

# Confirming Ipsen's specialist care globalisation

*Credit Suisse – Conference  
London, March 3<sup>rd</sup>, 2010*



## Disclaimer

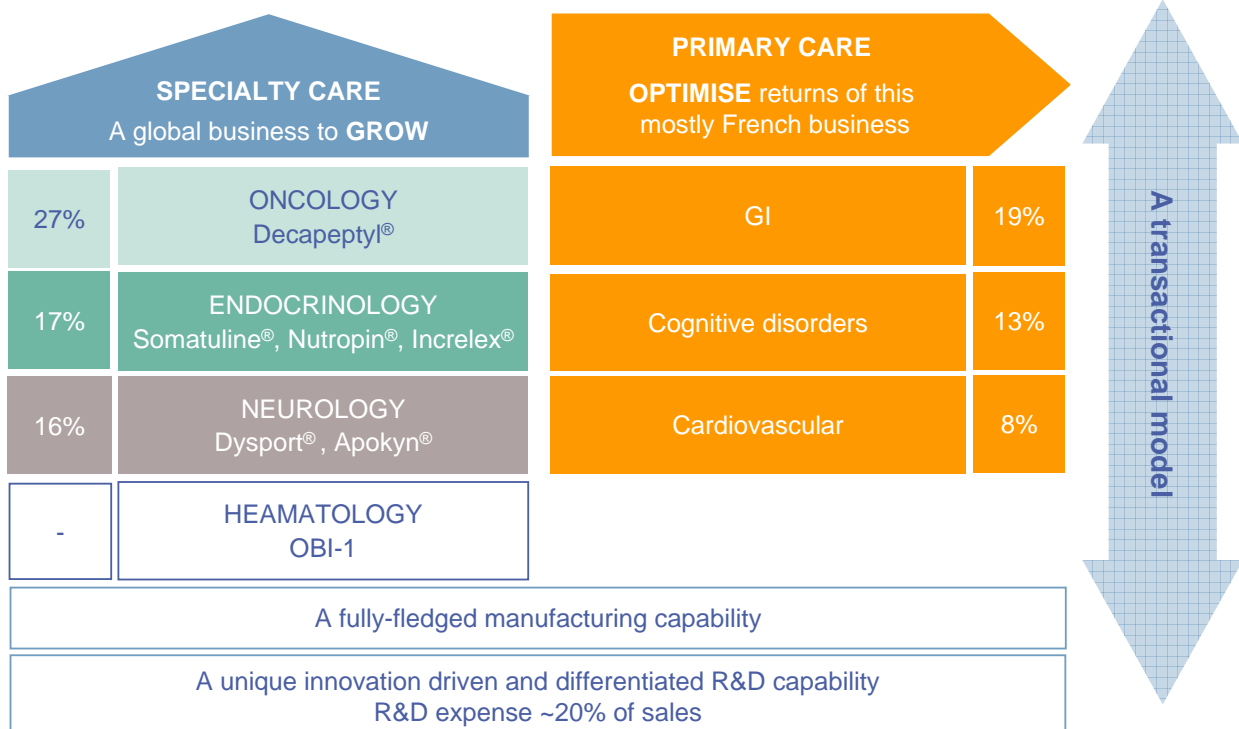
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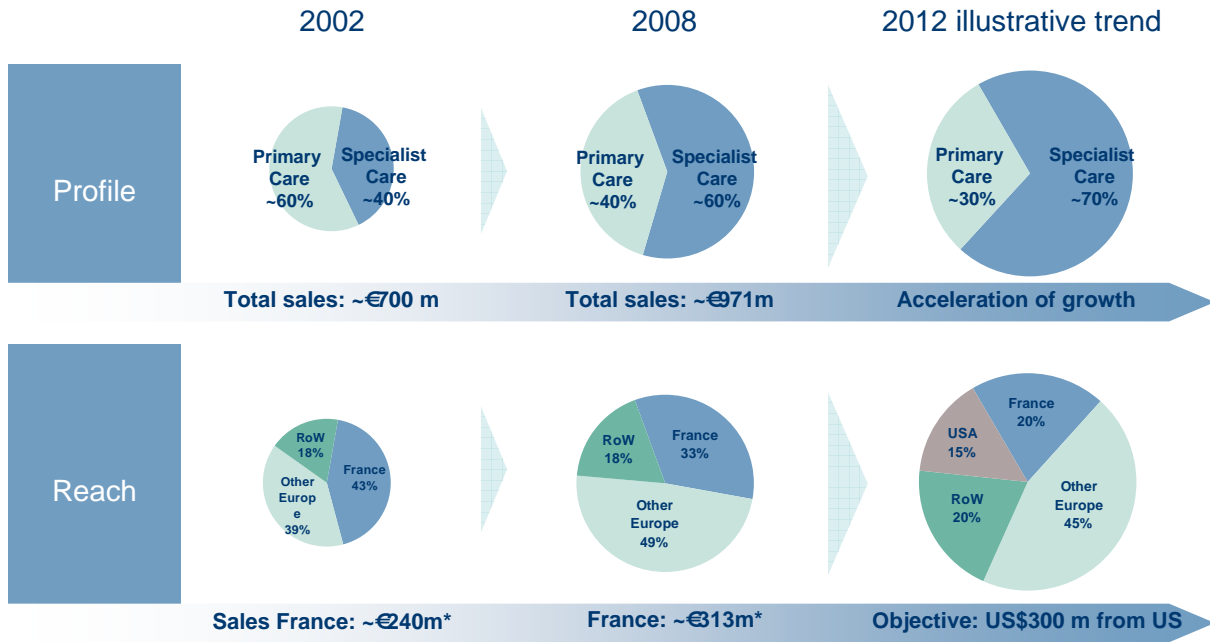
# Introduction



## Ipsen today : a global, innovation driven, specialty pharma

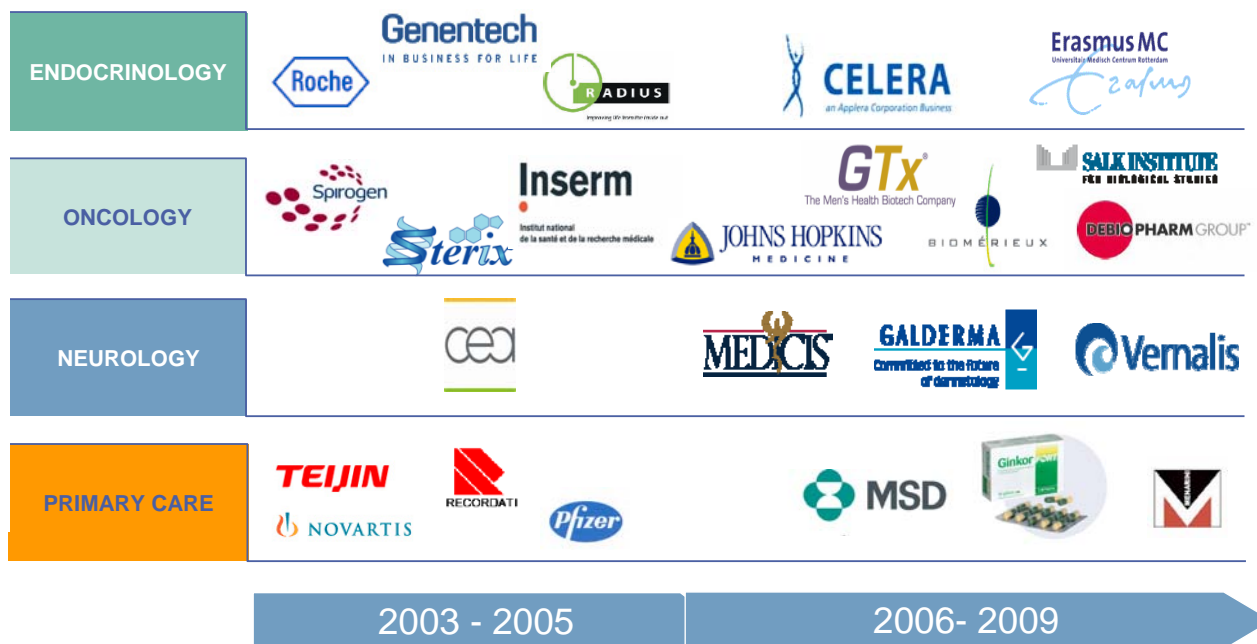


## A reinforced profile and reach



\* Excludes sales of Ginkor Fort (€61 million in 2002, €14 million in 2008)  
 specialist care and primary care relative weights are expressed as a % of total Drug sales

## An increasingly transactional model



## Ipsen today....

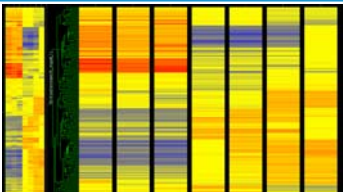


- ➔ Resilience of business in a **difficult macro-economic environment**
- ➔ A **strong and profitable specialty care** growth engine
- ➔ Substantial growth opportunities **through globalization and US entry**
- ➔ A rich and well balanced R&D pipeline, **with potential blockbusters**
- ➔ A strong cash flow generation and balance sheet

## Truly Differentiated R&D Capabilities

## Defining Ipsen's competitive edge in R&D

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

Resident know how based on the integration of basic discovery technologies

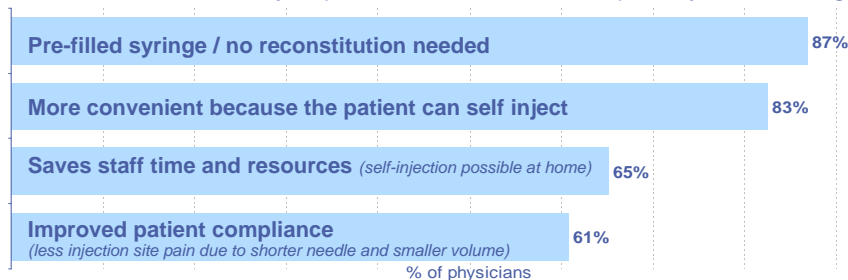
Technologies	Medicinal chemistry	Delivery systems
Target identification, validation and drugability based on clinical observations supported by ...omics technologies	Steroids peptides, proteins engineering aiming at enhanced efficacy, potency, selectivity and safety over the endogenous hormone	Emphasis on improved pharmacological properties, optimization of dosing regimen and improved patients compliance and convenience
		

## Example 1 : Somatuline<sup>®</sup> Depot, an improved presentation

	Sandostatin LAR <sup>®</sup>	Somatuline <sup>®</sup> Autogel <sup>®</sup>
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<sup>®</sup> Depot to your acromegaly patients?\*\*\*



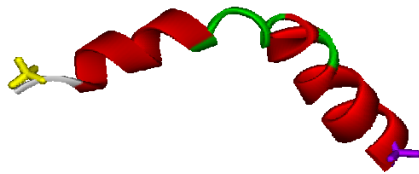
\* In selected countries



## Example 2 : a unique technology convergence, taspoglutide

### Once-a-week 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  
Quarter inch long
- Taspoglutide Liquid SRF → 29G  
**Insulin type needle** for subcutaneous injection

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



## Taspoglutide Toxicology Roche/Ipsen perspective on GLP-1s and C-cell thyroid tumors

### Results

- Results of carcinogenicity studies support the ongoing clinical development of taspoglutide;
- These results apply to mice as well

### Disclosure

- We will share the results of the 2 year toxicology studies with the regulatory authorities first and may share the data with the public at a later point in time

## Reminder - **ADA 2009** last toxicology update Roche/Ipsen perspective on GLP-1s and C-cell thyroid tumors

### Preliminary incidence

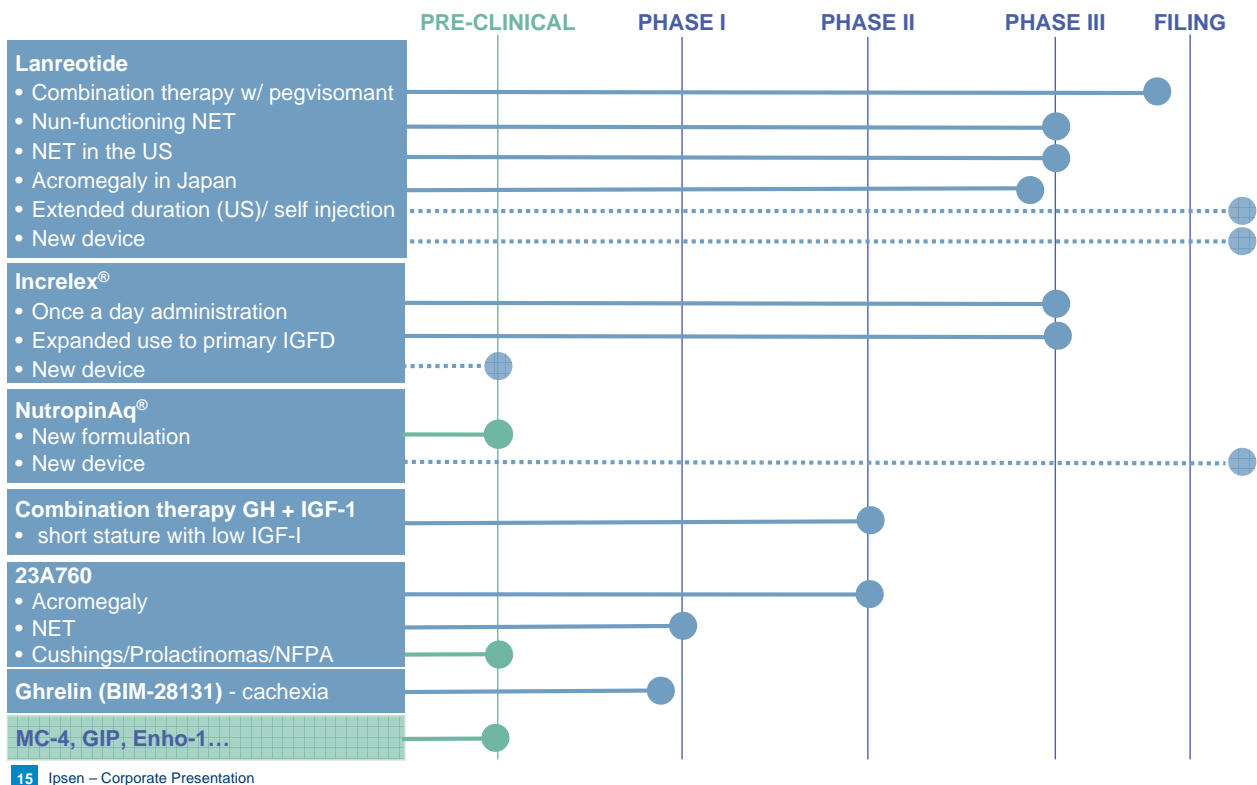
- Tasoglutide carcinogenicity program ongoing
  - Preliminary incidence of C-cell hyperplasia and adenoma was observed in a small number of animals
  - Safety data not final yet; aiming for high-quality analysis to obtain reliable results

### Disclosure

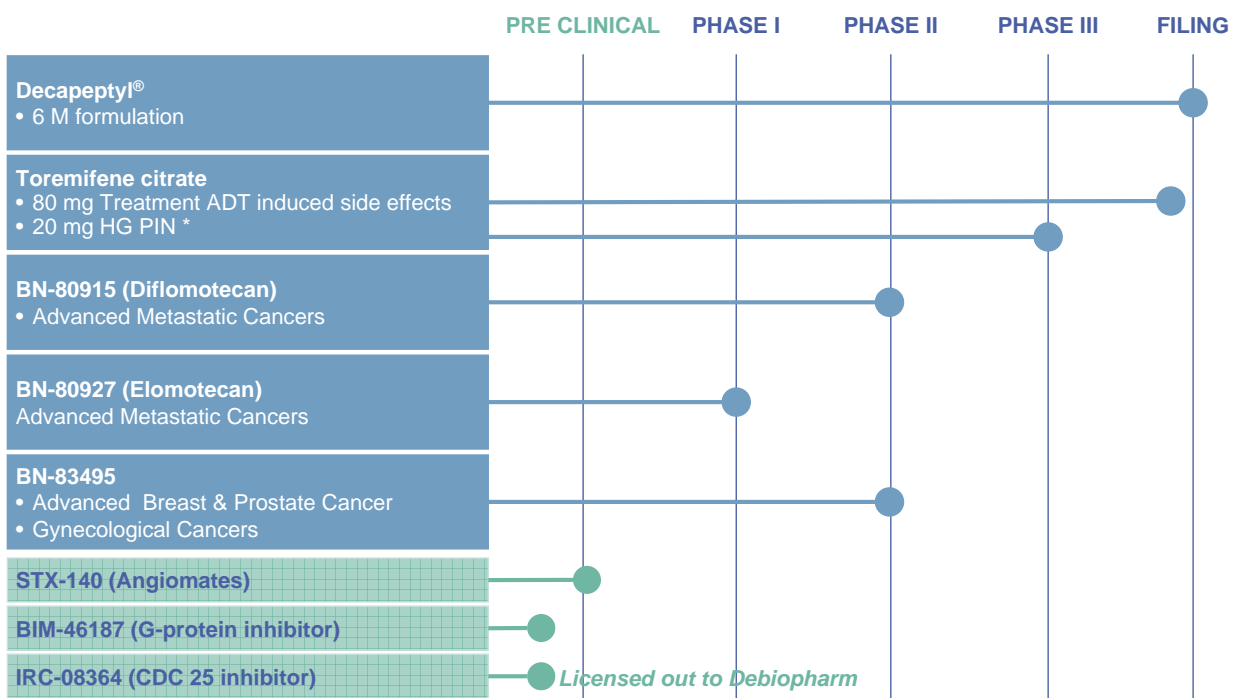
- Clinical relevance of proliferative lesions in rodents under investigation
  - Working hypothesis: C-cell effects are rodent-specific
  - Appropriate pre-clinical mechanistic studies underway
  - Calcitonin monitoring in phase III

## A rich and promising pipeline

## A rich endocrinology pipeline



## A promising Oncology pipeline

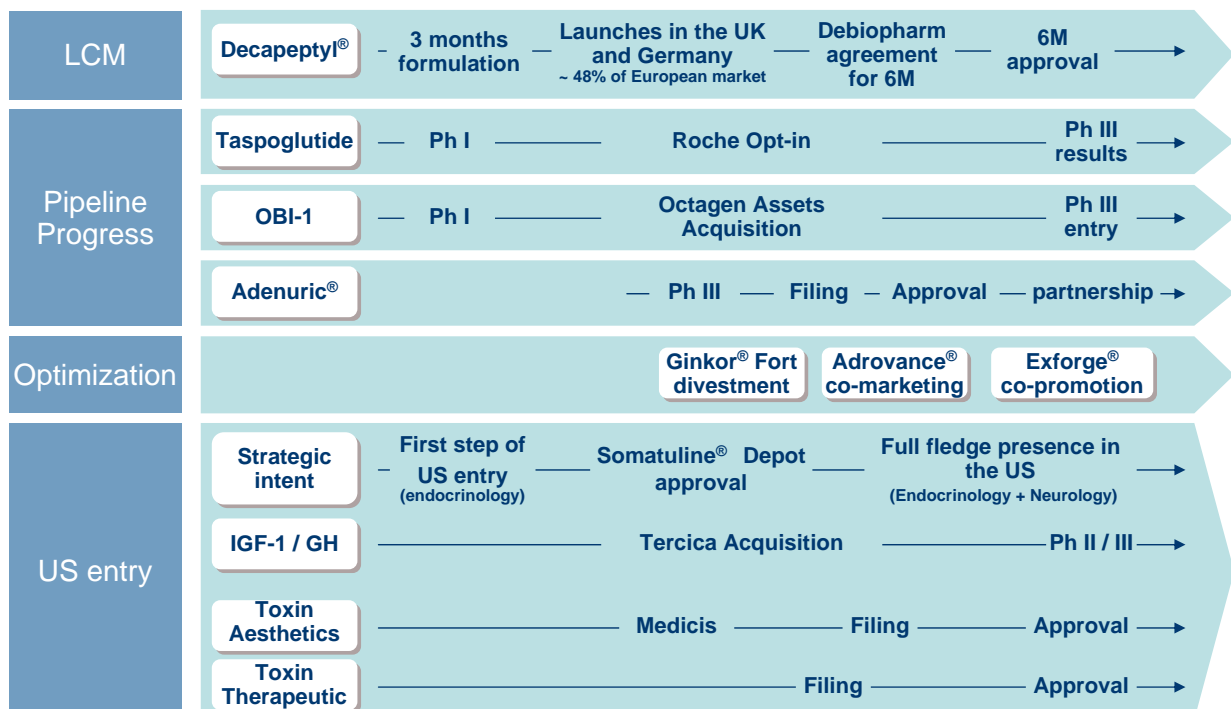




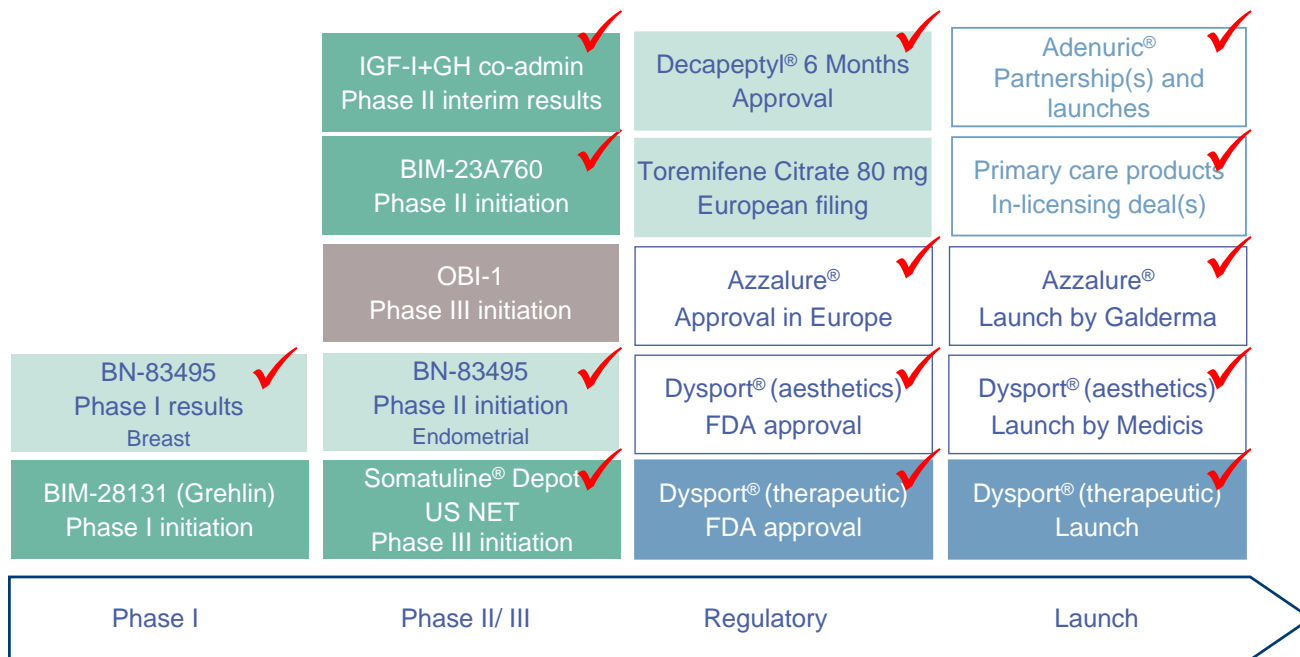
# Progress and Outlook



## A track record for consistently delivering on strategic milestones



## All key milestones delivered year-to-date



## 2009 financial objectives confirmed

**Drug sales growth of 7.0 to 9.0%**

**Other revenues<sup>1</sup> of approximately €30 million**

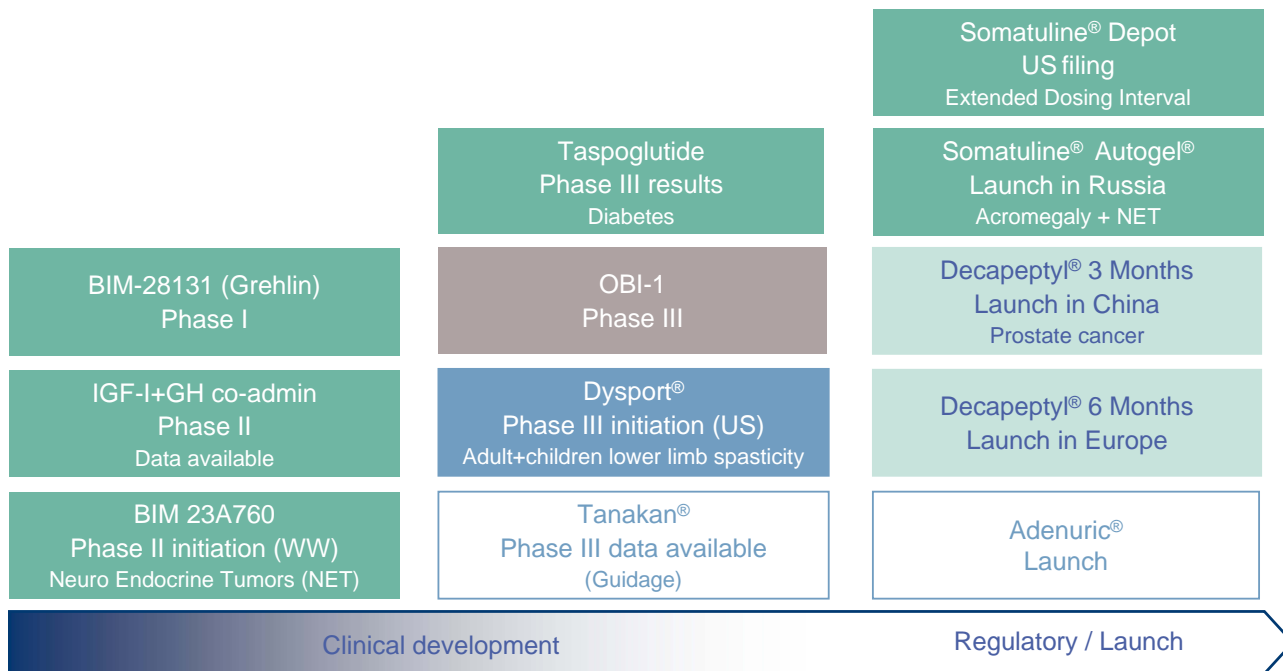
**Operating margin before goodwill allocation<sup>2</sup> of 17.0% - 17.5%**

*The above objectives include the full Kogenate® royalty stream*

1- Defined as the total of milestone payments received under licence agreements, royalties received from third parties and other revenue (including for example co-promotion revenues)

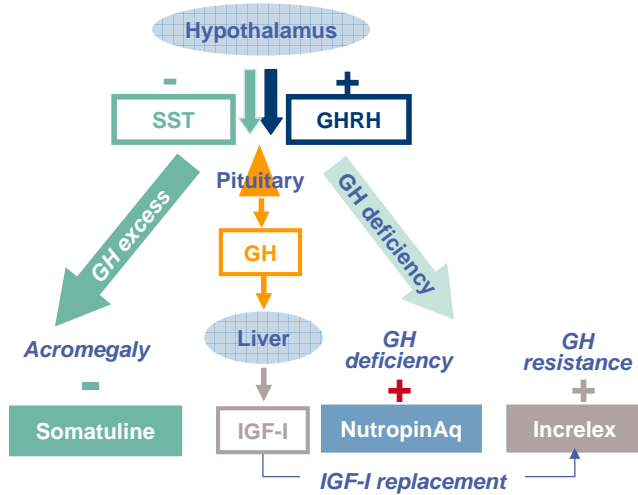
2- These financial objectives do not include items resulting from purchase price accounting impacts related to the Group's transactions in North America

## A rich newsflow in 2010



## An endocrinology franchise outgrowing competition

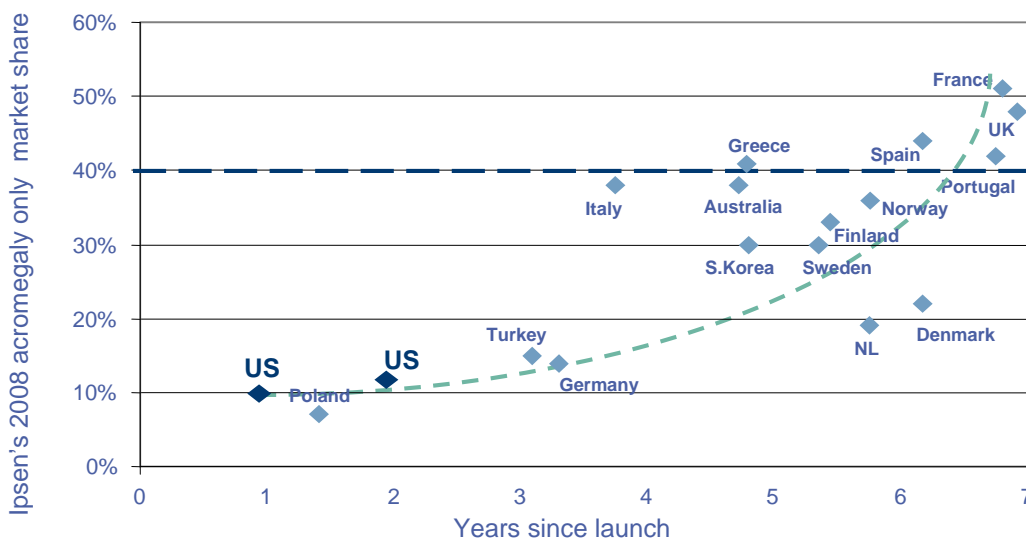
## A unique focus on pituitary disorders and hormone dependent diseases



### 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

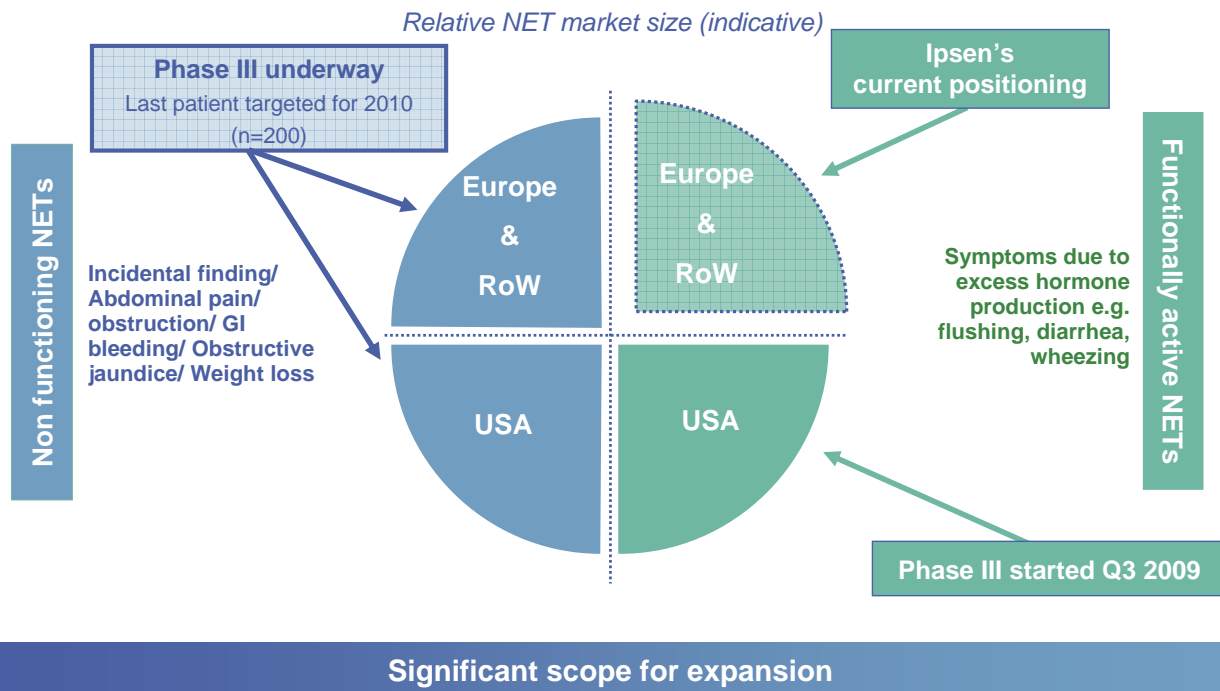
## Somatuline® Depot is poised to grow and gain market share



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



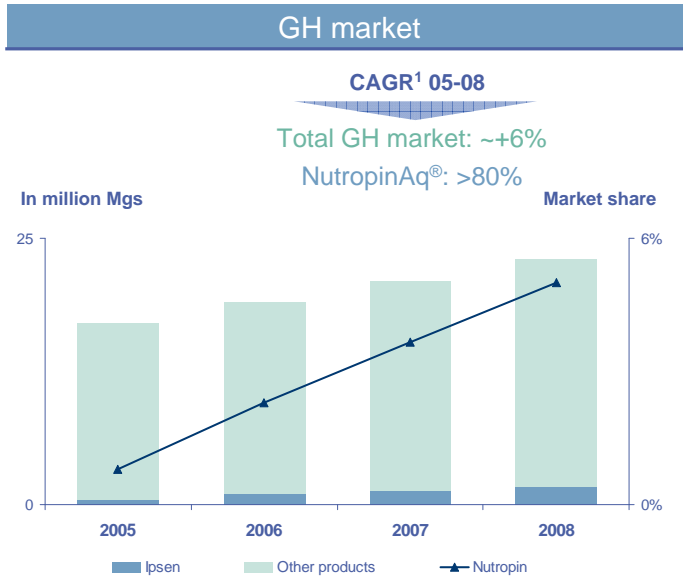
## Somatuline® offers significant life cycle growth opportunities



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

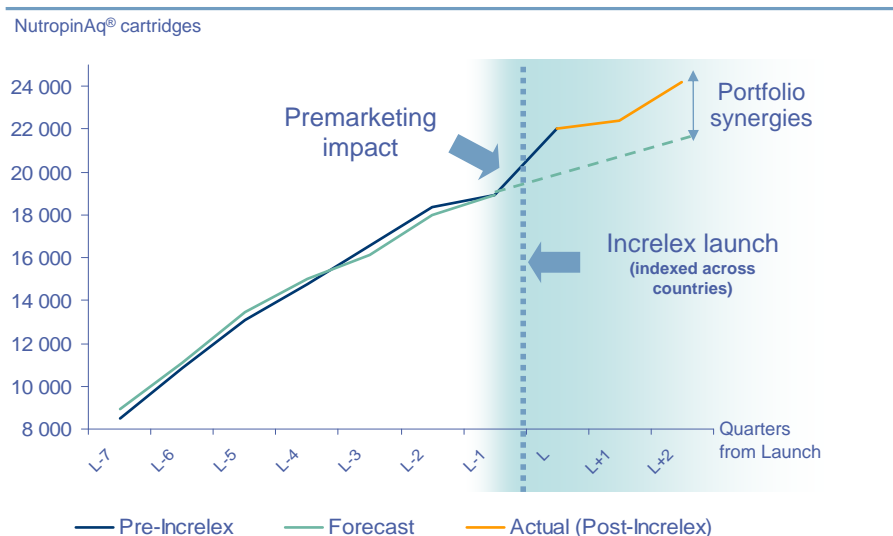
Physician demand	<ul style="list-style-type: none"> <li>Target audience : ~1,000 US paediatric endocrinologists</li> <li>Up to 20% of Rx come from new prescribers each month</li> <li>2/3 of pediatric endocrinologists have prescribed Increlex®; 78% continued prescription</li> </ul>
Reimbursement success	<ul style="list-style-type: none"> <li>~ 90% of private and public covered lives have formulary access</li> <li>75% Increlex patients approved upon final decision (similar to GH)</li> </ul>
Patient experience	<ul style="list-style-type: none"> <li>Sharp increase in patients on Increlex® initially GH-naïve to 60% in '08 from 30% in '07</li> <li>Dose increasing to appropriate targets, to 100 mcg/kg BID in '08 from 70 mcg/kg BID in '07</li> <li>Younger patients initiated with Increlex®, to average age at start of 10.0 years old in '08 from 11.5 years in '07</li> </ul>

## NutropinAq<sup>®</sup> in Ipsen territories is steadily gaining market share



- NutropinAq<sup>®</sup> attributes**
- 1<sup>st</sup> liquid formulation launched WW
  - A simple and user friendly pen
  - An experienced post marketing surveillance database
  - A dedicated experienced and professional team

## NutropinAq<sup>®</sup> + Increlex<sup>®</sup>: evidence of portfolio synergy

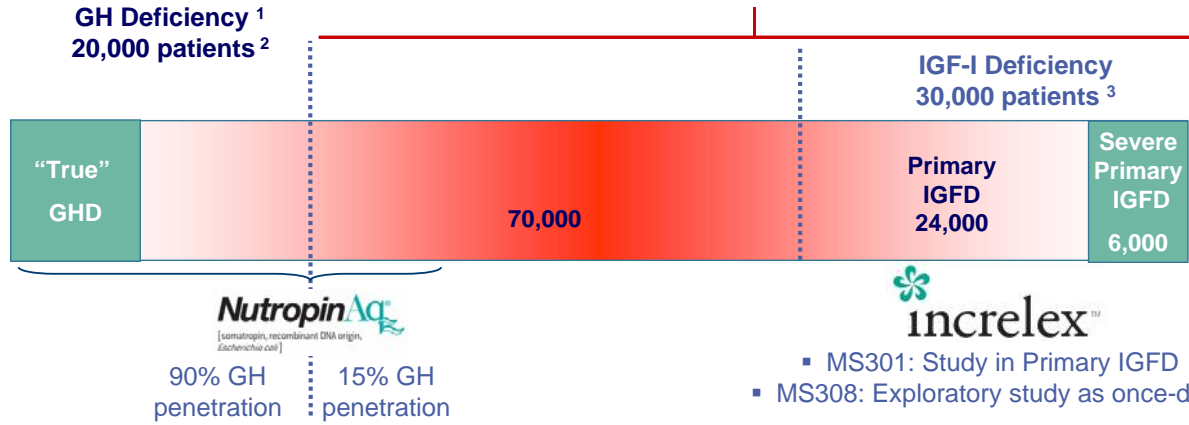


**More than 25% favorable impact**

“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

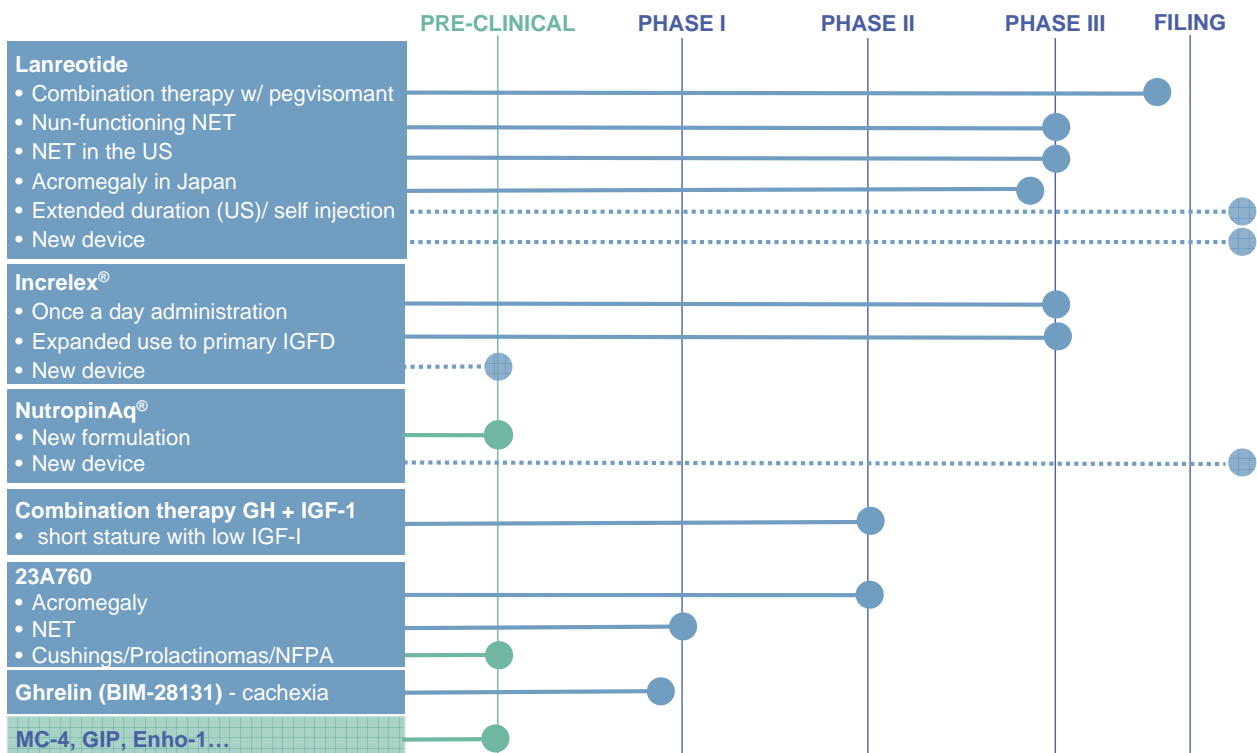
Non-GH Deficient Short Stature: 100,000 patients in the US



### COMBO in IGFD

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

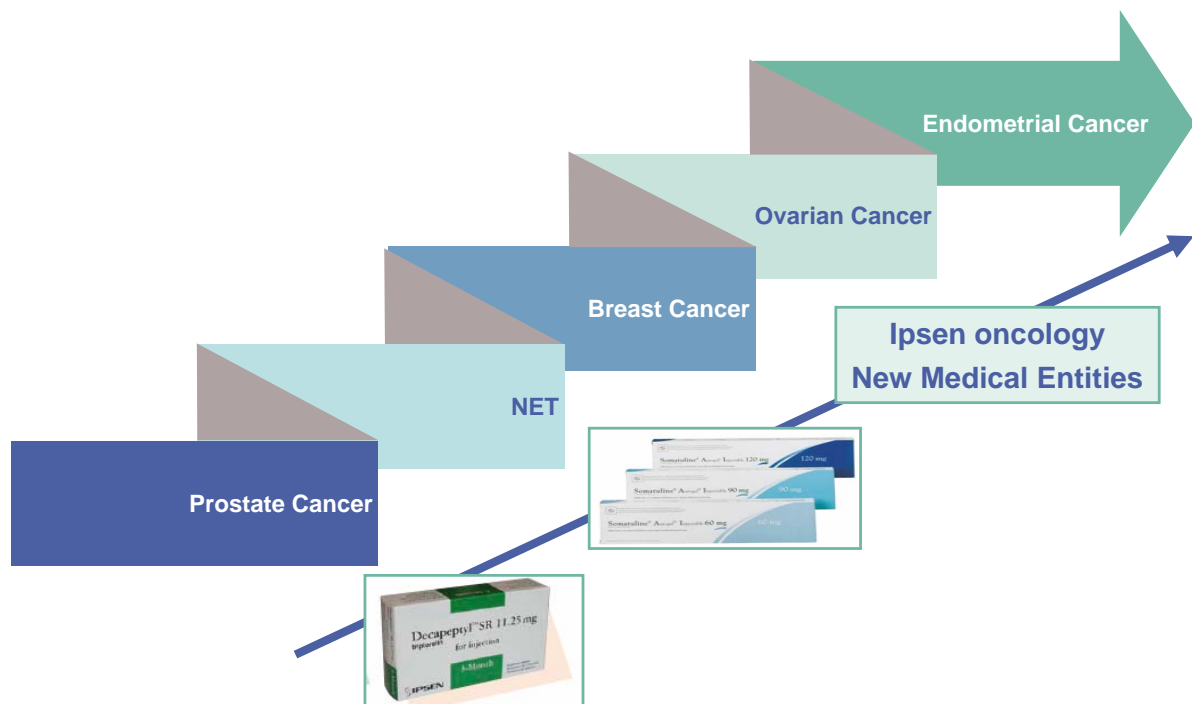
## A rich endocrinology pipeline



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



## Confirming Ipsen as a leader in Hormone Dependent Cancers

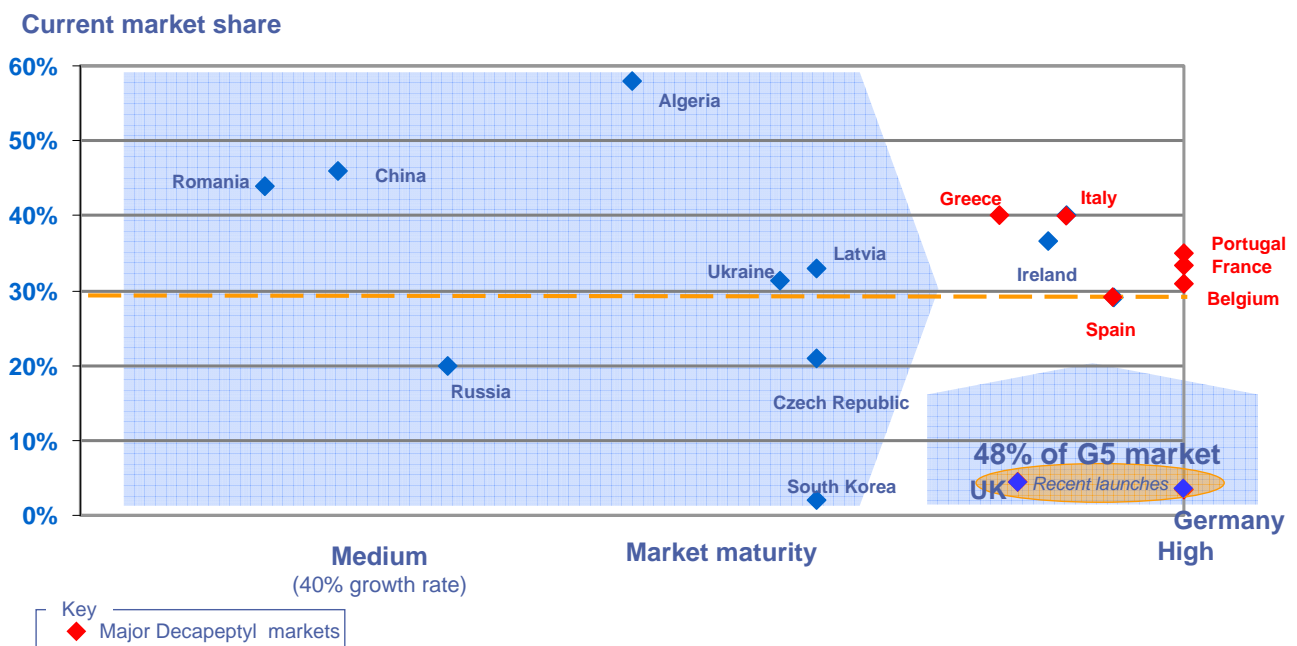




## Decapeptyl® 3 months formulation: a competitive product profile

<b>Formulation and efficacy</b>	<ul style="list-style-type: none"> <li>Marketed 1 month (1M) and 3 month (3M) formulations</li> <li>Maintenance of castrate testosterone levels at 3M in 98% of patients<sup>1</sup></li> <li>At 3M, 91% decrease of PSA levels, showing tumor control</li> </ul>		
<b>Local tolerance/ convenience</b>	<ul style="list-style-type: none"> <li>IM route of administration, good local tolerance</li> <li>Injection not visible for the patient</li> </ul>		
<b>Storage and reconstitution</b>	<ul style="list-style-type: none"> <li>Stored at room temperature</li> <li>5 steps reconstitution</li> <li>Safety needle system</li> </ul>		
<b>Formulation and efficacy</b>	<b>Competitor 1</b>	<b>Competitor 2</b>	<b>Competitor 3</b>
	<ul style="list-style-type: none"> <li>Various formulations across territories : 1M formulation = 3,75mg or 7,5mg and 3M formulation = 11,25mg or 22,5mg</li> <li>Increased survival rate at 9 months in triptorelin group vs competitor 1<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>Conservation between 2 - 4° = needs to be warmed up before reconstitution</li> <li>Manual reconstitution to obtain SR</li> <li>Risk of nodules, abscess</li> </ul>	<ul style="list-style-type: none"> <li>Ready to use implant</li> <li>Very large needle : need of local anesthesia</li> </ul>

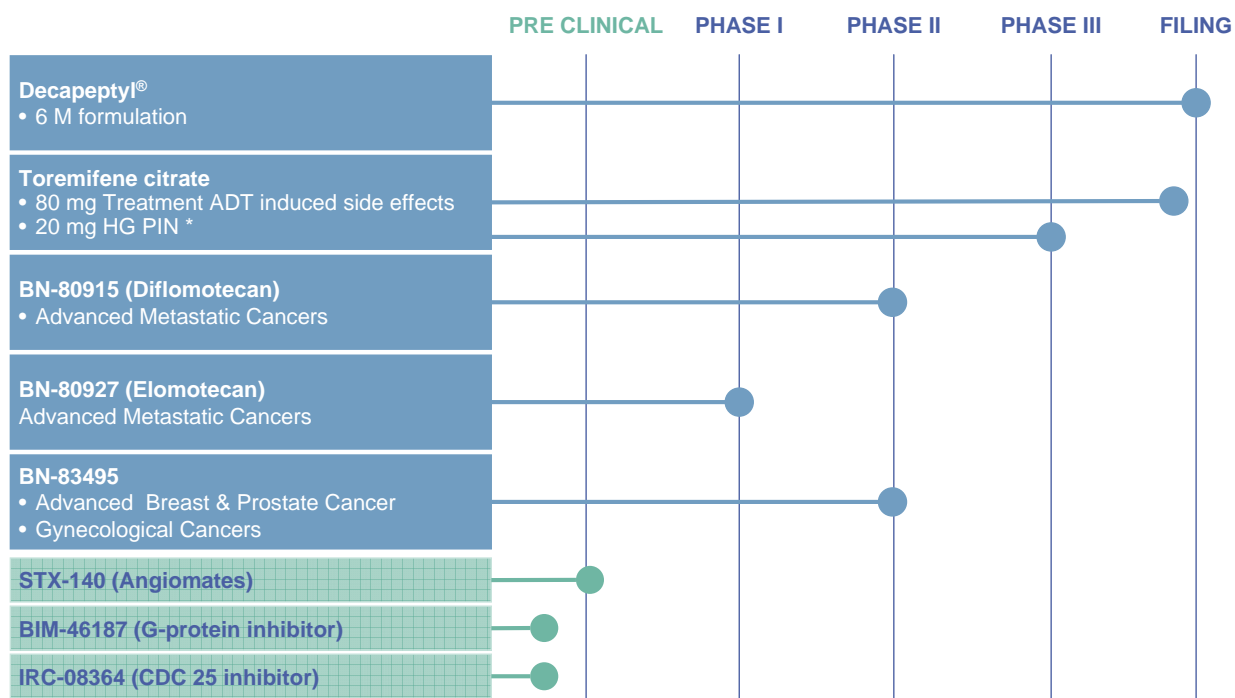
## Decapeptyl®: strong positions, and poised to grow



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

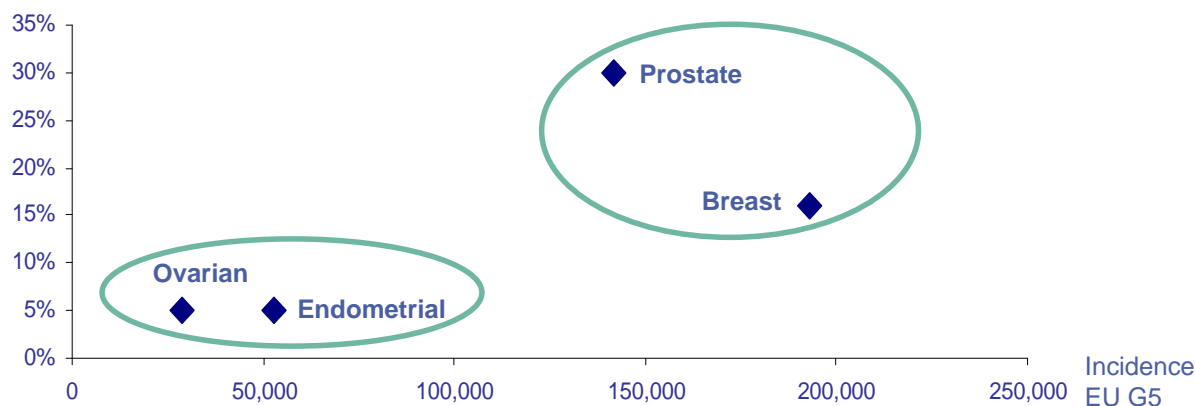
Efficacy	<ul style="list-style-type: none"> <li>▪ Comparable efficacy to 1 and 3 months formulation                             <ul style="list-style-type: none"> <li>• Castration levels (testosterone)</li> <li>• Disease control (PSA)</li> </ul> </li> </ul>				
Local Tolerance	<ul style="list-style-type: none"> <li>▪ Limited local side effects (6.7% of patients )</li> </ul>				
Storage and reconstitution	<ul style="list-style-type: none"> <li>▪ Storage at room temperature (no need to heat up before reconstitution)</li> <li>▪ 5 Steps to reconstitute, change needle, and inject - IM route</li> </ul>				
Formulation/ Efficacy	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #4F81BD; color: white; padding: 5px;">6 month competitor 1</th> <th style="background-color: #4F81BD; color: white; padding: 5px;">6 month competitor 2</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;"> <ul style="list-style-type: none"> <li>▪ 80% of patients castrated after 6M<sup>2</sup></li> <li>▪ Testosterone <u>to be tested</u> every 6M*<sup>1</sup></li> <li>▪ Formation of Nodules or abscess<sup>1</sup></li> </ul> </td> <td style="padding: 5px;"> <ul style="list-style-type: none"> <li>▪ Slow release formulation dependent on manual 60 mixture<sup>1</sup> step</li> <li>▪ Storage at 2-4°: need to heat up for reconstitution<sup>1</sup></li> </ul> </td> </tr> </tbody> </table>	6 month competitor 1	6 month competitor 2	<ul style="list-style-type: none"> <li>▪ 80% of patients castrated after 6M<sup>2</sup></li> <li>▪ Testosterone <u>to be tested</u> every 6M*<sup>1</sup></li> <li>▪ Formation of Nodules or abscess<sup>1</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ Slow release formulation dependent on manual 60 mixture<sup>1</sup> step</li> <li>▪ Storage at 2-4°: need to heat up for reconstitution<sup>1</sup></li> </ul>
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## A promising Oncology pipeline



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

5 year survival stage IV disease



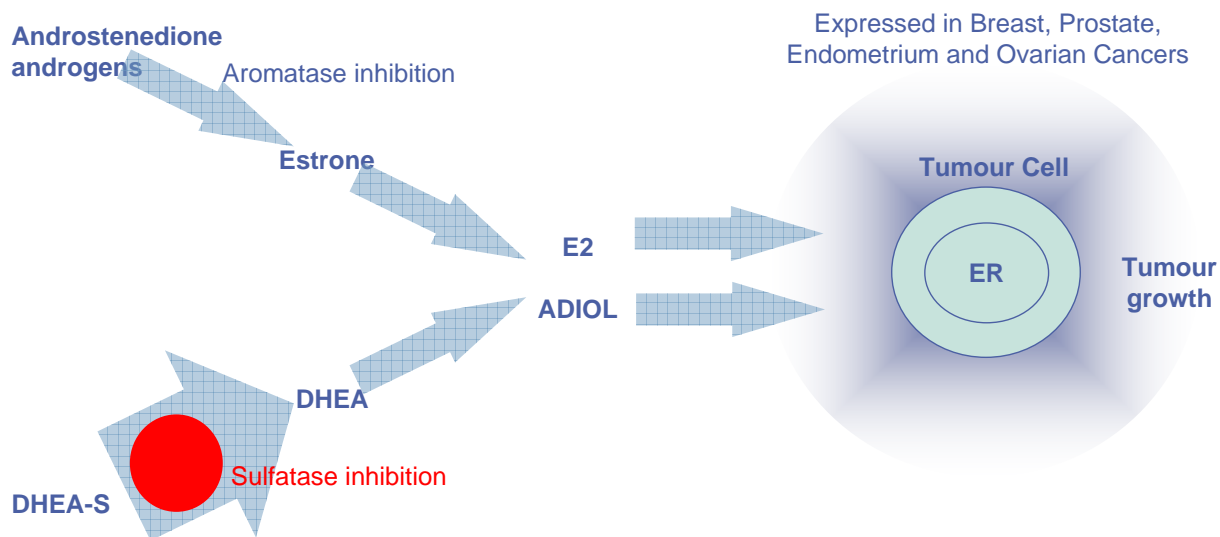
**Ipsen New Medical Entities: multi targeted agents aiming at large markets as well as niche indications with large unmet medical needs**  
**BN-83495 is potentially a company transforming product**

## Oristusane : Moving forward in the development stages

Endometrial	<ul style="list-style-type: none"> <li>Phase II initiated : Post-menopausal women with advanced or recurrent endometrial cancer (80 patients)               <ul style="list-style-type: none"> <li>First patient dosed on November 25</li> </ul> </li> </ul>
Breast	<ul style="list-style-type: none"> <li>Phase I/ II on going in ER-positive metastatic breast cancer (35 patients)               <ul style="list-style-type: none"> <li>Optimal biological dose determined :40 mg once daily oral administration</li> <li>95% inhibition of the target enzyme (STS) was achieved in peripheral blood mononuclear cells</li> <li>Additional 15 patients included to study target enzyme (STS) inhibition in cancerous cell</li> </ul> </li> </ul>
Prostate	<ul style="list-style-type: none"> <li>Phase II initiated – Dose escalation</li> </ul>
Ovarian	<ul style="list-style-type: none"> <li>Course of action being defined</li> </ul>

## Rationale for Sulfatase inhibitor development

Inhibition of Androstenediol synthesis from DHEA-S

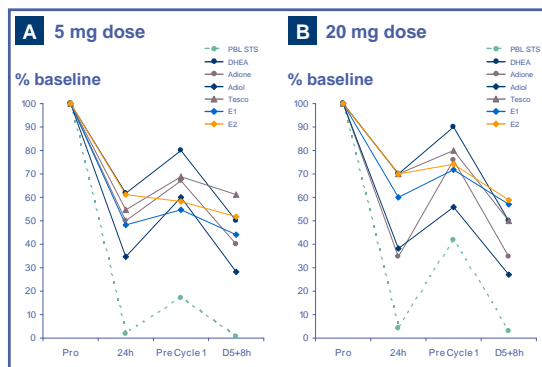
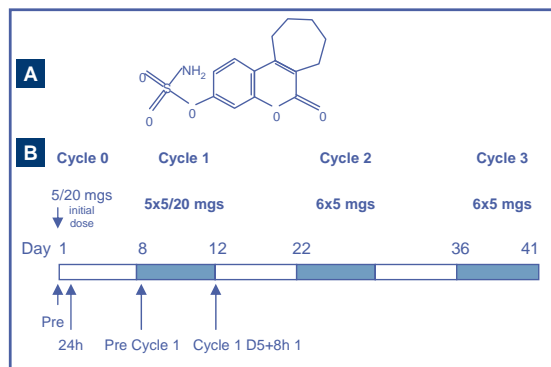


**Adiol can bind to oestrogen receptor and stimulate tumour growth (90% Adiol derived from DHEA-S in post-menopausal women)**

## First clinical study in Breast Cancer patients

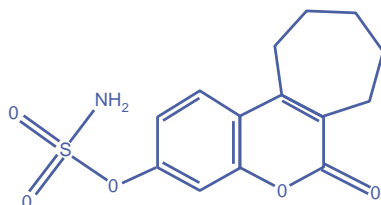
**STS inhibition leads to significant reduction in circulating steroids and induces clinical benefit\*\***

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**

## 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

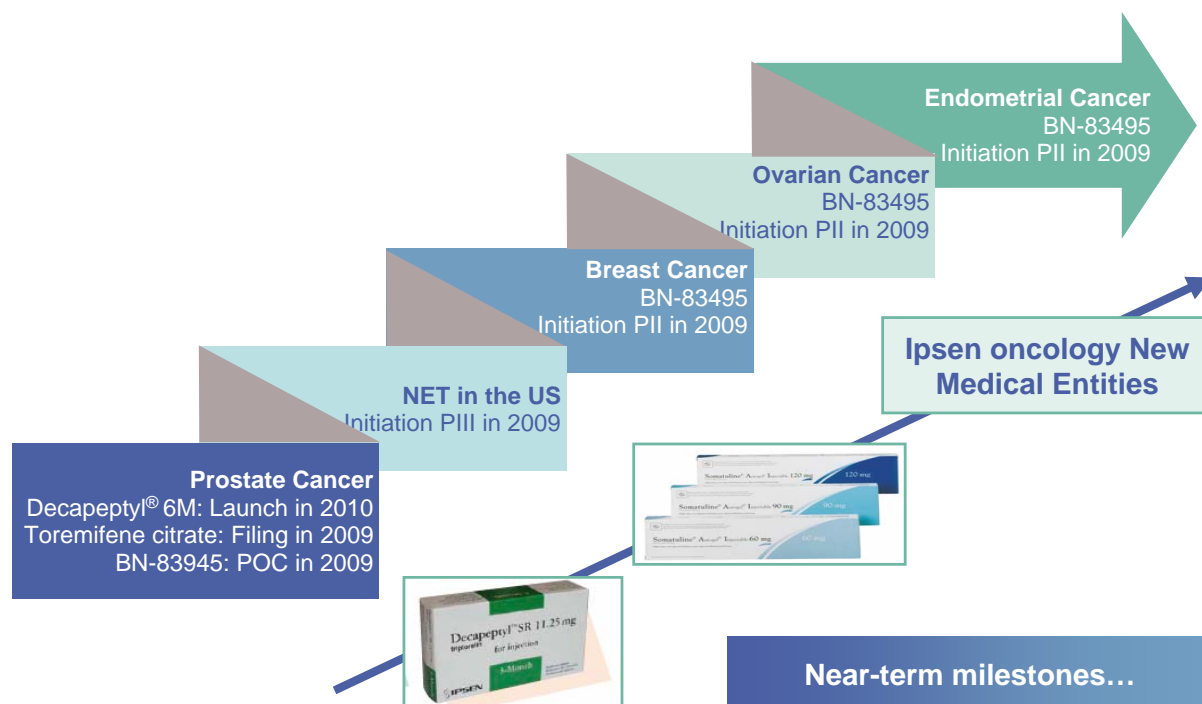
Early clinical POC in metastatic Breast Cancer

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

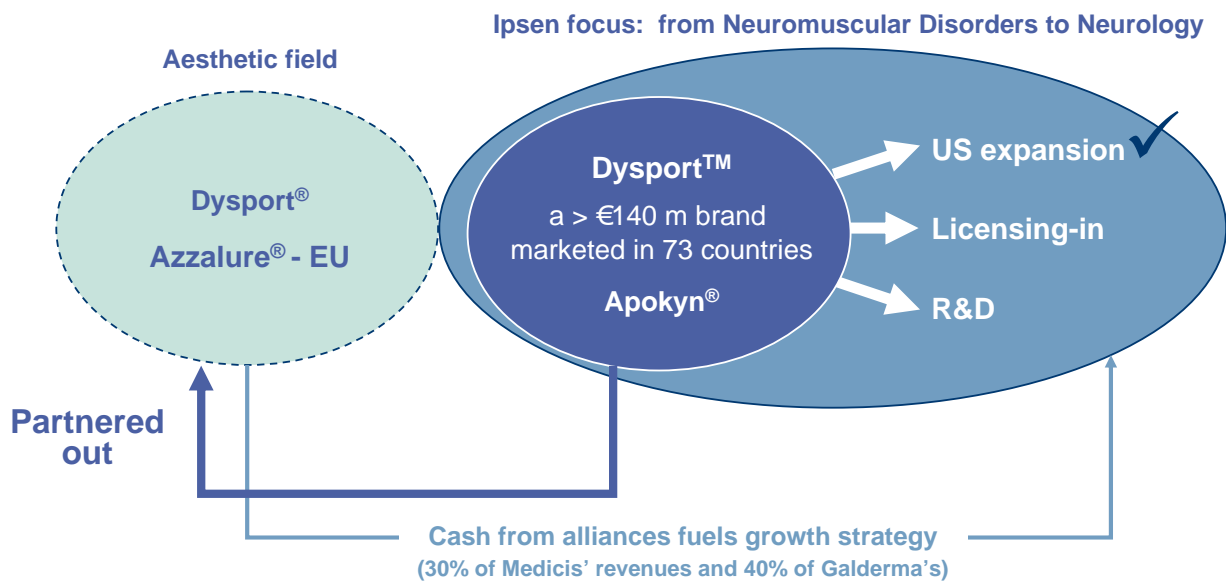
## Confirming Ipsen as a leader in Hormone Dependent Cancers



# From a Regional Neuromuscular Specialty to a Global Neurology Franchise

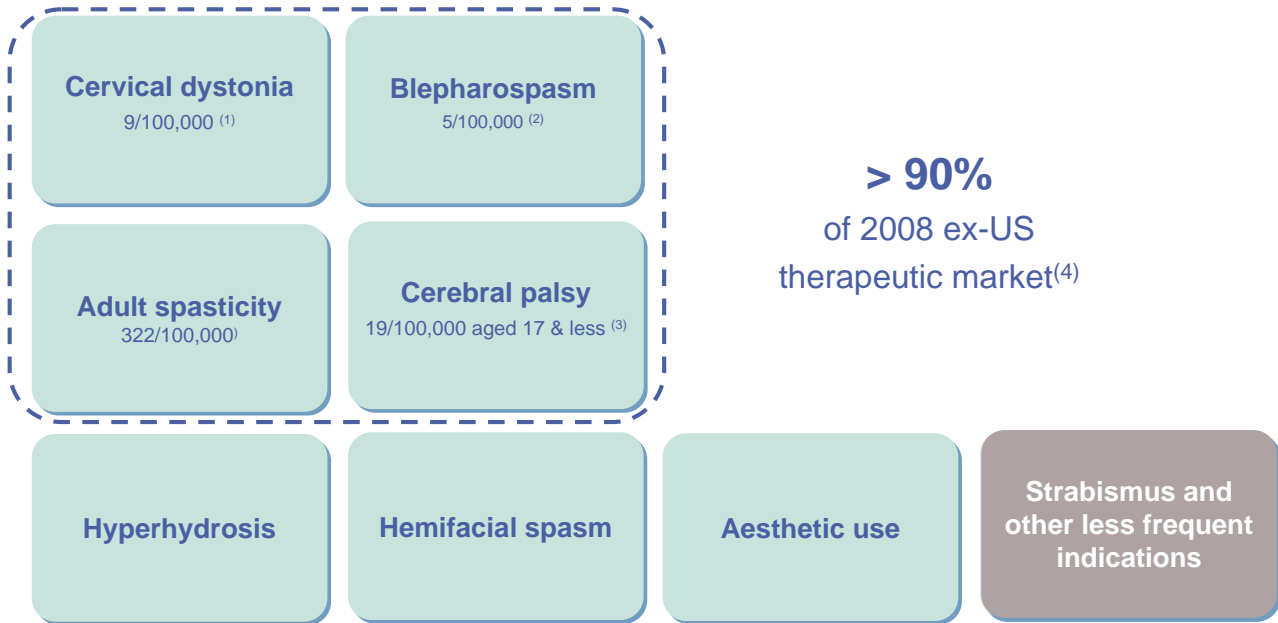


## A specific therapeutic focus



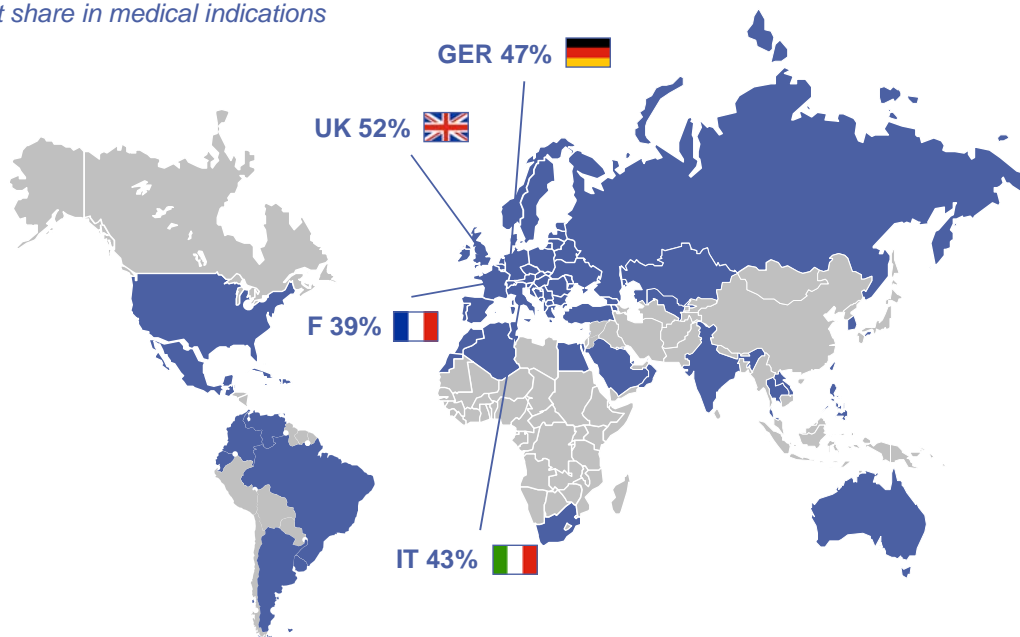
Dysport<sup>®</sup>: the cornerstone of a Neurology franchise

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



## Dysport®: launched in 1991, approved in more than 75 countries

Market share in medical indications



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

Market share in medical indications



## 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 post-partum 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**

## 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**

## First half 2009 achievements



### A strong commercial performance in the first half 2009

6.3% Drug sales growth,  
in line with our full-year objective

A solid 11.5% specialist care sales growth,  
with endocrinology up 32.7% year-on-year

Stabilisation in Eastern Europe, with Q2 sales up 1.0% year-on-year

Dynamic growth in the US, with Somatuline<sup>®</sup>,  
Increlex<sup>®</sup> and Apokyn<sup>®</sup> generating \$23 million, up 33% Q2 over Q1

## A strong profitability and cash generation

25.0% operating margin pre-goodwill allocation

A 'clean operating margin'\* of 18.0%, compared with 21.6% a year ago

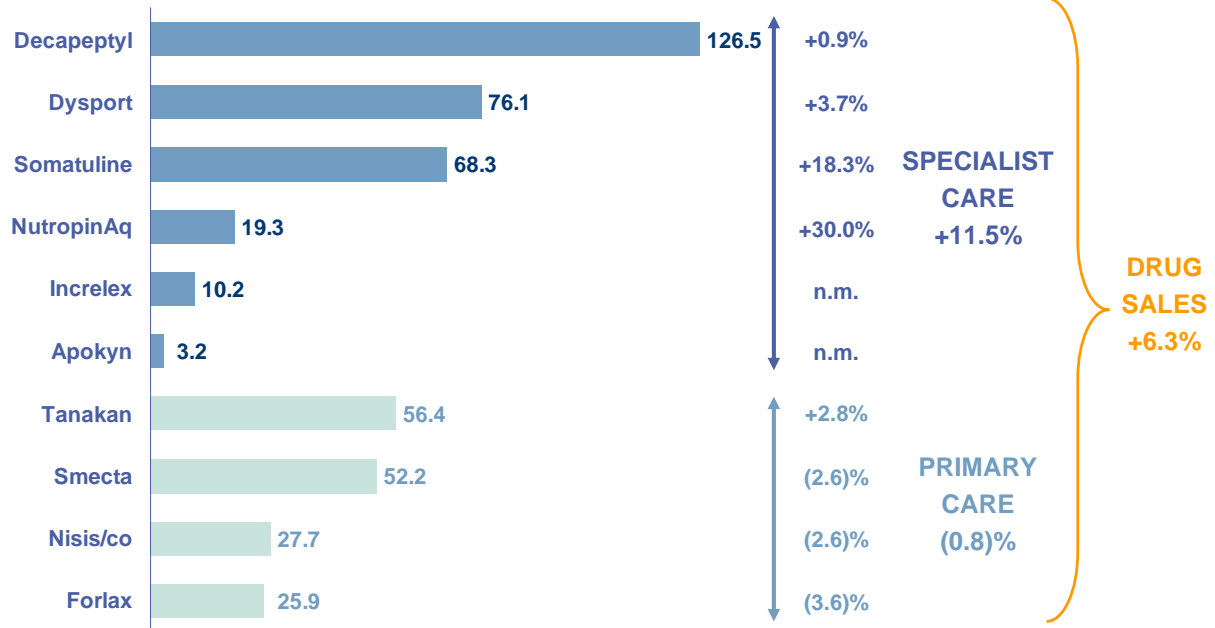
€147 m generated by operating activities, versus €124 m a year ago

€139 m net cash position as at June 30, 2009,  
post €203 m net cashed-out on US acquisitions in H2 08

## First half 2009 detailed financial performance

## Main products performances

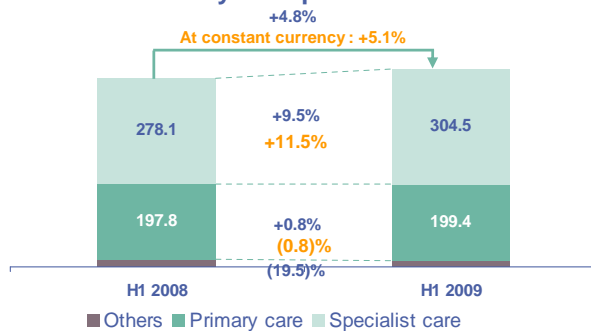
Sales in € million



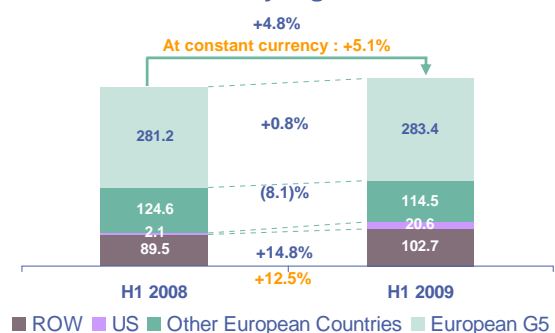
NOTE: % sales growth at constant currency

## Top line evolution

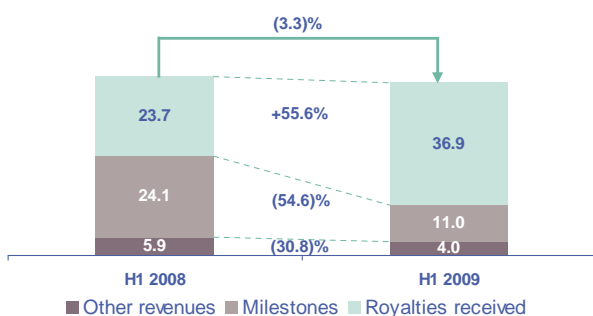
### Sales by therapeutic area



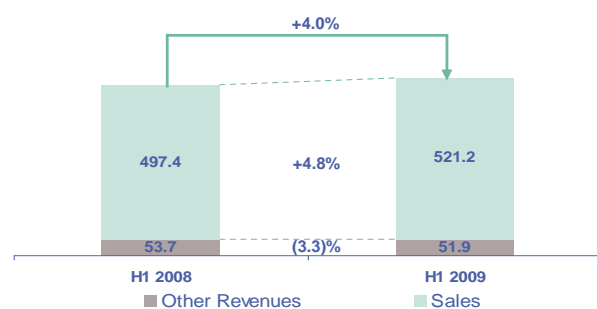
### Sales by region



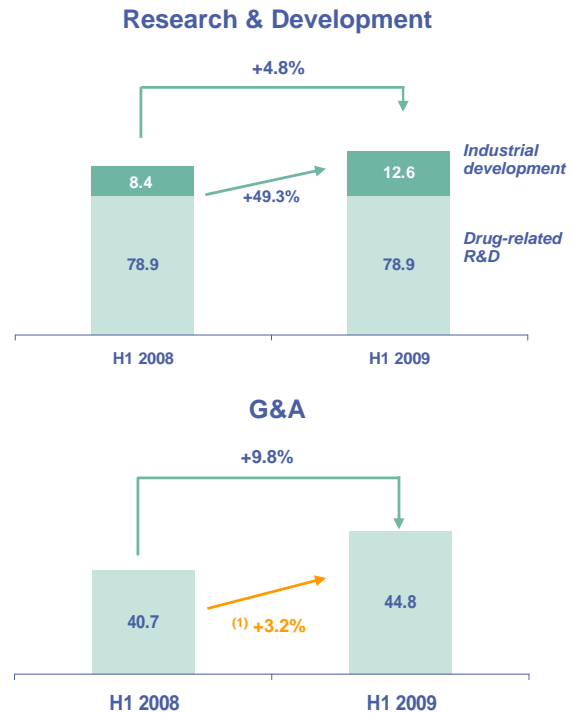
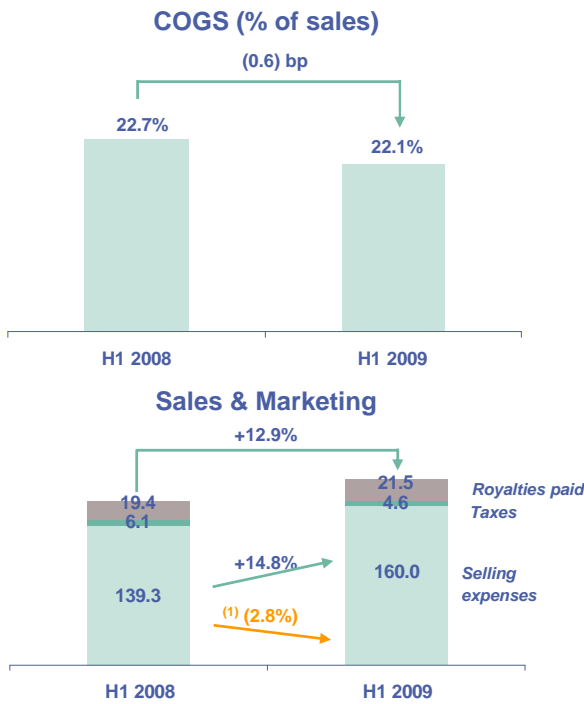
### Other revenues evolution



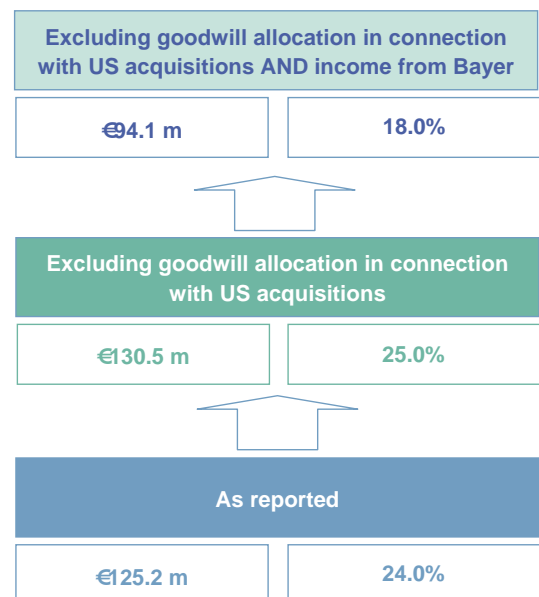
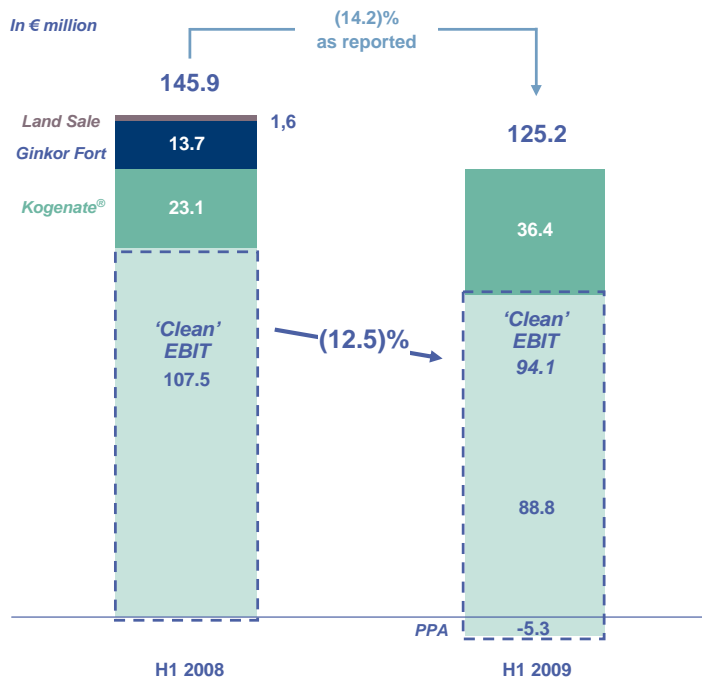
### Total revenues evolution



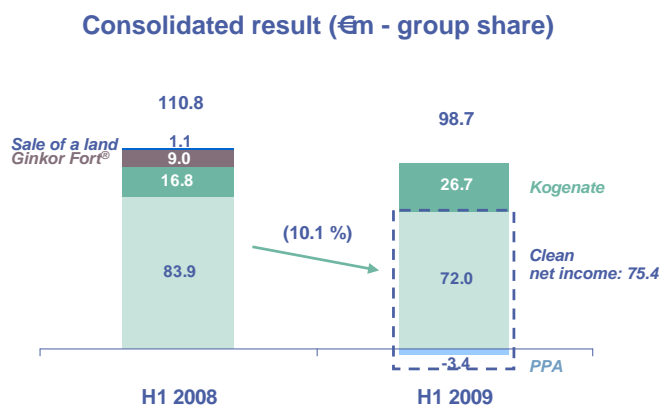
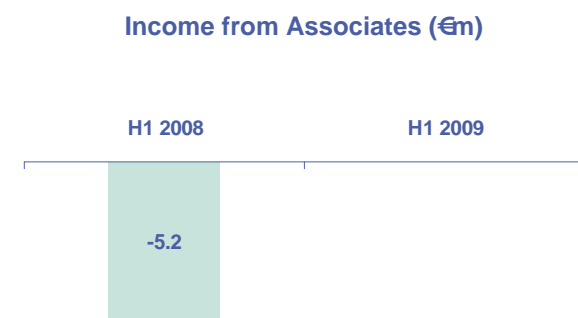
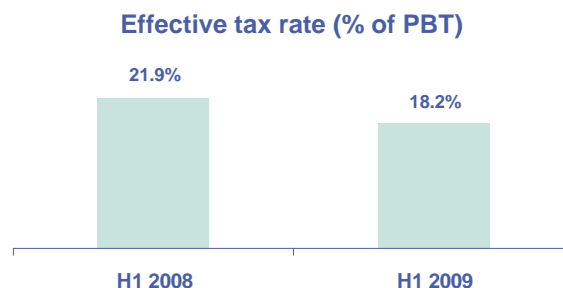
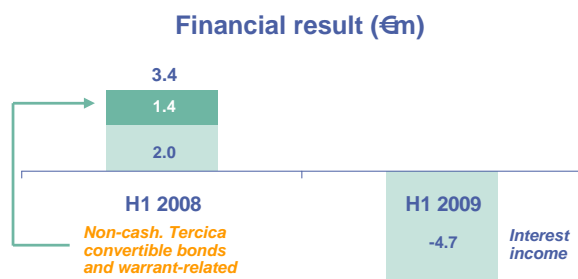
## P&L – above EBIT



## P&L - EBIT



## P&L – below EBIT



## Balance Sheet evolution

- In million of euros

	31 Dec 08	30 Jun 09
<b>Goodwill</b>	( <sup>1</sup> ) 290.8	290.8
<b>Property, plans &amp; equipments</b>	237.9	244.7
<b>Intangible assets</b>	( <sup>1</sup> ) 232.9	239.3
<b>Other non-current assets</b>	( <sup>1</sup> ) 112.9	140.5
<b>Total non-current assets</b>	( <sup>1</sup> ) 874.5	915.3
<b>Total current assets</b>	( <sup>1</sup> ) 688.6	589.7
<i>Incl. cash and cash equivalents</i>	239.6	140.2
<b>Assets / discontinued operations</b>	1.3	0.7
<b>Total assets</b>	1 564,4	1 505.8
<b>Net Cash</b>	66.2	118.9

- In million of euros

	31 Dec 08	30 Jun 09
<b>Equity</b>	( <sup>1</sup> ) 885.0	928.4
<b>Minority interests</b>	1.6	1.8
<b>Total equity</b>	( <sup>1</sup> ) 886.6	930.2
<b>Long-term financial debts</b>	160,4	12.7
<b>Other non-current liabilities</b>	( <sup>1</sup> ) 196,4	276.3
<b>Short-term debts</b>	8.3	8.0
<b>Other current liabilities</b>	307.8	275.1
<b>Liabilities / discontinued operations</b>	4.9	3.5
<b>Total Liabilities</b>	1 564,4	1 505.8

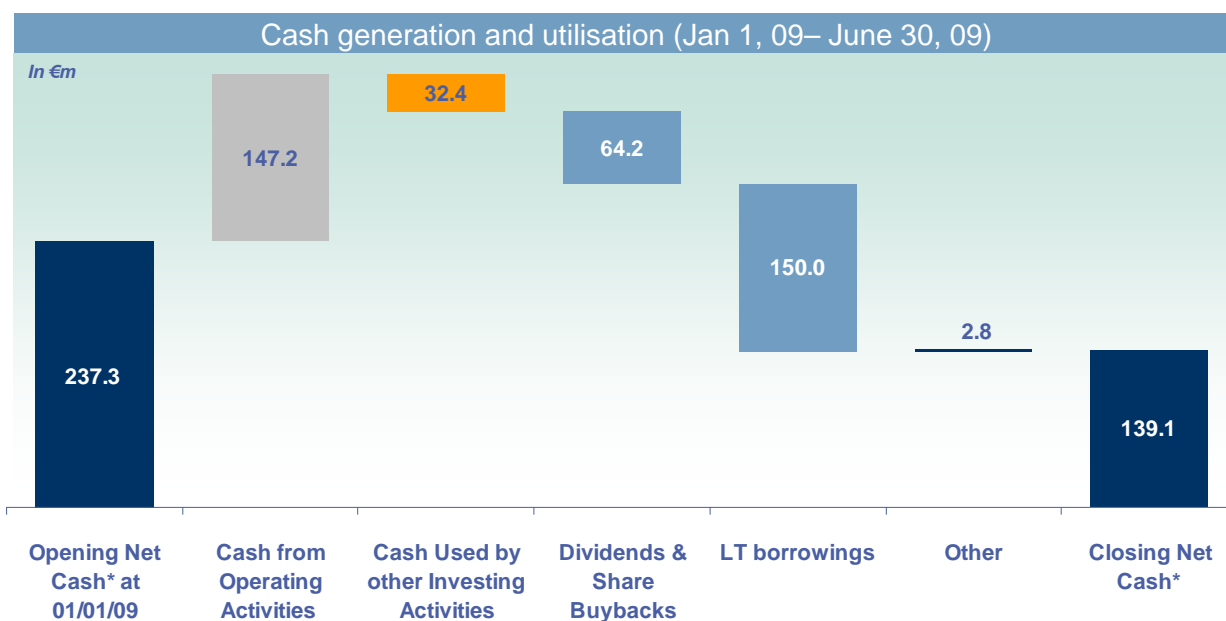
## Cash flow statement

	30 Jun 08	30 Jun 09	Comments
<i>- In million of euros</i>			
<b>Cash Flow before change in working capital</b>	<b>141.3</b>	<b>121.5</b>	
- Increase / Decrease in working capital	(17.1)	25.7	▪ Deferred revenues net increase: €+56.7m (Medicis / Galderma)
<b>Net cash flow generated by operating activities</b>	<b>124.1</b>	<b>147.2</b>	▪ Receivables, payables, inventory and others: €-31.0m
Investment in intangible assets and property, plant & equipment	(34.2)	(25.6)	
Others	1.8	(6.8)	▪ Tangible assets: €-14.7m
<b>Net cash flow used in investing activities</b>	<b>(32.4)</b>	<b>(32.4)</b>	▪ Intangible assets: €-10.9m
Net change in borrowings	(9.8)	(159.4)	
Dividends paid	(55.2)	(58.2)	
Others	0.1	-	▪ reimbursement of credit facility: €150m
<b>Net cash flow used in financing activities</b>	<b>(64.9)</b>	<b>(217.6)</b>	▪ Shares buy back: €6m
Discontinued operations	(1.0)	(0.2)	
<b>Change in cash and cash equivalent</b>	<b>25.8</b>	<b>(103.0)</b>	
Impact of exchange rate fluctuations	(3.0)	4.8	
<b>Closing cash &amp; cash equivalents</b>	<b>263.7</b>	<b>139.1</b>	
<b>Closing Net Cash</b>	<b>239.4</b>	<b>118.9</b>	

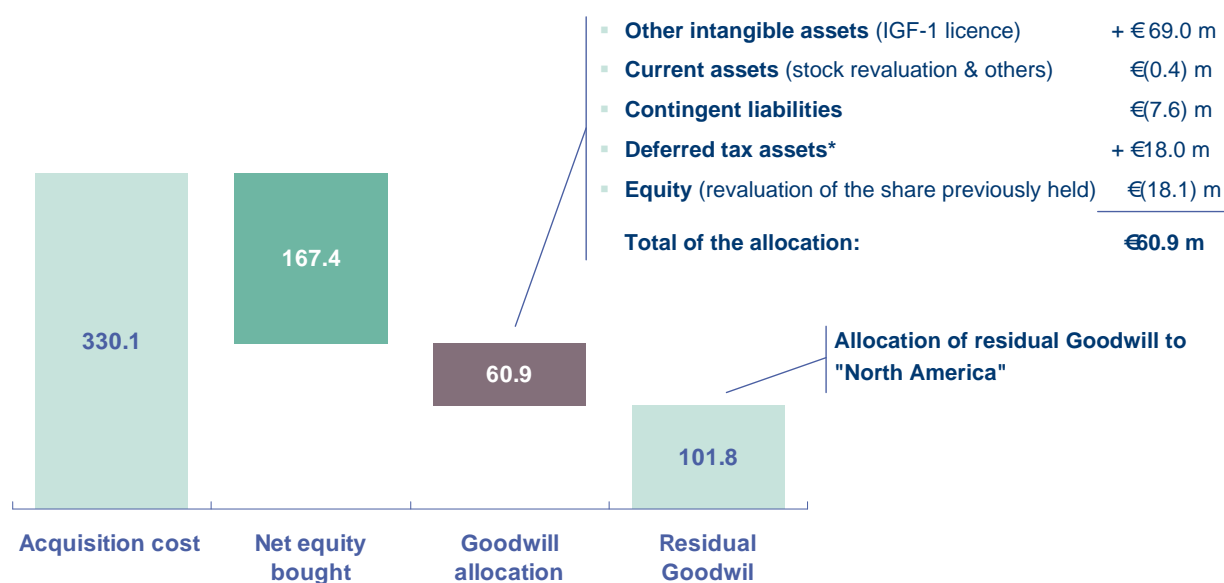
## Financial appendices



## Cash flow generation



## Allocation of the Tercica purchase price accounting





## Milestones Cashed in but not yet Recognised as Revenues

- In million of euros

	30 Jun 08	30 Jun 09
Payments recognised as revenues in year N+1	11.2	12.1
Payments recognised as revenues in years N+2 and beyond	205.7	195.2
<b>Total Milestones cashed in but not yet recognised as revenues</b>	<b>216.9</b>	<b>207.3</b>



Decrease linked to global consolidation of Tercica and elimination of deferred revenues on Somatuline US