

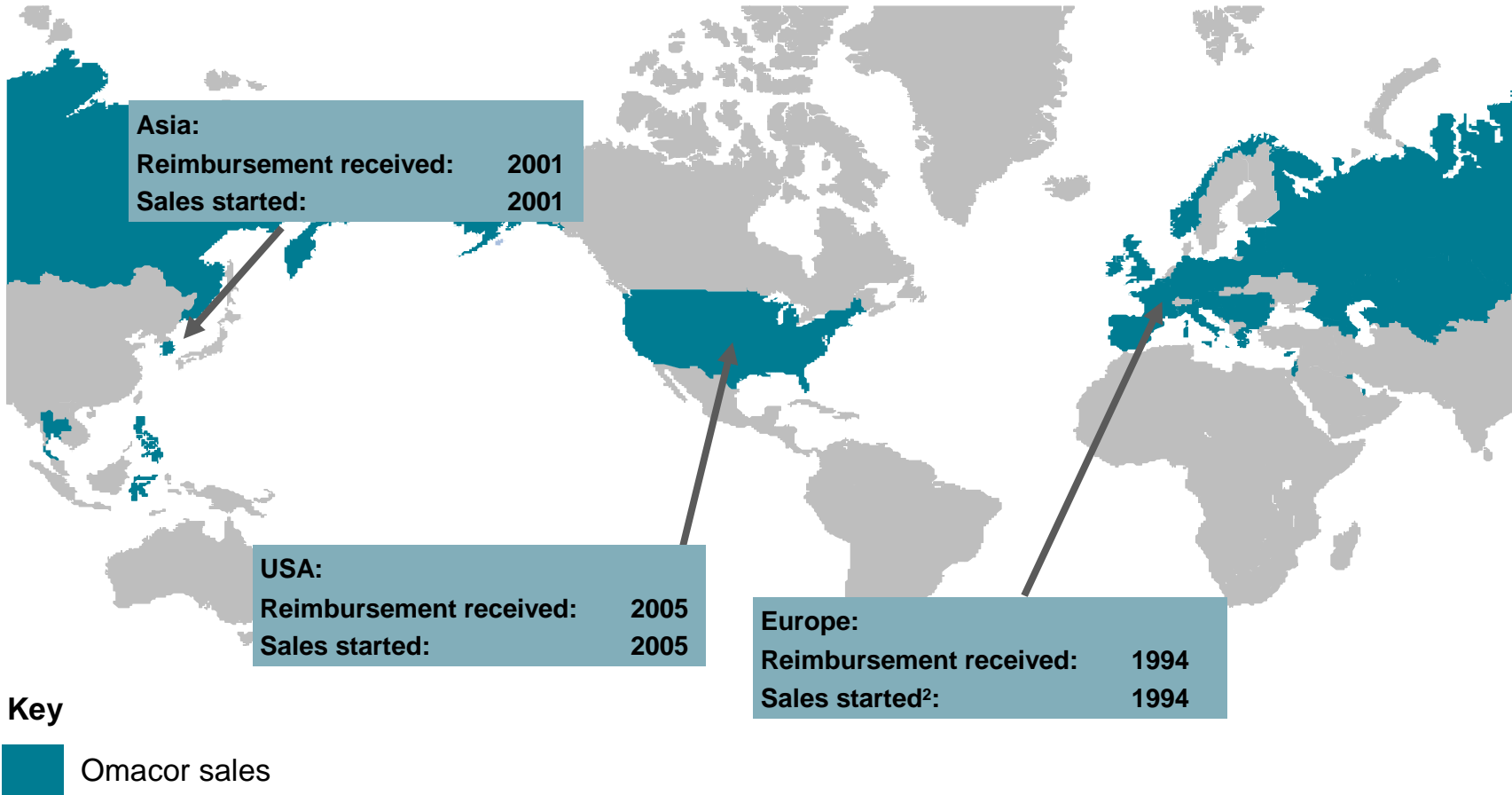
# Commercial update

*Hans Ivar Robinson*

*Vice President  
Pharmaceuticals & Business Development*



# Our markets



15 May 2008

Note:

1 South Korea launch in 2005, 2001 launch in Thailand

2 Launch in Italy in 1994, launch in UK in 2002, launch in Germany in 2003, launch in France in 2005, launch in Spain in 2005

# General Principles of Licensee Agreements

## Grant of rights

- Pronova grants to its partner an exclusive license under the IPRs to use, encapsulate, package, market, sell and distribute the product in the territory for the approved indications

## R&D

- Pronova has rights to all clinical data for the product which, in most cases, it can share with the partner network, partner will for regulatory filing and promotional purposes receive a royalty free license in the territory for data generated by other licensees

## Supply price & royalty

- Partner will pay an agreed supply price on API or Finished Product
- Partner shall pay an agreed royalty of the net sales of the product in the territory
- Partner is obligated to make minimum purchases of the product on an annual basis following the 1st commercial year

## Trademark

- Pronova is the owner of the trademark in most jurisdictions<sup>1</sup>. Licensee shall pack, distribute, market and sell the product in the territory under the trademark in accordance with the branding guidelines

# Strong partnerships serving global markets

- Proven licensee network which commercializes Omacor globally
- Extensive ongoing R&D collaborations with partner network

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
Kuhnle	Korea
Takeda	Japan
SPA	Italy

*>2 500 current sales representatives*

## Strong regional partners serving global markets

# Sales update – 8 major markets



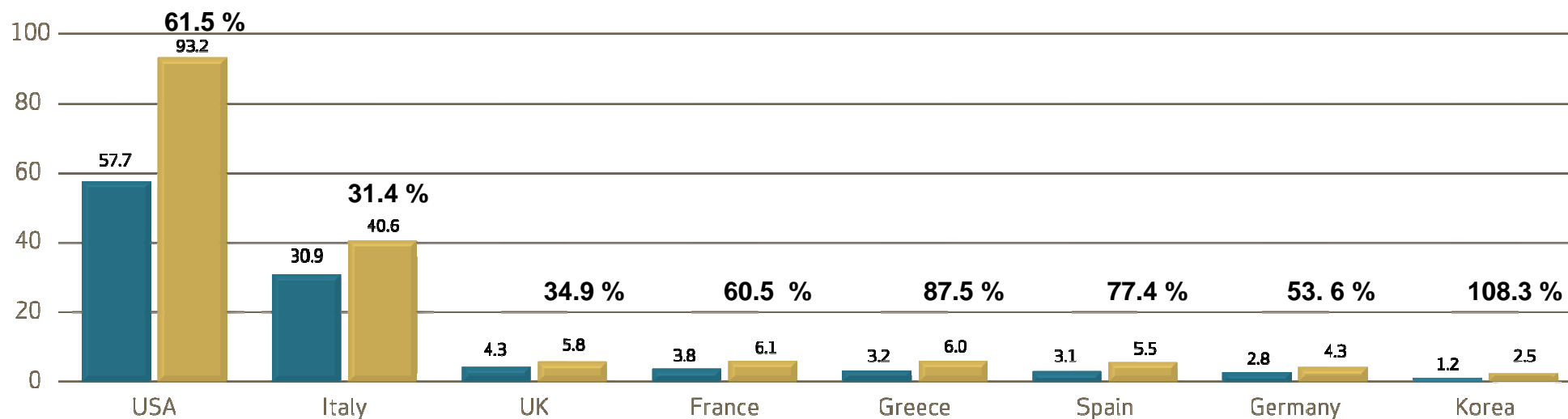
# Omacor / Lovaza end user sales YTD March (IMS)

Current run rate (March 2008): USD 720 mill

## End-user sales by major markets\*

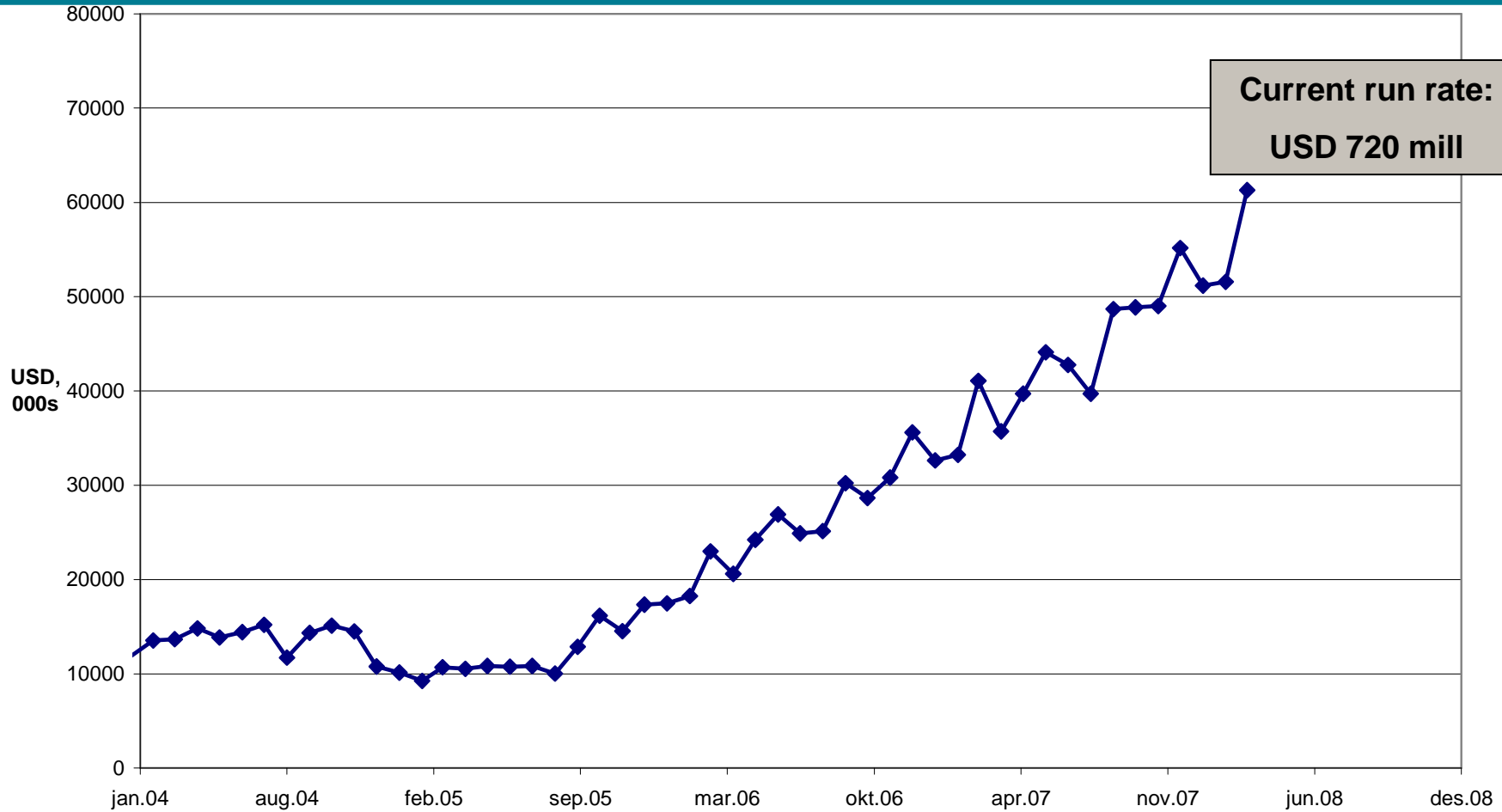
Amounts in USD million

→ 2007 YTD → 2008 YTD



\* Source: IMS

### IMS sales, 8 major markets



**Current run rate:  
USD 720 mill**

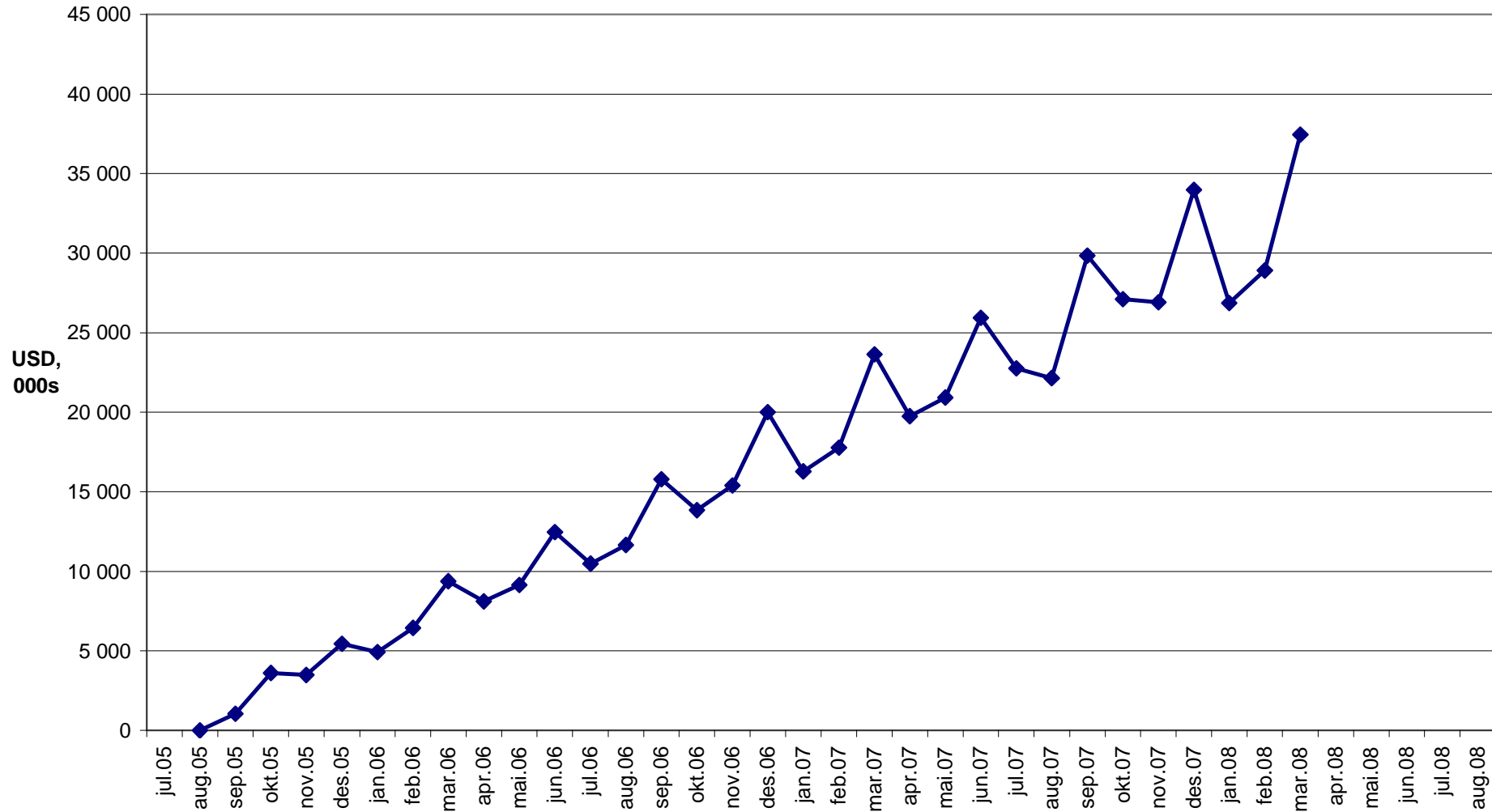
**YTD growth up 53% compared to the  
same period LY**

Source: IMS Health, MIDAS

YTD growth up **62%** compared to the same period LY

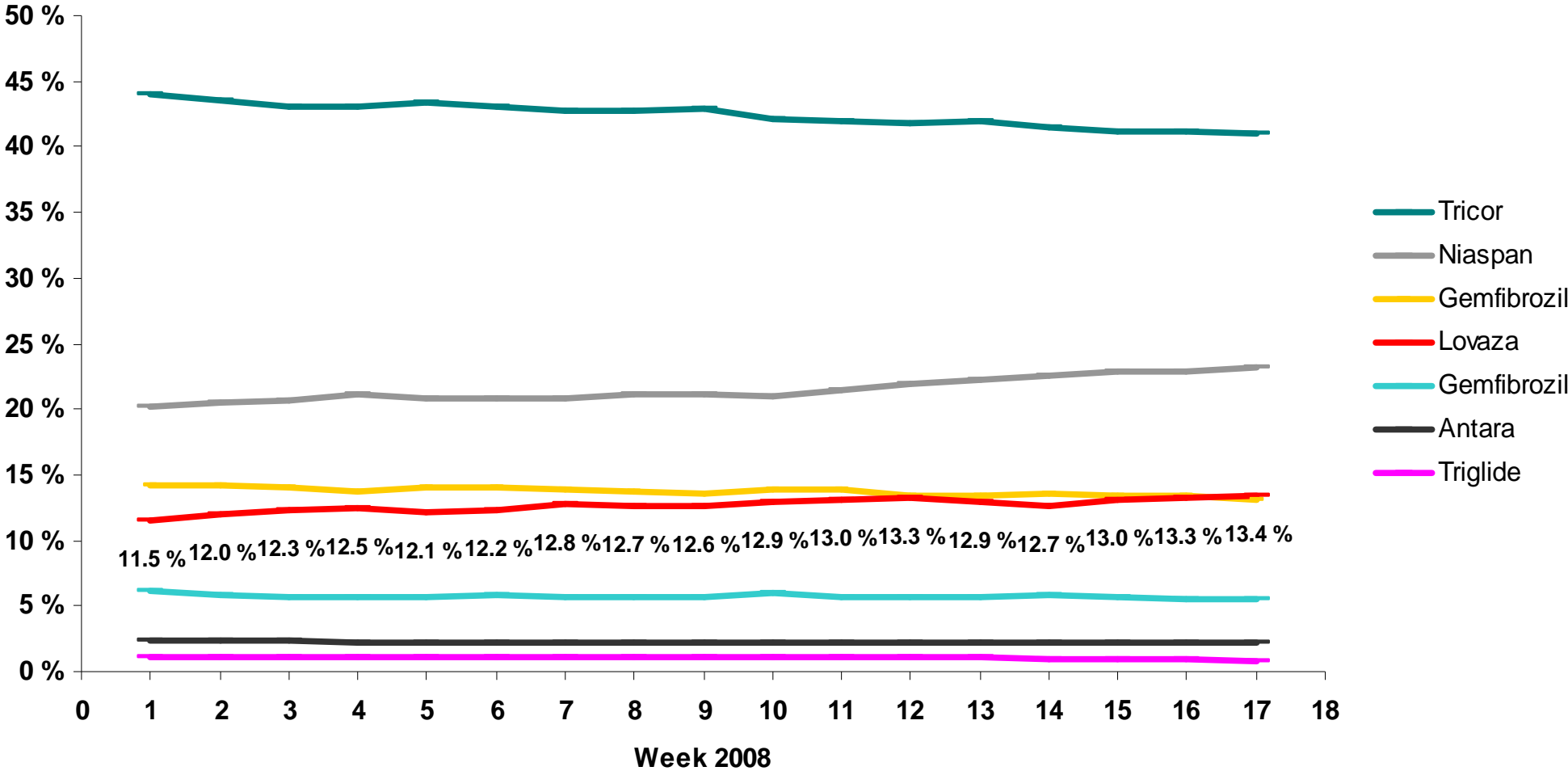


### IMS sales, USA



Source: IMS Health, MIDAS

# Market share - NRx Non-statin market

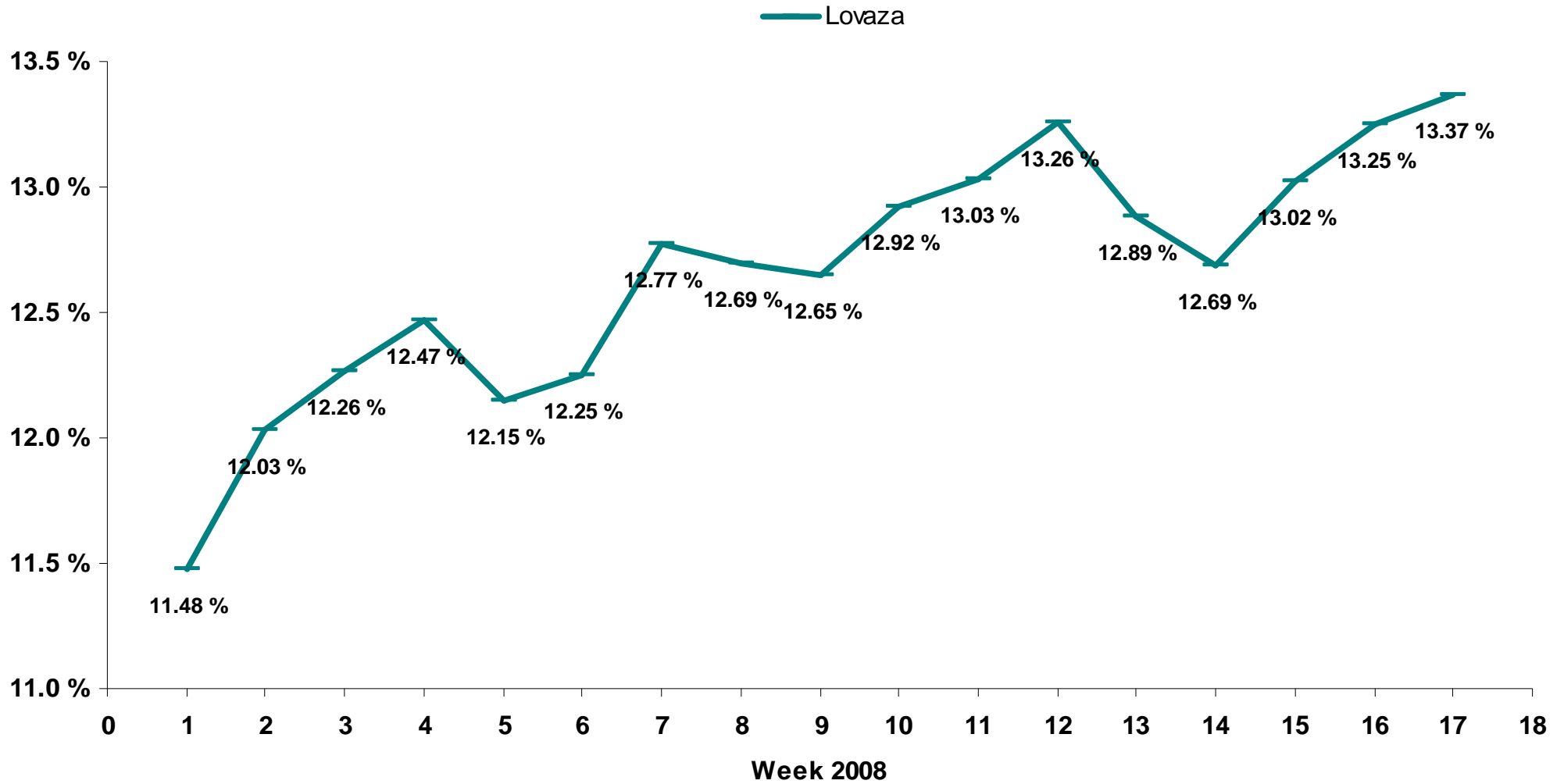


**Lovaza: Growth in market share (YTD): 16.4%**

Source: IMS Health, NPA



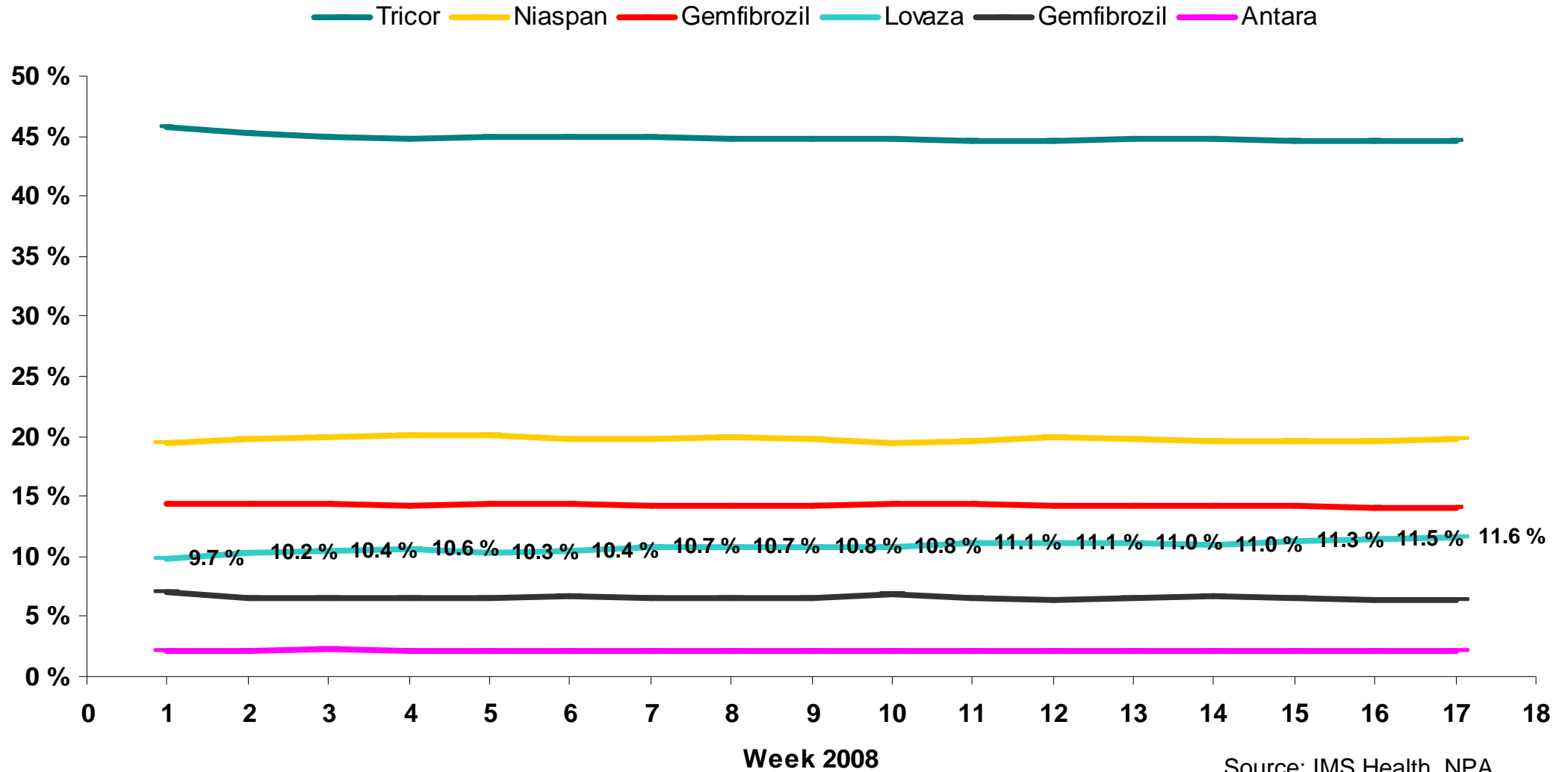
## Market share - NRx Non-Statin Market



Source: IMS Health, NPA

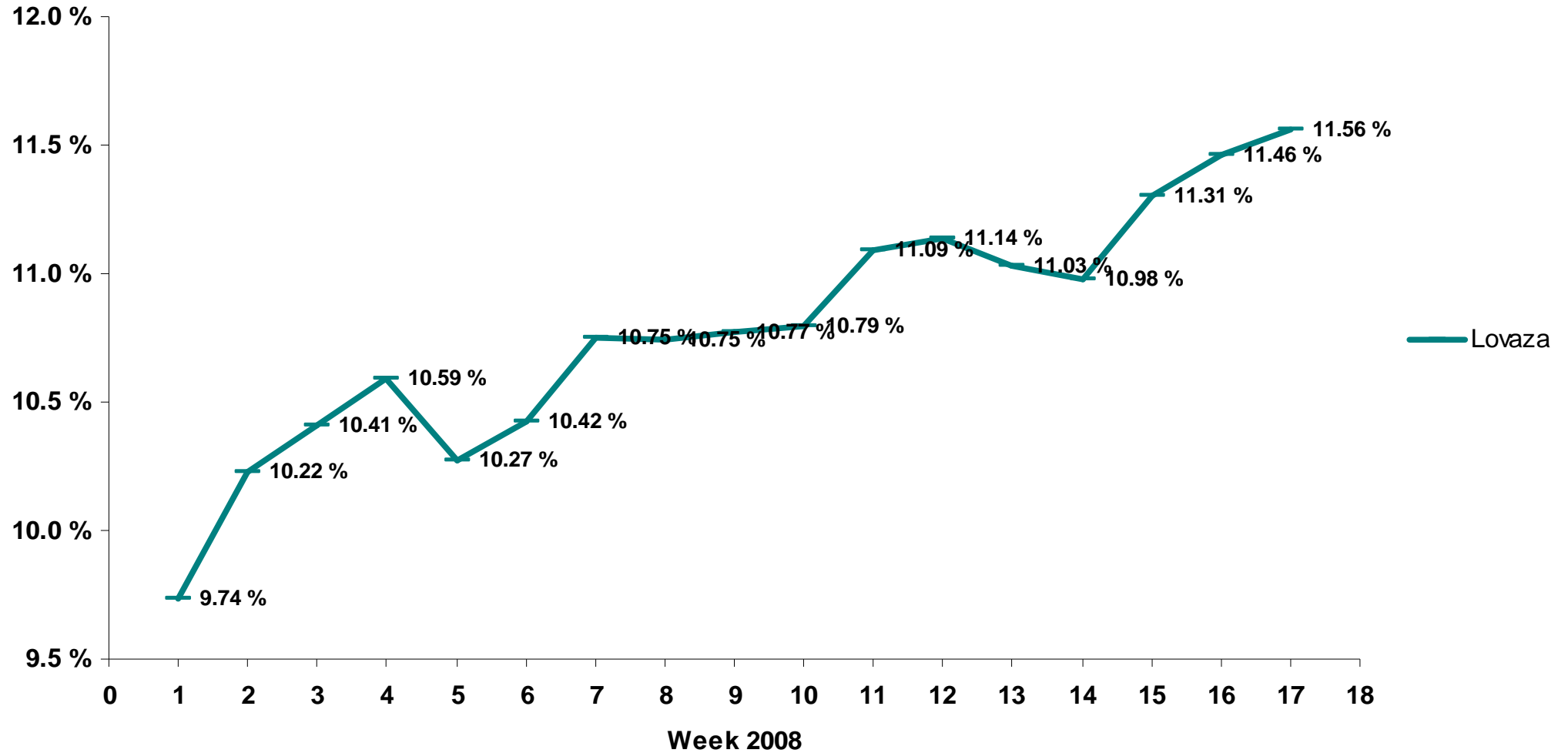
## Market share - TRx Non-Statin Market

**Lovaza:**  
Growth in Market share (YTD):  
**18,7%**



Source: IMS Health, NPA

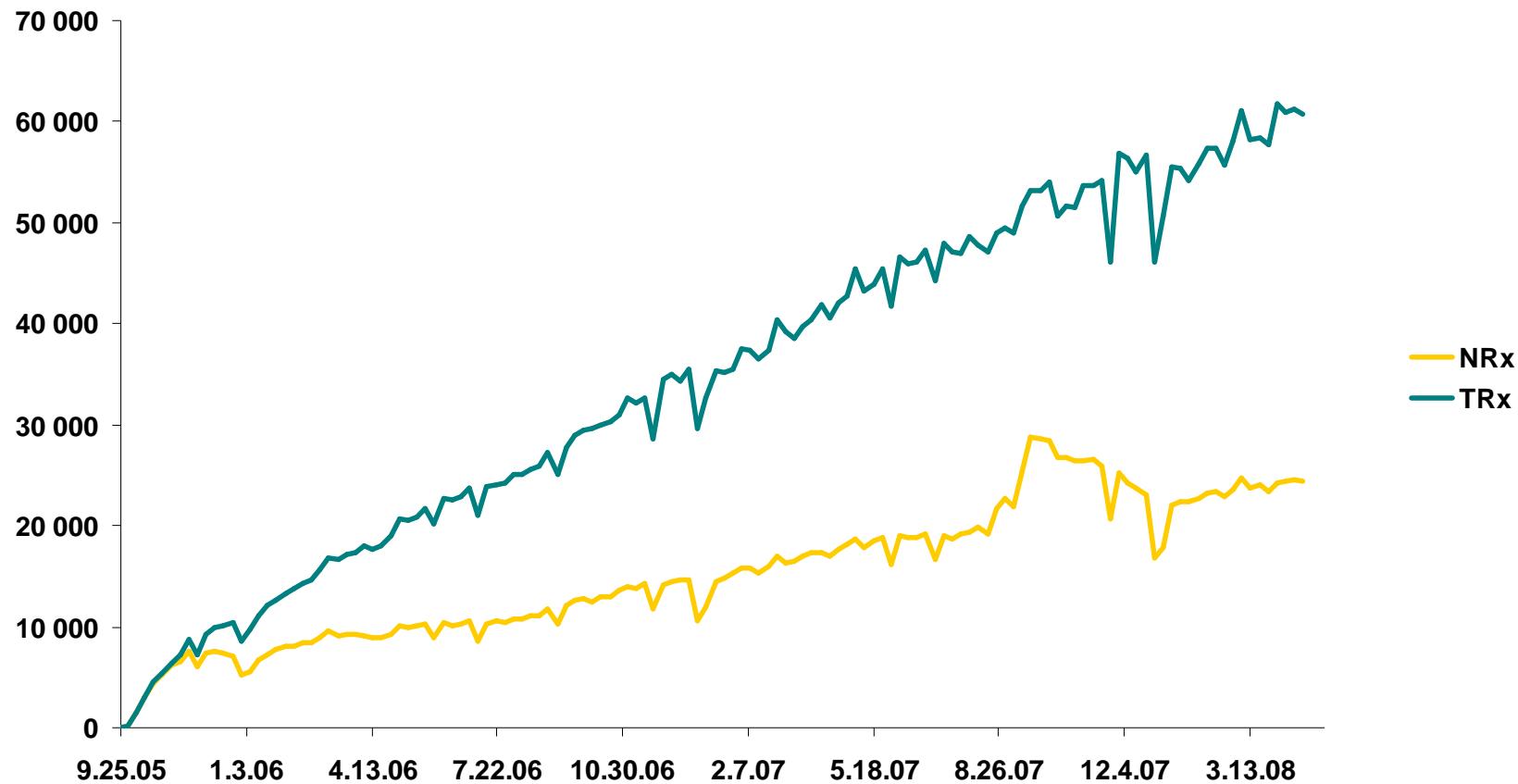
## Market share - TRx Non-Statin Market



Source: IMS Health, NPA

# Omacor/Lovaza

## Sales development since launch



### NRx:

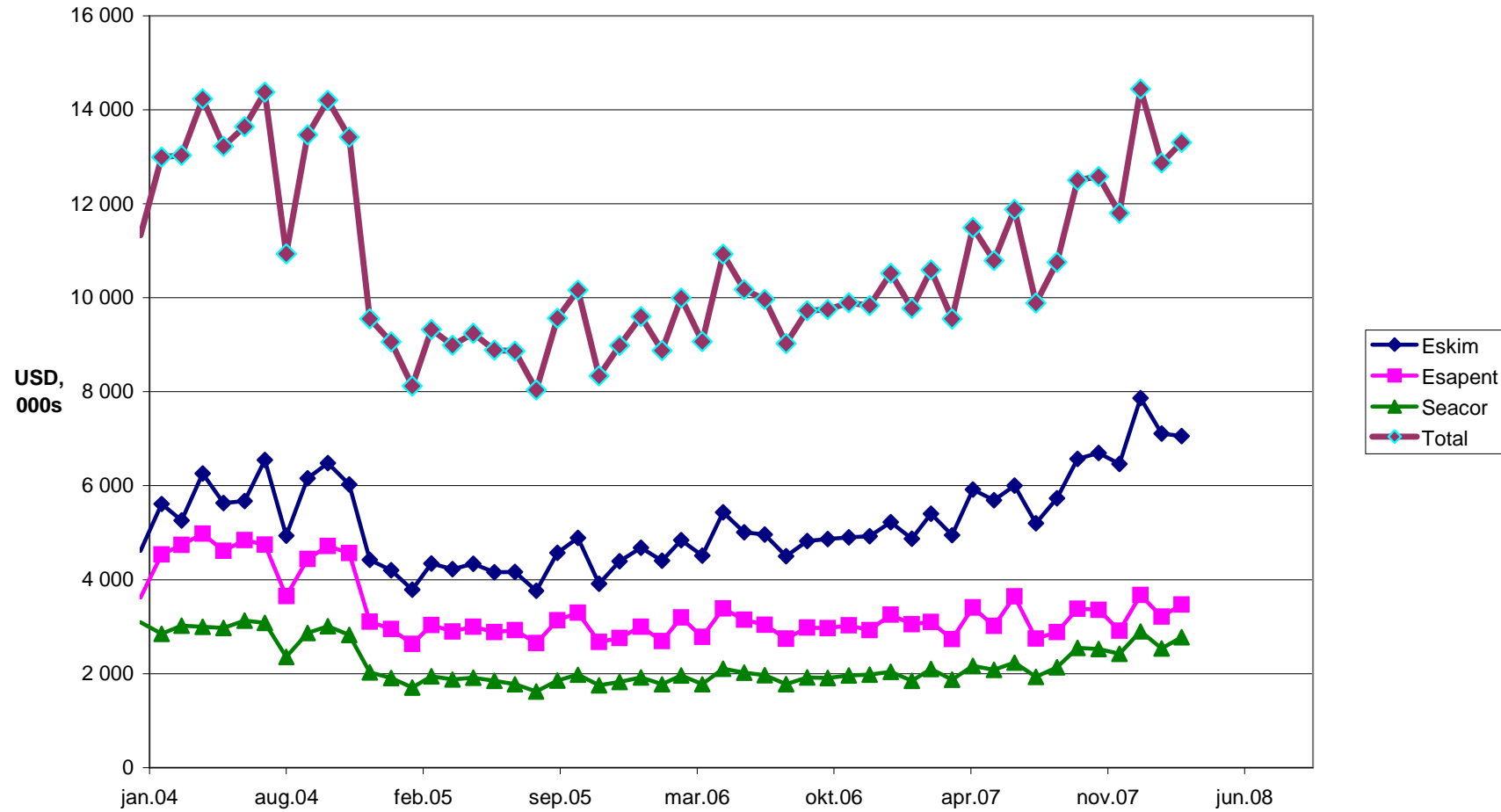
YTD growth NRx volume up **43.9%** compared to the same period LY

### TRx:

YTD growth TRx volume up **50.2%** compared to the same period LY



### IMS sales, Italy

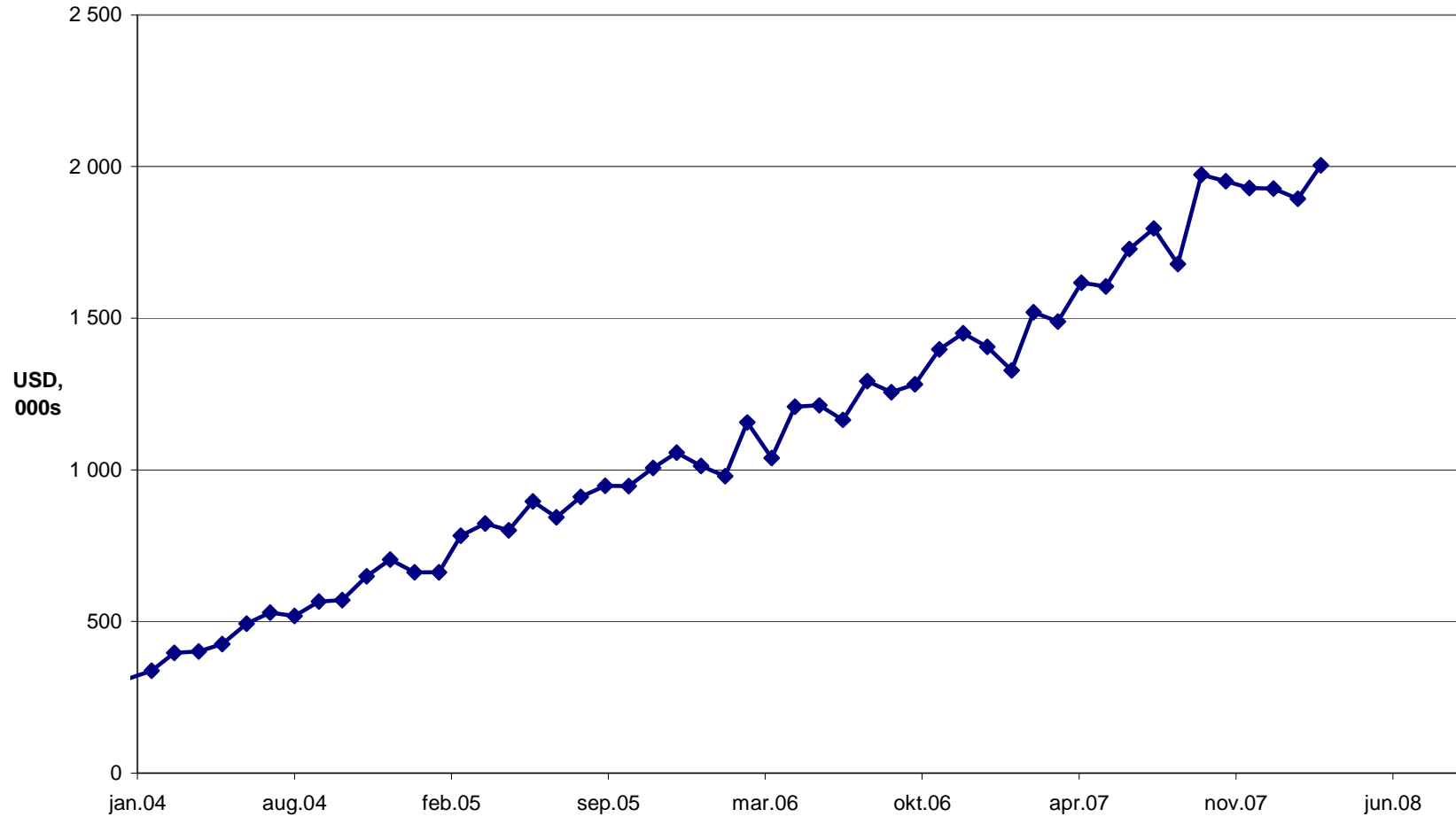


YTD growth up **31%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, UK

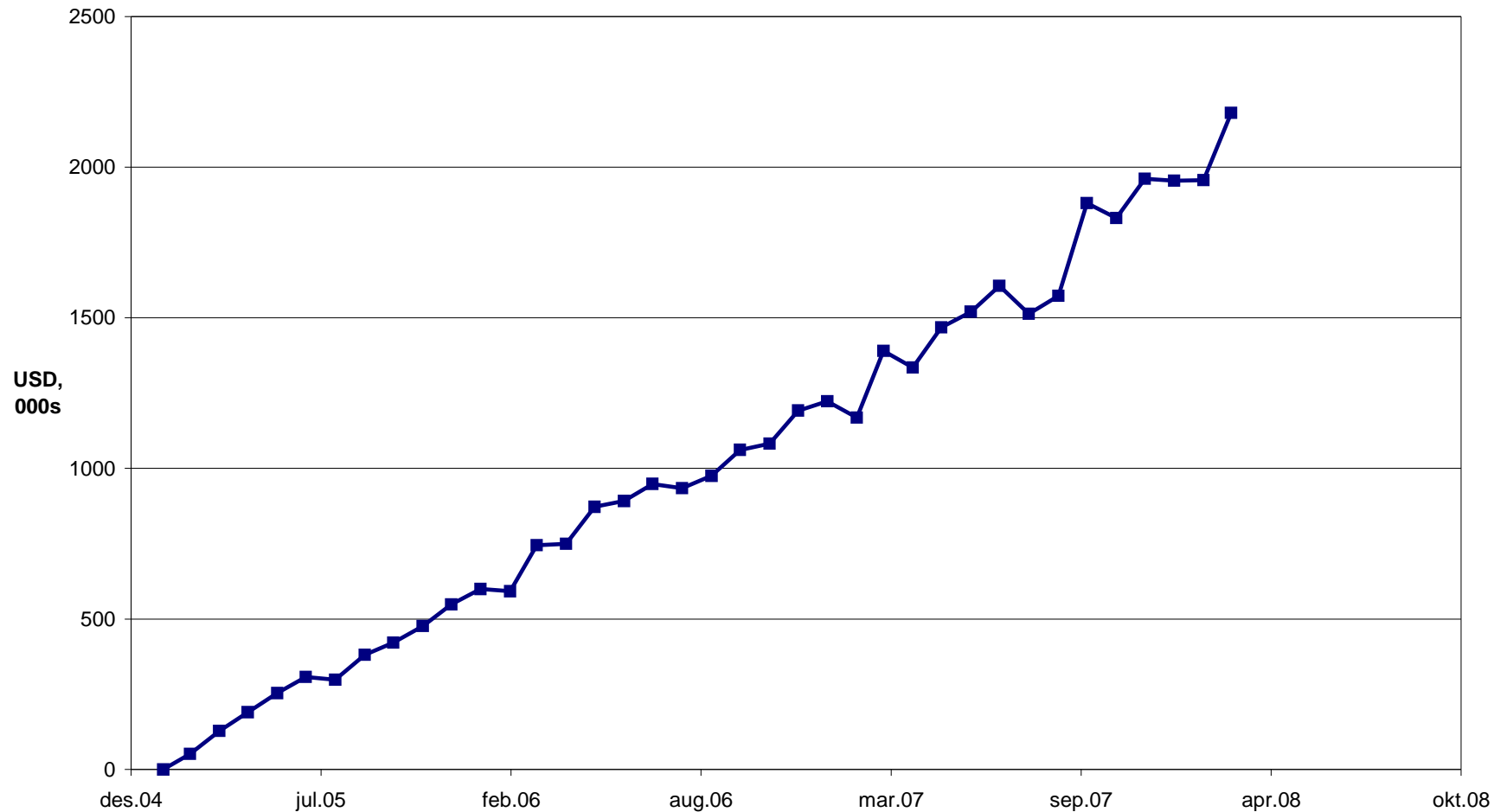


YTD growth up **37%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, France

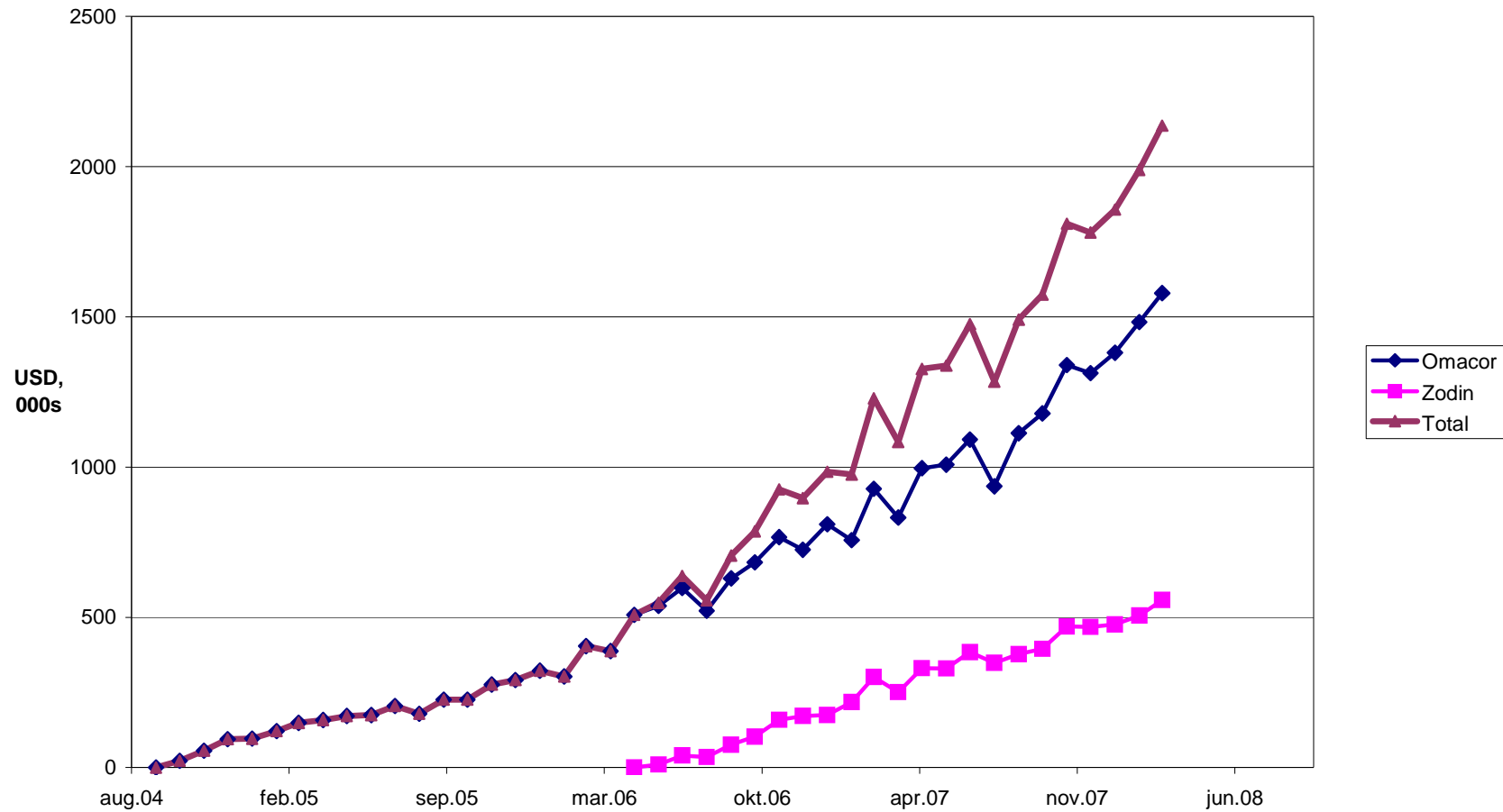


YTD growth up **61%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, Greece

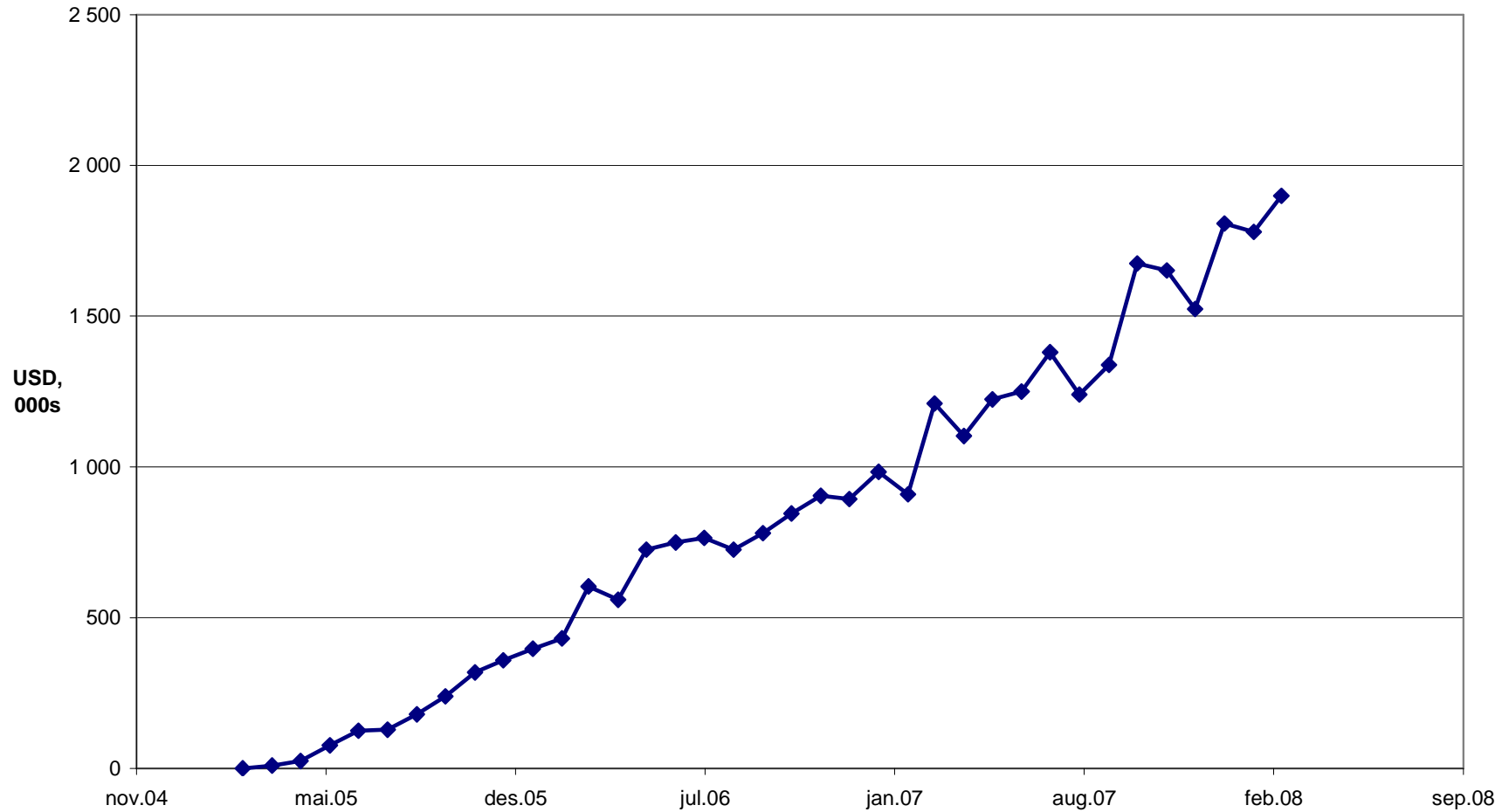


YTD growth up **88%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, Spain

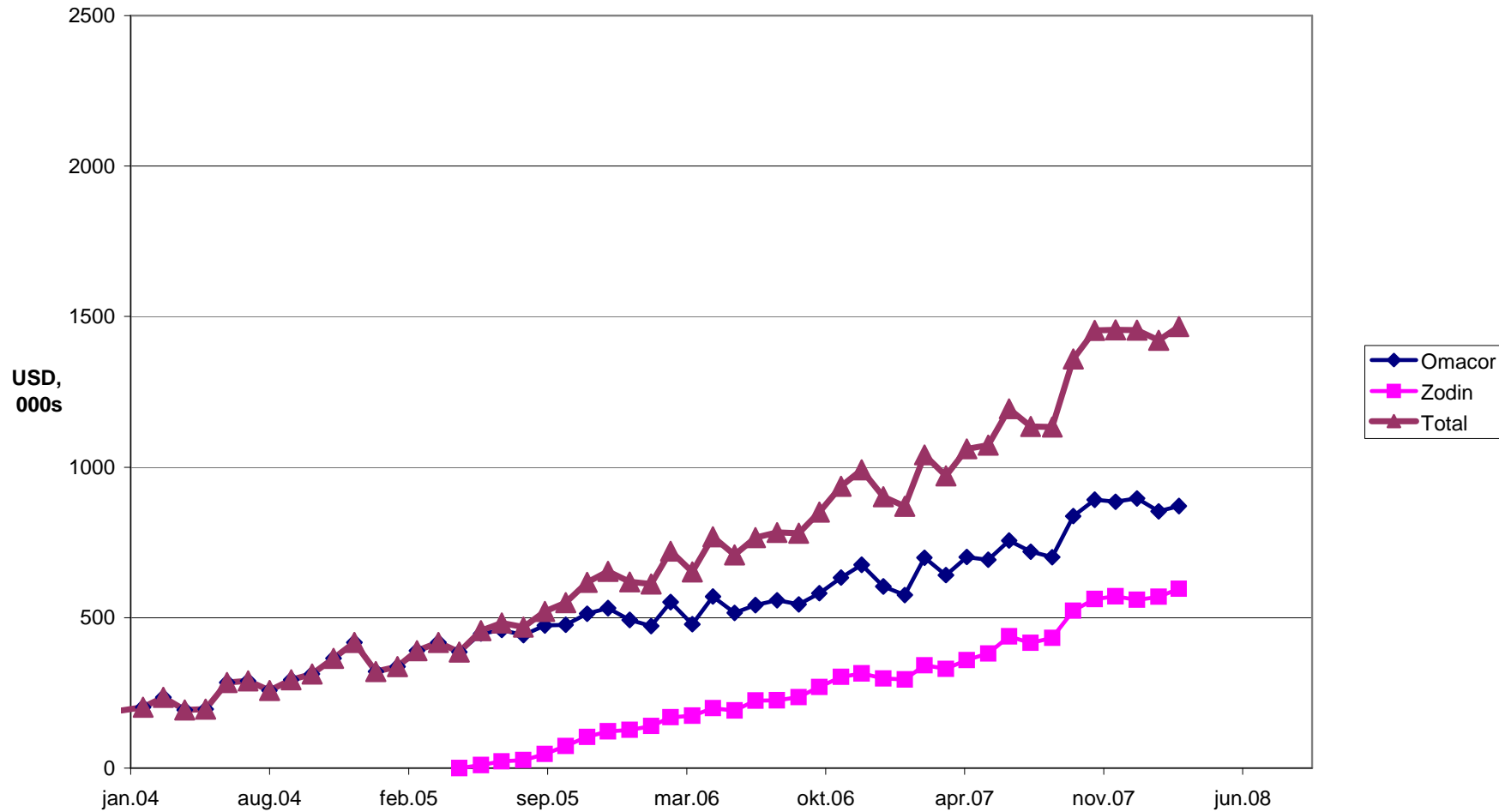


YTD growth up **77%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, Germany

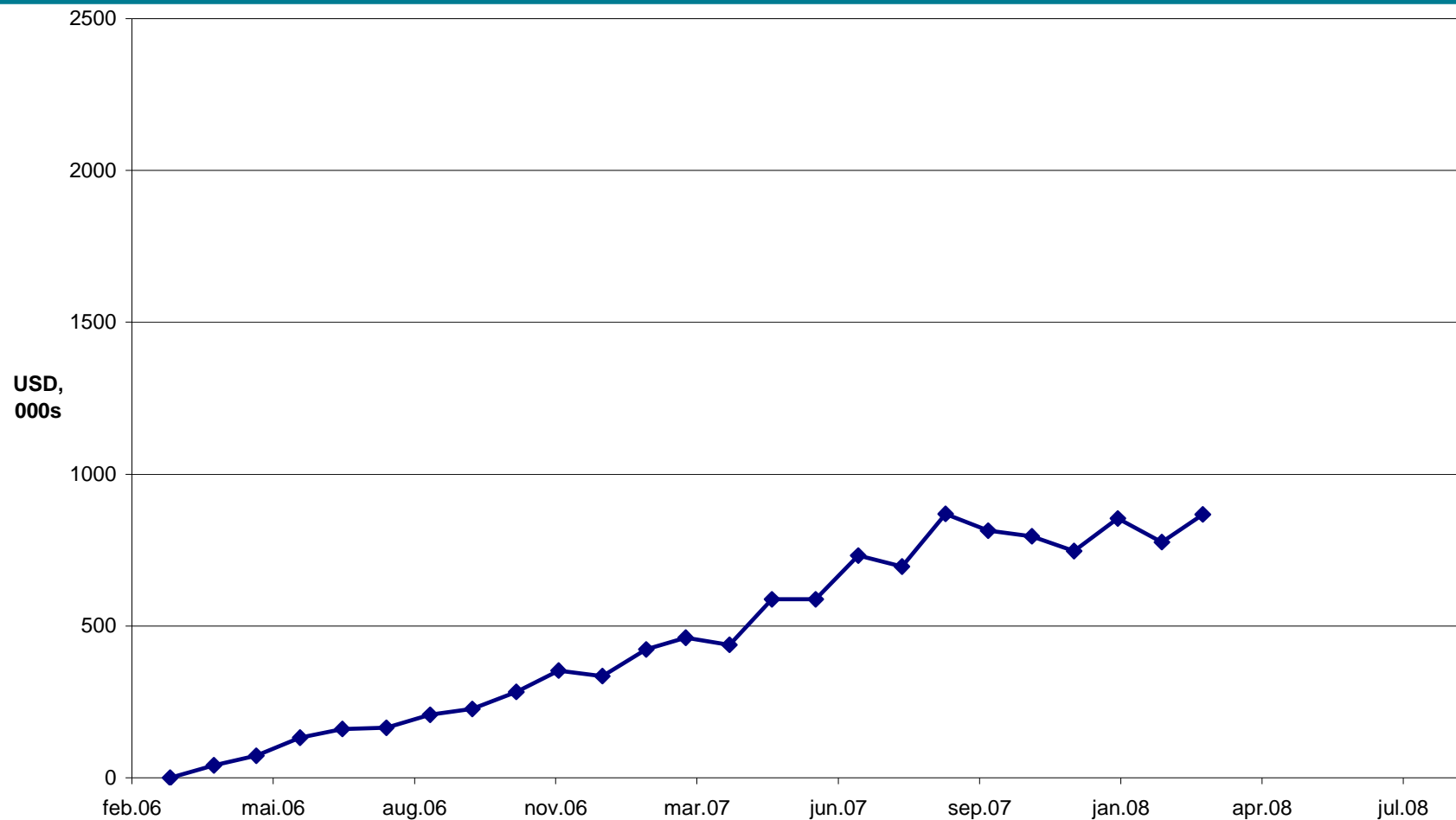


YTD growth up **54%** compared to the same period LY

Source: IMS Health, MIDAS



### IMS sales, Korea



YTD growth up **105%** compared to the same period LY

Source: IMS Health, MIDAS

# Life cycle management: Omacor potential



*Market potential:*

## **Post MI**

- **An estimated 3.71 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>
- **Current treatments include:**
  - *Statins to reduce cholesterol*
  - *Aspirin to thin blood*
  - *Beta-blockers to reduce workload on the heart*
  - *ACEs to reduce hypertension*
  - *Omacor*
- **Official recommendation:**
  - *1g supplementation of omega-3 (European Heart Journal. 2003; 24:28-66 and Circulation. 2002; 106:2747-2757)*
  - *AHA recommends patients with CHD take 1g of EPA+DHA and those requiring triglyceride lowering take 2-4g of supplementation of EPA+DHA*
  - *In May 2007, NICE recommended the prescription of 1g of omega-3 fatty acid to Post-MI patients*

*Market potential:*

# Atrial fibrillation

- **Prevalence of 8.6 million people in seven major pharmaceutical markets (2006)**
  - *Expected to grow at CAGR of 1.5% (2005-11) reaching 9.4 million*
  - *Three patient groups: Paroxysmal; Persistent; and Permanent*
- **Atrial fibrillation elevates the risk of heart attack**
- **Current treatment aims to control rapid heart rate and abnormal rhythm associated with atrial fibrillation and includes**
  - *Antarrhythmics (e.g., calcium channel blockers)*
  - *Beta blockers*
  - *Anticoagulation*
  - *Surgical means such as: Substrate ablation; Ablate and pace treatment; and Cardioversion*
- **The global market for anti-arrhythmics was US\$6.6 billion in 2005 (6.6% of cardiovascular market)**
  - *US\$2.7 billion of which was in Europe (9.1% of the European cardiovascular market)*

# Congestive heart failure

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- **18.5 million people in the seven major pharmaceutical markets have CHF (2006)**
  - *Expected to grow at CAGR of 6% (2005-15) reaching 33.2 million*
  - *Post-MI patients account for 34% of CHF patients*
    - This is likely to increase in the future due to improved Post-MI survival
- **Increased survival rates increase the market size**
- **Current treatments include:**
  - *ACE inhibitors*
  - *Diuretics*
  - *Beta blockers*
  - *Angiotensin receptor blockers*

# Diabetes

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- **Over 40 million people in the seven major pharmaceutical markets had diabetes in 2006 of which Type II accounts for ca. 90%**
  - *By 2011, the market is forecasted to reach over 49 million*
  - *The USA expects to reach over 22 million*
- **Dyslipidemia is highly prevalent in Type II diabetic patients and considered a cardiovascular risk equivalent**
  - *HTG is the most common form of dyslipidemia in diabetics*
- **Cardiovascular disease accounted for 65% of deaths among diabetic patients in the US in 2006**
  - *2–4x higher risk of CVD than non-diabetics*
- **Treatment focuses on the stabilising the glucose levels and a minority of patients currently receive drugs for dyslipidemia**
- **Current treatment for the prevention of cardiovascular disease include:**
  - *Statins*
  - *Glitazones (PPAR agonists)*

## *Alginate project:*

# Background

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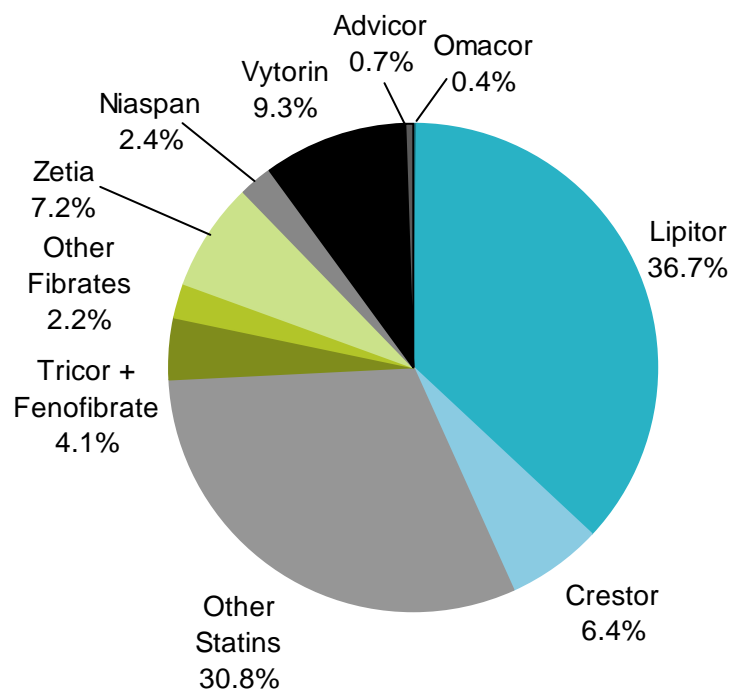
- **Pronova entered into a worldwide license and development agreement with FMC Corporation in Dec 07 to develop products using a novel capsule technology**
- **Patented technology based upon alginate**
  - *Polysaccharides based upon brown seaweed*
- **Key benefits of alginate capsules**
  - *Gastro resistant, dissolves in the intestine and not in the stomach, which will give less “fish burps”*
  - *Seamless, non sticky capsules with thinner shell wall, reducing the size of the capsules*
  - *Non animal*
- **FMC is responsible for further development of the technology**
- **Pronova responsible for clinical development and regulatory approval**

# Target for the Omacor-Simvastatin combination has the potential for first-line use in mixed dyslipidemia

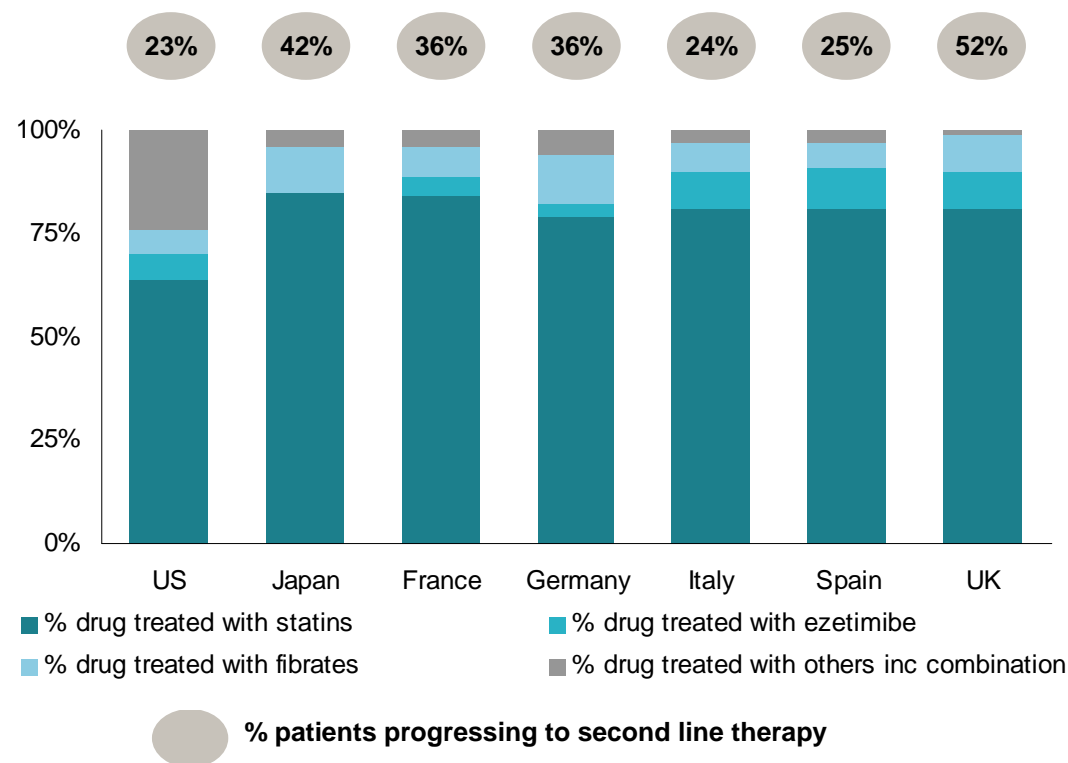
Lipid class	NCEP ATP III treatment objective	Omacor performance monotherapy	Statin performance monotherapy	Combined profile vs. statin monotherapy
TG	Reduce if >500 mg/dL	Strong reduction	Strong reduction	<b>Strong reduction; substantial incremental efficacy</b>
Non-HDL-C	Treat to Goal based on risk factors when LDL is at goal and TG 200-499 mg/dL	Moderate reduction	Moderate-Strong reduction	<b>Strong reduction; substantial incremental efficacy</b>
HDL-C	No objective	Moderate increase	Limited increase	Moderate increase
LDL-C	Treat to Goal based on risk factors	Slight increase, depending on baseline TG	Strong reduction	Neutral

# Competitive landscape within mixed dyslipidemia

## Mixed dyslipidemia US market 2006



## 1st / 2nd line therapy



Source: Datamonitor, 2005

**Patients not achieving target levels are moved onto 2nd line / combination therapies**

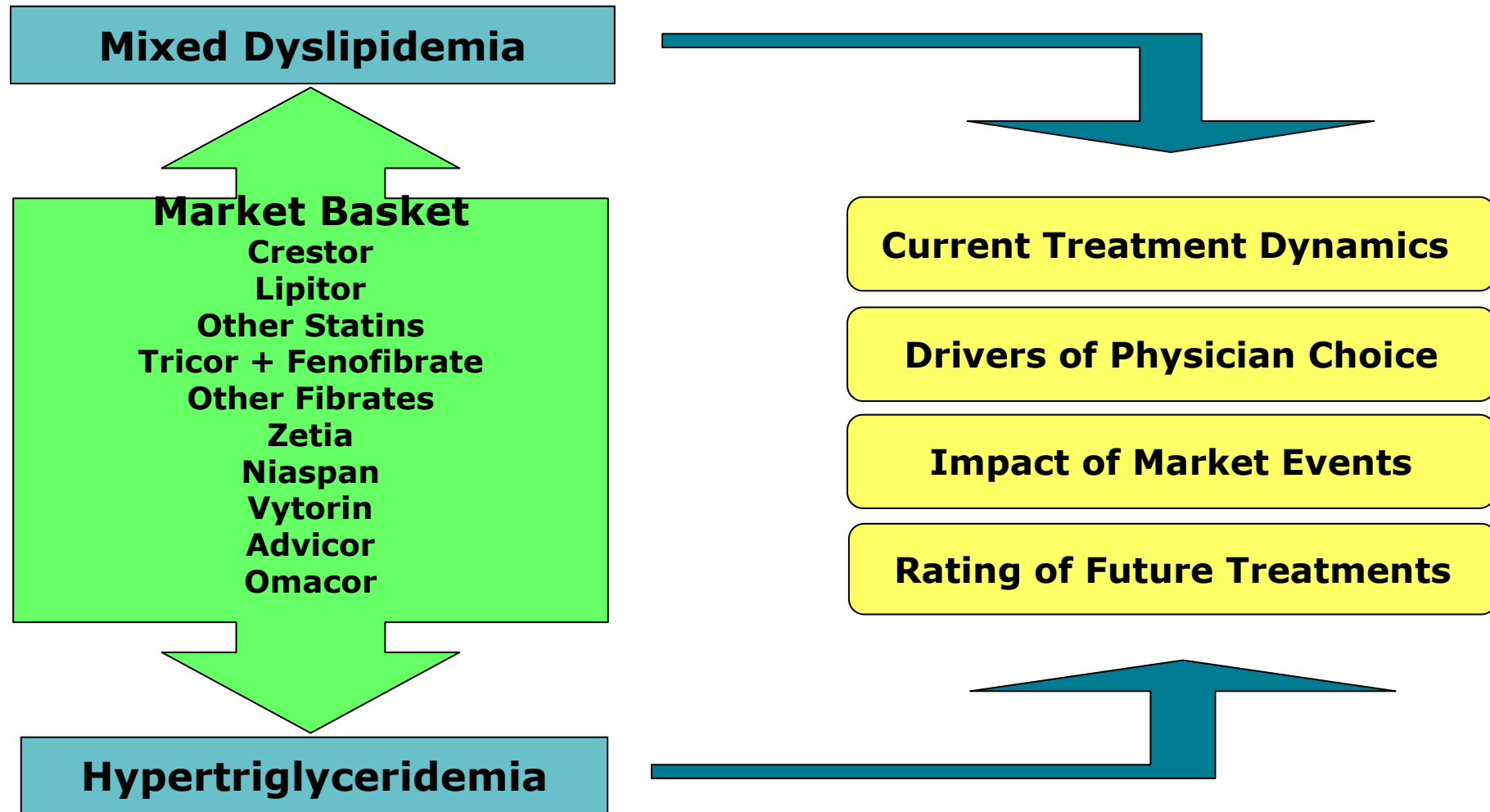
The primary objective of the quantitative study was to inform the forecast by quantifying the relative impact of future events on Omacor.

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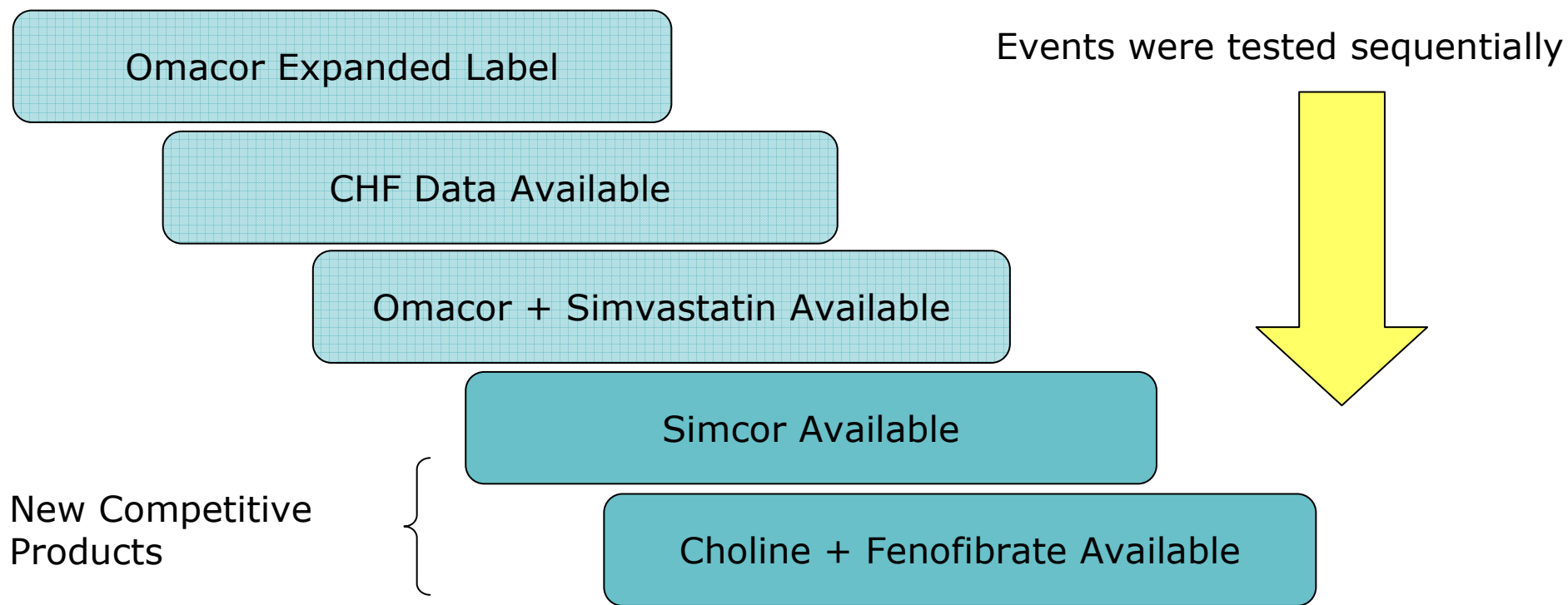
- **The events identified as have a potential impact on Omacor were:**
  - *Omacor Expanded Label*
  - *Launch of Simcor (combination of Niaspan and simvastatin)*
  - *Publication of the GISSI Heart Failure trial*
  - *Launch of MK-054A (combination of Nicotinic Acid & Anti flushing agent)*
  - *Launch of Choline Fenofibrate*
  - *Launch of Rosuvastatin and Choline Fenofibrate*
  - *Launch of fixed dose combination of Omacor & Simvastatin*
  - *Launch of MK-054B (combination of MK-054A and Simvastatin)*

## Quantitative Physician Assessment - Methodology

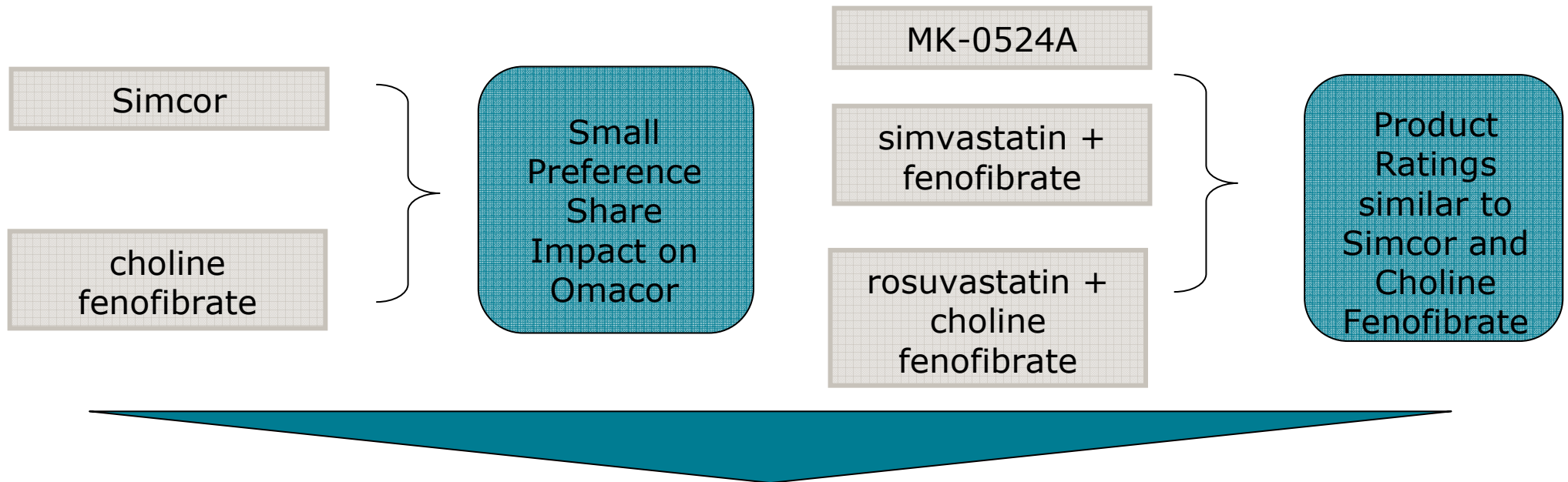
The internet survey was designed to measure aspects of physician prescribing practices in the context of mixed dyslipidemia and hypertriglyceridemia with the goal of understanding the impact of future events on products in the market basket



To understand the impact of future events on products in the forecast, we exposed physicians to event profiles and asked them to allocate their next 100 mixed dyslipidemia and 100 hypertriglyceridemia patients by therapy.



**Based on similarity to Simcor and choline fenofibrate, MK-524A, simvastatin + fenofibrate, and rosuvastatin + choline fenofibrate are expected to only have a small impact on Omacor**

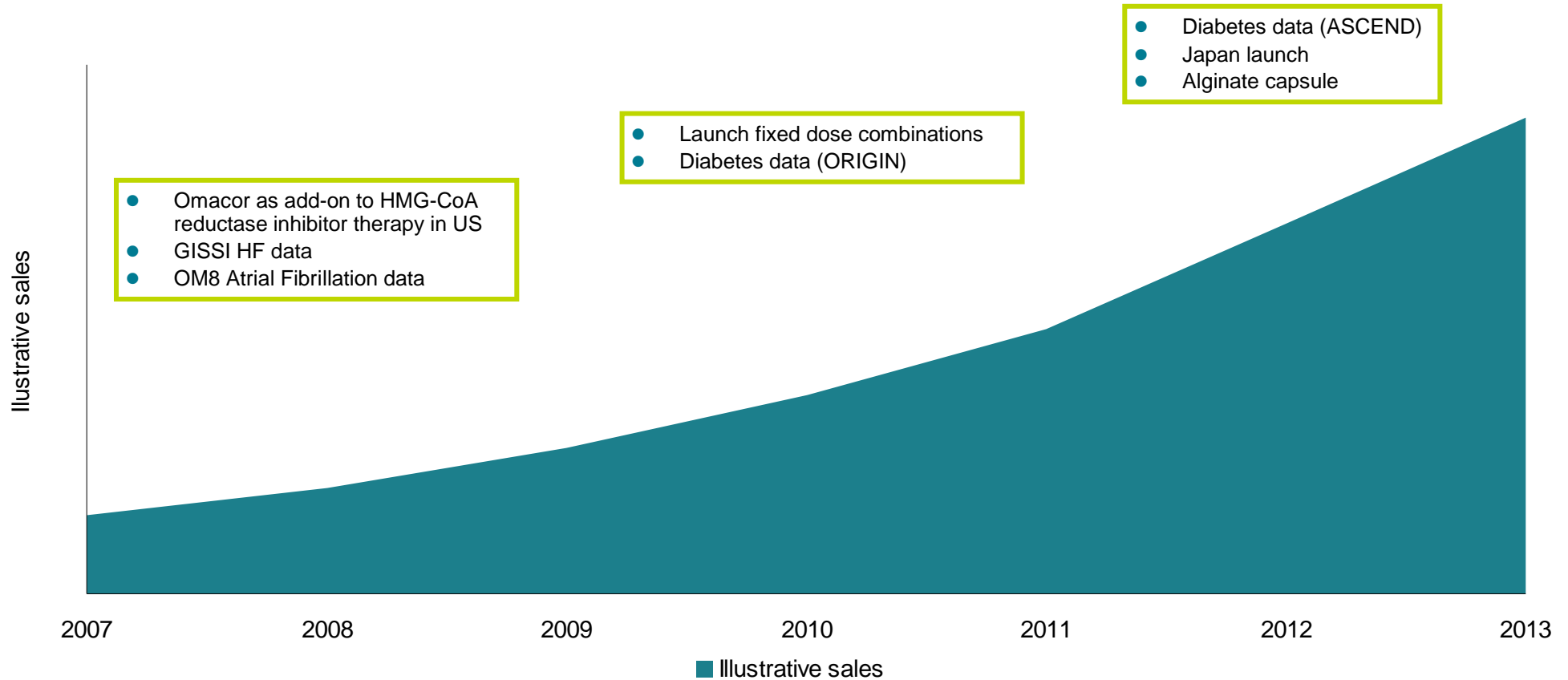


MK-524A, simvastatin + fenofibrate and rosuvastatin + choline fenofibrate are expected to have little impact on the Omacor franchise.

Estimated peak sales:  
USD 4 billion

# Key drivers for growth

## Potential future illustrative sales



Source: Pronova

**Future events support excellent growth profile**