

Truths & Untruths in the Global Pharma Industry

Smart Pharma Consulting analyses

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1. Introduction

Smart Pharma Consulting has reviewed and analyzed four key statements related to the global pharma business

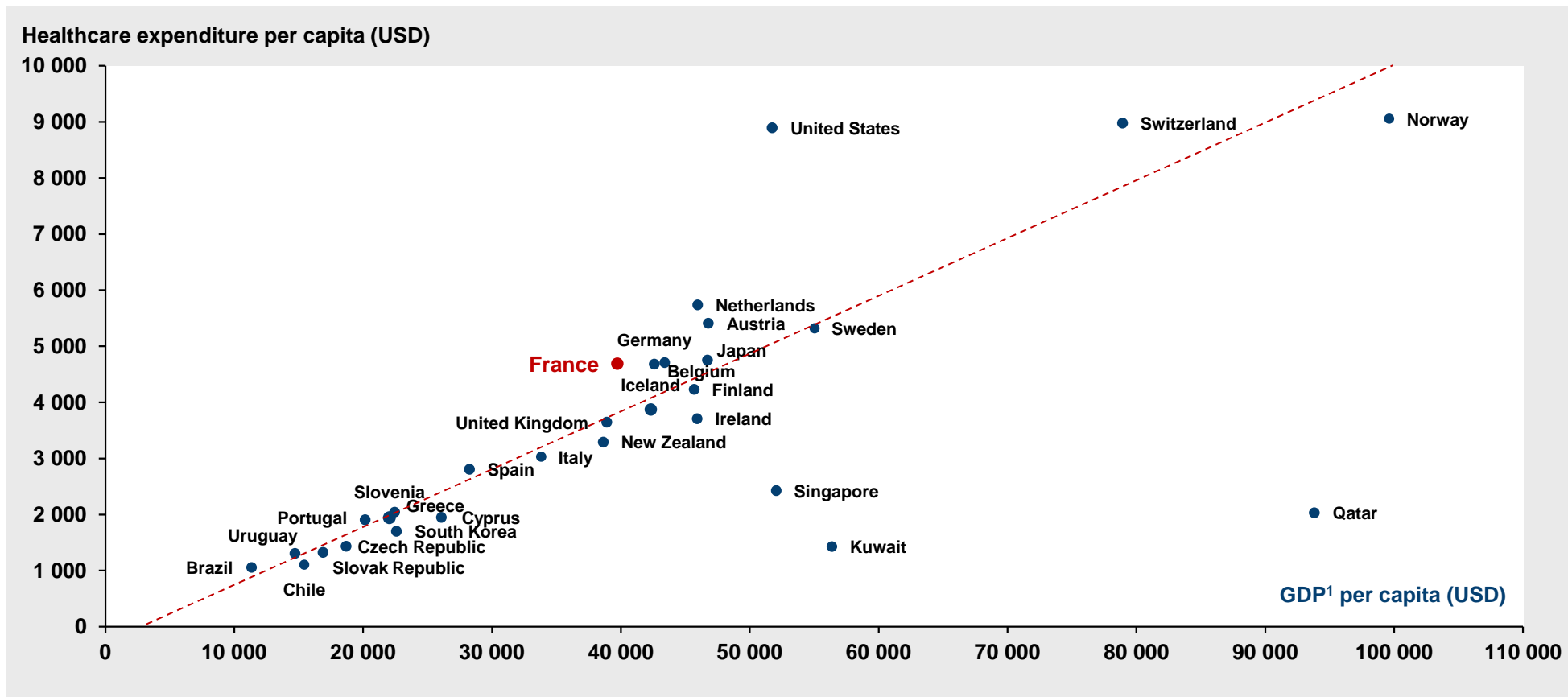
Four key statements: Truths & Untruths

- 1st Statement: The price pressure on pharma companies is temporary
- 2nd Statement: Pharma companies profitability keeps on shrinking
- 3rd Statement: The cost of new molecules is in the range of USD 1B
- 4th Statement: BRIC countries are the Eldorado of pharma companies

1st Statement: The price pressure on pharma companies is temporary

Healthcare expenditure per capita is highly related to growth domestic product per capita of each country

Relation between GDP¹ and healthcare expenditure per capita (2012)



Source: World Bank and WHO (2012)

- - - Linear trend line

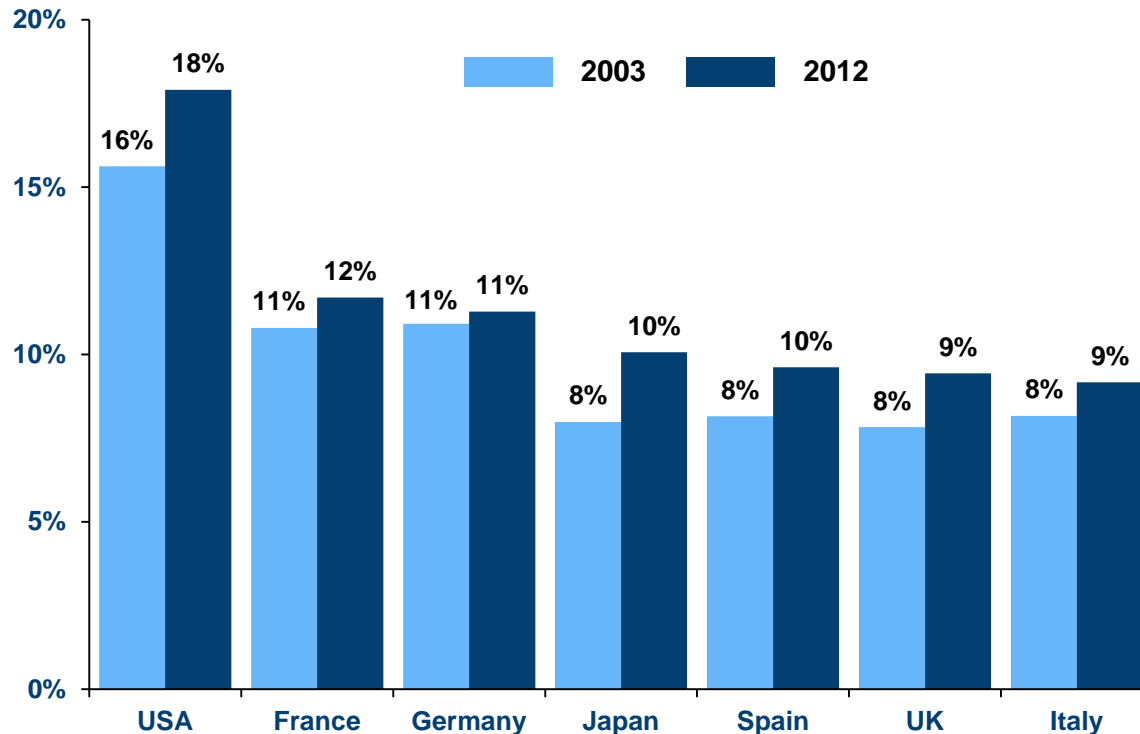
¹ Gross Domestic Product

1st Statement: The price pressure on pharma companies is temporary

The weight of healthcare expenditure in developed economies has risen between 2003 and 2012, despite the implementation of cost containment measures

Healthcare expenditure as a percentage of GDP¹

Healthcare expenditure as a % of GDP¹
(Local currency)



- In 2012, healthcare expenditure represented one of the largest public spending items in most developed economies: 1st (USA), 2nd (France, Germany, Japan, UK)² and 3rd (Italy³ and Spain⁴)
- At best, health authorities will manage to slow down the rise of healthcare expenditure as a percentage of GDP, but not to stop it
- In principle, there is no ideal or optimal ratio of healthcare expenditure over GDP
- The weight of healthcare expenditure is primarily a political decision based on public health considerations and national investment prioritization

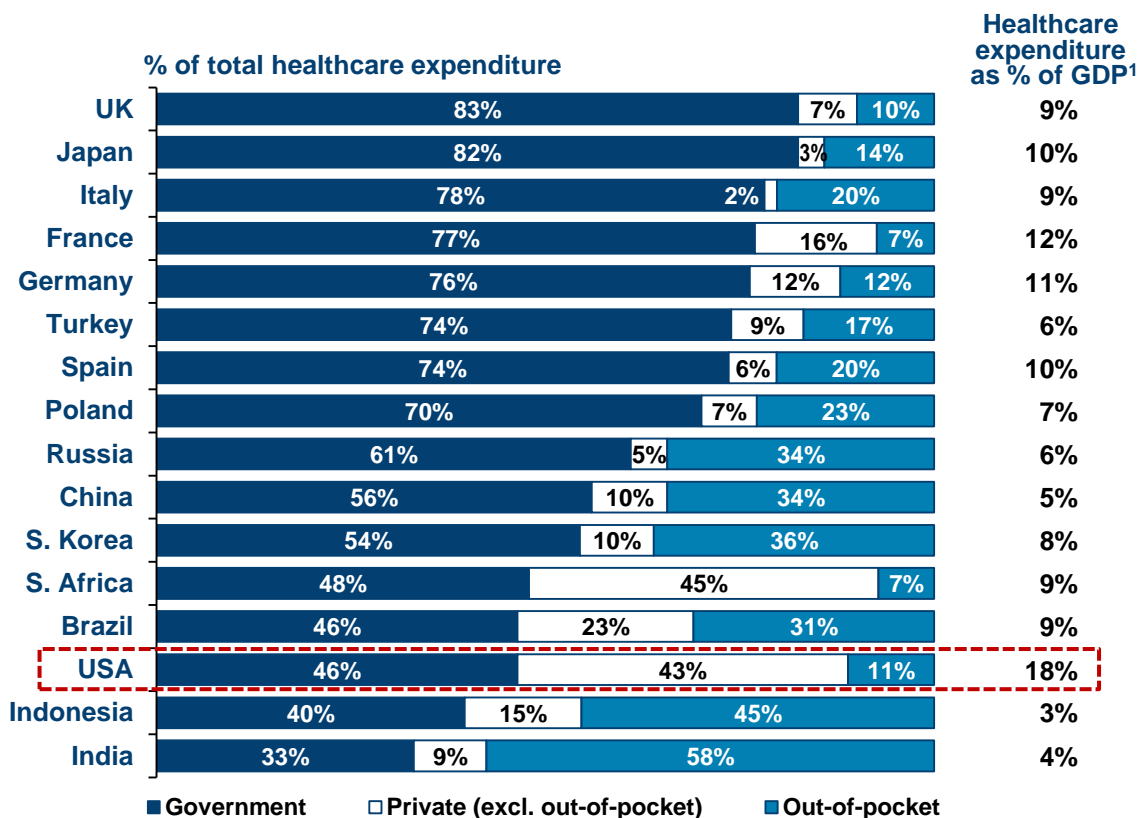
Source: World Bank's Open Data (2012) – OECD Government expenditure by function (2012) – Smart Pharma Consulting analyses

¹ Gross Domestic Product – ² After social protection – ³ After social protection and general public services – ⁴ After social protection and economic affairs

1st Statement: The price pressure on pharma companies is temporary

With the exception of the USA, governments play a more important role in covering healthcare expenditure in developed markets than in less developed ones

Share of public spending in total healthcare expenditure (2012)



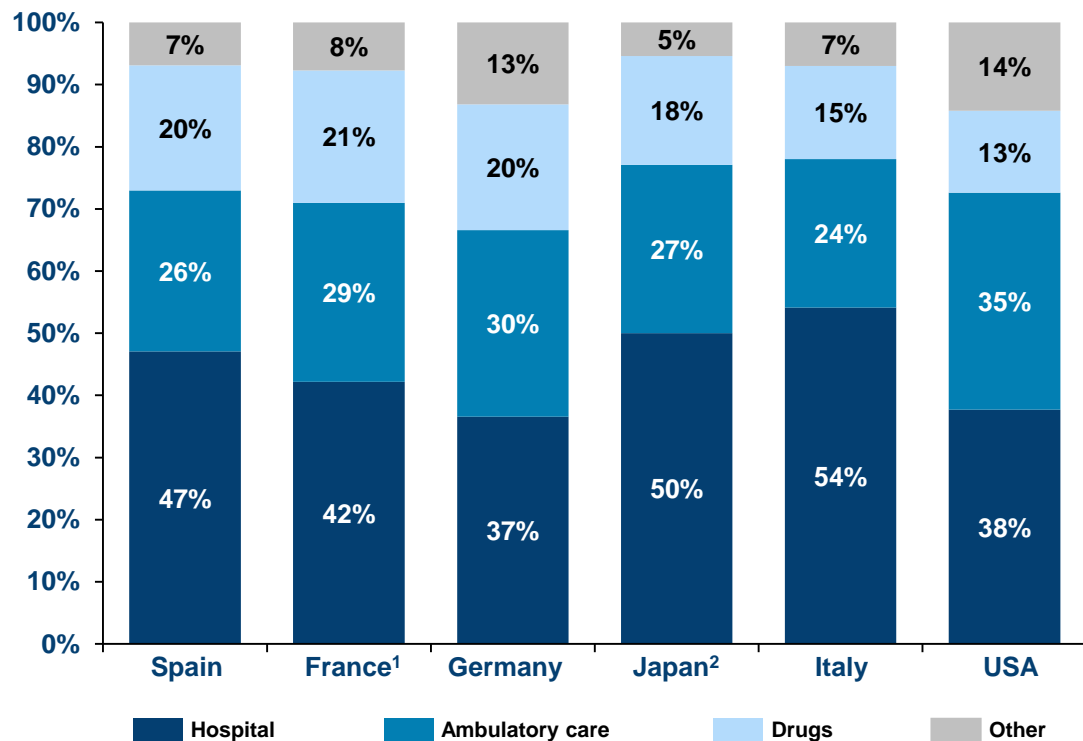
- In the USA, the level of public spending on healthcare is far below the one of other developed countries
- Nonetheless, the weight of healthcare expenditure in the GDP is also significantly higher, stimulated by favorable policies to the private sector
- The recent healthcare reform in the USA is expected to narrow the spending gap between the USA and other developed countries in the coming years
- In emerging countries, the public and private healthcare insurance systems are less advanced, resulting in a higher share of out-of-pocket spending and a lower weight of healthcare expenditure in the GDP

1st Statement: The price pressure on pharma companies is temporary

The cost of drugs is far behind that of hospital and ambulatory care, yet this segment is paradoxically targeted by governments because it is easier and quicker to reduce

Breakdown of healthcare expenditure (2011)

% of total healthcare expenditure



- Drugs represent the 3rd largest source of healthcare expenditure in major developed countries
- Drugs are typically the easiest segment to apply cost-containment measures on, as decisions are:
 - Made by payers (either public and/or private), with little or no negotiation with suppliers
 - Much better accepted by citizens than restriction measures on the other segments
- However, to significantly reduce total healthcare costs, governments will need to apply cost-optimization measures on all healthcare segments, irrespective of their relative importance

1st Statement: The price pressure on pharma companies is temporary

If drug price pressure will continue over the long-term, pharma companies will not be impacted the same way, due to differences of portfolio and socio-political strategy

True or Untrue?

- Irrespective of the considered country, the price pressure on drugs, from either public or private insurance companies, will keep on growing, over the long term
- Three main reasons support this assumption:
 - The cost of healthcare increases faster than the economy
 - Pharma companies do still make high profits (net profits ~15%)
 - Drug cost is not the biggest bucket, but the easiest on which price cuts can be applied (i.e. application is easy and effects immediate, no direct social nor political negative impacts)
- Pharma companies could negotiate, collectively (through their union) or individually a “Drug Price Stability Pact” that will guarantee a certain level on price depending on:
 - The medico-economic value of their products, at a national, regional and local levels
 - Their commitment to invest in research programs and facilities
 - Their logistic and manufacturing facilities
 - Their level of employment and its evolution overtime
 - Their contribution to exports

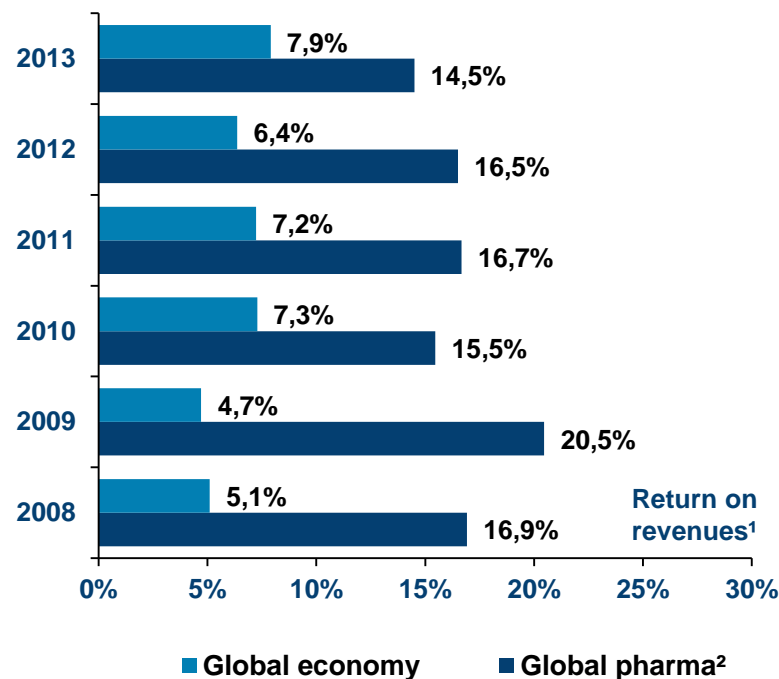
2nd Statement: Pharma companies profitability keep on shrinking

The pharma sector continues to be very attractive as it offers higher profitability and growth rates than the global economy, however its performance is deteriorating

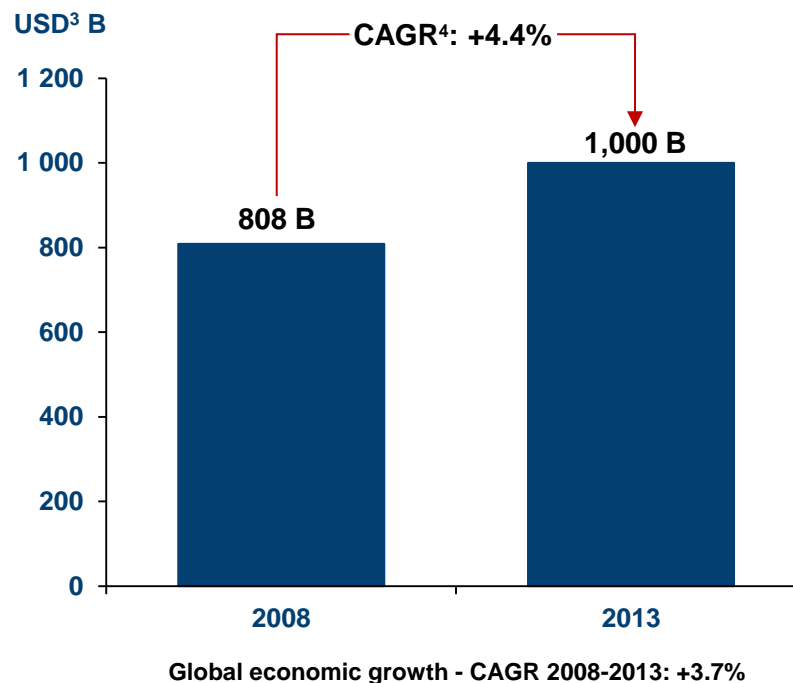
Global pharmaceutical market attractiveness (2008-2013)

Profitability trend

(Based on companies included in the Forbes Global 2000)



Market sales trend



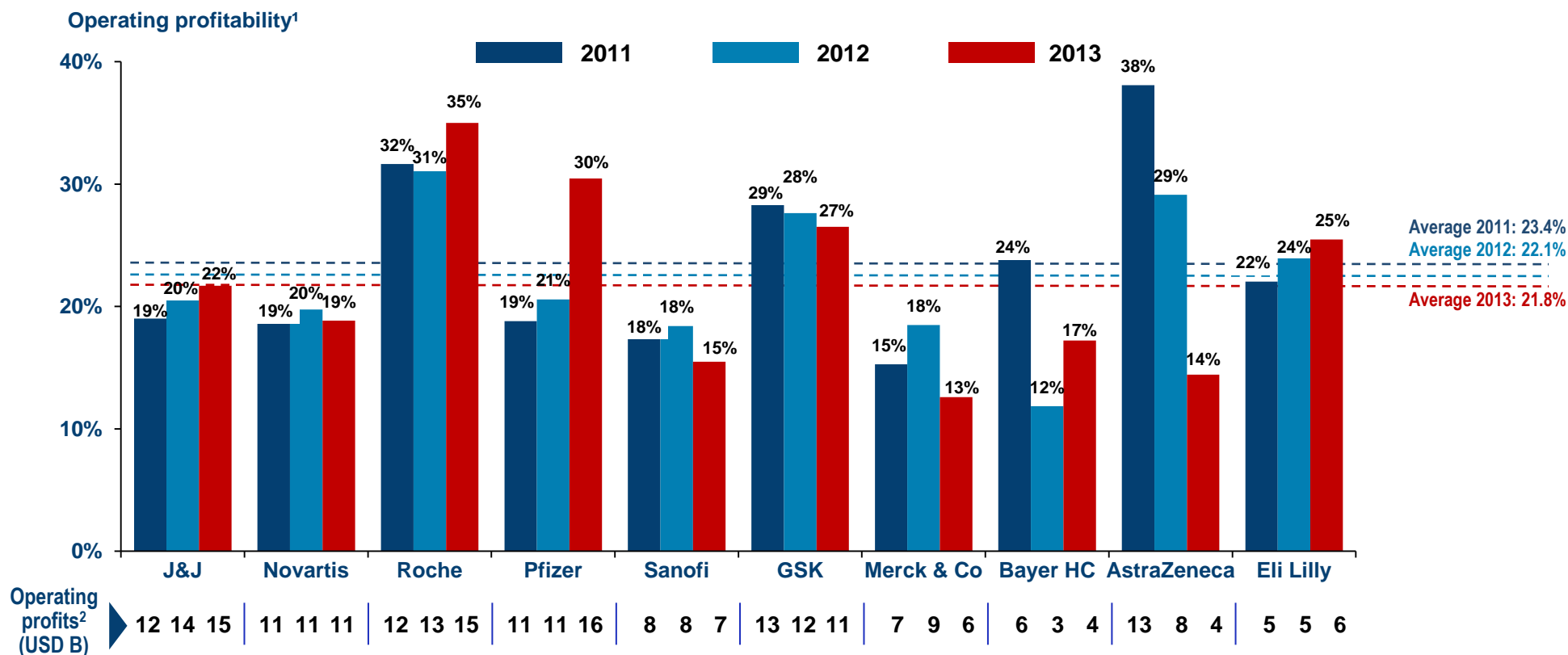
Source: IMS World Review Executive 2013 – Forbes: The Global 2000 (2014)
 – United Nations: World Economic Situation and Prospects 2011-2012-2013
 – IMF 2014 – Smart Pharma Consulting analyses

¹ Return on revenues = net profit / total revenues – ² Including biotech companies, J&J, Fresenius and Baxter, which are included in the medical equipment and other supplies industry and excluding companies whose business is mainly focused on distribution – ³ Constant USD (2012) – ⁴ Compound annual growth rate

2nd Statement: Pharma companies profitability keep on shrinking

The operating profitability of the top 10 pharma companies has decreased in 2013 compared to 2012, mostly driven by AstraZeneca's & Merck & Co profitability drop

Operating profitability of leading pharmaceutical companies (2011-2012-2013)



Note: Reported numbers have been adjusted to make them comparable – In 2013, Eli Lilly came back on the top 10 at the expense of Abbott/AbbVie

Source: Annual reports -2011-2012-2013 – Smart Pharma Consulting analyses

¹ Including profits from non-healthcare related businesses
² Average 2011 - 2013 Federal Reserve exchange rate –

2nd Statement: Pharma companies profitability keep on shrinking

If the pharma industry profitability has declined, it is still very profitable and should remain as such, provided they improve their operational and organizational efficiency

True or Untrue?

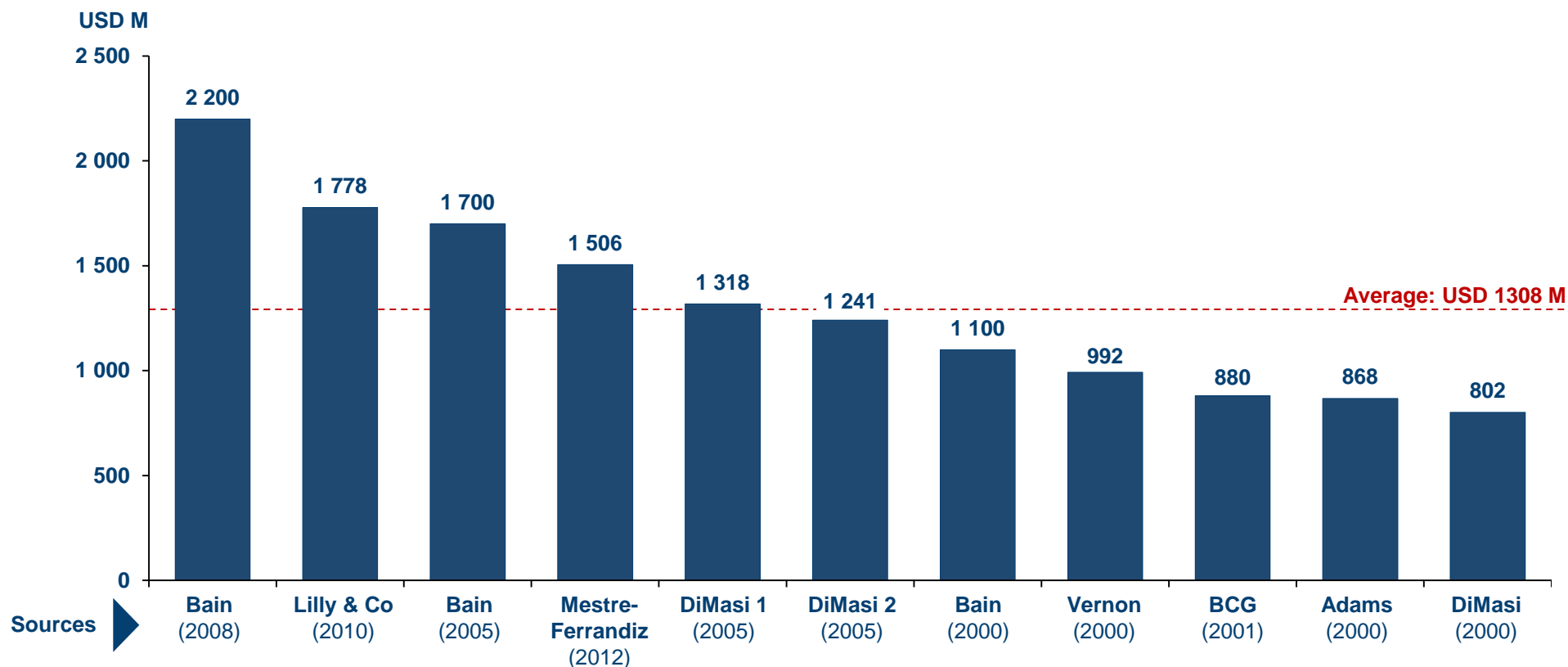
- We have observed over the past years, a deterioration of the profitability of the pharma industry and a slow down of its sales growth
- However, the analysis of the top selling pharma companies, shows that, with the exception of AstraZeneca, they manage to maintain they profitability level, over the past three years
- To achieve such a performance, the leading pharma companies have:
 - Refocused most of their research programs to address secondary care diseases with major unmet needs
 - Closed a large number of their production centers, and reallocated many of the remaining ones in countries benefiting from lower-cost manpower
 - Significantly downsized they sales forces
 - Divested or sold their low (lower) profit strategic segments
- In the years to come, pharma companies should not only keep on improving the efficiency of their operations (R&D, manufacturing, marketing & sales, etc.)...
- ... but also simplifying their internal processes and their structure to become leaner and more agile

3rd Statement: The cost of new molecules is in the range of USD 1B

According to the most recent study published, the R&D cost per approved new drug, including the cost of capital, is estimated at USD 1.5 B

Evolution of R&D costs (2000 – 2012)

Estimated capitalized cost per approved new drug (pre-tax)



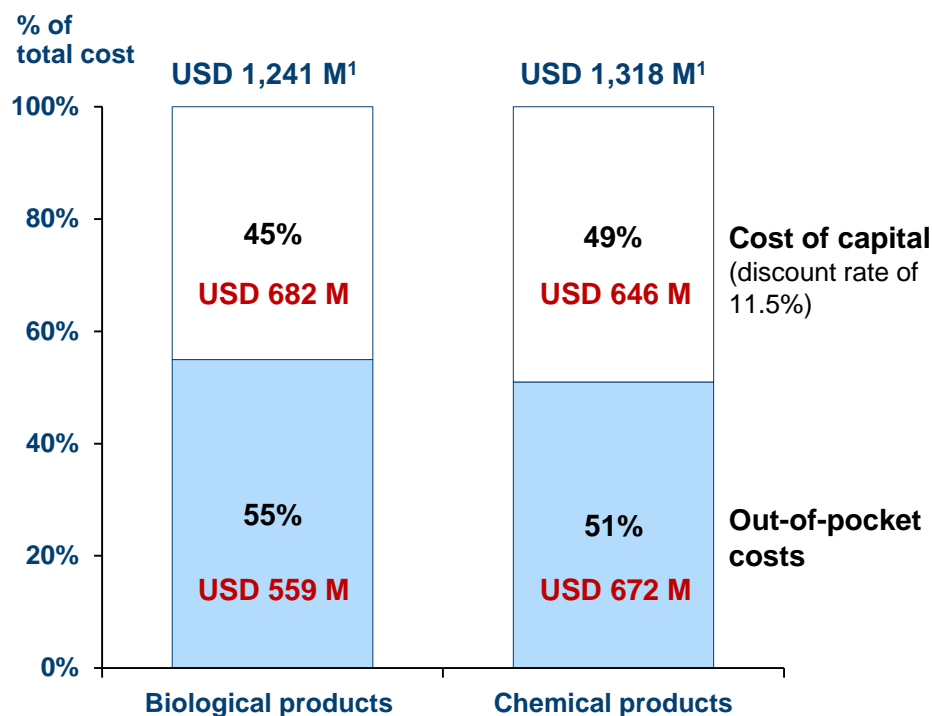
Source: Adams CP et al, 2006. health Affairs – O'Hagab P and Farkas C, 2009. Bain & Co, Mestre-Ferrandiz J. 2012 – Efpia key data 2013 – M. Steven 2010 – Smart Pharma Consulting analyses

3rd Statement: The cost of new molecules is in the range of USD 1B

No significant differences have been observed between the R&D costs of biological and chemical products (small molecule chemical entities)

R&D costs for biological & chemical products

Estimated capitalized cost per approved new drug (pre-tax)



Biological products

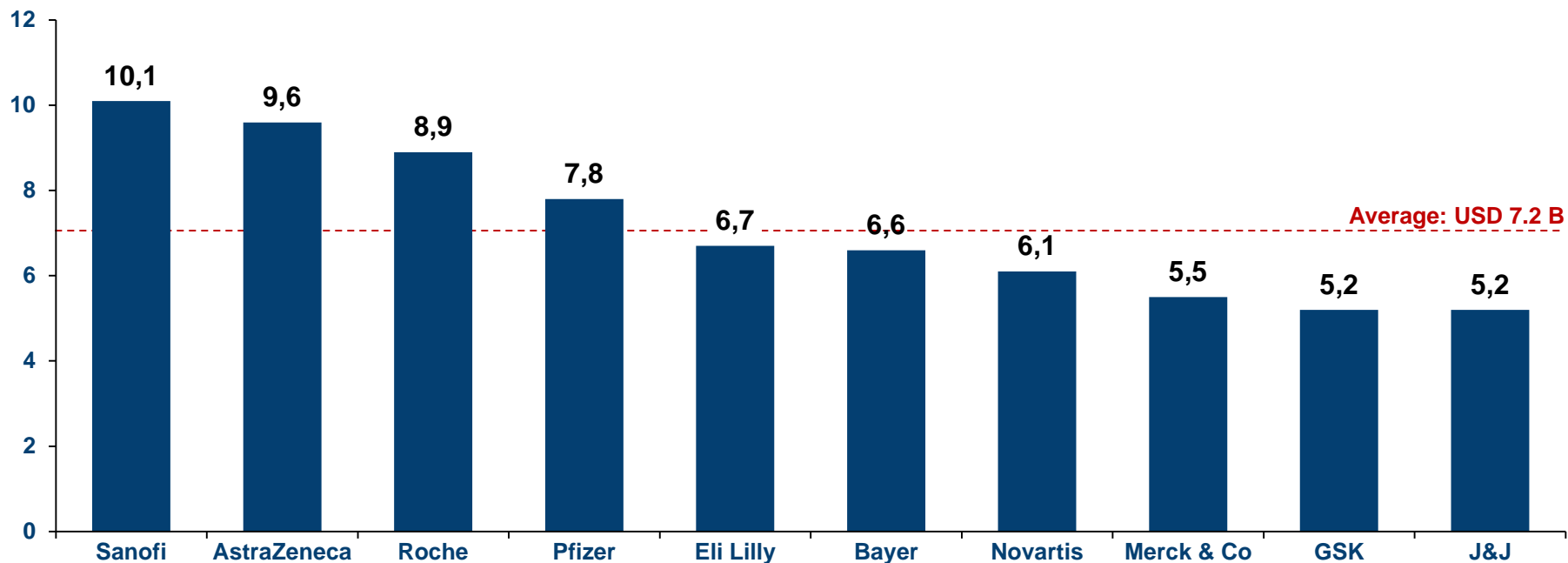
- Costs of 17 investigational biological products (9 recombinant proteins and 8 monoclonal antibodies) from 4 pharmaceutical companies were analyzed based on 2005 data
- Costs of compound failures were included
- Out-of-pocket costs were capitalized at a real discount rate of 11.5% until the date of marketing approval (~12.5 years)
- Development time costs of failed projects were allocated to those of marketed new products
- Out-of-pocket and capitalized preclinical costs were estimated at USD 198 M and USD 615 M, respectively
- Out-of-pocket and capitalized clinical costs were estimated at USD 361 M and USD 626 M, respectively

3rd Statement: The cost of new molecules is in the range of USD 1B

The overall cost per new drug differs significantly amongst top 10 pharma companies, with Sanofi spending twice as much as J&J or GSK per launched product

Estimated R&D costs of new drugs – Top 10 pharma companies

Average cost per new drug in US B



	Sanofi	AstraZeneca	Roche	Pfizer	Eli Lilly	Bayer	Novartis	Merck & Co	GSK	J&J
# of new drugs ¹	6	4	8	10	4	5	10	9	11	13
10-year spending USD B ²	61	38	71	78	26	33	61	49	56	68

Source: Forbes August 2013 after Innothink Center for Research in Biomedical Innovation

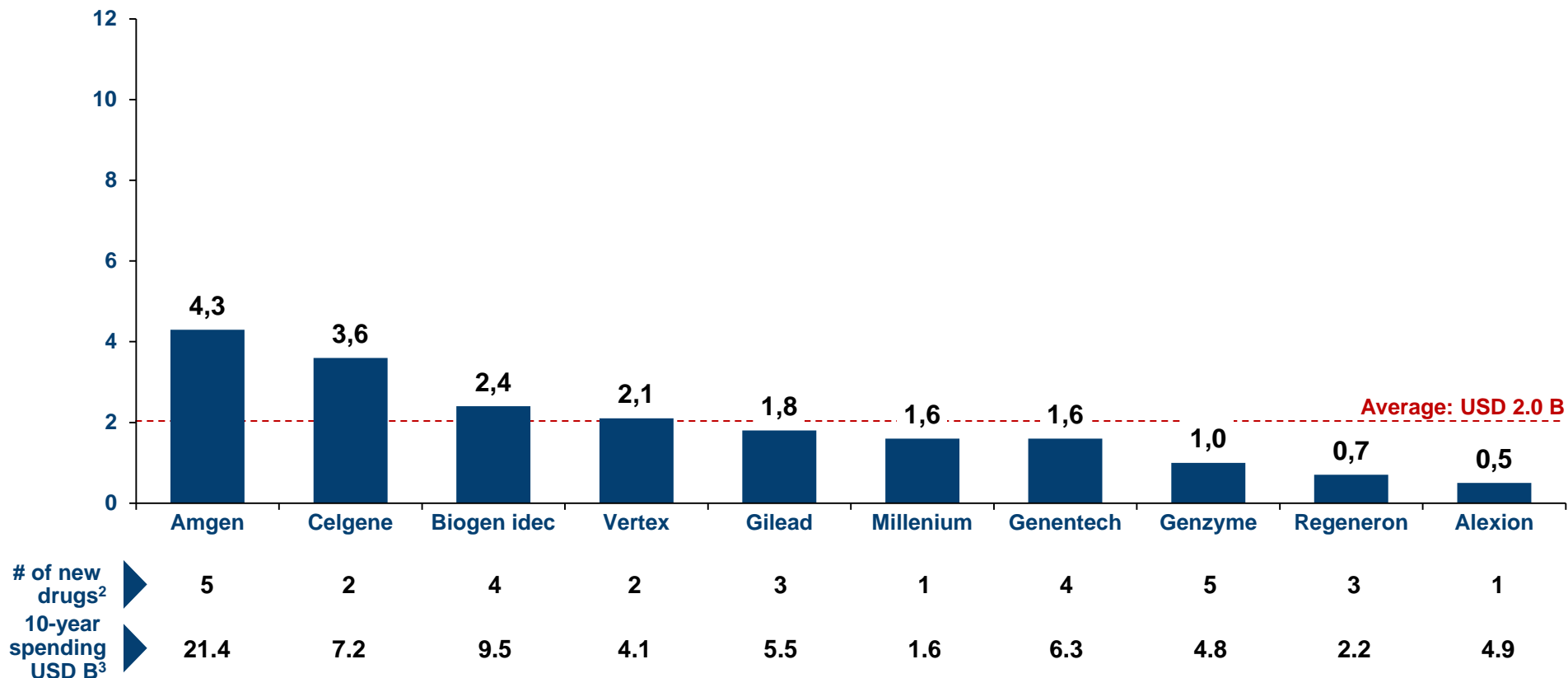
¹ Cumulated resulting from 2003 to 2012 – ² Period preceding new drugs approval

3rd Statement: The cost of new molecules is in the range of USD 1B

Biotech companies which spend much less than big pharma companies in R&D and focus on a limited number of projects show a cost per new drug 3.6 times lower¹

Estimated R&D costs of new drugs – Selection of 10 biotech companies

Average cost per new drug in US B



Source: Forbes August 2013 after Innothink Center for Research in Biomedical Innovation

¹ Average spending of top 10 big pharm companies = USD 7.2 B / USD 2.0 B for biotech companies = 3.6 times ² Cumulated resulting from 2003 to 2012 – ³ Period preceding new drugs approval

3rd Statement: The cost of new molecules is in the range of USD 1B

The median cost of a new drug is in the range of USD ~0.5 B, if one considers out-of-pocket costs only and one deducts tax savings

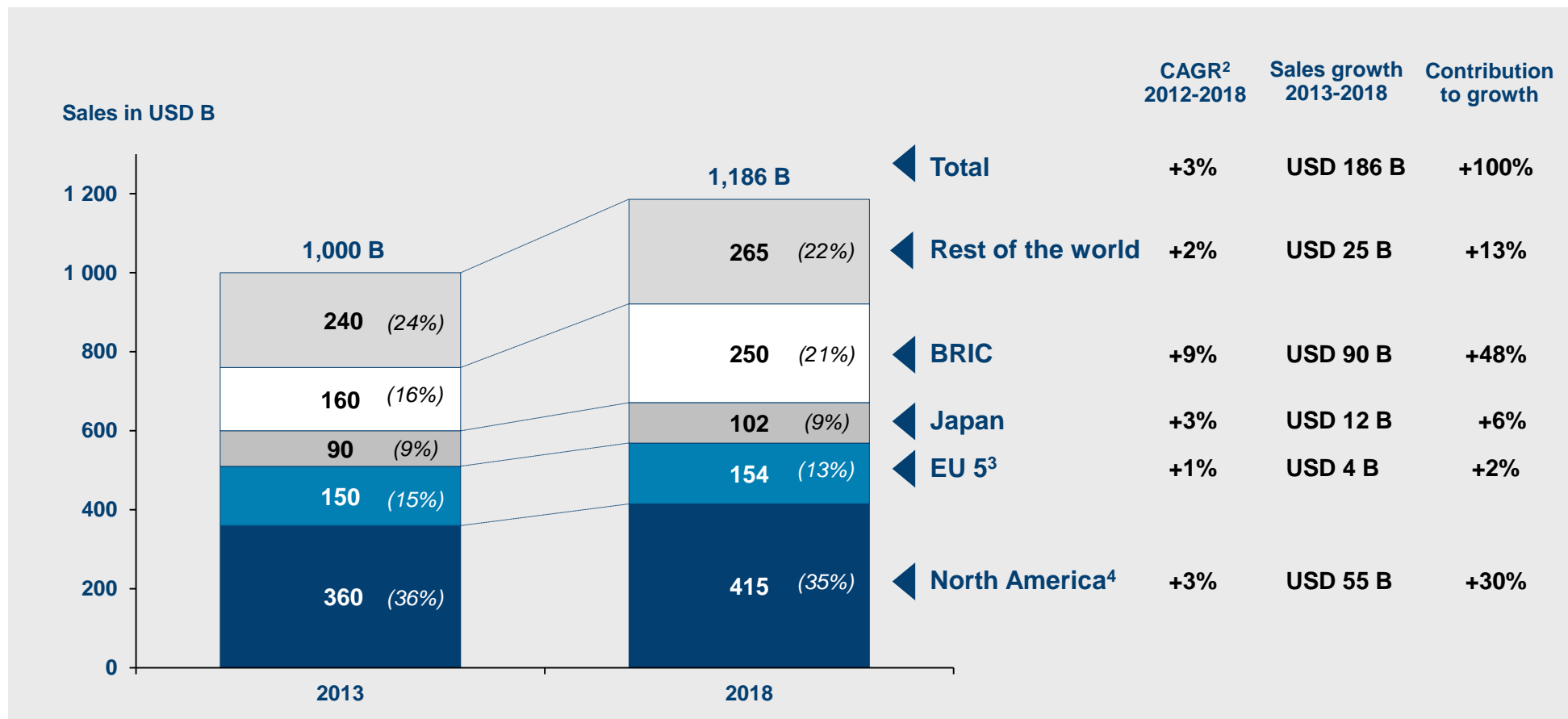
True or Untrue?

- The review of the main studies published since 2000, shows that the average cost of new drugs is estimated at USD ~1.3 B
- The average cost of a new drug is USD ~7.2 B for top 10 pharma companies and USD ~ 2.0 B for biotech companies that are focused on a more limited number of research projects
- The huge variations observed from one source to another one are due to differences in methodologies and cost assumptions used
- These figures should be analyzed with caution because:
 - They include the cost of drugs having failed during their development
 - They take into account the cost of capital invested (~50% of the total estimated cost)
 - They do not deduct corporate tax savings (estimated at ~35% of total R&D costs)
 - They use means while median would be more appropriate because of the huge difference of R&D costs observed according to pharma companies and the type of products being developed
- The median cost of one single successful new drug, without considering the associated opportunity costs and with deduction of tax savings should amount USD ~ 0.5 B

4th Statement: BRIC countries are the Eldorado of pharma companies

Almost 50% of the total pharma sales growth is expected to come from the BRIC¹ during the 2013 – 2018 period, while North America should contribute to 30% of that growth

Pharmaceutical market size and growth (2013-2018)



Source: IMS Medicines Outlook Through 2016 (July 2012) – Nicholas Hall's OTC Yearbook 2013 – Smart Pharma Consulting analyses

¹ Brazil, Russia, India, China – ² Compound annual growth rate – ³ France, Germany, Italy, Spain, UK – ⁴ USA and Canada

4th Statement: BRIC countries are the Eldorado of pharma companies

The BRIC¹ countries are expected to belong to the top 10 pharma markets by the end of 2018, while China and Brazil will be ahead of Germany, France and Italy

Evolution of the Top 20 national pharma markets in value (2013-2018)

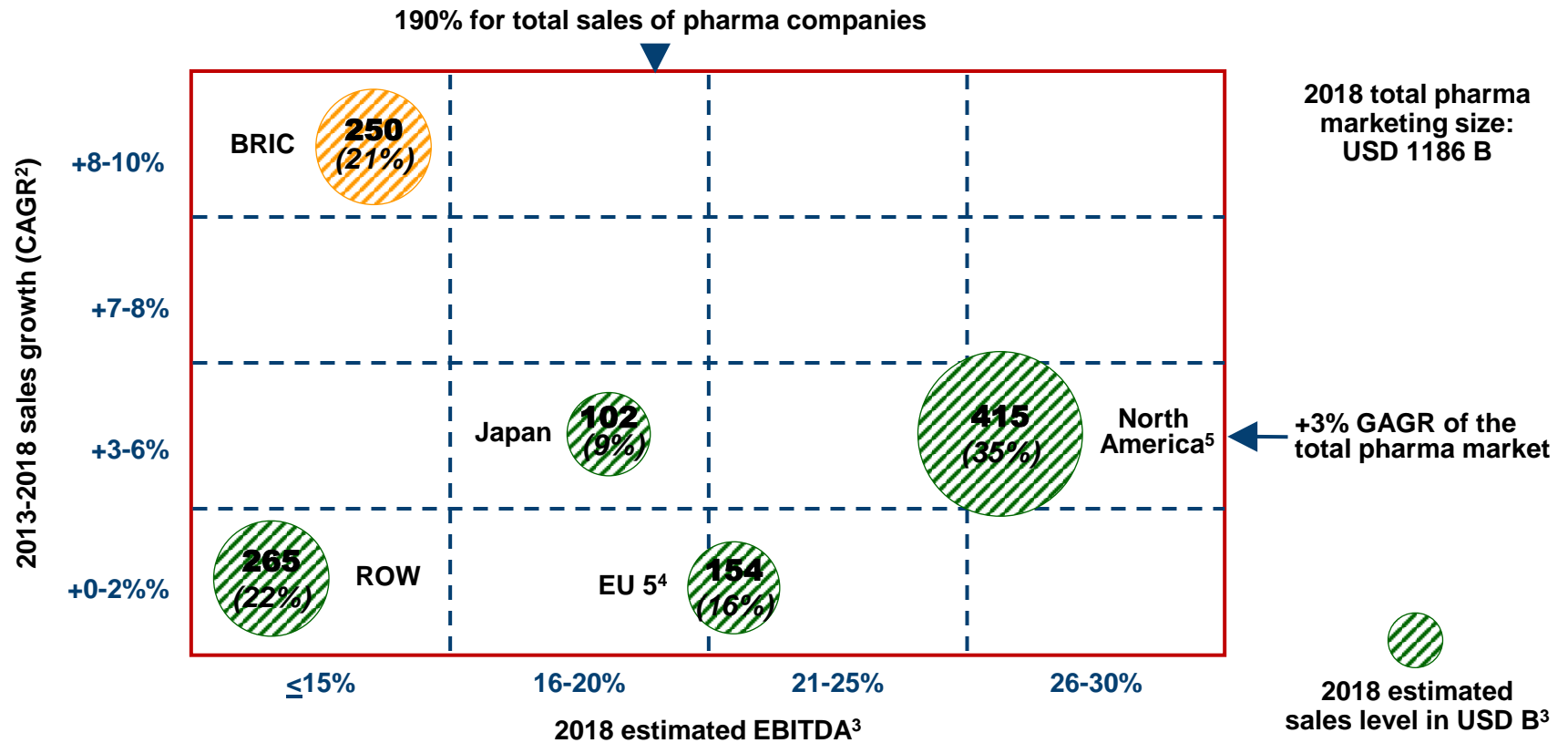
Ranking	2013	2018	Evolution 2013-2018
1.	USA	USA	+
2.	Japan	China	+++
3.	China	Japan	++
4.	Germany	Brazil	+++
5.	France	Germany	+
6.	Brazil	France	-
7.	Italy	Italy	+
8.	Canada	India	+++
9.	UK	Russia	+++
10.	Spain	Canada	+
11.	Russia	UK	+
12.	Australia	Spain	--
13.	India	Australia	+
14.	Mexico	Argentina	=
15.	South Korea	South Korea	+
16.	Turkey	Mexico	+
17.	Venezuela	Turkey	+
18.	Poland	Indonesia	+++
19.	Argentina	Venezuela	+
20.	Belgium	Poland	++

+++	→ 8 – 12%
++	→ 3 – 6%
+	→ 0 – 2%
-	→ -12 – 2%
--	→ -32 – 4%

4th Statement: BRIC countries are the Eldorado of pharma companies

BRIC¹ countries are likely to keep on driving the growth of the global pharma market but they are expected to be much less profitable than North America, EU 5 and Japan

Growth potential per socio-geographical area (2013-2018)



(x%): of total market

Source: Smart Pharma Consulting analyses

¹ Brazil, Russia, India, China – ² Compounded annual growth rate – ³ Earnings before interests, taxes, depreciation and amortizations – ⁴ France, Germany, Italy, Spain, UK – ⁵ USA and Canada

4th Statement: BRIC countries are the Eldorado of pharma companies

The profitability of foreign pharma companies operating in BRIC¹ countries remains a key issue for most of them and their situation is unlikely to improve in the short term

True or Untrue?

- The key question for pharma companies is not anymore: “Should we operate in BRIC countries?” but “How can we run a profitable business?”
- These emerging markets appear to be less attractive and more complicated than anticipated:
 - The Chinese market sales growth rate is lower than forecasted
 - Access through local registration procedures and affordability by local patients remain strong barriers to the development of global pharma companies in all BRIC countries
 - Governments tend to favor the development of domestic companies at the expense of foreign multinationals (e.g. Brazil, Russia, India, China) through the implementation drastic price controls, amongst other measures
 - Local rules and business practices are not always clear to understand and nor in line with the code of business ethics of foreign pharma companies
 - Low protection of Intellectual Property: India has declared compulsory licensing on several brands (e.g. In 2012, a compulsory license of Bayer’s Nexavar, indicated for hepatocarcinoma, was granted to the Indian generic company Natco Pharma Ltd)
 - Local currencies are weak and may fall significantly (e.g. Russia, recently)

Core capabilities

1 Strategy

- **Assessing the attractiveness of markets** (Hospital / retail innovative products - Vaccines - OTC - Generics)
- **Growth strategy**
 - Optimization of marketing / sales investments
 - Development of a company in the hospital market Business
 - Valuation for acquisition
 - Portfolio / franchise assessment
- **Extension of product life cycle performance**
 - Improvement mature products performance
 - Adaptation of price strategy
- **Defense strategies vs. new entrants**
- **Competitive strategies in the hospital market**
- **Strategic partnerships companies / pharmacies**

2 Management

- **Facilitation and structuring of strategic thinking for multidisciplinary product teams**
 - Key challenges identification
 - Strategic options formalization
 - Resource allocation optimization program
- **Training of marketing and market research teams to sales forecast techniques (modeling and scenarios development)**
- **Development and implementation of a "coaching program" for area managers**
 - Sales reps coaching
 - Regional action plans roll-out
- **Development and implementation of a "sales techniques program" for sales forces (STAR¹)**

¹ Sales Techniques Application for Results (training courser



3 Organization

- **Rethink of operational units organization**
- **Improvement of sales force effectiveness**
- **Improvement of the distribution channels covering the hospital and retail markets**
- **Development of a strategic planning process**