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2022

MEDIGENE AG

6-MONTHS REPORT 2022

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INTERIM GROUP MANAGEMENT'S DISCUSSION AND ANALYSIS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

1 ABOUT MEDIGENE

Medigene AG (FSE: MDG1, ISIN DE000A1X3W00, Prime Standard) is a publicly listed biotechnology company headquartered in Planegg/Martinsried near Munich, Germany. With its scientific expertise, Medigene is working on the development of innovative immunotherapies to enhance T cell activity against solid cancers in fields of high unmet medical need.

Medigene's strategy is to both develop its own therapies as well as to offer selected partners the opportunity to discover and develop therapies on the basis of its proprietary technology platforms. In return for such partnerships, Medigene expects to receive upfront and milestone payments as well as research and development funding and royalties on future product sales.

2 BUSINESS REVIEW SINCE THE BEGINNING OF 2022

2.1 Medigene's focus – Developing T cell receptor-modified T cell (TCR-T) therapies

T cells are at the center of Medigene's therapeutic approaches. With Medigene's proprietary, end-to-end screening, discovery, optimization and manufacturing platform, novel T-cell receptor (TCR) therapies are produced that activate the patient's own T cells, that are then able to detect and efficiently kill the patient's cancer cells.

2.1.1 MDG1011 – Clinically validated TCR-T therapy against PRAME in blood cancers

Preferentially expressed Antigen in MElanoma (PRAME) is a well-recognized and validated tumor antigen of the cancer-testis-antigen family, that is over-expressed in a range of both solid and blood cancers. Expression in healthy tissue is limited to the testis, which is an immune-privileged tissue that usually cannot be attacked by the body's own immune cells. This renders PRAME as a key target antigen for TCR-T therapies.

MDG1011 is Medigene's first proprietary TCR-T immunotherapy candidate directed against PRAME that has entered clinical development. In a multicenter, open-label Phase I/II study, MDG1011 is being evaluated in patients suffering from advanced-stage acute myeloid leukemia (AML), myelodysplastic syndrome (MDS) or multiple myeloma (MM), all forms of blood cancer.

In the Phase I part (3+3 dose-escalation), patients received MDG1011 as a single intravenous infusion at fixed dose levels of 0.1, 1, or 5 million TCR-T cells per kg body weight, following standard pre-conditioning. The primary trial objectives were to evaluate the safety, tolerability, and feasibility of manufacturing MDG1011 TCR-T cells. In addition, clinical efficacy and immune monitoring data were examined as exploratory findings, along with other secondary study objectives.

In June 2021, the last patient was enrolled in the third dose cohort and Medigene reported on safety, tolerability and feasibility in December 2021. In February 2022, the first efficacy and immune monitoring data were published.

MDG1011 was successfully produced in 92.3% of patients (12 out of 13) who were a severe group that had been heavily pretreated with existing therapies. 69.2% (9 out of 13) patients received MDG1011 in the Phase I portion of the trial, with the remaining 30.8% of patients (4 out of 13) succumbing to their disease before treatment could be administered, consistent with the severity of the population recruited.

Overall, MDG1011 was shown to be safe and well tolerated. All patients experienced manageable adverse events, with a preponderance of treatment emergent adverse events (TEAEs) expected for the underlying cancer. Two patients experienced grade 1 or 2 transient cytokine release syndrome (CRS) attributable to MDG1011. This is direct evidence of the biological activity of the infused T cells. No immune effector cell-associated neurotoxicity syndrome (ICANS) was observed, nor were any dose-limiting toxicities (DLT) reported.

In terms of efficacy, one MDS patient treated at the highest dose level remained without detectable progression to secondary AML nine months after MDG1011 administration. The last trial visit took place at the end of June 2022 and the final data are currently being analyzed. Another patient treated at the lowest dose level experienced complete remission in the fourth week after treatment; however, this clinical response was not durable and the disease continued to progress at eight weeks.

Immune monitoring of treated patients included detection of PRAME-specific T cells (MDG1011 TCR-T cells) in blood to determine their persistence over time, and biomarker tracking of PRAME in bone marrow and/or blood as an indicator of remaining cancer cells. PRAME levels were assessed in bone marrow samples from five patients, four weeks after MDG1011 administration and decreases vs. baseline were observed in 80% of patients (4 out of 5) with a slight increase noted in the fifth patient. PRAME levels from blood samples also showed decreases by week 4 in a further two patients treated at the highest dose. These biomarker data show strong evidence of biological activity and some consistency with the clinical outcomes seen and point to the potential utility of the immune monitoring platform in Medigene's future clinical programs.

2.1.2 Unique tumor-specific antigens (TSAs) – The “dark matter” of our genome

In January 2020, Medigene entered into a research collaboration focusing on novel cancer antigens for highly specific immunotherapies with the University of Montréal and IRICoR, a pan-Canadian drug discovery research commercialization center. The collaboration was expanded in December 2021.

Under the collaboration agreement, Medigene has gained access to 47 potential tumor-specific antigens (TSAs) stemming from non-coding regions of the DNA (“dark matter”). These peptides were found to be shared among specimens of several patients with solid tumors of different origin, such as ovarian, breast, and lung cancer, but were not detected in healthy tissues. This characterizes them as TSAs and renders them highly interesting for development of future effective and safe cancer immunotherapies.

Ten TSAs proved to be immunogenic and thus able to induce specific T cell responses. To date, Medigene has isolated more than 20 TCRs of T cell clones that recognize these novel TSAs and have the potential to become next-generation TCR-T therapy candidates. Their further functional and safety characterization is ongoing.

2.1.3 Discovery of novel TCRs against undisclosed target molecules in solid tumors

Using Medigene's proprietary TCR screening and discovery platform, the Company continuously evaluates novel target molecules in the solid tumor arena including molecules of the cancer-testis-antigen family (TSAs), the “dark matter” antigens described above, and as yet undisclosed targets. If these targets fulfil our target safety

criteria during screening, these candidates are selected for further TCR development, as part of our ongoing process to fill our pipeline.

2.2 Medigene's proprietary tools to optimize TCR-T therapies

In addition to the identification and characterization of new TCRs, Medigene has developed numerous proprietary tools to optimize our novel discovered TCRs, to further differentiate and potentially improve their safety and efficacy in solid cancers. Research is also continuously being conducted into how TCR-T cells could be maintained in patients for a longer time, and to make the manufacturing process of TCR-T cells faster, more efficient and more cost-effective.

2.2.1 PD1-41BB switch receptor – Enhancing persistence of function with potential for lower risk of adverse events and cost of treatment

The PD1-41BB switch receptor is the most advanced of the TCR-T product optimization technologies currently being developed by Medigene. Solid tumors can avoid the body's immune regulation by hiding from the immune system and evade T cells or to actively suppress T cell attack. This is achieved through mechanisms including the expression of the checkpoint molecule PD-L1 on the tumor cell surface. PD-L1 interacts with its PD-1 counterpart on T cells and delivers a signal that turns off T cell function. Medigene's PD1-41BB switch receptor is expressed on TCR-T cells and directly converts the off-signal sent by PD-L1 to the TCR-T cells into an activation signal instead, enhancing anti-tumor activity of the TCR-T therapy.

A current approach taken by other companies to avoid inhibition of TCR-T cells by PD-L1 is to use a combination therapy of TCR-T cells and a checkpoint inhibitor antibody that interferes with the PD1-PD-L1 axis. With Medigene's approach, combination therapies may not be necessary and the associated increased side effects of multiple therapies and higher therapy costs could be avoided.

Preclinical experiments have already demonstrated that the addition of the PD1-41BB switch receptor enhances both the effector functions of TCR-T cells and their ability to eradicate PD-L1-positive solid tumors. The data were published in March 2022 in the peer-reviewed scientific publication "T-Cells Expressing a Highly Potent PRAME-Specific T-Cell Receptor in Combination with a Chimeric PD1-41BB Co-Stimulatory Receptor Show a Favorable Preclinical Safety Profile and Strong Anti-Tumor Reactivity" in the scientific journal *Cancers*.

In February 2022, Medigene granted BioNTech SE (BioNTech) a license to the PD1-41BB switch receptor. For further details on this partnership, please refer to section 2.3.1.

2.2.2 Precision pairing library – Improving TCR-T cell function and safety

TCRs consist of an alpha and a beta chain that sit together as one receptor on the cell surface of T cells. Medigene's precision pairing library is designed to improve the functionality and safety of TCR-T cells by increasing the number of TCRs on the cell surface and/or by ensuring that the TCR-T cells carry only the intended, newly introduced TCR on their surface, and not arbitrary combinations of single chains of the new TCR and the TCR already contained in the recipient T cell.

In February 2022, Medigene granted BioNTech a license to the precision pairing library. For further details on this partnership, please refer to section 2.3.1.

2.2.3 iM-TCR – Inducible on-off technology to fine-tune and control efficacy and safety

Medigene has developed the inducible Medigene TCR (iM-TCR), a technology to improve the safety of TCR-T therapies. iM-TCRs are modified so that full control of TCR surface expression can be achieved and thereby

activity against tumor cells can be fine-tuned such that potential unwanted toxicity against normal cells can be controlled if needed. This property would be of great interest in brain or liver cancer, for example, as these organs could be damaged by a persistent inflammatory T cell response.

TCRs containing the iM-TCR signature only appear on the surface of TCR-T cells when the patient is given tamoxifen, a comparatively affordable, well-established and well-characterized drug that has been approved for years.

Preclinical experiments have already shown that the iM-TCR system only forms correctly paired TCRs and does not mis-pair with other TCR single chains originally present in TCR-T cells, and that iM-TCR-expressing T cells are tightly controlled by the dose and timing of tamoxifen-induced expression. In the future, this would allow physicians to finely regulate TCR-T activity or even turn it on and off as needed.

2.2.4 Dendritic cell (DC) technology

Dendritic cells (DCs) are an essential component of Medigene's platform for identifying and characterizing future TCR candidates. DCs serve as antigen-presenting cells to activate T cells that specifically recognize a selected target antigen.

In addition to the continuous use of DCs in the high-throughput TCR discovery process, Medigene has developed and clinically evaluated a new generation of vaccines based on antigen-tailored DCs. The positive results of the completed open-label Phase I/II trial in AML patients were confirmed even after more than 3.5 years of median follow-up, as reported in February 2021. The data indicate that patients who received the DC vaccine could potentially have persistent clinical benefit without experiencing serious adverse events (SAEs) associated with treatment.

However, as Medigene's development focus is on TCR-T therapies, DC vaccines per se as a stand-alone therapy will only continue in the context of partnerships such as the partnership in place with Hongsheng Sciences HK Limited (Hongsheng Sciences, formerly Roivant/Cytovant; see section 2.3.3). A competing product has been approved as maintenance therapy for patients with AML in the U.S. and Europe, and Medigene expects similar approvals to be granted in other regions, including China, in the near future. These current events affect the development of the DC vaccine under the existing partnership as well as inform Medigene's further partnering endeavors.

In Medigene's clinical trials of MDG1011 TCR-T cells and of the DC vaccine in blood cancers, the manufacturing processes needed to make patient-specific TCR-T cells or DCs from patients' leukapheresis material was established for both cell types. Both manufacturing processes obtained regulatory approval to be applied in the respective trials and the feasibility of manufacturing cellular products of high quality was established in the two clinical studies.

Medigene is currently investigating whether TCR-T therapies and DC vaccines could potentially be combined in the future to ensure that TCR-T cells are maintained and proliferate in patients for longer periods of time through DC vaccine boosters. The fact that both cell products could be manufactured from the same starting leukapheresis material would simplify the development of such a combination therapy.

2.3 Development partnerships – Continuing to generate value for Medigene

In addition to the discovery and development of TCRs and tools to further improve T cell-based immunotherapies in the future for its own product pipeline, out-licensing and partnerships with other companies form a second, very important value creation pillar for Medigene. A partnership generates revenue for Medigene in the form of upfront payments, potential for reimbursement of expenses incurred by Medigene for the continuation

of research and development required by the partner, and from potential future milestone payments as well as royalties based on commercial sales for products based on Medigene's discoveries and technologies.

2.3.1 New comprehensive TCR-T and technology partnership with BioNTech

In February 2022, Medigene and BioNTech signed a global strategic partnership to advance TCR-based immunotherapies against cancer. Under the terms of the agreement, Medigene has received a payment of €26 m and will be reimbursed for the research and development costs incurred for the period of the collaboration. The research collaboration will encompass several target structures and has an initial term of three years. Medigene will contribute its proprietary TCR discovery platform for the development of TCRs against multiple solid tumor targets nominated by BioNTech. BioNTech will be responsible for global development and hold exclusive worldwide commercialization rights on all TCR therapies resulting from this research collaboration.

BioNTech acquired Medigene's TCR-4 of the MDG10XX program targeting the cancer antigen PRAME. BioNTech also obtained the exclusive option to acquire additional existing TCRs in Medigene's discovery pipeline and received licenses to Medigene's PD1-41BB switch receptor and precision pairing library. This has the potential to augment TCR cell therapy efficacy and can be applied to all BioNTech cell therapy programs.

Medigene will also be eligible to receive future development, regulatory and commercial milestone payments up to a triple digit million Euro amount per program in addition to tiered deferred option payments on global net sales for products based on TCRs arising from the collaboration and royalties on products utilizing at least one of the licensed technologies.

2.3.2 TCR-T partnership with 2seventy bio (formerly: bluebird bio)

In 2016, Medigene and bluebird bio, Inc. (bluebird bio) entered into a strategic research and development collaboration and licensing agreement encompassing TCR immunotherapies against four targets. This agreement was expanded in 2018 to six targets. In November 2021, bluebird bio spun off its oncology business into the newly formed company 2seventy bio, Inc. (2seventy bio) and all contracts concluded with Medigene were transferred to 2seventy bio. At the end of June 2022, the research term for this partnership was concluded in accordance with the contract. Medigene remains eligible for milestone payments and royalties from 2seventy bio as per the existing agreement.

The most advanced project in the collaboration is a highly differentiated TCR specific for a peptide stemming from the MAGE-A4 protein, a tumor antigen from the cancer-testis-antigen family. This TCR is different to other MAGE-A4-specific TCRs being developed by other companies as it works independently of signaling through the co-receptor CD8, which is found on killer T cells. In this way, any helper T cells (which express CD4 and not CD8), equipped with Medigene's MAGE-A4 TCR can also detect and kill cancer cells presenting the MAGE-A4 antigen on their surface.

The research work describing the selection and activity of this TCR has been published recently in the Journal for Immunotherapy of Cancer and received the "Best Immune Cell Therapies and Immune Cell Engineering Paper Award" from the Society for Immunotherapy of Cancer (SITC) in 2021.

2.3.3 TCR-T and DC partnering with Hongsheng Sciences (formerly Roivant/Cytovant)

In 2019, Medigene entered into license and cooperation agreements with Cytovant Sciences HK Limited, a biopharmaceutical company founded by Roivant Sciences (Roivant/Cytovant), which cover a TCR that is directed against the tumor antigen NY-ESO-1, two additional TCR-T development projects as well as Medigene's DC vaccine, for Asia (including the People's Republic of China, Hong Kong, Macao, Taiwan, South Korea, and Japan).

Medigene was informed that Roivant Sciences divested its holding in Cytovant Sciences in July 2022, which subsequently became Hongsheng Sciences HK Limited. Due to financing constraints, Hongsheng Sciences has temporarily suspended its development activities within the Medigene partnership.

2.4 Changes in the Executive Management Board

Medigene's Supervisory Board has appointed Dr. Selwyn Ho as a member of the Executive Management Board effective 25 July 2022 and appointed him as the new Chief Executive Officer (CEO). As a consequence, Prof. Dolores Schendel stepped down as Chief Executive Officer at the end of 24 July 2022 and now fully focuses on her responsibilities as Chief Scientific Officer (CSO) and Head of Research and Development at Medigene.

Dr. Ho received his medical degree (MB BS) and Bachelor of Science (BSc) in Pharmacology from Imperial College, University of London, UK, and post-graduate qualifications (Dip Pharm Med) in Pharmaceutical Medicine from the Faculty of Pharmaceutical Physicians, Royal College of Physicians, UK. In addition to his medical and pharmaceutical background, he has over 20 years of international experience across Europe, US, and Asia in executive and senior management positions in both privately held and publicly traded biotech and pharma companies with a focus on inflammation and immunology, with various responsibilities in the areas of Product Development, Medical Affairs, Strategic Marketing and Market Access, Business Development and Licensing as well as Corporate Strategy and Financing.

Dr. Ho joins Medigene from Connect Biopharma (NASDAQ: CNTB), a global clinical-stage biopharmaceutical company developing therapies against chronic inflammatory diseases derived from T cell-driven research, where he held the position of Chief Business Officer and, amongst other responsibilities, jointly led the execution of the company initial public offering (IPO) which closed in March 2021. Dr. Ho also serves as an Executive-In-Residence at New Rhein Healthcare Investors, a venture capital and growth stage fund focused on healthcare therapeutics and medical devices and is a Non-Executive Director for Immodulon Therapeutics Ltd., a clinical stage company developing novel therapies for cancer based on bacterial derived immunomodulators.

Since the end of March 2022, Axel Malkomes, former Chief Financial Officer and Chief Business Development Officer (CFO&CBO), has left the Company's Executive Management Board by mutual consent at the expiry of his contract. Since then, Dr. Birger Kohlert acts as CFO, and has been Vice President Finance, Controlling, Procurement and IT at Medigene since January 2020. Dr. Kohlert has more than 20 years of international experience in finance and was previously CFO at S + P Samson, Kissing, Germany, EvoBus Sweden and EvoBus Denmark. Prior to that, he had several positions in the finance department of the Daimler Group in Germany and the USA and in the audit department of KPMG in Germany. He holds a doctorate in the field of international accounting.

3 RESULTS OF OPERATIONS, FINANCIAL POSITION AND NET ASSETS

3.1 Results of operations

3.1.1 Revenue

The Company's revenues increased by €20,993 k to €25,284 k in the first half of 2022 which mainly results from the comprehensive TCR-T and technology partnership with BioNTech. In addition, they include revenues from the partnerships with 2seventy bio and Hongsheng Sciences.

3.1.2 Selling and general administrative expenses

Selling and general administrative expenses increased from €3,034 k to €6,187 k in the reporting period. The underlying reason is the above-mentioned new partnership with BioNTech and the costs required for this in the course of preparation.

3.1.3 Research and development expenses

In the first half of 2022, research and development (R&D) expenses decreased by 42% to €3,656 k (6M 2021: €6,314 k). The background for the cost reduction is the refocusing on the development of TCR-T cells for the treatment of solid tumors and the associated efficiency gains.

R&D expenses incurred in the collaborations with 2seventy bio, Hongsheng Sciences and BioNTech are reimbursed by the companies. The reimbursements are recognized as R&D payments in immunotherapies revenue.

3.1.4 EBITDA

As expected, the Company's EBITDA improved by €19,862 k to €15,408 k in the first half of 2022 from €-4,454 k in the first half of 2021 due to the partnership with BioNTech. Medigene's EBITDA is derived from the result for the period and does not include any taxes, any financial result resulting from interest income and interest expenses, any foreign exchange gains/losses, any other financial result and any depreciation and amortization.

EBITDA			
IN € K	6M 2022	6M 2021	CHANGE
Net profit/loss for the period	13,919	-5,665	n/a
Taxes	552	0	n/a
Other financial result	0	-28	-100%
Foreign exchange losses	48	2	2,300%
Financial result	143	174	-18%
Depreciation and amortization	746	1,063	-30%
EBITDA	15,408	-4,454	n/a

3.1.5 Net profit/loss for the first half of 2022

Due to the described partnership with BioNTech and related revenues, the net result improved to €13,919 k in the first half of 2022 (6M 2021: €-5,665k).

3.1.6 Earnings per share

In the first half of 2022, earnings per share amounted to €0.57 (weighted average number of shares, basic and diluted: 24,562,658). In the comparable prior-year period, the figure was €-0.23 (weighted average number of shares, basic and diluted: 24,562,658).

3.2 Financial position

CHANGE IN CASH AND CASH EQUIVALENTS			
IN € K	6M 2022 UNAUDITED	6M 2021 UNAUDITED	CHANGE
Net cash used in/provided by			
operating activities	17,302	-7,380	-
investing activities	-11,229	10	-
financing activities	-258	-486	-47%
Increase/Decrease in cash and cash equivalents	5,815	-7,856	-
Effect of exchange rate changes	151	55	180%
Cash and cash equivalents, opening balance	22,417	30,033	-25%
Cash and cash equivalents, closing balance	28,383	22,232	28%
Time deposits, as of 30 June	11,000	0	-
Cash and cash equivalents and time deposits, as of 30 June	39,383	22,232	77%

3.2.1 Net cash used in/provided by operating activities

In the first half of 2022, the cash inflow from operating activities increased to €17,302 k (6M 2021: cash outflow of €7,380 k). This is mainly due to the new partnership with BioNTech.

The amount of the current average cash outflow from operating activities is only of limited significance for the future development of this amount, as it is significantly influenced by one-time payments in the context of partnerships as well as by R&D expenses, the amount of which depends on the project status.

3.2.2 Net cash used in investing activities

As a result of deposit investments of €11,000 k, Medigene recorded a cash outflow from investing activities of €11,229 k in the first half of 2022 (6M 2021: €10k).

3.2.3 Net cash used in financing activities

Medigene recorded a cash outflow from financing activities of €-258 k in the reporting period, which mainly resulted from the repayment of existing lease agreements and other financing (6M 2021: cash outflow €486 k).

3.2.4 Changes in cash and cash equivalents and time deposits

Cash and cash equivalents and time deposits amounted to €39,383 k at the end of the reporting period (31 December 2022: €22,417 k). There were no open credit lines.

3.3 Net Assets

3.3.1 Assets

3.3.1.1 Property, plant and equipment and intangible assets

The decrease in property, plant and equipment and intangible assets to €34,470 k as of 30 June 2022 (31 December 2021: €35,019 k) is mainly due to scheduled depreciation. According to management's assessment, the COVID-19 pandemic currently has no impact on recoverability.

3.3.1.2 Cash and cash equivalents and time deposits

Cash and cash equivalents and time deposits increased by 77% to €39,383 k as of the reporting date (31 December 2021: €22,417 k). In this regard, we also refer to Section 3.2.

3.3.2 Shareholders' equity and liabilities

The development of equity is shown in the consolidated statement of changes in equity.

Non-current liabilities increased by 58% to €10,444 k as of 30 June 2022 (31 December 2021: €6,621 k), while current liabilities decreased by 14% to €6,913 k (31 December 2021: €8,033 k). The changes are mainly related to the partnerships with BioNTech and Hongsheng Sciences.

3.4 Overall financial statement

Medigene's revenue increased compared to the prior-year period due to the newly entered partnership with BioNTech. In addition, the efficiency measures initiated in the second half of 2020 continue to show effect, which further led to cost relief.

4 EMPLOYEES

As of 30 June 2022, the number of full-time equivalents (FTEs) was 61 (31 December 2021: 58) excluding employees on parental leave. The number of employees as of 30 June 2022 was 68 (31 December 2021: 64).

The breakdown of employees by company as of 30 June 2022 is as follows:

EMPLOYEES BY COMPANY			
	30/06/2022	31/12/2021	CHANGE
Medigene Immunotherapies GmbH, Planegg/Martinsried	42	38	11%
Medigene AG, Planegg/Martinsried	24	24	0%
Medigene, Inc., San Diego	2	2	0%
Total	68	64	6%

Personnel expenses decreased by 2% to €4,087 k in the reporting period 2022 (6M 2021: €4,163 k), due to efficiency improvements in the context of Medigene's strategic focus, which started in the second half of 2020.

5 RELATED PARTIES

Detailed information on related parties can be found in Section (14) of the notes to the interim consolidated financial statements.

6 OPPORTUNITIES AND RISKS

6.1 Financial opportunities and risks

Since Medigene AG was founded in 1994, the Company has reported operating losses in almost every fiscal year, as R&D expenses exceeded the respective revenue or gross profit. The future achievement of profitability depends on operational progress as well as strategic decisions of the Company and is not yet assured.

Medigene currently has good liquidity, partly due to existing and newly entered partnerships. As of 30 June 2022, cash and cash equivalents and time deposits amounted to €39,383 k. Including the payment received of €26 m from the new partnership with BioNTech signed in February 2022, Medigene is financed into the fourth quarter of 2024 based on current planning. Additional funding from external sources will be required for further financing beyond this date.

At this point in time, the Executive Board assumes with overwhelming probability that these funds can be raised in a timely manner. The Company could obtain these funds, for example, from further partnerships with pharmaceutical companies or through capital measures. There are no significant concentrations of potential liquidity risks in the Group.

6.2 Other opportunities and risks

For a detailed description of the opportunities and risks associated with the Company's business activities as well as the risk management and internal control system, please refer to section 4 of the Annual Report 2021, as these have remained largely unchanged since the approval of the consolidated financial statements 2021 on 15 March 2022.

The occurrence of the risks described above and in the Group management's discussion and analysis could, individually or in combination, have a negative impact on Medigene's results of operations, financial position, and net assets.

7 OUTLOOK

7.1 Company outlook

In the second half of 2022, Medigene will continue to push forward on the development of its immunotherapies. The corporate objectives will remain focused on the field of T cell-based immunotherapies to fight solid cancers. This focus represents, in the Company's opinion, the most promising commercial business opportunity for Medigene's differentiated technologies.

Medigene will continue to characterize new target antigens, among others, in the context of the partnership with University of Montréal, and TCR candidates for future studies and to collect preclinical data in preparation for further clinical TCR trials to be initiated. In addition, the Company's proprietary tools for empowering TCR-T therapies shall further be substantiated with sound scientific data and continuously refined. The Company's scientists will continue to submit important results for presentation at upcoming scientific conferences.

At the end of June 2022, the last follow-up visit of the last patient of the Phase I part of the Phase I/II study with MDG1011 in AML, MDS and MM has taken place and the final data are currently being assessed. Depending on the final results of the Phase I part, the Company would intend to partner the project prior to the start of the Phase II part of the trial.

Medigene plans to continue its successful collaborations and will continue to evaluate new partnering opportunities related to its portfolio of product candidates and technologies to maximize the Company's value.

7.2 Financial guidance 2022

Medigene's development programs continue to progress despite the ongoing COVID-19 pandemic. Financial guidance for fiscal 2022 remains unchanged as announced on 25 March 2022. The Company expects to generate revenues of €23-28 m, R&D expenses of €11-15 m and EBITDA of €3-5 m.

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

Currently, Medigene does not expect the COVID-19 pandemic or the Ukraine crisis to have a material impact on revenues, R&D expenses, and EBITDA in 2022.

As of 30 June 2022, cash and cash equivalents and time deposits amounted to €39,383 k (31 December 2021: €22,417 k). Based on current planning, the Company is financed into the fourth quarter of 2024.

CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

IN € K, UNLESS STATED OTHERWISE	NOTES	Q2 2022 UNAUDITED	Q2 2021 UNAUDITED	6M 2022 UNAUDITED	6M 2021 UNAUDITED
Revenue	(5)	2,261	2,146	25,284	4,291
Cost of sales		-555	-349	-815	-633
Gross profit		1,706	1,797	24,469	3,831
Selling expenses	(6)	-128	-129	-2,090	-317
General administrative expenses	(6)	-1,697	-1,418	-4,097	-2,717
Research and development expenses	(7)	-1,640	-2,768	-3,656	-6,314
Other income		26	164	36	171
Operating results		-1,733	-2,354	14,662	-5,517
Interest expense		-69	-85	-143	-174
Foreign exchange losses / gains		-38	0	-48	-2
Other financial result		0	0	0	28
Earnings before tax		-1,840	-2,439	14,471	-5,665
Taxes	(8)	-552	0	-552	0
Net profit/loss for the period		-2,392	-2,439	13,919	-5,665
Basic and diluted earnings per share (€)		-0,10	-0.10	0,57	-0.23
Weighted average number of shares (basic and diluted)		24,562,658	24,562,658	24,562,658	24,562,658

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

OF MEDIGENE AG FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

IN € K	Q2 2022 UNAUDITED	Q2 2021 UNAUDITED	6M 2022 UNAUDITED	6M 2021 UNAUDITED
Net profit/loss for the period	-2,392	-2,439	13,919	-5,665
Other comprehensive income				
Other comprehensive income to be reclassified to profit or loss in subsequent periods				
Exchange differences on translation of foreign operations ¹⁾	178	-38	232	81
Other comprehensive income not to be reclassified to profit or loss in subsequent periods				
Loss from equity instruments designated as at fair value through other comprehensive income ¹⁾	0	1,543	0	1,543
Other comprehensive income, net of tax	178	1,505	232	1,624
Total comprehensive income	-2,214	-934	14,151	-4,041

¹⁾ No income tax effects were incurred.

CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS AT 30 JUNE 2022

ASSETS

IN € K	NOTES	30/06/2022 UNAUDITED	31/12/2021
A. Non-current assets			
I. Property, plant and equipment		4,366	4,904
II. Intangible assets		30,104	30,115
III. Other assets		287	287
Total non-current assets		34,757	35,306
B. Current assets			
I. Trade accounts receivable	(9)	1,075	1,039
II. Other assets		1,284	708
III. Deposits		11,000	0
IV. Cash and cash equivalents	(10)	28,383	22,417
Total current assets		41,742	24,164
Total assets		76,499	59,470

SHAREHOLDERS' EQUITY AND LIABILITIES

IN € K	NOTES	30/06/2022 UNAUDITED	31/12/2021
A. Shareholders' equity			
I. Subscribed capital	(11)	24,563	24,563
II. Capital reserve		479,763	479,588
III. Other reserves		2,581	2,349
IV. Accumulated deficit		-447,765	-461,684
Total shareholders' equity		59,142	44,816
B. Non-current liabilities			
I. Lease liabilities		2,760	2,965
II. Provisions		501	598
III. Financial liabilities		94	171
IV. Contract liabilities	(12)	4,810	372
V. Deferred taxes		2,279	2,515
Total non-current liabilities		10,444	6,621
C. Current liabilities			
I. Lease liabilities		725	700
II. Provisions		914	60
III. Trade accounts payable		688	498
IV. Financial liabilities		155	188
V. Other liabilities		2,533	3,202
VI. Contract liabilities	(12)	1,898	3,385
Total current liabilities		6,913	8,033
Total liabilities		17,357	14,654
Total shareholders' equity and liabilities		76,499	59,470

CONSOLIDATED STATEMENT OF CASH FLOWS

OF MEDIGENE AG FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

IN € K	6M 2022 UNAUDITED	6M 2021 UNAUDITED
Net cash from/used in operating activities		
Earnings before tax	14,471	-5,665
Adjustments:		
Share-based payments	175	343
Depreciation and amortization	746	1,063
Other financial results	0	-28
Sale of fixed assets	33	0
Interest income	0	0
Interest expense	143	174
Changes in:		
Trade accounts receivable, other receivables and other assets	-612	571
Trade accounts payable	190	641
Other liabilities and contract liabilities	2,299	-4,305
Subtotal	17,445	-7,206
Tax paid	0	0
Interest paid	-143	-174
Net cash used in operating activities	17,302	-7,380
Net cash from/used in investing activities		
Purchase of property, plant and equipment	-230	-50
Cash received from the sale of intangible assets	1	0
Cash received from the sale of tangible assets	0	32
Proceeds from sale of financial assets	0	28
Payments in deposits	-11,000	0
Net cash from in investing activities	-11,229	10
Net cash from/used in financing activities		
Principal repayment for finance lease	-180	-372
Principal repayment for financial liabilities	-78	-114
Net cash from financing activities	-258	-486
Decrease/increase in cash and cash equivalents	5,815	-7,856
Currency translation differences on cash and cash equivalents	151	55
Cash and cash equivalents, opening balance	22,417	30,033
Cash and cash equivalents, closing balance	28,383	22,232

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

OF MEDIGENE AG FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

IN € K	NUMBER OF SHARES	SUBSCRIBED CAPITAL	CAPITAL RESERVE	ACCUMULATED DEFICIT	EXCHANGE DIFFERENCES	PENSIONS	FINANCIAL ASSETS	TOTAL SHAREHOLDERS' EQUITY
Balance as at 1/1/2021	24,562,658	24,563	478,937	-451,701	-117	-39	1,511	53,154
Net profit/loss				-5,665				-5,665
Other comprehensive income					81		1,543	1,624
Comprehensive income								-4,041
Share-based payments			343					343
Balance as at 30/06/2021, unaudited	24,562,658	24,563	479,280	-457,366	-36	-39	3,054	49,456
Balance as at 1/1/2022	24,562,658	24,563	479,588	-461,684	91	6	2,252	44,816
Net profit/loss				13,919				13,919
Other comprehensive income					232			232
Comprehensive income								14,151
Share-based payments			175					175
Balance as at 30/06/2022, unaudited	24,562,658	24,563	479,763	447,765	323	6	2,252	59,142

NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, FOR THE PERIOD FROM 1 JANUARY TO 30 JUNE 2022

A. BUSINESS ACTIVITY AND INFORMATION ON THE COMPANY

Medigene AG was founded in 1994 as a limited liability company in Planegg, local district Martinsried, Germany. In 1996, the Company was converted into a stock corporation. The Company's headquarters are located at Lochhamer Strasse 11, 82152 Planegg, local district Martinsried, Germany. The Company is registered in the commercial register of the Munich Local Court under HRB 115761. Medigene AG has been listed since June 2000 (Frankfurt Stock Exchange, Prime Standard, German Security Identification Number (WKN) A1X3W0, symbol MDG1, International Securities Identification Number (ISIN) DE000A1X3W00).

Effects of the COVID-19 pandemic

Medigene's preclinical projects focusing on the development of TCR T therapies in the field of solid tumors as well as those related to Medigene's partnerships with 2seventy bio, Inc., Cambridge, MA, USA (2seventy bio), BioNTech SE Mainz, Germany (BioNTech) and Hongsheng Sciences HK Limited, HongKong (Hongsheng Sciences) are unaffected by the COVID-19 pandemic. Regarding the further development of RhuDex[®], which has been outlicensed to Dr. Falk Pharma GmbH, Freiburg, Germany (Falk Pharma), delays may potentially occur due to the impact of the COVID-19 pandemic. According to management's assessment, the COVID-19 pandemic currently has no impact on the recoverability of the intangible assets associated with the drug candidate RhuDex[®]. Medigene is in regular close communication with all business partners in order to anticipate potential COVID-19 implications accordingly.

Further effects on capitalized assets and liabilities cannot be identified at present.

B. RECOGNITION AND MEASUREMENT POLICIES

(1) Basis of preparation of the interim consolidated financial statements

As a parent and publicly traded company within the meaning of Article 4 of Regulation (EC) No. 1606/2002, Medigene AG prepares its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU). These unaudited interim consolidated financial statements have been prepared in accordance with IAS 34 "Interim Financial Reporting" as adopted by the EU.

The Company's Executive Management Board believes that the interim consolidated financial statements reflect all business transactions required to present the net assets, financial position, and results of operations for the period ended 30 June 2022.

The interim consolidated financial statements do not include all the information that is required to prepare annual consolidated financial statements. For this reason, the interim consolidated financial statements should be read in conjunction with the 2021 consolidated financial statements. These interim consolidated financial statements of Medigene AG were authorized for issue by the Executive Management Board on 22 July 2022.

(2) Financing risk

Medigene AG was founded in 1994 and the Company has reported operating losses in almost every fiscal year, as expenses for research and development in the relevant years exceeded the corresponding revenue or gross profit. The future achievement of profitability depends on progress in terms of operations as well as the Company's strategic decisions and is not yet secured.

Medigene currently has good liquidity, partly due to existing and newly entered partnerships. As of 30 June 2022, cash and cash equivalents and time deposits amounted to €39,383 k. Including the payment received in the amount of €26 m from the new partnership with BioNTech signed in February 2022, Medigene is financed into the fourth quarter of 2024 based on current planning. Additional funding from external sources will be required for further financing beyond this date.

At this point in time, the Executive Board assumes with a high probability that these funds can be raised in a timely manner. The Company could obtain these funds, for example, from further partnerships with pharmaceutical companies or capital measures. There are no significant concentrations of potential liquidity risks in the Group.

(3) Changes in recognition, measurement and presentation accounting policies

The recognition, measurement and presentation accounting policies used in these interim consolidated financial statements basically correspond to those already applied in the consolidated financial statements for 2021.

Some amendments and interpretations were to be adopted for the first time in 2022. However, these did not have any impact on the consolidated financial statements.

(4) Group companies

In addition to the parent company Medigene AG in Planegg/Martinsried, the Group includes the wholly owned subsidiary Medigene Immunotherapies GmbH, Planegg/Martinsried, since its acquisition in January 2014, and the wholly owned subsidiary Medigene, Inc., San Diego, California, USA, which was acquired in 2001.

C. NOTES TO THE STATEMENT OF INCOME

(5) Revenue

Medigene's revenues had increased by 489% to €25,284k in the first half of 2022 (6M 2021: €4,291k). The increase compared to the first half of 2021 results from the comprehensive TCR-T and technology partnership with BioNTech concluded in spring 2022. In addition, it includes revenues from the partnerships with 2seventy bio and Hongsheng Sciences.

In July 2022, Roivant Sciences sold its holding in Cytovant Sciences, which subsequently became Hongsheng Sciences HK Limited. Due to financing constraints, Hongsheng Sciences has temporarily suspended all development activities.

Under the contract for the TCR-T and technology partnership with BioNTech, revenues totaling €21,966 k were generated in the first half of 2022.

The contract for research on two additional target antigens for TCR-T immunotherapies with Hongsheng Sciences was paused as of 31 March 2022. Revenues totaling €972 k were generated from this contract in the first half of 2022 (6M 2021: €1,944 k). In the reporting period, these revenues with Hongsheng Sciences mainly include revenues from the advance payment of \$5 m (€4,465 k) received in 2019, which was recognized by 31 March (€372 k), and revenues from the reimbursement of research and development costs incurred under the collaboration during the reporting period (€600 k).

Revenues from the collaboration with 2seventy bio agreed in 2016 and extended in 2018 amounted to €2,346 k in the first half of 2022 (6M 2021: €2,346 k). These revenues consist of a pro rata realization of the upfront payments made in 2016 (\$15 m, equivalent to €13.4 m) and 2018 (\$8 m, equivalent to €6.7 m), as well as the reimbursement of research and development costs incurred under the collaboration during the reporting period. The contract relating to the research work ended as scheduled on 30 June 2022.

TOTAL REVENUE			
IN € K	6M 2022 UNAUDITED	6M 2021 UNAUDITED	CHANGE
Revenue from immunotherapies (2seventy bio cooperation)	2,346	2,346	-
thereof revenue from the derecognition of contract liabilities (over time, fixed consideration)	1,896	1,896	-
thereof R&D payments (over time, variable consideration)	450	450	-
Revenue from immunotherapies (Hongsheng Sciences cooperation)	972	1,944	-50%
thereof from the derecognition of contract liabilities (over time, fixed consideration)	372	744	-50%
thereof R&D payments (over time, fixed consideration)	600	1,200	-50%
Revenue from immunotherapies (BioNTech cooperation)	21,966	0	-
thereof from the derecognition of contract liabilities (over time, fixed consideration)	475	0	-
thereof R&D payments (over time, fixed consideration)	613	0	-
thereof revenue from product sales (point in time, fixed consideration)	20,877	0	-
Total revenue from contracts with customers	25,284	4,291	489%

(6) Selling and general administrative expenses

The company's selling and general administrative expenses increased by 104% to €6,187 k in the first half of 2022 (6M 2021: €3,034 k) due to specific required costs while preparing the BioNTech partnership.

(7) Research and development expenses

Medigene's research and development expenses decreased by 42% to €3,656 k in the first half of 2022 (6M 2021: €6,314 k). The background for the cost reduction is the refocusing on the development of TCR-T cells for the treatment of solid tumors and the associated efficiency gains.

(8) Taxes

The main components of income taxes are as follows:

INCOME TAX		
IN T€	6M 2022 UNAUDITED	6M 2021 UNAUDITED
Actual income tax		
Current tax expense	-787	0
Deferred tax	235	0
Tax expense recognized in the income statement	-552	0

D. NOTES TO THE BALANCE SHEET**(9) Trade receivables**

Trade receivables amounting to €1,075 k (31 December 2021: €1,039 k) were neither overdue nor impaired as of the reporting date.

Receivables from contracts with customers usually have a payment period of 30 days.

(10) Cash and cash equivalents and time deposits

Cash and cash equivalents and time deposits increased by 76% as at the balance sheet date to €39,383 k (31 December 2021: €22,417 k).

(11) Subscribed capital

Subscribed capital was unchanged €24,562,658 as of 30 June 2022. Subscribed capital was divided into 24,562,658 non-par registered shares, which were issued and outstanding as of the reporting date.

(12) Contract liabilities

CONTRACT LIABILITIES WITH CUSTOMERS			
IN € K	30/06/2022 UNAUDITED	31/12/2021	CHANGE
Contract liabilities from cooperation with 2seventy bio	0	1,897	-100%
thereof non-current	0	0	-
thereof current	0	1,897	-100%
Contract liabilities from cooperation with Hongsheng Sciences	1,488	1,860	-20%
thereof non-current	1,488	372	300%
thereof current	0	1,488	-100%
Contract liabilities from cooperation with BioNTech	5,220	0	-
thereof non-current	3,322	0	-
thereof current	1,898	0	-

E. OTHER NOTES

(13) Segment reporting

The Group has been a single-segment company since 2020, and only data relating to the Immunotherapies business area are reported. The original non-core business was already transferred to external partners in previous years.

More than 90% of the current segment assets and all the non-current segment assets are in Germany.

Sales have been allocated according to the location of the customer and are attributable to the cooperation agreements with 2seventy bio, Hongsheng Sciences and BioNTech. Sales with BioNTech account for more than 10% of total sales

IN € K	IMMUNOTHERAPIES	TOTAL
6M 2022		
United States	2,346	2,346
Asia	972	972
Germany	21,966	21,966
Revenue from contracts with customers	25,284	25,284
6M 2021		
United States	2,346	2,346
Asia	1,944	1,944
Revenue from contracts with customers	4,291	4,291

(14) Related parties

The parties deemed to be related are entities and individuals who can be significantly influenced by the Company or can exert significant influence on the Company. Related parties are the Company's Executive Management Board and Supervisory Board.

As of 30 June 2022, Medigene held 38.21% of the shares in Aettis, Inc., Bala Cynwyd, PA, USA, but is not represented on its Board of Directors and no significant influence is apparent by or upon the Company. No transactions were conducted with Aettis, Inc. in the 2022 reporting period.

The remuneration and shareholdings of the Company's Executive Management Board and Supervisory Board members are itemized for each member of these boards in section F.

F. EXECUTIVE MANAGEMENT BOARD AND SUPERVISORY BOARD

REMUNERATION, DIRECTORS' HOLDINGS AND NOTES ON SUBSCRIPTION RIGHTS

	REMUNERATION IN € K	SHARES TOTAL NUMBER		OPTIONS TOTAL NUMBER	
		6M 2022 UNAUDITED	30/06/2022 UNAUDITED	31/12/2021	30/06/2022 UNAUDITED
Dr. Gerd Zettlmeissl, Chairman since 23/05/2019	23	0	0	0	0
Antoinette Hiebeler-Hasner, Deputy Chair	19	0	0	0	0
Dr. Anthony Man	10	0	0	0	0
Dr. Keith Manchester ¹⁾	12	0	0	0	0
Dr. Frank Mathias	15	20,197	20,197	46,089	46,089
Ronald Scott	12	0	0	0	0
Total Supervisory Board	91	20,197	20,197	46,089	46,089
Prof. Dolores J. Schendel, CEO ²⁾	500	846,296	846,296	137,500	137,500
Axel Sven Malkomes, member of the board until 31/03/2022 ³⁾	286	0	0	95,000	95,000
Total Executive Management Board⁴⁾	786	846,296	846,296	232,500	232,500

¹⁾ Dr. Manchester is a partner and Head of Life Sciences QVT Financial LP New York, USA. According to the latest voting rights announcement dated 8 June 2018, the funds managed by QVT hold 1,072,879 shares in Medigene AG.

²⁾ Prof. Schendel indirectly holds 846,296 Medigene shares in her capacity as Managing Director of DJSMontana Holding GmbH, which can be allocated to Prof. Schendel directly.

³⁾ Due to a contractual non-competition clause, Mr. Malkomes will receive his salary until 30 September 2022.

⁴⁾ The remuneration paid to the members of the Executive Management Board comprises a fixed component and variable components based on the accrual recognized (not discounted) to cover a 100% pay-out and fringe benefits (pension expenses).

RESPONSIBILITY STATEMENT OF THE MEMBERS OF THE GOVERNING BODY

To the best of my knowledge, and in accordance with the applicable reporting principles, the interim consolidated financial statements give a true and fair view of the net assets, financial position and results of operations of the Group, and the interim management's discussion and analysis includes a fair review of the development and performance of the business and the position of the Group, together with a description of the material opportunities and risks associated with the expected development of the Group in the remaining fiscal year.

Planegg/Martinsried, 22 July 2022

Prof. Dolores J. Schendel
Chief Executive Officer (CEO/CSO)

Financial calendar 2022

Quarterly Statement Q3 2022	2 November 2022
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Trademarks

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