# Confirming Ipsen's specialist care globalisation

*Oddo Forum MidCap*

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# Introduction

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

**SPECIALTY CARE**
A global business to **GROW**

| | |
|---|---|
| 27% | ONCOLOGY<br>Decapeptyl® |
| 17% | ENDOCRINOLOGY<br>Somatuline®, Nutropin®, Increlex® |
| 16% | NEUROLOGY<br>Dysport® , Apokyn® |
| - | HEAMATOLOGY<br>OBI-1 |

**PRIMARY CARE**
**OPTIMISE** returns of this mostly French business

| | |
|---|---|
| GI | 19% |
| Cognitive disorders | 13% |
| Cardiovascular | 8% |

A transactional model

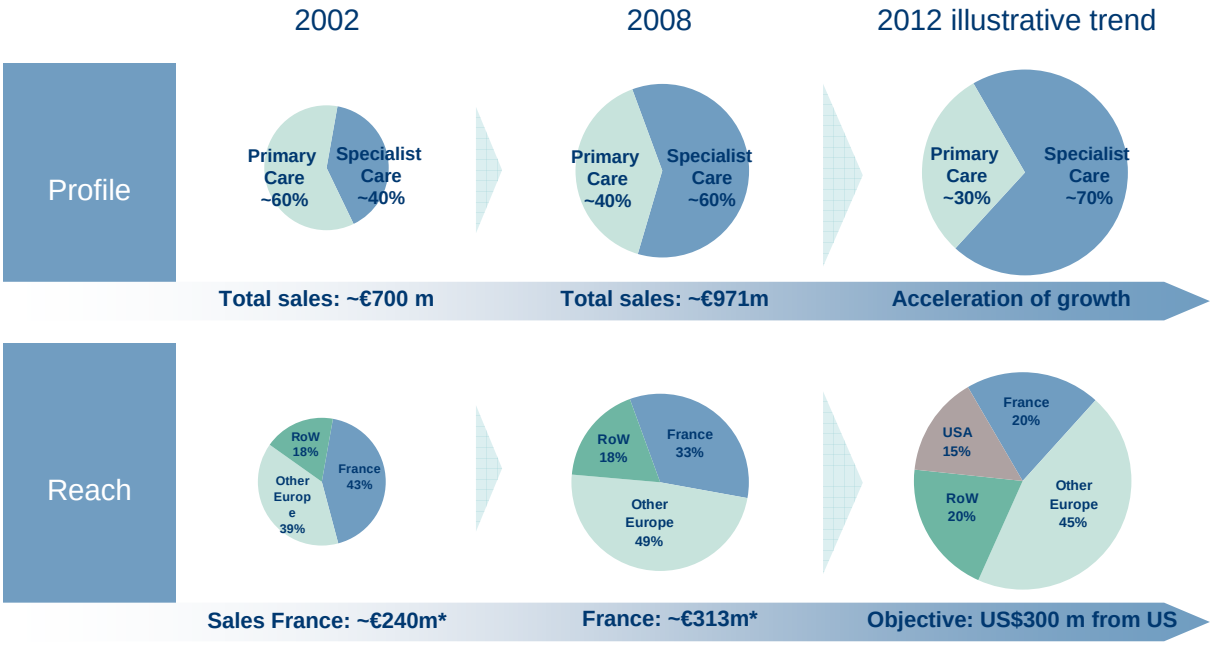
A fully-fledged manufacturing capability

A unique innovation driven and differentiated R&D capability
R&D expense ~20% of sales



* % are calculated on 2008 total Group Drug Sales of €936 million

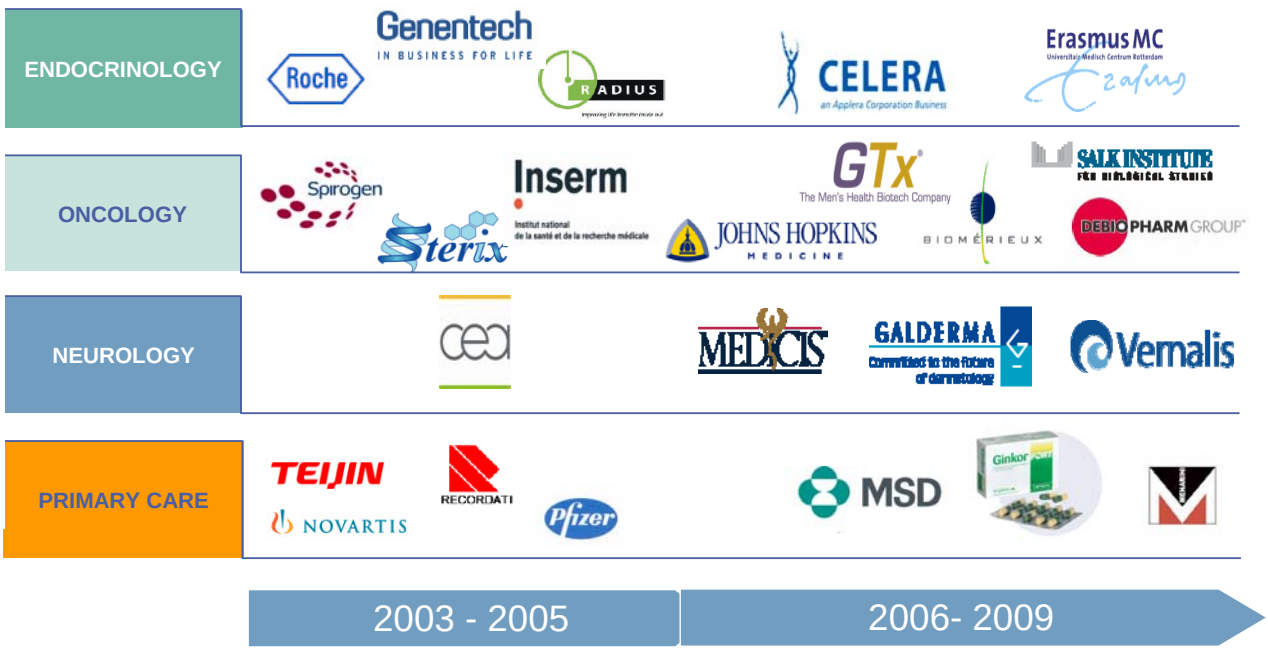
# A reinforced profile and reach






** 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

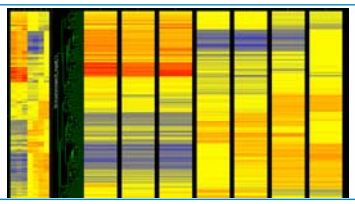


## Truly Differentiated R&D Capabilities

# 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**

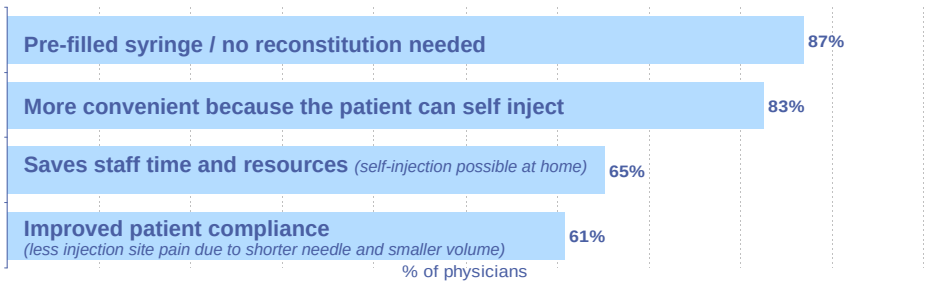
| Technologies | Medicinal chemistry | Delivery systems |
|---|---|---|
| Target identification, validation and drugability based on clinical observations supported by …omics technologies | Steroids peptides, proteins engineering aiming at enhanced efficacy, potency, selectivity and safety over the endogenous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



# Example 1 : Somatuline® Depot, an improved presentation

| | 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?***



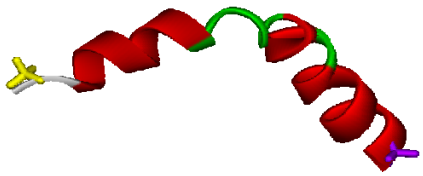

** In selected countries*

*** 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*

## 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

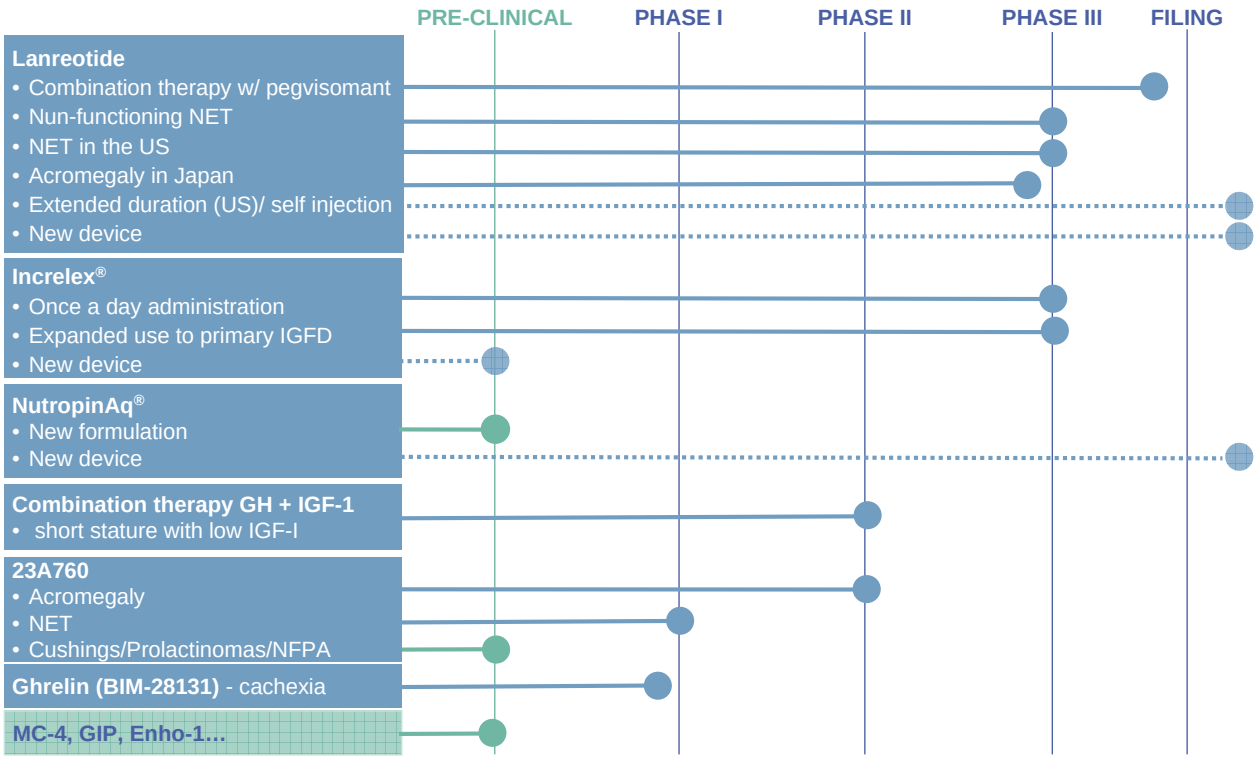
- (LAR) ➔ 23G
  Quarter inch long
- Taspoglutide Liquid SRF ➔ 29G
  **Insulin type needle** for subcutaneous injection

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



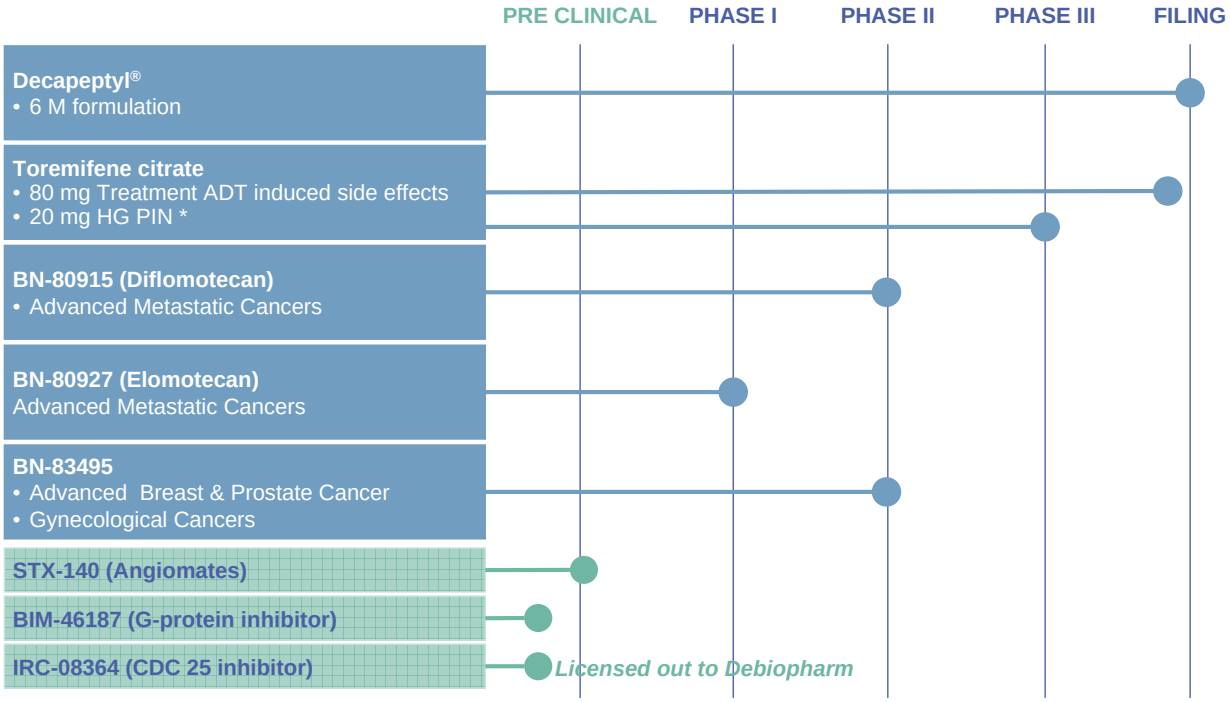
## A rich and promising pipeline

# A rich endocrinology pipeline






# A promising Oncology pipeline






* Option to in-license

# Outlook and progress on the remaining milestones

## 2009 financial objectives confirmed

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

**Other revenues[1] of approximately €80 million**

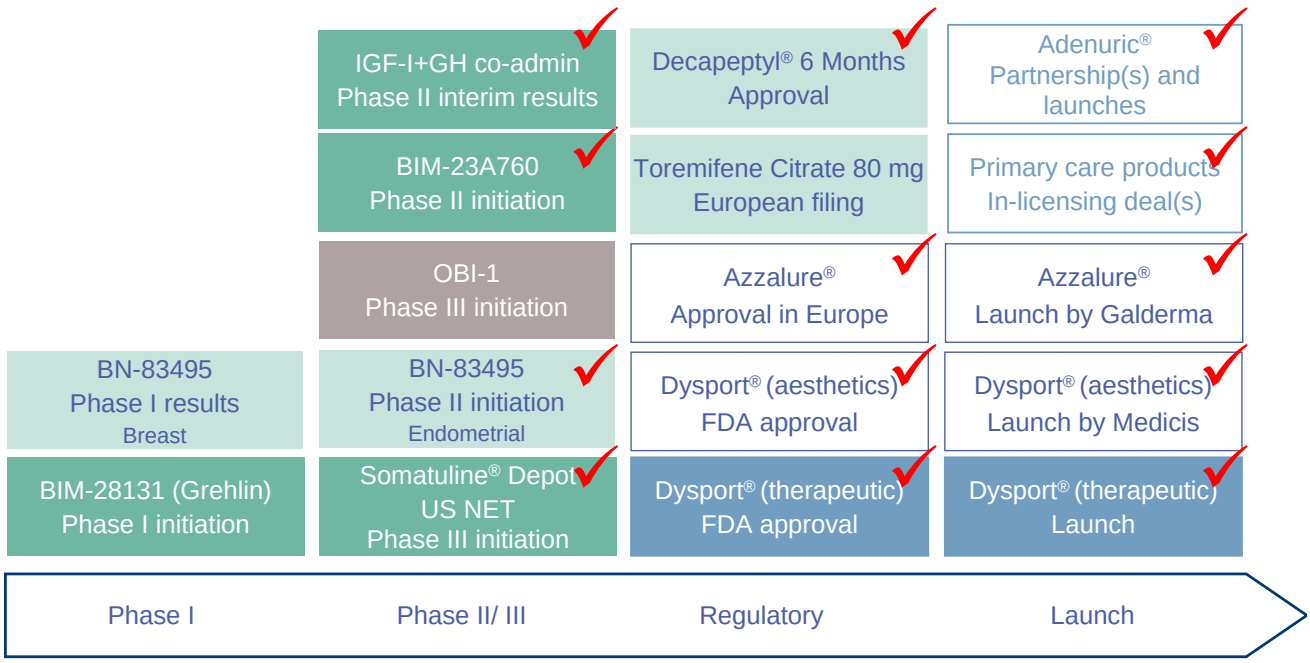
**Operating margin before goodwill allocation[2] of 17.0% - 17.5%**

*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)*

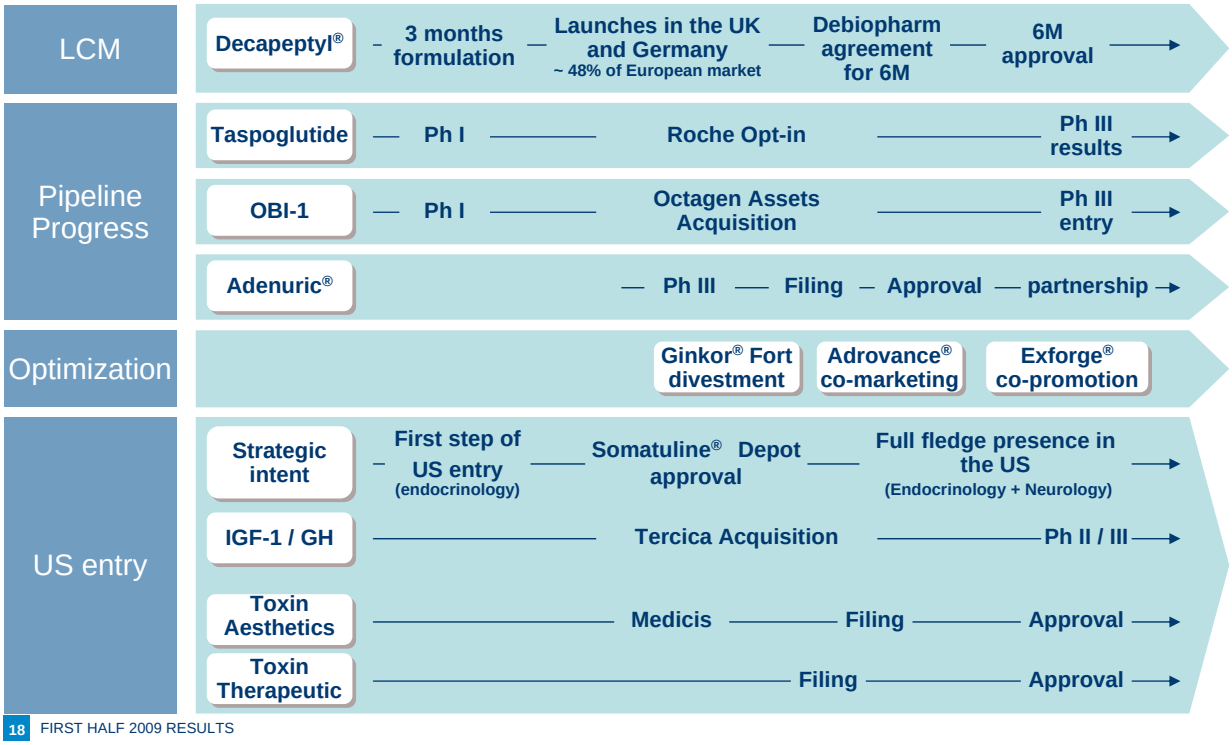
*2- These financial objectives do not include items resulting from purchase price accounting impacts related to the Group's transactions in North America*

# All key milestones delivered year-to-date



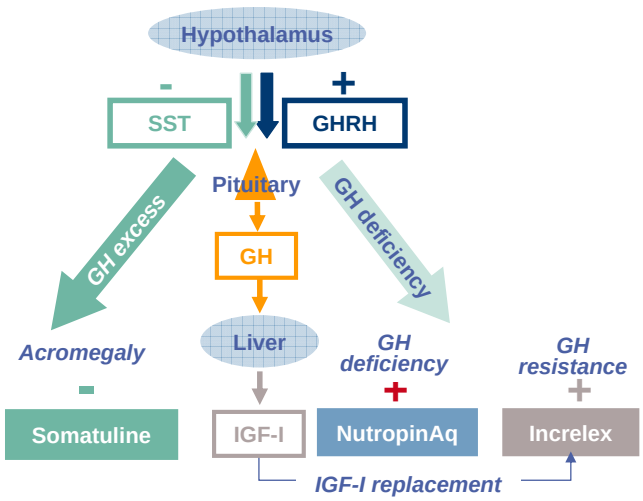



# A track record for consistently delivering on strategic milestones



# An endocrinology franchise outgrowing competition

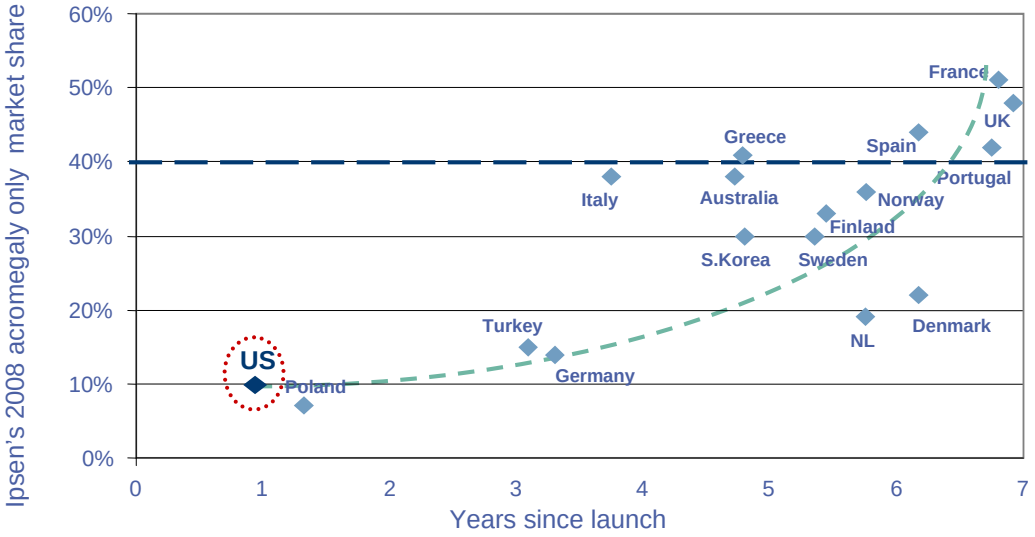
## A unique focus on pituitary disorders and hormone dependent diseases




### 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

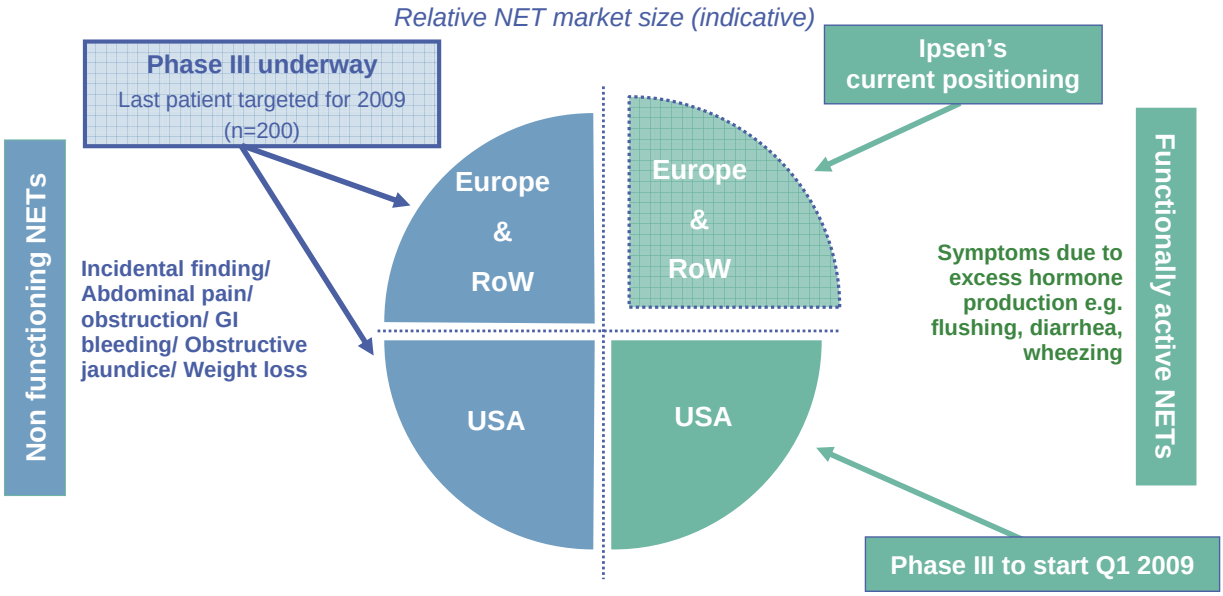



**Somatuline® market share is directly correlated to its time on market**



*SOURCE: Strategix*

# Somatuline® offers significant life cycle growth opportunities




**Significant scope for expansion**

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

| | |
|---|---|
| Physician demand | ▪ Target audience : ~1,000 US paediatric endocrinologists<br>▪ Up to 20% of Rx come from new prescribers each month<br>▪ 2/3 of pediatric endocrinologists have prescribed Increlex®; 78% continued prescription |
| Reimbursement success | ▪ ~ 90% of private and public covered lives have formulary access<br>▪ 75% Increlex patients approved upon final decision (similar to GH) |
| Patient experience | ▪ Sharp increase in patients on Increlex® initially GH-naïve to 60% in '08 from 30% in '07<br>▪ Dose increasing to appropriate targets, to 100 mcg/kg BID in '08 from 70 mcg/kg BID in '07<br>▪ Younger patients initiated with Increlex®, to average age at start of 10.0 years old in '08 from 11.5 years in '07 |



*Sources: Internal data & US Increlex registry*

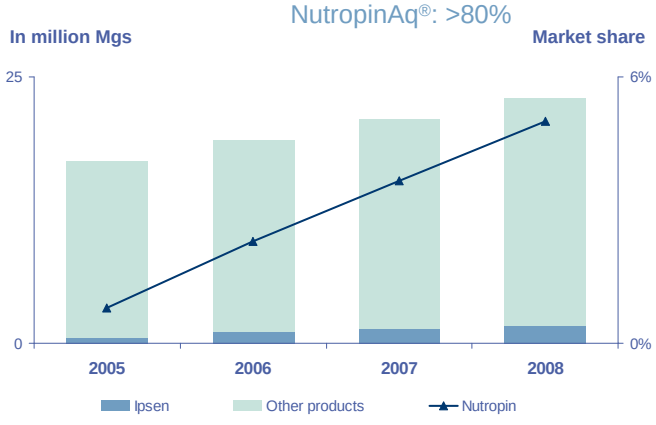
# NutropinAq® in Ipsen territories is steadily gaining market share

## GH market

**CAGR[1] 05-08**

Total GH market: ~+6%

NutropinAq®: >80%



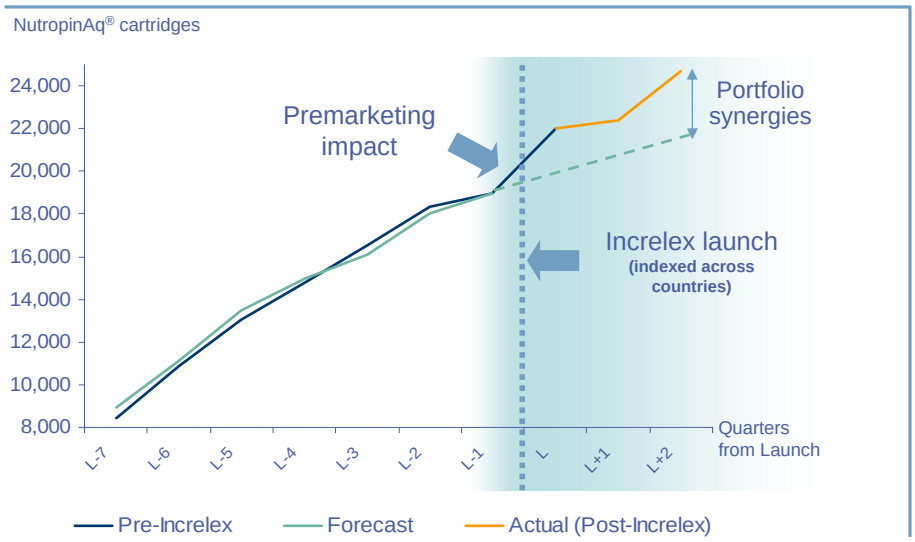

## NutropinAq® attributes

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



*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*



*NOTE 1: UK, Germany, Sweden, France, Italy, Spain*

# Ipsen is redefining the treatment of short stature

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

**GH Deficiency [1]**
**20,000 patients [2]**

**IGF-I Deficiency**
**30,000 patients [3]**

| "True" GHD | 70,000 | Primary IGFD 24,000 | Severe Primary IGFD 6,000 |
|---|---|---|---|

NutropinAq® (somatropin, recombinant DNA origin, Escherichia coli)

90% GH penetration | 15% GH penetration

increlex™

- MS301: Study in Primary IGFD
- MS308: Exploratory study as once-daily

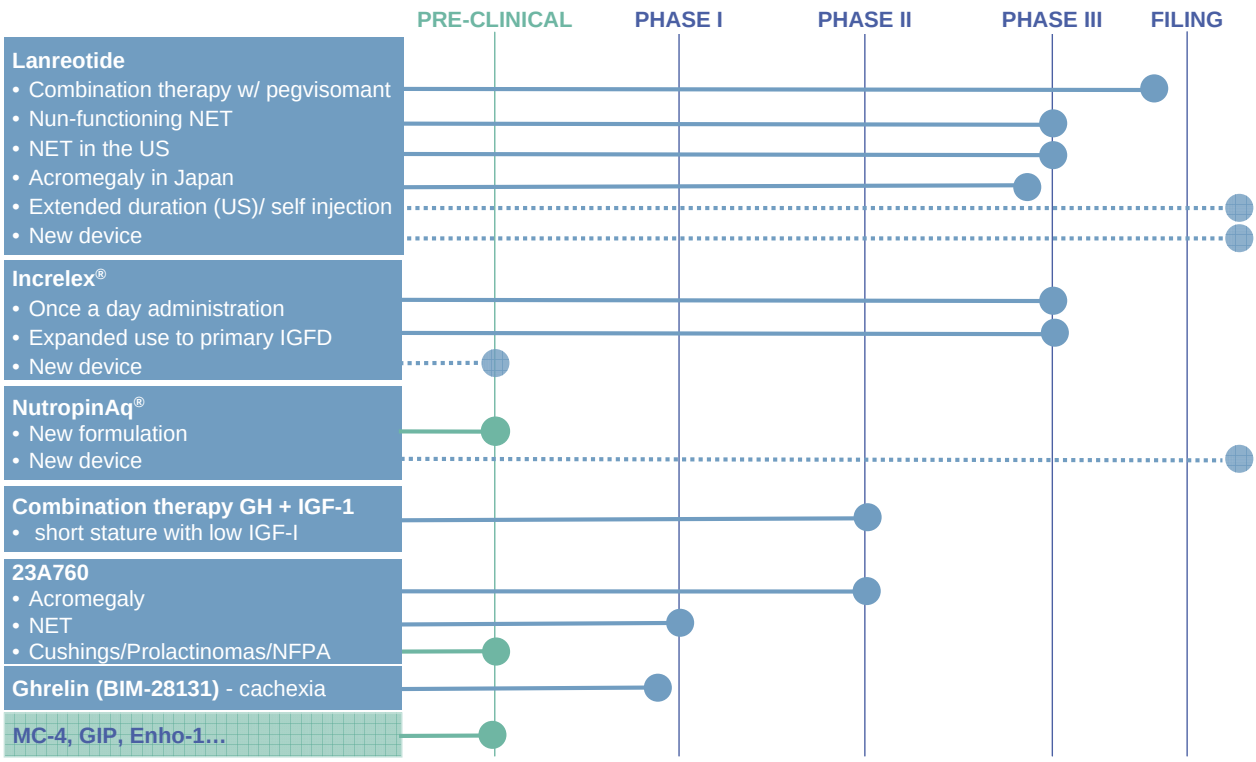
## COMBO in IGFD

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



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

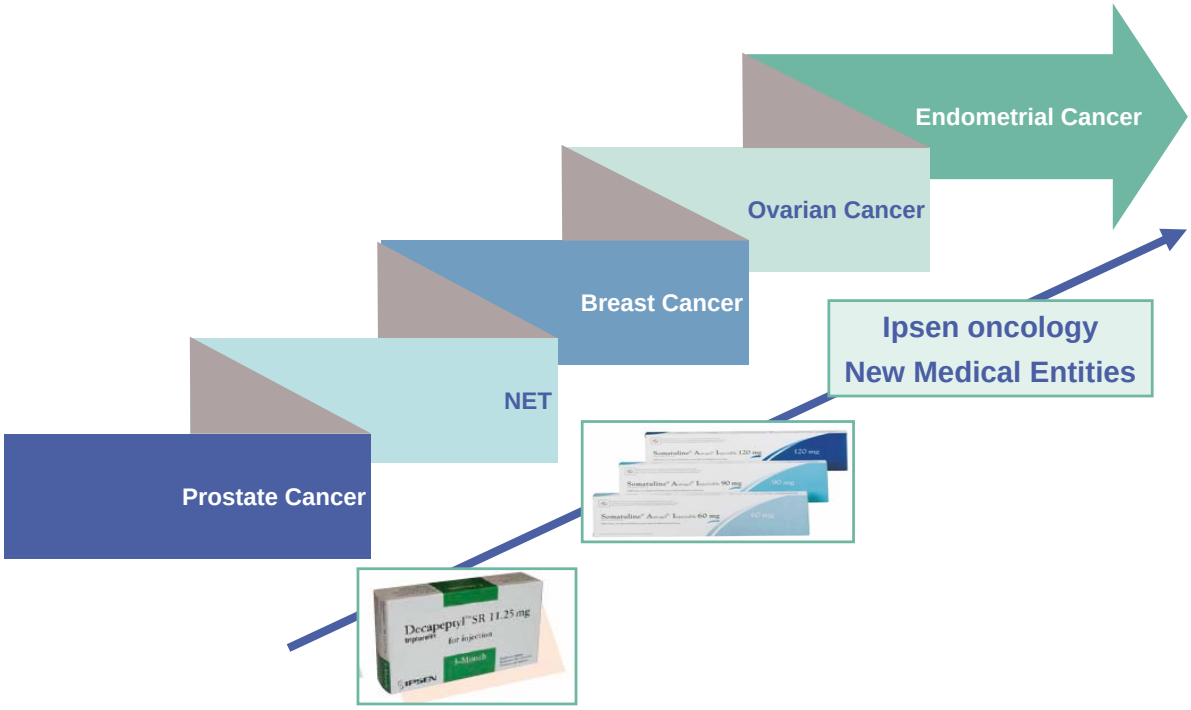
# A rich endocrinology pipeline






# 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<br>▪ Maintenance of castrate testosterone levels at 3M in 98% of patients[1]<br>▪ At 3M, 91% decrease of PSA levels, showing tumor control |
| Local tolerance/ convenience | ▪ IM route of administration, good local tolerance<br>▪ Injection not visible for the patient |
| Storage and reconstitution | ▪ Stored at room temperature<br>▪ 5 steps reconstitution<br>▪ Safety needle system |

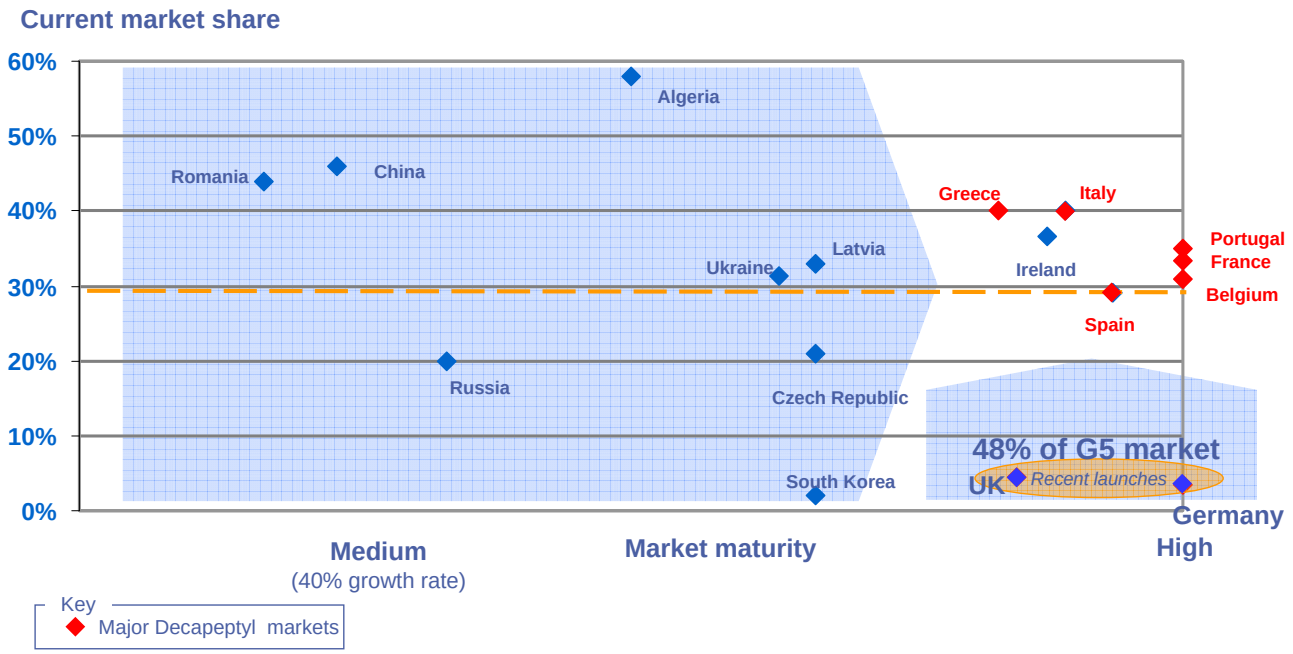
| | Competitor 1 | Competitor 2 | Competitor 3 |
|---|---|---|---|
| Formulation and efficacy | ▪ Various formulations across territories : 1M formulation = 3,75mg or 7,5mg and 3M formulation = 11,25mg or 22,5mg<br>▪ Increased survival rate at 9 months in triptorelin group vs competitor 1[2] | ▪ Conservation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



*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




*SOURCE: IMS – YTD June 2008 except for Italy: internal data*

*100 indicates most mature markets*



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

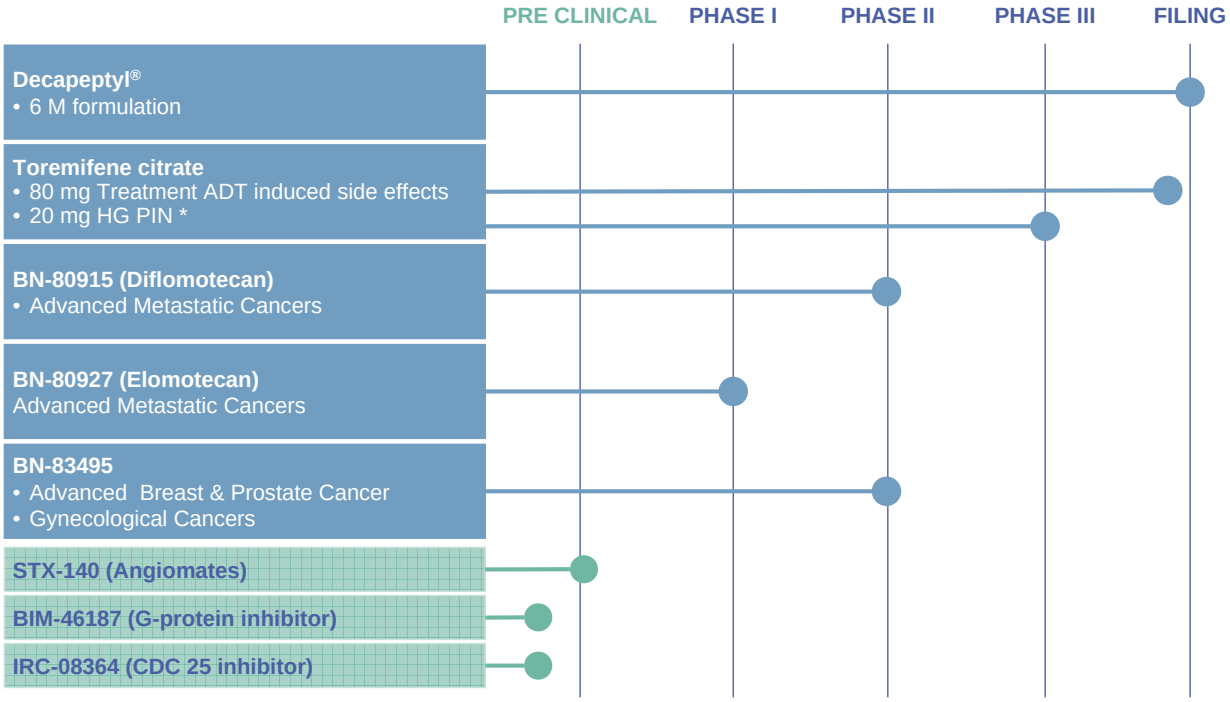
| | | | |
|---|---|---|---|
| Efficacy | ▪ Comparable efficacy to 1 and 3 months formulation<br>• **Castration levels (testosterone)**<br>• **Disease control (PSA)** | | |
| Local Tolerance | ▪ Limited local side effects (6.7% of patients ) | | |
| Storage and reconstitution | ▪ Storage at room temperature (no need to heat up before reconstitution)<br>▪ 5 Steps to reconstitute, change needle, and inject - IM route | | |
| Formulation/ Efficacy | | 6 month competitor 1<br>▪ 80% of patients castrated after 6M [2]<br>▪ Testosterone to be tested every 6M* [1]<br>▪ Formation of Nodules or abscess [1] | 6 month competitor 2<br>▪ Slow release formulation dependent on manual 60 mixture[1] step<br>▪ Storage at 2-4°: need to heat up for reconstitution [1] |



*Reference 1: French SmPC*

*[2]Avis de la commission de transparence*

# A promising Oncology pipeline



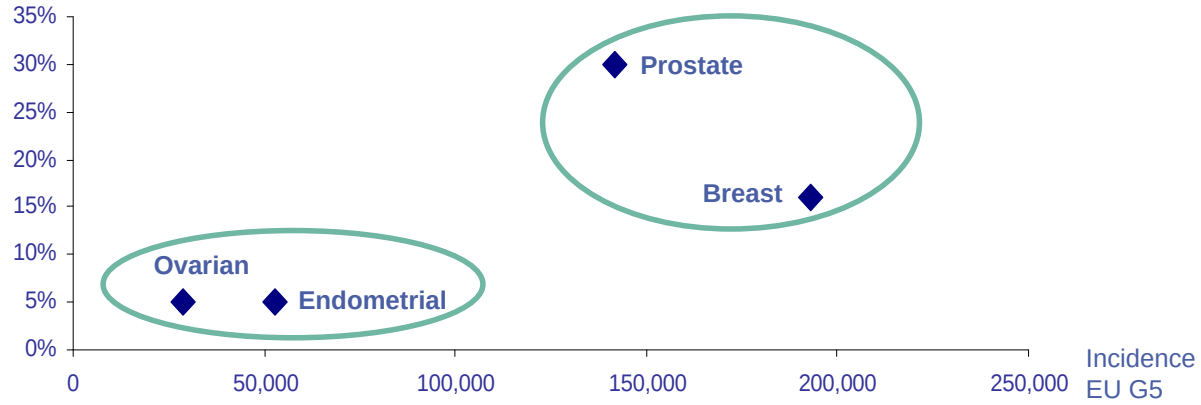



** Option to in-license*



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

5 year survival stage IV disease



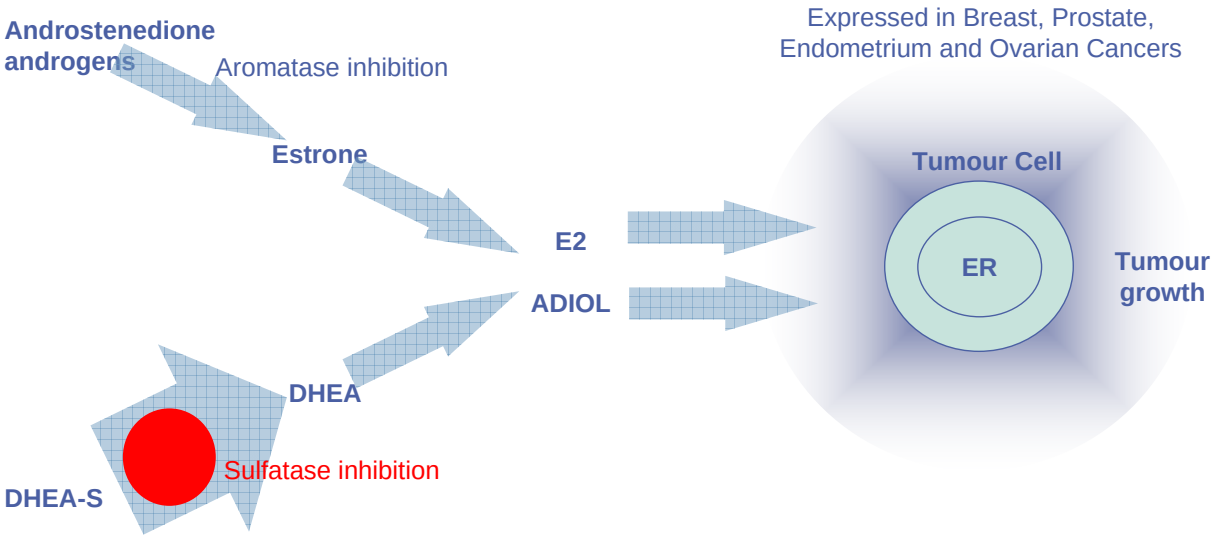

**Ipsen New Medical Entities: multi targeted agents aiming at large markets as well as niche indications with large unmet medical needs**
**BN-83495 is potentially a company transforming product**



*SOURCE: deVita (2008), Datamonitor*

# 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)**

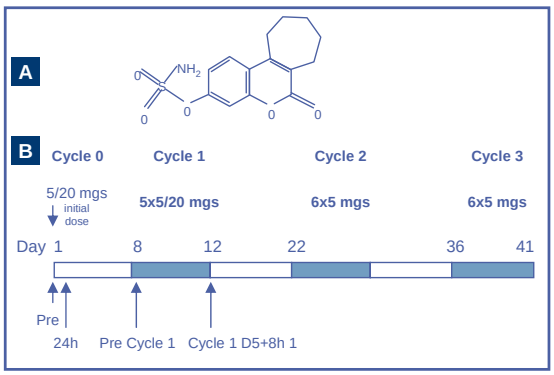


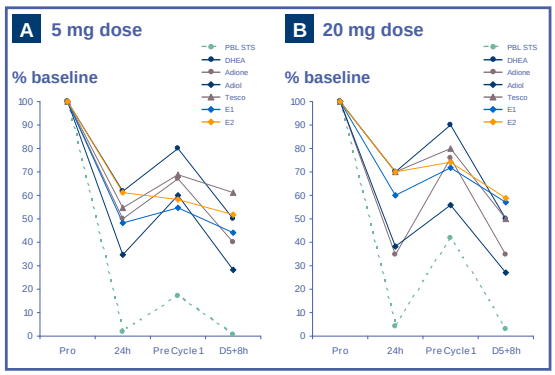


# First clinical study in Breast Cancer patients

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

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



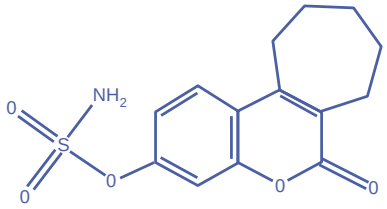

**Next step: confirmation of the results in Metastatic Breast Cancer and exploration of the full range of hormonal dependent tumours**



** SOURCE: Stanway, S. J. et al. Clin Cancer Res 2006;12:1585-1592*

*** 3 patients with stable disease >6M*

# 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

**Endometrial Cancer**
BN-83495
Initiation PII in 2009

**Ovarian Cancer**
BN-83495
Initiation PII in 2009

**Breast Cancer**
BN-83495
Initiation PII in 2009

**NET in the US**
Initiation PIII in 2009

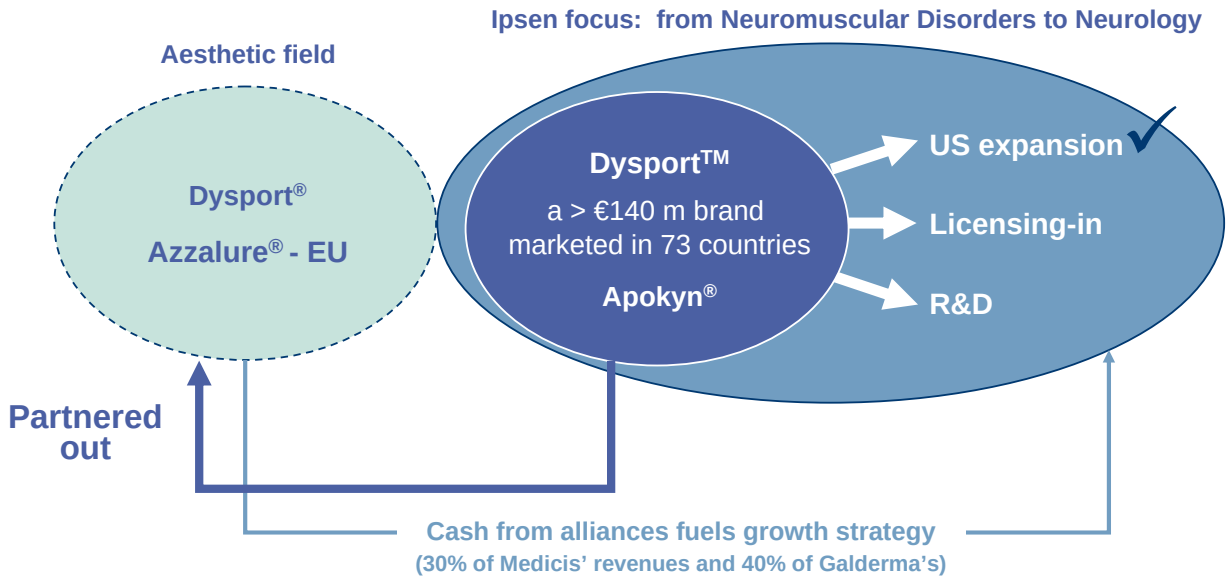
**Prostate Cancer**
Decapeptyl® 6M: Launch in 2010
Toremifene citrate: Filing in 2009
BN-83945: POC in 2009

**Ipsen oncology New Medical Entities**


**Near-term milestones…**

# From a Regional Neuromuscular Specialty to a Global Neurology Franchise

## A specific therapeutic focus




**Dysport®: the cornerstone of a Neurology franchise**

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

**Cervical dystonia**
9/100,000 (1)

**Blepharospasm**
5/100,000 (2)

**Adult spasticity**
322/100,000)

**Cerebral palsy**
19/100,000 aged 17 & less (3)

**> 90%**
of 2008 ex-US
therapeutic market(4)

**Hyperhydrosis**

**Hemifacial spasm**

**Aesthetic use**

**Strabismus and other less frequent indications**

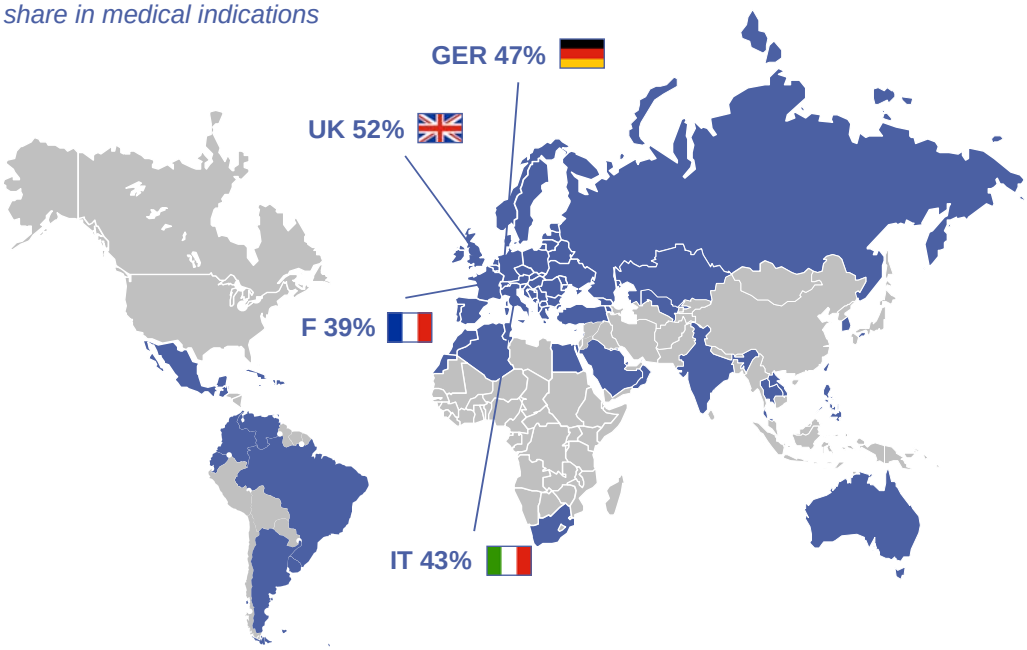
*Source of prevalences in inhabitants:(1) Movement disorders V10; (2) www.blepharospasm.org; (3) www.cdc.gov;*

** Source: Ipsen*



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

*Market share in medical indications*

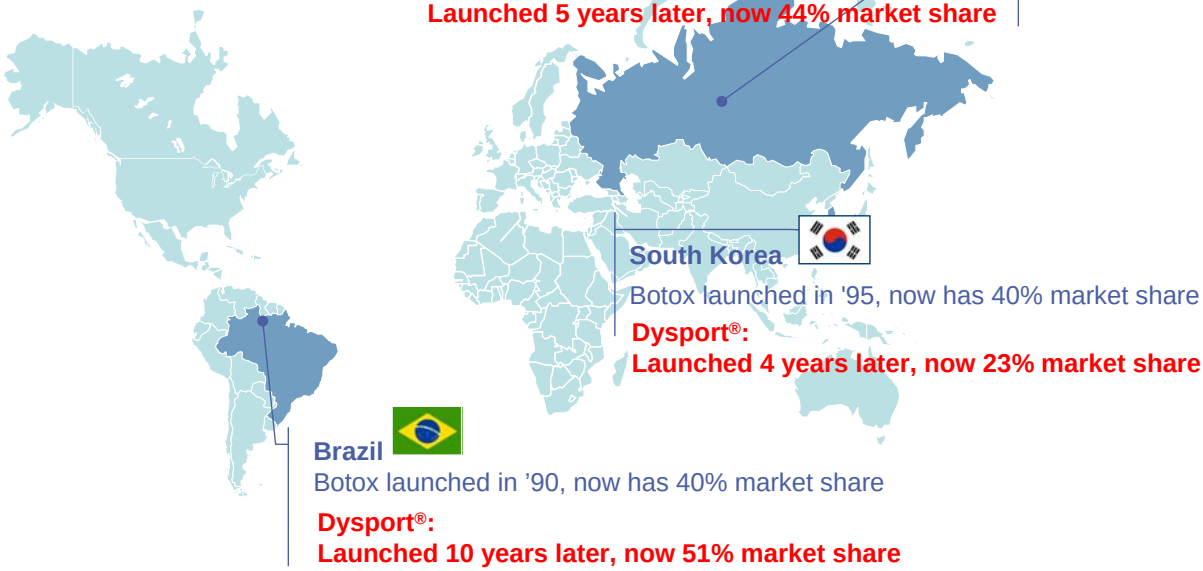



In dark blue, countries where Dysport® is marketed

*Sources: IMS, Insight Health/ODV, Ipsen estimates*

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

*Market share in medical indications*



**Russia**
Botox launched in '94, now 56% market share
**Dysport®:**
**Launched 5 years later, now 44% market share**

**South Korea**
Botox launched in '95, now has 40% market share
**Dysport®:**
**Launched 4 years later, now 23% market share**

**Brazil**
Botox launched in '90, now has 40% market share
**Dysport®:**
**Launched 10 years later, now 51% market share**



*Sources: Ipsen market intelligence*

# 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®,**
**Increlex® and Apokyn® generating $23 million, up 33% Q2 over Q1**



*NOTE: All % sales growth expressed at constant currency*

## 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**

*NOTE: All margins expressed in % of sales*

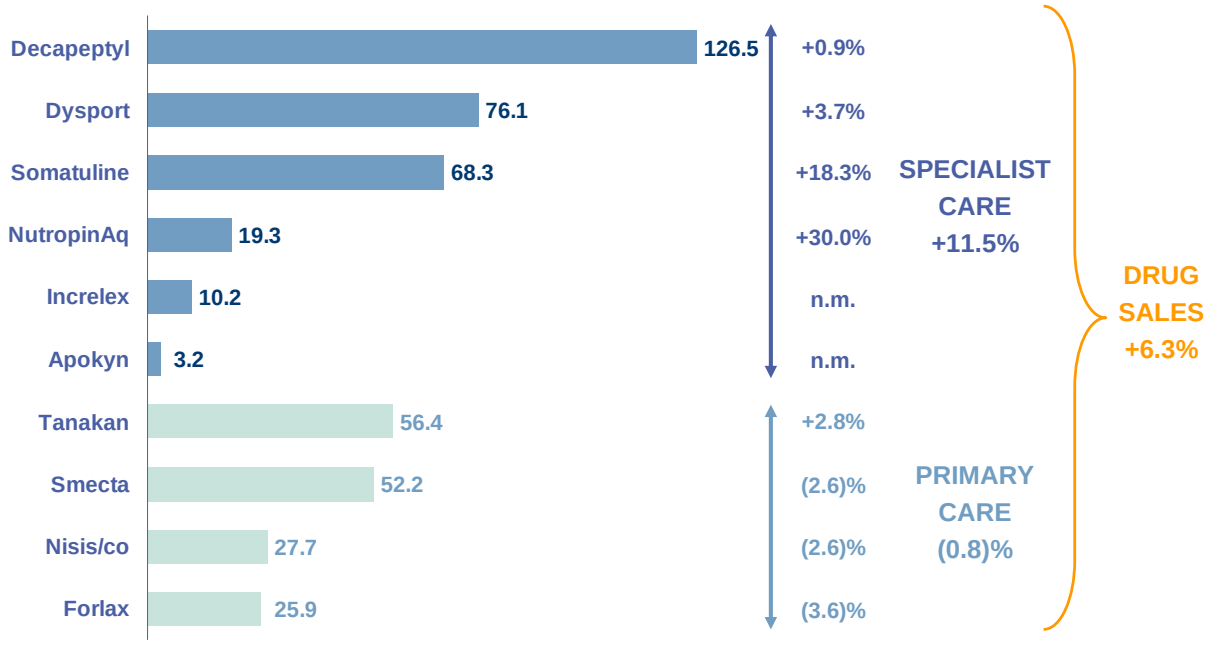


**Reported operating income excluding non-recurring elements (divestment of Ginkor Fort® & sale of land), purchase price accounting impacts AND all Kogenate royalties*

## First half 2009 detailed financial performance

# Main products performances

*Sales in € million*

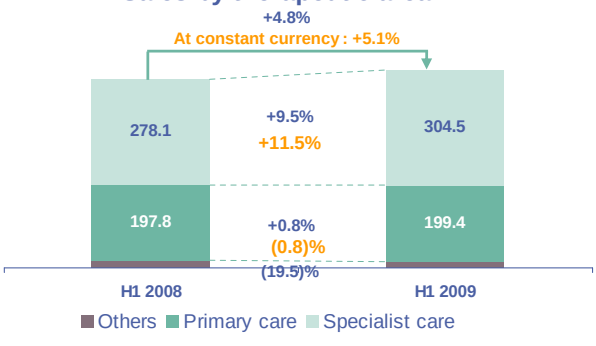




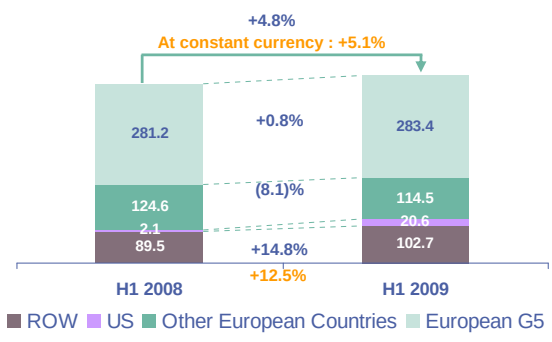

*NOTE: % sales growth at constant currency*

# Top line evolution

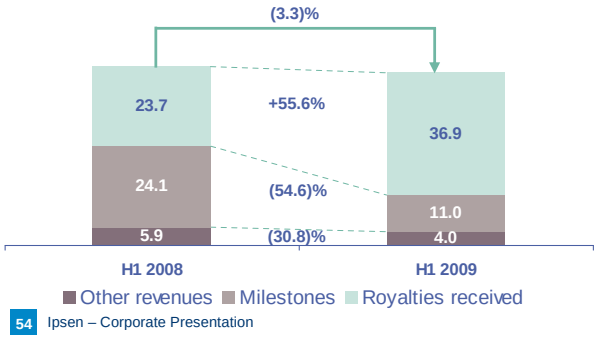
## Sales by therapeutic area



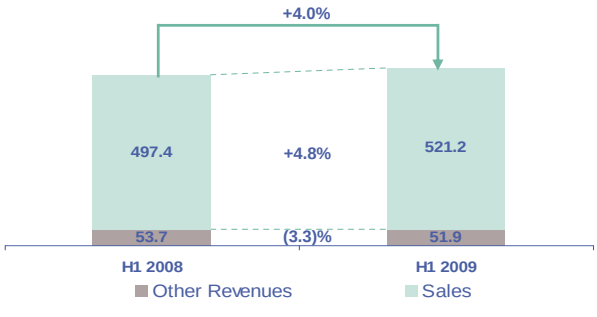

## Sales by region




## Other revenues evolution

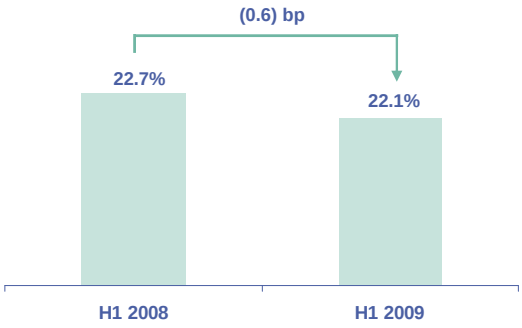



## Total revenues evolution

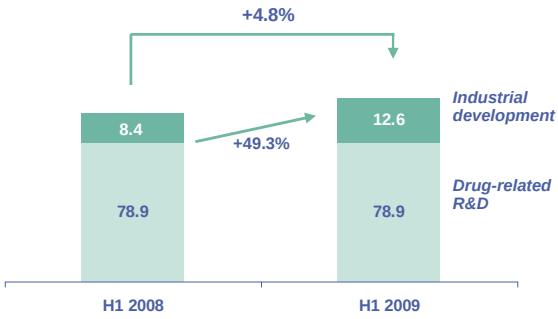


# P&L – above EBIT

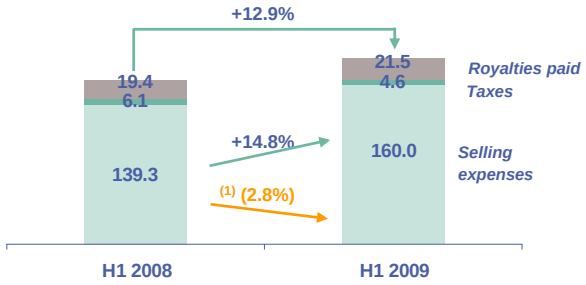
## COGS (% of sales)



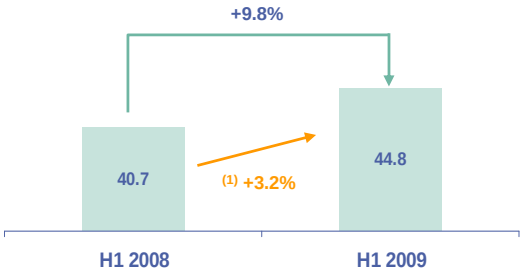

## Research & Development




## Sales & Marketing




## G&A




*NOTE 1: excluding US*



# P&L - EBIT

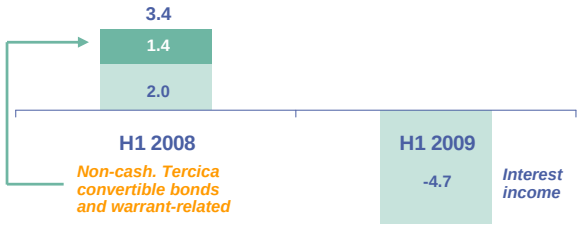

| Excluding goodwill allocation in connection with US acquisitions AND income from Bayer | |
|---|---|
| €94.1 m | 18.0% |

| Excluding goodwill allocation in connection with US acquisitions | |
|---|---|
| €130.5 m | 25.0% |

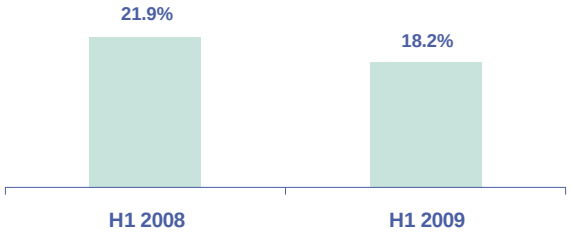
| As reported | |
|---|---|
| €125.2 m | 24.0% |

# P&L – below EBIT

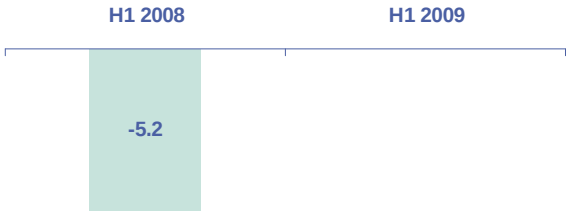
## Financial result (€m)



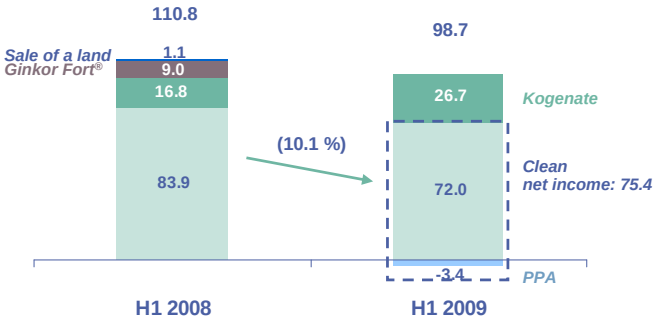

## Effective tax rate (% of PBT)




## Income from Associates (€m)




## Consolidated result (€m - group share)






# Balance Sheet evolution

*- In million of euros*

## Assets

| | 31 Dec 08 | 30 Jun 09 |
|---|---|---|
| **Goodwill** | (*) 290.8 | 290.8 |
| **Property. plans & equipments** | 237.9 | 244.7 |
| **Intangible assets** | (*) 232.9 | 239.3 |
| **Other non-current assets** | (*) 112,9 | 140.5 |
| **Total non-current assets** | (*) **874.5** | **915.3** |
| **Total current assets** | (*) **688.6** | **589.7** |
| *Incl. cash and cash equivalents* | 239.6 | 140.2 |
| **Assets / discontinued operations** | 1.3 | 0.7 |
| **Total assets** | **1 564,4** | **1 505.8** |
| **Net Cash** | **66.2** | **118.9** |

*- In million of euros*

## Liabilities

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

*(*) 31 Dec 08 restated after Purchase Price Allocation of Tercica Inc. and Vernalis Inc.*

# Cash flow statement

| - In million of euros | 30 Jun 08 | 30 Jun 09 |
|---|---|---|
| **Cash Flow before change in working capital** | **141.3** | **121.5** |
| - Increase / Decrease in working capital | (17.1) | 25.7 |
| **Net cash flow generated by operating activities** | **124.1** | **147.2** |
| Investment in intangible assets and property. plant & equipment | (34.2) | (25.6) |
| Others | 1.8 | (6.8) |
| **Net cash flow used in investing activities** | **(32.4)** | **(32.4)** |
| Net change in borrowings | (9.8) | (159.4) |
| Dividends paid | (55.2) | (58.2) |
| Others | 0.1 | - |
| **Net cash flow used in financing activities** | **(64.9)** | **(217.6)** |
| Discontinued operations | (1.0) | (0.2) |
| **Change in cash and cash equivalent** | **25.8** | **(103.0)** |
| Impact of exchange rate fluctuations | (3.0) | 4.8 |
| **Closing cash & cash equivalents** | **263.7** | **139.1** |
| **Closing Net Cash** | **239.4** | **118.9** |

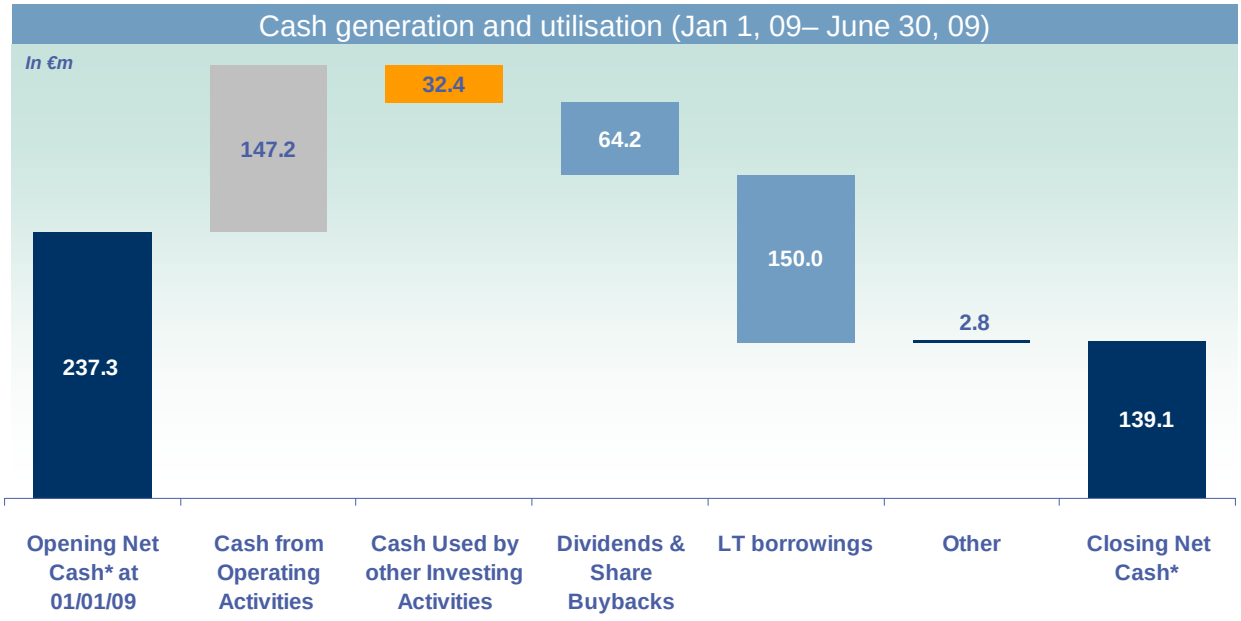
**Comments**

- Deferred revenues net increase: €+56.7m (Medicis / Galderma)
- Receivables, payables, inventory and others: €-31.0m
- Tangible assets: €-14.7m
- Intangible assets: €-10.9m
- reimbursement of credit facility: €-150m
- Shares buy back: €-6m



# Financial appendices

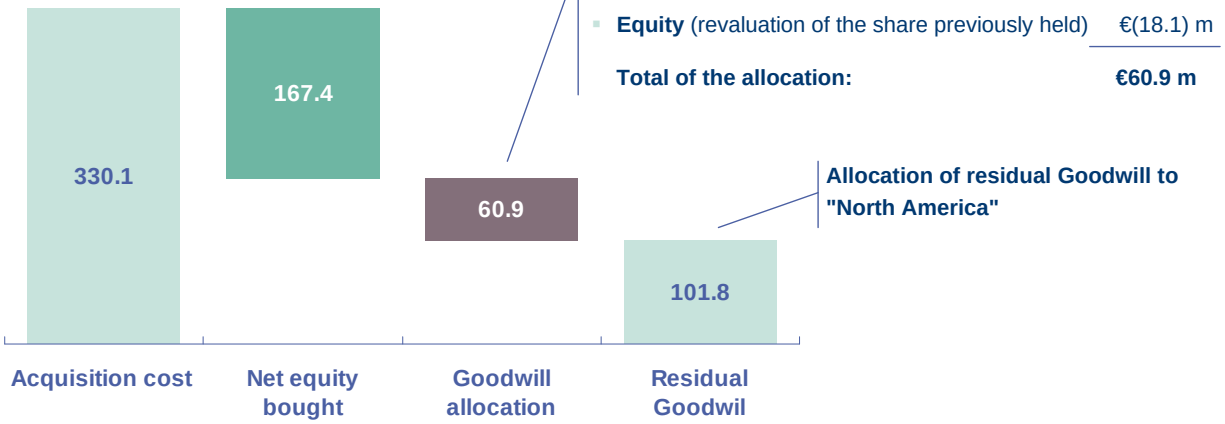
# Cash flow generation






** 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*

# Allocation of the Tercica purchase price accounting




- **Other intangible assets** (IGF-1 licence) + € 69.0 m
- **Current assets** (stock revaluation & others) €(0.4) m
- **Contingent liabilities** €(7.6) m
- **Deferred tax assets*** + €18.0 m
- **Equity** (revaluation of the share previously held) €(18.1) m

**Total of the allocation:** **€60.9 m**

**Allocation of residual Goodwill to "North America"**



** Net Operating Loss and temporary differences*

# 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 |
| **Total Milestones cashed in but not yet recognised as revenues** | **216.9** | **207.3** |

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