medigene

clinical-stage immunotherapies

ANALYST CONFERENCE CALL

Results for the first 3 months of 2016

Prof. Dolores J. Schendel, CEO/CSO
Dave Lemus, COO

"Safe Harbor" Statement

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.

Major events in 2016 to date

Patient recruitment and safety evaluation of Phase I part of AML study completed – study moved into Phase II

IIT clinical data presented at AACR by academic partner

Collaborations with University of Lausanne and EUFETS for TCRs

DC patent portfolio strengthened

Sale of 50% of Immunocore shares

New management structure and strengthened team

Medigene's new Management since Q1

Prof. Dolores J. Schendel
CEO/CSO

Dave Lemus
COO

Dr. Kai **Pinkernell**
SVP /Chief Medical Officer

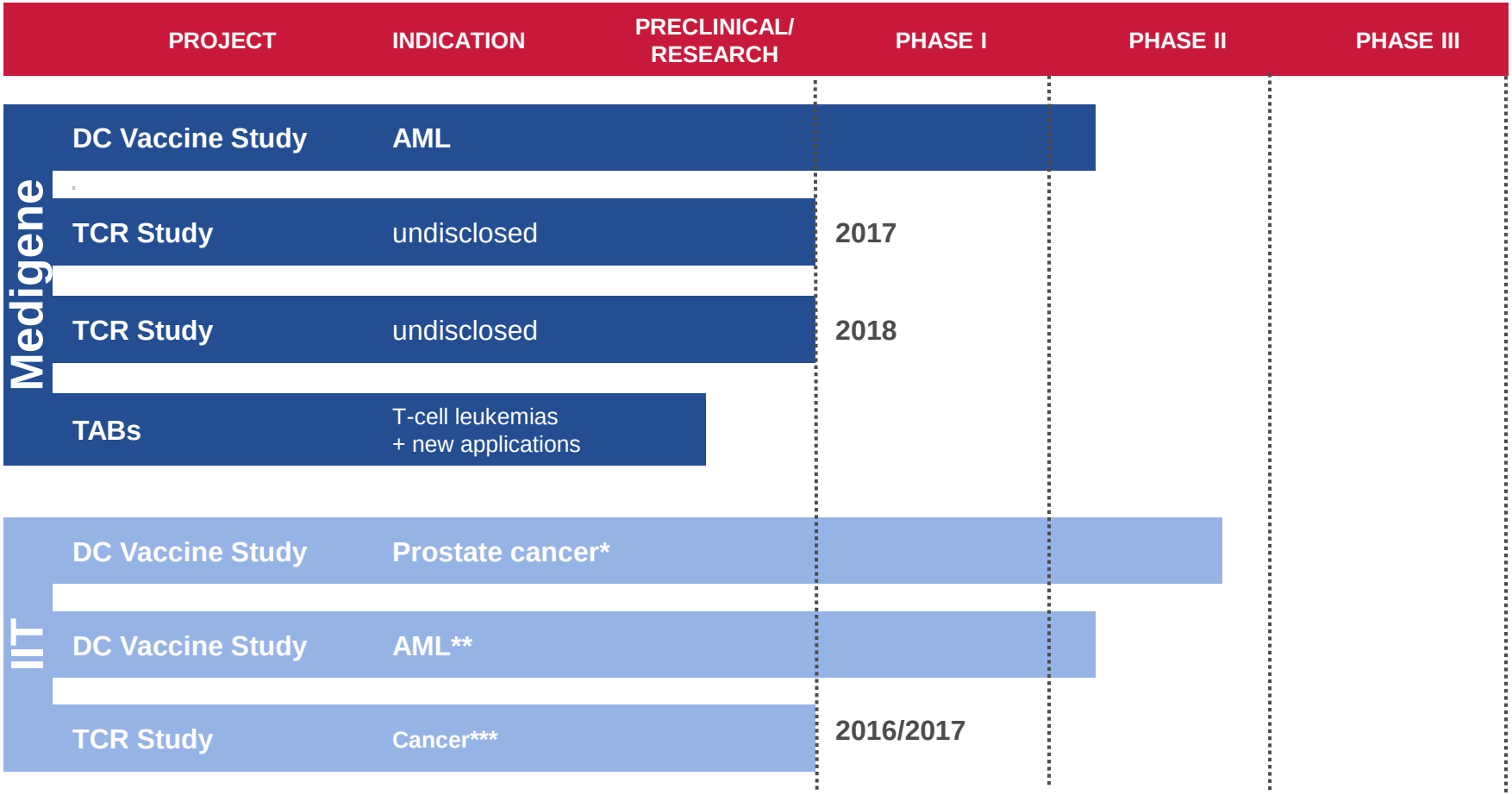
Dr. Dr. Olav **Zilian**
SVP Corporate Development

Dr. Markus **Dangl**
SVP Research & Pre-Clinical Development

Medigene‘s Immunotherapy Programs

Clinical Progress and Outlook

Medigene's immunotherapy pipeline and current IIT trials

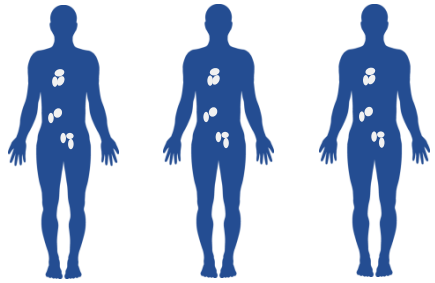


* Investigator initiated trial (IIT) Oslo University Hospital
** Investigator initiated trial (IIT) Ludwig-Maximilians University Hospital
***Investigator initiated trial (IIT) with Medigene being part of the consortium, pending grant funding

Further progress in Medigene's own DC trial in AML: Phase II part started in April 2016

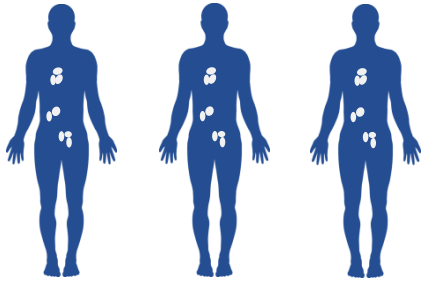
- **Trial design:**
  - **Phase I/II:** open-label, prospective, non-randomized trial
  - **20 AML patients:** 6 phase I + 14 phase II, complete remission after chemotherapy, not eligible for allo-transplantation
  - Patients selected with AML expressing the vaccine antigens: **WT-1** with or without **PRAME** (expressed on LIC/LSC)
  - **Persistent vaccination for 50** weeks and a follow-up period of one year or until progression
  - Primary objectives: **feasibility** and **safety**
  - Secondary objectives: induction of **immune responses**; control of minimal residual disease (**MRD**); clinical response: time to progression (**TTP**)

Treatment scheme of Medigene's DC trial

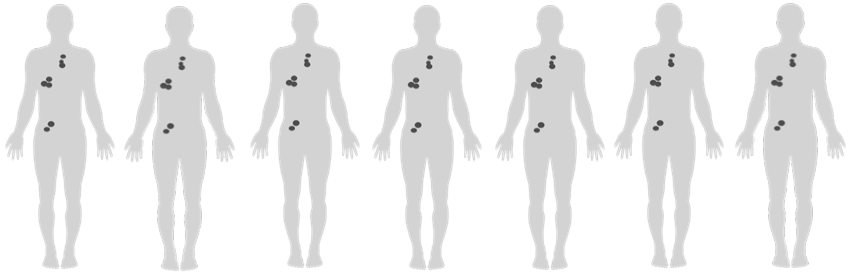


PHASE I
6 patients

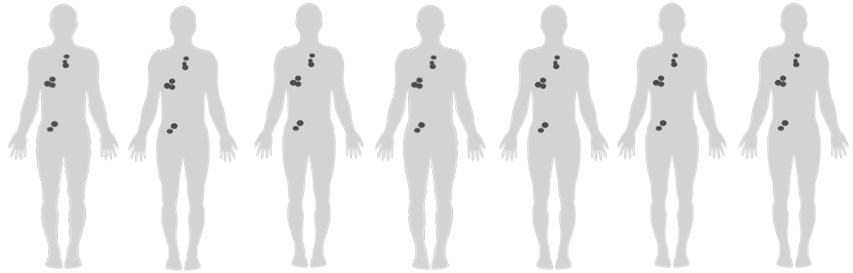
DSMB approval



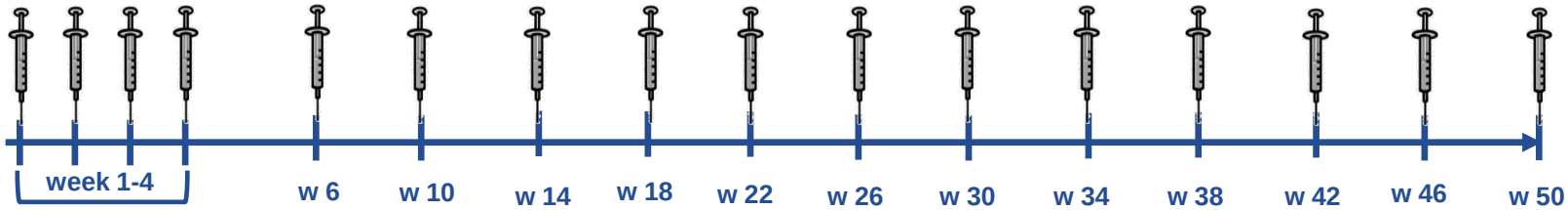
Phase II started in April 2016



PHASE II
14 patients



Treatments with Medigene's DC vaccines



IITs using Medigene's DC vaccine technology

	Study	Sponsor	Status
AML	**Clinical Study, Investigator-initiated** • AML, intermediate and high-risk patients. • Phase I/IIa • Opened: Q1/2014 • 10 of 20 patients enrolled (Q4 2015)	Prof. M. Subklewe Ludwig-Maximilians University Munich **NCT01734304**	Phase I completed Phase II opened Data presented at: • CRI-CIMT-EATI-AACR 09/2015 • ASH 12/2015
	Compassionate Use • 5 patients with AML (Q4 2015)	Prof. G. Kvalheim Dept. of Cellular Therapy Oslo University Hospital	Data presented at: • AACR 04/2015 • PIVAC 09/2015 • ASH 12/2015 • CIMT 5/2016
Non-hematological diseases	**Compassionate Use** • Different tumors and stages • 6 patients with solid tumors	**Prof. G. Kvalheim** Dept. of Cellular Therapy Oslo University Hospital	Data presented at: • AACR 04/2015 • PIVAC 09/2015
	Clinical Study, Investigator-initiated • Prostate cancer • Phase II • Opened: Q2/2014 • 20 patients recruited, 8 already completed three years of treatment	Oslo University Hospital **NCT01197625**	Patient treatment ongoing Data presented at: • PIVAC 09/2014 • AACR 04/2015 • AACR 04/2016

Clinical data from IIT presented by Oslo University at AACR conference in April 2016

- Preliminary data from ongoing phase I/II investigator-initiated trial in high risk prostate cancer
- First adjuvant DC vaccine study with 20 enrolled patients:
  - Use of two different maturation cocktails
  - The last five of 20 treated patients received DCs that were matured with new TLR7/8-agonist maturation cocktail developed by Medigene, allowing product manufacturing in less time, thereby increasing throughput and cost effectiveness .
- Three of 15 patients given DC vaccines derived with the old (standard) maturation cocktail have experienced a biochemical relapse.
- None of the five patients given the new type of DC vaccines has so far experienced a rise in PSA levels.
- Investigator concludes that “the study is feasible, safe and utmost promising.”

AML Compassionate Use data presented by Oslo University at CIMT conference

- Compassionate Use patients receive dendritic cell (DC) vaccines for the treatment of AML at OUH:
  - DC vaccines targeting WT-1 and PRAME
  - Vaccines made with Medigene's new generation monocyte-derived fast dendritic cells
- Five patients treated with DC vaccination after hematopoietic recovery from first line chemotherapy treatment
- Four patients have now been treated between 16 and 26 months

Medigene’s TCR studies in preparation

- Developments to start own clinical TCR studies:
  - Identification of TCRs and pre-clinical work
  - GMP-conform patient treatment development
- Medigene‘s first company sponsored trial:
  - Additional viral vector production capacities secured at EUFETS GmbH
  - In process of selecting commercial manufacturing partner

Outlook for Medigene's clinical programs

DCs:

- Continuation of Phase I treatment to completion of all patients at 50 weeks
- Sequential initiation of observation period for Phase I as patients complete treatment
- Recruitment and treatment of DC vaccinated AML patients at Oslo University Hospital for Phase II trial

TCRs:

- Isolation and further characterization novel TCRs for Medigene's TCR library
- Commence two Medigene-sponsored clinical phase I/II trials in 2017 and 2018
- Pioneering first TCR trial in Germany as IIT at Charité Hospital Berlin early 2017 with Medigene in a supporting role

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Excursion on IITs

Experience in IITs accelerates Medigene's own pipeline developments

- Use experience
- Logistics setup (i.e. cross-border)

- Early insight into potential toxicity

- Patient groups to be treated
- Dosing scheme

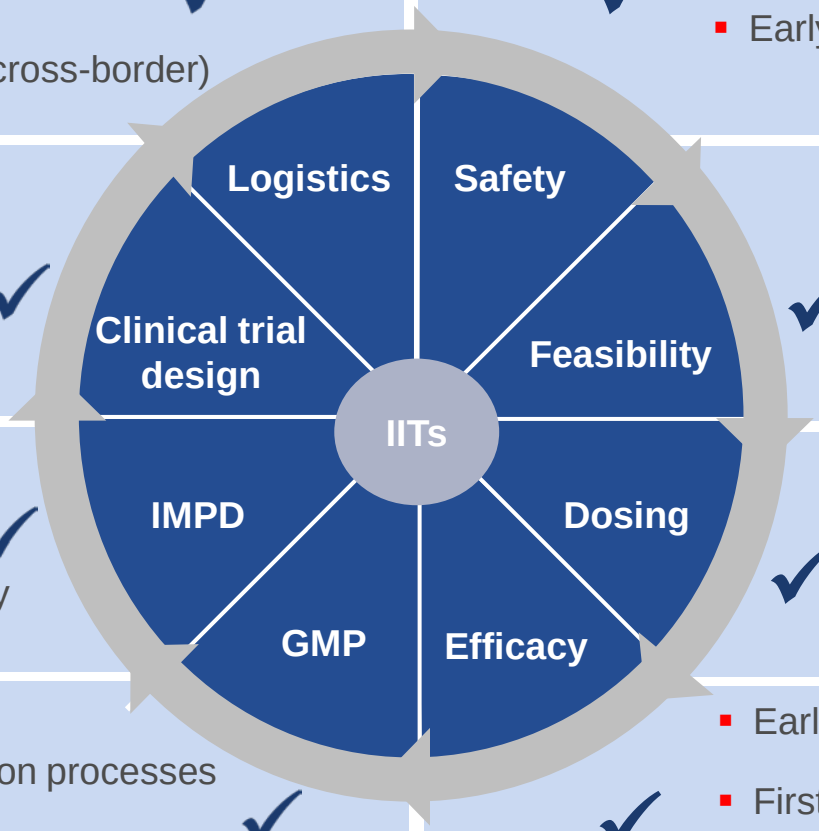
- Acquiring adequate patient materials
- Quality of patient cells for GMP processes

- Interaction with regulatory agencies
- Approval of regulatory documents

- First dosing information
- First insight into DLTs

- Establishing production processes
- Defining the right quality parameters

- Early insight into immune response
- First signs of clinical impact
- Exploratory testing in therapeutic areas outside company focus



Limitations of investigator initiated trials (IITs)

- Little or no influence on clinical trial design, feasibility, execution of the trial and timelines
- No or limited data ownership; access to trial data at the investigator's discretion
- Dependence on investigator's communication and publication plans
- Limited or no ownership of IP that results from investigator initiated work

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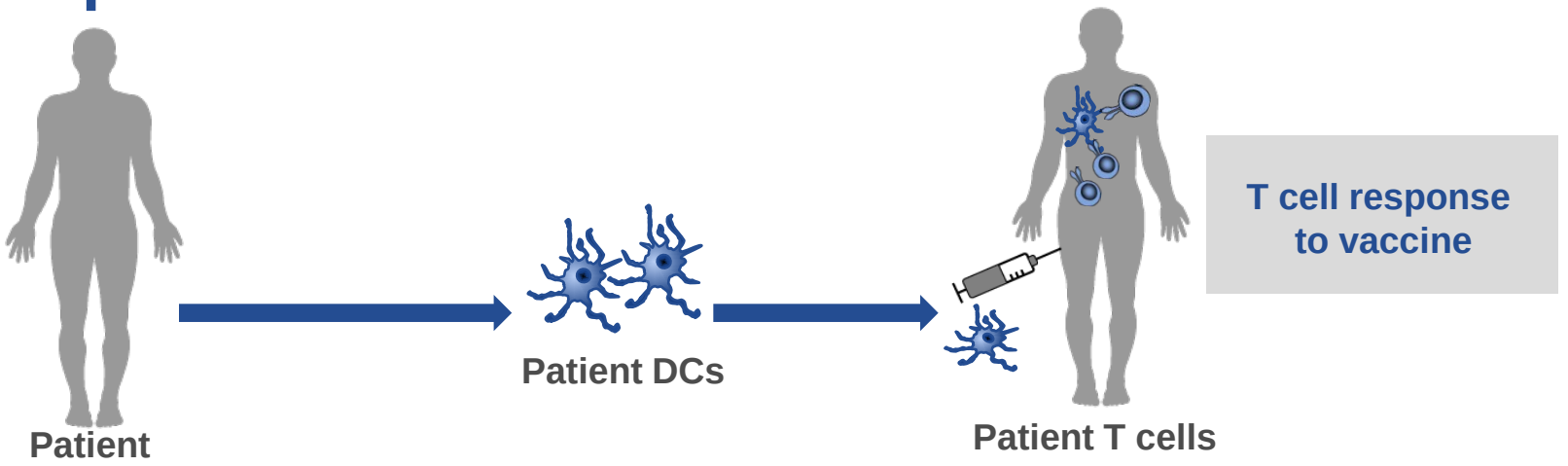
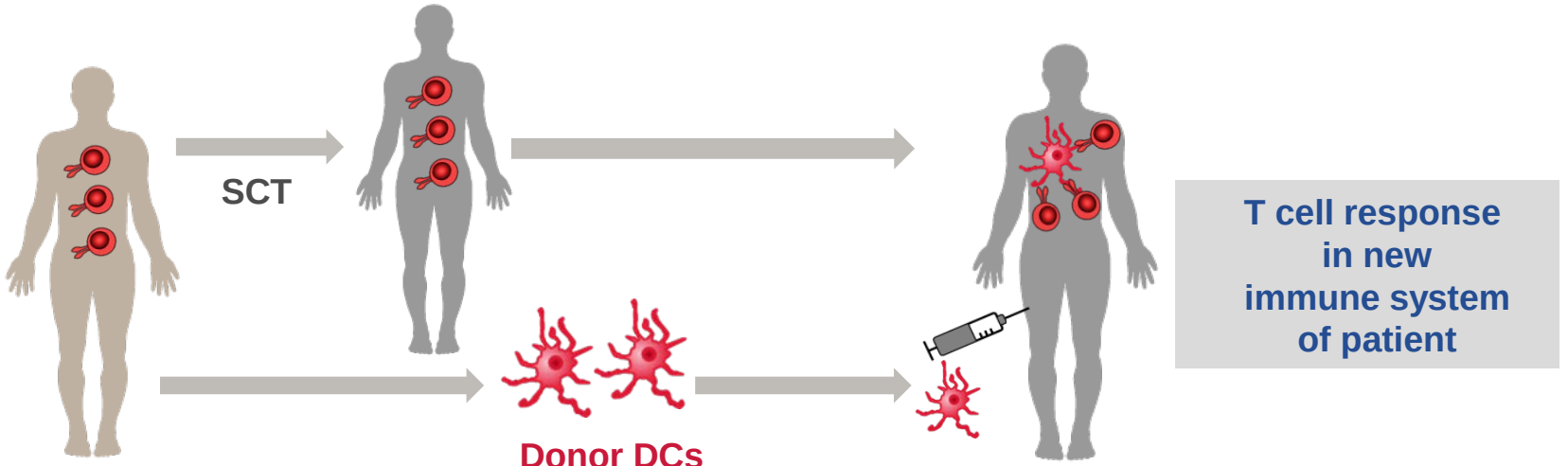
Granted patent for the treatment of stem cell or bone-marrow transplanted patients

- US patent 9,238,063 was granted by the US Patent Office in February 2016
- The patent claims a method of treating a tumor disease in patients by using semi-allogeneic antigen presenting cells of an HLA halpo-identical donor
- The method is highly important in the immunotherapy of stem cell or bone-marrow transplanted patients
- Medigene has an exclusive license to the patent that was issued to Helmholtz Zentrum München (German Research Center for Environmental Health)

DC vaccination before and after stem cell transplantation in AML



After stem cell transplantation



HLA-haplo family donor

Donor T cells in the SCT patient

Financial Report Q1 2016

Financial overview for the first 3 months of 2016

+132%

Total revenues increased by 132%

+64%
immunotherapies R&D

R&D expenses for immunotherapies increased by 64%

54%

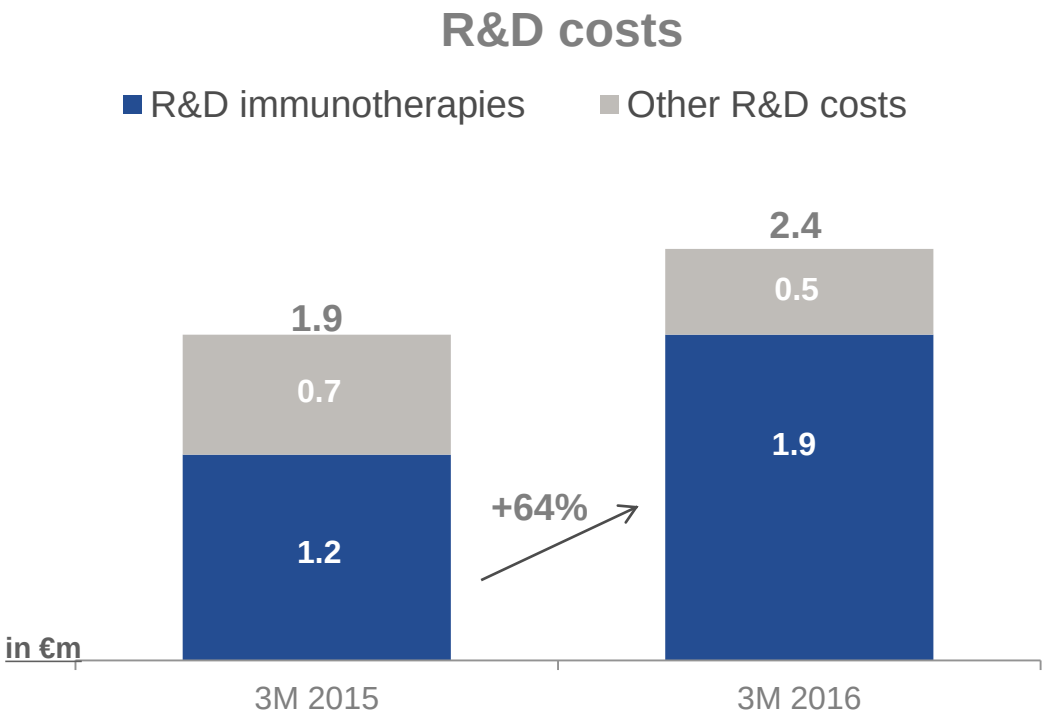
EBITDA loss reduced by 54%

€46.3m

Cash & cash equivalents of €46.3 m

Confirmation of financial guidance 2016

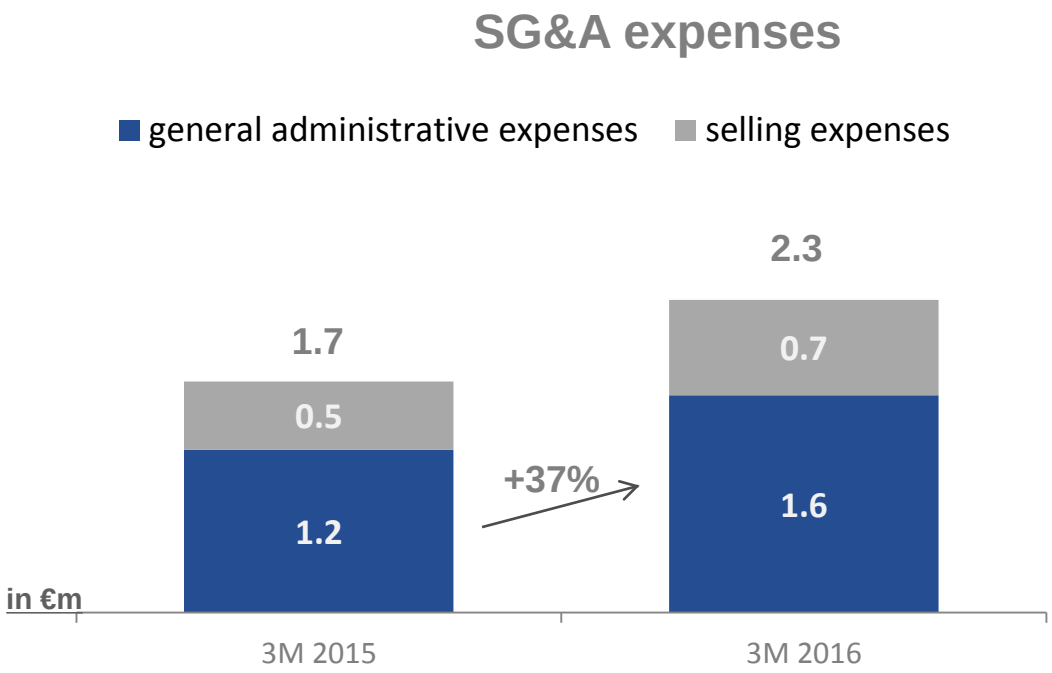
Increase in R&D expenses for immunotherapies by 64% due to progress in clinical programs



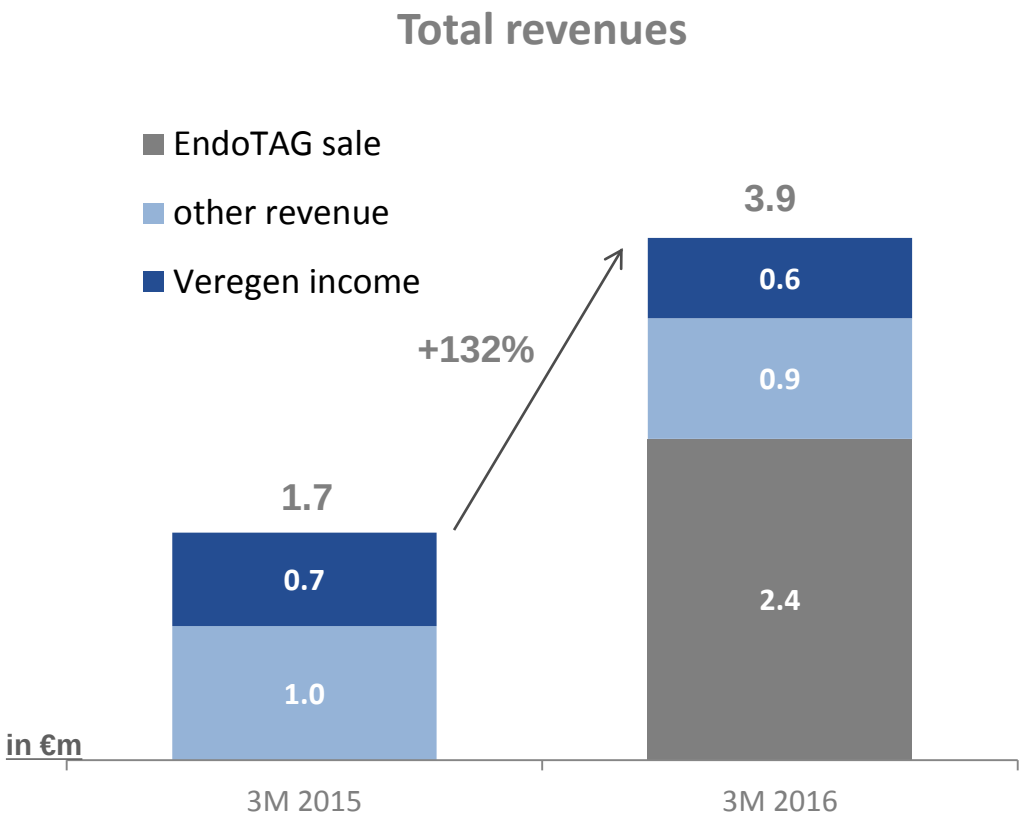
Increase due to:

- Medigene's progressing DC study
- Preparation of clinical development of TCRs
- New hirings

Higher General & Administrative Expenses relate to management changes

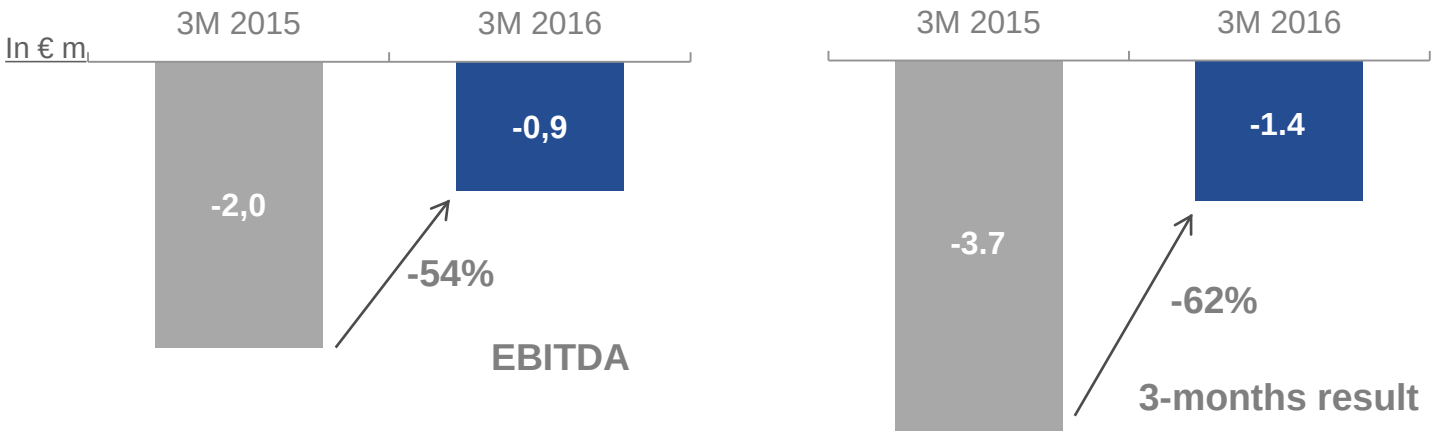


Increase in total revenue by 132% influenced by sale of EndoTAG®



- Increase in other operating income due to one-off effect:
  - EndoTAG income sale license (2016: €2.4 m, 2015: €0.0 m)

EBITDA loss reduced by 54%



- Decrease in EBITDA and net loss in spite of higher expenditures for immunotherapies mainly due to EndoTAG sale
- Difference between EBITDA and net result due to:
  - financial result
  - translational currency differences

Balance sheet – Strong cash position

Development of assets, shareholders' equity and liabilities (in € k)		31/03/2016	31/12/2015	Change
Assets				
Non-current assets		45.231	51.552	-12%
Current assets				
thereof:	Cash and cash equivalents and time deposits	46.310	46.759	-1%
	Inventories and trade accounts receivable and current other assets	18.554	13.141	41%
	Intangible assets held for sale	0	2.079	-
Total assets		**110.095**	**113.531**	**-3%**
				-
Shareholders' equity and liabilities				-
Shareholders' equity		88.112	89.988	-2%
Non-current liabilities		12.970	13.879	-7%
Current liabilities		9.013	9.664	-7%
Total shareholders' equity and liabilities		**110.095**	**113.531**	**-3%**

Medigene realized € 6m by partial sale of stake in Immunocore in April 2016

- Sale of 50% in private biotech company Immunocore, UK, for GBP4.9 m (approx. €6.1 m) on 4th April 2016
- Significant increase in value: Medigene held 64,815 ordinary shares in Immunocore which were valued at GBP2.8 m (approx. €3.6 m) in 2014
- Gain of sale will be realized as financial result in Q2

Start of phase II in DC vaccine trial triggers milestone payment in new shares

- Treatment start of first phase II-patient in Medigene‘s ongoing phase I/II trial with DC vaccine in AML announced on 1st April 2016
- Milestone payment of approx. €3.2 m to be made by Medigene to former contributing shareholders of Medigene Immunotherapies within 5 months
- Settlement through issuance of 392,875 new shares from authorized capital

Financial guidance 2016 confirmed

	2015	Guidance 2016
Total revenues	€6.8 m	Stable/increasing
Veregen® total revenue*	€3.1 m	€3 - 4 m
R&D expenses Immunotherapies	€5.5 m	€9 -11 m
EBITDA loss	€9.5 m	€10 - 12 m

* assuming constant exchange rates

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Questions & Answers

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