives shaping Ipsen's future

# Grow and Globalise Ipsen's specialty care business US entry: 2 global products 4 products in launch phase Filing of Decapeptyl 6M 4 products under regulatory review 5 programmes moving into phase II/III

Delivering on all key objectives

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### Our financial objectives have been met

		Adjusted <sup>(1)</sup> financial objectives	2008 performance
Sales	Performance 6.5-7.5%		✓ 8.2%
	Reported growth	3.2-4.2%	<b>√ 4.7%</b>
Operating margin	"Standalone"	20.5-21.5%	<b>✓ 21.6</b> %
	As reported excl. US acquisitions one-off costs	18.0-19.5%	<b>√</b> 19.2%

(1) IMPORTANT NOTE: Please refer to Appendix 1 for definitions of "adjusted", "performance growth", "standalone", and "post US acquisitions"



### First quarter 2009 trading update

A sustained activity across most regions (US, China, Western Europe) but...

Headwind in some Eastern European countries impacted by currency fluctuations (Russia, Ukraine, Romania, ...)

Slow start in certain other Western European countries (Greece...)



Temporary impact of consignment stocking in December 08 (China, Poland)

Actions taken.

Q1 2009 sales will come significantly below expectations.

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**Uncertainty in some geographies** 

The Eastern European countries where distribution channels have been disrupted by the steep decline of their local currencies against euro represented 10% of the Group's 2008 sales and 20% of its growth

Group 2009 sales will therefore be adversely impacted depending on the magnitude and the length of the difficulties encountered in these countries



### Reiterating our operating margin expectation for 2009

### Around €45 million expected in other revenues

### 14.0%\* adjusted operating margin\*\*

\* Corresponding to the operating margin objective given in June 2008
of 15.0% (in % sales) when the Group expected to receive €11 million from in 2009 Bayer for a license contract

\*\* Adjusted operating margin is defined as reported operating margin
before any transaction related impacts from the Group's acquisitions in North America





### **Expected 2009 Group tax rate**

Taking into account the effects of the Group's US acquisitions

Based on the information available today

And on the basis of the notices of tax reassessments received so far

Group tax rate expected to stand between 18.0 and 20.0% in 2009

# **Newsflow**





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

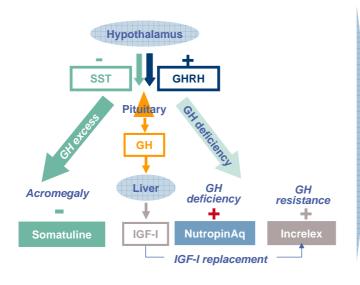
		Decapeptyl® 6 Months Approval	Adenuric® Partnership(s) and launches
	BIM-23A760 Phase II initiation	Toremifene Citrate 80 mg European filing	Primary care products In-licensing deal(s)
	OBI-1 Phase III initiation	Azzalure® Approval in Europe	Azzalure® Launch by Galderma
BN-83495 Phase I results Breast / Prostate	BN-83495 Phase II initiation prostate/gynecology	Reloxin® FDA approval	Reloxin® Launch by Medicis
BIM-28131 Phase I initiation	Somatuline® Depot US NET Phase III initiation	Dysport <sup>®</sup> FDA approval	Dysport <sup>®</sup> Launch
Phase I	Phase II/ III	Regulatory	Launch

# An endocrinology franchise outgrowing competition





### A unique focus on pituitary disorders and hormone dependent diseases



### A strong franchise

- A range of products addressing today Short Stature, Acromegaly and NET
  - High morbi-mortality
  - Debilitating pathologies
  - High unmet medical needs
- Somatuline®, NutropinAq® and Increlex® contributed to ~16 % of 2008 Group sales, ie. ~ €158 million.
- A fast growing franchise: sales doubled in the past 3 years





	Sandostatin LAR®	Somatuline® Autogel®
Administration	2.0 ml Intramuscular	0.3 ml – 0.5 ml Subcutaneous
Presentation	Powder vial + solvent filled syringe + 2 needles	Pre-filled syringe
Injection technique	10 steps needed to reconstitute	Ready to use Self administration*



For what reasons would you prescribe Somatuline® Depot to your acromegaly patients?\*\*

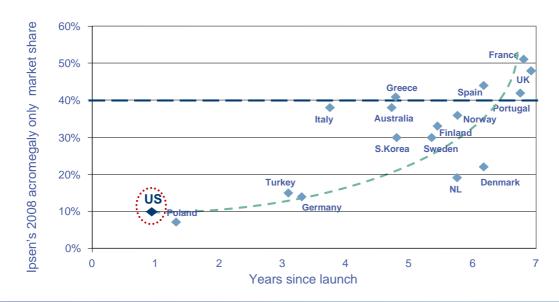


\* In selected countries

\*\* Study Sample: A total of 50 US endocrinologists completed a 30-minute online questionnaire between April 4 - 17, 2008 25 High Volume Endocrinologists: Endocrinologists who see 11 or more acromegaly patients in a year 25 Low Volume Endocrinologists: Endocrinologists who see between 5-10 acromegaly patients in a year



### Somatuline® Depot is poised to grow and gain market share



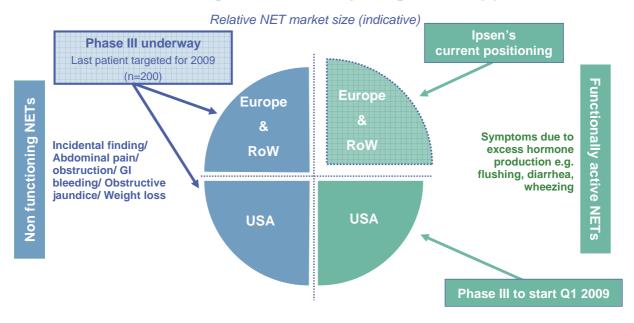
Somatuline® market share is directly correlated to its time on market

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### Somatuline® offers significant life cycle growth opportunities



### Significant scope for expansion

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# Increlex® in the US: steady performance with continued growth expectations

Physician demand

- Target audience : ~1,000 US paediatric endocrinologists
- Up to 20% of Rx come from new prescribers each month
- 2/3 of pediatric endocrinologists have prescribed Increlex<sup>®</sup>; 78% continued prescription

Reimbursement

- ~ 90% of private and public covered lives have formulary access
- 75% Increlex patients approved upon final decision (similar to GH)

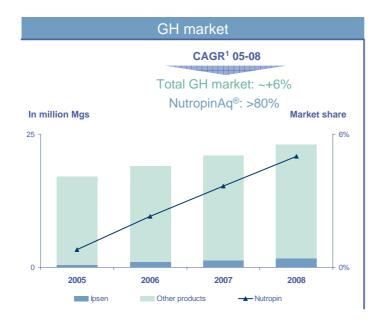
Patient experience

- Sharp increase in patients on Increlex<sup>®</sup> initially GH-naïve to 60% in '08 from 30% in '07
- Dose increasing to appropriate targets, to 100 mcg/kg BID in '08 from 70 mcg/kg BID in '07
- Younger patients initiated with Increlex®, to average age at start of 10.0 years old in '08 from 11.5 years in '07





# NutropinAq® in Ipsen territories is steadily gaining market share



### NutropinAq® attributes

- 1st liquid formulation launched WW
- A simple and user friendly pen
- An experienced post marketing surveillance database
- A dedicated experienced and professional team

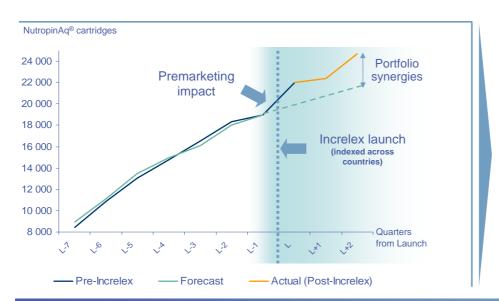
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Source: Strategix





### NutropinAq® + Increlex®: evidence of portfolio synergy



Up to 10% favorable impact

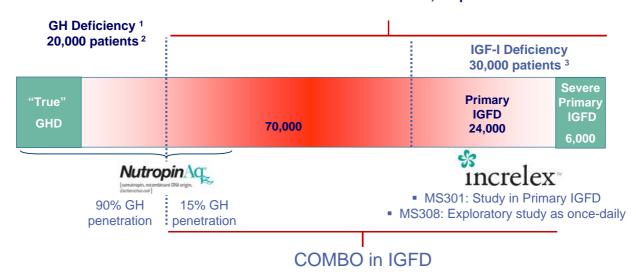
"Ipsen is the only company that can legitimately claim to treat all forms of growth failures through the spectrum of GH deficiency to GH resistance"

Pr. Martin Savage, St Bartholomew's Hospital, London



# Ipsen is redefining the treatment of short stature

### Non-GH Deficient Short Stature: 100,000 patients in the US



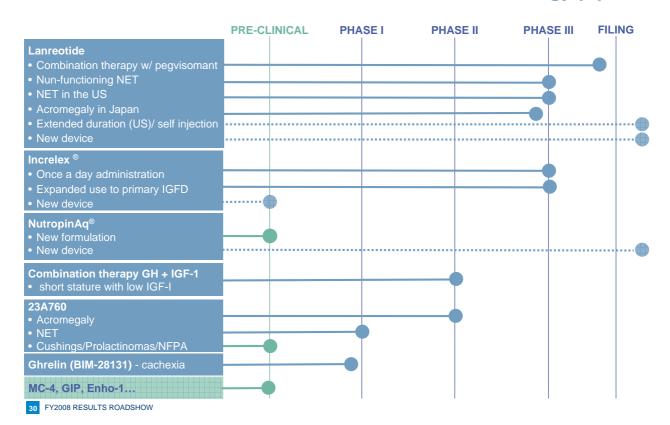
- MS316: Ph.II dose titration studyrecruitment to be completed by Q2 '09
  - Ph.II study in GH Deficient children to start by end '09

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1) Includes TS, SGA, CRI, PWS 2) Approximate number seen by Ped Endos; Finkelstein et. Al. 3) NCGS Analysis



### A rich endocrinology pipeline

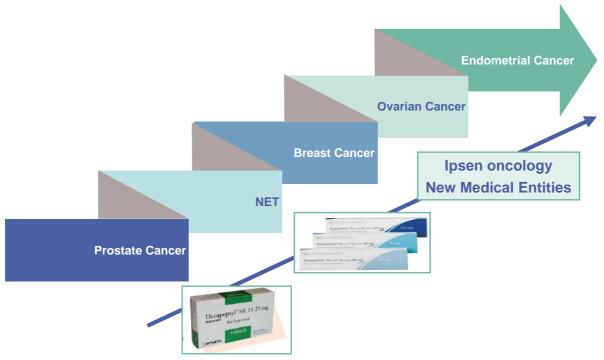


# Confirming Ipsen as a leader in the field of hormone dependent cancers





# **Confirming Ipsen as a leader in Hormone Dependent Cancers**





### Decapeptyl® 3 months formulation: a competitive product profile

# Formulation and efficacy

- Marketed 1 month (1M) and 3 month (3M) formulations
- Maintenance of castrate testosterone levels at 3M in 98% of patients<sup>1</sup>
- At 3M, 91% decrease of PSA levels, showing tumor control

# Local tolerance/convenience

- IM route of administration, good local tolerance
- Injection not visible for the patient

# Storage and reconstitution

- Stored at room temperature
- 5 steps reconstitution
- Safety needle system

### Competitor 1

### Competitor 2

### Competitor 3

# Formulation and efficacy

- Various formulations across territories:
   1M formulation = 3,75mg or 7,5mg and 3M formulation = 11,25mg or 22,5mg
- Increased survival rate at 9 months in triptorelin group vs competitor 1<sup>2</sup>
- Conservation between 2 4° = needs to be warmed up before reconstitution
- Manual reconstitution to obtain SR
- Risk of nodules, abscess
- Ready to use implant
- Very large needle : need of local anesthesia

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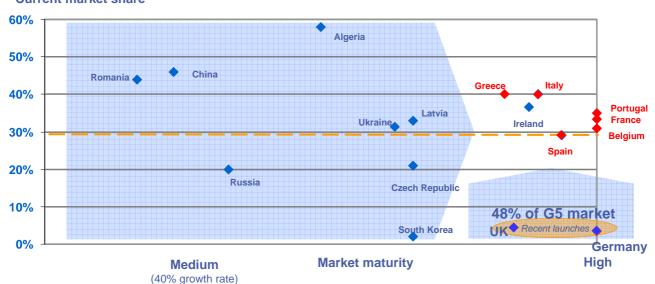
SOURCE: French SmPC

REFERENCE . 1: Teillac, Horm Res,2004, 252-58 2: Heyns, BJU Int, 2003, 226-231



# Decapeptyl®: strong positions, and poised to grow

### **Current market share**



Key
 Major Decapeptyl markets

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# Decapeptyl® 6 month formulation: a more differentiated product profile

Efficacy

- Comparable efficacy to 1 and 3 months formulation
  - Castration levels (testosterone)
  - Disease control (PSA)

Local Tolerance

Limited local side effects (6.7% of patients)

Storage and reconstitution

- Storage at room temperature (no need to heat up before reconstitution)
- 5 Steps to reconstitute, change needle, and inject IM route

### 6 month competitor 1

# Formulation/

- 80% of patients castrated after 6M<sup>2</sup>
- Testosterone to be tested every 6M\* 1
- Formation of Nodules or abscess <sup>1</sup>

### 6 month competitor 2

- Slow release formulation dependent on manual 60 mixture¹ step
- Storage at 2-4°: need to heat up for reconstitution ¹

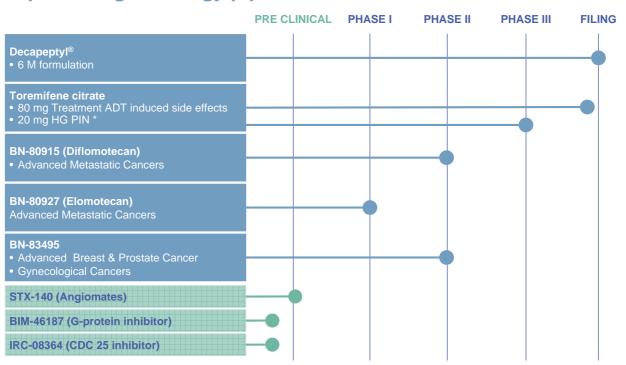
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Reference 1: French SmPC

<sup>2</sup>Avis de la commission de transparence



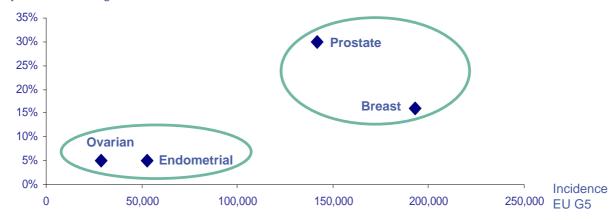
### A promising Oncology pipeline





### Moving up to higher prevalence diseases and higher unmet medical needs

5 year survival stage IV disease



Ipsen New Medical Entities: multi targeted agents aiming at large markets as well as niche indications with large unmet medical needs BN-83495 is potentially a company transforming product

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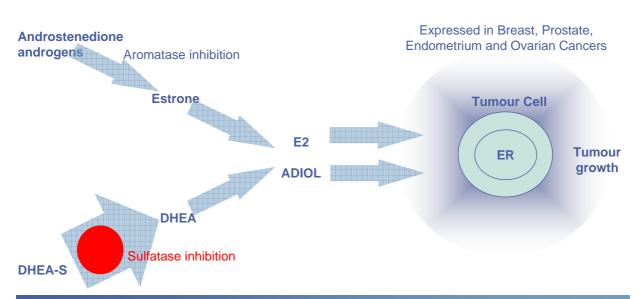
SOURCE: deVita (2008), Datamonitor

BN-83495



### Rationale for Sulfatase inhibitor development

Inhibition of Androstenediol synthesis from DHEA-S



Adiol can bind to oestrogen receptor and stimulate tumour growth (90% Adiol derived from DHEA-S in post-menopausal women)

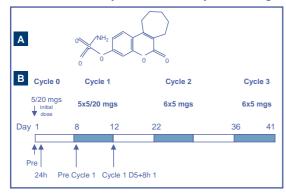


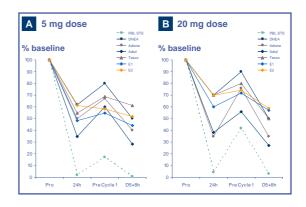


### First clinical study in Breast Cancer patients

STS inhibition leads to significant reduction in circulating steroids and induces clinical benefit\*\*

First clinical study CR UK \* - Daily x 5 dosing





Next step: confirmation of the results in Metastatic Breast Cancer and exploration of the full range of hormonal dependent tumours

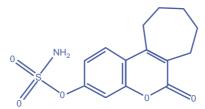
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\* SOURCE: Stanway, S. J. et al. Clin Cancer Res 2006;12:1585-1592 \*\* 3 patients with stable disease >6M

BN-83495



### BN-83495 in a nutshell: a new mechanism of action and potential therapeutic breakthrough



Tricyclic coumarin sulfamate

### Irreversible Oral steroid sulfatase (STS) inhibitor

Preclinical data supporting correlation between STS inhibition and tumour suppression in **Endocrine Cancers** 

Early clinical POC in metastatic Breast Cancer

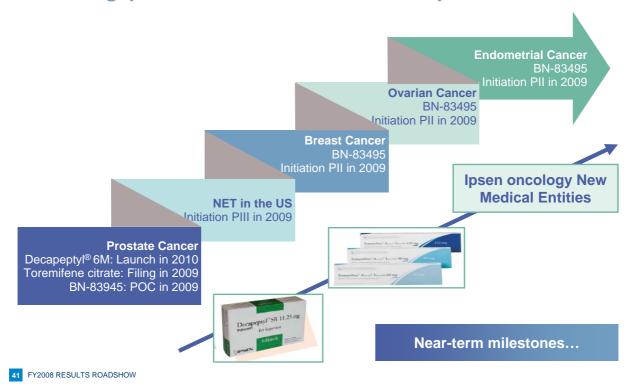
POC trial in HR Prostate Cancer commenced Jan. 2009

POC trials in Gynecological Cancers to commence in 2009

Strong patent platform position & available back-up



### **Confirming Ipsen as a leader in Hormone Dependent Cancers**

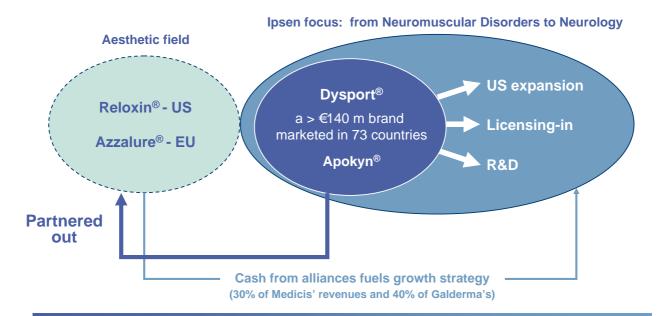


# From a Regional Neuromuscular Specialty to a Global Neurology Franchise





### A specific therapeutic focus

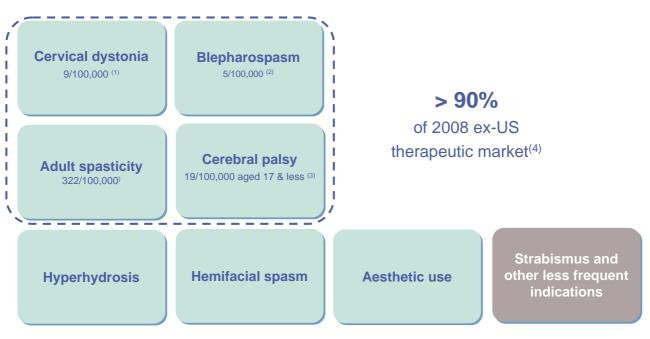


Dysport®: the cornerstone of a Neurology franchise

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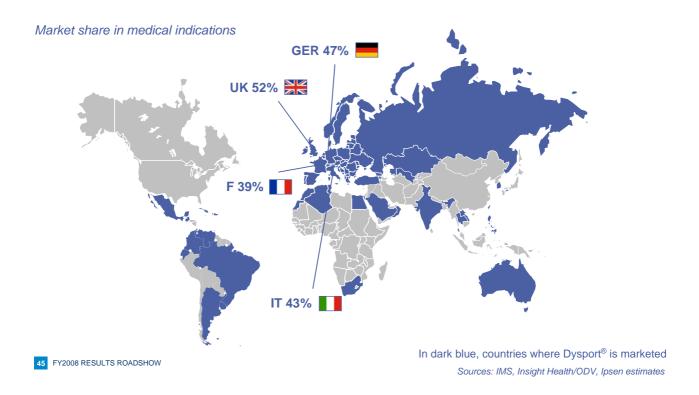


# Dysport®: approved ex-US in most key indications





# Dysport®: launched in 1991, approved in 73 countries





### A good track record at catching-up market shares...





# Dysport® in the US: a step further toward a global neurology franchise

- 1. Dysport®: a proven track record and field proven product
- 2. A true global product
- 3. A unique focus on medical use
- 4. Focus on US opportunity strong positioning with well prepared launch
  - Sound value proposition: the medical treatment alternative
  - Targeted and appropriate sales force
  - Managed care experience
- 5. Building up a neurology franchise leveraging the business development capability
- 6. Intense efforts in the discovery area



# A focused haematology presence





### An agent targeting both acquired and congenital hemophilia

### Congenital hemophilia A

with inhibitors to human FVIII

- Affects 1:4000 male births
- The development of neutralizing antibodies (inhibitors) to hFVIII following replacement therapy is a major complication
- Inhibitors develop in about 28% of severe patients and in between 3% to 13% of mild and moderate hemophilia A patients
- Patients no longer respond to hFVIII therapy

### Acquired hemophilia

Acquired factor VIII inhibitor

- Affects 1 to 2 individuals in 1,000,000. predominantly in older individuals
- A small proportion of younger patients may develop the disease, predominantly postpartum women
- Clinical manifestation is more severe and anatomically diverse than in congenital hemophilia A
- A mortality rate approaching 20%. Bleeding is often spontaneous or in response to minimal trauma

pFVIII is a promising treatment to stop bleeds in patients with inhibitors to hFVIII



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### Now preparing for phase 3...

2 prospective clinical trials, in liaison with Medical Community & Regulatory Agencies

Study in patients with acquired factor VIII inhibitor (acquired hemophilia)

> Treatment of all acute bleeding episodes

Study in patients with congenital hemophilia A and inhibitors to hFVIII

Treatment of life or limb threatening bleeding episodes

Both will be of similar design Open label, non comparative prospective studies, with about 40 patients in each study

Standards setting: first ever prospective trial in acquired hemophilia

Protocols finalization and pre-phase 3 CMC consultations with regulatory agencies to be completed in H1 2009



### A highly specialized hospital product addressing unmet need

First biologics to conclude Phase 2 resulting from strategic biotechnology platform

Patent protection until 2023 in Europe and US

World-wide commercialization rights

Lean commercial infrastructure

A commercial potential in excess of US\$200 million

Fourth specialty therapeutic focus in Haematology

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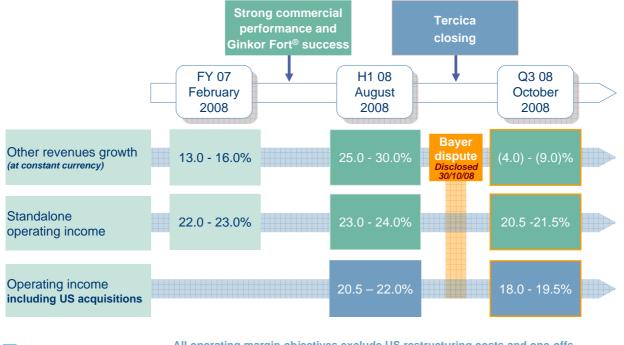
# **Appendix 1:**

**Evolution of our 2008 financial objectives** 





# **Evolution of our 2008 financial objectives**



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All operating margin objectives exclude US restructuring costs and one-offs and are stated in % of sales

# **Appendix 2:**

### **Financials**





# Key elements to take into consideration in 2008 over 2007

		2007	2008
Sales	Ginkor Fort® divestment	€37.0 m sales	€14.0 m sales
	Consolidation of US acquisitions	-	Q3&Q4 consolidated sales of €8.1 m
	Currency headwind	80 basis points negative impact on sales growth	
Other revenues	Dispute with Bayer		€25.0 m "miss"
	Ginkor Fort® milestones		€18.8 m net revenues booked





# Key elements to take into consideration in 2008 over 2007

		2007	2008	
COGS	R&D to COGS shift	+€.2 m Shifted <sup>(1)</sup>		
	Currency tailwind	R&D expenses up 4.5% at constant currency vs. (1.1)% as reported		
R&D	End of US filings preparation and FDA inspections	Industrial development expenses down 39% or €(10) million year on year		
	R&D to COGS shift	-	- €3.5 m shifted	
Taxes	US acquisitions	25.3% effective tax rate	17.4% effective rate vs. 20.9% w/o US losses	



### Top line evolution





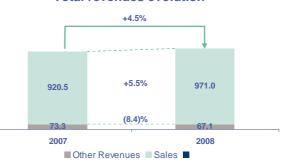
### Sales by region



#### Other revenues evolution



#### **Total revenues evolution**



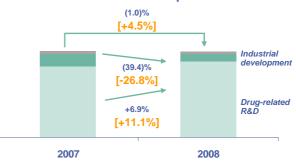
NOTE 1: At constant currency, excluding US & Ginkor Fort Sales NOTE 2:Impact from US acquisitions

# FIPSEN Innovation for patient core

### P&L - above EBIT

# 2007 COGS (% of sales) US and R&D shift impact

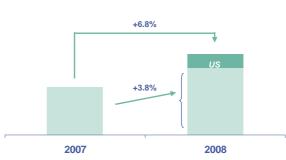
### **Research & Development**



### Sales & Marketing



G&A



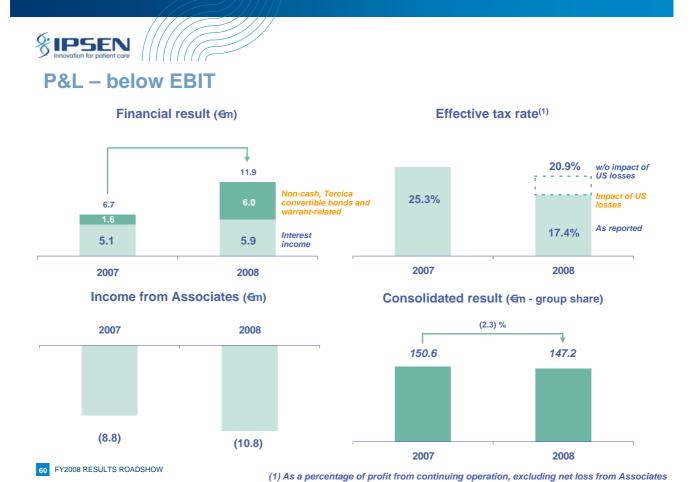


# P&L – operating result and margin



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Margins expressed in % of sales





### **Balance Sheet evolution**

- In million of euros Asset	S		- In million of euros Liabil	ities	
	31 Dec 07	31 Dec 08		31 Dec 07	31 Dec 08
Goodwill	189.0	351.7	Equity	799.9	866.9
Property, plans & equipments	221.9	237.9	Minority interests	1.2	1.6
Intangible assets	89.2	163.9	Total equity	801.1	868.5
Other non-current assets	185.3	125.9	Long-term financial debts	20.8	162.7
Total non-current assets	685.4	879.4	Other non-current liabilities	221.0	217.6
Total current assets	636.8	689.1	Short-term debts	9.2	8.3
Incl. cash and cash equivalents	247.1	239.6	Other current liabilities	265.5	307.8
Assets / discontinued operations	0.7	1.3	Liabilities / discontinued operations	5.3	4.9
Total assets	1322.9	1569.8	Total Liabilities	1322.9	1569.8
Net Cash (1)	217.8	66.2			



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### Cash flow statement

Cash flow statement			
	31 Dec 07	31 Dec 08	Comments
- In million of euros			Deferred revenues net increase :
Cash Flow before change in working capital	214.3	196.5	+ €17.0m
- Increase / Decrease in working capital	(38.3)	6.9	Decrease of Bayer receivables :
Net cash flow generated by operating activities	176.0	203.4	+€10.9m  Receivables, payables, inventory
Investment in intangible assets and property, plant & equipment excl. US acquisitions	(76.5)	(73.1)	and others – €21.0m
US acquisitions	(46.5)	(216.5)	Tangible assets : -€61.4m
Others	(17.3)	4.4	Intangible assets : - €33.8m
Net cash flow used in investing activities	(140.3)	(285.2)	■ Divestment & others : €22.1m
Net change in borrowings	(1.9)	141.0	US acquisitions
Dividends paid	(50.4)	(55.0)	o acquicitions
Others	(24.5)	(7.0)	\
Net cash flow used in financing activities	(76.8)	79.0	▶ Draw dawn of syndicated credit
Discontinued operations	1.3	0.7	facility +€150m
Change in cash and cash equivalent	(39.8)	(2.1)	
Impact of exchange rate fluctuations	(3.0)	(1.5)	
Closing cash & cash equivalents	240.9	237.3	
Closing Net Cash(1)	217.8	66.2	

(1) Net cash: cash, cash equivalents and securities held for sales minus bank overdrafts, bank borrowings and other financial liabilities plus or minus derivative financial instruments

### **Appendix 3: Definitions**





### 'Standalone' Group sales:

Group sales at constant currency, less its North American fourth quarter 2008 <u>consolidated</u> sales

### 'Performance' or 'underlying' growth:

Group sales growth at constant currency, excluding the sales of Ginkor Fort® in 2007 and 2008 as the product was divested on January 1, 2008) and excluding North American fourth quarter 2008 consolidated sales

### 'Adjusted' operating margin:

Group operating margin excluding US acquisition related impacts such as purchase price accounting elements or recurring elements