

# PAVING THE WAY FOR GROWTH

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## PROFILE AND STRATEGY



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### AN INNOVATION DRIVEN INTERNATIONAL SPECIALTY PHARMA

#### A strategic focus on specialist care worldwide

- Three targeted areas : Oncology, Endocrinology and Neuromuscular Disorders
- 5 key products accounting for ~ 57% of drug sales
- Growing at a double digit rate

#### A historic presence in primary care

- Focused on gastroenterology, cognitive disorders and cardiovascular diseases
- A presence focused on selected geographies including France, China and Russia
- A sound business yielding recurring cashflow and contributing to R&D financing

#### A truly differentiating and international R&D capability

- Focused on hormone-dependent diseases, peptide and protein engineering and innovative delivery systems
- R&D expense in excess of 20% of sales
- 4 centres in Boston, Paris, London and Barcelona

#### An integrated player

- A fully-fledged peptide manufacturing capability
- Two FDA-approved manufacturing facilities

#### A recognised strategic partner

- Alliances with international industry leaders in US, Europe and Japan and best-in-class universities around the world
- Ipsen's business partners include Galderma, Genentech, GTX, Medicis, Roche, Teijin...

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## JUNE 2008: IPSEN ANNOUNCES US ENTRY...

- 1 Agreement with Tercica Inc.'s Special Committee and Board of Directors to purchase the remainder of Tercica Inc.'s outstanding common stock
- 2 Agreement with Vernalis plc. to acquire its US operations and rights for Apokyn®

## ... IN LINE WITH ITS STRATEGY TO GROW AND GLOBALISE ITS SPECIALTY CARE BUSINESS

### MISSION STATEMENT

To be a worldwide best-in-class provider of innovative drugs, addressing unmet medical needs in its targeted therapeutic areas

### STRATEGIC PRIORITIES

- 1 **GROW** top-line and profits in specialist care by providing innovative drug therapy
- 2 **GLOBALIZE** through active geographical expansion policy
- 3 **OPTIMIZE** returns of primary care through selected product life cycle management, partnerships and focused investments

3 botulinum toxin dossiers under review (US and Europe)	Add a companion product to Dysport®	Somatuline® US sales ramp-up	Choice of a commercialisation option for Dysport® in the US	Adenuric® (febuxostat) partnership opportunities in Europe	Disclosure by Roche of GLP-1 (R1583) phase II results and phase III initiation
Increlex® sales ramp up in Europe	Enrich R&D pipeline	OBI-1 development optimisation	Reloxin® filing in the US		

## A UNIQUE CONVERGENCE OF TECHNOLOGIES

2 examples:  
Somatuline® and Taspoglutide



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### SOMATULINE®: AN IMPROVED PHARMACOKINETIC PROFILE



	Sandostatin LAR®	Somatuline® Autogel®
Indications	Acromegaly NET	Acromegaly NET (EU only)
Administration route	Intramuscular	Subcutaneous
Volume injected	2.0 ml	0.4 ml
Needle length	40mm	20mm
Formulation	Powder for reconstitution	Ready to use



Comparison Of pre-filled (RHS)  
Versus competitor Intramuscular  
Injection device (LHS)

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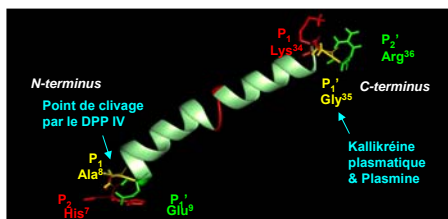
## TASPOGLUTIDE® (GLP-1): LEVERAGING OUR TECHNOLOGICAL PLATFORMS

- Equal / greater potency compared to native compound
- Extended metabolic half-life: 22x more stable in plasma
- Complete retention of incretin properties
- Strong patent positions
- **Once-a-week injection**

### FINANCIAL TERMS

- ~ €60 m paid upfront
- ~ €170 m potential additional milestones
- Mid-teens royalties on Roche's WW net sales

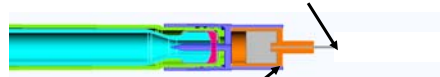
Designing the peptide itself...



Human GLP-1(7-36)NH<sub>2</sub> is cleaved in plasma at both N- & C termini: modification of positions 8 & 35

...so that it fits Ipsen's innovative delivery systems technologies

Insulin type needle for subcutaneous injection



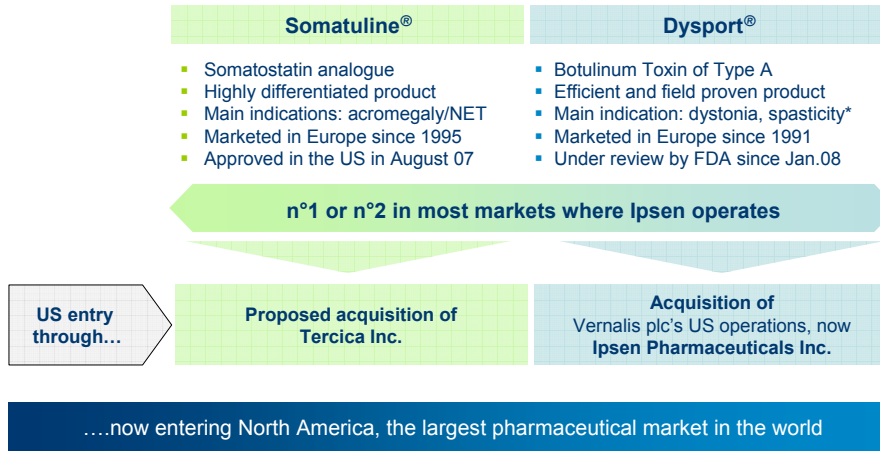
**50 to 300µl** of highly concentrated aqueous solution devoid of excipient

Example of a pre-filled delivery device presentation (eg. Preloaded pen injector)

## SOMATULINE® AND DYSPORT®

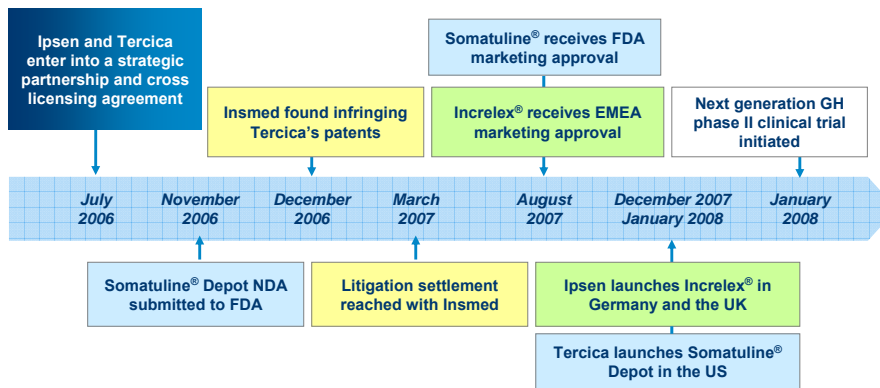
Field proven products entering the world's largest market

## LEADING FIELD-PROVEN PRODUCTS IN EUROPE...



\*cervical dystonia, cerebral palsy in children, muscle spasticity, blepharospasm/hemifacial spasm

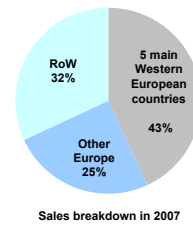
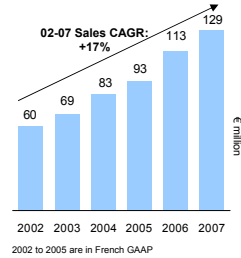
## ACQUISITION OF TERCICA: WHY NOW?



Ipsen believes that it is now time to be fully responsible for the execution of the commercialisation of Somatuline® Depot in North America and for the development of promising R&D projects

## ACQUISITION OF IPSEN PHARMACEUTICALS INC.: WHY NOW?

- Dysport® : a strong brand with well established positions
- Used globally for therapeutic indications: cervical dystonia, cerebral palsy in children, muscle spasticity, blepharospasm, hemifacial spasm
- Launched in the UK in 1991
- Marketing authorisations in over 70 countries (in Europe (including Russia), Asia and Latin America)
- Equivalent market share in therapeutic use to that of its main competitor in the 5 main European countries
- **Dysport® was filed for review by the FDA at the end of January 2008 for cervical dystonia**



Ipsen needs to prepare now for the US launch of Dysport®

## WHY CHOOSE IPSEN PHARMA INC. TO LAUNCH DYSPORT® IN THE US?

A CNS focused company rightly sized to maximize the launch of Dysport®, with 54 staffs

A team with operational and therapeutic expertise and strong track-record

Strong managed healthcare experience, especially for injectable drugs

A relevant and targeted market reach, with largely similar prescriber base between Dysport® and Apokyn® - Vernalis Inc. today covers ~75% of US movement disorder specialists and neurologists

A sound commercial strategy  
based on strong customer relationship and true value-added services provided to physicians

A lean organization, with no overlap with Ipsen's existing structures

A well positioned product on the market  
Apokyn®, the only product indicated in the treatment of "off" episodes of Parkinson's disease

A reasonable investment  
Total consideration of up to \$12.5 million, and investment in Vernalis plc. for \$5.0 million

## A RICH R&D PIPELINE



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## A STRONG PIPELINE TO FUEL FUTURE GROWTH

### NEW CHEMICAL ENTITIES

BN 83495 (STX 64)	Post-menopausal breast cancer	Phase I
BN 2629 (S.JG-136)	Advanced metastatic cancers	Phase I completed
Diflomotecan (BN 80915)	Advanced metastatic cancers	Phase II
Elomotecan (BN 80927)	Advanced metastatic cancers	Phase I
Acapodene®	Treatment of Androgen Deprivation Therapy induced iatrogenic effects	Phase III completed
Taspoglutide (R1583)	Type 2 diabetes	Phase III
Dopastatin	Acromegaly /Neuro endocrine tumors	Phase I
OBI-1	<b>Haemostasis</b>	<b>Phase II completed</b>

### LIFE CYCLE MANAGEMENT PROGRAMMES

Decapeptyl®	Pre-menopausal breast cancer	Phase III
Decapeptyl®	6 month SRF (prostate)	Phase III completed
Somatuline Autogel®	Non functioning neuro endocrine tumors	Phase III
Somatuline Autogel®	Co-administration with Pegvisomant	Phase III
<b>Somatuline Depot</b>	<b>Neuroendocrine tumors (US)</b>	<b>Phase III</b>
<b>Dysport®</b>	<b>Cervical Dystonia</b>	<b><u>Under regulatory review in the US</u></b>
Botulinum toxin A	Aesthetic medicine	<u>Under regulatory review in the EU</u>
<b>Reloxin®</b>	<b>Aesthetic medicine</b>	<b><u>Under regulatory review in the US</u></b>
Tanakan®	Mild cognitive impairment related to age	Phase III

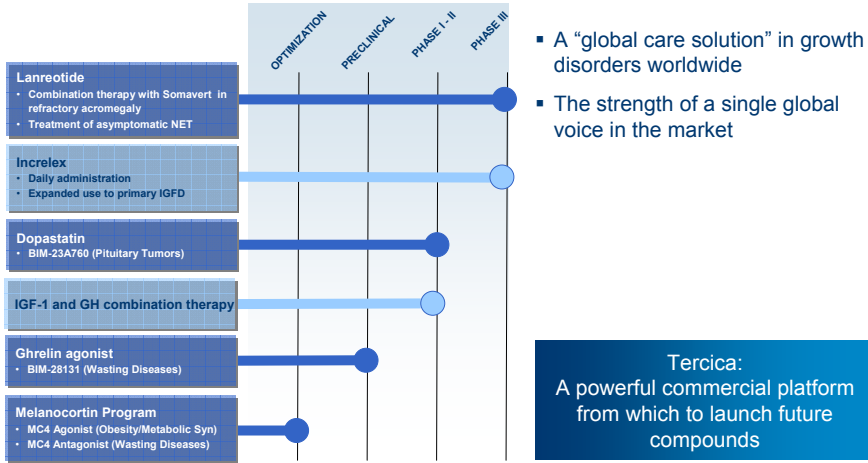
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Purple: Oncology / Green: Endocrinology / Blue: Neuromuscular disorders - In Bold: US projects  
This table excludes pre-clinical projects





## IPSEN AND TERCICA: AN UNRIVALLED ENDOCRINOLOGY PIPELINE



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## OUTLOOK



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## MAJOR KEY MILESTONES STILL AHEAD OF US...

### MISSION STATEMENT

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### STRATEGIC PRIORITIES

- 1 **GROW** top-line and profits in specialist care by providing innovative drug therapy
- 2 **GLOBALISE** through active geographical expansion policy
- 3 **OPTIMISE** returns of primary care through selected product life cycle management, partnerships and focused investments

Botulinum toxin in aesthetic use under review in Europe	STX-64 phase I data Dopastatin phase I data	Dysport® under review in the US OBI-1 end of phase II meeting with the FDA	Choice of a commercialisation option for Dysport® in the US ✓	Adenuric® (febuxostat) partnership opportunities in Europe	Disclosure by Roche of GLP-1 Taspoglutide phase II results and phase III initiation ✓
Reloxin® under review in the US	Decapeptyl® and Acapodene® submissions	Somatuline® phase III initiation in NET in the US			

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## A STRONG FIRST HALF 2008

Performance growth \*

**+11.2%**

Specialty care sales growth

**+13.4%**

Reported operating margin  
(in % of sales)

**29.3%**

Fully diluted EPS growth

**+42.1%**

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NOTE: H1 2008/2007 growth rates

\* Excluding Ginkor For® and at constant currency

## FULL YEAR 2008: STANDALONE FINANCIAL OUTLOOK

	2008 OLD objectives	2008 NEW objectives	2007 base
Sales growth	Underlying: 6.5 to 7.5% <sup>(1)</sup>	Upper end of the range	€883.6 millions
	Reported: 3.2 to 4.2%		€920.5 millions
Other revenues growth	13.0 to 16.0% <sup>(2)</sup>	25.0 to 30.0%	€73.3 millions
Operating margin	22.0 to 23.0% (in % of sales)	23.0 to 24.0% (in % of sales)	22.7%

Ipsen will revise its full-year financial objectives  
once all transactions announced on June 5, 2008 are closed

## LONGER TERM OUTLOOK

2009	Sales growth: 12.0 to 14.0% <sup>(1)</sup> compared to Ipsen's standalone objectives for 2008
	Operating margin: around 15% <sup>(2)</sup> (in % of total sales)

A continued commitment to innovation, with a R&D expense of 19.0 to 21.0% of total sales

Group operating margin expected to return to its 2007 level in 2011 <sup>(3)</sup>

Creating a North American platform expected to generate sales in excess of \$300 million in 2012<sup>(1)</sup>  
and potentially close to \$1 billion by the end of the next decade



## 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**

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## FIRST HALF 2008 RESULTS

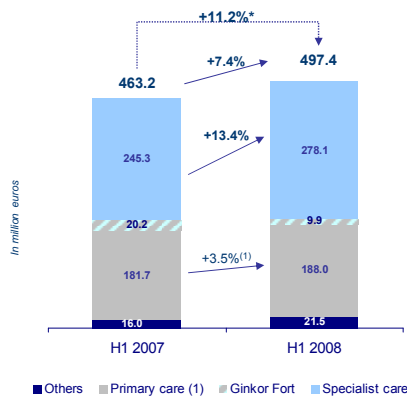
### Appendix 1



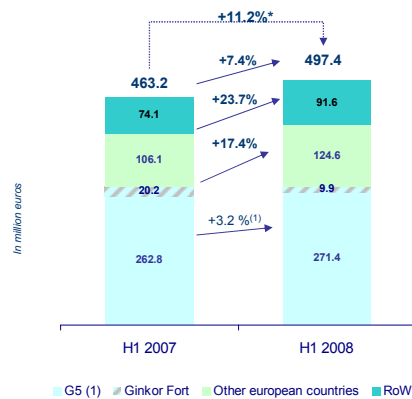
FIRST HALF 2008 RESULTS

## SALES PERFORMANCE

Sales performance by therapeutic area



Sales performance by region



Acceleration of growth

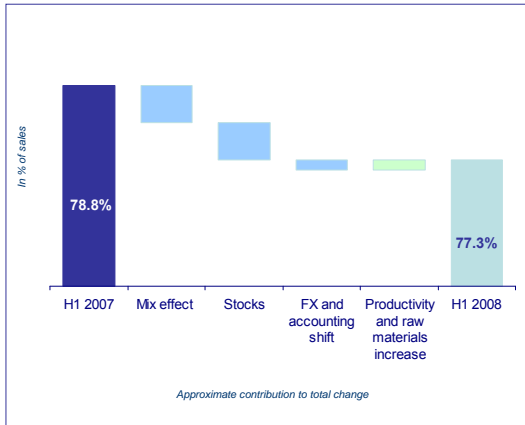
## OTHER REVENUES EVOLUTION



A strong performance, notably with the success of the Ginkor Fort® divestment

## GROSS MARGIN EVOLUTION

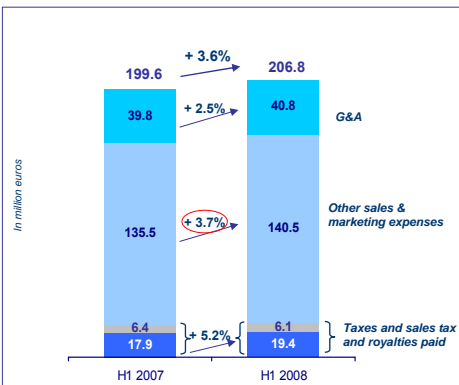
- + Continued productivity improvements despite an increase in some raw materials and energy costs
- Fast growing specialty care inducing a favorable "mix effect" more than offset by (i) fast growth of in-licensed products, (ii) strong growth of drug-related sales
- Some stock depreciations
- Negative FX impact
- Transfer of certain R&D costs to CoGS in connection with the progressive shift of a unit's production from R&D to commercialization purposes
- = Limited price cuts during the period



Fast growing in-licensed products, some stock depreciation and accounting shifts more than offset the mechanical positive mix effect

## SG&A EXPENSES EVOLUTION

- |                                   |  |
|-----------------------------------|--|
| Other sales & marketing expenses  | <ul style="list-style-type: none"> <li>▪ Efficient containment of actionable Sales &amp; Marketing expenses reflecting productivity improvements</li> <li>▪ Seasonality of Sales &amp; Marketing costs</li> <li>▪ Strong increase in royalties paid to third parties partly offset by lower taxes on sales (notably in Spain)</li> </ul> |
| General & Administrative expenses | <ul style="list-style-type: none"> <li>▪ Efficient cost containment</li> </ul>   |



Efficient cost containment and productivity improvements drive SG&A growth below sales growth level

## R&D EXPENSES EVOLUTION

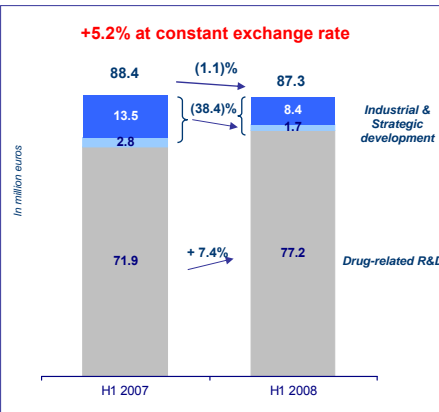
Drug-related R&D

Major research and development projects:

- Filing of Dysport® in the US
- Somatuline® in non-functioning NET
- Dopastatin phase I
- Sulfatase inhibitor (BN83495) phase I

Industrial development

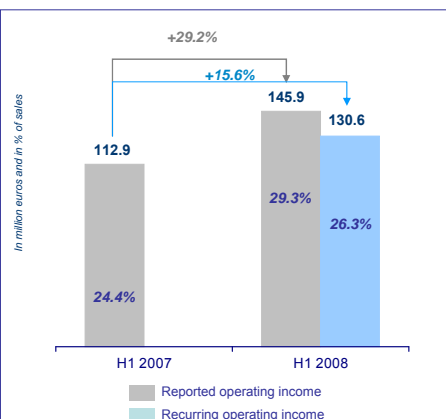
- End of preparation for pre-approval FDA inspections in certain manufacturing sites in the context of the filing of Dysport® and Somatuline® Depot in the US
- Transfer of certain R&D costs to CoGS



A sustained effort in R&D despite an expected decrease in Industrial development costs post US filings

## OPERATING INCOME EVOLUTION

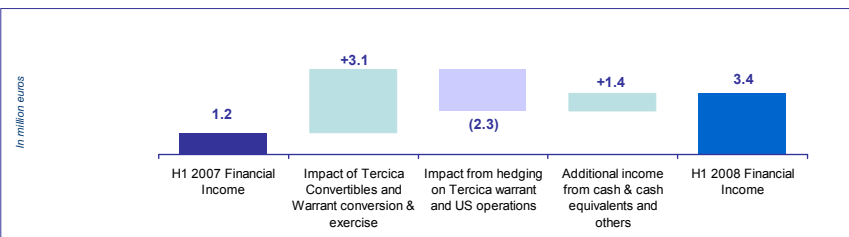
- Strong performance of all products
- Higher "other revenues", notably with the success of the Ginkor Fort® divestment
- Strong sales of in-licensed products and drug related activities as well as stock depreciations weight on CoGS ratio
- Limited overall FX impact on operating income
- Productivity efforts in the context of the continued launch costs for Increlex® and Adrovan®



A strong operating performance driven by a positive blend of business robustness and productivity efforts

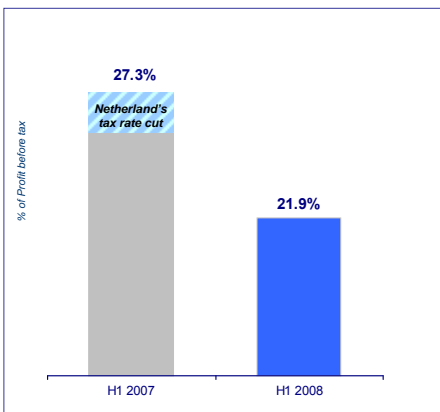
## FINANCIAL INCOME EVOLUTION

	H1 07	H1 08	Change
▪ Impact of Tercica convertibles and warrant conversion / exercise:	<b>€(2.2) m</b>	<b>€0.9 m</b>	<b>+€3.1 m</b>
- Increase of interests on convertible notes:	€0.7 m	€1.9 m	+€1.2 m
- Accelerated interests recognition on converts:	-	€8.3 m	+€8.3 m
- Fair value change on Tercica options and warrant:	€(1.5) m	€(6.3) m	-€4.7 m
- Exchange rate on Tercica convertibles and warrant:	€(1.4) m	€(3.1) m	-€1.6 m
▪ Impact from hedging on Tercica warrant and US operations:	-	€(2.3) m	€(2.3) m
▪ Additional income from cash/cash equivalents and others:	€3.4 m	€4.8 m	+€1.4 m
<b>Total financial income</b>	<b>€1.2 m</b>	<b>€3.4 m</b>	<b>+€2.2 m</b>



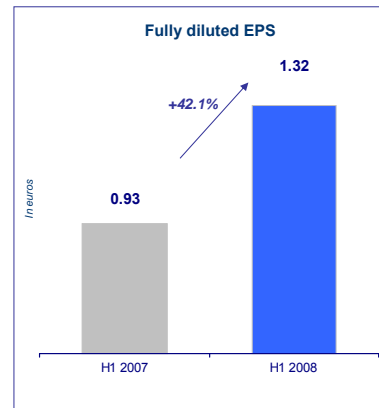
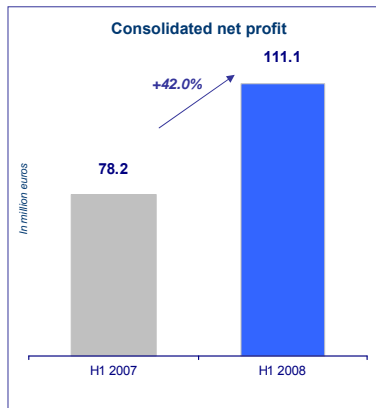
## INCOME TAX EVOLUTION

- H1 2008 benefited from a change in the computation rules of tax credits on research expenses in France
- H1 2007 was negatively impacted by a reduction in the value of deferred tax assets in the Netherlands, following the cut in tax rate





## NET INCOME AND EPS EVOLUTION



A strong overall performance

## CASH FLOW GENERATION

(In million of euros)

	30 June 07	30 June 08	Comments
<b>Cash Flow before change in working capital</b>	<b>112.6</b>	<b>141.3</b>	
(Increase) / Decrease in working capital	(65.3)	(17.1)	<ul style="list-style-type: none"> <li>Increase of receivables (-€36.8m)</li> <li>Increase of tax payables (+€24.4m) vs significant decrease in H1 2007</li> </ul>
<b>Net cash flow generated by operating activities</b>	<b>47.3</b>	<b>124.1</b>	
Investment in intangible assets and property, plant & equipment	(30.0)	(38.4)	<ul style="list-style-type: none"> <li>Capex required to maintain industrial facilities (-€26.2m)</li> <li>Intangible assets investment (-€8m)</li> </ul>
Deposits and other financial investments	(4.3)	-	
Others	(12.1)	6.0	
<b>Net cash flow used in investing activities</b>	<b>(46.4)</b>	<b>(32.4)</b>	<ul style="list-style-type: none"> <li>Revenues from Ginkor divestments (+€13.8m)</li> <li>Change in working capital linked to investing activities (-€12.6m)</li> </ul>
Net change in borrowings	2.4	(4.6)	
Dividends paid	(50.4)	(55.1)	
Others	(18.7)	(5.2)	
<b>Net cash flow used in financing activities</b>	<b>(66.8)</b>	<b>(64.9)</b>	<ul style="list-style-type: none"> <li>Sale of securities held for sale</li> </ul>
Discontinued operations	2.2	(1.0)	
<b>Change in cash and cash equivalent</b>	<b>(63.7)</b>	<b>25.8</b>	<ul style="list-style-type: none"> <li>Share buy back program</li> </ul>
Impact of exchange rate fluctuations	-	(3.0)	
<b>Closing cash &amp; cash equivalents</b>	<b>220.0</b>	<b>263.7</b>	
<b>Closing Net Cash<sup>(1)</sup></b>	<b>198.4</b>	<b>239.4</b>	

<sup>(1)</sup> 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

## TERCICA'S MAIN IMPACTS ON IPSEN'S ACCOUNTS

	H1 2007	H1 2008	
<i>(In thousand euros)</i>			
<b>Convertible notes and warrant</b>			<b>Comments</b>
Change in fair value of warrant	(1 058)	(2 360)	
– Incl. Exchange rate impact	(89)	(491)	▪ Exercice/conversion date (July 22, 2008) taken into account in the valuation model
Change in fair value of option	(609)	(4 944)	
– Incl. Exchange rate impact	(59)	(548)	▪ \$/€ exchange rate evolution
Exchange rate impact on notes w/o option	(1 278)	(1971)	▪ Accelerated recognition due to early exercise/conversion date
Interests on convertible Notes	634	10 160	
– Incl. Exchange rate impact	(2)	(43)	
<b>Impact on financial income</b>	<b>(2 309)</b>	<b>885</b>	
<b>Corresponding income tax impact</b>	<b>21</b>	<b>(42)</b>	▪ Reduced rate (1.7%)
Loss from associates	(2 999)	(4 817)	▪ Share in Tercica loss (~25%)
Purchase accounting	(463)	(408)	▪ Net amortization of Increlex™
<b>Loss from associates</b>	<b>(3 462)</b>	<b>(5 225)</b>	
<b>Impact on Ipsen consolidated net profit</b>	<b>(5 750)</b>	<b>(4 382)</b>	

## BALANCE SHEET EVOLUTION

	Assets			Liabilities	
	31 Dec 07	30 Jun 08		31 Dec 07	30 Jun 08
Goodwill	189.0	189.0	Equity	799.9	844.1
Property, plants & equipments	221.9	226.6	Minority interests	1.2	1.4
Intangible assets	89.2	92.5	<b>Total equity</b>	<b>801.1</b>	<b>845.5</b>
Other non-current assets	185.3	95.1	Long-term financial debts	20.8	16.3
<b>Total non-current assets</b>	<b>685.4</b>	<b>603.2</b>	Other non-current liabilities	221.0	223.0
<b>Total current assets</b>	<b>636.8</b>	<b>744.6</b>	Short-term debts	9.2	10.4
<i>Incl. cash and cash equivalents</i>	247.1	269.7	Other current liabilities	265.5	249.1
Assets / discontinued operations	0.7	-	Liabilities / discontinued operations	5.3	3.6
<b>Total assets</b>	<b>1,322.9</b>	<b>1,347.9</b>	<b>Total Liabilities</b>	<b>1,322.9</b>	<b>1,347.9</b>
<b>Net Cash <sup>(1)</sup></b>	<b>198.4</b>	<b>239.4</b>			

## MILESTONES CASHED IN BUT NOT YET RECOGNIZED AS REVENUES

(In million euros)

	30 June 07	30 June 08
Payments not yet recognised as revenues in H2	8.3	11.2
Payments not yet recognised as revenues in Y+1	17.2	22.4
Payments not yet recognised as revenues in Y+2 and beyond	167.2	183.3
<b>Total Milestones cashed in but not yet recognised as revenues</b>	<b>192.7</b>	<b>216.9</b>

## GAINING FULL CONTROL OF OBI-1'S DEVELOPMENT

### Appendix 2

## GAINING FULL CONTROL OVER A PROMISING COMPOUND

- 1 **Leveraging our know-how in haematology by gaining full rights to the product's development and commercialisation...**
  - Ipsen produced and commercialized the only plasma-derived porcine Factor VIII until 2004, Hyate:C
- 2 **... in order to fulfill a high unmet medical need...**
  - Acquired hemophilia is an orphan disease (prevalence of 1.5 per million): 6% to 22% of patients die from bleeding
- 3 **... and optimise its development and time to market...**
  - The development of OBI-1 will benefit from Ipsen's integrated approach and specific knowledge base in hemophilia A with inhibitor and plasma-derived porcine Factor VIII
- 4 **... for a highly specialized hospital product, generating high revenue per patient**
  - Potential peak sales worldwide in excess of \$200 million

An incremental investment to gain full control of the development of a promising compound

## TRANSACTION DETAILS

- **In 1998, Emory University licensed to Octagen its patents on OBI-1, who in turn granted a worldwide, exclusive sublicense to Ipsen**
  - Octagen was responsible for the pre-clinical and clinical development of OBI-1 and sublicensed certain rights to Ipsen in connection with the manufacturing, regulatory activities and commercialization of OBI-1.
  - Ipsen agreed to make milestone payments to Octagen and to pay royalties based on OBI-1 future net sales.
  - Ipsen purchased c.21.5% of Octagen's share capital
- **Ipsen to acquire all Octagen's assets related to OBI-1**
  - Upfront payment of \$10.5 million (€6.8 million) to Octagen,
  - Mid single digit royalty on net sales (including that to Emory)
  - Potential additional payments contingent on entry of the product into P.III and on marketing approvals
  - Redemption of its stake in Octagen

## A UNIQUE AGENT FOR THE EMERGENCY CARE OF ACQUIRED HEMOPHILIA

- **Incidence of this autoimmune disease on the increase with the ageing population**
- **Silent disease often revealed under elective or emergency surgery**
  - Uncontrollable bleed due to antibodies against patient's factor VIII
- **OBI-1 provides fast controllable dose-responsive formation of blood clots through the intrinsic pathway of coagulation**
  - Upon stabilization of hemostasis, patients are treated to full recovery (using Rituxan)
- **OBI-1 will benefit from a strong support from the hematology community built by Ipsen**
  - Ipsen produced and commercialized the only plasma-derived porcine Factor VIII until 2004
- **Ipsen will control all pre-clinical and clinical development activities**
  - OBI-1 development will benefit from this integrated approach and Ipsen's specific knowledge in hemophilia A with inhibitor and plasma-derived porcine Factor VIII
  - Ipsen will now seek to confirm next steps towards registration, in liaison with regulatory agencies, with first feedback expected in 2008

## ROCHE'S ADA TASPOGLUTIDE DATA

### Appendix 3

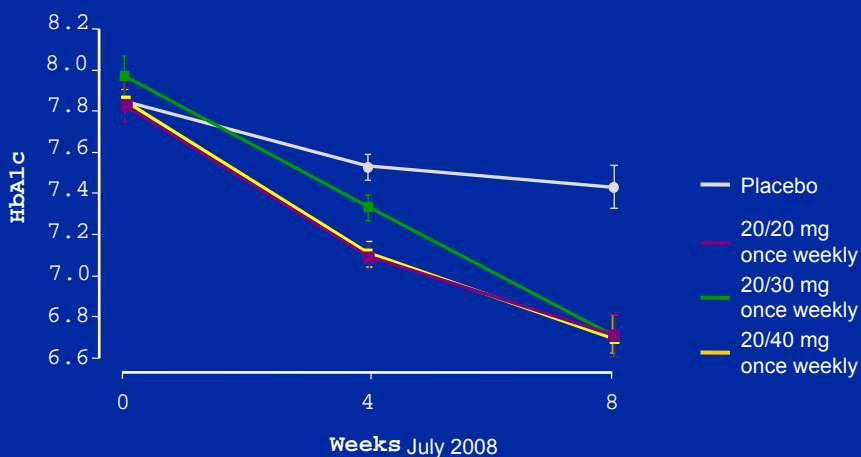
## Taspoglutide provided significant reductions in A1c and FPG along with weight loss in diabetic patients

- Once-weekly 10 mg and 20 mg were most effective at achieving A1c targets, body weight, and FPG reductions
  - Approx 80% of patients achieved ADA (7%) A1c target following 8 weeks of treatment
  - Significant reductions in A1c and weight loss were achieved after only 8 weeks of treatment in patients inadequately controlled on metformin monotherapy
  - Addition of taspoglutide resulted in no increased risk of hypoglycemia than metformin alone
  - Fasting plasma glucose (FPG) reductions observed following the first injection
  - Safety and tolerability profile supports entry into phase III

**Taspoglutide, the first investigational once-weekly, long-acting, human GLP-1 analogue, provided significant reductions in A1c and FPG as well as weight loss with an acceptable safety and tolerability profile for use in patients with type 2 diabetes**

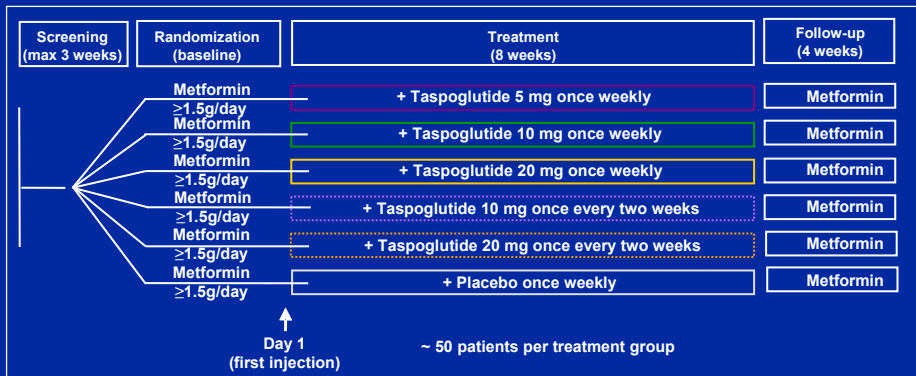
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## Main efficacy conclusion from the dose titration study (ADA presentation no. 10-OR)



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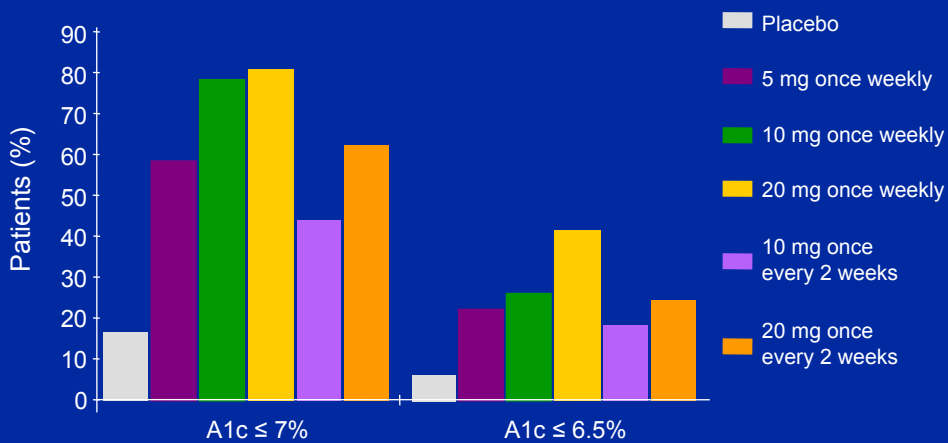
## Metformin combination study objectives were to characterize dose range, efficacy & safety of taspoglutide



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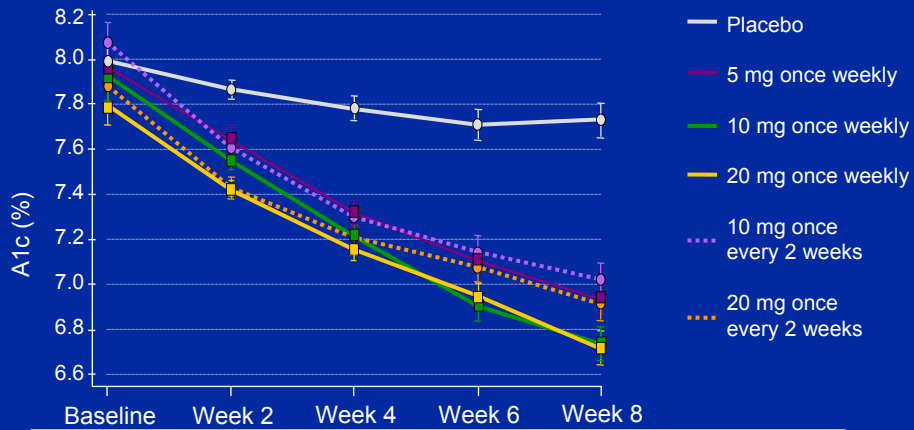
## 79 and 81% of patients treated with taspoglutide achieved ADA target A1c (≤7%)



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## Taspoglutide provided significant A1c reductions over only eight weeks (from baseline)

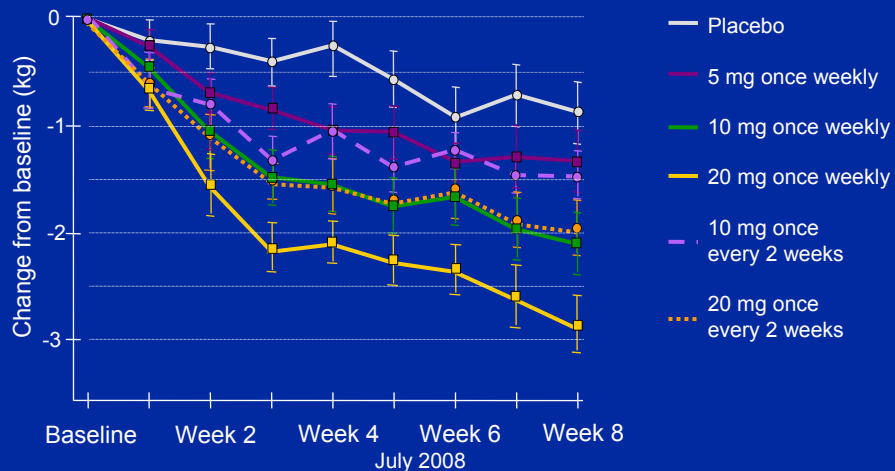


**Taspoglutide safely reduced A1c below 7.0% with more than 1%-point reduction after only eight weeks**

\* All taspoglutide doses were statistically significant ( $p < 0.001$ )

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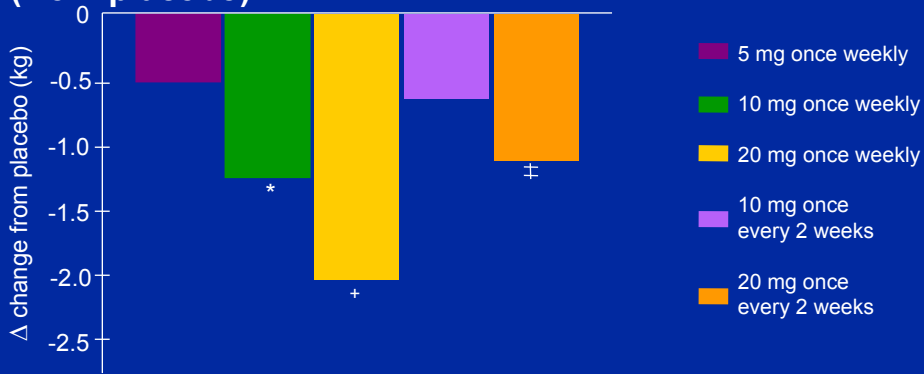
## Taspoglutide provided significant dose-related weight loss in only eight weeks (from baseline)



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## Taspoglutide provided significant dose-related weight loss in only eight weeks (from placebo)



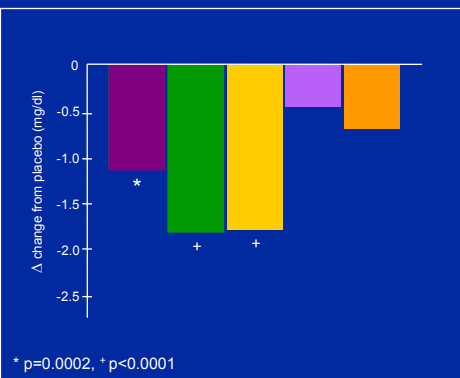
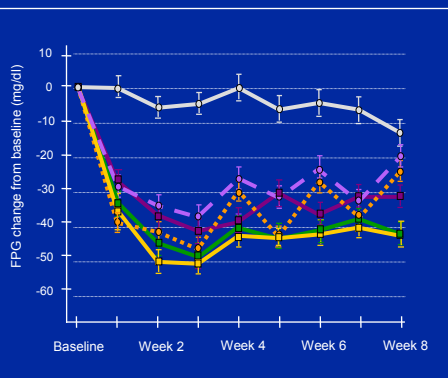
**Taspoglutide 20 mg once weekly provided a 2 kg weight loss in only eight weeks**

\* p=0.0035, + p<0.0001, ± p=0.0083

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## Taspoglutide provided significant reductions in FPG in only eight weeks

*Appreciable reductions seen by weeks 1-2*



\* p=0.0002, + p<0.0001

■ Placebo ■ 5 mg once weekly ■ 10 mg once weekly ■ 20 mg once weekly ■ 10 mg once every 2 weeks ■ 20 mg once every 2 weeks

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## Taspoglutide safety profile



- As expected, the most common adverse event was transient, dose-related, mild-to-moderate nausea
  - Episodes of nausea tended to occur during the first day after administration
  - 18% placebo-adjusted incidence in 10 mg once-weekly group
- The frequency of vomiting in the groups that received taspoglutide once-weekly was similar to placebo
  - In most patients, vomiting occurred only once and resolved within one day
- Most cases of nausea and vomiting resolved spontaneously while treatment continued
- Addition of taspoglutide resulted in no increased risk of hypoglycemia than metformin alone
- No acute pancreatitis was observed in the phase II program

**Safety and tolerability profile supports entry into phase III**

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## Taspoglutide is an investigational once-weekly, long-acting human GLP-1 analogue for the treatment of T2D



- Significantly improves both A1c and FPG over only eight weeks
- Provides substantial weight loss in a dose-response fashion
- Additional phase II titration study confirmed the safety and tolerability of taspoglutide
- Efficacy, safety and tolerability profile supports entry into phase III

**Data from this study shows that taspoglutide has the potential to be the first once weekly, long-acting human GLP-1 analogue**

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## Taspoglutide phase III program *Targeted and competitive*

- Taspoglutide phase III program designed to confirm promising phase II data and generate competitive launch label
  - Head-to-head comparisons: Sitagliptin, exenatide, insulin glargine
  - Patient population: Treatment-naïve → multiple OADs
    - Add-on to metformin
- Based on phase II data, two taspoglutide doses will be tested in all phase III studies:
  - 10 mg once weekly
  - 10 mg once weekly for 1 month → up-titrate to 20 mg once weekly
- First-patient-in expected 2H 2008
- 6 month treatment period with follow-up extension phases

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## Approximately 2,500 type 2 diabetic patients will be randomized into taspoglutide's phase III program

Study	Study	Sample size	Background OAD
1	Monotherapy vs. placebo	330	Treatment-naïve
2	Taspoglutide vs. sitagliptin vs. placebo	630	Metformin
3	Taspoglutide vs. insulin glargine	990	Metformin
4	Taspoglutide vs. exenatide	990	Metformin, TZDs, or metformin + TZDs
5	Add-on to sulfonylurea (± metformin) vs. placebo	200	Sulfonylurea (+/- metformin)
6	Add-on to pioglitazone + metformin vs. placebo	330	Pioglitazone + metformin

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## Taspoglutide's target product profile

### *Aiming for best-in-class*

