

# 6-months 2017 Earnings Call

August 3, 2017

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## Major events since the beginning of 2017



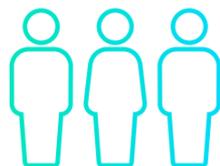
- Clinical trial authorization application (CTA) submitted for Medigene's first clinical trial with T cell receptor (TCR)-modified T cells, MDG1011



- €20.7 m raised through placement of new shares at institutional investors in the US and Europe
- Preclinical data presented on Medigene's first clinical TCR candidate for MDG1011 at AACR



- Academic partner Oslo University presented additional data on compassionate use for DC vaccines against AML
- "Cancer Research" paper published on a method to enhance adoptive T cell therapies.



- Dr. Keith Manchester, Ronald Scott and Dr. Gerd Zettlmeissl elected as new members of the Supervisory Board

# CTA submission triggering completion of Trianta acquisition

- CTA submission triggers third and final milestone payment of € 2m for Trianta acquisition (total purchase price € 9.7m)
- Medigene intends to settle this payment through the issuance of new shares from authorized capital
- Payment to former contributing shareholders of Trianta within the next five months from day of announcement
- Final milestone payment marks completion of Trianta acquisition, transforming Medigene into a clinical stage T cell immunology company

# Steady progress in research activities

- bluebird bio collaboration progressing according to plan:
  - Collaboration to identify up to four TCR receptors as development candidates against antigens selected by bluebird bio
  - Active ongoing collaboration between both companies
  - First revenues through R&D funding
  - Next step: identification of first TCR clinical development candidate
- Medigene's output in TCR discovery efforts over 12 month timeframe exemplifies the effectiveness of automated discovery platform
  - 46.560 wells automatically screened – 485 plates
  - 14.156 screened clones – 1.374 characterized specific T cell clones
  - Multiple TCR candidates under extensive evaluation for potential clinical development
- Medigene's research groups working on cutting-edge technologies to improve functional properties of T cell immunotherapies
  - Recently published **Cancer Research** paper addressing methods to enhance T cell effector function
  - A variety of innovative tools to improve safety and efficacy of next generation T cell therapies under evaluation and development

## Expanded Supervisory Board:

### Dr. Keith Manchester

Managing Director and the Head of Life Sciences at New York investment firm QVT Financial LP

**Former roles:** Vice President of Business Development at Applied Molecular Evolution, Inc., biotechnology company

Associate at private equity firm Vestar Capital Partners

Investment banker in the healthcare group at Goldman, Sachs & Co.

M.D. degree from Harvard Medical School.

### Ronald Scott

Chief Executive Officer of Swiss biotech company Basilea Pharmaceutical

**Former roles:** Management positions at Roche in Pharmaceutical Finance, Licensing, and the Roche Corporate Finance Mergers and Acquisitions group.

Director at Prudential Investment Corporation in the United States

Mr. Scott has a bachelor's degree from Utah State University and a master's degree from Harvard University

### Dr. Gerd Zettlmeissl

Representative of the Board of Directors of several non-profit organizations & biotech companies

**Former roles:** Chairman of Swiss vaccine company GlycoVaxyn

CEO of the Austrian-based biotechnology company Intercell AG (now Valneva SE)

Managing Director of Chiron Behring GmbH

Doctoral degree in biochemistry of the University of Regensburg and doctoral fellowship at the Institute Pasteur Paris in virology.

# Immunotherapy Pipeline, Clinical Progress and Outlook

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# Progress of immunotherapy pipeline

PROJECT	INDICATION (TARGET)	PRECLINICAL	PHASE I	PHASE II
DC vaccine	Acute myeloid leukemia (WT-1 / PRAME)			
TCR clinical trial 1	AML, MDS*, MM** (PRAME)		CTA submitted	
TCR clinical trial 2	Undisclosed			
TCR-IIT ***	Multiple myeloma (MAGE-A1)		CTA submitted	
TABs	T cell leukemias + new applications			

\* Myelodysplastic syndromes

\*\* Multiple myeloma

\*\*\* Investigator-initiated trial (IIT) of a publicly funded collaboration between MDC, Charité and Medigene.

Additional IITs utilizing Medigene's DC vaccine technology are ongoing at LMU Munich (Phase I/II in AML) and Oslo University Hospital (Phase II in prostate cancer)

# Clinical Trial Application (CTA) submitted for Phase I/II trial with TCR immunotherapy MDG1011

- Medigene expects to run one of the first German clinical trials of T cell receptor (TCR)-modified T cells
- In three blood cancer indications: acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and multiple myeloma (MM)
- Final study design will be made available after CTA approval by German authority Paul-Ehrlich-Institute (PEI)
- Medigene expects to start this trial by year end 2017

# MDG1011 Phase I/II study: CTA submitted

## Target:

- PRAME (**P**referentially **E**xpressed **A**ntigen in **M**elanoma)
- PRAME is a well characterized tumor antigen overexpressed in multiple hematological and solid tumor indications

## MDG1011:

- T cells expressing a HLA-A2:01 restricted T cell receptor (TCR) specific for PRAME
- Has demonstrated favorable preclinical safety and efficacy

## Clinical trial outline, pending regulatory discussion and approval:

- Planned is a combined Phase I/II safety and feasibility
- Disease indications are acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), multiple myeloma (MM); all in advanced stages
- Phase I part: dose escalation, testing up to 4 dose cohorts in a 3+3 design
- Phase II part: will expand the dose cohort from Phase I and include a prospective control group

# DC trial in AML: Phase II part ongoing

- Trial design:
  - **Phase I/II:** open-label, prospective, non-randomized trial
  - **20 AML patients:** 6 phase I + 14 phase II, complete remission after chemotherapy, not eligible for allo-transplantation
  - Patients selected with AML expressing the vaccine antigens: **WT-1** with or without **PRAME**
  - **Continuous vaccination for 2 years** or until progression/ death
  - Primary objectives: **feasibility** and **safety**
  - Secondary objectives: overall survival (**OS**), progression free survival (**PFS**), control of minimal residual disease (**MRD**), time to progression (**TTP**), induction of **immune responses**
- Medigene expects to complete recruitment for this study in 2017
- Final read-out of clinical data expected in 2019

# Financial Report 6M 2017

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# Financial overview for the first 6 months of 2017

€ 2.3m

First revenues from immunotherapies (bluebird bio)

+46%

Increase in R&D expenses due to progress in clinical programs

€ 4.9m

Total revenues decreased due to one-time effect EndoTAG<sup>®</sup> sale in 2016

€ 59.9 m

Cash & cash equivalents after successful capital raise in May 2017

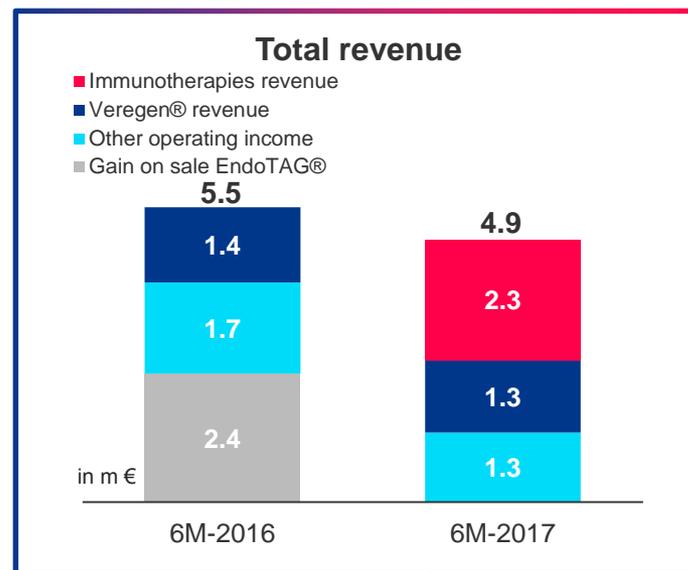
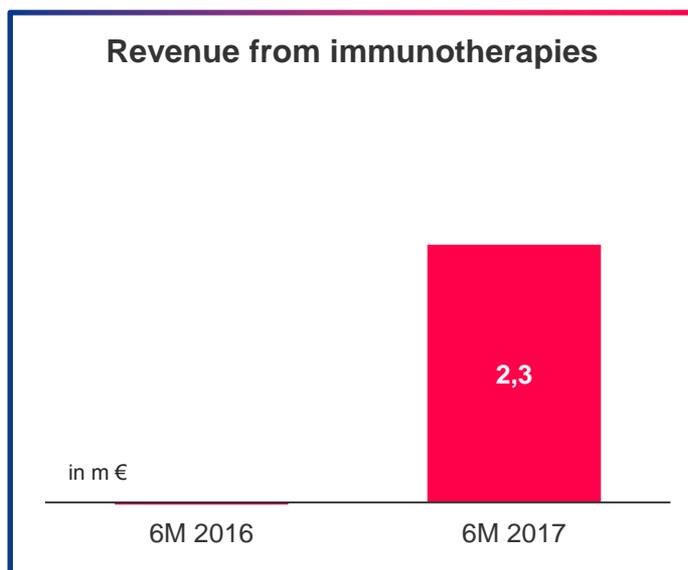
€ -6.9m

Increase in EBITDA loss as planned due to one-time effect EndoTAG<sup>®</sup> sale in 2016 and increased R&D expenses



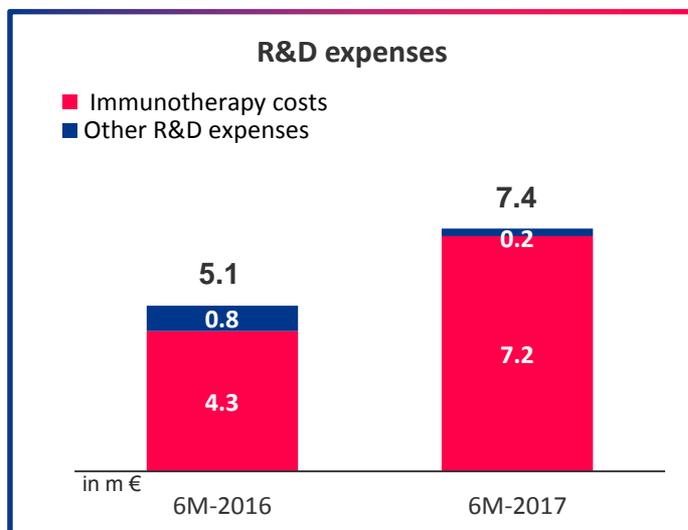
Confirmation of financial guidance 2017

# First revenues from core business immunotherapies



- Revenue of €2.3 m from bluebird bio (6m 2016: €0)
- Decrease in total revenue influenced by non-core business:
  - Last year's sale of EndoTAG® (€2.4 m)
  - Slightly decreased Veregen® revenues (-3%)

# Increase in R&D expenses by 46% due to progress in clinical programs

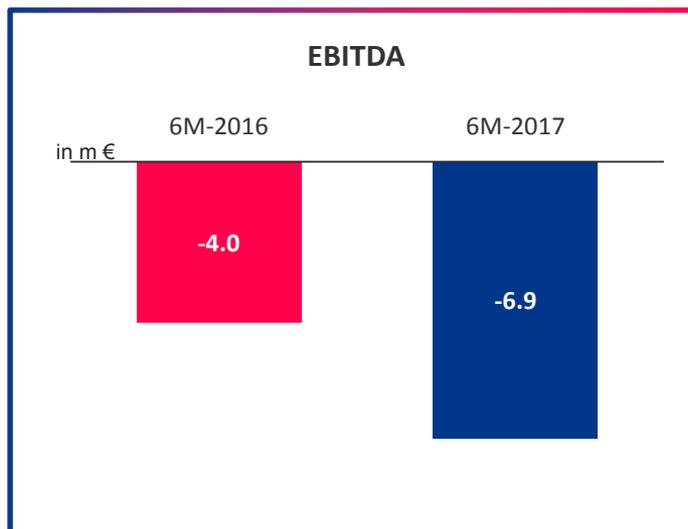


- Progress of DC study
- Preparation of clinical TCR study, establishment of manufacturing process
- Expansion of TCR discovery platform



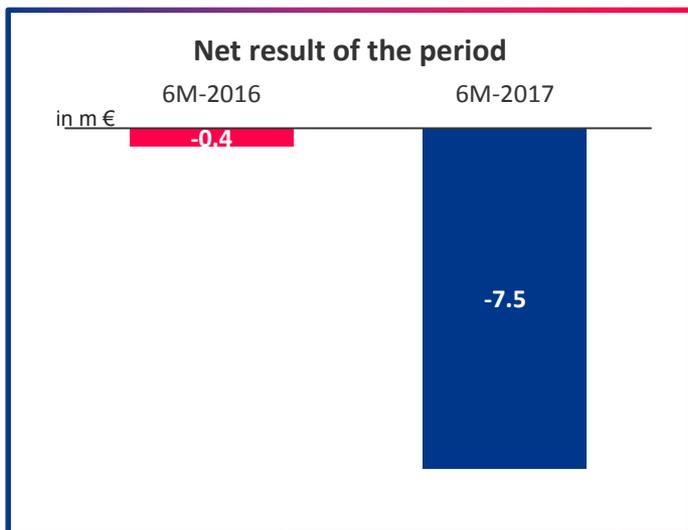
- One time management structure changes
- Increased expenditures in preparation of capital raise in May

# Intensified R&D activities led to increased EBITDA loss



## Differences EBITDA to previous period

- Lower revenues from non-core business
- Partially compensated by bluebird revenues
- Increase of operating costs (mainly in R&D)



## Differences between EBITDA and net result

- Foreign exchange gain, financial result, taxes

## Difference net result to previous period

- Mainly due to sale of Immunocore shares
- in 2016 (net gain €4.2 m)

## € 20.7m gross proceeds raised in private placement

- €20.7 million in gross proceeds raised through a significantly oversubscribed private placement
- Shares allocated to existing and new institutional, healthcare specialized investors, especially in the USA
- 1,964,599 new shares issued from authorized capital (9.7% of subscribed capital)
- Price: €10.55 per share
- Use of the net proceeds:
  - Intensify R&D activities in order to expand planned clinical TCR program into additional regions and indications as fast as possible

## Financial guidance for 2017 confirmed

	2016	GUIDANCE 2017
Total revenue	€ 9.7m	€ 8-10m
R&D expenses	€ 11.5m	€ 16-18m
EBITDA loss	€ 12.3m	€ 16-18m
Cash usage		€ 23-27m

- Cash & cash equivalents as of June 30, 2017: €59.9 m
- Sufficient financial resources beyond the forecast horizon of two years and to the time points that data from DC trial and TCR trials become available

# Outlook for 2017

## MDG1011, Medigene's first TCR trial:

- Clinical trial authorization
- Study start

## TCR IIT, Berlin:

- Clinical trial authorization
- Study start

## DC trial in AML, Oslo:

- Completion of enrollment
- Final read-out in 2019

## Progress in bluebird collaboration





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