

# **Analyst conference call**

## **Results for the first 6 months of 2014**

**7 August 2014**

**Peter Llewellyn-Davies, CFO**

This presentation contains forward-looking statements - that is, statements related to future, not past, events. These statements may be identified either orally or in writing by words as "expects", "anticipates", "intends", "plans", "believes", "seeks", "estimates", "will", "may" or words of similar meaning. Such statements are based on our current expectations and assumptions, and therefore are subject to various risks and uncertainties that could cause the actual results, performance or achievements to differ materially from any future results, performance or achievements that may be expressed or implied by such forward-looking statements. These factors include, without limitation, those discussed in our public reports filed with the Frankfurt Stock Exchange. The company does not assume any obligations to update or revise any of these forward-looking statements, even if new information becomes available in the future.

## Activities since beginning of 2014 – Pivotal events

- Transforming acquisition & integration of Trianta Immunotherapies
- Continued partnering of advanced products
- €15.9 m secured from capital increase mainly to fund immunotherapy programmes

# Activities since beginning of 2014 – Immunotherapies

- DC vaccines:
  - Ongoing investigator-initiated trials
  - US patent relating to the manufacturing of mature dendritic cells granted
  - m<sup>4</sup> Award project on the development of optimized DC vaccine formulation successfully completed
  
- TCR-modified T cells:
  - Ongoing development of GMP-compliant manufacturing process
  - Preparatory discussions with authorities
  - US patent relating to TCRs against the antigen tyrosinase granted
  - Extension of research funding in the Collaborative Research Centre of the DFG
  
- TABs:
  - Continuation of preclinical development with the aim of delivering proof of principle
  - Grant from the “m4 Leading-Edge Cluster Initiative“ awarded by the Federal Ministry of Education and Research (BMBF)

## Other activities since beginning of 2014 – Marketed drug and development project

- Worldwide partners: Veregen<sup>®</sup>:
  - Market launch in 8 European countries and Canada
  - Commercialisation agreement for UK and Ireland
- AAVLP:
  - Preclinical data from long-term study with Pennsylvania State University
  - Final data under evaluation

## Other activities since beginning of 2014 – Partnered drug candidates

- EndoTAG<sup>®</sup>-1:
  - Preparation of global Phase III study in breast cancer (TNBC) by partner SynCore Biotechnology Co. Ltd.
  
- RhuDex<sup>®</sup>:
  - Licensing agreement signed with Dr. Falk Pharma for RhuDex<sup>®</sup> in hepatology and gastroenterology with initial focus on primary biliary cirrhosis (PBC)
  - Preparation of further development by partner Dr. Falk Pharma

# Financial Report 6M 2014

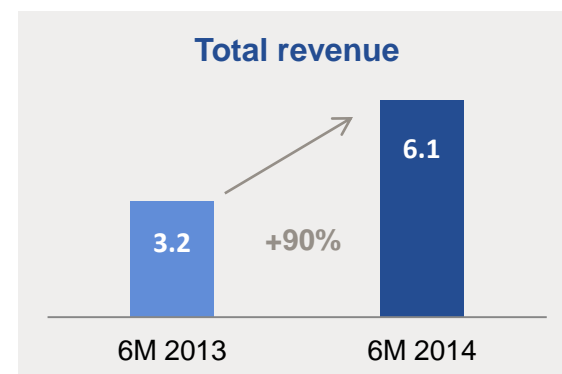
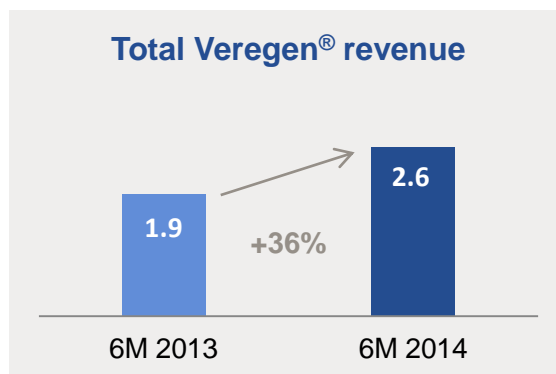
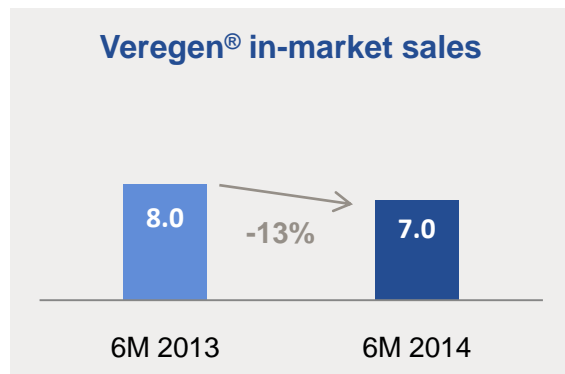
# Financial overview for the first 6 months of 2014

- Increase in revenue
  - Total revenue up by 90% to €6.1 m (6M 2013: €3.2 m)
  - Veregen<sup>®</sup> revenue increased by 36% to €2.6 m (6M 2013: €1.9 m)
- Reduction of loss
  - EBITDA loss reduced by 62% to €1.6 m (6M 2013: €4.3 m)
  - Net loss reduced by 50% to €2.8 m (6M 2013: €5.7 m)
- FTE total: 61 (31 Dec 2013: 48)
  - Integration of 13 Trianta employees



# Increase in revenue

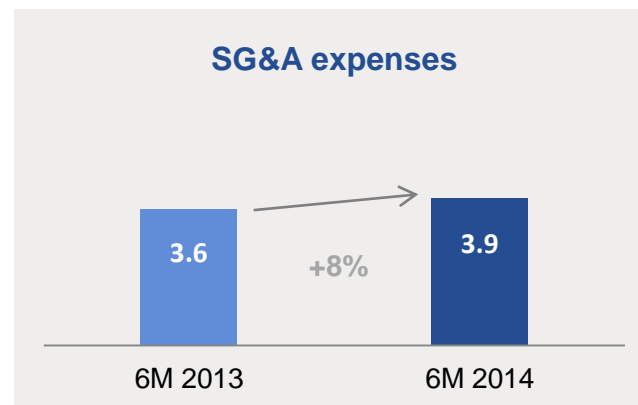
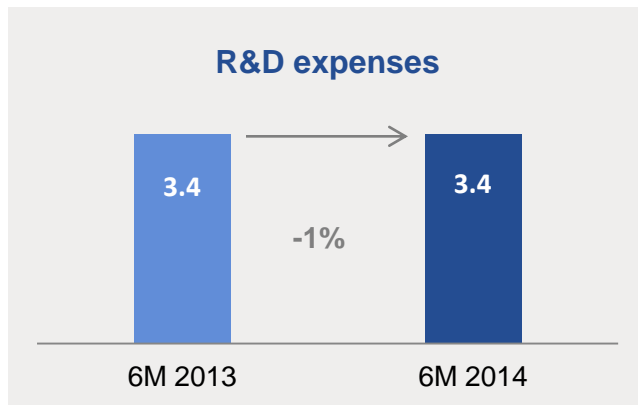
In € m



Revenue (in € k)		6M 2013	6M 2014	Change
Veregen®	Royalties	1,243	1,018	-18%
	Product revenue (supply chain)	554	837	51%
	Milestone payments	80	700	>200%
<b>Veregen® revenue</b>		<b>1,877</b>	<b>2,555</b>	<b>36%</b>
Other operating income		1,331	3,538	166%
<b>Total revenue</b>		<b>3,208</b>	<b>6,093</b>	<b>90%</b>

# Operating expenses within plan

In € m



■ R&D expenses:

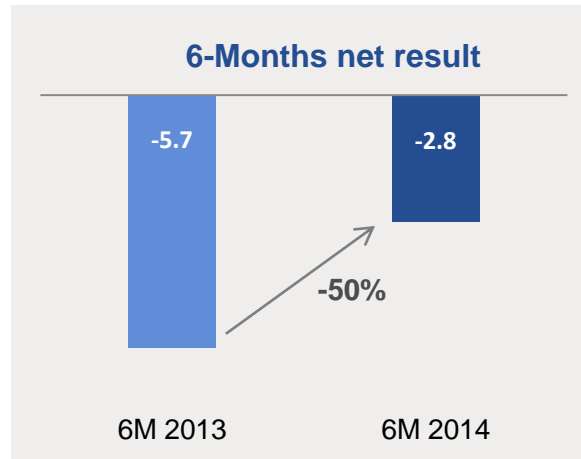
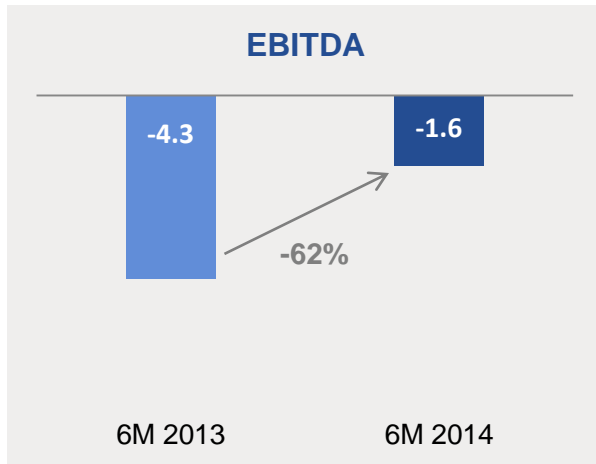
- Decrease due to lower costs for preclinical and clinical trials of partnered products
- Increase of personnel and patent expenses following the acquisition of Trianta

■ SG&A expenses:

- Higher costs due to Trianta acquisition
- Continued lower fixed costs

# Reduction of loss

In € m



- Improvement due to increase in total revenue by €2.9 m

## Financial guidance 2014 confirmed

	Actual 2013	Guidance 2014	Improvement 2014
Total revenue	€7.6 m	Double-digit percentage increase	20 - 30%
Veregen®	€4.2 m	€5 - 6 m	> 20%
EBITDA loss	€8.3 m	€4 - 6 m	> 25%

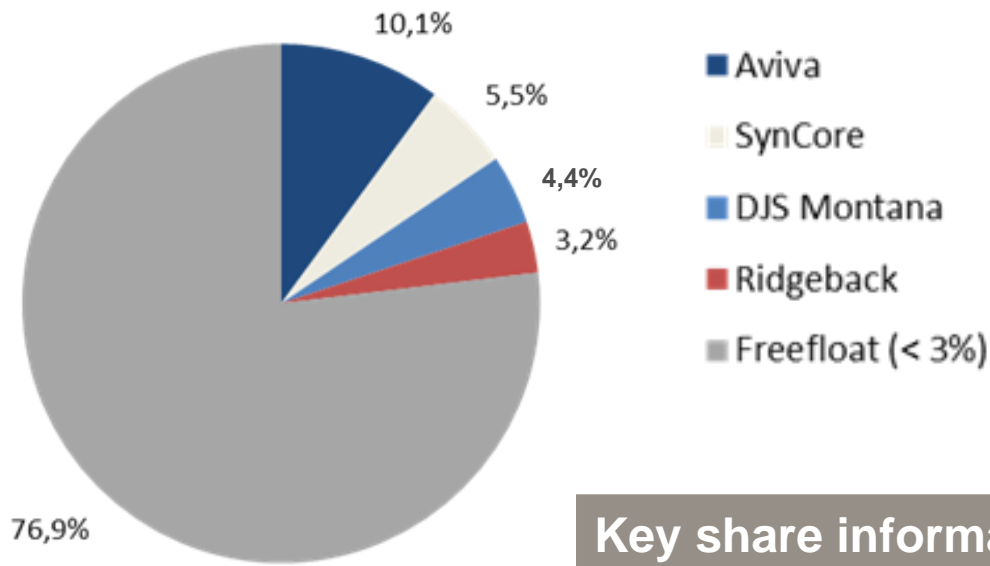
- Total revenue consists mainly of
  - Revenue Veregen®
  - Increase from R&D funding; grants
  - Non-cash payments from Cowen
  - Upfront and milestone payments from partners
- Cash reach extended through capital increase until end of 2016

## Funding for immunotherapy platforms through capital measure

- Raising of €15.9 m by issuance of 3,016,082 new shares and 818,658 convertible notes
- Placement of all available new shares close to the current market price (€5.00) without discount
- Participation of new renowned institutional investors, including leading biotechnology specialists

The capital measure enables Medigene to achieve important milestones in the clinical validation of the immunotherapy platforms.

# Capital measure added institutional investors\*



## Key share information

- Listed on the FSE (Prime Standard)
- Shares after capital increase: 13,906,032
- Share price development 6M 2014: +39%
- Current market cap of approx. ~ €65 m

\*Capital increase July 2014

# Outlook for immunotherapy platforms

- DC vaccines:
  - Continuation of investigator-initiated trials
  - Initiation of a further clinical study in AML in 2014
  - Additional clinical study in 2015
- TCR-modified T cells
  - Development of GMP-compliant manufacturing process will be continued
  - Preparation of clinical development with first product candidates
  - Ongoing preparatory talks with authorities
- TABs:
  - Preparation of preclinical studies
  - Aim of achieving proof of principle

# Outlook for marketed & partnered portfolio

- Worldwide partners: Veregen<sup>®</sup>
  - Growth in in-market sales to continue in double-digit percent range
  - Market authorization applications for further 8 European countries
- SynCore Biotechnology Ltd.: EndoTAG<sup>®</sup>-1
  - Further preparation for start of phase III TNBC trial
  - SynCore plans the study start end of 2014
- Dr. Falk Pharma: RhuDex<sup>®</sup>
  - Falk Pharma to pursue further development with focus on PBC





# Questions & Answers

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Listed on Frankfurt Stock Exchange (MDG1, Prime Standard)