

# JP Morgan Healthcare Conference

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## **Agenda**

- 1 Company overview
- 2 Biopharmaceuticals
- 3 Consumer Health
- 4 Summary

## The Group

# Merck KGaA Darmstadt · Germany

# Four attractive businesses with leading positions

#### The Group

Biopharma-
ceuticals

#### Total revenues<sup>1)</sup>

■ € 5.8bn

#### Operating margin<sup>2)</sup>

**22.7%** 

#### **Key strengths**

- Life cycle management
- Biologics
- Biomarkers

Leader in specialty pharma markets

#### **Consumer Health**

#### Total revenues<sup>1)</sup>

■ € 0.5bn

#### Operating margin<sup>2)</sup>

**9.2%** 

#### **Key strengths**

- Vitamins and supplements
- Probiotics

Leader in OTC niche markets

#### **Life Science Tools**

#### Total revenues<sup>1)</sup>

■ € 2.5bn

#### Operating margin<sup>2)</sup>

**19.1%** 

#### **Key strengths**

- Global presence
- Innovation power
- End-to-end solutions for pharma industry

Top 3 player in Life Science tools

# Performance Materials

#### Total revenues<sup>1)</sup>

■ € 1.4bn

#### Operating margin<sup>2)</sup>

**38.6%** 

#### **Key strengths**

- Customer intimacy
- Innovation power
- Cost and technology leadership

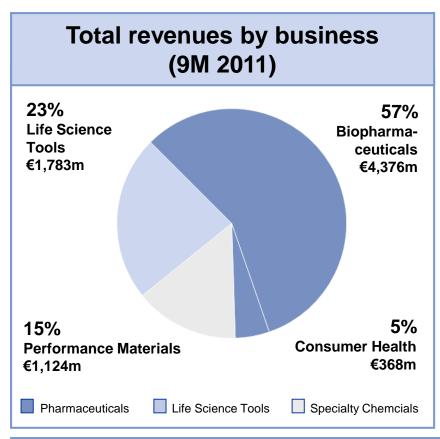
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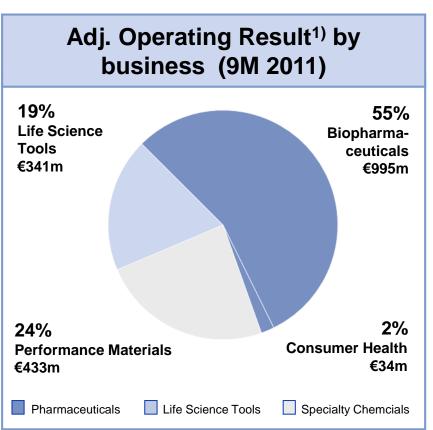
#### A balanced portfolio built on key strengths

## The Group

## **Balanced portfolio of businesses**







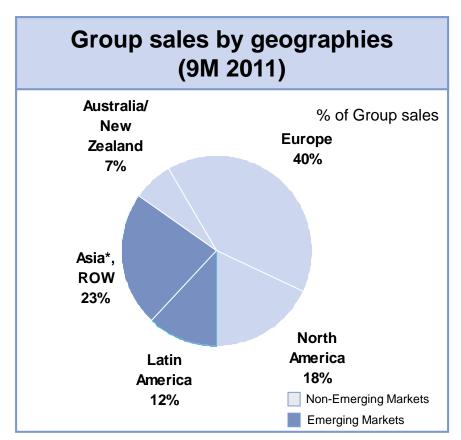
### Pharma contributing ~60% to revenues and profits

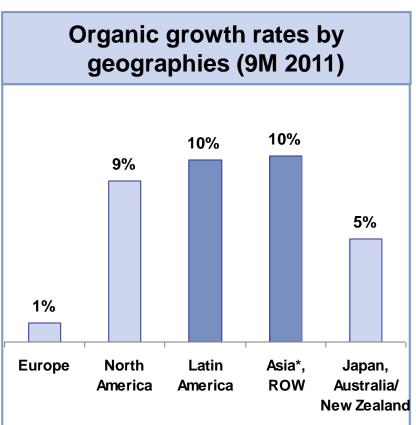
<sup>1)</sup> Adjusted Operating Result = Underlying Core Operating Result

## The Group

## Leveraging our global presence







## Organic growth drivers: Emerging Markets and U.S.

<sup>\*</sup> Excludes Japan



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## Biopharmaceuticals: Where are we today

We understand our strengths and weaknesses and believe we can fix the issues

Biologics portfolio limits patent cliff and Emerging Markets provide stable revenue stream

We are transforming the business and have a 2-3 year window to implement changes

New management and organization established

Our focus in 2012 is on cost efficiency and fixing the R&D engine



# Business characteristics

- Specialty biopharma
- Multiple Sclerosis, Oncology and Fertility
- Less risk from "patent cliff"



# Clear competencies

- Extensive network and ability to develop and scale biologics
- Life cycle management
- Biomarkers



# Market position

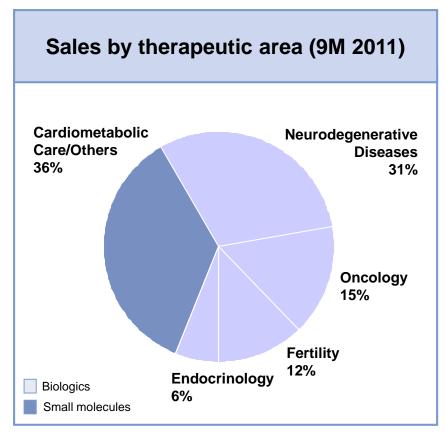
- Leading in key therapeutic areas
- Leading brands
- Strong in Emerging Markets



Addressing therapeutic areas with high unmet medical needs



# Market leading franchises with growth contributors

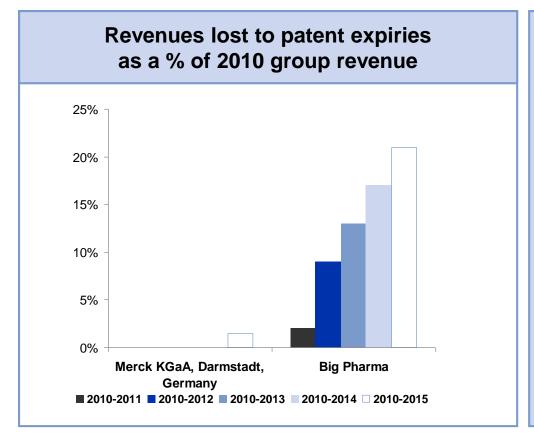


Historic growth rates and future growth trends		
	CAGR (2006-2010)	Future growth trend
Neurodegenerative Diseases	7.9%	
Oncology	24.2%	$\Rightarrow$
Fertility	5.9%	
Endocrinology	8.9%	
Cardiometabolic Care/Others	5.5%	

~60% of portfolio based on biologically manufactured products

# Key franchises well protected: no "patent cliff"



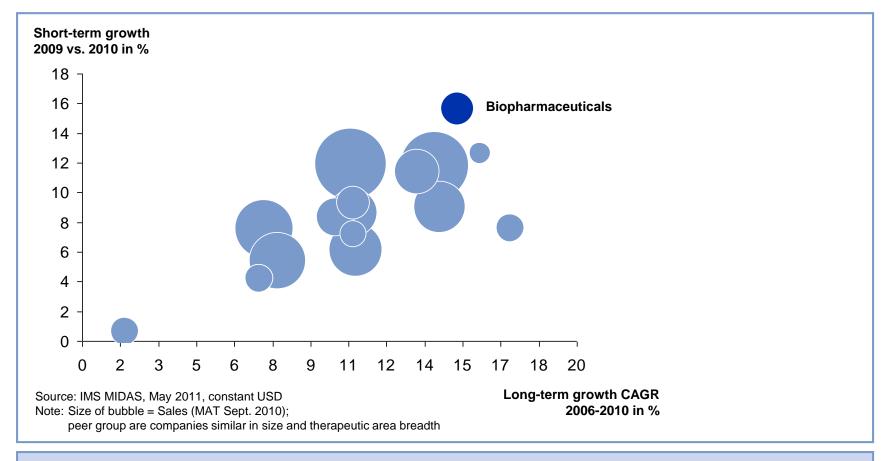


- Key products protected for next three years - patent expiries:
  - Rebif
    - first formulation: EU 2015, US 2022
    - HSA-free\* formulation: patent application pending; tentative expiry date 2024 (US, EU)
  - Erbitux
    - Data exclusivity: EU 2014, Japan 2016 (Post Marketing Surveillance)
  - Gonal-f
    - EU 2009, USA 2015
- Strong brands such as Gonal-f provide additional protection
- Built-in high barrier to entry due to complex molecule structure of biologics

#### Biologics and brands providing high barriers to entry and margin protection

# Merck KGaA Darmstadt · Germany

# High percentage of revenues derived from Emerging Markets benefits growth profile



**Growth from Emerging Markets helps to ensure stable revenues** 

## **Multiple Sclerosis: Rebif**



#### **Overview**

#### Rebif

- Injectable biological drug against relapsing forms of Multiple Sclerosis (MS)
- Well established risk/benefit profile
- Blockbuster with € 1.7bn sales in 2010



# Market position / strengths

- Leading market positions
- Strongest portfolio of devices
- Overall market expanding
- Effective life cycle management

#### **Organic growth**



Rebif performance benefiting from volume growth and price

## Multiple Sclerosis: defending the franchise



### Strategy

Capitalize on market leadership in Multiple Sclerosis:

- Fully exploit market potential of Rebif
  - Continue to focus on patient convenience and safety
  - Expand addressable market
  - Advance current pipeline assets
- Strengthen the pipeline

### **Actions**

- Opportunities to capture incremental value from pipeline additions:
  - ONO-4146 from Ono: Sphingosine-1-phosphate (S1P) agonist, an oral drug candidate with potential to provide better risk/benefit profile compared to other S1P agonists (Gilenya)
  - Phase I PI-2301 from Peptimmune: second-generation peptide copolymer (Copaxone)
- Continued life-cycle management, e.g. new devices and extended label for Rebif in CIS (clinically isolated syndrome)

#### Growing the value of our Multiple Sclerosis business

# **Oncology: Erbitux**



#### **Overview**

#### **Erbitux**

- Biological drug against metastatic colorectal cancer and head & neck cancer
- € 820m sales in 2010

#### **Pipeline projects**

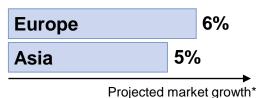
- Stimuvax: therapeutic vaccine against lung cancer
- Cilengitide: innovative compound to treat various cancer indications



- Strong position in niche markets in Europe:
  - High market share in metastatic colorectal cancer
  - Standard of care in head & neck cancer
- Leader in stratified medicine

Global Oncology market (2010): > US\$ 40bn

CAGR (2009-2019)



### Strong product in an expanding market

<sup>\*</sup>Source: Datamonitor, September 2010



# Oncology: strong player in a market with high unmet medical needs

<ul> <li>EU filing for Erbitux in high-EGFR expressing NSCLC; CHMP decision expected in H1 2012</li> <li>New data for Stimuvax and Erbitux expected in Q1 2012 and Cilengitide in H2 2012</li> <li>Partnerships established:         <ul> <li>Potential co-marketing of Stimuvax in Japan with Ono Inc.</li> <li>Co-development of MEK/PI3K inhibitors with Sanofi-Aventis (Phase I)</li> </ul> </li> </ul>	Strategy	<ul> <li>Leverage growth potential of Erbitux in existing indications</li> <li>Capitalize on biomarker expertise</li> <li>Leverage capabilities in biologics, small molecules &amp; immunotherapy</li> <li>Expand collaborations</li> </ul>
	Actions	<ul> <li>expected in H1 2012</li> <li>New data for Stimuvax and Erbitux expected in Q1 2012 and Cilengitide in H2 2012</li> <li>Partnerships established:         <ul> <li>Potential co-marketing of Stimuvax in Japan with Ono Inc.</li> </ul> </li> </ul>

## **Building new sources of growth**

## Fertility & Endocrinology



#### **Overview**

- € 973m sales in 2010 (nearly all biologics)
- Fertility: Broad range of products for reproductive health
- Endocrinology: treatments that replace or supplement natural molecules in growth and selected metabolic disorders

# Market position / strengths

- Excellent track record in life cycle management including devices
- Little impact from biosimilars

#### **Fertility**

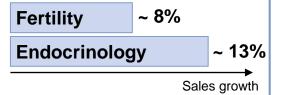
Pioneer and market leader

#### **Endocrinology**

- Among Top 5 in growth hormones
- "only in class" products for selected niche indications (e. g. AIDS wasting, HIV-patients with lipodystrophy, PKU)

#### **Biopharmaceuticals**

CAGR (2007-2010)



#### **Exploiting leading market positions**

## **Cardiometabolic Care & Others**



#### **Overview**

- € 1,940m sales in 2010 (small molecules) with >50% generated in Emerging Markets
- Effective treatments against a broad range of widespread diseases (e. g. cardiovascular and thyroid disorders, diabetes) mainly for primary care physicians

# Market position / strengths

- Leading market positions with gold standard products that have high brand equity
- Excellent track record in life cycle management (i. e. formulations)
- Comprehensive portfolio of complementary products
- Strong position in Emerging Markets to generate double digit regional growth

#### **Cardiometabolic Care & Others**

CAGR (2007-2010)



### Capitalizing on gold standard products

# **Building Biopharmaceuticals: change process gaining momentum**



## Change Agenda

- Optimizing cost structure and streamlining processes
- Increasing commercial effectiveness
- Improving the pipeline to enhance early stage projects
- Strengthening the R&D organization and shift focus from late stage to early stage
- Increase focus on licensing in across core areas

# Recent Progress

- Management strengthened with seasoned senior executives
- Tough pipeline decisions taken
- Continued actions to strengthen and defend leadership positions in Multiple Sclerosis and Oncology
- Definition of new R&D organization

Team and high-level organization in place, focus turns to efficiency improvements

# Progress on pipeline pruning in 2011: seven development programs discontinued

## Neurodegenerative Diseases

- Cladribine tablets for use in Multiple Sclerosis (Phase III)
- Safinamide for treatment of Parkinson indications (Phase III)
- New Formulation of Rebif in the U.S.

### Oncology

- Erbitux for use in metastatic triple-negative breast cancer (Phase II)
- No further clinical development for IMO-2055, currently in development for squamous cell carcinoma of the head and neck (Phase II)
- c-Met kinase inhibitor EMD 1204831 for use in solid tumors (Phase I)

### **Endocrinology**

ARX-201 for use in growth hormone deficiencies (Phase II)

Decisions made on stringent, fact-based scientific and strategic criteria

## Redefining the R&D organization



# Past R&D Organization

- One executive heading the combined R&D office
- Heavily matrixed organization with up to 12 layers
- High span of control at L1 and L2, very low span of control at lower levels of the organization
- No clear responsibility for strategy realization, unclear mandate of Portfolio Development function

# New R&D Organization

- One executive for separated R and D functions each
- Leaner organization with clear responsibilities on individuals rather than on committees
- Global functions for Drug Safety, Regulatory/QA and Medical
- Own unit for external innovation

New R&D organization geared toward speed and better execution



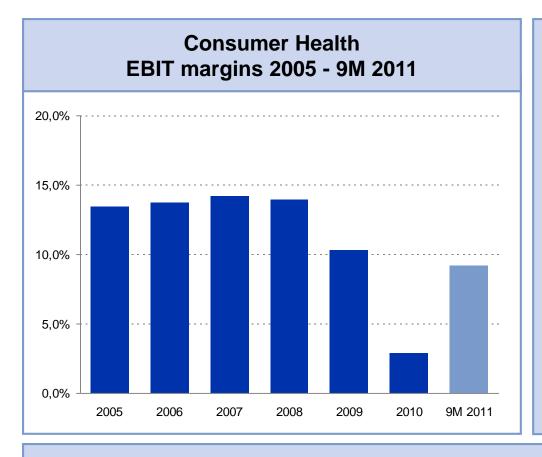
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#### **Consumer Health**



## Process of improving margins has begun



- Gross margin between 2005 and 2010 was approximately 65–68% of revenues
- Higher investments into R&D and SG&A in 2009 and 2010
- Generally healthy business
- More effective SG&A allocation leads to higher profitability

#### Potential to perform better



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# Summary: Why invest in Merck KGaA, Darmstadt, Germany

Balanced portfolio with businesses in leading market positions



Strong financial base and solid cash-flow generation



Willingness to change and address company & industry challenges



Change management & cost efficiency will lead to value creation





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