medigene

9M 2018

MEDIGENE AG
QUARTERLY STATEMENT 9M-2018

KEY FIGURES

OF MEDIGENE AG

IN € K	**Q3-2018 UNAUDITED**	Q3-2017 UNAUDITED	CHANGE	**9M-2018 UNAUDITED**	9M-2017 UNAUDITED	CHANGE
Results of operations						
Revenue from immunotherapies (bluebird bio cooperation)	**1,369**	1,183	16%	**4,728**	3,435	38%
Revenue Veregen®	**421**	417	1%	**1,257**	1,765	-29%
Other operating income	**710**	661	7%	**2,016**	1,976	2%
Total revenue	**2,500**	**2,261**	**11%**	**8,001**	**7,176**	**11%**
Gross profit	**2,253**	1,994	13%	**7,335**	6,315	16%
Selling and general administrative expenses	**-2,510**	-1,941	29%	**-5,912**	-6,279	-6%
Research and development expenses	**-4,603**	-3,638	27%	**-13,273**	-11,073	20%
Operating result	**-4,860**	-3,585	36%	**-11,850**	-11,037	7%
Net profit/loss for the period	**-4,916**	**-3,220**	**53%**	**-12,163**	**-10,690**	**14%**
EBITDA	**-4,467**	**-3,244**	**38%**	**-10,700**	**-10,143**	**5%**
Earnings per share (€)	**-0.20**	-0.15	33%	**-0.52**	-0.50	4%
Personnel expenses	**-3,916**	-2,424	62%	**-9,124**	-7,690	19%
Cash flow						
Net cash used in operating activities				**-5,702**	-16,124[1)]	-65%
Net cash used in investing activities				**-24,095**	-1,025[1)]	>200%
Net cash from financing activities				**29,402**	18,893	56%
Balance sheet data as at September 30, 2018 and December 31, 2017						
Cash and cash equivalents and time deposits				**76,329**	51,724	48%
Total assets				**133,991**	111,937	20%
Current liabilities				**10,290**	9,808	5%
Non-current liabilities				**18,756**	15,962	18%
Shareholders' equity				**104,945**	86,167	22%
Equity ratio (%)				**78**	77	1%
Employees as at September 30				**108**	99	9%
FTEs as at September 30				**99**	92	8%
Medigene share as at September 30						
Total number of shares outstanding				**24,555,262**	22,300,947	10%
Share price (XETRA closing price) (€)				**12.03**	13.02	-8%

[1)] In the figures for the previous year, the gain on the sale of financial assets of €366 k was reclassified from cash used in operating activities to cash flow used in investing activities.

QUARTERLY STATEMENT 9M-2018

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE PERIOD FROM JANUARY 1 TO SEPTEMBER 30, 2018

MAJOR EVENTS SINCE THE BEGINNING OF 2018

Immunotherapies:

- → Medigene starts Phase I/II clinical trial with T cell receptor-modified T cell therapy (TCR-T) MDG1011
- → Medigene presents data at the AACR conference on the successful production of dendritic cell (DC) vaccines for the current Phase I/II clinical trial in acute myeloid leukemia (AML)
- → Oslo University presents clinical data at the AACR conference for DC vaccines in prostate cancer investigator-initiated clinical trial (IITs)
- → Medigene strengthens its patent portfolio with a US patent for a tagged TCR and a European patent for a T cell identification method for CD4+-T cells for use in treating solid tumors
- → Medigene and Structured Immunity commence a collaboration on improved T cell receptor development

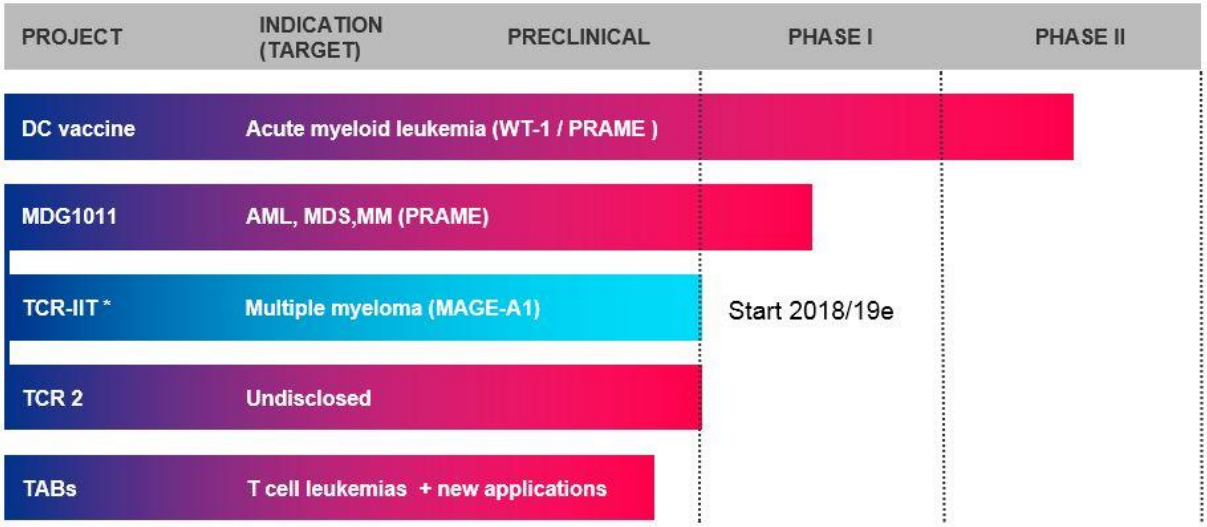
Company:

- → TCR alliance significantly expanded with bluebird bio with receipt of an additional one-time payment of US$8 m
- → €32.3 m gross proceeds generated from an oversubscribed private placement of new shares
- → Dr. Kai Pinkernell appointed as Chief Medical Officer and Chief Development Officer of the Executive Management Board
- → Dr. Thomas Taapken resigned from his position as Chief Financial Officer effective August 31, 2018
- → Medigene included in the restructured SDAX stock market index as the only biotech company

KEY FIGURES IN THE FIRST THREE QUARTERS OF 2018

- Total revenue increased by 11% to €8,001 k (9M 2017: €7,176 k)
- Revenue from the core business of immunotherapies increased by 38% to €4,728 k (9M 2017: €3,435 k)
- Research and development expenses increased as planned by 20% to €13,273 k (9M 2017: €11,073 k) due to extension of the preclinical and clinical development activities for immunotherapy programs
- Selling and general administrative expenses decreased by 6% to €5,912 k (9M 2017: €6,279 k)
- EBITDA loss increased as planned by 5% to €10,700 k (9M 2017: €10,143 k)
- Net loss for the period increased as planned by 14% to €12,163 k (9M 2017: €10,690 k)
- Cash and cash equivalents and time deposits of €76,329 k as at September 30, 2018 (December 31, 2017: €51,724 k)
- Further improvement of the financial guidance raised in the 6M-2018 quarterly statement

MEDIGENE'S IMMUNOTHERAPY PIPELINE



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

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)

PROGRESS WITHIN THE CORE BUSINESS OF IMMUNOTHERAPIES SINCE THE BEGINNING OF 2018

T cell receptor-based adoptive T cell therapy (TCRs)

End of 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. MDG1011 is Medigene's first clinical TCR-T immunotherapy product candidate and the trial with MDG1011 is the first clinical trial with a TCR-T therapy in Germany.

In Phase I of the trial, approximately 12 blood cancer patients with acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or multiple myeloma (MM) are to be treated. In total (Phase I and Phase II) roughly 92 patients should be included in the trial. Patients are first tested for suitable Human Leukocyte Antigen (HLA) status and then whether their tumor cells are positive for the expression of the PRAME antigen. Only if these basic requirements are met, among other inclusion criteria, can the respective patient 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 TCRs 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.

For this "first-in-country" TCR-therapy trial in Germany, Medigene has trained and opened three study centers to conduct this personalized cell therapy so far. The university hospitals in Regensburg, Erlangen and Würzburg are actively screening to identify suitable patients and enroll them in the trial. Medigene is undertaking intensive preparations with a number of additional hospitals in order to increase the number of centers to allow for an accelerated patient recruitment.

In this context, Medigene announces that the German regulatory authority, the Paul-Ehrlich-Institut (PEI), has approved an amendment of the trial inclusion criteria that should also allow more flexible and rapid enrollment of patients. To date the trial protocol required at least one patient per indication (AML, MDS, MM) in a dose cohort of three patients. After implementing the approved change, at least one patient with MM and at least one patient with AML or MDS is required to complete the dose cohort. This enables more flexibility and potentially more rapid enrollment of patients. Moreover, an analytical method for determining PRAME expression has been optimized, which results in an increase in the number of potential patients for the clinical trial.

Medigene also announces that in the course of the trial the first personalized MDG1011 cell product was successfully manufactured with patient-specific T cells in compliance with the clinical trial protocol. A sufficient number of therapeutic TCR-modified T cells with autologous T cells were generated despite the advanced disease stage of the patient. However, the patient could not be treated with the therapeutic product because he dropped out of the trial beforehand on account of the rapid progression of the underlying disease.

In March 2018, Medigene announced the grant of a European patent that covers antigen specific human MHC-class II restricted CD4+ T cells for use in a method for the treatment of solid tumors. The CD4+ T cells are being obtained by Medigene's proprietary ex vivo method of generating allo-restricted T cells. Current research shows that CD4+ T cells fulfill a much broader function in the human immune system than previously thought. CD4+ T cells can enter tumor tissue and exert anti-tumor functions in the tumor. The CD4+ T cells, which can be obtained with Medigene's patented method hold great potential to supplement the cytotoxic capabilities of adoptive T cell therapies. The underlying patent family additionally comprises patents granted in the US and Japan. In February 2018, Medigene announced the grant of a US patent, covering a high affinity T cell receptor with a specific tag. These patents expand Medigene's growing patent portfolio in the field of TCR-T immunotherapies.

In May 2018, Medigene announced a significant expansion of its successful strategic alliance with bluebird bio Inc. ("bluebird bio") to identify and develop TCR-Ts. (see p. 5)

In August 2018, Medigene announced a research cooperation with Structured Immunity, USA, a biotech company that specializes in optimizing and validating T cell receptor (TCR) proteins. Under the agreement, Medigene will provide Structured Immunity with a lead TCR candidate for a high profile solid tumor target. Structured Immunity will evaluate the specificity and recognition properties of this TCR using its established structural immunology technologies with the goal to better understand how to select highly effective TCRs for cell therapies.

DC vaccines (DCs)

In April 2018, Medigene and researchers from Oslo University Hospital presented a poster at the annual conference of the American Association for Cancer Research (AACR) 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 critically ill and heavily pretreated AML patients, allowing for long-term vaccination of trial subjects in the ongoing trial.

Also at the AACR conference in April 2018, Medigene's academic partner, Oslo University Hospital, presented an update of a Phase I/II investigator initiated trial (IIT). The data show that adjuvant dendritic cell vaccines in high-risk prostate cancer patients following radical surgery can potentially 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, partially utilizing Medigene's DC vaccine technology.

EVENTS IN CORPORATE DEVELOPMENT

Management

Effective August 31, 2018, Dr. Thomas Taapken resigned from his position as Chief Financial Officer (CFO) for personal reasons. The tasks and duties of the CFO have since been performed by the other members of the Executive Management Board and the Finance Department of the Company until a new CFO is on board. The Company has commenced the executive search for a suitable successor. In order to ensure a seamless transition, Dr. Taapken is available as a consultant to the Executive Management Board until the end of the year.

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 Dr. Pinkernell reflects the growing clinical focus of Medigene and its advancement as a clinical stage immuno-oncology company.

Expansion of the TCR alliance with bluebird bio

On May 14, 2018, Medigene announced a significant expansion of its successful strategic alliance with bluebird bio, a global leader in gene and cell therapies. Under the revised terms of the agreement, the number of target antigen/MHC restriction combinations for the discovery of specific TCR lead candidates by Medigene will be increased from four to six. As part of this contractual expansion, Medigene received an additional upfront payment of US$8 m (€6.7 m). R&D funding for all work performed by Medigene in this collaboration will grow proportionally to address the broader scope of the collaboration. If successfully developed and marketed through several indications and markets, Medigene could receive up to USD 250 million in milestone payments per TCR program in addition to tiered royalty payments on net sales up to a double-digit percentage. Following the amendment of this agreement, Medigene also received an additional payment of US$1 m (€0.8 m) associated with reaching the first collaboration milestone.

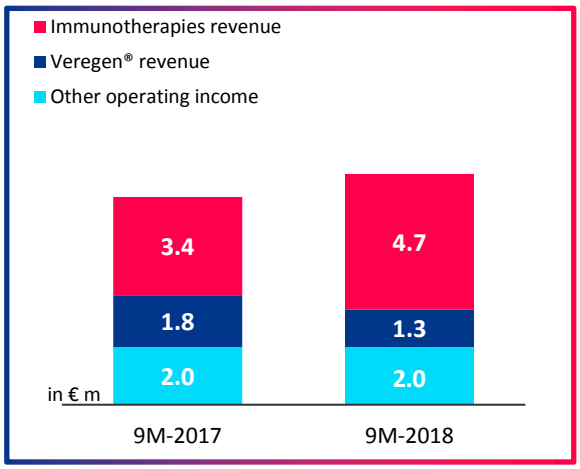
Medigene share in the SDAX

Since September 24, 2018, and subsequent to the restructuring of the stock market indices of Deutsche Börse, the Medigene share has been included in the small caps index for German companies, the SDAX. Medigene is the only biotech firm listed in the new SDAX, having met the corresponding criteria for inclusion in terms of market capitalization, free float and trading volume.

Placement of new shares with institutional investors

On May 24, 2018, the Company announced that it has raised €32.3 m in gross proceeds through a significantly oversubscribed private placement via an accelerated book building transaction. Medigene issued 2,230,000 new shares from authorized capital to institutional investors at a price of €14.50 per share. The capital increase represents approximately 10% of shares outstanding before the transaction. In addition to existing and new institutional investors, Medigene was able to win Tongyang Networks Co. from South Korea, as a new long-term-oriented anchor investor.

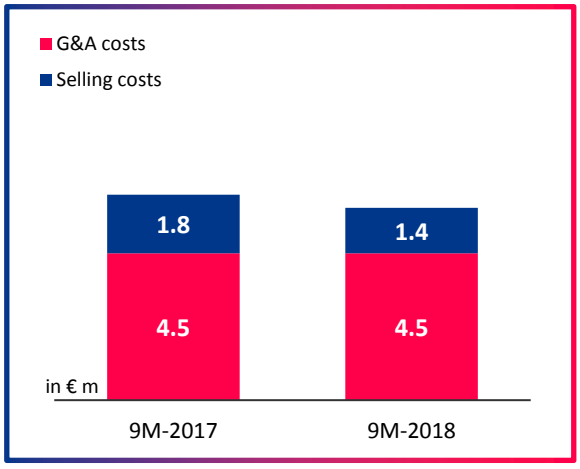
RESULTS OF OPERATIONS



Total revenue

Medigene's total revenue increased by 11% to €8,001 k in the first nine months of 2018 (9M 2017: €7,176 k) mainly due to significantly higher revenue generated from the core business of immunotherapies.

Revenue generated by the cooperation agreed in 2016 and expanded in 2018 with bluebird bio increased by 38% to €4,728 k (9M-2017: €3,435 k) in the first three quarters of 2018. This revenue results from the payment of US$1 m (€0.8 m) associated with the first collaboration milestone, a pro rata recognition of the upfront payments received in 2016 (US$15 m, equivalent to €13.4 m) and 2018 (US$8 m, equivalent to €6.7 m) and the reimbursement of research & development expenses arising from this cooperation during the reporting period.



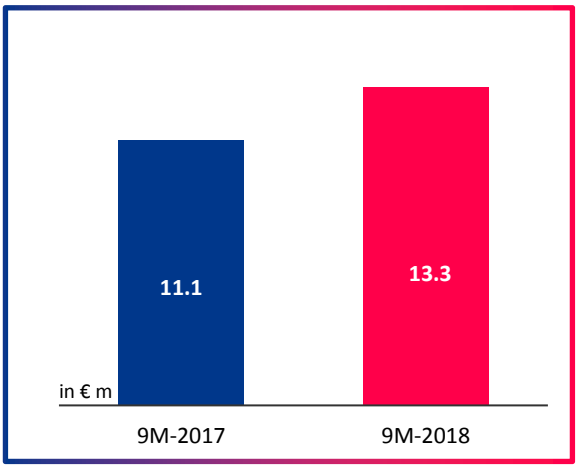
Selling and general administrative expenses

The selling and general administrative expenses decreased by 6% to €5,912 k (9M 2017: €6,279 k) in the first nine months of 2018. The main factors in the decrease are lower selling expenses as a result the terminated agreement with the provider of the active pharmaceutical ingredient of Veregen® in the previous year.

Research and development expenses

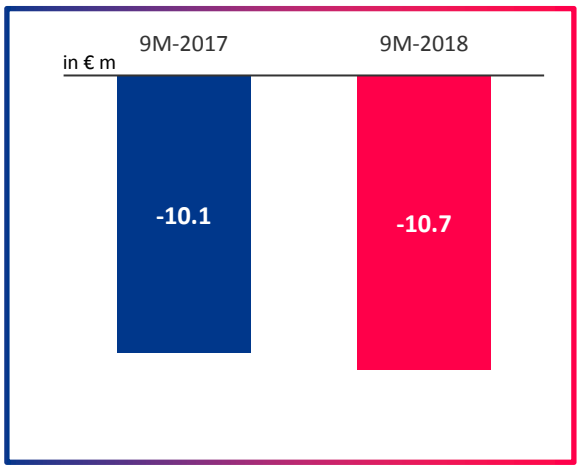
Medigene's research and development expenses increased as planned by 20% in the first nine months of 2018 to €13,273 k (9M 2017: €11,073 k).

The increase in these expenses was due to Medigene's extension of the preclinical and clinical development activities for the immunotherapy programs and the deployment of extra staff in this area.



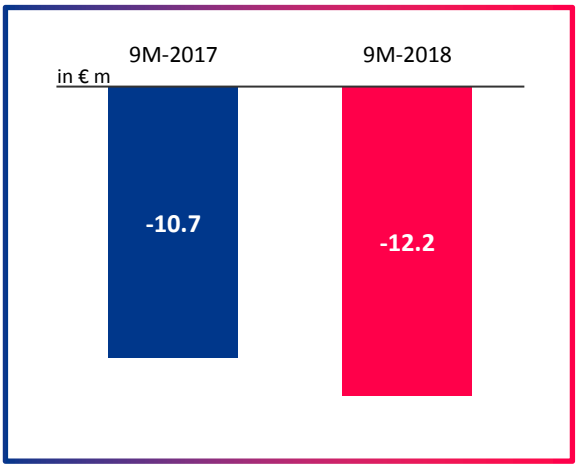
EBITDA

In spite of higher outlays for research and development, the loss at EBITDA level only increased marginally to €10,700 k (9M 2017: €10,143 k) as higher revenue was generated in the core business of immunotherapies and selling and general administrative expenses were scaled back. Medigene's EBITDA is derived from the net profit/loss for the period and does not include any taxes, financial result (comprising interest income, interest expense and other financial result), foreign exchange gains or losses, and depreciation or amortization.



Net profit/loss for the first nine months of 2018

As budgeted, the net loss generated by Medigene in the first nine months of 2018 increased to €12,163 k (9M 2017: €10,690 k). The factors in this development include the effects described under EBITDA and the stronger US dollar which resulted in foreign exchange losses (previous year: foreign exchange gains) that were partly compensated by lower interest expenses in the reporting period.



FINANCIAL POSITION

Net cash used in operating activities

Net cash used in operating activities decreased in the first nine months of 2018 to €5,702 k (9M 2017: €16,124 k) due to one-off effects such as the payments from bluebird bio amounting to €7.5 m in association with the expansion of the cooperation in 2018.

The current level of cash used in operating activities is not particularly indicative of future trends as it is significantly impacted by non-recurring payments in partner arrangements and research and development expenses which depend on the project status.

Net cash used in investing activities

Medigene invested most of the funds received from bluebird bio and from the capital increase carried out in May 2018 in time deposits with first class banks. Primarily because of these investments, the Company recognized net cash used in investing activities of €24,095 k (9M 2017: €1,025 k) in the first nine months of 2018.

Net cash provided by financing activities

Medigene recorded net cash provided by financing activities of €29,402 k (9M 2017: €18,893 k) due to the capital increase conducted in May 2018 which led to gross proceeds of €32.3 m (previous year: €20.7 m).

Cash and cash equivalents and time deposits

The cash and cash equivalents and time deposits of the Company amounted to €76,329 k as at the end of the reporting period (December 31, 2017: €51,724 k).

NET ASSETS

Assets

Cash and cash equivalents and time deposits increased by 48% to €76,329 k on the reporting date (December 31, 2017: €51,724 k) due to the effects described under the financial position. The long-term time deposits have a term of up to 21 months.

Shareholders' equity and liabilities

Within shareholders' equity and liabilities, non-current liabilities increased by 18% to €18,756 k as at September 30, 2018 (December 31, 2017: €15,962 k), primarily due to the increase in contractual liabilities relating to an additional upfront payment of US$8 m (€6.7 m) from bluebird bio in 2018.

OUTLOOK

Financial guidance 2018

Medigene further improves the financial guidance for 2018 which was raised in the 6M financial statement:

The Company continues to expect total revenue of €9.5 – 10.5 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 resulting non-recurring net gain in fiscal year 2017 as well as from planned lower revenues of Veregen® in the future. However, the declines were partially compensated by higher revenues from the bluebird bio collaboration.

Due to lower than estimated clinical trial costs in 2018, the company now expects to spend €19 - 21 m for the full year 2018 (previous guidance: €21 – 23 m). The increase in research and development expenses in comparison to the previous year (2017: €14.9 m) can be attributed to the advances made in the clinical and preclinical development programs in the core business of immunotherapies.

As a result, Medigene is expecting to make a loss at EBITDA level of €16 - 18 m (previous guidance: €18 – 20 m). The increase on the previous year (2017: €12.1 m) is attributable to the advances made in the development of the immunotherapy programs.

Without considering the proceeds from the capital increase conducted in May 2018, Medigene forecasts now a total cash usage of €12 - 14 m for 2018 (previous guidance: €15 – 17 m).

This forecast does 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 depend to a large extent 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)

The Company is planning to commence treatment of the first dose cohort in the Phase I/II clinical trial of Medigene's TCR-T MDG1011 therapy for acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) and multiple myeloma (MM). Medigene is undertaking intensive preparations with a number of additional clinics to increase the current number of three active clinical centers and to expand screening activities accordingly.

The Phase I part of the clinical trial involves a dose escalation of MDG1011 with 3-4 dose cohorts (depending on the results). Phase I focuses on the safety and tolerability of the treatment with MDG1011.

In addition to the MDG1011 clinical trial, Medigene will also work on characterizing new TCR candidates for future Medigene-sponsored clinical trials and collecting preclinical data to prepare applications for further clinical TCR-T trials. In addition, Medigene will continue its successful and expanded 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 (IIT) under the responsibility of Max-Delbrück-Center and Charité University Hospital in Berlin, Germany.

Dendritic cell vaccines (DCs)

Medigene continues its ongoing Phase I/II clinical trial with the DC vaccine to treat acute myeloid leukemia (AML). Data from all patients over a treatment duration of one year is expected in the fourth quarter of 2018. This corresponds to the half-way point of the full treatment period. This interim analysis is planned to be presented at scientific conferences in 2019. The final clinical data from the Phase I/II trial are expected at the conclusion of the two-year treatment for all patients towards the end of 2019.

CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO SEPTEMBER 30, 2018 AND 2017

IN € K	**Q3-2018 UNAUDITED**	Q3-2017 UNAUDITED	**9M-2018 UNAUDITED**	9M-2017 UNAUDITED
Revenue	**1,790**	1,600	**5,985**	5,200
Other operating income	**710**	661	**2,016**	1,976
Total revenue	**2,500**	**2,261**	**8,001**	**7,176**
Cost of sales	**-247**	-267	**-666**	-861
Gross profit	**2,253**	**1,994**	**7,335**	**6,315**
Selling expenses	**-685**	-670	**-1,370**	-1,789
General administrative expenses	**-1,825**	-1,271	**-4,542**	-4,490
Research and development expenses	**-4,603**	-3,638	**-13,273**	-11,073
Operating result	**-4,860**	**-3,585**	**-11,850**	**-11,037**
Interest income	**52**	**70**	**164**	205
Interest expense	**-222**	-269	**-710**	-1,416
Foreign exchange gains/losses	**-41**	402	**-70**	1,229
Other financial result	**156**	163	**405**	403
Earnings before tax	**-4,915**	**-3,219**	**-12,061**	**-10,616**
Taxes	**-1**	-1	**-102**	**-74**
Net profit/loss for the period	**-4,916**	**-3,220**	**-12,163**	**-10,690**
Basic and diluted loss per share (€)	**-0.20**	-0.15	**-0.52**	-0.50
Weighted average number of shares (basic and diluted)	**24,554,191**	**22,144,377**	**23,370,342**	**21,231,520**

CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS AT SEPTEMBER 30, 2018 AND DECEMBER 31, 2017

ASSETS

IN € K	9/30/2018 UNAUDITED	12/31/2017
A. Non-current assets		
I. Property, plant and equipment	**3,985**	4,329
II. Intangible assets	**34,019**	34,080
III. Goodwill	**2,212**	2,212
IV. Financial assets	**5,693**	5,696
V. Time deposits	**32,000**	0
VI. Other assets	**1,235**	2,278
Total non-current assets	**79,144**	**48,595**
B. Current assets		
I. Inventories	**7,382**	7,724
II. Trade accounts receivable	**915**	1,699
III. Other assets	**2,221**	2,195
IV. Time deposits	**17,000**	24,000
V. Cash and cash equivalents	**27,329**	27,724
Total current assets	**54,847**	**63,342**
Total assets	**133,991**	**111,937**

SHAREHOLDERS' EQUITY AND LIABILITIES

IN € K	9/30/2018 UNAUDITED	12/31/2017
A. Shareholders' equity		
I. Subscribed capital	**24,555**	22,301
II. Capital reserve	**477,661**	449,034
III. Accumulated deficit	**-401,112**	-388,949
IV. Other reserves	**3,841**	3,781
Total shareholders' equity	**104,945**	**86,167**
B. Non-current liabilities		
I. Finance lease liabilities	**725**	1,049
II. Financial liabilities	**5,373**	6,523
III. Pension obligations	**405**	405
IV. Other financial liabilities	**461**	444
V. Contractual liabilities	**9,613**	5,362
VI. Deferred taxes	**2,179**	2,179
Total non-current liabilities	**18,756**	**15,962**
C. Current liabilities		
I. Finance lease liabilities	**702**	679
II. Trade accounts payable	**924**	725
III. Other financial liabilities	**5,168**	4,829
IV. Contractual liabilities	**3,496**	3,575
Total current liabilities	**10,290**	**9,808**
Total liabilities	**29,046**	**25,770**
Total shareholders' equity and liabilities	**133,991**	**111,937**

FINANCIAL CALENDAR

March 27, 2019

Annual report 2018
Press and analyst conference call

May 14, 2019

Quarterly statement Q1 2019
Press and analyst conference call

IMPRINT

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