

**inspired by  
immunotherapies**

# KEY FIGURES

OF MEDIGENE AG

IN € K	2014	2013	CHANGE
<b>INCOME STATEMENT</b>			
Veregen® revenue	<b>5,195</b>	4,209	23%
thereof royalties	<b>2,352</b>	2,585	-9%
thereof revenue from product sales	<b>2,118</b>	1,326	60%
thereof milestone payments	<b>725</b>	298	143%
Other operating income	<b>8,589</b>	3,383	154%
<b>Total revenue</b>	<b>13,784</b>	<b>7,592</b>	<b>82%</b>
Cost of sales	<b>-2,086</b>	-1,735	20%
Gross profit	<b>11,698</b>	5,857	100%
Selling, general and administrative expenses	<b>-7,081</b>	-8,273	-14%
Research and development expenses	<b>-7,498</b>	-6,605	14%
Operating result	<b>-2,881</b>	-9,021	-68%
Earnings before tax	<b>-5,912</b>	-10,264	-42%
Net profit/loss for the year	<b>-5,757</b>	-10,282	-44%
<b>EBITDA</b>	<b>-2,071</b>	<b>-8,270</b>	<b>-75%</b>
Earnings per share (basic/diluted) (€)	<b>-0.47</b>	-1.07	-56%
Personnel expenses	<b>-6,622</b>	-5,493	21%
<b>CASH FLOWS</b>			
Net cash used in operating activities	<b>-8,756</b>	-12,246	-30%
Net cash used in investing activities	<b>-935</b>	-142	>200%
Net cash from financing activities	<b>14,502</b>	2,378	>200%
<b>BALANCE SHEET</b>			
Cash and cash equivalents	<b>14,976</b>	10,166	47%
Total assets	<b>71,283</b>	52,655	35%
Current liabilities	<b>7,755</b>	5,092	52%
Non-current liabilities	<b>14,457</b>	11,287	28%
Shareholders' equity	<b>49,071</b>	36,276	35%
Equity ratio (%)	<b>69</b>	69	0%
Employees as of 31 December	<b>72</b>	51	41%
FTEs as of 31 December	<b>65</b>	48	28%
<b>MEDIGENE SHARE</b>			
Total number of shares outstanding as at 31 December	<b>13,927,428</b>	9,872,139	41%
Share price (XETRA closing price) as at 31 December (€)	<b>3.72</b>	3.50	6%
Dividend (€)	<b>0</b>	0	

# CONTENT

## **GROUP MANAGEMENT'S DISCUSSION AND ANALYSIS**

- 02** Pivotal events in 2014
- 02** Financial highlights in 2014
- 03** Company overview
- 09** General conditions
- 10** Performance indicators
- 11** Results of operations
- 14** Financial position
- 15** Net assets
- 17** Employees
- 17** Remuneration of the executive management board and supervisory board
- 18** Risk report
- 23** Other information
- 30** Opportunities and outlook

## **CONSOLIDATED FINANCIAL STATEMENTS AND FURTHER INFORMATION**

- 32** Consolidated income statement
- 33** Consolidated statement of comprehensive income
- 34** Consolidated balance sheet
- 36** Consolidated statement of cash flows
- 37** Consolidated statements of changes in shareholders' equity
- 38** Notes to the consolidated financial statements
- 90** Consolidated statement of changes in non-current assets

## **MISCELLANEOUS**

- 92** Audit opinion
- 94** Responsibility statement
- 95** Report of the supervisory board
- 99** Glossary
- 106** Financial calendar / trademarks / imprint

# GROUP MANAGEMENT DISCUSSION AND ANALYSIS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, AS AT 31 DECEMBER 2014

## PIVOTAL EVENTS IN 2014:

- Acquisition of Trianta Immunotherapies GmbH (now “Medigene Immunotherapies GmbH”)
- Focus on immunotherapies
- Successful completion of capital increase to further fund development of immunotherapy programmes
- RhuDex® outlicensed to Falk Pharma

## FINANCIAL HIGHLIGHTS IN 2014

- Total revenue increased by 82% to €13.8 m (2013: €7.6 m)
- Total revenue from sales of Veregen® increased by 23% to €5.2 m (2013: €4.2 m)
- EBITDA loss reduced by 75% to €-2.1 m (2013: €-8.3 m)
- Net profit/loss for the year improved by 44% to €-5.8 m (2013: €-10.3 m)

## COMPANY OVERVIEW

Medigene AG ("Medigene"), a biopharmaceutical company, concentrates on the research and development of novel drugs for treating cancer and autoimmune diseases. Since taking over Trianta Immunotherapies GmbH (now Medigene Immunotherapies GmbH) in January 2014, it has focused on personalised T cell immunotherapies. In November 2014, Medigene announced the change of name of its wholly-owned subsidiary Trianta Immunotherapies GmbH ("Trianta") to Medigene Immunotherapies GmbH ("Medigene Immunotherapies").

### Organisational and legal structure of the Group

Medigene AG was founded in 1994 in Planegg/Martinsried near Munich, Germany. In 1996, the Company was converted into a joint stock corporation. The Company's headquarters are located at Lochhamer Strasse 11, 82152 Planegg/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 (Deutsche Börse: Regulated Market, Prime Standard; German security identification number A1X3W0; code MDG1).

In addition to the parent company Medigene AG in Planegg/Martinsried, the Medigene Group includes the wholly owned subsidiary Medigene, Inc., San Diego, CA, USA, which was acquired in 2001, and, since its acquisition in January 2014, the wholly owned subsidiary Medigene Immunotherapies GmbH, Munich. Medigene is managed by the Executive Management Board of the parent company, Medigene AG. The subsidiaries' management reports directly to the Group's Executive Management Board.

### Segments

Medigene's business activities are comprised of the two business units "Marketed drugs" and "Drug candidates". The regional segmentation differentiates between the USA, Europe and Asia.

### Management structure

The Executive Management Board of Medigene AG comprises the Chief Executive Officer Dr. Frank Mathias, and the board members Peter Llewellyn-Davies and, since 1 May 2014, Prof. Dolores J. Schendel.

### Status of the product portfolio

Medigene has one approved drug on the market, Veregen<sup>®</sup>, which generates revenues. Veregen<sup>®</sup> is distributed by several partners. Through its wholly owned subsidiary Medigene Immunotherapies, Medigene develops three complementary immunotherapy platforms (DC vaccines, T cell receptor- (TCR) modified T cells and T cell-specific monoclonal antibodies, TABs) with programmes in clinical development. In addition, Medigene owns the AAVLP vaccine technology. The clinical drug candidates EndoTAG<sup>®</sup>-1 and RhuDex<sup>®</sup> are licenced to partners who will assume responsibility for the further clinical development.

### Immunotherapies under development

#### DC vaccines (DCs)

With Medigene's most advanced platform the Company develops new generation antigen-tailored dendritic cell (DC) vaccines. Dendritic cells can take up antigens efficiently, process them and present them on their surface in a form that can induce antigen-specific T cells to proliferate and mature. This way T cells can recognise and eliminate antigen-bearing tumour cells. Dendritic cells can also induce natural killer cells (NK cells) to become active and attack tumour cells. Scientists of Medigene Immunotherapies have developed new, fast and efficient methods for generating autologous (patient-specific) mature dendritic cells which have relevant characteristics to activate both T cells and NK cells. The dendritic cells can be loaded with various tumour antigens to treat different types of cancer.

DC vaccines are being evaluated in two ongoing, externally funded investigator-initiated trials: a clinical phase I/II trial in acute myeloid leukaemia (AML) at the Ludwig-Maximilian University Hospital Großhadern, Munich, in cooperation with Prof. Marion Subklewe and Prof. Wolfgang Hiddemann, and a clinical phase II trial in prostate cancer at the Oslo University Hospital in cooperation with Prof. Gunnar Kvalheim. Moreover, a compassionate use programme<sup>1</sup> is being conducted at the Department of Cellular Therapy at the Oslo University Hospital, Norway, under the responsibility of Prof. Gunnar Kvalheim.

Positive clinical data of these programmes were presented by Medigene's cooperation partners at several international conferences in 2014. The abstracts of these presentations are available at Medigene's company website [www.medigene.com](http://www.medigene.com).

In September 2014, the Oslo University Hospital presented initial clinical data on their investigator-initiated clinical phase II trial at the 14<sup>th</sup> International Conference on Progress in Vaccination Against Cancer (PIVAC) in Rome, Italy. The poster presentation was entitled "A Phase I/II trial of adjuvant therapeutic vaccination in resected prostate cancer patients using autologous dendritic cells loaded with mRNA from primary prostate cancer tissue, hTERT and survivin."

In November 2014, initial clinical data on Medigene's DC vaccine for the treatment of AML were presented at the SITC (Society for Immunotherapy of Cancer) 29<sup>th</sup> Annual Meeting in National Harbor/Washington D.C., USA. The poster entitled "Next generation dendritic cells for immunotherapy of acute myeloid leukemia" shows clinical data collected in the current investigator-initiated phase I/II clinical trial for the treatment of acute myeloid leukaemia (AML) conducted at the Ludwig-Maximilians University Hospital Großhadern, Munich, Germany.

Additionally, the Oslo University Hospital presented early clinical data collected in its compassionate use programme at the 56<sup>th</sup> American Society of Hematology (ASH) Annual Meeting in San Francisco, USA, in December 2014. The poster presentation entitled "Vaccination with a New Generation of Fast Dendritic Cells Transfected with mRNA from hTERT, Survivin and Autologous Tumor Mount Strong Immune Responses and Prolong Survival" showed data from patients with various types of tumour which were included in this programme.

Preclinical data on its DC vaccine programme were presented by Medigene at the 13<sup>th</sup> International Dendritic Cell Symposium (DC 2014) in Tours, France, and at the 14<sup>th</sup> International Conference on Progress in Vaccination Against Cancer (PIVAC) in Rome, Italy, in September 2014 as well as in the October 2014 volume of the scientific journal "Cancer Immunology, Immunotherapy."

In March 2014, the US Patent Office issued a patent relating to the manufacturing of mature, polarised dendritic cells. The patent has a term until 2028 and is licenced exclusively to Medigene Immunotherapies (formerly Trianta) by Helmholtz Zentrum München - German Research Center for Environmental Health (HMGU).

Moreover, Medigene announced that the development team for dendritic cell (DC) vaccines has successfully concluded a project for the development of an optimised formulation of a DC vaccine for the specific treatment of prostate cancer. The project was carried out at the HMGU, and was supported by the Bavarian Ministry of Economic Affairs as part of the m<sup>4</sup> Award. This optimised vaccine formulation will form the basis of discussions that Medigene will have with potential partners on the continued clinical development of DC vaccines for prostate cancer.

---

<sup>1</sup> Compassionate Use: Prescription of as-yet unapproved drugs in particularly severe cases where there are no treatment alternatives

At the end of December the Norwegian Medicines Agency (NoMA) and the relevant Ethic Committee granted Medigene the approval to conduct a phase I/II clinical trial with its dendritic cell (DC) vaccine. Thereby, all regulatory prerequisites for the study start are fulfilled. The trial for the treatment of acute myeloid leukaemia (AML) will enable Medigene to evaluate its personalised DC vaccines in its first company-sponsored trial and generate further clinical feasibility and safety data. It will enrol AML patients after chemotherapy to reduce their risk of relapse by using Medigene's DC vaccines.

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

Medigene's second platform in the field of immunotherapy aims to arm the patient's own T cells with tumour-specific T cell receptors. The receptor-modified T cells are then able to detect and efficiently kill tumour cells. This form of immunotherapy aims to overcome the patient's tolerance to cancer cells, and the tumour-induced immunosuppression in the patient, by activating and modifying the patient's T cells outside the body (*ex vivo*). A large army of specific T cells to fight the tumour is made available to patients within a short period of time.

Medigene is developing a comprehensive library of recombinant T cell receptors. Moreover, a good manufacturing practice (GMP)-compliant process for their combination with patient-derived T cells is currently being established. First discussions with regulatory authorities for the preparation of first clinical trials with defined product candidates have already taken place.

In April 2014, the US Patent Office issued a patent relating to a T cell receptor against the tumour associated antigen tyrosinase. In October 2014, Medigene announced that the Australian Patent Office had issued a similar patent. The patents have a term until 2030 in the US and 2029 in Australia and have been licenced exclusively to Medigene Immunotherapies by Helmholtz Zentrum München (HMGU).

In July 2014, Medigene announced that Medigene Immunotherapies will be an active project partner in the transregional Collaborative Research Centre (SFB-TR36) "Principles and Applications of Adoptive T Cell Therapy" of the German Research Foundation (DFG). The DFG has continued the funding period of the SFB-TR36, started in 2006, for another four years. The project of the former Trianta is an integral part of the consortium that includes other projects of acclaimed scientists from Charité Universitätsmedizin Berlin, the Max Delbrück Center for Molecular Medicine (MDC), Humboldt University of Berlin (HU), Ludwig Maximilian University of Munich (LMU), Munich University of Technology (TUM) and the HMGU. The scientists' aim is to develop effective approaches to treat tumours using adoptive T cell transfer. Medigene's participation in SFB-TR36 secures established scientific and project-related cooperation with these leading German research institutions in the field of cancer immunotherapy. In particular, the promotion of technology transfer in a joint project with the HMGU facilitates access for Medigene to highly innovative preclinical tumour models for testing the efficacy of its own therapeutic concepts developed.

Moreover, at the Annual Meeting of Society for Immunotherapy of Cancer (SITC Conference) in November 2014 Medigene presented a poster entitled "Generation of tumour antigen-specific CD4<sup>+</sup> and CD8<sup>+</sup> T cells by simultaneous MHC-I and -II epitope presentation *in vitro* and *in vivo*". It outlined parts of Medigene's immunotherapeutic TCR programme, particularly the isolation and identification of tumour-specific T cells.

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

The third product platform serves to generate monoclonal antibodies which are able to recognise different T cells (TABs = T cell-specific AntiBodies). These TABs are intended to remove unwanted T cells from the body in order to treat T cell-induced diseases such as T cell leukaemia or various autoimmune diseases. This platform is used to produce and characterise monoclonal antibodies which are able to distinguish between different T cells. Proof of technology was established in preclinical experiments.

In June 2014, it was announced that Medigene Immunotherapies receives public funding for the development of its TABs immunotherapy platform for the treatment of various types of cancer and autoimmune diseases. The grant is awarded by the Federal Ministry of Education and Research, (Bundesministerium für Bildung und Forschung, BMBF) within the scope of the "m4 - Personalized Medicine and Targeted Therapies: a new Dimension of Drug Development" Munich Leading-Edge Cluster initiative. The sponsored project intends to provide evidence of the elimination of pathogenic T cells in T cell leukemia and autoimmune diseases, applying in vivo and in vitro methods with T cell-specific monoclonal antibodies. The project is financed by Medigene (60%) as well as the BMBF grant (40%). In September 2014, Medigene announced an increase of this public funding support.

Moreover, in September 2014 Medigene announced that Medigene Immunotherapies has entered into two new research collaborations in the field of TABs. In the future, scientists of the Max Delbrück Center for Molecular Medicine (MDC) and Helmholtz Zentrum München - German Research Center for Environmental Health, Munich (HMGU) will undertake certain research and development tasks in this specialised field. In the context of this collaboration monoclonal antibodies for the treatment of autoimmune diseases and T cell leukaemia will be tested. The in vivo data generated during the granted period will be of great value for further clinical development of this immunotherapy platform. Overall, the collaboration with both research institutions offers Medigene extended scientific synergies regarding technology transfer, infrastructure and exchange of knowledge.

### ***AAVLP technology***

The AAVLP (adeno-associated virus-like particles) programme is an innovative technology platform for the generation of new prophylactic and therapeutic vaccines. For this purpose, non-infectious virus-like particles derived from adeno-associated viruses (AAV) are used as epitope carriers. Epitopes delivered to the immune system in this way result in the production of specific antibodies. These antibodies in turn recognise the relevant epitope, e.g. on pathogens or mutant cancer cells, and consequently fight and/or protect against the relevant disease. Research into the use of the AAVLP technology to treat infectious diseases and cancer is being conducted by pursuing two different approaches. One is the direct integration of known epitopes. The second approach is based on the use of AAV libraries. Rather than defined epitopes, AAV libraries contain random sequences. Appropriate screening strategies enable the targeted selection of novel vaccine candidates from these libraries. The key benefit of this technology is the possibility of directly transferring the mode of action of existing therapeutically effective antibodies into an active vaccine.

A preclinical long-term study completed in cooperation with Pennsylvania State University with the aim of demonstrating long-term cross-protection against various human papilloma virus (HPV) infections has recorded positive results.

## Marketed drug

### **Worldwide partners: Veregen®**

Veregen®, a drug for the treatment of genital warts, was developed by Medigene AG and generates revenue from royalties, product sales (supply chain) and milestone payments.

Veregen® is an innovative drug formulation based on a defined extract from green tea leaves, which is obtained in a complex and specifically developed production process. In several clinical studies, Veregen® showed complete clearance of genital warts in more than 60% of the patients, and was very well tolerated. In its current treatment guidelines for sexually transmitted diseases, the US Center for Disease Control and Prevention recommends Sinecatechins 15% ointment (Veregen®) as a possible option for treating genital warts. In addition, Sinecatechins 10% and 15% ointment (Veregen®) were included in the current European guideline ("2012 European Guideline for the Management of Anogenital Warts") as a recommended treatment option for genital warts.

Medigene has marketing agreements for Veregen® in place with numerous partners worldwide. Medigene receives one-time upfront payments, revenues from milestone payments and from the supply of the finished product, as well as royalties on the sales of Veregen® in these countries.

Veregen® is currently available in the US and Canada, in 15 European countries (Germany, Austria, Switzerland, Spain, Serbia, the Netherlands, Norway, Sweden, the Czech Republic, Slovakia, Hungary, Poland, Belgium, Denmark, Finland) and Taiwan and has been approved in additional countries.

The market launch in several countries is preceded by negotiations with the national authorities on the price of the drug that can be reimbursed by the statutory health insurance schemes. Medigene was notified in September 2014 that the authorities in France decided against a reimbursement for Veregen®. In February 2015, the French marketing partner Laboratoires Expanscience returned its marketing rights for Veregen® to Medigene. Medigene is now evaluating options for the marketing of Veregen® without reimbursement in France with an alternative partner. Veregen® is available on the market without reimbursement in Scandinavia and the majority of eastern European countries.

In the third quarter of 2014 Medigene filed marketing authorisation applications in eight additional European countries (UK, Ireland, Italy, Portugal, Croatia, Latvia, Lithuania and Estonia) using the mutual recognition procedure. These marketing authorisation applications were positively assessed in February 2015. In November 2014, a marketing authorisation application for Veregen® was submitted in Russia.

In April 2014, Medigene and the pharmaceutical company Kora Healthcare concluded an exclusive agreement for the supply and commercialisation of Veregen® in the United Kingdom and Ireland. In October 2014, Medigene's US licensee, Fougere Pharmaceuticals Inc, a Sandoz company, signed a promotion agreement with Women's Choice Pharmaceuticals LLC (WCP), a US specialty pharmaceutical company to expand product sales within the obstetrics, gynaecology and urology medical specialties.

### Partnered drug candidates

The following drug candidates are out-licensed to and developed by Medigene's partners:

#### **SynCore Biotechnology Co., Ltd.: EndoTAG<sup>®</sup>-1**

The clinical drug candidate EndoTAG<sup>®</sup>-1 is an innovative composition of the established cytostatic drug paclitaxel combined with neutral and positively charged lipids. Due to the positive charge, EndoTAG<sup>®</sup>-1 interacts with newly formed, negatively charged endothelial cells, which are specifically required for the growth of tumour blood vessels. The EndoTAG<sup>®</sup>-1 paclitaxel component attacks the activated endothelial cells as they divide, thus targeting the blood supply to tumours without affecting endothelial cells of healthy tissues. By doing this, EndoTAG<sup>®</sup>-1 is expected to prevent the formation of new tumour blood vessels and to inhibit tumour growth.

Medigene successfully completed two clinical phase II trials with EndoTAG<sup>®</sup>-1 in the indications of pancreatic cancer and triple-negative breast cancer (TNBC). Furthermore, Medigene published positive results from an investigator-initiated trial (IIT) with EndoTAG<sup>®</sup>-1 in HER2-negative high-risk breast cancer at the ASCO 2013 Annual Meeting.

As part of the licence agreement with the partner SynCore Biotechnology Co., Ltd. ("SynCore"), SynCore is fully responsible for the development and financing of the planned phase III clinical trial with EndoTAG<sup>®</sup>-1 in the indication of TNBC, and has in turn received the global marketing rights for EndoTAG<sup>®</sup>-1. Medigene received an upfront and a milestone payment from SynCore and is entitled to further payments upon certain development and approval milestones as well as royalties after market approval of EndoTAG<sup>®</sup>-1.

#### **Dr. Falk Pharma GmbH: RhuDex<sup>®</sup>**

The drug candidate RhuDex<sup>®</sup> is an oral, disease modifying agent to treat autoimmune diseases. It serves as a CD80 antagonist that blocks undesired T-cell activation and production and therefore has an immune modulating and anti-inflammatory effect.

The safety and tolerability of RhuDex<sup>®</sup> was demonstrated in a number of phase I clinical trials. Medigene successfully completed a pilot Phase IIa trial in the indication rheumatoid arthritis. In 2013, Medigene outlined preparations for further clinical development of RhuDex<sup>®</sup> in the indication primary biliary cirrhosis (PBC). In March 2014, a licence agreement was concluded with the pharmaceutical company Dr. Falk Pharma GmbH, Freiburg ("Falk Pharma"), for the development and marketing rights to RhuDex<sup>®</sup> in the indications hepatology and gastroenterology. Falk Pharma will assume responsibility and all costs relating to the clinical development and marketing of RhuDex<sup>®</sup> in these therapeutic areas. Medigene received an upfront payment and is entitled to future milestone payments from Falk Pharma, plus double-digit royalties on sales of RhuDex<sup>®</sup>. Falk Pharma initially concentrates on development in primary biliary cirrhosis (PBC). Medigene retains the rights for RhuDex<sup>®</sup> in rheumatoid arthritis, psoriasis and other autoimmune diseases.

## GENERAL CONDITIONS

### Procurement

As part of its business activities, Medigene AG is responsible for the procurement of supplies for the marketed drug Veregen® and for drug candidates for clinical and preclinical test purposes, services, chemicals and laboratory supplies for research and development. Medigene is intensively involved in the development and optimisation of production processes for future drugs in order to efficiently organise the procurement of required ingredients at a later stage.

#### Procurement of drugs

Medigene has a contract with Mitsui Norin Co., Ltd., Tokyo, Japan, ("Mitsui Norin"), for the production and supply of the active pharmaceutical ingredient for Veregen®. The formulation of the ointment is carried out by a contract manufacturer in Germany by order of Fougera for the US market and on behalf of Medigene for other markets. The raw material, which consists of green tea leaves, is obtained from Chinese tea farms. Mitsui Norin is responsible for monitoring the Chinese raw material suppliers.

#### Procurement management for research and development supplies

Generally, Medigene is not dependent on any single raw material supplier for research and development. Rather, the Company solicits various bids as a matter of principle and places its orders with the most advantageous supplier, taking into account quality considerations. Procurement is organised in such a way that Medigene is able to ensure that the supply is sufficiently stable and resilient in the face of possible bottlenecks or quality problems while at the same time optimising its purchase prices. Given a price trend within the usual range, procurement costs are of secondary importance in Medigene's cost structure.

#### Complex demands on service providers

Medigene avails itself of extensive services, primarily for the large-scale production and formulation of therapeutic active ingredients as well as when conducting pharmacological, toxicological and clinical trials. Outsourcing these activities ensures that Medigene is able to respond quickly to changes in its development portfolio with the required flexibility. The demands on services of this kind are highly complex, calling for extensive expertise and experience on the part of the purchaser. Criteria for selecting partners for such projects – apart from quality and efficiency – include adherence to delivery dates, reliability and flexibility.

## PERFORMANCE INDICATORS

### Financial performance indicators

Medigene's management uses revenue, EBITDA, gross margin, the cash to total assets ratio and the equity ratio as performance indicators for the commercial success of the Group's activities. Medigene's EBITDA is derived from the net profit/loss for the year; it does not include any taxes, financial result, foreign exchange gains or losses, share of result of associates nor amortisation or depreciation → *see EBITDA on page 12 et seq.*

#### PERFORMANCE INDICATORS

		2014	2013
Gross margin of total revenue (%)	$\frac{\text{Gross profit} \times 100}{\text{Total revenue}}$	85	77
EBITDA (€ k)		-2,071	-8,270

#### ASSET AND GEARING INDICATORS

IN %		2014	2013
Cash to total assets ratio	$\frac{\text{Cash and cash equivalents} \times 100}{\text{Total assets}}$	21	19
Equity ratio	$\frac{\text{Shareholders' equity} \times 100}{\text{Total shareholders' equity and liabilities}}$	69	69

The gross margin of the Company improved by 10% in 2014 to 85% (2013: 77%) on account of higher revenue from milestone payments. The cash to total assets ratio rose to 21% (2013: 19%), mainly because of the increase in cash and cash equivalents due to proceeds from the capital increase. The equity ratio remained unchanged at 69%. Management expects to raise additional funds from external sources, e.g. from additional partnerships with pharmaceutical companies or capital measures in good time → *see Financing risks in the Risk report on page 18.*

A report on the development of cash and cash equivalents can be found in the group management discussion and analysis under → *Changes in cash and cash equivalents on page 14 and in Opportunities and outlook on page 30 et seq.* For details of the objectives and methods of the financial risk management → *see Notes to the consolidated financial statements E) note (50).*

### Non-financial performance indicators

Medigene's commercial success will also essentially depend on the extent to which patent protection is obtained and maintained for its products and technologies in the respective regional target markets. Medigene's patent situation is therefore the Company's most critical non-financial performance indicator along with progress in the development of its drug pipeline.

#### Patent position

Medigene AG currently holds rights to a large number of patents and patent applications in the capacity as either owner or licensee, and further strengthened its portfolio's patent situation in 2014.

#### Consistent patent strategy provides the basis for commercial success

The Company aims to obtain patent protection for its proprietary products, processes and technologies. In line with the strategy of obtaining patents for technologies and products in development, Medigene has submitted numerous applications for various results of its work on proprietary technologies and products, or has exclusively licenced patents for the relevant segments.

## RESULTS OF OPERATIONS

### Revenue and other income

Medigene increased its total revenue by 82% in 2014 to €13,784 k (2013: €7,592 k). The revenue generated by Veregen<sup>®</sup> rose by 23% to €5,195 k (2013: €4,209 k). The revenue from Veregen<sup>®</sup> comprises royalties, product sales and also milestone payments. Royalties decreased by 9% in a year-on-year comparison, totalling €2,352 k (2013: €2,585 k) due to an overall weak US dermatology market for branded pharmaceuticals. However, the market share of Veregen<sup>®</sup> on the US market and Veregen<sup>®</sup> sales and market share in other markets rose constantly. At the same time, revenue from product sales of Veregen<sup>®</sup> to distribution partners rose by 60% in 2014 to €2,118 k (2013: €1,326 k). In addition, Medigene received Veregen<sup>®</sup> milestone payments from partners amounting to €725 k (2013: €298 k).

Medigene's other operating income rose by 154% in 2014 to €8,589 k (2013: €3,383 k). This consists of regular non-cash income of €2,493 k (2013: €2,493 k) p.a. from licencing the rights to Eligard<sup>®</sup>, a former product of Medigene, to the US financial investor, Cowen Healthcare Royalty Partners in 2012 → *see Notes to the consolidated financial statements B) note (4)* and sales of RhuDex<sup>®</sup> material (active pharmaceutical ingredient, API) amounting to €503 k (2013: €0 k) to the partner, Falk Pharma, as well as grants of €153 k (2013: €0 k). In addition, Medigene recovered costs of €1,936 k (2013: €833 k) from SynCore, another partner, related to the development of EndoTAG<sup>®</sup>-1 and realised €2,699 k (2013: €13 k) for milestones reached. Medigene also received a one-off payment of €700 k from a licence agreement entered into with Falk Pharma in March 2014.

The distribution of income can be found in the → *Notes to the consolidated financial statements D) note (27) on page 56 et seq.*

### CONSOLIDATED INCOME STATEMENT (ABBREVIATED)

IN €K	2014	2013	CHANGE
<b>Veregen<sup>®</sup> revenue</b>	<b>5,195</b>	<b>4,209</b>	<b>23%</b>
thereof royalties	2,352	2,585	-9%
thereof revenue from product sales	2,118	1,326	60%
thereof milestone payments	725	298	143%
Other operating income	8,589	3,383	154%
<b>Total revenue</b>	<b>13,784</b>	<b>7,592</b>	<b>82%</b>
Cost of sales	-2,086	-1,735	20%
<b>Gross profit</b>	<b>11,698</b>	<b>5,857</b>	<b>100%</b>
Selling, general and administrative expenses	-7,081	-8,273	-14%
Research and development expenses	-7,498	-6,605	14%
<b>Operating result</b>	<b>-2,881</b>	<b>-9,021</b>	<b>-68%</b>
<b>Net profit/loss for the year</b>	<b>-5,757</b>	<b>-10,282</b>	<b>-44%</b>

### Cost of sales

The cost of sales increased to €2,086 k in 2014 (2013: €1,735 k) as a result of higher revenue from product sales for Veregen<sup>®</sup>.

### Gross profit

Gross profit improved by 100% in 2014 to €11,698 k (2013: €5,857 k). The gross profit amount is determined by the ratio of revenue from product sales and royalties to milestone payments. The gross profit generated from the drug Veregen<sup>®</sup> is dependent on the euro to the US dollar exchange rate.

### Selling, general and administrative expenses

In a year-on-year comparison, selling, general and administrative expenses decreased by 14%, falling from €8,273 k (2013) to €7,081 k (2014) mainly on account of the one-off payment of €740 k made in the previous year to revoke a contract made with Abbott Arzneimittel GmbH for the marketing of Veregen® in Germany. Administrative expenses decreased to €5,090 k in the reporting period (2013: €5,152 k). This is primarily due to higher consulting fees in the previous year due to the acquisition of Medigene Immunotherapies. The composition of selling, general and administrative expenses can be found in the → *Notes to the consolidated financial statements D) notes (29) and (30) on page 57 et seq.*

### Research and development expenses

Total expenses for research and development (R&D) increased by 14% to €7,498 k (2013: €6,605 k) as budgeted on account of the higher expenses for developing the new immunotherapy platforms acquired by the Company. The reduction in the expenses for RhuDex® due to the partnering with Falk Pharma was partly offset by a rise in personnel expenses, patent and development costs from taking over Medigene Immunotherapies. R&D expenses incurred for EndoTAG®-1 are reimbursed by the partner SynCore and posted in other operating income as R&D funding from partners. The composition of R&D expenses can be found in the → *Notes to the consolidated financial statements D) note (31) on page 58.*

### EBITDA

Medigene's EBITDA amounted to €-2,071 k in 2014, which represents an improvement of 75% on the EBITDA posted in the previous year (2013: €-8,270 k). Medigene's EBITDA is derived from net profit/loss for the year; it does not include any taxes, financial result, foreign exchange gains or losses, share of result of associates nor amortisation or depreciation.

<b>EBITDA</b>			
IN €K	2014	2013	CHANGE
Net profit/loss for the year	-5,757	-10,282	-44%
Taxes	-155	18	>-200%
Financial result	1,774	1,553	14%
Foreign exchange gains/losses	1,201	-412	>-200%
Share of result of associates	56	102	-45%
Depreciation and amortisation	810	751	8%
<b>EBITDA</b>	<b>-2,071</b>	<b>-8,270</b>	<b>-75%</b>

### Depreciation and amortisation

Depreciation and amortisation amounted to €810 k in 2014 (2013: €751 k).

### Financial result

The financial result amounted to €-1,774 k during the reporting period (2013: €-1,553 k), consisting mainly of non-cash interest expenses of €1,449 k (2013: €1,566 k) which resulted from the measurement of the financial liability to Cowen.

### Foreign exchange gains/losses

On account of the high EUR/USD exchange rate, the Company incurred an unrealised loss of €1,201 k in 2014 (2013: a gain of €412 k). These foreign exchange losses originate primarily from the measurement of the financial liability to Cowen.

### Share of result of associates

The result from investments in associates amounted to €-56 k in 2014 (2013: €-102 k) and relates mainly to the associate Catherex, Inc. As at 31 December 2014, the Group held 40.40% of the shares in Catherex, Inc. and a 38.95% shareholding in Aettis, Inc.

### Taxes

In the reporting period, tax income of €155 k (2013: a tax expense of €18 k) was posted in the income statement. It is generally a result of recognition of additional deferred tax assets on unused tax losses of Medigene AG on account of the profit and loss transfer agreement and a consolidated tax group between Medigene AG and Medigene Immunotherapies GmbH.

### Net profit/loss for the year

The net profit/loss for the year amounts to €-5,757 k. This represents an improvement of 44% on the net profit/loss for the previous year of €-10,282 k (2013).

### Earnings per share

In 2014, the loss per share amounted to €0.47 (basic and diluted weighted average number of shares: 12,210,949) compared with a loss of €1.07 per share in the previous year (basic and diluted weighted average number of shares: 9,631,559). For both fiscal years, the diluted earnings per share were the same as the basic earnings per share, since taking into account the weighted average number of shares to be issued upon the exercise of stock options would produce an anti-dilutive effect.

### Segments

The activities of Medigene AG are broken down into the segments »Marketed drugs« and »Drug candidates« → *see Notes to the consolidated financial statements F) »Segment reporting« on page 78 et seq.* The »Marketed drugs« segment includes Veregen®. The »Drug candidates« segment is used to report on Medigene's activities in immunotherapies under development and the drug candidates, EndoTAG®-1, RhuDex® and AAVLP.

## FINANCIAL POSITION

### CHANGES IN CASH AND CASH EQUIVALENTS

IN €K	2014	2013	CHANGE
<b>Net cash</b>			
used in operating activities	<b>-8,756</b>	-12,246	-28%
used in investing activities	<b>-935</b>	-142	>200%
from financing activities	<b>14,502</b>	2,378	>200%
<b>Increase/decrease in cash and cash equivalents</b>	<b>4,811</b>	<b>-10,010</b>	<b>-148%</b>
Cash and cash equivalents at the beginning of the period	<b>10,166</b>	20,113	-49%
Foreign exchange differences	<b>-1</b>	63	-102 %
<b>Cash and cash equivalents at the end of the period</b>	<b>14,976</b>	<b>10,166</b>	<b>47%</b>

#### Net cash used in operating activities

Medigene managed to reduce its cash outflow from operating activities in the reporting period by 28% to €8,756 k (2013: €12,246 k). This represents an average monthly cash outflow for operating activities of €0.7 m in 2014 (2013: €1.0 m). The cash usage from operating activities is not particularly indicative of future trends as it is significantly impacted by one-off payments for partnering and research and development expenses which depend on the respective progress of the project.

#### Net cash used in investing activities

The cash outflow from investing activities rose in 2014 to €935 k (2013: €142 k). The increase is primarily attributable to the purchase of property, plant and equipment for research and development activities of Medigene Immunotherapies. This was offset to some extent by the cash of €21 k acquired from Medigene Immunotherapies.

#### Net cash from financing activities

The cash inflow from financing activities amounted to €14,502 k in the reporting period (2013: €2,378 k) and consists of the proceeds from the capital increase of €15.9 m less the costs related the issue of Medigene shares from the capital measures. The cash inflow in the previous year was due to a capital increase related to the strategic partnership with SynCore.

#### Changes in cash and cash equivalents

The closing balance of cash and cash equivalents at the end of the reporting period was €14,976 k (2013: €10,166 k). The cash to total assets ratio was 21% as at the reporting date (2013: 19%). There were no open credit lines. For comments on the financing risks and the Company's cash reach → see *Risk report on page 18 et seq. and Opportunities and outlook on page 30 et seq.*

## NET ASSETS

### DEVELOPMENT OF ASSETS, SHAREHOLDERS' EQUITY AND LIABILITIES

IN €K	31 DEC 2014	31 DEC 2013	CHANGE
<b>Assets</b>			
Property, plant and equipment and intangible assets	<b>37,116</b>	27,363	36%
Goodwill	<b>2,212</b>	2,212	0%
Financial and other non-current assets	<b>4,508</b>	4,304	5%
Investment in an associate	<b>2,781</b>	2,513	11%
Cash and cash equivalents	<b>14,976</b>	10,166	47%
Inventories and accounts receivable	<b>6,139</b>	4,409	39%
Other current assets	<b>3,551</b>	1,688	110%
<b>Total assets</b>	<b>71,283</b>	<b>52,655</b>	<b>35%</b>
<b>Shareholders' equity and liabilities</b>			
Shareholders' equity	<b>49,071</b>	36,276	35%
Non-current liabilities	<b>14,457</b>	11,287	28%
Current liabilities	<b>7,755</b>	5,092	52%
<b>Total shareholders' equity and liabilities</b>	<b>71,283</b>	<b>52,655</b>	<b>35%</b>
<b>Cash to total assets ratio (%)</b>	<b>21</b>	<b>19</b>	
<b>Equity ratio (%)</b>	<b>69</b>	<b>69</b>	

### Assets

Total assets rose by 35% on the previous year to €71,283 k (2013: €52,655 k). This increase is primarily due to the increase in cash and cash equivalents, inventories and accounts receivable.

Property, plant and equipment and intangible assets rose to €37,116 k in the reporting period (2013: €27,363 k), of which €951 k (2013: €405 k) was property, plant and equipment. Intangible assets increased to €36,165 k (2013: €26,958 k) on account of the acquisition of Medigene Immunotherapies. Goodwill remained unchanged on the previous year at €2,212 k.

Financial and other non-current assets amounted to €4,508 k as at the reporting date (2013: €4,304 k). The carrying amount of the investment in an associate, Catherex, Inc., increased by 11% in the reporting period from €2,513 k (2013) to €2,781 k (2014). The carrying amount of the investment in Immunocore Ltd. rose to €3,620 k (2013: €3,533 k). As a result of the restructuring of shares in 2014, Medigene's investment in Immunocore Ltd totals 64,815 ordinary shares, corresponding to a shareholding of 2.93% as at 31 December 2014.

Trade accounts receivable as at the end of the reporting period amounted to €1,733 k (2013: €1,363 k). They primarily comprise receivables from the Veregen® partner, Fougera/Sandoz. Inventories in respect of Veregen® amounted to €4,406 k as at the reporting date (2013: €3,046 k).

Other current assets amounted to €3,551 k (2013: €1,688 k), of which expenses incurred for future periods accounted for €567 k (2013: €574 k) → *Notes to the consolidated financial statements E) note (41)*.

### Shareholders' equity and liabilities

In the reporting period, shareholders' equity increased by 35% to a total of €49,071 k (31 December 2013: €36,276 k). This increase is largely on account of the capital measures performed in July 2014, which added capital of €15,899 k. The equity ratio at the end of the reporting period 2014 remained unchanged on the previous year at 69%. For further details of the capital structure and the objectives and methods of financial risk management → *see Notes to the consolidated financial statements E) notes (43) and (50), on page 66 et seq and page 74.*

Current and non-current liabilities totalled €22,212 k as at the reporting date (2013: €16,379 k). This constitutes 31% of the total shareholders' equity and liabilities. Current liabilities comprise trade accounts payable of €1,785 k (2013: €1,419 k) and other financial liabilities of €5,913 k (2013: €3,651 k) → *see Notes to the consolidated financial statements E) note (46).*

Non-current liabilities comprise the long-term portion of the share in royalties transferred to Cowen, as mentioned above, of €10,597 k (2013: €10,356 k), pension obligations amounting to €413 k (2013: €304 k) and deferred income of €226 k (2013: €336 k). In addition, this line item includes other financial liabilities of €868 k (2013: €291 k) which in the reporting year primarily contain liabilities to the former shareholders of Medigene Immunotherapies for potential milestone payments.

Working capital, the difference between current assets and current liabilities was up from €11,171 k (2013) to €16,911 k (2014), primarily as a result of an increase in cash and cash equivalents → *see Notes to the consolidated financial statements E) note (44).*

### Overall statement

In the 2014 fiscal year, Medigene achieved an increase in total revenue of 82% to €14 m and reduced the EBITDA loss by 75% to €2 m. The Company's financial resources were strengthened by a capital increase in 2014. Medigene repositioned itself in 2014 by acquiring Medigene Immunotherapies GmbH and licencing out RhuDex<sup>®</sup>. It now focuses on developing innovative immunotherapies with the goal of ensuring a sustainable pipeline of drugs as well as new partnerships and financing options. Future success and achieving profitability will depend on operating progress in research, drug development, strategic decisions by the Company and on attracting external funding, e.g. through partnerships or capital measures, and is not yet secured → *see Financing risks in the Risk report on page 18.*

## EMPLOYEES

### Number of employees in the Group

As at the end of 2014, the number of employees was 72 (2013: 51). The number of full-time equivalent employees (FTEs) increased to 65 as at 31 December 2014 (2013: 48). Personnel expenses rose by 21% during the reporting period due to the integration of 18 Medigene Immunotherapies employees, coming to a total of €6,622 k (2013: €5,493 k).

#### EMPLOYEES BY REGION

	31 DEC 2014	31 DEC 2013	CHANGE
Medigene AG, Planegg/Martinsried	51	48	6%
Medigene Immunotherapies GmbH, Planegg/Martinsried	18	0	-
Medigene, Inc., San Diego	3	3	0%
<b>Total</b>	<b>72</b>	<b>51</b>	<b>41%</b>

## REMUNERATION OF THE EXECUTIVE MANAGEMENT BOARD AND SUPERVISORY BOARD

### Executive Management Board remuneration

Remuneration of members of the Executive Management Board, which now has three members, totalled €1,303 k in the past fiscal year (2013: €1,030 k) including pension expenses of €48 k (2013: €48 k) and vehicle leasing costs for company cars of €33 k (2013: €29 k). In addition, stock options with a total fair value of €51 k (2013: €31 k) were issued to the Executive Management Board. Total remuneration of the Executive Management Board members comprises fixed and variable components as well as other remuneration. The fixed component includes remuneration which is not performance-related and is paid in monthly instalments. Variable remuneration includes an annual performance-based payment and stock options. The amount and composition of the remuneration paid to the individual members of the Executive Management Board is reported in the [Notes to the consolidated financial statements G\) note \(55\) on page 81 et seq.](#) including a detailed remuneration report.

### Supervisory Board remuneration

The remuneration paid to the Supervisory Board, which now also has three members, amounted to €109 k in 2014 (2013: €224 k). The total remuneration paid to the members of the Supervisory Board comprises a fixed portion as well as meeting attendance fees. In addition, expenses are reimbursed. The greater scope of activities of the chairman of the Supervisory Board and his deputy are taken into account and accordingly reflected by higher remuneration. The amount of remuneration paid to individual members of the Supervisory Board and disclosures regarding subscription rights of the members of the Supervisory and Executive Management Boards are provided in the [Notes to the consolidated financial statements G\) notes \(56\) and \(57\) on page 87 et seq.](#) Medigene AG's Supervisory Board was reduced from six to three members through a resolution taken by the Annual General Meeting in July 2013.

## RISK REPORT

### Financial risks faced by Medigene

#### Financing risks

Since Medigene AG was founded in 1994, 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 Medigene's strategic decisions and is not yet secured.

Due to the gross cash inflow of €15.9 m from the capital increase completed in July 2014 and the associated current liquidity planning, the Executive Management Board assumes that the Company is fully financed into the second quarter of 2016 without considering any measures to raise capital or additional income from licencing deals. Financing beyond the second quarter 2016 will require further external financial resources. The ability to raise additional funds depends on financial, economic and other factors which, in the majority of cases, cannot be influenced by the Company's management. These factors also include the results achieved as part of Medigene's research and development activities. Medigene may not always have sufficient funds under acceptable terms and conditions at its disposal when required. Should this be the case, Medigene may need to reduce its spending on research and development, production or marketing. The Executive Management Board currently considers it to be predominantly probable that these additional funds can be raised early enough. Possible sources of capital may be additional partnerships with pharmaceutical companies or capital measures. Regarding the planned development in the coming fiscal years, we refer to the → Financial forecast in Opportunities and Outlook on page 31 et seq.

#### Planning risks

At least once a year, Medigene's management prepares a detailed business plan incorporating the results of portfolio management and evaluation. This plan contains numerous assumptions relating to issues such as project progress, the outcome of clinical trials, the conclusion of new licensing agreements and development partnerships, the trend in product revenues and general conditions within the relevant pharmaceutical market segments. These assumptions may deviate substantially from actual future developments. Important prerequisites for achieving financial targets include the success of research and development activities as well as progress with the commercialisation of drugs and drug candidates. There is no guarantee that Medigene will achieve the product revenues, additional market approvals and product launches as well as newly concluded development and marketing partnerships required to meet its financial targets. Medigene's plans are based on assumptions regarding future research and development results and on estimates of the market and competitive environment. These assumptions may prove to be inaccurate.

### Risks inherent in the drug development and approval process

#### Industry and market risks

Medigene is subject to the typical industry and market risks inherent in the development of pharmaceutical products using innovative technologies. Experience shows that the development of a drug takes 10 to 15 years. In principle, there is a risk that some or all of Medigene's products may not be developed or marketed successfully. There is also the possibility that some product candidates may fail to obtain the regulatory approval required for marketing or further development, that one or all of the product candidates turn out to be hazardous or ineffective, that not all the financing required to develop product candidates can be raised, that the products cannot be manufactured in large quantities or marketed profitably, or that they are not sufficiently competitive. Furthermore, proprietary rights held by third parties may pose an obstacle to marketing a product, or other companies may launch drugs that are superior in terms of quality or market price.

### Risks of unsuccessful drug development

Prior to commercial use, Medigene's drug candidates have to pass through the preclinical development stages, followed by the individual phases of clinical trials with patients. In these trials, the effectiveness of the drugs and side effects are investigated. Once the preclinical and clinical trials have been concluded positively, the application for marketing approval can be submitted to the appropriate authorities. Once the application and data presented have been evaluated, the authorities decide whether or not to grant approval for marketing the particular product. There is a possibility that approval will be denied on the basis of the data submitted, or granted only on certain conditions, or that additional data will be required for a final decision on the product's approval. Delays in a clinical trial or in patient recruitment may result in higher costs and delay the market launch. It is not possible to predict the results of preclinical and clinical trials. Equally, the results of previous trials do not facilitate an accurate forecast of the outcome of future trials.

Many pharmaceutical and biotechnology companies, including Medigene, have experienced setbacks in clinical trials despite achieving promising results in earlier phases. Medigene works closely together with the regulatory authorities and performs an annual risk assessment for each project in discussion with in-house and external experts. The Company achieves risk diversification with a product portfolio which is based on different technological and scientific approaches that are independent of each other.

The Company commissions specialised service providers to conduct the required clinical trials. Some of these contracts include a right of cancellation for the respective service provider. Cancellation of a contract by a service provider might cause a serious delay in the execution of clinical trials and thereby prolong product development significantly. Medigene places a great deal of importance on consulting only experienced and well-known service providers to undertake clinical trials. Nevertheless, it is possible that a service provider may fail to conduct a trial properly in all respects, which could also cause delays in development.

### Risks from partnerships

Payments upon the achievement of milestones and payment of royalties to Medigene depend on the performance of its development partners with respect to drug candidates. In case the development by third parties is not successful, Medigene may not receive milestone payments and/or royalties. Medigene has signed development partnerships with regard to its drug candidates Rhudex® and EndoTAG®-1 with third parties. Such third parties are responsible for the development of Medigene's drug candidates and Medigene is eligible to payments upon certain development and approval milestones as well as royalties after market approval of Rhudex® and/or EndoTAG®-1. However, under specific circumstances such third parties are eligible to stop or to postpone the development of the drug candidates. In case that the development by such third parties is not successful, is delayed or stopped, Medigene may receive milestone payments or royalties at a later date or not at all. This may have a negative impact on the net assets, financial position and results of operations of the Company.

### Manufacturing and delivery risks

Medigene relies on third parties supplying the active agents in its drugs and may not find alternative suppliers. Medigene currently depends on only one or very few supply sources, in particular for the active pharmaceutical ingredient in the Veregen® ointment for which a supply agreement with Mitsui Norin is in place. If any of these sources should cease to supply Medigene with the relevant products or if respective supply agreements are not extended, Medigene may not be able to find alternatives which could result in Medigene having to stop its production or supply. The Company depends on third party delivery contracts for the active agents which play a decisive role in developing Medigene's technologies and drug candidates. Should these active agents not be available in a satisfactory quality, in time, in sufficient quantities or at acceptable costs, this could delay Medigene's clinical development and marketing of products and product candidates. Any of the above may have a negative impact on the net assets, financial position and results of operations of the Company.

### Approval risks

For the reasons mentioned, there is a risk of Medigene not being granted market approval for its drug candidates. However, even if market approval is granted, such approval may be contingent on the fulfilment of certain obligations which may be detrimental to the marketability of the product or products. Obligations may consist of additional clinical trials or restrictions on the application of a product. Approval may, for instance, be granted only for a sub-group of patients. In addition, the holder of the approval must fulfil a multitude of regulatory duties, such as monitoring the approved drug's safety. Even without additional requirements, approval obliges Medigene to set up and run an organisation within the Company to fulfil these legal requirements.

Approval of a drug for one particular regional market does not automatically mean that it will be approved for other markets. The individual regional and national markets are subject to different legal requirements that can vary significantly in some cases. This also applies to the approval of a drug for treating different diseases. Adherence to approval requirements may delay and/or increase the cost of product commercialisation.

Finally, there is the possibility of losing previously granted market approval for drugs in whole or in part if serious quality shortcomings or safety risks are subsequently ascertained. The risks mentioned may have a negative impact on the net assets, financial position and results of operations of the Company.

### Employees

Medigene AG relies on its highly qualified research and development staff. There is intense competition among companies to recruit employees with industry-specific expertise. Medigene's commercial success will continue to depend on recruiting and retaining appropriately skilled employees for these areas. The possibility of a lack of qualified employees becoming an obstacle to Medigene's growth cannot be ruled out, a fact that may adversely affect the Company's net assets, financial position and results of operations.

### Drug commercialisation risks

#### Procurement risks

A contract is in place with the Japanese company Mitsui Norin for the production and supply of the active pharmaceutical ingredient for Veregen®. The raw material, which consists of green tea leaves, is obtained from Chinese tea farms and is subject to the usual risks inherent in agricultural products, such as crop failures caused by environmental factors or the chemical and biological contamination of harvested crops.

Supply bottlenecks may adversely affect Medigene's business activities and consequently its net assets, financial position and results of operations.

#### Reimbursement risks

The commercial success of a drug's distribution also depends on whether and to what extent the costs for the approved drug are covered by public or private health insurance providers in individual countries. In the EU and many other countries, there are price controls and/or other limitations on the reimbursement of drug costs. Companies may even be forced to reduce the price of a drug in order to be included in such a reimbursement system. This risk affects Medigene indirectly, since the drug Veregen® is marketed by sales partners, and Medigene receives royalties on the drug sales.

### **Competitive risks and risks of low drug sales**

The development and marketing of drugs are subject to fierce competition. This applies especially to the therapeutic areas of autoimmune diseases and oncology, which are the focus of Medigene's activities. Given their commercial potential, these market segments are the focal point of the activities of numerous major pharmaceutical and specialised biotechnology companies as well as universities and other research facilities. The drugs developed by Medigene target serious diseases and/or unmet medical needs. A successful drug would have significant market potential for any of these indications. If a competitor were the first to launch a product successfully, the drug developed by Medigene could become less competitive or even be placed in an inferior position, depending on the competing product's profile and commercial success. Medigene's portfolio strategy is designed to minimise such sales risks, although they cannot be ruled out completely.

Medigene's drug Veregen® is currently marketed and sold by partner companies. There are also plans to market further drug candidates through existing or future partners. There is no guarantee that these partners are able to market and sell the drugs to the extent that Medigene expects. The Company has only limited influence on the partner companies' marketing activities. This limited influence could result in adverse effects on Medigene's business activities and consequently its net assets, financial position and results of operations.

The ability of Medigene or Medigene's marketing partners to sell proprietary drugs on the market may also be adversely affected by competing generic drugs. Generics are drugs launched on the market under the international non-proprietary name or a new trade name after the patent for the original drug has expired. The marketing of generic drugs may also adversely affect the marketing of Medigene's drugs.

### **Risks of dependence on future cooperation agreements**

The Company uses the services of cooperation partners for marketing its products. These partners maintain their own sales and marketing organisations. Medigene also pursues cooperation with partner companies for developing drug candidates. If the Company fails to enter into cooperation agreements of this kind under favourable conditions, this may delay or hinder the Company's ability to develop and market its products or make such activities unreasonably expensive. This may adversely affect the Company's net assets, financial position and results of operations.

### **Development liability risks and product liability**

Medigene is exposed to the risk of substantial compensation claims in the event that a patient suffers adverse effects from participating in a clinical trial or taking a drug developed by Medigene. In particular, such compensation claims could exceed Medigene's insurance coverage and consequently have a negative impact on the Company's financial position and results of operations, as well as its net cash. Although the procedures used in clinical trials are devised in such a way that potential adverse effects are identified and assessed, the possibility can never be ruled out that a drug may cause unexpected adverse side effects even after it has been approved. Such adverse effects may be detrimental to the drug's safety profile and could be so severe that the drug has to be withdrawn from the market.

## Legal risks and patent risks

### Patent risks

Medigene's success also depends on its ability to acquire comprehensive patents for its technologies and products, to protect its trade secrets, to defend infringements effectively and assert its own rights without infringing the rights of third parties. To protect its legally patented technologies and products, Medigene also has confidentiality agreements and contractual licence restrictions in place with its partners, employees, consultants and other contractual parties.

There is no guarantee that patents will not be challenged, declared invalid or circumvented, or that they will be of commercial benefit to the Company. The Company intends to take appropriate action against any infringements and to continue expanding its technology and product portfolio. However, in the areas concerned, third parties may assert legally protected interests based on industrial property rights or cooperation, research and licence agreements.

In 2010, a third party opposed the granting of European Patent No. EP 1530465 to Medigene AG. The patent relates to the manufacturing process for EndoTAG<sup>®</sup>-1 and to compositions that can be manufactured using this process. In 2011, the European Patent Office ruled at the first hearing that the patent is upheld to an extent which continues to protect the product EndoTAG<sup>®</sup>-1. In the course of the opposition proceedings, Medigene AG had restricted its patent claims to the features that are relevant to EndoTAG<sup>®</sup>-1. The opponent filed a notice of appeal against the decision of the European Patent Office. This appeal was withdrawn in March 2015. The opposition proceeding has thus been closed and the decision is non-appealable. The patent has been upheld to an extent which continues to protect the product EndoTAG<sup>®</sup>-1.

The European Patent EP 2108362 was granted in 2013 from a divisional application of the above-mentioned patent. The patent refers to specific liposomal compositions comprising taxanes with a specific stability. In February 2014, an opposition proceeding was also filed against this patent. This opposition was withdrawn in March 2015. Medigene assumes that the patent will be upheld unchanged. The first decision in this proceeding is not expected until mid-2015.

The risk situation in terms of patent protection for EndoTAG<sup>®</sup>-1 has improved considerably compared to the previous year by the withdrawal of the appeal against patent EP 1530465 and the withdrawal of the opposition against patent EP 2108362.

### Legal risks

No law suits that could have a major influence on the Company's financial situation or that of its subsidiaries are pending. Further law-suits cannot be ruled out in future.

## OTHER INFORMATION

### Environmental and health protection

#### Safety and environmental protection at a high level

Medigene is committed to safety and environmental protection. The Company meets stringent statutory requirements and also strives to keep its laboratory facilities and equipment state-of-the-art. In order to monitor compliance with regulatory requirements, Medigene has appointed an in-house officer for biological safety, a project manager in accordance with the provisions of the German Genetic Engineering Act (Gentechnikgesetz) as well as officers for infection prevention, safety and waste management, all of whom are experienced employees specifically trained for their specialist tasks. Medigene also employs a working safety specialist who has been trained in accordance with the guidelines of the statutory employers' liability insurance scheme for the chemical industry.

Medigene's laboratory systems are serviced on an ongoing basis and are continuously maintained and expanded. Medigene enlists the help of external service providers to ensure that all accumulated waste materials are properly sorted and disposed of professionally or recycled in accordance with requirements. In order to guarantee safety in the workplace for each laboratory employee, the safety engineer performs hazard analyses and conducts training sessions. In addition, preventive medical check-ups are carried out at regular intervals. Medigene complies with all key requirements in respect of environmental protection and health and safety. The Company holds the requisite authorisations and permits. The Company has passed all random inspections and tests carried out by the various authorities to date without any relevant objections.

### Notes on risk management pursuant to Section 315 (2) Nos. 2 and 5 of the German Commercial Code (HGB)

#### Key features of the internal control and risk management system

Medigene, the parent company, is a publicly traded stock corporation as defined in Section 264(d) of the German Commercial Code (HGB). A description of the key features of its accounting-related internal control and risk management system for both the consolidated companies and the Group is therefore required pursuant to Section 315 (2) No. 5 of the HGB.

There is no statutory definition of accounting-related internal control and risk management system for individual companies and the Group. Medigene considers its internal control and risk management system to be comprehensive and bases its approach on the definitions of accounting-related internal control systems and risk management systems provided by the Institute of Public Auditors in Germany, Düsseldorf (IDW). This approach defines an internal control system as consisting of the principles, procedures and measures introduced in the Company by the management with the purpose of implementing management decisions in the organisation. These decisions pursue the following goals:

- To deliver effective and efficient business activities (this also encompasses asset protection, including prevention and detection of losses);
- To ensure proper and reliable internal and external financial reporting;
- To comply with the legal provisions applicable to the Company.

The risk management system is the totality of all organisational regulations and measures introduced to identify and manage the risks of entrepreneurial activity.

The Executive Management Board bears overall responsibility for the accounting-related internal control and risk management system of the companies included in the consolidated financial statements and the Group. All companies, divisions and departments included in the consolidated financial statements are covered by a defined leadership and reporting organisation.

Medigene has defined the following principles and implemented the following processes:

#### **Principles, administration and controlling**

Entrepreneurial success involves taking risks and acting with the appropriate degree of responsibility. With this in mind, Medigene's management utilises a risk management system that can be flexibly adapted to new situations and is subject to continuous review. Organisational safeguards have been established by separation of duties. Activities or business transactions with inherent risks involving amounts of over €25,000 are not carried out by one employee alone - in all such cases, several persons are generally responsible for the decision-making process and the decision itself. Operating instructions and workflows are standardised to ensure the consistent execution of each individual operation. IT risks are minimised by means of access restrictions and regulations for systems development and maintenance. Forms, worksheets and laboratory journals are used to fully record and document all data. Medigene's controlling department is responsible for target-orientated coordination of planning, information supply, and management and monitoring. In order to identify any deviations, projects undergo a monthly target-performance comparison, the results of which are regularly discussed with project managers and the Executive Management Board.

#### **Portfolio strategy to reduce overall risk**

Medigene's overall risk with regard to its success and existence as a going concern is essentially determined by the individual risks arising in clinical development and product marketing, as well as entering into successful strategic partnerships with the pharmaceutical industry and corporate financing. The commercial success and future existence of the Company therefore depend primarily on successful drug development and product commercialisation, as well as prevailing conditions on the capital market. Medigene counters the intrinsically high risk that individual projects might fail by maintaining a product portfolio based on different technological and scientific approaches that are independent of each other.

#### **Portfolio management and evaluation**

Medigene's project portfolio is managed proactively and assessed at regular intervals. The management process includes drawing up development plans for each individual project. These are then adopted by a development committee and compliance with the plan is monitored by the Executive Management Board. The regular assessment of the individual projects is based on the analysis and evaluation of their opportunities and risks, covering the technical risk as well as intellectual property and scientific hypotheses of potential competitors. Other areas covered by the assessment are clinical development considerations, market approval conditions, process development and portfolio strategy. Another significant element is the analysis of the current and future development of the segment of the drug market under consideration.

Results are summarised in a scenario analysis that includes a profitability assessment based on discounted cash flows. This feasibility study then provides the basis for any decision relating to Medigene's overall portfolio and future strategic orientation of the Company. Medigene is supported by internationally renowned scientists and pharmaceutical experts in its research and development activities. Such consultations are based on the most up-to-date findings from research and clinical application.

Particular attention is devoted to patent-related work. Medigene's paramount goal is to ensure comprehensive patent protection for technology and products in order to protect the Company from potential competitors. Medigene does not depend on any one technology or any one product, but it possesses a diversified portfolio which is safeguarded by means of far-reaching international patents that are either pending or have been granted. In addition, cooperation with external scientific institutes, universities and other companies provides access to state-of-the-art developments and technologies.

### Business planning and forecasting

Medigene's management regularly prepares a detailed business plan, at least once a year, incorporating the results of portfolio management and evaluation. This plan contains numerous assumptions relating to issues such as project progress, the outcome of clinical trials, the conclusion of new licencing agreements, the trend in product revenue and general conditions within the relevant pharmaceutical market segments. These assumptions may deviate substantially from actual future developments. In order to be able to manage the Company in spite of the resulting uncertainties, a variety of scenarios are developed regarding key assumptions with the aim of securing the Company's further financing from the end of the reporting period → *see Financial risks on page 18.*

Adherence to the business plan is subject to continuous monitoring. The Company is managed on the basis of monthly target-performance comparisons. Furthermore, the business plan is adjusted as soon as there are any changes in the assumptions that have been made. A monthly liquidity and shareholders' equity plan is also drawn up.

### Quality assurance

Medigene's quality assurance system complies with the requirements of the German Pharmaceuticals Act (Arzneimittelgesetz), the Good Manufacturing Practice (GMP) guidelines as well as the guidelines on Good Clinical Practice (GCP) and Good Pharmacovigilance Practices (GVP). GMP contains quality assurance guidelines for all processes regarding the manufacture of medicinal products and active pharmaceutical ingredients. GCP encompasses requirements for quality assurance during clinical trials to protect trial participants and the quality of the trial results. GVP is centred on detecting, assessing, understanding and preventing side effects and other medicine-related issues. In addition, Medigene commissions preclinical trials of regulatory relevance to guarantee the quality and reliability of the data collected in line with good laboratory practice (GLP). Following these guidelines ensures compliance with defined standards in the development, production, testing, and monitoring of pharmaceutical products. Medigene has a large number of standardised workflows in the field of quality assurance at its disposal.

### Accounting-related control system

Medigene considers those features of the internal control and risk management system that can significantly influence Group reporting and the overall statement in the consolidated financial statements and the group management discussion and analysis to be key with regard to the accounting processes of the consolidated companies and the Group accounting processes. They include, in particular, the following elements:

- Identification of key risk zones and controlling areas relevant to the group-wide accounting process;
- Checks to monitor the group-wide reporting system and its findings at the divisional and departmental levels and at the companies included in the consolidated financial statements;
- Control measures for the finance and accounting systems of the Group and of those companies, units and divisions included in the consolidated financial statements that generate information which is fundamental to the preparation of the consolidated financial statements and the group management discussion and analysis. These control measures include the separation of duties and pre-defined approval processes in the relevant divisions;
- Internal checks of the Group's accounting-related internal control and risk management system by management;

Moreover, the Group has implemented a risk management system for the group-wide accounting process that includes measures to identify and assess major risks, as well as measures designed to limit such risks in order to ensure that the consolidated financial statements are properly prepared.

## **Statements in accordance with Sections 289 (4) and 315 (4) of the German Commercial Code (HGB) and explanatory report**

### **No. 1: Composition of subscribed capital**

The Company's share capital as at 31 December 2014 amounts to €13,927,428.00 and is divided into 13,927,428 registered no-par shares representing a proportional share of the capital of €1.00 per share. Of these, the 21,396 new shares issued for the convertible loans converted had not been entered in the Commercial Register as at 31 December 2014. They were entered in February 2015. Shareholders have no claim to certification of their shares, unless certification is required under the rules of a particular stock exchange on which the Company's shares are listed for trading. In accordance with Section 67 (2) of the German Stock Corporation Act (AktG), only persons who have been entered in the shareholders' register are deemed to be shareholders in relation to the Company. All shares grant the same rights. Each share provides one vote at the Annual General Meeting and the same profit share. The detailed rights and obligations of shareholders result from the provisions of the German Stock Corporation Act (AktG), in particular Sections 12, 53a et seq., 118 et seq. and 186 et seq. of the AktG as well as the Company's Articles of Association.

### **No. 2: Restrictions on voting rights or the transfer of shares**

In the cases specified in Section 136 of the German Stock Corporation Act (AktG), the voting rights arising in connection with the relevant shares are excluded by law. Within the framework of the acquisition of Medigene Immunotherapies GmbH (formerly: Trianta Immunotherapies GmbH), a contribution agreement was entered into with the shareholders of Trianta on 27 January 2014 by which Medigene obtained 100% of the shares in Trianta. The former shareholders of Trianta received 1,017,811 newly issued shares in Medigene with a value of about €4 m and will receive a maximum of €5.875 m in instalments in Medigene shares or in cash as contingent consideration upon certain milestones being reached. Through the partial use of its authorised capital, Medigene issued 1,017,811 new shares with a lock-up period of 12 months up to 26 January 2015. We are not aware of any other restrictions relating to the exercise of voting rights or the transfer of shares. Each share entitles the bearer to one vote at the Annual General Meeting and determines the bearer's share in the profits of the Company.

### **No. 3: Investments in capital exceeding 10% of the voting rights**

In accordance with the German Securities Trading Act (WpHG), every investor who achieves, exceeds or falls below a certain threshold for voting rights by buying or selling shares or by any other means must advise the Company and the German Federal Financial Supervisory Authority (BaFin) accordingly. The lowest limit in respect of this duty of notification is 3%. On 29 July 2014 Aviva Investors Global Services Limited notified Medigene AG, by means of its voting rights notification, that its shareholding in the Company had exceeded the thresholds of 3%, 5% and 10% and stood at 10.07%. Other than the above, Medigene AG has not been notified of any direct or indirect investments in the share capital of Medigene AG which amount to or exceed 10% of the voting rights, nor is the Company aware of such investments.

### **No. 4: Shares that grant special control privileges**

The Company has not issued any shares that grant special control privileges.

### **No. 5: Nature of voting control if employees have a share in the capital and do not directly exercise their right of control**

Employees who hold Medigene AG shares exercise their control rights directly like any other shareholder in accordance with the law and the Articles of Association. In the event that employees hold a share in the capital and do not directly exercise their right of control, voting control does not exist.

### **No. 6: Statutory provisions and stipulations in the Articles of Association on the appointment and dismissal of members of the Executive Management Board and on amendments to the Articles of Association**

The Executive Management Board of the Company, in accordance with Art. 7 (1) of the Articles of Association, consists of one or more persons and is appointed, in accordance with Section 84 (1) of the German Stock Corporation Act (AktG), by the Supervisory Board for a period of no more than five years. Reappointments or term extensions are permissible, in each case for a maximum period of five years. The Supervisory Board appoints one of the members of the Executive Management Board as Chief Executive Officer.

In accordance with Section 84 (3) of the German Stock Corporation Act (AktG), the Supervisory Board may also revoke the appointment of a member of the Executive Management Board and the appointment of the Chief Executive Officer on important grounds. Such grounds include gross breach of duty, inability to duly manage the Company and vote of no confidence by the Annual General Meeting – unless the vote of no confidence was evidently based on unrelated reasons. If a required member of the Executive Management Board is missing, in urgent cases the relevant member is appointed by the courts upon request by one of the parties concerned, in accordance with Section 85 of the German Stock Corporation Act (AktG).

Provisions regarding amendments to the Articles of Association are contained in Sections 179 and 133 of the German Stock Corporation Act (AktG). Under these provisions, any amendment to the Articles of Association requires a resolution of the Annual General Meeting for which a simple majority is needed and which at least three quarters of the capital represented at the time of the resolution must approve, unless the Articles of Association specify a different capital majority. Art. 18 (1) of the Company's Articles of Association stipulates that shareholders' resolutions must be adopted by a simple majority of the votes cast, unless a larger majority is compulsory by law. This would be the case when, for example, creating authorised capital (Section 202 (2) Sentence 2 of the German Stock Corporation Act (AktG)) or conditional capital (Section 193 (1) Sentence 1 of the Act) and issuing non-voting preferred shares (Section 182 (1) Sentences 1 and 2 of the Act), each of which requires a three-quarters majority of the capital represented at the vote on the resolution. According to Art. 15 of the Articles of Association, the Supervisory Board has the right to make amendments to the Articles of Association, provided they affect only the wording.

#### **No. 7: Powers of the Executive Management Board, especially with regard to issuing and repurchasing shares**

In accordance with Section 76 (1) of the German Stock Corporation Act (AktG), the Executive Management Board shall manage the Company on its own authority and in accordance with Section 78 (1) of the German Stock Corporation Act (AktG), it represents the Company in and out of court and, with regard to issuing and repurchasing shares, it is authorised as follows:

##### **a) Authorised capital**

By a shareholders' resolution dated 10 July 2012 entered into the Commercial Register on 9 August 2012, Medigene's Annual General Meeting created authorised capital of €18,541,379.00 and adjusted Art. 5 (4) of the Articles of Association accordingly. Through the resolution, the Executive Management Board of Medigene is authorised – with the approval of the Supervisory Board – to increase the share capital of Medigene by a total of up to €18,541,379.00 until 9 July 2017 on one or more occasions in return for contribution in cash or in kind (Authorised Capital 2012/I). The Executive Management Board of Medigene is authorised – with the approval of the Supervisory Board – to exclude the subscription right of shareholders one or several times, for example when new shares are issued in return for contribution in kind. The Executive Management Board of Medigene undertook at the Annual General Meeting on 16 July 2013 only to utilise the authorised capital in accordance with the restrictions on utilisation as set out in Item 8 (3) of the invitation to the Annual General Meeting. By resolution dated 14 August 2014, the Annual General Meeting revoked the voluntary restriction undertaken by the Executive Management Board at the Annual General Meeting on 16 July 2013. In the course of the acquisition of Trianta in January 2014, Medigene partly used authorised capital 2012/I to issue 1,017,811 new shares. Medigene issued 3,016,082 new shares from authorised capital (authorised capital 2012/I) to perform the cash capital increase passed by resolution on 27 June 2014 and entered in the Commercial Register on 17 July 2014.

Authorised capital I amounting to €12,101,686 remained available as at 31 December 2014.

##### **b) Conditional capital**

The Company's share capital was increased conditionally through a number of conditional capital items on 31 December 2014 by up to €16,297,114.00 overall, divided into up to 16,297,114 ordinary shares (approx. 117% of the share capital).

In detail, the conditional capital consists of conditional capital I of up to €136,897.00 (1997), conditional capital II of up to €106,429.00 (1998), conditional capital III of up to €125.00 (2000), conditional capital IV of up to €13,770.00 (2000), conditional capital V of up to €652,329.00 (2000 and 2001), conditional capital VI of up to €3,000.00 (2000), conditional capital VIII of up to €3,000.00 (2001), conditional capital X of up to €3,000.00 (2002), conditional capital XI of up to €1,400.00 (2003), conditional capital XII of up to €498,560.00 (2003), conditional capital XVI of up to €300,000.00 (2006), conditional capital XVIII of up to €1,200,000.00 (2007), conditional capital XXII of up to €10,978,604 (2012) and conditional capital XXIII of up to €2,400,000.00 (2012).

Medigene issued 818,658 convertible bonds within the framework of the capital increase by cash subscription passed by resolution on 27 June 2014. During the reporting period, 21,396 shares were issued on account of 106,980 convertible bonds being exercised. Conditional capital XXII decreased by €21,396.00 in the reporting period from €11,000,000 (as at 31 December 2013) to €10,978,604.

The voluntary commitment made by the Executive Management Board at the Annual General Meeting on 16 July 2013 only to utilise these individual conditional capital items in line with the restrictions on utilisation as indicated in Item 8 (3) of the invitation to the Annual General Meeting, was revoked by resolution of the Annual General Meeting dated 14 August 2014.

The conditional capital items are divided into the same number of ordinary shares (no-par shares) in each case.

***The purpose of the conditional capital items is:***

- a) In the case of conditional capital I, II, V, XII, XVI, XVIII and XXIII, exclusively to issue new shares to holders of option or conversion rights which were issued within the scope of employee and management stock option programmes by the Company to members of the Executive Management Board, members of management of affiliated companies in Germany and abroad, employees of the Company and employees of affiliated companies in Germany and abroad;
- b) In the case of conditional capital III, exclusively to service conversion rights arising from a profit sharing bond issued to Technologie-Beteiligungs-Gesellschaft mbH der Deutschen Ausgleichsbank;
- c) In the case of conditional capital IV, exclusively to service conversion rights arising from contracts with IKB Nachrangkapital GmbH and Technologie-Beteiligungs-Gesellschaft mbH der Deutschen Ausgleichsbank;
- d) In the case of conditional capital VI, VIII, X and XI, exclusively to issue shares to the holders of conversion rights which were granted to members of the Supervisory Board in accordance with the provisions of the shareholders' resolutions at the Annual General Meetings of 15 May 2000, 23 May 2001, 22 May 2002 and 4 June 2003;
- e) In the case of conditional capital XXII, exclusively to issue new shares to the holders of conversion and option rights to be granted in accordance with the provisions of the shareholders' resolution at the Annual General Meeting of 10 July 2012.

***Notes on authorised and conditional capital:***

The authorisations of the Executive Management Board to issue new shares from authorised capital described above and the conditional capital items in connection with the associated resolutions for issuing convertible or warrant-linked bonds as outlined above are intended to enable the Executive Management Board to cover any need for capital that may arise and to take advantage of attractive financing options depending on the state of the market. The ability to settle the acquisition of entities, parts of entities or interests in entities in individual cases by issuing shares of the Company to the seller allows the Company to expand without burdening its cash position. The issue of stock options secured by conditional capital is a component of the remuneration of employees and Executive Management Board members in German stock corporations.

**c) Share repurchase**

The Executive Management Board may acquire shares in the Company in the cases mentioned in Section 71 (1) of the German Stock Corporation Act (AktG). The Executive Management Board is not currently authorised to repurchase the Company's shares pursuant to Section 71 (1) No. 8 of the German Stock Corporation Act (AktG). The Company does not hold any treasury shares at the moment.

**No. 8: Significant company agreements that are conditional on a change in control as a result of a takeover bid**

No such arrangement exists.

**No. 9: Compensation agreement with members of the Executive Management Board or employees in the event of a takeover bid**

The contract of employment for Dr. Frank Mathias, who has been an Executive Management Board member since 1 April 2008 and Chief Executive Officer since 29 April 2009, the contract of employment for Peter Llewellyn-Davies, who has been an Executive Management Board member since 1 October 2012, and the contract of employment for Prof. Dolores Schendel, who has been an Executive Management Board member since 1 May 2014, include special termination rights for both the Company and the respective Executive Management Board members, applicable in the event of a change in control and agreed severance arrangements. For more detailed information see → *Notes to the consolidated financial statements G) note (55) on page 81 et seq.*

**Statement on corporate governance pursuant to Section 289a of the German Commercial Code (HGB)**

The corporate governance report and statement on corporate governance pursuant to Section 289a of the German Commercial Code (HGB) along with a description of the procedures followed by the Executive Management Board and the Supervisory Board are publicly available on the Company's website at <http://www.medigene.com/media-investors/corporate-governance>.

## OPPORTUNITIES AND OUTLOOK

### Immunotherapies under development

#### DC vaccines

The current investigator-initiated trials (IITs) being conducted at the University Hospital in Oslo (phase II trial in prostate cancer) and at the University Hospital in Munich (phase I/II trial in acute myeloid leukaemia, AML) will be continued. Additionally, a compassionate use programme, including patients with different types of tumour is currently ongoing at the Oslo University Hospital in order to test Medigene's DC vaccine. Medigene plans to start its own clinical trial in AML shortly which will generate further clinical feasibility and safety data for Medigene's personalised DC vaccines. The trial will enrol AML patients after chemotherapy to reduce their risk of relapse by using Medigene's DC vaccines.

#### TCR-modified T cells

The development of a GMP-compliant manufacturing process for adoptive T cell therapy using TCR-modified T cells will be continued. Medigene prepares the clinical development of the first product candidates. First preparatory talks with the authorities have already taken place. In addition, novel TCRs with specificities for promising tumour-associated antigens will be isolated and further characterised.

#### TABs

Preclinical development of the T cell specific monoclonal antibodies (TABs) continues with the aim of achieving proof of principle.

#### AAVLP technology

The final results of the preclinical trial conducted in cooperation with Pennsylvania State University to demonstrate long-term protection against infection and cross-reactivity to various types of HPV are available. The data is positive and is expected to be published as part of a scientific publication as soon as possible.

### Marketed drug

#### Veregen®

Medigene's partners anticipate the successive market launches of Veregen® in the UK, Ireland, Italy, Portugal, Croatia, Latvia, Lithuania and Estonia to start in the second half of 2015.

### Partnered drug candidates

The following drug candidates are out-licensed to and developed by Medigene's partners:

#### EndoTAG®-1

SynCore is preparing a pivotal international phase III trial with EndoTAG®-1 in the indication of triple-negative breast cancer (TNBC) and assumes full responsibility and the entire financing for this trial.

#### RhuDex®

Falk Pharma is conducting a comprehensive development programme with the aim of developing RhuDex® optimally in the indication primary biliary cirrhosis (PBC). The start of clinical trials will be announced at the start of each trial.

### Financial forecast for 2015

According to assumptions made by Medigene's partners, the Company expects in 2015 a double-digit percentage increase in Veregen<sup>®</sup> royalties (2014: €2.4 m) and, in spite of lower milestone payments, stable development of Veregen<sup>®</sup> total revenue. Medigene also expects to generate other revenue consisting mainly of reimbursements of development costs for EndoTAG<sup>®</sup>-1 by SynCore and of stable non-cash income from Cowen. Medigene plans to significantly increase its R&D expenses for its immunotherapy programmes. In 2015, these expenses are planned to amount to €7 - 9 m (2014: €2.9 m). Due to this increased investment in Medigene's innovation the anticipated EBITDA loss will increase to €11 - 13 m in 2015 (2014: €2.1 m).

Based on the current business planning and the resulting scenarios, management expects that Medigene will be financed into the second quarter of 2016 without considering any potential licencing partner agreements or any measures to raise capital. Financing beyond the second quarter of 2016 will require further external financial resources and the Executive Management Board currently assumes that these funds can be obtained. Possible sources may be additional partnerships with pharmaceutical companies or capital measures.

### Future sourcing

Medigene will continue to source the drug Veregen<sup>®</sup> through contract manufacturers in Japan and Germany in 2015.

### Dividends

In view of the current earnings situation, Medigene will not distribute a dividend. In the medium term, Medigene will invest available funds for the development of drugs. Dividend payouts are therefore not likely for the time being.

## THE EXECUTIVE MANAGEMENT BOARD

Planegg/Martinsried, 19 March 2015  
Medigene AG

Dr. Frank Mathias  
Chief Executive Officer

Peter Llewellyn-Davies  
Chief Financial Officer

Prof. Dolores J. Schendel  
Chief Scientific Officer

# CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE FISCAL YEARS FROM 1 JANUARY TO 31 DECEMBER 2014 AND 2013

IN € K	NOTE	2014	2013
Revenue		5,195	4,209
Other operating income		8,589	3,383
<b>Total revenue</b>	(27)	<b>13,784</b>	<b>7,592</b>
Cost of sales	(28)	-2,086	-1,735
<b>Gross profit</b>		<b>11,698</b>	<b>5,857</b>
Selling expenses	(29)	-1,991	-3,121
General administrative expenses	(30)	-5,090	-5,152
Research and development expenses	(31)	-7,498	-6,605
<b>Operating result</b>		<b>-2,881</b>	<b>-9,021</b>
Interest income	(32)	27	24
Interest expense	(32)	-1,801	-1,577
Foreign exchange losses/gains		-1,201	412
Share of result of associates	(39)	-56	-102
<b>Earnings before tax</b>		<b>-5,912</b>	<b>-10,264</b>
Taxes	(45)	155	-18
<b>Net profit/loss for the year</b>		<b>-5,757</b>	<b>-10,282</b>
<b>Basic/diluted earnings per share after taxes (€)</b>	(33)	<b>-0.47</b>	<b>-1.07</b>

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

OF MEDIGENE AG FOR THE FISCAL YEARS FROM 1 JANUARY TO 31 DECEMBER 2014 AND 2013

IN T€	NOTE	2014	2013
<b>Net profit/loss for the year</b>		<b>-5,757</b>	<b>-10,282</b>
<b>Other comprehensive income</b>			
Other comprehensive income to be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations <sup>1)</sup>		156	-54
Available-for-sale financial assets <sup>1)</sup>		112	8
<b>Subtotal</b>		<b>268</b>	<b>-46</b>
Other comprehensive income not to be reclassified to profit or loss in subsequent periods:			
Remeasurement of defined benefit plans <sup>1)</sup>		-101	-1
<b>Subtotal</b>		<b>-101</b>	<b>-1</b>
<b>Other comprehensive income after tax</b>		<b>167</b>	<b>-47</b>
<b>Total comprehensive income for the year, net of tax</b>		<b>-5,590</b>	<b>-10,329</b>

<sup>1)</sup> No income tax effects were incurred.

# CONSOLIDATED BALANCE SHEET

OF MEDIGENE AG AS OF 31 DECEMBER 2014 AND 2013

<b>ASSETS</b>			
IN € K	NOTE	31 DEC 2014	31 DEC 2013
<b>A. Non-current assets</b>			
I. Property, plant and equipment	(36)	951	405
II. Intangible assets	(37)	36,165	26,958
III. Goodwill	(35)	2,212	2,212
IV. Financial assets	(38)	4,185	3,929
V. Investment in associates	(39)	2,781	2,513
VI. Other assets	(41)	323	375
<b>Total non-current assets</b>		<b>46,617</b>	<b>36,392</b>
<b>B. Current assets</b>			
I. Inventories	(40)	4,406	3,046
II. Trade accounts receivable	(41)	1,733	1,363
III. Cash and cash equivalents	(42)	14,976	10,166
IV. Other assets	(41)	3,551	1,688
<b>Total current assets</b>		<b>24,666</b>	<b>16,263</b>
<b>Total assets</b>		<b>71,283</b>	<b>52,655</b>

**SHAREHOLDERS' EQUITY AND LIABILITIES**

IN € K	NOTE	31 DEC 2014	31 DEC 2013
<b>A. Shareholders' equity</b>			
I. Subscribed capital	(43)	13,927	9,872
II. Capital reserve		387,916	373,586
III. Accumulated deficit		-352,865	-347,007
IV. Other reserves		93	-175
<b>Total shareholders' equity</b>		<b>49,071</b>	<b>36,276</b>
<b>B. Non-current liabilities</b>			
I. Financial liabilities	(17)	10,597	10,356
II. Pension obligations	(44)	413	304
III. Other financial liabilities		868	291
IV. Deferred income	(47)	226	336
V. Deferred taxes	(45)	2,353	0
<b>Total non-current liabilities</b>		<b>14,457</b>	<b>11,287</b>
<b>C. Current liabilities</b>			
I. Trade accounts payable	(46)	1,785	1,419
II. Other financial liabilities	(46)	5,913	3,651
III. Deferred income	(47)	57	22
<b>Total current liabilities</b>		<b>7,755</b>	<b>5,092</b>
<b>Total liabilities</b>		<b>22,212</b>	<b>16,379</b>
<b>Total shareholders' equity and liabilities</b>		<b>71,283</b>	<b>52,655</b>

# CONSOLIDATED STATEMENT OF CASH FLOWS

OF MEDIGENE AG FOR THE FISCAL YEARS FROM 1 JANUARY TO 31 DECEMBER 2014 AND 2013

IN € K	2014	2013
<b>Net cash from/used in operating activities</b>		
Earnings before tax	-5,912	-10,264
<b>Adjustments:</b>		
Share-based payments	66	60
Other non-cash income	-2,493	-2,493
Depreciation and amortisation	810	751
Losses on the disposal of property, plant and equipment	2	2
Interest income	-27	-24
Interest expense	1,801	1,577
<b>Changes in:</b>		
Inventories	-1,360	-842
Other assets and trade accounts receivable	-2,660	-1,317
Trade accounts payable	266	700
Other financial liabilities and deferred income	686	151
Share of result of associates	56	102
<b>Subtotal</b>	<b>-8,765</b>	<b>-11,597</b>
Tax paid	0	-661
Interest received	9	12
<b>Net cash used in operating activities</b>	<b>-8,756</b>	<b>-12,246</b>
<b>Net cash from/used in investing activities</b>		
Purchase of property, plant and equipment	-873	-142
Loans to associates	-83	0
Net cash acquired with the subsidiary <i>→ section (C)</i>	21	0
<b>Net cash used in investing activities</b>	<b>-935</b>	<b>-142</b>
<b>Net cash from/used in financing activities</b>		
Proceeds from capital increase	15,899	2,406
Costs of capital increase and reduction	-1,397	-28
<b>Net cash from financing activities</b>	<b>14,502</b>	<b>2,378</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>4,811</b>	<b>-10,010</b>
Cash and cash equivalents, opening balance	10,166	20,113
Foreign exchange differences	-1	63
<b>Cash and cash equivalents, closing balance</b>	<b>14,976</b>	<b>10,166</b>

# CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

OF MEDIGENE AG FOR THE FISCAL YEARS FROM 1 JANUARY TO 31 DECEMBER 2014 AND 2013

IN € K	NUMBER OF SHARES	SUBSCRIBED CAPITAL	CAPITAL RESERVE	ACCUMULATED DEFICIT	EXCHANGE DIFFERENCES	FINANCIAL ASSETS	TOTAL SHAREHOLDERS' EQUITY
<b>Balance at 1 Jan 2013</b>	<b>37,082,758</b>	<b>37,082</b>	<b>343,938</b>	<b>-336,724</b>	<b>-123</b>	<b>-6</b>	<b>44,167</b>
Net profit/loss for the year				<b>-10,282</b>			<b>-10,282</b>
Other comprehensive income				<b>-1</b>	<b>-54</b>	<b>8</b>	<b>-47</b>
<b>Total comprehensive income</b>							<b>-10,329</b>
Share issue	<b>2,405,800</b>	<b>2,406</b>					<b>2,406</b>
Costs of share issue			<b>-14</b>				<b>-14</b>
Capital reduction	<b>-29,616,419</b>	<b>-29,616</b>	<b>29,616</b>				<b>0</b>
Costs of capital reduction			<b>-14</b>				<b>-14</b>
Share-based payments			<b>60</b>				<b>60</b>
<b>Balance at 31 Dec 2013</b>	<b>9,872,139</b>	<b>9,872</b>	<b>373,586</b>	<b>-347,007</b>	<b>-177</b>	<b>2</b>	<b>36,276</b>
<b>Balance at 1 Jan 2014</b>	<b>9,872,139</b>	<b>9,872</b>	<b>373,586</b>	<b>-347,007</b>	<b>-177</b>	<b>2</b>	<b>36,276</b>
Net profit/loss for the year				<b>-5,757</b>			<b>-5,757</b>
Other comprehensive income				<b>-101</b>	<b>156</b>	<b>112</b>	<b>167</b>
<b>Total comprehensive income</b>							<b>-5,590</b>
Share issue → <i>section (43)</i>	<b>3,037,478</b>	<b>3,037</b>	<b>12,862</b>				<b>15,899</b>
Costs of share issue			<b>-1,333</b>				<b>-1,333</b>
Share issue for business combinations	<b>1,017,811</b>	<b>1,018</b>	<b>2,799</b>				<b>3,817</b>
Costs of share issue for business combinations → <i>section (C)</i>			<b>-64</b>				<b>-64</b>
Share-based payments			<b>66</b>				<b>66</b>
<b>Balance at 31 Dec 2014</b>	<b>13,927,428</b>	<b>13,927</b>	<b>387,916</b>	<b>-352,865</b>	<b>-21</b>	<b>114</b>	<b>49,071</b>

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE FISCAL YEAR 2014

## A) DESCRIPTION OF BUSINESS ACTIVITY, INFORMATION ABOUT THE COMPANY

Medigene AG ("Medigene"), a biopharmaceutical company, concentrates on the research and development of novel drugs for treating cancer and autoimmune diseases.. Medigene has one drug on the market.

The Group's main activities are described in [→ section F\) »Segment reporting«](#).

Medigene AG was founded in 1994 in Planegg/Martinsried near Munich, Germany, with share capital of €26 k. In 1996, the Company was converted into a stock corporation. Its headquarters are located at Lochhamer Strasse 11, 82152 Planegg/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 (Deutsche Börse: Regulated Market, Prime Standard; German Security Identification Number (WKN) A1X 3W0; code MDG1).

In addition to the parent company Medigene AG in Planegg/Martinsried, the Medigene Group (»Medigene«) includes the wholly owned subsidiary Medigene, Inc., San Diego, CA, USA, which was acquired in 2001, and, since its acquisition in January 2014, the wholly owned subsidiary Trianta Immunotherapies GmbH, Munich [→ section \(C\)](#).

Since the acquisition of Trianta Immunotherapies GmbH in January 2014, Medigene is focused on personalised T cell immunotherapies. In November 2014, Medigene announced it had changed the name of the wholly-owned subsidiary Trianta Immunotherapies GmbH to Medigene Immunotherapies GmbH (»Medigene Immunotherapies«).

Medigene is managed by the Executive Management Board of the parent company, Medigene AG. The management of the respective subsidiaries reports directly to the Executive Management Board or is composed of members who sit on the Executive Management Board.

### Financing risks

Since Medigene AG was founded in 1994, 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 Medigene's strategic decisions and is not yet secured.

Due to the gross cash inflow of €15.9 m from the capital increase completed in July 2014 and the associated current liquidity planning, the Executive Management Board assumes that the Company is fully financed into the second quarter 2016. Financing beyond the second quarter 2016 will require further external financial resources. The ability to raise these additional funds depends on financial, economic and other factors which, in the majority of cases, cannot be influenced by the Company's management. These factors also include the results achieved as part of Medigene's research and development activities. Medigene may not always have sufficient funds under acceptable terms and conditions at its disposal when required. Should this be the case, Medigene may need to reduce its spending on research and development, production or marketing. The Executive Management Board currently considers it to be predominantly probable that these additional funds will be raised early enough. Possible sources may be additional partnering agreements with pharmaceutical companies or capital measures.

## B) ACCOUNTING POLICIES

### (1) Basis of preparation

The consolidated financial statements are generally prepared in accordance with the historical cost convention. Exceptions to this rule are available-for-sale financial assets and assets acquired in the course of business combinations. The consolidated financial statements have been prepared in German using the euro as the presentation currency. All figures are rounded to the nearest thousand euro (€ k), unless otherwise stated.

### (2) Statement of compliance with IFRSs and the requirements of Section 315a of the German Commercial Code (HGB)

As a parent and publicly traded company within the meaning of Article 4 of Regulation (EC) No. 1606/2002, the Company prepares its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the EU.

The Company's Executive Management Board is of the opinion that these consolidated financial statements reflect all business transactions required to present the net assets, financial position and results of operations for the periods ended 31 December 2013 and 2014 respectively. Additionally, these consolidated financial statements meet the requirements of Section 315a of the German Commercial Code (HGB).

These consolidated financial statements of Medigene AG for the fiscal year ended 31 December 2014 were prepared and authorised for issue by the Executive Management Board on 19 March 2015.

### (3) Changes in accounting policies and disclosures

Medigene has made no changes to its accounting policies beyond the adoption of the new or amended accounting standards or new interpretations of standards described below.

#### 1) First-time adoption of new and amended accounting standards

The consolidated financial statements for fiscal year 2014 adopted the following new or amended International Financial Reporting Standards:

---

IFRS 10 - Consolidated Financial Statements

---

IFRS 11 - Joint Arrangements

---

IFRS 12 - Disclosure of Interests in Other Entities

---

#### IFRS 10 Consolidated Financial Statements

This standard replaces IAS 27 and SIC 12 by introducing one uniform consolidation model for all entities that is based on the concept of control regardless of the nature of the investee (i.e. regardless of whether the entity is controlled by the voting rights of investors or other contractual arrangements such as those customary for special purpose entities). IFRS 10 does not have any impact on the consolidation of the equity investments of the Group.

#### IFRS 11 Joint Arrangements

IFRS 11 introduces new accounting treatment for joint arrangements and replaces IAS 31 Interests in Joint Ventures. The option of proportionate consolidation for jointly controlled entities has been revoked. In addition, IFRS 11 revokes the notion of jointly controlled assets. Only joint operations and joint ventures remain. The adoption of IFRS 11 did not have any effect on the treatment of the Company's existing collaborations, licence and development agreements.

## IFRS 12 Disclosure of Interests in Other Entities

The new standard IFRS 12 generally combines the various disclosure requirements previously found in IAS 27, IAS 28, and IAS 31 on investments in subsidiaries, joint arrangements, associates, and non-consolidated structured entities and has resulted in much more extensive disclosures in the notes to the consolidated financial statements. Detailed disclosures can be found in → notes (5) and (7).

## 2) Future changes in accounting policies

The following new standards and amendments issued by the IASB become effective for reporting periods beginning on or after 1 January 2015. Medigene has opted not to early adopt these standards.

STANDARDS/INTERPRETATIONS/AMENDMENTS	RELEVANT REPORTING PERIOD (BEGINNING ON)
IFRS 14 Regulatory Deferral Accounts	1 January 2016
IFRS 15 Revenue from Contracts with Customers	1 January 2017
IFRS 9 Financial Instruments	1 January 2018
Amendments to IFRS 10 and IAS 28 Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	1 January 2016
Amendment to IFRS 11 Accounting for Acquisitions of Interests in Joint Operations	1 January 2016
Amendment to IAS 16 and IAS 38 Clarification of Acceptable Methods of Depreciation and Amortisation	1 January 2016
Annual Improvements cycles 2010-2012, 2011-2013 and 2012-2014	1 July 2014 and 1 January 2016

The standards and interpretations indicated are not likely to result in any significant changes in the accounting policy of the Company upon adoption, with the following exceptions:

The standard IFRS 15 published by the IASB in May 2014 regulates when and in what amount revenue is recognised. For this purpose, IFRS 15 offers a principle-based five-step model applicable to all contracts with customers. According to the new standard, revenue is recognised on the basis of transfer of control at the amount of consideration to which the entity expects to be entitled in exchange for its goods or services. IFRS 15 replaces IAS 11 “Construction Contracts” and IAS 18 “Revenue” as well as all related interpretations. The Company is currently analysing the potential impact of adopting the new standard IFRS 15.

## (4) Significant accounting judgements, estimates and assumptions

Preparing the consolidated financial statements in accordance with generally accepted accounting principles requires the Executive Management Board to make judgements and estimates which influence the income, expenses, assets, liabilities and contingent liabilities listed in the financial statements as at the reporting date. By nature, these estimates and assumptions are subject to considerable uncertainty which may result in significant adjustments to the carrying amounts of the relevant assets and liabilities in future reporting periods.

### Judgements

In applying the accounting policies, management made the following judgements which significantly impact the figures reported in the financial statements.

### Recognition of certain sales transactions

Management exercises judgement when determining whether certain sales transactions essentially represent financing agreements, which means that no revenue is generated on the basis of these transactions. With effect from 1 April 2012, Medigene assigned future cash flows in connection with the 2% share in revenue from European Eligard<sup>®</sup> net sales from Astellas to Cowen Healthcare Partners II, L.P., USA (»Cowen«) in return for a payment of \$17.7 m (equivalent to €14.1 m at the time of cash inflow). The cash inflow from this transaction was treated as a financial liability and classified as financial liability carried at amortised cost. The assigned outstanding royalties are recognised on a pro rata basis (€208 k monthly) as other operating income over the Eligard<sup>®</sup> patent term of approximately ten years through profit or loss, and the financial liability associated with the assignment is amortised, taking into account the interest. The financial liabilities reported in the balance sheet include the non-current portion of this liability (2014: €10,597 k; 2013: €10,356 k). The current portion of the liability is reported under other financial liabilities (2014: €1,177 k; 2013: €1,044 k). For further details see → *notes (27) and (51)*.

### Recognition of one-off payments

The recording of one-time payments requires an assessment of whether the services for which the agreed payment is made have already been rendered or are still to be rendered. If, in the view of management, all contractually agreed services have been performed and the remaining criteria the revenue recognition are met, the one-time payments are recognised immediately as income.

### Deferred tax assets on unused tax losses

The recognition of deferred tax assets requires certain assumptions to be made within management's judgement. They mainly concern the assessment of the circumstances and the period in which tax assets can be realised by the use of existing loss carryforwards. Management has decided not to recognise tax assets to the extent to which they exceed the tax liabilities, since the generation of taxable income in the future is associated with too much uncertainty.

### Capitalisation of development expenses

Development expenses must be capitalised if the criteria of IAS 38 are met. This requires management to make a number of estimates and assumptions. In the period ended on 31 December 2014, no development expenses were capitalised due to the fact that management did not believe all the recognition criteria of IAS 38 had been met. This was due to the usual uncertainties in drug development and the unpredictability of regulatory requirements.

### Estimates and assumptions

The most important assumptions regarding the future and other key sources of estimation uncertainty as at the reporting date which entail an appreciable risk that it might become necessary to adjust the carrying amounts of assets and liabilities within the next fiscal year are explained below:

### Impairment of goodwill and intangible assets

The Group tests goodwill for impairment at least once every year. This requires, among other things, estimating the value in use of the underlying research and development projects which are allocated to both the goodwill and the cash-generating units. As the projects are not yet available for use, they are tested for impairment once a year. In order to estimate the value in use, management must assess the expected future cash flows of the individual projects and the chances of the underlying projects showing successful development and select an appropriate discount rate.

Given the length of the planning periods (up to 21 years), the assumptions and forecasts associated with this are subject to a significant degree of uncertainty. Please refer to → *note (35)* for the methodology of the impairment test and its results and presentation

**Fair value**

Fair value is generally determined on the basis of market prices. The fair value of financial assets and liabilities for which no market prices can be determined is ascertained using valuation methods which include the discounted cash flow method. The input parameters incorporated in the model are based, wherever possible, on observable market data. If this is not possible, fair value is determined to a certain extent on the basis of judgement. These judgements concern input parameters such as liquidity risk, credit risk, and volatility. Changes in the assumptions relating to these factors could affect the fair values reported for financial instruments. Medigene has measured some financial assets and liabilities at fair value → note (51).

**(5) Business combinations**

Business combinations are accounted for using the purchase method in accordance with IFRS 3 “Business Combinations”. The consideration paid for the combination was measured at fair value. This is determined as the sum of the assets transferred measured at acquisition-date fair value, the liabilities assumed from the former owners of the entity and the equity instruments issued by the Group in exchange for control over the acquiree. The contingent consideration was recognised as a liability at acquisition-date fair value in accordance with IAS 39. Changes in fair value are recognised in profit or loss. Transaction costs attributable to the business combination are recognised through profit or loss as incurred.

The identifiable assets and liabilities acquired in the combination are measured at fair value (exception: deferred taxes).

Goodwill arises from the excess of the consideration paid plus non-controlling interests over the acquisition-date fair value of the identifiable assets acquired and liabilities assumed in the combination.

**(6) Consolidation of subsidiaries****Consolidation principles**

The consolidated financial statements include the separate financial statements of Medigene AG and its subsidiaries as at 31 December of any given fiscal year. The financial statements of the entities within the consolidated group are prepared according to uniform accounting policies.

All intragroup balances, transactions, income, expenses, and profits and losses arising from intragroup transactions included in the carrying amount of assets have been eliminated in full.

**Consolidated group**

In contrast to the previous year, Medigene Immunotherapies was included in the consolidated group for the first time → section (C).

**Subsidiaries**

Subsidiaries are all entities where the Group has the power to govern financial and operating policies. The Company obtains control when it can exercise power over the investee, is exposed, or has rights, to variable returns on its involvement with the investee and it has the ability to affect those returns through its power over the investee. Subsidiaries are included in the consolidated financial statements (full consolidation) when the Group obtains control. Consolidation ceases as soon as the parent company loses control.

## **(7) Investment in associates**

The Group's investments in associates are accounted for using the equity method. An associate is an entity which is neither a subsidiary nor a joint venture, but over which the Group has significant influence. Significant influence is where the Group has the power to participate in the financial and operating policy decisions of the investee, but does not control or have joint control of those policies.

Using the equity method, investments in associates are recognised in the balance sheet at acquisition cost plus the changes in the Group's share of the associate's net assets occurring after the acquisition. Goodwill relating to the associate is included in the carrying amount of the investment and is neither subject to amortisation nor a separate impairment test.

The income statement reflects the Group's share of the associate's profit or loss. The Group recognises its share of any changes reported directly in the shareholders' equity of the associate and discloses this, if applicable, in the statement of changes in shareholders' equity. Unrealised gains and losses from transactions between the Group and the associate are eliminated in proportion to the interest in the associate.

After using the equity method, the Group determines whether it is necessary to recognise an impairment loss for its investment in an associate. At each reporting date, the Group determines whether there is any objective evidence of impairment of an investment in an associate. If so, the impairment loss is determined as the difference between the recoverable amount of the investment in an associate and its carrying amount, and the loss is recognised through profit or loss as a »share of result of associates«.

### **Associates**

As part of the establishment of Catherex, Inc., Medigene, Inc. transferred the programme to develop cancer-killing oncolytic herpes simplex viruses (oHSV) to Catherex, Inc. Part of Catherex, Inc. was spun off to the newly founded co-subsidiary Aettis, Inc. in 2014. This involved some of the patents of Catherex, Inc., which originated from a very early stage of research, being transferred to Aettis, Inc. In addition, Medigene is supporting the further development of the oHSV technology by appointing two members to the supervisory board of Catherex, Inc. and Aettis, Inc. As at 31 December 2014 Medigene, Inc. held 40.40% of the shares in Catherex, Inc. as well as 38.95% of the shares in Aettis, Inc. and thus is the company's biggest shareholder. → *note (39)*.

## **(8) Functional currency/foreign currency translation**

Foreign currency transactions and foreign operations are reported in the consolidated financial statements of Medigene AG in accordance with IAS 21 »The Effects of Changes in Foreign Exchange Rates«.

### **Functional currency and reporting currency**

The consolidated financial statements are presented in euro, the functional currency of the parent company and reporting currency of the Group. Each entity within the Group determines its own functional currency. The items included in the separate financial statements of the relevant entity are measured on the basis of this functional currency. The functional currency of Medigene, Inc. is the US dollar (\$).

### Transactions and balances

Transactions in foreign currencies are translated into the functional currency at the exchange rates that applied on the date of the transaction. Gains and losses resulting from the settlement of such transactions and from translating monetary assets and liabilities denominated in foreign currency using the closing rate are posted through profit or loss. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rate that was in effect when fair value was determined. Receivables and payables not carried in the functional currency are translated using the closing rate. Purchases and sales in foreign currencies are translated using the historical exchange rate. Any resulting currency differences are posted through profit or loss.

### Group companies

When foreign subsidiaries are consolidated the balance sheet items are translated using the closing rate. The translation of income and expenses for the purposes of consolidation is carried out using the relevant historical rate on the date of the transaction. The resulting differences arising from currency translation are recognised directly in other comprehensive income.

The following exchange rates were used in 2014 and on the reporting date 31 December 2014:

EXCHANGE RATE	CLOSING RATE		ANNUAL AVERAGE RATE	
	31 Dec 2014	31 Dec 2013	2014	2013
€1 in \$	1.21250	1.37380	1.32598	1.32508

Commerzbank AG, reference exchange rate

## (9) Property, plant and equipment

Property, plant and equipment are valued at cost in accordance with IAS 16 »Property, Plant and Equipment« and are subject to regular depreciation using the straight-line method and any impairment losses. Property, plant and equipment are depreciated on a straight-line basis over their expected useful life or, in the case of leasehold improvements, over the contract lease period which may be shorter.

Technical equipment and laboratory facilities	3 - 13 years
Leasehold improvements	5 - 8 years

Subsequent costs are only recorded as part of the cost of the asset or, if appropriate, as a separate asset if it is likely that future economic benefits resulting from these will flow to the Group and that the cost of the asset can be determined reliably. All other repairs and maintenance are charged as expenses to the income statement in the fiscal year in which they are incurred. Upon the sale of property, plant and equipment, the acquisition costs and the accumulated depreciation associated with these are removed from the accounts in the year of the disposal. Gains and losses on disposal are posted in other income and expenses and recognised in net profit or loss. The purchase and sale of property, plant and equipment within the Group is eliminated during the process of consolidation. The useful life, the depreciation method, and the residual carrying amount are examined on each reporting date.

Details on the development of property, plant and equipment can be found in the statement of changes in non-current assets → *page 90 et seq.*

## (10) Intangible assets

### Accounting policies for intangible assets

A summary of the accounting policies applied to the Group's intangible assets is as follows:

	TECHNOLOGY RIGHTS, PATENTS, LICENCES AND SOFTWARE	RESEARCH AND DEVELOPMENT PROJECTS ACQUIRED THROUGH BUSINESS COMBINATIONS	GOODWILL
Useful life	Limited to term of patent or contract	Limited to term of patent	Indefinite
Amortisation method	Straight-line amortisation over patent or contract life; amortisation period up to 16 years	Impairment test at least once a year, straight-line amortisation subsequent to market approval	Impairment test at least once a year
Internally developed or acquired	Acquired	Acquired	Acquired

Details on the development of intangible fixed assets can be found in the statement of changes in non-current assets  
→ *page 90 et seq.*

### Technology rights, patents, licences and software

Individually acquired intangible assets with a finite useful life are measured at cost. Any acquired technology rights, patents, licences and software, as well as research and development projects for which the licences have been acquired are recognised as intangible assets if all three of the following criteria are met:

- The intangible asset can be identified.
- It is probable that future economic benefits attributable to the asset will flow to the Group.
- The costs of the asset can be measured reliably.

Following their initial recognition, intangible assets are carried at cost less any amortisation and impairment losses accumulated. The useful life of intangible assets is basically defined as either finite or indefinite. Intangible assets with a finite useful life are amortised over their useful life and tested for impairment whenever there is any indication that the asset may be impaired. For intangible assets with a finite useful life, the amortisation period and amortisation method are examined at least at the end of every fiscal year.

Gains or losses arising from the derecognition of intangible assets are determined as the difference between the net disposal proceeds and the carrying amount of the asset and are recognised in the income statement in the same period the asset is derecognised.

Medigene has recognised patents and licences for patents at acquisition cost. The licences are amortised over the term of the patent. The patents and licences recognised relate to the EndoTAG<sup>®</sup>-1 product candidate.

### Research and development projects acquired through business combinations

The capitalised research and development projects acquired through business combinations relate to drug candidate RhuDex<sup>®</sup> and Medigene Immunotherapies. They are capitalised at acquisition cost, which equals the acquisition-date fair value. Following their initial recognition, intangible assets are carried at cost less any amortisation and impairments accumulated. Intangible assets are amortised from the date at which the respective drug candidate has obtained market approval. Until that date, an annual impairment test is carried out. In addition, a further impairment test is carried out immediately if there are any indications of impairment.

## Goodwill

After initial recognition, goodwill is valued at acquisition cost less accumulated impairment losses. Goodwill is examined for impairment at least once a year. An impairment test is also carried out if any events or circumstances indicate that the carrying amount may be impaired.

The carrying amount of goodwill of €2,212 k (2013: €2,212 k) is allocated to the RhuDex® cash-generating unit → *note (35)*.

## (11) Impairment of non-financial assets

The Group establishes on each reporting date whether there are any indications of an impairment of non-financial assets. If there are such indications or an annual impairment test is required, the Group estimates the recoverable amount of the relevant asset. The recoverable amount of an asset is the higher of the fair value of an asset or cash-generating unit (CGU) less costs to sell and the value in use. The recoverable amount must be determined for each asset, unless an asset produces no cash inflows which are largely independent of those of other assets or other groups of assets. If the carrying amount of an asset or CGU exceeds the recoverable amount, the asset is impaired and written down to the recoverable amount.

To carry out an impairment test, the goodwill acquired as part of a business combination is allocated, starting as at the acquisition date, to the CGUs (cash-generating units) that benefit from the synergy effects. A CGU to which goodwill is allocated,

- represents the lowest level within the entity at which goodwill is monitored for internal management purposes, and
- is no larger than a segment based on the primary or secondary reporting format of the Group as defined in IFRS 8 »Operating Segments«.

If the carrying amount of the CGU exceeds the recoverable amount, first the allocated goodwill and then the intangible assets allocated to this CGU are written down accordingly.

The value in use calculation is based on cash flow forecasts adopted by management and a discount rate before tax which reflects current market anticipations regarding interest effects and the specific risks inherent in the asset or the CGU. The planning period under review encompasses development and approval, as well as the period of time commencing with market launch, for which patent terms of slightly over ten years are generally assumed. To determine the fair value less costs to sell, any recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used.

Impairment losses relating to continued operations, including write-downs of inventories, are recognised through profit or loss in the expense categories which correspond to the function of the impaired asset in the Company.

On each reporting date, a review is carried out for assets, with the exception of goodwill, to test whether there is any indication that a previously recognised impairment loss no longer exists or has decreased. If there is any such indication, the Group estimates the recoverable amount of the asset or CGU. A previously recognised impairment loss is only reversed if there has been a change in the assumptions on the basis of which the recoverable amount was determined since the impairment loss was recorded. The increase in value is limited to the extent that the carrying amount of an asset must not exceed its recoverable amount or the carrying amount which would have resulted after taking into account amortisation if no impairment loss had been recognised for the asset in previous years. Any reversal of an impairment loss is recognised through profit or loss.

## **(12) Financial assets**

### **Initial recognition**

Financial assets within the scope of IAS 39 are classified as financial assets at fair value through profit or loss, loans and receivables, held-to-maturity investments, or available-for-sale financial assets. The Group determines the classification of its financial assets upon initial recognition.

Financial assets are initially recognised at fair value. Financial assets not included in the category of »assets at fair value through profit or loss« are initially recognised at fair value plus transaction costs. The fair value of investments traded on organised markets is determined by the quoted market price (bid price) on the reporting date. The fair value of investments for which there is no active market is determined using valuation methods. These include the use of the most recent transactions between knowledgeable and independent business partners willing to enter into a contract, the comparison with the current fair value of another largely identical financial instrument, the analysis of the discounted cash flows, and the use of other valuation models.

All purchases and sales of financial assets requiring delivery of the assets within a period determined by regulations or conventions of the respective market (regular way purchases) are recognised on the trading date, i.e. the date on which the Group committed itself to purchasing or selling the asset.

### **Subsequent measurement**

The subsequent measurement of financial assets depends on their classification as follows:

#### ***a) Assets at fair value through profit or loss***

encompass (1) financial assets held for trading and (2) financial assets which are allocated to this category upon their initial recognition. Financial assets are classified as held for trading if they are acquired for the purpose of selling or repurchasing in the near future. They are reported on the balance sheet at fair value, with changes in the fair value shown net in the income statement under financial expenses or financial income. The Group includes cash and cash equivalents in financial assets held for trading. In the reporting periods, the Group had no investments that were classified as at fair value through profit or loss upon initial recognition.

**b) Held-to-maturity investments**

are non-derivative financial assets with fixed or determinable payments and fixed maturities which management intends and is able to hold until they fall due. In the reporting periods, the Group did not have investments in this category.

**c) Loans and receivables**

are non-derivative financial assets with fixed or determinable payments that are not listed on an active market. These arise when the Group makes money, goods, or services directly available to a debtor with no intention of trading these receivables. They are included among current assets provided that their term to maturity does not exceed twelve months after the reporting date. Otherwise, they are classified as non-current assets. Loans and receivables are included in the balance sheet under trade accounts receivable and in other assets.

**d) Available-for-sale financial assets**

are non-derivative financial assets either designated as available for sale or not classified in any of the categories already described. They are classified as non-current assets if management has no intention of selling them within twelve months after the reporting date. Following initial recognition, available-for-sale financial assets are measured at fair value with unrealised gains and losses being recognised directly in shareholders' equity in the consolidated statement of comprehensive income. If investments are disposed of and/or impaired, the cumulative gain or loss previously recorded in shareholders' equity is transferred to the income statement. For example, financial assets which do not qualify as plan assets recognised within the framework of pension commitments or the investment in Immunocore Ltd. are allocated to this category → *note (38)*.

**Impairment**

As at every reporting date, a test is carried out to determine whether there is any objective evidence that a financial asset or a group of financial assets might be impaired. In the event of equity instruments classified as available-for-sale financial assets, a significant or prolonged decline in the fair value of these instruments below their acquisition cost is considered when determining to what extent the equity instruments are impaired.

With regard to outstanding amounts from customer receivables valued at amortised cost, the Company initially determines whether there is any objective evidence of significant financial assets being individually impaired or of insignificant financial assets being individually or collectively impaired. If the Group determines that there is no objective evidence of impairment for an individually tested financial asset – significant or not – it incorporates the asset into a group of financial assets with comparable credit risk profiles and tests them collectively for impairment. Assets tested individually for impairment and for which an impairment loss is or continues to be recorded are not included in a collective impairment assessment. Any impairment loss determined in this way is recognised through profit or loss.

### Derecognition

A financial asset (or, if applicable, part of a financial asset or part of a group of similar financial assets) is derecognised if one of the following requirements is met:

- The contractual rights to receive cash flows from a financial asset have expired.
- The Group has transferred its contractual rights to receive cash flows from the financial asset to a third party or has assumed a contractual obligation to immediately pay the cash flow to a third party as part of an arrangement that meets the condition in IAS 39 (pass-through arrangement) and has thereby either (a) transferred substantially all the risks and rewards associated with ownership of the financial asset or (b) neither transferred nor retained substantially all the risks and rewards associated with ownership of the financial asset but instead transferred control of the asset.

### (13) Inventories

Inventories are stated at the lower of purchase cost and net realisable value in accordance with IAS 2 »Inventories«. In the process, the purchase costs are generally determined on the basis of direct costs including incidental purchase costs.

### (14) Cash and cash equivalents

Cash and cash equivalents include cash on hand as well as credit balances at banks and bank deposits with an original maturity of up to three months. They are classified as financial assets held for trading and reported at their fair value. If an investment is to be classified as a cash equivalent, it must be readily convertible into a particular cash amount. In addition, it must only be subject to insignificant value fluctuations.

### (15) Shareholders' equity

Ordinary shares are classified as shareholders' equity. Costs that are directly attributable to the issue of new shares are included in shareholders' equity net of tax as a deduction from the issue proceeds.

### (16) Share-based compensation: options

As an incentive to share in the Group's long-term success, its employees and the members of its Executive Management Board receive share-based compensation in the form of equity instruments. For this purpose, the Group has set up a share-based compensation plan that is settled by issuing new shares. These equity instruments, such as options, are stated in accordance with IFRS 2. The fair value of stock options which Medigene grants as compensation for work performed by employees is recorded as an expense. The instruments are measured when granted with the help of the binomial model. The binomial model takes into consideration freeze periods, exercise thresholds, the volatility of the underlying instrument, and interest rates among other things. The expenses resulting from the granting of equity instruments and the corresponding rise in shareholders' equity are recognised over the period in which the exercise and performance conditions must be met (vesting period). This period ends on the first possible exercise date, i.e., the date on which the relevant employee is irrevocably entitled to subscribe. In individual cases, the benefit conditions have already been fulfilled upon issue of the stock options. In those cases, the expense is recorded upon granting of the options. No expenses are recognised for forfeited compensation rights.

The estimated number of options expected to be exercised is examined on each reporting date. The effects of any possible changes to the original estimates are included in the income statement and accounted for by carrying out the respective adjustment to shareholders' equity over the remaining vesting period.

When stock options are exercised, €1 per option is reported in the share capital with the remaining amount shown in the capital reserve.

The dilution effect of the outstanding stock options is considered in the calculation of earnings per share as additional dilution.

## **(17) Financial liabilities**

### **Initial recognition**

Financial liabilities within the scope of IAS 39 are classified as financial liabilities as at fair value through profit or loss or as loans. The Group determines the classification of its financial liabilities upon initial recognition and measures them at fair value, net of directly attributable transaction costs in the case of loans. Financial liabilities at fair value through profit or loss comprise financial liabilities held for trading as well as other financial liabilities which are classified as at fair value through profit or loss upon initial recognition. The contingent consideration from the business combination with Medigene Immunotherapies is recognised as a financial liability and measured at fair value through profit or loss → *section (C)*.

### **Subsequent measurement**

Financial liabilities classified as loans are measured in subsequent periods at amortised cost. Any difference between the amount paid out (after deducting transaction costs) and the amount repayable is recognised in the income statement over the term of the loan using the effective interest method.

### **Derecognition**

A financial liability is derecognised when the obligation under the liability is discharged, cancelled or expires.

## **(18) Accruals**

Accruals are recognised in accordance with IAS 37 »Provisions, Contingent Liabilities and Contingent Assets« provided that there is a current obligation to third parties arising from a past event that will probably lead to the outflow of resources in the future and that this amount can be estimated reliably. The cost of recording the accrual is reported in the income statement. Accruals for obligations that are not likely to lead to an outflow of resources embodying economic benefits in the subsequent year are recognised at the present value of the expected outflow of resources. The carrying amount of accruals is reviewed every reporting date.

## **(19) Pension obligations**

Pension obligations are accounted for in accordance with IAS 19 »Employee Benefits« (revised 2011). There are various pension plans within the Group. These include both defined benefit and defined contribution plans.

A defined benefit plan is a pension plan which defines the pension benefits that an employee will receive upon retiring. The amount normally depends on one or more factors such as age, length of service, and salary. The obligation recognised in the balance sheet for defined benefit plans corresponds to the present value of the defined benefit obligations (DBO) on the reporting date less the fair value of plan assets that arise from pension liability insurance. The DBO is calculated annually by an independent actuary using the projected unit credit method. The 2005 G mortality tables by Prof. Dr. Klaus Heubeck were used as the biometric calculation basis. The pension obligations have a term of 15 years. The present value of the DBO is calculated by discounting the expected future cash payments using the interest rate of the highest-quality corporate bonds. These must be denominated in the currency in which the benefits are also paid and their terms to maturity must equal those of the pension obligations. Actuarial gains and losses based on experience adjustments and changes to actuarial assumptions are recognised in full in other comprehensive income.

A defined contribution plan is a pension plan under which the Group pays fixed contributions to an independent entity (fund). With these plans, the Group has no legal or constructive obligations to make additional contributions if the fund does not hold sufficient assets to pay the pension claims of all employees for their service in current and previous fiscal years. The contributions are recognised in personnel expenses upon maturity. Prepaid contributions are recognised as assets to the extent that there is a right to a refund or a reduction in future payments.

## **(20) Taxes**

### **Current taxes**

Current tax assets and liabilities are measured using the amount expected to be repaid by or paid to tax authorities. The amount is calculated on the basis of the tax rates and laws applicable on the reporting date.

Current taxes pertaining to items recognised directly in shareholders' equity are not posted in the income statement, but rather in shareholders' equity.

### **Deferred taxes**

Deferred tax is recognised in accordance with IAS 12 »Income Taxes« using the liability method for all temporary differences between the tax base of assets/liabilities and their carrying amounts in the financial statements according to IFRS. Deferred tax is valued using the tax rates (and laws) enacted or substantively enacted on the reporting date and are expected to apply when the deferred tax asset is realised or the deferred tax liability is settled.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- where the deferred tax liability arises from the initial recognition of goodwill or of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit of loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates, and interests in joint ventures where the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, unused tax losses, and unused tax credits to the extent that deferred tax liabilities exist, or that taxable income is likely to be available against which the deductible temporary differences and the unused tax losses and tax credits can be used except:

- where the deferred tax asset from deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor the taxable profit or loss, and
- in respect of deductible temporary differences associated with investments in subsidiaries, associates, and interests in joint ventures provided that the temporary differences are not likely to reverse in the foreseeable future or it is probable that insufficient taxable profit will be available against which the temporary differences can be used.

The carrying amount of deferred tax assets is examined on every reporting date and reduced to the extent that it is no longer likely that sufficient taxable profit will be available against which the deferred tax asset, or a part thereof, can be used. In addition, the statutory limitations regarding the recognition of deferred tax assets for unused tax losses in accordance with Section 10d (2) of the German Income Tax Act (EStG) are taken into account.

Deferred taxes which relate to items reported in other comprehensive income or directly in shareholders' equity are also stated in other comprehensive income or shareholders' equity.

Deferred tax assets and liabilities are measured using tax rates expected to be valid for the period in which an asset is realised or a liability is settled. This is based particularly on country-specific tax rates and laws applicable as at the reporting date. Deferred tax assets and liabilities are offset against each other if the tax assets and income taxes pertain to the same taxable entity, have matching maturities, and are levied by the same tax authority.

## **(21) Leases**

Lease agreements in which the Group is the lessee and substantially all of the risks and rewards associated with ownership of the leased asset remain with the lessor are classified as operating leases. Payments made in connection with operating leases are recognised in the income statement over the period of the lease using the straight-line method.

There are no leases for property, plant or equipment in which the Group is the lessee and bears substantially all risks.

## **(22) Revenue recognition**

Revenue is recognised when it is probable that the economic benefit will flow to the Group and the amount of revenue can be determined reliably. In the reporting period, Medigene posted revenue from product sales, milestone payments and royalties and other income.

### **Revenue from product sales and recurring royalties**

Revenue from product sales is realised as soon as the risks and rewards associated with ownership have been transferred and the product or active ingredient has been delivered to the buyer. Moreover, Medigene receives royalties from licensees for the product sales generated in the market. These are invoiced on a quarterly basis.

### **Revenue from upfront and milestone payments and non-recurring royalties**

Upfront (one-time) payments which Medigene receives from pharmaceutical partners upon concluding a new contract are accrued on the liabilities side in accordance with IAS 18 »Revenue« over a period that matches the estimated term over which the services promised will be provided and corresponds to the relevant contractual or patent term or a shorter period until market launch of the development product, and are stated on a straight-line basis or collected in instalments once certain milestones are achieved. The amounts released are reported in revenue under milestone payments from product sales. Provided that all criteria of IAS 18.14 are fulfilled, revenue is immediately recognised in full. Non-recurring royalties which entail all risks and rewards being transferred to the licensee are immediately recognised as revenue.

Medigene receives milestone payments for the official acceptance of applications submitted to authorities, the market approval of products by the authorities, the market launch of new products by partners, the achievement of certain contractually agreed annual revenue targets, and the achievement of research and development milestones defined in cooperation agreements. Accordingly, these payments are recognised immediately as income provided that no additional performance has been agreed.

**R&D payments received from partners and other income**

Income from research cooperation is collected as income in accordance with IAS 18 if the contractually agreed targets are reached and/or the relevant research and development services have been supplied. Contractually agreed payments and scheduled payments not linked to a future performance are collected as income on the condition that the cooperation partner confirms that the contractual agreements have been met.

**Interest income**

Interest income is recognised when interest accrues.

**(23) Research and development expenses**

Research and development expenses are recognised as expenses in the period in which they arise. These expenses include personnel expenses, purchased services, laboratory material costs, patent and licence fees, consultancy fees and other costs such as rent and electricity. They also include depreciation and amortisation.

**(24) Earnings per share**

Earnings per share are determined in accordance with IAS 33 »Earnings per Share«.

**Basic earnings per share**

Basic earnings per share is calculated by dividing total comprehensive income for the period, net profit/loss for the period to which the equity owners are entitled (the numerator), by the weighted average number of shares issued that are in circulation during the fiscal year (the denominator).

**Diluted earnings per share**

Diluted earnings per share is calculated by adding option rights to the weighted average number of shares in circulation (denominator). The total comprehensive income for the period and net profit/loss for the year are adjusted for all changes in income or expense that would result from the conversion of the potential ordinary shares with dilution effects. For the stock options, it is calculated how many shares could be acquired at fair value (determined by the average stock market value of the Company's shares over the course of the year). The number of shares thereby calculated is compared with the number that would have resulted had the stock options been exercised. The conversion of potential ordinary shares is deemed to be completed on commencement of the period, or on the day, when the potential ordinary shares were issued.

**(25) Statement of cash flows**

The statement of cash flows was prepared in accordance with IAS 7 »Statement of Cash Flows«. The Company applied the indirect method when determining the net cash used in operating activities and classified cash flows into operating, investing, and financing activities. The cash flows from investing activities and financing activities are each determined based on the actual payments made.

**(26) Segment reporting/operating segments**

Segment reporting in accordance with IFRS 8 »Operating Segments« uses the management approach to determine individual segment data. The individual segment data are provided by internal reporting, so that the determination of individual data reflects the Company's management concept.

An operating segment is a component of an entity that engages in business activities from which it may earn revenues and incur expenses and whose operating results are regularly reviewed by the entity's chief operating decision maker and for which discrete financial information is available.

For corporate management purposes, the Group is organised into business units based on products and services and has two reportable operating segments: »Marketed drugs« and »Drug candidates«. Financial information that cannot be assigned to either of the operating segments is reported under »Reconciliation«.

In addition, the Group reports revenue with external customers and non-current assets including property, plant, equipment, intangible assets, and goodwill, classified by the country in which the Company has generated revenue and/or holds assets.

The figures for the individual operating segments are presented in *→ F) »Segment reporting«*.

**C) ACQUISITION OF SUBSIDIARIES**

On 27 January 2014 Medigene AG announced that it had taken over Trianta Immunotherapies GmbH (now trading as "Medigene Immunotherapies GmbH"), a spin-off from Helmholtz Zentrum Munich (HMGU). In the course of the acquisition, Medigene acquired 100% of the shares. The former shareholders of Trianta received 1,017,811 newly issued shares in Medigene with a value of €3.8 m and will receive a maximum of €5.9 m in instalments in Medigene shares or in cash as contingent consideration upon certain milestones being reached.

The purchase price (consideration paid) of €7,105 k breaks down into the fair value of the shares issued (€3,817 k) and the liability to pay contingent consideration at a fair value of €3,288 k to the former shareholders of Medigene Immunotherapies upon future milestones being reached. Whereas Medigene may choose to pay future milestones either by issuing new Medigene shares or in cash, the Executive Management Board intends to settle them with new shares. As the number of new shares to be issued has not been contractually defined and is based on the average stock market price, contingent consideration is accounted for at acquisition-date fair value as a financial liability in accordance with IAS 39.

The fair value of the shares issued corresponds to the closing price of Medigene shares on the XETRA exchange (Deutsche Börse, Frankfurt) as at the acquisition date, 27 January 2014. The liability to the former shareholders, which the Executive Management Board estimates might fall due in 2015-2016, is contingent upon the future development of the development projects led by Medigene Immunotherapies and certain milestones being reached. The fair value of contingent consideration has been determined using the discounted cash flow method on the basis of observable market data and unobservable inputs and is therefore allocable to level 3 of the fair value hierarchy → *note (51)*. This involved weighting the contractual consideration (€5.9 m) with the probability customary in the industry for reaching certain development milestones within a range from 30% to 100% and discounting it using a cost of capital rate of 10.65% after considering a risk-free interest rate, market risk premium, beta factor from a peer group, a corresponding tax rate and the risk of non-performance of Medigene.

#### CONSIDERATION PAID

IN € K

Fair value of shares issued		<b>3,817</b>
Number of shares issued	<b>1,017,811</b>	
Fair value per share (€)	<b>3.75</b>	
Fair value of liability contingent upon reaching certain milestones		<b>3,288</b>
<b>Total consideration paid</b>		<b>7,105</b>

As at 31 December 2014, the liability to pay contingent consideration relating to future milestones amounted to €3,611 k (€3,076 k thereof is reported under current and €535 k under non-current other financial liabilities). The change in fair value of €323 k was recognised under interest expenses.

The assets and liabilities of Medigene Immunotherapies acquired in the combination were identified. As at the acquisition date, they comprise:

#### IDENTIFIABLE ASSETS AND LIABILITIES OF MEDIGENE IMMUNOTHERAPIES ACQUIRED IN THE COMBINATION

IN € K

Fair value of current assets (cash and cash equivalents)	<b>21</b>
Intangible assets associated with the development projects led by Medigene Immunotherapies at fair value	<b>9,692</b>
Trade accounts payable at fair value	<b>-100</b>
Deferred taxes	<b>-2,508</b>
<b>Identifiable assets and liabilities acquired in the combination</b>	<b>7,105</b>

Medigene Immunotherapies has three highly innovative and complementary immunotherapy platforms with programmes in clinical and preclinical development to treat various tumour types. The intangible assets were identified and measured for the two most advanced platforms: the platform for developing antigen-tailored dendritic cell (DC) vaccines for the treatment of acute myeloid leukaemia (AML) and the platform for developing tumour-specific T cell receptors (TCR). With respect to one technology, the preclinical phase has already been completed and clinical development has commenced. The second technology is still in the lead optimisation phase and its preclinical phase has already started. Detailed disclosures can be found in → *note (35)*.

The costs directly attributable to the acquisition of Medigene Immunotherapies of €796 k were reported as an expense within general and administrative expenses. The costs of share issue of €64 k were offset directly within shareholders' equity.

**NET CASH FLOW ON ACQUISITION**

IN € k

Net cash acquired with the subsidiary (included in net cash used in investing activities)	21
Costs directly attributable to the acquisition <sup>1)</sup> (included in net cash used in operating activities)	-796
Transaction costs attributable to the share issue (included in net cash from financing activities)	-64
<b>Net cash flow</b>	<b>-839</b>

<sup>1)</sup> An amount of €512 k thereof was incurred in 2013.

Since being acquired, Medigene Immunotherapies has contributed €153 k to other operating income and a loss of €4,345 k to the Group's earnings before tax. Assuming that Medigene Immunotherapies had already been included in the basis of consolidation as at 1 January 2014, it would not have placed any additional burden on the Group's earnings.

The Company has entered into a profit and loss transfer agreement with Medigene Immunotherapies to create a consolidated tax group. Since the consolidated tax group was created on 1 May 2014, the date on which the contract came into effect, deferred tax assets on unused tax losses of Medigene AG could be offset against the deferred tax liabilities of Medigene Immunotherapies up to the limits prescribed by the law. The resulting deferred tax income was recognised in profit or loss in 2014 in accordance with IAS 12.67 → *note (45)*.

**D) NOTES TO THE INCOME STATEMENT**

The income statement was prepared in accordance with the cost of sales method.

**(27) Total revenue**

Total revenue amounted to €13,784 k in the 2014 fiscal year (2013: €7,592 k). This revenue originates from product sales and royalties on the revenues generated by the drug Veregen<sup>®</sup> of €4,470 k (2013: €3,911 k) and also includes milestone payments totalling €725 k (2013: €298 k) for Veregen<sup>®</sup> from partner companies.

Other operating income amounted to €8,589 k in the past fiscal year (2013: €3,383 k). It essentially comprised regular non-cash income of €2,493 k (2013: €2,493 k) from the assignment of the rights to Medigene's former drug Eligard<sup>®</sup> agreed with Cowen in 2012 → *note (4)*, sales of €503 k (2013: €0 k) of RhuDex<sup>®</sup> material (active pharmaceutical ingredient, API) to the partner firm Dr. Falk Pharma GmbH (»Falk Pharma«), and grants of €153 k (2013: €0 k). In addition, Medigene is reimbursed for costs incurred as part of a global partnering agreement for EndoTAG<sup>®</sup>-1 signed in May 2013 with SynCore Biotechnology Co., Ltd. (hereinafter referred to as »SynCore«), a member of the Sinphar Pharmaceutical group and milestone payments for the development of this drug candidate. Within the scope of this cooperation, Medigene received cost reimbursements of €1,936 k in the reporting period (2013: €833 k) and realised milestone payments totalling €2,699 k (2013: €13 k). Medigene received a one-off payment of €700 k (2013: €0 k) from entering into a partnering agreement with Falk Pharma.

**TOTAL REVENUE**

IN € K	2014	2013	CHANGE
Revenue from product sales and royalties	<b>4,470</b>	3,911	14%
thereof royalties	2,352	2,585	-9%
thereof revenue from product sales	2,118	1,326	60%
Milestone payments from product sales	725	298	143%
<b>Revenue</b>	<b>5,195</b>	<b>4,209</b>	<b>23%</b>
R&D milestone payments	2,699	13	>200%
R&D payments from partners	1,936	833	132%
Other revenue	3,954	2,537	56%
<b>Other operating income</b>	<b>8,589</b>	<b>3,383</b>	<b>154%</b>
<b>Total</b>	<b>13,784</b>	<b>7,592</b>	<b>82%</b>

**(28) Cost of sales**

Cost of sales amounting to €2,086 k (2013: €1,735 k) includes procurement costs for the product Veregen® and royalty payments to partner companies as a share in revenue.

**COST OF SALES**

IN € K	2014	2013	CHANGE
Purchases	1,368	979	40%
Royalties	718	756	-5%
<b>Total</b>	<b>2,086</b>	<b>1,735</b>	<b>20%</b>

**(29) Selling expenses**

Expenses for business development and marketing are reported under selling expenses. These include personnel expenses, marketing and regulatory costs (incl. FDA fees), consultancy fees, market studies and other services. Selling expenses decreased by €1,130 k in the reporting period on account of a one-off payment made in the previous year to cancel the contract with Abbott Arzneimittel GmbH for the marketing and distribution of Veregen®.

**SELLING EXPENSES**

IN € K	2014	2013	CHANGE
Personnel expenses	<b>924</b>	1,186	-22%
One-off payment for the termination of the Abbott contract	<b>0</b>	740	-
Marketing/regulatory costs	<b>524</b>	636	-18%
Consultancy fees/market surveys	<b>180</b>	223	-19%
Office rent and utilities	<b>123</b>	164	-25%
Depreciation and amortisation	<b>2</b>	2	-
Other	<b>238</b>	170	40%
<b>Total</b>	<b>1,991</b>	<b>3,121</b>	<b>-36%</b>

**(30) General and administrative expenses**

Administrative expenses decreased to €5,090 k in the reporting period (2013: €5,152 k). This is primarily due to higher consulting fees in the previous year due to the acquisition of Medigene Immunotherapies.

**GENERAL AND ADMINISTRATIVE EXPENSES**

IN € K	2014	2013	CHANGE
Personnel expenses	2,504	2,386	5%
Consultancy fees	1,383	1,687	- 18%
Office rent and utilities	331	316	5%
Depreciation and amortisation	142	137	4%
Other	730	626	17%
<b>Total</b>	<b>5,090</b>	<b>5,152</b>	<b>-1%</b>

**(31) Research and development expenses**

Research and development expenses rose to €7,498 k in the reporting period (2013: €6,605 k) on account of the acquisition of Medigene Immunotherapies GmbH, mainly due to personnel expenses and the cost of laboratory supplies. The increase is countered to some extent by a fall in development expenses for RhuDex<sup>®</sup> related to the partnering of Falk Pharma.

The R&D costs incurred for EndoTAG<sup>®</sup>-1 are reimbursed by the partner SynCore and stated under other operating income as income from R&D payments from partners.

Third party expenses totalling €888 k (2013: €1,906 k) comprise the following items: clinical trials amounting to €252 k (2013: €168 k), production services of €173 k (2013: €678 k), preclinical development services of €237 k (2013: €880 k) and approval costs of €226 k (2013: €180 k).

**RESEARCH AND DEVELOPMENT EXPENSES**

IN € K	2014	2013	CHANGE
Personnel expenses	3,194	1,921	66%
Third party expenses	888	1,906	- 53%
Consultancy fees	736	772	-5%
Depreciation and amortisation	666	612	9%
Office rent and utilities	598	516	16%
Patent and licence fees	595	382	56%
Laboratory supplies	254	128	98%
Other	567	368	54%
<b>Total</b>	<b>7,498</b>	<b>6,605</b>	<b>14%</b>

**(32) Financial result****FINANCIAL RESULT**

IN € K	2014	2013	CHANGE
Interest income	27	24	13%
Interest expenses	-1,801	-1,577	14%
thereof non-cash interest expenses from the financial liability to Cowen → <i>note (4)</i>	-1,449	-1,566	- 7%
thereof changes in fair value of the liability for contingent consideration → <i>section (C)</i>	-323	0	-
thereof net interest cost for pension obligations → <i>note (44)</i>	-10	-10	-
Other	-19	-1	>200%
<b>Total</b>	<b>-1,774</b>	<b>-1,553</b>	<b>14%</b>

### (33) Basic and diluted earnings per share

The following table shows the calculation of the basic and diluted earnings per share:

#### BASIC AND DILUTED EARNINGS PER SHARE

NUMBER	2014	2013	CHANGE
<b>Weighted average number of shares</b>	<b>12,210,949</b>	<b>9,631,559</b>	<b>27%</b>
Effect of dilution: Stock options	-	-	
<b>Weighted average number of ordinary shares adjusted for the effect of dilution</b>	<b>12,210,949</b>	<b>9,631,559</b>	<b>27%</b>
<b>Basic and diluted earnings per share in €</b>	<b>-0.47</b>	<b>-1.07</b>	<b>-56%</b>

For fiscal years 2014 and 2013, the diluted earnings per share from continued operations were the same as the basic earnings per share, since taking into account the weighted average number of shares to be issued upon the exercise of stock options would produce an anti-dilutive effect. Of the total 469,380 stock options, 328,485 had no dilutive effect in 2014, since the exercise price of most of the stock options was above the average share price of €4.49 for the year (Deutsche Börse; XETRA closing price).

### (34) Personnel expenses

The expense items in the income statement include the following personnel expenses:

#### PERSONNEL EXPENSES

IN € K	2014	2013	CHANGE
Wages and salaries	<b>5,642</b>	4,692	20%
Social security	<b>790</b>	591	34%
Pension expenses			
Defined contribution plans	<b>33</b>	35	-6%
Defined benefit plans $\rightarrow$ note (44)	<b>21</b>	55	-62%
Stock options issued to executives and employees	<b>66</b>	60	10%
Other	<b>70</b>	60	17%
<b>Total</b>	<b>6,622</b>	<b>5,493</b>	<b>21%</b>

#### EMPLOYEE BY FUNCTION

	31 DEC 2014	31 DEC 2013	CHANGE
General administration	<b>18</b>	16	13%
Business development	<b>9</b>	9	0%
Research and development	<b>45</b>	26	73%
<b>Total</b>	<b>72</b>	<b>51</b>	<b>41%</b>

The number of full-time equivalents (FTEs) increased to 65 as at 31 December 2014 (2013: 48) mainly as a result of the acquisition of Medigene Immunotherapies GmbH.

**(35) Impairment of goodwill and intangible assets not yet available for use**

The carrying amounts of goodwill and intangible assets not yet available for use break down as follows as at 31 December 2014:

<b>CARRYING AMOUNTS OF GOODWILL AND INTANGIBLE ASSETS</b>				
IN € k	2014		2013	
	CGU 1	CGU 2	CGU 1	CGU 2
Carrying amount of goodwill	<b>2,212</b>	<b>0</b>	2,212	0
Carrying amount of RhuDex® intangible assets not yet available for use	<b>23,750</b>	<b>0</b>	23,750	0
Carrying amount of Medigene Immunotherapies' intangible assets not yet available for use	<b>0</b>	<b>9,692</b>	0	0

The development projects and technologies underlying the intangible assets not yet available for use are allocated to the CGUs as follows:

RhuDex® (CGU 1)  
Immunotherapies (CGU 2)

The carrying amounts of goodwill and intangible assets not yet available for use came to €35,654 k as at the reporting date 31 December 2014 (31 December 2013: €25,962 k) and were attributable to a total of two cash-generating units (CGUs). An amount of €25,962 k (2013: €25,962 k) thereof is attributable to RhuDex® (CGU 1) and €9,692 k (2013: €0 k) to Immunotherapies (CGU 2) from the acquisition of Medigene Immunotherapies → (section C).

**Annual impairment test as at 31 December 2014 (CGU 1)****Methodology for determining the recoverable amount:**

The recoverable amount for each CGU is estimated on the basis of value-in-use calculations using discounted cash flow models. Value in use can be determined for each of the projects at research stage and allocated to the CGU since the clinical development and subsequent marketing of the drug candidates for a specific indication have been firmly established.

**Basic assumptions for calculating value in use for the CGU**

Starting in 2024, the cash flow models are based on the assumption that RhuDex® is approved and marketed in the three largest pharmaceutical markets worldwide: the USA, Europe and Japan. The cash flow forecasts used include assumptions regarding the probability of market entry, future competition, project progress, the product profile and its lifecycle, as well as the market share of the future drug candidate. The impairment model includes the out-licensing of the drug candidate RhuDex® in the areas of hepatology and gastroenterology to Falk Pharma. The assumptions used in the impairment test are based on Falk Pharma's development plan. Remaining indications such as rheumatoid arthritis or Crohn's disease are also included in this out-licensing model.

The forecast period usually spans the expected term of the patents, i.e. the period between 2015 and 2035. Cash flow after tax was discounted based on a discount rate after tax which reflects current market assessments of the interest rate level and the risks specific to indications, to which the estimated future cash flows were not adjusted. The Executive Management Board used discount rates and cash flows after tax, since it is their opinion that discounting the cash flows after tax at a discount rate after tax will not yield results that differ significantly from discounting cash flows before tax at a discount rate before tax.

There are estimation uncertainties regarding the following assumptions that form the basis of the calculation of the value in use of the CGU:

- Probability of market entry
- Development periods and project progress
- Anticipated market share and number of patients treated in the relevant sub-market

#### Probability of market entry

Medigene has made assumptions on the probability of market entry for the drug candidates. The necessity for those assumptions arises from the typical drug development risks. These risks vary depending on the class of substance and API, as well as the medical indication. Accordingly, management has applied the customary probability of success within the industry for its valuation models. In addition, project-specific assumptions supplement these estimations. The development risks are taken into consideration in determining the project-specific interest rate.

#### Development periods and project progress

According to pharmaceuticals industry statistics, the development of a drug generally takes 10 to 15 years. This period of time is divided into successive phases. Significant factors which influence the length of the development period are the results for efficacy and side effects of a drug candidate, which are obtained during the individual phases. The assumptions made by Medigene's management for each indication are based on the current development status, the results obtained so far and the empirical data regarding the medical indication and class of drugs.

#### Anticipated market share

Management compares the data available for the development project, the target profile and the development data, if accessible, and on this basis makes an assessment of the anticipated market share. In order to estimate the number of patients who will be treated in the future, Medigene also relies on estimates of external consulting and valuation specialists.

#### PROJECT-SPECIFIC ASSUMPTIONS CGU 1

Planning period in years	22
Project-specific cumulative probability of market entry (%)	11-25
Discount rate after taxes (%)	10.65

On the basis of these assumptions, no impairment requirement was identified for the CGUs. The actual value in use of the CGU as at 31 December 2014 exceeds its carrying amount.

#### Sensitivity of the assumptions made - CGU 1 (RhuDex<sup>®</sup>)

In the basic assumptions made to determine the value in use of the CGU which are based on management's best estimate and judgement, changes are reasonably possible, which would cause the carrying amount of the CGU to exceed the value in use. This would trigger an impairment loss. In order to analyse the effects of basic and/or project-specific assumptions on value in use, Medigene made the following sensitivity calculations at CGU 1 level for the research and development projects assessed:

The first approach examines the influence of greater risks with regard to the safety and effectiveness profile during clinical development. The increased development risks are reflected in a risk factor that takes the probability of market approval into account. If the probability of market approval is reduced by 1%, value in use approximates the carrying amount of CGU 1.

The second approach examines how postponing the planned market entry by five months would affect the recoverable amount. In this scenario, value in use approximates the carrying amount of CGU 1.

The third approach assumes that, in contrast to the current benchmark analysis of comparable partnering agreements, the anticipated income from milestone and upfront payments under a further partnering agreement are only half as high (50% deduction). In this case, value in use falls 2% below the carrying amount of CGU 1.

In addition, the impact of a higher discount rate is analysed: if the discount rate is increased by 45 base points, value in use approximates the carrying amount of CGU 1.

In the worst case, if no development and marketing partnering agreement can be concluded for rheumatic arthritis, or in case several unfavourable changes are considered in the basic assumptions, the value in use may drop to zero, and the carrying amounts of goodwill and intangible assets not yet available for use would have to be fully written off.

### **Intangible assets associated with the development projects led by Medigene Immunotherapies (CGU 2)**

The assumptions used in determining the fair value of intangible assets acquired in the course of the business combination have not changed materially since the acquisition date (27 January 2014) or as at the end of the reporting period. Accordingly, no impairment losses had to be recognised on intangible assets associated with the development projects led by Medigene Immunotherapies as at 31 December 2014.

The fair value of the intangible assets acquired was determined using a risk-adjusted net present value (rNPV) cash flow model. Product-specific and financing risks relating to the development stage are reflected by deductions in the cash flows or in the discount rate. The amounts attributed to the assumptions correspond to the Executive Management Board's assessment of future developments and are based on internal planning scenarios and external sources of information and market data. The fair value of the acquired intangible assets is therefore allocable to level 3 of the fair value hierarchy.

The cash flow models cover the horizon until 2036. The dates assumed for market introduction were 2021-2022 for the EU and 2023-2024 for the US.

Revenue forecasts are based on the number of patients treated and estimates relating to frequency, scope and price of treatment. The number of patients was determined on the basis of the most recent market data available for the EU and the US using growth rates of 0.3% and 0.8% p.a., respectively. The price estimates take account of current market prices. As is customary, in such estimates Medigene also relies on assessments by external consulting and valuation specialists. The expected future market shares are estimated taking into account the lifecycle of the development project and reach double-digit figures in peak years. It has been assumed that revenue will decrease after the end of the patent term.

The likelihood of success customary in the industry is used. For one technology a marketing probability of 11% was assumed as the technology is ready for clinical development. For the second technology, a marketing probability of 3.6% was assumed as this technology is still in lead optimisation phase. Gross margin was assumed to be about 60%. Further, it is assumed that production will be outsourced completely; accordingly no investment in the Company's own plant, except for research purposes, has been budgeted. Marketing costs are planned as a percentage of annual revenue. In the year prior to market introduction, the same amount is assumed for initial marketing costs as for the following year. General and administrative expenses are planned based on the last planning year in the detailed budget statement at a growth rate of 2% p.a. and are thus not linked to revenue. Future milestone payments and royalties pursuant to the licence agreement with HMGU have been taken into account.

Cost of capital rates between 17.5% and 18.6% have been applied for the technologies according to the stage of development of the product.

In accordance with German tax legislation, the tax amortisation benefit is based on a maximum useful life for tax purposes of 15 years. Based on the local levy rate for Planegg/Martinsried of 300%, a local tax rate of 26.33% is assumed.

The above assumptions correspond to the best estimate of the Executive Management Board on the acquisition date and the reporting date. Nevertheless, the sensitivity of the fair value of the acquired intangible assets to changes in significant measurement parameters was tested, such as the discount rate, number of patients and prices or costs for treatment.

The first scenario examines the impact of a change in development risks, which are reflected in the discount rate. If the discount rate falls by 0.5%, the fair value of intangible assets acquired rises by 15% in comparison to their carrying amount. If the discount rate rises by 0.5%, fair value falls by 14%.

The second scenario examines the impact of the number of patients on the measurement of fair value. If the number of patients rises by 10%, the fair value of intangible assets acquired increases by 33%. If the number of patients falls by 10%, fair value falls by 34%.

The impact of changes in the prices or costs of treatment is examined as well. If the price of treatment rises or falls by 5%, the fair value of intangible assets acquired rises or falls respectively by 28%. If the costs of treatment rise or fall by 5%, fair value falls or rises by 12% respectively.

## **E) NOTES TO THE BALANCE SHEET**

### **ASSETS**

#### **(36) Property, plant and equipment**

The composition and development of property, plant and equipment is provided in the statement of changes in non-current assets → *page 90 et seq.*

#### **(37) Intangible assets**

The detailed composition and development of intangible assets is provided in the statement of changes in non-current assets → *page 90 et seq.* The increase in intangible assets from €26,958 k to €36,165 k is primarily attributable to the acquisition of Medigene Immunotherapies which accounts for €9,692 k.

As at the reporting dates of 31 December 2014 and 2013, there were no indications of impairment for the EndoTAG<sup>®</sup>-1 patents and licences. At Medigene, these assets are amortised over the life of the underlying patents. Please refer to → *note (35)* for more information on the impairment tests for the intangible assets not yet available for use allocated to RhuDex<sup>®</sup> and Immunotherapies.

Medigene has not recognised any internally generated intangible assets.

### (38) Financial assets

Financial assets comprise the following items:

<b>FINANCIAL ASSETS</b>			
IN € k	31 DEC 2014	31 DEC 2013	CHANGE
Pension liability insurance policies (available-for-sale financial assets)	180	154	17%
Loans to Catherex, Inc. (loans and receivables)	385	242	59%
Shares in Immunocore Ltd. (available-for-sale financial assets)	3,620	3,533	2%
<b>Total</b>	<b>4,185</b>	<b>3,929</b>	<b>7%</b>

The loan to the associate Catherex, Inc. is a fixed-interest loan. It was increased to €385 k in the reporting year (2013: €242 k) and matures on 31 December 2015. Management of Medigene currently assumes that this loan will be extended beyond the agreed loan term.

The shares in Immunocore Ltd. were measured at €3,620 k as at the reporting date (2013: €3,533 k). Subsequent to the restructuring of the shares performed in 2014, Medigene holds 64,815 ordinary shares corresponding to a holding of 2.93% as at 31 December 2014. These shares participate directly in the development of the value of the company. The remeasurement of the shares as at the reporting date resulted in a gain of €86 k that is posted under "Available-for-sale financial assets" in the statement of comprehensive income. The shares in Immunocore Ltd. are allocated to available-for-sale financial assets and are recognised at a fair value according to level 3 of the fair value hierarchy of financial instruments → *note (51)*. The fair value of these shares was established with the help of an external expert. According to the best estimates of the Executive Management Board, this corresponds to the current fair value.

### (39) Investment in associates

The investment in associates came to €2,781 k as at 31 December 2014 (31 December 2013: €2,513 k) and relates to the 40.40% shareholding in Catherex (€2,781 k) and the 38.95% shareholding in Aettis (€0 k).

**INVESTMENT IN MATERIAL ASSOCIATES**

IN € K	31 DEC 2014	31 DEC 2013
Summarised financial information of the Group's investment in Catherex:		
Current assets	15	3
Non-current assets	37	0
Current liabilities	-1,288	-948
<b>Shareholders' equity</b>	<b>-1,236</b>	<b>-945</b>
<b>Group's shareholding</b>	<b>40.40%</b>	<b>40.40%</b>
Equity attributable to equity holders of the parent	-499	-382
Intangible assets attributable to equity holders of the parent (fair value)	3,280	2,895
<b>Carrying amount of the investment</b>	<b>2,781</b>	<b>2,513</b>
Revenue	3	30
Profit/loss	-139	-252
Group's shareholding	40.40%	40.40%
Share in profit or loss of the associate	-56	-102

**(40) Inventories**

Inventories of Veregen® amounted to €4,406 k as at the reporting date (2013: €3,046 k). There was no impairment to lower net realisable value.

**(41) Other assets and trade accounts receivable****OTHER ASSETS AND TRADE ACCOUNTS RECEIVABLE**

IN € K	31 DEC 2014	31 DEC 2013	CHANGE
Receivables from licence partners	2,748	878	>200%
Prepaid expenses with a term < 1 year	567	574	-1%
Rent deposits > 1 year	323	375	-14%
Grants	105	0	-
VAT receivables	95	223	-57%
Other	36	13	177%
<b>Total other assets</b>	<b>3,874</b>	<b>2,063</b>	<b>88%</b>
<b>Trade accounts receivable</b>	<b>1,733</b>	<b>1,363</b>	<b>27%</b>

The accounts receivable and other assets were neither past due nor impaired as at the reporting date. Receivables from licence partners consist primarily of receivables for outstanding milestone payments agreed with SynCore. The maturities of trade accounts receivable and other assets are as follows:

**AGING ANALYSIS OF ACCOUNTS RECEIVABLE AND OTHER ASSETS**

IN € K	MATURITY					TOTAL
	UP TO 30 DAYS	30-180 DAYS	180-360 DAYS	1-5 YEARS	>5 YEARS	
<b>Balance at 31 Dec 2014</b>						
Other assets	1,990	200	1,361	323	0	3,874
Trade accounts receivable	1,733	0	0	0	0	1,733
<b>Total</b>	<b>3,723</b>	<b>200</b>	<b>1,361</b>	<b>323</b>	<b>0</b>	<b>5,607</b>
<b>Balance at 31 Dec 2013</b>						
Other assets	1,464	223	1	375	0	2,063
Trade accounts receivable	1,363	0	0	0	0	1,363
<b>Total</b>	<b>2,827</b>	<b>223</b>	<b>1</b>	<b>375</b>	<b>0</b>	<b>3,426</b>

**(42) Cash and cash equivalents**

<b>CASH AND CASH EQUIVALENTS</b>			
IN € K	31 DEC 2014	31 DEC 2013	CHANGE
Cash and cash equivalents < 3 months	<b>14,976</b>	10,166	47%
<b>Total</b>	<b>14,976</b>	<b>10,166</b>	<b>47%</b>

**SHAREHOLDERS' EQUITY AND LIABILITIES****(43) Shareholders' equity****a) Subscribed capital**

Subscribed capital rose by €4,055 k, increasing from €9,872 k to €13,927 k as at 31 December 2014, due to the shares issued for the non-cash capital increase for the acquisition of Medigene Immunotherapies (1.017.811 → *section* (C)) and the cash capital increase placed in July 2014 (3.016.082) as well as the convertible bonds converted into shares (21.396). The new shares issued for the convertible bonds converted were recorded in the Commercial Register in February 2015.

Subscribed capital was divided into 13,927,428 no-par registered shares as at 31 December 2014, 100% of which had been issued and was in free float as at the reporting date.

**b) Stock options**

Equity instruments such as stock options are valued and reported in accordance with IFRS 2.

Stock options are issued to Executive Management Board members and employees. They are initially issued within one year following their joining the Company. The exercise price per option on the issue date equals the average closing price in the last 30 trading days on the XETRA trading system of the Deutsche Börse plus a premium of 20%. Holders of subscription rights may exercise their option rights at the earliest after expiry of a vesting period of four years, starting from the allotment date of the respective subscription right. The options have a contractual term of ten years. The Group has no legal or constructive obligation to repurchase options or offer a cash settlement.

In December 2014, a total of 24,277 stock options were issued to Executive Management Board members according to the shareholders' resolution by the Annual General Meeting on 10 July 2012 (conditional capital XXIII), (2013: 16,250 stock options). These stock options are not forfeited in the event that the holder of subscription rights leaves the Company, and Medigene has accordingly recognised the stock options immediately as an expense.

In December 2014, a further 18,050 stock options were issued to employees from conditional capital XXIII according to the shareholders' resolution dated 10 July 2012 (2013: 16,397 stock options). If an employee's contract of employment is terminated on grounds of personal capability or conduct, or if the option holder hands in his/her notice of resignation before the end of the relevant vesting period, all stock options are forfeited without entitlement to replacement or compensation if the vesting period for exercising such stock options has not yet expired when the contract of employment is terminated. The corresponding option expense is recognised over four years.

The average exercise price of stock options issued to Executive Management Board members and employees in December 2014 was €4.05.

**TOTAL CHANGE IN STOCK OPTIONS OUTSTANDING**

IN € K	2014		2013	
	AVERAGE EXERCISE PRICE IN €	NUMBER	AVERAGE EXERCISE PRICE IN €	NUMBER
<b>Outstanding stock options, balance at 1 January</b>	<b>18.41</b>	<b>455,363</b>	19.11	467,181
Issued	<b>4.05</b>	<b>42,327</b>	3.64	32,647
Forfeited	<b>3.95</b>	<b>-3,235</b>	4.17	-13,167
Expired	<b>31.41</b>	<b>-25,075</b>	19.50	-31,298
<b>Outstanding stock options, balance at 31 December</b>		<b>469,380</b>		<b>455,363</b>
Weighted average exercise price in € per option		<b>16.52</b>		18.41

The instruments are valued using a binomial model. The following parameters are taken into consideration:

**MEASUREMENT PARAMETERS FOR STOCK OPTION PLAN**

	2014	2013
Vesting period	<b>4 years</b>	4 years
Option term	<b>10 years</b>	10 years
Exercise threshold	<b>120%</b>	120%
Expected volatility	<b>48%</b>	48%
Risk-free interest rate	<b>0.66%</b>	1.98%

The expected volatility was determined on a historical basis and is based on the floating 250-day average prevailing at the time when options are issued. The risk-free interest rate corresponds to the yield of a hypothetical zero coupon bond excluding any credit default risk. On the issue date of the stock options it was 0.66% (source: Deutsche Bundesbank). The fair value of the stock options issued in December 2014 amounted to €2.03 per stock option (2013: €1.89). For 2014, an expense for share-based compensation totalling €66 k (2013: €60 k) was reported in accordance with IFRS. It breaks down as follows:

**EXPENSES FOR STOCK OPTIONS**

IN € K	2014	2013
Expenses for stock options from the year		
2011	<b>0</b>	19
2012	<b>10</b>	13
2013	<b>7</b>	28
2014	<b>49</b>	0
<b>Total</b>	<b>66</b>	<b>60</b>

As at 31 December 2014, the stock options outstanding were classified by exercise price, number of options issued, remaining term and options that are still convertible as follows:

<b>EXPENSES FOR STOCK OPTIONS</b>			
EXERCISE PRICE IN €	NUMBER OF STOCK OPTIONS OUTSTANDING	REMAINING TERM IN YEARS	NUMBER OF EXERCISABLE STOCK OPTIONS <sup>1)</sup>
49.48	32,794	1	32,794
40.88	27,864	2	27,864
23.52	58,530	3	58,530
17.36	74,498	4	74,498
15.56	57,897	4	57,897
14.76	42,669	5	42,669
7.48	34,233	6	34,233
4.12	38,508	7	38,508
4.20	28,858	8	0
3.64	31,202	9	0
4.05	42,327	10	0
	<b>469,380</b>		<b>366,993</b>

1) Provided the statutory vesting period has been met.

The weighted average remaining term of stock options outstanding is 4.25 years.

#### c) Authorised capital

By a shareholders' resolution dated 10 July 2012 entered into the Commercial Register on 9 August 2012, Medigene's Annual General Meeting created authorised capital of €18,541,379.00 and adjusted Art. 5 (4) of the Articles of Association accordingly. Through the resolution, the Executive Management Board of Medigene is authorised – with the approval of the Supervisory Board – to increase the share capital of Medigene by a total of up to €18,541,379.00 until 9 July 2017 on one or more occasions in return for contribution in cash or in kind (Authorised Capital 2012/I). The Executive Management Board of Medigene is authorised – with the approval of the Supervisory Board – to exclude the subscription rights of shareholders one or several times, for example when new shares are issued in return for contribution in kind. The Executive Management Board of Medigene undertook at the Annual General Meeting on 16 July 2013 only to utilise the authorised capital in accordance with the restrictions on utilisation as set out in Item 8 (3) of the invitation to the Annual General Meeting. By resolution dated 14 August 2014, the Annual General Meeting revoked the voluntary restriction undertaken by the Executive Management Board at the Annual General Meeting on 16 July 2013. In the course of the acquisition of Medigene Immunotherapies GmbH in January 2014, Medigene partly used authorised capital 2012/I to issue 1,017,811 new shares. Medigene issued 3,016,082 new shares from authorised capital (authorised capital 2012/I) to perform the cash capital increase passed by resolution on 27 June 2014 and entered in the Commercial Register on 17 July 2014.

Authorised capital 2012/I amounting to €12,101,686 remained available as at 31 December 2014.

#### d) Conditional capital and classification of conditional capital

As at 31 December 2014, the Company's share capital had been increased conditionally through a number of conditional capital items by up to €16,297,114.00, divided into a total of up to 16,297,114 ordinary shares (approx. 117% of the share capital), divided in each case into the same number of ordinary shares (no-par shares).

**CLASSIFICATION OF CONDITIONAL CAPITAL BY STOCK OPTIONS AND CONVERTIBLE BONDS**

(NUMBER)	NUMBER 31 DEC 2014 IN €	PURPOSE: TO SERVICE
I	136,897	Options
II	106,429	Options
III	125	TBG <sup>1)</sup> loan
IV	13,770	Convertible bonds
V	652,329	Convertible bonds
VI	3,000	Convertible bonds
VIII	3,000	Convertible bonds
X	3,000	Convertible bonds
XI	1,400	Convertible bonds
XII	498,560	Options
XVI	300,000	Options
XVIII	1,200,000	Options
XXII <sup>2)</sup>	10,978,604	Convertible bonds and options
XXIII	2,400,000	Options
	<b>16,297,114</b>	

<sup>1)</sup> Technologie-Beteiligungs-Gesellschaft mbH

<sup>2)</sup> Revoked in full or in part by resolution of the Annual General Meeting on 10 July 2012; some converted in 2014

Medigene issued 818,658 convertible bonds within the framework of the capital increase by cash subscription passed by resolution on 27 June 2014. During the reporting period, 21,396 shares were issued on account of 106,980 convertible bonds being converted. Conditional capital XXII decreased by €21,396.00 in the reporting period from €11,000,000 (as at 31 December 2013) to €10,978,604.

The voluntary commitment made by the Executive Management Board at the Annual General Meeting on 16 July 2013 only to utilise these individual conditional capital items in line with the restrictions on utilisation as indicated in Item 8 (3) of the invitation to the Annual General Meeting, was revoked by resolution of the Annual General Meeting dated 14 August 2014.

**(44) Pension obligations**

The amount of the pension obligations is determined as follows:

<b>PENSION OBLIGATIONS</b>		
IN € K	31 DEC 2014	31 DEC 2013
Present value of benefit obligation	<b>2,406</b>	2,250
Fair value of plan assets	<b>-1,993</b>	-1,946
<b>Defined benefit obligation</b>	<b>413</b>	<b>304</b>

The plan assets comprise pension liability insurance policies. These assets are not listed and no prices are quoted in an active market for these assets. Employer's contribution expected in 2015 totals €60 k.

The following amounts were recognised in the income statement:

<b>EXPENSES RECOGNISED IN THE INCOME STATEMENT</b>		
IN € K	2014	2013
Current service cost	<b>65</b>	55
Interest cost	<b>10</b>	10
<b>Total expenses recognised in the income statement</b>	<b>75</b>	<b>65</b>

**ACTUARIAL ASSUMPTIONS**

IN %	2014	2013
Discount rate	2.0	3.7
Future pension increases	1.0/2.0	1.0/2.0
Future salary increases	0.0	0.0

The change in the present value of the defined benefit obligations is as follows:

IN € K	
<b>Defined benefit obligation at 1 January 2013</b>	<b>2,115</b>
Interest cost	76
Current service cost	55
Employee contributions	8
Actuarial gains	-4
<b>Defined benefit obligation at 31 December 2013</b>	<b>2,250</b>
Interest cost	83
Current service cost	65
Plan settlements	-71
Employee contributions	7
Actuarial losses	72
<b>Defined benefit obligation at 31 December 2014</b>	<b>2,406</b>
thereof	
funded	1,993
unfunded	413

The change in the present value of plan assets is as follows:

IN € K	
<b>Fair value of plan assets as at 1 January 2013</b>	<b>1,812</b>
Interest income	66
Employer contributions	65
Employee contributions	8
Actuarial losses	-5
<b>Fair value of plan assets as at 31 December 2013</b>	<b>1,946</b>
Interest income	73
Employer contributions	60
Employee contributions	7
Plan settlements	-64
Actuarial losses	-29
<b>Fair value of plan assets as at 31 December 2014</b>	<b>1,993</b>

**(45) Taxes**

The major income tax components for the 2014 and 2013 fiscal years are as follows:

INCOME TAXES		2014	2013
IN € K			
<b>Current income taxes</b>			
Current income tax expenses (foreign withholding tax on royalties and milestone payments)		0	-18
Adjustments in respect of current income tax of previous year		0	0
<b>Deferred taxes</b>		155	0
<b>Income tax income/expense reported in income statement</b>		155	-18

In the reporting period, deferred tax income of €155 k was posted in the income statement. It is generally a result of recognition of additional deferred tax assets on unused tax losses of Medigene AG on account of the profit and loss transfer agreement and a consolidated tax group between Medigene AG and Medigene Immunotherapies GmbH. In the previous year 2013, the Group reported a tax expense of €18 k from foreign withholding tax on royalties received by Medigene AG and a net loss for the year.

Deferred taxes as at 31 December 2014 related to the following items:

DEFERRED TAXES IN € K	CONSOLIDATED BALANCE SHEET		CONSOLIDATED INCOME STATEMENT	
	31 DEC 2014	31 DEC 2013	2014	2013
	<b>Deferred tax assets</b>			
Deferred taxes on unused tax losses				
Germany	51,412	49,905	1,507	2,672
United States	17,118	16,964	154	-700
Subtotal	68,530	66,869	1,661	1,972
thereof unrecognised	-65,422	-63,886	-1,536	-1,901
<b>Net</b>	<b>3,108</b>	<b>2,983</b>	<b>125</b>	<b>71</b>
Property, plant and equipment	18	13	5	0
Other taxes from subsidies/relief	1,990	1,757	233	-77
Investment in associates	222	170	52	36
Other assets	0	16	-16	12
Other liabilities and accruals	546	72	474	59
Pension liability insurance	337	350	-13	29
Subtotal	3,113	2,378	735	59
thereof unrecognised	-2,212	-1,944	-268	31
<b>Net</b>	<b>901</b>	<b>434</b>	<b>467</b>	<b>90</b>
Total deferred tax assets	4,009	3,417	592	161
<b>Deferred tax liabilities</b>				
Intangible assets	5,986	3,166	2,820	267
Property, plant and equipment	115	1	114	1
Other assets	66	0	66	0
Pension accruals	192	218	-26	8
Other liabilities and accruals	3	32	-29	-115
Total deferred tax liabilities	6,362	3,417	2,945	161
<b>Net deferred tax liabilities</b>	<b>2,353</b>	<b>0</b>	<b>2,353</b>	<b>0</b>
thereof deferred tax liabilities recognised outside of profit or loss from purchase price allocation			-2,508	0
thereof deferred tax income			155	0

The calculation of deferred tax in Germany has been based on a combined tax rate of 26.33% since 1 January 2008. This is composed as follows: 15% corporate income tax, 5.5% solidarity surcharge on the corporate income tax and 10.5% trade tax.

Country-specific tax rates were applied for the deferred taxes of foreign operations.

The reported tax expenses differ from the expected tax expenses which would have resulted from the application of the nominal tax rate to profit or loss under IFRS. A reconciliation of the difference can be seen in the following table, in which the tax rate applicable in the respective period was used.

The increase in unrecognised deferred tax assets shown below does not correspond to the amount of unrecognised deferred tax assets on unused tax losses mentioned above, due to the different exchange rates (transaction exchange rate at the date of business transaction, or the average rate for the conversion of earnings before tax versus the corresponding closing rate for unrecognised deferred tax assets).

<b>INCOME TAXES</b>		
IN € K	2014	2013
<b>Earnings before tax</b>	<b>-5,912</b>	<b>-10,264</b>
Expected tax income	1,557	2,702
Increase in unrecognised deferred tax assets	-1,381	-2,734
Non-deductible expenses	-58	-42
International tax rate differences	22	32
Other	15	24
<b>Reported tax expense</b>	<b>155</b>	<b>-18</b>
<b>Effective tax rate (%)</b>	<b>2.6</b>	<b>0</b>

The breakdown of unused tax losses is as follows:

<b>UNUSED TAX LOSSES</b>		
IN € K	2014	2013
Corporate income tax Germany	197,066	190,595
Trade tax Germany	193,676	188,030
State tax USA	44,683	40,575
Federal tax USA	21,791	39,344

In Germany, tax losses may generally be carried forward for an unlimited period of time. The deduction of existing loss carryforwards is ruled out in the event of harmful changes in the shareholder structure.

The unused tax losses of Medigene, Inc. will expire between 2015 and 2034. In the USA, unused tax losses based on federal tax may be utilised for 20 years, whereas those based on state tax expire after between 10 and 20 years, unless an extension is granted.

#### **(46) Trade accounts payable and other current financial liabilities**

The trade accounts payable of €1,785 k (2013: €1,419 k) as at the end of the reporting period consisted of unpaid invoices issued primarily for services utilised by Medigene. For the maturity analysis of the financial liabilities, please refer to → *note (50)*.

Other current financial liabilities amounting to €5,913 k (2013: €3,651 k) include the current portion of the liability relating to the assignment of the future cash flows from the 2% share in Eligard® revenue to Cowen totalling €1,177 k (2013: €1,044 k) → *note (4)*, bonus payments due of €747 k (2013: €621 k), the current portion of liabilities to former shareholders of Medigene Immunotherapies relating to milestones amounting to €3,076 k (2013: €0 k) and liabilities for vacation accrued and overtime amounting to €193 k (2013: €162 k).

## (47) Deferred income

Deferred income in the reporting period totalled €283 k (2013: €358 k). It mainly resulted from current deferred income of €57 k (2013: €22 k) and non-current deferred income of €226 k (2013: €336 k). It includes the non-recurring upfront payment from the development and marketing partnering agreement agreed on with SynCore for EndoTAG<sup>®</sup>-1.

## (48) Contingent liabilities

No accruals were recognised for the contingent liabilities listed below, as the risk of claims being made is deemed unlikely.

In 2004, Medigene concluded an agreement with the insolvency administrator of MBT, under which payments by Medigene to the insolvency administrator were agreed in the event of certain milestones being achieved, including a milestone payment upon commencement of a clinical phase III trial for EndoTAG<sup>®</sup>-1. In connection with signing the SynCore agreement in July 2012, the Company came to an agreement with the insolvency administrator, which provides for Medigene not making any milestone payments and only having to transfer a low percentage of the income achieved. According to the agreement, the amount is limited to a total amount of €11 m and is payable in instalments. Management does not believe that accruals need to be formed for this, since the relevant payments will not become due until specific events occur. At the reporting date the occurrence of these events was not probable.

Expenses of €1,002 k (2013: €950 k) were incurred for operating leases in the reporting period.

The future annual rent and lease payments for operating leases are as follows:

IN € K	RENT AND LEASE PAYMENTS
2015	1,283
2016	1,226
2017	1,152
2018	1,090
thereafter	1,673
<b>Minimum lease obligations</b>	<b>6,424</b>

The Company leases office and laboratory facilities, office furnishings, laboratory equipment and vehicles. These constitute operating leases, as the contractual agreement does not transfer any risks or rewards to the Group. The conditions, rental increase clauses and extension options of the lease agreements vary.

The Group can terminate these lease agreements upon notice of one month to six years, depending on the contract.

## (49) 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 well as the associates Catherex, Inc. and Aettis and partner company SynCore.

Dr. Frank Mathias, CEO of Medigene AG, and Peter Llewellyn-Davies, CFO of Medigene AG, were appointed to the supervisory board of Catherex, Inc. and Aettis, Inc. Medigene, Inc. extended an interest-bearing loan to Catherex, Inc., stepping this up to €352 k (2013: €242 k) in the reporting period → *note (38)*. An interest-bearing loan of €33 k was granted to Aettis.

Medigene AG recognised revenue from R&D payments of €1,936 k arising from its partnering agreement with SynCore for EndoTAG<sup>®</sup>-1 as well as milestone payments totalling €2,699 k. For Veregen<sup>®</sup>, Medigene AG received milestone payments amounting to €76 k as well as revenue from product sales of €129 k.

Dr. Yita Lee, Chief Scientific Officer of the Sinphar group in Taiwan, was appointed to the Supervisory Board of Medigene AG at the Annual General Meeting in 2013. As at 31 December 2014, SynCore held 5.5% of the shares in Medigene AG.

The remuneration and shareholdings of the Company's Executive Management Board and Supervisory Board members are itemised for each member of these boards under → *1) »Executive Management Board and Supervisory Board«* in *notes (55) and (56)*. In the past fiscal year, there were no further transactions between the Group and related parties.

## (50) Objectives and methods of financial risk management

The main financial liabilities are trade accounts payable, other financial liabilities and loans. The Group possesses various financial assets, trade accounts receivable and cash.

Through its business activities, the Group is exposed to various financial risks: market risks (including interest rate risks and foreign currency risks), credit risks, liquidity risks and cash flow interest rate risks.

Below is a description of the financial risk factors and the associated financial risk management of the Group. Management does not consider the financial risks to the following items to be significant.

### Market risks

#### Interest rate risk

Fluctuations in market interest rates impact the cash flows relating to variable interest-bearing assets and additionally the fair value of pension obligations. Medigene's management has deliberately decided not to carry out transactions aimed at hedging interest-based cash flows because short-term availability for financing operating activities is a priority when investing cash.

#### SENSITIVITY ANALYSIS OF INTEREST RATE RISK (CASH FLOWS)

	INTEREST RATE CHANGE IN BASE POINTS	EFFECTS ON EARNINGS BEFORE TAX IN € K
2014	50	58
2013	50	71

### Foreign currency risk

Foreign currency risks arise when future business transactions and assets and liabilities reported in the balance sheet are denominated in a currency other than the Company's functional currency. The Group operates internationally and is therefore exposed to foreign currency risks based on exchange rate fluctuations between the US dollar, yen and euro. The subsidiary Medigene Inc. uses the US dollar as its functional currency.

The foreign currency risk mainly relates to revenue generated in US dollars from Veregen<sup>®</sup> sales, as well as milestone payments received for Veregen<sup>®</sup> from partner companies. In addition, the cost of purchasing the active pharmaceutical ingredient in Veregen<sup>®</sup> as well as the licence payments to licensors associated with sales of this product depend on the exchange rates of foreign currencies. Of the total revenue earned by the Group, 39% is generated in US dollars. In total, 57% of procurement costs were incurred in US dollars.

The Group reduces the foreign currency risks resulting from its subsidiary's operating activities by utilising the proceeds in US dollars generated from products marketed to finance the purchase of goods and other activities by the US subsidiary. The table below shows the sensitivity of the Group's earnings before tax and of shareholders' equity to exchange rate fluctuations of the euro against the US dollar. All other variables in this presentation remain constant.

#### SENSITIVITY ANALYSIS OF FOREIGN CURRENCY RISK (€)<sup>1)</sup>

	EXCHANGE RATE DEVELOPMENT OF \$	EFFECTS ON EARNINGS BEFORE TAX IN € K	EFFECTS ON SHAREHOLDERS' EQUITY IN € K
<b>2014</b>	<b>+5%</b>	<b>-83</b>	<b>-83</b>
	<b>-5%</b>	<b>71</b>	<b>71</b>
<b>2013</b>	<b>+5%</b>	<b>-84</b>	<b>-84</b>
	<b>-5%</b>	<b>71</b>	<b>71</b>

<sup>1)</sup> Referring to the exchange rate as at the reporting date 31 December.

### Securities-related market risk

The Group is exposed to the usual market fluctuations relating to pension liability insurance policies → *note (38)*.

### Credit risk

There is no significant risk concentration of potential credit risks within the Group. Two business relationships exist with major customers, Fougera Pharmaceuticals, Inc., Melville, New York, USA and SynCore. Creditworthiness is monitored on the basis of publicly available management reports and consolidated financial statements.

With regard to the Group's other financial assets, such as cash and cash equivalents, the maximum credit risk in the event of default by the counterparty is the equivalent of the carrying amount of these instruments.

### Liquidity risk

→ *see also »Financing risks« in A) »Description of business activity, information about the Company«.*

As at 31 December 2014, the Group's financial liabilities were due as shown below. With the exception of non-cash financial liabilities to Cowen, all information is given based on contractual undiscounted payments.

**FINANCIAL LIABILITIES**

IN € K	MATURITY					TOTAL
	UP TO 30 DAYS	30-90 DAYS	3-12 MONTHS	1-5 YEARS	>5 YEARS	
<b>Balance at 31 Dec 2014</b>						
Trade accounts payable	1,785	0	0	0	0	<b>1,785</b>
Financial liabilities to Cowen $\rightarrow$ note (4)	0	0	1,177	6,402	4,195	<b>11,774</b>
Liabilities to former shareholders of Medigene Immunotherapies $\rightarrow$ section (C)	0	700	3,175	2,000	0	<b>5,875</b>
Other financial liabilities	676	843	141	354	0	<b>2,014</b>
<b>Total</b>	<b>2,461</b>	<b>1,543</b>	<b>4,493</b>	<b>8,756</b>	<b>4,195</b>	<b>21,448</b>
<b>Balance at 31 Dec 2013</b>						
Trade accounts payable	1,419	0	0	0	0	<b>1,419</b>
Financial liabilities to Cowen $\rightarrow$ note (4)	0	0	1,044	5,681	4,675	<b>11,400</b>
Other financial liabilities	554	1,870	162	312	0	<b>2,898</b>
<b>Total</b>	<b>1,973</b>	<b>1,870</b>	<b>1,206</b>	<b>5,993</b>	<b>4,675</b>	<b>15,717</b>

**Capital management**

The primary objective of Medigene's management is to secure sufficient liquidity to finance ongoing research and development programmes. The most important management indicator aside from the absolute amount of cash and cash equivalents is the ratio of cash to total assets. A sufficiently high equity ratio is needed to make flexible use of the equity and debt financing opportunities arising on the market.

**KEY CAPITAL MANAGEMENT RATIOS**

IN %	2014	2013	
Cash to total assets ratio	$\frac{\text{Cash and cash equivalents} \times 100}{\text{Total assets}}$	<b>21</b>	<b>19</b>
Equity ratio	$\frac{\text{Shareholders' equity} \times 100}{\text{Total shareholders' equity and liabilities}}$	<b>69</b>	<b>69</b>

The cash received from the capital increase led to an improvement in the cash to total assets ratio to 21% (2013: 19%) while the equity ratio remained constant at 69%.

**(51) Other financial assets and liabilities including hierarchy of fair values**

The table below indicates the carrying amounts and fair values of all financial instruments recognised in the consolidated financial statements as at 31 December 2014:

**OTHER FINANCIAL ASSETS AND LIABILITIES**

IN € K	CARRYING AMOUNT		FAIR VALUE	
	2014	2013	2014	2013
<b>Available-for-sale financial assets and financial liabilities at fair value</b>				
Pension liability insurance policies	180	154	180	154
Investment in Immunocore Ltd.	3,620	3,533	3,620	3,533
Liability to pay contingent consideration to the former shareholders of Medigene Immunotherapies	3,611	0	3,611	0
<b>Assets and liabilities recognised at fair value</b>				
<b>Financial assets</b>				
Cash and cash equivalents	14,976	10,166	14,976	10,166
Trade accounts receivable	1,733	1,363	1,733	1,363
Loans and receivables	385	242	385	242
<b>Financial liabilities</b>				
Financial liabilities to Cowen → <i>note (4)</i>	11,774	11,400	11,774	11,400
Trade accounts payable	1,785	1,419	1,785	1,419
Other financial liabilities (without Cowen)	1,993	2,898	1,993	2,898

**Hierarchy of fair values**

The Group uses the following hierarchy for determining and disclosing the fair value of financial instruments by valuation technique:

Level 1: Quoted (unadjusted) prices on active markets for identical assets or liabilities

Level 2: Valuation techniques for which all the input parameters that are significant to fair value measurement are directly or indirectly observable

Level 3: Valuation techniques that use input parameters that are significant to fair value measurement and are not based on observable data

The fair values of cash and cash equivalents as well as trade accounts receivable and trade accounts payable approximate their carrying amounts, mainly because of their short-term nature.

Level 1 includes the pension liability insurance policies reported under available-for-sale financial assets, which are valued at the stock exchange price as at the reporting date. Shares in Immunocore Ltd. → *note (38)*, which are also allocated to available-for-sale financial assets, are classified to level 3 of the hierarchy.

Loans and receivables are allocated to level 2 of the hierarchy. The financial liability to Cowen → *note (4)* as well as the liability to pay contingent consideration to the former shareholders of Medigene Immunotherapies → *section (C)* and other current and non-current financial liabilities are classified to level 3. The fair value of the liability owed to Cowen is determined on the basis of the estimated future royalty income.

## F) SEGMENT REPORTING

### Business units

The Group was made up of two main business units as at 31 December 2014. The business units »Marketed drugs« and »Drug candidates« identified within the Group in accordance with IFRS 8 consist of the following:

#### Marketed drugs:

→ Veregen<sup>®</sup> for the treatment of genital warts

#### Drug candidates & technologies:

- Immunotherapies
  - Dendritic cell vaccines (DC)
  - T cell receptor (TCR) modified T cells
  - T Cell-specific monoclonal antibodies (TABs)
- EndoTAG<sup>®</sup>-1
- RhuDex<sup>®</sup>
- AAVLP technology

Revenue earned by the individual segments is generated by external business relationships.

Transfer prices between the business units and regions are determined on the basis of arm's length conditions.

The investment in an associate amounting to €2,781 k (2013: €2,513 k) is shown in segment reporting under »Reconciliation«.

IN € K	MARKETED DRUGS	DRUG CANDIDATES	TOTAL OPERATING SEGMENTS	RECONCILIATION <sup>1)</sup>	TOTAL
<b>2014</b>					
Revenue with external customers	5,195	0	5,195	0	<b>5,195</b>
Other revenue	6	6,073	6,079	2,510	<b>8,589</b>
Inter-segment sales <sup>2)</sup>	329	2,863	3,192	-3,192	<b>0</b>
<b>Total revenue</b>	<b>5,530</b>	<b>8,936</b>	<b>14,466</b>	<b>-682</b>	<b>13,784</b>
<b>Segment operating result<sup>3)</sup></b>					
Depreciation and amortisation	-2	-666	-668	-142	<b>-810</b>
Share of result of associates	0	0		-56	<b>-56</b>
<b>Assets</b>					
Investment in associates	0	0	0	2,781	<b>2,781</b>
Segment investments <sup>4)</sup>	0	10,490	10,490	75	<b>10,565</b>
<b>Segment assets<sup>5)</sup></b>	<b>6,139</b>	<b>38,377</b>	<b>44,516</b>	<b>26,767</b>	<b>71,283</b>
<b>Segment liabilities<sup>6)</sup></b>	<b>1,284</b>	<b>283</b>	<b>1,567</b>	<b>20,645</b>	<b>22,212</b>
<b>2013</b>					
Revenue with external customers	4,209	0	4,209	0	<b>4,209</b>
Other revenue	18	851	869	2,514	<b>3,383</b>
Inter-segment sales <sup>2)</sup>	307	0	307	-307	<b>0</b>
<b>Total revenue</b>	<b>4,534</b>	<b>851</b>	<b>5,385</b>	<b>2,207</b>	<b>7,592</b>
<b>Segment operating result<sup>3)</sup></b>					
Depreciation and amortisation	-1	-571	-572	-179	<b>-751</b>
Share of result of associates	0	0	0	-102	<b>-102</b>
<b>Assets</b>					
Investment in associates	0	0	0	2,513	<b>2,513</b>
Segment investments <sup>4)</sup>	0	0	0	142	<b>142</b>
<b>Segment assets<sup>5)</sup></b>	<b>4,409</b>	<b>29,170</b>	<b>33,579</b>	<b>19,076</b>	<b>52,655</b>
<b>Segment liabilities<sup>6)</sup></b>	<b>0</b>	<b>358</b>	<b>358</b>	<b>16,021</b>	<b>16,379</b>

<sup>1)</sup> »Reconciliation« includes information that cannot be allocated to either the »Marketed drugs« segment or the »Drug candidates« segment, as it does not constitute any activity. The liabilities to Cowen were reclassified in 2013 from »Marketed drugs« to »Reconciliation«.

<sup>2)</sup> Inter-segment sales are eliminated for consolidation purposes.

<sup>3)</sup> Segment operating result does not include any interest income (2014: €27 k; 2013: €24 k), any interest expenses (2014: €1,801 k; 2013: €1,577 k), any foreign exchange losses/gains (2014: €-1,201 k; 2013: €412 k), or any share of losses of associates (2014: €56 k; 2013: €102 k). The segment result for the previous year was adjusted according to the changed presentation of the segment result for the fiscal year.

<sup>4)</sup> Segment investments relate to additions to property, plant and equipment and intangible assets.

<sup>5)</sup> Segment assets under »Reconciliation« include non-current assets (2014: €8,240 k; 2013: €7,222 k), cash and cash equivalents (2014: €14,976 k; 2013: €10,166 k), and other current assets (2014: €3,551 k; 2013: €1,688 k).

<sup>6)</sup> Segment liabilities under »Reconciliation« include non-current liabilities (2014: €11,878 k; 2013: €10,951 k), trade accounts payable and other financial liabilities (2014: €7,698 k; 2013: €5,070 k).

## Geographic or regional segments

The Group operates mainly in Europe and the US.

### REVENUE WITH EXTERNAL CUSTOMERS

IN € K	2014	2013
United States	<b>2,613</b>	3,246
Europe	<b>2,453</b>	769
Other	<b>129</b>	194
<b>Total</b>	<b>5,195</b>	<b>4,209</b>

Information about segment revenue is based on the relevant customer locations.

The majority of non-current assets are held in Germany. In addition, a shareholding is held in the associates in the USA (Catherex, Inc. and Aettis, Inc.).

## (52) Legal disputes and appeals

In June 2010, a third party opposed the granting of European Patent No. EP 1530465 to Medigene AG. The patent relates to the manufacturing process for EndoTAG<sup>®</sup>-1 and to compositions that can be manufactured using this process. In December 2011, the European Patent Office ruled at the first hearing that the patent is upheld to an extent which continues to protect the product EndoTAG<sup>®</sup>-1. In the course of the opposition proceeding, Medigene AG had restricted its patent claims to the features that are relevant to EndoTAG<sup>®</sup>-1. The opponent filed a notice of appeal against the decision of the European Patent Office. This appeal was withdrawn in March 2015. The opposition proceeding has thus been closed and the decision is non-appealable. The patent has been upheld to an extent which continues to protect the product EndoTAG<sup>®</sup>-1.

The European Patent EP 2108362 was granted in May 2013 from a divisional application of the above-mentioned patent. The patent refers to specific liposomal compositions with a specific stability comprising taxanes. In February 2014, an opposition proceeding was also filed against this patent. This opposition was withdrawn in March 2015. Medigene assumes that the patent will be upheld unchanged. Even if, contrary to expectations, limitations should have to be made, the Company expects the product EndoTAG<sup>®</sup>-1 to remain protected. The risk situation in terms of patent protection for EndoTAG<sup>®</sup>-1 has improved considerably compared to the previous year by the withdrawal of the appeal against patent EP 1530465 and the withdrawal of the opposition against patent EP 2108362. Further judicial disputes in the future cannot be ruled out.

## (53) German Corporate Governance Code

Medigene AG's Executive Management Board and Supervisory Board confirmed in their declaration of compliance pursuant to Section 161 of the German Stock Corporation Act (AktG) of 3 December 2014 that Medigene AG complies with the recommendations of the German Corporate Governance Code in the versions dated 13 May 2013 and 24 June 2014, with the exceptions mentioned in the declaration of compliance. The recommendations of the Code which Medigene AG does not implement are explained and justified in the declaration of compliance. This declaration is available in English and German on the Medigene AG website at <http://www.medigene.de/presse-investoren/corporate-governance>. The declarations of compliance of Medigene AG are available on the website of the Company for at least five years.

## (54) Audit fees

The auditors of the Company and the Group received the following fees for the past fiscal year:

<b>AUDIT FEES</b>		
IN € K	2014	2013
Audit services	137	128
Audit related services (review of quarterly reports)	14	7
Tax advisory services	0	6
Other services (including fees in the context of the business combination and for the comfort letter procedures in the scope of the capital increase completed in July 2014)	393	145
<b>Total</b>	<b>544</b>	<b>286</b>

## **G) EXECUTIVE MANAGEMENT BOARD AND SUPERVISORY BOARD**

### **(55) Executive Management Board**

#### **Remuneration of the Executive Management Board**

Remuneration of the members of the Executive Management Board totalled €1,303 k in the past fiscal year (2013: €1,030 k), including pension expenses of €48 k (2013: €48 k) and vehicle leasing costs for company cars of €33 k (2013: €29 k). In addition, stock options with a fair value of €51 k (2013: €31 k) were issued to the Executive Management Board.

In fiscal year 2014, Medigene made a payment of €6 k (2013: €6 k) to the Company's welfare fund in connection with a pension commitment to a former member of the Executive Management Board.

Pursuant to no. 2.2.1 (2) of the German Corporate Governance Code, the Annual General Meeting may pass a resolution to approve the remuneration system for Executive Management Board members. The resolution approving the current remuneration system was passed at the Annual General Meeting on 11 May 2010. A majority of 96% of the share capital represented adopted the remuneration system for Executive Management Board members.

#### **Report on the remuneration system for members of the Executive Management Board of Medigene AG**

The full Supervisory Board is responsible for setting the remuneration of Medigene AG's Executive Management Board members. It is regularly reviewed, taking into account the regulations relating to the Supervisory Board pursuant to Section 87 (1) and (2) of the German Stock Corporation Act (AktG) and the recommendations of the German Corporate Governance Code.

The most recent adjustments made by the Supervisory Board in light of the German Act on Appropriate Executive Board Remuneration (VorstAG), which came into force on 5 August 2009. At the Annual General Meeting 2010, the Executive Management and Supervisory Boards presented the current remuneration system for Executive Management Board members. It was adopted by a majority of 96% of the share capital represented. The remuneration system has been implemented in all current employment contracts for Executive Management Board members as described below:

The amount and structure of the remuneration of Executive Management Board members depend on the respective responsibilities of each Executive Management Board member, the Company's economic and financial position and the sustained growth of the Company as well as common practice regarding remuneration, taking into account the amount and structure of the remuneration which is paid to others by the Company and that is paid in similar companies.

In addition, remuneration is based on the individual performance of Executive Management Board members as well as the achievements of the Executive Management Board as a whole. Remuneration is designed as an incentive for achieving sustainable corporate growth and a sustained increase in business value.

Total remuneration comprises fixed and variable components as well as other benefits, as described below:

#### **a) Fixed remuneration**

Each member of the Executive Management Board receives fixed remuneration, which is not performance-related and is paid in monthly instalments. The amount of the fixed remuneration is determined on the basis of the principles described above.

#### **b) Variable remuneration**

##### **1) Annual performance-related remuneration**

In addition to fixed remuneration, Executive Management Board members are entitled to variable remuneration, which is dependent on the achievement of several targets specified by the Supervisory Board in advance. The annual performance-related remuneration amounts to 50% of fixed remuneration if 100% of the targets are met and may be a maximum of 75% of fixed remuneration.

**(1) Setting of objectives**

The Supervisory Board sets annual objectives, both comprehensively for all Executive Management Board members and, in addition, separately for each member of the Executive Management Board. The objectives are weighted by the Supervisory Board.

**(2) Establishing the amount of annual performance-related remuneration**

The individual objectives set by the Supervisory Board are allocated to one of three possible objectives achievement scenarios: low case, base case and best case.

- The low case scenario corresponds to a 50% achievement of targets, the base case to 100% and the best case to 150%.
- In the event that achievement of objectives is below the low case threshold, no variable remuneration is paid. If the achievement of objectives is in the range between the low case and base case, variable remuneration increases on a straight-line basis according to the objective percentage achieved. If the target achievement is in the range between base case and best case, there is no straight-line increase and only the fulfilment of the best case scenario corresponds to an objective achievement of 150%. Objective achievement which surpasses the best case is not reflected in terms of higher remuneration. To this extent, variable remuneration is capped.
- The amount of the annual performance-related remuneration is calculated on the basis of the objective achievement percentage in relation to the specific targets, taking into account the weighting of the relevant objective.

**(3) Short-term and long-term components of annual performance-related remuneration**

- 65% of the annual performance-related payment granted is paid after the Company's financial statements for the relevant fiscal year have been adopted. Payment of the remaining 35% of the annual performance-related remuneration granted in a specific fiscal year is deferred for a period of three years.
- At the end of this three-year period, the Supervisory Board decides whether and to what extent sustained corporate growth can be affirmed. Based on this decision, the Supervisory Board resolves whether and to what extent the remaining 35% of the relevant annual performance-based remuneration will be paid to the respective Executive Management Board member with appropriate interest.
- The Supervisory Board's decision regarding sustained corporate growth is primarily based on the long-term trend in business value and, therefore, also the share price of the Company's shares. The members of the Executive Management Board thus participate in the Company's long-term growth on the basis of this remuneration component, and they also share in any negative developments.

**2) Stock options**

- In addition, Executive Management Board members are granted stock options on the basis of the Company's stock option programme. Stock options represent another long-term remuneration component. They are aimed at providing a performance incentive which is geared to sustainable long-term corporate growth.
- Stock options are initially granted to each Executive Management Board member within the first year of their joining the Company. Subsequently, Executive Management Board members receive further stock options every year. The exercise price corresponds to the average closing price of the last 30 trading days prior to the issue of the stock option plus a 20% premium.
- Executive Management Board members may exercise their stock options at the earliest after a vesting period of four years, starting from the date of allotment of the relevant subscription right. The options have a contractual term of ten years.
- Based on the principles stated in this paragraph relating to the remuneration system, each Executive Management Board member receives a specific number of stock options, which is separately set for each member every year.

**c) Other benefits**

In addition to the above-mentioned remuneration components, members of the Executive Management Board are granted additional benefits, in particular

- a company car,
- reimbursement of business travel expenses,
- accident insurance coverage and payment of the relevant insurance premiums,
- D&O insurance with a deductible according to the statutory minimum amount and
- payment of an amount of €2 k per month as a pension contribution.

The proportional structure of annual performance-related remuneration with a three-year sustainability component and the terms of stock options with a four-year vesting period prior to exercising the stock options create a significant incentive to achieve sustained corporate growth, ensuring a balanced mix of short-term and long-term remuneration components.

**d) Special termination right in the event of a change in control**

The contracts of employment for Executive Management Board members Dr. Frank Mathias, Mr. Peter Llewellyn-Davies and Prof. Dolores Schendel include special termination rights for both the Company and the Executive Management Board members in the event of a change in control.

A change in control within the meaning of the contractual agreement valid for Dr. Frank Mathias exists in the event of direct or indirect purchase of company shares by a third party, which results in the third party directly or indirectly holding within the meaning of Section 30 of the German Securities Acquisition and Takeover Act (WpÜG), at least 30% of the Company's voting rights or more than 50% of the voting rights present on average at the Company's Annual General Meetings during the past three calendar years.

A change in control within the meaning of the contractual agreement valid for Mr. Peter Llewellyn-Davies and Prof. Schendel exists in the event of direct or indirect purchase of company shares by a third party, which results in the third party directly or indirectly holding at least 30% of the Company's voting rights within the meaning of Section 30 of the German Securities Acquisition and acquisition Act (WpÜG).

In the event of a change in control, the Company has a special termination right for a period of one year following the date of the change in control in each case.

The above-mentioned Executive Management Board members each have a special termination right for a period of one year after the date of the change in control if this change results in an unacceptable shift in the previous duties and responsibilities of the relevant Executive Management Board member (budget, number of employees supervised and his/her role on the Board), or if the Company informs him/her that his/her appointment as Executive Management Board member will not be renewed and denial of such renewal is not based on significant cause for which he/she bears responsibility justifying extraordinary termination of the relevant Executive Management Board member's contract.

If the term of office of Executive Management Board member Dr. Frank Mathias comes to an end as a result of the Company exercising its special termination right referred to above, he will be entitled to receive a severance payment in the amount of the gross remuneration up to the regular end of his contract, a pro rata temporis gross bonus (without stock options) up to the regular end of his contract on the basis of the average annual bonus of the past three full years prior to termination of that contract and a severance payment amounting to 2.5 times the annual remuneration owed to him (without stock options).

This severance payment may exceed neither the sum of three times the total annual remuneration plus the average annual bonus agreed at the time of the termination of employment, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract, nor the sum of €750 k (caps). However, the Company's Supervisory Board may at its discretion waive the last mentioned cap in recognition of Dr. Mathias' outstanding achievements and extraordinary commitment in the situation leading to this special termination.

In the event that Executive Management Board member Dr. Frank Mathias resigns under the special termination conditions listed above, he will be entitled to receive a severance payment in the amount of three times the gross monthly sum for every completed year of his membership of the Company's Executive Management Board. The gross monthly amount is comprised of one twelfth of the current gross remuneration at the time of resignation and one twelfth of the average annual bonus. The severance payment may exceed neither the total of 36 gross monthly salary payments, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract, nor the sum of €750 k (caps). However, the Company's Supervisory Board may at its discretion waive the last mentioned cap in recognition of Dr. Mathias' outstanding achievements and extraordinary commitment in the situation leading to this special termination. The minimum severance payment amounts to six gross monthly salary payments (lower limit).

If the term of office of Executive Management Board member Peter Llewellyn-Davies comes to an end as a result of the Company exercising its special termination right referred to above, he will be entitled to receive a severance payment in the amount of the gross remuneration up to the regular end of his contract, a pro rata temporis gross bonus (without stock options) up to the regular end of his contract on the basis of the average annual bonus of the past three full years prior to termination of that contract and a severance payment amounting to 2.5 times the annual remuneration owed to him (without stock options). This severance payment may exceed neither the sum of three times the total annual remuneration plus the average annual bonus agreed at the time of the termination of employment, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract, nor the sum of €429 k (caps).

In the event that Executive Management Board member Peter Llewellyn-Davies resigns under the special termination conditions listed above, he will be entitled to receive a severance payment in the amount of three times the gross monthly sum for every completed year of his membership of the Company's Executive Management Board. The gross monthly amount is comprised of one twelfth of the current gross remuneration at the time of resignation and one twelfth of the average annual bonus. The severance payment may exceed neither the total of 36 gross monthly salary payments, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract (caps). The minimum severance payment amounts to six gross monthly salary payments (lower limit).

If the term of office of Executive Management Board member Prof. Dolores Schendel comes to an end as a result of the Company exercising its special termination right referred to above, she will be entitled to receive a severance payment in the amount of the gross remuneration up to the regular end of her contract, a pro rata temporis gross bonus (without stock options) up to the regular end of her contract on the basis of the average annual bonus of the past three full years prior to termination of that contract and a severance payment amounting to 2.5 times the annual remuneration owed to her (without stock options). This severance payment may exceed neither the sum of three times the total annual remuneration plus the average annual bonus agreed at the time of the termination of employment, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract, nor the sum of €410,130 (caps).

In the event that Executive Management Board member Prof. Dolores Schendel resigns under the special termination conditions listed above, she will be entitled to receive a severance payment of an amount three times her gross monthly sum for every completed year of her membership of the Company's Executive Management Board. The gross monthly amount is comprised of one twelfth of the current gross remuneration at the time of resignation and one twelfth of the average annual bonus. The severance payment may exceed neither the total of 36 gross monthly salary payments, nor 1.5 times the remuneration anticipated for the remaining term of the employment contract (caps). The minimum severance payment amounts to six gross monthly salary payments (lower limit).

The following table shows the benefits granted as management remuneration, which amounted to €1,354 k in the 2014 fiscal year (2013: €1,061 k).

#### REMUNERATION OF THE EXECUTIVE MANAGEMENT BOARD - BENEFITS GRANTED

IN € K	DR. FRANK MATHIAS		PETER LLEWELLYN-DAVIES		PROF. DOLORES J. SCHENDEL	
	CHIEF EXECUTIVE OFFICER SINCE 1 APRIL 2008		CHIEF FINANCIAL OFFICER SINCE 1 OCTOBER 2012		CHIEF SCIENTIFIC OFFICER SINCE 1 MAY 2014	
	2014	2013	2014	2013	2014	2013
Fixed remuneration	356	375	277	260	198	0
Fringe benefit <sup>1)</sup>	44	40	37	37	0	0
<b>Total</b>	<b>400</b>	<b>415</b>	<b>314</b>	<b>297</b>	<b>198</b>	<b>0</b>
Variable performance-based components <sup>2)</sup>	171	188	133	130	87	0
<b>Total</b>	<b>571</b>	<b>603</b>	<b>447</b>	<b>427</b>	<b>285</b>	<b>0</b>
Variable components in the form of stock options						
Number of stock options on the reporting date	9,839	8,750	9,438	7,500	5,000	0
Fair value	18	17	15	14	18	0
<b>Total</b>	<b>589</b>	<b>620</b>	<b>462</b>	<b>441</b>	<b>303</b>	<b>0</b>

<sup>1)</sup> Fringe benefits include pension expenses amounting to €48 k (2013: €48 k), and vehicle leasing amounting to €33 k (2013: €29 k) for the members of the Executive Management Board.

<sup>2)</sup> On the basis of the accruals for 2014/2013 (without discounting) and a 100% pay-out based on an estimated target achievement of 96% in 2014 and 100% in 2013.

The following table shows the remuneration paid out, which amounted to €1,130 k in the 2014 fiscal year (2013: €806 k).

#### REMUNERATION PAID TO THE EXECUTIVE MANAGEMENT BOARD

IN T€	DR. FRANK MATHIAS		PETER LLEWELLYN-DAVIES		PROF. DOLORES J. SCHENDEL	
	CHIEF EXECUTIVE OFFICER SINCE 1 APRIL 2008		CHIEF FINANCIAL OFFICER SINCE 1 OCTOBER 2012		CHIEF SCIENTIFIC OFFICER SINCE 1 MAY 2014	
	2014	2013	2014	2013	2014	2013
Fixed compensation	356	375	277	260	198	0
Fringe benefit <sup>1)</sup>	44	40	37	37	0	0
<b>Total</b>	<b>400</b>	<b>415</b>	<b>314</b>	<b>297</b>	<b>198</b>	<b>0</b>
Variable performance-based components						
thereof for 2013 <sup>2)</sup>	129	0	89	0	0	0
thereof for 2012 <sup>2)</sup>	0	94	0	0	0	0
<b>Total</b>	<b>129</b>	<b>94</b>	<b>89</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total remuneration paid out</b>	<b>529</b>	<b>509</b>	<b>403</b>	<b>297</b>	<b>198</b>	<b>0</b>

<sup>1)</sup> Fringe benefits include pension expenses and vehicle leasing for the members of the Executive Management Board.

<sup>2)</sup> Corresponds to 65% of the variable compensation of the respective previous year.

**The members of the Executive Management Board additionally hold positions on the following supervisory boards and/or similar bodies:**

**Dr. Frank Mathias**

***External positions***

Positions on other supervisory boards/advisory boards in Germany:

- Faller KG, Waldkirchen
- Mediatum AG, Heidelberg
- Rentschler Biotechnologie GmbH, Laupheim

Positions outside Germany:

- Catherex, Inc., Bala Cynwyd, Pennsylvania, USA
- Aettis, Inc., Bala Cynwyd, Pennsylvania, USA

**Peter Llewellyn-Davies**

***External positions***

Positions outside Germany:

- Immunocore Ltd., Abingdon, United Kingdom (until 6 October 2014, retrospectively to 8 July 2014)
- Catherex, Inc., Bala Cynwyd, Pennsylvania, USA
- Aettis, Inc., Bala Cynwyd, Pennsylvania, USA

## (56) Supervisory Board

### Supervisory Board remuneration

Supervisory Board remuneration amounted to €109 k in 2014 (2013: €224 k). The total remuneration paid to the members of the Supervisory Board comprises fixed remuneration as well as meeting attendance fees. In addition, expenses are reimbursed. The greater scope of activities of the chairman of the Supervisory Board and his deputy are taken into account and reflected accordingly by higher remuneration. Details regarding the subscription rights of members of the Supervisory Board and Executive Management Board are provided in [note \(61\)](#). No advances were paid to members of the Supervisory Board and Executive Management Board.

#### SUPERVISORY BOARD REMUNERATION 2014

SUPERVISORY BOARD MEMBERS	FIXED REMUNERATION IN € K	MEETING FEES IN € K
Prof. Horst Domdey Chairman, co-founder	26	17
Dave Lemus Deputy chairman	20	17
Dr. Yita Lee Ordinary member	13	16
<b>Total</b>	<b>59</b>	<b>50</b>

### Supervisory Board members of Medigene AG:

#### Prof. Horst Domdey

Managing director of Bio<sup>M</sup> Biotech Cluster Management GmbH and member of the management board of Bio<sup>M</sup> AG Munich Biotech Development, Munich

#### External positions

Positions outside Germany:

→ Oasmia Pharmaceutical AB, Uppsala, Sweden

#### Dave Lemus

Chief Executive Officer, Sigma-Tau Pharmaceuticals, Inc., Maryland, USA

#### External positions

Positions on other supervisory boards/advisory boards in Germany:

→ Proteros BioStructures GmbH, Planegg/Martinsried

Positions outside Germany:

→ Axela Inc., Toronto, Canada

→ PhRMA (Pharmaceutical Manufacturers Association of America), Washington, D.C., USA

→ BioHealth Innovation, Inc., Rockville, Maryland, USA

#### Dr. Yita Lee

Chief Scientific Officer of Sinphar Group, Yilan, Taiwan

#### External positions

Positions outside Germany:

→ Sinphar Pharmaceutical Co., Ltd., Yilan, Taiwan

→ SynCore Biotechnology Co., Ltd., Yilan, Taiwan

→ ZuniMed Biotech Co., Ltd., Yilan, Taiwan

→ CanCap Pharmaceutical Ltd., Richmond, Canada

**(57) Directors' holdings and notes on subscription rights****DIRECTORS' HOLDINGS AND NOTES ON SUBSCRIPTION RIGHTS**

NUMBER OF SHARES/OPTIONS	SHARES		OPTIONS	
	31 DEC 2014	31 DEC 2013	31 DEC 2014	31 DEC 2013
Prof. Horst Domdey Chairman, co-founder	39,125	39,125	0	0
Dave Lemus Deputy chairman	0	0	0	0
Dr. Yita Lee Ordinary member	0	0	0	0
<b>Total Supervisory Board</b>	<b>39,125</b>	<b>39,125</b>	<b>0</b>	<b>0</b>
Dr. Frank Mathias Chief Executive Officer	1,499	1,499	59,214	49,375
Peter Llewellyn-Davies Chief Financial Officer	4,000	3,000	18,813	9,375
Prof Dolores J. Schendel Chief Scientific Officer	611,704 <sup>1)</sup>	0	5,000	0
<b>Total Executive Management Board</b>	<b>617,203</b>	<b>4,499</b>	<b>83,027</b>	<b>58,750</b>

<sup>1)</sup>Prof. Schendel indirectly holds 611,704 Medigene shares in her capacity as Managing Director of DJSMontana Holding GmbH. Of these 519,084 Medigene shares are allotted to Prof. Schendel:

## **EXECUTIVE MANAGEMENT BOARD**

Planegg/Martinsried, Germany, 19 March 2015  
Medigene AG

**Dr. Frank Mathias**  
Chief Executive Officer

**Peter Llewellyn-Davies**  
Chief Financial Officer

**Prof. Dolores J. Schendel**  
Chief Scientific Officer

# CONSOLIDATED STATEMENT OF CHANGES IN NON-CURRENT ASSETS

OF MEDIGENE AG FROM 1 JANUARY TO 31 DECEMBER 2014 AND 2013

IN € K	COST					
	1 JAN 2014	CHANGE IN CONSOLIDATED GROUP	EXCHANGE DIFFERENCES	ADDITIONS	DISPOSALS	31 DEC 2014
Property, plant and equipment	6,727	0	9	831	-99	<b>7,468</b>
Intangible assets	31,170	9,692	0	42	0	<b>40,904</b>
thereof RhuDex®	23,750	0	0	0	0	<b>23,750</b>
thereof EndoTAG®-1	7,131	0	0	0	0	<b>7,131</b>
thereof MDG Immunotherapies	0	9,692	0	0	0	<b>9,692</b>
thereof other	289	0	0	42	0	<b>331</b>
Goodwill	3,141	0	0	0	0	<b>3,141</b>
<b>Total</b>	<b>41,038</b>	<b>9,692</b>	<b>9</b>	<b>873</b>	<b>-99</b>	<b>51,513</b>

IN € K	COST					
	1 JAN 2013	CHANGE IN CONSOLIDATED GROUP	EXCHANGE DIFFERENCES	ADDITIONS	DISPOSALS	31 DEC 2013
Property, plant and equipment	6,730		-3	69	-69	<b>6,727</b>
Intangible assets	31,096		0	74	0	<b>31,170</b>
thereof RhuDex®	23,750		0	0	0	<b>23,750</b>
thereof EndoTAG®-1	7,131		0	0	0	<b>7,131</b>
thereof MDG Immunotherapies	0		0	0	0	
thereof other	215		0	74	0	<b>289</b>
Goodwill	3,141		0	0	0	<b>3,141</b>
<b>Total</b>	<b>40,967</b>		<b>-3</b>	<b>143</b>	<b>-69</b>	<b>41,038</b>

ACCUMULATED DEPRECIATION AND AMORTISATION					NET CARRYING AMOUNT	
1 JAN 2014	EXCHANGE DIFFERENCES	ADDITIONS	DISPOSALS	31 DEC 2014	31 DEC 2014	31 DEC 2013
6,322	9	283	-97	<b>6,517</b>	<b>951</b>	405
4,212	0	527	0	<b>4,739</b>	<b>36,165</b>	26,958
0	0	0	0	<b>0</b>	<b>23,750</b>	23,750
4,160	0	446	0	<b>4,606</b>	<b>2,525</b>	2,971
0	0	0	0	<b>0</b>	<b>9,692</b>	0
52	0	81	0	<b>133</b>	<b>198</b>	237
929	0	0	0	<b>929</b>	<b>2,212</b>	2,212
<b>11,463</b>	<b>9</b>	<b>810</b>	<b>-97</b>	<b>12,185</b>	<b>39,328</b>	<b>29,575</b>

ACCUMULATED DEPRECIATION AND AMORTISATION					NET CARRYING AMOUNT	
1 JAN 2013	EXCHANGE DIFFERENCES	ADDITIONS	DISPOSALS	31 DEC 2013	31 DEC 2013	31 DEC 2012
6,126	-3	266	-67	<b>6,322</b>	<b>405</b>	604
3,727	0	485	0	<b>4,212</b>	<b>26,958</b>	27,369
0	0	0	0	<b>0</b>	<b>23,750</b>	23,750
3,714	0	446	0	<b>4,160</b>	<b>2,971</b>	3,417
0	0	0	0	<b>0</b>	<b>0</b>	0
13	0	39	0	<b>52</b>	<b>237</b>	202
929	0	0	0	<b>929</b>	<b>2,212</b>	2,212
<b>10,782</b>	<b>-3</b>	<b>751</b>	<b>-67</b>	<b>11,463</b>	<b>29,575</b>	<b>30,185</b>

## AUDIT OPINION

We have audited the consolidated financial statements prepared by Medigene AG, Planegg/Martinsried, comprising the consolidated income statement, the consolidated statement of comprehensive income, the consolidated balance sheet, the consolidated statement of cash flows, the consolidated statement of changes in shareholders' equity and the notes to the consolidated financial statements, together with the group management report for the fiscal year from 1 January 2014 to 31 December 2014. The preparation of the consolidated financial statements and the group management report in accordance with IFRSs as adopted by the EU, and the additional requirements of German commercial law pursuant to Sec. 315a (I) HGB ["Handelsgesetzbuch": "German Commercial Code"] are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and on the group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with Sec. 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the group management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRSs as adopted by the EU as well as the additional requirements of German commercial law pursuant to Sec. 315a (I) HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development.

Munich, 19 March 2015

Ernst & Young GmbH  
Wirtschaftsprüfungsgesellschaft

Barth  
Wirtschaftsprüfer  
(German Public Auditor)

Gallowsky  
Wirtschaftsprüfer  
(German Public Auditor)

## RESPONSIBILITY STATEMENT

To the best of our knowledge and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the Group, and the Group management report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group.

Planegg/Martinsried, March 19, 2015

The Executive Board



Dr. Frank Mathias



Peter Llewellyn-Davies



Prof. Dr. Dolores Schendel

# REPORT OF THE SUPERVISORY BOARD

Dear Shareholders,

During the 2014 financial year, the Supervisory Board performed the duties, assigned to it by law and according to the Articles of Association completely and with great care. On the basis of verbal and written reports by the Executive Management Board, the Supervisory Board regularly advised and continuously observed the Executive Management Board. The Executive Management Board directly involved the Supervisory Board in all decisions that were of critical significance for the Company and in the strategic development of the Company. The Supervisory Board voted on the resolutions proposed by the Executive Management Board after in-depth examination and discussion.

In addition to the reporting which took place during regular Supervisory Board meetings, the Executive Management Board routinely and promptly issued comprehensive written and verbal reports on the current status of the research and development projects, the financial situation and the business development of the Company and its subsidiaries as well as on corporate planning, major business transactions and fundamental matters of corporate policy, including the Company's strategic and organisational focus, cost and earnings trend, investment measures and financial planning. All documents prepared by the Executive Management Board or the responsible departments and forwarded to the Supervisory Board were examined without exception. The Supervisory Board members and, in particular, the Chairman of the Supervisory Board were also in regular contact with the Chief Executive Officer and other members of the Executive Management Board outside the scheduled Supervisory Board meetings to obtain information about current business developments promptly and discussed these internally, also during conference calls. The Chairman of the Supervisory Board regularly spoke with Dr. Frank Mathias, the Company's Chief Executive Officer, obtaining information for himself and his Supervisory Board colleagues about important business transactions, and supported the Executive Management Board by providing advice. The Supervisory Board Chairman took care that important matters were discussed by the Supervisory Board or in the appropriate Supervisory Board committees. The parties which provided information, in particular the Executive Management Board members, were interrogated about key matters.

The Supervisory Board continuously observed, monitored and examined the Company's risk situation and its risk management, and ensured that the Company was managed in conformity with the law. Any deviation of business activities from plans and objectives were explained in detail to the Supervisory Board, and the Executive Management Board cleared the Company's strategic focus with the Supervisory Board. All business transactions of importance to the Company and its subsidiaries were discussed in detail by the Supervisory Board. The Executive Management Board provides information on the risk management system implemented by the Company in the risk report of the Annual Report.

## **Supervisory Board meetings**

The Supervisory Board carried out its duties on the basis of the Executive Management Board's detailed written and verbal reports, which provided timely and comprehensive information. During the 2014 financial year, nine ordinary meetings were held, some of them as conference calls in view of the international composition of the Supervisory Board. All members of the Supervisory Board participated in each of these meetings. Furthermore, several conference calls took place in addition to the ordinary meetings as part of regular monitoring of and advice provided to the Executive Management Board.

All business transactions submitted to the Supervisory Board requiring either statutory approval or approval pursuant to the Articles of Association by the Supervisory Board were discussed in depth with the Executive Management Board. In addition to the financial position and the trend in revenue, earnings and projects as well as the current business trend, in the financial year 2014 the Supervisory Board, in particular, discussed the Company's strategic direction and the further development of immunotherapies regarding the acquisition of

Trianta Immunotherapies GmbH (now Medigene Immunotherapies GmbH). The Supervisory Board also advised the Executive Management Board on the partnering of the RhuDex® project with the pharmaceutical company Dr. Falk Pharma GmbH and obtained information about the EndoTAG®-1 project, licensed to partner Syncore Biotechnologies Ltd. Finally, the ongoing approval and commercialisation activities relating to the product Veregen® were closely observed by the Supervisory Board and regularly discussed with the Executive Management Board.

Additionally, the Supervisory Board focused on the following capital measures in financial year 2014, all of which required approval:

- Partial utilisation of authorised capital 2012 for contributions-in-kind, involving 1,017,811 shares, as part of the acquisition of Trianta Immunotherapies GmbH (now Medigene Immunotherapies GmbH)
- Issuing convertible bonds totalling a nominal amount of up to €13,749,996 and partial utilisation of authorised capital 2012 for cash contributions, involving up to 3,016,082 new shares
- Specifying the scope of issuance of convertible bonds with a total nominal amount of €818,658 and setting the level of the capital increase at 3,016,082 new shares

Furthermore, the appointment of Prof. Dolores J. Schendel to the Executive Management Board with effect from 1 May 2014 was resolved.

A major part of the deliberations of the Supervisory Board and discussion between the Supervisory Board and Executive Management Board was dedicated to the acquisition of Trianta Immunotherapies GmbH (now Medigene Immunotherapies GmbH) and its strategy, coupled with discussing the relevant contribution agreement with the former Trianta shareholders. Its implementation necessitated a capital increase through contributions-in-kind, which was also discussed during Supervisory Board meetings. In the months following the acquisition, the integration of the company acquired by Medigene AG was carried out and, in parallel, an intensive discussion took place on the further development for immunotherapies.

### Supervisory Board committees

The Company's Supervisory Board established two committees to fulfil its duties more efficiently, the Compensation and Nomination Committee as well as the Audit Committee.

The Compensation and Nomination Committee held five meetings in the course of 2014 and the Audit Committee also held five meetings in the reporting period.

#### SUPERVISORY BOARD COMMITTEES

COMMITTEE	MEMBERS
Compensation and Nomination Committee	Prof. Horst Domdey (Chairman) Dave Lemus Dr. Yita Lee
Audit Committee	Dave Lemus (Chairman) Prof. Horst Domdey Dr. Yita Lee

The duties of the Compensation and Nomination Committee covered preparations related to employment matters of Executive Management Board members. Its main tasks were the conclusion and amendment of the Executive Management Board members' employment contracts as well as stipulating their remuneration. In particular, the appointment of Prof. Dolores J. Schendel as a member of the Company's Executive Management Board with effect from 1 May 2014 was discussed as well as the relevant employment contract for this new Executive Management Board member. Key topics for consultation also included the setting of bonuses and stock options relating to the remuneration system for the Executive Management Board.

The members of the Audit Committee deal with issues relating to accounting and risk management, the required independence of the auditor, issuing the audit assignment to the auditor, determining audit priorities and agreeing the audit fee with the auditors. The Audit Committee obtained the auditor's declaration of

independence pursuant to Section 7.2.1 of the German Corporate Governance Code and monitored the auditor's impartiality. In the presence of the auditor and the Chief Financial Officer, the Audit Committee discussed the audit of the individual and consolidated financial statements of Medigene AG. Furthermore, the Audit Committee regularly discussed the half-yearly and quarterly reports with the Executive Management Board prior to their publication. Moreover, the Audit Committee provided the Supervisory Board with a recommendation with regard to proposing an auditor for election by the Annual General Meeting. The Audit Committee also monitored the accounting process, the efficacy of the internal control system, the risk management system and the internal auditing system.

The Supervisory Board formed no other committees.

### **Corporate governance**

On 3 December 2014, the Supervisory Board together with the Executive Management Board decided to largely implement the recommendations and suggestions of the German Corporate Governance Code (DCGK). On the same day, the new declaration of conformity pursuant to Section 161 of the German Stock Corporation Act (AktG) was adopted by the Supervisory Board and Executive Management Board. The declaration is permanently available to shareholders on the Company's website.

In their corporate governance report, the Executive Management Board and Supervisory Board reported on corporate governance at Medigene pursuant to Section 3.10 of the German Corporate Governance Code.

In the event of conflicts of interest on the Supervisory Board pursuant to Section 5.5 of the German Corporate Governance Code, these are generally disclosed to the other Supervisory Board members. In the 2014 financial year, no conflicts of interest arose on the part of the members of the Supervisory Board.

For reasons of transparency, it is pointed out here that the Chairman of the Supervisory Board of Medigene AG is also the Executive Manager of BioM AG, Planegg/Martinsried, Germany, which in turn was a minority shareholder of Trianta Immunotherapies GmbH (now Medigene Immunotherapies GmbH), Planegg/ Martinsried, Germany. Medigene AG acquired the shares BioM AG held in Trianta Immunotherapies GmbH based on the contribution agreement dated 27 January 2014. The Chairman of the Supervisory Board was present at the Supervisory Board meetings of Medigene AG which dealt with the acquisition of Trianta Immunotherapies GmbH, however, he did not actively participate in the deliberations and abstained in any votes on this matter. He also declined to vote on the BioM AG side regarding the selling of the shares in Trianta Immunotherapies GmbH held by BioM AG. This ensured that any temporary conflict of interest relating to this topic for discussion and decision-making was avoided.

Some members of the Supervisory Board are also members of supervisory bodies of other companies in the pharmaceutical and biotechnology industry. However, in line with the requirements of the German Corporate Governance Code, none of these are considered to be key competitors of Medigene.

### **Individual and consolidated financial statements**

The auditor elected by the Annual General Meeting and commissioned by the Supervisory Board, Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Munich, Germany, audited the financial statements of Medigene AG as of 31 December 2014 and the management's discussion and analysis of Medigene AG for the 2014 financial year. The financial statements were prepared by the Executive Management Board in accordance with the regulations of the German Commercial Code (HGB). The auditor issued an unqualified audit opinion. The Audit Committee had commissioned the audit in accordance with the shareholders' resolution dated 14 August 2014. The consolidated financial statements of Medigene AG were prepared on the basis of the International Financial Reporting Standards (IFRS) as applicable throughout the EU, and the additional requirements pursuant to Section 315a (I) of the German Commercial Code (HGB). The auditor also issued an unqualified audit opinion for the consolidated financial statements and the Group management's discussion and analysis.

The Audit Committee established the priorities of the audit for the reporting year together with the auditor.

The Supervisory Board members received the financial statements as well as the auditor's reports in a timely manner. They were reviewed in detail by the Audit Committee and the Supervisory Board on 19 March 2015 and discussed in the presence of the Executive Management Board and the auditor. The auditor attended the deliberations and discussions about the annual financial statements and the auditor's report and reported in detail on the most important results of his audit, especially the results of his examination of the in-house control and risk management system and those relating to the accounting process. It was noted that the risks and opportunities described in the Group management's discussion and analysis provide a true and fair view and the measures taken by the Executive Management Board pursuant to Section 91 (II) of the German Stock Corporation Act (AktG) are appropriate for identifying any developments which may jeopardise the Company's ongoing existence at an early stage.

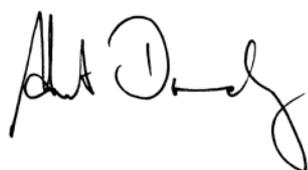
The Supervisory Board endorsed the auditor's findings after examination of the individual and consolidated annual financial statements, the management's discussion and analysis and the Group management's discussion and analysis. In the meeting on 19 March 2015, the Supervisory Board approved the individual and consolidated financial statements as at 31 December 2014 in accordance with the recommendation of the Audit Committee. The financial statements have therefore been adopted.

#### **Acknowledgement of commitment and performance**

The Supervisory Board wishes to thank the Executive Management Board and all employees of Medigene AG and its subsidiaries for their successful efforts on behalf of the Company in the 2014 financial year. Their collective commitment ensured the achievement of important milestones and further development of the business model.

On behalf of the Supervisory Board, I also would like to thank you, the shareholders of Medigene AG, for your continued trust.

For the Supervisory Board

A handwritten signature in black ink, appearing to read 'Horst Domdey', written in a cursive style.

Prof. Horst Domdey  
Chairman of the Supervisory Board

Planegg/Martinsried, Germany, March 2015

# GLOSSARY

## A

### **AAVLP**

Adeno-associated virus-like particle, AAV-like particle

### **Acute myeloid leukemia (AML)**

Malignant disease of the hematopoietic system

### **Adoptive T-cell therapy**

Means the treatment of patients by transfer of defined T-cells to the patient

### **AktG**

Aktiengesetz

German Stock Corporation Act

### **AMG**

Arzneimittelgesetz

German Medicines Act

### **Antibody**

Protein substance produced by the immune system as a reaction to antigens for reasons of a body's own defence mechanisms

### **Antigen**

Substance recognised as being foreign by the immune system

### **Autologous**

Natural to the body

### **Authorised capital**

Value or number of shares authorised in advance by the company's General Meeting for the purpose of a possible capital increase against cash or non-cash contribution

### **Autoimmune diseases**

Diseases caused by an overreaction of the immune system against the body's own tissues

## B

### **B-cell epitope**

Part of the antigen that is recognised by the antibody or B-cell receptor

### **Biopharmaceutical**

Research into and development of drugs and therapies (pharmaceutics), based on biotechnology and molecular biology

**Biotechnology**

Research into and development of drugs and therapies (pharmaceuticals), based on biotechnology and molecular biology

**C****CD28 protein, CD80 protein**

Proteins on the surface of immune cells, involved in the onset of inflammatory processes  
(See also T-cell activation)

**CD80 antagonist**

Prevents the interaction of the surface protein CD80 with specific receptors

**CGU**

Cash-generating unit

**Combination therapy**

The simultaneous treatment of a patient with several therapeutic methods for the same disease

**Compassionate use**

Prescription of as-yet unapproved drugs in particularly severe cases where there are no treatment alternatives

**Conditional capital**

Capital resolved by shareholders' resolution for the issue of stock options or convertible bonds

**Controlled trial**

Trial with a control group of test persons who do not receive the active ingredient tested but a placebo

**D****D&O insurance**

Directors and officers insurance  
A managers' liability insurance effected by a company for its board members and executives

**DBO**

Defined benefit obligation  
Value of an obligation arising from company pension scheme

**Dendritic cells**

Cells of the immune system specialized in antigen uptake and presentation. Dendritic cells are the most potent cells for activating a primary T cell based immune response

**Dermatology**

Branch of medicine dealing with the treatment of skin conditions and benign and malignant skin tumours

**Drug candidate**

Drug which is still at the development stage

**E****EBITDA**

Earnings before interests, depreciation and amortization.

Medigene's EBITDA is derived from the net profit/loss for the year and does not include any taxes, financial result, foreign exchange gains or losses, share of result of associates nor amortisation or depreciation

**Endothelial cells**

Line the interior surface of lymphatic and blood vessels

**Exploratory trials**

Intended for initial clarification and classification of problem areas. They are often conducted in order to get an overview, and thus serve as preparation for further studies

**F****FDA**

Food and Drug Administration

Government agency of the United States Department of Health and Human Services

**Formulation**

The way in which an active ingredient is combined with suitable carrier substances and excipients and the form in which it is administered

**G****Generic drug**

Copy of a drug already available on the market, containing the same active ingredient

**Genital warts**

Benign, but painful and disfiguring skin tumours in the genital and anal areas

**GMP**

Good Manufacturing Practice

Quality assurance guidelines for production processes and environments in the manufacture of drugs

**H****HER2 receptor**

Human Epidermal Growth Factor Receptor 2, a protein found on the surface of many human organs (See also "triple negative breast cancer")

## **HGB**

Handelsgesetzbuch  
German Commercial Code

## **Human papillomaviruses (HPV)**

Viruses that infect the epithelium of the skin and may cause uncontrolled tumour-like growth

## **I**

### **IAS**

International Accounting Standards  
Part of the International Financial Reporting Standards

### **IFRIC**

International Financial Reporting Interpretations Committee

### **IFRS**

International Financial Reporting Standards

### **IIT (Investigator Initiated Trial)**

Clinical trial of a drug candidate that is initiated, organised and financed by the medical profession. Such trials focus on enhancing a specific therapy for patients

### **Immunotherapy**

Treatment methods which influence and activate the immune system

### **Indication**

Disease; reason for the execution of a medical examination or treatment

## **L**

### **Leukapheresis**

Process for collection of white blood cells (leucocytes) from a donors' blood

### **Leucocytes**

White blood cells

### **Licensing**

Sale or acquisition of development and/or marketing rights to a product

### **Liposomes**

Minute, hollow globules, composed of fat molecules

**M****Major histocompatibility complex (MHC)**

Group of genes and proteins which are relevant in immune recognition

**Minimal residual disease**

The stage of a tumour in which only very few isolated tumour cells are present in the patient's body following surgical removal of the primary tumour or chemotherapy or radiotherapy

**Monoclonal antibody**

Antibodies which are produced from a single cell line and can be traced back to an individual B lymphocyte

**Monocytes**

Belong to the class of white blood cells and have an important function in the human immune system

**N****NK (natural killer) cells**

Cells of the immune system which can identify and destroy cancer cells and virally infected cells

**O****Oncology**

Science of tumours and tumour-related diseases

**Orphan drug**

Pharmaceutical drugs that are developed specifically to treat a rare medical condition

**Orphan drug designation**

Drugs developed for the treatment of rare diseases may obtain orphan drug designation from the European Commission or the FDA, allowing benefits in development, approval procedures, and possibly even the commercialisation of the product

**P****Paclitaxel**

Drug in the treatment of e.g. breast cancer. Paclitaxel prevents cancer cells from dividing

**Pancreatic cancer**

Malignant tumour of the pancreas

**PCT**

Patent Cooperation Treaty

International agreement under which a patent application may be filed for currently 146 countries worldwide. For the issue of a patent, this application has to be transferred to a national application at a later date

**Peptide**

A peptide (short protein) consists of amino acids linked together

**Pharmaceutics**

Science that deals with the composition, effect, development, testing, production, and dispensing of drugs

**Pipeline**

All of the drug candidates that are under development

**Primary biliary cirrhosis (PBC)**

Chronic liver disease that initially affects the bile ducts. The bile ducts are progressively destroyed by inflammatory processes, causing biliary stasis and build-up of bile in the liver. Liver tissue is destroyed and replaced by connective tissue, liver cirrhosis develops

**Preclinical**

Stages of development of an active substance prior to testing in humans

**Proof of concept**

Evidence of the fundamental feasibility of a plan

**Proof of principle**

Evidence on the feasibility at an early stage of drug development

**Prophylactic vaccine**

Administered to prevent a disease, prepares the immune system for the defence against infection

**Prostate Cancer**

Prostate cancer is a malignant, slow-growing cancer that develops in the prostate

**R****R & D**

Research and development

**Receptor**

Protein molecule which can bind different substances

**Resistance**

Ability of an organism to withstand external influences

**Rheumatoid arthritis**

Inflammatory disease affecting the joints

**T****T-cells**

T-cells or T lymphocytes belong to a group of white blood cells known as lymphocytes, and play a central role in cell-mediated immunity

**T-cell activation**

Pivotal step in the onset of inflammatory processes

**T-cell receptor (TCR)**

Receptor by which T-cells recognise antigens bound to other cells of the body

**TecDAX**

Index of the German Stock Exchange listing the thirty major technology equities with respect to market capitalisation and order book turnover

**Technology platform**

Technology which is the basis for the development of different drug candidates

**Therapeutic vaccine**

Stimulates the immune system against acute infection or an existing tumour

**Triple negative breast cancer**

Malignant breast tumours that display neither oestrogen/gestagen nor HER2 receptors on the cell surface are termed "triple negative"

**V****Vaccines**

Inoculants

**W****WpHG**

Wertpapierhandelsgesetz  
German Securities Trading Act

## FINANCIAL CALENDAR

### **25 March 2015**

Annual Report 2014  
Press and Analyst conference call

### **12 May 2015**

3-Month Report 2015  
Press and Analyst conference call

### **06 August 2015**

6-Month Report 2015  
Press and Analyst conference call

### **12 November 2015**

9-Month Report 2015  
Press and Analyst conference call

## TRADEMARKS

### **EndoTAG®**

is a trademark of Medigene AG

### **Medigene®**

is a trademark of Medigene AG

### **Medigene Immunotherapies™**

is a trademark of Medigene Immunotherapies GmbH

### **RhuDex®**

is a trademark of Medigene AG

### **Trianta™**

is a trademark of Medigene Immunotherapies GmbH

### **Trianta Immunotherapies™**

is a trademark of Medigene Immunotherapies GmbH

### **Veregen®**

is a trademark of Medigene AG

### **Eligard®**

is a trademark of Tolmar Therapeutics, Inc.

# IMPRESSUM

## Published by

Medigene AG  
Lochhamer Str. 11  
82152 Planegg/Martinsried  
T +49-89-200033-0  
F +49-89-200033-2920

## Contact

Public & Investor Relations  
Julia Hofmann, Anja Clausnitzer  
T +49-89-200033-3301  
investor@medigene.com

## Text

Medigene AG, Planegg/Martinsried  
Design Kirchhoff Consult AG, Hamburg

## Production

Viaprinto, CEWE Stiftung & Co. KGaA

## Disclaimer

This annual report contains forward-looking statements that are based on certain assumptions and expectations made by the management of Medigene AG at the time of its publication. These forward-looking statements are therefore subject to unpredictable risks and uncertainties, so there is no guarantee that these assumptions and expectations will turn out to be accurate. Many of those risks and uncertainties are determined by factors that are beyond the control of Medigene AG and cannot be gauged with any certainty at this point in time. This includes future market conditions and economic developments, the behaviour of other market participants, the achievement of targeted synergy effects as well as legal and political decisions.

Medigene AG cannot preclude that actual results may differ substantially from those expectations expressed in or implied by the forward-looking statements. Medigene AG does not intend or assume any obligation to update any forward-looking statements to reflect events or circumstances after the date of this annual report.

The English version of the annual report is a translation of the original German version; in the event of variances, the German version shall take precedence over the English translation.

