

# Key Strategic Trends shaping the Pharmaceutical Industry to 2014

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Bornadata Bain, PhD

Vice President and Global Research and Analysis Director

Datamonitor Healthcare

(e) [bbain@datamonitor.com](mailto:bbain@datamonitor.com)

## Presentation Agenda

- ▶ Outlook to 2014
  - ▶ **Resistors** for the Pharmaceutical industry
  - ▶ **Drivers** for the Pharmaceutical industry
  - ▶ **Neutral** for the Pharmaceutical industry
- ▶ **Summary: Positioning for success**



2014

OUTLOOK



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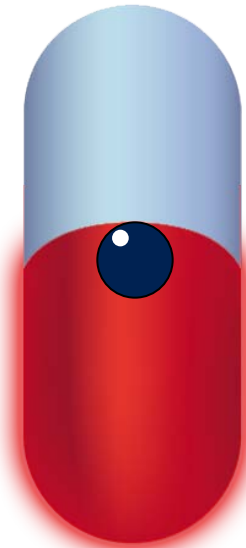
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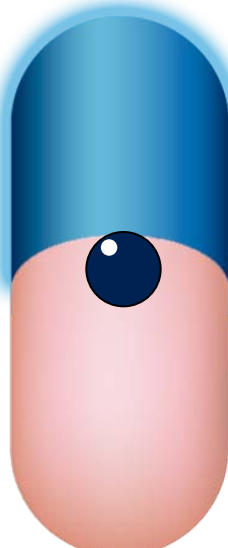


SUMMARY



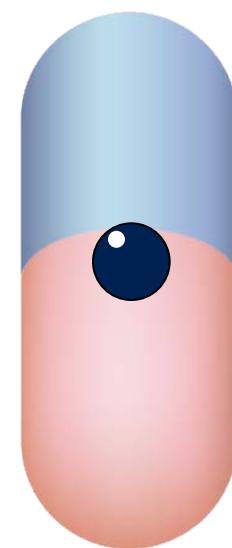
### **Resistors** for Pharma

- The 'patent cliff'
- Price and reimbursement cuts
- Growing regulatory pressure



### **Drivers** for Pharma

- Biologics market expansion
- Emerging market expansion
- Cost-saving initiatives



### **Neutral** for Pharma

- US Healthcare Reform
  - Short-term sales dip
  - Mid-term growth
  - Long-term negative impact

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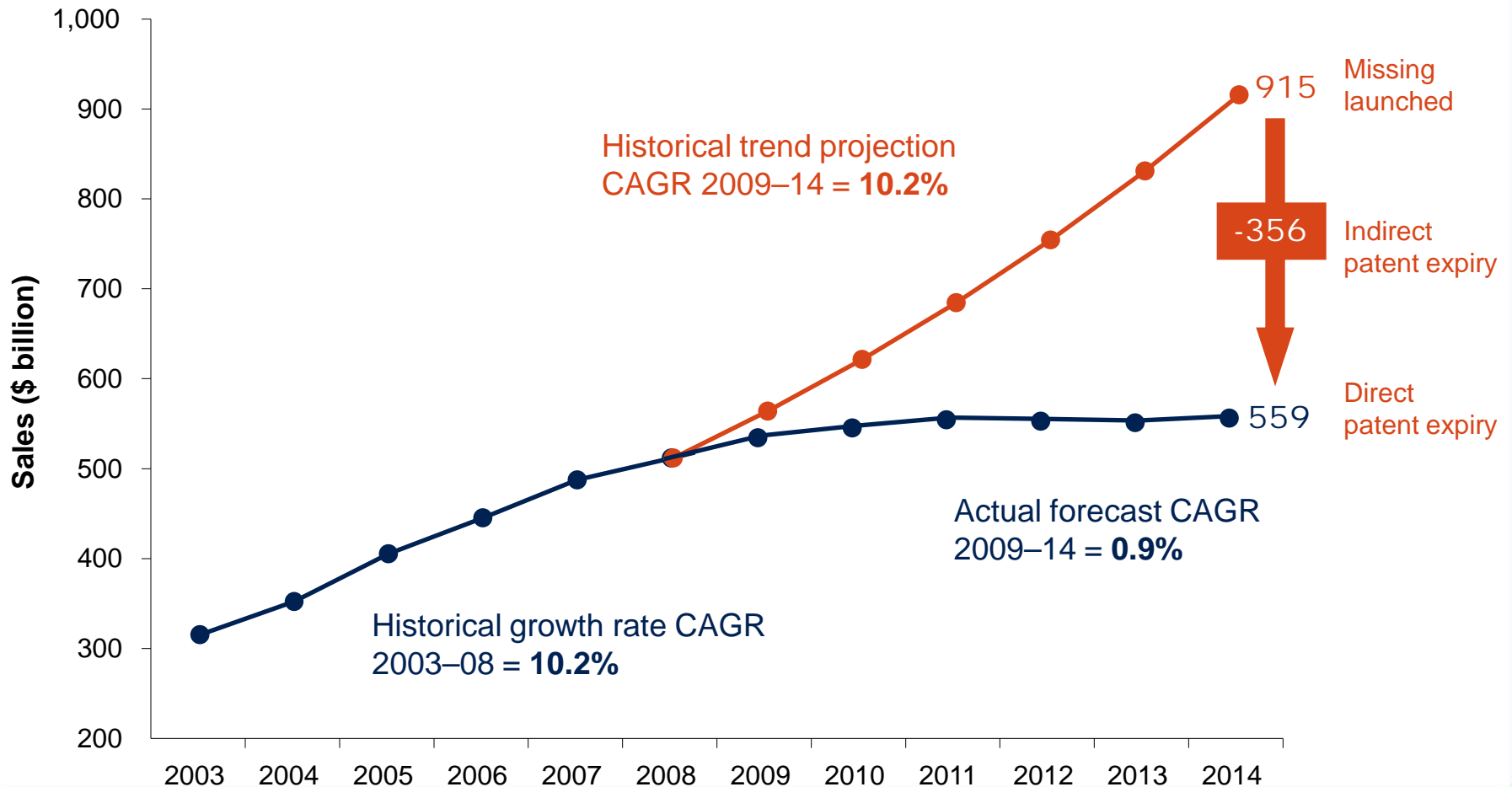


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SUMMARY

The pharmaceutical industry's sales growth rate will flat-line to 2014...





## Resistors for the Pharmaceutical industry

- The patent cliff
- Price and reimbursement cuts
- Growing regulatory pressure

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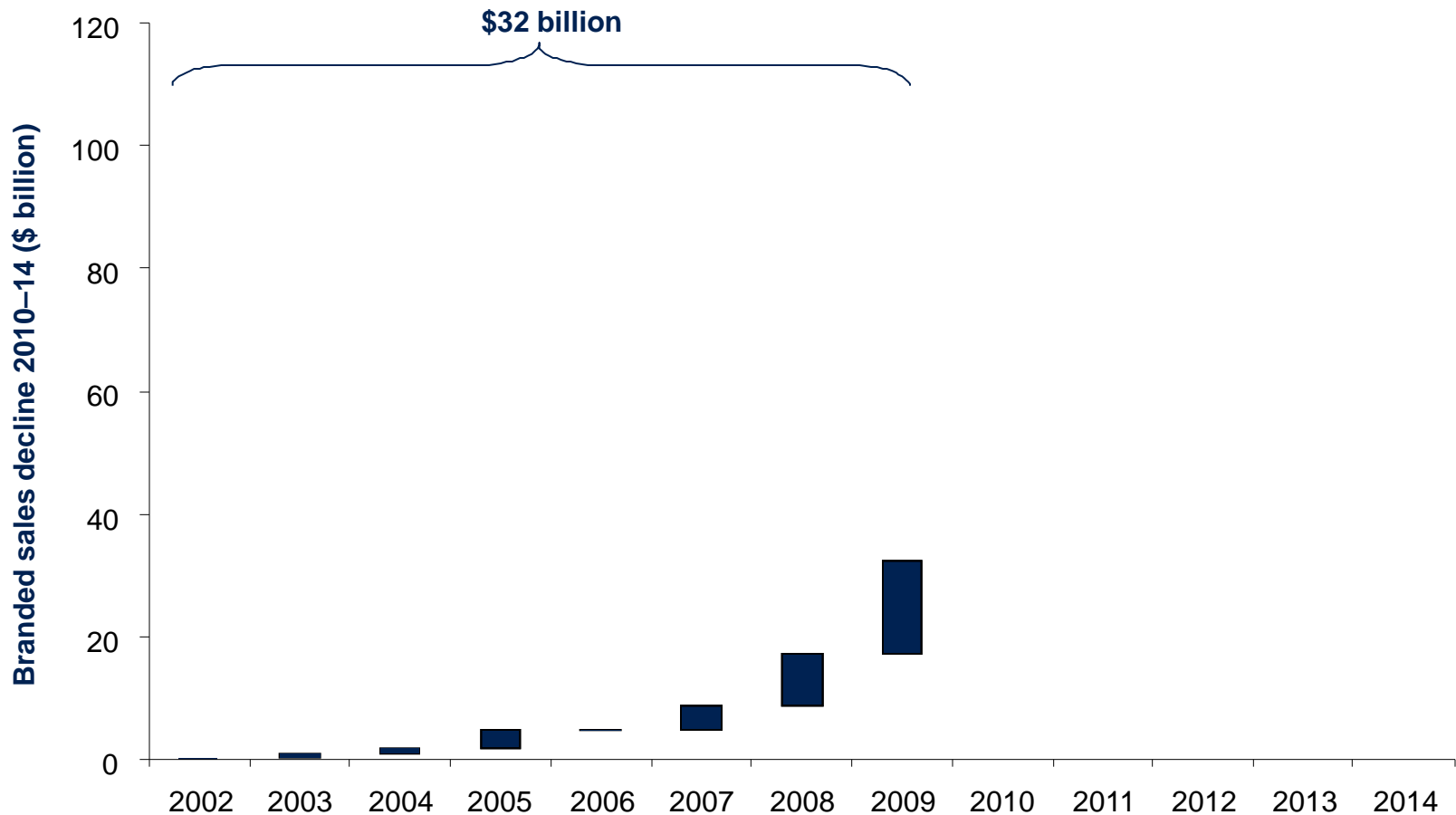


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## Patent Expiries

Pharma will lose \$78 billion in sales during 2009–2014 due to the patent cliff



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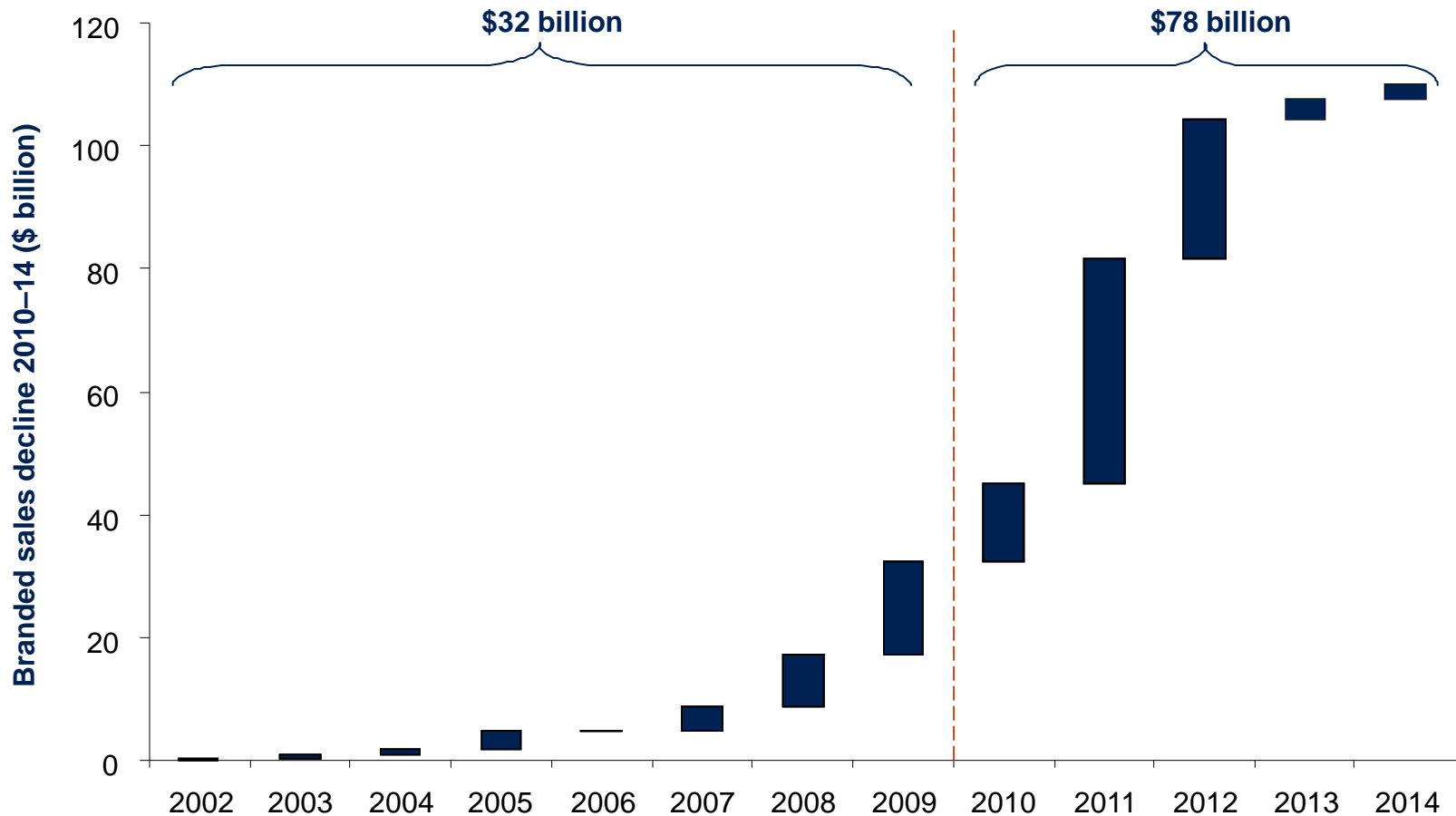


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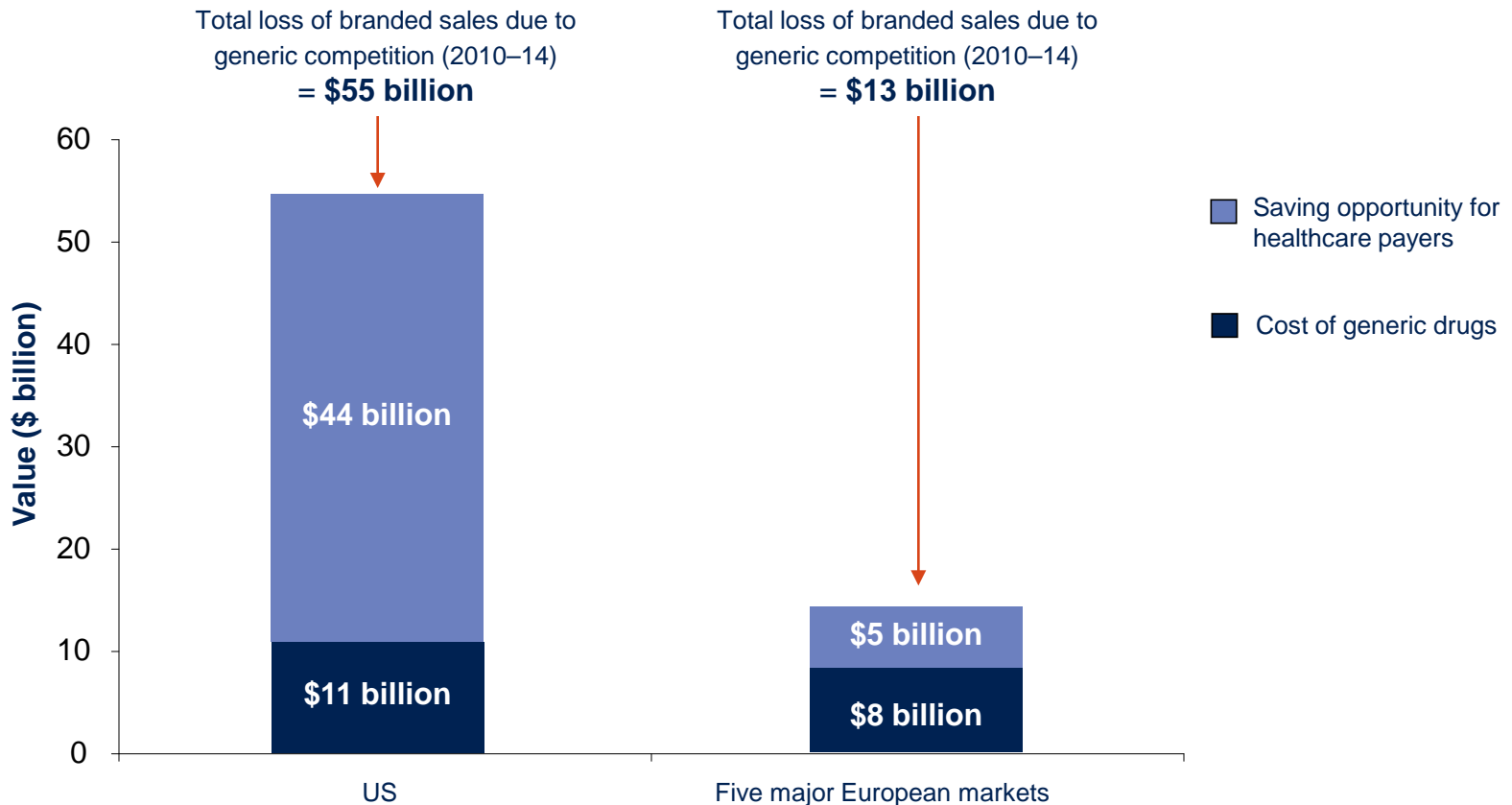


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## Patent Expiries

Generics players and healthcare payers set to benefit in the short term



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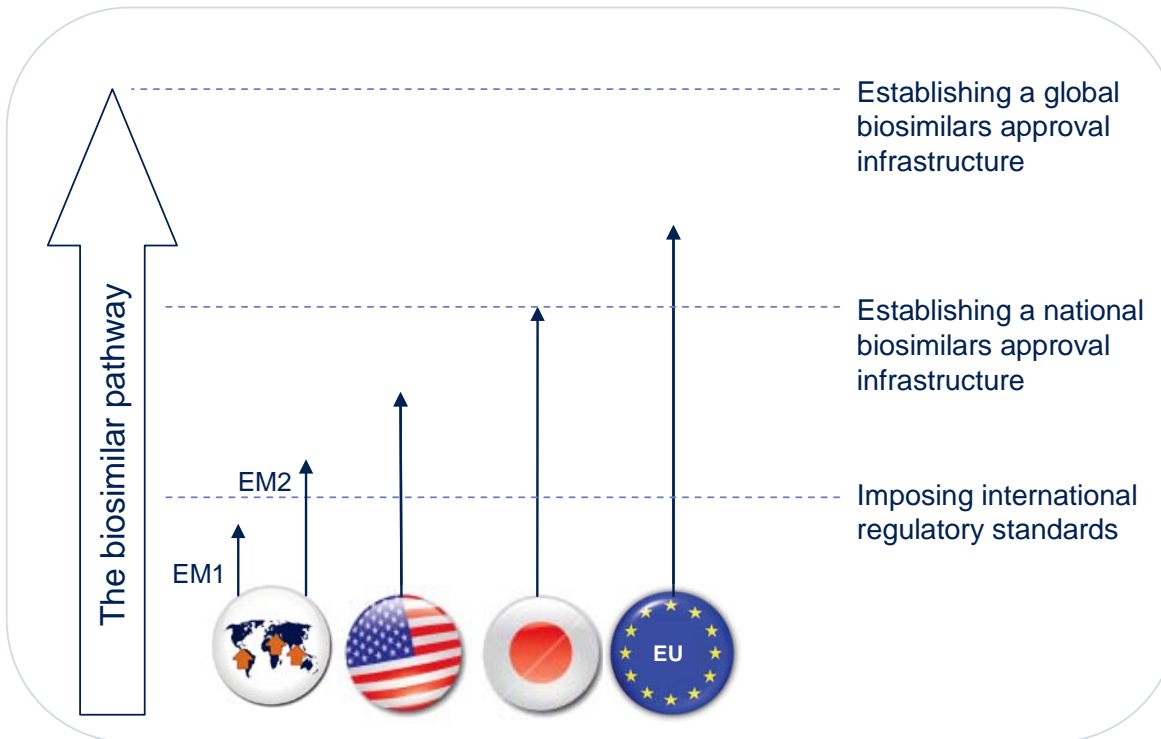


SUMMARY



## Patent Expiries

The growing threat of biosimilars...



EM = Emerging Markets; 1 = Asia; 2 = Latin America and the Middle East

- \$50b out of the ~\$80b global branded biologics business set to lose patent protection by 2015 or 2016
- The biosimilars market is estimated to reach \$76b through 2020 (Teva, 2010)
- Approval pathways exist in Europe and Japan, with biosimilars already launched in both regions; US lags behind

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## Price and Reimbursement Cuts

New regulations set to dampen market growth...



**Cost-containment focuses on price cuts and reimbursement restrictions**



**Downward price pressures**  
**Difficult to obtain desired formulary placement**  
**Greater competitive pressure**  
**Transition to volume- rather than value-driven markets**



### Flexible drug pricing to maximize overall returns

- Increased price elasticity
- Lower prices for emerging markets
- Increasing price negotiation in the western markets
- Focus on payer- and patient-centric sales model

### Drug portfolios to match unmet need

- Disruptive rather than incremental innovation
- Demonstrate value of a treatment pathway
- Offer disease management solutions

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## Growing Regulatory Pressures

Regulatory pressure on drug approvals, intellectual property and marketing practices

REMS

Safety

IP

Pharmaco-  
vigilance

DTC

Fines

Sunshine

CME

Pharma's response

- Earlier dialogue with the FDA
- Longer and better clinical trials
- Improve data and value proposition
- Tailor portfolio to individual market needs
- Reducing CME funding
- Disclosure – transparency
- Reduce and tone down DTC
- Payers as key decision makers

**REMS** = risk evaluation and mitigation strategies; **DTC** = direct-to-consumer; **CME** = continuing medical education



## Drivers for the Pharmaceutical Industry

- Emerging market expansion
- Biologics market expansion
- Cost saving initiatives

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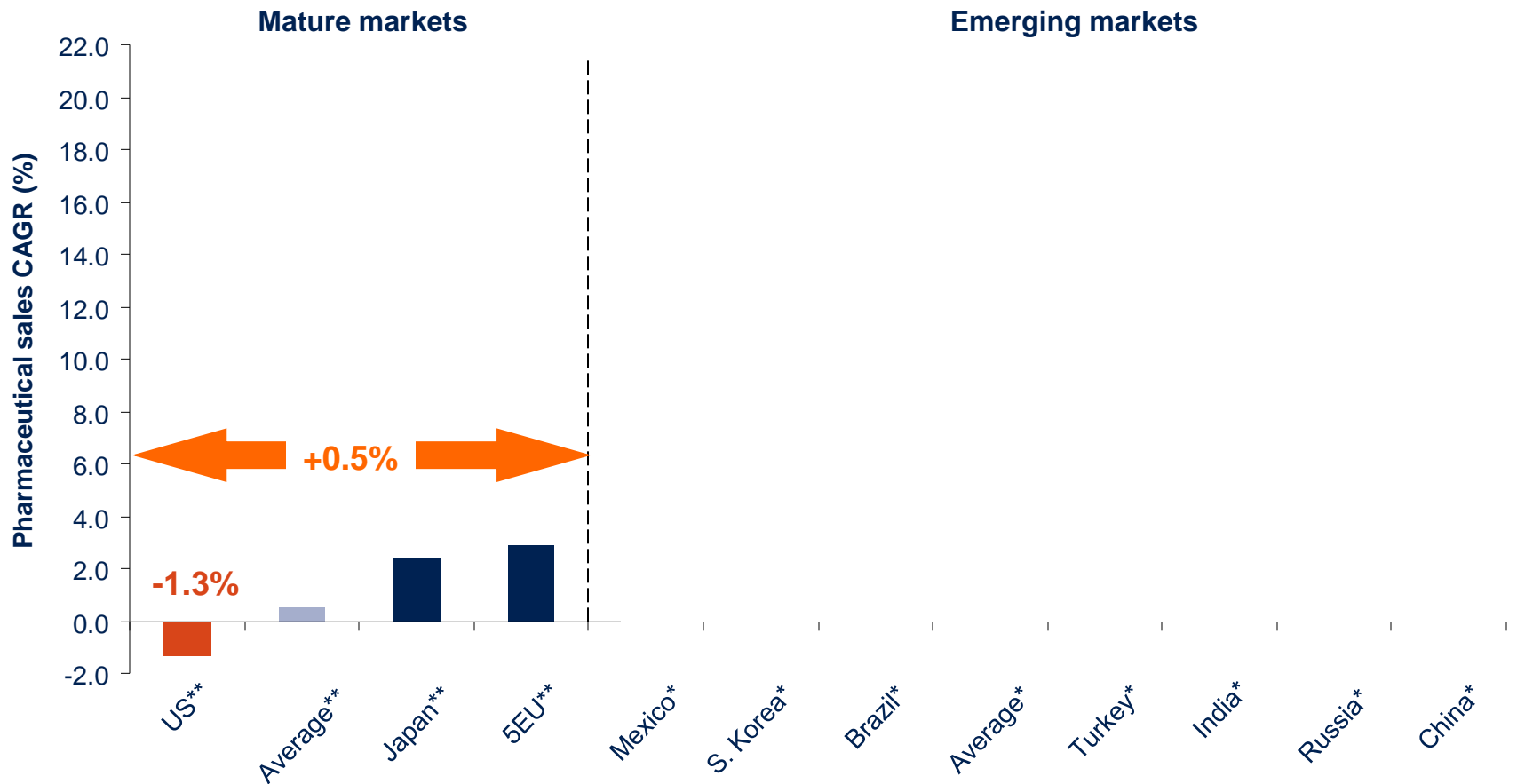


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## Emerging Market Expansion

Pharma could offset the patent cliff through expansion in the emerging markets



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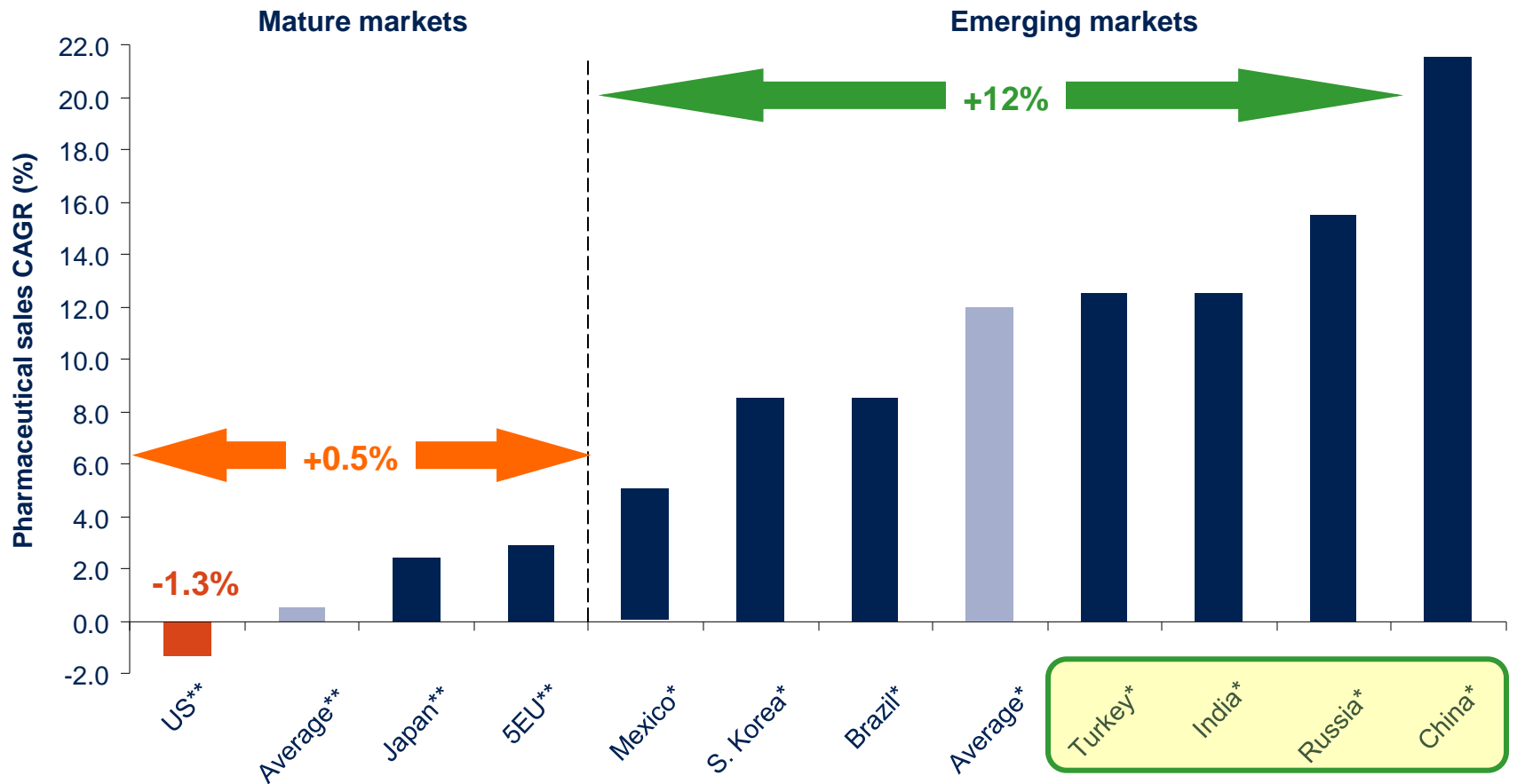


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## Emerging Market Expansion

Pharma could offset the patent cliff through expansion in the emerging markets





## Emerging Market Expansion:

Access to the emerging markets is driven by acquisition of domestic generics and manufacturing

### Key factors driving growth in the emerging markets

- Rapidly growing economies and populations
- Expansion of healthcare systems and health insurance policies, increasing access to drugs
- Emergence of middle classes with disposable incomes
- Gradual shift from communicable diseases to more chronic "Western" diseases

### Market access through acquisition of domestic (generics) players

#### The benefits of acquiring domestic companies

- Quick market access
- High generic penetration
- Fast growth of domestic generics players
- Low manufacturing and distribution costs

#### Challenges for foreign companies in the emerging markets

- Intellectual property (IP) issues
- Pressures to cut healthcare costs

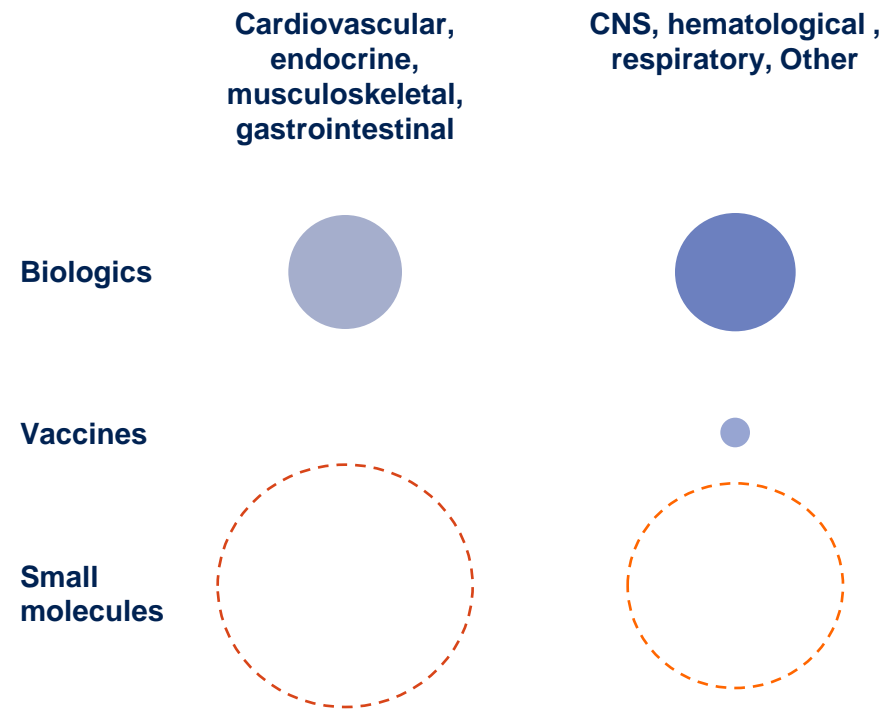
### Pharmaceutical products marketed by international pharma players in the emerging markets

- Branded off-patent drugs
- Branded generics (bearing the acquiring company's name/logo)
- Local brands owned or licensed by the acquiring pharma company



## Biologics Market Expansion

Secondary care markets set to drive sales growth in face of waning primary care model



Bubble size illustrates forecast 2009–2014 sales growth as a percentage of 2009 annual sales. Dotted line denotes negative sales growth.

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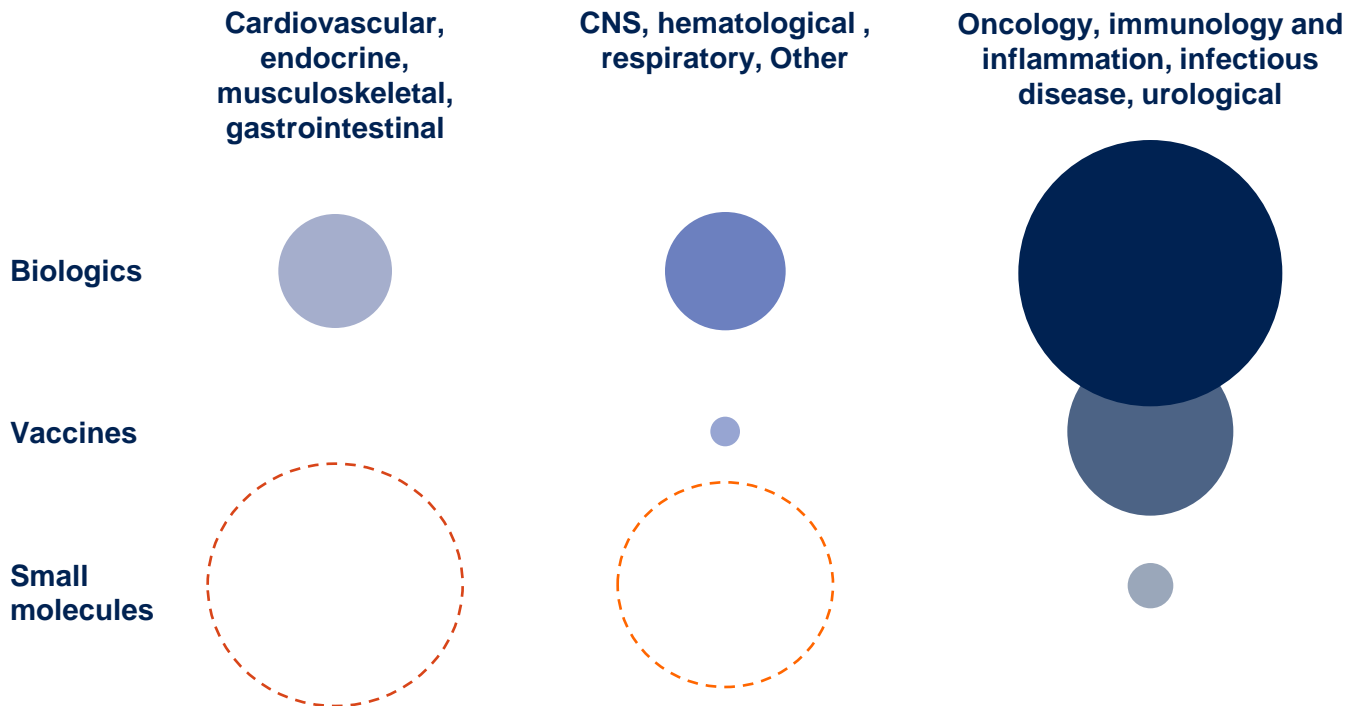


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## Biologics Market Expansion Factors driving the shift away from the primary care blockbuster... towards high value therapies

### Shift away from primary care blockbuster model...

- R&D costing \$1 billion per launched drug
- Competition from me-too drugs
- Blockbusters genericization...
- ...primary care sales forces cuts
- Risk of side effects and pharmacovigilance issues

### ...towards targeting more niche patient populations

- Little or no competition
- Small patient size but still commercially attractive
- Faster and often cheaper R&D including regulatory incentives for Orphan drugs
- No large scale patient/physician marketing ⇒ cost savings + smaller sales forces
- But... competition for reimbursement is set to intensify

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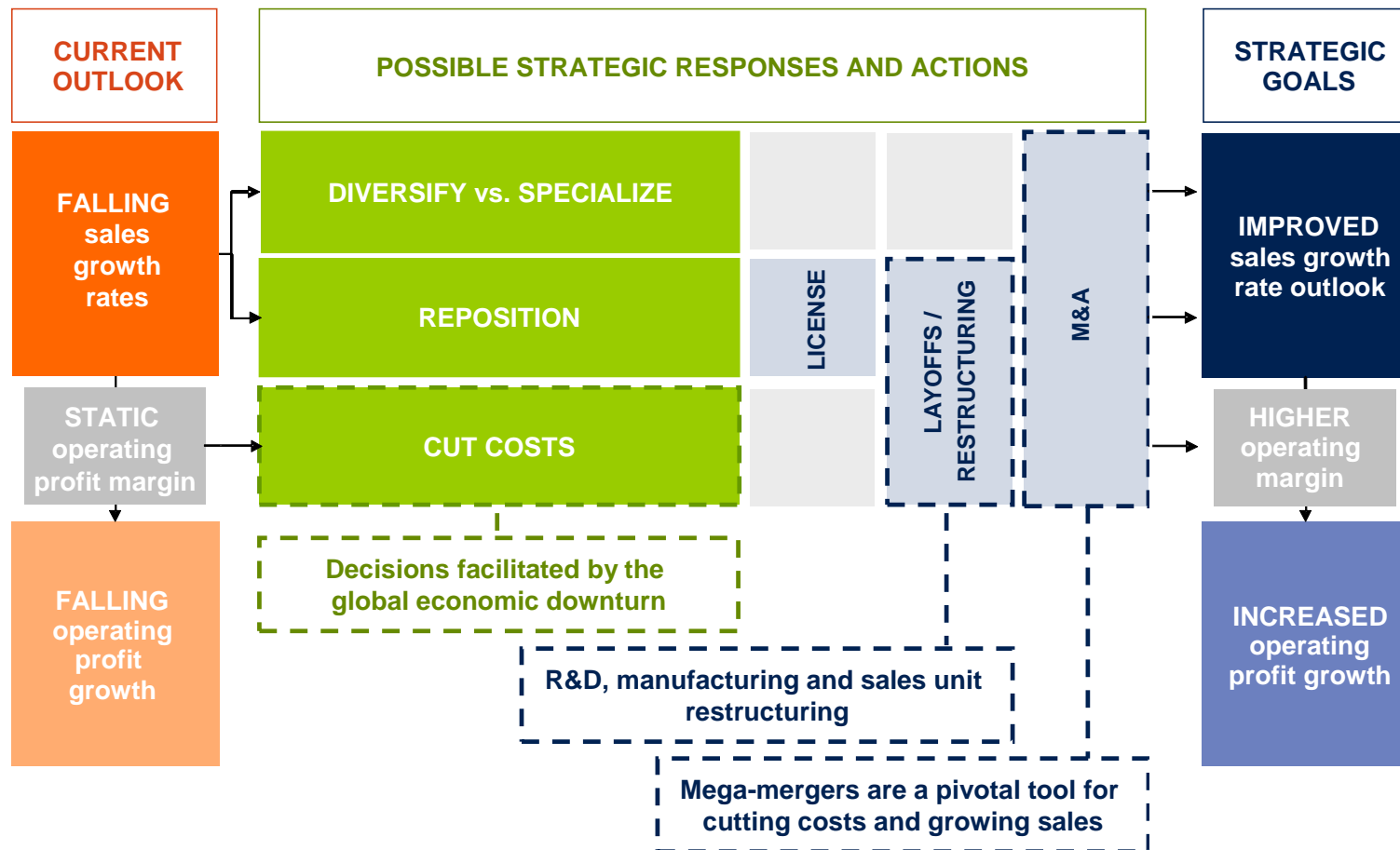


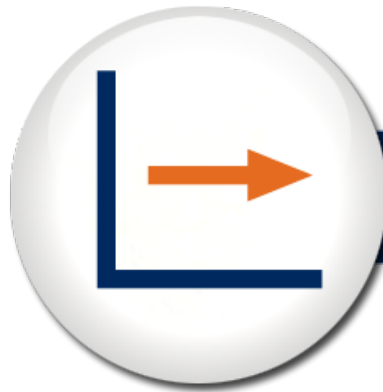
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## Cost Saving Initiatives

Key cost saving trends initiated by Big Pharma





**Neutral** for the Pharmaceutical industry

- Impact of US Healthcare reform

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## US Healthcare Reform

Landmark event bringing mixed news for healthcare industry if it happens

### Individuals/Society

- Increased access to healthcare
- Expenditure growth unlikely to be contained

### Key reform measures:

- Individual mandate
- Premium subsidies
- Insurance regulations – ban on pre-existing condition exclusion
- Part D donut hole discounts/closure
- Medicaid rebates
- Biosimilars approval pathway; 12-yr exclusivity
- Ban on pay-for-delay pharma-generics settlements
- Sunshine provisions: pharma disclosures on financials

### Private Insurers

- Increased customer volume
- Harsher competitive environment & lower profitability
- Drive towards cost cutting & consolidation

### Generics Cos.

- Volume growth
- Reduced incentive for Gx use in Part D
- Later entry of biosimilars

### Branded Pharma

- Volume growth
- Greater cost-containment pressures & drug discounts
- Limitations on marketing practices



**Summary: Positioning for success**

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The events and trends of today, indicate the winners and losers of tomorrow

### So far we have seen

- Greater cost constraints and decreasing margins
- Growing regulatory pressures
- Emerging markets expansion
- Shift from primary care model to secondary indications
- Cost savings via M&A and diversification

### Still to come:

- Impact of US Healthcare reform
- Pathway for biosimilars in the US
- Impending patent cliff
- Full impact of biosimilars

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**2014** Strategies employed by Merck and Roche will make them the big winners of tomorrow

Company	Patent Cliff impact	Biologics sales growth	Emerging markets sales growth	Cost-Savings	Short-term impact of US HC reform	Operating profit growth (2009-14, %)
Merck & Co.	↓	↑↑	↑↑↑	↑↑↑	↓↓	253
Roche	↓	↑↑↑		↑↑	↓↓	51
GlaxoSmithKline	↓↓↓	↑	↑↑	↑↑	↓↓	43
Pfizer	↓	↑↑↑	↑↑↑	↑↑↑	↓↓	42
Johnson & Johnson	↓↓	↑		↑	↓↓↓	31
Abbott	↓	↑		↑	↓↓↓	28
Novartis	↓↓	↑↑	↑↑	↑	↓↓	23
AstraZeneca	↓↓↓	↓	↑	↑	↓↓	5
Sanofi-Aventis	↓↓	↑↑	↑	↓	↓↓	(20)
Eli Lilly	↓↓	↑		↓	↓↓	(24)



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Explore 1,500+ drugs by company, therapy area, ATC code, molecule type and lifecycle stage.



### Pipeline Analysis

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### Company Analysis

Assess the sales, pipeline and financial performance of a single company.



### M&A Analysis

Perform a virtual merger of two companies.



### Financial Analysis

Compare multiple companies by financial metrics such as R&D spend, profit and ROI.

