

# Analyst Conference Call

## Financial Results for the First 6 Months of 2012

August 3, 2012

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Arnd Christ, CFO

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# Overview H1 2012

Dr. Frank Mathias, CEO

## We are delivering on our strategy

### Increase financial capabilities

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- Eligard® rights monetized

### Optimize costs

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- Restructuring successfully completed

### Strengthen pipeline

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- Internally: Progress on all current projects
- Externally: Assessment of various strategic options ongoing

# Major achievements since the beginning of 2012

- Eligard<sup>®</sup>
  - Milestone payment of €5 million received from Astellas
  - 2% royalties monetized for €14.1 million with Cowen
- Veregen<sup>®</sup>:
  - Market launch in Spain with new partner BIAL
  - Positive decision on marketing authorization for 17 European countries
  - Market approval for France, Switzerland, Denmark, Sweden, Norway, Poland, Serbia, Slovakia and Israel received
  - EIP Eczacibasi new partner in Turkey, Azanta in Nordic Countries

# Major achievements since the beginning of 2012

- EndoTAG<sup>®</sup>-1:
  - Exclusive license granted to SynCore for the co-development and commercialization of EndoTAG<sup>®</sup>-1 in Asia, Australia and New Zealand
  - US patent for treatment on triple-negative breast cancer (TNBC) obtained with a regular term until 2029
- RhuDex<sup>®</sup>:
  - Clinical formulation study successfully completed
  - Phase II PoC study in PBC to be started end of 2012
- AAVLP: Data presented at World Vaccine Congress, Washington

## EndoTAG<sup>®</sup>-1: Co-development and commercialization agreement with SynCore

- SynCore receives exclusive rights for the co-development and commercialization of EndoTAG<sup>®</sup>-1 in Asia, Australia and New Zealand
- Medigene retains all US, European and remaining RoW rights
- Deal includes upfront and milestone payments as well as royalties
- Additionally, SynCore assumes costs for the Asian part of the global pivotal phase III trial (appr. 200 out of appr. 400 patients) in TNBC

# EndoTAG<sup>®</sup>-1: Positive mOS data in phase II TNBC trial: Patients ECOG 0/1 and 1<sup>st</sup> line treatment\* benefit most

Patient population	EndoTAG <sup>®</sup> -1 + Paclitaxel		EndoTAG <sup>®</sup> -1		Paclitaxel	
	mOS**	n	mOS**	n	mOS**	n
<b>Total</b>	13	51	11,9	57	10,1	25
ECOG*** 0/1	17,8	46 (90%)	12,5	53 (93%)	10,1	24 (96%)
ECOG 0/1 & 1st*	17,8	44 (86%)	12,5	48 (84%)	10,1	24 (96%)

\* first line treatment for relapsed and/or metastatic disease

\*\* mOS: median Overall Survival

\*\*\* medical condition: ECOG-Stage 0/1 at the beginning of treatment



# EndoTAG<sup>®</sup>-1: Phase III study planned to achieve worldwide marketing approval

- Indication TNBC: high unmet medical need
- Basis: EndoTAG<sup>®</sup>-1 has demonstrated encouraging efficacy in a phase II trial in combination with paclitaxel in patients with TNBC
- Significantly smaller number of patients needed compared to trials in other indications, e.g. pancreatic cancer: appr. 400 patients planned (subject to approval)
- 2 study arms (randomized 1:1):
  - EndoTAG<sup>®</sup>-1 + Paclitaxel weekly
  - Paclitaxel mono weekly
- Goal: positive overall survival data
- Submission for market approval for EndoTAG<sup>®</sup>-1 anticipated for 2018

# RhuDex<sup>®</sup> 2012: Phase II proof-of-concept study to start by end of 2012

- Goal: verifying both the mechanism of action and the overall clinical profile of RhuDex<sup>®</sup> for the treatment of autoimmune diseases
- Indication: autoimmune disease Primary Biliary Cirrhosis (PBC)
- Why PBC?
  - Activation of T cells via a CD28-CD80 interaction has been described as involved in the pathogenesis of PBC, a process that is to be inhibited by RhuDex<sup>®</sup> treatment
  - Patients with PBC do not receive immuno-modulating baseline therapy, as is the case, for example, in the treatment of rheumatoid arthritis
  - Possibility to generate widely accepted clinical data on relevant disease parameter modification after only three months of treatment
  - Positive study result to confirm clinical efficacy in autoimmune diseases

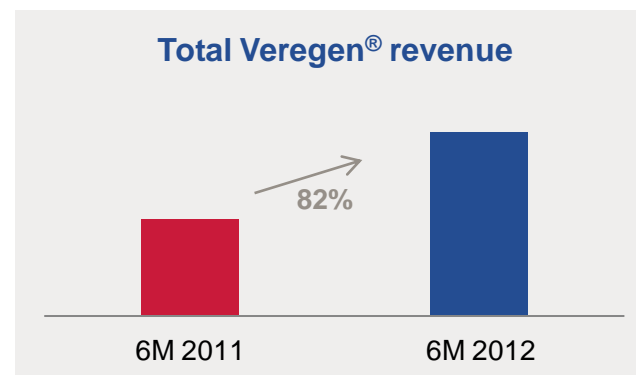
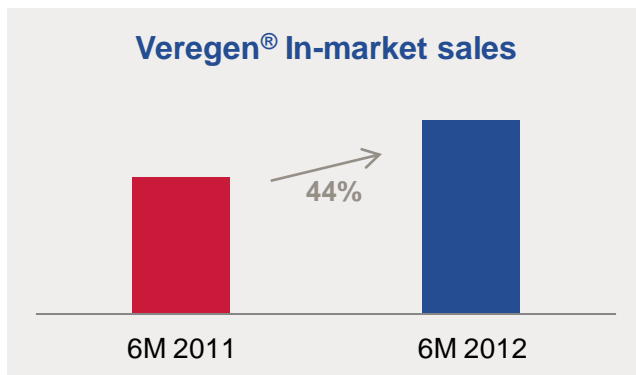
# Financial Report H1 2012

## Positive result for first half of 2012

- Total revenue from continued operations significantly increased
- €5 million milestone payment from Astellas recognized in Q2 2012 (discontinued operations)
- Total operating expenses remained almost unchanged
- Positive EBITDA and net result
- Very strong cash position through monetization of Eligard<sup>®</sup> royalty (2%) with Cowen

# Increasing Veregen® revenues

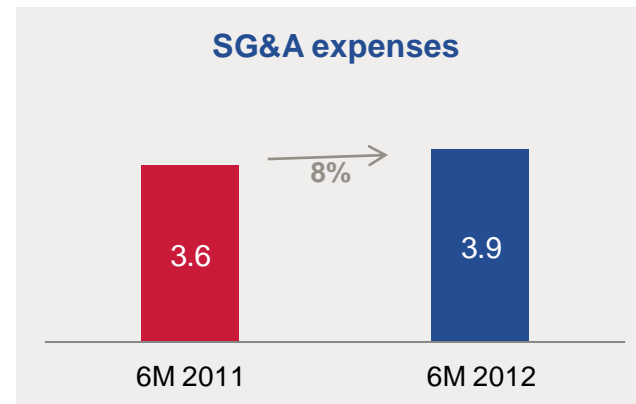
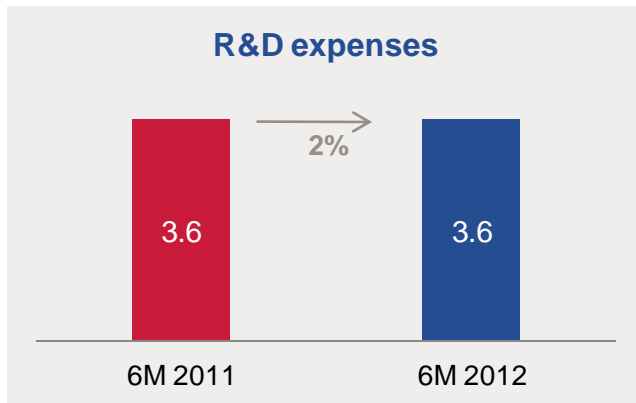
In € million



Veregen® revenue (in T€)	6M 2011	6M 2012	Change
Product sales (supply chain)	177	225	27%
Royalties	597	849	42%
Milestones	135	580	>200%
<b>Total Veregen® revenue</b>	<b>909</b>	<b>1,654</b>	<b>82%</b>

# Total operating expenses remain almost unchanged

In € million

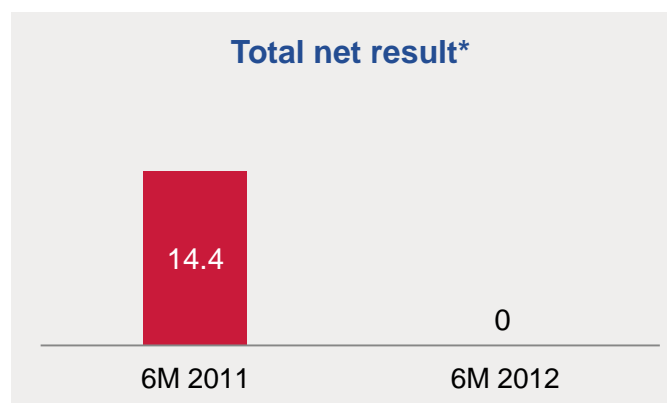
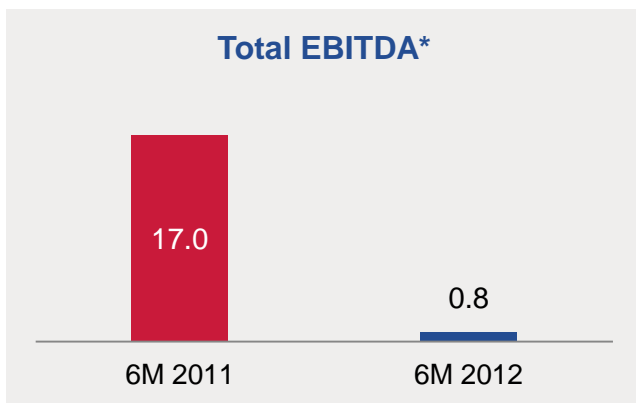
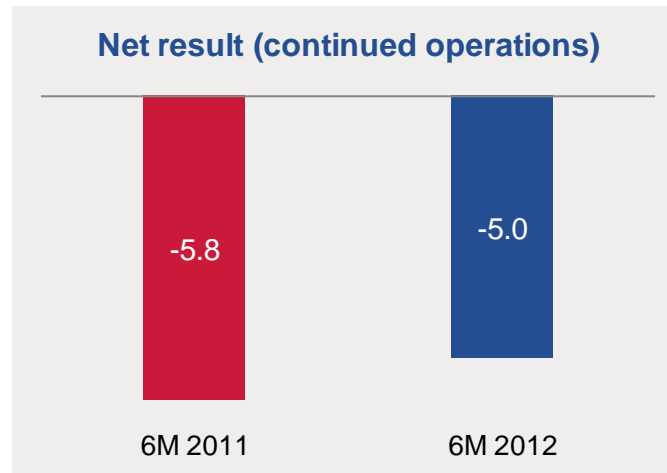
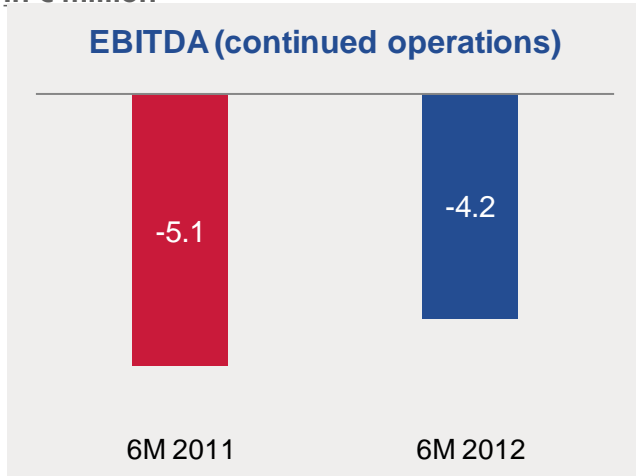


- Higher clinical, non-clinical and regulatory costs
- Lower personnel and facility expenses

- Higher legal transaction costs
- Higher costs connected to Veregen<sup>®</sup> approval process

# Improved EBITDA and net result from continued operations

In € million



\* Includes €20 million milestone payment in Q1 2011 and €5million in Q2 2012

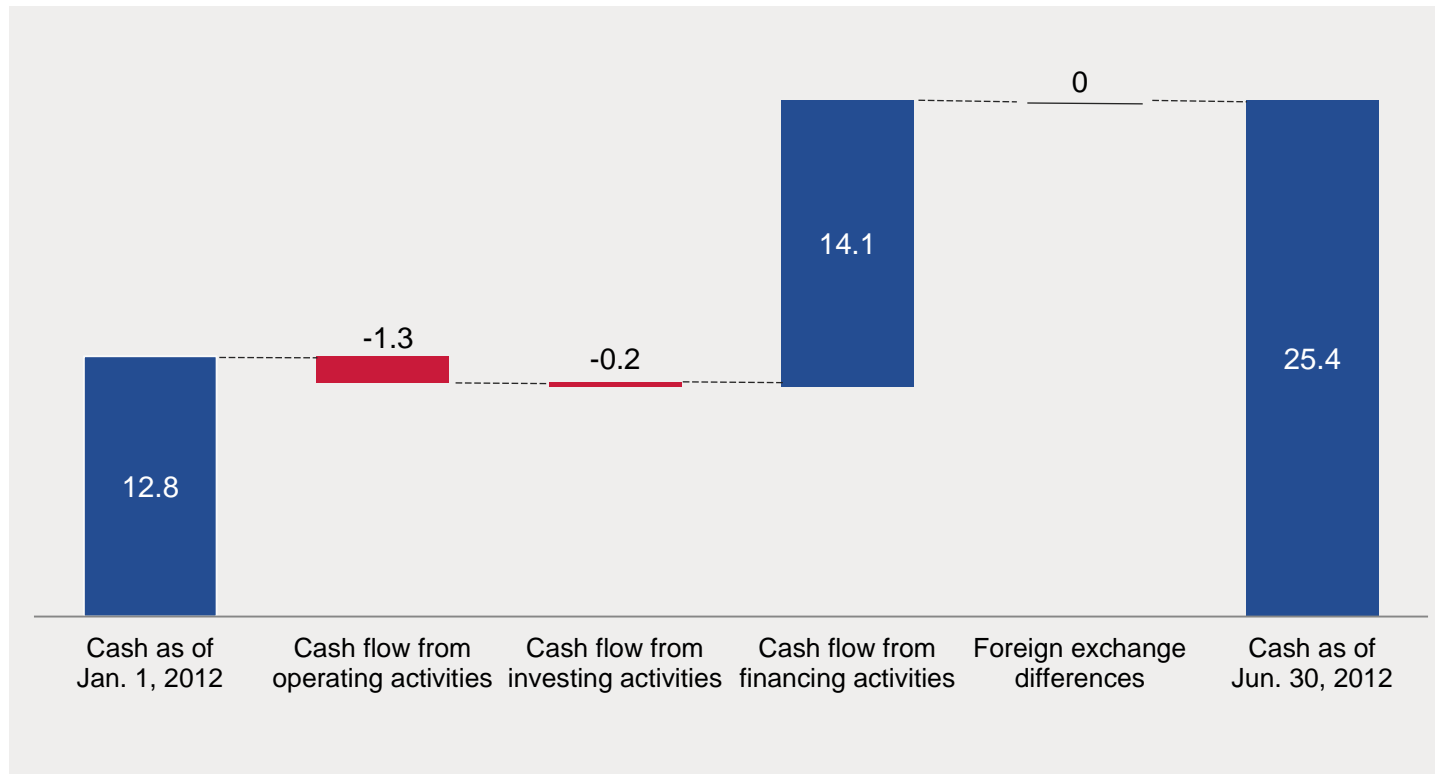
## Eligard<sup>®</sup> monetized for €14.1 million

- Medigene transferred 2% Eligard<sup>®</sup> royalty to US-based investor Cowen Royalty
- One-time cash payment of USD 17.68 million (€14.1 million) received
- Proceeds of this transaction accounted for as a financial liability
- Eligard<sup>®</sup> revenue recognized pro rata over the period of the Eligard<sup>®</sup> patent term of approximately 10 years
- All future Eligard<sup>®</sup> revenue, interest expenses and amortization are not cash-relevant



# Financing secured beyond 2013

In € million



- Cash flow from operating activities includes €5 million milestone payment from Astellas
- Average monthly operating cash burn adjusted by one-time effects: €1.0 million
- Cash flow from financing activities includes €14.1 million from Eligard® monetization

## Confirmed financial guidance for 2012

	Guidance 2012
Revenue from continued operations	greater than €5 million
Revenue from discontinued operations	€5 million ✓
EBITDA	loss in mid-single digit million range

# Product and project outlook

- Veregen<sup>®</sup>
  - Approvals and market launches in additional countries
  - Additional marketing partnership agreements
  - Revenue growth
- EndoTAG<sup>®</sup>-1
  - Preparation of global pivotal phase III trial in TNBC
- RhuDex<sup>®</sup>
  - Start of phase II proof-of-concept study in PBC by end of 2012
- AAVLP
  - Additional validation through non-clinical studies

# Questions & Answers

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