

# Quarterly Statement Q1 2016

of Medigene AG, Planegg/Martinsried, for the period from 1 January to 31 March 2016

## MAJOR EVENTS SINCE THE BEGINNING OF 2016

Immunotherapies:

- Phase II of Phase I/II trial with DC vaccine for the treatment of acute myeloid leukaemia (AML) initiated following positive recommendation by DSMB
- Early IIT clinical data for DC vaccines presented at AACR Annual Meeting by academic partner Oslo University
- DC patent portfolio strengthened
- Additional viral vector production capacities secured for clinical TCR studies
- Research collaboration started with University of Lausanne for TCRs

Company:

- Management change: CSO Prof Dolores Schendel appointed CEO/CSO, Dave Lemus takes over as COO
- Strengthened management team with appointment of three Senior Vice Presidents

## KEY FIGURES IN THE FIRST QUARTER OF 2016

- Increase in total revenue by 132% to €3,909 k (3M 2015: €1,686 k)
- Increase in R&D expenses for immunotherapies by 64% to €1,907 k (3M 2015: €1,166 k)
- EBITDA loss reduced by 54% to €939 k (3M 2015: €2,042 k)
- Cash and cash equivalents and time deposits of €46,310 k as at 31/3/2016 (31/12/2015: €46,759 k)
- Confirmation of financial guidance 2016

**Prof. Dolores Schendel, Chief Executive Officer of Medigene AG**, comments: "In the first quarter of 2016, the clinical development of our immunotherapy programmes progressed further. We are making extensive efforts now towards putting into practice our first clinical studies with TCRs. As Medigene's new CEO, I'm delighted about these important examples of progress."

**Dave Lemus, Chief Operating Officer of Medigene AG**, adds: "Medigene's transformation into a leading immuno-oncology company begins increasingly to take shape. Accordingly, the planned increase in expenses for immunotherapy-driven research and development in the first quarter of 2016 evidences this change, and is enabled by the company's positive financial condition."

**KEY FIGURES OF MEDIGENE**

IN € K	Q1 2016 UNAUDITED	Q1 2015 UNAUDITED	CHANGE
<b>Results of operations</b>			
Total revenue	3,909	1,686	132%
Veregen® revenue	624	714	-13%
Other operating income	3,285	972	>200%
thereof gain on sale of intangible assets, net (EndoTAG)	2,365	0	-
Gross profit	3,594	1,418	153%
Selling and general administrative expenses	-2,312	-1,740	33%
Research and development expenses	-2,395	-1,932	24%
Operating result	-1,113	-2,254	-51%
<b>Net profit/loss for the period</b>	<b>-1,387</b>	<b>-3,672</b>	<b>-62%</b>
<b>EBITDA</b>			
Earnings per share (€)	-0.07	-0.26	-73%
Personnel expenses	-2,452	-1,758	39%
<b>Cash flows</b>			
Net cash used in operating activities	-1,064	-1,777	-40%
Net cash provided by/used in investing activities	626	-53	>-200%
Net cash used in financing activities	-11	0	-
<b>Balance sheet data as at 31 March 2016 and 31 December 2015</b>			
Cash and cash equivalents and time deposits	46,310	46,759	-1%
Total assets	110,095	113,531	-3%
Current liabilities	9,013	9,664	-7%
Non-current liabilities	12,970	13,879	-7%
Shareholders' equity	88,112	89,988	-2%
Equity ratio (%)	80	79	1%
<b>Employees as at 31 March</b>			
<b>FTE as at 31 March</b>	<b>81</b>	<b>69</b>	<b>17%</b>
<b>Medigene share as at 31 March</b>			
Total number of shares outstanding	19,688,202	13,956,417	41%
Share price (XETRA closing price) (€)	7.19	12.31	-42%
3-month high <sup>1)</sup>	9.27	13.50	
3-month low <sup>1)</sup>	6.16	3.70	
Free float <sup>2)</sup> (%)	58	65	

<sup>1)</sup> Daily closing price<sup>2)</sup> Shareholding below 3%. Source: Medigene AG, Deutsche Börse [German Stock Exchange]

## **PROGRESS WITHIN CORE BUSINESS OF IMMUNOTHERAPIES SINCE BEGINNING OF 2016**

### **DC vaccines (DCs)**

Since March 2015 Medigene AG has been conducting a Phase I/II clinical trial with its DC vaccine for the treatment of acute myeloid leukaemia (AML). In March 2016 the independent Data and Safety Monitoring Board (DSMB) came to a positive evaluation of the safety and tolerability data obtained after the first six patients were treated with the DC vaccine at least four times and recommended advancing the study to Phase II. In April 2016 Medigene announced the treatment start of the first patient for the Phase II part.

In February 2016 Medigene announced the grant of US patent 9,238,063 by the US Patent Office (USPTO) covering semi-allogeneic anti-tumour vaccines with HLA-haplo-identical antigen presenting cells (APCs). Medigene holds an exclusive license to the patent that was issued to Helmholtz Zentrum München (German Research Center for Environmental Health).

In April 2016 Medigene's academic partner, Oslo University, presented positive early clinical data of an ongoing investigator-initiated clinical Phase I/II trial (IITs) on dendritic cell (DC) vaccines for the treatment of prostate cancer (relapse prophylaxis in high risk patients) at the American Association for Cancer Research (AACR) Annual Meeting in New Orleans, LA, USA. The poster presented was entitled "Clinical results of a Phase I/II trial of adjuvant therapeutic vaccination in high risk resected prostate cancer patients using autologous dendritic cells loaded with mRNA from primary prostate cancer tissue, hTERT and survivin".

### **TCR-modified T cells (TCRs)**

Medigene announced in January 2016 a collaboration agreement with the University of Lausanne to explore new technologies for the characterisation of Medigene's T-cell receptors (TCRs). The objective is to establish a better and faster method for selecting tumour-specific T cells characterised by expression of suitable T-cell receptors (TCRs) for Medigene's expanding TCR library.

In February 2016, Medigene signed an agreement with the contract manufacturer EUFETS GmbH for the production and delivery of viral vectors. EUFETS is an experienced contract manufacturing organisation (CMO) that will take over further process development tasks and vector optimisation processes, the establishment of different cell banks, and the batch production of viral vectors for Medigene's T-cell receptor (TCR) based cancer therapies.

### **T cell-specific antibodies (TABs)**

Preclinical development continued on T-cell-specific-monoclonal antibodies (TABs).

## **STRENGTHENED MANAGEMENT STRUCTURE**

As Medigene AG announced in December 2015, Prof. Dolores J. Schendel took over from Dr. Frank Mathias as Chief Executive Officer (CEO) in addition to her responsibilities as Chief Scientific Officer (CSO) starting February 2016. Dr. Mathias left the Company effective as at the end of March 2016.

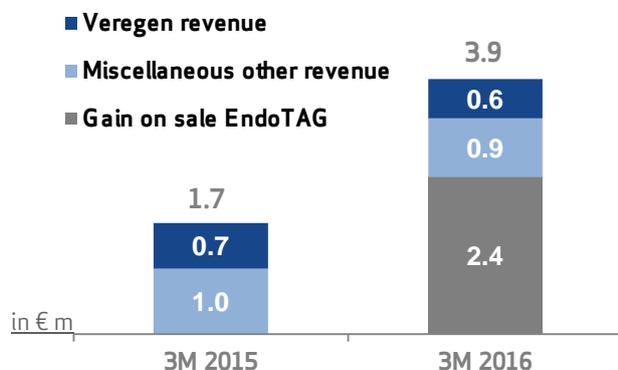
Dave Lemus, member of the Supervisory Board of the Company until December 2015, assumed the newly created position of Chief Operating Officer (COO) with effect from January 2016 as well as the duties of Chief Financial Officer (CFO) from April 2016. Executive Management Board member Peter Llewellyn-Davies left the Company at the end of March 2016.

In January 2016 Medigene announced the expansion of the management team by appointing Dr. Dr. Olav Zilian as Senior Vice President Corporate Development, Dr. Kai Pinkernell as Senior Vice President Medical Affairs/Chief Medical Officer (CMO) and Dr. Markus Dangl as Senior Vice President Research & Pre-Clinical Development.

These management changes are a next step in sharpening Medigene's focus on research, clinical development and commercialisation of its innovative immunotherapies.

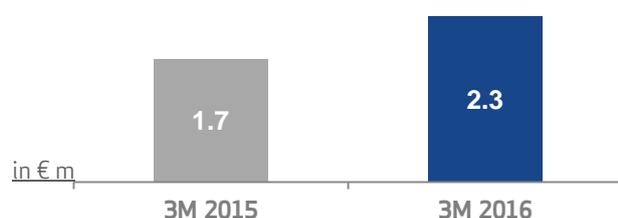
## RESULTS OF OPERATIONS

### Total revenue



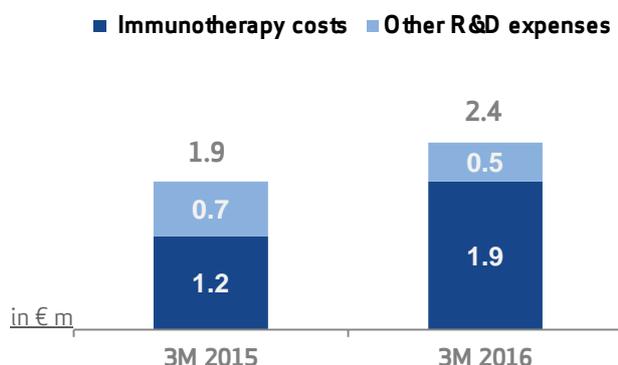
The Company generates its revenue and other operating income from non-core business. Total revenue of the Company increased by 132% to €3,909 k in the reporting period (3M 2015: €1,686 k) on account of extraordinary effects related to the sale of EndoTAG<sup>7</sup> agreed in December 2015.

### Selling and general administrative expenses



Selling and general administrative expenses rose in the first three months of 2016 as budgeted to €2,312 k (3M 2015: €1,740 k). The increase in administrative expenses is primarily due to the changes and reinforcements to the management team.

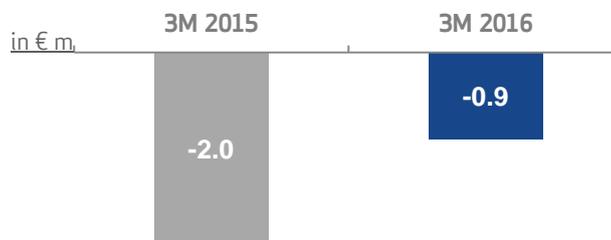
### Research and development expenses



Research and development expenses increased by 24% in the first three months of 2016 to €2,395 k (3M 2015: €1,932 k). The increase in these expenses is mainly due to the intended increase in expenditure for preclinical and clinical trials for Medigene's immunotherapies, which increased significantly by 64% to €1,907 k in the first three months of 2016 (3M 2015: €1,166 k).

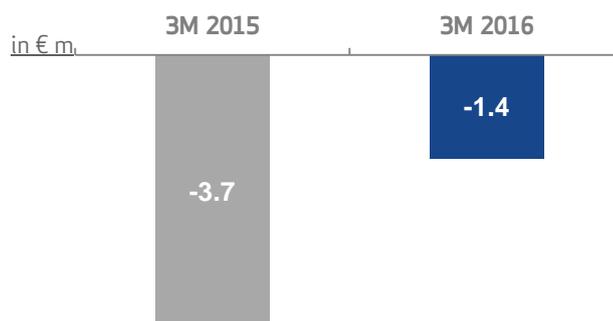
## EBITDA

In spite of higher development expenses for its immunotherapy programmes, Medigene reduced its EBITDA loss in the first three months of 2016 by 54% to €939 k (3M 2015: EBITDA loss of €2,042 k). Medigene's EBITDA is derived from the net profit/loss for the period; it does not include any taxes, financial result, foreign exchange gains or losses, share of result of associates, or depreciation or amortisation.



## Net profit/loss for the first three months of 2016

Medigene reduced its net loss in the first three months of 2016 by 62% to €1,387 k (3M 2015: €3,672 k).



## FINANCIAL POSITION

### Net cash used in operating activities

Medigene reduced its net cash used in operating activities significantly in the first three months of 2016 to €1,064 k (3M 2015: €1,777 k). This represents an average monthly cash outflow of €0.4 m in the first three months of 2016 (3M 2015: €0.6 m). The major part of the cash used was directed at research and development as well as sales and administration.

### Cash and cash equivalents and time deposits

The cash and cash equivalents and time deposits of the Company amounted to €46,310 k as at the end of the reporting period (31/12/2015: €46,759 k).

## NET ASSETS

### Assets

Financial assets of €6,005 k were reclassified from non-current financial assets to current other assets in the first quarter of 2016. This reclassification is due to the sale of 50% of the shares held by Medigene in Immunocore Inc., which was realised on 4 April 2016.

Moreover, the intangible asset held for sale, EndoTAG, of €2,079 k was derecognised in the first quarter of 2016 due to the sale agreed at the end of 2015.

## SUBSEQUENT EVENTS

The following major events in terms of corporate development occurred after the end of the reporting period:

### Upcoming milestone payment to former contributing shareholders of Medigene Immunotherapies GmbH

Medigene announced on 1 April 2016 the treatment start of the first Phase II patient in its DC vaccine clinical Phase I/II trial in AML triggering a milestone payment in the value of approx. €3.2 m to the former contributing shareholders of Medigene Immunotherapies GmbH and that Medigene intended to settle this payment by issuing new shares. On 10 May 2016, Medigene announced that the payment will be settled through the issuance of 392,875 new shares from authorised capital. Thereby, the company will increase its share capital of 19,688,960.00 EUR up to 20,081,835.00 EUR as part of a capital increase through contributions in kind. The number of these new shares was calculated on the basis of the volume weighted average price (VWAP) of Medigene shares in the 30-day period prior to and the 30-day period from 1 April 2016 being the date on which the achievement of the milestone was announced. The calculated VWAP is approx. EUR 8.08. The milestone payment was an agreed part of the purchase price in the acquisition of Medigene Immunotherapies in January 2014.

### Sale of partial stake in Immunocore for €6.1 m

On 4 April 2016, Medigene AG sold 50% of its stake in the private biotech company Immunocore Ltd., UK, for approximately GBP4.9 m (approx. €6.1 m). Medigene held a total of 64,815 ordinary shares in Immunocore as at 31/3/2016.

## OUTLOOK

### Financial guidance 2016

Medigene confirms its financial guidance for 2016 published in the 2015 annual report. In 2016, Medigene is planning to expand its clinical development programs, which will significantly increase R&D expenses in the field of immunotherapies to €9 - 11 m (2015: €5.5 m). The EBITDA loss is estimated to be €10 -12 m (2015: €9.5 m).

Medigene expects total Veregen<sup>®</sup> revenue of €3 - 4 m (2015: €3.1 m), and stable or increasing total revenue for 2016 (2015: €6.8 m). Since this revenue is not generated in the Company's core business of immunotherapies, these figures are not indicative of the same. This financial guidance does not include any possible proceeds from potential new partnership agreements, or any exchange rate fluctuation.

### Outlook on immunotherapies:

#### DC vaccines (DCs)

In 2016 Medigene will continue, as planned, the Phase I/II clinical trial for the treatment of acute myeloid leukaemia (AML) which started in March 2015.

#### TCR-modified T cells (TCRs)

The development of a GMP-compliant manufacturing process for adoptive T-cell therapy using TCR-modified T cells will be continued. Medigene is preparing the clinical development of the first product candidates. In addition, novel TCRs with specificities for promising tumour-associated antigens will be isolated and further characterised. In the coming years, Medigene aims to initiate up to three clinical TCR trials, the first to be started by the end of 2016 or early 2017 (IIT Phase I study with participation of Medigene, subject to grant funding). Medigene-sponsored trials are planned to start in the second half of 2017 and in the second half of 2018.

#### T cell-specific antibodies (TABs)

Preclinical development of the T-cell-specific monoclonal antibodies (TABs) will be continued with the aim of achieving preclinical proof of principle.

# CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIODS FROM 1 JANUARY TO 31 MARCH 2016 AND 2015

IN € K	Q1 2016 UNAUDITED	Q1 2015 UNAUDITED
Revenue	624	714
Other operating income	3,285	972
<b>Total revenue</b>	<b>3,909</b>	<b>1,686</b>
Cost of sales	-315	-268
<b>Gross profit</b>	<b>3,594</b>	<b>1,418</b>
Selling expenses	-682	-554
General administrative expenses	-1,630	-1,186
Research and development expenses	-2,395	-1,932
<b>Operating result</b>	<b>-1,113</b>	<b>-2,254</b>
Interest income	58	25
Interest expense	-663	-388
Foreign exchange gains/losses	422	-1,036
Other financial result	9	0
Share of result of associates	0	-19
<b>Earnings before tax</b>	<b>-1,287</b>	<b>-3,672</b>
Taxes	-100	0
<b>Net profit/loss for the period</b>	<b>-1,387</b>	<b>-3,672</b>
Basic and diluted earnings per share (€)	-0.07	-0.26
Weighted average number of shares (basic and diluted)	<b>19,684,602</b>	<b>13,941,923</b>

# CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS AT 31 MARCH 2016 AND 31 DECEMBER 2015

IN € K	31/3/2016 UNAUDITED	31/12/2015
<b>ASSETS</b>		
<b>A. Non-current assets</b>		
I. Property, plant and equipment	2,717	2,502
II. Intangible assets	33,486	33,501
III. Goodwill	2,212	2,212
IV. Financial assets	6,529	13,014
V. Other assets	287	323
<b>Total non-current assets</b>	<b>45,231</b>	<b>51,552</b>
<b>B. Current assets</b>		
I. Inventories	7,399	6,654
II. Trade accounts receivable	543	763
III. Other assets	10,612	5,724
IV. Time deposits	38,000	38,000
V. Cash and cash equivalents	8,310	8,759
<b>Total current assets</b>	<b>64,864</b>	<b>59,900</b>
C. Intangible assets held for sale	0	2,079
<b>Total assets</b>	<b>110,095</b>	<b>113,531</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>		
<b>A. Shareholders' equity</b>		
I. Subscribed capital	19,687	19,678
II. Capital reserve	426,744	426,671
III. Accumulated deficit	-367,216	-365,829
IV. Other reserves	8,897	9,468
<b>Total shareholders' equity</b>	<b>88,112</b>	<b>89,988</b>
<b>B. Non-current liabilities</b>		
I. Finance lease liabilities	497	548
II. Financial liabilities	9,747	10,605
III. Pension obligations	359	359
IV. Other financial liabilities	416	416
V. Deferred taxes	1,951	1,951
<b>Total non-current liabilities</b>	<b>12,970</b>	<b>13,879</b>
<b>C. Current liabilities</b>		
I. Finance lease liabilities	199	196
II. Trade accounts payable	708	1,354
III. Other financial liabilities	8,106	7,888
IV. Deferred income	0	226
<b>Total current liabilities</b>	<b>9,013</b>	<b>9,664</b>
<b>Total liabilities</b>	<b>21,983</b>	<b>23,543</b>
<b>Total shareholders' equity and liabilities</b>	<b>110,095</b>	<b>113,531</b>

## FINANCIAL CALENDAR

### 5 August 2016

6-Month Report 2016  
Press and analyst conference call

### 11 August 2016

Annual General Meeting 2016  
Munich

### 11 November 2016

Quarterly Statement Q3 2016  
Press and analyst conference call

## TRADEMARKS

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## IMPRINT

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