



***The global leader in omega-3 derived life saving therapies***

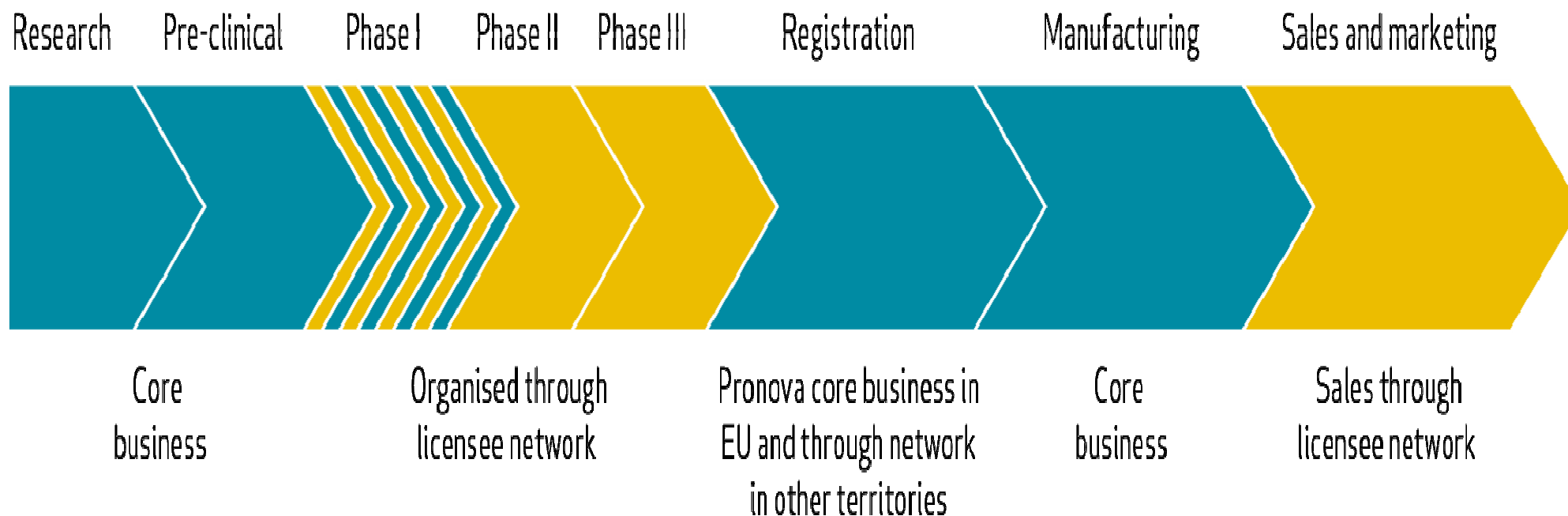


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# Strategic areas



**The only FDA and EU approved omega-3 derived pharmaceutical**

# Global licensees and marketing partners



Pierre Fabre



Partner	Geographic Territory
GSK	US
Grupo Ferrer	Spain, Germany, Portugal, Greece, Central South America
Pierre Fabre Santé	France, West/Central Africa
Solvay	UK, Canada, Australia, Eastern Europe, Greece, Middle East, Russia, China, India, South Africa
Kuhnil	Korea
Takeda	Japan
SPA	Italy

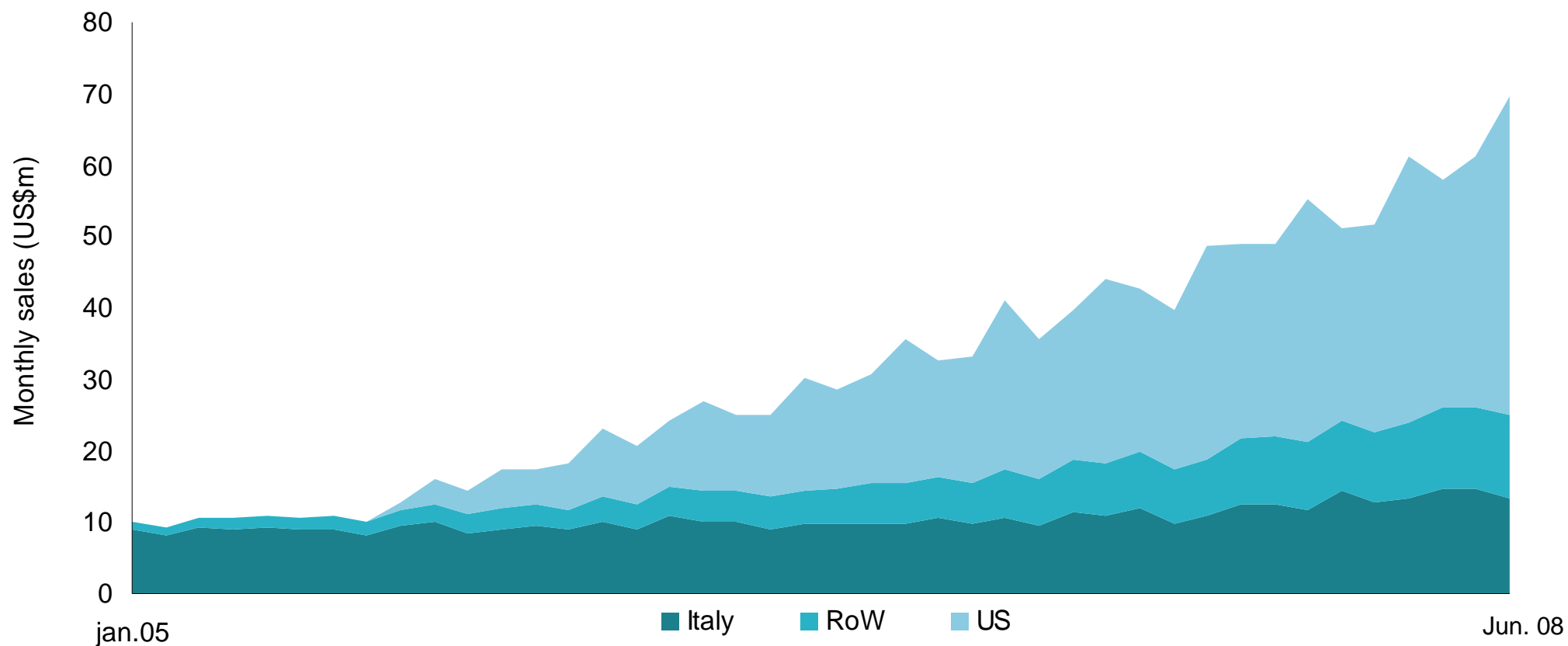
*>2 500 sales representatives*

# Omacor® / Lovaza® / Zodin®

Potent Proven Pure Patented



# Omacor / Lovaza = blockbuster potential



**End user sales run-rate of >US\$835 million in June 2008**

## Growth in all markets:

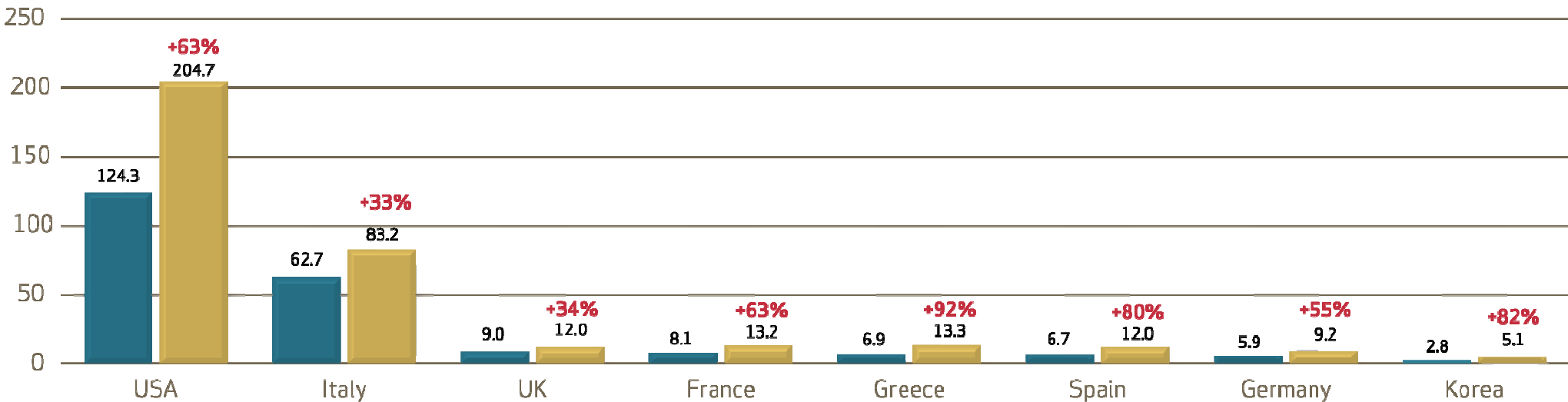
# Omacor/Lovaza January-June 2008



## End-user sales by major markets at 30 June\*

Amounts in USD million

→ 2007 YTD → 2008 YTD



\* Source: IMS

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# US market development



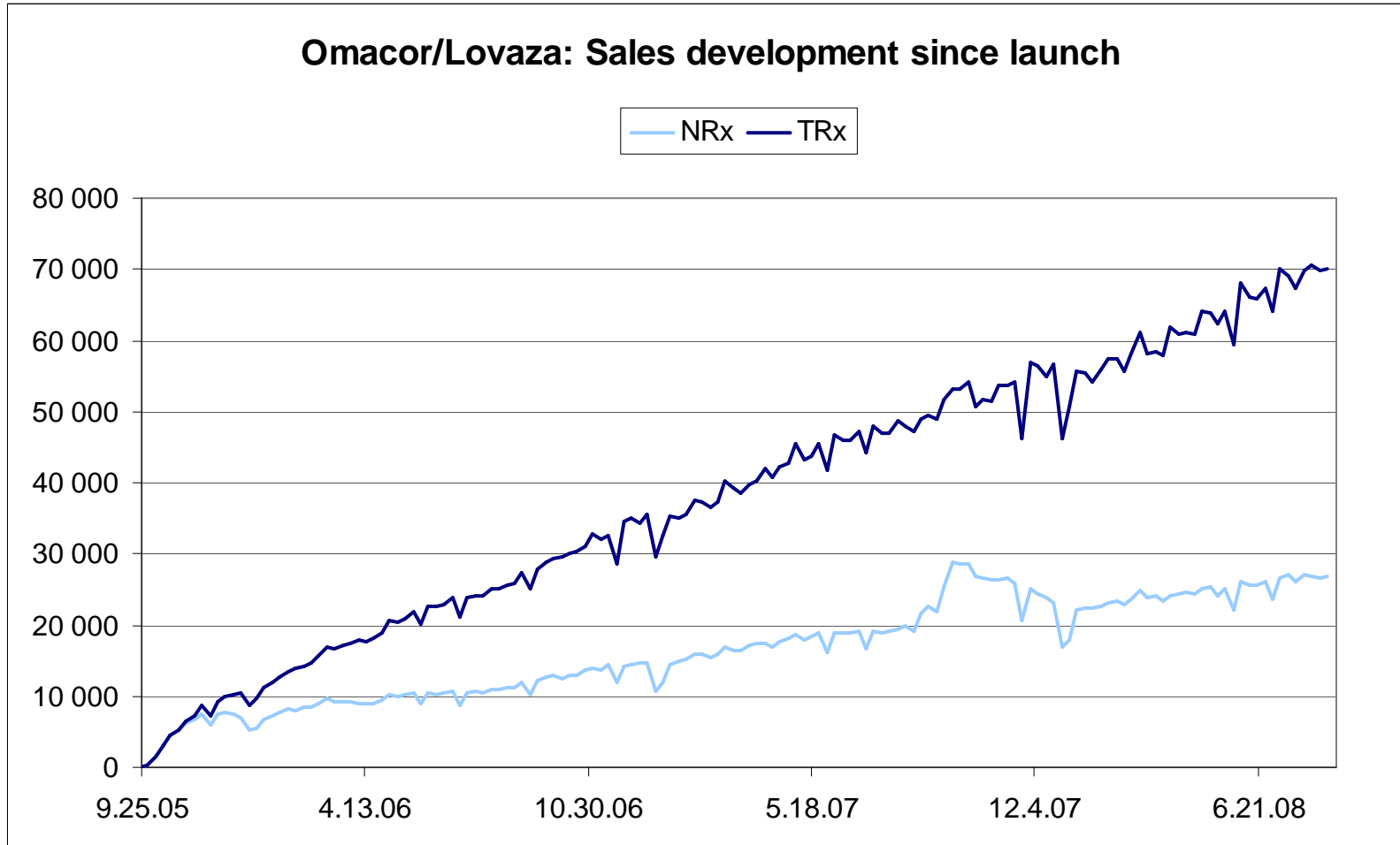
**NRx:**

YTD growth NRx volume up **39,8%** compared to the same period LY

**TRx:**

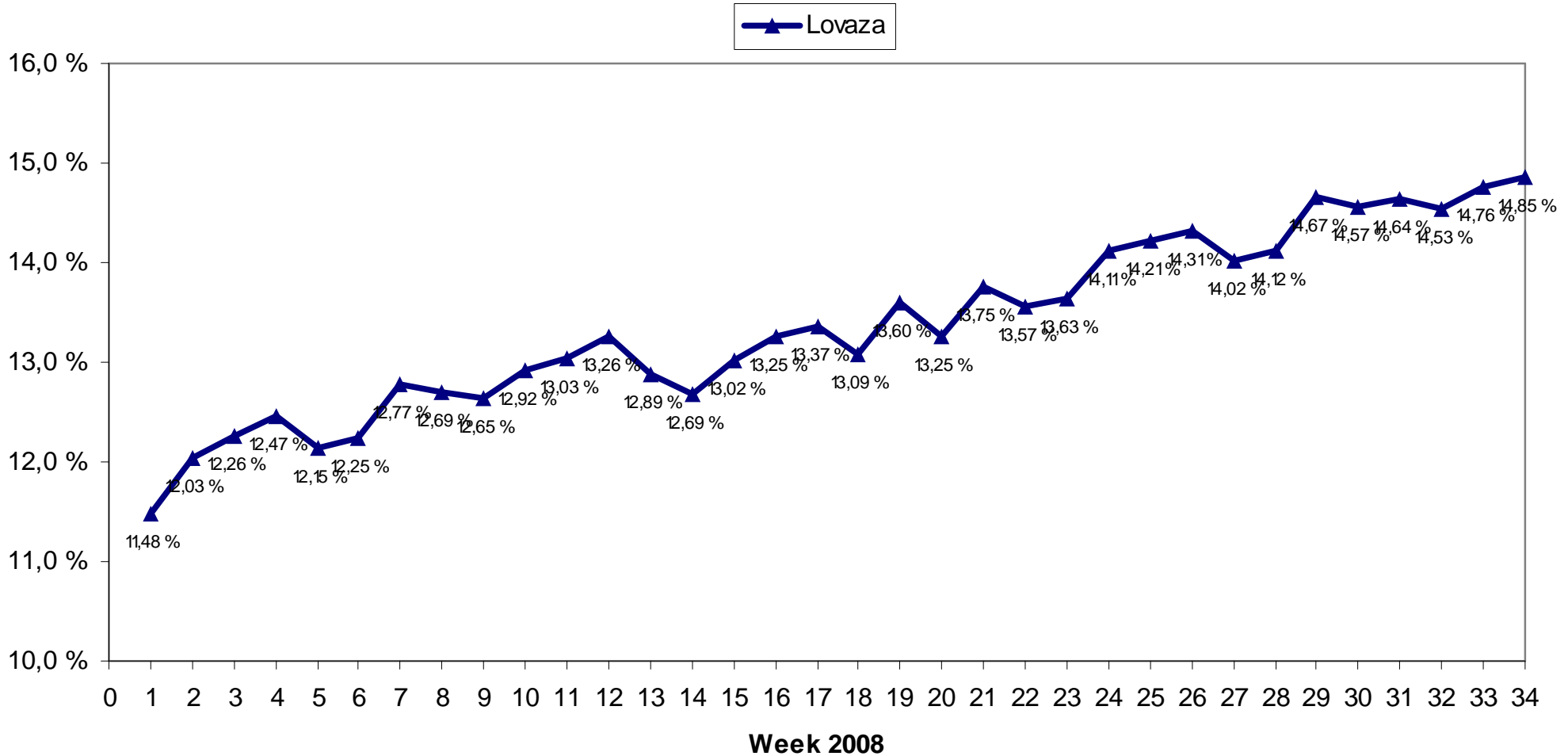
YTD growth TRx volume up **40,0%** compared to the same period LY

**Omacor/Lovaza: Sales development since launch**



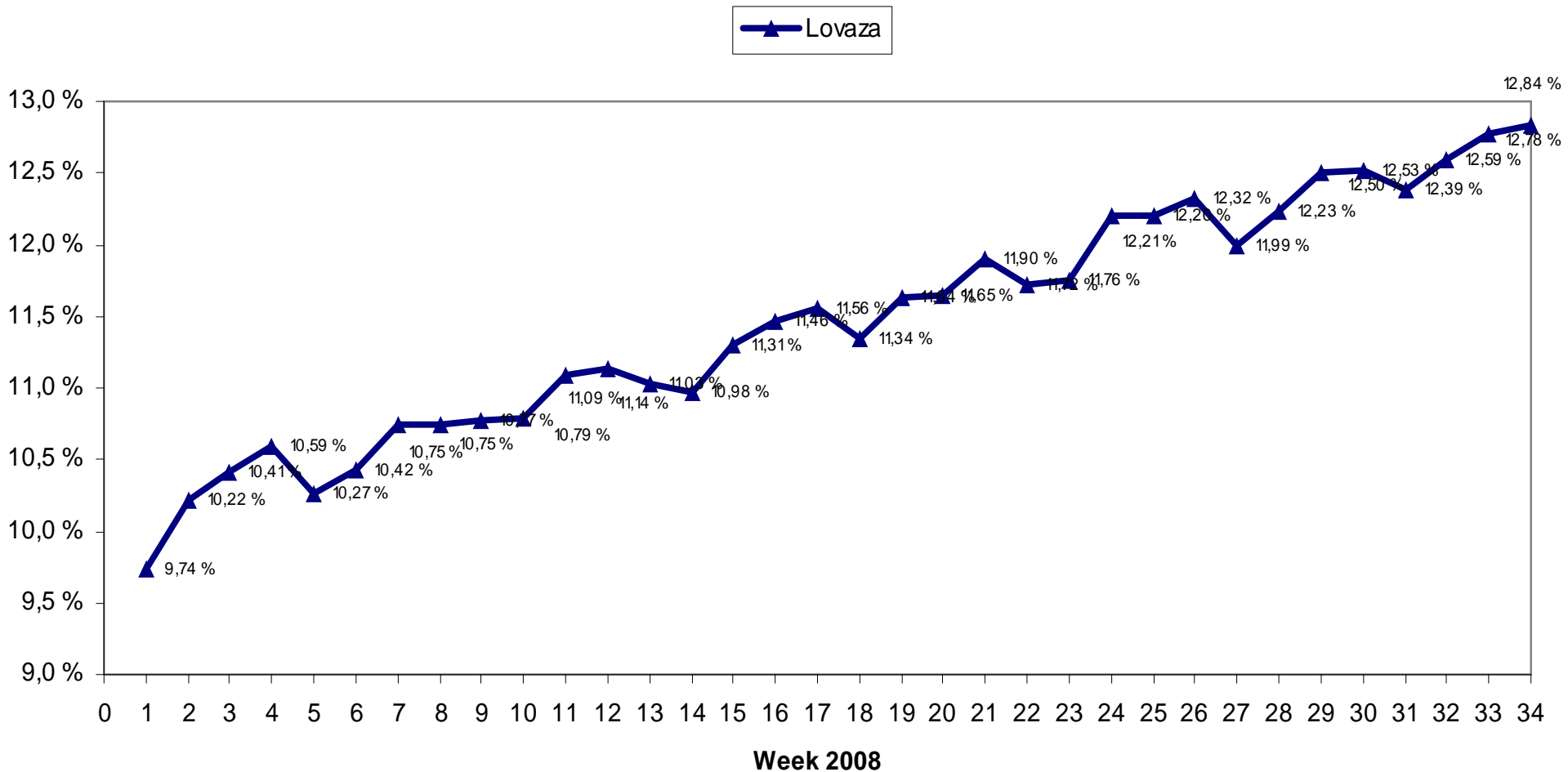
**Market share - NRx  
Non-Statin Market**

**Lovaza:**  
Growth in Market share (YTD):  
**29,3 %**



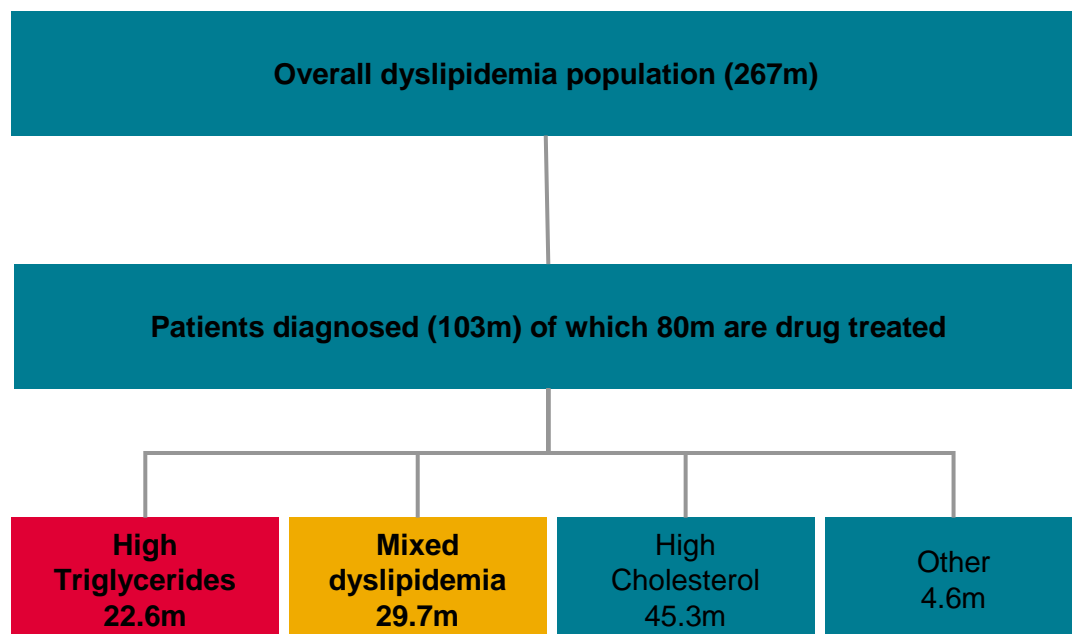
## Market share - TRx Non-Statin Market

**Lovaza:**  
Growth in Market share (YTD):  
**31,8%**



# Global Cardiovascular Drug Market >US\$100bn

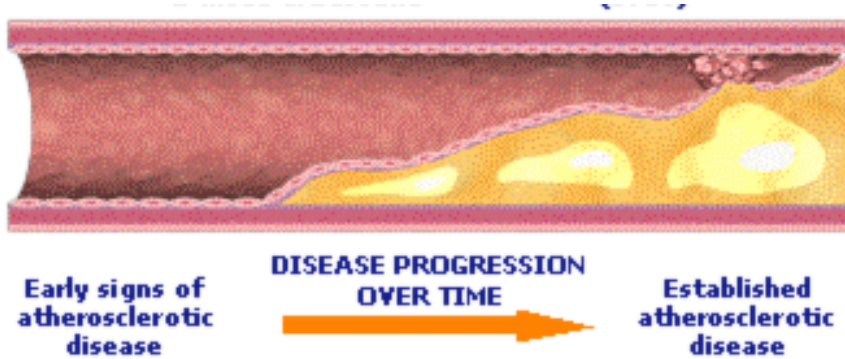
## Breakdown of dyslipidemic population in the seven major markets<sup>1</sup>



- An estimated 3.71<sup>2</sup> million people p/a in the seven major pharmaceutical markets suffer a myocardial infarction (MI), of which 1.11 million are in the five major European markets
  - Global prevalence expected to grow at CAGR of 4.5% (from 2005-11)<sup>1</sup>
  - c.2 / 3 of MI patients survive for more than 24 hours<sup>2</sup>

**Total cost of cardiovascular diseases in US & EU >US\$600bn**

# Therapeutic areas



## Approved indications:

- Lovaza (US) - Very High Triglycerides
- Omacor/Zodin (EU)
  - *Post Myocardial Infarction*
  - *Hypertriglyceridaemia*

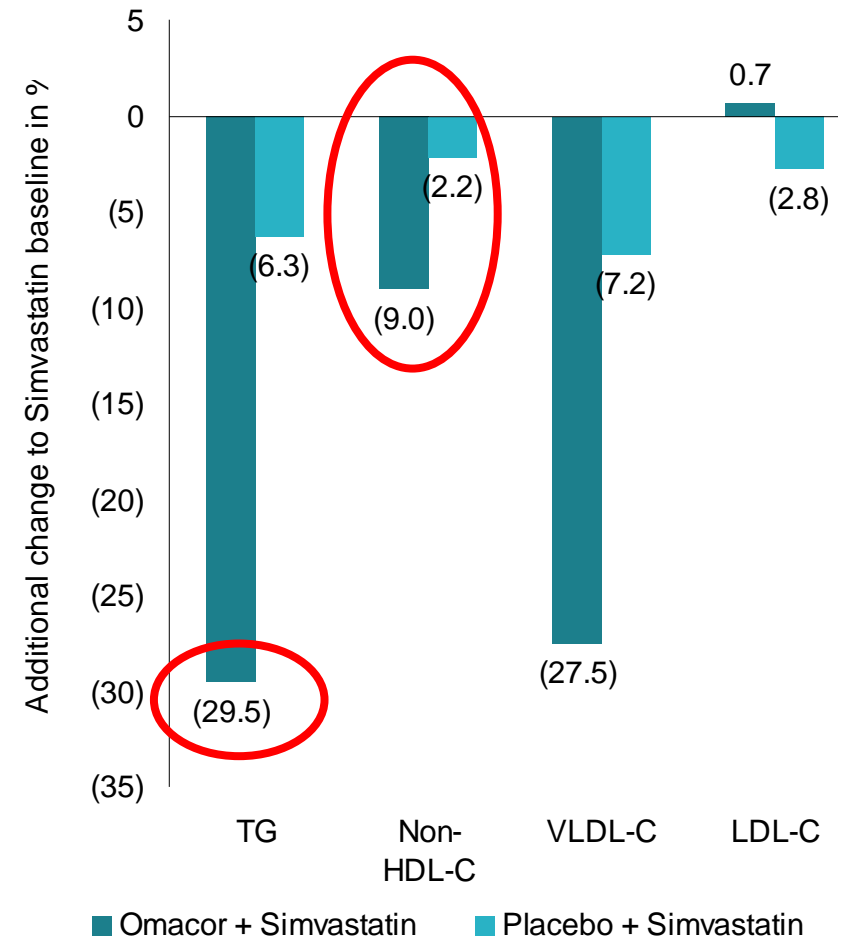
## Important markers:

- ↑ Total cholesterol
- ↑ LDL (“bad cholesterol”)
- ↓ HDL (“good cholesterol”)
- ↑ Triglycerides (HTG)

**Efficacious and safe**

# Mixed Dyslipidemia Combination Therapy – OM6 (Phase III)

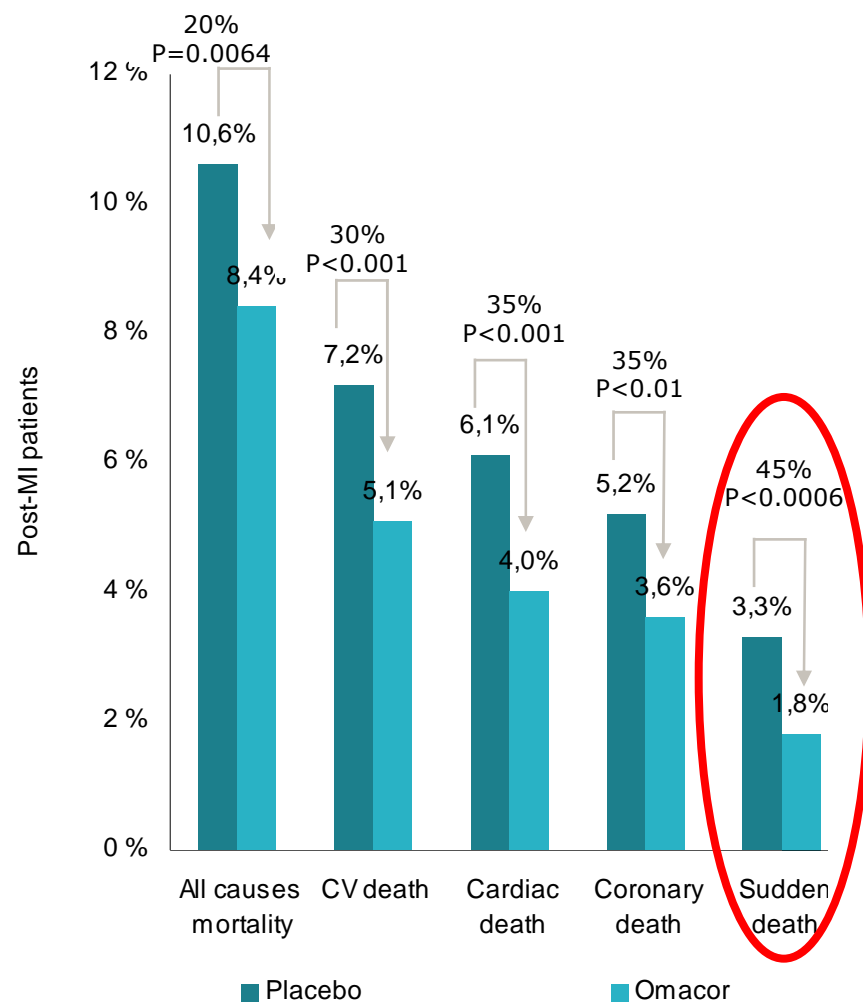
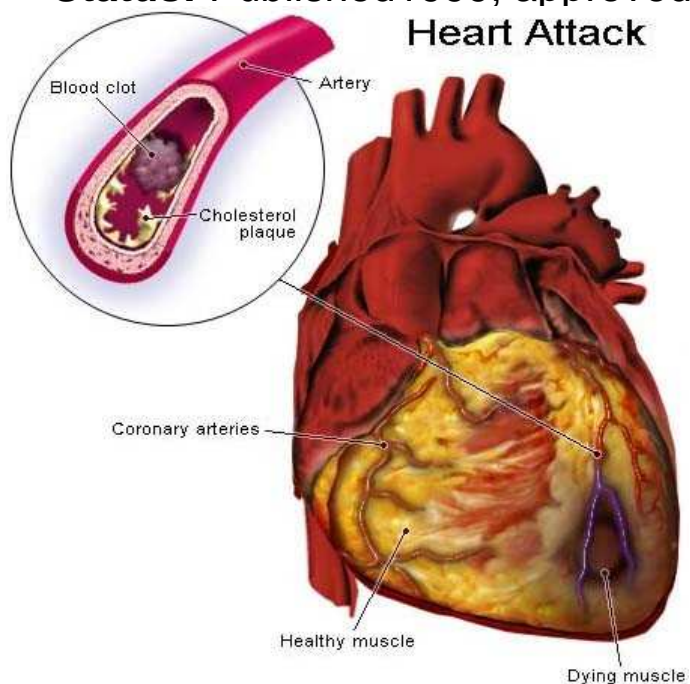
- **Objective:** Efficacy and safety of Omacor in combination with simvastatin for HTG 200-499 mg/dL patients
- **Study:** 8 week treatment (with 8 weeks run-in), 254 patients split into two groups:
  - *Omacor 4g and simvastatin 40mg*
  - *Placebo and simvastatin 40mg*
- **Primary endpoint:** Change in non-HDL-C from baseline
- **Secondary endpoint:** Change from baseline in TG and cholesterol fractions (VLDL-C, LDL-C)
- **Status:** Completed, published 2007. Included in FDA label



**Clinical data included in the US label**

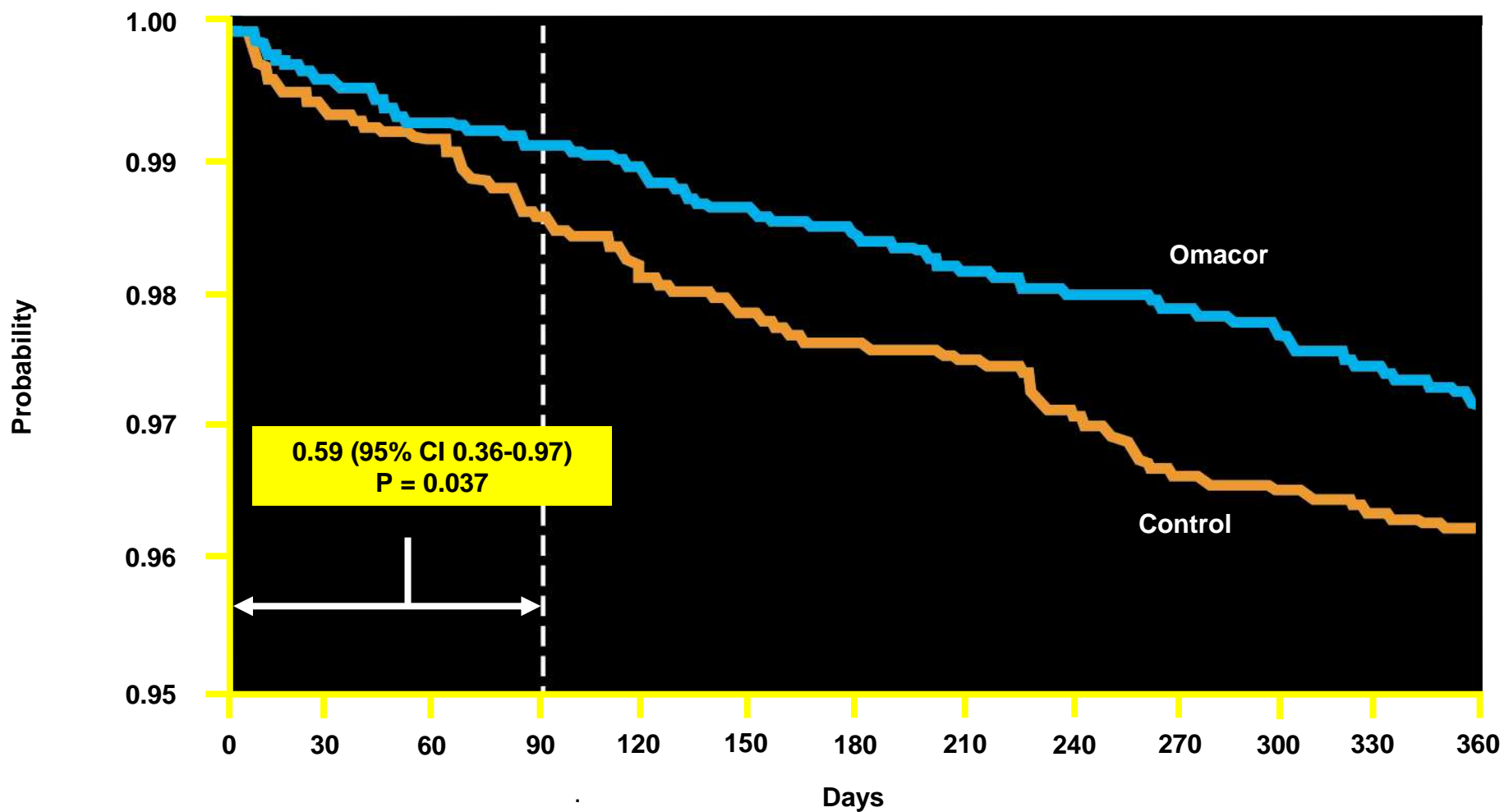
# Post MI – GISSI Prevenzione (Phase III)

- **Objective:** Omacor cardiac mortality
- **Study:** 3.5 year treatment duration, 11,324 post-MI patients, split into four groups:
- **Primary endpoint:** Hard endpoint of 3.5 years. Cumulative rate of all-cause death, non-fatal MI and non-fatal stroke
- **Status:** Published 1999, approved in EU



# GISSI Prevenzione Results

Early onset of action on all-causes of mortality



# Research & development



# Diversified pipeline of clinical programmes

	Indications	Pre-clinical	Phase I	Phase II	Phase III	Market
<b>Monotherapy</b>						
Omacor/Lovaza	HTG	→	→	→	→	→
	Post MI	→	→	→	→	→
	Atrial fibrillation	→	→	→	→	→
	<b>Heart failure</b>	→	→	→	→	→
	Primary prevention of cardiovascular disease (Diabetes type II)	→	→	→	→	→
<b>New formulations (bioequivalence)</b>						
Omacor + Simvastatin <sup>1</sup>	Dyslipidemia				→	
Capsule technology <sup>2</sup>					→	
<b>New products</b>						
PRB programmes	Cardiovascular	→				
	Metabolic	→				
	Chronic inflammation	→				

<sup>1</sup>) Fixed combination expected to be in clinical trials in 2008

<sup>2</sup>) Alginate capsule expected to be in clinical trials in 2010

# GISSI Heart failure study



Prospective, Multicenter, Double blind, Randomized, Placebo controlled



## Two co-primary endpoints:

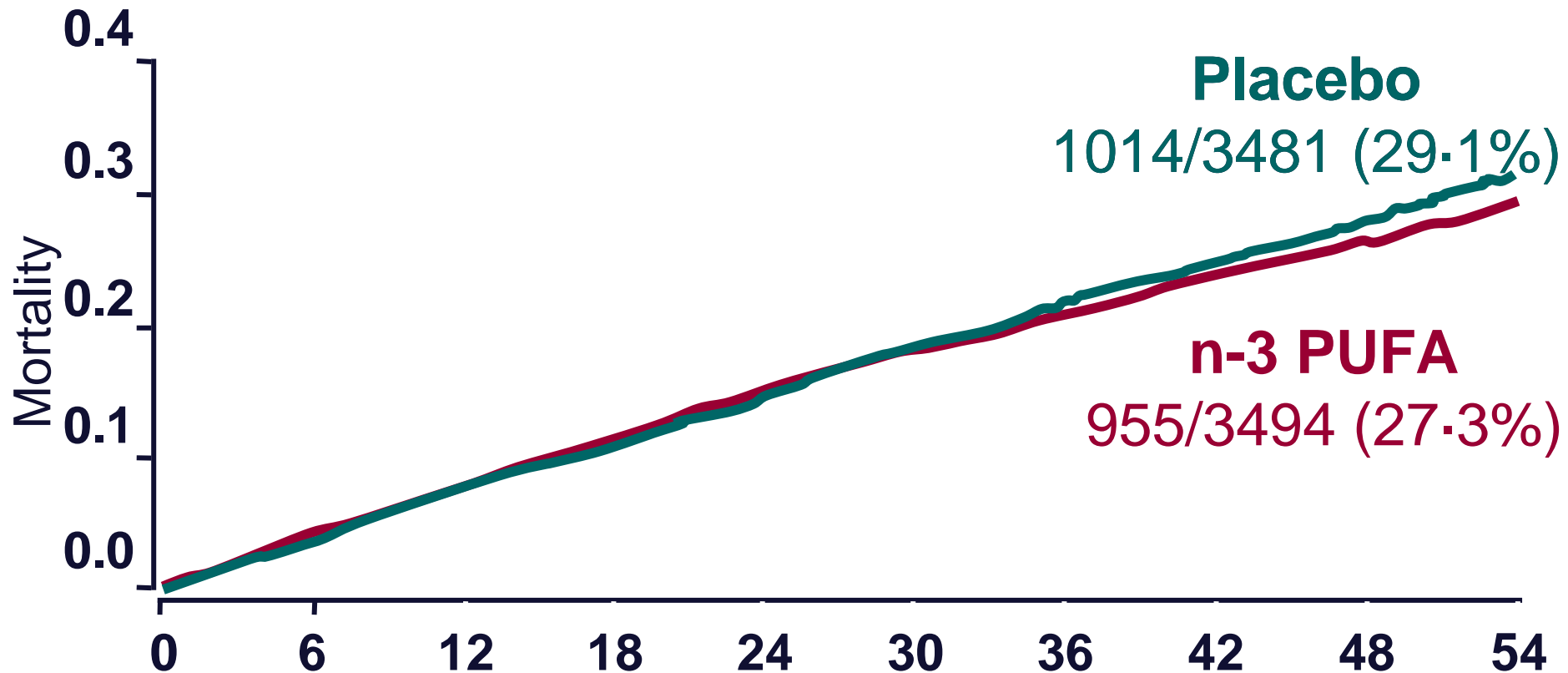
- All-cause death
- All-cause death or cardiovascular hospitalization

- **Treatment period:** Above 3 years
- **Expected presentation forum:** ESC 2008, Munich

Tavazzi L et al: Rationale and design of the GISSI heart failure trial: a large trial to assess the effects of n3-polyunsaturated acids and rosuvastatin in symptomatic congestive heart failure. *European Journal of Heart Failure* 2004; 6: 635-641

## GISSI-HF:

# Omacor reduced mortality by 9 per cent



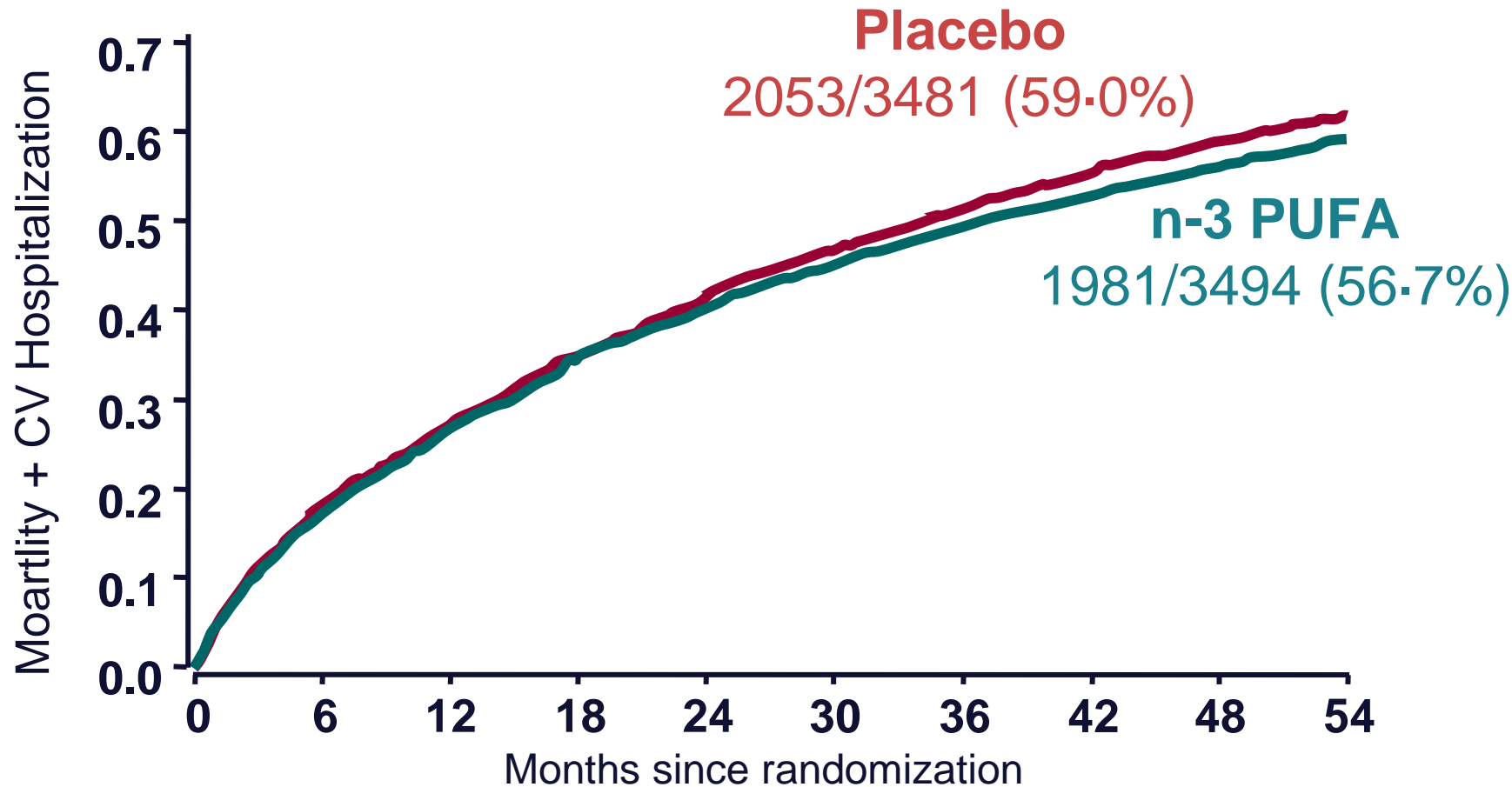
Relative risk reduction: 9%\*

HR (95.5% CI)\* **0.91 (0.833 – 0.998)** p value **0.041**

NNT = 56

# GISSI-HF:

## Omacor reduced mortality and cardiovascular hospitalisations by 8 per cent

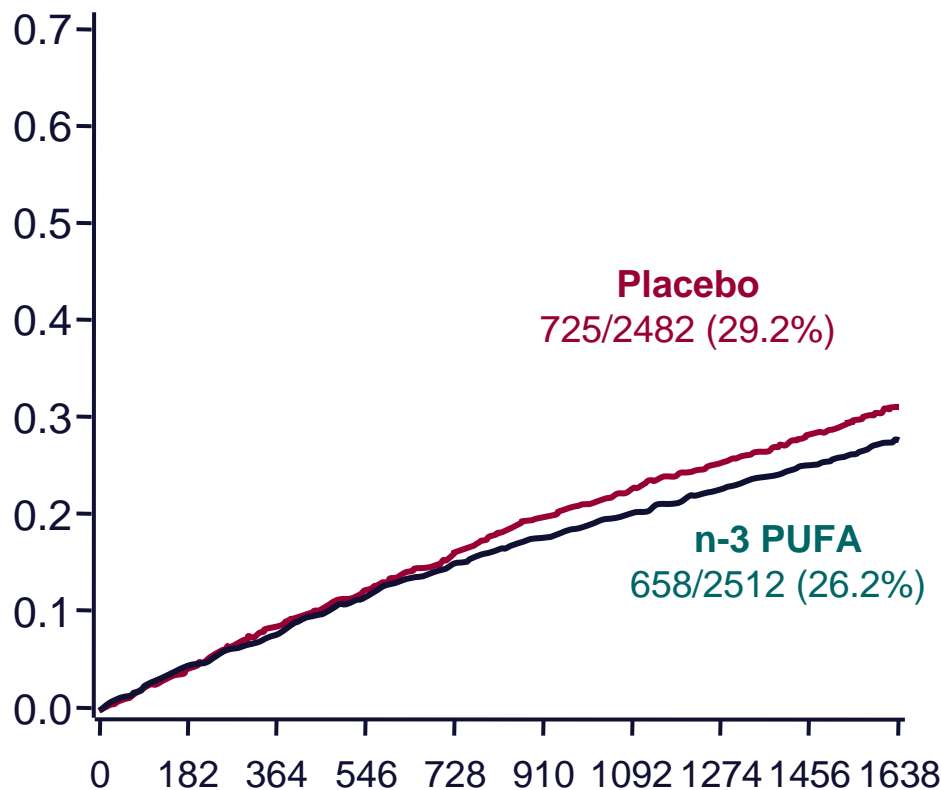


Relative risk reduction: 8%\*

HR (95.5% CI)\* 0.92 (0.849 – 0.999) p value 0.009

# Per protocol analysis (4 994 patients)

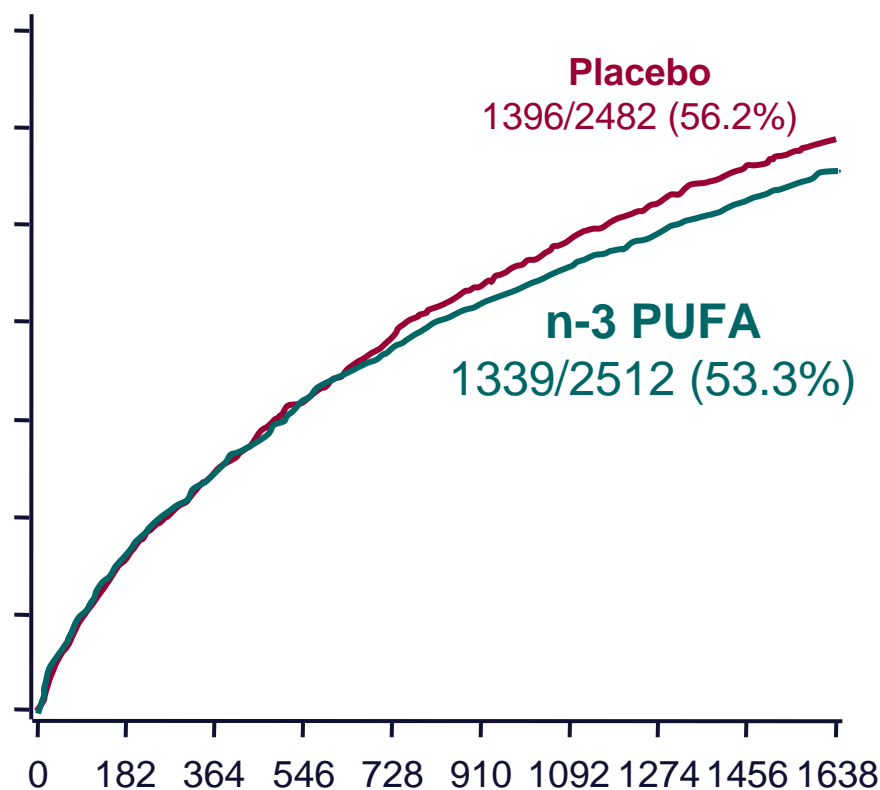
## Time to all-cause death



**Relative risk reduction: 14%\***

**HR (95.5% CI)\* 0.86 (0.77 – 0.95) p value 0.004**

## Time to Combined Endpoint



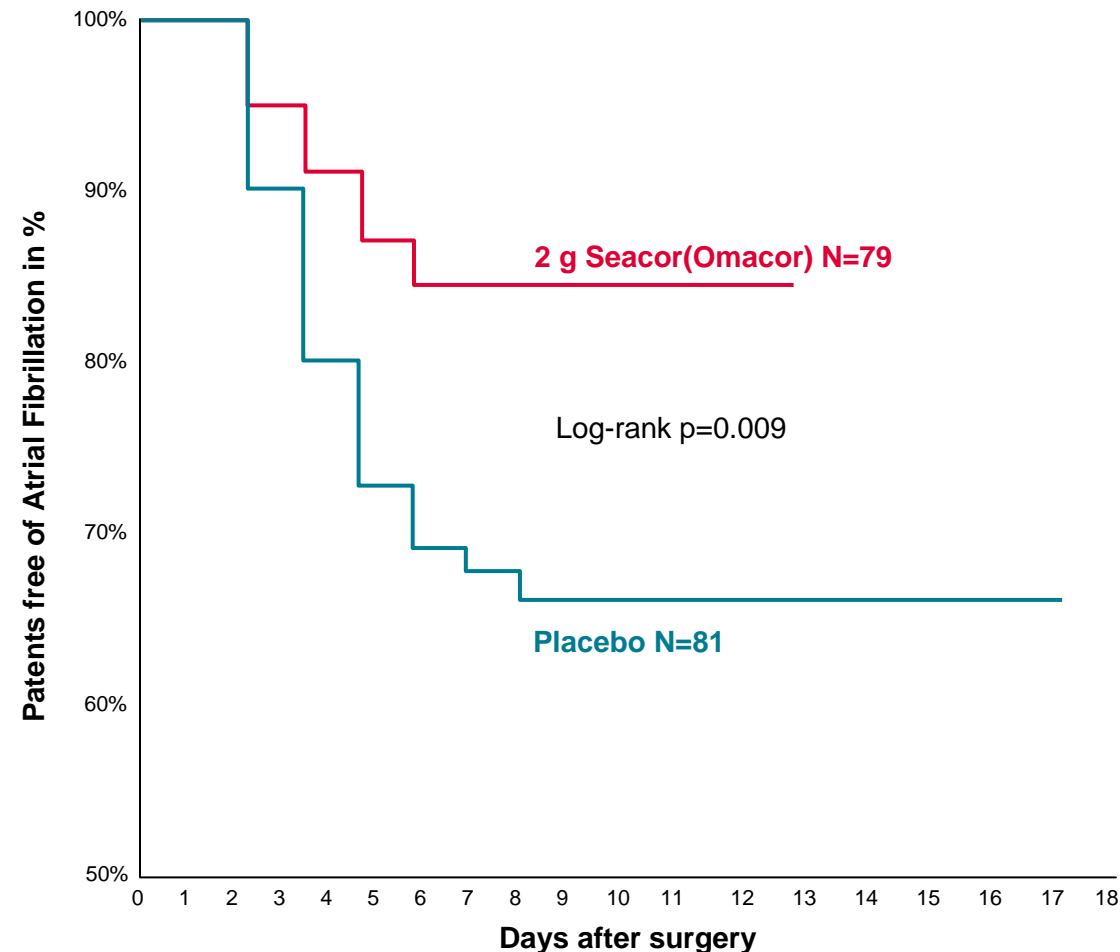
**Relative risk reduction: 8%\***

**HR (95.5% CI)\* 0.92 (0.84 – 1.02) p value 0.036**

# Atrial fibrillation: Clinical results

- Epidemiological evidence of reduced incidence of AF with increased intake of EPA and DHA in 4815 elderly US adults
- GISSI-P showed 45% reduction in sudden death (which might be caused by cardiac arrhythmia)
- Animal data have shown that treatment with omega-3 fatty acids prevented arrhythmias

Omacor reduce incidence of post operative atrial fibrillation.



*Alginate project:*

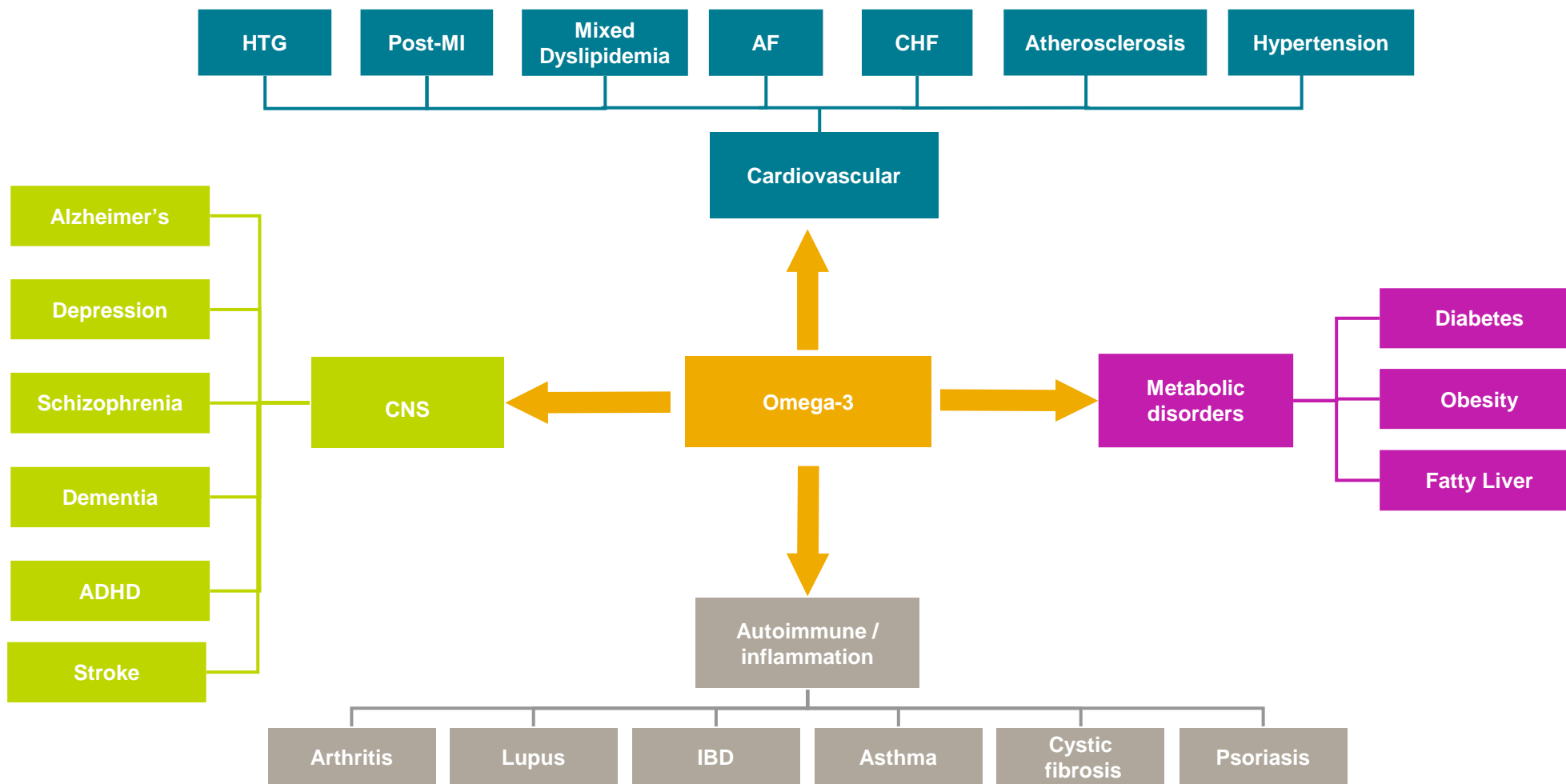
# Status development

- **Preclinical studies are ongoing**
- **Pilot plant to be set up Q1/Q2-09**
- **Clinical study is planned to be undertaken in 2009**
- **Potential launch: 2010 - 2011**

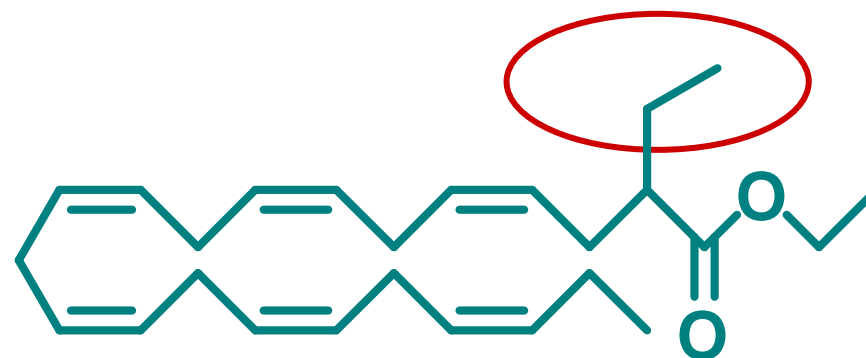
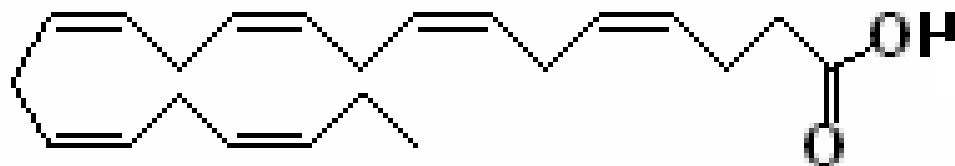


# R&D

*A substantial amount of pharmacological and clinical data the last 15-20 years show a wide spectrum of biological effects for  $\omega$ -3 PUFAs*



# Lipid derived pharmaceuticals



PRB-2

- New drug concept with novel structural features
- Based on unique experience- and competence within the lipid area
- Biological targets affected by natural omega-3 polyunsaturated fatty acids
- Huge potential within major disease areas
- Broad new patent portfolio
- Identified a new drug candidate: PRB-2
- PRB-2 tested in a toxicology program, expected to be in clinical phase I in 2009

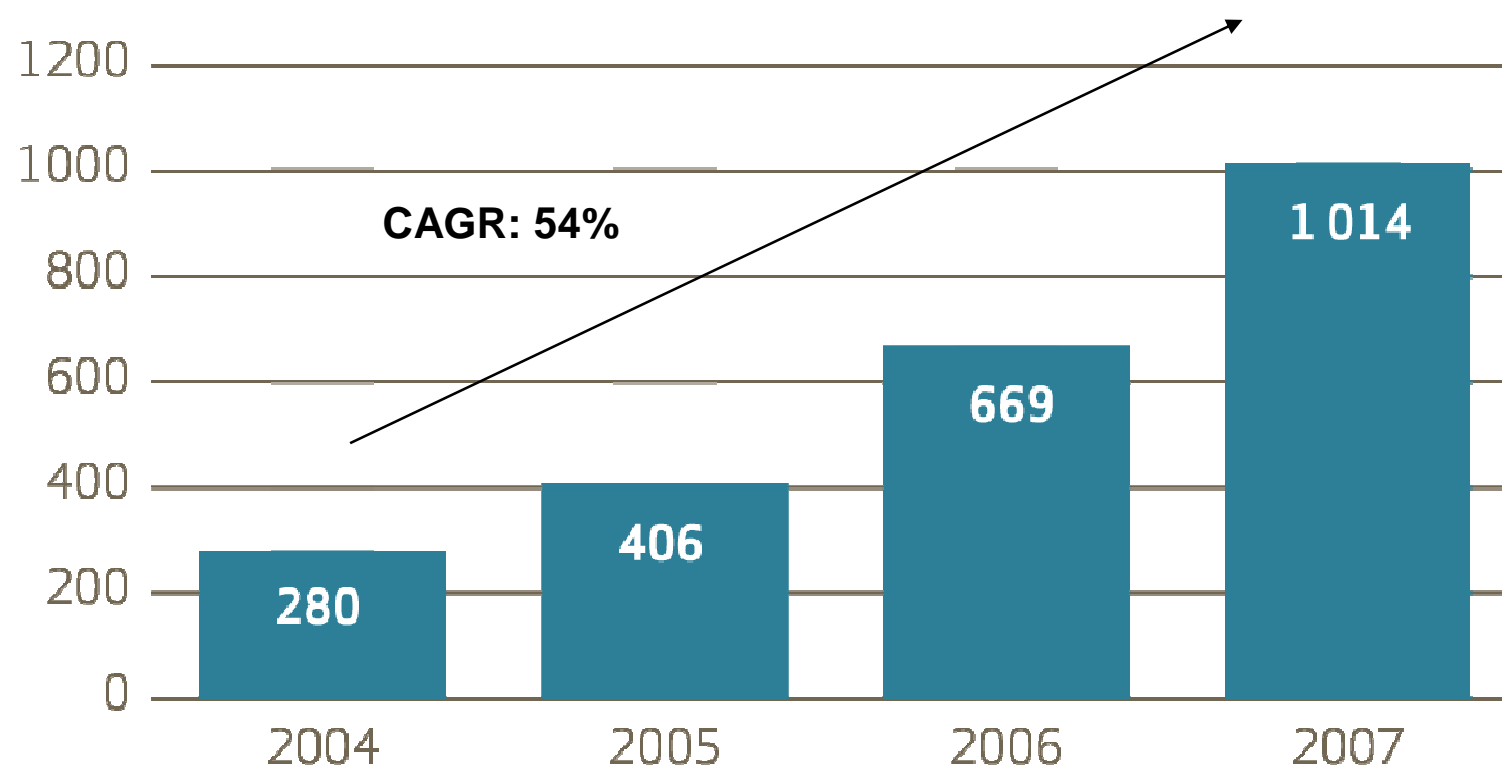
# Financials



# Revenue growth, 2004-2007

## Revenues 2004-2007

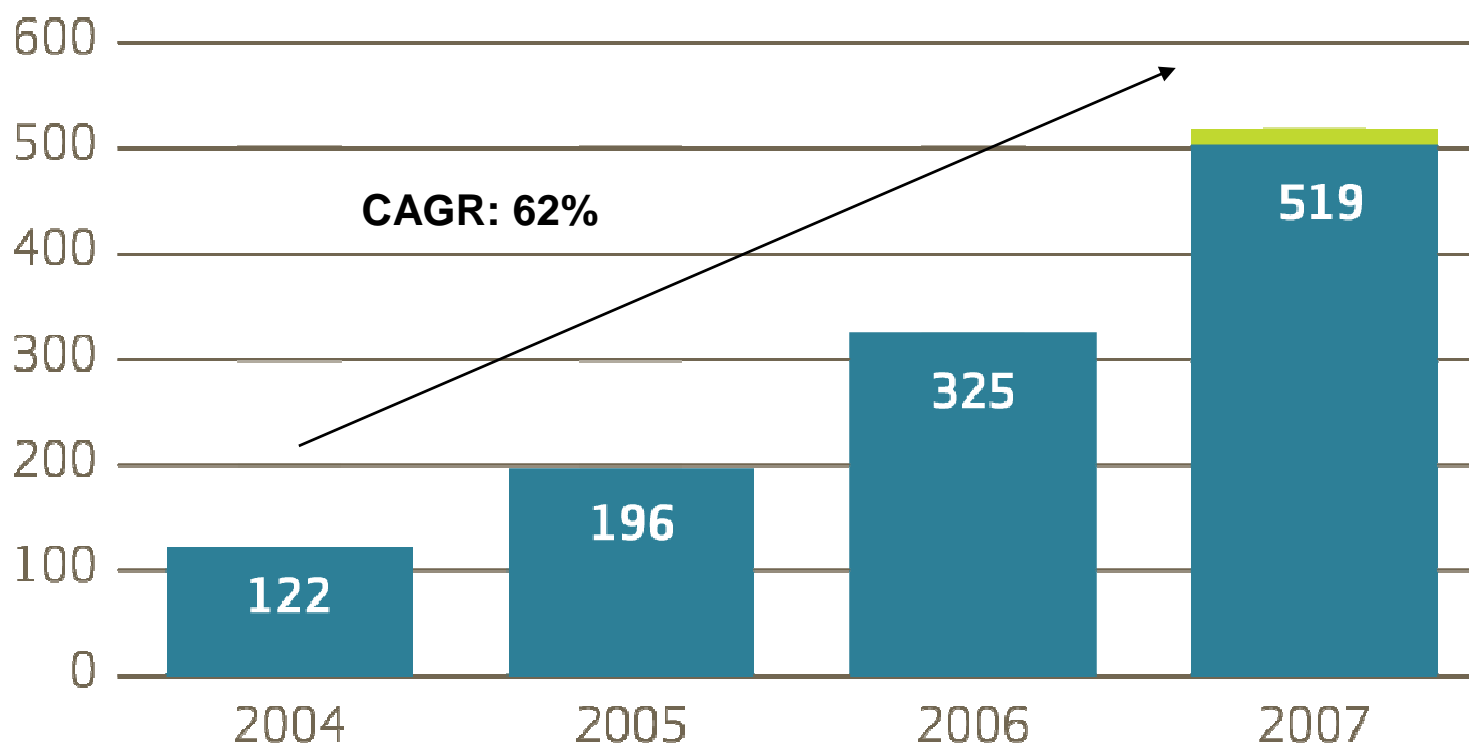
NOK million



# EBITDA growth 2004-2007

## EBITDA 2004-2007

NOK million



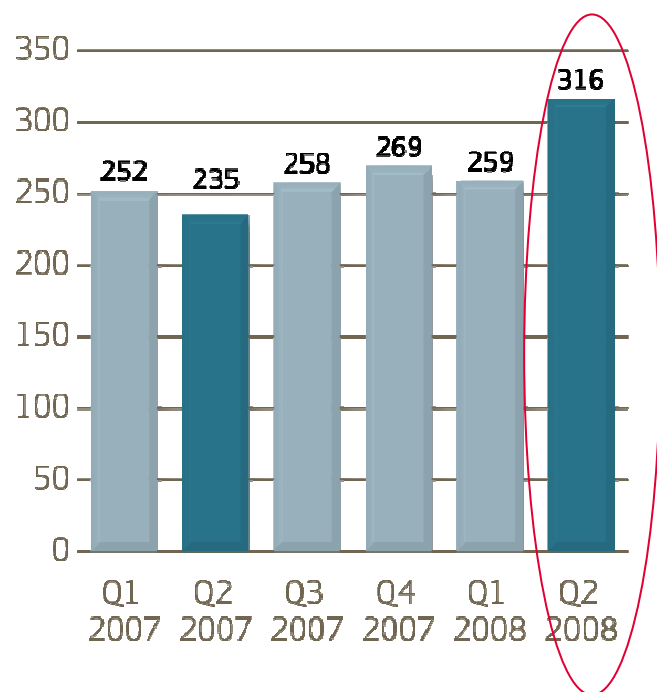
IPO bonus: NOK 16 mill.

Q2 2008:

# Pronova BioPharma's strongest quarter

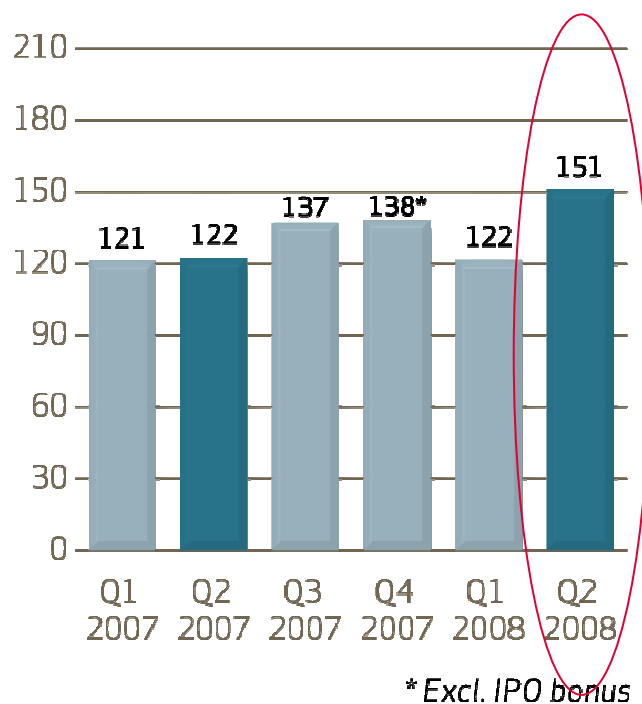
## Revenues

NOK million



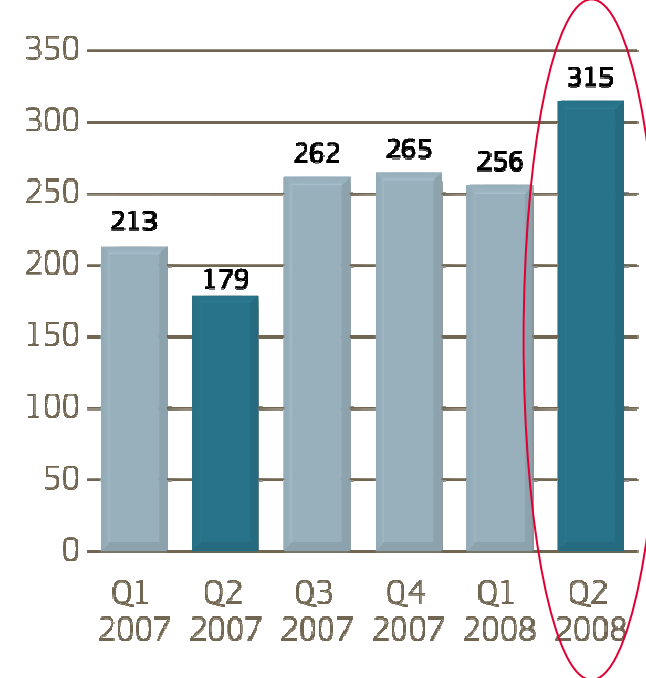
## EBITDA

NOK million



## Production volume

In tonnes



# Condensed consolidated income statement-Q2 2008

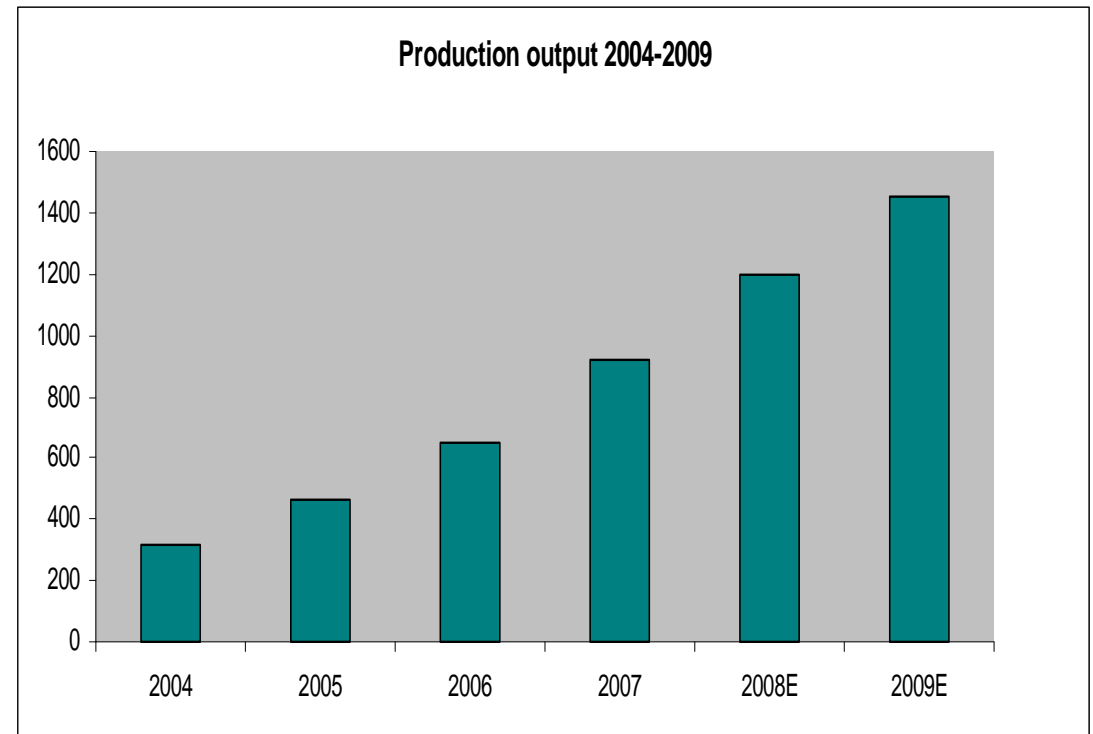
(All amounts in NOK mill.)	Q2 2008	Q2 2007	1.1 - 30.06 2008	1.1 - 30.06 2007	Year ended 2007
<b>Total revenues and income</b>	<b>316.3</b>	<b>235.5</b>	<b>575.2</b>	<b>487.4</b>	<b>1 014.4</b>
Gross profit	249.8	192.1	456.1	385.8	812.0
Gross margin	79.0 %	81.6 %	79.3 %	79.2 %	80.1 %
Operating expenses	(98.7)	(69.8)	(183.4)	(142.0)	(309.0)
<b>EBITDA</b>	<b>151.1</b>	<b>122.3</b>	<b>272.7</b>	<b>243.8</b>	<b>503.0</b>
<i>EBITDA%</i>	<i>47.8 %</i>	<i>51.9 %</i>	<i>47.4 %</i>	<i>50.0 %</i>	<i>49.6 %</i>
Depreciation property, plant and equipment	(20.3)	(13.7)	(38.3)	(26.7)	(58.5)
Amortisation intangible assets	(23.8)	(39.6)	(47.6)	(79.1)	(158.1)
<b>EBIT</b>	<b>106.9</b>	<b>69.1</b>	<b>186.8</b>	<b>137.9</b>	<b>286.3</b>
Net financial items	3.2	(8.5)	(18.1)	(16.0)	(84.4)
<b>Profit before tax</b>	<b>110.1</b>	<b>60.5</b>	<b>168.7</b>	<b>121.9</b>	<b>202.0</b>
<b>NET PROFIT FOR THE PERIOD</b>	<b>78.9</b>	<b>43.5</b>	<b>122.3</b>	<b>87.6</b>	<b>143.4</b>
EPS (in NOK), basic and diluted	0.26	0.15	0.41	0.30	0.45
Average number of shares (1 000's)	300 833	232 658	300 833	226 565	256 949

# Production



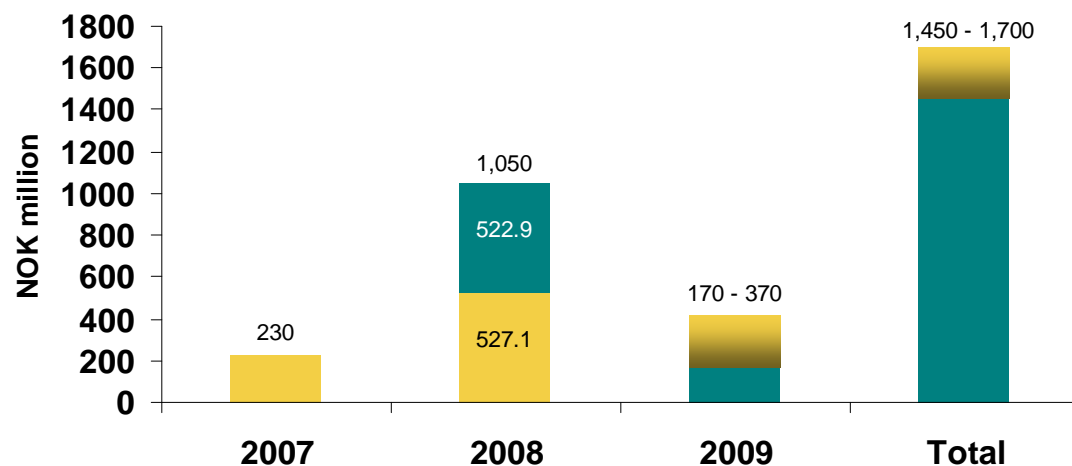
# Unique and Complex Manufacturing Process Technology

- **Automated highly complex production process**
  - *Unique process steps*
  - *Proprietary know-how*
- **Capacity increased to 1,200 tonnes (annualised) in 2007 (cGMP) at Sandefjord, Norway**
- **New facility in Kalundborg, Denmark under development**

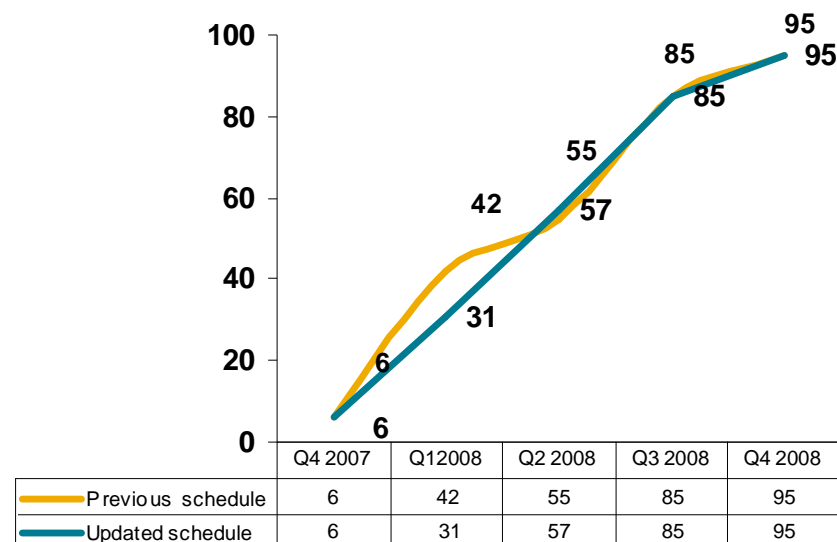


# According to plan in Kalundborg

Expected investment profile

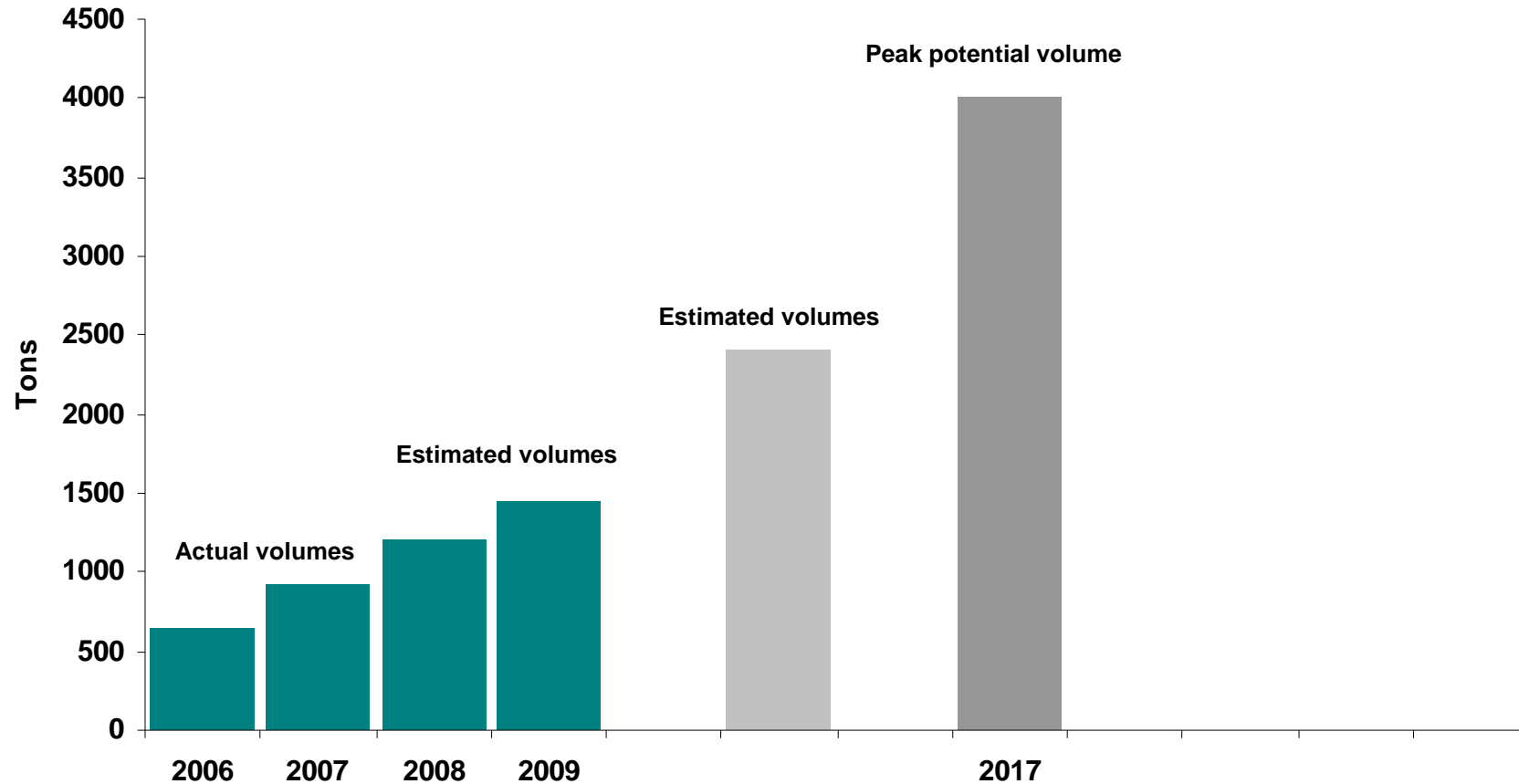


Estimated employee ramp-up

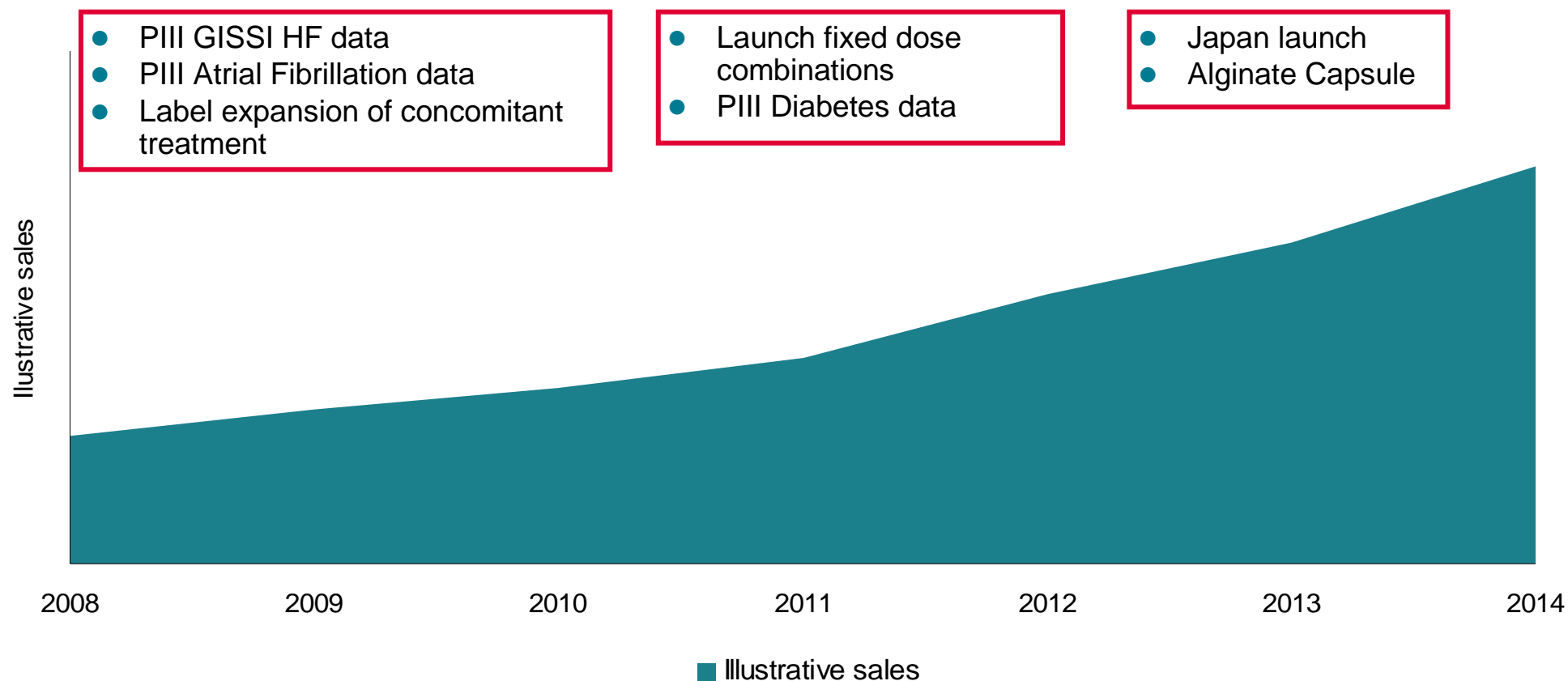


- Capital expenditure according to plan
- Time-line according to plan
- Mechanical completion Q3 2009
- First commercial shipment of API Q1 2010
- Design capacity of 1 300 tons

# Potential supply and demand

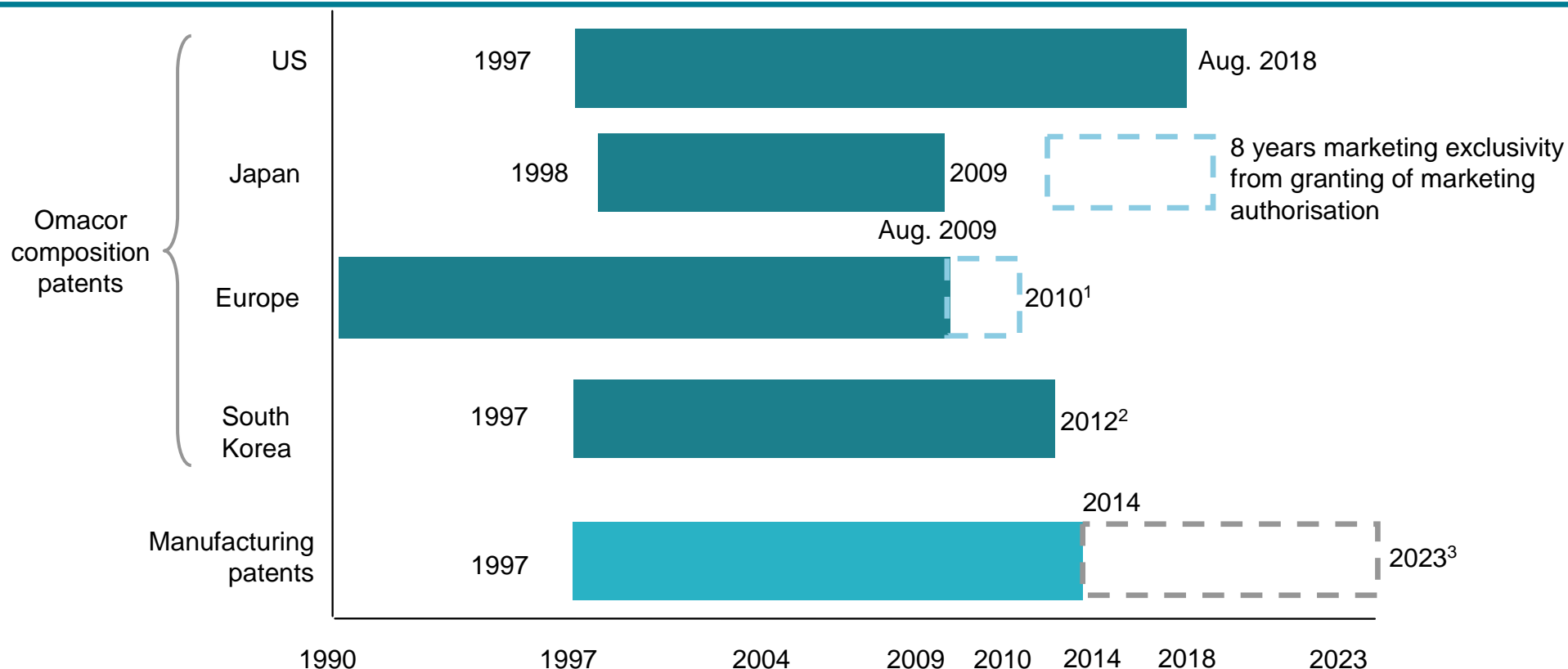


# Drivers for Growth



**Future events support excellent growth profile**

# Patent Estate for Omacor/Lovaza



- **LOVAZA™ qualifies for 5 years of exclusive marketing under § 314.108(b)(2).**
  - US data exclusivity November 10, 2004 – November 10, 2009
  - Potential ANDA filing earliest November 10, 2008
- **Potential add-on data exclusivity for new indications- and formulations**
  - New indications planned for heart failure, atrial fibrillation, etc.
- **New patented indications, capsule and combination formulation under development**
  - Clinical trials to support registration

Notes:

- 1 In France and Austria the patent expires in October 2010
- 2 South Korean patent extension may be possible for a further 2 years until 2014
- 3 First manufacturing patent until 2014, last patent granted until 2023 in Australia and Japan, pending elsewhere

# Outlook

- On track to meet full-year production target of 1 200 tonnes in 2008
- Kalundborg on time and on budget
  - *previously announced acceleration of project will impact 2008 EBITDA margin*
  - *total estimated CAPEX unchanged*
  - *target of first shipment unchanged and expected in Q1 2010*
- Important life-cycle and extension programmes expected in 2008/2009
  - *OM8Afib (atrial fibrillation)*
  - *OM9L (concomitant treatment of Omacor/Lovaza with atorvastatin) clinical trials*
- Continued strong sales growth expected
  - *driven by the US and the investment from GSK*
- In-sourcing of intermediaries in Q3 and Q4 2009
- Revised estimate of total annual production volumes is 1400 – 1500 tons of API in 2009.

