medigene
developing innovative therapies

Annual Report 2012

March 22, 2013

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Agenda

- **Overview & Marketing Activities:**
  Dr. Frank Mathias (CEO)
- **Drug Pipeline:**
  Dr. Norman Neville (Senior Vice President R&D)
- **Financial Report 2012 & Outlook:**
  Peter Llewellyn-Davies (CFO)
- **Q&A-Session**

2012: progress in marketing, drug pipeline and financial structure

- Refocussing of pipeline
  - Monetization of Eligard®
- Successful concentration on three core projects:
  - Veregen®:
    further market launches, approvals and partnerships
  - EndoTAG®-1:
    co-development and marketing partnership for Asia
  - RhuDex®:
    phase II clinical trial in preparation
- Change in the Executive Board
  - Peter Llewellyn-Davies joined Executive Board of Medigene AG

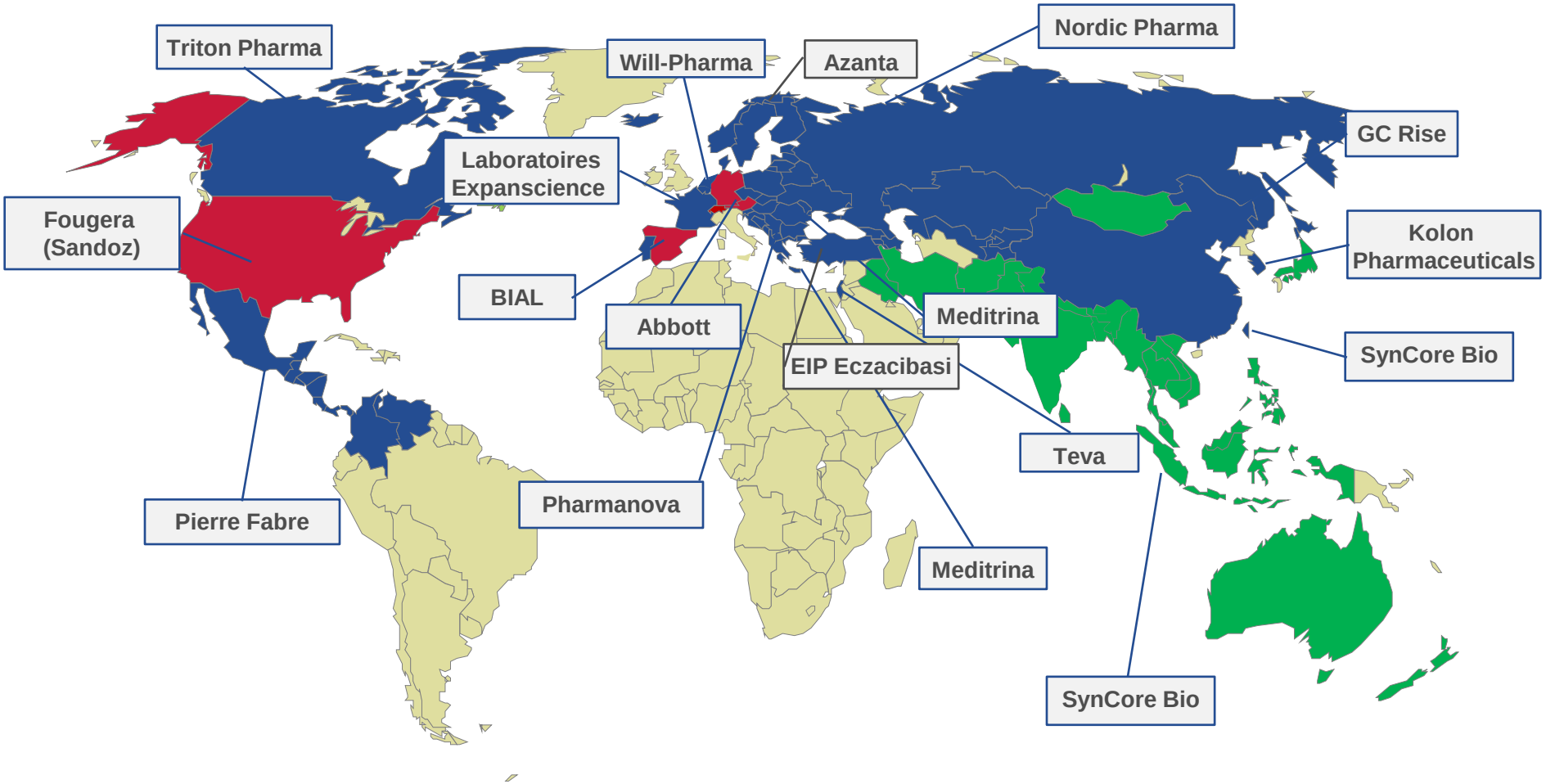
Marketing Activities

Dr. Frank Mathias, CEO

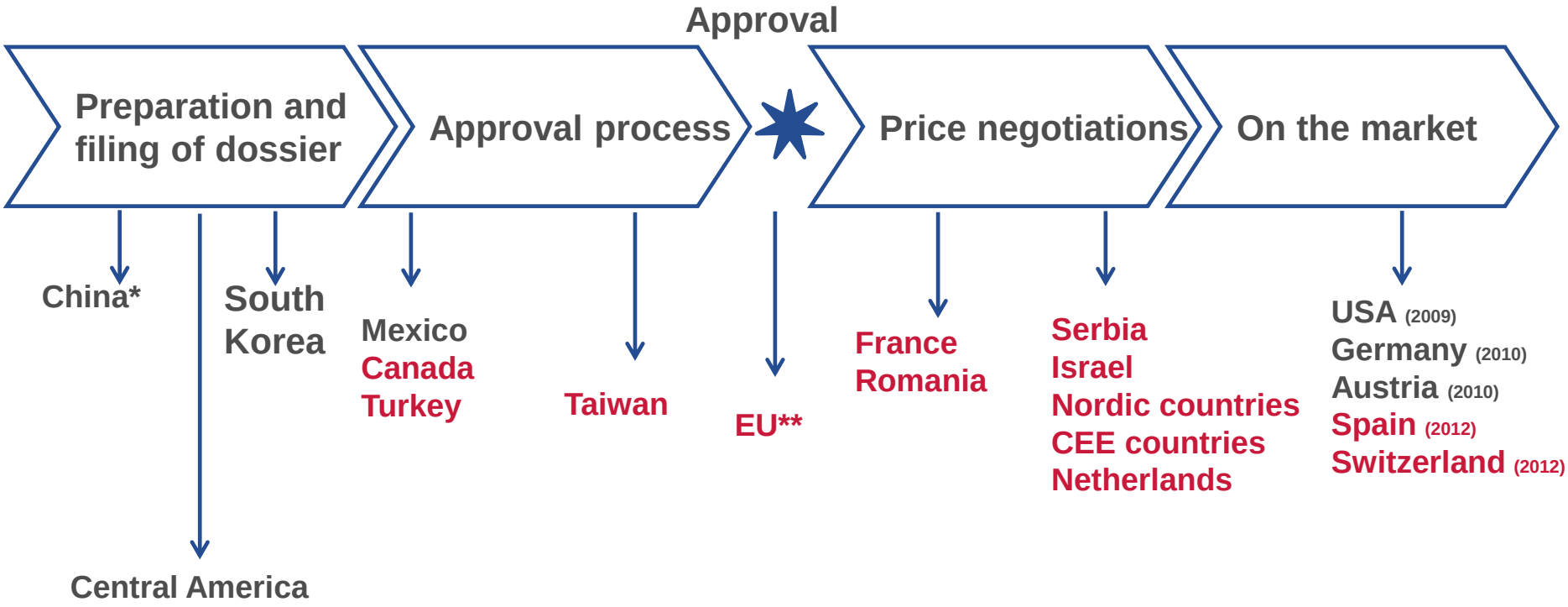
Veregen®: further market launches and approvals

- Market launch in Spain and Switzerland
- Market approval in 17 European countries and Israel
  - including France, the Nordic countries and growth markets in Eastern Europe
  - Market launch of most of these countries in 2013
- Partnership agreements for the marketing of Veregen® in Turkey, the Nordic countries as well as Eastern Europe, Russia and the other CIS countries

Veregen®: Worldwide partnerships expanded



Veregen®: Global regulatory and reimbursement progress

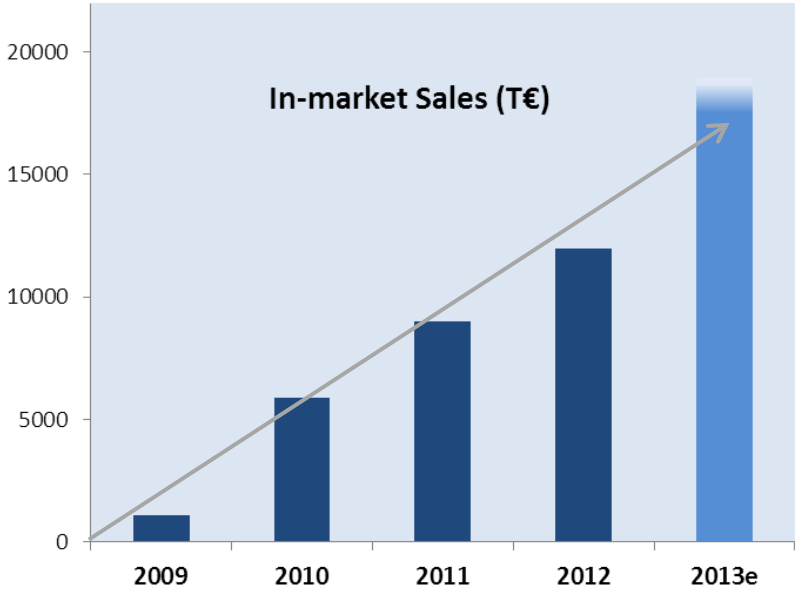


* Preparations for the start of the necessary clinical studies are in progress

** Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Hungary, Luxembourg, The Netherlands, Norway, Poland , Romania, Sweden, Slovakia, and Slovenia

Veregen®: Solid foundation for company with rising sales

- Global in-market sales generated by multiple partners
- Medigene receives three revenue components on Veregen:
  - Product supply revenues at pre-agreed terms
  - Blended royalty on sales of 10-15%
  - Regulatory and commercial milestones
- Growth being driven by:
  - Sales uptake in current markets
  - New market launches
  - New partnerships



Drug pipeline

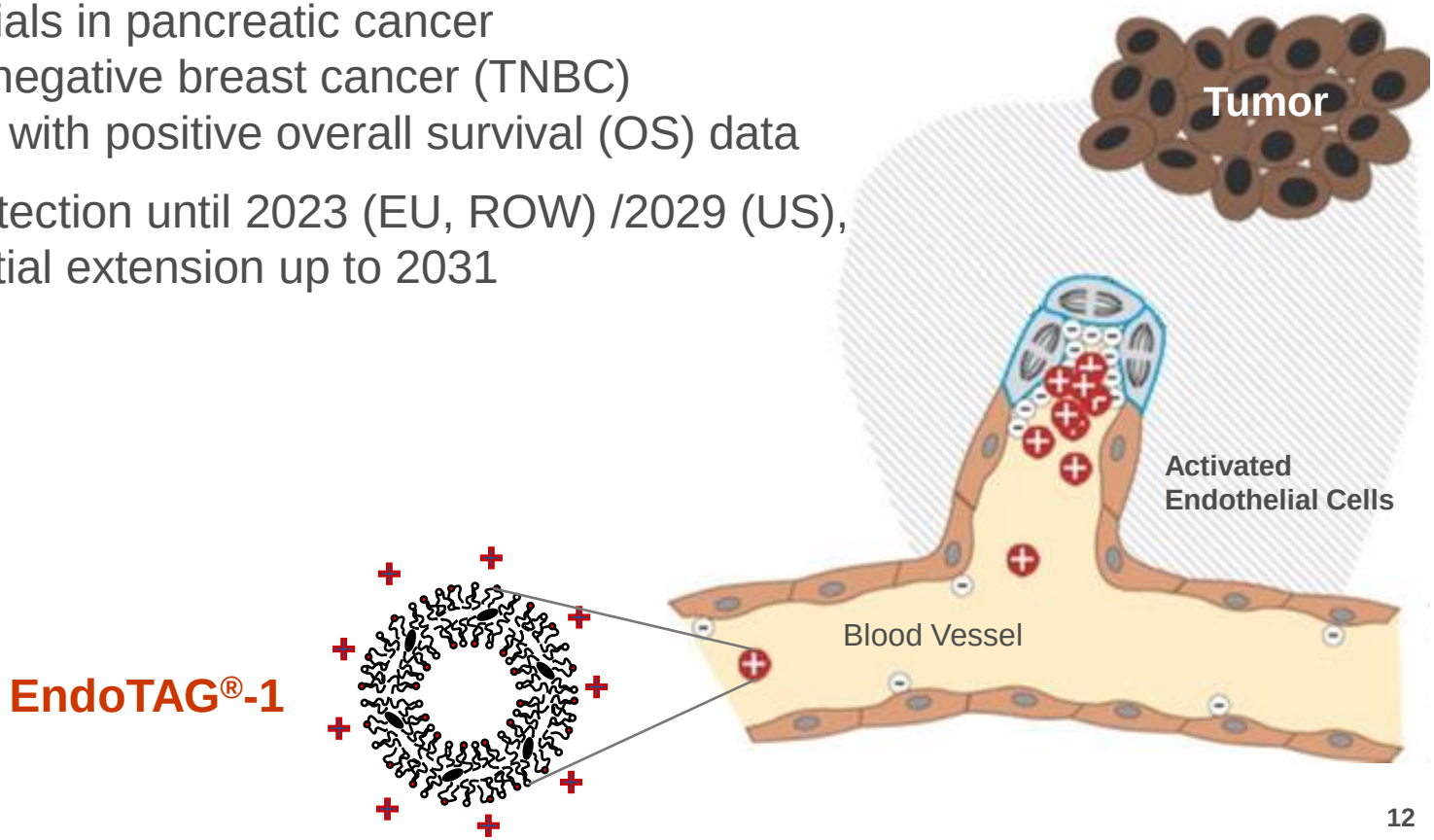
Dr. Norman Neville, Senior Vice President R&D

Our product portfolio

PRODUCT	INDICATION	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKETED	RIGHTS
Eligard®	Prostate cancer						Fully monetized
Veregen®	Genital warts						Multiple partners
EndoTAG®-1	Pancreatic & breast cancer						Medigene / Syncore
RhuDex®	Autoimmune diseases						Medigene
AAVLP	Vaccine platform						Medigene
Chance of reaching the market		<10 %	<15 %	<30 %	<70 %		

EndoTAG®-1 for triple-negative breast cancer (TNBC)

- Novel composition of Paclitaxel combined with neutral and cationic lipids
- Phase II trials in pancreatic cancer and triple-negative breast cancer (TNBC) completed with positive overall survival (OS) data
- Patent protection until 2023 (EU, ROW) /2029 (US), with potential extension up to 2031



EndoTAG®-1: Two Phase II studies completed with positive clinical data for OS

Phase II in pancreatic cancer

- Controlled, randomized trial in 200 patients
- Three dose groups (EndoTAG®-1 + Gemcitabine)
- Control group (Gemcitabine only)
- Primary endpoint: Overall survival met in combination arm

mOS up to 13.6 months (versus control Gemcitabine 6.8 months) in patients with repeated cycles

Phase II in triple-negative breast cancer

- Controlled, randomised, open label trial in 135 patients
- Three dose groups (EndoTAG®-1; EndoTAG®-1 + Paclitaxel; control group: Paclitaxel only)
- Primary endpoint: 16 weeks PFS rate of at least 30% met in combination arm

mOS (41 weeks) up to 13 mths versus control paclitaxel 10 mths

mOS in subgroup (ECOG 0/1, first line) up to 17.8 months

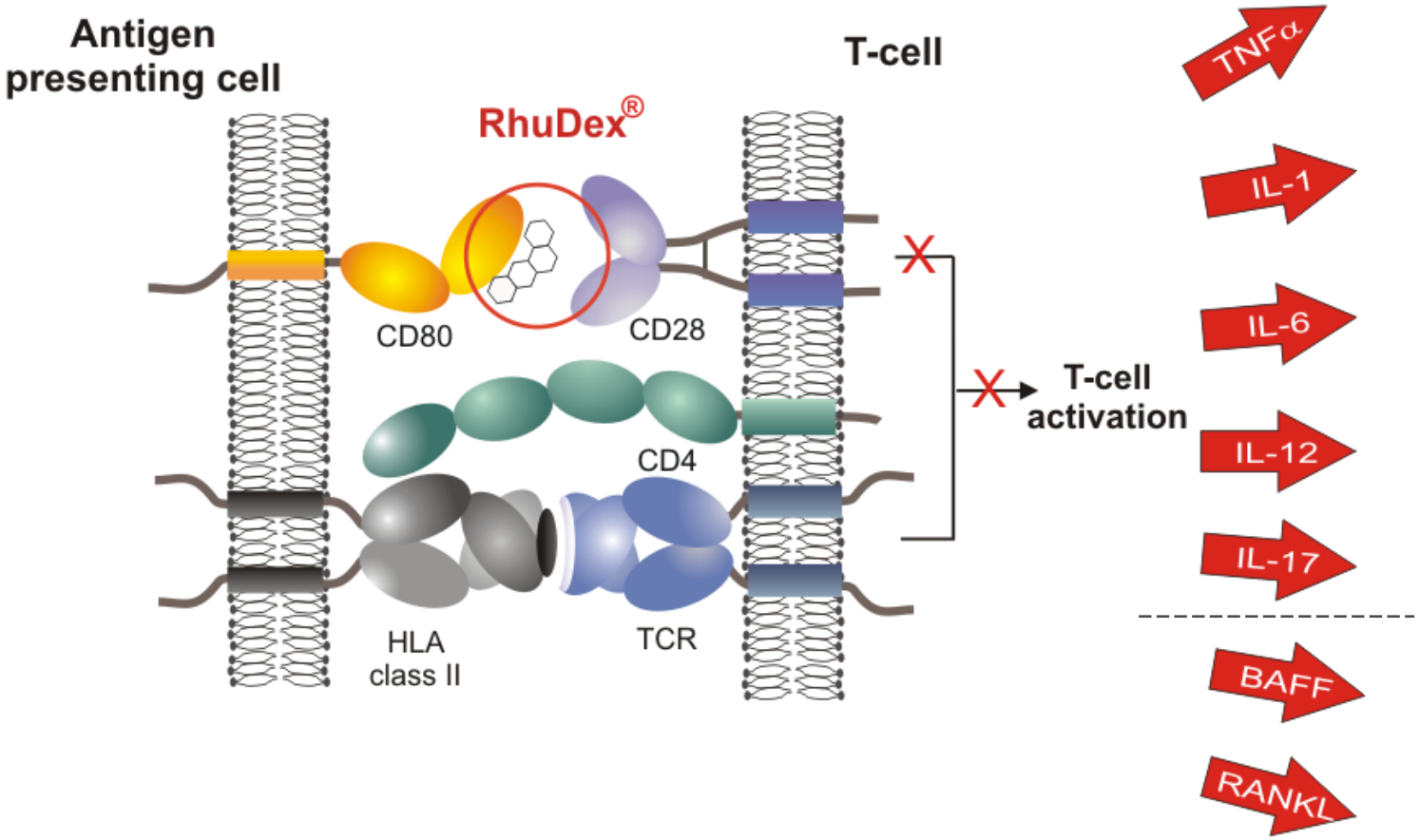
EndoTAG®-1: Development and commercialization plan

- Global development plan for triple-negative breast cancer (TNBC)
  - TNBC affects approx. 15% of all breast cancer patients
  - Phase III trial planned post commercial manufacturing scale up
- Partnership with SynCore in Asia, Australia and New Zealand co-funds trial approx. 50%
- Medigene retains all US, European and remaining RoW rights
  - Potential for further partnerships to close financing gap
- Potential to develop in additional indications
  - HER2 negative breast cancer (70-85% of BC pts)
  - Data of Investigator initiated trial (IIT) in combination with paclitaxel completed and support activity of EndoTAG®-1
  - Pancreatic cancer trial successful completed with OS benefit data

Innovative mode of action: RhuDex® inhibits CD80 mediated T-cell activation

RhuDex® inhibits T-cell activation, proliferation and related cytokine secretion

Most current therapies block only individual mediators



RhuDex®: Innovative small molecule, oral therapy for autoimmune disease

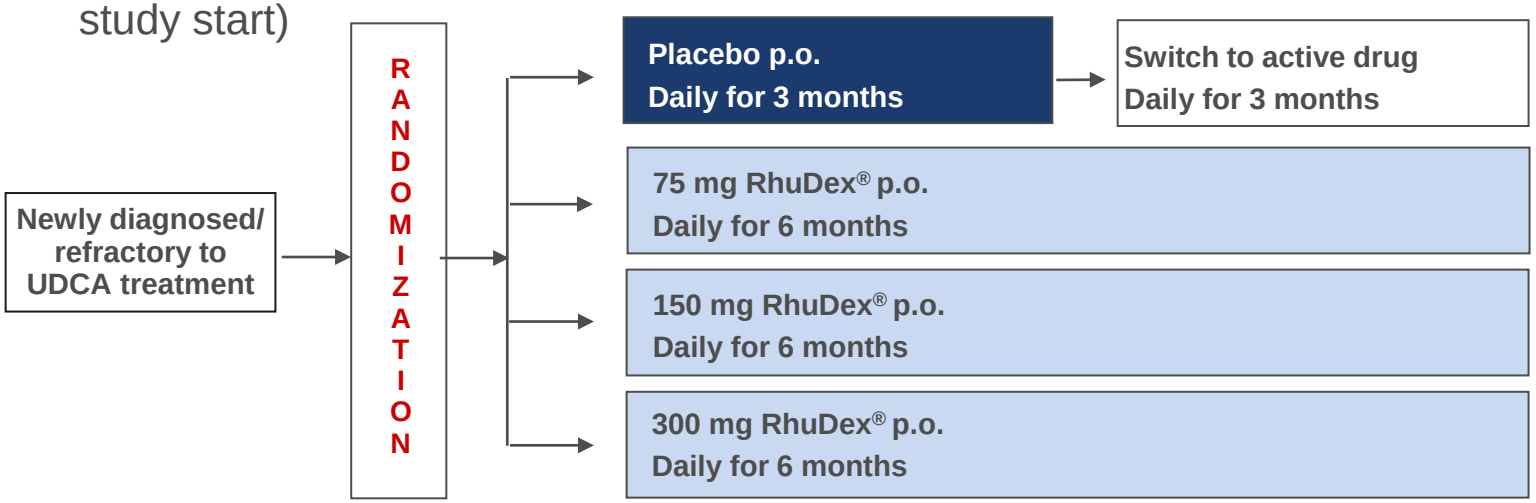
- Blocks T-cell activation and proliferation via CD80 pathway
- Well characterized clinical safety/tolerability in 6 Phase I and 1 Phase IIa studies
- Tested in 66 healthy volunteers and 20 patients with rheumatoid arthritis (RA)
- Clinical formulation study successfully completed; current data appear suitable for chronic dosing
- Plan to verify clinical relevance of mode of action in Phase II trial in primary biliary cirrhosis (PBC)
- Broad patent protection until 2024/27 (possible extension of up to 5 years)

RhuDex®: Overview of development strategy

- Obtain market approval in PBC – attractive niche market
  - Orphan disease, high medical need for disease-modifying drugs
  - CD80 identified as risk gene
  - RhuDex® could become the first etiological and disease-modifying treatment
- Suitable indication to verify autoimmune modulating mode of action of RhuDex® in a Phase II monotherapy trial
  - Potential to generate widely accepted clinical data on relevant, easily accessible disease parameter modification
  - PBC patients do not receive immunomodulating baseline therapy (as e.g. in RA). RhuDex® safety and efficacy advantage can be addressed simultaneously
- Comprehensive translational data package

RhuDex®: Phase II study planned in primary biliary cirrhosis (PBC)

- Randomized, placebo-controlled, double-blind Phase II study to evaluate efficacy and safety of RhuDex® in subjects with PBC
- International, multicenter study
- Commence study H1/2014
- Subject to successful completion of necessary preparatory work and approval by regulatory authorities
- Placebo patients will switch to active drug after 3 months
- Results for primary endpoint expected by end of 2015 (approx. 18 months after study start)

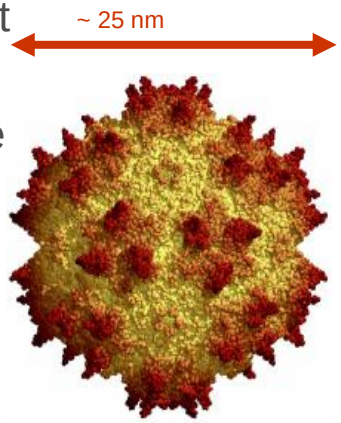


RhuDex®: PBC trial endpoints reflect current clinical and regulatory acceptance to support market authorization

- Primary endpoint:
  - Change from baseline in serum alkaline phosphatase (sAP) levels
  - 3-month readout combined with 6-month efficacy and safety data
- Secondary endpoints to evaluate liver function:
  - Change from baseline for AST and/or ALT (GOT/GPT), bilirubin (total and unconjugated), gamma GT, total serum bile acid concentrations, anti-AMA and ANA titer, in health-related quality of life (PBC-40)
  - Voluntary liver biopsies at baseline and End of Trial / follow-up in addition to current translational strategy

AAVLP: Novel vaccination technology with promising preclinical data

- Chimeric adeno-associated virus-like particles (AAVLP) are non-infectious and non-replicating protein particles
  - Multiple presentation of two different peptides within one particle possible
- Promising preclinical data from cooperation with Johns Hopkins University presented at World Vaccine Congress in spring 2012
  - Vaccination of mice with an AAVLP vaccine carrying HPV L2 epitopes induces in vitro cross-neutralizing antibodies active against several HPV serotypes
  - Stable protection against vaginal HPV serotype 16 in vivo challenge over three months
- Long term preclinical in vivo study ongoing in cooperation with the Pennsylvania State University with the aim to show:
  - Stable cross protection after in vivo challenge with several HPV serotypes
  - Longevity of titers up to 12 months



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Financial Report 2012

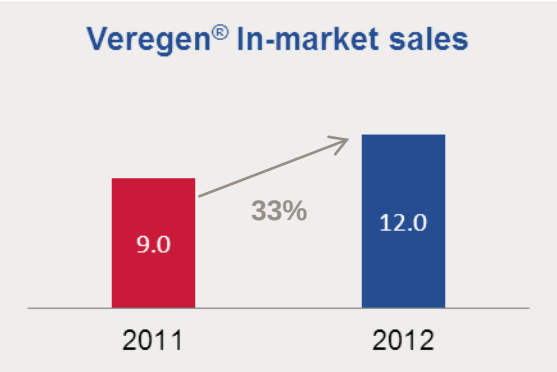
Peter Llewellyn-Davies, CFO

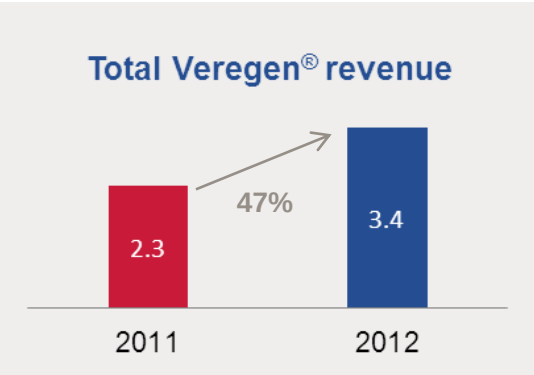
Financial highlights: Increasing sales and solid financial development

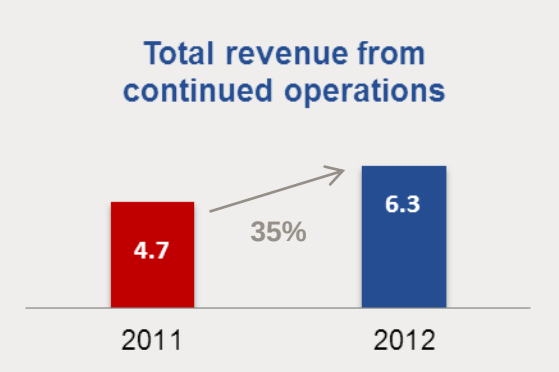
- Continued operations:
  - Total revenue increased by 35% to €6.3 million (2011: €4.7 million)
  - Veregen® revenue increased by 47% to €3.4 million (2011: €2.3 million)
  - EBITDA: €-9.4 million improved by 14% (2011: €-11.0 million)
- Discontinued operations: revenue of €5 million from Astellas
- Financial guidance for 2012 surpassed
- Operative business with higher revenue and reduced costs
- Solid financial situation with cash reach at least until end of 2014

Increase in revenue from continued operations

In € million

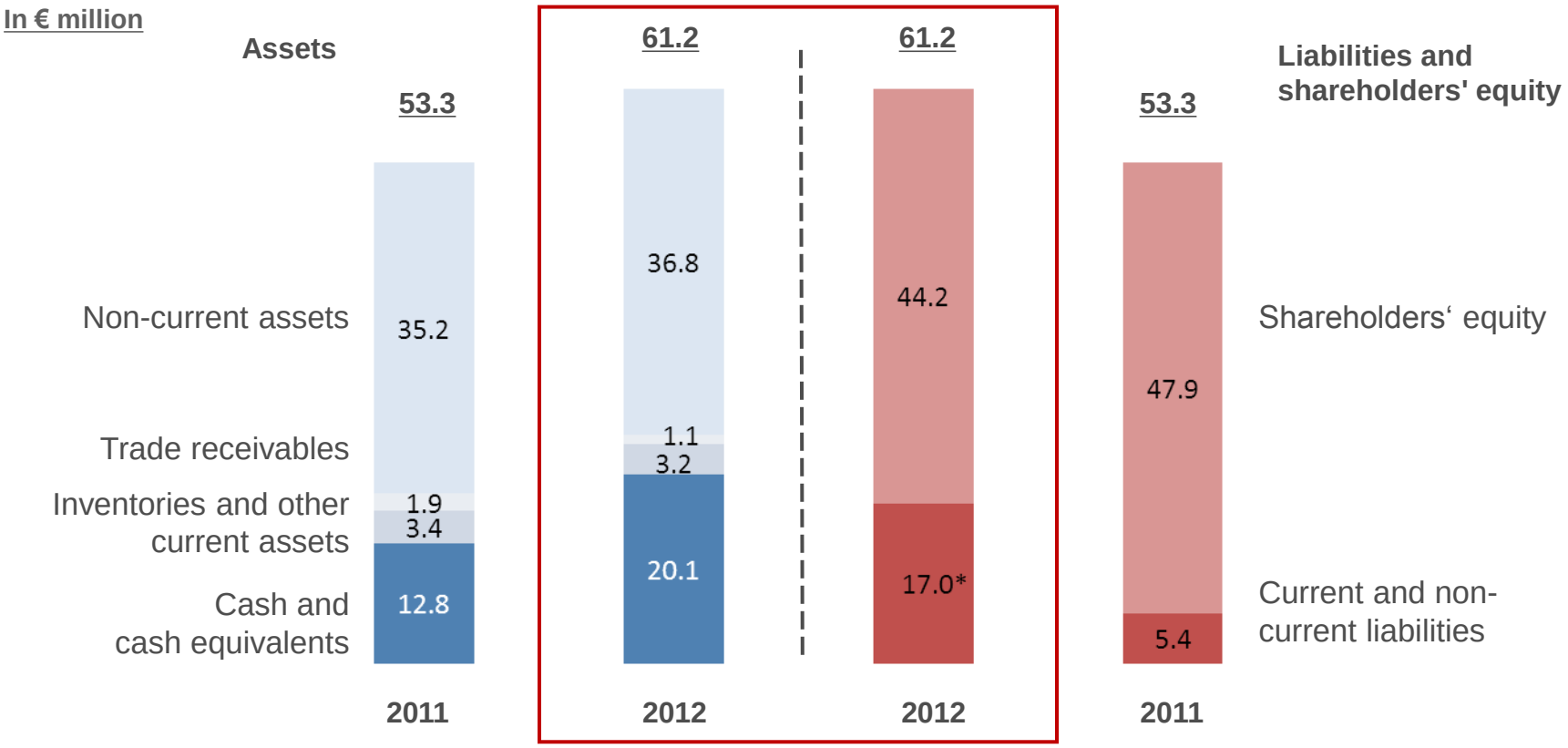






Revenue (in € million)		**FY 2012**	**FY 2011**	**Change**
Total Veregen® revenue		**3.4**	**2.3**	**47%**
thereof	Product revenue (supply chain)	0.9	0.6	40%
	Royalties from In-market sales	1.9	1.4	33%
	Milestones	0.6	0.3	144%
Other operating income		2.9	2.4	23%
Total revenue from continued operations		**6.3**	**4.7**	**35%**

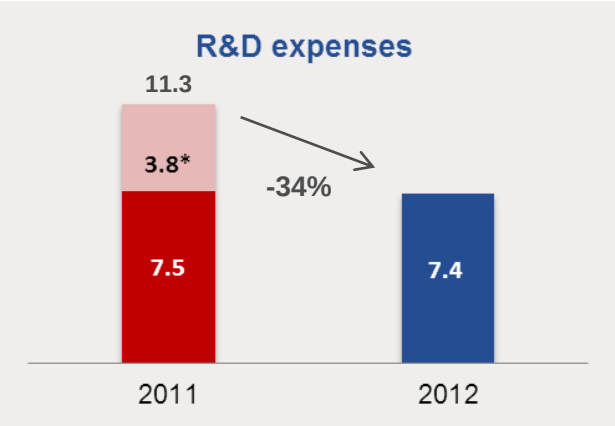
Consolidated balance sheet

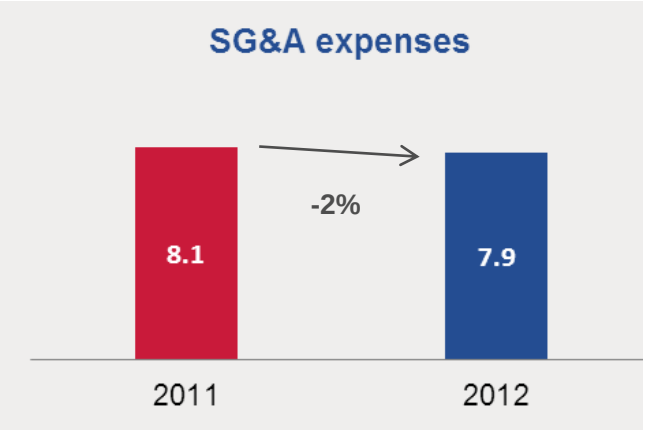


* Incl. liability to Cowen amounts to €12.8m

Reduced cost structure

In € million



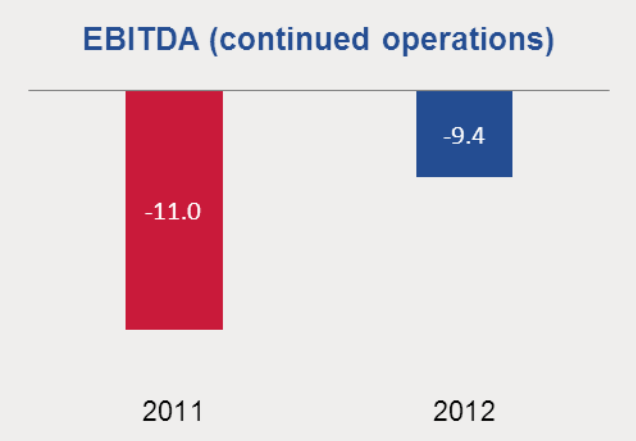


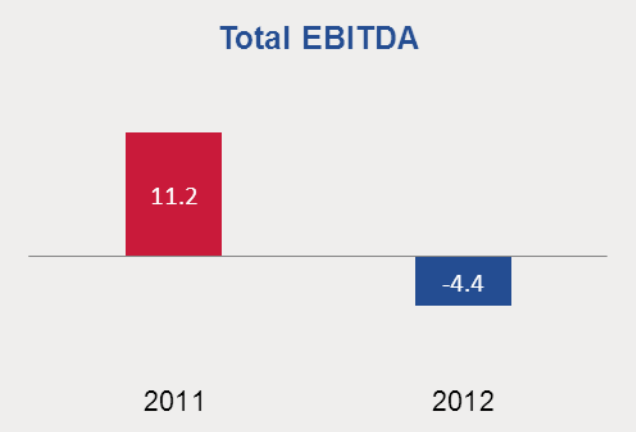
*write-down of a research stage project

- Lower clinical and regulatory and higher CMC costs
- Lower personnel and facility expenses
- Higher legal transaction costs (Eligard®/Cowen)
- Lower office rent

EBITDA within published financial guidance

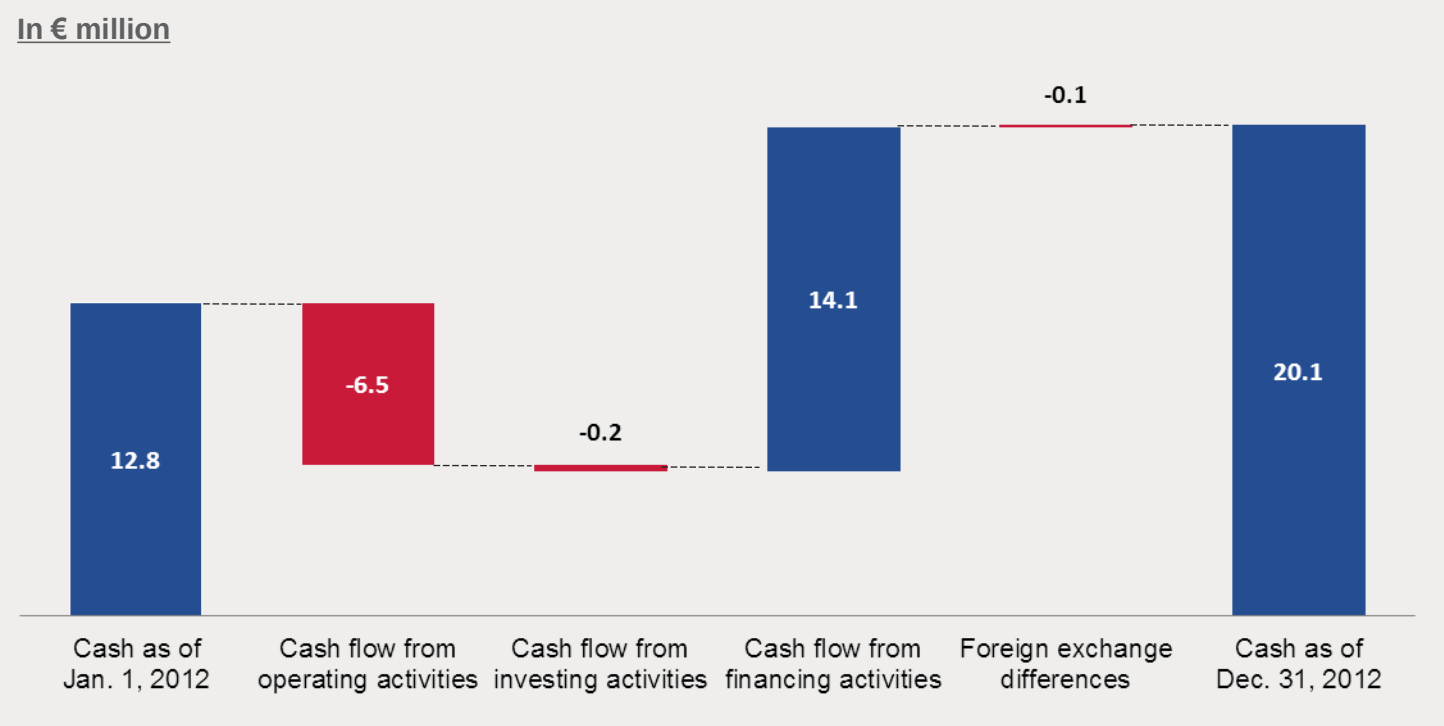
In € million





- Improvement of 14% on EBITDA from continued operations
- Previous year's profit due to one-time effect of €20 million relating to transfer of Eligard® rights

Cash flow influenced through Eligard® transaction



- Cash flow from operating activities includes €5 million milestone payment for Eligard® from Astellas
- Cash flow from financing activities includes €14.1 million from Cowen transaction for Eligard®
- Average monthly operating cash usage adjusted by one-time effect: €1.0 million

Financial guidance surpassed in 2012

	Guidance 2012	Actual 2012
Revenue from continued operations	greater than €5 million	€6.3 million
Revenue from discontinued operations	€5 million	€5.0 million
EBITDA (total)	loss in mid-single digit million range	€-4.4 million

Financial guidance for 2013

	Guidance 2013	Actual 2012
Total revenue	€7 – 8 million	€6.3 million
Veregen®	€4.5 – 5.5 million	€3.4 million
Non-cash income	€2.5 million	€1.9 million
EBITDA loss	€9 - 11 million	€9.4 million*

*from continued operations

- Expected expansion in commercialization of Veregen® may significantly increase revenue in 2014
- Cash reach expanded until at least end of 2014

Product and project outlook

- Veregen®
  - Growth in revenue in significant double-digit percent range
  - Approvals and market launches in additional countries
  - Additional marketing and partnership agreements
- EndoTAG®-1
  - Further progress in preparation of clinical material for phase III trial
  - Seeking for further partners for remaining part of the trial
- RhuDex®
  - Preparatory work for phase II trial in PBC
  - Study start planned no later than H1 2014
- AAVLP:
  - Additional validation through non-clinical studies

Think ahead. Act ahead.

Summary

Questions & Answers

Financial calendar

Publication	Date
3-Month Report 2013	16.05.2013
Annual General Meeting	16.07.2013
6-Month Report 2013	09.08.2013
9-Month Report 2013	14.11.2013

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