medigene

3M 2018

MEDIGENE AG
QUARTERLY STATEMENT 3M-2018

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OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE PERIOD FROM JANUARY 1 TO MARCH 31, 2018

MAJOR EVENTS SINCE THE BEGINNING OF 2018

Immunotherapies:

- Medigene starts Phase I/II clinical trial with T cell receptor (TCR)-modified T cell therapy MDG1011 and initiated patient recruitment
- Medigene presented data on the successful production of acute myeloid leukemia (AML) dendritic cell (DC) vaccines in the current Phase I/II clinical trial at the AACR conference
- Oslo University presented clinical data for DC vaccines in prostate cancer investigator-initiated clinical trials (IITs) at the AACR conference
- Medigene strengthened its patent portfolio with a US patent on a tagged TCR and a European patent covering a T cell identification method

Company:

- Medigene appointed Dr. Kai Pinkernell as Chief Medical Officer and Chief Development Officer of the Executive Management Board
- '*Deutsche Krebshilfe Preis*' awarded to CEO Prof. Dolores Schendel

KEY FIGURES IN THE FIRST QUARTER OF 2018

- Revenue from bluebird bio partnership increased by 24% to €1,384 k (3M 2017: €1,118 k)
- Total revenue increased by 6% to €2,766 k (3M 2016: €2,609 k)
- Research and development expenses increased as planned by 20% to €4,319 k (3M 2017: €3,612 k) due to progress in proprietary immunotherapy programs
- Selling and general administrative expenses decreased by 12% to €1,633 k (3M 2017: €1,854 k)
- EBITDA loss increased as planned by 6% to €3,188 k (3M 2017: €3,020 k)
- Net loss for the period decreased by 3% to €3,550 k (3M 2017: €3,678 k)
- Cash and cash equivalents and time deposits of €49,104 k as of March 31, 2018 (December 31, 2017: €51,724 k)
- Confirmation of financial guidance 2018

OUTLOOK 2018

- → TCR-Ts: Ongoing patient recruitment and patient treatment in all indications with the aim of conducting the first study cohorts of Phase I
- → TCR-Ts IIT: Start of the academic TCR clinical trial by the Max-Delbrück-Center and Charité University Hospital in Berlin, Germany
- → DCs: Presentation of provisional data on specific aspects of the current Phase I/II AML clinical trial
- → Further progress in the bluebird bio cooperation

Prof. Dolores Schendel, CEO/CSO of Medigene AG, comments: “We made encouraging progress in the first quarter of 2018, most notably by starting the clinical trial with our cancer immunotherapy MDG1011. With a TCR-based cell product in clinical stage development, Medigene is now among the few leading companies worldwide exploring this promising therapy field. The appointment of Dr. Kai Pinkernell to the Board as Chief Medical Officer and Chief Development Officer underlines Medigene’s commitment to ramping up our clinical focus and reflects the progress Medigene has made in the clinical development of TCR-Ts and DC-vaccines for the treatment of severe cancer indications. In-line with our operational progress, our financial figures are also on track.”

KEY FIGURES OF MEDIGENE

IN € K	**Q1-2018 UNAUDITED**	Q1 2017 UNAUDITED	CHANGE
Results of operations			
Total revenue	**2,766**	**2,609**	**6 %**
thereof revenue from immunotherapies	**1,384**	1,118	24 %
Gross profit	**2,390**	2,189	9 %
Selling and general administrative expenses	**-1,633**	-1,854	-12%
Research and development expenses	**-4,319**	-3,612	20 %
Operating result	**-3,562**	-3,277	9 %
Net profit/loss for the period	**-3,550**	**-3,678**	**-3 %**
EBITDA	**-3,188**	**-3,020**	**6 %**
Earnings per share (€)	**-0.16**	-0.18	-11 %
Personnel expenses	**-2,436**	-2,408	1 %
Cash flow			
Net cash used in operating activities	**-3,185**	-4,865	-35 %
Net cash from investing activities	**2,941**	272	>200 %
Net cash used in/from financing activities	**-376**	8	--
Balance sheet data as at March 31, 2018 and December 31, 2017			
Cash and cash equivalents and time deposits	**49,104**	51,724	-5%
Total assets	**107,862**	111,937	-4 %
Current liabilities	**10,869**	9,808	11 %
Non-current liabilities	**14,183**	15,962	-11 %
Shareholders' equity	**82,810**	86,167	-4 %
Equity ratio (%)	**77**	77	-
Employees as at March 31	**101**	92	10 %
FTEs as at March 31	**94**	86	9 %
Medigene share as at March 31			
Total number of shares outstanding	**22,311,127**	20,148,059	
Share price (XETRA closing price) (€)	**14.45**	11.35	27 %

PROGRESS WITHIN CORE BUSINESS OF IMMUNOTHERAPIES SINCE BEGINNING OF 2018

TCR-modified T cells (TCR-Ts)

In March 2018, Medigene announced the start of the Phase I/II clinical trial with TCR-T cell immunotherapy MDG1011 for the treatment of various types of blood cancer, which plans to include approximately 92 blood cancer patients with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or multiple myeloma (MM). MDG1011 is Medigene's first clinical TCR-T immunotherapy product candidate.

The Phase I part of the clinical trial is a dose escalation of the T cell therapy product with 3-4 dose cohorts (depending on the results). Each dose cohort will include one patient for each of the three indications AML, MDS und MM respectively. The patients will first be included in the clinical trial sequentially in compliance with requirements imposed by the authorities to ensure patient safety. Following approval for the start of the trial by the regulatory authority, Medigene announced the start of the trial at the end of March 2018 and was able to begin patient screening.

In February 2018 Medigene announced the grant of US patent 9.862.755, covering a high affinity T cell receptor with an epitope tag. Applying an epitope tag to a high affinity T cell receptor potentially allows *ex vivo* and *in vitro* assessment of adoptively transferred T cell therapeutics. In March 2018, Medigene announced the granting of European patent EP2327763, a member of Medigene's core patent family protecting the company's allo-restricted *ex vivo* method of identifying T cells. The underlying patent family additionally comprises patents granted in the US and Japan. The two patents expand Medigene's growing patent portfolio in the field of TCR-T immunotherapies.

DC vaccines (DCs)

In April 2018 Medigene and researchers from Oslo University Hospital presented a poster on the generation of dendritic cell vaccines for Medigene's ongoing Phase I/II clinical trial with AML patients. The results clearly demonstrate the feasibility and robustness of Medigene's production protocol for clinical grade TLR7/8-polarized fast mature DCs from heavily pretreated AML patients, allowing for long-term vaccination of trial subjects in the ongoing trial.

Medigene's academic partner, Oslo University Hospital, also presented an update of a Phase I/II investigator initiated trial (IIT) at the annual general meeting of the American Association for Cancer Research (AACR) in April 2018. The data shows that adjuvant dendritic cell vaccines in high-risk prostate cancer patients following radical surgery can reduce the incidence of early biochemical relapse. The subset data from the DC vaccines produced utilizing Medigene's DC vaccine technology are encouraging for this patient population with limited curative options. The clinical data was collected at the Department of Cellular Therapy at Oslo University Hospital, Norway, led by Prof. Gunnar Kvalheim, partially utilizing Medigene's DC vaccine technology.

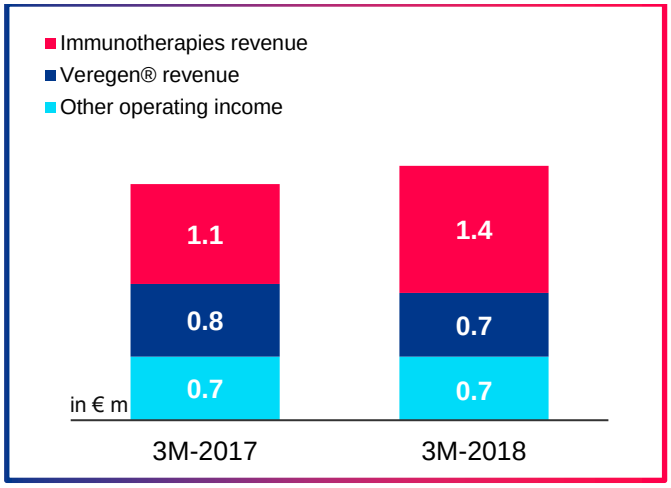
MANAGEMENT

In April 2018 Medigene announced the appointment of Dr. Kai Pinkernell as Chief Medical Officer (CMO) and Chief Development Officer (CDO) to the Executive Management Board of the Company. Dr. Pinkernell has been with Medigene as Senior Vice President and Chief Medical Officer (CMO) since February 2016. The appointment of Kai Pinkernell and the expansion of the Executive Management Board is in line with Medigene's advancement as a clinical stage immuno-oncology company.

Medigene's CEO/CSO Prof. Dolores Schendel received the '*Deutsche Krebshilfe Preis 2016*' (German Cancer Aid Prize 2016) in February 2018 for her significant contribution to the development of highly innovative immunotherapy technologies. This award of the German Cancer Aid is an important distinction in the field of oncology. With the award, German Cancer Aid wants to express the great significance of cancer research and acknowledge the efforts of those who help to improve the care of people with cancer.

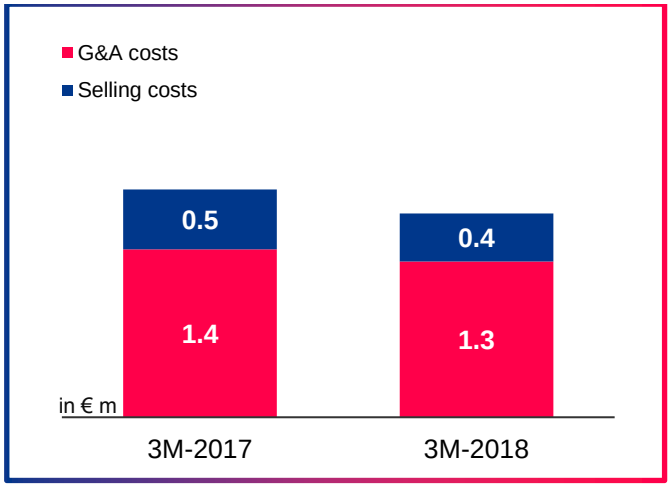
RESULTS OF OPERATIONS

Total revenue



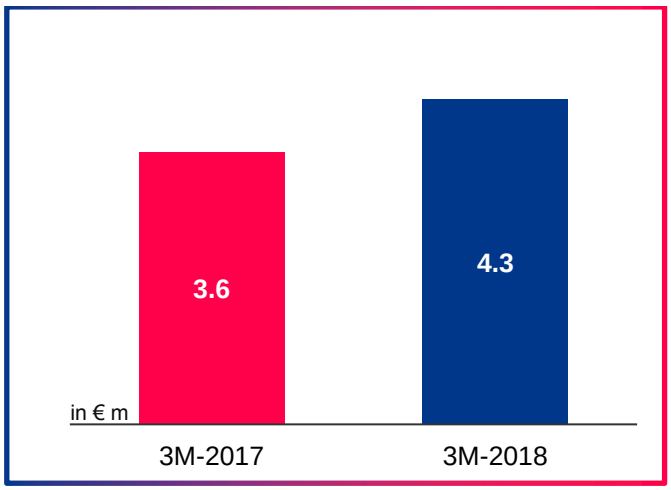
Total revenue of the Company increased by 6% to €2,766 k in the first three months of 2018 (3M 2017: €2,609 k) as a result of growing revenue generated from the core business of immunotherapies. Revenue generated by the cooperation with the US company bluebird bio increased due to higher reimbursement of research and development expenses by 24% to €1,384 k (3M 2017: €1,118 k). This includes constant revenue amounting to €894 k (3M 2017: €894 k) from a pro rata recognition of the upfront payment received in 2016 from Medigene's partner.

Selling and general administrative expenses



Medigene reduced its selling and general administrative expenses by 12% to €1,633 k (3M 2017: €1,854 k) in the first quarter 2018, partly due to lower selling expenses following the sale of the US rights to Veregen® at the end of 2017.

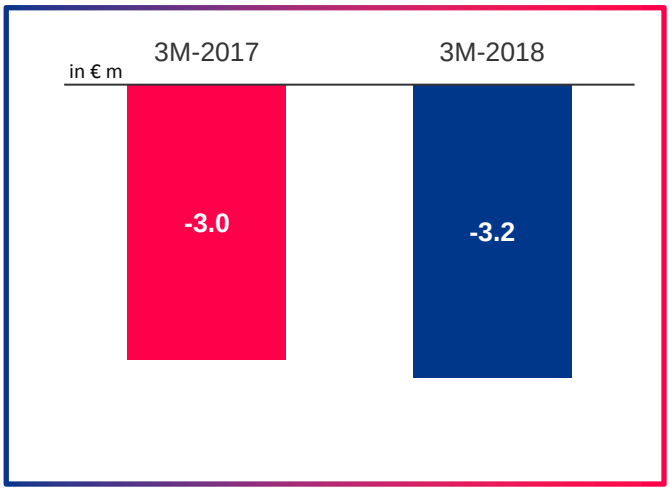
Research and development expenses



Medigene's research and development expenses increased by 20% in the first three months of 2018 to €4,319 k (3M 2017: €3,612 k). This increase was mainly caused due to the progress in the design and preparation of clinical trials for Medigene's immunotherapy programs.

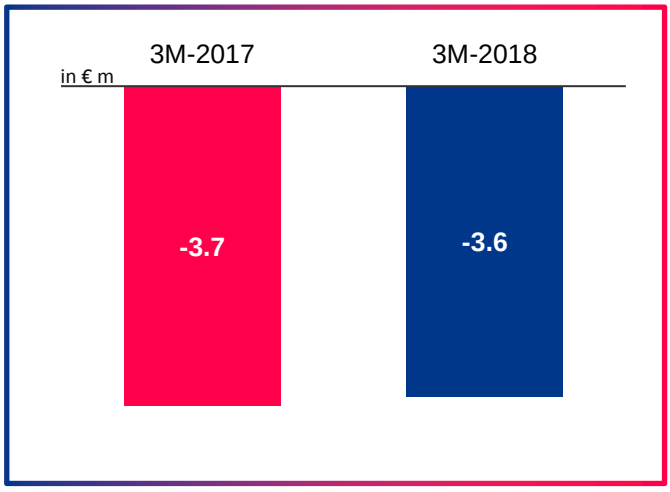
EBITDA

Mainly as a result of the intensified development activities for Medigene's immunotherapy programs, the Company increased its EBITDA loss in the first three months of 2018 to €3,188 k (3M 2017: €3,020 k). Medigene's EBITDA is derived from the net profit/loss for the period. and does not include any taxes, financial result (comprising interest income and interest expense), foreign exchange gains or losses, other financial result, or depreciation or amortization.



Net profit/loss for the first three months of 2018

Medigene reduced its net loss in the first three months of 2018 by 3% to €3,550 k (3M 2017: €3,677 k) due to the above-mentioned factors. The difference to the previous-year quarter resulted mainly from the interest expense in the first quarter of 2017.



FINANCIAL POSITION

Net cash used in operating activities

Medigene decreased its net cash used in operating activities in the first three months of 2018 to €3,185 k (3M 2017: €4,865 k). This represents an average monthly cash burn of €1.1 m in the first three months of 2018 (3M 2017: €1.6 m). The major part of the net cash used was directed at research and development as well as changes in cash and cash equivalents (working capital). The decrease in the first three months of 2018 mainly stems from the increase in liabilities attributable to trade payables.

Net cash from investing activities

An increase in net cash from investing activities in the first three months of 2018 to €2,941 k (3M 2017: €272 k), mainly resulted from net proceeds from the disposal of time deposits amounting to €2,000 k.

Cash and cash equivalents and time deposits

Cash and cash equivalents and time deposits of the Company decreased by €2,620 k to €49,104 k as at the end of the reporting period (December 31, 2017: €51,724 k).

NET ASSETS

Assets

Non-current other assets decreased to €1,131 k (December 31, 2017: €2,278 k), mainly due to the third instalment in the amount of €1,000 k received from the 2015 sale of EndoTAG® to SynCore in the first quarter of 2018.

Shareholders' equity and liabilities

Current liabilities increased to €10,869 k (December 31, 2017: €9,808 k) on the reporting date, primarily as a result of the temporary increase in trade payables.

OUTLOOK

Financial guidance 2018

Medigene confirmed its financial forecast for 2018 published in the 2017 annual report, which reflects the Company's focus on and progress in the core immunotherapy business.

The Company is expecting to generate total revenue of between €7.5 – 9.5 m in 2018. The expected decrease from 2017 (€11.4 m) results from the sale of rights to a non-core product (Veregen®) in fiscal year 2017 and the related net gain as well as to declining revenues of Veregen®.

Due to the progress of the clinical development programs in the core area of immunotherapies and the start of Medigene's first clinical TCR trial in 2018, the Company is forecasting significantly increasing research and development expenses of €22 – 24 m (2017: €14.9 m) and a loss at EBITDA level of €21 – 23 m (2017: €12.1 m). For 2018, Medigene anticipates total cash burn of €21 – 26 m (cash (on hand) as at December 31, 2017: €51.7 m consisting of cash and cash equivalents and time deposits).

These estimates do not include potential future milestone payments or cash flows from existing or future partnerships or transactions, as the occurrence of such events and their timing and amount to a large extent depend on external parties and therefore cannot be reliably predicted by Medigene.

Based on its current planning, the Company has sufficient financial resources to fund business operations beyond the planning horizon of two years.

Outlook for immunotherapies:

T cell receptor-modified T cells (TCR-Ts)

Medigene started patient recruitment for the Phase I/II clinical trial with its TCR-T cell immunotherapy MDG1011 in March 2018. Patients are first tested for suitable HLA status and then whether their tumor cells are positive for the expression of the PRAME antigen. Only if patients meet these basic requirements, among other inclusion criteria, they can be enrolled into the clinical trial. As a first step, an apheresis is performed to isolate the patient's own T cells. These are then equipped with Medigene's specific PRAME TCR and subsequently expanded. After comprehensive quality testing of the T cell therapy product the patient undergoes a preparative chemotherapy and a one-time infusion of MDG1011. In the early stages of this clinical development, Medigene expects a production time of about six weeks from the beginning of an apheresis process until completion of the cell product.

The Phase I part of the clinical trial is a dose escalation of the T cell product with 3-4 dose cohorts (depending on the results). Each dose cohort includes one patient for each of the three indications AML, MDS und MM respectively. Phase I focuses on the safety and tolerability of the treatment with MDG1011. In the early stages of the trial, the patients will be included in the clinical trial sequentially in compliance with requirements imposed by the authorities to ensure patient safety. Medigene expects to conduct the first trial cohorts of Phase I in the course of 2018.

In addition to the ongoing MDG1011 clinical trial, Medigene will also work on characterizing new TCR candidates for future clinical trials under the responsibility and funding of Medigene and collecting preclinical data to prepare an application for a further clinical TCR T cell therapy trial. In addition, Medigene continues its successful collaboration with bluebird bio and expects to make further progress on TCR candidate discovery.

In addition to the Company's own development activities, Medigene expects the start of the academic investigator initiated TCR-modified T cell therapy clinical trial under the responsibility of Max-Delbrück-Center and Charité University Hospital in Berlin, Germany.

Dendritic cell vaccines (DCs)

Medigene will continue the current Phase I/II clinical trial for DC vaccines for the treatment of acute myeloid leukemia (AML) as planned, and intends to present preliminary data on certain aspects of the trial at scientific conferences. The final data will be available towards the end of 2019.

CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO MARCH 31, 2018 AND 2017

IN € K	**Q1-2018 UNAUDITED**	Q1-2017 UNAUDITED
Revenue	**2,110**	1,951
Other operating income	**656**	658
Total revenue	**2,766**	**2,609**
Cost of sales	**-376**	-420
Gross profit	**2,390**	**2,189**
Selling expenses	**-351**	-478
General administrative expenses	**-1,282**	-1,376
Research and development expenses	**-4,319**	-3,612
Operating result	**-3,562**	**-3,277**
Interest income	**45**	65
Interest expense	**-240**	-714
Foreign exchange gains	**180**	150
Other financial result	**128**	170
Earnings before tax	**-3,449**	**-3,606**
Taxes	**-101**	-72
Net profit/loss for the period	**-3,550**	-3,678
Basic and diluted loss per share (€)	**-0.16**	-0.18
Weighted average number of shares (basic and diluted)	**22,309,317**	20,144,897

CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS AT MARCH 31, 2018 AND DECEMBER 31, 2017

IN € K		31 MARCH 2018 UNAUDITED	31 DECEMBER 2017
ASSETS			
A. Non-current assets			
I.	Property, plant and equipment	**4,418**	4,329
II.	Intangible assets	**34,064**	34,080
III.	Goodwill	**2,212**	2,212
IV.	Financial assets	**5,765**	5,696
V.	Other assets	**1,131**	2,278
Total non-current assets		**47,590**	**48,595**
B. Current assets			
I.	Inventories	**7,479**	7,724
II.	Trade accounts receivable	**1,373**	1,699
III.	Other assets	**2,316**	2,195
IV.	Time deposits	**22,000**	24,000
V.	Cash and cash equivalents	**27,104**	27,724
Total current assets		**60,272**	**63,342**
Total assets		**107,862**	**111,937**
SHAREHOLDERS' EQUITY AND LIABILITIES			
A. Equity			
I.	Subscribed capital	**22,311**	22,301
II.	Capital reserve	**449,184**	449,034
III.	Accumulated deficit	**-392,499**	-388,949
IV.	Other reserves	**3,814**	3,781
Total shareholders' equity		**82,810**	**86,167**
B. Non-current liabilities			
I.	Finance lease liabilities	**835**	1,049
II.	Financial liabilities	**5,853**	6,523
III.	Pension obligations	**405**	405
IV.	Other financial liabilities	**442**	444
V.	Deferred income	**4,469**	5,362
VI.	Deferred taxes	**2,179**	2,179
Total non-current liabilities		**14,183**	**15,962**
C. Current liabilities			
I.	Finance lease liabilities	**741**	679
II.	Trade accounts payable	**1,586**	725
III.	Other financial liabilities	**4,967**	4,829
IV.	Deferred income	**3,575**	3,575
Total current liabilities		**10,869**	**9,808**
Total liabilities		**25,052**	**25,770**
Total shareholders' equity and liabilities		**107,862**	**111,937**

FINANCIAL CALENDAR

May 15, 2018

Annual General Meeting of Medigene 2018
in Munich

August 7, 2018

6 Months Report 2018
Press and analyst conference call

November 13, 2018

Quarterly statement 9M-2018
Press and analyst conference call

IMPRINT

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