

Living Immunotherapies

3-months 2019 Earnings Call

May 14, 2019

Prof. Dolores J. Schendel, CEO/CSO

Axel Malkomes, CFO/CBDO

Dr. Kai Pinkernell, CMO/CDO

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Major events since the beginning of 2019



- Treatment of first patient with T cell receptor-modified T cell immunotherapy MDG1011, first of additional new trial sites opened



- Strategic partnership with Roivant/Cytovant for the research and development of cellular immunotherapies in Asia



- Sale of remaining rights and stocks of Veregen[®] to Aresus Pharma

- In-license of chimeric co-stimulatory receptor to enhance TCR therapies for solid tumors



- Two European patents for dendritic cell (DC) vaccine platform and for a TCR building block library to develop neoantigen-specific TCRs



- Two presentations: On the selective killing of tumor cells by PRAME TCR-transduced T cells at AACR and *in vitro* tests to assess the potential TCR-mediated off-target toxicity for neuronal cells on ASGCT

Strategic R&D partnership with Roivant/Cytovant for cellular therapies in Asia

- It's Medigene's strategy to generate tailored TCRs and license them out to certain territories and markets
- Cytovant licenses rights for Greater China, South Korea and Japan for a research-stage TCR against the tumor antigen NY-ESO-1 and for Medigene's dendritic cell (DC) vaccine
- Medigene to discover two further TCRs tailored for the Asian population against targets to be chosen by Cytovant
- Medigene receives an upfront payment of USD 10 m, complete R&D funding from Cytovant, potential development, regulatory, and commercial milestone payments which in aggregate could total over USD 1 billion for the four products across multiple indications and royalties of a low double-digit percentage in the relevant countries.
- Cytovant is part of the Roivant Sciences Group

Sale of remaining rights and stocks of legacy product Veregen[®] to Aresus Pharma



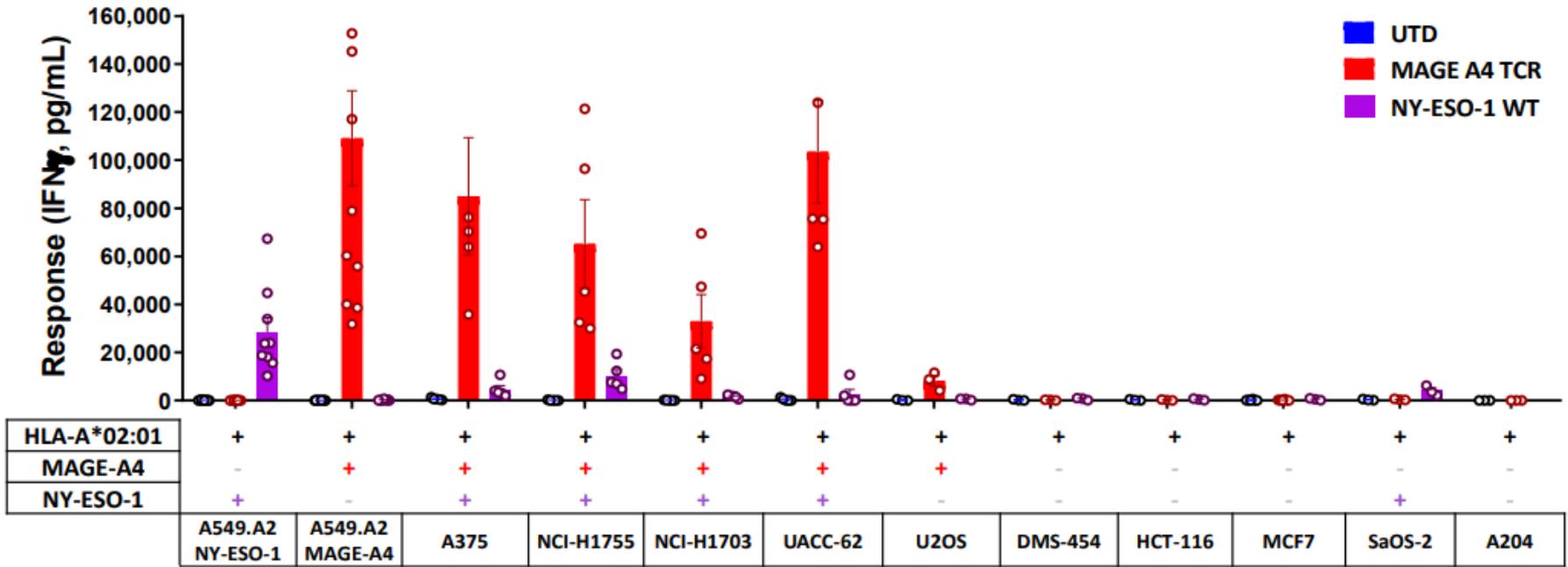
- The sale of the non-core product Veregen[®] completes Medigene's transformation into a pure play immunotherapy company
- Aresus takes over all existing relevant contracts with distribution partners and external service providers for the Veregen[®] business including API stock
- Aresus Pharma will focus on the further global commercialization and clinical development of Veregen[®] in further indications and markets
- Aresus Pharma is led by an experienced team with a sound background in dermatology and clinical research
- Medigene will receive up to approx. EUR 7.75 m, thereof EUR 300 k upfront and from 2021 onwards, the rest of the balance within the next ten years as annual revenue-based earn-out payment

bluebird bio presented data and clinical plans on the first TCR

- Selected TCR candidate targets the MAGE-A4 tumor antigen which is expressed on a variety of solid tumor types
- Preclinical data confirm high antigen sensitivity and strong recognition of tumor cell lines
- MAGE-A4 TCR showed functional response in both CD8+ and CD4+ T cells (turns also CD4+ T cells into effective killer cells)
- TCR candidate displays activity against solid tumors without need of a co-receptor
- Bluebird bio plans to bring the MAGE-A4 TCR candidate into clinical development in 2020

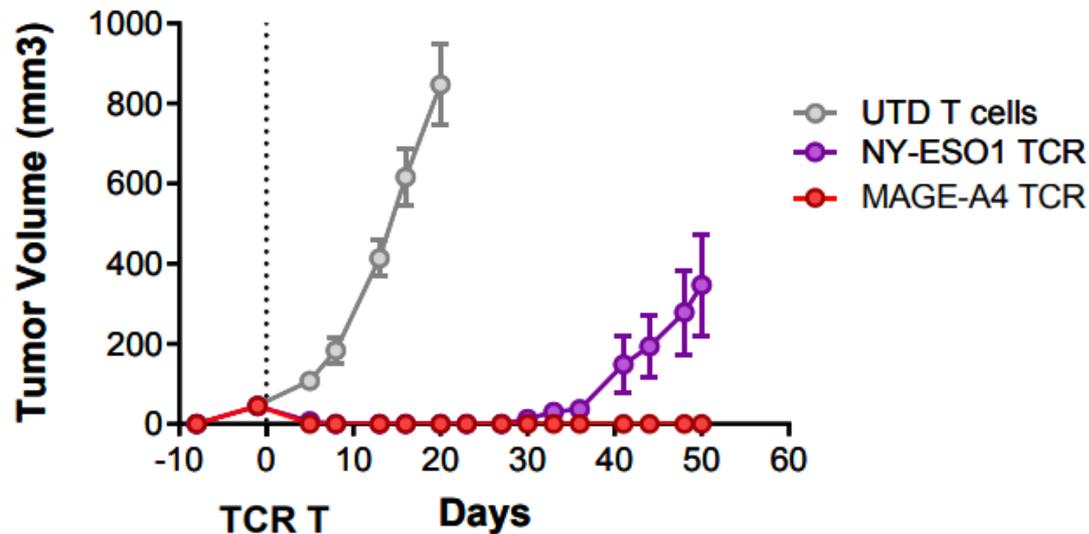


MAGE-A4 TCR T Cells Respond Vigorously to Tumor Cell Lines



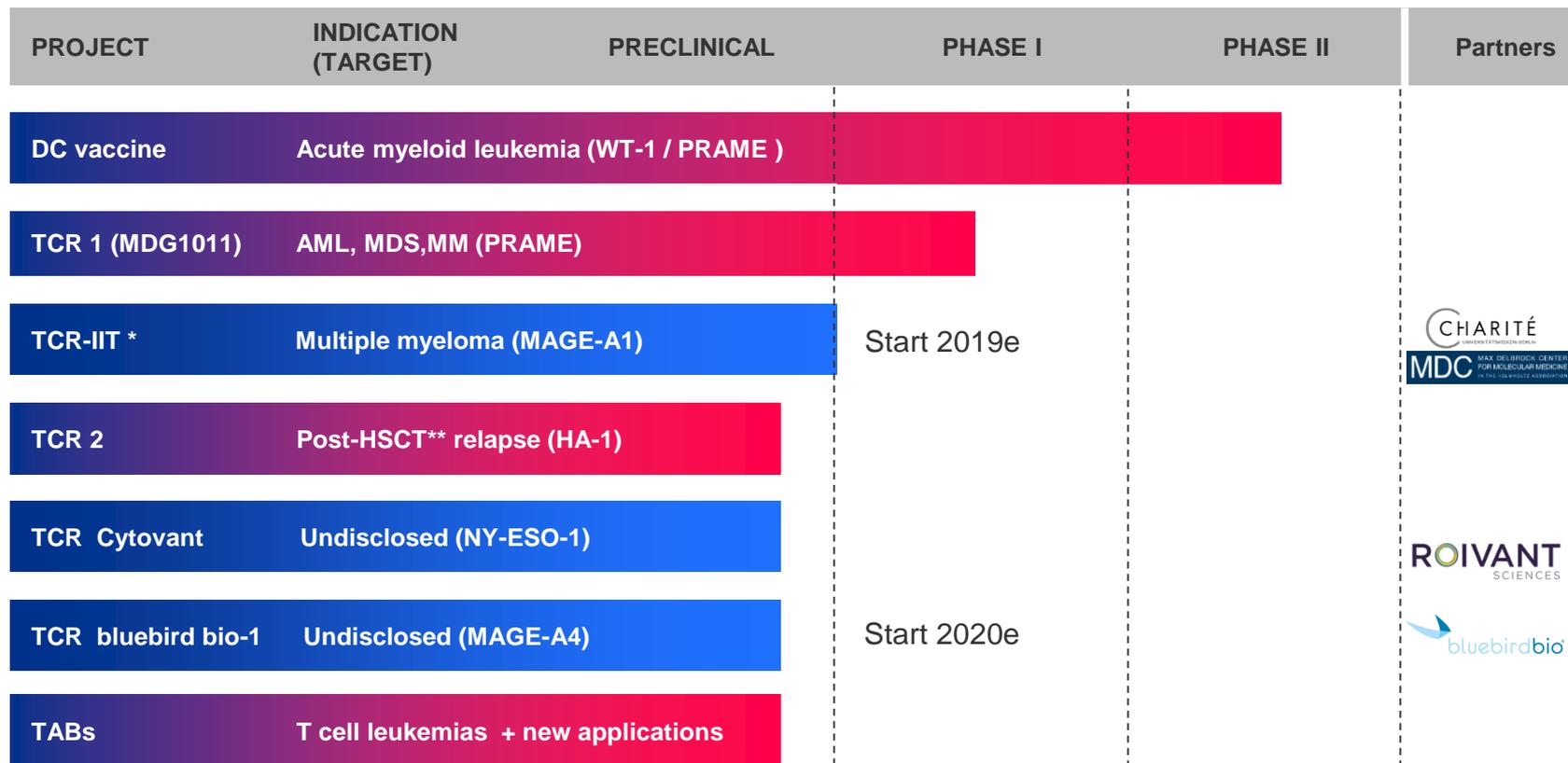
High-magnitude, specific responses to 6-of-6 MAGE-A4⁺ cell lines

Potent MAGE-A4 TCR T Cell Activity *in vivo* Against Tumor Xenografts



Durable tumor elimination in a subcutaneous melanoma model

Medigene's immunotherapy pipeline



* Investigator-initiated trial (IIT) under the responsibility of Max Delbrück Center and Charité, Berlin

** Hematopoietic stem cell transplantation

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)

MDG1011

First TCR therapy clinical trial started

First patient in Phase I/II trial dosed – Clinical trial center expansion

- In February 2019, the first patient in this first-in-human clinical trial was dosed with the TCR therapy candidate MDG1011
- T cell receptor (TCR)-modified T cells targeting the tumor antigen **PRAME** (**PR**eferentially expressed **Antigen** in **ME**lanoma) were administered to a multiple myeloma patient at the Universitätsklinikum Erlangen, Germany
- The clinical trial is currently being conducted in four university hospitals in Regensburg, Erlangen, Würzburg and Dresden (added in May 2019)
- Up to four additional clinical centers in Germany are currently being opened and are anticipated to open recruitment in Q2/early Q3 and screen additional patients for their suitability to participate in the study

Phase I/II clinical trial of MDG1011 in myeloid and lymphoid malignancies

Target:

- PRAME is a well characterized tumor antigen overexpressed in multiple hematological and solid tumor indications

The drug, MDG1011:

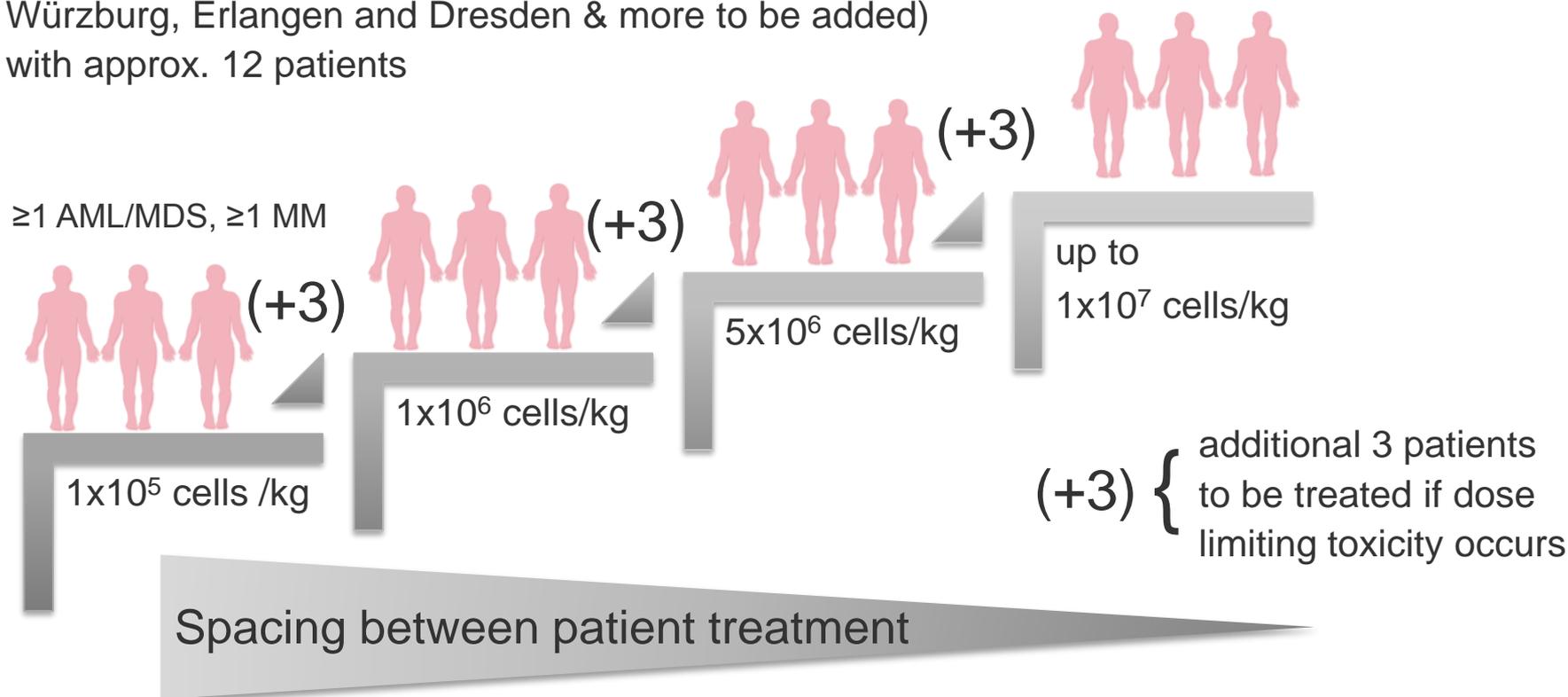
- T cells expressing a HLA-A*02:01-restricted T cell receptor specific for PRAME

Trial outline:

- Combined Phase I/II clinical trial
- Primary endpoints: Safety and feasibility (Phase I), Safety and early efficacy (Phase II)
- Disease indications for Phase I, all in advanced stages:
 - acute myeloid leukemia (AML)
 - myelodysplastic syndrome (MDS)
 - multiple myeloma (MM)
- 2 of the 3 indications will be carried over into Phase II

Outline of Phase I trial

Multi-center study at currently three sites (University of Regensburg, Würzburg, Erlangen and Dresden & more to be added) with approx. 12 patients



▲ = independent Data and Safety Monitoring Board (DSMB) decides on progression between dose cohorts.

DC vaccine trial in AML

Abstract on previously published topline data accepted at EHA conference

- Medigene will present data on the 12 months interim analysis at the **European Hematology Association (EHA)** conference in June
- First topline data published on 19 Dec 2018:
 - Very good feasibility for manufacture of vaccines from patient-derived monocytes
 - Excellent safety and tolerability profile
- The final 24 months read out of data will happen at the end of 2019

Financial Report 3M-2019

Financial overview for the first 3 months of 2019

€ 2.1m

Stable total revenues

+28%

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

€ 1.4m

Stable revenues from immunotherapies

€ 65.6m

Cash & cash equivalents

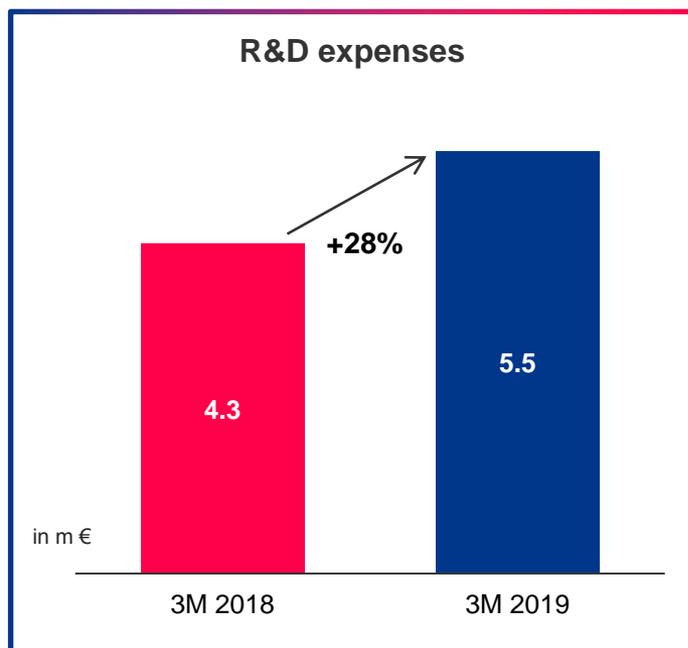
€ -5.0m

Increase in EBITDA loss by 31% as planned



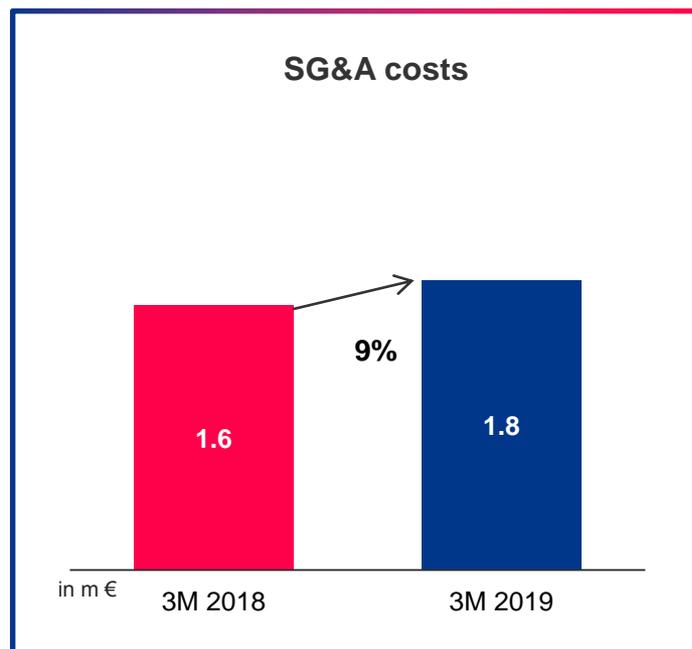
Financial guidance 2019 revised. Revenue guidance changed due to Roivant deal

Increase in R&D expenses by 28% reflect progress in preclinical and clinical development



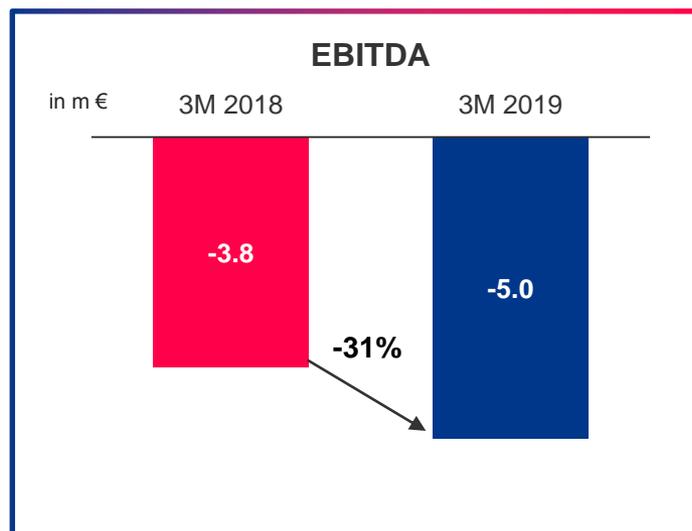
- Steady progress of DC clinical trial
- Ongoing clinical trial for MDG1011
- Expansion of clinical team and of internal TCR discovery platform (headcount increase, expansion of activities)
- Development and expansion of GMP manufacturing

Increased general & administrative costs due to BD activities and transactions



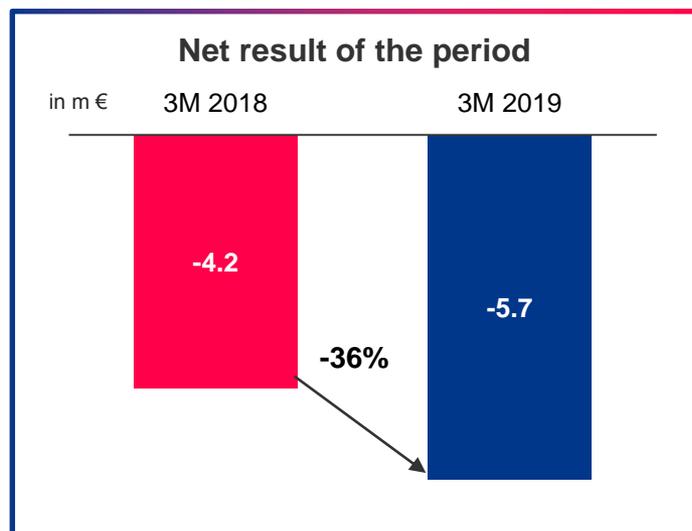
- General and administrative expenses remained stable
- Increase in selling costs, mainly due to business development activities

Increased EBITDA loss as planned



Comparison of EBITDA to previous period

- EBITDA loss increased by 31% due to higher R&D costs € 1.2 m



Differences between EBITDA and net result

- Foreign exchange, depreciation, financial result, taxes

Revised financial guidance 2019 due to recent transactions

	2018	GUIDANCE 2019	REVISED GUIDANCE 2019
Total revenues	€ 7.8 m	€ 5.5-6.5 m	€ 10-11 m
R&D expenses	€ 17.1 m	€ 24-29 m	€ 24-29 m
EBITDA loss	€ 16.3 m	€ 23-28 m	€ 23-28 m

- Liquid assets and time deposits as of March 31, 2019 amounted to € 65.6 m
- Medigene has sufficient financial resources for beyond the forecasting horizon of two years
- No milestone payments or cash inflows are included from existing or future partnerships or transactions

Outlook 2019

MDG1011, Medigene's first TCR trial:

- Treatment of first dose cohorts

Medigene's DC trial in AML:

- Analysis of 1-year-treatment (half of treatment period) to be presented at EHA in June 2019
- Final read-out (2-years-treatment) expected end of 2019/early 2020

HA-1 TCR:

- Further preclinical evaluation
- Decision on clinical development

TCR IIT by MDC & Charité:

- Study start

Progress in partnerships with bluebird bio and Roivant/Cytovant

Questions & Answers

IR Contact



Julia Hofmann
 Head of IR and PR
 T +49 89 2000 3333 24
 j.hofmann@medigene.com



Dr Robert Mayer
 Senior Manager IR and PR
 T +49 89 2000 3333 01
 r.mayer@medigene.com

IR Calendar 2019

Annual General Meeting	22/05/2019
Half-year Report	07/08/2019
Q3 Report	13/11/2019

Medigene AG

Lochhamer Straße 11
 82152 Planegg / Martinsried
 Germany

www.medigene.com

T +49 89 2000 33 0
 F +49 89 2000 3329 20
 investor@medigene.com