ANNUAL REPORT 2017

PRESS & ANALYST CONFERENCE CALL

MARTINSRIED, MARCH 22, 2018

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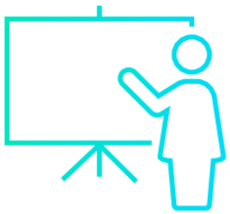
Highlights 2017

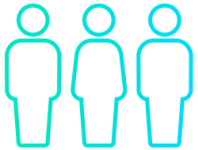
Highlights of 2017 and beginning of 2018

- Clinical trial authorization application (CTA) submitted for Medigene's first clinical trial with T cell receptor (TCR)-modified T cells, MDG1011 and approved by regulatory authorities
- Patient treatment to start in the first half of 2018

- Recruitment completed for Phase I/II DC vaccine clinical trial
- €20.7 m raised through placement of new shares at institutional investors in the US and Europe and capital increase through contribution in kind to settle third and final milestone payment for Trianta acquisition

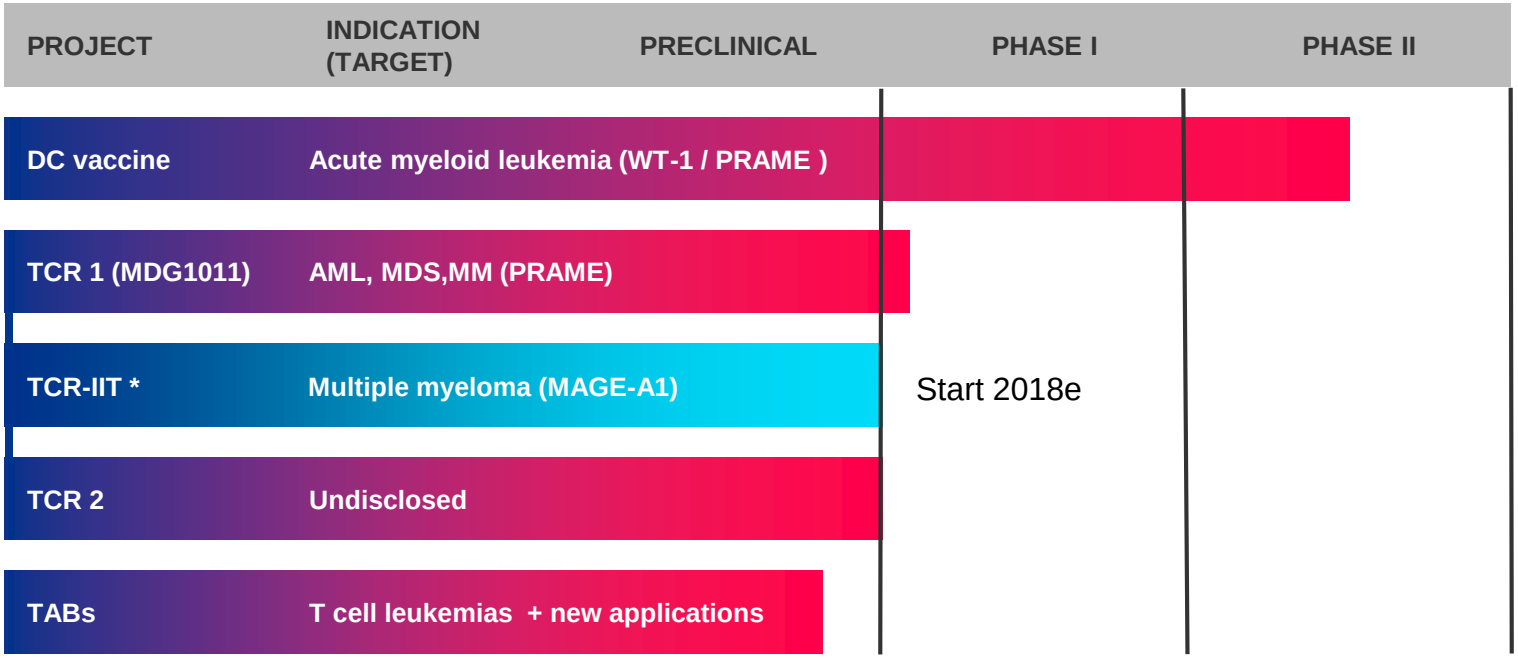


- Automated high throughput screening (HTS) platform for the identification of T cell receptors and its application to identify neoantigens presented at scientific conferences
- Preclinical data presented on Medigene’s first clinical TCR trial with MDG1011 targeting PRAME at AACR Annual Meeting, USA



- Expanded Supervisory Board and new Scientific Advisory Board

Progress of immunotherapy pipeline



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

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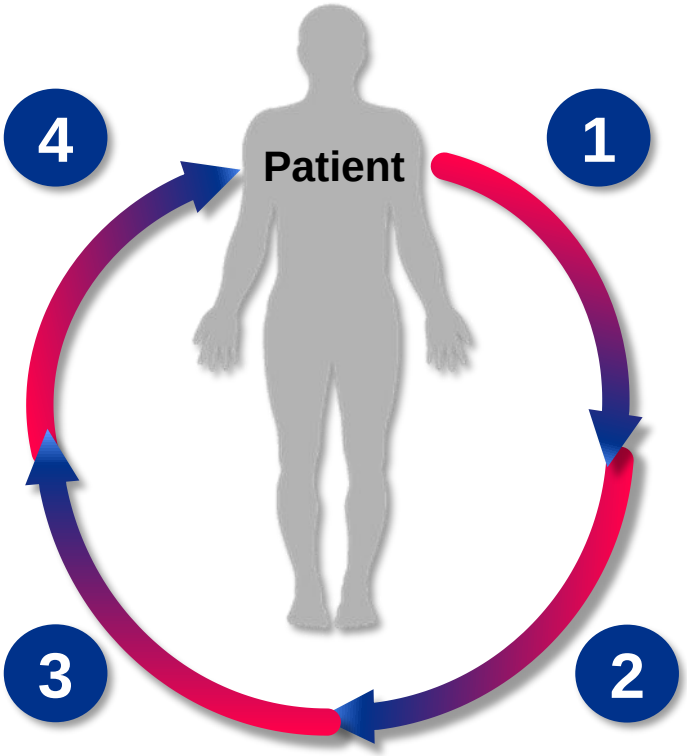
MDG1011

First TCR therapy clinical trial starts

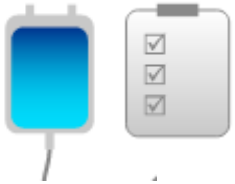
Personalized cancer treatment with TCRs

Thawing and re-infusion into patient

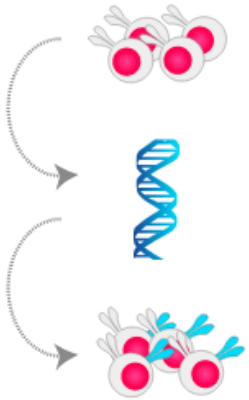


Leukapheresis & T cell isolation

TCR-T cell product



GMP: expansion, freezing and quality tests



GMP: activation of T cells and transfer of TCR from TCR pipeline

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

Target:

- PRAME (**Pr**eferentially Expressed **A**ntigen in **Me**lanoma)
- 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 (TCR) specific for PRAME

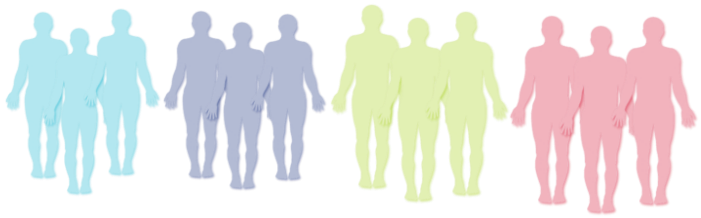
Trial outline:

- Combined Phase I/II safety, feasibility and early efficacy clinical trial
- 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

https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000440-18/DE

MDG1011 clinical trial design

Phase I



Approx. 12 patients
in up to 4 dose cohorts

- 3+3 dose escalation design, up to 4 cohorts
- Each indication needs to be represented in a cohort
- Dose ranges from 100,000 to 10,000,000 transduced T cells per kg body weight
- Progression between dose cohorts will be decided by an independent Data and Safety Monitoring Board (DSMB).
- Multi-center study at three sites (University of Regensburg, Würzburg and Erlangen, Germany)

Phase II

40 treated + 40 control patients

- 2 of 3 indications to be carried into Phase II after a positive DSMB assessment and PEI/ethics committee vote
- 40 HLA-A*02:01 and PRAME positive patients to be treated with MDG1011 (20 per indication)
- Another 40 patients, PRAME positive but HLA-A*02:01 negative, serve as control groups (20 control patients per indication)

https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000440-18/DE

MDG1011 clinical trial endpoints

Phase I:

Primary endpoint:

- Safety (incidence, severity of adverse events (AEs) at 3 months, maximum tolerated dose (MTD) based on dose limiting toxicities up to 28 days)
- Feasibility (percent of patients receiving the planned dose) at 3 months

Secondary endpoints:

- Safety (incidence, severity of AEs at 6 and 12 months)
- Overall response rate (ORR), duration of response (DoR), time to progression (TTP), progression-free survival (PFS), overall survival (OS), quality of life (QoL) and the correlation of PRAME expression with the antitumor response, measured at 3, 6 and 12 months

Phase II:

Co-primary endpoints:

- Safety (incidence, severity of AEs) at 3 months
- Efficacy (ORR) at 3 months

Secondary endpoints:

- Safety (incidence, severity of AEs) at 6 and 12 months
- ORR at 6 and 12 months, DoR, TTP, PFS, OS, QoL and the correlation of PRAME expression with the antitumor response at 3, 6 and 12 months

DC vaccine clinical trial

Ongoing DC Phase II part of clinical trial in AML

Target:

- WT-1 with or without PRAME
- WT-1 = Wilms' tumor 1
  PRAME = preferentially expressed antigen in melanoma

Clinical product:

- Dendritic cells of AML patients presenting WT and PRAME antigens

Clinical trial outline:

- AML patients in complete remission after chemotherapy, not eligible for allo-transplantation. Goal is to assess prevention of relapse
- Phase I/II: open-label, prospective, non-randomized trial
- Completed recruitment of 20 AML patients: 6 phase I + 14 phase II
- Continuous vaccination for 2 years or until progression/death
- Primary study objectives: feasibility and safety
- Secondary study objectives: overall survival (OS), progression free survival (PFS), control of minimal residual disease (MRD), time to progression (TTP), induction of immune responses
- Single center trial at Oslo University Hospital

ClinicalTrials.gov Identifier: NCT02405338

Presentation on DC vaccine production success at AACR, April 2018

- Poster entitled “Generation of clinical grade autologous TLR7/8-polarized fast dendritic cell vaccines for active immunotherapy of patients with AML” to be presented at AACR Annual Meeting in Chicago, USA, from 14-18 April 2018
- Final data of ongoing Phase II part of the trial is expected towards the end of 2019

Technology update

European patent covering T cell identification method

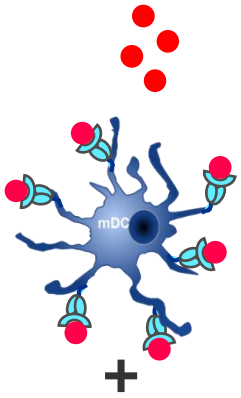
- Patent EP2327763 covers $CD4^+$ T cells obtainable by Medigene's proprietary allo-restricted T cell identification method
- Covers antigen-specific human MHC-class II-restricted $CD4^+$ T cells for use in a method for the treatment of solid tumors
- $CD4^+$ T cells can control cancer by their capacities to directly recognize and kill tumor cells
- $CD4^+$ T cells orchestrate the activities of other cells involved in anti-tumor responses, particularly $CD8^+$ killer T cell responses
- $CD4^+$ T cells can enter tumor tissue and exert anti-tumor functions in the tumor

Three approaches to gain high-affinity TCRs

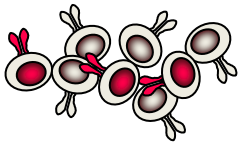
DCs with self-HLA only

DCs plus selected non-self-HLA

foreign antigen

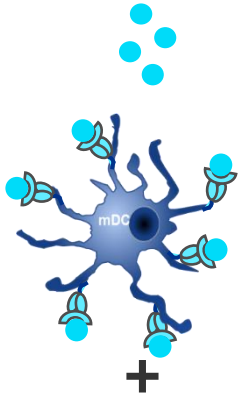


autologous T cells

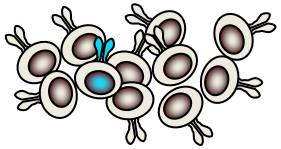


Abundant T cell clones
(self-HLA + foreign ag)

self antigen



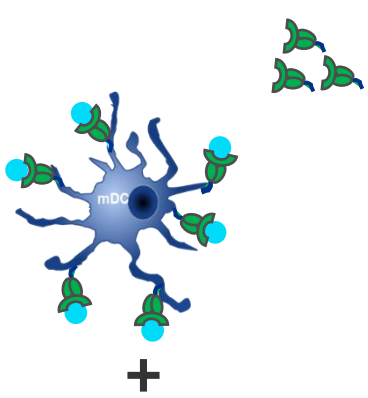
autologous T cells



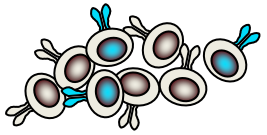
Rare T cell clones
found by HTS robotics
(self-HLA + self ag)

self antigen

non-self/foreign-HLA as *ivt*-RNA



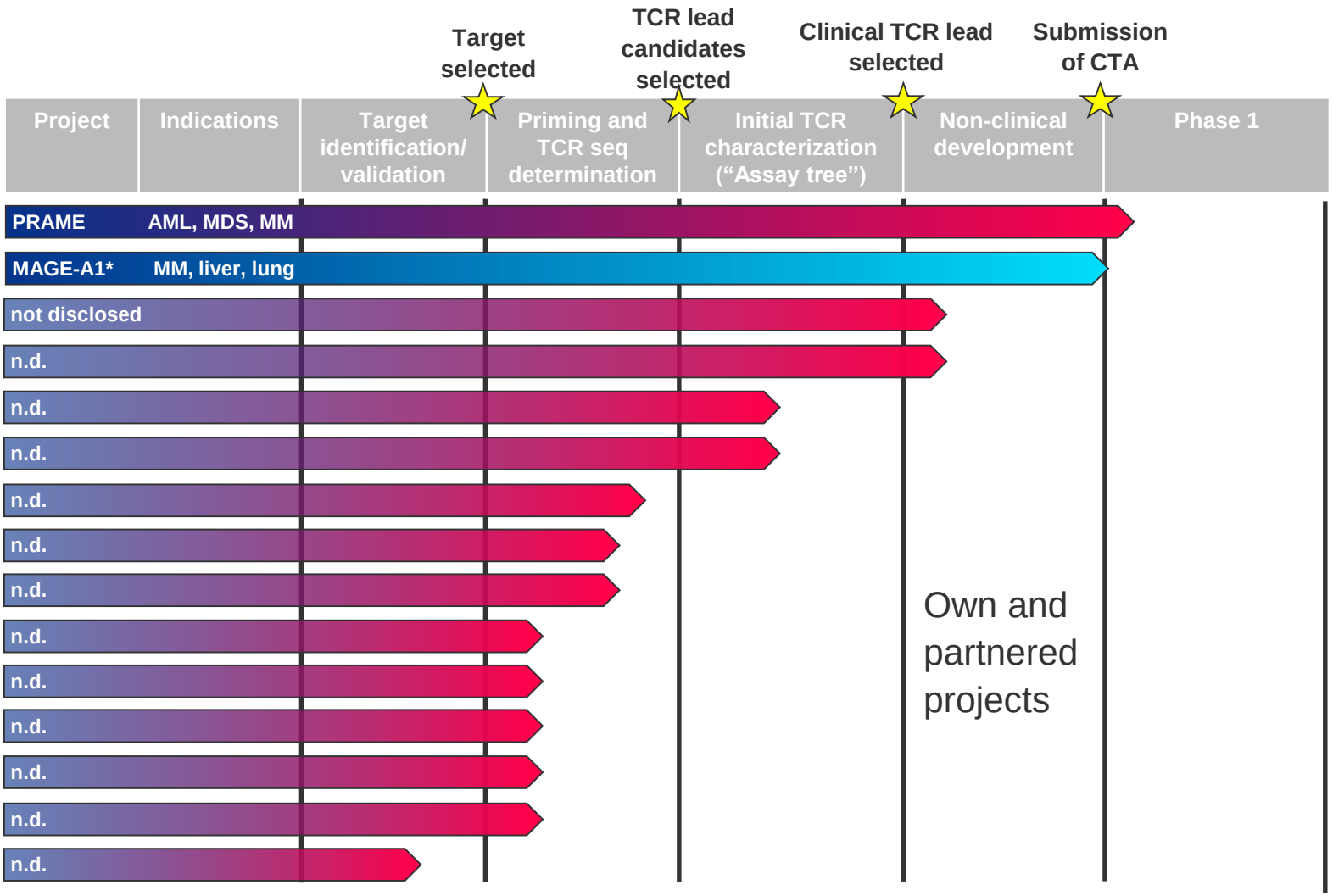
autologous T cells



Abundant T cell
clones
(non-self-HLA + self ag)

T cell clones are sources of **unique TCRs** for further studies

TCR research pipeline demonstrates power of platform



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

bluebird bio collaboration on TCR discovery

- T cell receptor (TCR) therapeutic candidates to be discovered and assessed against four targets
- Medigene generates and delivers TCRs to bluebird bio
- Joint preclinical assessment of multiple lead candidates ongoing
- bluebird bio gains worldwide development and commercial rights and exclusive license for IP covering the TCRs

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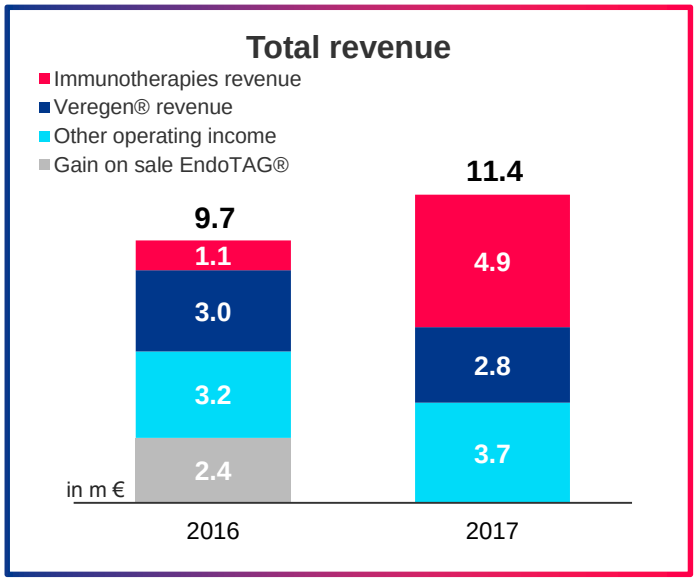
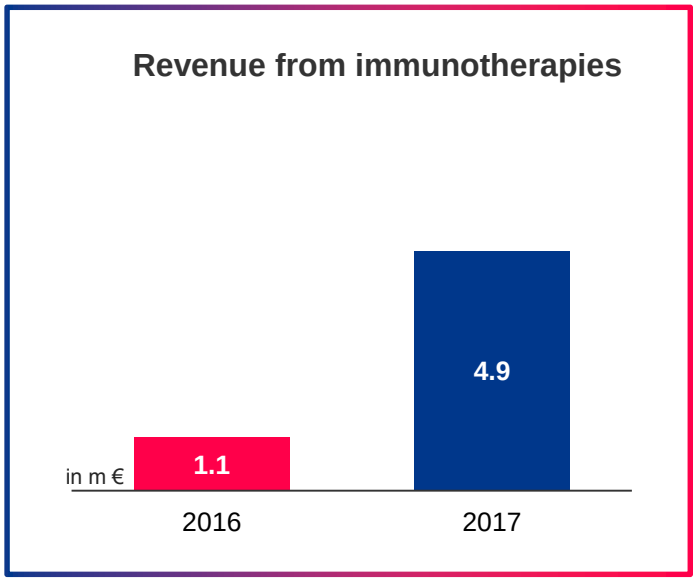
Financial Report 2017

Financial statements 2017 - highlights

€11.4 m	**Total revenues increased by 17%**
+29%	**Increase in R&D expenses due to progress in clinical programs**
€4.9 m	**Revenues from immunotherapies increased**
€51.7 m	**Cash & cash equivalents after successful capital raise in May 2017**
€-12.1 m	**Decrease in EBITDA loss**
☑	**Raised financial guidance 2017 met and exceeded**

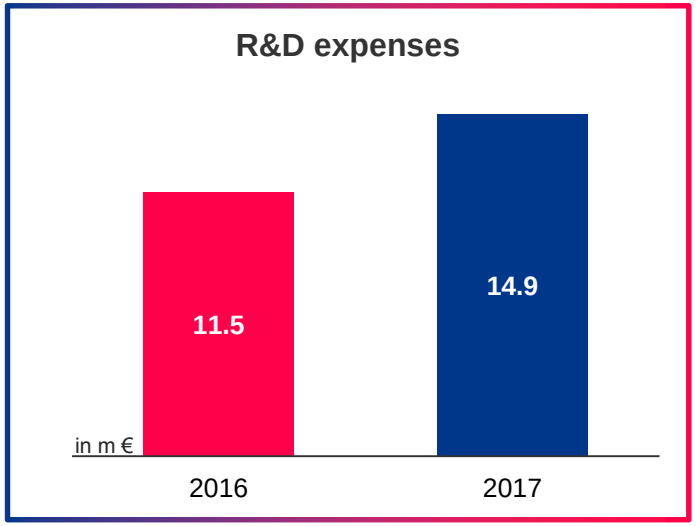
Increasing revenues from TCR collaboration



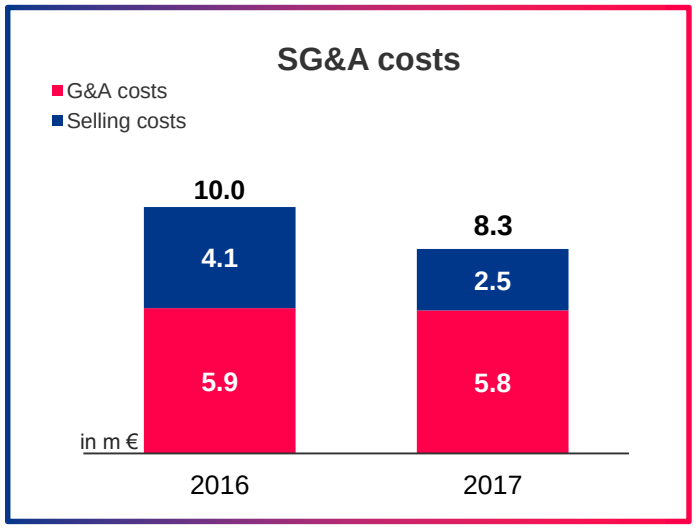


- Revenue of €4.9 m from bluebird bio (2016: €1.1 m) – revenue recognition of upfront payment and R&D reimbursement
- Revenue influenced by non-core business:
  - Sale of EndoTAG® (€2.4 m) in 2016
  - Decreased Veregen® revenues (-8%) – mainly US business

Increase in R&D expenses by 29%

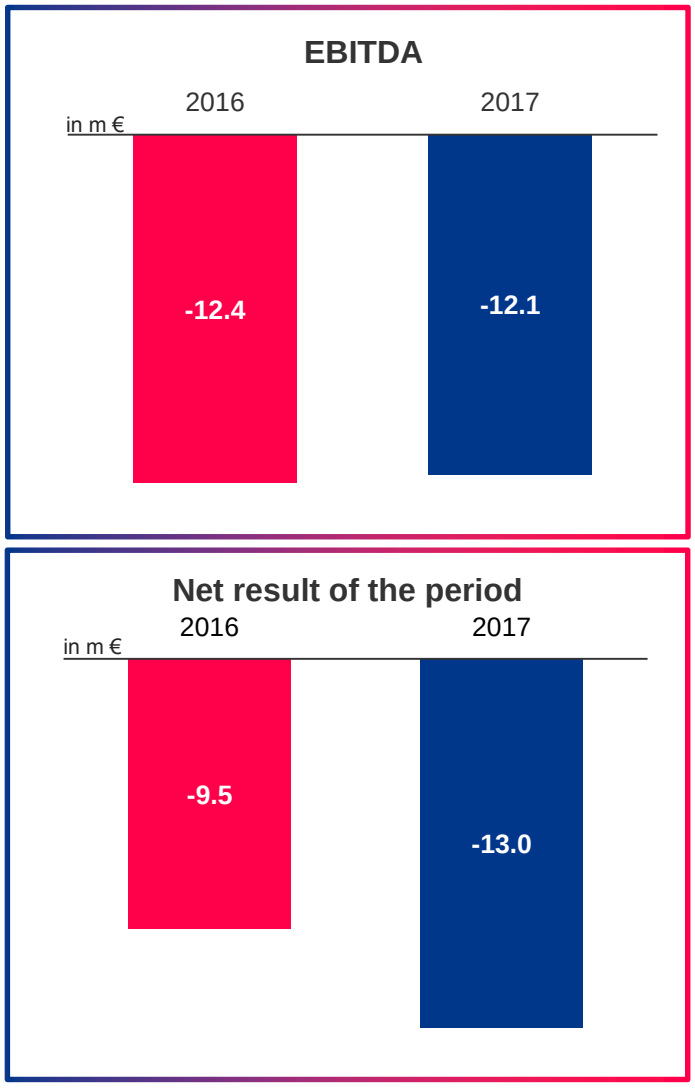


- Ongoing DC clinical trial
- Preparation of clinical trial for MDG1011, establishment of manufacturing process
- Expansion of TCR discovery platform



- Decrease of 18%, mainly due to one-time effects in 2016
- Higher Veregen® costs (accrual) in 2016 in connection with MNK license

Decreased EBITDA loss



Comparison of EBITDA to previous period

- Lower revenues from non-core business, but one-time effect from sale of Veregen® rights in the US
- Over-compensated by bluebird revenues
- Increase of operating costs (mainly in R&D)

Differences between EBITDA and net result

- Foreign exchange gain, financial result, taxes
- Mainly due to sale of Immunocore shares, positive impact in 2016 (net gain €4.2 m)

Raised financial guidance 2017 met and exceeded

	2016	ADJUSTED GUIDANCE 2017	2017
Total revenue	€9.7 m	€10.5-11.5 m	€11.4 m
R&D expenses immunotherapies	€11.5 m	€16-18 m	€14.9 m
EBITDA loss	€12.3 m	€14-15 m	€12.1 m
Cash usage		€20-22 m	€20.4 m

- Guidance raised after sale of US rights of legacy product Veregen to Fougera
- Cash & cash equivalents as of December 31, 2017: €51.7 m
- Sufficient financial resources to fund operations to the time points that data from DC trial and TCR trial become available

Financial guidance 2018

	2017	GUIDANCE 2018
Total revenue	€11.4 m	€7.5-9.5 m
R&D expenses	€14.9 m	€22-24 m
EBITDA loss	€12.1 m	€21-23 m
Cash usage	€20.4 m	€21-26 m

- Medigene has sufficient financial resources for beyond the planning horizon of two years
- No milestone payments or cash inflows are included from existing or future partnerships or transactions

Outlook 2018

MDG1011, Medigene's first TCR trial:

- Treatment of first patient
- Treatment of first dose cohorts

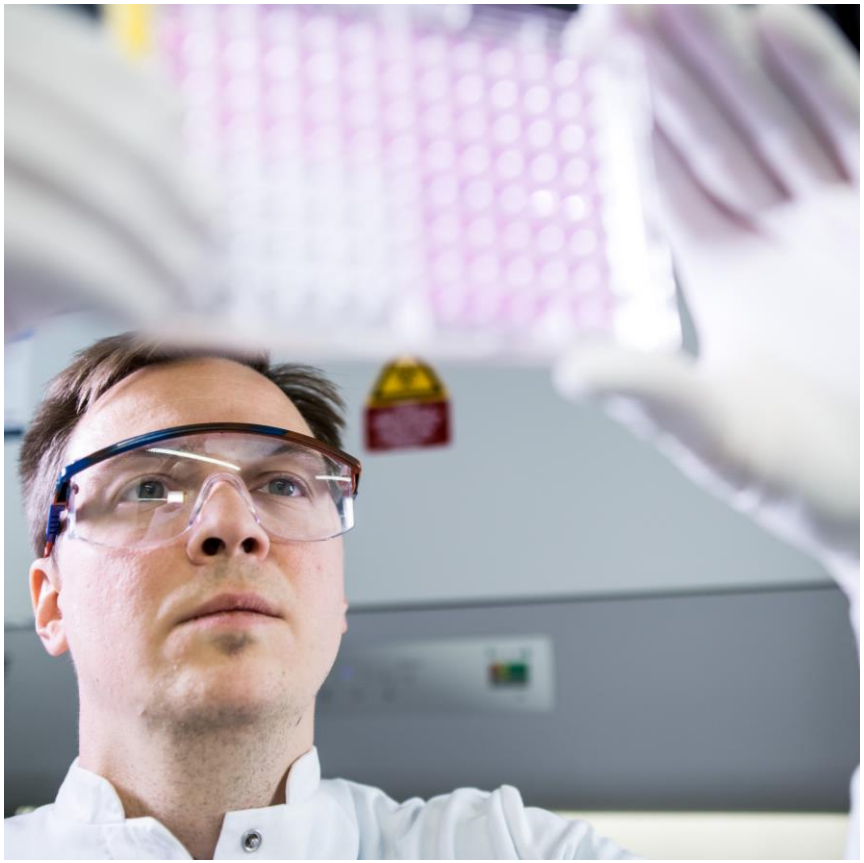
DC trial in AML, Oslo:

- Presentation of preliminary data on certain aspects of the trial, starting at AACR
- Final read-out in 2019

TCR IIT, Berlin:

- Clinical trial authorization
- Study start

Progress in bluebird collaboration



Questions & Answers

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