



Biopharmaceuticals Investor & Analyst Day

Roadmap to sustainable success

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Merck KGaA

Darmstadt · Germany

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Agenda

Our strategic priorities for sustainable success

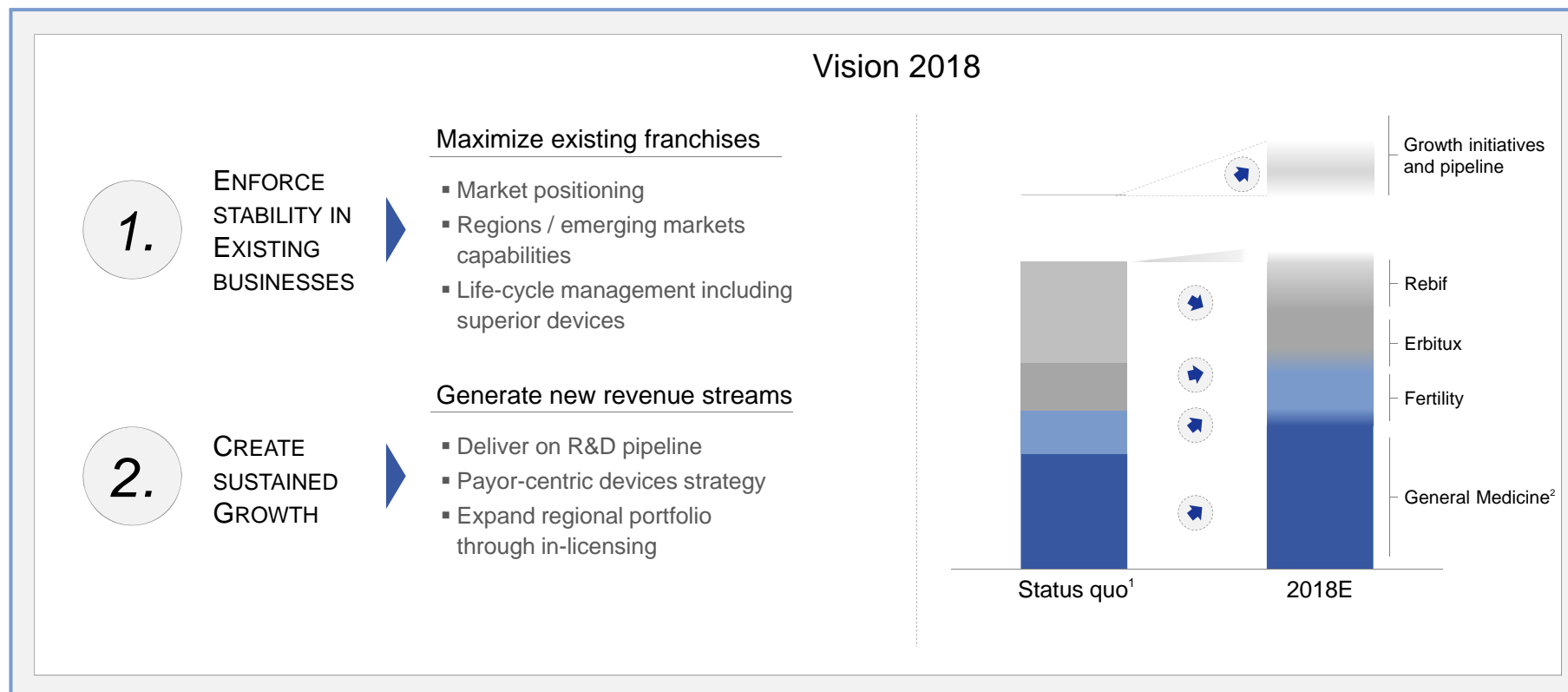
Maximizing our core franchises

Driving Emerging Markets leadership

R&D for long-term sustainable growth

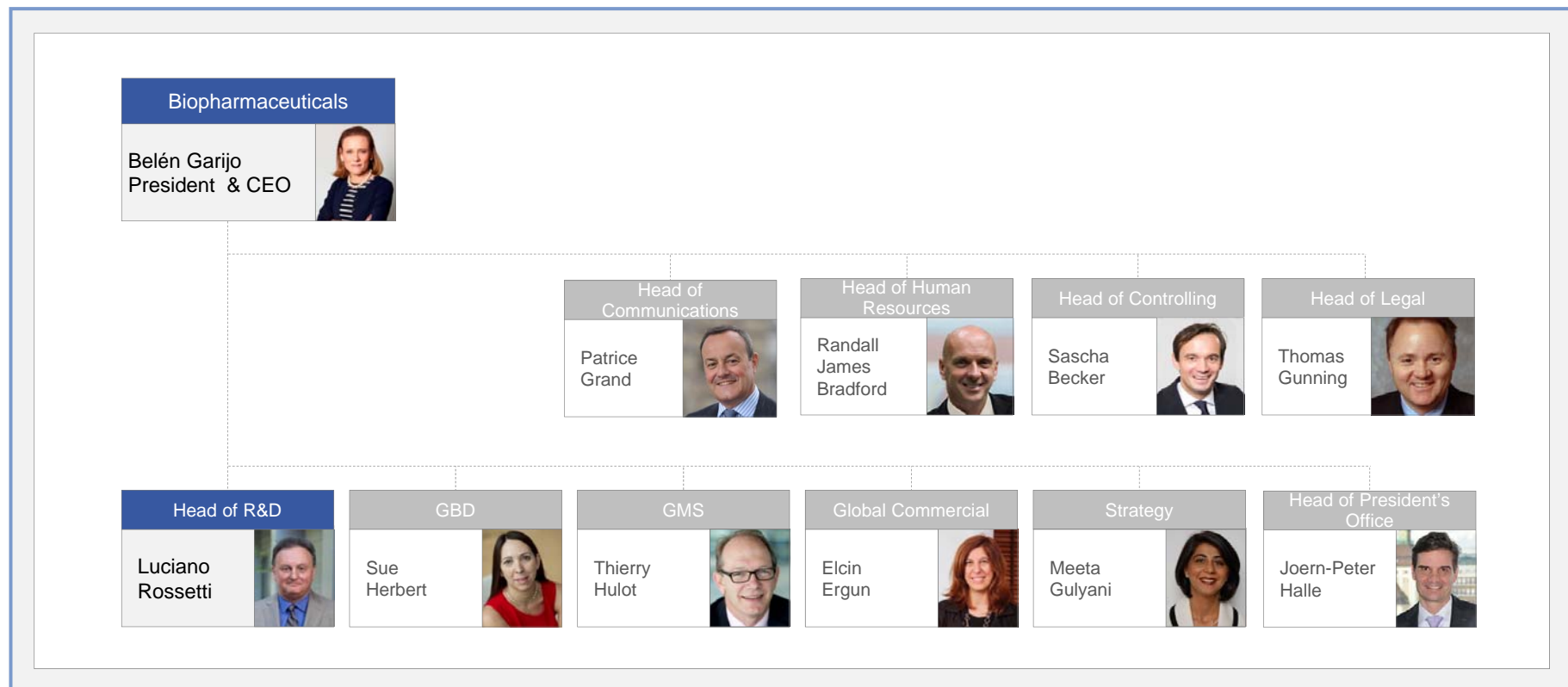
Executive summary

Strategic priorities for sustainable success: New revenue streams and maximizing existing franchises



¹FY 2013; excludes Allergopharma and Biosimilars; ²including Cardiomatabolic Care, Endocrinology, General Medicine and Others

Global, diverse and talented Biopharmaceuticals executive management team ensures flawless execution



GBD = Global Business Development; GMS = Global Manufacturing and Supply

Agenda

Our strategic priorities for sustainable success

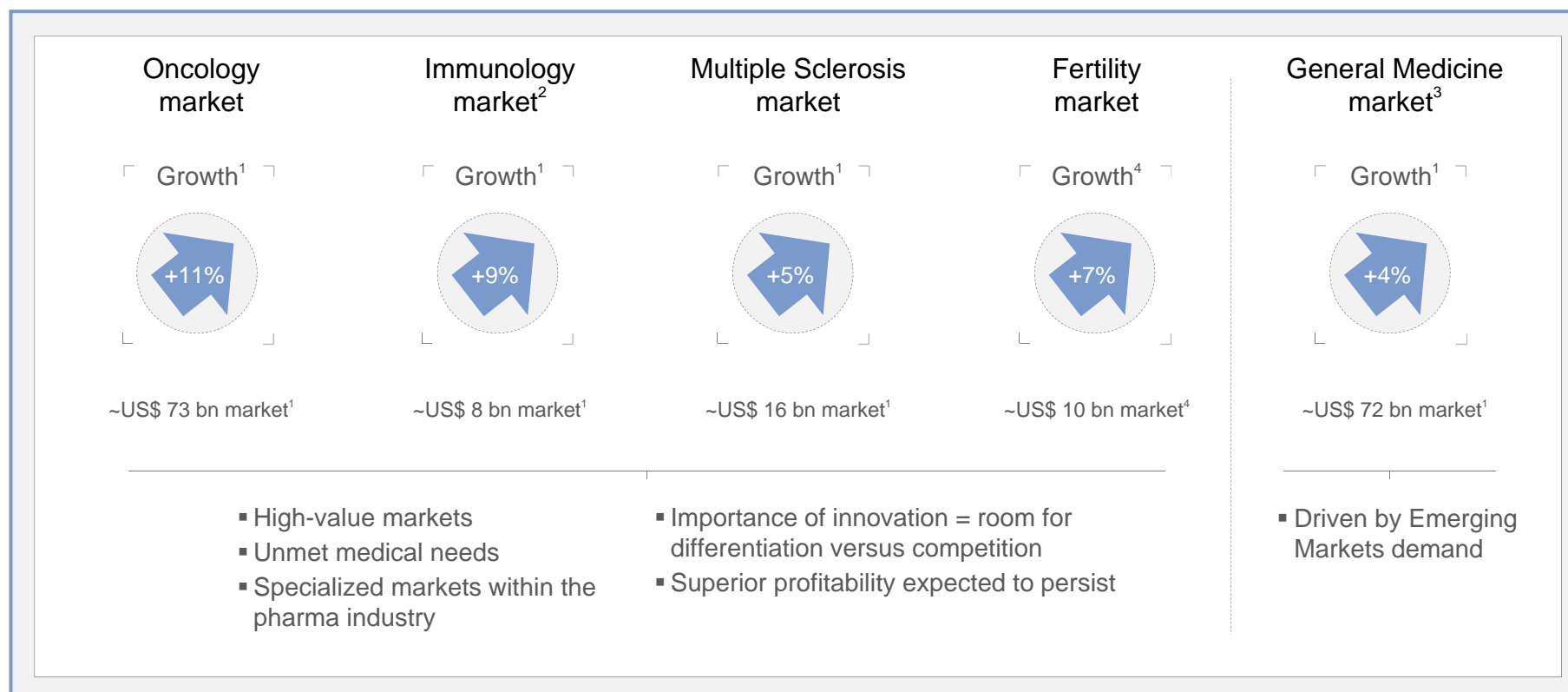
Maximizing our core franchises

Driving Emerging Markets leadership

R&D for long-term sustainable growth

Executive summary

Biopharmaceuticals' existing franchises focus on attractive markets



¹Data for global market 2013, CAGR for 2013-2018 (2020 for multiple sclerosis); Source: Sales data according to EvaluatePharma® a service of Evaluate Ltd. (UK), www.evaluategroup.com, accessed July 2014

²Immunosuppressants ³Includes cardiovascular, diabetes treatment ⁴Growth 2013-2021; Source: Biopharmaceuticals based on Transparency market research 2010; US IV Clinics 2011, CDC, ESHRE, press

Strategic priorities are well defined to maximize core franchises

Oncology	<ul style="list-style-type: none"> Promote Erbitux' value to personalized treatments Increase RAS testing adoption and usage
Multiple Sclerosis	<ul style="list-style-type: none"> Strengthen Rebif's competitive position as a leading treatment Drive differentiation via smart devices and first MS* e-health platform
Fertility	<ul style="list-style-type: none"> Provide innovative services and technologies beyond drugs Drive Emerging Markets presence, especially in China and Russia
Devices and services	<ul style="list-style-type: none"> Promote as key differentiator of Biopharmaceuticals' business Build as a focus area of innovation and service to patients
General Medicine and others	<ul style="list-style-type: none"> Focus on growth in Emerging Markets Enhance life-cycle management and recover growth levers in core markets



*MS = multiple sclerosis

Erbitux® – First choice in personalized treatments for mCRC and champion in head and neck

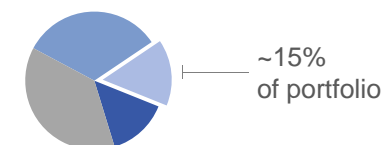
Top 4 priorities to support Erbitux

1. Further focus on the value of personalized treatments
2. Highlight importance of RAS testing², raise RAS testing rates and roll out blood-based RAS test (Sysmex collaboration)
3. Continue to highlight advantages for targeted patient populations based on current data (Fire3, CALGB-80405, new Crystal retrospective)
4. Maximize head and neck opportunity globally, especially in Japan and other Asian countries

Erbitux



Sales¹



Outlook 2015 +

- Stable to slight organic sales growth
- Growing balance between mCRC³ and SCCHN⁴
- Testing to offer upside potential

¹FY 2013; ²Determination of tumor gene status for RAS in all patients with mCRC – especially emphasized in the updated NCCN Guidelines v.1.2015; ³mCRC = metastatic colorectal cancer

⁴SCCHN = squamous cell cancer of the head and neck

Rebif® – Capitalizing on efficacy and active life-cycle management to support long-term prospects

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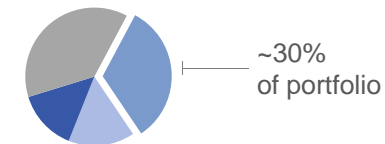
Top 4 priorities to drive Rebif

1. Focus on Rebif's efficacy in reducing relapse rates and delaying disability progression
2. Raise differentiation via smart injection devices², and online and mobile patient applications as tools to drive adherence and improve patient experience
3. Defend Rebif's leadership position in Europe within the injectables segment and strengthen position in the US; implement tactics to drive patient acquisition and retention
4. Secure long-term profitability upgrade of the US franchise after Pfizer contract expiry

Rebif



Sales¹



Outlook 2015 +

- Manage revenue erosion
- Leverage profitability
- Maximize payers' value (devices)

¹FY 2013; ²Not all devices are available in all markets

Fertility – Expanding the franchise to the next level: beyond drugs

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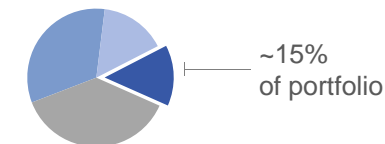
Top 3 strategic priorities

1. Expand leadership position and build on No.1 brand growing globally, especially in high-potential Emerging Markets
2. Bolster underlying growth with potential label expansion (e.g. Pergoveris) and life-cycle and devices management versus entry of biosimilars competition
3. Leverage existing strong presence and knowledge in the fertility clinic channel to provide innovative technologies & services in the ART² lab to drive innovation and increase success rates

Fertility



Sales¹



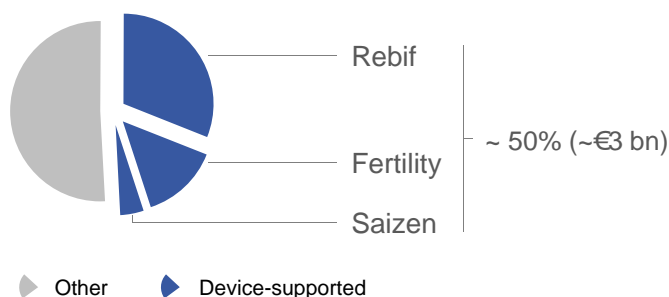
Outlook 2015 +

- Continuous sales growth driven by changing demographics in EM
- Ongoing contribution from beyond drugs strategy in Europe and Canada

¹FY 2013; ²ART = Assisted reproductive technology

Medical devices – Further enhancing the value of Biopharmaceuticals and harnessing existing strengths

Device-supported franchises at Biopharmaceuticals¹



Strategy

- Build on existing competencies in devices and integrate across therapeutic areas
- Drive innovation and differentiation versus competition in existing product franchises
- Expand to selected specialty chronic diseases
- Provide solution to payers to better manage healthcare costs

Current product offering²

Rebig

- Rebigdose
- Rebigject
- Rebigslide
- RebiSmart³
- MSdialog³



Fertility

- Family of pens for Gonal-F, Pergoveris, Ovidrel



Saizen

- Easypod
- Cool.click2
- Easypod Connect³



¹Supported by Biopharmaceuticals' current portfolio of 13 medical devices; based on FY 2013 sales; ²Not all devices are available in all markets; ³Software and mobile applications linked to RebiSmart (allowing – among others – monitoring of treatment adherence and patient reported outcomes, and visualization over time to patient and physicians) and Easypod (allowing, among others, monitoring of treatment adherence and visualization to physicians)

Medical devices – Driving Biopharmaceuticals towards an integrated business model

Top 3 strategic priorities

1. Enhance existing competencies in devices and integrate across therapeutic areas
2. Drive development of long-term Chronic Treatment Solution Platform on the basis of advanced MS care concept*
3. Expand current technological lead to specialty chronic diseases outside of current multiple sclerosis franchises

Devices



Outlook 2015 +

- Ongoing product and concept development (currently 21 projects in all therapeutic areas)
- Launch MS care concept in multiple sclerosis as blueprint business model
- Potential first drug-agnostic revenue stream after 3 years

*Not all devices are available in all markets

General Medicine – Strong Emerging Markets platform enables continued growth

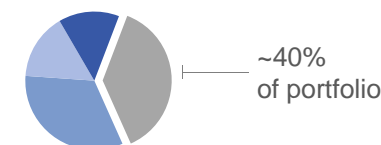
Top 4 strategic priorities to build on track record

1. Foster role as solid cash generator based on strong brands, focused life-cycle management and customized innovation model with ring-fenced R&D budget
2. Accelerate growth in already strong Emerging Markets platforms, especially in China, Brazil, Russia, Middle and Near East
3. Renew and strengthen portfolio through life-cycle management, e.g. Concor FDCs³, Glucophage label changes, Euthyrox reformulations
4. Continue to recover main growth levers in core markets and assets (e.g. BMS China)

General Medicine¹



Sales²



Outlook 2015 +

- Solid organic sales growth
- Rising earnings contribution from growth initiatives

¹including Cardiometabolic Care, Endocrinology, General Medicine and Others; ²FY 2013; ³FDC = Fixed-dose combination

The road to maximizing Biopharmaceuticals' existing franchises is clear



Continue to drive front-line mCRC share by increasing patient testing and expanding head and neck coverage



Capitalize on strong efficacy and new smart devices to maximize differentiation and defend franchise



Build on No.1 position and ART¹ channel access with embryo diagnostics and other innovative technologies



Harness strengths of existing business and build a new focus area driven by innovative devices and services for patients



Build on existing track record in Emerging Markets, drive brand and life-cycle management and expand business including asset repatriation



¹ART = Assisted Reproductive Technology

Agenda

Our strategic priorities for sustainable success

Maximizing our core franchises

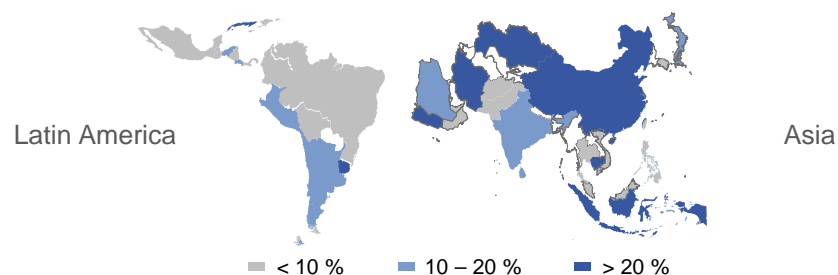
Driving Emerging Markets leadership

R&D for long-term sustainable growth

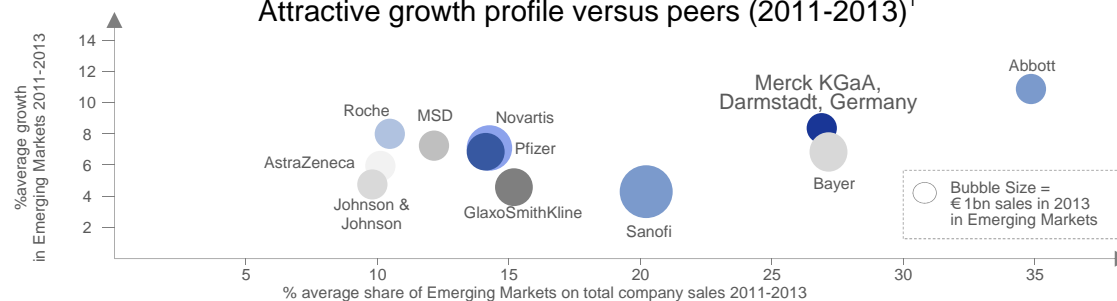
Executive summary

Emerging Markets are a key pillar of growth for Biopharmaceuticals

2013 Organic growth rates of Biopharmaceuticals in Emerging Markets



Attractive growth profile versus peers (2011-2013)¹



Key facts

- Emerging Markets are a key driver for the branded products as well as for Biopharmaceuticals overall
- ~30% of sales in Emerging Markets
- ~50:50 breakdown between Latin America and Asia
- Emerging Markets account for >60% of organic growth 2011-2013²

Emerging Markets support existing business and serve as a platform for strategic growth initiatives

¹Source: IMS MIDAS, 2012/2013 constant USD; ²Source: Biopharmaceuticals
 Note: Size of bubble = €bn sales in Emerging Markets (2013)

Emerging markets dynamics support future growth prospects

Growing middle class



- Changing lifestyles and treatment needs (e.g. fertility)
- Higher healthcare spending

Extended healthcare coverage



- Rising government spending
- Higher healthcare requirements (e.g. service, quality)

Shift to chronic diseases



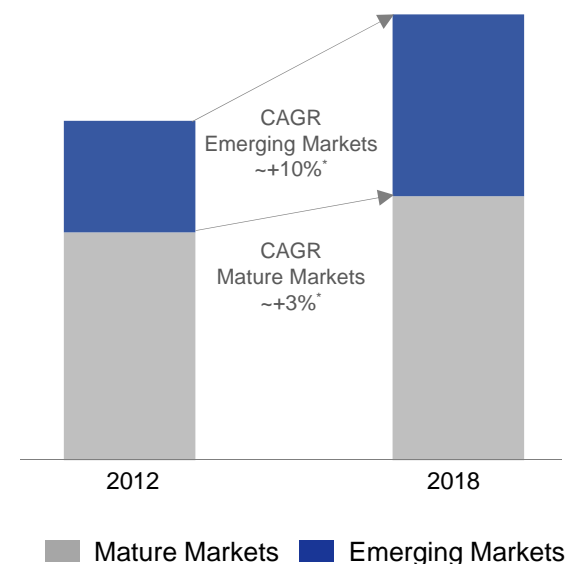
- Higher healthcare costs
- Need for medical support and devices

Rising demand for biologics



- Changing disease profiles
- Rising treatment requirements (e.g. biologics)

Global pharma market*



*Source: IMS market prognosis 2014-18; Emerging Markets defined as China, LATAM, APAC, ITC, CEE; Mature Markets defined as USA, EU5 + WE, Japan

Biopharmaceuticals – Well-positioned to address market needs and build growth platform

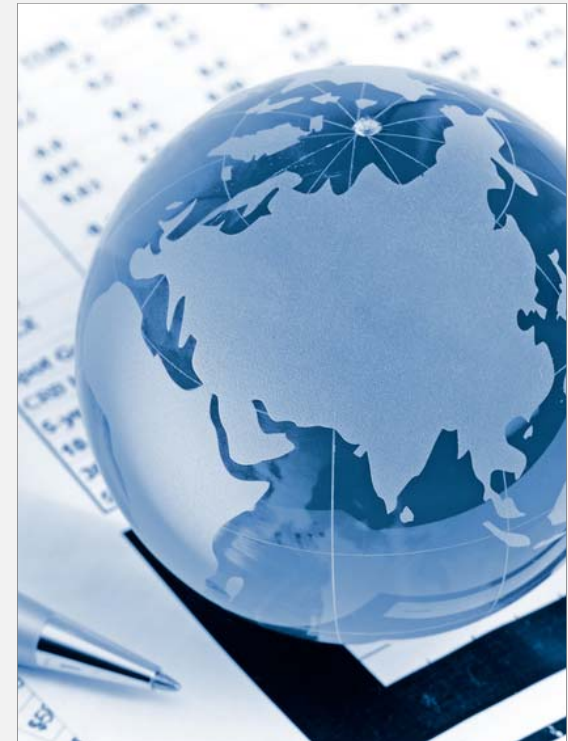
OUR INITIATIVES TO ADDRESS MARKET NEEDS

Tailored products and services

- Provide innovative affordable products
- Increase access to biologics drugs
- Local/adapted products (e.g. formulations)
- Offer out-of-pocket drugs (e.g. fertility)

Positioning as recognized partner

- Openness for public private partnerships
- Be local (e.g. infrastructure = Glucophage)
- Build brand



Emerging Markets – Initiatives in China support above-market growth and strong brand presence

Strategic roadmap for China underpinned by strong leadership team and clear portfolio focus

Metabolism

- Glucophage co-promotion with BMS in China
- New product launches, e.g. Glucophage XR
- Expand diabetes portfolio via licensing, e.g. Glufast
- Grow Thyroid franchise by improving diagnosis rates with the 2015 TSH test kit⁴

Oncology

- Expand access on Erbitux mCRC through PAP⁵
- Pursue China-specific indications, cater for local needs and establish as local innovator
- In-license “China-differentiated” assets, e.g. BeiGene collaboration
- Explore Biosimilars options

China



- Sales 2013 ~€300m¹
- Organic CAGR 2010-2013 20%²
- Pharma market CAGR 2013-2018 ~13%³

General Medicine

- Capitalize on high brand equity and value proposition
- Increase coverage to capture market growth via “deeper & wider” initiative
- Adapt product and formulations (e.g. Euthyrox)
- Leverage market leadership in thyroids; drive awareness and diagnosis rates

Fertility

- Build on strong brand perception in high-growth markets
- Create targeted patient assistance program
- Support IVF⁶ centers through the new Fertility “technology and services for IVF clinics” initiative

¹Rough indication; ²Source: Merck, KGaA, Darmstadt, Germany; ³Source: IMS market prognosis 2014-18; ⁴TSH = thyroid stimulating hormone; expected launch in January 2015

⁵Patient Access Program; ⁶IVF = In-vitro fertilization

Emerging Markets – Partnerships and capability building to differentiate in Brazil

Our strategy: Winning in biologics and in retail

Biologics

- Biologics account for >50% of growth potential
- Key area of focus for the government
- Long-term strategic partnerships with government for key biological brands via PDP⁴ secure growth
- Prepare Biosimilars: e.g. Bionovis collaboration for oncology and auto-immune diseases
- Leverage multi-channel-marketing to tap opportunities in Fertility franchise (e.g. awareness)

Brazil



- Sales 2013 ~€300m¹
- Organic CAGR 2010-2013 +19%²
- Pharma market CAGR 2013-2018 ~14%³

Retail

- Retail to remain biggest segment of Brazilian pharma market
- Focus on strong brands: Concor, Euthyrox, Glucophage
- Invest in growth opportunities through portfolio expansion partnerships
- Raise market penetration, e.g. less affluent patients
- Invest in sales force and capability enhancement
- Invest in medical capabilities (e.g. MSLs⁵)

¹Rough indication; ²Source: Merck KGaA, Darmstadt, Germany; ³Source: IMS market prognosis 2014-18; ⁴Product Development Partnerships; ⁵Medical Scientific Liaison

Emerging Markets – Strategic growth initiatives align market needs and our strengths

Leverage capabilities and local channels

Extend breadth and depth of promotion in China, leverage brand by portfolio extensions via regional/local licensing, market development (e.g. Fertility)

Invest selectively and grow flagship brands

New formulations (Euthyrox, Glucophage), fixed-dose combinations (Concor), and devices (Saizen)

Repatriate businesses

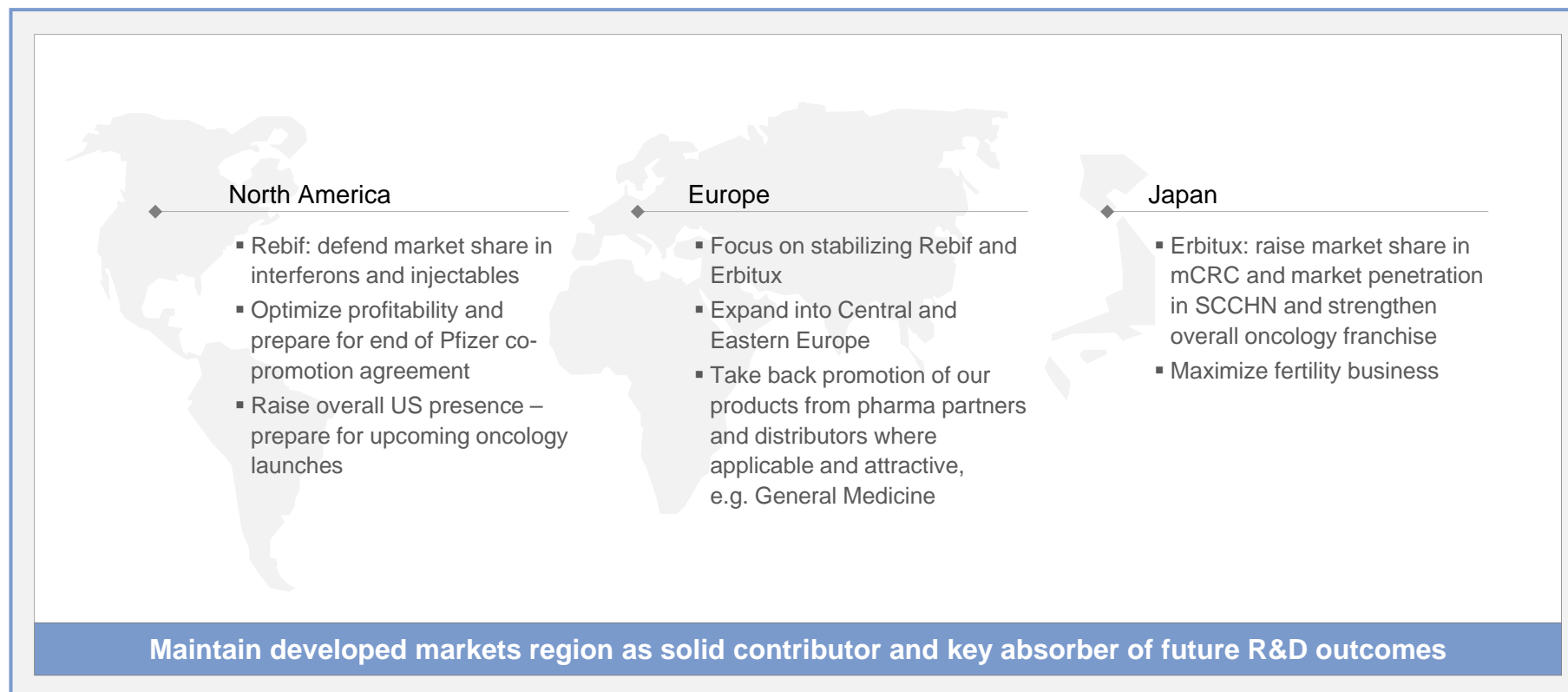
Continue taking back promotion of our products from pharma partners and distributors where applicable and attractive

Expand portfolio focus

Emerging Markets as a platform for Biopharmaceuticals' strategic growth initiatives in biologics

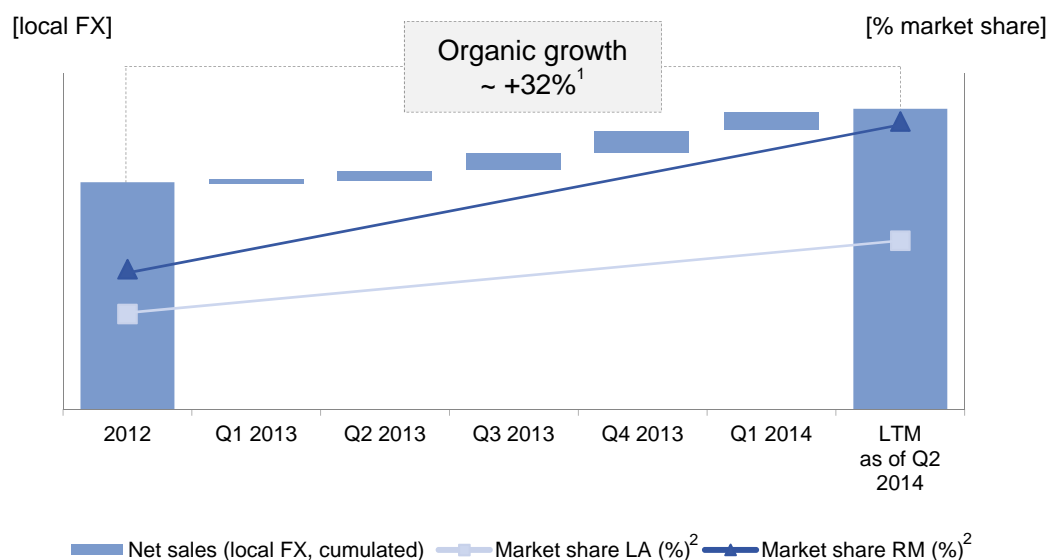


Developed Markets – Key strategic priorities for the company adapted to core markets



Developed Markets – Our ability to innovate and launch improves prospects

Eribitux SCCHN Japan – Track record of fast market launch and ramp-up



Our strategic priorities

- Innovation-driven markets
- Core regions to commercialize our R&D pipeline outcomes
- Local approach to optimize each individual country's potential
- Medical organization enhanced in recent years
- Ensure launch readiness

Developed Markets expected to remain Biopharmaceuticals' key pillar by 2018 (~50% of sales)

¹Source: Biopharmaceuticals; ²local market shares for 1st line usage in LA = locally advanced; and RM = recurrent metastatic

Agenda

Our strategic priorities for sustainable success

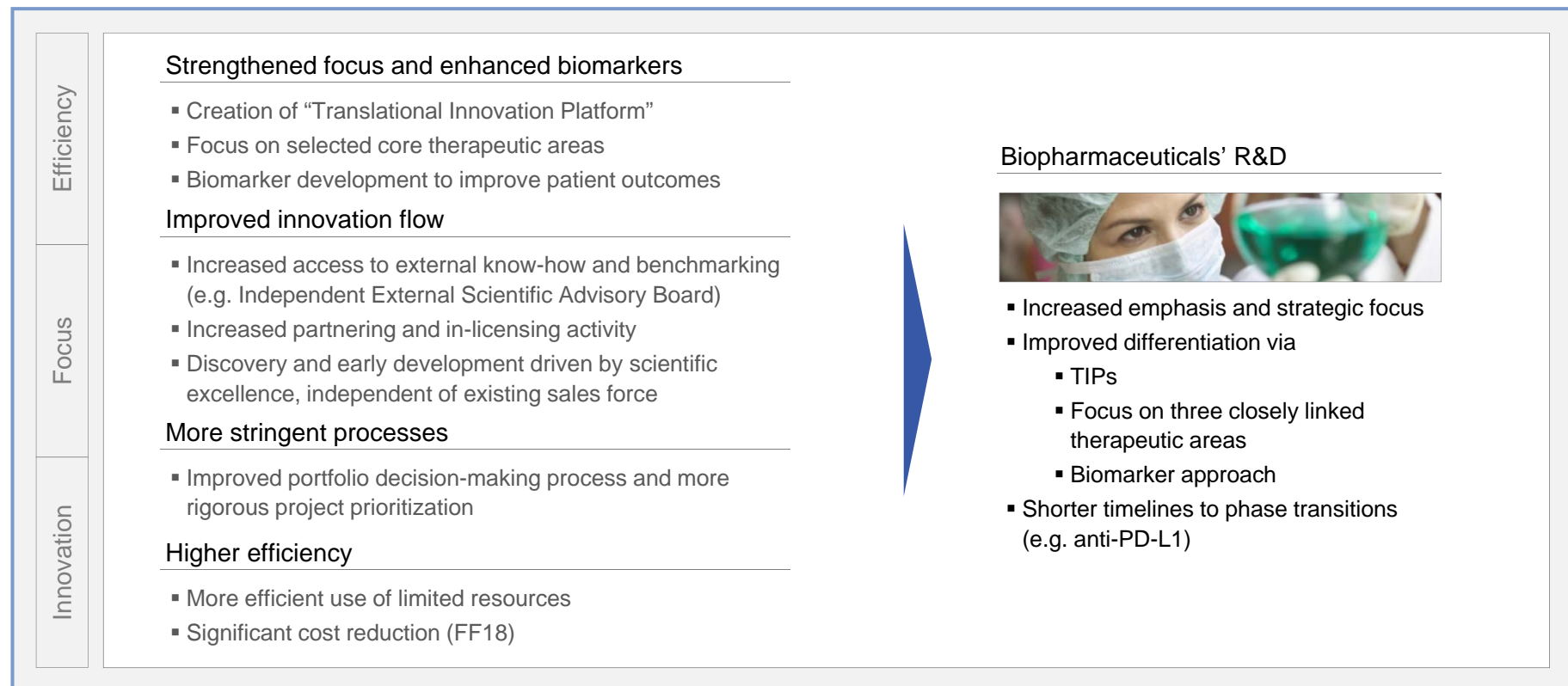
Maximizing our core franchises

Driving Emerging Markets leadership

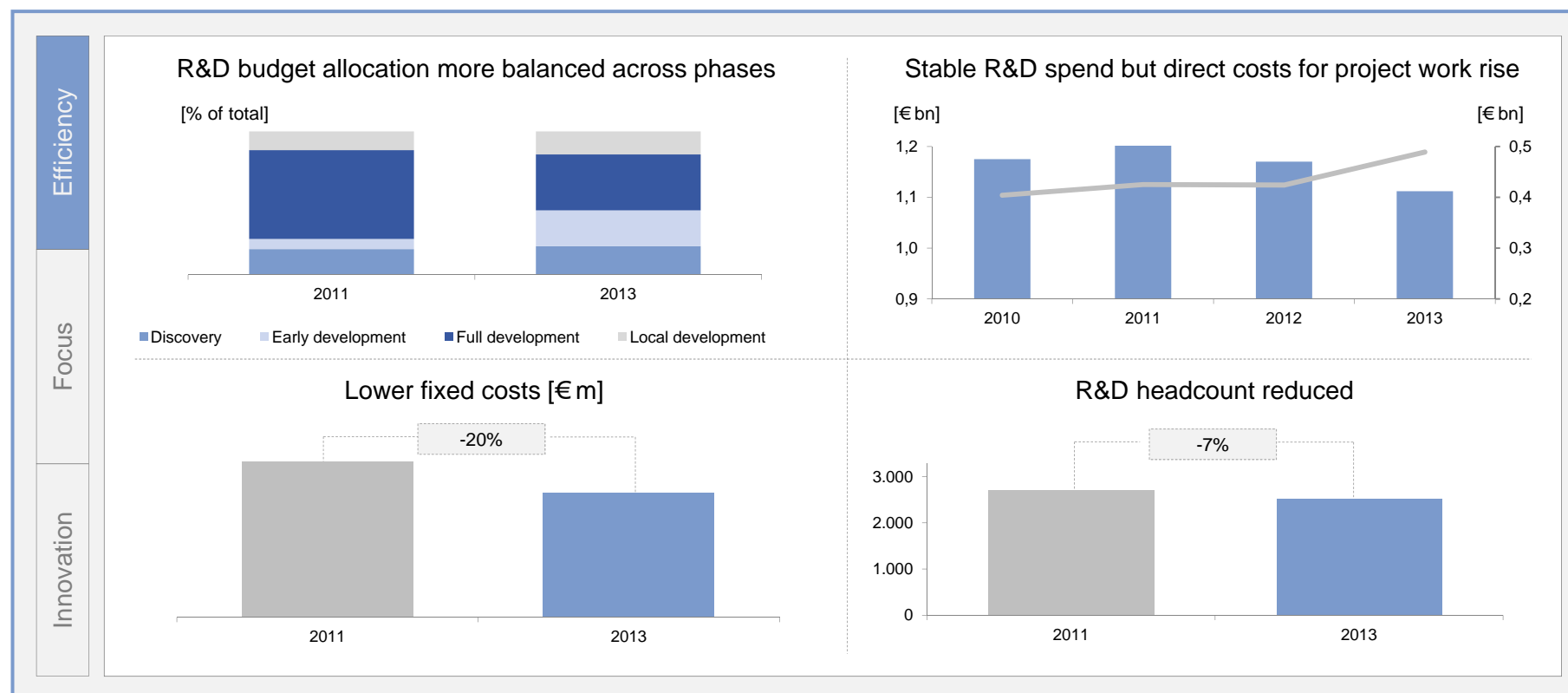
R&D for long-term sustainable growth

Executive summary

New 2012 R&D approach improves focus



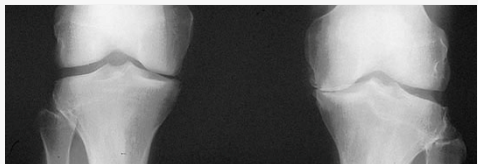
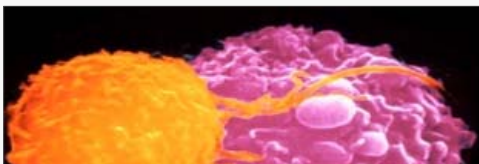

R&D efficiency continues to improve



Source: Biopharmaceuticals

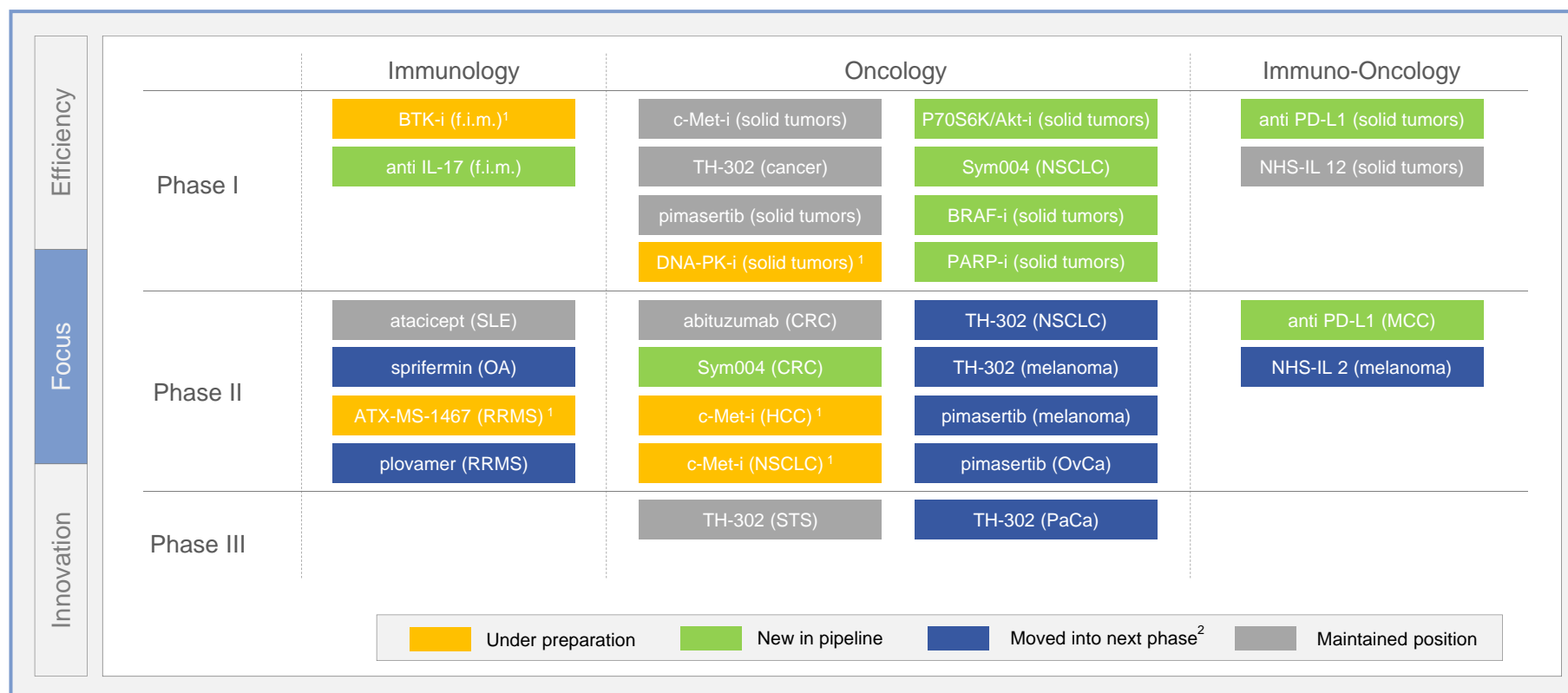
Commitment to scientific innovation makes a meaningful difference

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Efficiency Focus Innovation	Immunology & Neurology	Oncology	Immuno-Oncology
			
	<p>Vision</p> <p>Understand disease-led human immunology to build a competitive drug portfolio</p> <p>Key projects*</p> <ul style="list-style-type: none"> ▪ Atacicept ▪ ATX-MS-1467 ▪ BTK inhibitor 	<p>Vision</p> <p>Leverage our presence in oncology to deliver the best benefit possible to patients</p> <p>Key projects*</p> <ul style="list-style-type: none"> ▪ TH-302 ▪ c-Met inhibitor ▪ p7056K & Akt inhibitor 	<p>Vision</p> <p>Transform cancer into a chronic disease</p> <p>Key projects*</p> <ul style="list-style-type: none"> ▪ Anti-PD-L1 ▪ NHS-IL2LT ▪ NHS-IL-12

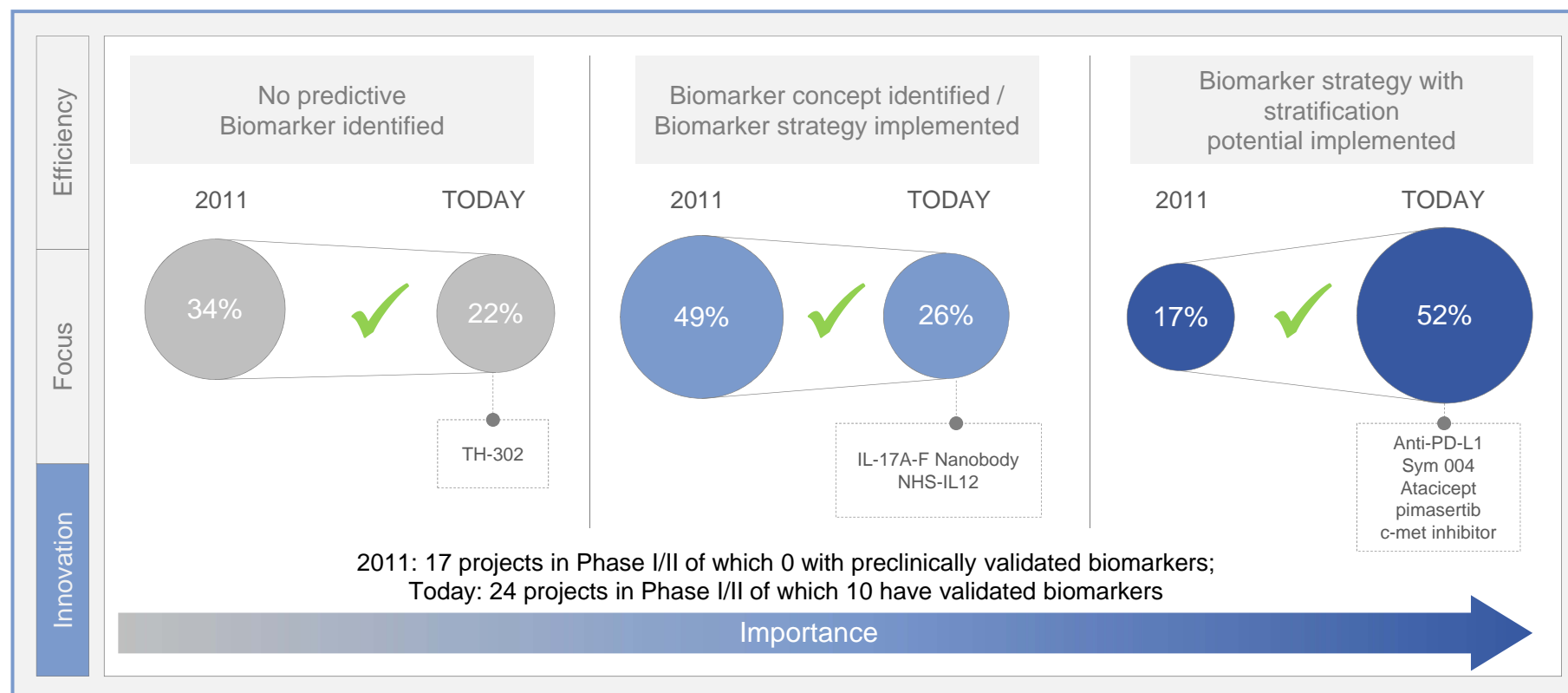
*Examples

Therapeutic areas of focus determine revamped R&D pipeline



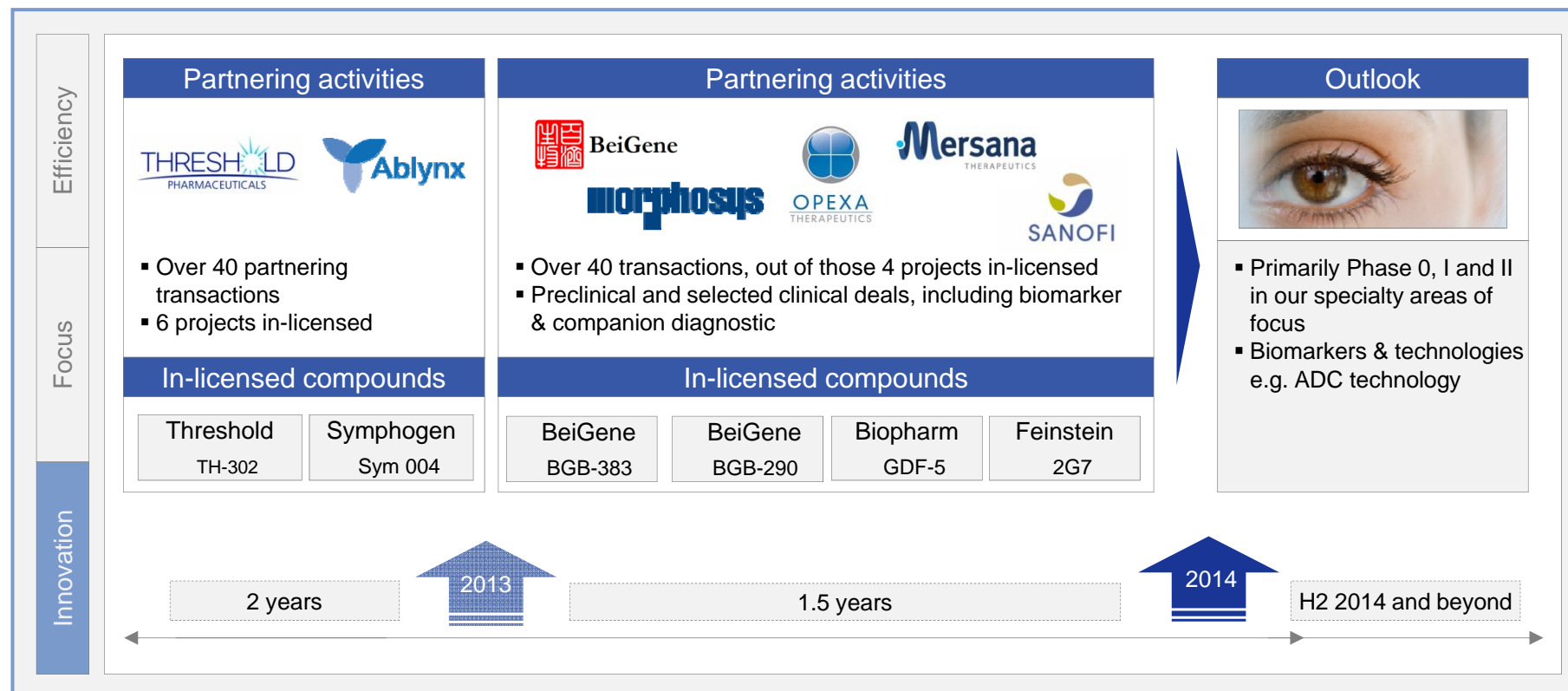
As of September 2014; ¹Under preparation for this phase; ²Since Capital Markets Day in May 2012

Implementation of biomarker strategy enables treatment of patients, not diseases



*% for all projects in phase I/II/III, selected examples provided

External innovation continuously supports pipeline expansion



Rigorous value analysis of target product profiles drives portfolio decisions

Project type

- High unmet medical need
- Specialty / niche indication
- Fit into Biopharmaceuticals' strategic focus areas

Project quality¹

- Adding value to patients
- Compound's potential to differentiate from competitors
- Potential for patient stratification / biomarker identification
- Expected change in the market environment until launch



Project financials

- Expected peak sales
- Expected costs until launch
- Time until launch
- Expected necessary launch costs / investments

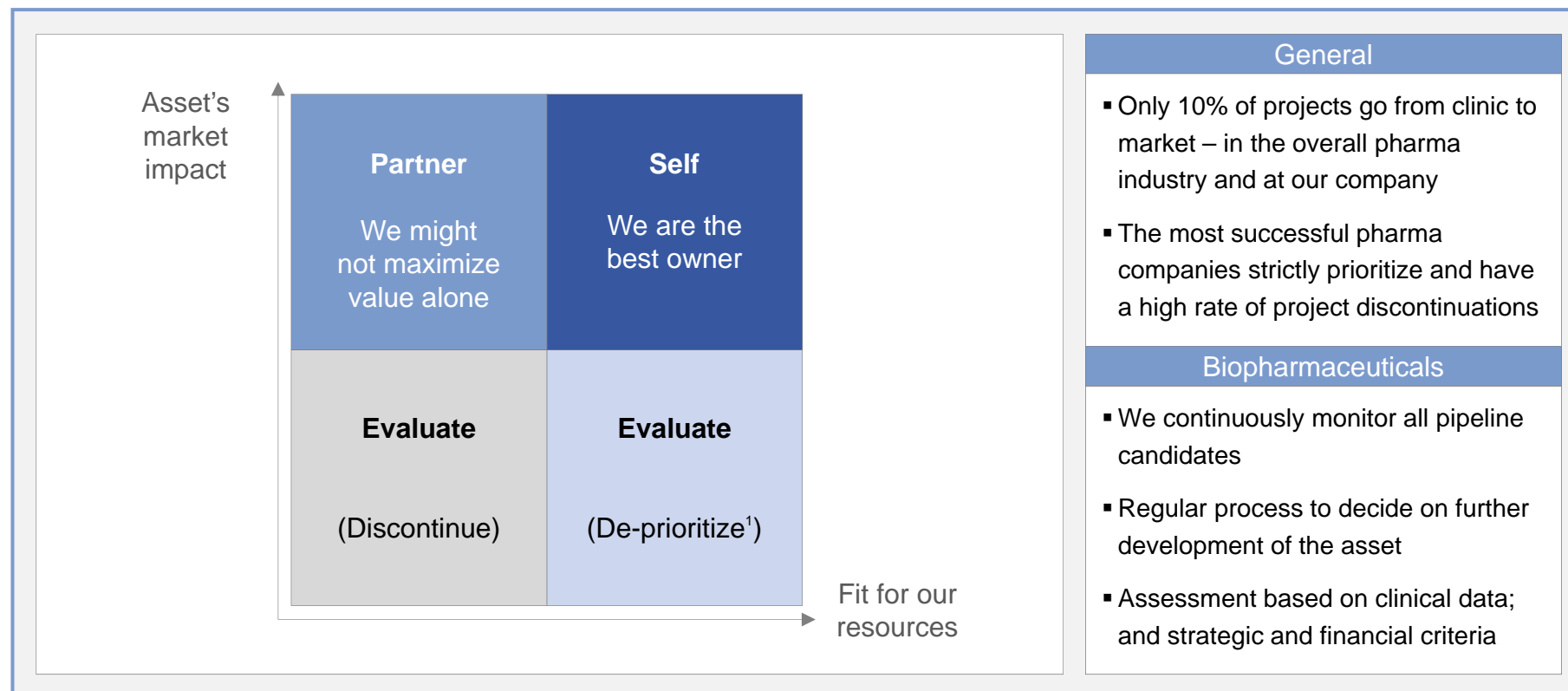
Project fit for us

- Sufficient capacity to maximize sales
- Access to the relevant market
- Being the best owner of the asset

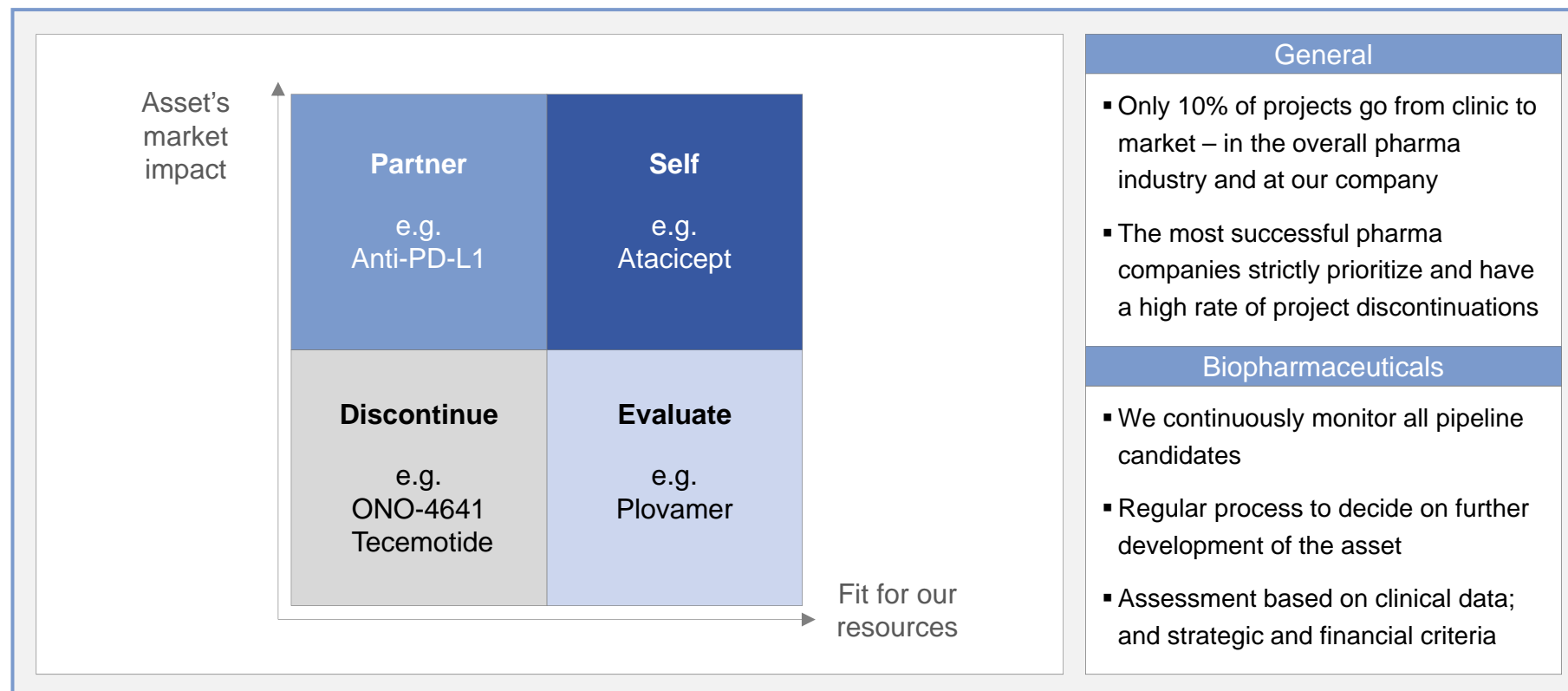
Project decisions depend on an asset's potential market impact and its value to the company

¹Pre-condition for all pipeline candidates: solid efficacy/safety data

Current view on R&D project prioritization in Phase II and III



Current view on R&D project prioritization in Phase II and III



Anti-PD-L1 – A promising asset

PRODUCT PROFILE

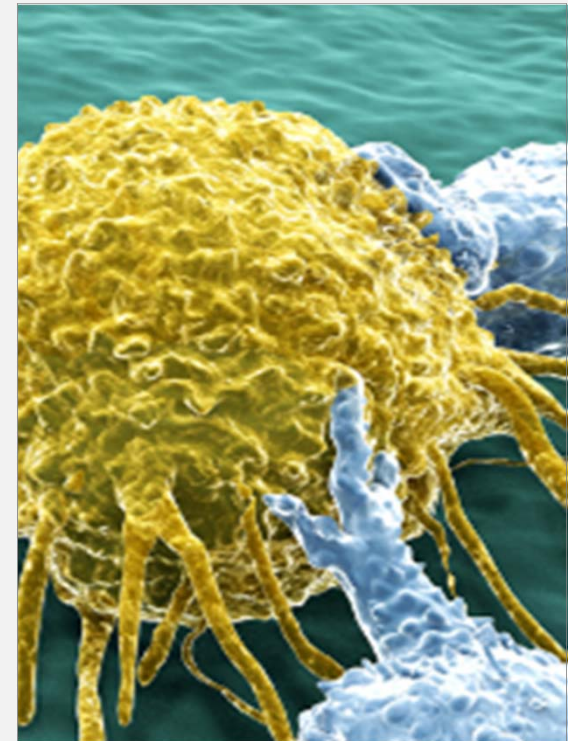
Increasing clinical evidence of competitive product profile

- Over 500 patients treated in Phase I study across multiple tumor types
- Interim analysis of expansion cohorts confirms promising risk/benefit on 2nd line NSCLC and heavily pre-treated ovarian cancer patients
- On-going Phase II study in m-Merkel cell carcinoma

GLOBAL CO-DEVELOPMENT AND CO-COMMER- CIALIZATION

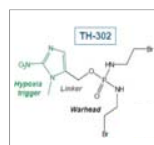
Strategic approach

- Competitive process for global co-development and co-commercialization has been initiated
- Decision will be driven by development, regulatory and commercial track record as well as deal financials
- Currently in advanced discussions with several oncology players



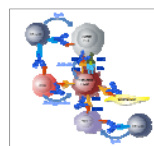
Indicative timeline for pipeline priority projects in selected indications

Pipeline Priority Projects¹



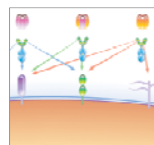
TH-302

Phase III	Soft Tissue Sarcoma	Interim Analysis	H2 2014
		Primary Analysis Date	H2 2015
Phase III	Pancreatic Cancer	Primary Analysis Date	H1 2016



Anti-PD-L1

Phase I	Various Indications	Interim Analysis	H2 2014
Phase II	mMCC ²	Primary Completion Date	H1 2016
Phase III	Various Indications	Under Preparation	H2 2014



Atacicept

Phase II	SLE ³	Primary Completion Date	H1 2016
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¹As of September 2014; ²Metastatic Merkel Cell Carcinoma; ³Systemic Lupus Erythematosus

Agenda

Our strategic priorities for sustainable success

Maximizing our core franchises

Driving Emerging Markets leadership

R&D for long-term sustainable growth

Executive summary

Biopharmaceuticals – Poised for sustainable growth

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Underlying business expected to remain resilient, stable and profitable

Improved R&D pipeline management will lead to improved pipeline productivity

Enhanced R&D to deliver long-term sustainable growth in specialty areas

Continuous upgrade of critical talent in core country and focus positions

Solid prospects of sustainable success



Back-up information

Erbitux

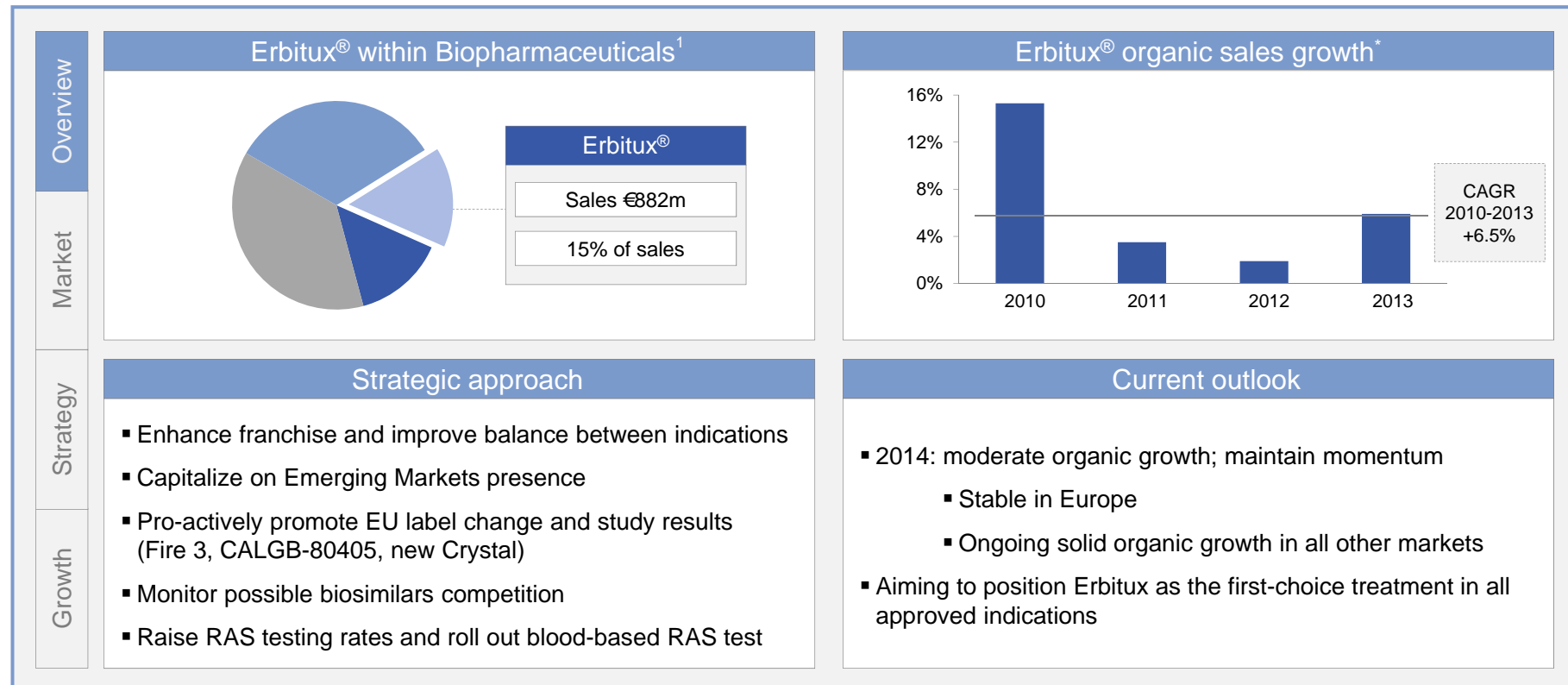
Rebif

Fertility

General Medicine

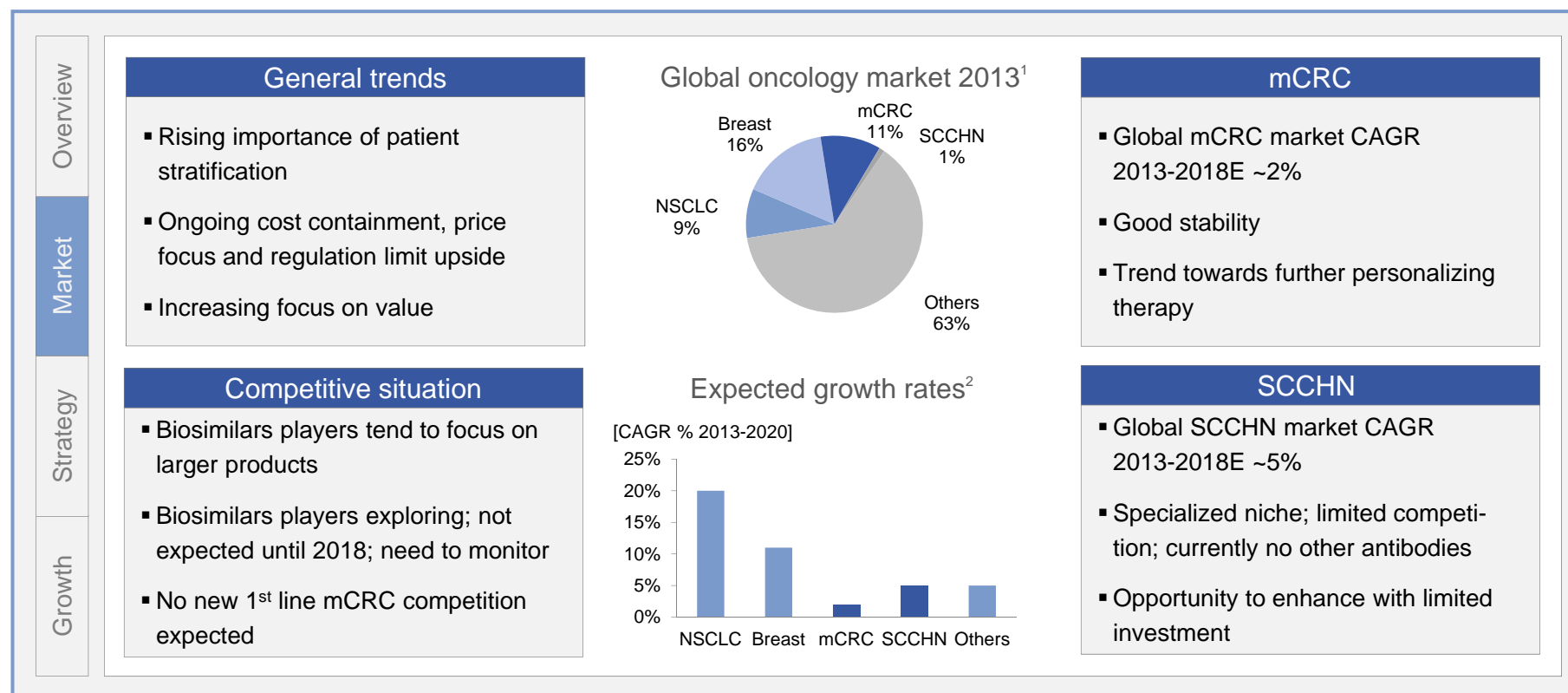
Erbitux® – Further enhancing the value of personalized treatments

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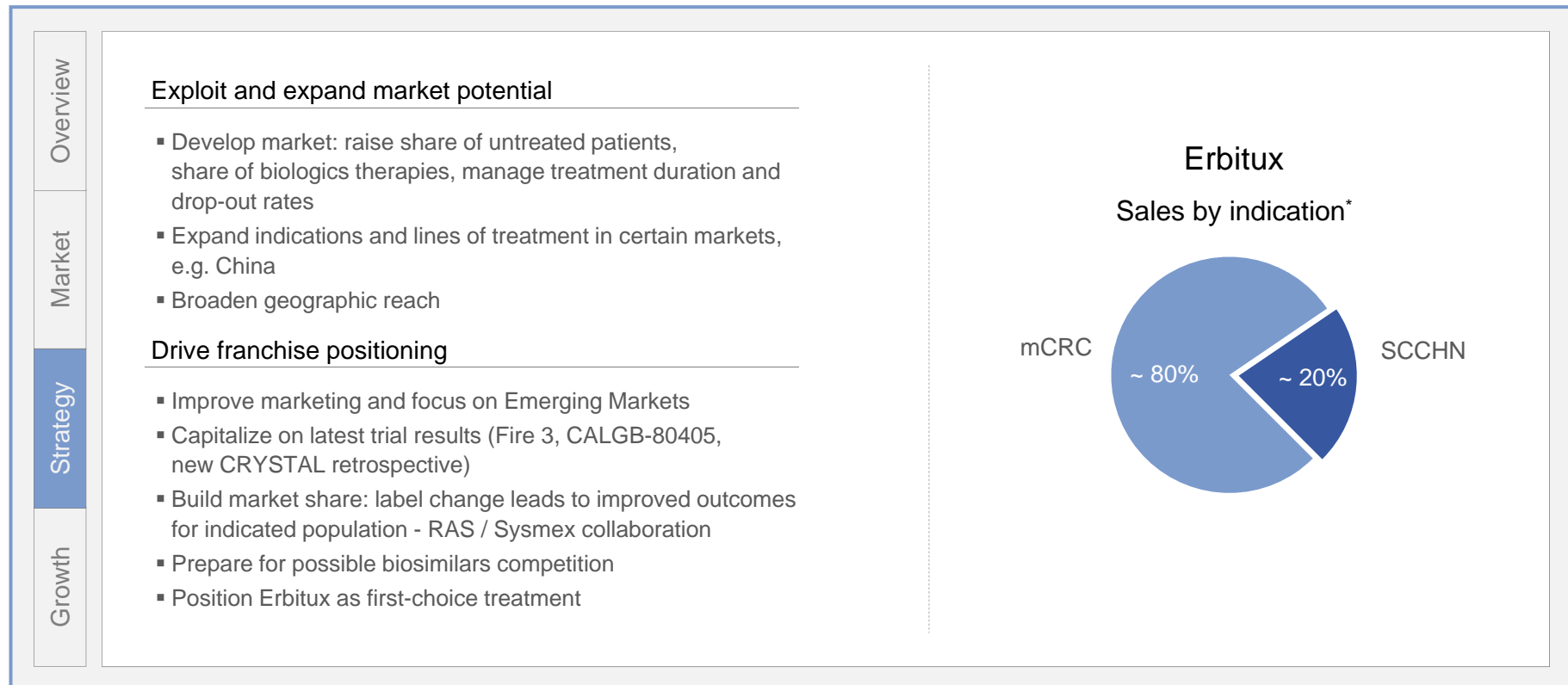
¹Source: Annual Report 2013

Erbitux® – Niche indications secure stability and competitiveness





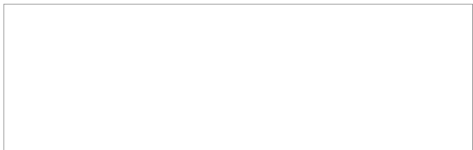
¹Source: Evaluate Pharma - All Cancer types & all products; ²Source: Evaluate Pharma - All Cancer types & all products by 2020 (currently marketed, filed, PhIII, PhII risk adjusted)
Sales data according to EvaluatePharma® a service of Evaluate Ltd. (UK), www.evaluategroup.com, accessed July 2014

Erbitux® – Strategies to raise value contribution for our company



*Only indicative

Erbitux® – Focusing on three areas of growth

Overview			
Market			
Strategy	<h3>Capitalize on clinical data</h3>  <ul style="list-style-type: none"> ▪ Clinical data: new CRYSTAL, Fire 3, CALGB-80405 ▪ Highlight Erbitux' advantages for targeted patient populations and relevance of RAS testing ▪ Prepare for possible biosimilars competition but not immediate effects expected 	<h3>Drive patient stratification</h3>  <ul style="list-style-type: none"> ▪ EU Label change (RAS*) in December 2013 allows to position Erbitux as an "all-RAS" therapy in mCRC in a crowded market ▪ Helps identify patients who are most likely to benefit from Erbitux, thus benefiting patients and payers ▪ Continuously raise RAS testing, supported by blood-based RAS test (Sysmex) which further reduces turn-around times for results 	<h3>Develop regions</h3>  <ul style="list-style-type: none"> ▪ Expand into indications and regions (e.g. SSCHN China) and into new lines of treatment ▪ Japan: gradual improved marketing shows visible results in mCRC; successful launch into head & neck indication ▪ Emerging Markets: Focus on Latin America (Brazil / reimbursement); China (ongoing trials)
Growth			

*RAS = rat sarcoma

Back-up information

Erbitux

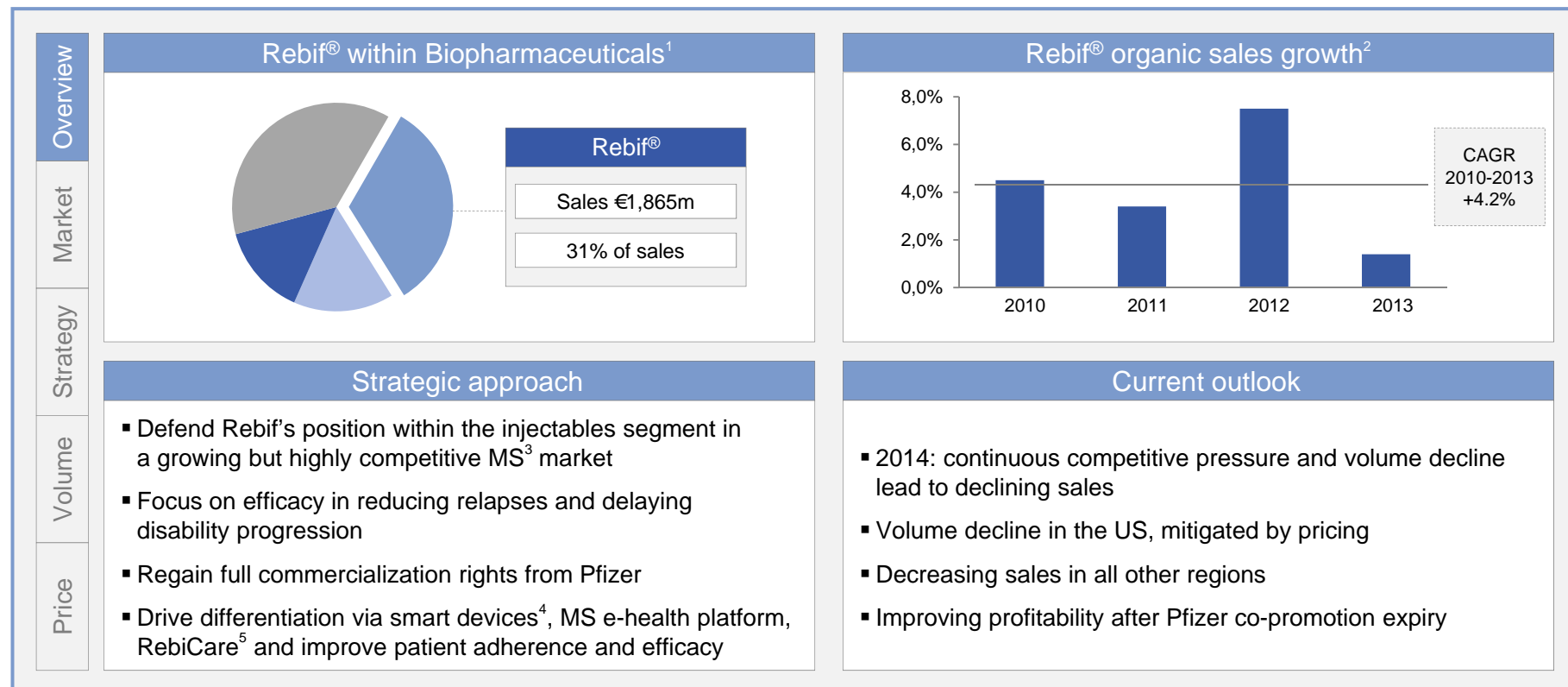
Rebif

Fertility

General Medicine

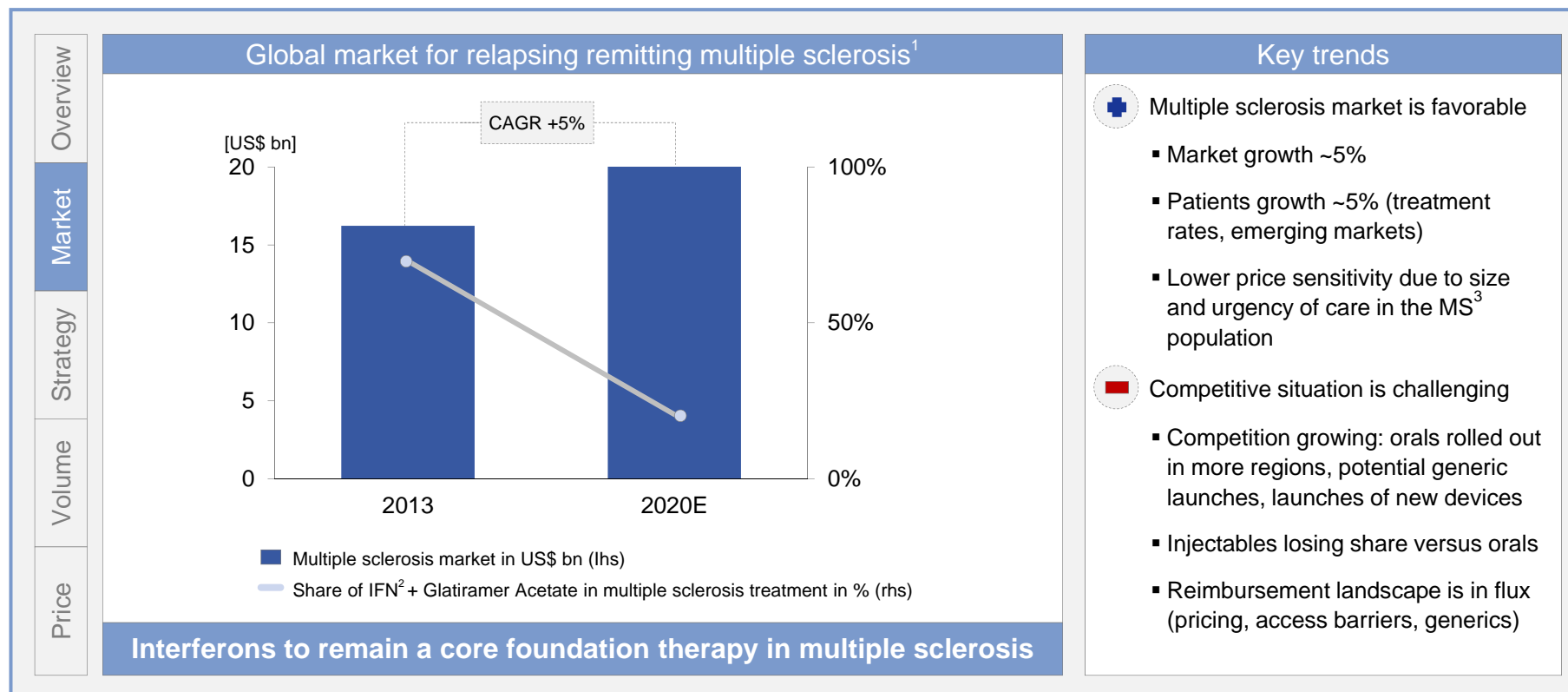
Rebif® – Defending the franchise

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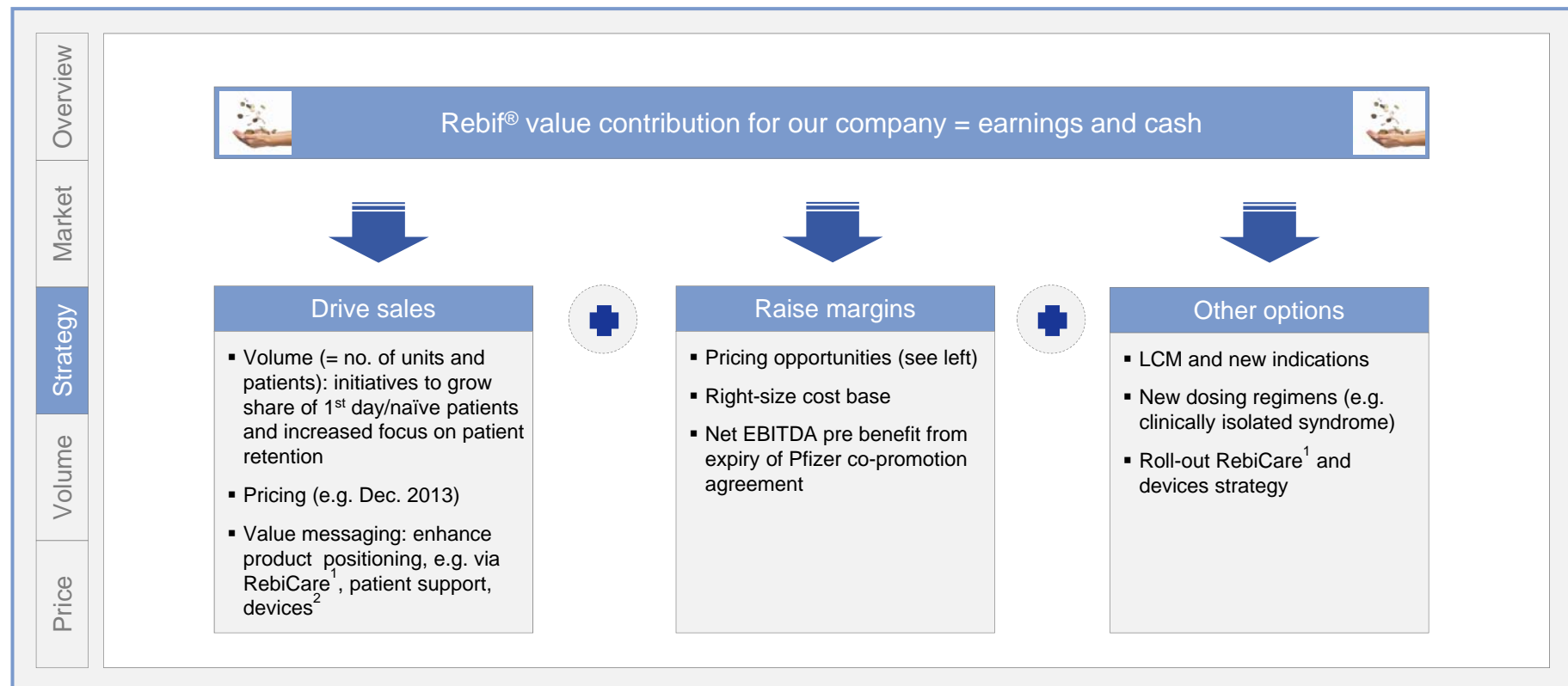
¹Source: Annual Report 2013; ²Source: Biopharmaceuticals; ³MS = multiple sclerosis; ⁴Not all devices are available in all markets; ⁵Not available in the U.S.

Rebif® – Competitively challenging but growing market



¹Source: Sales data according to EvaluatePharma® a service of Evaluate Ltd. (UK), www.evaluategroup.com, accessed September 2014; ²IFN = interferons; ³MS = multiple sclerosis

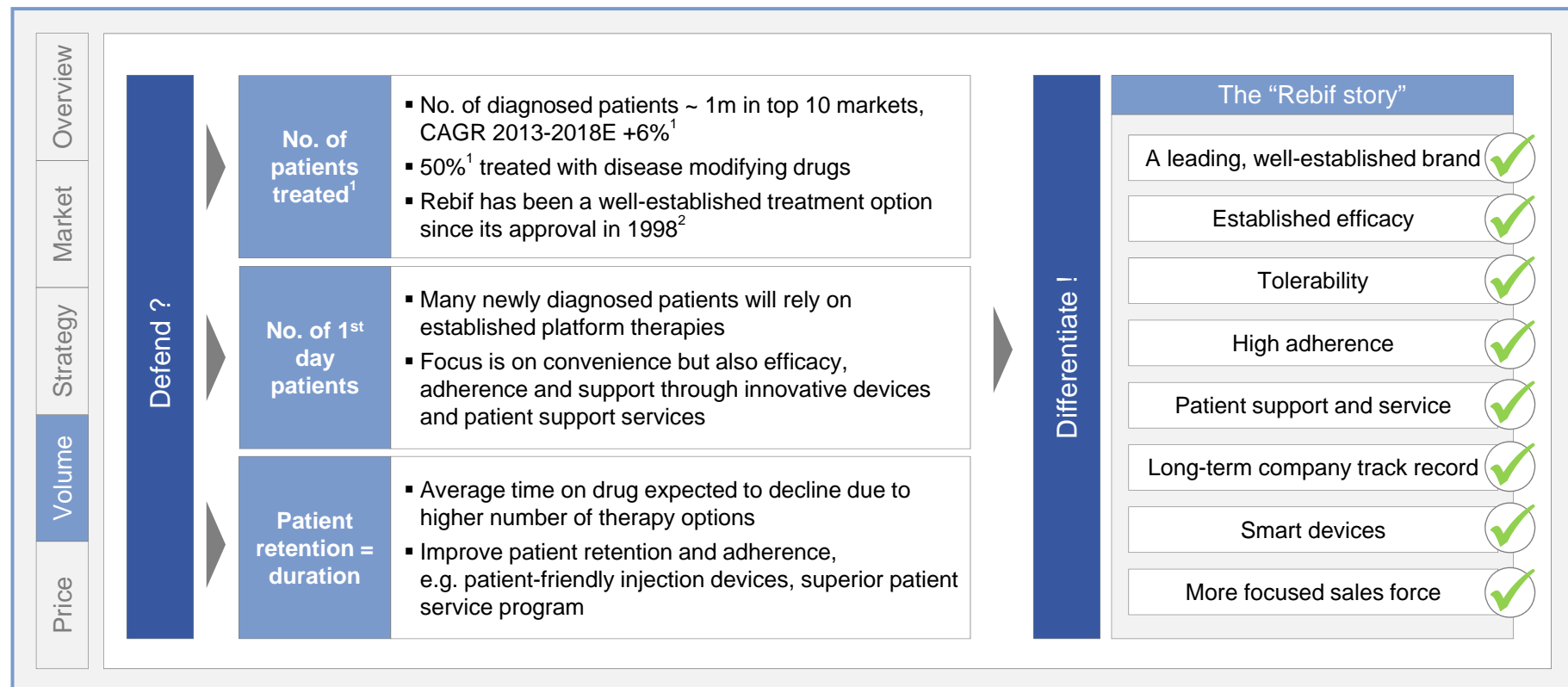
Rebif® – Several levers to sustain Rebif's value



¹Not available in the U.S.; ²Not all devices are available in all markets

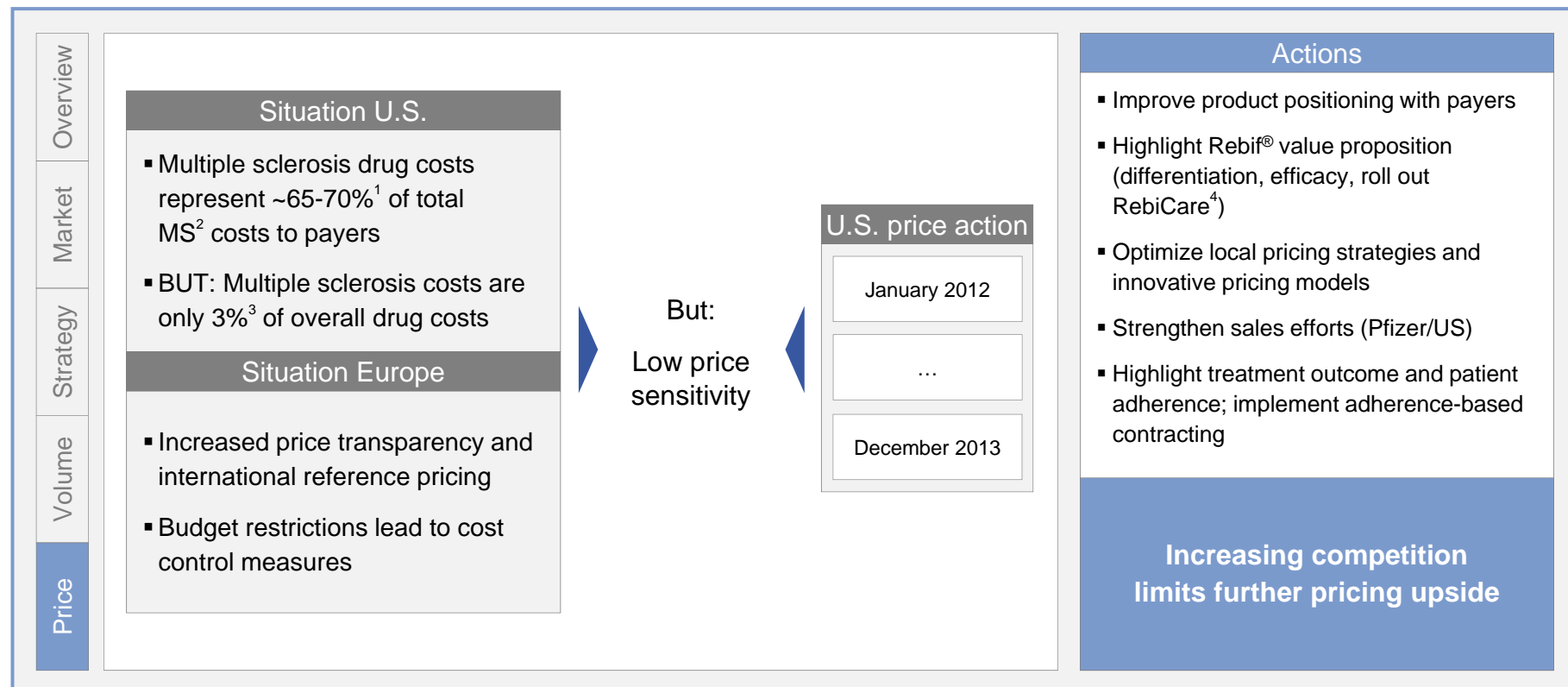
Rebif® – Initiatives to differentiate and defend share

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¹Multiples sclerosis; Source: Biopharmaceuticals; ²Approval in the EU, approval in the U.S. in 2002

Rebif® – Priorities for value pricing



¹Source: Biopharmaceuticals with 2013 data from GBI and IMS Health ; ²MS = multiple sclerosis ; ³Source: Prime Therapeutics' Abstract 2012; ⁴Not available in the U.S.

Back-up information

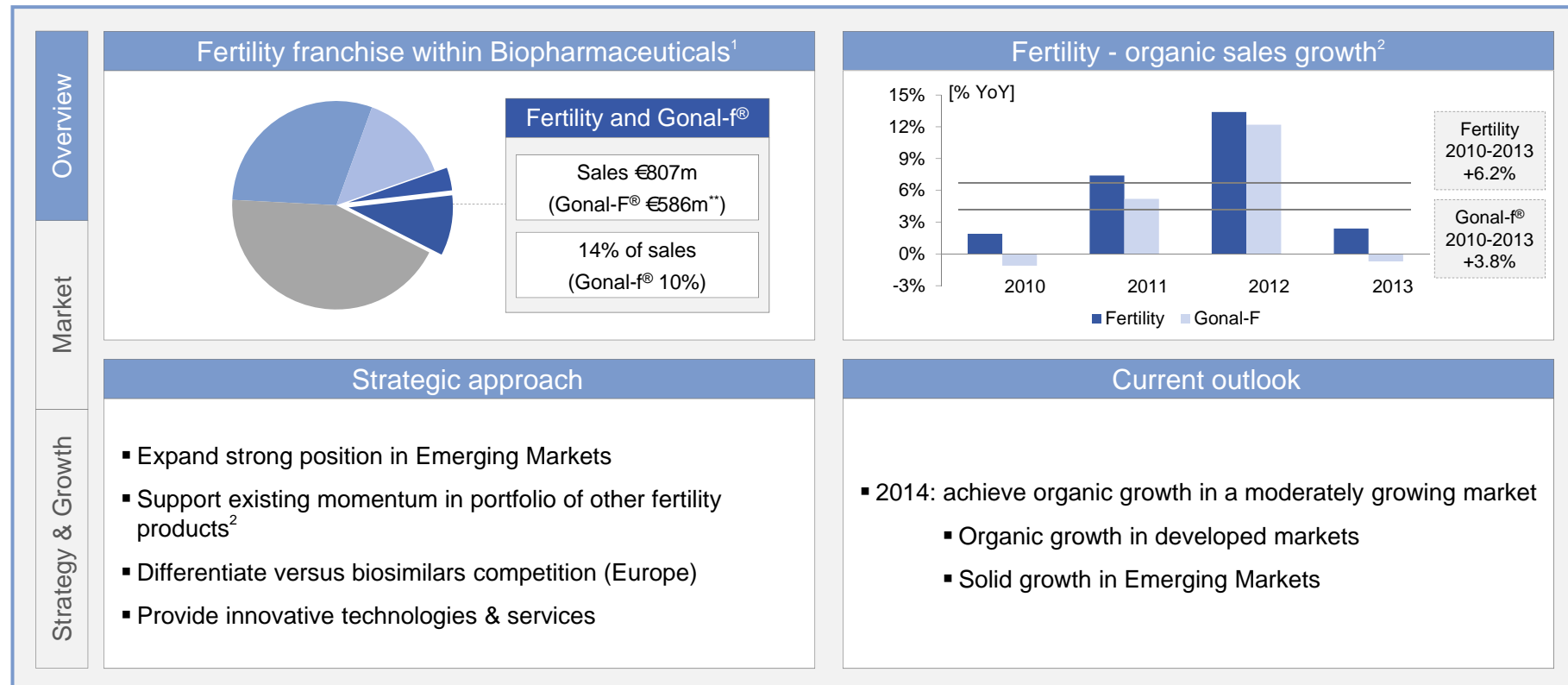
Erbitux

Rebif

Fertility

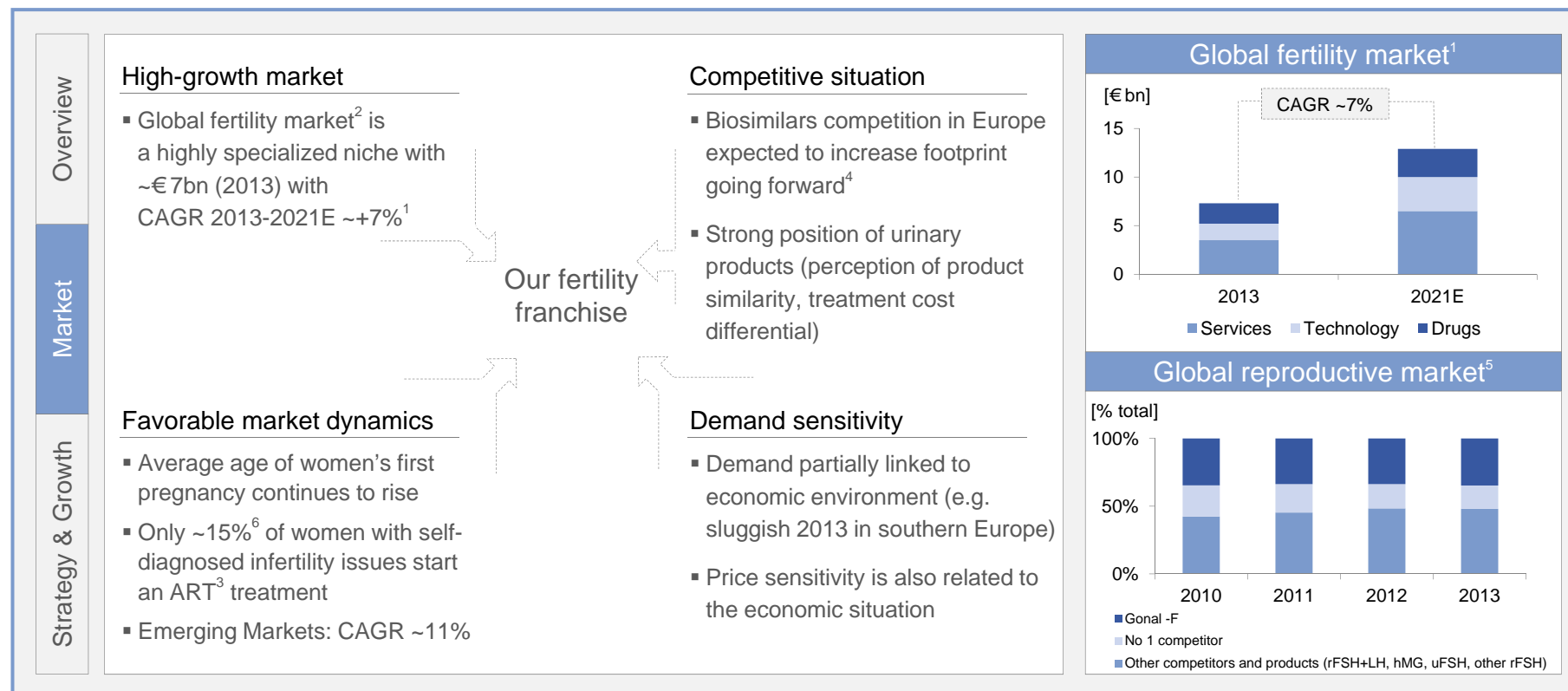
General Medicine

Fertility – Taking the franchise to beyond drugs



¹Source: Annual Report 2013; ²Other products included in the Fertility franchise: Cetrotide, Ovidrel, Crinone, Pergoveris

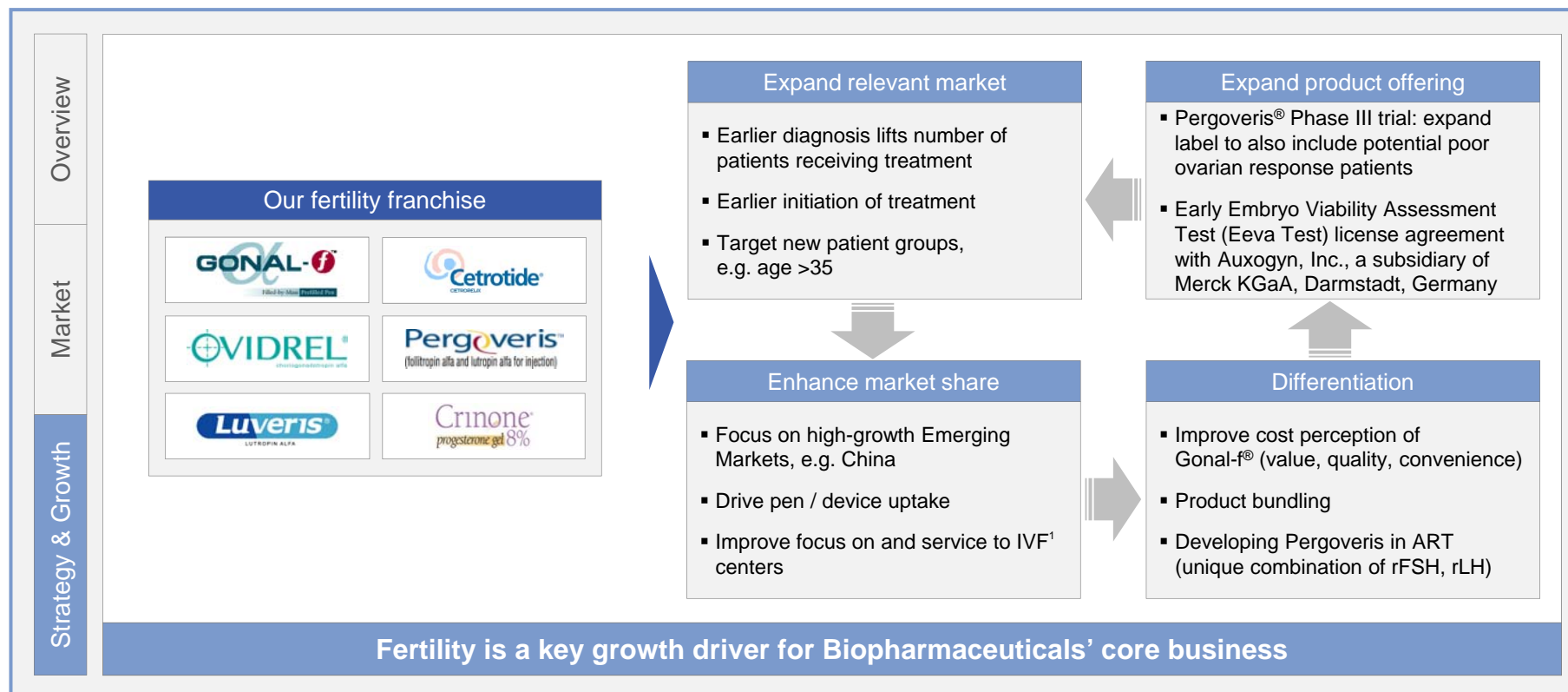
Fertility – Sustainable market trends key drivers of continued growth



¹Source: Biopharmaceuticals based on Transparency market research 2010; US IV Clinics 2011, CDC, ESHRE, press; ²Includes drugs, technology, services; Source: Biopharmaceuticals based on Transparency market research 2010; US IV Clinics 2011, CDC, ESHRE, press; ³ART = Assisted Reproductive Technology; ⁴Approved and launched in various markets;

⁵Source: Biopharmaceuticals based on own research, BCG; ⁶Biopharmaceuticals market research

Fertility – Four opportunities to drive franchise growth



¹IVF = in-vitro fertilisation

Back-up information

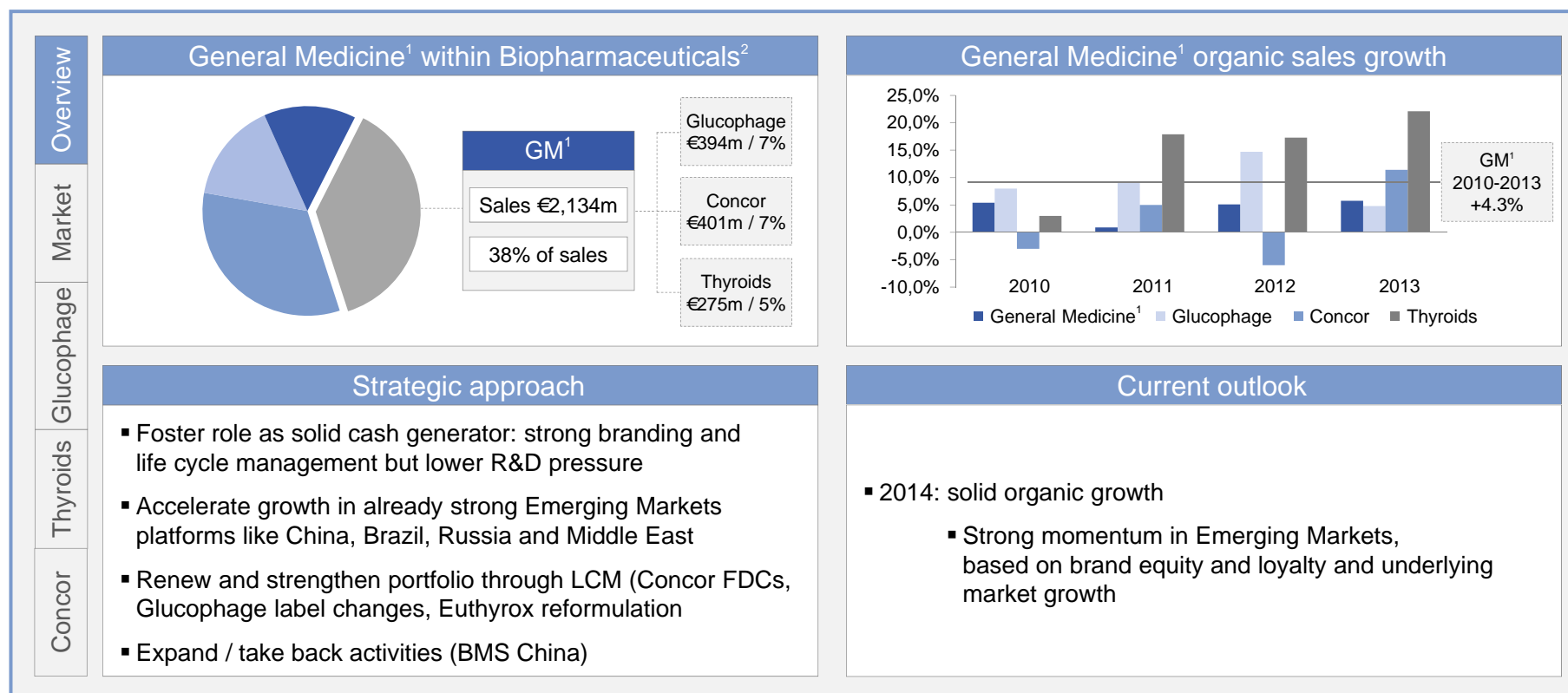
Erbitux

Rebif

Fertility

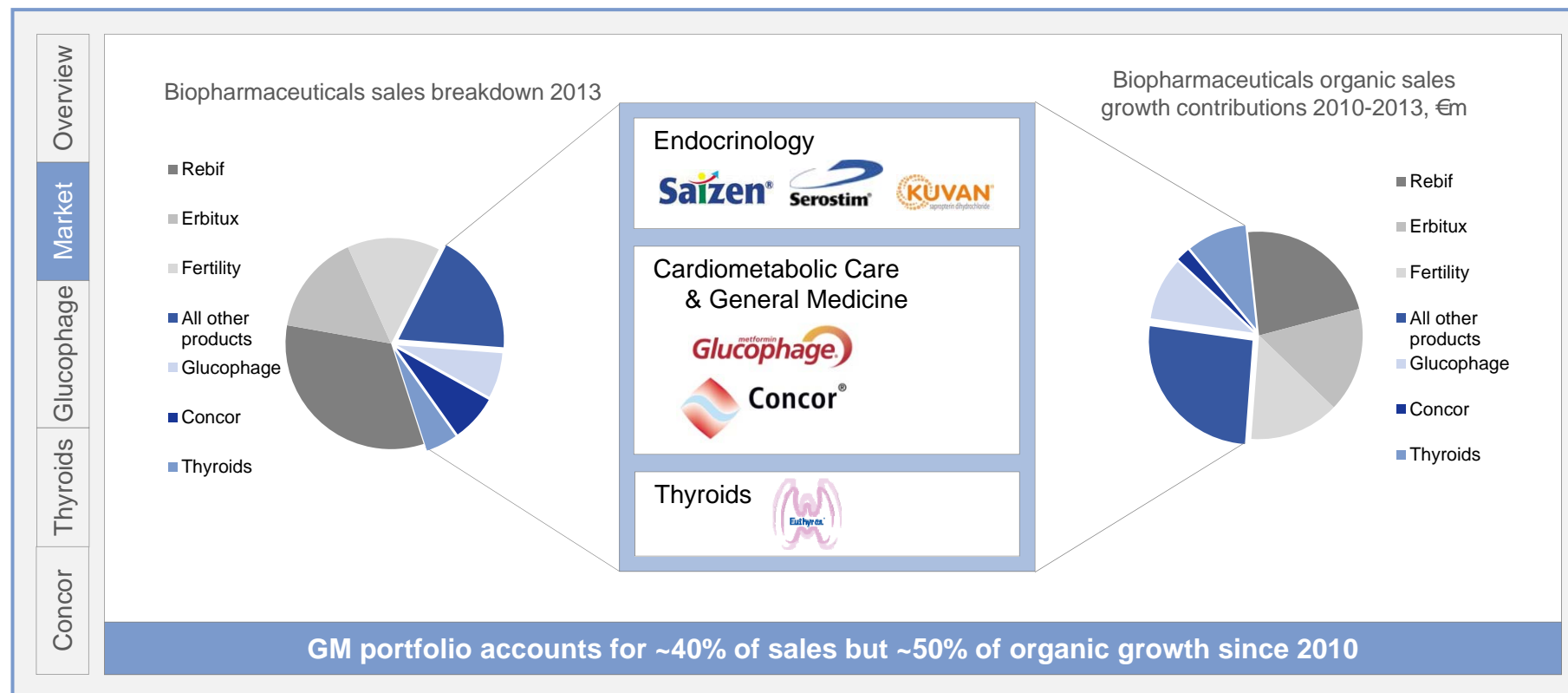
General Medicine

General Medicine¹ – Strong Emerging Markets franchise enables continued profitable growth



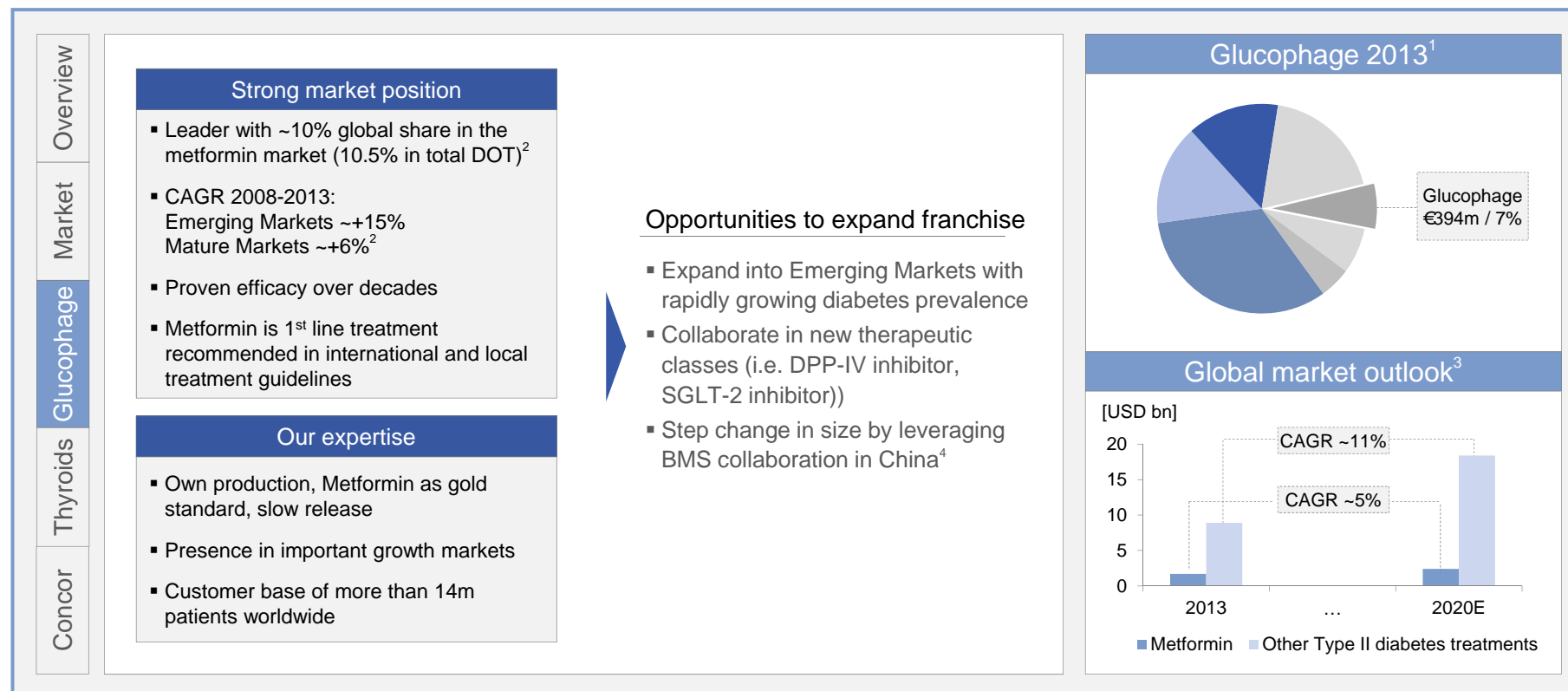
¹GM = General Medicine including General Medicine, Cardiomatabolic Care, Endocrinology, Others; ²Source: Annual Report 2013

General Medicine – Growth engine for Biopharmaceuticals in the past and future



General Medicine – Glucophage®

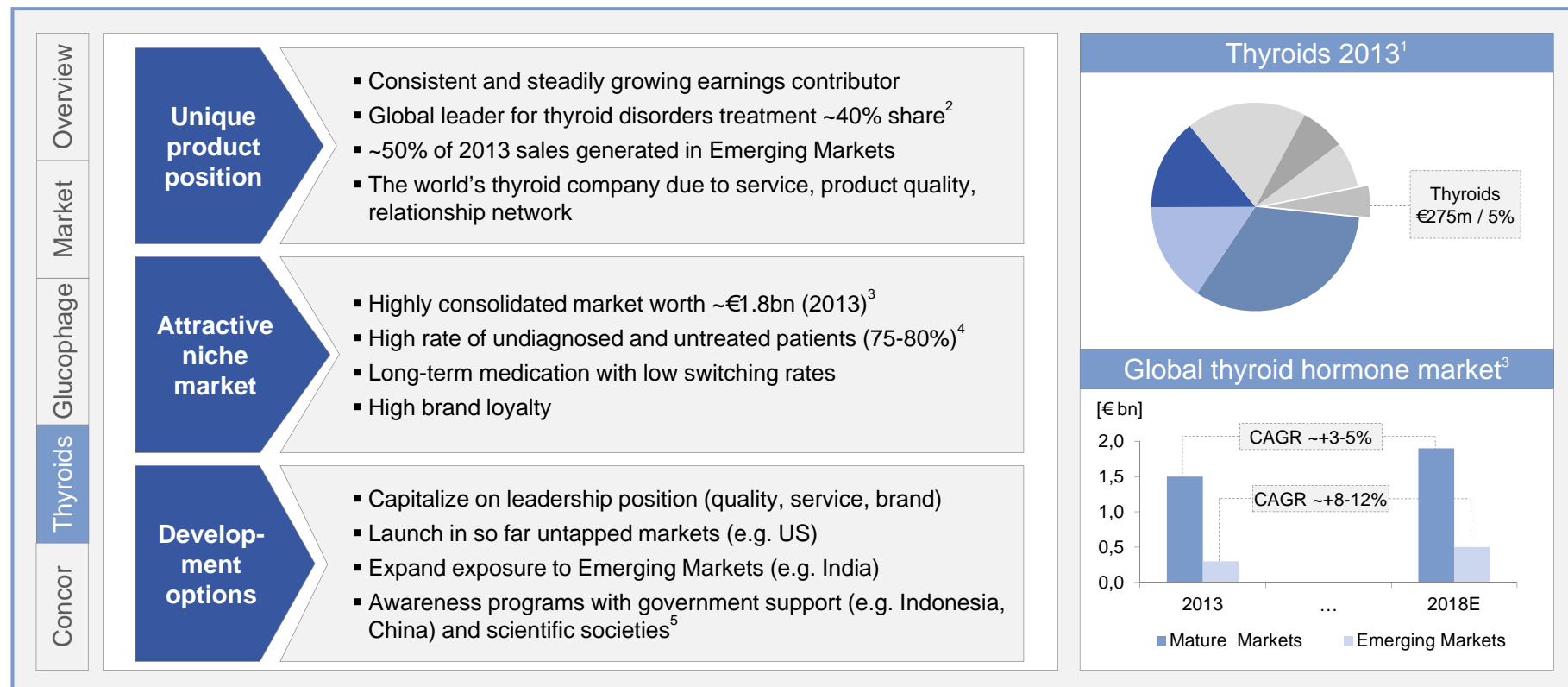
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¹Source: Annual Report 2013; ²Source: IMS Midas; ³Source: Sales data according to EvaluatePharma® a service of Evaluate Ltd. (UK), www.evaluategroup.com, accessed July 2014;

⁴Current co-promotion to end at the end of 2016; new plant as of 2018

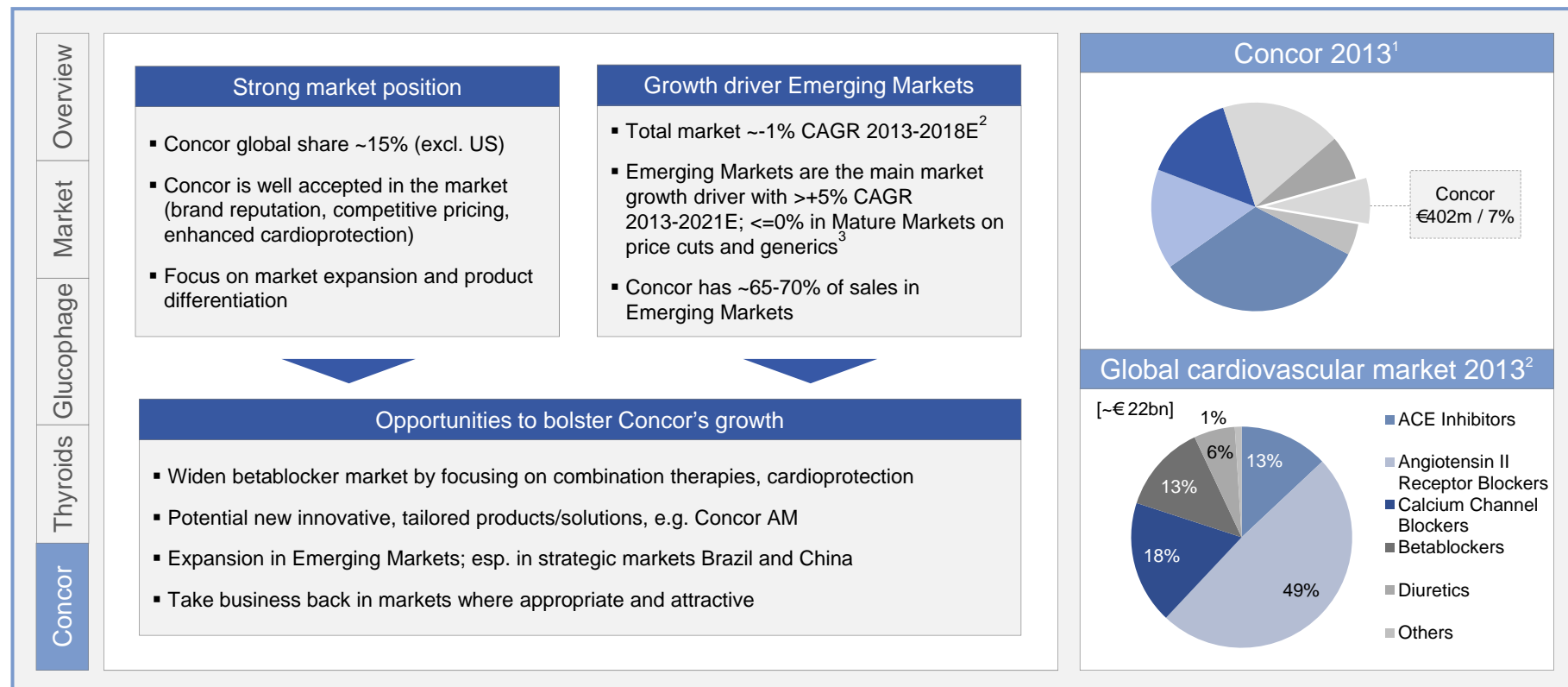
General Medicine – Thyroids



¹Source: Annual Report 2013; ²Source: IMS, Midas, 2013 without US-Market (incl. US = 13%); ³Source: IMS, Dataview, 2013; excluding U.S.; ⁴Own Estimate (Expert Opinion, CTY expectation); ⁵E.g. International Awareness Thyroid Week

General Medicine – Concor®

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¹Source: Annual Report 2013; ²Source: Sales data according to EvaluatePharma® a service of Evaluate Ltd. (UK), www.evaluategroup.com, accessed July 2014;

³Sources: Cardiovascular: IMS, Biopharmaceuticals, validation by regions

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