

— 3M —
— 2019 —

MEDIGENE AG
QUARTERLY STATEMENT 3M-2019

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OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE PERIOD FROM JANUARY 1 TO MARCH 31, 2019

KEY FIGURES OF MEDIGENE

IN € K	Q1-2019 UNAUDITED	Q1-2018 ¹ UNAUDITED	CHANGE
Results of operations			
Total revenue	2,098	2,143	-2%
thereof revenue from immunotherapies	1,394	1,384	1%
Gross profit	1,717	1,767	-3%
Selling and general administrative expenses	-1,786	-1,633	9%
Research and development expenses	-5,536	-4,319	28%
Operating result	-5,605	-4,185	34%
Net profit/loss for the period	-5,674	-4,168	36%
EBITDA	-4,988	-3,812	31%
Earnings per share (€)	-0.23	-0.19	21%
Personnel expenses	-2,900	-2,436	19%
Cash flow			
Net cash used in operating activities	-5,564	-3,185	75%
Net cash from investing activities	557	2,941	-81%
Net cash used in financing activities	-854	-376	127%
Balance sheet data as at March 31, 2019 and December 31, 2018			
Cash and cash equivalents and time deposits	65,547	71,408	-8%
Total assets	128,218	129,590	-1%
Current liabilities	9,487	8,821	8%
Non-current liabilities	16,577	13,344	24%
Shareholders' equity	102,154	107,425	-5%
Equity ratio (%)	80	83	-4%
Employees as at March 31			
Employees as at March 31	125	101	24%
FTEs as at March 31			
FTEs as at March 31	115	94	22%
Medigene share as at March 31			
Total number of shares outstanding	24,557,137	22,311,127	10%
Share price (XETRA closing price) (€)	8.52	14.45	-41%

¹⁾ IAS 8 correction - see note (3) to the consolidated financial statements for 2018

MAJOR EVENTS SINCE THE BEGINNING OF 2019

Immunotherapies:

- Medigene treated the first patient within the framework of the Phase I/II clinical trial of the T cell receptor-modified T cell immunotherapy (TCR-T) MDG1011 to treat the blood cancers, acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) as well as multiple myeloma (MM)
- Medigene and Roivant affiliate Cytovant entered into a strategic partnership for the research and development of cell therapies in Asia
- bluebird bio presented preclinical data of first TCR candidate from ongoing collaboration, plans to start clinical development in 2020
- Medigene licensed a chimeric co-stimulatory receptor to enhance TCR therapies for solid tumors
- Medigene presented positive results from *in vitro* tests to assess the potential TCR-mediated off-target toxicity for neuronal cells at the annual meeting of the American Society of Gene & Cell Therapy (ASGCT)
- Medigene presented preclinical data on the selective killing of tumor cells by PRAME TCR-transduced T cells at the AACR conference
- Medigene obtained two European patents for its dendritic cell (DC) vaccine platform and for the TCR building block library to develop neoantigen-specific TCRs

Company:

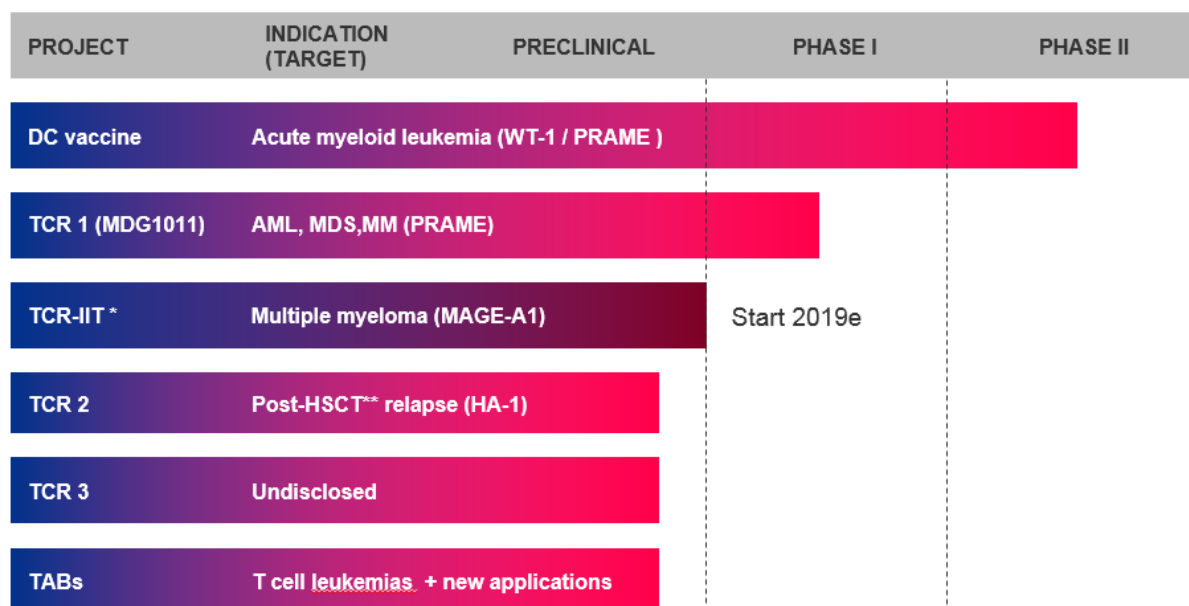
- In the second quarter of 2019 Medigene received an upfront payment of US\$10 m from the new partnership with RoviAnt/Cytovant and, in the future, receives reimbursement of R&D expenses, potential milestone payments and royalties
- Medigene sold the remaining rights and stocks of Veregen® to Aresus Pharma and thereby completed its transformation into a pure-play immunotherapy company
- Medigene appointed Axel-Sven Malkomes as CFO/CBDO

KEY FIGURES IN THE FIRST QUARTER OF 2019

- Revenue from immunotherapies stable at €1,394 k (3M-2018: €1,384 k)
- Research and development expenses (R&D) increased as planned by 28% to €5,536 k (3M-2018: €4,319 k) due to expansion of clinical activities
- EBITDA loss increased as planned by 31% to €4,988 k (3M-2018: €3,812 k²) due to progress in immunotherapy programs
- Net loss for the period increased by 36% to €5,674 k (3M-2018: €4,168 k²)
- Cash and cash equivalents and time deposits of €65,547 k as at March 31, 2019 (December 31, 2018: €71,408 k)
- Revision of financial guidance for 2019 due to two transactions announced in April 2019 (Roivant/Cytovant partnership and sale of Veregen®)

MEDIGENE'S IMMUNOTHERAPY PIPELINE

(EXCLUDING PARTNERED PROGRAMS)



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

** Hematopoietic stem cell transplantation

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)

² IAS 8 correction - see note (3) to the consolidated financial statements for 2018

PROGRESS WITHIN THE CORE BUSINESS OF IMMUNOTHERAPIES SINCE THE BEGINNING OF 2019

TCR-modified T cells (TCR-Ts)

Medigene commenced the Phase I/II clinical trial of its TCR-based T cell therapy MDG1011 and began treating patients in the first quarter of 2019. In February, Medigene announced that it had dosed the first patient, suffering from multiple myeloma, with the therapy that is designed as a single-dosage treatment. MDG1011 targets the tumor antigen PRAME. The multi-center, open-label Phase I/II clinical trial treats blood cancer patients with advanced stage acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or multiple myeloma (MM). Phase I of this first-in-human clinical trial is a dose escalation trial with approximately 12 patients, which evaluates the safety and feasibility as well as other secondary endpoints. Phase II of 80 patients contains a control group (40 of 80 patients) and investigates the safety and initial efficacy of the therapy as co-primary endpoints.

In January 2019, Medigene announced an exclusive license agreement with Helmholtz Zentrum Munich (HMGU) for a chimeric co-stimulatory receptor. This fusion protein of PD-1 and 4-1BB was developed as a strategy to potentially overcome the blockade of T cells by solid tumors. Medigene acquired the exclusive license to improve the functionality of its proprietary TCR-Ts and thereby to potentially mediate more effective immune responses against solid tumors. Medigene plans to evaluate the use of the co-stimulatory receptor in combination with its own TCRs in preclinical models. Medigene paid an upfront fee and the HMGU is entitled to an annual maintenance fee, milestone payments and royalties on marketed therapeutic and diagnostic products containing the chimeric co-stimulatory receptor. The payments are expensed through profit or loss and are immaterial to the Group's earnings.

In February 2019, Medigene announced that the European Patent Office intended to issue a European patent for the T cell receptor building block library. Patent EP 3303591A1 was issued at the beginning of April 2019. It provides protection for a plasmid library that is suitable for rapid reconstruction and testing of newly discovered TCR sequences against classical antigens as well as neoantigens. The plasmid library was initially developed for rapid high-throughput reconstruction of large numbers of candidate TCRs specific for selected antigens. Recent advances in TCR sequencing of single T cells now also allow multiple TCRs that are potentially specific for neoantigens to be identified in patient tumors.

At the annual meeting of the American Association for Cancer Research (AACR) from March 29 to April 3, 2019 Medigene presented a poster on its innovative methods for the evaluation of efficacy and toxicity of TCRs as well as the preclinical data on the selective killing of tumor cells using PRAME TCR-transduced T cells.

At the annual meeting of the American Society of Gene & Cell Therapy (ASGCT), held from April 29 to May 2, 2019 in Washington (USA), Medigene presented the positive results from *in vitro* tests to assess the potential TCR-mediated off-target toxicity for neuronal cells.

DC vaccines (DCs)

In December 2018, Medigene published the first interim clinical results from its ongoing company-sponsored Phase I/II clinical trial of a dendritic cell (DC) vaccine in 20 patients with AML. The data represents topline data from an interim dataset after half of the treatment period, i.e. after vaccination of all patients and a treatment of one year in each case. After one year of treatment, the interim results show that Medigene's personalized DC vaccines display an excellent safety profile and excellent manufacturing potential. Initial data on the efficacy of the therapy are pointing in the right direction. However, a final assessment cannot be made until the full two-year treatment is completed. Medigene will present data from the interim analysis at the annual congress of the European Hematology Association (EHA) from 13 – 16 June in Amsterdam. The completion of the ongoing trial is scheduled for the end of 2019 following a two-year treatment period.

In January 2019, the European Patent Office issued an additional European patent for the DC vaccine platform. The European patent EP 2918673 covers an isolated mature dendritic cell or an isolated population of mature dendritic cells obtainable by a method for in vitro maturation, for example, as described in the patent. The patent expires in 2027.

MANAGEMENT

Axel-Sven Malkomes was appointed Chief Financial Officer and Chief Business Development Officer effective April 1, 2019. Mr. Malkomes has worked in the healthcare sector for over 25 years. He combines financial expertise and many years of management experience on the corporate, banking and investor sides in the fields of pharma and biotechnology.

SUBSEQUENT EVENTS

Strategic partnership with Cytovant, a subsidiary of Roivant, to develop cell therapies in Asia

In April 2019, Medigene entered into a license and cooperation agreement with Cytovant Sciences, a subsidiary of the US biopharmaceutical company, Roivant Sciences Ltd. The partnership relates to four programs of Medigene's T cell receptor modified T cell therapy (TCR-T) and its dendritic cell (DC) vaccine. Cytovant was founded by the Roivant Group as a biopharmaceutical company concentrating on the development and marketing of innovative cell therapies in Asia. With this partnership, Medigene continues its strategy to generate tailored T cell immunotherapies and license them out to certain territories and markets.

Medigene issues Cytovant an exclusive license to develop, manufacture and commercialize a T cell receptor (TCR), that is currently in the research stage, targeting NY-ESO-1, as well as a dendritic cell vaccine targeting antigens WT-1 and PRAME, in the regions of Greater China, South Korea and Japan. In addition, Cytovant and Medigene have entered into a strategic agreement to collaborate on the research of two additional target antigens for T cell receptor immunotherapies. Medigene is responsible for the generation and delivery of the TCR constructs using its proprietary TCR discovery platform. Following this research collaboration period, Cytovant will assume sole responsibility for the development and commercialization of the TCR-T therapies in the relevant countries above. The TCRs to be discovered by Medigene will be tailored specifically to Asian patients.

Under the terms of the transaction agreements, Medigene received an overall upfront payment of US\$10 m and will receive potential development, regulatory, and commercial milestone payments, which, in aggregate, could total over US\$1 b for the four products across multiple indications. Furthermore, Medigene will be eligible to receive royalty payments on net sales of the products in a low double-digit percentage in the relevant countries. Additionally, Cytovant will reimburse all R&D costs incurred by Medigene within the collaboration.

The contracting parties to the collaboration agreement are Medigene Immunotherapies GmbH, a wholly-owned subsidiary of Medigene AG, and Roivant Asia Cell Therapy Holdings Ltd., a wholly-owned subsidiary of Roivant Sciences Ltd.

Medigene sells the remaining rights and stocks of Veregen® to Aresus Pharma and completes its transformation into a pure-play immunotherapy company

In April 2019, Medigene sold its remaining rights to the dermatological drug Veregen® and its complete stock of the corresponding active pharmaceutical ingredient (API) to the German pharmaceutical company Aresus Pharma GmbH. In the course of the sale, all existing relevant contracts with distribution partners and external service providers will be transferred from Medigene to Aresus. Medigene sold the US rights to the drug at the end of 2017 to the US company Fougere Pharmaceuticals Inc. With this sale of the last product from its “non-core business”, Medigene AG completed the transformation into a pure-play immunotherapy company.

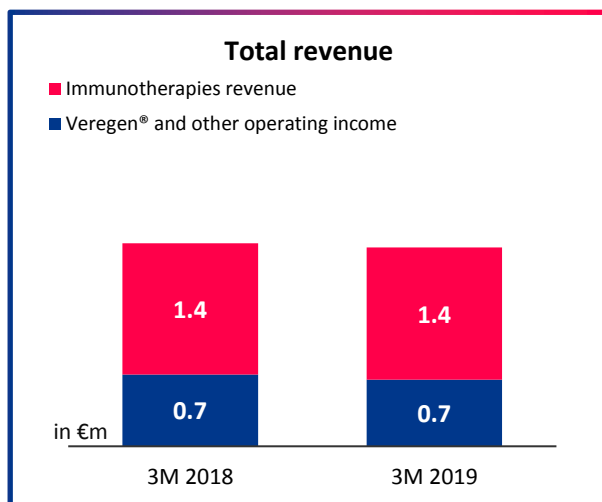
Medigene will receive approximately €7.75 m from Aresus for the remaining Veregen® rights and all existing API stock. Of this amount, Medigene will receive €300 k upfront and the balance within the next ten years as annual revenue-based earn-out payments from 2021 onwards. These expected payments will be recognized as receivables and discounted in accordance with International Financial Reporting Standards (IFRS) and the measurement method adopted for the receivable at the date of the transaction. Therefore, Medigene’s EBITDA will be affected by a non-cash effect of between €-4 and -5 m. In the future, this non-cash effective loss will be offset by the corresponding interest income as the payment period becomes continuously shorter.

bluebird presented preclinical data of first TCR candidate from ongoing collaboration and plans to start the clinical development with the candidate in 2020

On May 9 2019, Medigene’s strategic partner bluebird bio presented at its analyst plans to start clinical development in 2020 with the first therapeutic T cell receptor (TCR) candidate resulting from the research and development partnership. bluebird bio presented preclinical data of the TCR candidate targeting the tumor antigen MAGE-A4, which is expressed on a variety of solid tumor types. Preclinical data confirm high antigen sensitivity and strong recognition of tumor cell lines and the TCR candidate also displays activity against solid tumors without the need of a co-receptor.

RESULTS OF OPERATIONS³

Total revenue

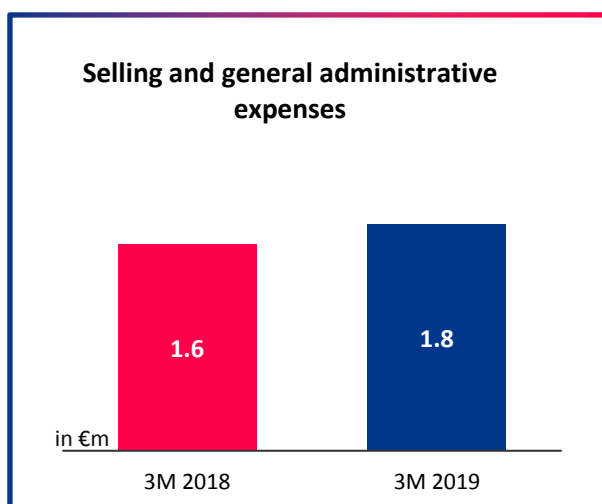


Revenue originating from the collaboration with the US company, bluebird bio, rose slightly by 1% to €1,394 k (3M-2018: €1,384 k). This includes revenue of €869 k (3M-2018: €894 k) from the pro rata recognition of upfront payments made by the partner and the reimbursement of research and development costs of €525 k (3M-2018: €490 k).

Total revenue decreased marginally by 2% to €2,098 k (3M-2018: €2,143 k) from revenue of €687 k (3M-2018: €727 k) from the non-core product, Veregen®. Due to the sale of Veregen®, which was closed in April 2019, no revenue from supply chain business and no royalties from sales of Veregen® will be generated in the coming quarters.

The transactions mentioned in the section on subsequent events (Roivant/Cytovant partnership and sale of Veregen®) are not included in the figures for the first quarter of 2019.

Selling and general administrative expenses



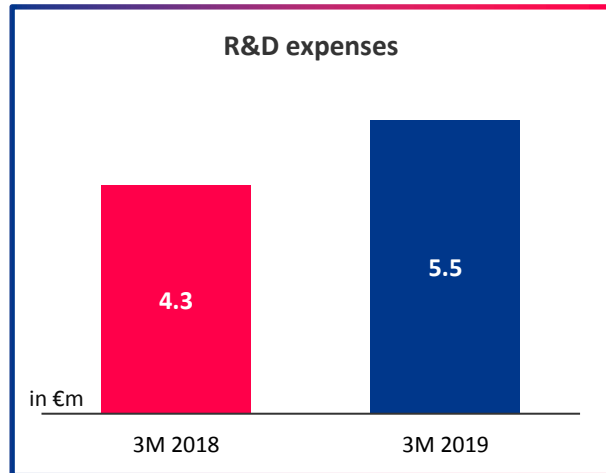
The selling and general administrative expenses increased by 9% in the first three months of 2019 to €1,786 k (3M-2018: €1,633 k).

General and administrative expenses remained stable at €1,308 k (3M-2018: €1,282 k), while selling expenses rose to €478 k (3M-2018: €351 k), partly on account of higher legal expenses and consulting fees related to the contracts mentioned in the section on subsequent events.

³ The Group has corrected an accounting error identified by the German Financial Reporting Enforcement Panel (FREP) during a random audit of the consolidated financial statements for the year ended December 31, 2016 (Sec. 342B (2) Sentence 3 No. 3 German Commercial Code (HGB)) and adjusted the comparative information in this quarterly reporting accordingly. Reference is made to the notes to the consolidated financial statements for 2018 – note (3).

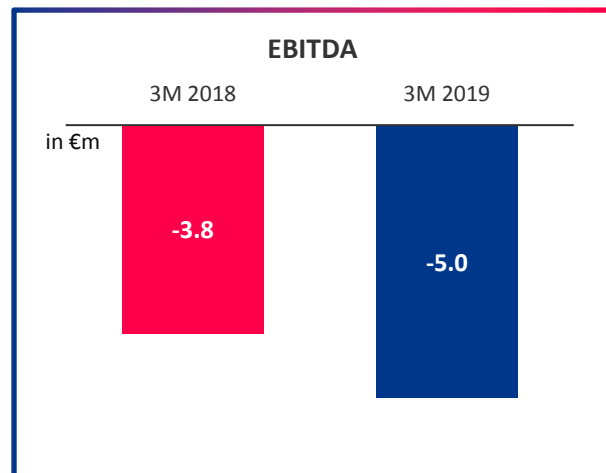
Research and development expenses

Medigene’s research and development expenses increased by 28% in the first three months of 2019 to €5,536 k (3M-2018: €4,319 k). The increase in these costs can be largely attributed to a rise in the headcount assigned to R&D, including the reinforcements to the clinical team. In addition, expenses were incurred to develop and expand GMP manufacturing of clinical trial materials.



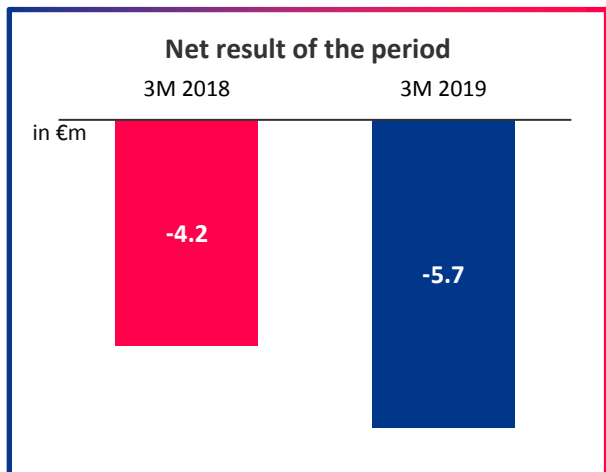
EBITDA

The Company increased its EBITDA loss in the first three months of 2019 to €4,988 k (3M-2018: €3,812 k), mainly as a result of the intensified development activities for Medigene’s immunotherapy programs. 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 2019

Medigene’s net loss rose by 36% to €5,674 k (3M-2018: €4,168 k) in the first three months of 2019 as budgeted, mainly on account of higher research and development expenses and rising costs for clinical development.



FINANCIAL POSITION

Net cash used in operating activities

Cash used in operating activities rose in the first three months of 2019 to €5,564 k (3M-2018: €3,185 k). This represents an average monthly cash burn of €1.9 m in the first three months of 2019 (3M-2018: €1.1 m), with most cash outlays directed at research and development.

Net cash from investing activities

The decrease in net cash from investing activities in the first three months of 2019 to €557 k (3M-2018: €2,941 k), mainly arises from time deposits of €2,000 k released in the first quarter of 2018.

Cash used in financing activities

The increase in cash used in financing activities can be explained by the higher obligations from leases due to the adoption of the new accounting standard on leases, IFRS 16, on January 1, 2019.

Cash and cash equivalents and time deposits

The cash and cash equivalents and time deposits of the Company decreased by €5,861 k to €65,547 k as at the end of the reporting period (December 31, 2018: €71,408 k).

NET ASSETS

Assets

The increase in property, plant and equipment to €9,306 k (December 31, 2018: €4,261 k) can be attributed to the adoption of the new accounting standard on leases, IFRS 16, which has been applied since January 2019. This requires lessees to recognize right-of-use assets for all leases with terms of more than 12 months and a corresponding lease liability. Medigene has applied the new standard for the fiscal year beginning on January 1, 2019 using the modified retrospective method.

Shareholders' equity and liabilities

Primarily, the recognition of lease liabilities pursuant to IFRS 16 led to an increase in non-current and current finance lease liabilities to €5,753 k (December 31, 2018: €1,512 k) in the first three months.

In addition to this, current liabilities increased to €9,487 k (December 31, 2018: €8,821 k) on the reporting date as a result of a temporary increase in trade payables.

OUTLOOK

Financial guidance 2019

Medigene revises the financial guidance for 2019 published in the 2018 Annual Report following the Roivant/Cytovant partnership in cellular immunotherapies and the sale of remaining rights to Veregen[®], both closed in April 2019.

The Company improves its revenue guidance and expects to generate total revenues of between €10 – 11 m (previous guidance: €5.5 – 6.5 m) in 2019, approximately €5 m anticipated from the cell therapy deal with Roivant/Cytovant.

Medigene continues to expect research and development expenses of € 24 -29 m in 2019 due to the progress of the preclinical and clinical development programs of Medigene's immunotherapies including manufacturing costs for clinical trial material.

The Company also confirms its EBITDA-guidance and continues to expect a loss at EBITDA level of €23 - 28 m, as the additional revenue from the Roivant/Cytovant deal will be compensated by a non-cash effect of €-4 and -5 m resulting from the Veregen[®] deal, as announced in the press release from April 8, 2019.

This assessment does not include potential future milestone payments or cash flows from existing or future partnerships or transactions, as the timing and extent of such events 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 forecasting horizon of two years.

Outlook for immunotherapies:

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

Current Phase I/II clinical trial with MDG1011

Medigene commenced the Phase I/II clinical trial of its TCR-based T cell therapy MDG1011 and began patient treatment in the first quarter of 2019. In addition to the three active study centers to date, it is anticipated that up to five new centers will begin recruiting patients in the second quarter and early third quarter of 2019. The University Clinic of Dresden was the first new study center to open. In 2019, the focus of the trial will be the recruitment of the first dose cohorts to assess the safety and tolerability of the treatment with MDG1011.

Development of additional TCR candidates

Now that a robust platform for the discovery and characterization of new TCR candidates has been fully established, building a solid pipeline of potential TCR-development candidates is an important goal to secure future clinical programs for both internal and existing or future partners.

In 2019, in addition to the MDG1011 clinical trial, Medigene will therefore work on characterizing new TCR candidates for future clinical trials under the responsibility and funding of Medigene and collecting preclinical data to prepare further clinical TCR trials.

Evaluation of HA-1 TCR as a potential clinical candidate

Medigene is assessing the in-licensed HA-1-specific T cell receptor to determine if it is a suitable candidate for expansion of Medigene's TCR-T clinical development program.

Optimization of future TCR therapies for solid tumors

In addition, the chimeric co-stimulatory receptor (the PD-1/4-1BB molecule) exclusively licensed from HMGU will be assessed in combination with Medigene's tumor-specific T cells (TCR-Ts) in preclinical models in order to optimize future TCR therapies for solid tumors.

TCR partnerships

In addition, Medigene continues its successful collaboration with bluebird bio and expects to make further progress on TCR candidate discovery. Within the framework of the collaboration entered into with Roivant/Cytovant, Medigene will now, together with the collaboration partner, undertake the preparations to generate TCR constructs tailored specifically to Asian patients using its proprietary TCR discovery platform. In addition, Medigene continues the successful collaboration with bluebird bio,

IIT from academic partners

In addition to the Company's own development activities, 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 is expected.

Dendritic cell vaccines (DCs)**Conclusion of the Phase I/II clinical trial at the end of 2019**

Medigene will continue the current Phase I/II clinical trial for DC vaccines for the treatment of acute myeloid leukemia (AML) as planned and bring it to a conclusion at the end of 2019. Data from the interim analysis will be presented beforehand at the annual congress of the European Hematology Association (EHA) from 13 – 16 June in Amsterdam. The final data will be available towards the end of 2019/beginning of 2020.

CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO MARCH 31, 2019 AND 2018

IN € K	Q1-2019 UNAUDITED	Q1-2018 ⁴ UNAUDITED
Revenue	2,081	2,110
Other operating income	17	33
Total revenue	2,098	2,143
Cost of sales	-381	-376
Gross profit	1,717	1,767
Selling expenses	-478	-351
General administrative expenses	-1,308	-1,282
Research and development expenses	-5,536	-4,319
Operating result	-5,605	-4,185
Interest income	56	45
Interest expense	-125	-19
Foreign exchange losses	-21	-37
Other financial result	122	128
Earnings before tax	-5,573	-4,068
Taxes	-101	-100
Net profit/loss for the period	-5,674	-4,168
Basic and diluted earnings per share (€)	-0.23	-0.19
Weighted average number of shares (basic and diluted)	24,557,137	22,309,317

⁴⁾ IAS 8 correction - see note (3) to the consolidated financial statements

CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS AT MARCH 31, 2019 AND DECEMBER 31, 2018

IN € K	3/31/ 2019 UNAUDITED	12/31/2018
ASSETS		
A. Non-current assets		
I. Property, plant and equipment	9,306	4,261
II. Intangible assets	33,990	34,013
III. Goodwill	2,212	2,212
IV. Financial assets	5,858	5,622
V. Time deposits	10,000	20,000
VI. Other assets	287	1,286
Total non-current assets	61,653	67,394
B. Current assets		
I. Inventories	7,048	7,298
II. Trade accounts receivable	977	787
III. Other assets	2,993	2,703
IV. Time deposits	34,000	24,000
V. Cash and cash equivalents	21,547	27,408
Total current assets	66,565	62,196
Total assets	128,218	129,590
SHAREHOLDERS' EQUITY AND LIABILITIES		
A. Equity		
I. Subscribed capital	24,557	24,557
II. Capital reserve	477,876	477,768
III. Accumulated deficit	-404,362	-398,687
IV. Other reserves	4,083	3,787
Total shareholders' equity	102,154	107,425
B. Non-current liabilities		
I. Finance lease liabilities	4,944	827
II. Pension obligations	414	414
III. Other financial liabilities	407	442
IV. Contract liabilities	7,815	8,684
V. Deferred taxes	2,997	2,997
Total non-current liabilities	16,577	13,344
C. Current liabilities		
I. Finance lease liabilities	809	685
II. Trade accounts payable	2,307	1,358
III. Other liabilities	2,897	3,304
IV. Contract liabilities	3,474	3,474
Total current liabilities	9,487	8,821
Total liabilities	26,064	22,165
Total shareholders' equity and liabilities	128,218	129,590

FINANCIAL CALENDAR

May 22, 2019

Annual General Meeting of Medigene AG 2019
in Munich

August 7, 2019

6-Month Report 2019
Press and analyst conference call

November 13, 2019

Quarterly statement Q3-2019
Press and analyst conference call

TRADEMARKS

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IMPRINT

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FORWARD-LOOKING STATEMENTS

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