# **STATUS REPORT**

### **Drive innovation – achieve sustainability.**

MediGene is developing innovative drugs for the treatment of cancer and autoimmune diseases, with the aim of providing better treatment options for patients in areas of high unmet medical need. We strive to create sustainable value through scientific innovation and the targeted use of our resources, which will benefit both patients and our shareholders.

In 2011, we made significant progress on our products and drug candidates and continued the implementation of our strategic goals of increasing MediGene's financial capabilities, optimizing costs and strengthening our pipeline.

## KEY FIGURES

In € thousand	2011	2010	Change
Income statement			
Product sales	2,300	2,214	4%
Other operating income	2,356	78	>200%
Total revenue	4,656	2,292	103%
Cost of sales	-953	-781	22%
Gross profit	3,703	1,511	145%
Selling, general and administrative expenses	-8,103	-9,399	-14%
Research and development expenses	-11,254	-13,494	-17%
EBITDA	11,180	-12,756	-
Loss resulting from spin-off	0	-6,212	-
Operating result from continued operations	-15,654	-27,594	-43%
Result from continued operations before tax	-15,474	-27,177	-43%
Result from continued operations	-14,233	-27,177	-48%
Product sales from discontinued operations	27,828	47,398	-41%
Result from discontinued operations	20,514	9,308	120%
Net result for the year	6,281	-17,869	-
Basic and diluted earnings per share after tax in €	0.17	-0.49	-
Weighted average number of shares (basic)	37,082,758	36,563,966	1%
Personnel expenses	-6,145	-9,946	-38%
Cash flow statement			
Cash flow from operating activities	6,864	-11,411	-
Cash flow from investing activities	1,423	-321	-
Cash flow from financing activities	0	4,469	-
Balance sheet statement			
Cash and cash equivalents	12,811	4,770	169%
Balance sheet total	53,292	58,201	-8%
Current liabilities	4,824	17,156	-72%
Non-current liabilities	536	247	117%
Shareholders' equity	47,932	40,798	17%
Equity ratio in %	90	70	29%
Employees as at Dec. 31	52	92	-43%
MediGene share			
Total number of shares outstanding as at Dec. 31	37,082,758	37,082,758	0%
Share price (closing price, XETRA) as at Dec. 31	0.97	1.99	-51%
Dividend in €	0	0	

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### **KEY EVENTS IN 2011**

We achieved numerous milestones in 2011, and we are working on efficiently achieving our goals also in the future.

- Completed transfer of the Eligard<sup>®</sup> rights for EU countries to Astellas
- Market approval granted for Veregen<sup>®</sup> in Spain
- Marketing authorization applications for Veregen® filed in several other countries
- Mumerous new Veregen<sup>®</sup> partnership agreements concluded
- ☑ Overall survival data from EndoTAG<sup>®</sup>-1 phase II trial in TNBC presented at the San Antonio Breast Cancer Symposium
- Start of a phase II Investigator Initiated Trial (IIT) with EndoTAG®-1 in HER-2 negative breast cancer at the Institut Jules Bordet
- Mew formulation for RhuDex<sup>®</sup> preclinically developed
- Official approval granted to conduct a clinical formulation study for RhuDex®
- Development collaboration for the first vaccine candidates from the AAVLP platform started with The Johns Hopkins University
- Data from the AAVLP vaccine program presented together with DKFZ at the International Papillomavirus Conference

## LETTER TO THE SHAREHOLDERS

Martinsried, March 2012

Dear shareholding,

2011 was an important year for our Company, and a year in which we achieved further milestones in the implementation of our strategy for long-term growth. This applies for all three key objectives we developed in the previous year of increasing the Company's financial capabilities, optimizing the cost structure and strengthening our drug pipeline.

As a result of the increase in product sales and the disposal of the Eligard<sup>®</sup> rights to our long-term business partner Astellas, we strengthened our cash position from €4.8 million to €12.8 million, and reported net income totaling €6.3 million in 2011. At the same time, the restructuring measures introduced in 2010 and our efforts to focus on the key value drivers have considerably reduced our operating cash burn rate. In parallel, we made substantial progress with our products and development projects. Approval processes are underway for Veregen<sup>®</sup> in a further 21 countries, 17 of them took already a positive decision. We have signed partnership agreements with renowned companies covering an additional 25 countries for marketing the drug on approval. For EndoTAG®-1, we presented the median overall survival data from a phase II trial in patients with a form of breast cancer which is difficult to treat. Furthermore, the principal investigator of this study launched a new clinical trial investigating EndoTAG®-1 in another breast cancer indication. We have resumed the clinical development of RhuDex<sup>®</sup> by starting a clinical formulation study aimed at optimizing oral delivery for patients with chronic diseases such as rheumatoid arthritis. Provided that the outcome of the study is positive, this would considerably improve the competitiveness of RhuDex®. Our innovative

AAVLP vaccine technology has generated promising preclinical data in cooperation with renowned institutes, The Johns Hopkins University and the German Cancer Research Center (DKFZ).

We still face many challenges on the path to sustainable corporate growth, however each and everyone in the MediGene team is embracing these challenges with outstanding commitment and professionalism. We are focused on making rapid progress with our products, Veregen<sup>®</sup>, EndoTAG<sup>®</sup>-1, RhuDex<sup>®</sup> and AAVLP, and are also looking into possibilities for strengthening our pipeline on the basis of external product candidates. Therefore, we have structured this status report as a work in progress report. It is designed to highlight the fact that we have come a long way and continue to make every effort with regard to the further implementation of our goals.

MediGene has a proven track record of converting scientific innovation into patient benefits – this is evident from the European approval and partnership agreement we achieved with Eligard<sup>®</sup> and the successful development of Veregen<sup>®</sup> from preclinical to market launch. We are confident that our strategy will generate long-term sustainable value for Your Company, and I look forward to you joining us on this path.

Sincerely,

Dr. Frank Mathias Chief Executive Officer

### MANAGEMENT

OF MEDIGENE AG

#### Dr. Frank Mathias (right) Chief Executive Officer

Dr. Frank Mathias has been Chief Executive Officer of MediGene AG since May 2009. Since April 2008, he had been Chief Operating Officer. Dr. Mathias, previously General Manager of Amgen Germany, possesses over twenty years of relevant experience in the pharmaceutical and biotech industries. Dr. Mathias holds a PhD in pharmacy and worked for Hoechst and Albert-Roussel, among other companies, prior to assuming the Head of Marketing position at Servier Deutschland GmbH in Munich where he took over as General Manager in 1996. In 2002, he joined Amgen GmbH, Munich, as Head of Marketing. He then served as the company's General Manager from 2003–2008.

#### Arnd Christ (left)

#### **Chief Financial Officer**

Arnd Christ was appointed CFO of MediGene AG in April 2010. He comes with more than 17 years experience in the international management of corporate finance, business management and Mergers and Acquisitions mainly in the biotechnology and pharmaceutical industries. Prior to joining MediGene, Arnd Christ was the CFO of Swiss biotechnology company, Novimmune from 2007 to 2010 and before that, he spent five years as CFO for Probiodrug AG, a biopharmaceutical company based in Halle, Germany. At the beginning of his career, Arnd Christ worked in different positions, among others as financial director of various companies belonging to the Hoechst Group in Germany and in the UK. He holds a diploma in business administration.



## STRATEGY WE ARE DELIVERING ON OUR STRATEGY.



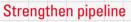
Increase financial capabilities

## Eligard<sup>®</sup> rights monetized

**Optimize costs** 

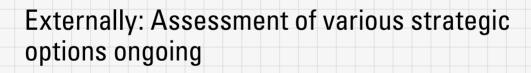


Restructuring successfully completed





Internally: Progress on all current projects



In 2010, MediGene defined three strategic key tasks, which the Company continued to implement in 2011. They are to increase MediGene's financial capabilities, optimize the Company's cost structure and further strengthen the pipeline.

In March 2011, MediGene transferred the EU rights for its drug Eligard<sup>®</sup> to sales partner Astellas and received a tranche of €15 million as part payment towards the total sales price of €25 million. In addition, MediGene has since participated in Eligard<sup>®</sup> sales with a 2% share. As a result of the successful completion of the corporate restructuring in 2011 and thanks to various cost optimization measures, MediGene has considerably strengthened its financial position. Moreover, MediGene has advanced its drug projects for Veregen<sup>®</sup>, RhuDex<sup>®</sup>, EndoTAG<sup>®</sup>-1 and AAVLP and is considering various options for expanding the pipeline on the basis of one or more external projects. We are well positioned to do this.

The sector average for developing a new drug is 10–15 years. The costs of taking an active ingredient from research stage to market launch are considerable and the risks of drug projects failing are high. Biotechnology companies, which focus on the development of drugs, therefore generally work without making a profit for several years before actually starting to record gains.

In 2011, MediGene generated positive annual results. We reported a positive EBITDA of €11.2 million, with net profit amounting to €6.3 million. This was primarily attributable to the transfer of the Eligard<sup>®</sup> rights, largely implemented in 2011. Excluding this non-recurring factor, the Company also improved its financial results and reduced the operating cash burn rate by 40% to an average of €0.8 million per month.

## FINANCE WE ACHIEVED A POSITIVE ANNUAL RESULT IN 2011.

# €32.5 million

SALES FROM CONTINUED AND DISCONTINUED OPERATIONS



INCREASE IN REVENUE FROM VEREGEN® PRODUCT SALES AND ROYALTIES

# €11.2 million

POSITIVE EBITDA RESULT

## PIPELINE WE HAVE MADE PROGRESS ON ALL PROJECTS.

roduct	Indication	Pre-clinic	Clinical phase I	Clinical phase II	Clinical phase III	Approval	Market
ligard®1)	Prostate cancer						
eregen®	Genital warts						
ndoTAG®-1	Pancreatic cancer TNBC						
huDex®2)	Autoimmune diseases						
AVLP	Vaccine candidates	_					
hance of reachir	ng the market: 3)	< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>11</sup> Sold to Astellas
 <sup>21</sup> RhuDex<sup>®</sup> was successfully tested in a phase IIa clinical trail
 <sup>31</sup> Industrial average, estimates of MediGene AG

MediGene is focused on the research and development of innovative drugs to treat cancer and autoimmune diseases. MediGene is the first biotech company in Germany to generate income from products on the market, which are sold by partner companies. Two candidates are in clinical development. In addition, MediGene is developing a new vaccine technology. In 2011, the Company made progress with all products and projects in its portfolio.

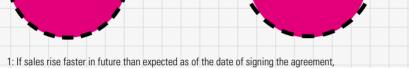
Increasing in-market sales, as is the case with cancer drug Eligard<sup>®</sup>, are positive. However, from a financial point of view, the margin and profits are more important for MediGene. With regard to the Eligard<sup>®</sup> project, action was required in this respect, because the margin for MediGene reduced once a certain level of in-market sales of Eligard<sup>®</sup> was reached. Furthermore, MediGene faced the risk of not being able to pass on price increases imposed by the manufacturer of Eligard<sup>®</sup> to marketing partner Astellas. In order to optimize the economics, MediGene transferred the Eligard<sup>®</sup> rights to Astellas for an amount totaling €25 million (€20 million of which posted as sales revenue in 2011) and a 2% share of future net sales revenue, which corresponds to the calculated net present value of the Eligard<sup>®</sup> project.

Largely implemented in 2011, this transaction has reduced MediGene's obligations, minimized risk and at the same time improved the Company's financial position.

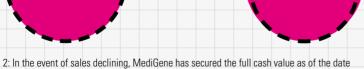
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## ELIGARD®

## WE HAVE OPTIMIZED THE FINANCIAL FACTORS.



MediGene will continue to participate in revenue growth on the basis of its 2% participation.



of signing the agreement for the entire original term of the contract.

- Cash value as of signing date
- Future cash value
- ••• Sales development

### **VEREGEN**<sup>®</sup>

## WE ARE DEVELOPING NEW MARKETS WORLDWIDE.

partnered marketed March 2012: Status: March 2012 MediGene has signed agreements for the marketing of Veregen<sup>®</sup> with the following partners:

Europe: Abbott (Germany, Austria and Switzerland), Juste (Spain and Portugal), Laboratoires Expanscience (France), Meditrina Pharmaceuticals (Greece, Cyprus, Romania and Bulgaria), Will-Pharma (Belgium, Netherlands and Luxembourg), Pharmanova (Serbia, Bosnia & Herzegovina, Montenegro, Macedonia, Croatia, Slovenia and Albania) and Eczacibasi (Turkey) America: Fougera Pharmaceuticals (USA), Triton Pharma (Canada) and Pierre Fabre Medicament (Mexico, Central America, Venezuela and Colombia)

Asia: Teva Pharmaceutical Industries (Israel), GC Rise (China), JS BioPharm (South Korea) and SynCore Biotechnology (Taiwan)

Authorities take positive decision on market approval for 17 additional countries in Europe

MediGene achieved an increase in sales with its drug Veregen<sup>®</sup> in 2011. Furthermore, the Company created important conditions for developing further markets for Veregen<sup>®</sup> in the future.

New agreements signed with seven partner companies form the basis for distributing Veregen<sup>®</sup> in 25 additional countries in Europe, America and Asia in future. MediGene now has distribution agreements for Veregen<sup>®</sup> with partners in 37 countries, including some of the largest markets worldwide.

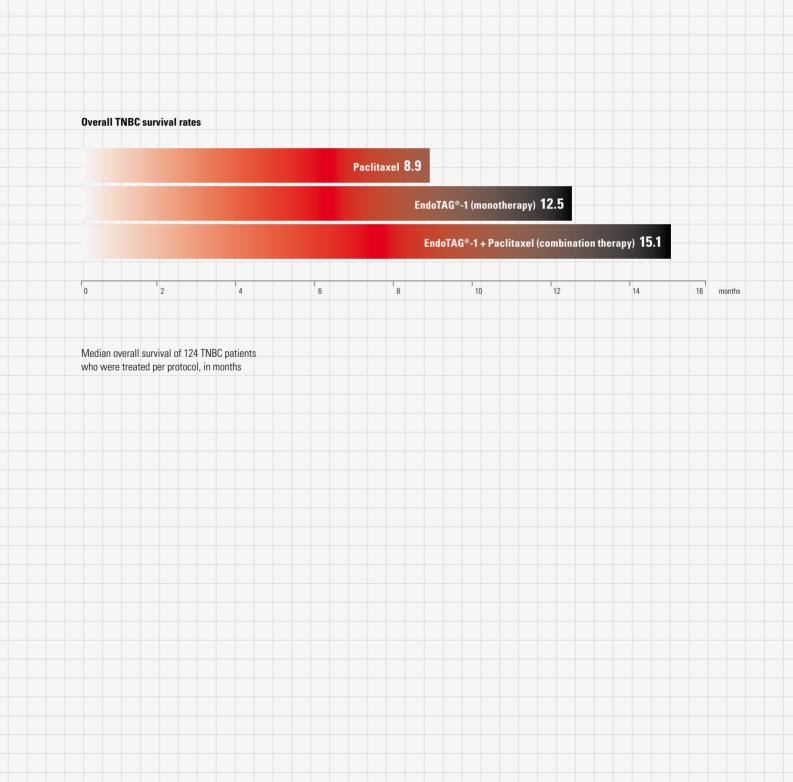
In addition, MediGene submitted applications for marketing authorization of Veregen<sup>®</sup> in 17 European countries. Beginning of March 2012, these were positively assessed by the regulatory authorities within the mutual recognition procedure. This binding decision guarantees that national marketing authorizations will be formally granted in the next few months.

Data is the basis of all scientific development. Discussing data with experts is a valuable part of every research and development project. In 2011, the final EndoTAG®-1 data from MediGene's phase II trial in breast cancer (TNBC) was selected by the renowned Breast Cancer Symposium in San Antonio, USA, to be presented and discussed as part of the conference to high-level experts. The data on median overall survival first published at this conference confirmed the positive efficacy trend of EndoTAG®-1 in combination with standard paclitaxel as already demonstrated in earlier analyses.

Prof. Ahmad Awada from the Institut Jules Bordet in Brussels, the principal investigator of the study, has also initiated a phase II Investigator Initiated Trial (IIT) of EndoTAG<sup>®</sup>-1 to examine its efficacy in a further breast cancer indication.

## ENDOTAG<sup>®</sup>-1

## WE HAVE GENERATED ADDITIONAL CLINICAL DATA.



#### MEDIGENE AG

### **RHUDEX**<sup>®</sup>

## WE ARE CONTINUING THE CLINICAL DEVELOPMENT WITH A NEW FORMULATION.

January 2012 Start of a clinical formulation study

For the efficacy of drugs, the formulation of the active ingredient plays a major role, in other words, the way in which it is combined with suitable carrier substances and excipients and the form in which it is administered. All this has a decisive influence on when and for how long the active ingredient is effective in the body. For patients, drug delivery is particularly important. For example, it is easier for patients to take medication which is available for oral administration than drugs which need to be injected intravenously.

RhuDex<sup>®</sup> is being developed as an oral therapy for autoimmune disease and therefore offers a potential advantage over most other products in this drug category, the disease modifying antirheumatic drugs (DMARDs). The previous clinical trials of RhuDex<sup>®</sup> were conducted with provisional formulations of the agent that were not optimal for the treatment of chronic conditions.

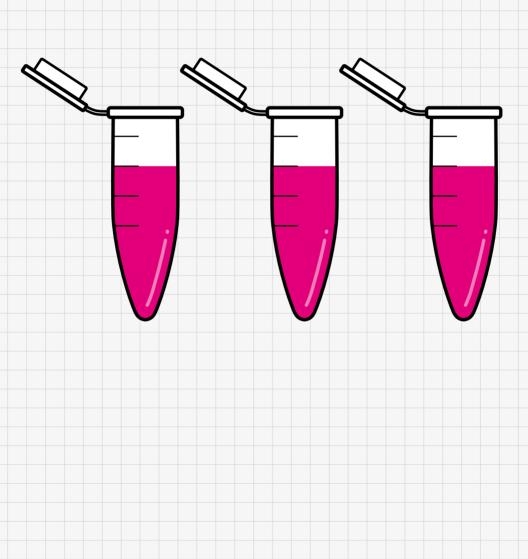
MediGene has therefore developed a new oral formulation of RhuDex<sup>®</sup>, customized for treating chronic disease. For its clinical testing, MediGene initiated a formulation study in January 2012, which marks the continuation of the clinical development of RhuDex<sup>®</sup>.

Vaccines are developed for the targeted activation of the body's immune system, in order to prevent or fight infection or disease. To achieve this, antigens are administered that trigger the production of certain antibodies and start the body's own immune system. For the body to actually recognize antigens and initiate an effective immune response, they need to be presented in a certain manner. MediGene is evaluating new technology to this end based on AAVLPs. These are virus-like particles, which do not themselves trigger infections. Antigens are embedded in the surface structure of these virus shells, making them identifiable to the immune system so that they can act as a vaccine.

In addition, a unique property of the AAVLP technology is that it may help to identify suitable antigens for known, clinically relevant antibodies. This may facilitate active immunization against diseases for which no vaccine exists to date.

MediGene gained promising preclinical data in 2011 using the AAVLP technology in cooperation with the renowned research institutes The Johns Hopkins University and the German Cancer Research Center.

## AAVLP WE ARE DEVELOPING THE BASIS FOR NEW VACCINES.



# DRUG DEVELOPMENT **DRUG DEVELOPMENT PHASES**



<sup>1)</sup> Industrial average, MediGene estimates

Developing a drug is a complex process. The active compounds are first examined as drug candidates in preclinical trials. If trials of a new active ingredient are successful and it meets the strict regulatory criteria, the three phases of the clinical trial on humans can begin. In phase I, the effects of the drug on the body and how well it is tolerated are examined in a small number of mostly healthy volunteers (patients are required in the field of oncology). Phase II determines the optimal dose and includes first-time administration to patients. Phase III verifies the efficacy and tolerability for a large number of patients compared to the standard therapy. Finally, the drug must be approved by the respective national authorities before it can be launched onto the market.

## **ELIGARD**<sup>®</sup>

Product	Indication	Pre-clinic		<b>Clinical phase</b>	Approval	Market	
			I	П	III		
Eligard®	Prostate cancer						
Chance of reaching	the market <sup>1)</sup>	< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>1)</sup> Industrial average, estimates of MediGene AG

#### **About Eligard**

Eligard<sup>®</sup> is a hormone compound for the treatment of advanced, hormone-dependent prostate cancer. The active ingredient (leuprolide acetate) significantly reduces the level of the male sex hormone testosterone, thus suppressing testosterone-dependent tumor growth. The established active ingredient is combined with a novel drug delivery system known as Atrigel<sup>®</sup> depot technology. The liquid drug is injected subcutaneously and Eligard<sup>®</sup> forms a gel-like implant which slowly disintegrates, steadily releasing the drug over a period of one, three or six months, depending on the dosage administered.

MediGene acquired the European marketing rights to Eligard<sup>®</sup> from Atrix Laboratories, Inc. (now Tolmar Therapeutics, Inc.) and successfully brought the drug through the market approval procedure in Germany. The European market launch of Eligard<sup>®</sup> by MediGene's partner Astellas Pharma Europe, Ltd. started as early as 2004. Eligard<sup>®</sup> in its one-month, three-month and six-month dosage forms is now available in most European countries.

In mid-2010, MediGene sold the exclusive European marketing and distribution rights for Eligard<sup>®</sup> to Astellas Pharma Europe Ltd. against payment of €25 million and royalties of 2% on product sales. With the sale of the Eligard<sup>®</sup> rights, MediGene no longer bears any obligations or risks associated with the supply of Eligard<sup>®</sup> to Astellas. In addition, MediGene will no longer be liable for any procurement costs and license payments to Tolmar.

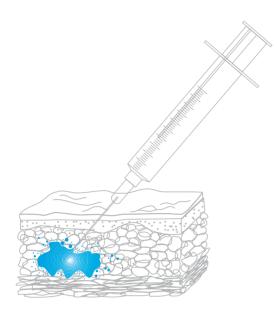
#### Outlook

Eligard<sup>®</sup> will continue to contribute considerably to MediGene's result in the future.

#### SALE OF THE ELIGARD® RIGHTS TO ASTELLAS – A DEAL OF FINANCIAL AND STRATEGIC IMPORTANCE

By selling the Eligard® rights to Astellas, MediGene secured the full cash value of all future income from Eligard® under the previous arrangement. In addition, MediGene has considerably reinforced the Company's financial strength without diluting shares. The significant improvement in cash holdings and the simplified structure of the Eligard® contract provide growth opportunities for MediGene and facilitate strengthening of the pipeline for the future.

#### Administration of Eligard<sup>®</sup> (formation of gel-like implant)



#### **INDICATION – PROSTATE CANCER**

Prostate cancer occurs in the cells of the prostate gland. This gland in the male body envelops the first section of the urethra and produces part of the semen. With around 25,000 new cases diagnosed per year in Germany and 180,000 in the USA, prostate cancer is the second most common type of terminal cancer in men after lung cancer. The standard treatment methods for localized tumors are surgery and radiation. In patients with prostate cancer metastases, androgen suppressants are used to reduce testosterone levels. The relative 5-year survival rate of patients with prostate cancer that is localized at the time of diagnosis is almost 100%. However, the 5-year survival rate of patients where the cancer has spread is significantly lower at 33%.

## J

€ MILLION

The first milestone payment was due upon signing the agreement. MediGene already received this payment in August 2010, which increased the Company's liquidity. This payment was not posted as sales revenue until March 2011 when the second milestone was achieved. Consequently, it contributed to the positive result for 2011.



€ MILLION

Upon transfer of the Eligard® rights for the EU countries to Astellas, the second milestone payment of €15 million became due. The transfer took place on March 1, 2011. Since that date, MediGene has participated in the drug's market success with a 2% share of net sales revenue.



€ MILLION

This milestone is linked to the transfer of the Eligard® rights for non-EU countries to Astellas. MediGene expects the milestone payment to be made in 2012.



#### € MILLION

In total MediGene receives payments from Astellas totaling €25 million as well as a 2% share in product sales.

### **MILESTONES 2011**







€2.2 MILLION FROM 2% ROYALTY

### **VEREGEN**<sup>®</sup>

Product	Indication	Pre-clinic		Clinical phase	Approval	Market	
			I.	II	III		
Veregen®	Genital warts						
Chance of reaching	the market <sup>1)</sup>	< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>1)</sup> Industrial average, estimates of MediGene AG

#### About Veregen®

Veregen<sup>®</sup> is an ointment used to treat external genital warts. In the USA, Germany and Austria, Veregen<sup>®</sup> is already successfully marketed by our partners. Sales and marketing partnerships are also in place for this drug in a large number of other countries in Europe, Asia and America <u>(see page 14)</u>. The sales generated with Veregen<sup>®</sup> are continually rising and making a valuable contribution to financing the Company.

As an innovative drug, Veregen<sup>®</sup> is based on a defined extract from green tea leaves obtained in a highly complex and specifically developed process.

MediGene licensed the basic rights to the active ingredient in 1999 and then completed the clinical development of Veregen® as a proprietary drug. Subsequently, MediGene was responsible for bringing the drug successfully through the approval process of the US Food and Drug Administration (FDA). Veregen® is the first, and to date the only, innovative botanical drug approved by the FDA. Furthermore, MediGene is the first German biotech company to have a drug on the US market. In Europe, marketing authorization for Germany, Austria and Spain was granted to date. As part of the mutual recognition procedure, MediGene applied for additional marketing authorization for a further 17 European countries in 2011 (Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia and Sweden). Beginning of March 2012, the applications were positively assessed by the regulatory authorities. This binding decision guarantees that national marketing authorizations will be formally granted in the next few months. Outside the EU, applications for approval have been submitted by our partners in Switzerland (in 2010), Israel, Mexico, Serbia and Taiwan (all in 2011).

Veregen<sup>®</sup> is also listed in recognized treatment guidelines. Sinecatechins 15% ointment (Veregen<sup>®</sup>) is recommended in the US Department of Health and Human Services Center for Disease Control and Prevention's Sexually Transmitted Diseases Treatment Guidelines 2010 as a possible option for treating genital warts.

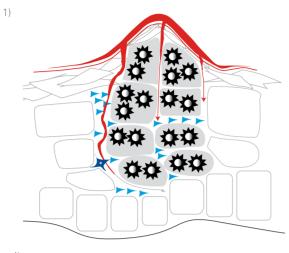
#### Outlook

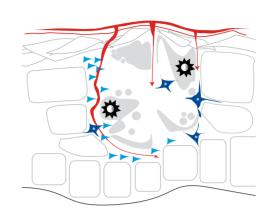
MediGene expects that the national marketing authorizations for Veregen<sup>®</sup> will be formally granted by the respective regulatory authorities for a further 17 European countries within the next few months. The successive launch of Veregen<sup>®</sup> ointment in these new territories is anticipated to start end of 2012. Our partner Juste is scheduled to launch Veregen<sup>®</sup> in the Spanish market in the first half of 2012. In addition, MediGene expects positive decisions with regard to approval in further non-EU countries. MediGene intends to conclude further partnership agreements for the global marketing of Veregen<sup>®</sup>.

#### **INDICATION – GENITAL WARTS**

Genital warts are tumors caused by infection with certain human papillomaviruses (HPV). Although the tumors are not malignant, they disfigure the genital and anal areas, and may be associated with discomfort, including itching, a burning sensation, discharge, bleeding and pain. Genital warts are one of the fastest spreading sexually transmitted diseases. An estimated 30 million people are affected worldwide. Depending on anatomic location and size, various surgical and drug-based treatment methods are available. Alongside the conservative removal of existing warts, stopping warts from recurring is a key treatment objective. For example, Veregen® is safe and effective in the treatment of genital warts and boasts a particularly low rate of wart recurrence in patients.

#### Changes in a skin tumor induced by Veregen®





- HPV infection of skin cells induces formation of warts
- → Veregen<sup>®</sup> penetrates the skin, unfolds its assumed immuno-modulatory and antiviral effect
- Messengers (Cytokines, Interferones) are released
- Cells of the immune system invade and destroy infected cells

#### Worldwide approval and marketing process for Veregen®



2)

> Process

High standards apply worldwide for bringing a fully developed drug to market. In Europe, the approval of Veregen<sup>®</sup> for the various countries is based on mutual recognition, a decentralized procedure. Approval in Germany, the reference member state for this decentralized procedure, provides the basis for approval in other countries. Outside the EU, the approval process varies according to national regulations and is managed by our local partners. Once market approval has been granted, the national authorities usually conduct a procedure to determine the price eligible for reimbursement prior to the drug finally becoming available in pharmacies in the relevant country.

#### 2011 MILESTONES





START OF APPROVAL PROCESS FOR 21 COUNTRIES



MARKETING PARTNERSHIPS FOR 25 ADDITIONAL COUNTRIES

### ENDOTAG<sup>®</sup>-1

Product	Indication	Pre-clinic		<b>Clinical phase</b>	Approval	Market	
			I.	П	III		
EndoTAG <sup>®</sup> -1	Pancreatic cancer						
	Triple-negative breast cancer						
Chance of reaching the market <sup>1)</sup>		< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>1)</sup> Industrial average, estimates of MediGene AG

#### About EndoTAG®-1

The clinical drug candidate EndoTAG®-1 is a novel composition of the established cytostatic drug paclitaxel combined with neutral and positive lipids. The positively charged lipids mean that EndoTAG®-1 interacts with newly developed, negatively charged endothelial cells, which are primarily required for the growth of tumor blood vessels. The EndoTAG®-1 paclitaxel component attacks the endothelial cells as they divide, thus targeting the blood supply to tumors without affecting the supply to healthy tissue. By doing this, EndoTAG®-1 is expected to prevent the formation of new tumor blood vessels and to inhibit tumor growth. Compared to tumor cells, endothelial cells are genetically stable. MediGene assumes that due to this characteristic, EndoTAG®-1 can be used in the targeted treatment of those tumors that have already developed a resistance to conventional paclitaxel therapy.

MediGene has successfully provided proof of concept of EndoTAG®-1 in two clinical trials. A controlled phase II clinical trial for pancreatic cancer showed significantly increased survival rates of those patients treated with EndoTAG®-1 and gemcitabine combination therapy. A phase II clinical trial in triple-negative breast cancer also showed a positive efficacy trend of EndoTAG®-1 combination therapy. European and US authorities have granted orphan drug status for EndoTAG®-1 in the treatment of pancreatic cancer. This status affords benefits in the development, approval and, under certain circumstances, the commercialization of the drug.

#### Outlook

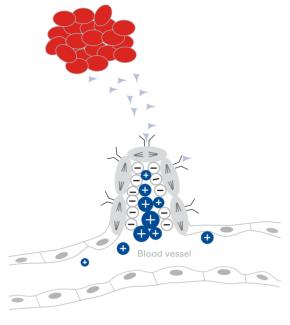
MediGene intends to enter into one or more partnerships for EndoTAG®-1 with pharmaceutical or biotech companies and envisages the partner or partners taking over the further development and future commercialization of the drug candidate.

#### INDICATIONS – BREAST CANCER AND PANCREATIC CANCER

BREAST CANCER: According to the latest estimates, around 230,000 new cases of breast cancer were diagnosed and 40,000 patient deaths recorded in the USA alone in 2011. Breast cancer is by far the most common type of cancer in women. In approximately 15% of all cases, malignant breast tumors display neither estrogen/gestagen nor HER-2 receptors on the cell surface – these are termed »triple negative« (TNBC). The prognosis is significantly worse for patients diagnosed with this form of breast cancer. There is practically no suitable therapy for the disease, as traditional anti-hormonal treatment or treatment options that target HER-2 receptors cannot be used. In 70%–85% of all breast cancer cases, the tumor cells have no HER-2 receptors and are thus HER-2 negative. This type of breast cancer cannot be treated with methods that target the HER-2 receptor, such as monoclonal antibodies.

PANCREATIC CANCER: Pancreatic carcinoma is one of the most aggressive types of cancer. Around 44,000 new cases in the USA and about 12,000 in Germany occur each year – the number of deaths is about the same level. This makes pancreatic cancer one of the most common tumor-related causes of death. So far, there are only unsatisfactory systemic treatment options, so that the average survival time of patients is only around six months after diagnosis. After one year, only approximately 19% of patients are still alive and after five years, the number is as low as 4%. The requirement for new therapeutic approaches to treat this type of cancer is accordingly high.

#### EndoTAG®-1 attacking tumor-activated endothelial cells



#### Tumor cells

- Tumor releases signals inducing growth of blood vessels
- Endothelial cells divide, blood vessels grow toward tumor
- EndoTAG®-1 interacts with the tumor-activated endothelial cells and reduces the tumor blood supply

#### IIT - Investigator Initiated Trial

At the end of 2011, Prof. Ahmad Awada, principal investigator in the clinical phase II trial of EndoTAG®-1 in triple negative breast cancer, startet an Investigator Initiated Trial (IIT) of EndoTAG®-1 in hormone-receptor positive, HER-2 negative breast cancer, a further indication in which the drug may potentially be used. Investigator initiated trials are clinical trials of drug candidates that are instigated, organized and financed by the medical profession. They focus on enhancing a specific therapy for patients with no commercial interests involved. The sponsoring function, in other words overall responsibility, lies with the physician and/or the relevant institute.

#### Clinical trial with EndoTAG®-1 in breast cancer

The final data from the phase II trial of EndoTAG®-1 in triple negative breast cancer (TNBC) confirms a positive efficacy trend for EndoTAG®-1 in combination with weekly standard paclitaxel administration. In addition, further analysis carried out of a patient sub-group not defined in the trial protocol (119 of 140 patients: ECOG 0/1, initial therapy for advanced disease) demonstrates encouraging overall survival data where the EndoTAG®-1 combination therapy was used.

The primary endpoint was achieved with EndoTAG®-1 combination therapy. In addition, the analysis of the secondary endpoints (median progressionfree survival, non-progression rate, safety, and tolerability) shows further positive results for EndoTAG®-1 combination therapy.

#### Positive data from the TNBC trial confirms the efficacy trend of EndoTAG®-1 in combination with paclitaxel

Median overall survival in months (week 41, 95% confi- dence intervals)	EndoTAG®-1 + Paclitaxel	EndoTAG®-1	Paclitaxel
TNBC patients <sup>1)</sup> (133)	13.0	11.9	10.1
	(51)	(57)	(25)
TNBC patients <sup>1)</sup>	15.1	12.5	8.9
treated per protocol (124)	(48)	(52)	(24)
Subgroup <sup>1)</sup> ECOG 0/1,	17.8	11.7	10.1
first line treatment (119)	(45)	(50)	(24)

Progression free survival week 16	EndoTAG®-1 + Paclitaxel	EndoTAG®-1	Paclitaxel
Evaluable patients for central review	59.1%	34.2%	48.0%
	(26/44 pts)	(13/38 pts)	(12/25 pts)
mITT population,	47.3%	29.8%	42.9%
local review	(26/55 pts)	(17/57 pts)	(12/28 pts)

pts: patients

mITT: modified intention to treat

<sup>1)</sup> centrally verified

#### MILESTONES 2011





IIT IN FURTHER BREAST CANCER INDICATION STARTED



#### ACTIVITIES TO CONCLUDE PARTNERSHIP UNDERWAY

### **RHUDEX**<sup>®</sup>

Product	Indication	Pre-clinic		Clinical phase	Approval	Market	
			I	П	Ш		
RhuDex®	Autoimmune diseases						
Chance of reaching	the market <sup>1)</sup>	< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>1)</sup> Industrial average, estimates of MediGene AG

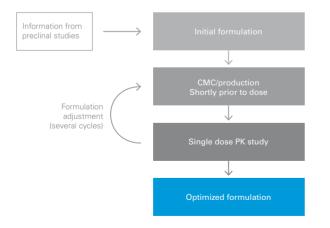
#### About RhuDex®

RhuDex<sup>®</sup> is being developed by MediGene as a disease modifying agent for the oral treatment of autoimmune diseases such as rheumatoid arthritis.

T-cell activation is pivotal in the onset of these diseases. It is triggered by interaction between specific proteins of immune cell surfaces. In this, the interaction of CD80 protein and CD28 protein, a receptor on the surface of T cells, plays a key role. RhuDex<sup>®</sup> has the ability to bind to CD80, thus preventing interaction with CD28 and, in so doing, interrupting an important signaling pathway of T-cell activation. Consequently, the drug candidate RhuDex<sup>®</sup> can be classified with the group of drugs called »Disease Modifying Antirheumatic Drugs« (DMARDs). RhuDex<sup>®</sup> has already been tested in initial clinical trials. In a phase IIa trial in 29 patients, RhuDex<sup>®</sup> showed initial signs of biological activity relevant for the treatment of rheumatoid arthritis. Based on preclinical trials, MediGene developed a new formulation concept for RhuDex<sup>®</sup> in 2011, customized for the treatment of chronic diseases. It is currently being tested and optimized as part of a clinical trial.

#### Outlook

MediGene expects the results from the formulation trial to be ready by mid-2012. Upon successful conclusion of this study, MediGene plans to continue clinical development of RhuDex<sup>®</sup>. The Company intends to outlicense RhuDex<sup>®</sup> once proof of concept has been established, if not earlier.



#### Development of the formulation

The optimum release of the relevant active ingredient in the human body plays an important role in the development of drugs. For the development of a RhuDex<sup>®</sup> formulation, this means that after oral administration, the drug needs to achieve the most constant efficacy level in the blood possible. In addition, taking the drug must be made as easy as possible for the patient, e.g. by adapting the size and quantity of tablets or pills to be taken.

#### Optimal formulation for RhuDex<sup>®</sup> via RapidFACT™

Developing the formulation by means of a RapidFACT<sup>™</sup> trial (Rapid Formulation Development and Clinical Testing) enables MediGene to efficiently test and optimize the new formulation concept of RhuDex<sup>®</sup>.

The development includes the following steps

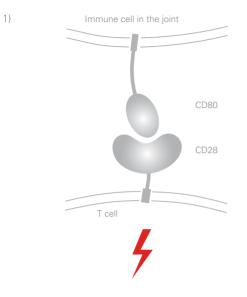
1. Development of the initial formulation based on information from preclinical trials

2. Analysis of the efficacy level

3. Formulation adjustment

4. Repeat steps 2–3 until the optimum formulation has been identified

#### RhuDex® inhibits autoimmune-mediated inflammation

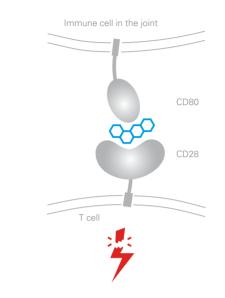


T-cell activation by certain immune cells in the diseased joint is an important process in the onset of rheumatoid arthritis.

1) T-cell activation requires interaction between the surface proteins CD80 and CD28

#### **DMARDs**

The family of disease-modifying drugs will be used as an ancillary supporting treatment for inflammatory rheumatic conditions. The family includes drugs offering the most varied spectrum of active relief mechanisms. Anti-rheumatics of this nature are frequently prescribed over sustained periods to treat or reduce acute and chronic symptoms. DMARDs have the capability of reducing the damage caused by chronic inflammation and so have a positive effect on pain caused by inflammation, although they do not in themselves cure the underlying condition. Unlike symptomatic treatments, this group of drugs is solely intended to have a positive effect on the manifestations of the condition.



2)

2) RhuDex  $^{\otimes}$   $\ref{eq:schwarz}$  prevents the interaction between CD80 and CD28, thus acting as an anti-inflammatory agent

#### INDICATION – RHEUMATOID ARTHRITIS

Rheumatoid arthritis (RA) is a chronic inflammation of the connective tissue, which affects over 1% of the world's population. RA primarily affects the joints and results in painful restriction of movement and deformities. The disease is approximately three times more common in women than men. It may occur at any age, with initial symptoms most frequently emerging between the age of thirty and fifty.

#### **MILESTONES 2011**







FORMULATION TRIAL

### AAVLP

Product	Indication	Pre-clinic		<b>Clinical phase</b>	Approval	Market	
			I.	П	III		
AAVLP	Vaccine candidates						
Chance of reaching	the market <sup>1)</sup>	< 10%	< 15%	< 30%	< 70%	< 90%	

<sup>1)</sup> Industrial average, estimates of MediGene AG

#### About AAVLP

Adeno-associated virus-like particles offer potential as prophylactic and therapeutic vaccines against cancer and infections, for example. The idea of using adeno-associated viruses (AAV) as a vaccine was developed in MediGene's laboratories. The adeno-associated virus is non-pathogenic, i.e. it does not cause disease. The virus protein shell, the capsid, is suited for the production of so-called virus-like particles (VLP), which can be used as a basis for novel vaccines.

By inserting short antigenic peptides (B-cell epitopes) into the AAV capsid, a highly specific antibody reaction against selected target molecules can be induced. These antibodies can protect the body from disease (i.e. have a prophylactic effect) or act as a therapy against existing diseases.

MediGene is currently conducting research into the application of AAVLP technology for the treatment of cancer and viral infections, and is examining the possibility of using AAV libraries to systematically identify suitable vaccine candidates. The key benefit of this innovative technology is the possibility of transferring the mode of action of existing therapeutic antibodies directly into a vaccine. In preclinical studies, AAVLP-based vaccines have shown promising data. This approach constitutes an interesting alternative to conventional vaccines and may also significantly widen the range of applications for vaccines against cancer and other diseases.

#### Outlook

MediGene will conduct further preclinical studies on AAVLP technology. On the basis of these studies, MediGene will decide on the further development or strategic options for the AAVLP project.

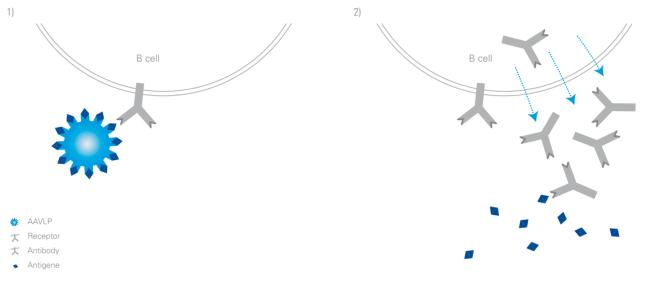
#### INDICATIONS – HPV AND CERVICAL CANCER

HPV: Human papillomaviruses are a group of very common viruses which infect the epithelium of the skin and various mucous membranes and may cause tumor-like growth. They are primarily sexually transmitted. Depending on the HPV type, the health effects of infection vary considerably. Some particularly aggressive HPV types may cause malignant changes, e.g. cervical cancer.

CERVICAL CANCER: Cervical cancer is the second most common type of cancer in women and is mainly caused by high-risk types HPV 16, 18, 31 and 45. Despite extensive screening programs, more than 450,000 new cases of cervical cancer are diagnosed worldwide per year, and 350,000 women die each year from the disease. Between 1% and 4% of the female population experience profound changes (dysplasia) of the cervix.

ANNUAL REPORT 2011						PRODUCTS

#### Antigenes on the AAVLP surface trigger the production of specific antibodies.



1) The AAVLP is injected into the body. On its surface a specific antigen is presented. B cell receptors recognize this antigen and activate the immune system 2) Upon infection and availability of antigens in the body, B cells increasingly proliferate and higher amounts of specific antibodies against the antigens will be produced 33

#### DEVELOPMENT IN COOPERATION WITH RENOWNED INSTITUTIONS

In May 2011, MediGene signed a development collaboration agreement with The Johns Hopkins University, Baltimore, USA. The objective of the collaboration is to test the first vaccine candidates of the AAVLP platform for the prevention of HPV-associated cancers and to further the development of the AAVLP project. The vaccine candidates examined target at at a number of carcinogenic human papillomaviruses (HPV), which, for example, cause cervical cancer. The studies are being directed by Dr. Richard B. S. Roden, Professor of Gynecology/ Obstetrics and Oncology at The Johns Hopkins University School of Medicine, one of the leading scientists in the field of HPV research. In September 2011, MediGene presented preclinical data on AAVLP vaccine technology at the 27th International Papillomavirus Conference in Berlin, Germany. The data was obtained in cooperation with the German Cancer Research Center (DKFZ) and demonstrates that particles derived from MediGene's AAVLP technology, which comprise serotype 16 and 31 peptides of human papillomaviruses (HPV), induce neutralizing antibodies against a wide range of HPV serotypes in vaccine tests with mice. The in-vivo studies provide evidence of the potential this technology offers in the development of a prophylactic vaccine against infections of cancer-inducing HPV serotypes.

#### MILESTONES 2011







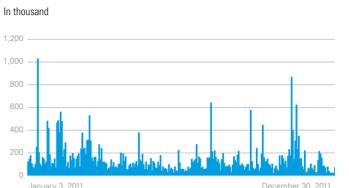
ADDITIONAL PRECLINICAL DATA GENERATED

# THE SHARE

#### 2011 share price performance

(Index opening price January 3, 2011, €1.99 indexed to 100)





# Share price

On January 3, 2011, MediGene shares started trading at an opening price of €1.99. In the first two months of the year, the share price outperformed the market as a whole and achieved the high for the year on February 9, 2011 at €2.71 with a very high volume of trading. This performance was associated with several reports on the conclusion of new partnership agreements for the marketing of Veregen®. In March 2011, support for the shares declined in the absence of news on the Company and by mid-March, the share price was back to the opening price at the start of the year. In the course of the first half of the year, the share price then fell in line with the stock market in difficult overall conditions. The two share price spikes in this period could be linked to the presentation of the annual results for 2010 and the announcement of a development collaboration agreement with The Johns Hopkins University on the AAVLP project. On August 5, 2011, the date of the Annual General Meeting, the share price was down significantly to €1.08 while trading was high. Subsequently, more of the value was wiped off the shares, with the share price falling below the €1.00 mark for the first time at the close of trading on September 5, 2011. However, the shares recovered and the price rose again to €1.18 towards the end of the month. With no corporate news release and in a market environment dominated by the European financial crisis, the share price fell to its lowest

level of €0.86 on November 4, 2011, but climbed again to €1.14 in mid-November when positive news was released about the approval of the clinical trial of RhuDex<sup>®</sup>, the announcement of an IIT trial and further data on EndoTAG<sup>®</sup>-1 as well as good quarterly results. Towards the end of the year, the share price settled around the €1.00 mark and trading closed at €0.97 on December 30, 2011. At the beginning of 2012 the share price rose and clearly exceeded the 1-euro-mark.

# Liquidity

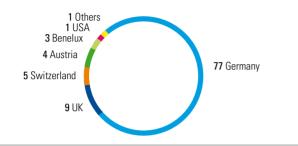
Market volume

The liquidity of MediGene shares was consistently high during 2011: The average daily trading volume totaled approximately 142,220 shares. On January 13, 2011, almost 1.1 million shares were traded (approx. 3% of the share capital) and a further peak was recorded on November 8, 2011 when almost 900,000 shares were traded. This correlated with the publication of a press release by the Company on its EndoTAG®-1 drug candidate.

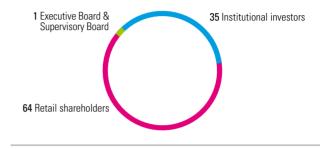
### Positive analyst coverage

MediGene is monitored by analysts from renowned investment banks in Germany and abroad. MediGene AG and its products and technologies have been analyzed in detailed reports. At the 2011 year-end, four out of five analysts issued a buy recommendation for MediGene shares.





Ownership information by type of investor In %



As per December 31, 2011, figures rounded, data based on information from WestLB and MediGene assessment

As per December 31, 2011, figures rounded, data based on MediGene assessment

In 2011, MediGene presented the company at the following international investor conferences:

San Francisco
Paris
New York
Zurich
Frankfurt

Analysts' assessments of MediGene shares

Buy	4
Neutral	1
Reduce	0

As of December 2011, basis: 5 analysts' studies

#### In 2011, the following investment banks reported on MediGene

DZ Bank AG	Dr. Elmar Kraus
Landesbank Baden-Württemberg	Dr. Hanns Frohnmeyer*
Nomura Code Securities Ltd.	Samir Devani
Viscardi AG	Robert Willis
WestLB AG	Dr. Cornelia Thomas, Mark Belsey

\* Landesbank Baden-Württemberg discontinued its coverage following job cuts in its team of analysts in the first half of 2011.

# **Ownership development**

At year-end 2011, approximately 64% of the shares issued were held by private investors (2010: 59%) and around 35% by institutional investors (2010: 40%). Directors' holdings remained roughly unchanged at 1% in 2011. Approximately three quarters of the shares are held by investors in Germany (77%), followed by the UK (9%), Switzerland (5%), Austria (4%) and the Benelux countries (3%).

# Intensive investor relations work

In 2011, MediGene continued its proactive investor relations activities, in order to keep the Company's investors, financial analysts and the business press informed about developments at MediGene. In addition to press and analysts' conferences, MediGene gave interviews to the relevant finance media and had discussions with investors in Germany and abroad. Company presentations at renowned investor conferences underlined MediGene's presence on the international capital market.

# International award for the Annual Report

MediGene's Annual Report 2010 won an award at the biggest international competition in 2011: at the Vision Awards of the League of American Communications Professionals (LACP) in the USA, MediGene received the Silver Award in the biotechnology category. With this award, MediGene was once again honored for its professional and transparent reporting to shareholders and the public.

# Share data

Stock ID code	MDG
Securities identification number	502090
International Securities Identification code	DE0005020903
Common Code	1107 3026
CUSIP	993 906 FV5
Reuters symbol	MDGGn
Bloomberg symbol	MDG
Market segment	Prime Standard
Indices	Prime All Share, DAXSubsector Biotechnology
Trading floors	XETRA, Berlin, Bremen, Düsseldorf, Frank- furt, Hamburg, Hanover, Munich, Stuttgart
Designated Sponsors	DZ Bank AG, WestLB AG

# Key figures of the MediGene share

Key figures of the MediGene share		
In€	2011	2010
52-week high	2.71	3.92
52-week low	0.86	1.66
Opening price	1.99	3.64
Year-end closing price	0.97	1.99
Average price since beginning of the year	1.58	2.81
Weighted average number of shares (basic)	37,082,758	36,563,966
Average daily trading volume (in shares)	142,220	232,772
Average market capitalization (in € million)	59	103
Total number of shares outstanding (Dec. 31)	37,082,758	37,082,758
Earnings per share <sup>1)</sup> (basic and diluted)	0.17	-0.49
Shareholders' equity per share1)	1.29	1.10
Operating cash flow per share <sup>1)</sup>	0.19	-0.31
Dividend per share	0	0
Freefloat <sup>2)</sup> (in %)	94	93

<sup>1)</sup> Reference amount: Total number of outstanding shares
 <sup>2)</sup> Source: MediGene AG, Deutsche Börse

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

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, AS OF DECEMBER 31, 2011

- Total revenue:
- from continued operations €4.7 million (2010: €2.3 million)
- from discontinued operations €27.8 million (2010: €47.4 million)
- EBITDA: €11.2 million (2010: €-12.8 million)
- Net profit for the year: €6.3 million (2010: €-17.9 million)
- Average monthly cash flow: €0.6 million, adjusted by one-time effects:
  €-0.8 million (2010: €-1.0 million, adjusted by-one time effect: €-1.4 million)

# **Company overview**

MediGene AG, Planegg/Martinsried, Germany, is a biopharmaceutical company that specializes in the research and development of innovative drugs to treat cancer and autoimmune diseases.

#### Organizational and legal structure of the Group

MediGene AG was founded in 1994 in Planegg/Martinsried near Munich in 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; SIN 502090; code MDG).

In addition to MediGene AG in Planegg/Martinsried, Germany, which is the parent company, the MediGene Group includes two wholly owned subsidiaries, MediGene, Inc., San Diego, California, USA and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom. The subsidiaries were acquired in 2001 (MediGene, Inc.) and 2006 (MediGene Ltd.) respectively. In the year under review, MediGene AG commenced the procedure for winding up MediGene Ltd., since the company's operations ceased when all patents were transferred to MediGene AG. The shares of MediGene Ltd. in Immunocore Ltd., Abingdon, Oxfordshire, United Kingdom, amounting to 21.69% will be transferred to MediGene AG as part of winding up MediGene Ltd. The subsidiary MediGene, Inc. holds 41.89% of the shares in Catherex, Inc., Philadelphia, Pennsylvania, USA, which was founded in 2010. The MediGene Group is also referred to as »MediGene« for short in this report. The Group is managed by the Executive Board of the parent company, MediGene AG. The subsidiaries' management entities report directly to the Group's Executive Board.

#### Segments

MediGene's business activities are comprised of the two market segments Marketed Products and Drug Candidates. The regional segmentation differentiates between the regions Germany, United Kingdom, USA and other countries.

#### **Management structure**

The Executive Board of MediGene AG consists of CEO Dr. Frank Mathias and CFO Arnd Christ.

# **Products and marketing**

In 2011, MediGene generated revenue from two drugs that are already marketed: Eligard<sup>®</sup> for the treatment of prostate cancer and Veregen<sup>®</sup> for the treatment of genital warts. Both drugs are marketed by partners.

MediGene also has ongoing research and development projects in the fields of oncology and immunology. The drug candidate EndoTAG®-1 has successfully undergone two phase II clinical trials for the indications pancreatic cancer and breast cancer. RhuDex®, which is used to treat autoimmune diseases such as rheumatoid arthritis, produced positive data in a phase IIa pilot trial. In January 2012, MediGene launched a clinical trial to test and optimize a new formulation concept for the drug. In addition, MediGene has projects at the preclinical and research stages, in particular the AAVLP technology for the identification and development of potential vaccine candidates.

# Status of the product portfolio and research and development activities

### **Eligard**<sup>®</sup>

Eligard<sup>®</sup>, a drug developed to treat hormone-dependent prostate cancer, is marketed in most European countries by Astellas Pharma Europe Ltd. (hereinafter referred to as »Astellas«), Staines, UK. MediGene acquired a license for the European rights in 2001 from Atrix Laboratories, Inc. (now Tolmar Therapeutics, Inc., Fort Collins, Colorado, USA, hereinafter referred to as »Tolmar«) and successfully took the product through the German approval process. Since 2004, marketing of Eligard<sup>®</sup> in Europe has been the subject of a contract with MediGene's partner Astellas, who launched the drug in Europe and markets it successfully in the form of one-month, three-month and sixmonth depot formulations. In 2010, MediGene agreed to transfer its Eligard<sup>®</sup> rights to Astellas against payments totaling €25 million, of which €20 million were posted in the income statement in 2011. Since the date of transfer of the EU rights to Astellas in March 2011, MediGene has also participated in net product sales with 2% royalties. Following the transfer of the rights, MediGene no longer bears any performance obligations or risks that arise in connection with the supply of the product to Astellas. This includes the procurement costs and license fees that MediGene paid to licensor Tolmar to date. The transaction has considerably strengthened MediGene's financial position.

#### **Veregen**<sup>®</sup>

Veregen<sup>®</sup>, a drug used to treat external genital warts, was clinically developed by MediGene. It is currently available in the US, German and Austrian markets, where the drug is marketed by partner companies. At the end of 2011, MediGene applied for marketing authorization of Veregen<sup>®</sup> in 17 other European countries (Belgium, Bulgaria, the Czech Republic, Cyprus, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia and Sweden). The approval obtained for Veregen<sup>®</sup> in Germany, the reference country, formed the basis in the mutual recognition procedure. Outside the EU, marketing authorization applications have been submitted by MediGene's partners in Switzerland (in 2010) as well as Israel, Mexico, Serbia and Taiwan (all in 2011).

A partnership agreement is in place with Fougera Pharmaceuticals Inc. (hereinafter referred to as »Fougera«, the former Nycomed US, Inc.), Melville, NY, USA for marketing Veregen® in the USA. In Germany and Austria, Veregen® has been marketed by regional sales companies of the Abbott Group (the former Solvay, hereinafter referred to as »Abbott«) since 2010. The group has also acquired the rights from MediGene to market the drug in Switzerland. In 2011, MediGene signed partnership agreements for distributing Veregen® in France (Laboratoires Expanscience), Mexico, Central America, Venezuela and Colombia (Pierre Fabre Medicament SAS), Canada (Triton Pharma Inc.), the Benelux countries (L.F. Will-Pharma & Cie), Romania and Bulgaria (Meditrina Pharmaceuticals, Ltd.), Serbia, Bosnia & Herzegovina, Montenegro, Macedonia, Croatia, Slovenia and Albania (Pharmanova d.o.o.) as well as Taiwan (SynCore Biotechnology Co., Ltd.). Further marketing partnerships are in place for Spain and Portugal (Juste S.A.Q.F.), Greece and Cyprus (Meditrina Pharmaceuticals Ltd.), Israel (Teva Pharmaceutical Industries Ltd.), China (GC-RISE Pharmaceutical Ltd.) and South Korea (JS Bio Pharm Co., Ltd.). MediGene receives successive payments from these partners depending on the achievement of specific milestones and also has a share in Veregen<sup>®</sup> revenue. MediGene earns further revenue from product sales to the respective partner company.

Veregen<sup>®</sup> is an innovative drug based on a defined extract from green tea leaves, which is obtained in a highly complex and specifically developed process. Sinecatechins 15% ointment (Veregen<sup>®</sup>) is recommended in the current US Department of Health and Human Services Center for Disease Control and Prevention's Sexually Transmitted Diseases Treatment Guidelines 2010 as a possible option for treating genital warts.

# EndoTAG®-1

The clinical drug candidate EndoTAG®-1 is a novel composition of the established cytostatic drug paclitaxel combined with neutral and positive lipids. The positively charged lipids mean that EndoTAG®-1 interacts with newly developed, negatively charged endothelial cells, which are primarily required for the growth of tumor blood vessels. The EndoTAG®-1 paclitaxel component attacks the endothelial cells as they divide, thus targeting the blood supply to tumors without affecting the supply to healthy tissue. By doing this, EndoTAG®-1 is expected to prevent the formation of new tumor blood vessels and to inhibit tumor growth.

EndoTAG<sup>®</sup>-1 has been designated orphan drug status in Europe and the USA for the treatment of pancreatic cancer. This designation has advantages for the development, approval and, under certain circumstances, the marketing of drugs.

MediGene has successfully completed two clinical phase II trials of EndoTAG®-1 in the indications pancreatic cancer and triplenegative breast cancer (TNBC). In December 2011, the overall survival data from the phase II trial in TNBC was published at the San Antonio Breast Cancer Symposium. These secondary endpoint data (overall survival) confirmed the positive efficacy trend of EndoTAG®-1 in combination therapy with standard weekly paclitaxel, which was previously reported by the primary endpoint data (progression-free survival rate). *(see page 29)*  In 2011, MediGene announced that Prof. Achmad Awada from the Jules-Bordet Institute in Brussels, Belgium, principal investigator in the clinical TNBC trial, would conduct a phase II Investigator Initiated Trial (IIT). The trial objective is to analyze EndoTAG®-1 in hormone-receptor positive, HER2-negative breast cancer, which is an additional potential indication for EndoTAG®-1. The results of this trial, which started at the end of 2011, are expected to be available in 2013.

### **RhuDex**<sup>®</sup>

MediGene is developing RhuDex<sup>®</sup> as an oral, disease modifying drug for the treatment of autoimmune diseases such as rheumatoid arthritis. RhuDex<sup>®</sup> is a CD80 antagonist that blocks undesired T-cell activation and thus has an immunomodulating and anti-inflammatory effect. This drug candidate can be classified with the group of »Disease-Modifying Antirheumatic Drugs« (DMARDs). In a phase IIa trial in 29 patients, RhuDex<sup>®</sup> showed initial signs of biological activity.

In 2011, MediGene developed a new formulation concept for RhuDex<sup>®</sup> based on preclinical trials, which is customized for the treatment of chronic diseases. It is currently being tested and optimized since January 2012 as part of a clinical trial. MediGene was granted official approval to conduct this formulation trial in October 2011.

# **AAVLP** technology

Under the AAVLP program, MediGene is developing an innovative technology platform for producing prophylactic and therapeutic vaccines designed to permanently protect against infectious diseases. To this end, virus-like particles (VLP or AAVLP) based on adeno-associated viruses (AAV) are used as a basis for the innovative vaccines. MediGene is currently conducting research into the use of AAVLP technology to treat infection and cancer, and into the application of AAV libraries to identify suitable vaccine candidates systematically.

In June 2011, MediGene signed a development collaboration agreement with The Johns Hopkins University, Baltimore, USA. The objective of the collaboration is to test the first vaccine candidates of the AAVLP platform for the prevention of HPVassociated cancers in preclinical experiments and to advance the development of the AAVLP project. The vaccine candidates examined target at a number of carcinogenic human papillomaviruses (HPV), which, for example, cause cervical cancer. The studies are being directed by Dr. Richard B. S. Roden, Professor of Gynecology/Obstetrics and Oncology at The Johns Hopkins University School of Medicine.

In September 2011, MediGene presented preclinical data on AAVLP vaccine technology at the International Papillomavirus Conference in Berlin, Germany. The data was obtained in cooperation with the German Cancer Research Center (DKFZ) and demonstrates that particles derived from MediGene's AAVLP technology, which comprises peptides from human papillomavirus (HPV) serotypes 16 and 31, induce neutralizing antibodies against a wide range of HPV serotypes in mice-vaccination studies. The in-vivo studies provide evidence of the potential this technology offers in the development of a prophylactic vaccine against infections of cancer-inducing HPV serotypes.

# **General conditions**

# General economic and regulatory conditions

According to information from the European Central Bank, global economic growth ran out of momentum in the last few months of 2011, although a certain level of stability appears to be emerging (ECB, monthly report for January 2012). In Germany, the sharp rise in economic output during summer 2011 is likely to have been followed by a period of flat economic growth in the last quarter of the year (Deutsche Bundesbank, monthly report for January 2012).

In 2011, the trend in the pharmaceutical industry in Germany was impacted by new legislation which had come into force, namely the Statutory Health Insurance Restructuring Act (GKVÄndG, in August 2010) and the Drug Market Restructuring Act (AMNOG, in January 2011). The legislation is aimed at dampening the rise in costs in the healthcare sector, partly by reducing drug prices. In the USA, no amendments were introduced to existing pharmaceutical industry legislation in 2011 that had a major impact on MediGene's business.

#### Procurement

Procurement is focused on the approved drugs Eligard<sup>®</sup> (until end of February, 2011) and Veregen<sup>®</sup> as well as drug candidates for clinical and preclinical test purposes, services, chemicals and laboratory supplies for research and development. MediGene is intensely involved in the development and optimization of production processes for future drugs, in order to efficiently organize the procurement of required ingredients at a later stage.

### **Procurement of drugs**

Up to the transfer of the EU rights to Astellas with effect as of March 1, 2011, MediGene purchased the drug Eligard<sup>®</sup> from Tolmar.

MediGene has a contract with Mitsui Norin Co., Ltd. (hereinafter referred to as »Mitsui Norin«), Tokyo, Japan for the production and supply of the active pharmaceutical ingredient for Veregen<sup>®</sup>. The formulation of the ointment is carried out by a contract manufacturer in Germany by order of Fougera for the US market and by order 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 MediGene is not dependent on single raw material suppliers for research and development. Rather, the company solicits various quotes as a matter of principle and places its orders with the most advantageous supplier, taking into account quality considerations. Procurement is organized 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 optimizing 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.

# **Performance indicators**

# **Financial performance indicators**

MediGene's management uses revenue, EBITDA, gross revenue margin, liquidity cover ratio and equity ratio as performance indicators for the commercial success of the Group's activities. MediGene's EBITDA is derived from net profit/loss for the year excluding taxes, the financial result, depreciation, amortization and impairment.

**Performance indicators** 

		2011	2010
Gross margin as a share of total revenue from continued operations and product sales from discontinued operations	<u>Gross profit x 100</u> Total revenue	81%	20%
EBITDA		€11,180 thousand	€-12,756 thousand

Asset and finance indicators

		2011	2010
Liquidity cover ratio	<u>Cash x 100</u> Balance sheet total	24%	8%
Equity ratio	<u>Equity x 100</u> Balance sheet total	90%	70%

# Non-financial performance indicators

MediGene's commercial success will 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 AG's patent situation is therefore the Company's most critical non-financial performance indicator.

#### **Patent position**

MediGene currently holds rights to a large number of patents and patent applications in the capacity of either owner or licensee.

### Patents granted and scheduled to be granted

	Marketed Products	Drug Candidates
Europe/Germany	4	17
USA	4	39

**Pending patent applications** 

	Marketed Products	Drug Candidates
Europe/Germany	4	22
USA	2	23
International (PCT)	2	37

# Consistent patent strategy provides the basis for commercial success

The Company's aim is 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 patent applications for various results of its work on proprietary technologies and products, or has exclusively licensed patents for the relevant segments.

# **Income position**

# Product sales and other income

In 2011, MediGene approximately doubled revenue from continued operations to  $\notin$ 4,656 thousand (2010:  $\notin$ 2,292 thousand) and achieved revenue from discontinued operations totaling  $\notin$ 27,828 thousand (2010:  $\notin$ 47,398 thousand).

Revenue from continued operations was generated from the commercialization of Veregen<sup>®</sup> in the USA, Germany and Austria amounting to €2,050 thousand (2010: €1,529 thousand), as well as from milestone payments for Veregen<sup>®</sup> of €250 thousand (2010: €685 thousand). Other operating income amounted to €2,356 thousand (2010: €78 thousand). Since March 2011, this has comprised a 2% share amounting to €2,157 thousand of the net sales of Eligard<sup>®</sup> achieved by Astellas.

Revenue from discontinued operations comprised milestone payments of €20,000 thousand, which MediGene posted in connection with the transfer of the EU Eligard® rights to Astellas on March 1, 2011. The Eligard® product sales achieved and license payments received up to the end of February 2011 are also reported under this item.

Revenue distribution is presented in the *Notes to the consolidated financial statements D) note (28) on page 81.* 

#### **Consolidated income statement (abbreviated)**

In€thousand	2011	2010	Change
Total revenue	4,656	2,292	103%
thereof Veregen® product revenue and royalties	2,050	1,529	34%
Cost of sales	-953	-781	22%
Gross profit	3,703	1,511	145%
Selling, general, and administrative expenses	-8,103	-9,399	-14%
Research and development expenses	-11,254	-13,494	-17%
Loss resulting from spin-off	0	-6,212	-
Operating result from continued operations	-15,654	-27,594	-43%
Result before tax from continued operations	-15,474	-27,177	-43%
Taxes	1,241	0	-
Result from continued operations	-14,233	-27,177	-48%
Product sales from discontinued operations	27,828	47,398	-41%
Result from discontinued operations	20,514	9,308	120%
Net result for the year	6,281	-17,869	_

# Cost of sales

Cost of sales from continued operations amounted to  $\notin$ 953 thousand in the reporting year compared with  $\notin$ 781 thousand in the previous year. The cost of sales incurred in connection with the commercialization of the drug Eligard<sup>®</sup> and hence from discontinued operations totaled  $\notin$ 5,326 thousand (2010:  $\notin$ 39,210 thousand).

### **Gross profit**

Gross profit from continued operations totaled €3,703 thousand in 2011 (2010: €1,511 thousand) and gross profit from discontinued operations totaled €22,502 thousand (2010: €8,188 thousand). Gross margins achieved from the drugs Eligard<sup>®</sup> and Veregen<sup>®</sup> depend to some degree on the euro-US dollar exchange rate.

#### Selling, general and administrative expenses

Selling, general and administrative expenses from continued operations decreased year-on-year from €9,399 thousand (2010) to €8,103 thousand (2011). This amount consists of €2,272 thousand (2010: €2,030 thousand) in selling expenses and €5,831 thousand (2010: €7,369 thousand) in general administrative expenses. Selling expenses from discontinued operations totaled €343 thousand (2010: €397 thousand).

# **Research & development expenses**

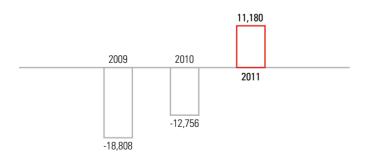
Total expenses for research and development (R&D) were down to €11,254 thousand (2010: €13,494 thousand). A large part of the cost for research and development consisted of expenses for the evaluation of the clinical trial with the drug candidate EndoTAG®-1 for the indication triple negative breast cancer. In addition, the write-down of an early-stage research project which MediGene is no longer pursuing, amounting to €3,827 thousand, was posted as an expense. Other costs arose in connection with additional development projects. The composition of research and development expenses can be found in the *Notes to the consolidated financial statements D) note (32) on page 82*.

# **EBITDA**

MediGene AG's EBITDA is derived from net profit/loss for the year excluding taxes, the financial result, depreciation, amortization and impairment. The use of this indicator instead of the EBIT figure provides a good indication of cash flow and is aimed at facilitating a comparison of the actual operating results before depreciation and amortization in separate periods. In 2011, MediGene's profit based on EBITDA amounted to €11,180 thousand (2010: €-12,756 thousand). The reporting of EBITDA does not require a differentiation between continued and discontinued operations.

#### **EBITDA**

In € thousand



# EBITDA

In€thousand	2011	2010	Change
Net result for the year	6,281	-17,869	-
Taxes	630	0	-
Financial result	586	-371	-
Share of result of associates	-766	-46	>200%
Derivative financial instrument	-226	-1,517	-85%
Depreciation and amortization	4,675	835	>200%
Loss resulting from spin-off	0	6,212	_
Total	11,180	-12,756	_

#### **Depreciation, amortization and impairment**

In total, depreciation, amortization and impairment decreased from  $\in 10,061$  thousand (2010) to  $\in 4,675$  thousand (2011). Scheduled amortization relates to intangible assets, including patents and product licenses. Scheduled depreciation relates to property, plant and equipment. During the reporting period, a project at the early research stage which MediGene is no longer pursuing was written down in full and derecognized ( $\in 3,827$  thousand). In the same period of the previous year, the impairment of goodwill as per IAS 36 occurred in connection with derecognition of the oHSV program, which was transferred to Catherex, Inc.

# **Financial result**

The financial result, consisting mainly of foreign currency exchange gains/losses and net interest income, amounted to €-586 thousand in the reporting period (2010: €371 thousand). The financial result from discontinued operations includes a gain from the financial derivative as per IAS 39 of €226 thousand (2010: €1,517 thousand) which relates to the product Eligard<sup>®</sup>. Following the transfer of the Eligard<sup>®</sup> rights to Astellas on March 1, 2011, this derivative no longer exists.

# **Result of associates**

The result from investments in associates amounted to €766 thousand in 2011 (2010: €46 thousand). This figure comprises the profit on the disposal of shares in Immunocore Ltd. totaling €1,540 thousand and the profit realized from the rise in pro rata shareholders' equity of €1,002 thousand following the issue of new Immunocore Ltd. shares. At the same time, the share in the loss of associates amounted to €1,776 thousand. As of December 31, 2011, the Group held 21.69% of the shares in associate Immunocore Ltd. and 41.89% of the shares in Catherex, Inc.

# Taxes

In the reporting period, a tax liability of €630 thousand was recognized. The calculation is based on a combined tax rate of 26.33%, which comprises the corporation tax rate (15%), the solidarity surcharge (5.5%) on the corporation tax and the trade tax rate (10.5%). In the same period of the previous year, neither a tax expense nor tax income was posted. The existing loss carryforwards were partially utilized. The total tax ratio amounts to approx. 9%.

# Net result for the year

In the reporting period, net profit for the year amounted to  $\epsilon$ 6,281 thousand compared with a loss of  $\epsilon$ -17,869 thousand in the previous year. The result for the year from continued operations improved to  $\epsilon$ -14,233 thousand (2010:  $\epsilon$ -27,177 thousand) and the result from discontinued operations to  $\epsilon$ 20,514 thousand (2010:  $\epsilon$ 9,308 thousand).

#### Earnings per share

In 2011, earnings per share amounted to  $\notin 0.17$  (basic weighted average number of shares: 37,082,758, diluted: 37,200,471) compared with a loss of  $\notin -0.49$  in the previous year (weighted average number of shares, basic and diluted: 36,563,966). In view of the low number of potentially exercisable options, there is no difference between basic and diluted earnings per share.

#### Segments

MediGene AG's activities are broken down into the segments Marketed Products and Drug Candidates (see page 100 et seq. "Business units«). The segment Marketed Products consists of the drugs Eligard® and Veregen®. The Drug Candidates segment reports on MediGene's activities relating to product candidates EndoTAG®-1, RhuDex® and AAVLP.

# **Financial position**

Change in cash reserves

In€thousand	2011	2010	Change
Net cash			
from/used by operating activities	6,864	-11,411	-
from/used by investing activities	1,423	-321	-
from financing activities	0	4,469	_
In-/Decrease in cash and cash equivalents	8,287	-7,263	-
Cash and cash equivalents at the beginning of the period	4,770	12,251	-61%
Foreign exchange differences	-246	-218	13%
Cash and cash equivalents at the end of the period	12,811	4,770	169%

### Change in cash reserves

In the reporting period, MediGene generated net cash from operating activities of €6,864 thousand (2010: €-11,411 thousand), of which €15 million (2010: €5 million) resulted from the sale of the Eligard<sup>®</sup> rights to Astellas. Net of the non-recurring milestone payments and the sale of shares in Immunocore Ltd. in the third quarter of 2011, net cash used by operating activities

amounted to €-9,910 thousand (2010: €-16,411 thousand). The major portion of net cash used related to expenses for research and development.

The net funds inflow from investing activities in 2011 totaled €1,423 thousand (2010: net cash used of €-321 thousand). In the reporting period, MediGene earned €1,774 thousand from the sale of shares in Immunocore Ltd.

Investments in property, plant and equipment as well as software amounted to €406 thousand in the reporting period (2010: €321 thousand). These investments consisted primarily of purchases of laboratory equipment and information technology. The Group made no investments on the basis of financial lease contracts.

No net cash flow from financing activities was recorded in 2011. In the previous year, MediGene reported a net cash inflow as part of capital increases which, deducting the repayment of convertible bonds, amounted to €4,469 thousand.

In total, cash and cash equivalents were up by €8,287 thousand in the 2011 reporting year (2010: net decrease of €-7,263 thousand). The closing balance of cash and cash equivalents in the year under review was €12,811 thousand (2010: €4,770 thousand). The liquidity cover ratio, calculated as the proportion of cash and cash equivalents in total assets/liabilities, was 24% as of the reporting date (2010: 8%). There were no open credit lines.

### Average monthly cash flow from operating activities

The consolidated statement of cash flows for 2011 shows an average monthly net cash inflow from operating activities of €572 thousand (2010: cash burn rate of €-951 thousand). Net of the above-mentioned non-recurring items, the monthly cash burn rate for 2011 was an average of €-826 thousand (2010: €-1,368 thousand). Net cash used by operating activities is only of limited informative value with regard to future developments, as it is significantly influenced by one-off payments under partnership agreements and by research and development expenses, the amount of which depends on the status of projects.

# **Asset position**

Development of assets and	d capita	l structure a	s of Dec. 31
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In€thousand	2011	2010	Change
Assets			
Property, plant, and equipment and intangible assets	28,554	32,846	-13%
Goodwill	2,212	2,212	0%
Financial and other non-current assets	263	157	68%
Investment in associates	4,183	5,059	-17%
Cash and cash equivalents	12,811	4,770	169%
Inventories and receivables	4,100	6,209	-34%
Other current assets	1,169	6,948	-83%
Total assets	53,292	58,201	-8%
Liabilities and shareholders' equity			
Shareholders' equity	47,932	40,798	17%
Non-current liabilities	536	247	117%
Current liabilities	4,824	17,156	-72%
Total liabilities and shareholders' equity	53,292	58,201	-8%
Liquidity cover ratio in %	24	8	
Equity ratio in %	90	70	

# Assets

Compared with the previous year, total assets decreased by 8% to €53,292 thousand (2010: €58,201 thousand). This decline was mainly due to a reduction in other non-current assets, inventories and receivables as well as intangible assets.

Property, plant and equipment and intangible assets decreased to €28,554 thousand in the reporting period (2010: €32,846 thousand). Property, plant and equipment accounted for €829 thousand (2010: €960 thousand). Intangible assets were down from €31,886 thousand to €27,725 thousand as a result of a one-off write-down of a project in the early research stage which MediGene is no longer pursuing. Goodwill remained unchanged on the previous year's figure and amounted to €2,212 thousand.

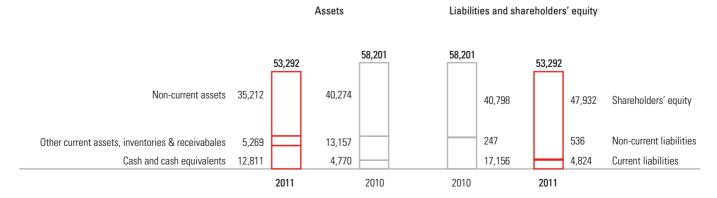
The carrying amount of interests in associates fell from  $\notin$ 5,059 thousand (2010) to  $\notin$ 4,183 thousand (2011).

Accounts receivable as of the end of the reporting period amounted to  $\notin$ 1,897 thousand (2010:  $\notin$ 4,516 thousand). This amount essentially represents receivables from Astellas and Fougera.

Inventories of Veregen<sup>®</sup> totaled €2,203 thousand as of the reporting date (2010: €1,693 thousand).

**Balance sheet structure** 

In € thousand



Other current assets totaled €1,169 thousand (2010: €6,948 thousand), of which €670 thousand were expenses incurred for future periods (2010: €826 thousand). In the same period of the previous year, deferred product and licensing sales that had not yet been billed accounted for €5,732 thousand. The remaining amount includes other current assets and rent deposits.

### Liabilities and shareholders' equity

In the reporting period, shareholders' equity rose to a total of  $\notin$ 47,932 thousand (December 31, 2010:  $\notin$ 40,798 thousand). The rise was mainly due to the net profit for 2011. As a result, the equity ratio also climbed to 90% (December 31, 2010: 70%). At reporting date December 31, 2011, total subscribed equity capital exceeded market capitalization. However, based on the impairment analyses of the assets at the reporting date, the Executive Board assumes that no further value adjustment is required.

Current and non-current liabilities amounted to €5,360 thousand as of the reporting date (2010: €17,403 thousand). This constitutes 10% of total liabilities. Current liabilities mainly include trade payables totaling €1,773 thousand (2010: €2,354 thousand), other liabilities totaling €2,344 thousand (2010: €9,488 thousand), tax liabilities of €630 thousand (2010: €0) and deferred income of €77 thousand (2010: €5,088 thousand). The liabilities arise from outstanding invoices and services utilized by MediGene.

Working capital, the difference between current assets and current liabilities, was up from  $\notin$ 771 thousand (2010) to  $\notin$ 13,256 thousand (2011).

#### **Overall statement**

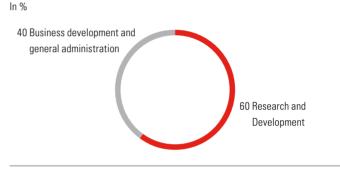
In the 2011 fiscal year, MediGene again achieved a marked improvement in its EBITDA and net result. The Company achieved the targets it published at the beginning of 2011 (revenue from continued and discontinued operations ranging between €32 million and €38 million as well as EBITDA of €10 million to €16 million, with the range in each case depending on the €5 million milestone payment upon transfer of the non-EU rights to Eligard<sup>®</sup>). MediGene is financially and structurally well-positioned to generate future growth.

### Employees

# Number of employees in the Group

In connection with the restructuring measures implemented in 2010, the number of employees was reduced to 63 as of January 1, 2011. As of December 31, 2011, the number of employees was 52. Personnel expenses fell by 38% in the reporting period to  $\notin$ 6,145 thousand (2010:  $\notin$ 9,946 thousand).

Employees by area of activity



as of Dec. 31, 2011

Employees by region as of Dec. 31

	2011	2010	Change
MediGene AG, Planegg/Martinsried	49	89	-45%
MediGene, Inc., San Diego	3	3	0%
MediGene Ltd., Abingdon	0	0	_
Total	52	92	-43%

# Remuneration of the Executive Board and Supervisory Board

### **Executive Board remuneration**

Remuneration of members of the Executive Board in the past fiscal year totaled €944 thousand (2010: €997 thousand), including pension expenses of €48 thousand (2010: €52 thousand) and vehicle leasing costs for company cars of €26 thousand (2010: €22 thousand). In addition, stock options with a fair value of €33 thousand (2010: €56 thousand) were issued to the Executive Board. The amount and composition of the remuneration paid to the individual members of the Executive Board is reported in the *Notes to the consolidated financial statements I) note (67) page 102 et seq.* including a detailed remuneration report.

Total remuneration of the Executive 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 installments. Variable remuneration includes an annual performance-based payment and stock options.

The criteria for the annual performance-based payment are established by the Supervisory Board annually in advance, both comprehensively for all Executive Board members and in addition separately for each member of the Executive Board. Of the annual performance-based payment granted, 65% 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-based 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 Board member with appropriate interest.

A detailed presentation of the remuneration system for the members of MediGene AG's Executive Board is provided in the *remuneration report on page 103 et seq.* 

#### **Supervisory Board remuneration**

Supervisory Board remuneration amounted to €229 thousand in 2011 (2010: €261 thousand). 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. Both the chairmanship and deputy chairmanship of the Supervisory Board are taken into account in the evaluation of the Supervisory Board members' scope of activities. 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 Boards are provided in the *Notes to the consolidated financial statements under I) notes (68) and (69), page 105 et seq.* 

# **Risk report**

# 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 ten to fifteen 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 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 stage, followed by the individual phases of clinical trials with human subjects. In these trials, side effects and the effectiveness of the drugs are investigated. Once the preclinical and clinical trials have 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 postpone the market launch. The results of preclinical and clinical trials are unpredictable. 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 maintains close relations 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 specialized 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.

#### **Approval risks**

Even if MediGene is granted market approval for a drug, such approval may be contingent on the fulfillment of certain obligations. This may be detrimental to the product's marketability. 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 fulfill a multitude of regulatory duties, such as monitoring the approved drug's safety. Approval – even without additional requirements – obliges MediGene to set up and run an organization within the Company to fulfill these legal requirements. The requirements may have a negative impact on the assets, financial and income position of the Company.

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 commercialization, which may have a negative impact on the assets, financial and income position 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 assets, financial and income position.

# **Risks of drug commercialization**

#### **Procurement risks**

A contract is in place with Mitsui Norin for the production and supply of the active pharmaceutical ingredient for Veregen<sup>®</sup>. The raw material, which consists of green tea leaves, is obtained from Chinese tea farmers and is subject to the usual risks inherent in agricultural products, such as crop failures caused by environmental factors or the chemical or biological contamination of harvested crops. Supply bottlenecks may adversely affect MediGene's business activities and, therefore, its assets, financial and income position.

### **Reimbursement risks**

The commercial success of drug 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 European Union and many other countries, there are price controls and/or other limitations on the reimbursement of drug costs. MediGene may even be forced to reduce the price of a drug in order to be included in such a reimbursement system.

# Competitive risks and risks of low drug sales

The development and marketing of drugs are subject to fierce competition. This applies especially to the fields 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 specialized biotechnology companies as well as universities and other research facilities. The drugs developed by MediGene target highly serious and/or still insufficiently treatable diseases. 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 placed in an inferior position, depending on the competing product's profile and sales performance. MediGene's portfolio strategy is designed to minimize such sales risks, although they cannot be ruled out completely.

MediGene's products are currently marketed and sold by partner companies. 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, therefore, its assets, financial and income position. The ability of MediGene or its 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 organizations. If the Company fails to enter into cooperation agreements of this kind under favorable conditions, this may delay or hinder the Company's ability to market its products or make such activities unreasonably expensive. This may adversely affect the Company's assets, financial and income position.

#### **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 and income position, 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.

# Financial risks faced by MediGene

Since MediGene AG was founded in 1994, the Company reported operating losses in every fiscal year up to and including 2010, as expenses for research and development in each year exceeded the corresponding revenue or gross profit. In 2011, MediGene generated a profit for the first time. The Company's future profitability depends on progress in terms of operations as well as MediGene's strategic decisions and is not yet secured.

#### **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, and 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 commercialization of drugs and drug candidates. There is no guarantee that MediGene will achieve the product revenues, additional market approvals and 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.

#### **Financing risks**

MediGene's present shareholders' equity and operating cash flow may be insufficient to cover the expected investment expenses and working capital that will be required in the foreseeable future of approximately 24 months. It is possible that MediGene will need to raise additional funds from external sources. The ability to raise additional capital 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. This may have significant adverse effects on the Company's assets, financial and income position, and on its future prospects. To date, MediGene has always been able to raise sufficient capital to ensure the continuous financing of its activities. In order to ensure that such opportunities continue to exist, MediGene pursues ongoing public relations and investor relations activities as well as proactive business development. Regarding the planned development of the coming fiscal years, we refer to the financial forecast on page 58.

#### Foreign exchange risks

The Group's subsidiaries and shareholdings in the US and UK expose it to certain exchange rate fluctuations in terms of the euro to US dollar and British pound exchange rates. However, in view of the limited scope of the relevant activities, the impact of foreign exchange differences is minimal.

The partnership agreement with Fougera for Veregen<sup>®</sup> is transacted in US dollars. The active pharmaceutical ingredient for this drug is also purchased in US dollars. This means that the contractually agreed milestone payments and the margin resulting from product sales are subject to foreign exchange differences. The contracts for Veregen<sup>®</sup> with additional marketing partners were concluded on a euro basis and will not therefore be subject to exchange rate risks.

#### Environmental, health and safety risks

In the United States, the United Kingdom and Germany, MediGene must observe a large number of different laws and standards relating to health and environmental protection, as well as occupational safety. These laws include provisions on the handling of exhaust emissions and the disposal of solid and liquid waste. Compliance with these regulations and requirements will necessitate investments and operating expenses within the scope of operating activities. Compliance with the regulations may result in additional future expenses. Adjustments to future changes in the law could require major investments. The resulting costs may have a significant negative impact on the Company's assets, financial and income position.

#### 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 to assert its own rights without infringing the rights of third parties. To protect its legally patented technologies and products, MediGene also uses confidentiality agreements and contractual license restrictions in its cooperation with 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 license agreements.

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®-1 and to compositions that can be manufactured using this process. In December 2011, the European Patent Office decided in a first-instance ruling that the patent is upheld to an extent which continues to protect the product EndoTAG®-1. In the course of opposition proceedings, MediGene AG had restricted its patent claims to the features that are relevant to EndoTAG®-1. The decision can be appealed.

#### Legal risks

In the past twelve months, no judicial disputes that could have a major influence on the Company's financial situation or that of its subsidiaries have been pending, nor is there currently a threat of any such dispute.

Further judicial disputes cannot be ruled out in the 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 in-house officers for biological safety and a project manager in accordance with the provisions of the German Genetic Engineering Act (Gentechnikgesetz), as well as officers for safety, infection prevention and waste management, all of whom are experienced employees trained specifically for their specialist tasks. MediGene also employs a 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 at work for each laboratory employee, the safety engineer analyzes hazards 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 Group holds the requisite authorizations 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 the risk management pursuant to Section 315 (II) (2) and (5) of the German Commercial Code (Handelsgesetzbuch, HGB)

Key features of the internal control and risk management system As MediGene, the parent company, is a publicly traded stock corporation as defined in Section 264d of the German Commercial Code (HGB), a description of the key features of its internal control and risk management system in respect of the accounting processes for both the associated companies and the Group is required pursuant to Section 315 (II) (5) of the HGB.

There is no statutory definition of the internal control and risk management system for the accounting processes relating to the individual companies and the Group. MediGene considers its internal control and risk management system to be comprehensive and bases its approach on the definitions provided by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer in Deutschland, e.V.), Düsseldorf, of internal accounting control systems and risk management systems. 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 organization. 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 accounting;
- To comply with the legal provisions applicable to the Company.

The risk management system is the totality of all organizational regulations and measures introduced to identify and deal with the risks of entrepreneurial activity.

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

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, Medi-Gene's management utilizes a risk management system that can be flexibly adapted to new situations and is subject to continuous review. Organizational safeguards have been established by separation of duties. Activities or business transactions that involve risk are never 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 standardized to ensure the consistent execution of each individual operation. IT risks are minimized 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 coordinating the planning, information supply, handling 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 Board.

#### Portfolio strategy to reduce overall risk

MediGene's overall risk with regard to its success and existence as a going concern is determined primarily 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 commercialization, 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 Board. The regular assessment of the individual projects is based on the analysis and evaluation of their opportunities and risks. This analysis and evaluation covers 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 summarized 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. 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. It possesses a highly diversified portfolio, which is safeguarded by means of farreaching 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**

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, 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 financing over a period of at least 24 months.

Adherence to the business plan is subject to continuous monitoring. The Company is managed on the basis of monthly targetperformance 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 and the guidelines on »Good Clinical Practice (GCP)« as well as Pharmacovigilance. 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. Pharmacovigilance is centered on identifying, assessing, understanding and preventing of side effects and other drug-related issues. Following these guidelines ensures compliance with defined standards in the development, testing, production and monitoring of pharmaceutical products. MediGene has a large number of standardized workflows in the field of quality assurance at its disposal.

#### Accounting 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 including the Group management's discussion and analysis to be key with regard to the accounting processes of the associated 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 finances and accounting 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, including the Group management's discussion and analysis. These control measures include the separation of duties and pre-defined approval processes in the relevant divisions;
- Internal checks of the consolidated internal accounting control and risk management system.

 Moreover, the Group has implemented a risk management system for Group-wide accounting 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 (IV) and 315 (4) of the German Commercial Code (HGB) and explanatory report

No. 1: Composition of subscribed capital

The Company's share capital amounts to €37,082,758.00 and is divided into 37,082,758 registered no-par shares representing a proportional share of the capital of €1.00 per share. 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 (II) of the German Stock Corporation Act (AktG), only persons who have already been entered in the shareholders' ledger 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, 53(a) et seq., 118 et seq. and 186 et seq. AktG.

#### 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 is excluded by law. The Executive Board is not aware of any other restrictions relating to the exercise of voting rights or the transfer of shares.

**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 deceeds a certain threshold for voting rights on the basis of buying or selling shares or by any other means must advise the Company and the German Financial Services Authority (BaFin) accordingly. The lowest limit in respect of this duty of notification is 3%. 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 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 Incorporation. In the event that employees hold a share in the capital and do not directly exercise their right of control, voting control do not exist.

No. 6: Statutory provisions and stipulations in the Articles of Incorporation on the appointment and dismissal of members of the **Executive Board and amendments to the Articles of Incorporation** The Executive Board of the Company, in accordance with Section 7 (I) of the Articles of Incorporation, consists of one or more persons and is appointed, in accordance with Section 84 (I) 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 Board as Chief Executive Officer. In accordance with Section 84 (III) of the German Stock Corporation Act (AktG), the Supervisory Board may also revoke the appointment of a member of the Executive 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 Board is missing, the relevant member is appointed by the courts upon request by one of the parties concerned in urgent cases, in accordance with Section 85 of the German Stock Corporation Act (AktG).

Provisions regarding amendments to the Articles of Incorporation are contained in Sections 179 and 133 of the German Stock Corporation Act (AktG). Under these provisions, any amendment to the Articles of Incorporation requires a shareholders' resolution 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 Incorporation specify a different capital majority. Section 18 (I) of the Company's Articles of Incorporation 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, setting up authorized capital (Section 202 (II) (2) of the German Stock Corporation Act (AktG)) or conditional capital (Section 193 (I) (1) of the Act) and issuing non-voting preferred shares (Section 182 (I) (1) and (2) of the Act), each of which requires a three-quarters majority of the capital represented at the vote on the resolution. The Supervisory Board has the right to make amendments to the Articles of Incorporation, provided they affect only the wording.

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

In accordance with Section 76 (I) of the German Stock Corporation Act (AktG), the Executive Board shall manage the Company on its own authority in accordance with Section 78 (I) 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 authorized as follows:

# a) Authorized capital

The Executive Board is authorized – with the approval by the Supervisory Board - by a shareholders' resolution dated May 11, 2010 to increase the share capital by a total of up to €18,066,102.00 (approximately 49.5% of the share capital at the date of the shareholders' resolution) until May 10, 2015 by issuing up to 18,066,102 new registered ordinary shares (no-par shares) on one or more occasions against payment in cash or in kind (2010/l authorized capital). This authorization can be used in partial amounts. The Executive Board, with the approval of the Supervisory Board, is authorized to stipulate the further content of share rights and the conditions of issuing shares. Due to the issuance of 588,235 new registered no-par shares against cash, a further 17,477,867 new shares against contributions in cash or in kind with a total value of up to €17,477,867.00 were still available to be issued as authorized capital as of December 31, 2011.

### b) Conditional capital

The Company's share capital was increased conditionally through a number of conditional capital items on December 31, 2011 by up to  $\notin$ 14,318,510.00 overall, divided into up to 14,318,510 ordinary shares (approx. 38.6% of the share capital).

This concerns the following individual conditional capital items: 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 VIII of up to €3,000.00 (2001), conditional capital VIII of up to €3,000.00 (2001), conditional capital XII of up to €1,400.00 (2003), conditional capital XII 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 (2007), conditional capital XVIII of up to €1,600,000.00 (2007) and conditional capital XXI of up to €11,000,000.00 (2010). The conditional capital items are in each case divided into the same number of ordinary shares (no-par shares).

# The purpose of the conditional capital items is:

- a) In the case of conditional capital I, II, V, XII, XVI and XVIII, exclusively to issue new shares to the holders of option or conversion rights which were issued within the scope of employee and management stock option programs by the Company to members of its Executive Board, members of the management of affiliated companies in Germany and abroad, to employees of the Company and to employees of affiliated companies in Germany and abroad;
- b) In the case of conditional capital III, exclusively to service option rights arising from profit sharing bonds issued to Deutsche Ausgleichsbank Technologie-Beteiligungs-Gesellschaft mbH;
- c) In the case of conditional capital IV, exclusively to service option rights arising from contracts with IKB Nachrangkapital GmbH and Deutsche Ausgleichsbank Technologie-Beteiligungs-Gesellschaft mbH;
- d) In the case of conditional capital VI, VIII, X and XI, exclusively to issue shares to the holders of option rights which were granted to members of the Supervisory Board in accordance with the provisions of the shareholders' resolutions of May 15, 2000, May 23, 2001, May 22, 2002, and June 4, 2003;
- e) In the case of conditional capital XXI, 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 of May 11, 2010.

### Notes on authorized and conditional capital:

The authorizations of the Executive Board to issue new shares from authorized 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 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 pay for the acquisition of holdings in enterprises or the acquisition of enterprises or enterprise parts in individual cases by issuing shares of the Company to the vendor 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 Board members in German stock corporations.

#### c) Buyback of shares

The Executive Board may acquire shares in the Company in the cases mentioned in Section 71 (I) of the German Stock Corporation Act (AktG). The Executive Board is not currently authorized to repurchase the Company's shares pursuant to Section 71 (I) (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 arrangements exist.

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

The contract of employment for Executive Board member Dr. Frank Mathias, who has been an Executive Board member since April 1, 2008 and Chief Executive Officer since April 29, 2009, includes special termination rights for both the Company and Dr. Mathias, applicable in the event of a change in control.

A change in control within the meaning of the contractual agreement 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 Takeover Act (WpÜG), or more than 50% of the voting rights present on average at the Company's Annual General Meetings during the past three calendar years.

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.

The Executive Board member Dr. Frank Mathias has 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 his previous duties and responsibilities (budget, number of employees supervised and his role on the Board), or if the Company informs him that his appointment as Executive Board member will not be renewed and denial of such extension is not based on significant cause justifying extraordinary termination of the Executive Board member's contract for which he bears responsibility.

If the term of office of Executive 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 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 the term of the Executive Board member's contract on the basis of the average annual bonus of the past three full years prior to termination of that contract and a lump-sum payment amounting to 2.5 times the annual remuneration owed to him (without stock options). This lump-sum 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 thousand (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 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 Board. The gross monthly amount is comprised of one twelfth of the actual 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 thousand (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).

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

The statement on corporate governance pursuant to Section 289a of the German Commercial Code (HGB) is publicly available on the Company's website at <u>www.medigene.de/E\_corporate\_governance\_erklaerung/</u>. It is also provided on <u>pages 121 et seq</u>. of this Annual Report.

# Major events since the end of the reporting period

The following major events in terms of corporate development have occurred in 2012 to date:

# Conclusion of a partnership agreement for marketing Veregen<sup>®</sup> in Turkey

In January 2012, MediGene and Turkish company EIP Eczacibasi Ilac Pazarlama A.S. signed an exclusive license and supply agreement for the delivery and marketing of Veregen® ointment in Turkey. MediGene is entitled to successive payments, due upon the achievement of set regulatory and sales milestones, and will receive double-digit royalties on sales of Veregen®. EIP Eczacibasi will be responsible for the regulatory approval procedure activities for Veregen® for the treatment of genital warts in Turkey.

# Start of a clinical formulation trial of RhuDex®

MediGene started the planned formulation trial of RhuDex<sup>®</sup> in January 2012, which marks the further clinical development of this drug candidate. The trial objective is to develop an optimized oral formulation of the active substance suitable for the treatment of chronic diseases.

# Positive decision regarding marketing authorization of Veregen® in 17 additional European countries

At the beginning of March 2012, the Veregen® ointment marketing authorization applications were positively assessed by the regulatory authorities of seventeen additional European countries within the mutual recognition procedure. This binding decision guarantees that national marketing authorizations will be formally granted by the respective regulatory authorities within the next months in Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden.

# Other income from reimbursement of expenses

In the first quarter of 2012, MediGene received a compensation payment from a service provider for incurred costs totaling €390 thousand.

# **Opportunities and outlook**

This outlook covers the 2012 and 2013 fiscal years.

# **General economic conditions**

According to the assessment of the European Central Bank (ECB), global economic growth will remain modest in 2012. In the ECB's view this is attributable to the increased level of uncertainty, tensions in the international financial markets and the continuing process of economic adjustments in the major developed economies. With regard to the economic outlook for the eurozone, downside risks remain considerable despite first signs of economic stabilization (ECB, monthly report for January 2012). In terms of economic growth in Germany, the German Bundesbank (monthly report for January 2012) believes that flat growth is emerging for the early part of 2012.

Due to continuously rising cost pressure in the healthcare sector, additional statutory measures may be taken to reduce the price of drugs, which may also affect the biopharmaceutical industry in Europe, America and Asia.

# **Products on the market**

The following developments are expected in the Marketed Products segment:

### Eligard® – transfer of rights for non-EU countries in Europe

MediGene expects the transfer of the rights for European countries outside the EU by the competent authorities in 2012. This will be accompanied by a milestone payment from Astellas to MediGene amounting to €5 million. In addition, MediGene will have a 2% share in net revenue from the Eligard<sup>®</sup> product sales Astellas achieves in the marketplace.

#### **Objectives achieved in 2011:**

Expectations	Expectations at the beginning of 2011 Status end of 2011						
Marketed Products							
Eligard®	Transfer of rights to Astellas, receipt of milestone payments associated with the transfer end of 2011/early in 2012 (non-EU countries)Achieved (transfer of r for EU countries)						
Veregen®	Submission of additional marketing authorization applications in Europe	Achieved					
	Conclusion of additional marketing partnerships	Achieved					
Drug Candida	ites						
EndoTAG®-1	Conclusion of one or several development and marketing partnership agreements (date not specified)	Partnering activities ongoing					
	Publication of overall survival data obtained in phase II clinical trial in triple-negative breast cancer	Achieved					
RhuDex®	Decision on further development strategy	Achieved					
AAVLP technology	Further validation through preclinical trials	Achieved					

**Objectives and forecast:** 

Objective	Scheduled date						
Marketed Pro	Marketed Products						
Eligard®	Transfer of rights for non-EU countries to Astellas	2012					
Veregen®	Market launch in additional countries	2012					
	Market approval in additional countries	2012					
	Conclusion of additional marketing partnerships	2012					
Drug Candida	ates						
EndoTAG®-1	Conclusion of one or more development and marketing partnership agreements	Date not specified					
RhuDex®	Initiation and conclusion of a clinical formulation study	2012					
	Continuation of clinical development	2012					
AAVLP technology	Further validation through preclinical trials	2012					

# Veregen<sup>®</sup> – market launch in Spain and marketing authorization for numerous countries expected

The market launch of Veregen® in Spain by MediGene's partner Juste is scheduled for the first half of 2012. On the basis of the regulatory decision at the beginning of March 2012 to grant marketing authorization of Veregen® for 17 additional European countries (Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden), the relevant national marketing authorizations will be issued by the authorities in each country. Furthermore, MediGene anticipates favorable decisions in 2012 regarding approval in selected countries outside the EU. MediGene intends to sign additional partnership agreements for marketing Veregen® at global level. For 2012, MediGene assumes a further increase in sales revenue generated with Veregen®. In 2013, the market launch of Veregen<sup>®</sup> is expected in several countries, with the associated significant growth in sales revenue.

# **Development projects**

The following targets have been set for the »Drug Candidates« segment:

# EndoTAG®-1 – activities for establishing development and marketing partnerships

MediGene aims to establish one or more partnerships with pharmaceutical or biotechnology companies for EndoTAG®-1. The Company envisions the partner or partners taking over the drug candidate's further development and subsequent marketing.

### RhuDex® – continuation of the clinical development

MediGene expects the results of the current formulation study to be ready by mid 2012. Provided that the outcome of this trial is positive, MediGene plans to continue the clinical development of RhuDex<sup>®</sup>. The Company aims to out-license this immunological drug candidate no later than once proof of concept has been provided.

#### AAVLP technology – preclinical studies for further validation

Further preclinical studies will be conducted in 2012 in connection with MediGene's proprietary AAVLP vaccine technology. On the basis of these studies, MediGene will decide about the further development or strategic options for the AAVLP project.

# Financial outlook for 2012 and 2013

In 2012, MediGene expects revenue from continued operations to be greater than €5 million. In addition, the Company expects revenue from discontinued operations of €5 million, relating of the transfer of the rights to Eligard® for non-EU countries. Higher R&D expenses for RhuDex® are expected to lead to a loss on an EBITDA basis in the mid single-digit million euro range.

For 2013, MediGene anticipates growth in revenue from continued operations as a result of the expected expansion in the commercialization of Veregen<sup>®</sup>.

In the event that MediGene achieves the intended drug pipeline expansion, the financial forecast will be adjusted accordingly.

Based on current business planning and scenarios developed on the basis of this planning, the MediGene management expects the Company's funding to be secured beyond the end of 2013.

MediGene assumes that the number of employees will remain relatively stable during the current year.

At present, no major individual investments in property, plant and equipment (>  $\in$ 100 thousand) are planned in 2012 and 2013. The expenses for research and development will continue to be the largest cost pool.

#### **Future procurement**

In 2012, MediGene will continue to obtain the drug Veregen<sup>®</sup> from contract manufacturers in Japan and Germany.

# Dividends

In view of the current income position, MediGene will not distribute any dividends. MediGene pursues the concept of residual dividend distribution. Under this approach, dividends are paid whenever the Company's financial resources cannot be reinvested in such a way that they will yield at least the same risk-equivalent return that shareholders could achieve on the capital market. In the medium term, MediGene will invest available funds in the development of drugs. For this reason, no distribution of dividends can be expected for the time being.

# **The Executive Board**

Planegg/Martinsried, Germany, March 15, 2012 MediGene AG

Dr. Frank Mathias Chief Executive Officer

Arnd Christ Chief Financial Officer

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# CONSOLIDATED INCOME STATEMENT

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2011 AND 2010

In € thousand	Note	2011	2010
Product sales		2,300	2,214
Other operating income		2,356	78
Total revenue	(28)	4,656	2,292
Cost of sales	(29)	-953	-781
Gross profit		3,703	1,511
Selling expenses	(30)	-2,272	-2,030
General and administrative expenses	(31)	-5,831	-7,369
Research and development expenses	(32)	-11,254	-13,494
Loss resulting from spin-off	(36)	0	-6,212
Operating result		-15,654	-27,594
Interest income	(33)	131	26
Interest expense	(33)	0	-1
Foreign exchange gains/losses	(33)	-717	346
Share of result of associates	(37)	766	46
Result from continued operations before tax		-15,474	-27,177
Taxes	(54)	1,241	0
Result from continued operations		-14,233	-27,177
Product sales from discontinued operations	(28)	27,828	47,398
Cost of sales from discontinued operations	(29)	-5,326	-39,210
Selling expenses from discontinued operations	(30)	-343	-397
Gains from derivative financial instruments from discontinued operations	(33)	226	1,517
Taxes from discontinued operations	(54)	-1,871	0
Result from discontinued operations		20,514	9,308
Net result for the year		6,281	-17,869
Basic and diluted earnings per share from continued operations in €	(34)	-0.38	-0.74
Basic and diluted earnings per share from discontinued operations in €	(34)	0.55	0.25
Basic gain/loss per share after tax in €	(34)	0.17	-0.49
Diluted gain/loss per share after tax in €	(34)	0.17	-0.49

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2011 AND 2010

In€thousand	Note	2011	2010
Net result for the year		6,281	-17,869
Exchange differences on translation of foreign operations <sup>1)</sup>	(52)	713	1,022
Unrealized gains on hedge of a net investment <sup>1)</sup>	(52)	0	1,029
Available-for-sale financial assets 1)	(52)	-4	1
Other comprehensive income for the year, net of tax		709	2,052
Total comprehensive income for the year, net of tax		6,990	-15,817

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

# CONSOLIDATED BALANCE SHEET OF MEDIGENE AG AS OF DECEMBER 31, 2011 AND 2010

Asset	ts			
ln€tl	housand	Note	Dec. 31, 2011	Dec. 31, 2010
A. No	on-current assets			
١.	Property, plant and equipment	(42)	829	960
II.	Intangible assets	(43)	27,725	31,886
III.	Goodwill	(39)	2,212	2,212
IV.	Financial assets	(44)	262	153
V.	Investment in associates	(45)	4,183	5,059
VI.	Other assets		1	4
Total	l non-current assets		35,212	40,274
B. Cu	irrent assets			
١.	Inventories	(46)	2,203	1,693
II.	Trade accounts receivable	(47)	1,897	4,516
III.	Cash and cash equivalents	(48)	12,811	4,770
IV.	Other current assets	(47)	1,169	6,948
Total	l current assets		18,080	17,927
Total	assets		53,292	58,201

# Liabilities and shareholders' equity

In€tł	housand	Note	Dec. 31, 2011	Dec. 31, 2010
A. Sh	areholders' equity			
١.	Subscribed capital	(49)	37,082	37,082
١١.	Additional paid-in capital	(50)	343,848	343,704
.	Accumulated deficit	(51)	-326,817	-333,098
IV.	Other reserves	(52)	-6,181	-6,890
Total	shareholders' equity		47,932	40,798
B. No	on-current liabilities			
I.	Financial liabilities		0	2
١١.	Pension obligations	(53)	255	245
.	Other liabilities	(61)	287	0
Total	non-current liabilities		536	247
C. Cu	rrent liabilities			
١.	Trade accounts payable	(55)	1,773	2,354
١١.	Derivative financial instruments	(56)	0	226
.	Other current liabilities	(55)	2,344	9,488
IV.	Deferred income	(57)	77	5,088
V.	Tax liabilities	(54)	630	0
Total	current liabilities		4,824	17,156
Total	liabilities		5,360	17,403
Total	liabilities and shareholders' equity		53,292	58,201

# CONSOLIDATED STATEMENT OF CASH FLOWS

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2011 AND 2010

In € thousand	2011	2010
Cash flows from operating activities		
Net result for the year (before tax)	6,911	-17,869
Non-cash adjustment to reconcile net result before tax to net cash flows:		
Stock-based compensation	144	264
Effect from foreign currency translation	822	0
Other non-cash income	0	-3,014
Depreciation and impairment	4,675	10,061
Gain/Loss on disposal of sale of property, plant and equipment	-32	273
Interest income	-131	-26
Interest expense	0	1
Changes in:		
Inventories	-510	-239
Other assets and accounts receivable	8,289	-4,402
Trade accounts payable	-581	-98
Accruals	0	-470
Other liabilities and deferred income	-12,090	4,129
Share of result of associates	-766	-46
Subtotal	6,737	-11,436
Interest received	133	26
Interest paid	0	-1
Net cash from/used by operating activities	6,864	-11,411
Cash flows from investing activities		
Purchase of property, plant and equipment	-406	-321
Proceeds from sale of property, plant and equipment	55	0
Disposal of financial assets	1,774	0
Net cash from/used by investing activities	1,423	-321
Cash flows from financing activities		
Proceeds from capital increase	0	4,500
Expenses on capital increase	0	-22
Repayment of convertible bonds	0	-9
Net cash from financing activities	0	4,469
In-/Decrease in cash and cash equivalents	8,287	-7,263
Cash and cash equivalents at the beginning of the year	4,770	12,251
Foreign exchange differences	-246	-218
Cash and cash equivalents at the end of the year	12,811	4,770

# CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2011 AND 2010

In€thousand	Subscribed capital	Capital reserve	Accumulated deficit	Currency translation	Hedge of a net investment	Financial assets	Total shareholders' equity
Balance at Jan. 1, 2010	35,557	340,487	-315,229	-7,913	-1,029	0	51,873
Net loss for the year			-17,869				-17,869
Unrealized gains on hedge of a net investment					1,029		1,029
Net gain on available-for-sale financial assets						1	1
Currency translation adjustments				1,022			1,022
Comprehensive income							-15,817
Shares issued	1,525	2,975					4,500
Expenses on shares issued		-22					-22
Stock-based compensation		264					264
Balance at Dec. 31, 2010	37,082	343,704	-333,098	-6,891	0	1	40,798
Balance at Jan. 1, 2011	37,082	343,704	-333,098	-6,891	0	1	40,798
Net gain for the year			6,281				6,281
Net loss on available-for-sale financial assets						-4	-4
Currency translation adjustments				713			713
Comprehensive income							6,990
Stock-based compensation		144					144
Balance at Dec. 31, 2011	37,082	343,848	-326,817	-6,178	0	-3	47,932

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE FISCAL YEAR 2011

# A) Description of business activity, information about the Company

MediGene AG, Planegg/Martinsried, Germany is a biopharmaceutical company that specializes in the research and development of innovative drugs to treat cancer and autoimmune diseases.

The Group's main activities are described in *Note (H) »Segment reporting«*.

MediGene AG was founded in 1994 in Planegg/Martinsried near Munich, Germany, with share capital of €26 thousand. 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 (German Stock Exchange, Regulated Market, Prime Standard; SIN 502090; code MDG).

In addition to the parent company, MediGene AG in Planegg/ Martinsried, Germany, the MediGene Group includes two subsidiaries, MediGene, Inc., San Diego, California, USA and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom. The subsidiaries were acquired in 2001 (MediGene, Inc.) and 2006 (MediGene Ltd.) respectively.

In the reporting period, MediGene started the process for winding up the British subsidiary MediGene Ltd. In August 2010, all patents were transferred to MediGene AG. Current projects are continued by employees of MediGene AG. Consequently, MediGene Ltd. no longer conducts operations.

Since September 2008, MediGene Ltd. has held shares in the associate Immunocore Ltd., Abingdon, Oxfordshire, United Kingdom. Due to new shares in Immunocore Ltd. being issued and the sale of shares in Immunocore Ltd. to co-shareholders, MediGene's stake decreased to 21.69% as of December 31, 2011. Since April 2010, MediGene, Inc. has held 41.89% of the shares in the company Catherex, Inc., Philadelphia, Pennsylvania, USA. The MediGene Group is referred to in this report as either »MediGene« or the »Group«.

# **B)** Accounting and valuation principles

# (1) Basic principles for preparing the consolidated financial statements

The consolidated financial statements are basically prepared using the historical cost principle. Exceptions to this rule are available-for-sale financial assets, derivative financial instruments and assets acquired in the course of business combinations. The consolidated annual financial statements are prepared in German and in euro. All figures are rounded to the nearest thousand euro (€ thousand), unless otherwise stated.

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

As a parent company geared to the capital markets 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 (IFRS) as applicable in the EU.

The Company's Executive Board is of the opinion that these consolidated financial statements reflect all business transactions required to present the assets, financial and income position for the periods which ended on December 31, 2010 and 2011 respectively. Additionally, these consolidated financial statements meet the requirements of section 315a of the German Commercial Code (HGB).

The consolidated financial statements of MediGene AG for the fiscal year ending on December 31, 2011 were approved for publication by a resolution of the Executive Board on March 15, 2012.

# (3) Changes in accounting, valuation, and reporting principles

MediGene has made no changes to accounting and valuation methods beyond the application of new and amended accounting standards and new interpretations described below.

1) First-time application of new and revised accounting rules In the consolidated financial statements for 2011, the following new and revised International Financial Reporting Standards, Interpretations and amendments to these were applied for the first time:

Amendments to IAS 24	Related Party Disclosures
Improvements to IFRSs 2010	Third omnibus edition
IAS 1 R	Presentation of Financial Statements
IFRS 7 R	Financial Instruments: Disclosures

The revised standards replace the previous versions of these standards and apply to fiscal years beginning on or after January 1, 2011. The application of new and revised standards impacts the 2011 consolidated annual financial statements of MediGene AG as follows:

### Amendments to IAS 24 (»Related Party Disclosures«)

The IASB amended IAS 24 Related Party Disclosures to provide a partial exemption from the disclosure requirements for government organizations and clarify the definition of a related party. The Board has not revised the basic approach of IAS 24 to related parties. The standard merely emphasizes the symmetric view of related parties and outlines how a person or key managers influence a company's relationship with related parties. The change applies for fiscal years beginning on or after January 1, 2011. At present, the amendments have no impact on the financial position or disclosures of MediGene.

# Improvements to IFRSs 2010 (»Third omnibus edition«)

In May 2010, the IASB issued the third omnibus edition as part of its Annual Improvements Process (AIP) comprising a total of eleven separate amendments to six existing IFRS standards and one interpretation, mainly to make minor necessary but non-urgent amendments to clarify the wording of certain sections of the IFRS rules. This omnibus edition of amendments was implemented in EU law on February 19, 2011 and applies to reporting periods beginning on or after January 1, 2011. The application of the omnibus edition had no impact on the presentation of the assets, financial and income position.

# Amendments to IAS 1 (»Presentation of Financial Statements«)

The amendments clarify that companies may present the analysis of each component of other income in either the statement of changes in shareholders' equity or in the notes to the financial statements. The Group makes the relevant disclosure in the *consolidated statement of comprehensive income on page 60.* 

### Amendments to IFRS 7 (»Financial Instruments: Disclosures«)

The aim of the amendments was to simplify the disclosures by reducing the required level of disclosure relating to collateral held and to improve disclosures through additional qualitative information, which is intended to supplement quantitative information. At present, the amendments have no impact on the financial position or disclosures of MediGene.

2) Amended standards and interpretations with no impact on the Group

Most of the following standards and interpretations came into force in mid-2010, however, they are not applied for the Group because they neither impact the assets, financial and income position of the Group nor the presentation of disclosures in the notes to the financial statements. This is explained below:

Standard/ Interpretation/ Amendments	Title	Relevant for reporting period	Incorporation into EU law (endorsement date)
IFRS 1 R	Limited Exemption from Comparative IFRS 7 Disclosures for First-time Adopters	July 1, 2010	June 23, 2010
IAS 32 R	Classification of Rights Issues	February 1, 2010	December 23, 2009
IAS 27 R	Consolidated and Separate Financial Statements	July 1, 2010	June 3, 2009
IFRS 3 R	Business Combinations	July 1, 2010	June 3, 2009
IFRIC 13	Customer Loyalty Programmes	January 1, 2011	December 16, 2008
IFRIC 14	Prepayments of a Minimum Funding Requirement	January 1, 2011	July 19, 2011
IFRIC 19	Extinguishing Financial Liabilities with Equity Instruments	July 1, 2010	July 23, 2010

# 3) Future changes in accounting and valuation methods

The application of the following newly published and revised standards and interpretations will be mandatory from 2012. MediGene is currently evaluating whether these amendments will have a material impact on the consolidated financial statements. At present, the Group is not in a position to assess the impact of the amendments definitively. Early application is therefore dispensed.

Standard/Interpretation/ Amendments	Date of coming into effect (IASB)
Amendment to IFRS 1 First-time Adoption of International Financial Reporting Standards	July 1, 2011
Amendment to IFRS 7 Financial Instruments: Disclosures	July 1, 2011
Improvements to IFRS 2011 Fourth omnibus edition	Various, no earlier than July 1, 2011
Amendment to IAS 1 Presentation of Financial Statements	July 1, 2012
Amendment to IAS 12 Deferred taxes: Realization of Underlying Assets	January 1, 2012
Amendment to IAS 19 Employee Benefits	January 1, 2013
Amendment to IAS 27 Separate Financial Statements (revised in 2011)	January 1, 2013
Amendment to IAS 28 Investments in Associates and Joint Ventures	January 1, 2013
IFRS 9 – Financial Instruments: Classification and Measurement	January 1, 2013
IFRS 10 – Consolidated Financial Statements	January 1, 2013
IFRS 11 – Joint Arrangements	January 1, 2013
IFRS 12 – Disclosure of Interests in Other Entities	January 1, 2013
IFRS 13 – Fair Value Measurement	January 1, 2013

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

Preparing the consolidated financial statements in accordance with the generally recognized accounting principles requires that the Executive Board make judgments and estimates which influence the income, expenses, assets, debt, and contingent liabilities listed in the financial statements as per the balance sheet date. These estimates and assumptions are, of course, subject to considerable uncertainty and only very rarely correspond to the actual subsequent circumstances.

### **Discretionary judgments**

The company's management made the following discretionary judgments which significantly impact the figures in the financial statements when applying the accounting and valuation methods.

# Discontinued operation

In the 2010 fiscal year, MediGene AG signed a contract to sell the exclusive European distribution and marketing rights for the cancer drug Eligard® to its current marketing partner Astellas Pharma Europe Ltd. (hereinafter referred to as »Astellas«), Staines, United Kingdom. The Eligard® rights within the countries of the EU were transferred effective from March 1, 2011. According to IFRS 5, a decision must be made as to whether this transaction constitutes a discontinued operation. The management is granted some discretionary scope in judging whether the discontinued operation is a major segment of the company's business activities. In light of the size of the transaction, the management takes the view that the segment must be described as a discontinued operation according to IFRS 5.

# Recording of one-off payments

The recording of one-off payments requires an assessment of whether the agreed payment will be made for services rendered or for those still to be rendered. If, in the view of the management, all contractually agreed services have been performed and the remaining requirements for the realization of revenue are met, the one-off payments are recognized immediately as income.

# Deferred tax assets from loss carryforwards

The recognition of deferred tax assets requires certain assumptions to be made within the management's discretion. They mainly concern the assessment of the circumstances and the period in which tax assets can be realized by the use of existing loss carryforwards. The management has decided not to recognize tax assets in the extent to which they exceed the tax liabilities.

#### Capitalization of development expenses

Development expenses must be capitalized if the requirements for this in accordance with IAS 38 are met. This requires the management to make a number of estimates and assumptions. In the period ending on December 31, 2011, no development expenses were capitalized due to the fact that the management did not believe all the necessary requirements in accordance with IAS 38 had been met.

# **Estimates and assumptions**

The most important assumptions regarding the future and other key sources of estimation uncertainty as of the balance sheet 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 examines at least once per year whether goodwill is impaired. 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 cashgenerating 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, the 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 18 years), the assumptions and forecasts associated with this are subject to a significant degree of uncertainty. Please refer to <u>Note (39)</u> for the methodology of the impairment test and its results and presentation.

#### Fair value

Fair values are generally determined on the basis of market prices. The fair values of financial assets and liabilities for which no market prices can be determined are 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 values are determined to a certain extent on the basis of discretionary judgments. These discretionary judgments 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 the financial instruments. MediGene has measured financial assets and derivative financial instruments at fair value (*cf. Note (62)*).

#### Share-based payment

The costs of issuing stock options to Executive Board members and employees are valued within the Group at the fair values of these equity instruments at the time of their being granted. To estimate the fair value of share-based payment it is necessary to determine the most suitable valuation procedure which depends on the terms under which the payment was granted. In order to make the estimation it will still be necessary to determine suitable input parameters, including in particular the likely option term and volatility, and to make appropriate assumptions. The assumptions and procedures used to estimate fair value of share-based payment are described in <u>Note (16)</u>.

#### Defined benefit plans

The Group has concluded agreements on pension plans with employees and members of the company's management. The expenses accrued from defined benefit plans are determined using actuarial calculations. These are based on assumptions with regard to discount rates, expected income from plan assets, future wage and salary increases, mortality rates, and future pension increases. Given the long-term nature of these plans, such estimates are subject to a considerable degree of uncertainty (cf. Note (53)).

# (5) Consolidation of subsidiaries

#### **Consolidation principles**

The consolidated financial statements are comprised of the individual financial statements of MediGene AG and its subsidiaries as per December 31 of any given fiscal year. The financial statements of the companies within the reporting entity are prepared according to uniform accounting and valuation methods.

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.

#### **Reporting entity**

There were no changes in the reporting entity compared with the previous year.

**Subsidiaries** 

MediGene, Inc.	MediGene Ltd.
San Diego, USA	Abingdon, United Kingdom
100	100
1,888	3,185
-290	1,253
	San Diego, USA 100 1,888

Subsidiaries are all companies for which the Group has the capacity to determine financial and commercial policy. This regularly entails a share of over 50% in the voting rights. When it is being assessed whether there is a controlling interest, the existence and effect of potential voting rights that can be exercised or converted at that time are taken into consideration. Subsidiaries are included in the consolidated financial statements (full consolidation) starting at the point in time when the Group acquired a controlling interest. The consolidation is concluded as soon as the parent company no longer has control.

In addition to those of the parent company, MediGene AG, Planegg/Martinsried, Germany, the MediGene Group's consolidated financial statements include the financial statements of the two wholly owned subsidiaries, MediGene, Inc., San Diego, California, USA, and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom (in liquidation). The subsidiaries were acquired in 2001 (MediGene, Inc.) and 2006 (MediGene Ltd.), respectively. In the reporting period, the liquidation of MediGene Ltd. started to wind up.

#### (6) Investment in associates

The Group's investments in associates are reported at equity in accordance with IAS 28. An associate is an entity which is neither a subsidiary nor a joint venture, but over which the Group has control.

Using the equity method, investments in associates are recognized 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 scheduled amortization nor a separate impairment test.

The income statement reflects the Group's share of the associate's profit. The Group recognizes 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. Unrealized gains and losses from transactions between the Group and the associate are eliminated in line with the interest in the associate.

#### Associates

Associates as at Dec. 31, 2011	Immunocore Ltd.	Catherex, Inc.
Registered office	Abingdon, Großbritannien	Philadelphia, USA
Percentage of share in %	21.69	41.89
Shareholders' equity in € thousand <sup>1)</sup>	4,932	2,481
Net loss for the year in € thousand <sup>1)</sup>	-5,998	-417

### a) Immunocore Ltd.

MediGene Ltd. has had a stake in Immunocore Ltd. since September 2008. As a result of the issue of new shares in several steps as well as the sale of shares in Immunocore Ltd. in the third quarter of 2011, MediGene's shareholding decreased to 21.69% as of September 30, 2011. As of February 3, 2012, the remaining Immunocore Ltd. shares were transferred to MediGene AG. Immunocore Ltd. is a research and development company that focuses on the development of the mTCR technology. The fiscal year of Immunocore Ltd. differs from that of the Group and starts on October 1 of the respective reporting year. For inclusion in the consolidated financial statements, Immunocore Ltd. prepared interim financial statements as of December 31, 2011 in accordance with standard accounting and valuation principles.

### b) Catherex, Inc.

Since April 2010, MediGene, Inc. has held 41.89% of the shares in Catherex, Inc. and thus is the company's biggest shareholder. As part of the establishment of Catherex, Inc., MediGene, Inc. transferred the program to develop cancer-killing oncolytic herpes simplex viruses (oHSV) to Catherex, Inc. In addition, MediGene is supporting the further development of the oHSV technology by appointing two members to the Supervisory Board of Catherex, Inc.

# (7) Discontinued operations

Discontinued operations are stated separately in accordance with IFRS 5 as soon as a division with business activities and cash flows that can be clearly delimited operationally from the remainder of the company for accounting purposes is classified as available for sale or has already been disposed of, and the division constitutes a separate and material line of business or regional business area, forms part of a coordinated overall plan to dispose of a specific and material line of business or regional business area, or is a subsidiary that was acquired solely with the intention of disposing of it.

In the income statement for the reporting period and the period with which it is compared, income and expenses from the discontinued operation that result from the disposal of European rights to the drug Eligard<sup>®</sup> are shown separately from income and expenses from continuing business operations and are stated separately in the consolidated statement of comprehensive income as the result after tax of the discontinued operation.

# (8) Functional currency/foreign currency translation

Foreign currency transactions and foreign business operations are reported in the consolidated annual 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 and reporting currency of the Group. The items included in the annual financial statements of the subsidiaries MediGene, Inc. and MediGene Ltd. are evaluated on the basis of the currency used in the primary business environment in which the company operates (functional currency). The functional currency of MediGene, Inc. is the US dollar (\$) and that of MediGene Ltd. is the British pound (£).

# **Transactions and balances**

Transactions in foreign currencies are translated into the functional currency at the exchange rates that applied on the day of the transaction. Gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currency as per the exchange rate on the balance sheet date are recorded in the income statement. Non-monetary items valued at fair value in a foreign currency are translated using the rate that was in effect as per the time when the fair value was determined. The translation of receivables and payables not carried in the functional currency is carried out as per the daily exchange rate on the balance sheet date. Purchases and sales in foreign currencies are translated using the daily exchange rate as per the time of the transaction. Any resulting currency differences are included in the income statement.

#### **Group companies**

Every company within the Group determines its own functional currency. The items included in the respective company's financial statements are valued using this functional currency. When the foreign subsidiaries MediGene, Inc. and MediGene Ltd. are consolidated, in principle, the balance sheet items are translated as per the exchange rates on the balance sheet date. The goodwill arising from the acquisition of MediGene Ltd. and the fair value adjustments to the carrying amounts of assets and liabilities of MediGene Ltd. are reported in the functional currency of the foreign company and translated into euro using the rate as per the balance sheet date. Any resulting exchange rate differences are recognized as a separate component of shareholders' equity. Expenses and income are translated into the reporting currency for the purpose of consolidation at the transaction exchange rate. Any differences arising from currency translation in the balance sheet compared with the previous year are recognized directly in shareholders' equity with no effect on income.

The following exchange rates were used in 2011 and as per the balance sheet date December 31, 2011:

**Exchange rates** 

Rate as at closing date Average rate for the year Dec. 31, 2011 Dec. 31, 2010 2011 2010 1€ in \$ 1.29020 1.3380 1.39064 1.32707 1€ in £ 0.83470 0.8625 0.86658 0.85836

Source: Commerzbank AG, Reference Exchange Rates

## (9) Property, plant and equipment

Property, plant and equipment are valued at acquisition cost in accordance with IAS 16 »Property, Plant and Equipment« and are subject to regular depreciation and impairment using the straight-line method. 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 acquisition expenses are only included as part of the acquisition expenses 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 in a reliable manner. 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 or write-off are posted in other income and expenses and recognized 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 balance sheet date.

Details on the development of property, plant and equipment can be found in the statement of fixed assets (page 108 et seq.).

## (10) Intangible assets

Accounting policies for intangible assets

The accounting principles used for the Group's intangible assets are summarized as follows:

	Technology rights, patents, and licenses, 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
Amortization method	Straight-line amortization over patent or contract life; amortization period up to 16 years	Impairment test at least once a year, straight-line amortization 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 fixed assets (*page 108 et seg.*).

#### Technology rights, patents, and licenses, software

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

- The intangible asset can be identified.
- The company is likely to derive future commercial benefits from the asset.
- The costs of the asset can be measured reliably.

The acquisition cost of an intangible asset acquired in the scope of a business combination equals the fair value as per the date of the company acquisition. Following their initial recognition, intangible assets are carried at acquisition or production cost less any amortization and impairments accumulated. The useful life of intangible assets is basically defined as either finite or indefinite. Intangible assets with a finite useful life are amortized over their useful economic life and always assessed immediately if there are any triggering events. For intangible assets with a finite useful life, the amortization period and amortization method are examined at least at the end of every fiscal year.

Gains or losses arising from write-off of intangible assets are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognized in the income statement in the same period the asset is derecognized.

MediGene has recognized patents and licenses for patents at acquisition cost. The licenses are amortized over the term of the patent. The capitalized patents and licenses concern the product candidate EndoTAG®-1.

# Research and development projects arising from business combinations

Any acquired intangible asset with a finite useful life arising from business combinations is capitalized at acquisition cost. The acquisition cost of an intangible asset acquired in the scope of a business combination equals the fair value as per the date of the company acquisition. Following their initial recognition, intangible assets are carried at acquisition or production cost less any amortization and impairments accumulated. Regular amortization of an intangible asset takes place as 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

The goodwill that usually arises from the acquisition of other companies is assessed for impairment at regular intervals. For this purpose, an impairment test as defined by IAS 36 is carried out.

#### **Capitalization of research and development expenses**

According to IAS 38, development expenses must be capitalized depending on the possible outcome of development activities and subject to the cumulative existence of certain prerequisites. The management believes that the company's development projects do not fulfill all of the criteria demanded by IAS 38 for capitalization as intangible assets. The reasons for this are the usual uncertainties inherent in drug development and regulatory imponderables.

#### (11) Impairment of non-financial assets

#### Assets with a finite useful life

Assets with a finite useful life are subject to regular depreciation and amortization. They are tested for impairment if any relevant events or changes in circumstances show that the carrying amount may potentially no longer be recoverable. An

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impairment loss is reported in the amount by which the carrying amount exceeds the recoverable amount. This is the greater of the fair value less costs to sell and the value in use.

## Intangible assets not yet available for use

Drug candidates still awaiting market approval by the authorities are not yet available for use. Accordingly, intangible assets based on drug candidates are not subjected to scheduled amortization but are tested for impairment at least once annually as per December 31. Potential causes of impairment can be found, for example, in preclinical and clinical research and development results.

#### Assets with an indefinite useful life

Assets with an indefinite useful life are not subject to regular depreciation or amortization but are tested annually for impairment. In addition, they are tested for impairment in case any relevant events or changes in circumstances show that the carrying amount may potentially no longer be recoverable.

#### Goodwill

Goodwill is examined for impairment at least once a year. Impairment testing is also carried out if any events or circumstances indicate that the carrying amount may be impaired.

## **Execution of impairment testing**

To carry out an impairment test, the goodwill acquired as part of a business combination is allocated, starting on the date of acquisition, 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 company in which the goodwill is monitored for the internal company management, and
- is no larger than a segment based on the primary or secondary reporting format of the Group as defined in IFRS 8 »Segment reporting«.

Insofar as cash flows cannot be identified and assessed separately for the respective intangible assets, they are allocated to the defined CGUs at the lowest level. The impairment is determined by assessing the recoverable amount of the CGU. The recoverable amount is the greater of the fair value less costs to sell and the value in use. 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 to this amount. The value in use calculation and the calculation of fair value less costs to sell are based on cash flow forecasts adopted by the management and a discount rate before tax which reflects current market anticipations regarding impact on interest and the specific risks inherent in the asset or the CGU. The planning period under review encompasses the development and approval stages, as well as the period of time commencing with market launch, for which patent terms of slightly over ten years are generally assumed.

In case an individual asset generates cash proceeds largely independent from those of other assets or other CGUs, the recoverable amount of this individual asset is determined for the execution of the impairment test. If the carrying amount of this individual asset exceeds the recoverable amount, it is amortized to this value.

## (12) Financial assets

## **Initial recognition**

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

Financial assets are initially entered at fair value. The fair value of financial investments traded on organized markets is determined by the market price (bid price) listed as per the balance sheet date. The fair value of financial investments for which there is no active market is determined using valuation methods. These include the use of the most recent business transactions between expert 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 flow, and the use of other valuation models. Financial assets not included in the category of «assets at fair value through profit and loss» are initially recognized at fair value plus transaction costs. They are removed from the balance sheet if the rights to payments from the investment have expired and the Group has, for the most part, transferred all risks and rewards associated with ownership.

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 recognized 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 measured at fair value through profit and loss

encompass the financial assets held for trading which are allocated to this category upon their initial recognition. Derivatives embedded in host contracts are included separately if their risks and characteristics are not closely related to those of the host contracts and the host contracts are not carried at fair value. These embedded derivative financial instruments are assigned to this category. Overall, the assets classified in this category are carried in the balance sheet at fair value and any gains and losses are recognized through profit and loss.

#### b) Held-to-maturity investments

are non-derivative financial assets with fixed or determinable payments and fixed terms which the 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 maturity does not exceed twelve months following the balance sheet date. Otherwise, they are classified as non-current assets. Loans and receivables are included in the balance sheet under 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 the management has no intention of selling them within twelve months after the balance sheet date. Following initial recognition, available-for-sale financial assets are held at fair value with unrealized gains and losses being recognized directly in shareholders' equity in the consolidated statement of comprehensive income. If financial investments are disposed of and/ or impaired, the cumulative gain or loss previously recorded in shareholders' equity is transferred to the income statement. Within the framework of pension commitments, for example, capitalized financial assets are allocated to this category.

#### Impairment

As per every balance sheet date, an examination is carried out as to whether there are any objective indications of a financial asset or a group of financial assets being impaired. In the event of shareholders' equity instruments classified as available for sale, a significant or lasting decline in the fair value of these instruments below their acquisition cost is considered when determining to what extent the shareholders' equity instruments are impaired.

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With regard to outstanding amounts from customer receivables valued at amortized acquisition cost, the company initially determines whether there is any objective indication of significant financial assets being individually impaired or of insignificant financial assets being individually or jointly impaired. If the group determines that there is no objective indication 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 jointly for impairment. Assets tested individually for impairment and for which a new or recurrent impairment is recorded are not included in a joint impairment assessment. Any determined impairment loss is recognized through profit and loss.

#### Derecognition

A financial asset (or, if applicable, part of a financial asset or part of a group of similar financial assets) is derecognized 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 agreement that meets the condition in IAS 39 (pass-through agreement) and has thereby either (a) transferred all the significant risks and rewards associated with owning the financial asset or (b) neither transferred nor retained all the significant risks and rewards associated with owning the financial asset but instead transferred control of the asset.

#### **Hedge accounting**

Hedge accounting is not shown in the balance sheet.

## (13) Inventories

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

## (14) Cash and cash equivalents

Cash and cash equivalents include cash on hand as well as bank deposits with an original maturity of up to three months. These are accounted for in the balance sheet at their present value. If a financial investment is to be classified as a cash equivalent, it must be possible to easily convert it 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 payment plans: stock options

As an incentive to share in the Group's long-term success, its employees and the members of its Executive Board receive share-based payment in the form of equity instruments. For this purpose, the Group has set up a share-based compensation plan that is fulfilled by issuing new shares. These equity capital instruments, such as options, are stated in accordance with IFRS 2. The costs arising from granting these instruments are measured at fair value at the time they are granted. The fair value of stock options which MediGene grants as compensation for work performed by employees is recorded as an expense. The instruments are valued 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 entire expense to be reported over the vesting period of the options is comprised of the fair value of the options at the time they were granted. The expenses resulting from the granting of shareholders' equity instruments and the corresponding rise in shareholders' equity are recognized 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 recognized for forfeited compensation rights.

The estimated number of options expected to be exercised is examined on each balance sheet 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 debt

#### Initial recognition

Financial liabilities as per IAS 39 are classified as financial liabilities at fair value through profit and loss or as loans. The Group determines the classification of its financial liabilities upon initial recognition and assesses them at fair value, plus directly attributable transaction costs in the case of loans.

#### **Subsequent measurement**

Financial debt classified as loans is valued in subsequent periods at amortized acquisition cost. Every difference between the net loan proceeds (after deducting transaction costs) and the amount repayable is recognized in the income statement over the term of the loan using the effective interest rate method.

Financial liabilities recognized at fair value through profit and loss include embedded derivatives. Gains and losses are recognized through profit and loss.

## (18) Accruals

Accruals are formed 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 in a reliable manner. The cost of forming the accrual is reported in the income statement. Accruals for obligations that are not likely to impact assets in the subsequent year are formed in the amount of the present value of the expected outflow of assets. The valuation of accruals is examined on every closing date.

## (19) Pension obligations

Pension obligations are accounted for in accordance with IAS 19 «Employee Benefits». 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 obligations recognized in the balance sheet for defined benefit plans equals the present value of the defined benefit obligations (DBO) as per the balance sheet date less the fair value of the plan assets that arise from liability insurance, adjusted for cumulative unrecognized actuarial gains and losses and past unrecognized service costs. The DBO is calculated annually by an independent actuary using the projected unit credit method. 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 derived using empirically established adjustments and changes to actuarial assumptions are recognized in income over the employees' expected remaining period of service if the balance of the cumulative, unrecognized actuarial gains and losses for each individual plan exceed 10% of the defined benefit obligations as per the end of the previous reporting period or 10% of the fair value of the plan assets, whichever is higher.

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 factual obligations to make additional contributions if the fund holds insufficient assets to pay all employees the pension claims for their service in current and previous fiscal years. The contributions are recognized in personnel expenses upon maturity. Prepaid contributions are recognized as assets to the extent that there is a right to a refund or a reduction in future payments.

Past service expenses are immediately recognized in income unless the changes to the pension plan are dependent on the employee remaining with the company for a set period of time (vesting period). In this case, the past service expenses are recognized through profit and loss throughout the vesting period using the straight-line method.

#### (20) Taxes

#### **Actual taxes**

Actual 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 as per the balance sheet date.

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

The result from continued and discontinued operations is charged with the standard effective tax rate as the tax burden resulting thereof is mainly arising from the taxable income of MediGene AG.

#### **Deferred tax**

Deferred tax is recognized 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 regulations) applicable on the balance sheet date or those that are widely legally adopted. In addition, tax rates and regulations are expected to be legally applicable at the time when the deferred tax receivable is recognized or the deferred tax liability is settled. Deferred tax liabilities are recognized 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
- the deferred tax liability arising from 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 recognized for all deductible temporary differences, as yet unused tax loss carryforwards, and unused tax credits to the extent that taxable income is likely to be available against which the deductible temporary differences and the as yet unused tax loss carryforwards and tax credits can be used. Exceptions are:

- deferred tax assets from deductible temporary differences arising from the initial recognition of an asset or debt from a business transaction that is not a business combination and which, at the time of the transaction, impacts neither the net income for the period using German commercial law nor the taxable income, and
- deferred tax assets from deductible temporary differences in connection with investments in subsidiaries, associated companies, and shares in joint ventures provided that the temporary differences are not likely to reverse in the foreseeable future or it is probable that insufficient taxable income will be available against which the temporary differences can be used.

The carrying amount of deferred tax assets is examined on every balance sheet date and reduced to the extent that it is no longer likely that sufficient taxable income will be available against which the deferred tax asset can be used, at least in part.

Deferred tax pertaining to items recognized directly in shareholders' equity is also recognized in shareholders' equity.

Deferred tax assets and liabilities are measured using tax rates expected to be valid for the period in which an asset is realized or a debt is settled. This is based particularly on country-specific tax rates and laws applicable as per the balance sheet date. Deferred tax assets and liabilities are offset against one another if the tax assets and income taxes pertain to the same taxable entity and are levied by the same tax authority.

## (21) Leasing

Lease agreements in which the Group is the lessee and a significant share of the risks and rewards associated with owning the leasing object remain with the lessor are classified as operating leases. Payments made in connection with operating leases are recognized 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 the significant risks.

## (22) Revenue recognition

Revenue is recognized when the economic benefit is likely to flow to the Group and the amount of the income can be determined reliably. In the reporting period, MediGene posted revenue from product sales, milestone and license fee payments, research grants, and other income.

#### **Revenue from product sales and recurring license payments**

Revenue from product sales are realized 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 license fee payments for the product sales generated by the licensee in the market. These are invoiced on a quarterly basis.

# Revenue from upfront, milestone, and non-recurring license fee payments

Upfront (one-off) payments which MediGene receives from pharmaceutical partners upon concluding a new contract are accrued on the liabilities side in accordance with IAS 18 »Revenue«. These are collected in installments once certain approval milestones are reached. This reversal is posted in the income statement under «product revenue and royalties». Non-recurring license payments which entail all risks and rewards being transferred to the licensee are recognized immediately as income.

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. No accrual is needed in these cases. Accordingly, these payments are recognized immediately as income provided that no additional payments have been agreed.

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

Income from research cooperations is collected as income in accordance with IAS 18 if the contractually agreed targets are reached. 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 recognized when interest becomes payable.

## (23) Public grants

Income from public research grants is accounted for in accordance with IAS 20 »Accounting for Government Grants and Disclosure of Government Assistance«. MediGene receives pro rata grants when expenses arise. The grants are recognized as income once the expense is recognized.

#### (24) Research and development expenses

Research and development expenses are accounted for in accordance with IAS 38 »Intangible Assets«. Research and development expenses are recognized as expenses in the period in which they arise. These expenses include personnel expenses, consultancy fees, material and laboratory expenses, services, and other costs such as rent and electricity, as well as depreciation of laboratory equipment. In the management's opinion, development expenses do not meet all the criteria for recognition in accordance with IAS 38. These costs are, therefore, recognized as expenses in the period in which they arise.

## (25) Earnings per share

The net result per share is determined in accordance with IAS 33 »Earnings per share«. This result is also subdivided into continued and discontinued operations in accordance with IFRS 5.

#### **Basic earnings per share**

The basic earnings per share are calculated by dividing the overall result for the period, the result for the period of continued operations, and the result for the period of discontinued operations to which the equity providers are entitled (the numerator), by the weighted average number of shares issued (the denominator) that are in circulation during the fiscal year.

#### **Diluted earnings per share**

The diluted earnings per share are calculated by increasing the weighted average number of shares in circulation by all of the option rights (denominator). The total comprehensive income for the period and result from discontinued and discontinued operations 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.

## (26) Statement of cash flows

The statement of cash flows was prepared in accordance with IAS 7 »Cash Flow Statements«. The company applied the indirect method when determining the net cash used by operating activities and classified these into operating, investing, and financing activities.

## (27) Segment reporting/operating segments

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

An »operating segment« is a company division in which business activities are performed which generate income, in which costs are incurred, the income situation of which is periodically reviewed by the company's key decision maker, and for which the relevant financial information is available.

For corporate management purposes, the Group is organized into business units based on products and services and has two operating segments subject to reporting requirements: »Marketed Products« 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 the Notes under (H) »Segment reporting«.

# **C)** Discontinued operations

In accordance with IFRS 5, the item »discontinued operations« provides disclosures on discontinued operations that are either classified as available for sale or have already been sold. This segment comprises the transfer of Eligard<sup>®</sup> rights to Astellas at the beginning of March 2011. All income and expenses attributable to Eligard<sup>®</sup> up to this date are stated under this heading.

MediGene sold the exclusive European marketing and distribution rights to the cancer drug Eligard<sup>®</sup> to Astellas by means of an agreement signed in July 2010. The concluded agreement provides for the Company to receive one-off payments totaling €25 million in three tranches. When the contract was signed, MediGene received a €5 million payment that was carried as a deferred income item in fiscal year 2011. The second payment, amounting to €15 million, was received after the transfer of the rights for EU countries on March 3, 2011. MediGene expects to receive the final payment of €5 million upon transfer of the rights for non-EU countries in 2012.

After the transfer of Eligard<sup>®</sup> rights for the EU countries to Astellas, which was published on March 1, 2011, MediGene has continued to be entitled to 2% of net revenue from Eligard<sup>®</sup> product sales in Europe. At the same time, MediGene will no longer be liable for any obligations arising in connection with the product.

# The key figures for continued and discontinued operations are shown below:

Key figures from continued and discontinued operations

In€thousand		2011			2010	
	Continued	Discontinued	Total	Continued	Discontinued	Total
Product sales	2,300	27,668	29,968	2,214	47,398	49,612
Other operating income	2,356	160	2,516	78	0	78
Total revenue	4,656	27,828	32,484	2,292	47,398	49,690
Cost of sales	-953	-5,326	-6,279	-781	-39,210	-39,991
Gross profit	3,703	22,502	26,205	1,511	8,188	9,699
Selling expenses	-2,272	-343	-2,615	-2,030	-397	-2,427
General and administrative expenses	-5,831	0	-5,831	-7,369	0	-7,369
Research and development expenses	-11,254	0	-11,254	-13,494	0	-13,494
Loss resulting from spin-off	0	0	0	-6,212	0	-6,212
Operating result	-15,654	22,159	6,505	-27,594	7,791	-19,803
Interest income	131	0	131	26	0	26
Interest expense	0	0	0	-1	0	-1
Foreign exchange gains/losses	-717	0	-717	346	0	346
Gains from derivative financial instruments	0	226	226	0	1,517	1,517
Share of result of associates	766	0	766	46	0	46
Result from continued operations before tax	-15,474	22,385	6,911	-27,177	9,308	-17,869
Taxes	1,241	-1,871	-630	0	0	0
Result from continued operations	-14,233			-27,177		
Result from discontinued operations		20,514			9,308	
Result for the year			6,281			-17,869

Revenue from discontinued operations consists of product sales (2011:  $\in$ 5,380 thousand; 2010:  $\in$ 27,801 thousand), royalties (2011:  $\notin$ 2,287 thousand; 2010:  $\notin$ 19,597 thousand) and milestone payments (2011:  $\notin$ 20,000 thousand; 2010:  $\notin$ 0) for Eligard<sup>®</sup> in Europe as well as other operating income (2011:  $\notin$ 160 thousand; 2010:  $\notin$ 0).

The cash inflow from operating activities allocated to discontinued operations amounted to  $\notin$ 20,572 thousand in the past fiscal year (2010:  $\notin$ 10,748 thousand).

# D) Notes to the income statement

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

## (28) Total revenue

Total revenue from continued operations amounted to €4,656 thousand in fiscal year 2011 (2010: €2,292 thousand). This revenue originates from product sales and license fees for the drug Veregen<sup>®</sup> and also includes milestone payments totaling €250 thousand (2010: €685 thousand) for Veregen<sup>®</sup> from partner companies.

Revenue from discontinued operations amounted to  $\in$ 27,828 thousand (2010:  $\in$ 47,398 thousand). It was earned from the commercialization of the drug Eligard<sup>®</sup> in the period up to the end of February 2011 and milestone payments totaling  $\in$ 20,000 thousand for the transfer of the European Eligard<sup>®</sup> rights.

Other operating income amounted to €2,356 thousand (2010: €78 thousand). Since March 2011, this item has included a 2% share totaling €2,157 thousand of the net sales of Eligard<sup>®</sup> achieved by Astellas.

**Total revenue** 

In€thousand	2011	2010	Change
Product revenue and royalties	2,050	1,529	34%
Milestones	250	685	-64%
Product sales	2,300	2,214	4%
Grants	0	65	_
Other	2,356	13	>200%
Total from continued operations	4,656	2,292	103%
Discontinued operations	27,828	47,398	-41%

## (29) Cost of sales

The cost of sales from continued operations amounting to €953 thousand (2010: €781 thousand) include procurement costs for the product Veregen<sup>®</sup> and a share in sales revenue in the form of license payments. For the commercialization of Eligard<sup>®</sup>, procurement costs for discontinued operations of €5,326 thousand (2010: €39,210 thousand) were incurred.

#### **Cost of sales**

In€thousand	2011	2010	Change
Cost of sales	549	522	5%
Royalties	404	259	56%
Total from continued operations	953	781	22%
Discontinued operations	5,326	39,210	-86%

#### (30) Selling expenses

Expenses for business development and marketing are reported under selling expenses. These include personnel expenses, marketing and regulatory costs (FDA fee), consulting fees, market studies and other services. No further selling activities relating to products were conducted in the reporting period. Selling expenses for discontinued operations were incurred in relation to discontinued activities.

#### Selling expenses

In€thousand	2011	2010	Change
Personnel expenses	1,098	871	26%
Marketing/regulatory fees	554	436	27%
Office rent and utilities	227	93	144%
Consultancy fees/market surveys	152	342	-56%
Depreciation	1	3	-67%
Other	240	285	-16%
Total from continued operations	2,272	2,030	12%
Discontinued operations	343	397	-14%

## (31) General and administrative expenses

In the reporting period, administrative expenses were down 21% on the same period in the previous year. This was mainly due to downsizing the administration department as part of the restructuring announced in 2010 and a reduction in consulting costs. As a result of downsizing the space rented for business premises before the end of the rental term, there was a non-recurring increase in rent expenses.

#### General and administrative expenses

In€thousand	2011	2010	Change
Personnel expenses	2,448	3,694	-34%
Consultancy fees	1,070	1,428	-25%
Office rent and utilities	886	396	124%
Depreciation	91	93	-2%
Other	1,336	1,758	-24%
Total	5,831	7,369	-21%

## (32) Research and development expenses

**Research and development expenses** 

R&D expenses fell by 17% compared with the previous year. The major portion of R&D expenses is attributable to depreciation and amortization, personnel expenses and services in connection with the evaluation of a clinical trial of drug candidate EndoTAG®-1 as well as the preclinical development of RhuDex® and AAVLP. In addition, a project at the early research stage, which MediGene is no longer pursuing, was written down in full and derecognized (€3,827 thousand). The decrease in expenses resulted from a reduction in spending on services for preclinical and clinical development as well as the downsizing of the R&D department.

In € thousand	2011	2010	Change
Depreciation	4,583	739	>200%
Personnel expenses	2,405	5,142	-53%
Third party expenses	2,031	4,850	-58%
Patent and license fees	726	638	14%
Office rent and utilities	667	895	-25%
Laboratory material costs	183	228	-20%
Consultancy fees	161	368	-56%
Other	498	634	-21%
Total	11,254	13,494	-17%

#### (33) Financial result

The financial result was down to  $\epsilon$ -586 thousand in the fiscal year ended (2010:  $\epsilon$ 371 thousand). This decrease was mainly attributable to currency exchange losses. Such losses arose in connection with the translation of US dollar and British pound amounts.

Interest income was generated from the investment of available cash.

The financial result from discontinued operations comprised a profit of €226 thousand from a derivative instrument in accordance with IAS 39 (2010: €1,517 thousand), which relates to the product Eligard<sup>®</sup>. The agreement signed with Astellas for marketing Eligard<sup>®</sup> encompassed an embedded derivative denominated in foreign currency, because the agreement was settled in US dollars rather than the functional currency used by one of the two parties to the agreement. Following the transfer of Eligard<sup>®</sup> rights to Astellas on March 1, 2011, this derivative no longer exists.

#### Financial result

In€thousand	2011	2010	Change
Interest income	131	26	>200%
Interest expense	0	-1	_
Subtotal	131	25	>200%
Foreign exchange gains/losses	-717	346	_
Total	-586	371	_
Discontinued operations (derivative financial instrument)	226	1,517	-85%

## (34) Basic and diluted earnings per share

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

#### Adjusted result for the year

In€thousand	2011	2010	Change
Net result for the year	6,281	-17,869	-
Interest on convertible bonds	0	1	_
Result adjusted for effects from convertible bonds	6,281	-17,868	_

Basic and diluted earnings per share

2011	2010	Change
37,082,758	36,563,966	1%
117,713	153,264	-23%
37,200,471	36,717,230	1%
0.17	-0.49	_
-0.38	-0.74	-49%
0.55	0.25	120%
	37,082,758 117,713 37,200,471 0.17 -0.38	37,082,758      36,563,966        117,713      153,264        37,200,471      36,717,230        0.17      -0.49        -0.38      -0.74

Of the total 1,722,955 stock options, 1,542,385 had no dilutive effect since the exercise price of most of the stock options was above the average share price of €1.58 for the year (German Stock Exchange; XETRA closing price).

In view of the low number of options which may potentially be exercised, there is no difference between diluted and basic earnings per share.

## (35) Personnel expenses

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

#### **Personnel expenses**

In€thousand	2011	2010	Change
Salaries and wages	5,219	8,194	-36%
Social security	590	1,079	-45%
Pension expenses			
defined contribution plans	37	36	3%
defined benefit plans	84	118	-29%
Stock options issued to executives and employees	144	264	-45%
Other	71	255	-72%
Total	6,145	9,946	-38%

Employees by function

	Dec. 31, 2011	Dec. 31, 2010	Change
Business development and general administration	21	25	-16%
Research and development	31	67	-54%
Total	52	92	-43%

The average number of employees in 2011 fell to 52 (2010: 97). This decline was mainly due to the restructuring measures announced in September 2010, as a result of which the number of employees was down to 63 as of January 1, 2011. Personnel expenses decreased by 38% in the reporting period to  $\epsilon$ ,145 thousand (2010:  $\epsilon$ 9,946 thousand).

## (36) Loss resulting from spin-off

In 2010, MediGene, Inc. made a contribution in kind <u>(see Notes (6)</u> <u>and (45))</u> in transferring the oHSV program to Catherex, Inc. In this connection, an impairment test was carried out in accordance with IAS 36 and the goodwill of €9,226 thousand was fully amortized as of December 31, 2010 <u>(see Note (39))</u>. In the course of the transfer, MediGene recognized revenue of €3,014 thousand. Overall, the transaction resulted in a loss of €6,212 thousand.

#### (37) Share of result of associates

The profit from investments in associates Immunocore Ltd. and Catherex, Inc. totaled €766 thousand in the fiscal year ended (2010: €46 thousand). This result comprises the profit on the sale of shares in Immunocore Ltd. amounting to €1,540 thousand and the profit recognized on the basis of the rise in pro rata shareholders' equity of €1,002 thousand as a result of the issue of new shares in Immunocore Ltd. At the same time, the share in the loss of associates amounted to €1,776 thousand (see Note (45)).

## (38) Depreciation and impairment of fixed assets

In line with the use of the cost of sales method, the amortization, depreciation and impairment of intangible assets and property, plant and equipment are not reported separately in the income statement. Instead, they are allocated to general, selling and administrative expenses, research and development expenses and loss resulting from spin-off.

#### Depreciation and impairment of fixed assets

In€thousand	2011	2010	Change
Regular depreciation			
of property, plant & equipment	402	389	3%
of intangible assets	446	446	0%
Subtotal	848	835	2%
Impairment/Write-off			
of intangible assets	3,827	0	_
of goodwill	0	9,226	_
Total	4,675	10,061	-54%

# (39) Impairment of goodwill and intangible assets not yet available for use

The carrying amounts of goodwill and intangible assets not yet available for use have been combined in a single CGU since 2010 and, as of December 31, 2011, comprised the following:

Carrying amounts of goodwill and intangible assets

	MediGene AG		
In€thousand	2011	2010	
Carrying amount of goodwill	2,212	2,212	
Carrying amount of intangible assets not yet available for use	23,750	27,577	

A project in the early research stage, which MediGene is no longer pursuing, with a carrying amount of €3,827 thousand was written down in full and derecognized in the reporting period.

#### Annual impairment test as of December 31, 2011

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. A 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 the value-in-use for the CGU** The cash flow models are based on the assumption that the drugs are approved and marketed on 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 the market share of the future drug candidate. The forecast period usually spans the expected term of the patents. There are valuation uncertainties regarding the following assumptions that form the basis of the calculation of the fair value 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 class of drugs, as well as the medical indication. Accordingly, the management has applied the customary probability of success within the industry for its valuation models. In addition, project-specific assumptions supplement these valuations. The development risks are taken into consideration in determining the projectspecific 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 project are based on the current status of the project, the results obtained so far and the empirical data regarding the medical indication and class of drugs.

### Anticipated market share

The 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 assessment specialists.

Project-specific assumptions	
Planning period in years	18
Risk adjusted project-specific discount rate in %	40

On the basis of these assumptions, no impairment requirement was identified for the CGU.

#### Sensitivity of the assumptions made

In the basic assumptions made to determine the values-in-use of the CGU, reasonable judgment shows that changes may occur which would cause the carrying amount of the CGU to exceed the value-in-use. This would trigger an amortization requirement.

The actual value-in-use of the CGU exceeds its carrying amount.

In order to analyze the effects of basic and/or project-specific assumptions on the value-in-use, MediGene made the following sensitivity calculations at CGU 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 7%, the value-in-use would approach the carrying amount of the CGU.

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

The third approach assumes that, in contrast to the current benchmark analysis of comparable partnership agreements, the anticipated income from milestone and advance payments under a partnership agreement are only half as high (50% discount). In this case, the value-in-use approaches the carrying amount of the CGU.

# (40) Impairment of other intangible assets

As of the reporting date of December 31, 2011, there was no indication of an impairment of the EndoTAG<sup>®</sup> patents and licenses stated. At MediGene, these assets are subject to scheduled amortization over the life of the underlying patents.

## (41) Cost of materials and cost of services

The expense items in the income statement contain the following cost of materials:

Cost of materials and cost of services

In€thousand	2011	2010	Change
Cost of sales	953	781	22%
Expenses for R&D material	183	228	-20%
Subtotal	1,136	1,009	13%
Cost of services	2,031	4,850	-58%
Total from continued operations	3,167	5,859	-46%
Discontinued operations	5,326	39,210	-86%

Purchase of the active ingredient for Veregen® and license payments to partners are shown separately under cost of sales. The cost of R&D materials includes expenses for laboratory materials and chemicals amounting to €183 thousand (2010: €228 thousand). The cost of services totaling €2,031 thousand (2010: €4,850 thousand) comprises the following items: Implementation of clinical trials amounting to €1,149 thousand (2010: €2,299 thousand), production services of €197 thousand (2010: €1,566 thousand), preclinical development services of €500 thousand (2010: €883 thousand) and approval costs of €185 thousand (2010: €102 thousand). Cost of sales for the purchase of the drug Eligard® and license payments to the partner are stated under discontinued operations.

# E) Notes on the balance sheet

## ASSETS

## (42) Property, plant and equipment

The detailed composition and development of property, plant and equipment is provided in the statement of fixed assets (page 108 et seq.).

### (43) Intangible assets

The decrease in intangible assets from €31,886 thousand to €27,725 thousand is mainly accounted for by the write-down and write-off amounting to €3,827 thousand of a project at the early research stage, which is no longer pursued. The patents and licenses for RhuDex<sup>®</sup> and EndoTAG<sup>®</sup> as well as software are also stated as intangible assets.

MediGene has not capitalized any internally generated intangible assets.

## (44) Financial assets

Financial assets comprise the following items:

Financial assets

In€thousand	Dec. 31, 2011	Dec. 31, 2010	Change
Listed fund shares (pension)	148	153	-3%
Loan to Catherex, Inc.	114	-	_
Total	262	153	71%

Available-for-sale financial assets are based on the value derived from the market price and include assets resulting from pension agreements that are not to be categorized as plan assets.

The loan to associate Catherex, Inc. is a fixed-interest loan with a loan term up to December 31, 2012.

## (45) Investment in associates

As of the end of the reporting period, the Group held 21.69% of the shares in Immunocore Ltd. and 41.89% in Catherex, Inc. The fiscal year of Immunocore Ltd. differs from that of the Group and starts on October 1 of the respective reporting year. For inclusion in the consolidated financial statements, Immunocore Ltd. prepared the relevant interim financial statements as of December 31, 2011.

The carrying amount of the shares in the two associates as of December 31, 2011 decreased to €4,183 thousand (2010: €5,059 thousand). This reduction in the carrying amount is attributable to the loss relating to the shareholdings of €1,776 thousand and foreign exchange losses of €102 thousand. The rise in pro rata shareholders' equity of Immunocore Ltd. generated a profit of €1,002 thousand.

Investment in associates

In€thousand	Dec. 31, 2011	Dec. 31, 2010 <sup>1)</sup>
Share of the associates' balance sheet:		
Current assets	979	1,678
Non-current assets	1,657	286
Current liabilities	-307	-169
Non-current liabilities	-219	0
Pro rata net assets	2,110	1,795
Share of the associates' revenue and result:		
Revenue	91	87
Result	-1,476	-1,919

<sup>1)</sup> 2010 does not include any figures for Catherex, Inc.

#### (46) Inventories

Inventories in respect of Veregen<sup>®</sup> amounted to €2,203 thousand (2010: €1,693 thousand) as of the reporting date. In the previous year, inventories arose in respect of Eligard<sup>®</sup> and Veregen<sup>®</sup>. There was no impairment to the lower net sales price.

#### (47) Other current assets and trade accounts receivable

Other current assets and trade accounts receivable

In€thousand	Dec. 31, 2011	Dec. 31, 2010	Change
Prepaid expenses with a term <1 year	670	826	-19%
Rent deposit	323	323	0%
VAT receivables	145	10	>200%
Accrued royalties	0	5,732	_
Grants	0	17	_
Other	31	40	-23%
Total other assets	1,169	6,948	-83%
Trade accounts receivable	1,897	4,516	-58%

Other assets totaled €1,169 thousand in the reporting period ended (2010: €6,948 thousand). They consisted for the most part of spending relating to expenses for future periods with a remaining term of less than twelve months amounting to €670 thousand (2010: €826 thousand). In the previous year, the license fees due accounted for the largest block in this item and amounted to €5,732 thousand.

# The due dates of trade accounts receivable and other current assets are as follows:

Aging analysis of trade accounts receivable and other current assets

				Maturity			
In € thousand	impaired	up to 30 days	30–180 days	180–360 days	1–5 years	> 5 years	Total
Balance at Dec. 31, 2011							
Other current assets	0	585	467	117	0	0	1,169
Trade accounts receivable	0	1,896	0	1	0	0	1,897
Total	0	2,481	467	118	0	0	3,066
Balance at Dec. 31, 2010							
Other current assets	0	6,324	27	597	0	0	6,948
Trade accounts receivable	0	4,515	0	1	0	0	4,516
Total	0	10,839	27	598	0	0	11,464

In the fiscal year ended, no adjustments were made to the value of receivables.

## (48) Cash and cash equivalents

**Cash and cash equivalents** 

In€thousand	Dec. 31, 2011	Dec. 31, 2010	Change
Cash and cash equivalents < 3 months	12,811	4,770	169%
Total	12,811	4,770	169%

Cash and cash equivalents were invested in the form of cash investments with a term of less than three months. The carrying amount of cash and cash equivalents corresponds to their fair value. The effective interest rate for short-term bank deposits is variable and ranged from 0.13% to 1.48% in the reporting period. The change in cash and cash equivalents compared with the previous year is shown in the statement of cash flows.

As of the reporting date, December 31, 2011, an amount of  $\notin$ 1,774 thousand was held in a trust account. This amount was released on February 3, 2012.

## LIABILITIES AND SHAREHOLDERS' EQUITY

## (49) Shareholders' equity

## a) Subscribed capital

As of December 31, 2011, the subscribed capital amounting to €37,082 thousand was unchanged compared with the previous reporting period. It is divided into 37,082,758 no-par registered shares, 100% of which had been issued and were tradable as of the balance sheet date.

#### **Subscribed capital**

	Number of shares	Subscribed capital in € thousand	Capital reserve in€thousand	Total in€thousand
Balance at Jan. 1, 2010	35,557,493	35,557	340,487	376,044
Executives and employees stock option plan				
Value of services provided			264	264
Shares issued				
Cash	1,525,265	1,525	2,953	4,478
Balance at Dec. 31, 2010	37,082,758	37,082	343,704	380,786
Executives and employees stock option plan				
Value of services provided			144	144
Balance at Dec. 31, 2011	37,082,758	37,082	343,848	380,930

#### b) Stock options

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

Stock options are issued to Executive 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 German Stock Exchange plus a premium of 20%. Holders of subscription rights may exercise their option rights at the earliest after expiry of a waiting period of two years, starting from the allotment date of the respective subscription right. From 2011 onwards, the waiting period for Executive Board members is four years. The options have a contractual term of ten years. The Group has no legal or de facto obligation to repurchase options or offer a cash settlement. In the reporting year, a total of 65,000 stock options were issued to Executive Board members as per the shareholders' resolution dated May 25, 2007 (conditional capital XVIII), (2010: 60,958 stock options issued to Executive Board members from conditional capital XVIII). MediGene AG has dispensed with the expiry of these stock options in the event that the holder of subscription rights leaves the Company and has accordingly stated stock options as an expense.

In December 2011, a further 115,570 stock options were issued to employees from conditional capital XVIII as per the shareholders' resolution dated May 25, 2007. 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 waiting period, all stock options expire without entitlement to replacement or compensation if the waiting period for exercising such stock options has not yet expired when the contract of employment is terminated.

# The average exercise price of stock options issued to Executive Board members and employees in December 2011 was €1.03.

Total change in stock options outstanding

	2011		2010		2009	
	Average exercise price in €	Number	Average exercise price in €	Number	Average exercise price in €	Number
Stock options outstanding, balance at Jan. 1	5.52	1,567,719	6.10	1,389,276	6.23	1,441,108
lssued	1.03	180,570	2.63	263,574	0	0
Issued, not accepted in the reporting year	0	0	0	0	3.69	81,350
Exercised	0	0	0	0	0	0
Forfeited	2.77	-25,334	3.80	-18,610	3.92	-10,976
Lapsed	0	0	6.48	-66,521	6.29	-122,206
Stock options outstanding, balance at Dec. 31		1,722,955		1,567,719		1,389,276
Weighted average exercise price in € per option		5.09		5.52		6.10

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

Valuation parameters for stock option plan

1			
	2011	2010	2009
Vesting period	2/4 years	2 years	2 years
Option term	10 years	10 years	10 years
Exercise hurdle rate	120%	120%	120%
Expected volatility	50%	51%/50%	51%
Risk-free interest rate	2,08%	3,66%/3,18%	3,66%

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 2.08% (source: German Central Bank). The fair value of the stock options issued in the 2011 fiscal year amounted to €0.50 per stock option (December 2011). For 2011, an expense for share-based payments totaling €144 thousand (2010: €264 thousand) was reported in accordance with IFRS.

The breakdown of these payments is as follows:

#### Expenses for stock options

In€thousand	2011	2010
Expenses for stock options		
2008	0	119
2009	0	0
2010	112	145
2011	32	0
Total	144	264

As of December 31, 2011, the stock options outstanding were classified by exercise price, number of options issued, time remaining until expiry and options that are still convertible as follows:

xercise					

Number o exercisable stock options	Residual term in years	Number of stock options outstanding	Exercise price in €
45,179	2	45,179	4.60
80,000	2	80,000	4.68
60,237	3	60,237	7.69
40,000	3	40,000	8.10
131,062	4	131,062	12.37
111,341	5	111,341	10.22
234,029	6	234,029	5.88
297,860	7	297,860	4.34
231,547	7	231,547	3.89
81,350	8	81,350	3.69
_1	9	89,316	3.69
_1	9	140,464	1.87
_1	10	180,570	1.03
1,312,605		1,722,955	

<sup>1)</sup> Stock options issued in 2010 and 2011 could not be exercised as at December 31, 2011.

The weighted average remaining term of stock options in circulation is 5.49 years.

#### c) Authorized capital

The Executive Board was authorized by a shareholders' resolution dated May 11, 2010 to increase the share capital, with the approval of the Supervisory Board, by a total of up to  $\in$ 18,066,102 (approx. 49.5% of the share capital on the date of the shareholders' resolution) until May 10, 2015 by issuing a total of up to 18,066,102 new registered ordinary shares (nopar shares) on one or more occasions against payment in cash

or in kind (authorized capital 2010/I). This authorization can be used in partial amounts. The Executive Board, with the approval of the Supervisory Board, is authorized to stipulate the further content of share rights and the conditions of issuing shares. As of December 31, 2011, the Company still had 17,477,867 new registered no-par shares from authorized capital 2010/I at its disposal.

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

As of December 31, 2011, the Company's share capital had been increased conditionally through a number of conditional capital items by up to €14,318,510, divided into a total of up to 14,318,510 ordinary shares (approx. 38.6% 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

(No.)	Amount as at Dec. 31, 2011	Usage <sup>1)</sup>
	136,897	Options
II	106,429	Options
	125	TBG <sup>2)</sup> Ioan
IV	13,770	Convertible bonds
V	652,329	Convertible bonds
VI	3,000	Convertible bonds
VIII	3,000	Convertible bonds
Х	3,000	Convertible bonds
XI	1,400	Convertible bonds
XII	498,560	Options
XVI	300,000	Options
XVIII	1,600,000	Options
XXI	11,000,000	Convertible bonds and options
	14,318,510	

<sup>1)</sup> to provide for

<sup>2)</sup> Technologie-Beteiligungs-GmbH

# (50) Capital reserve

No stock options were exercised and no convertible bonds were converted in 2011 and 2010.

Capital reserve					
In € thousand	Jan. 1, 2010	Change	Dec. 31, 2010	Change	Dec. 31, 2011
Shares issued	350,342	2,975	353,317	0	353,317
Expenses on shares issued	-16,264	-22	-16,286	0	-16,286
Exercise of stock options	890	0	890	0	890
Exercise of convertible bonds	1,455	0	1,455	0	1,455
Expenses on new options	4,064	264	4,328	144	4,472
Total	340,487	3,217	343,704	144	343,848

# (51) Accumulated deficit

Accumulated deficit

In€thousand	Jan. 1, 2010	Change	Dec. 31, 2010	Change	Dec. 31, 2011
Net gain/loss	-315,229	-17,869	-333,098	6,281	-326,817
Total	-315,229	-17,869	-333,098	6,281	-326,817

# (52) Other reserves

# Other reserves

In € thousand	Jan. 1, 2010	Change	Dec. 31, 2010	Change	Dec. 31, 2011
Unrealized gains/losses on hedge of a net investment	-1,029	1,029	0	0	0
Net gain/loss on available-for-sale financial assets	0	1	1	-4	-3
Currency translation adjustments	-7,913	1,022	-6,891	713	-6,178
Total	-8,942	2,052	-6,890	709	-6,181

Currency differences arising from the translation of assets or goodwill denominated in foreign currencies or from the translation of financial statements of foreign subsidiaries are stated directly in equity under other reserves.

## (53) Pension obligations

MediGene offers all of its employees in Germany defined benefit plans in the form of a benevolent fund. These pension plans are fully reinsured. In addition, the Group has come to individual agreements with the members of its senior management and some employees in the form of direct commitments with guaranteed interest rates. These commitments allow for the conversion of bonus payments into pension entitlements for defined benefit plans. In accordance with IAS 19.7, the assets allocated to these pension entitlements do not constitute plan assets. The amount of pension obligations is determined as follows:

Pension obligations		
In€thousand	Dec. 31, 2011	Dec. 31, 2010
Present value of benefit obligations	1,835	1,687
Fair value of plan assets	-1,601	-1,491
Subtotal	234	196
Unrecognized actuarial gains	21	49
Obligations in the balance sheet	255	245

The plan assets comprise reinsurance policies. As of the reporting date December 31, 2011, the actual income from the reinsurance policies amounted to  $\notin$ 59 thousand (2010:  $\notin$ 32 thousand). The following amounts were recognized under personnel expenses in the income statement:

Expenses recognized in the income statement

In € thousand	2011	2010
Current service cost	54	94
Interest expense	91	90
Expected return on plan assets	-61	-54
Actuarial losses	0	-12
Total included in personnel expenses	84	118

**Actuarial assumptions** 

In %	2011	2010
Discount rate	4.9	5.4
Expected rate of return on plan assets	4.0	4.0
Future salary increases	4.0	4.0
Future pension increases	1.0/2.0	1.0/2.0

The 2005G guideline tables by Professor Klaus Heubeck were used as the biometric calculation basis.

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

In€thousand	
Benefit obligations at Jan. 1, 2010	1,608
Interest expense	90
Current service cost	94
Plan members contributions	49
Benefits paid	-225
Actuarial gains	71
Benefit obligations at Dec. 31, 2010	1,687
Interest expense	91
Current service cost	54
Plan members contributions	13
Benefits paid	-37
Actuarial gains	27
Benefit obligations at Dec. 31, 2011	1,835
of which	
funded by plan assets	1,601
not funded by plan assets	234

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

In € thousand	
Fair value of plan assets at Jan. 1, 2010	1,528
Expected return on plan assets	54
Employer contributions	108
Member contributions	49
Benefits paid	-225
Actuarial losses	-23
Fair value of plan assets at Dec. 31, 2010	1,491
Expected return on plan assets	61
Employer contributions	75
Plan member contributions	13
Benefits paid	-37
Actuarial losses	-2
Fair value of plan assets at Dec. 31, 2011	1,601

In€thousand	2011	2010	2009	2008	2007
Benefit obligations	1,835	1,687	1,608	1,414	1,152
Fair value of plan assets	-1,601	-1,491	-1,528	-1,303	-997
Deficit	234	196	80	111	155
Actuarial gains	21	49	91	76	83
Experience adjustments on plan liabilities	-1	50	-16	-40	-1
Experience adjustments on plan assets	3	23	25	57	-4

The figures for the current and previous reporting periods since the pension obligations first arose are as follows: Deferred taxes as of December 31, 2011 related to the following items:

# (54) Income taxes

The major components of the income tax expenses for the 2011 and 2010 fiscal years are as follows:

#### Income taxes

In € thousand	2011	2010
Current income taxes:		
Current income tax expense	-630	0
Deferred taxes	0	0
Income tax expense reported in income statement	-630	0

In the reporting period, a tax expense of €630 thousand was posted in the income statement. It essentially resulted from positive net income for the year at MediGene AG. In the previous year, the Group posted neither a tax expense nor a tax income.

In€thousand	Consoli balance		Consolidated income statement		
	Dec. 31, 2011	Dec.31, 2010	2011	2010	
Deferred tax assets					
Deferred taxes on tax loss carryforwards					
Germany	45,412	45,354	58	3,141	
USA	18,004	16,034	1,970	256	
United Kingdom	1,911	1,911	0	-5,283	
	65,327	63,299	2,028	-1,886	
non deductible	-62,847	-60,840	-2,007	-3,010	
Net	2,480	2,459	21	-4,896	
Different useful lives of tangible assets	20	50	-30	-(	
Other taxes from grants	1,870	1,676	194	-28	
Derivative financial instruments	0	59	-59	-399	
Share of result of associates	112	0	112	(	
Prepaid expenses	20	23	-3	-3	
Liability pension insurance	293	268	25	102	
Valuation of accruals	12	35	-23	29	
	2,327	2,111	216	-308	
non deductible	-1,990	-1,741	-249	3	
Net	337	370	-33	-305	
Deferred tax liabilities					
Capitalization of acquired licenses	2,634	2,665	31	5,202	
Pension accruals	183	164	-19	-1	
	2,817	2,829	12	5,201	
Deferred tax income/ expenses			0	(	
Deferred tax asset/ liabilities (balance)	0	0			

In 2011 and 2010, neither tax income nor a tax expense from deferred taxes was posted in shareholders' equity.

Tax assets from loss carryforwards are shown to the extent to which deferred tax liabilities exist. Deferred tax assets and liabilities have been balanced against one another if they relate to the same tax authorities and congruent periods.

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

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

The recognized tax expenses differ from the expected tax expenses which would have resulted from the application of the nominal tax rate for the earnings under IFRS. A reconciliation of the differential effects can be seen in the following table, in which the tax rate applicable in the respective period was used.

As the subsidiaries have no retained earnings, no deferred tax liabilities were recognized in this respect.

			tax	

In € thousand	2011	2010
Result before income tax from continued operations	-15,474	-27,177
Result before income tax from discontinued operations	22,385	9,308
Result before income tax	6,911	-17,869
Expected tax income/expense	-1,819	4,704
Use of US tax loss carryforwards	0	933
Use of German tax loss carryforwards	2,040	0
Increase of deferred taxes on tax loss carryforwards not posted	-1,198	-3,010
Non-deductible impairment of goodwill	0	-2,429
Temporary differences not posted	0	3
Non-deductible expenses	-31	-45
Difference from German trade tax	-17	0
Difference from UK tax rate	-21	27
Difference from US tax rate	48	-208
Tax-free revenue	351	0
Other	17	25
Income tax expense	-630	0
thereof from continued operations	1,241	0
thereof from discontinued operations	-1,871	0
Effective tax rate in %	9	0

The breakdown of tax loss carryforwards is as follows:

#### Tax loss carryforwards

In€thousand	Dec. 31, 2011	Dec.31, 2010 adjusted	Dec. 31, 2010
Corporate income tax Germany	173,352	177,904	173,054
Trade tax Germany	171,228	175,875	171,122
State tax USA	43,066	41,333	41,333
Federal tax USA	41,754	40,067	40,067
Corporate tax UK	6,826	6,826	6,826

The loss carried forward for 2010 and earlier years has been adjusted following external tax audits.

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 detrimental changes in the shareholder structure.

The loss carryforwards of the subsidiary MediGene Ltd. in the United Kingdom may be used for an unlimited period of time, provided that the company's tax identity remains in place. In view of the ongoing process of winding up MediGene Ltd., it is expected that the relevant loss carryforwards will lapse in 2012. In contrast, the loss carryforwards of MediGene, Inc. will expire between 2016 and 2031. In the USA, tax loss carryforwards based on federal tax may be utilized for 20 years, whereas those based on state tax generally expire after ten years, unless an extension is granted.

### (55) Trade accounts payable and other current liabilities

The trade accounts payable of  $\notin 1,773$  thousand (2010:  $\notin 2,354$  thousand) as of the end of the reporting period consisted in unpaid invoices issued primarily for services utilized by MediGene. For the maturity analysis of the financial liabilities, please refer to *Note (61)*.

Other financial liabilities amounting to  $\notin 2,344$  thousand (2010:  $\notin 9,488$  thousand) include license payments not yet billed of  $\notin 891$  thousand (2010:  $\notin 6,261$  thousand), bonus payments due of  $\notin 725$  thousand (2010:  $\notin 871$  thousand), holiday entitlements amounting to  $\notin 175$  thousand (2010:  $\notin 167$  thousand) and severance payments of  $\notin 157$  thousand (2010: 440 thousand).

## (56) Derivative financial instruments

The contract concluded with Astellas for the commercialization of Eligard<sup>®</sup> includes an embedded foreign currency derivative, as the contract is settled in US dollars rather than the functional currency of one of the two contracting parties. Following the transfer of the European Eligard<sup>®</sup> rights to Astellas on March 1, 2011, the derivative was recognized in the income statement and then taken off the books.

## (57) Deferred income

Deferred income totaled €77 thousand in the reporting period (2010: €5,088 thousand). In 2010, it mainly resulted from the sale of the Eligard<sup>®</sup> rights to Astellas and the associated payment of €5,000 thousand received when the contract was signed.

## (58) Contingent liabilities

No accruals were recognized in liabilities for the contingent liabilities listed below, as the risk of their being utilized is deemed unlikely.

Within the framework of existing license agreements, MediGene is committed to making milestone payments of approximately €9.5 million to the respective licensors. The management does not believe that accruals need to be formed for this since the corresponding obligations will not become due until certain milestones are reached.

The pro rata financial obligations of Immunocore Ltd. amounted to  $\in 1$  thousand (2010:  $\in 2$  thousand).

As of the balance sheet date, deposit guarantees of €397 thousand (2010: €323 thousand) had been granted to property lessors.

Expenses of  $\in$ 1,747 thousand (2010:  $\in$ 1,339 thousand) were incurred for operating leases in the reporting period.

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

In€thousand	Rent and lease payments
2012	1,041
2013	959
2014	873
2015	811
Later	482
Minimum lease obligations	

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 lease agreements vary.

The Group has a notice period of one month to ten years for these lease agreements, depending on the contract.

#### (59) Total amount of unused/open credit lines

In addition to the cash and cash equivalents reported under <u>Note</u> (48), no open credit lines were available as of December 31, 2011.

## (60) Related parties

The parties deemed to be related are individuals and/or entities that can be significantly influenced by the Company or can exert significant influence on the Company. Related parties are the Company's Executive Board and Supervisory Board as well as the associates Immunocore Ltd. and Catherex, Inc.

Arnd Christ, Chief Financial Officer of MediGene AG, is a member of the Board of Directors, the supervisory body of associate Immunocore Ltd. In the reporting period, MediGene Ltd. sold a block of shares in Immunocore Ltd. to co-shareholders of Immunocore Ltd. *(see Notes (37) and (45))*.

Dr. Frank Mathias, Chief Executive Officer of MediGene AG, and Elias Papatheodorou, Senior Vice President of Business Development at MediGene AG, were appointed as directors of Catherex, Inc. MediGene, Inc. has granted a fixed-rate loan amounting to €114 thousand to Catherex, Inc. (see Note (44)).

The remuneration and shareholdings of the Company's Executive Board and Supervisory Board members are itemized for each member of these boards under <u>II Executive Board and</u> <u>Supervisory Board</u>. In the fiscal year ended, there were no further transactions between the Group and related parties.

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

The main financial liabilities, with the exception of derivative financial instruments, are trade accounts payable and other financial liabilities. The main purpose of these liabilities is to finance the Group's business activities. The Group possesses various financial assets, accounts receivable and cash.

The Group additionally reported a derivative financial instrument for the period up to February 2011 that was embedded in the contract with Astellas regarding the commercialization of the drug Eligard<sup>®</sup>. The derivative related to the settlement of product deliveries in US dollars, which is not the Group's functional currency. The Group's business activities expose it to various financial risks: market risks (including foreign exchange risks and fair value interest rate 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. The management does not see the following, currently existing items resulting from financial risks as significant.

## Market risks

# Interest rate risk

Fluctuations in market interest rates impact the cash flows relating to interest-bearing assets and additionally the fair value of pensions. MediGene's management has deliberately decided to avoid carrying out transactions aimed at hedging interestbased cash flows because short-term availability for financing operating activities is a priority when investing cash and cash equivalents.

Sensitivity analysis of interest rate risk (cash flows)

	Interest rate change in basis points	Effects on result before income taxes in € thousand
2011	50	69
2010	50	39

Interest rate changes also impact the fair value of the CGU derived from financial projections based on intangible assets and goodwill. Accordingly, the rise in the interest rates used for the valuation may lead to an impairment of intangible assets or goodwill through profit and loss. For example, the increase in the risk-free interest rate may cause the CGU fair values to drop to such an extent that an impairment of goodwill or an intangible asset may become necessary.

#### Foreign exchange risk

Foreign exchange 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 exchange risks based on exchange rate fluctuations between the US dollar and the euro as well as between the British pound and the euro. MediGene AG subsidiaries use the US dollar (MediGene, Inc.) and the British pound (MediGene Ltd.) as their functional currencies.

The foreign exchange risk mainly relates to revenue generated in US dollars from Veregen® sales, as well as milestone payments received for Veregen® from partner companies. In addition, the cost of purchasing the active ingredient in Veregen® as well as the license 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, 29% is generated in US dollars. In total, 95% of procurement costs were incurred in US dollars.

The MediGene Group reduces the foreign exchange risks resulting from its subsidiaries' operating activities by utilizing 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 result before tax and of shareholders' equity to exchange rate fluctuations of the euro against the US dollar. All other variables in this statement remain constant.

#### Sensitivity analysis of foreign exchange risk (\$)<sup>1)</sup>

	Exchange rate development of \$	Effects on results before income taxes in € thousand	Effects on shareholders' equity in€thousand
2011	+5%	-41	-41
	-5%	31	31
2010	+5%	158	158
	-5%	-121	-121

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

At Group level, foreign exchange risks arise in connection with the operating activities of the subsidiaries and the assets and liabilities allocated accordingly.

2	1	9	
	Exchange rate development of £	Effects on results before income taxes in € thousand	Effects on shareholders' equity in€thousand
2011	+5%	-12	-12
	-5%	13	13
2010	+5%	-36	-36
	-5%	40	40

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

Securities-related share price risks

The Group is exposed to the usual market fluctuations relating to listed fund units (see Note (44)).

## **Credit risk**

The Group has no significant concentration in terms of potential credit risks. Business relationships exist with two major customers, Astellas and Fougera Pharmaceuticals, Inc. (the former Nycomed US, Inc.), Melville, New York, USA. The creditworthiness of the relevant customers 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

MediGene's liquidity management is aimed at having sufficient cash, cash equivalents and tradable securities available for the Company and securing the option of issuing Company shares on the market, in order to overcome any liquidity bottlenecks. MediGene assumes that, under the current conditions, it is in a position to issue tradable securities on the market.

As of December 31, 2011, the Group's financial liabilities were due as shown below. The amounts disclosed are based on contractual payments discounted at a rate of 4.09%.

#### Sensitivity analysis of foreign exchange risk (£)<sup>1)</sup>

#### **Financial liabilities**

			Matur	ity		
In€thousand	up to 30 days	30–90 days	3–12 months	1–5 years	> 5 years	Total
Balance at Dec. 31, 2011						
Trade accounts payable	1,773	0	0	0	0	1,773
Other current liabilities	640	1,433	271	281	0	2,625
Deferred income	0	2	8	10	57	77
Total	2,413	1,435	279	291	57	4,475
Balance at Dec. 31, 2010						
Trade accounts payable	1,897	457	0	0	0	2,354
Financial liabilities	0	0	0	2	0	2
Other current liabilities	717	8,507	264	0	0	9,488
Deferred income	0	5,002	8	10	68	5,088
Total	2,614	13,966	272	12	68	16,932

## **Capital control**

The primary goal of MediGene's management is to secure sufficient liquidity to finance ongoing research and development programs. The most important control variable aside from the absolute amount of cash and cash equivalents is the liquidity cover ratio, i.e. the share of cash and cash equivalents and securities in the balance sheet total. A sufficiently high equity ratio is needed to make flexible use of the equity and debt financing opportunities arising on the market.

#### Key figures for capital control

		2011	2010
Liquidity cover ratio in %	<u>Cash x 100</u> Balance sheet total	24	8
Equity ratio in %	<u>Equity x 100</u> Balance sheet total	90	70

# (62) Other financial assets and liabilities including the hierarchy of fair values

The table below indicates the carrying amounts and fair values of all financial instruments recognized in the consolidated financial statements as of December 31, 2011:

#### Other financial assets and liabilities

In€thousand	Carrying amount		Fair value	
	2011	2010	2011	2010
Financial assets				
Cash and cash equivalents	12,811	4,770	12,811	4,770
Trade accounts receivable	1,897	4,516	1,897	4,516
Available-for-sale financial assets	148	153	148	153
Loans and receivables	114	0	114	0
Financial liabilities				
Financial debt	0	2	0	2
Other non-current liabilities	281	0	281	0
Derivative financial instruments	0	226	0	226
Trade accounts payable and other current liabilities including deferred income	4,824	16,930	4,824	16,930

Financial assets capitalized in connection with pension commitments totaling €148 thousand (2010: €153 thousand) are allocated to the category of financial assets available for sale. The gains and losses resulting from this category are stated in the consolidated statement of comprehensive income with no effect on profit.

The fixed-interest loan to Catherex, Inc. amounting to  $\in$ 114 thousand is allocated to the loans and receivables category (see Notes (12) and (44)).

The embedded derivatives were financial liabilities stated at fair value through profit or loss. At the end of the reporting period, no derivatives existed any longer (2010: €226 thousand). Gains and losses resulting from this category are recognized in the income statement through profit or loss.

## **Hierarchy of fair values**

The Group uses the following hierarchy to determine and report the fair values of financial instruments for each valuation procedure:

Stage 1: Listed (unadjusted) prices on active markets for similar assets or liabilities;

Stage 2: Procedures in which all the input parameters that have a significant effect on the recorded fair value can be observed either directly or indirectly;

Stage 3: Procedures that use input parameters which have a significant effect on the recorded fair value and are not based on observable market data.

The first stage includes the fund units reported under availablefor-sale financial assets which are valued at the stock market price as of the reporting date. The fair value of the derivative financial instrument, which was determined on the basis of existing Eligard<sup>®</sup> orders and orders forecast by the partner company, is included in stage two. On March 1, 2011, this derivative ceased to exist. The second stage also includes loans and receivables.

#### (63) Major events since the end of the reporting period

The following major events in corporate development occurred since closing date:

# Conclusion of a partnership agreement for marketing Veregen® in Turkey

In January 2012, MediGene and Turkish company EIP Eczacibasi Ilac Pazarlama A.S. signed an exclusive license and supply agreement for the delivery and marketing of Veregen<sup>®</sup> ointment in Turkey. MediGene is entitled to successive payments, due upon the achievement of set regulatory and sales milestones, and will receive double-digit royalties on sales of Veregen<sup>®</sup>. EIP Eczacibasi will be responsible for the regulatory approval procedure activities for Veregen<sup>®</sup> for the treatment of genital warts in Turkey.

### Start of a clinical formulation trial of RhuDex®

MediGene started the planned formulation trial of RhuDex<sup>®</sup> in January 2012, which marks the further clinical development of this drug candidate. The trial objective is to develop an optimized oral formulation of the active substance suitable for the treatment of chronic diseases.

## Positive decision regarding marketing authorization of Veregen<sup>®</sup> in 17 additional European countries

At the beginning of March 2012, the Veregen® ointment marketing authorization applications were positively assessed by the regulatory authorities of seventeen additional European countries within the mutual recognition procedure. This binding decision guarantees that national marketing authorizations will be formally granted by the respective regulatory authorities within the next months in Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden.

#### Other income from reimbursement of expenses

In the first quarter of 2012, MediGene received a compensation payment from a service provider for incurred costs totaling €390 thousand.

# F) Consolidated statement of changes in shareholders' equity

The consolidated statement of changes in shareholders' equity for the 2011 and 2010 fiscal years forms a separate part of the consolidated financial statements.

# G) Notes to the statement of cash flows

The statement of cash flows shows the origins and application of the cash flows in the 2011 and 2010 fiscal years. It is therefore of crucial significance for assessing the Company's financial position.

The cash flows from investing and financing activities are each determined on a cash basis. The cash flow from operating activities, on the other hand, is derived indirectly on the basis of the net result for the year.

Within the scope of non-cash financing activities, no new lease obligations for laboratory and office equipment were entered into in 2011.

Cash and cash equivalents at the end of the period consisted solely of cash and cash equivalents in accordance with IAS 7.7. The cash and cash equivalents illustrated in the cash flow statement correspond to the »cash and cash equivalents« item in the consolidated balance sheet.

# **H) Segment reporting**

## **Business units**

The Group was made up of two main business units as of December 31, 2011. The business units »Marketed Products« and »Drug Candidates« identified within the Group in accordance with IFRS 8 consist of the following:

**Marketed Products** 

- Eligard<sup>®</sup> for the treatment of hormone-dependent, advanced prostate cancer
- Veregen® for the treatment of genital warts

## **Drug Candidates & technologies**

- EndoTAG®-1 for the treatment of solid tumors
- RhuDex<sup>®</sup> for the treatment of autoimmune diseases such as rheumatoid arthritis
- 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 the usual market terms among third parties.

Investment in associates amounting to €4,183 thousand (2010: €5,059 thousand) are shown in segment reporting under »Reconciliation«.

#### Segment reporting by business units

In€thousand	Marketed Products	Drug Candidates	Total segments	Recon- ciliation <sup>1)</sup>	Adjustments discontinued operation	Total
2011					-	
Revenue with external customers	29,968	0	29,968	0	-27,668	2,300
Other income	2,321	56	2,377	139	-160	2,356
Inter-segment sales <sup>2)</sup>	230	8	238	-238	0	0
Total revenue	32,519	64	32,583	-99	-27,828	4,656
Segment operating result <sup>3)</sup>	21,803	-14,774	7,029	-524	-22,159	-15,654
Depreciation and impairment	-1	-4,554	-4,555	-120		-4,675
Share of result of associates	0	0	0	766		766
Assets						
Investment in associates	0	0	0	4,183		4,183
Segment investments <sup>4)</sup>	0	69	69	337		406
Segment assets <sup>5)</sup>	4,100	29,937	34,037	19,255		53,292
Segment liabilities <sup>6)</sup>	77	0	77	5,283		5,360
2010						
Revenue with external customers	49,612	0	49,612	0	-47,398	2,214
Other income	0	76	76	2	0	78
Inter-segment sales <sup>2)</sup>	422	85	507	-453	-54	0
Total revenue	50,034	161	50,195	-451	-47,452	2,292
Segment operating result <sup>3)</sup>	6,317	-25,615	-19,298	-451	-7,845	-27,594
Depreciation and impairment	-2	-9,952	-9,954	-107		-10,061
Share of result of associates	0	0	0	46		46
Assets						
Investment in associates	0	0	0	5,059		5,059
Segment investments <sup>4)</sup>	0	249	249	72		321
Segment assets <sup>5)</sup>	6,209	34,098	40,307	17,894		58,201
Segment liabilities <sup>6)</sup>	5,314	0	5,314	12,089		17,403

<sup>1)</sup> Segment »Reconciliation« includes information that can be allocated to neither the »Marketed Products« segment nor the »Drug Candidates« segment,

as it does not depict any activities of its own.

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

<sup>3</sup> Segment operating result does not include any interest income (2011: €131 thousand; 2010: €26 thousand), any interest expense (2011: €0; 2010: €1 thousand), foreign exchange gains or losses (2011: €-717 thousand; 2010: €346 thousand), or any share of gain of associates (2011: €766 thousand; 2010: €46 thousand). Segment operating result includes gains from inter-segment sales (2011: €238 thousand; 2010: €507 thousand).

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

<sup>®</sup> Segment assets under »Reconciliation« include in part non-current assets (2011: €5,275 thousand; 2010: €6,176 thousand), cash and cash equivalents

<sup>e</sup> Segment liabilities under »Reconciliation« include non-current liabilities (2011: €536 thousand; 2010: €6,948 thousand), trade accounts payable and other liabilities

(2011:  $\leq 4$ , 117 thousand; 2010:  $\leq 11$ ,842 thousand), and tax liabilities (2011:  $\leq 630$  thousand; 2010:  $\leq 247$  thousand; 1 add accounts payable and other liabilities (2011:  $\leq 630$  thousand; 2010:  $\leq 11$ ,842 thousand), and tax liabilities (2011:  $\leq 630$  thousand; 2010:  $\leq 0$ ).

# **Geographic or regional segments** The Group operates in Europe and the USA.

**Revenue with external customers** 

In€thousand	2011	2010
UK	27,668	47,398
USA	1,744	1,114
Other	556	1,100
Total	29,968	49,612

Information about segment revenue is arranged according to the relevant customer's location. In the »Marketed Products« segment, the revenue from discontinued operations achieved with the main customer in the United Kingdom amounted to  $\notin$ 27,668 thousand.

Since the transfer of the patents for RhuDex<sup>®</sup> and for a further project at research stage from MediGene Ltd. to MediGene AG at the end of August 2010, the major portion of non-current assets are held in Germany. In addition, shareholdings are held in associates in the United Kingdom (Immunocore Ltd.) and the USA (Catherex, Inc.).

## (64) 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®-1 and to compositions that can be manufactured using this process. In December 2011, the European Patent Office decided in a first-instance ruling that the patent is upheld to an extent which continues to protect the product EndoTAG®-1. In the course of opposition proceedings, MediGene AG had restricted its patent claims to the features that are relevant to EndoTAG®-1. The decision can be appealed.

In the past twelve months, no judicial disputes that could have a major influence on the Company's or its subsidiaries financial situation have been pending, nor is there currently a threat of any such dispute.

Further judicial disputes cannot be ruled out in the future.

## (65) German Corporate Governance Code

MediGene AG's Executive Board and Supervisory Board confirmed on December 9, 2011 that MediGene AG complies with most of the recommendations of the German Corporate Governance Code in the current version dated May 26, 2010. The recommendations of the Code which MediGene AG does not implement are explained in detail in the statement of compliance pursuant to Section 161 of the German Stock Corporation Act (AktG). This statement is permanently made available in English and German on the MediGene AG website at <u>www.</u> <u>medigene.de/E\_corporate\_governance\_erklaerung/</u> MediGene AG's corporate governance report can be found <u>on pages 118 et seq</u>.

## (66) Auditing fees

The auditors and Group auditors received the following fees for the fiscal year ended:

## Auditing fees

In€thousand	2011	2010
Auditing services	136	148
Tax consulting services	0	27
Other services	30	52
Total	166	227

# I) Executive Board and Supervisory Board

## (67) Executive Board

## **Remuneration of the Executive Board**

Remuneration of members of the Executive Board totaled  $\notin$ 944 thousand in the fiscal year ended (2010:  $\notin$ 997 thousand), including pension expenses of  $\notin$ 48 thousand (2010:  $\notin$ 52 thousand) and vehicle leasing costs for company cars of  $\notin$ 26 thousand (2010:  $\notin$ 22 thousand). In addition, stock options with a fair value of  $\notin$ 33 thousand (2010:  $\notin$ 56 thousand) were issued to the Executive Board.

In fiscal year 2011, MediGene made a payment of  $\in 6$  thousand (2010:  $\in 6$  thousand) to the benevolent fund in connection with a pension commitment to a former member of the Executive Board.

Pursuant to point 2.2.1 (II) of the German Corporate Governance Code, the Annual General Meeting may pass a resolution approving the remuneration system for Executive Board members. A resolution regarding the future remuneration system was passed for the first time at the Annual General Meeting on May 11, 2010. It was adopted with a majority of 96%.

# Report on the remuneration system for members of the Executive Board of MediGene AG

The full Supervisory Board is responsible for setting the remuneration of MediGene AG's Executive Board members. It is regularly reviewed, taking into account the provisions relating to the Supervisory Board as per section 87 (I) and (II) of the German Stock Corporation Act (AktG) and the recommendations of the German Corporate Governance Code.

The Supervisory Board resolved adjustments in light of the German act on appropriate management board remuneration (Gesetz zur Angemessenheit der Vorstandsvergütung, VorstAG), which came into force on August 5, 2009. The Company intends to implement the remuneration system described below in respect of all future contracts of employment for Executive Board members.

The amount and structure of the remuneration of Executive Board members depend on the respective responsibilities of each Executive 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 paid in similar companies.

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

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

## a) Fixed remuneration

Each member of the Executive Board receives fixed remuneration, which is not performance-related and is paid in monthly installments. 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 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 Board members and, in addition, separately for each member of the Executive 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 objectives, 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 fulfillment of the best case scenario corresponds to a 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 performancerelated 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 Board member with appropriate interest.

The Supervisory Board's decision regarding sustained corporate growth is primarily based on the long-term trend in the Company value and therefore also the share price of the Company's shares. The members of the Executive 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 Board members are granted stock options on the basis of the Company's stock option program. 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 Board member within the first year of their joining the Company. Subsequently, Executive Board members receive further stock options every year. The exercise price corresponds to the average closing price of the last 60 trading days prior to the issue of the stock option plus a 20% premium.

Executive Board members may exercise their stock options at the earliest after a waiting period of four years, starting from the date of allotment of the relevant subscription right. This means that the new requirement introduced of a four-year waiting period for exercising stock options (section 193 (II) (4) of the German Stock Corporation Act, AktG) has already been implemented. The stock options have a contractual term of ten years.

Based on the principles stated in this paragraph relating to the remuneration system, each Executive Board member receives a specific number of stock options, which is separately set for each member every year and ranges from 20,000 to 40,000 stock options.

#### c) Other benefits

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

- a company car,
- reimbursement of business travel expenses,
- accident insurance cover and payment of the relevant insurance premiums,
- D&O insurance with excess according to the statutory minimum amount and
- payment of an amount of €2 thousand 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 waiting 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 rights in the event of a change in control

The contract of employment for Executive Board member Dr. Frank Mathias includes special termination rights for both the Company and the Executive Board member in the event of a change in control. A change in control within the meaning of contracts of employment for Executive Board members exists if more than 30% of the Company's shares with 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 are acquired by a third party.

If the term of office of Executive 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 the term of the Executive Board member's 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 thousand (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 Board member Dr. Frank Mathias resigns under the special termination conditions, 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 Board. The gross monthly amount is comprised of one twelfth of the actual 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 thousand (caps). However, in the situation leading to this special termination, the Company's Supervisory Board may at its discretion waive the last mentioned cap in recognition of Dr. Mathias' outstanding achievements and extraordinary commitment. The minimum severance payment amounts to six gross monthly salary payments (lower limit).

No such arrangement is in place for Arnd Christ.

#### **Executive Board remuneration 2011**

Executive Board member	e Board member Fixed compensation Variable and Fringe benefit <sup>2)</sup> performance based	Fringe benefit <sup>2)</sup>	Variable components in the form of stock options		
	in€thousand	components <sup>1)</sup> in€thousand in€thousand in€thousand	in€thousand	Number of stock options	Fair value of options in € thousand
Dr. Frank Mathias Chief Executive Officer Pharmacist, Munich, Germany	370	185	40	35,000	18
Arnd Christ Chief Financial Officer Diploma in business administration, Krailling, Germany	210	105	34	30,000	15
Total	580	290	74	65,000	33

<sup>1)</sup> On the basis of the accruals for 2011 (without discounting) in the event of 100% payment.

<sup>2)</sup> Fringe benefits include pension expenses, and vehicle leasing for the members of the Executive Board.

## (68) Supervisory Board

## **Supervisory Board remuneration**

Supervisory Board remuneration amounted to €229 thousand in 2011 (2010: €261 thousand). 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. Both the chairmanship and deputy chairmanship of the Supervisory Board are taken into account in the evaluation of the Supervisory Board member's scope of activities. Details regarding the subscription rights of members of the Supervisory Board and Executive Board are provided in <u>Note</u> (69). No advances were paid to members of the Supervisory Board.

#### Supervisory Board remuneration 2011

Supervisory Board member	Fixed compensation in€thousand	Fees for attending meetings in € thousand
Prof. Dr. Ernst-Ludwig Winnacker Chairman	48	15
Prof. Dr. Norbert Riedel Deputy Chairman	36	15
Dr. Pol Bamelis Member	24	8
Dr. Mathias Albert Boehringer Member	24	10
Dr. Thomas Werner Member	24	10
Klaus Kühn Member (since August 4, 2011)	10	5
Total	166	63

The members of the Supervisory Board possess the following occupational titles:

## Prof. Dr. Ernst-Ludwig Winnacker

since November 26, 1996 Chairman of the Supervisory Board Secretary General of Human Frontier Science Program (HFSP), Strasbourg, France

## Prof. Dr. Norbert Riedel

since October 27, 2003 Deputy Chairman of the Supervisory Board Corporate Vice President, Chief Scientific Officer, Baxter International, Inc., Deerfield, Illinois, USA

#### Dr. Pol Bamelis

since May 23, 2001 former Executive Board member, Bayer AG, Leverkusen, Germany

#### Dr. Mathias Albert Boehringer

since July 16, 2008 Diploma in business administration, Ingelheim, Germany

# Dr. Thomas Werner

# since February 2, 2010

Freelance management consultant, Utting am Ammersee, Germany

## Klaus Kühn

since August 4, 2011 former Executive Board member, Bayer AG, Leverkusen, Germany

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106,778

171,778

2,000

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

### Prof. Dr. Ernst-Ludwig Winnacker

- Bayer AG, Leverkusen, Germany
- Wacker Chemie AG, Munich, Germany

#### Prof. Dr. Norbert Riedel

• ARIAD Pharmaceuticals, Inc., Cambridge, MA, USA (since May 2, 2011)

#### Dr. Pol Bamelis

- Actogenix N.V., Belgium
- PolyTechnos, Ltd., Guernsey, United Kingdom
- Recticel, Belgium (until June 17, 2011)
- Sioen N.V., Belgium (until May 31, 2011)
- Hemacon GmbH, Düsseldorf, Germany

#### Dr. Mathias Albert Boehringer

**Total Executive Board** 

- · Boehringer Ingelheim shareholders' committee, Ingelheim, Germany
- Phenex Pharmaceutical AG, Ludwigshafen, Germany
- Phorms Management AG, Berlin, Germany

## (69) Directors' holdings and notes on subscription rights

#### Memher Shares Options Dec. 31, 2011 Dec. 31, 2011 Dec. 31, 2010 Dec. 31, 2010 Prof. Dr. Ernst-Ludwig Winnacker Chairman of Supervisory Board, Co-founder 274,476 274,476 0 Prof. Dr. Norbert Riedel Deputy Chairman of Supervisory Board 3,300 3,300 0 Dr. Pol Bamelis Supervisory Board member 400 400 0 Dr. Mathias Albert Boehringer Supervisory Board member 0 0 0 Dr. Thomas Werner Supervisory Board member 0 0 0 Klaus Kühn Supervisory Board member (since August 4, 2011) 0 0 0 278,176 0 **Total Supervisory Board** 278,176 Dr. Frank Mathias Chief Executive Officer 2.000 127.500 6,000 92.500 Arnd Christ **Chief Financial Officer** 5,000 0 44,278 14,278

11,000

#### Dr. Thomas Werner

- Pharma Swiss AG, Switzerland (until March 10, 2011)
- 4SC AG, Munich, Germany
- CM&D Pharma Ltd., United Kingdom (until February 1, 2011)
- SkyePharma plc., United Kingdom
- Accera, Inc., USA (until September 15, 2011)
- Basilea Pharmaceutical Ltd., Switzerland (since November 29, 2011)
- SuppreMol GmbH, Planegg, Germany (since June 1, 2011)

#### Klaus Kühn (since August 4, 2011)

- Flossbach von Storch AG, Cologne, Germany
- Hella KGaA Hueck & Co., Lippstadt, Germany

#### Dr. Frank Mathias

- Catherex, Inc., USA
- Faller KG, Waldkirchen, Germany (since May 9, 2011)

#### Arnd Christ

- Immunocore Ltd., United Kingdom
- DNS Beteiligungsgesellschaft mbH, Bessenbach, Germany

## (70) Notification in accordance with Section 21 of the German Securities Trading Act (WpHG) and publication in accordance with Sections 25 and 26 of the German Securities Trading Act (WpHG)

The Company has been notified of the following shareholdings pursuant to section 20 (I) or (IV) of the German Stock Corporation Act (AktG) or according to section 21 (I) or (Ia) of the German Securities Trading Act (WpHG):

The MLawGroup, Munich, Germany notified MediGene AG on March 26, 2010 on behalf of its client Advent Management III Ltd. Partnership, Edinburgh, United Kingdom that Advent Management III Ltd. Partnership's shareholding in MediGene AG exceeded the 5% threshold on December 11, 2006 and at that time amounted to 8.1985%. This corresponded to 2,348,965 votes at that time. Of these, 2,348,965 votes – corresponding to 8.1985% of the voting rights at that time – were attributable to Advent Management III Ltd. Partnership in accordance with section 22 (I) (1) no. 2 in conjunction with section 22 (I) (2) of the German Securities Trading Act (WpHG).

The MLawGroup, Munich, Germany notified MediGene AG on March 26, 2010 on behalf of its client Advent Management III Ltd., Edinburgh, United Kingdom that the shareholding of Advent Management III Ltd. in MediGene AG exceeded the 5% threshold on December 11, 2006 and amounted to 8.1985% at that time. This corresponded to 2,348,965 votes. Of these, 2,348,965 votes – corresponding to 8.1985% of the voting rights at that time – were attributable to Advent Management III Ltd. in accordance with section 22 (I) (1) no. 2 in conjunction with section 22 (I) (2) of the German Securities Trading Act (WpHG). Santo Holding (Deutschland) GmbH, Königstrasse 1 A, 70173 Stuttgart, Germany notified MediGene AG on November 6, 2009 that its shareholding fell below the 5% threshold on November 2, 2009 and amounted to 4.95% at that time. This corresponded to 1,706,001 voting rights.

Santo Holding AG, Alte Landstrasse 106, 8702 Zollikon, Switzerland notified MediGene AG on November 5, 2009 that its shareholding fell below the 5% threshold on November 2, 2009 and amounted to 4.95% at that time. This corresponded to 1,706,001 voting rights. Of these, 4.95% of voting rights (which corresponds to 1,706,001 voting rights) were attributable to Santo Holding AG in accordance with section 22 (I) (1) no. 1 of the German Securities Trading Act (WpHG). Attributable votes are held by Santo Holding (Deutschland) GmbH, Königstrasse 1 A, 70173 Stuttgart, Germany, which is controlled by Santo Holding and whose share of the MediGene AG voting rights amounted to 4.95% (corresponding to 1,706,001 voting rights).

## **THE EXECUTIVE BOARD**

Planegg/Martinsried, Germany, March 15, 2012 MediGene AG

### **Dr. Frank Mathias**

Chief Executive Officer

#### **Arnd Christ**

Chief Financial Officer

## CONSOLIDATED STATEMENT OF CHANGES IN FIXED ASSETS

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2011 AND 2010

In€thousand	Initial cost					
	Jan. 1, 2011	Currency translation adjustments	Addition	Disposal	Dec. 31, 2011	
Property, plant and equipment	7,033	4	294	-604	6,727	
Intangible assets	34,968	9	112	-4,096	30,993	
Goodwill	3,141	0	0	0	3,141	
Total	45,142	13	406	-4,700	40,861	

In € thousand			Initial cost			
	Jan. 1, 2010	Currency translation adjustments	Addition	Disposal	Dec. 31, 2010	
Property, plant and equipment	7,011	8	321	-307	7,033	
Intangible assets	33,121	2,085	0	-238	34,968	
Goodwill	14,046	166	0	-11,071	3,141	
Total	54,178	2,259	321	-11,616	45,142	

Accumulated depreciation					Carrying	amount
Jan. 1, 2011	Currency translation adjustments	Addition	Disposal	Dec. 31, 2011	Dec. 31, 2011	Dec. 31, 2010
6,073	4	402	-581	5,898	829	960
3,082	9	4,273	-4,096	3,268	27,725	31,886
929	0	0	0	929	2,212	2,212
10,084	13	4,675	-4,677	10,095	30,766	35,058
	6,073 3,082 929	Jan. 1, 2011 Currency translation adjustments 6,073 4 3,082 9 929 0	Jan. 1, 2011Currency translation adjustmentsAddition6,07344027,073773,08294,27392900	Jan. 1, 2011      Currency translation adjustments      Addition      Disposal        6,073      4      402      -581        7      7      4      402      -581        7      7      7      4      402      -581        7      7      7      7      4      402      -581        7 <td>Jan. 1, 2011      Currency translation adjustments      Addition      Disposal      Dec. 31, 2011        6,073      4      402      -581      5,898        6,073      4      402      -581      5,898        3,082      9      4,273      -4,096      3,268        929      0      0      0      929</td> <td>Jan. 1, 2011      Currency translation adjustments      Addition      Disposal      Dec. 31, 2011      Dec. 31, 2011        6,073      4      402      -581      5,898      829        6,073      4      402      -581      5,898      829        3,082      9      4,273      -4,096      3,268      27,725        929      0      0      0      929      2,212</td>	Jan. 1, 2011      Currency translation adjustments      Addition      Disposal      Dec. 31, 2011        6,073      4      402      -581      5,898        6,073      4      402      -581      5,898        3,082      9      4,273      -4,096      3,268        929      0      0      0      929	Jan. 1, 2011      Currency translation adjustments      Addition      Disposal      Dec. 31, 2011      Dec. 31, 2011        6,073      4      402      -581      5,898      829        6,073      4      402      -581      5,898      829        3,082      9      4,273      -4,096      3,268      27,725        929      0      0      0      929      2,212

Accumulated depreciation					amount
Currency translation adjustments	Addition	Disposal	Dec. 31, 2010	Dec. 31, 2010	Dec. 31, 2009
8	389	-272	6,073	960	1,063
18	446	0	3,082	31,886	30,503
0	9,226	-11,071	929	2,212	11,272
26	10,061	-11,343	10,084	35,058	42,838
	Currency translation adjustments 8 18 0	Currency translation adjustmentsAddition83891844609,226	Currency translation adjustmentsAdditionDisposal8389-27218446009,226-11,071	Currency translation adjustmentsAdditionDisposalDec. 31, 20108389-2726,0730-2723,082-09,226-11,071929	Currency translation adjustments      Addition      Disposal      Dec. 31, 2010      Dec. 31, 2010        8      389      -272      6,073      960        6      7      7      7      960        18      446      0      3,082      31,886        0      9,226      -11,071      929      2,212

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## AUDITORS' REPORT

We have audited the consolidated financial statements prepared by MediGene AG, Martinsried/Planegg, comprising the consolidated statement of financial position, the consolidated income statement, the consolidated statement of comprehensive income, the consolidated statement of cash flows, the consolidated statement of changes in equity and the notes to the consolidated financial statements, together with the group management report for the fiscal year from January 1, 2011 to December 31, 2011. 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 (1) HGB [»Handelsgesetzbuch«: »German Commercial Code«] are the responsibility of the parent company's management. Our responsibility is to express an opinion on the consolidated financial statements and 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, the additional requirements of German commercial law pursuant to Sec. 315a (1) 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, March 15, 2012

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Dr. Napolitano German Public Auditor Breyer 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 15, 2012

The Executive Board

1

Dr. Frank Mathias

Arnd Christ

## **REPORT OF THE SUPERVISORY BOARD**

During the 2011 fiscal year, the Supervisory Board performed the duties it is charged with under the law and according to the Articles of Incorporation fully and with great care. On the basis of verbal and written reports by the Executive Board, the Supervisory Board continuously monitored the Company's management and regularly advised the Executive Board on related issues. The Executive Board directly involved the Supervisory Board in all decisions that were of critical significance for the Company and in agreeing the strategic direction for the Company. The Supervisory Board voted on the resolutions proposed by the Executive Board after in-depth examination and discussion.

In addition to the reporting which took place during regular Supervisory Board meetings, the Executive Board routinely and promptly issued both comprehensive written and verbal reports on the current status of research and development projects, the Company's financial position and business development, corporate planning, major business transactions and fundamental matters of corporate policy, including the Company's strategic and organizational focus, cost and earnings trends, investment measures and financial planning. In addition to the regular Supervisory Board meetings, the Supervisory Board members and Supervisory Board Chairman were in regular contact with the Executive Board and obtained information about current business developments and discussed these internally, e.g. in conference calls.

The Supervisory Board continuously and attentively observed, monitored and reviewed the Company's risk situation and its risk management, and ensured that the Company was managed in conformity with the law. Any deviations of business activities from plans and objectives were explained in detail to the Supervisory Board, and the Executive Board discussed and agreed the Company's strategic focus with the Supervisory Board. All business transactions of importance to the Company were explored in detail during the Supervisory Board plenary sessions. Information on the risk management system implemented by the Company is provided in the risk report of the Annual Report.

### **Supervisory Board meetings**

The Supervisory Board carried out its duties on the basis of the Executive Board's detailed verbal and written reports, which provided topical and comprehensive information. During the 2011 fiscal year, four meetings (March 16, 2011, June 1, 2011,

September 15, 2011 and December 9, 2011) were held. None of the members of the Supervisory Board participated in less than half of the meetings. In 2012, prior to the meeting that approved the financial statements on March 15, 2012, the audit committee held one conference call (March 8, 2012) and a meeting (March 14, 2012). When required, resolutions were documented in writing. Employees of the Company or external experts were brought in to consult on specific topics. The Supervisory Board usually spoke with the CEO at least once a week, keeping himself and his Supervisory Board colleagues updated about major business transactions and offering advice and support to the Executive Board.

All business transactions submitted to the Supervisory Board requiring either statutory approval or approval pursuant to the Articles of Incorporation were discussed in depth with the Executive Board. Revenue, earnings, and employment trends were the topics of regular plenary discussions. In fiscal year 2011, the Supervisory Board directed its particular attention to the financial position and the current business trend as well as to the strengthening of the EndoTAG®-1, RhuDex® and AAVLP projects, activities relating to new partnerships for EndoTAG®-1, approval and commercialization related activities in connection with the Veregen® project and possible strategic transactions to strengthen MediGene AG's pipeline.

Furthermore, the Supervisory Board also took personnel decisions concerning the Executive Board in the 2011 fiscal year. Based on the resolution dated June 1, 2011, the Supervisory Board extended the contract of Executive Board member Arnd Christ, which was originally concluded for a period of two years, by a further two years with effect from May 1, 2012.

During its meeting on March 16, 2011, the Supervisory Board examined the annual and consolidated financial statements as of December 31, 2010 in detail in the presence of the auditors. The Executive Board gave a presentation to the Supervisory Board on developments relating to the AAVLP project and provided information about the latest business development related activities. Moreover, the Executive Board and Supervisory Board discussed the business plan for 2011. The Supervisory Board members discussed the targets for fiscal year 2011 amongst themselves and also with the Executive Board. On June 1, 2011, the Supervisory Board dealt in detail with the development projects of MediGene AG. To this, the individual project managers presented the latest work results as well as planned activities and discussed the relevant budget with the Supervisory Board, including any necessary changes. Arnd Christ extensively explained his opinion on these matters and the Company's financial position. On this basis, the Supervisory Board resolved changes to the budget for 2011. Furthermore, the Executive Board informed the Supervisory Board of the business development activities relating to EndoTAG®-1 and activities relating to approval and partnership agreements for Veregen<sup>®</sup>. In addition, the Supervisory Board deliberated on the strategic options relating to the interest in Immunocore Ltd. Finally, the Supervisory Board prepared the 2011 Annual General Meeting on the occasion of this meeting and reviewed the efficiency of its own activities.

In its meeting on September 16, 2011, the Supervisory Board first dealt with appointing the committees. The Executive Board reported on the Company's economic and financial position. MediGene AG's products and development projects were also reported on. In addition, the Supervisory Board discussed the strategic planning, in particular with regard to strengthening the pipeline.

During the meeting on December 9, 2011, the Supervisory Board heard a report on the activities to strengthen the pipeline. It was also informed by the Executive Board on the planned IIT of EndoTAG®-1, progress, plans and the costs of the RhuDex® and AAVLP projects as well as current business development activities. The Executive Board provided explanations on the Company's financial position, and the Supervisory Board discussed the 2012 budget scenarios presented by the Executive Board and then adopted the 2012 budget. In this meeting, the Supervisory Board also obtained information about the content of the German Corporate Governance Code and approved the declaration pursuant to section 161 of the German Stock Corporation Act (AktG). Finally, the remuneration system for the Executive Board was reviewed.

#### **Supervisory Board committees**

A Compensation Committee, an Audit Committee and a SEDA Committee existed throughout the 2011 fiscal year.

The Compensation Committee held two meetings in the course of 2011 and the Audit Committee held three meetings, two of which were conference calls. The SEDA Committee did not meet in 2011.

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Committee	Members				
Compensation Committee	Prof. Dr. Ernst-Ludwig Winnacker (Chairman) Dr. Pol Bamelis Prof. Dr. Norbert Riedel				
Audit Committee	Dr. Mathias Boehringer (Chairman until September 15, 2011) Dr. Pol Bamelis (until September 15, 2011) Dr. Thomas Werner Klaus Kühn (from September 15, 2011, Chairman)				
SEDA Committee (dissolved effective December 31, 2011)	Prof. Dr. Ernst-Ludwig Winnacker (Chairman) Dr. Pol Bamelis Dr. Mathias Boehringer				

The duties of the Compensation Committee cover matters related to the employment of Executive Board members. Its main tasks are the conclusion and amendments to the Executive Board members' employment contracts as well as the fixing of their remuneration. Key topics for consultation included the setting of bonuses and stock options relating to the remuneration system for the Executive Board and the extension of the employment contract for Arnd Christ by a further two years. Due to the importance of these personnel issues, the discussions and decisions in this regard were taken by the entire Supervisory 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. The Audit Committee obtained the auditor's declaration of impartiality pursuant to point 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. The Audit Committee regularly discussed the half-yearly and quarterly reports with the Executive Board prior to their publication. The Audit Committee made a suggestion to the Supervisory Board for the proposal to the General Annual Meeting on the election of the auditor. Furthermore, it monitored the accounting process, the efficacy of the internal monitoring system, the risk management system and the internal audit.

The SEDA Committee is a decision-making body which deals with all decisions relevant to the Supervisory Board arising in on August 4, 20 on August 4, 20 visory Board at wisory Board at wisor

connection with the »Standby Equity Distribution Agreement« (SEDA) entered into with the company YA Global Investments L. P. for subscribing to new MediGene AG shares. These decisions include in particular Supervisory Board approvals on the issuance of new shares, definition of share rights, the conditions of share issuance, and exclusion of subscription rights. A separate resolution regarding the above-mentioned aspects must be passed for each individual tranche. In addition, the SEDA Committee is responsible for amendments to the Articles of Incorporation, which each issuance of shares under the SEDA program entails. The SEDA Committee held no meetings in 2011 and was dissolved with effect from December 31, 2011, since this was the date on which the agreement with YA Global Investments L. P. expired.

The committees informed the Supervisory Board about their work at regular intervals in the subsequent plenary sessions.

#### **Corporate Governance**

In 2011, the Supervisory Board again addressed the subject of MediGene AG's compliance with the recommendations of the German Corporate Governance Code. The Executive and Supervisory Boards discussed intensively the implementation of the Code at MediGene AG at the Supervisory Board meeting on December 9, 2011 and issued the annual declaration of compliance pursuant to section 161 of the German Stock Corporation Act (AktG) on the same day. The declaration is available at all times to shareholders on the Company's website. The Executive and Supervisory Boards have made a commitment to follow the recommendations of the German Corporate Governance Code as is relevant.

In its corporate governance report, the Executive Board reported on corporate governance at MediGene AG, also on behalf of the Supervisory Board, pursuant to point 3.10 of the German Corporate Governance Code.

In the 2011 fiscal year, no conflicts of interest arose on the part of the members of the Executive and Supervisory Boards which they would be obliged to disclose immediately to the Supervisory Board or report at the Annual General Meeting.

### Members of the Supervisory Board

On August 4, 2011, Klaus Kühn stood for election to the Supervisory Board at the Annual General Meeting, with a view to filling the post which had been vacant since the resignation of Sebastian Freitag on September 30, 2010. The Company's shareholders approved his election. Klaus Kühn was thus elected for the period of office for which Sebastian Freitag was originally elected. This period will run until the end of the Annual General Meeting that decides on the Supervisory Board's discharge for fiscal year 2012.

The Supervisory Board evaluates at regular intervals whether at least one of its members possesses the necessary independence and expertise required in the fields of accounting and/ or auditing. This was again affirmed for the 2011 fiscal year.

#### Individual and consolidated financial statements

The auditor elected by the Annual General Meeting and commissioned by the Supervisory Board, Ernst&Young GmbH Wirtschaftsprüfungsgesellschaft, Munich, audited the financial statements of MediGene AG as of December 31, 2011 and the management's discussion and analysis of MediGene AG for the 2011 fiscal year. The financial statements were prepared by the Executive 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 August 4, 2011. 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 these 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 auditors.

All 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 March 15, 2012, and discussed in the presence of the Executive Board and the auditor, who reported on the results of the audit. The auditor participated in the meeting in which the annual financial statements were approved and reported in detail on the most important results of his audit, especially those results of his examination of the in-house controlling and the risk management system and those relating to the accounting process. Both the Executive Board and auditor were available for any additional questions and information. All questions were answered to the Supervisory Board's full satisfaction.

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 March 15, 2012, the Supervisory Board approved the individual and consolidated annual financial statements as of December 31, 2011 in accordance with the recommendation of the Audit Committee. The financial statements have thus been adopted.

At the meeting on March 15, 2012, the Audit Committee also recommended that Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Munich be proposed by the Supervisory Board for election by the Annual General Meeting as auditors for the 2012 fiscal year. The Supervisory Board will act in accordance with this recommendation.

The Supervisory Board wishes to thank the Executive Board and all MediGene employees for their successful efforts on behalf of the Company in the 2011 fiscal year. Once again, due to their collective efforts, they achieved a good result.

Planegg/Martinsried, March 2012

Ernt- ledy Winnew

Prof. Dr. Ernst-Ludwig Winnacker Chairman of the Supervisory Board

## **CORPORATE GOVERNANCE**

The Executive Board reports on corporate governance at MediGene AG, also on behalf of the Supervisory Board, in accordance with point 3.10 of the German Corporate Governance Code. The corporate governance report also includes the declaration on corporate governance pursuant to section 289a of the German Commercial Code (HGB).

## **Corporate governance report**

Good corporate governance is the basis of our decision-making and monitoring processes. It stands for responsible and valuebased leadership and control of the Company for long-term success, goal-oriented and efficient cooperation between the Executive Board and Supervisory Board, respect for the interests of our shareholders and employees, consistently transparent and responsible corporate decisions and an appropriate risk management system.

Corporate governance ensures the following basic principles:

- It defines key shareholder rights.
- It demonstrates clear management principles and the associated responsibilities of corporate bodies.
- It governs the cooperation between these bodies.
- It calls for open and transparent communication with the public.
- It demands that accounting and auditing be conducted in a conscientious and reliable manner.

MediGene AG's implementation of corporate governance includes:

#### **Relations with the Company's shareholders**

MediGene AG respects the rights of its shareholders and ensures the exercise of these rights to the extent possible within the applicable statutory framework. In particular, these rights include the free purchase and sale of shares, equal voting rights for each share (one share – one vote), participation in the Annual General Meeting and exercise of voting rights there, and meeting the shareholders' information needs to a satisfactory level.

In accordance with the relevant legal provisions, MediGene provides information in a timely manner about the venue and date of the Annual General Meeting, which takes place at least once a year. The notice of the Annual General Meeting as well as the reports and information required for resolutions are published pursuant to the regulations of the German Stock Corporation Act (AktG), held available at the Company's premises and made available on MediGene AG's website. Every shareholder who

registers in time has the right to attend the Annual General Meeting in person. In the event that a shareholder is unable to exercise his voting right in person at the Annual General Meeting, he has the option of voting by nominating an authorized representative of his choice or through the Company's proxy, who is bound by instructions. Furthermore, shareholders may also transfer their vote to a proxy of the Company or nominate an authorized representative online in advance of the Annual General Meeting.

#### **Communication with the public**

In relaying information to entities outside, the Executive Board complies with the principles of transparency, promptness, openness, understandability and equal treatment of share-holders. For this purpose, the Company provides information such as press releases, financial and conference calendars, annual and quarterly reports, announcements of transactions for which disclosure is mandatory and corporate governance information under the heading »Media&Investors« on its website, <u>www.medigene.com</u>. MediGene AG regularly reports on the status of its research and development programs as well as other business operations in conference calls, analyst meetings, and at international investor conferences.

The Annual General Meeting of MediGene AG is prepared with the goal of effectively providing all shareholders with comprehensive information. MediGene AG also aims to facilitate the process of registration for the Annual General Meeting and exercise of rights for shareholders. Prior to the Annual General Meeting, shareholders are informed in detail about the past fiscal year via the annual report. In the invitation to the Annual General Meeting, the requirements for participation, for the exercise of voting rights, as well as the procedure of voting by proxy and the shareholder rights related to the Annual General Meeting are explained. All documents and information pertaining to the Annual General Meeting are available on the MediGene AG website. Prior to the Annual General Meeting, members of the Company's Investor Relations department are available to answer any questions that shareholders may have by telephone, fax or email. Following the Annual General Meeting, MediGene AG publishes the ascertained voting results for each agenda item for which a resolution was passed, the number of shares for which a valid vote was given, the proportion of share capital represented by valid votes, the number of votes in favor of the resolution, the number of dissenting votes and, if applicable, the number of abstentions. This ensures and simplifies the exchange of information between MediGene AG and the shareholders regarding the Annual General Meeting.

## Composition of the Executive Board and Supervisory Board

**Executive Board** 

When appointing Executive Board members, the Supervisory Board will ensure in the future that there is a diverse range of expertise and experience, and that female candidates are given adequate consideration (diversity).

#### **Supervisory Board**

There is no former member of the Executive Board on the Supervisory Board of MediGene AG. This guarantees impartial consultation and supervision of the Executive Board. In its meeting on December 9, 2011, the Supervisory Board confirmed the specific goals regarding its composition resolved in 2010 pursuant to point 5.4.1 (2) of the German Corporate Governance Code. They are outlined below:

- The Supervisory Board of MediGene AG shall be constituted in such a way that its entirety possesses the knowledge, skills and professional experience required for the proper exercise of its duties. Each individual Supervisory Board member, however, must exhibit the minimum knowledge and skills needed to understand and appropriately assess without assistance all ordinary business processes arising at MediGene AG.
- In view of the highly competitive international environment in which MediGene AG practices the research, development and commercialization of novel drugs, international experience of Supervisory Board members is of vital importance for the composition of the Supervisory Board. For this reason, the Supervisory Board seeks to retain its composition with members showing an international background, at least to the present extent.
- Women shall be represented on the Supervisory Board of MediGene AG in an adequate manner in future. At the moment, there are no female members on the Supervisory Board. It is intended that there will be at least one female Supervisory Board member by the end of the year 2014.
- Moreover, the Supervisory Board aims to ensure that the Supervisory Board is composed of independent members and to avoid any conflicts of interest.
- No age limits have been defined for the Supervisory Board members, which means that this shall not be a criterion in itself to be considered when constituting the Supervisory Board, since such age limits are considered by the Supervisory Board to be an inappropriate restriction of the shareholders' right to elect the Supervisory Board members.

The Supervisory Board will take the above-mentioned aspects into account in its decision-making process regarding proposals to the Annual General Meeting for the election of Supervisory Board members.

# Cooperation between the Executive Board and the Supervisory Board

The Executive and Supervisory Boards cooperate closely for the benefit of the Company. The Chairman of the Supervisory Board maintains regular and close contact with the Executive Board, especially with the Chief Executive Officer. The Executive and Supervisory Boards coordinate the Company's strategic direction and discuss at regular intervals the status of research and development projects, business planning and development, strategy implementation, as well as the Company's risk situation and risk management. Deviations from the established business plans and objectives are explained and justified during these sessions. The Supervisory Board specifies in the Executive Board's bylaws that transactions of major significance are subject to Supervisory Board consent. This includes, for example, decisions or measures that have a fundamental impact on the Company's assets, financial, and income position.

#### **Remuneration of the Executive Board and Supervisory Board**

In its version dated May 26, 2010, point 4.2.5, the German Corporate Governance Code recommends the inclusion of a remuneration report as part of the corporate governance report. The German Commercial Code (HGB), section 289 (II) (5) stipulates a statutory recommendation to include a remuneration report on the remuneration of the Executive Board members in the management's discussion and analysis (MD&A). In order to comply with both statutory provisions and Corporate Governance Code requirements, and in the interests of transparency and clarity, the remuneration of the members of the corporate bodies is reported in a consistent and focused manner in the remuneration report chapter of the management's discussion and analysis and in the notes to the consolidated financial statements, thereby implementing the provisions of the Corporate Governance Code. Remuneration of Executive and Supervisory Board members is reported on pages 46 et seq. and 102 et seq. of the Annual Report and can be accessed on the Company's website at www. medigene.com. Information on each member and each component of the remuneration is provided.

Pursuant to point 2.2.1 (II) of the German Corporate Governance Code, the Annual General Meeting may pass a resolution approving the remuneration system for Executive Board members. A resolution regarding the future remuneration system was passed for the first time at the Annual General Meeting on May 11, 2010. It was adopted by 96%.

Total remuneration of the Executive Board members is comprised of fixed and variable components, as well as other remuneration. Variable remuneration includes annual performance-related compensation and stock options. The criteria for the annual performance-related compensation are established by the Supervisory Board annually in advance. Targets geared to sustainable longterm corporate success and stock options represent long-term incentives. By delaying payment of a part of the annual performance-related compensation for three years and subsequent review and decision-making by the Supervisory Board whether and to what extent a sustainably positive corporate development can be affirmed, additional incentives for future Executive Board member employment contracts are to be created.

The Supervisory Board members' total remuneration is comprised of fixed remuneration and meeting attendance fees. Both the chairmanship and deputy chairmanship of the Supervisory Board are included in the assessment of the Supervisory Board members' scope of activities. Committee activities are not considered separately in the remuneration.

For further information regarding the remuneration of Executive Board members and Supervisory Board members, please refer to *page 102 et seq.* 

#### Forward-looking risk management

A well-structured risk management system geared to practical requirements helps the Company to identify any risks at an early stage and quickly take the appropriate steps. Information about current business risks and details regarding risk management in the MediGene Group are provided in the risk report on <u>pages 47</u> <u>et seq.</u> of the management's discussion and analysis. The report on the accounting-related internal control and risk management system can be found on <u>page 51 et seq.</u> of this report.

#### **Reporting and audit of financial statements**

MediGene AG keeps shareholders and interested parties informed at regular intervals by means of its consolidated financial statements and the interim reports prepared in the course of the fiscal year. The Supervisory Board discusses the consolidated financial statements as well as the six-monthly and quarterly reports with the Executive Board prior to their publication. Consolidated reporting takes place in compliance with the International Financial Reporting Standards (IFRS) as applicable within the EU. Annual financial statements, which also provide the basis for taxation, are prepared in accordance with national regulations (German Commercial Code, HGB) for the purpose of observing German corporate law (calculation of dividends, creditor protection). The consolidated financial statements and individual financial statements are prepared by the Executive Board and reviewed by the auditors and the Supervisory Board. The Supervisory Board issues the audit assignment and concludes a fee agreement with the auditors. The auditors participate in the Supervisory Board's discussions about the annual and consolidated financial statements and report on key audit findings.

The consolidated financial statements and the financial statements of MediGene AG were audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Munich, the auditors elected by the 2011 Annual General Meeting. Their audit was carried out in accordance with the current German auditing regulations, taking into account the principles of proper auditing stipulated by the Institute of Public Auditors in Germany (Institut der Wirtschaftsprüfer) and additionally taking into account the International Standards on Auditing. The audit also included an audit of the risk management.

## Stock option plans and similar securities-based incentive systems

The Executive Board was authorized by resolution of the Annual General Meeting on May 25, 2007 to issue stock options to employees and executives with the Supervisory Board's consent (2007 stock option plan). In December 2011, a total of 180,570 stock options were issued to Executive Board members and employees of MediGene AG under this stock option plan. For more detailed information about MediGene AG's employee stock ownership programs, please refer to *pages 88 et seq.* of this Annual Report.

#### **Directors' dealings**

Pursuant to section 15a of the German Securities Trading Act (WpHG), the Executive and Supervisory Board members of MediGene AG, as well as any persons who have a close relationship with these members (family members), must undertake to report any trading in MediGene AG shares. The purchase and sale of MediGene AG shares and any transactions in securities which relate to MediGene AG shares (e.g. the sale or purchase of options on MediGene AG shares) must be reported. The Company must be notified of such transactions within five business days, and it must then disclose such transactions without delay. The reporting obligation is inapplicable if the total value of trading does not exceed the statutory minimum limit of €5,000 during one calendar year.

The following directors' dealings took place in 2011:

Directors' dealings in 2011

Name of Board Member	Function	Classifica- tion of share	ISIN	Trans- action	Place of transaction	Date of transaction	Price per share in €	Number of shares	Deal € volume in
	Executive					August 5,			
Dr. Frank Mathias	Board Member	Share	DE0005020903	Purchase	Xetra	2011	1.03	2,000	2,060
	Executive					August 5,			
Dr. Frank Mathias	Board Member	Share	DE0005020903	Purchase	Frankfurt	2011	1.04	2,000	2,080
	Executive					August 5,			
Arnd Christ	Board Member	Share	DE0005020903	Purchase	Xetra	2011	1.14	5,000	5,700

## Non-compliance with the recommendations of the German Corporate Governance Code

Pursuant to section 161 of the German Stock Corporation Act (AktG), any non-compliance with the recommendations of the German Corporate Governance Code must be described and justified in the declaration of compliance. MediGene reports on non-compliance with certain recommendations of the German Corporate Governance Code as described in the following declaration on corporate governance.

# Declaration on corporate governance in accordance with section 289a of the German Commercial Code (HGB)

#### I. Declaration of compliance pursuant to section 161 AktG

MediGene AG makes the German Corporate Governance Code available on the Company website (<u>www.medigene.com</u>). This also applies to the official declaration of compliance by the Executive Board and the Supervisory Board pursuant to section 161 AktG (<u>http://www.medigene.com/E\_corporate\_governance\_erklaerung/161</u>).

The Executive Board and Supervisory Board of MediGene AG adopted the following declaration of compliance as of December 9, 2011:

»Declaration by the Board of Management and the Supervisory Board of MediGene AG pursuant to § 161 of the German Stock Corporation Act (AktG)

Section 161 (I) (1) of the German Stock Corporation Act (AktG) requires the Executive and the Supervisory Boards of a listed stock corporation to declare annually that the recommendations of the Government Commission on the German Corporate Governance Code published by the Federal Ministry of Justice in the official section of the electronic Federal Gazette have been and are complied with, and which recommendations have not been or are not being applied, and for what reason. The public has to be given permanent access to this declaration on the company's website, pursuant to section 161 (II) of the German Stock Corporation Act.

In addition to the presentation of the applicable German Stock Corporation Act, the German Corporate Governance Code (>Code() also includes recommendations from which a company may deviate. However, any deviation has to be disclosed and accounted for annually.

For the period starting December 11, 2010, the declaration on hand refers to the Code as amended on May 26, 2010 and published in the electronic Federal Gazette on July 2, 2010.

The Executive and Supervisory Boards declare compliance with the Code since the issue of the preceding declaration of compliance on December 10, 2010, with the following exceptions, and declare their intention to comply in the future as follows:

#### **1. Absentee voting**

In its next Annual General Meeting, the company will refrain from making use of the alternative of absentee voting granted by the Articles of Incorporation (point 2.3.3 (II) of the Code).

Both the Executive and Supervisory Boards of MediGene AG believe that the existing voting methods are adequate and provide sufficient options for the shareholders to vote on the respective items of the agenda.

#### 2. Deductible in the case of D&O insurance

The D&O insurance (so-called directors' and officers' liability insurance) taken out by MediGene AG for its Supervisory Board members does not provide for any deductible (compare point 3.8 (III) of the Code).

MediGene AG does not intend to agree a general deductible for its Supervisory Board members with its D&O insurance carrier. Since July 1, 2010, the legal obligation to adapt D&O insurance contracts pursuant to section 93 (II) (3) of the German Stock Corporation Act (AktG) in conjunction with section 23 (I) (1) of the Introductory Act to the German Stock Corporation Act (EGAktG) is applicable only to Executive Board members. In section 116 (I) of the German Stock Corporation Act (AktG), the legislator did not require any deductible for Supervisory Board members, but expressly excluded the Supervisory Board instead. The Executive and Supervisory Board of MediGene AG believe that the nature of the position as a Supervisory Board member, which is also emphasized by the different remuneration, calls for a distinction between D&O insurances for Executive and Supervisory Board members. Both the Executive and Supervisory Boards also believe that the motivation and sense of responsibility applied by the members of the Supervisory Board of MediGene AG in the fulfillment of their duties are fully guaranteed without any general deductible as recommended under the Code.

**3. Age limits for Executive and Supervisory Board members** The German Corporate Governance Code recommends in points 5.1.2 (II) and 5.4.1 that age limits be set for Executive Board and Supervisory Board members. There is no age limit for the Executive and Supervisory Board members of MediGene AG, and there is no intention to introduce such age limits in the future.

Both the Executive and Supervisory Boards consider such age limits to be an inappropriate restriction not only on the shareholders' right to elect the Supervisory Board members, but also on the Supervisory Board' selection of qualified Executive Board members. The Supervisory and Executive Boards are well-balanced in their age structures, even without a mandatory age limit.

#### 4. Constitution of a nomination committee

The German Corporate Governance Code recommends in point 5.3.3 that the Supervisory Board constitute a nomination committee made up exclusively of shareholder representatives. Such a nomination committee has not hitherto been constituted by MediGene AG's Supervisory Board and is not under consideration for the future.

The members of the Executive and Supervisory Boards believe that in view of the overall size of the Supervisory Board, it is neither necessary nor advisable to constitute such a committee, and that the Supervisory Board is able to perform this task on its own without sacrificing its efficiency.

# 5. Consideration of committee work in the remuneration of Supervisory Board members

The German Corporate Governance Code recommends in point 5.4.6 (I) that membership in Supervisory Board committees be taken into consideration in the remuneration of Supervisory Board members. Any membership in committees of the Supervisory Board is not taken into account when fixing the remuneration of MediGene's Supervisory Board members, nor is this planned for the future.

Both the Executive and Supervisory Boards believe that the Supervisory Board members show a high degree of commitment in their committee work without any such arrangement.

## 6. Performance-based remuneration of the Supervisory Board members

The German Corporate Governance Code recommends in point 5.4.6 (II) that the members of the Supervisory Board receive performance-based remuneration in addition to their fixed remuneration. MediGene AG's Supervisory Board members have up to now received no performance-based remuneration, and this is also not planned for the future.

The Executive and Supervisory Boards believe that the Supervisory Board's activities are efficient and geared toward maximum corporate success at all times, regardless of whether or not remuneration is performance-related.

Martinsried, December 9, 2011

For the Executive Board, Dr. Frank Mathias For the Supervisory Board, Prof. Dr. Ernst-Ludwig Winnacker «

#### II. Function of the Executive Board and Supervisory Board

#### **Function of the Executive Board**

The Executive Board in its entirety and each individual Board member engage in Company business with the due care and diligence of proper and conscientious management in accordance with the law, the Articles of Incorporation and the Executive Board bylaws. The Executive Board assumes responsibility for the management of the Company. In doing so, it is obliged to act in the Company's best interest and is committed to sustainably enhancing enterprise value. In managing the Company, the Executive Board bears in mind the interests of the Company's shareholders, employees and other stakeholders. Currently, MediGene AG's Executive Board is composed of two members. They cooperate closely and keep each other informed about important measures taken and processes in their departments. The Executive Board passes resolutions during sessions which take place at regular intervals, usually once a month.

The Executive Board bylaws lay down the processes and approaches that form the basis of the Executive Board's work. The bylaws also include regulations for business transactions which require the Supervisory Board's consent, the Company's organizational chart and basic behavior policy guidelines.

The Executive Board works closely with the Supervisory Board. It keeps the Supervisory Board informed regularly, promptly and comprehensively about all issues relevant to the Company.

#### **Function of the Supervisory Board**

It is the duty of MediGene AG's Supervisory Board to appoint the Executive Board members, to advise them regularly and to monitor and support the management and the achievement of MediGene AG's long-term goals. The Supervisory Board of MediGene AG is composed of six members, pursuant to section 10 (I) (1) of the Articles of Incorporation and to sections 95, 96 (I) and 101 (I) of the German Stock Corporation Act (AktG). The term of office of the Supervisory Board ceases at the end of the Annual General Meeting in 2013, which decides on the Supervisory Boards discharge for the 2012 fiscal year.

In fiscal year 2011, Klaus Kühn was elected to the Supervisory Board by the Annual General Meeting on August 4, 2011. Klaus Kühn has filled the post that became vacant when Sebastian Freitag resigned.

To exercise its duties, the Supervisory Board has constituted three committees:

#### **Compensation Committee**

The duties of the Compensation Committee include matters related to the employment of Executive Board members. The Committee's main tasks are the preparation of the Executive Board members' employment contracts and to present proposals for their remuneration. It is the entire Supervisory Board's responsibility to decide on these issues. Prof. Dr. Ernst-Ludwig Winnacker (chairman), Dr. Pol Bamelis and Prof. Dr. Norbert Riedel are the members of the Compensation Committee.

#### Audit Committee

The Audit Committee members deal with issues relating to accounting and risk management, the required independence

of the auditor, the issuing of the audit mandate to the auditor, determination of audit priorities and agreement of the audit fee. The Audit Committee was comprised of Dr. Pol Bamelis, Dr. Thomas Werner and Dr. Mathias Boehringer as its chairman (until September 15, 2011). On August 4, 2011, the Annual General Meeting elected a further financial expert to the Supervisory Board in Klaus Kühn. In its meeting on September 15, 2011, the Supervisory Board elected Klaus Kühn to the Audit Committee and appointed him as chairman of the committee. Dr. Bamelis left the committee at the same time.

#### SEDA Committee

The SEDA Committee is a decision-making body which deals with all decisions relevant to the Supervisory Board arising in connection with the »Standby Equity Distribution Agreement« (SEDA) entered into with the company YA Global Investments L.P. for subscribing to new MediGene AG shares. These decisions include, in particular, Supervisory Board approval on the issuance of new shares, definition of share rights, the conditions of share issuance and exclusion of subscription rights. Separate decisions must be taken for each individual tranche. In addition, the SEDA Committee is responsible for amendments to the Articles of Incorporation which each issuance of shares under the SEDA program entails. The SEDA Committee was comprised of Prof. Dr. Ernst-Ludwig Winnacker, Dr. Mathias Boehringer and Dr. Pol Bamelis. In view of the expiry of the agreement with YA Global Investments L.P. at the end of 2011, the SEDA Committee was dissolved with effect from December 31, 2011.

#### III. Key corporate governance practices

MediGene attaches major importance to compliance with legislation and in-house guidelines. For this purpose, a Compliance Officer has been appointed to concentrate on a number of central points, such as securities law and the statutory prohibition of insider trading. MediGene has developed its own insider policy to complement the latter. Furthermore, Medi-Gene has committed to the Code of Conduct of the German Association for the Voluntary Self-Regulation of the Pharmaceutical Industry (Verband Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V. - http://www.fs-arzneimittelindustrie.de/en/ verhaltenskodex/). The association monitors appropriate cooperation of pharmaceutical companies with physicians, pharmacists and other healthcare professionals as well as patient self-help organizations and imposes sanctions in the event of a breach of rules. In combination with the above-mentioned principles, this forms the basis of corporate actions at MediGene AG.

# GLOSSARY

#### A AAVLP

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

### AktG

»Aktiengesetz« German Stock Corporation Act

## **Authorized capital**

Value or number of shares authorized 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 to one's own body tissue

## В

**B-cell epitope** 

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

### **Biopharmaceutical**

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

### **Biotechnology**

Utilization of natural and modified biological systems and their elements

## 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

### Conditional capital

Capital authorized 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

### **Depot formulation**

Drug in the form of an implant which slowly disintegrates and releases the active substance over a set period of time

**Dermatology** Branch of medicine that deals with the treatment of skin diseases as well as benign and malignant skin tumors

**Drug candidate** Drug which is still at the development stage

## Ε

## **EBITDA**

Earnings before interest, taxes, depreciation, and amortization EBITDA is used to describe the result for the year excluding taxes, financial result, depreciation, amortization, and impairment.

### **Endothelial cells**

Line the interior surface of lymphatic and blood vessels

Estrogen

Female sex hormone See also »triple-negative breast cancer«

## F

**FDA** Food and Drug Administration Government agency of the United States Department of Health and Human Services

## 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 tumors in the genital and anal areas

#### Gestagen

Female sex hormone See also »triple-negative breast cancer«

#### 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

Viruses that infect the epithelium of the skin and may cause uncontrolled tumor-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

## Indication

Reason for the execution of a medical examination or treatment

## L

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

### Liposomes

Minute, hollow globules, composed of fat molecules

## 0

**Oncology** Science of tumors and tumor-related diseases

### **Orphan drug designation**

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

## Ρ

Pancreatic cancer Malignant tumor of the pancreas

### PCT

### Patent Cooperation Treaty

International agreement under which a patent application may be filed for currently 142 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

#### **Preclinical**

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

### Proof of concept

Evidence of the fundamental feasibility of a plan

#### **Prophylactic vaccine**

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

#### **Prostate cancer**

Malignant tumor of the prostate gland (part of the male sexual organs)

## R

## Receptor

Protein molecule which causes binding of different particles that are transported into a cell

**Resistance** Ability of an organism to withstand external influences

Rheumatoid arthritis Inflammatory disease affecting the joints

## S

## SEDA

Standby Equity Distribution Agreement Method of financing where a company's partner agrees to subscribe to tranches of new shares against capital contribution

## Ţ

## 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**

Receptor by which T cells recognize antigens bound to other cells of the body  $% \left( {{{\rm{T}}_{{\rm{T}}}}_{{\rm{T}}}} \right)$ 

## TecDAX

Index of the German Stock Exchange listing the thirty major technology equities with respect to market capitalization 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 tumor

#### **Triple-negative breast cancer**

Malignant breast tumors that display neither estrogen/ gestagen nor HER2 receptors on the cell surface are termed »triple negative«

## FINANCIAL CALENDAR

March 23, 2012 Annual report 2011 Financial press conference and analysts teleconference

May 11, 2012 3-month report, analysts teleconference

August 3, 2012 6-month report, analysts teleconference

**November 6, 2012** 9-month report, analysts teleconference

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## IMPRINT

## Published by

MediGene AG Lochhamer Str. 11 82152 Planegg/Martinsried Germany T +49-89-856529-0 F +49-89-85652920

## Contact

## **Public & Investor Relations**

Julia Hofmann (analysts, institutional investors, press) Kerstin Langlotz (retail investors, press) T +49-89-85653301 investor@medigene.com public.relations@medigene.com

## **Human Resources**

Silvia Kandlbinder T +49-89-85652986 human.resources@medigene.com

#### **Business Development**

Elias Papatheodorou T +49-89-85652956 business.development@medigene.com

#### **Commercial Operations**

Michaela Fabry T +49-89-85652956 commercial.operations@medigene.com

## Concept and text MediGene AG, Planegg/Martinsried

## Concept, design and realization

Kirchhoff Consult AG, Hamburg

Photographs Matthias Tunger, Munich

#### Production

Druckerei Kriechbaumer, Munich

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