

Market dynamics of the pharmaceutical industry and the dyslipidemic market going forward

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9th September 2009

Prepared for Pronova Biopharma



2009 Pronova Biopharma presentation

The World pharmaceutical market

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An overview of trends to 2013

1. Growth moves to emerging markets
2. Manufacturing moves East
- 3. Biosimilars are approved in all strategic markets**
- 4. Biologicals patents harmonised with other patents**
5. Tendering becomes standard practice for patented products
6. Safety concerns mandate post launch patient monitoring
- 7. Generics to dominate first line therapy in key chronic markets**
8. Risk: reward deals with regulators drive Specialist markets
9. Internal governance of marketing and sales practices becomes mandatory

Today's discussion



Impact of the global economic crisis on pharma

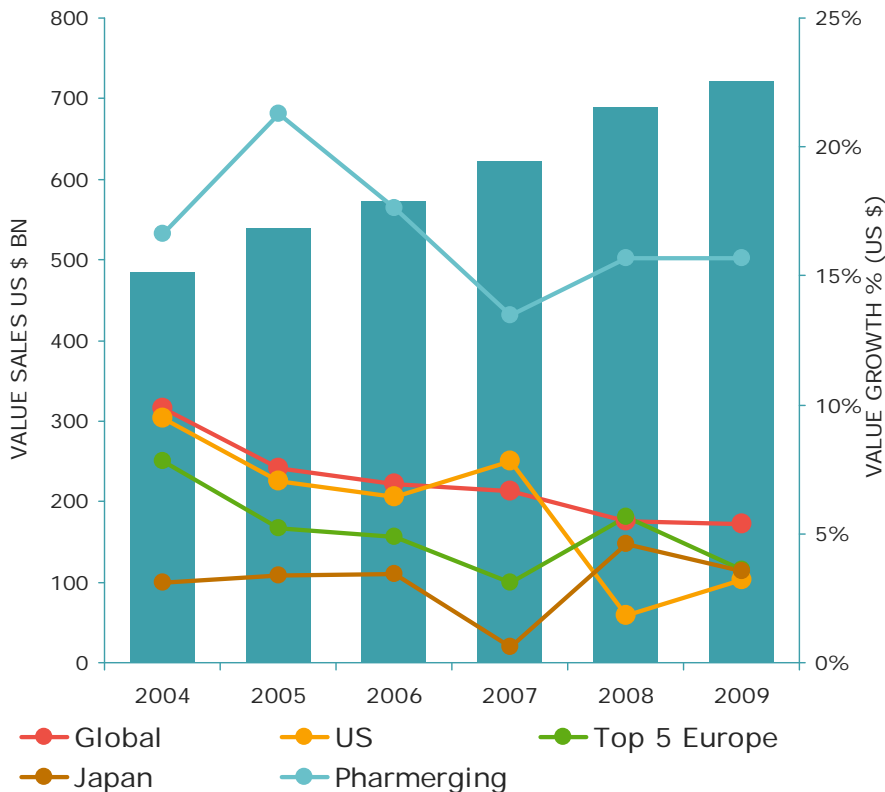
- Global pharmaceutical market outlook
- Prospects in the dyslipidemia market
- Conclusions and key takeaways

Global Pharma growth declining for the past 5 years

USA growth flat: only 'Pharmerging' markets shine

Global Pharma Historical Market Dynamics & Current Economic Environment

Global Sales and Market Growth



Pharmaco challenges

- The USA/top 5 Europe/Japan no longer 'Mr Atlas'
- Lower GDP growth and tax revenues will impact healthcare budgets/promote more aggressive cost containment
- Biotechnology, a big growth area, affected by lack of investment funds
- New product launches are not replacing revenues lost to generic competition, especially in primary care
- The most attractive areas for growth are in emerging markets

Source: IMS Health MIDAS MAT June 2009, Pharmerging markets = China, India, Russia, Brazil, Mexico, Turkey and South Korea.

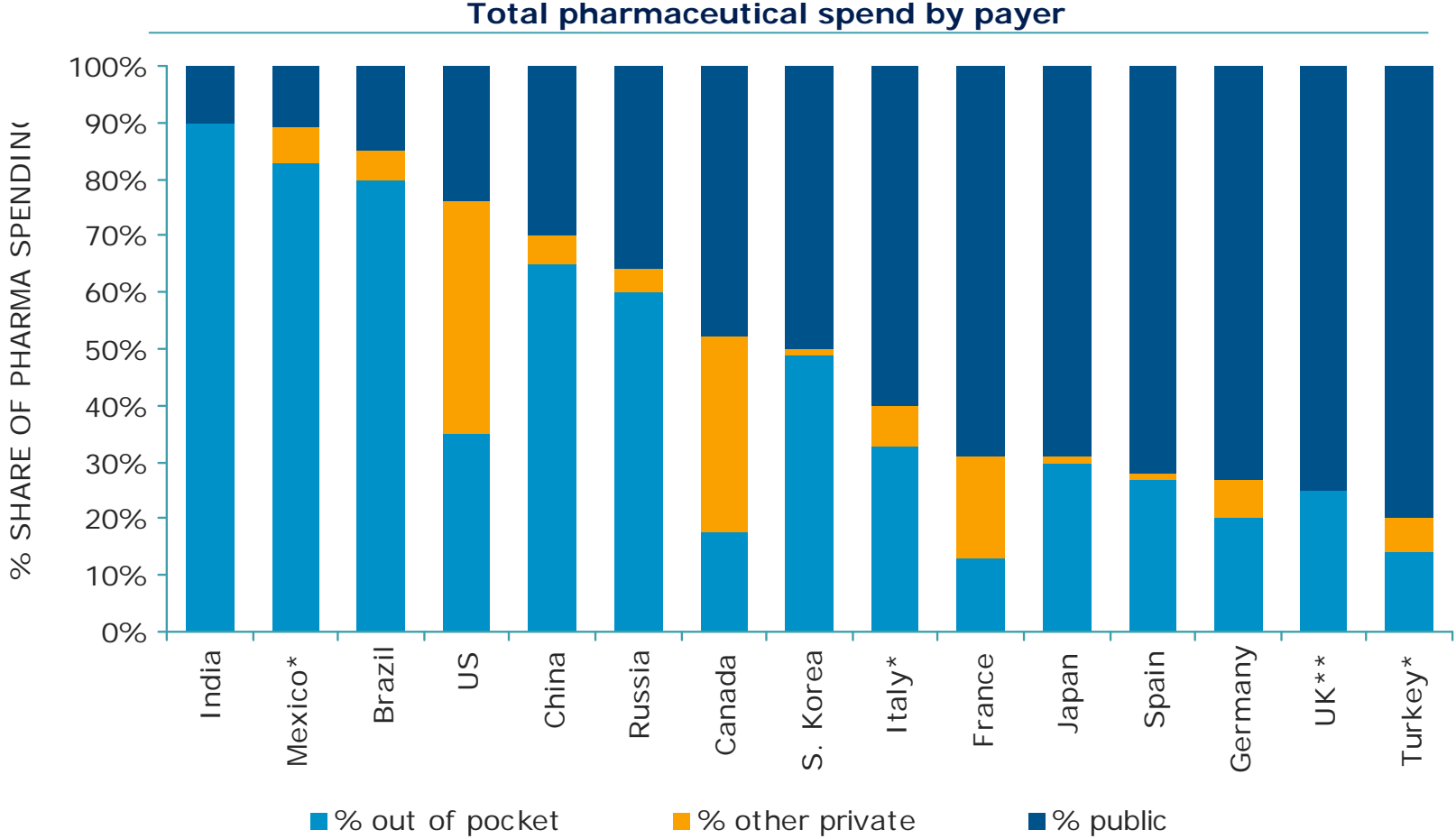
The financial crisis and accompanying recession has changed expectations about future Pharma growth

- The pharma market will be affected by a combination of patient and policy responses, but there has been limited evidence of this impact to date
- In the short term, the relative importance of the cash-pay/out of pocket market will determine impact, while in the longer term changes in GDP and tax revenues will influence growth in the pharmaceuticals market
- Sensitivity analysis combined with event modeling highlight key country differences in short and long-term responsiveness of markets to the crisis

Overall, global sales are expected to show a lower growth rate in the years up to 2013 than historical trends and likely future events would have suggested before the onset of the recession

Source: IMS Health Consulting 2009

Impact on pharma of patient and policy responses is influenced by the relative importance of funding sources



Source: OECD 2008; WHO 2008; Canada, CIHI 2007; *Estimated from available sources; **OOP vs other private not available



A quick recovery will bring pressure to the status quo but leave systems more or less intact

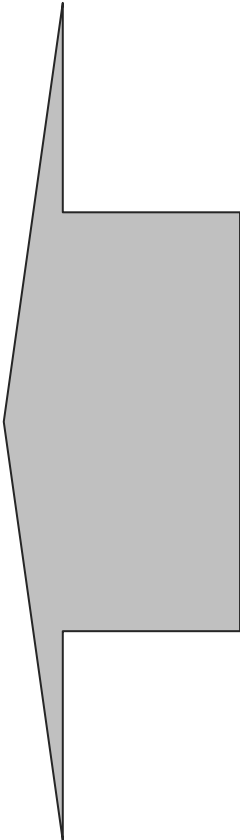
1 Patients

2 Government

3 Payers

4 Providers

5 Distributors



Affordability levels

Funding pressures

Credit squeeze

Source: IMS Health Consulting 2009

A "slow recovery" could trigger structural changes in several areas of the healthcare system



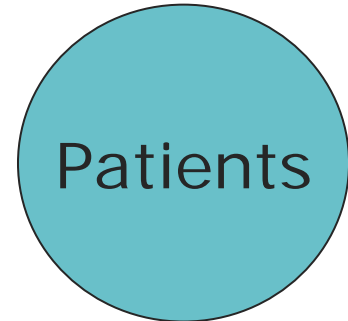
300 biotechs may run out of cash

UK aiming for 80% generic volume, but favourable to premium rising for 20% innovative

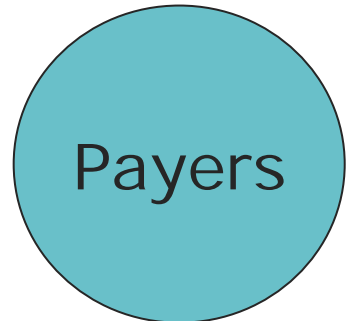
Preventative therapy Will need to produce stronger cost benefit evidence: many tradeoffs

Source: IMS Health Consulting 2009

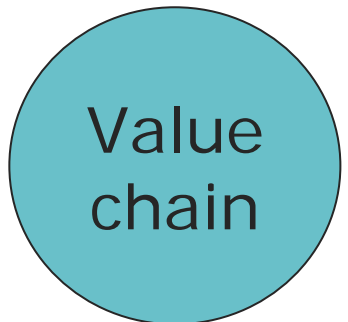
New inflection points may be triggered by the crisis



- Once stopped, therapy not resumed
- Once generic, always generic
- Lower-quality healthcare is acceptable



- Good enough is good enough
- Blunt instruments work well
- Accelerated adoption of biosimilars



- Reduced private capital role in innovation
- Power shift with retailers/wholesalers

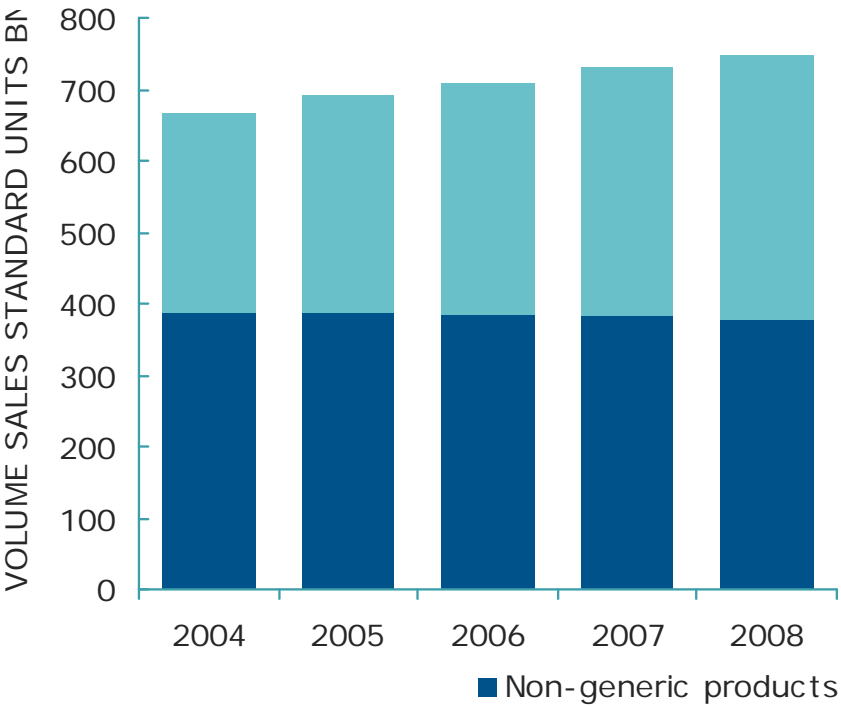
Source: IMS Health Consulting 2009

Generics already make up one half of volume sales, but merely 15% of the value market

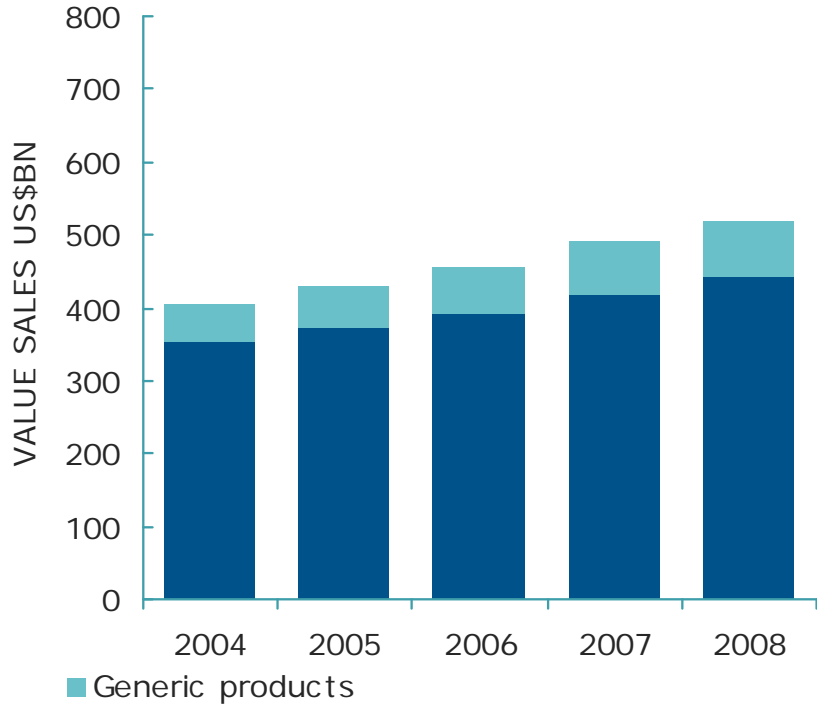
So 80% not so far away: mandated first line generics common

Generic penetration across mature markets

Volume trends



Value trends



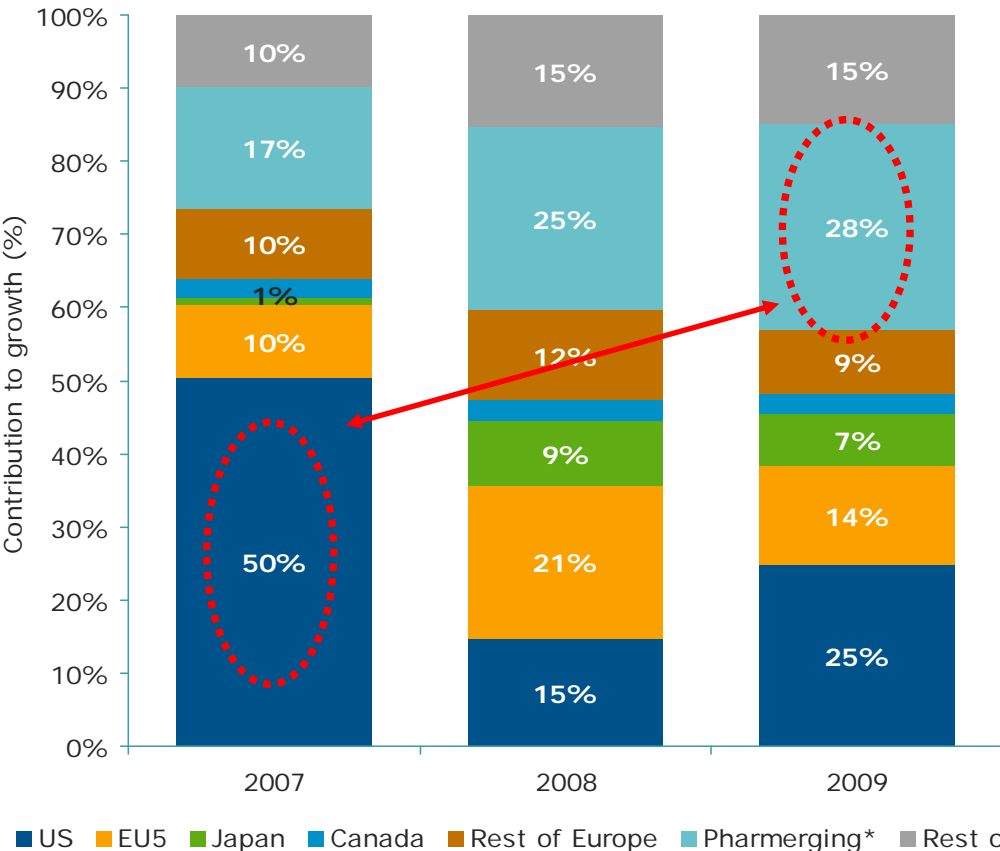
Source: IMS Health MIDAS Market Segmentation MAT December 2008, RX bound market only

Today's discussion

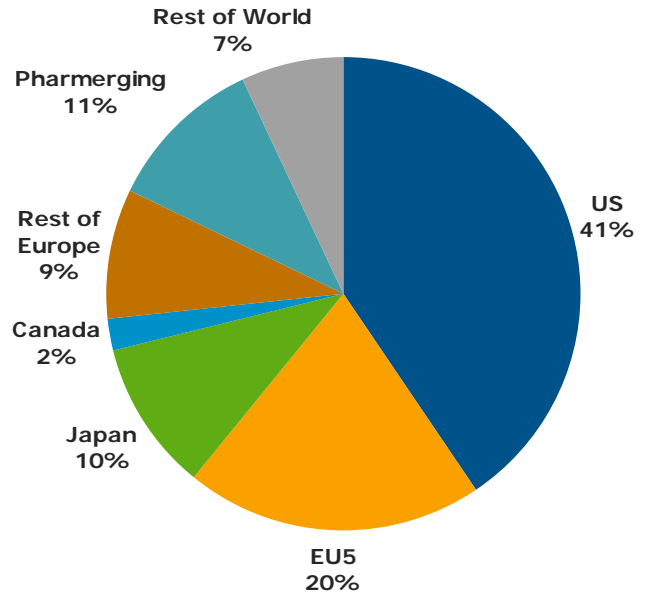
- Impact of the global economic crisis on pharma
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US traditional role as the largest contributor to global growth has been replaced by pharmerging region

Contribution to global growth, Const US\$



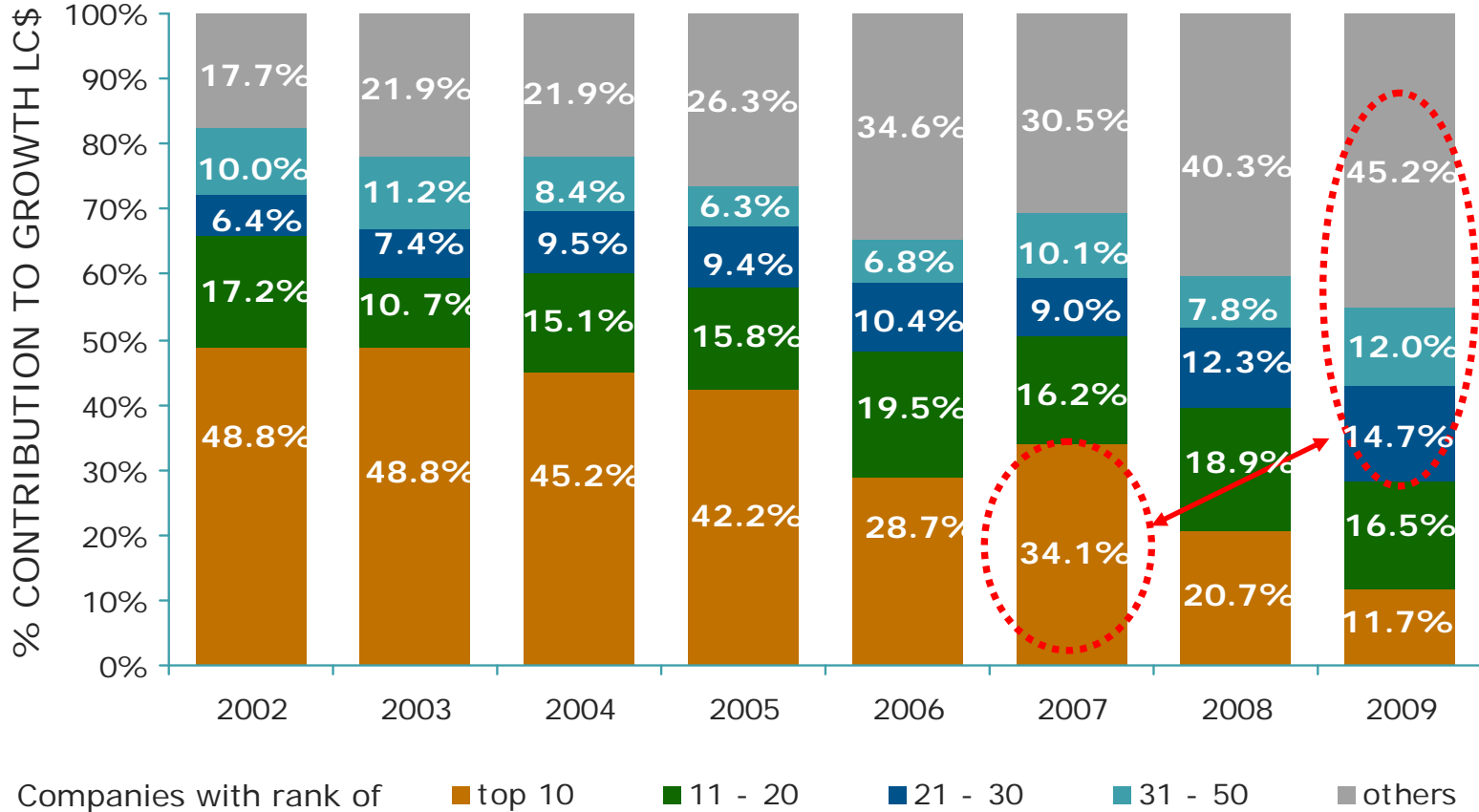
MAT JUNE 2009 Market share, US\$



Source: IMS Health MIDAS MAT June 2009. *Pharmerging markets = China, India, Russia, Brazil, Mexico, Turkey and South Korea.

Growth has skewed from the multinationals to smaller companies

Global Pharma Distribution by Size of Corporations

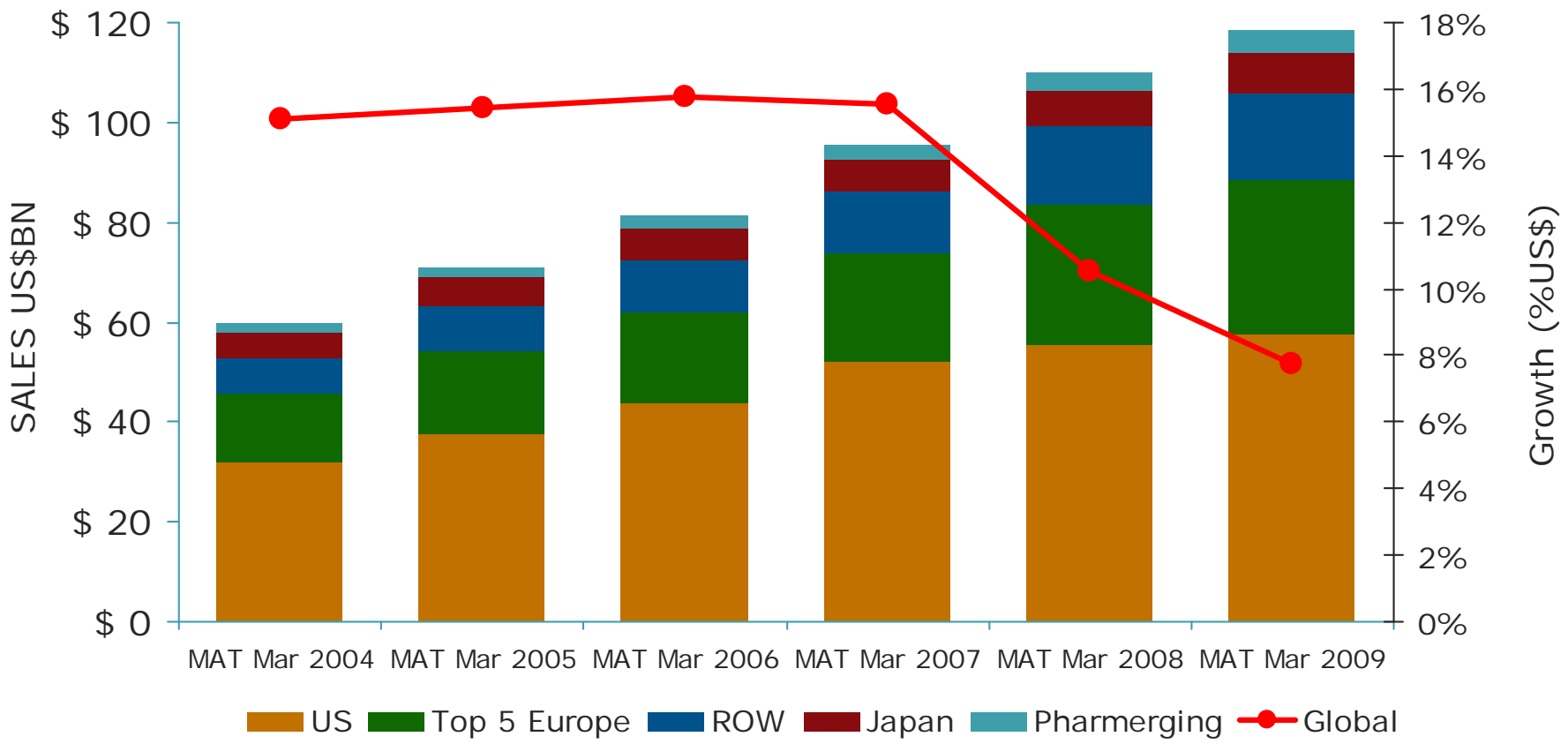


Source: IMS MIDAS March 2009



Biologic sales exceed \$100 billions and have 17% of global pharma sales

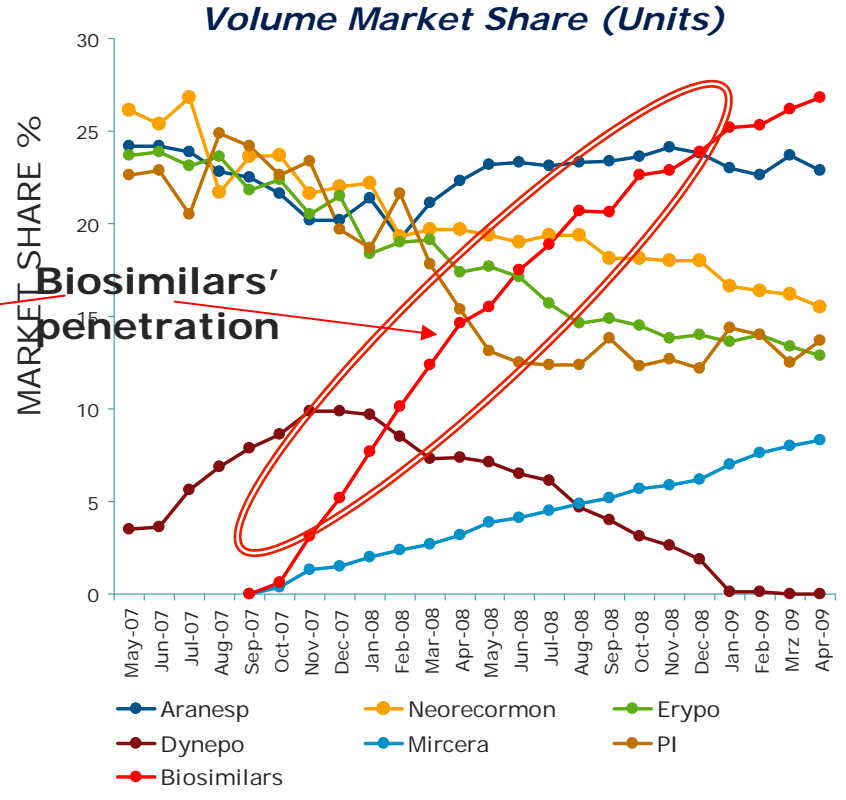
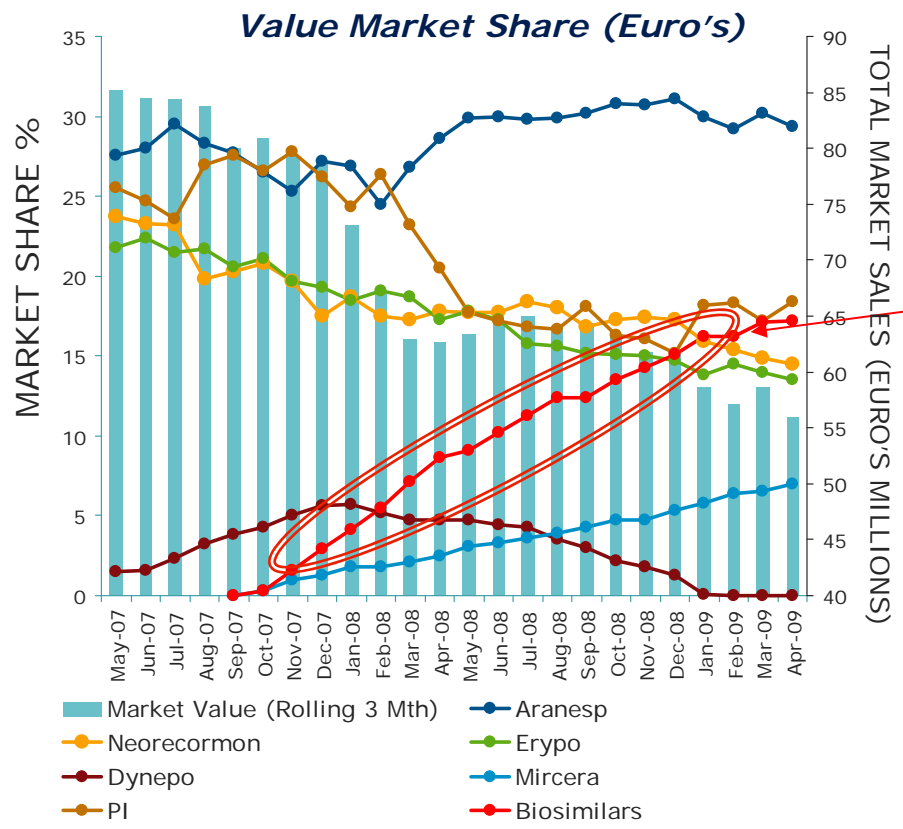
Growth decline due to epo and innovation lull



Source: IMS Health, MIDAS, MAT Mar 2009

In Germany, total market value for EPOs falling whilst biosimilars gaining volume share

Germany: Biosimilars in Erythropoeitin Market (Sell Out)

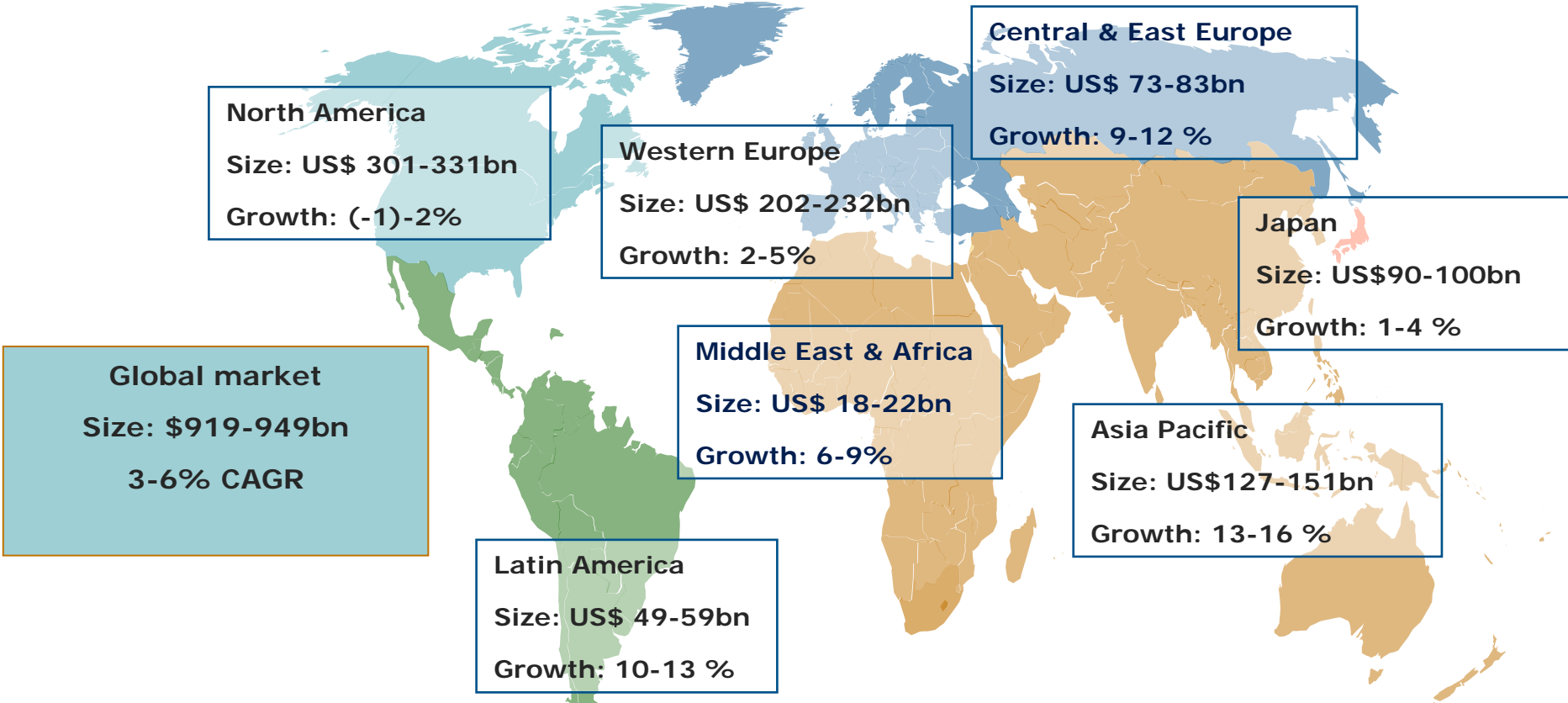


(*) this analysis just covers sales out from pharmacies

Source: IMS Health, PharmaScope, Germany

Over the next 5 years, growth opportunities will continue to move away from traditional markets*

Global: IMS Regional Pharmaceutical Outlook in 2013 (US\$ Billions)



* Revised forecast pending

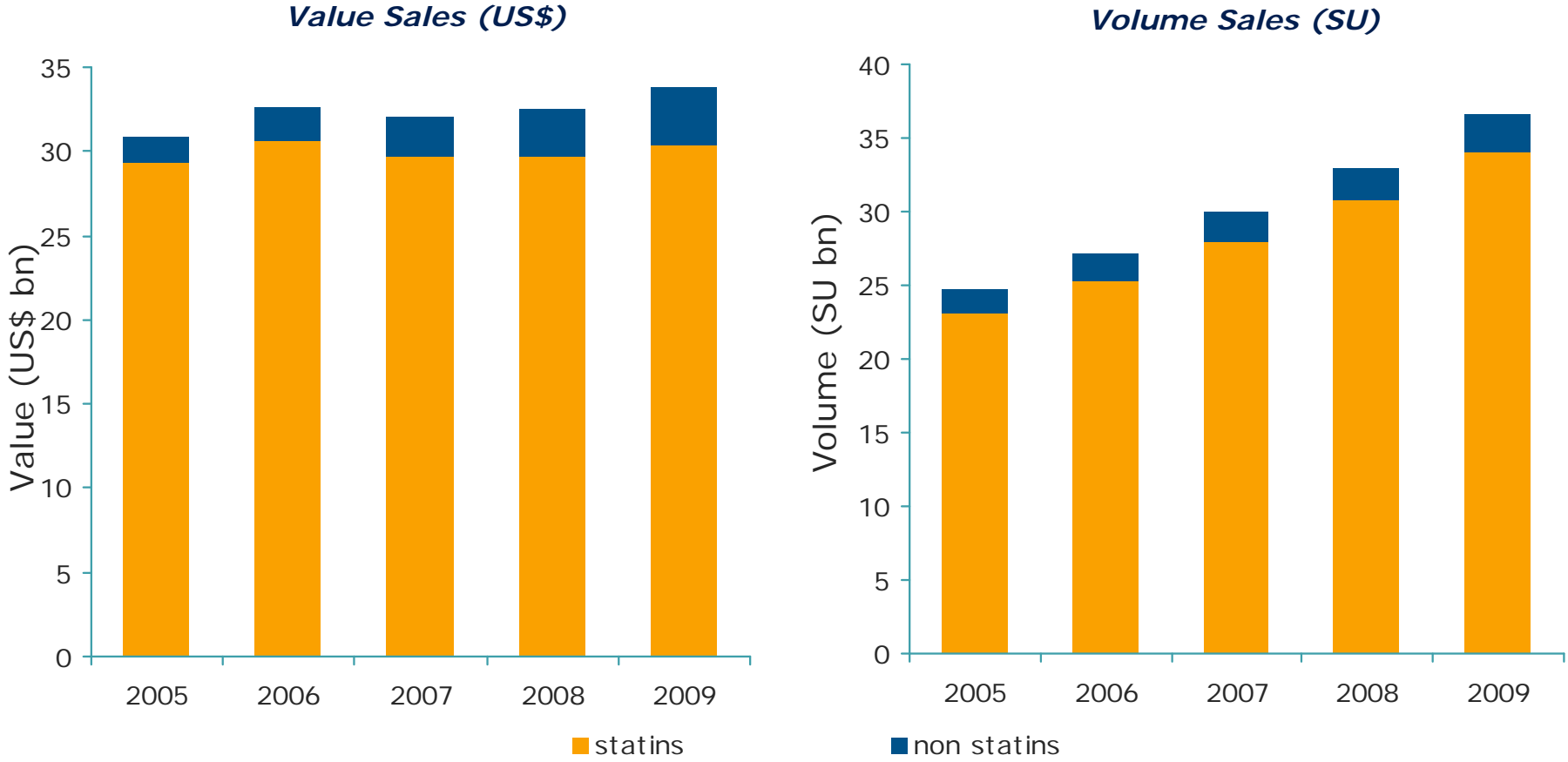
Source: IMS Health, Market Prognosis, June 2009.

Today's discussion

- Impact of the global economic crisis on pharma
- Global pharmaceutical market overview
- Prospects in the dyslipidemia market
- Conclusions and key takeaways

Global value sales of dyslipidemia has stabilised, although volume sales have increased steadily

Dyslipidemia Market Value and Volume Global

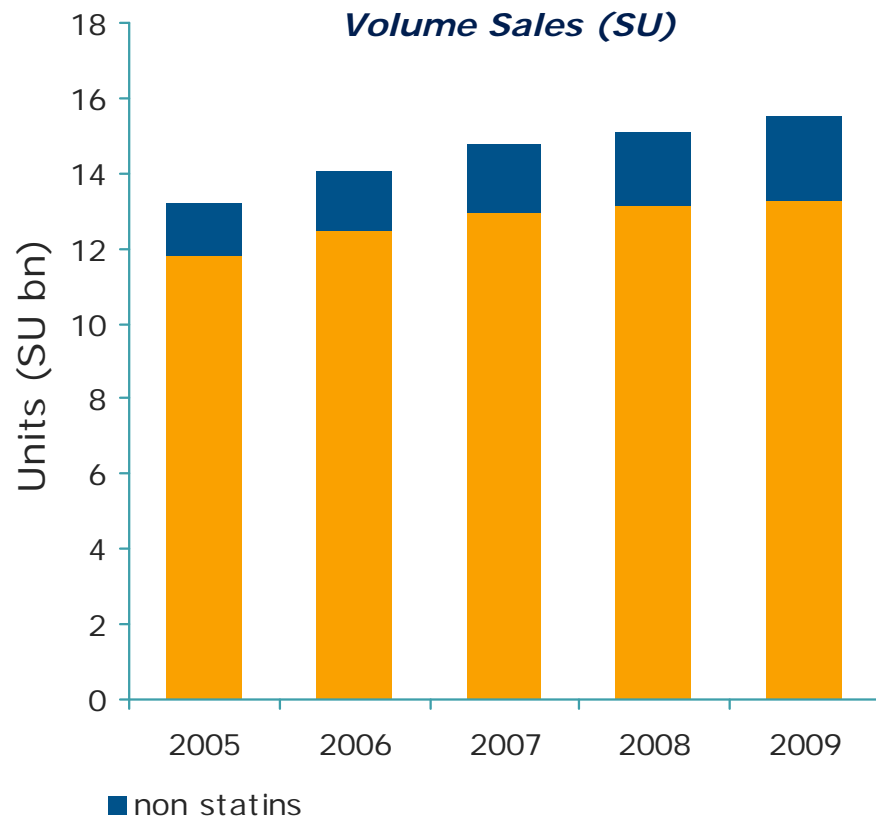
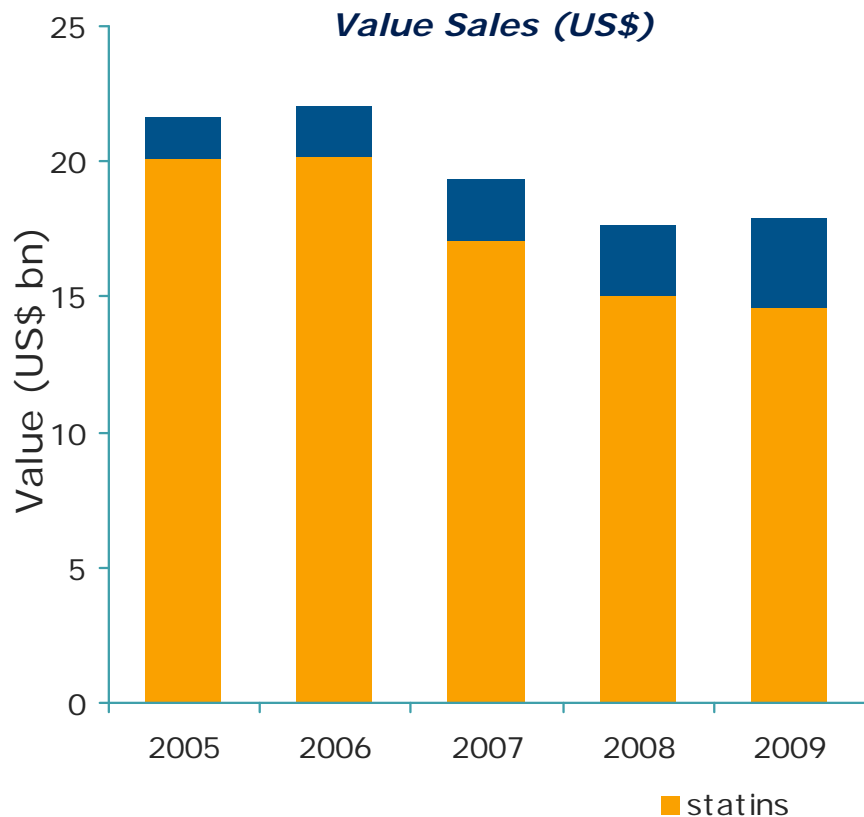


Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lipid

Statins have largest share of the dyslipidemia market

Total sales peaked in 2006 although now stabilised

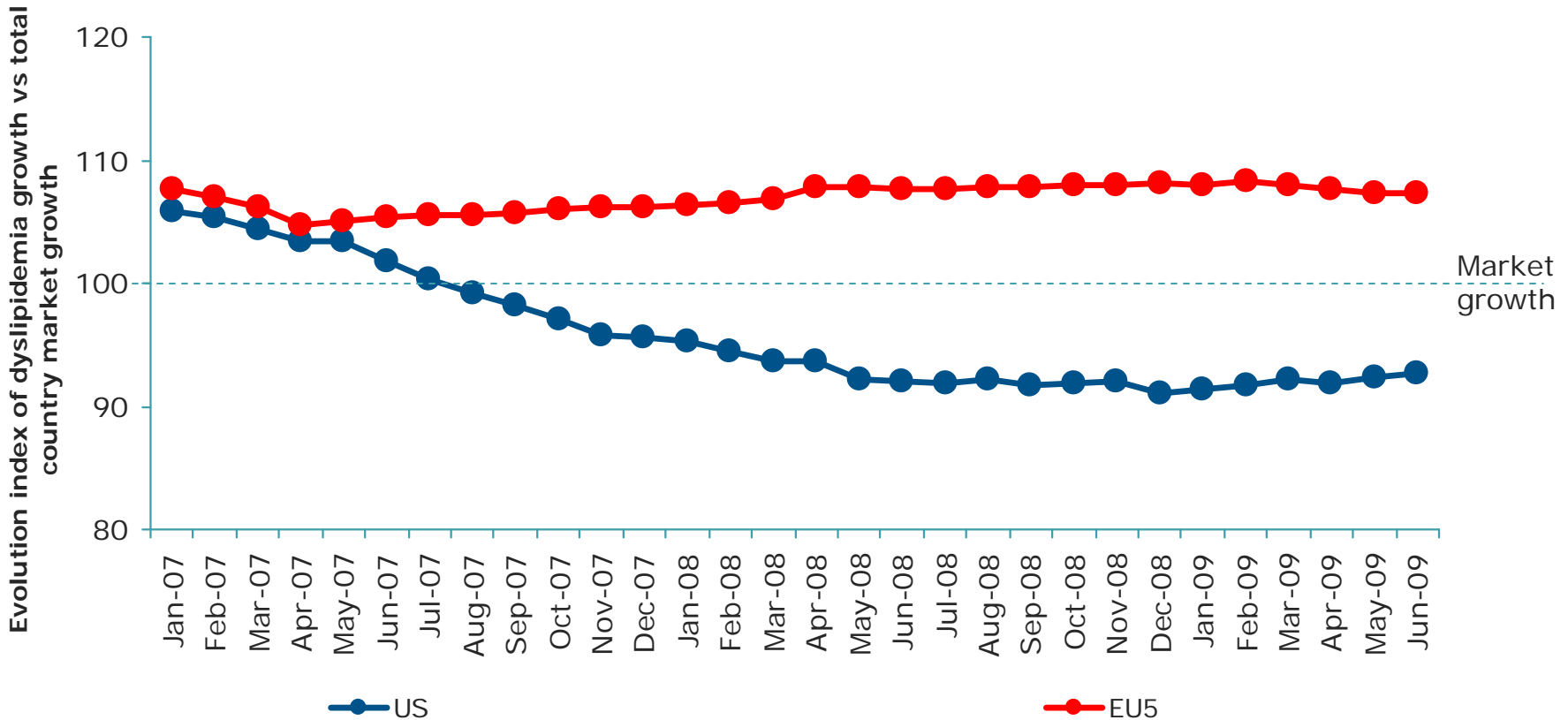
Dyslipidemia Market Value and Volume US+EU5



Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

The dyslipidemia volume market is outperforming in EU5, whilst US shows an opposing picture

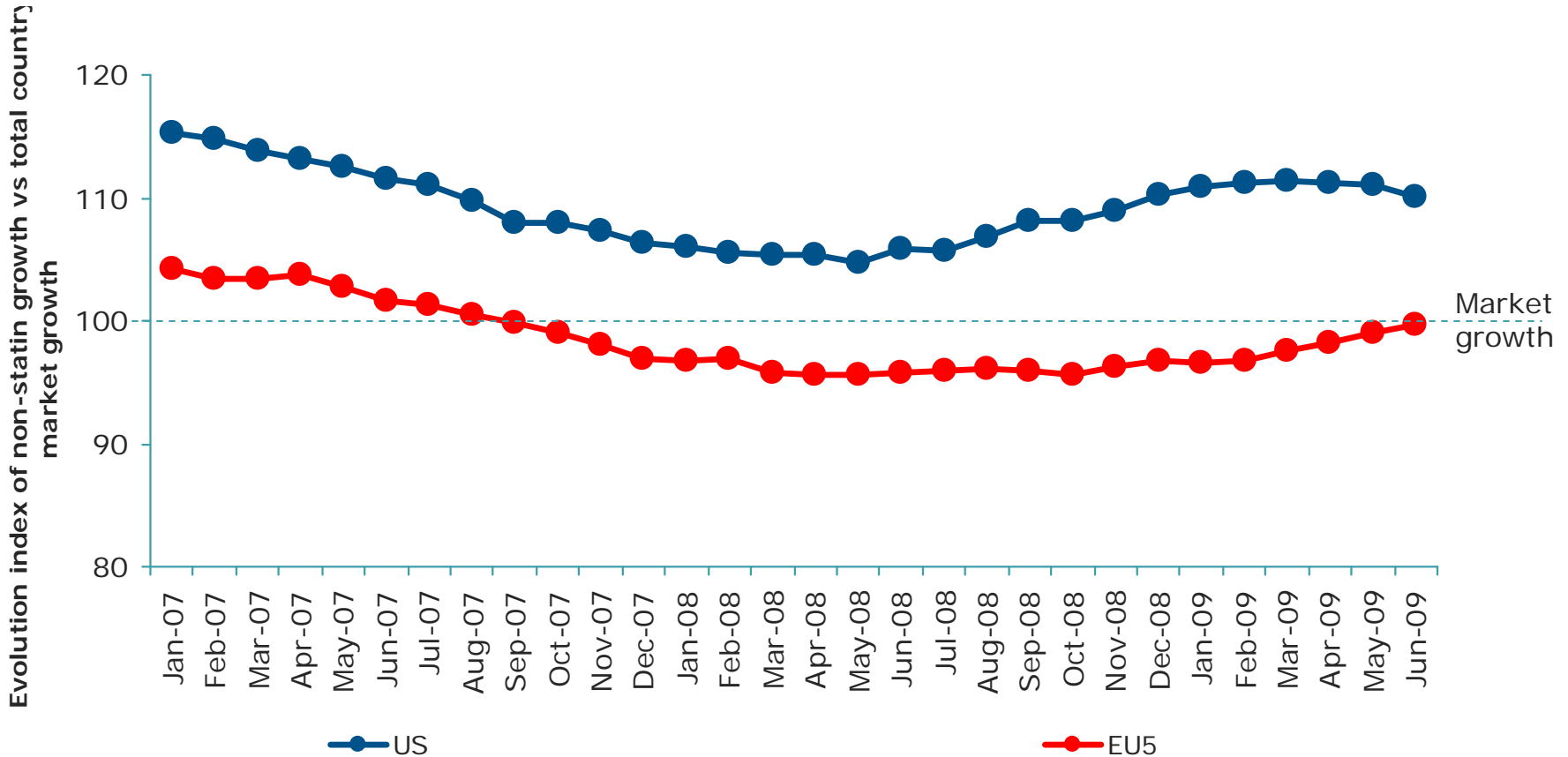
Volume; Dyslipidemia, EU5 + US markets vs. total market performance; rolling monthly MAT



Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

However, the opposite can be said for the non-statin market, with the US outperforming major Europe

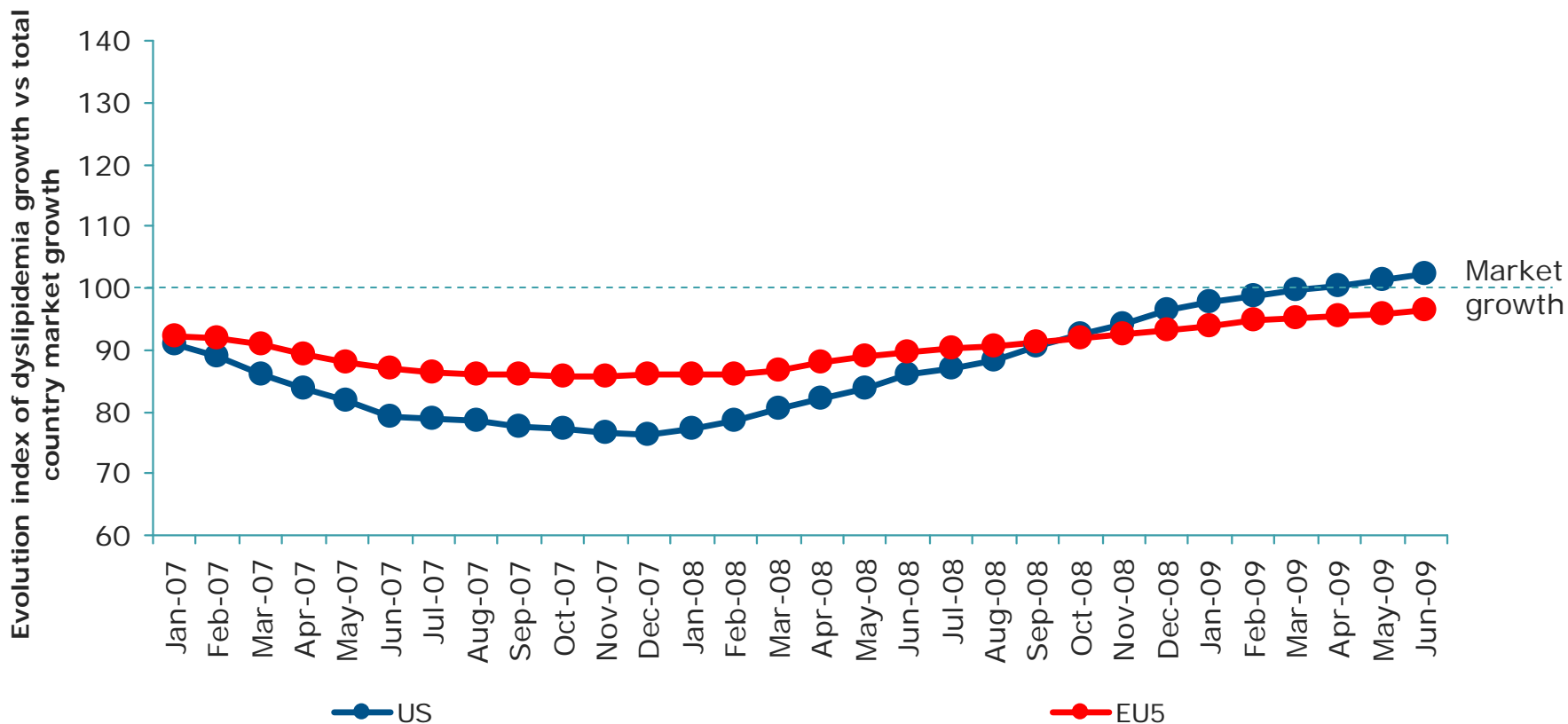
Volume; Non-statins, EU5 + US markets vs. total market performance; rolling monthly MAT



Source: IMS Health MIDAS MAT Jun 2009. Rx Bound only; non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

Dyslipidemia sales growing at the market rate

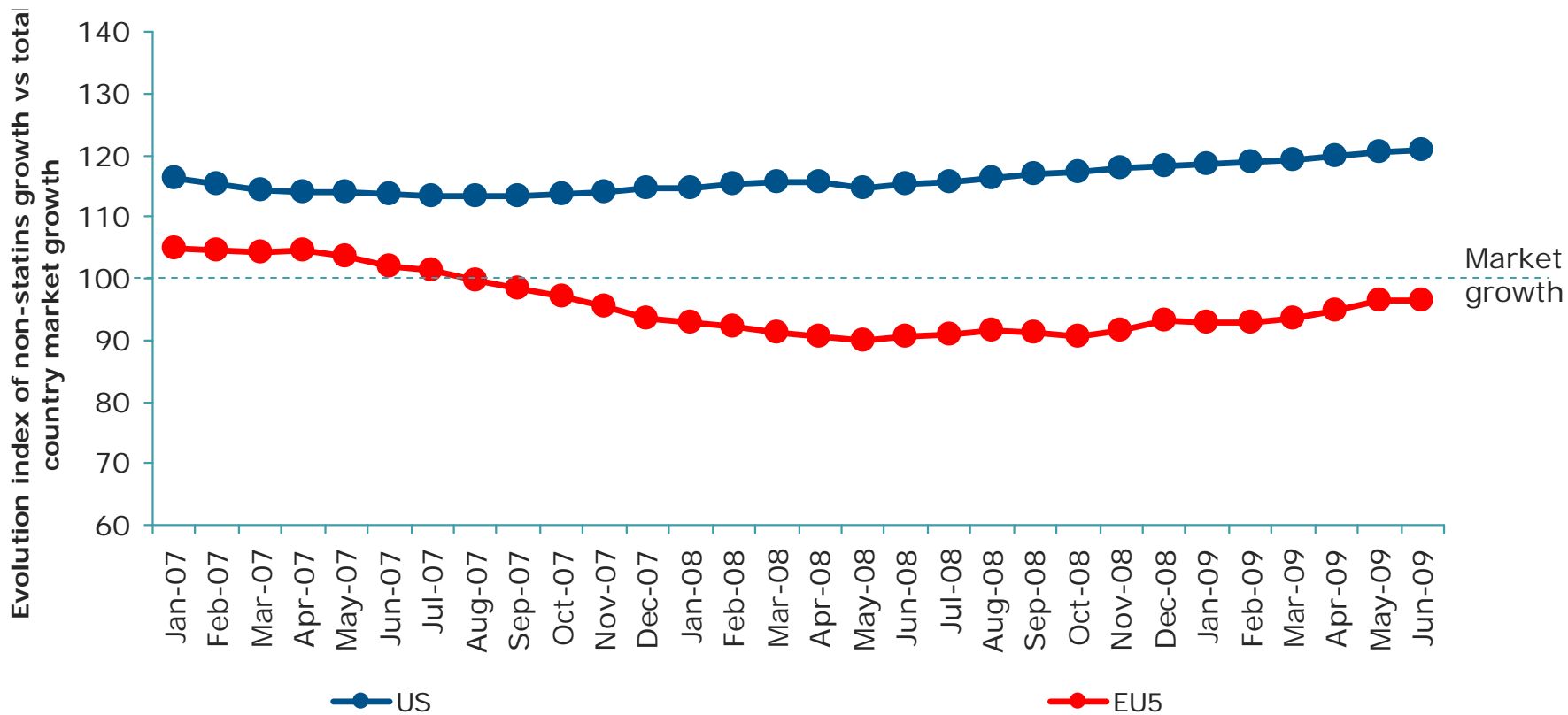
Value; Dyslipidemia, EU5 + US markets vs. total market performance; rolling monthly MAT



Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

For non-statins, growth well above the market average in the US and recovering in EU5

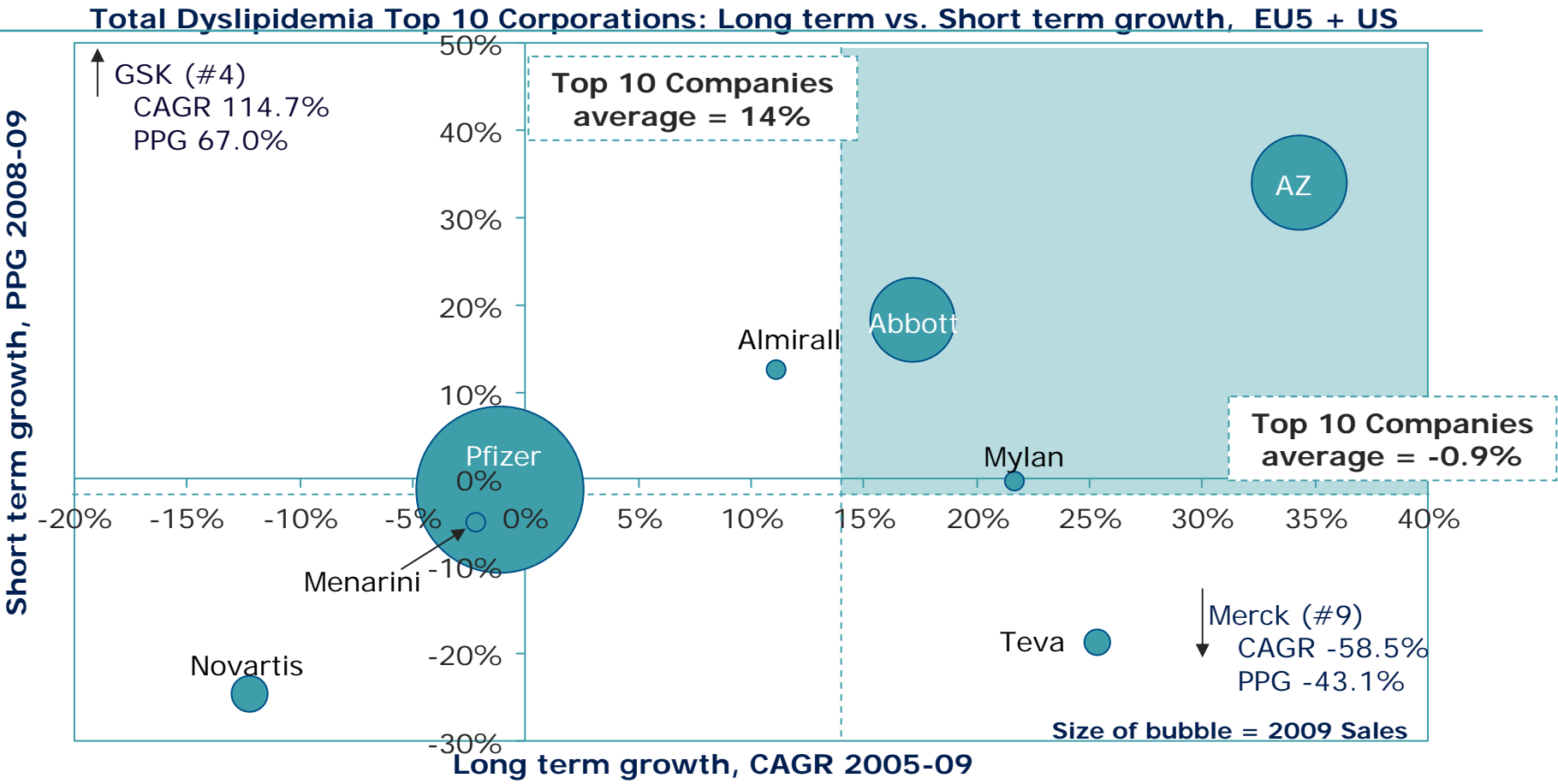
Value; Non-statins, EU5 + US markets vs. total market performance; rolling monthly MAT



Source: IMS Health MIDAS MAT Jun 2009. Rx Bound only; non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

Pfizer dominates the dyslipidemia market

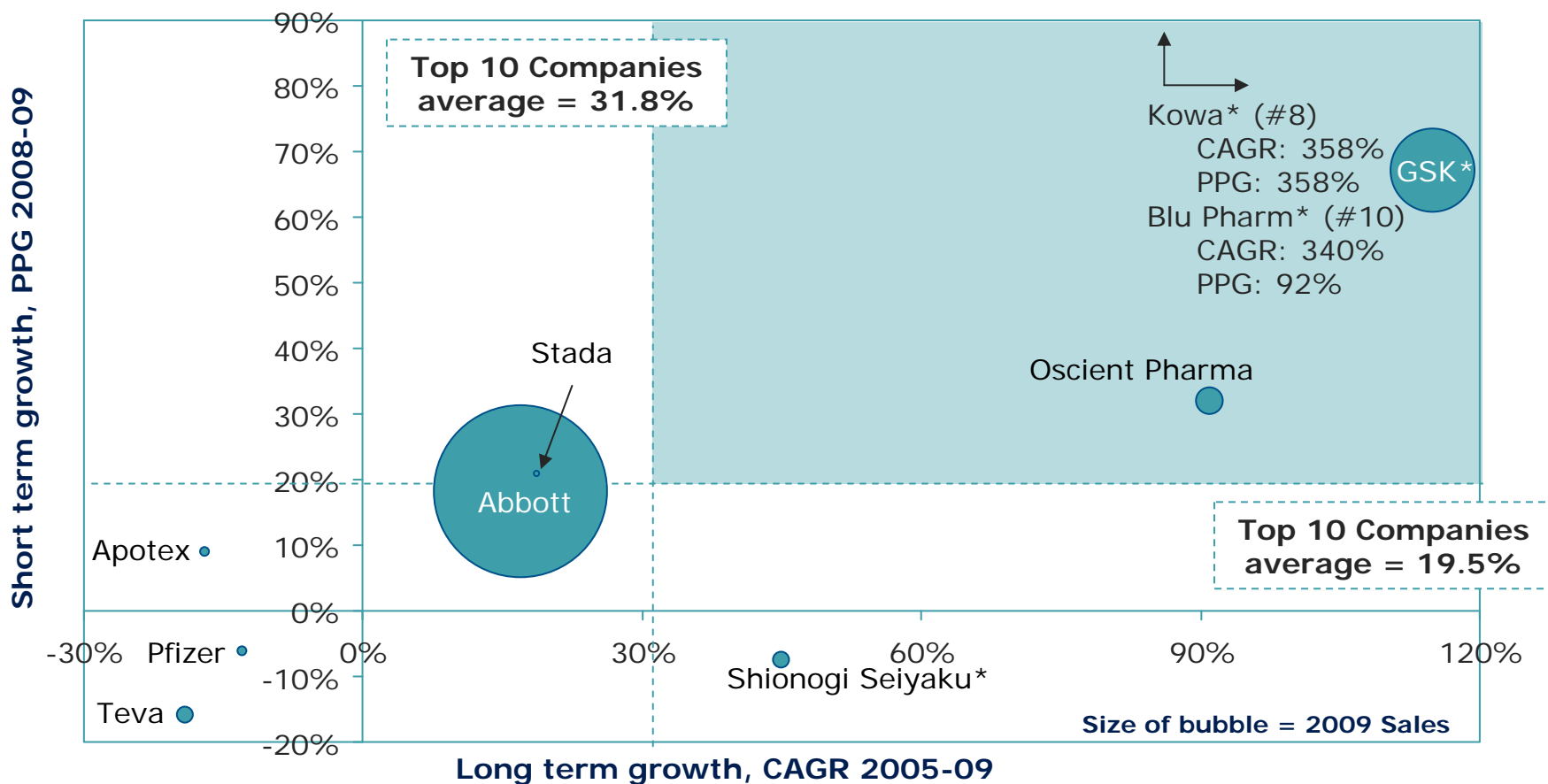
AZ's growth has surpassed market average



Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

Abbott is the leading corp in the non-statin market, however, its growth is below market average

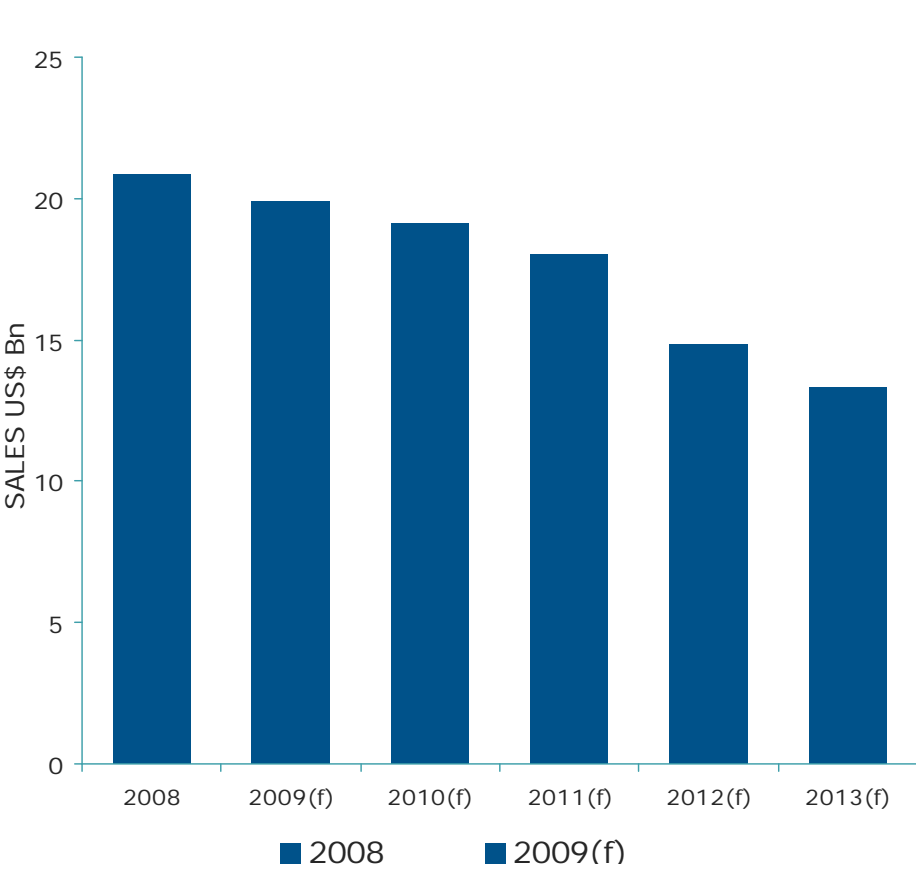
Non-Statins Top 10 Corporations: Long term vs. Short term growth, EU5+US




Source: IMS Health MIDAS MAT June 2009. Rx Bound only; non-statin defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lipid

Further cost containment and loss of exclusivity will continue to have a downward effect on statins


Top 8 markets: Statins forecast



Drivers

- 
- ↑ Improved awareness and treatment
 - ↑ Availability of fixed – combination therapies
 - ↑ Approval of statins for non-cardiovascular indications

Constraints

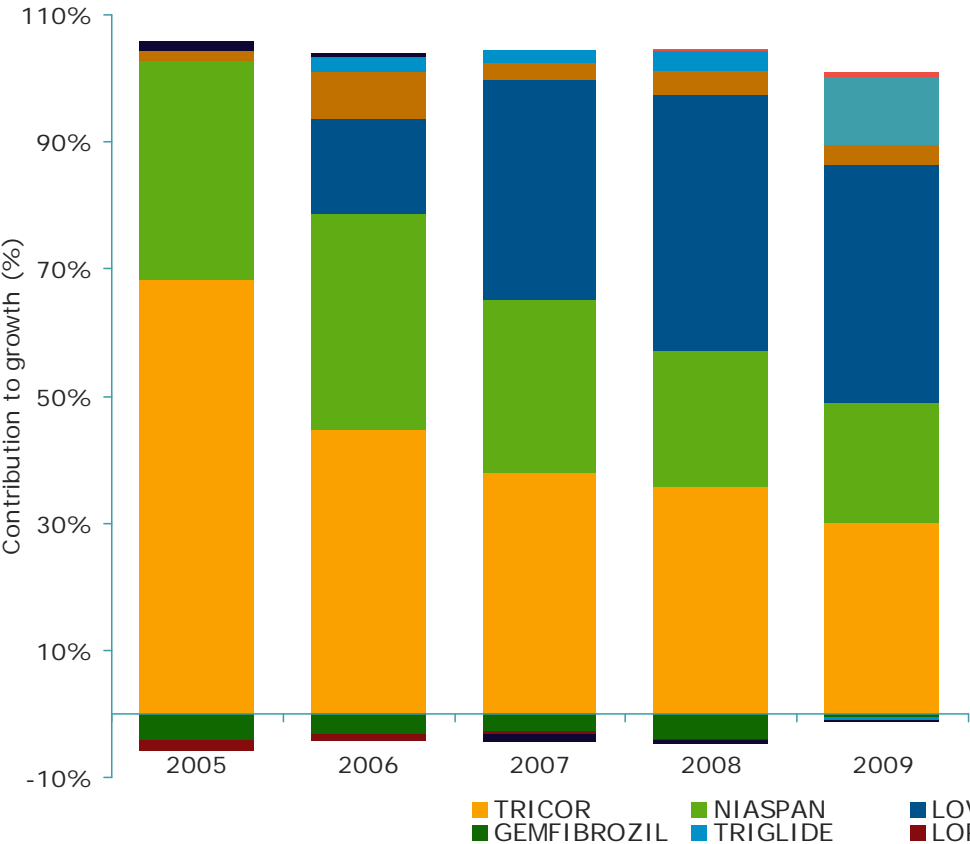
- 
- ↓ Cost-containment strategies and increasing generics usage suppress drug prices and expenditures
 - ↓ Healthcare plans push more costs onto patients
 - ↓ Generic availability of leading brands

Source: IMS Health Therapy Forecaster and IMS Health Consulting, 2009

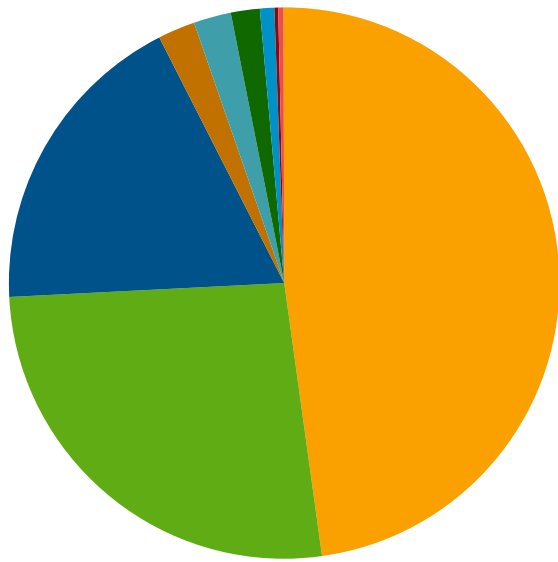
Lovaza has overtaken Tricor as the leading growth contributor in the non-statin dyslipidemia market

However, Tricor continues to dominate sales

US+EU5: Contribution to global growth, Const US\$



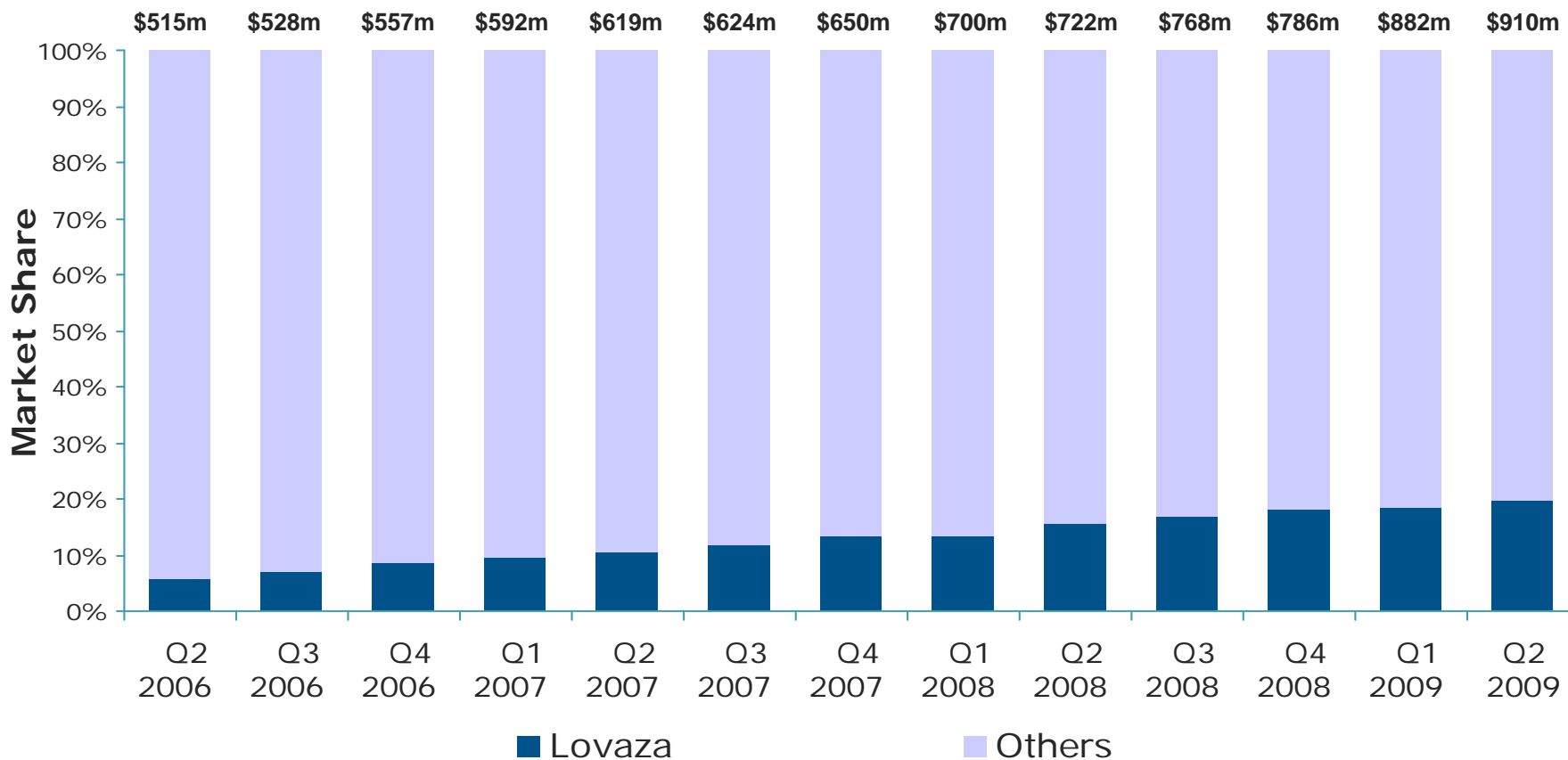
US+EU5: 2009 Market share, US\$



Source: IMS Health MIDAS MAT Jun 2009. Rx Bound only; non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lipid

Lovaza's uptake in the non-statin dyslipidemia market has increased steadily: market almost \$1 billion

US Non-Statin Dyslipidemia Market by Product

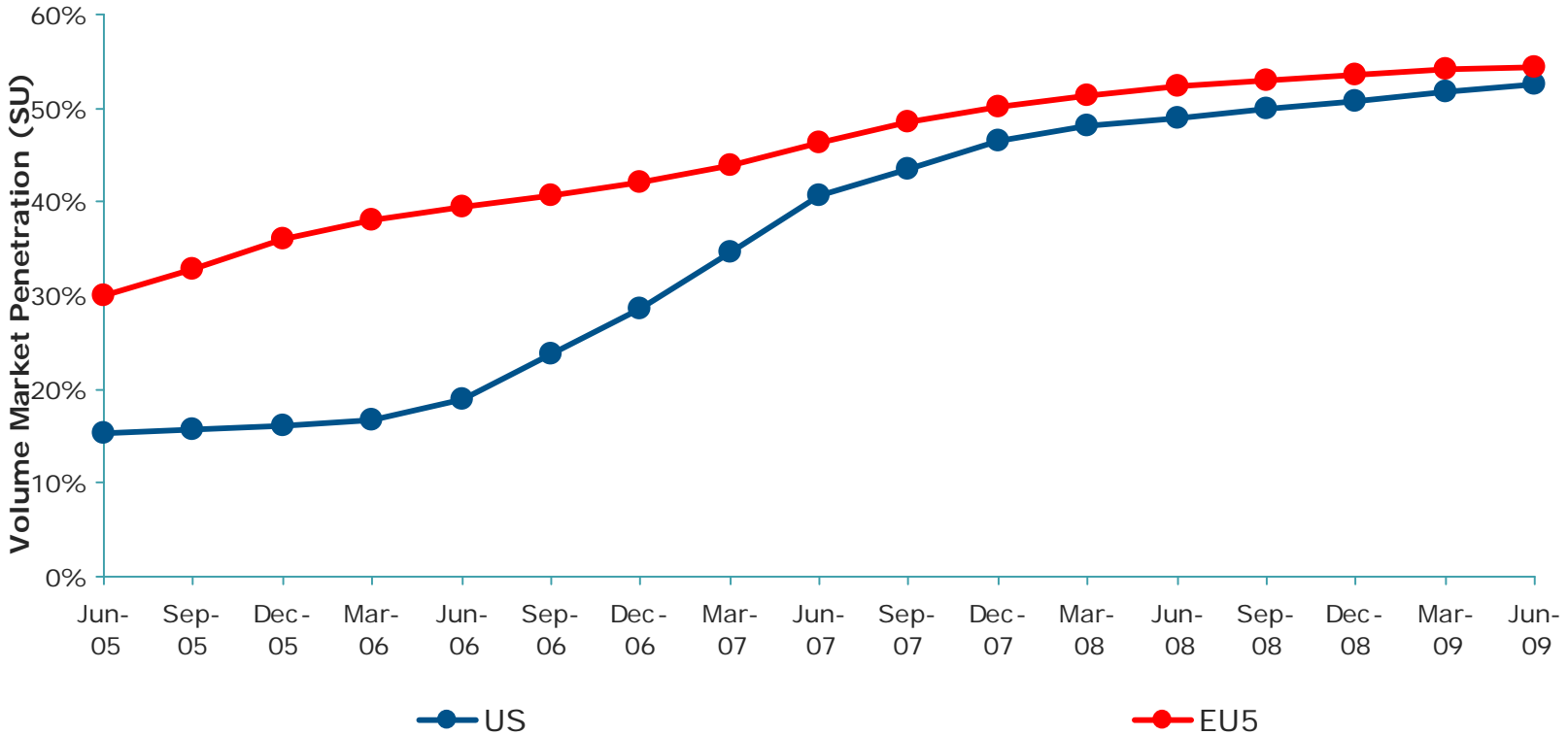


Source: IMS Midas MAT Jun 2009. Market size in US\$ Mn on top of each bar. Market defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

Generic penetration is a rising threat to the dyslipidemia market

Pronova need to concentrate efforts on differentiation


Dyslipidemia Volume: Generic Penetration across EU5 + US (SU)



Source: IMS Health MIDAS MAT Jun 2009. Rx-bound only. Dyslipidemia defined as statins (C10A1 class) + non-statins defined as: Tricor, Niaspan, Lovaza, Gemfibrozil, Trilipix, Antara, Lipofen, Triglide, Lofibra, Lopid

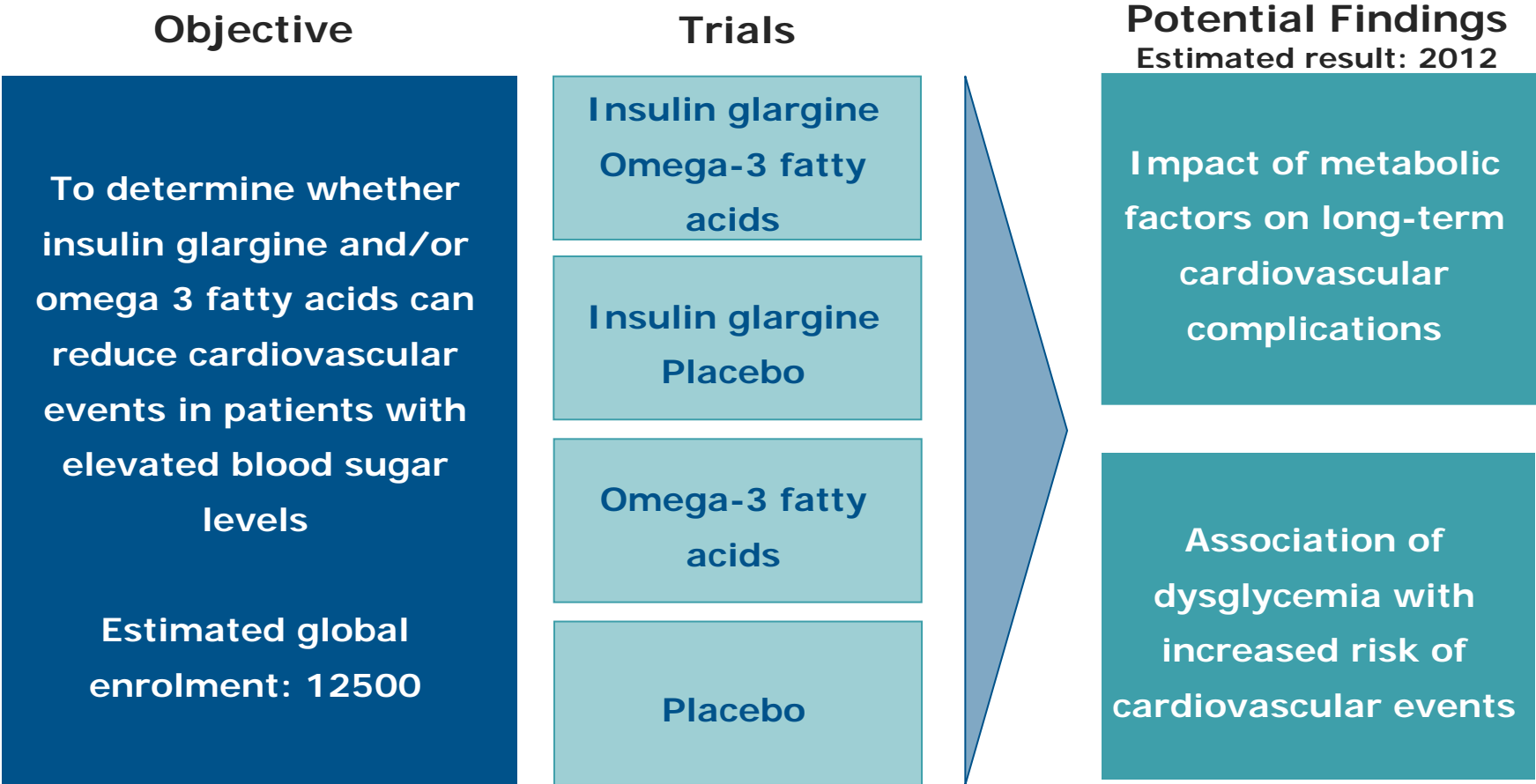
But generic defence strategies will only do so much There is no magic wand – differentiation is key

- With increased use of generics, differentiation will be key to ensuring that brands do not experience 90% brand erosion after losing protection
- Clinical trial results could help to boost value proposition against cheap alternatives, or to prevent brands being pushed back in the treatment pathway. **Crestor has succeeded here**

- 
- What is Pronova's generic and biogeneric defence strategy?
 - How will Pronova best utilise results from the ORIGIN trial to their advantage?
 - Will further investment into additional indications pay off?
 - Should Pronova look to penetrate additional markets to increase footprint?

The ORIGIN trial may provide significant benefit to Lovaza's value proposition

ORIGIN trial investigates the reduction of heart disease risk with insulin and omega 3 oils



Source: clinicaltrials.gov

Additional approvals may enhance penetration of Lovaza in the cardiovascular market



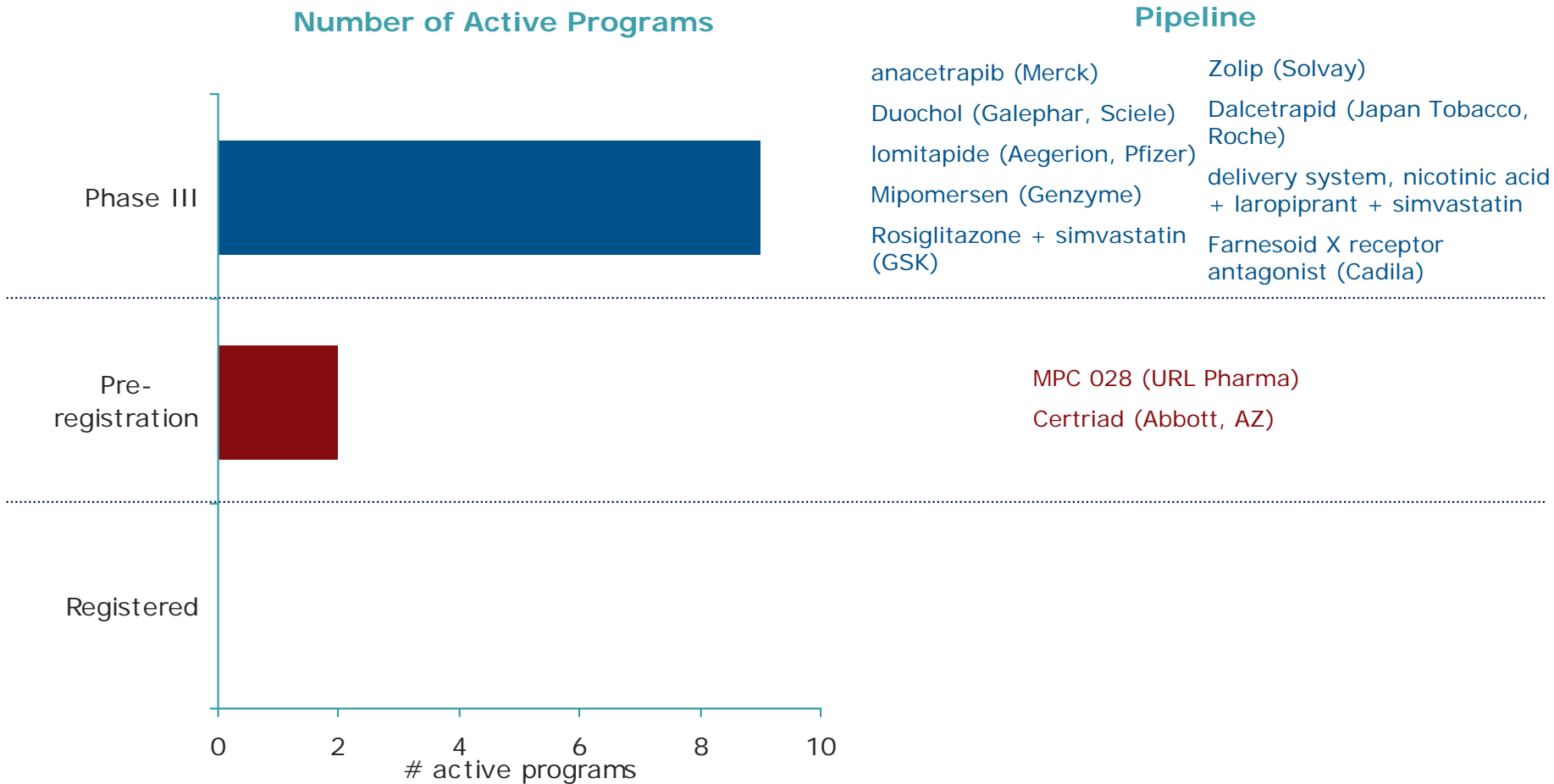
- Indicated for secondary prevention of myocardial infarction and the primary treatment of hypertriglyceridemia
- Phase III trials in chronic heart failure and atrial fibrillation began in 2008 in the US
- CHF trials showed that Lovaza significantly lengthened time to death and improved time to death or admission to the hospital for cardiovascular disease

- Can Lovaza extend out to additional indications successfully?
- Will Lovaza experience a “halo” effect with further clinical trials and indication approval across the market?
- Will Pradaxa, Xarelto etc become leaders in SPAF?
- Brilinta also a threat

Source: IMS Health Knowledge Link;

The non-statin market will continue to get more crowded as new products enter the market

Non-statin Dyslipidemia: Late Pipeline



Source: IMS Health LifeCycle R&D Focus August 2009

Today's discussion

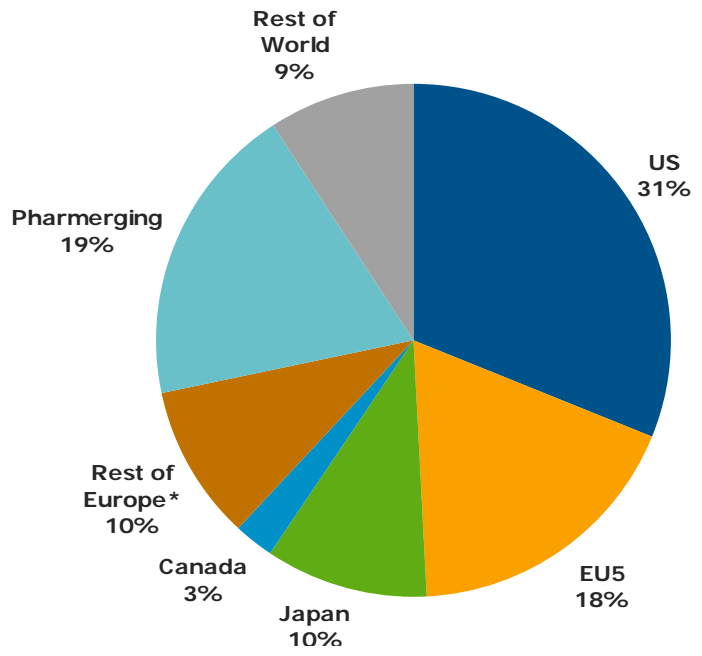
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Growth rates will remain in low single digits to 2013*
 Pharmerging markets will almost double in size in the next five years (\$155-\$185 billions)

2013: Share of global sales (Const US\$bn)



Mature Markets CAGR 2008-2013	
US	(-2)-1%
Japan	1-4%
France	(-1)-2%
Germany	3-6%
Italy	0-3%
UK	0-3%
Spain	6-9%
Canada	3-6%
Mature	0-3%

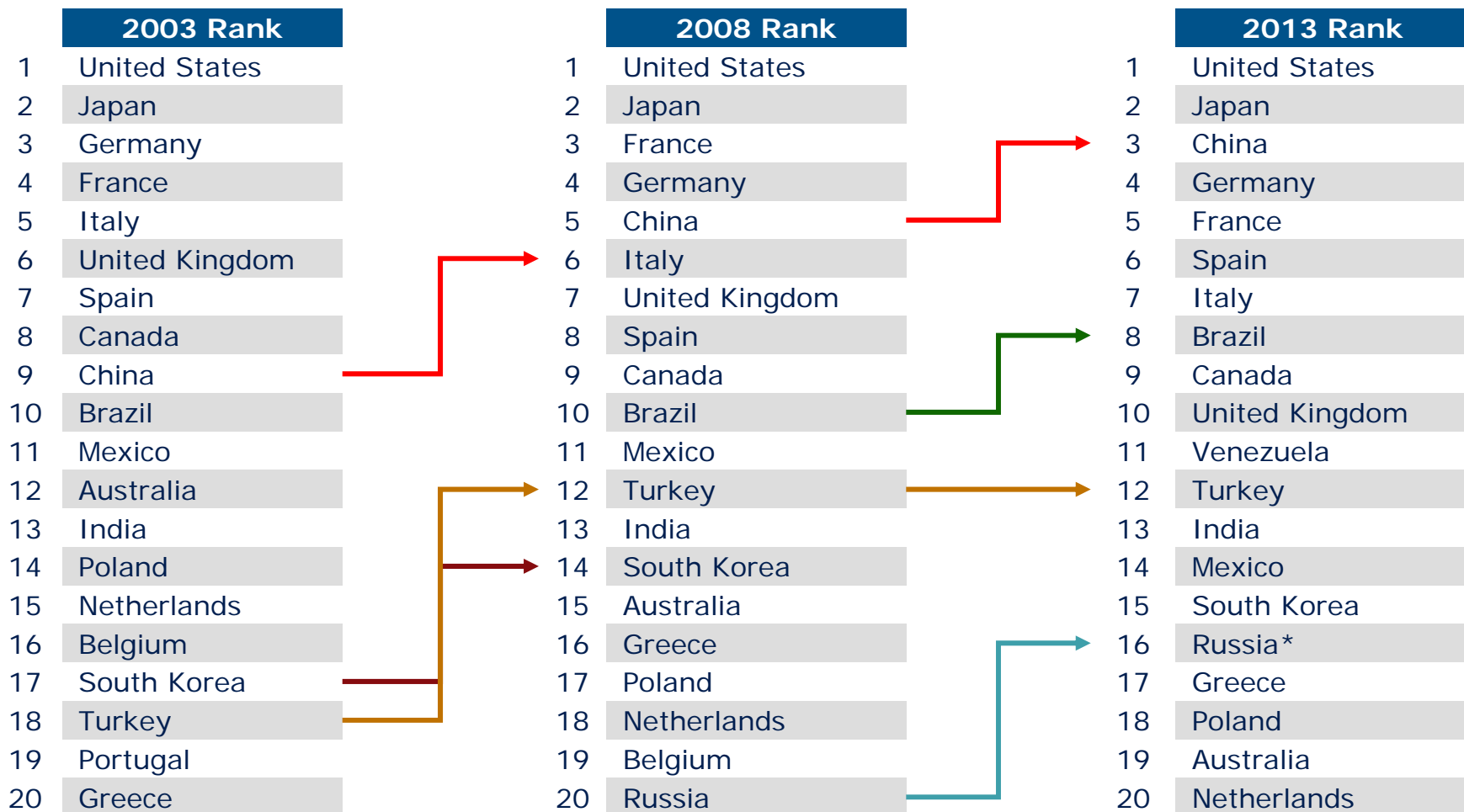
Pharmerging Markets CAGR 2008-13	
China	21-24%
Brazil	7-10%
Mexico	4-7%
Turkey	11-14%
India	11-14%
S. Korea	7-10%
Russia	14-17%
Pharmerging	13-16%
Global market	3-6%

* Revisions due end September 09

Source: IMS Health, Market Prognosis, June 2009.

A new world order will evolve through 2013, with China becoming #3








UK at risk of losing top 10 status



Source: IMS Health Market Prognosis, Mar 2009. Market size ranking in Constant US\$. *Russia 2013 Market Insights estimate


Our research shows significant shifts in stakeholder power

Don't confuse customer with consumer!

Influence & power of Stakeholder from 2008-2013							
		National Payers	Local Payers	Physician	Pharmacist	Patient Groups	Key Opinion Leader
 US	Primary	↑↑	↑↑	↓↓	↔	↑↑	↑↑
	Specialty	↑↑	↑↑	↓	↔	↑↑	↑↑
 Canada	Primary	↑	↑	↓↓	↑	↑	↔
	Specialty	↑	↑	↓	↔	↔	↔
 UK	Primary	↑	↑	↓	↑	↔	↓
	Specialty	↑↑	↑↑	↔	↔	↑	↔
 France	Primary	↑	↑↑	↓	↑	↔	↓
	Specialty	↑	↑	↓	↔	↑	↓
 Germany	Primary	↑	↑↑	↓↓	↑	↑	↔
	Specialty	↑↑	↑	↑	↓	↑	↔
 Spain	Primary	↔	↑↑	↓↓	↑	↔	↑
	Specialty	↔	↑↑	↓	↑	↑	↔
 Italy	Primary	↔	↑↑	↓↓	↑	↔	↓
	Specialty	↑	↑	↓	↑↑	↑	↓

Results based on country-level expert Delphi panel: charged with identifying stakeholders with power over whether launch products used and their relative power in the country now and in 2013.

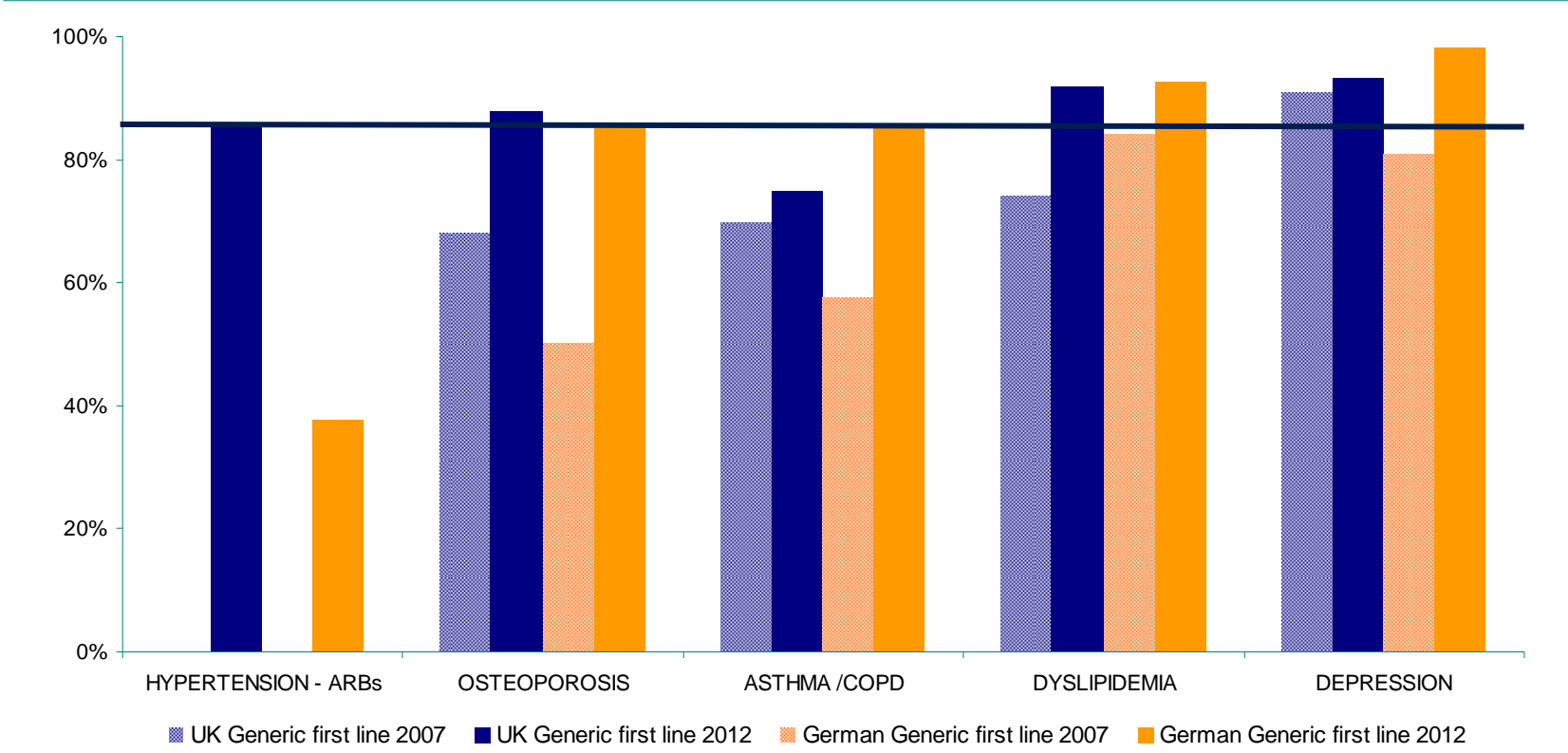
KEY

 Increase
  Decrease
  Stay the same

Payers will demand a generic as first line in many key primary care areas

May involve the entire hyperlipidemia market

Percentage of first line patients receiving a generic, now and by 2012, in key primary care areas



Source: IMS Disease Analyser Germany, UK, 1st line use defined as new to pharmacotherapy – ARBs=Angiotensin II receptor antagonists (antihypertensive class)

Non-statins will be central to the future growth of the dyslipidemia market

But only if long term value proposition reinforced

Potential growth drivers for Non-Statins

Opportunities for Non-statins

- Potential for use in statin-intolerant patients
- Alternative to cases where statin treatment is inadequate
- To avoid the side effects of statins

Market Expansion

- Combination therapy - many non-statins are used alone or in conjunction with statins
- Indication - several cardiovascular products are being tested for multiple indications eg Lovaza
- Type of dyslipidemia – eg ABT335/Crestor for mixed dyslipidemia

Launches and increasing sales of new non-statin lipid-lowering therapies - particularly those that increase concentrations of HDL cholesterol - will compensate for the decrease in statin revenues

Source: IMS Health Consulting 2009

Thank You

Graham Lewis, VP Global Pharma Strategy

Prepared for Pronova Biopharma

