# medigene



THINK AHEAD.
ACT AHEAD.

# **KEY FIGURES**

OF MEDIGENE AG

IN € THOUSAND	2012	2011	CHANGE
INCOME STATEMENT			
Continued operations			
Product sales	3,384	2,300	47%
Other operating income	2,900	2,356	23%
Total revenue	6,284	4,656	35%
Cost of sales	-1,250	-953	31%
Gross profit	5,034	3,703	36%
Selling, general and administrative expenses	-7,909	-8,103	-2%
Research and development expenses	-7,399	-11,254	-34%
Other expenses	-6,166	0	-
EBITDA	-9,427	-10,979	-14%
Operating result	-16,440	-15,654	5%
Result from continued operations before tax	-14,795	-15,474	-4%
Result from continued operations	-14,877	-14,233	5%
Discontinued operations			
Revenue from discontinued operations	5,032	27,828	-82%
Result from discontinued operations	5,018	20,514	-76%
Total			
Net result for the year	-9,859	6,281	-
EBITDA	-4,409	11.180	-
Basic and diluted earnings per share after tax in €	-0.27	0.17	-
Personnel expenses	-5,818	-6,145	-5%
CASH FLOW STATEMENT			
Cash flow from operating activities	-6,507	6,864	_
Cash flow from investing activities	-255	1,423	_
Cash flow from financing activities	14,094	0	-
BALANCE SHEET STATEMENT			
Cash and cash equivalents	20,113	12,811	57%
Balance sheet total	61,255	53,292	15%
Current liabilities	4,317	4,824	-11%
Non-current liabilities	12,723	536	>200%
Shareholders' equity	44,215	47,932	-8%
Equity ratio in %	72	90	-20%
. ,			
Employees as at Dec. 31	53	52	2%
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 in €	1.00	0.97	3%
Dividend in €	0	0	

# **CONTENT**

#### **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. Through scientific innovation and targeted use of our resources as well as thinking ahead and acting with foresight, we strive to create sustainable value that will benefit both patients and our shareholders.

Medigene has developed a marketed drug and currently has two candidates in clinical testing. We will continue with our research.

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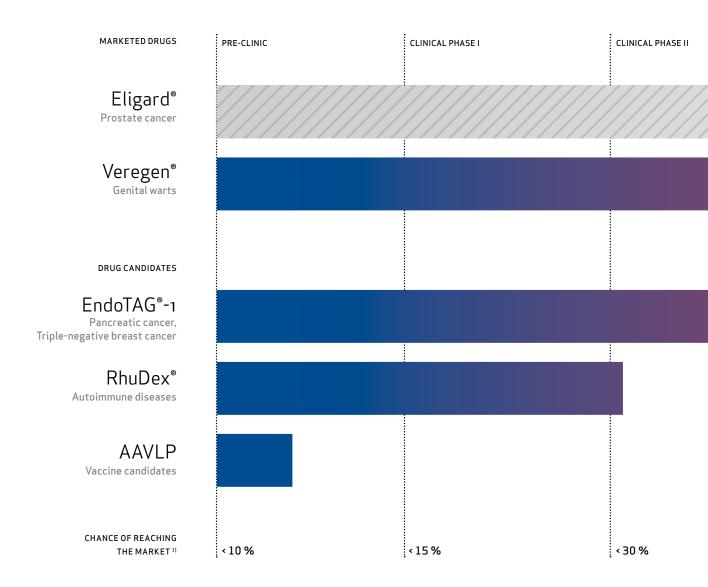
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# **PIPELINE**



#### Note:

The rights for Eligard have been transferred to third parties.

CLINICAL PHASE III	APPROVAL	MARKET
<70 %	< 90 %	

## INTERVIEW WITH THE EXECUTIVE BOARD

Dr. Frank Mathias, CEO of Medigene AG, and Peter Llewellyn-Davies, CFO, reflect on 2012 and discuss the strategic and financial outlook for the upcoming financial year, during which Medigene will strive to make further progress.

# The title of the 2012 annual report reads: »Think ahead. Act ahead. « To what extent does this apply to Medigene?

DR. FRANK MATHIAS: The challenge to us as a biotech company is to be flexible, creative and persistent in our actions. On the long road of research and development before a drug's market approval, proactive decision-making is imperative to successfully lead the company in the right direction over the longer term. To this end, we have put Medigene on a stable footing in recent years and laid the foundation for growth in the coming years. 2012 has been a successful year for us, in which we made progress in the marketing of our approved product, as well as with our drug pipeline and the financial structure of the company. Veregen® has gained market share, and we have also acquired an important partner for EndoTAG®-1. With the recently announced expansion of the clinical trial plan for RhuDex®, we are aiming to enhance the value of the candidate drug from both a scientific and commercial perspective. The monetization of Eligard® has increased our cash reserves and, at the same time, provided us with some financial flexibility for the future. In 2013, we will continue to pursue our long-term goal of sustainable value creation for the company by means of proactive strategic decision-making.

# Mr. Llewellyn-Davies, you joined Medigene as CFO in October 2012: what are the challenges you have identified for the company?

PETER LLEWELLYN-DAVIES: The recent refocusing of our product portfolio and the corporate restructuring provide Medigene with a good starting point for a new growth phase. The key issues now are to generate

additional value, to promote growth and to exploit existing potential. All this puts a spotlight firmly on the financial capability and, consequently, the funding of the company. The financial statements for 2012 show rising sales, and this trend also demonstrates – that we are heading in the right direction. In 2013, we aim to leverage this potential to raise the profile of Medigene, a public listed company, on the capital markets and to increase interest in our shares.

#### Turning now to the current position of the company, what makes Medigene different? What are the company's distinguishing features?

PETER LLEWELLYN-DAVIES: The company's main focus is on researching and developing innovative drugs for an improved treatment of cancer and auto-immune diseases. We are however unique in being the first biotech company in Germany to have successfully brought to market two drugs, Eligard\* and Veregen\*. The marketed drug Veregen\* is a solid foundation for the company with rising sales, which are likely to continue to grow in the future. The focused business model of Medigene is sustainable and has further development potential.

DR. FRANK MATHIAS: We have introduced a number of changes in recent years to reach this goal. We have cut back on the risks, streamlined our business model and identified our value drivers, so that we now can fully concentrate on advancing these projects. With EndoTAG\*-1, RhuDex\* and AAVLP we have three research and development projects that apply innovative approaches. All three projects have shown promising data in their current development phases. We are aiming to continue the targeted development of these projects with financially

powerful partners. In order to further strengthen our product pipeline, we are discussing and evaluating options to include external candidate products. We are of the conviction that we have put the company on the right footing to record growing success over the coming years.

With EndoTAG\*-1 in the product pipeline, you have a candidate who has shown promising phase II data for the treatment of pancreatic cancer and triple receptor negative breast cancer. In summer 2012, Medigene announced a development and marketing partnership: what are the plans for EndoTAG\*-1?

DR. FRANK MATHIAS: With regards to the two indications, pancreatic cancer is a very aggressive form of cancer and triple receptor negative breast cancer is difficult to treat. In the two phase II studies carried out, EndoTAG\*-1 gained "proof of concept". Based on experience with EndoTAG\*-1, the investigator of the phase II breast cancer study, Prof. Ahmad Awada of the Jules Bordet Institute in Brussels, decided to finance and carry out a study with EndoTAG\*-1 in a more broadly defined type of breast cancer. The results of this investigator initiated trial will soon be published. Together with a development and marketing partner for Asia, we have also been able to further consolidate our plans for future trials of EndoTAG\*-1 in a phase III study. The basis of the contract is that our partner, Syncore, will assume the funding of the new study in the Asian regions. With regards to the financing of the remaining countries involved in this study, which is designed to be global, we are still looking to identify one or more partners.

Medigene is not only active in oncology, but also has RhuDex\*, a candidate product for the treatment of auto-immune diseases. However, this project is still at an early stage of development. What are your plans in this direction for the coming financial year?

PETERLLEWELLYN-DAVIES: RhuDex\* is being developed as an orally administered treatment and this gives it a potential advantage over most other products in its drug class. In 2012, we worked intensively on the formulation and successfully conducted a corresponding formulation study. The next step is to research the effectiveness of RhuDex\* in primary biliary cirrhosis (PBC). PBC is potentially an interesting indication for RhuDex\*, since it belongs to the orphan diseases, i.e. a group of rare and severe medical conditions. If RhuDex\* proves to be effective for the treatment of PBC, it could well become the first etiological and disease-modifying treatment in this indication.

»We have cut back on the risks, streamlined our business model and identified our value drivers, so that we now can fully concentrate on advancing these projects.«

The anticipated phase II study, which replaces the initially planned phase IIa study, will consist of four trial groups including a control group and the participating patients will be treated with the drug over a six month period. We are currently anticipating that the study will begin in the first half of 2014 at the latest. This is subject to the successful conclusion of the preparatory work for the study which became neccessary as a consequence of the expanded study design. The advantage of an expanded phase II study is that we may obtain findings of a higher quality regarding the clinical relevance of the mode of action of RhuDex\* and this may facilitate the future approval for PBC.

You just mentioned that Veregen° is one of the company's value drivers and that it is the first product from a German biotech company to achieve market approval. It is currently sold in five countries: what other plans do you have for Veregen°?

DR. FRANK MATHIAS: Veregen\* has a firm place in our product portfolio and provides our business model with a stabilizing element. Step by step, we are developing new markets all over the world and making the product available to patients through our commercial partners. In 2012, we added Switzerland and Spain to our sales markets and these countries are increasing the revenues we are already earning from the USA, Germany and Austria. We are pleased to announce that the coming months will see the market launch of Veregen\* in

»Our aim is to generate confidence and sustainable value, to gain new investors and to give our shares growth potential.«

PETER LLEWELLYN-DAVIES

many new countries, because Medigene gained additional partners in a total of 24 countries during 2012. This gives us sales networks for Veregen\* in 62 countries. These commercial partnerships will ensure further growth in our sales revenues from Veregen\* in the coming years. In 2012, the sales growth was evident, with Veregen\* generating EUR 3.4 million in sales, representing a 47% increase on the prior year. We are convinced of the sales potential of the drug and shall continue to pursue our strategy of achieving the broadest possible country coverage for Veregen\*.

# The key word being finance: Medigene has been unable to sustain the profit recorded in 2011 in 2012: what are we to make of that?

PETER LLEWELLYN-DAVIES: The prior year's profit is largely the result of non-recurring special effects relating to the transfer of Eligard\* rights. Eligard\* has been discontinued by Medigene, which is why it has been reported as discontinued operations since 2011. All other projects are posted under the segment on continued operations. In 2012, we can report a positive trend in this segment. The rising proceeds from the marketing of Veregen\* generated a 35% improvement in sales, which total EUR 6.3 million. Last year, Medigene's EBITDA from current operations amounted to EUR -9.4 million, representing an improvement of 14% in a year-on-year comparison with the EUR -11.0 million recorded in the prior year. In total we achieved an EBITDA result of EUR -4.4 million, and with this, we surpassed the 2012 forecast.

Medigene shares improved slightly in 2012 with ups and downs during the year. However, the positive trend in the company's financial results and the successful refocusing of Medigene do not appear evident in the share price. How do you account for this?

PETER LLEWELLYN-DAVIES: We monitor our share value very closely and are dissatisfied with the way in which our share price has developed, in spite of the successful steps Medigene has taken. Like many other companies in our industry, we have been subjected to turbulent times in a difficult environment in the sector. According to a report on the sector by Ernst & Young, the willingness to invest in German biotech companies, in particular, has declined over the past few years. Our aim for the future is to generate increased confidence and sustainable value, to gain new investors and give our shares growth potential.

# To conclude our interview, let us look to the future: what aims have you set yourself for the coming years?

DR. FRANK MATHIAS: Our plans for the future are focused on opening new markets for Veregen® and on the development of our pipeline products with the aim of bringing them to market. In 2013, we will see further market launches for Veregen®, and we shall continue our search for partners to handle the international marketing of the drug. Our next clinical milestones are the start of the phase II study for RhuDex® and the further development of EndoTAG®-1, for which we would like to engage additional partners. In terms of our AAVLP (adeno associated virus-like particles) project, we are planning to carry out further preclinical studies shortly. The project is available for partnerships and licensing.

PETERLLEWELLYN-DAVIES: Beyond this, we shall be investigating our options for expansion of the product pipeline. From a financial perspective, we are anticipating rising sales within the EUR 7 – EUR 8 million range for the next year, and an EBITDA loss to within the EUR 9 – EUR 11 million range compared to an EBITDA loss of EUR 9 million from continued operations in 2012. Based on current business projections, we are assuming that the company is funded at least until the end of 2014. Consequently, we can look forward to the coming financial year with confidence.

MEDIGENE AG ANNUAL REPORT 2012 MANAGEMENT

## **MANAGEMENT**



# DR. FRANK MATHIAS 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.

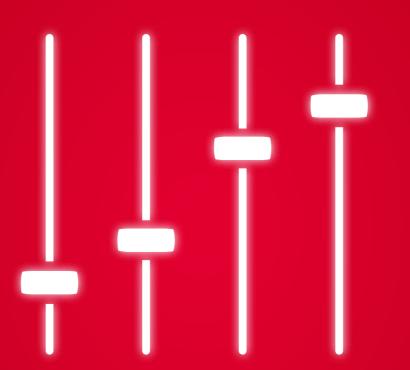
# PETER LLEWELLYN-DAVIES Chief Financial Officer

Peter Llewellyn-Davies was appointed as Chief Financial Officer and Member of the Executive Board of Medigene AG with effect from 1 October 2012. He has over 25 years of experience in senior positions in medium-sized companies in the commercial as well as the financial sector, most recently from 2006 to 2012 as Chief Financial Officer and Member of the Executive Board of WILEX AG, Munich. Prior to this, he was Managing Director of Müller Dairy (UK) and Executive Finance Director at Süd-Chemie AG. Mr. Llewellyn-Davies read business management, banking, marketing and controlling in London, St. Gallen and Munich, and has a certificate in business studies from the University of London.



# MARKETING **VOLUME INCREASED**

Medigene is the first biotech company in Germany which has developed a marketed drug. Veregen® is currently available in pharmacies in Germany, Austria, Switzerland and Spain, as well as the USA. A world-wide market reach for the product is targeted. Further prerequisites to achieve this were already fulfilled in 2012: Veregen® was granted market approval in a number of European countries, including France, the Nordic countries and growth markets in Eastern Europe. In most of these countries Veregen® will be introduced on the market in 2013. Medigene has also been working on its distribution networks outside Europe, concluding a number of additional marketing partnerships. In collaboration with these partners, preparations for approval processes are being made in many new markets to ensure that the successful expansion of Veregen® continues and the market volume is increased further in future.



# PIPELINE **PROJECTS ADJUSTED**

Innovative drug development requires creativity, endurance and the ability to rapidly adapt to changes. If a medical innovation is successful, then the benefits for patients and the company are considerable. In 2012, Medigene made good progress with its projects. For drug candidate EndoTAG°-1, Medigene found a co-development and commercialization partner for Asia and an IIT (investigator initiated trial) for one further type of breast cancer was completed. Medigene has revised the clinical development plan for RhuDex°, which should increase the informative value of the trial data collected and facilitate the future approval of RhuDex° for PBC. In early-stage research, the Company presented positive preclinical data for the AAVLP project. Ensuring a well balanced pipeline will continue to be the focus in the next fiscal year. Medigene will seek further partners in order to be able to advance drugs from bench to market.



# FINANCIALS CONTINUED IMPROVEMENT

Applying resources responsibly and at the same time investing in the future is both the aim and challenge for Medigene. In 2012, the Company was able to considerably improve both revenue and EBITDA from continued operations as well as raise cash reserves. The 35% increase in revenue to  $\leqslant$ 6 million was above all generated by income from Veregen°. At the same time, Medigene reduced the EBITDA-based loss from continued operations by 14% to  $\leqslant$ -9 million. Overall, Medigene reported EBITDA of  $\leqslant$ -4 million and therefore met and exceeded the Company's guidance. The transfer of Eligard° rights helped considerably improve cash reserves to total  $\leqslant$ 20 million at the end of 2012. Medigene therefore started fiscal year 2013 in a well-financed position and is working towards continuing the positive trend of rising income.

## **VEREGEN®**

PRODUCT	INDICATION	PRE-CLINIC	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	APPROVAL	MARKET
Veregen <sup>®</sup>	Genital warts						
Chance of reaching the marks	rt¹)	< 10 %	< 15 %	< 30 %	< 70 %	< 90 %	

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

#### About Veregen®

Veregen\* is an ointment for the treatment of genital warts. In the USA, Germany, Austria Spain and Switzerland, Veregen\* is already marketed by Medigene's partners. Veregen\* has been granted market approval for a number of other countries <u>see page 21</u>. 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 21 et seq</u>. The sales generated by Veregen\* are continually rising and make an important contribution to financing the Company.

The first in class topical drug for the treatment of genital warts, Veregen\* is based on a defined extract from green tea leaves produced in a highly complex and specifically developed process.

Medigene in-licensed the basic rights to the active ingredient of Veregen® in 1999 and then completed the clinical development of Veregen®. Subsequently, Medigene successfully obtained a marketing authorization by the approval process of the US Food and Drug Administration (FDA). Veregen® is the first, and to date one of a very small number of innovative plant-based drug approved by the FDA. Furthermore, Medigene is the first German biotech company to have a drug on the US market.

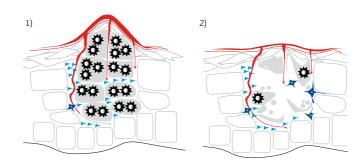
In the European Union, market approval for Belgium, Bulgaria, Cyprus, Denmark, Finland, France, Hungary, Luxembourg, the Netherlands, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden was granted in 2012. Market approval was granted for the Czech Republic early 2013 and is expected for Greece within the next few months. Outside the EU, Veregen\* was approved in Switzerland, Serbia and Israel. In addition, market authorization applications were filed by partner companies in Mexico, Taiwan and Canada and are currently being evaluated by the respective regulatory authorities.

Veregen® is also listed in recognized treatment guidelines. The US Center for Disease Control and Prevention In its current treatment guidelines for sexually transmitted diseases, recommends Sinecatechins 15% ointment (Veregen®) as a possible option for treating genital warts. In addition, the "2012 European Guideline for the Management of Anogenital Warts" includes Sinecatechins 10% & 15% ointment (Veregen®) as a recommended treatment option for genital warts.

#### Outlook

In 2013, the market launch of Veregen\*, as well as the conclusion of further marketing partnerships are planned in a number of other countries.

#### CHANGES IN A WART INDUCED BY VEREGEN®



- HPV infection of skin cells induces warts formation
- Veregen\* penetrates the skin, acts directly acts on infected cells and unfolds its presumed immune-modulatory and antiviral effect
- Messengers (cytokines, interferons) are released
- Cells of the immune system invade and destroy infected cells

# **ENDOTAG®-1**

PRODUCT	INDICATION	PRE-CLINIC	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	APPROVAL	MARKET
EndoTAG*-1	Pancreatic cancer						
	Triple-negative breast cancer						
Chance of reaching th	ne market¹¹	< 10 %	< 15 %	< 30 %	< 70 %	< 90 %	

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

#### About EndoTAG®-1

The clinical drug candidate EndoTAG\*-1 is an innovative composition of the established cytostatic drug paclitaxel combined with neutral and positive lipids. Due to the positively charged lipids, EndoTAG\*-1 interacts with newly developing, negatively charged endothelial cells, which are especially required for the growth of tumor blood vessels. The EndoTAG\*-1 paclitaxel component attacks the activated endothelial cells as they divide, thus targeting the blood supply to tumors without affecting the supply to not activated endothelial cells of healthy tissue. By doing this, EndoTAG\*-1 is expected to prevent the formation of new tumor blood vessels and to inhibit tumor growth.

Medigene presumes that the genetic stability of endothelial cells as compared to tumor cells will permit the use of EndoTAG\*-1 in the targeted treatment of those tumors that have already developed a resistance to conventional paclitaxel therapy.

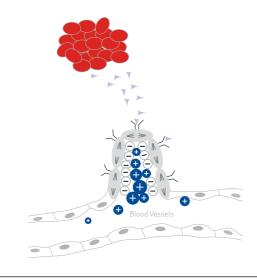
Medigene has successfully demonstrated clinical efficacy of EndoTAG®-1 in two clinical trials. A controlled phase II clinical trial in pancreatic cancer showed significantly increased survival rates for those patients treated with combination of EndoTAG®-1 and gemcitabine. A phase II clinical trial in triple negative breast cancer (TNBC) also showed a positive efficacy trend for EndoTAG®-1 combination therapy.

In 2012, the principal investigator of the TNBC trial, Prof. Dr. Ahmad Awada from the Institut Jules Bordet in Brussels, Belgium, successfully conducted an exploratory IIT (investigator initiated trial) in early stage HER2-negative breast cancer patients in a neoadjuvant setting, which is an additional potential indication for EndoTAG\*-1. In July 2012, Medigene entered into a partnership with the Taiwanese company SynCore Biotechnology for the co-development and commercialization of EndoTAG\*-1 in Asia. Australia and New Zealand.

#### Outlook

The final data of the IIT are expected in the first half of 2013 and are targeted to be presented at a scientific conference in the course of the year. Medigene plans to conduct a phase III trial of EndoTAG\*-1 in breast cancer. SynCore will fund a major part of the trial. Medigene is seeking further partners for the full funding of the phase III trial.

#### **ENDOTAG°-1 ATTACKING TUMOR-ACTIVATED ENDOTHELIAL CELLS**



- Tumor cells
- Tumor releases signals inducing growth of blood vessels
- Endothelial cells divide, blood vessels grow towards tumor
- EndoTAG\*-1 attacks tumor-activated dividing endothelial cells and prevents formation
  of additional blood vessels. In this way, blood supply to the tumor is interrupted.

# **RHUDEX®**

PRODUCT	INDICATION	PRE-CLINIC	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	APPROVAL	MARKET
Rhudex®	Autoimmune diseases						
Chance of reaching the marke	t <sup>1)</sup>	< 10 %	< 15 %	< 30 %	< 70 %	< 90 %	

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

#### About RhuDex®

RhuDex\* is being developed by Medigene as a first in class modifying agent for the oral treatment of autoimmune diseases.

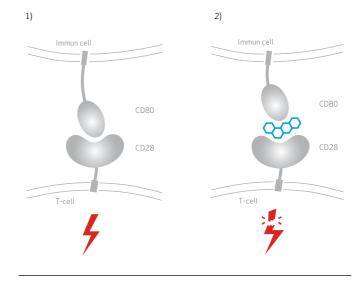
Autoimmune diseases are characterized by the inappropriate activation of immune reactions, as well as T-cell activationand proliferation. T-cell mediated release of inflammatory mediators is also known to play a major role in these diseases. Pivotal in this process is the interaction of the CD28 protein receptor on the surface of T-cells with the CD80 protein on the surface of other immune cells. RhuDex\* has the ability to bind to CD80, thus preventing interaction with CD28. By doing so, an important signaling pathway of T-cell activation is interrupted.

The safety and tolerability of RhuDex\* has been demonstrated in a number of clinical trials. In 2012, Medigene achieved positive results with a clinical formulation trial and worked out a concept for the further clinical development of RhuDex\* for treating autoimmune diseases.

#### Outlook

Medigene plans to initiate a phase II clinical trial with RhuDex\* in autoimmune diseases in primary biliary cirrhosis (PBC) to verify the clinical relevance of RhuDex\*'s mode of action. Subject to the successful conclusion of required preparatory work and approval by the appropriate authorities, the trial is scheduled to start by the first half of 2014.

#### RHUDEX® INHIBITS AUTOIMMUNE-MEDIATED INFLAMMATION



 $T-cell\ activation\ by\ certain\ immune\ cells\ is\ an\ important\ process\ in\ the\ onset\ of\ tissue\ destruction\ in\ autoimmune\ diseases.$ 

- $1)\,\hbox{T-cell activation requires interaction between the surface proteins CD80 and CD28}$
- 2) RhuDex\* 😙 prevents the interaction between CD80 and CD28, therefore acting as an anti-inflammatory agent

## **AAVLP**

PRODUCT	INDICATION	PRE-CLINIC	CLINICAL PHASE I	CLINICAL PHASE II	CLINICAL PHASE III	APPROVAL	MARKET
AAVLP	Vaccine candidates						
Chance of reaching the marke	t <sup>1)</sup>	< 10 %	< 15 %	< 30 %	< 70 %	< 90 %	

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

#### About AAVLP

Adeno-associated virus-like particles (AAVLP) offer potential as prophylactic and therapeutic vaccines, for example against cancer and infections. 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 any 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 new types of 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.

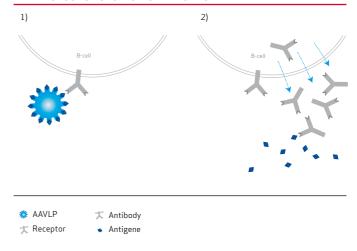
Medigene is currently conducting research into the application of AAVLP technology for the treatment of cancer and viral infections, and is examining the possibility of using AAV libraries to systematically identify suitable vaccine candidates. The key benefit of this innovative technology is the possibility of transferring the mode of action of existing therapeutic antibodies directly into a vaccine.

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. In nonclinical studies, AAVLP-based vaccines candidates have shown promising data. In 2012, Medigene presented positive nonclinical data generated during a collaboration with renowned researchers of The Johns Hopkins University School of Medicine. USA.

#### Outlook

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

# ANTIGENES ON THE AAVLP SURFACE TRIGGER THE PRODUCTION OF SPECIFIC ANTIBODIES



- 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

## THE SHARE

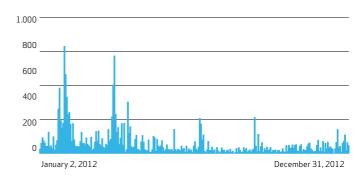
#### SHARE PRICE PERFORMANCE IN THE PERIOD JANUARY TO DECEMBER 2012

(INDEX OPENING PRICE JANUARY 2, 2012, €0.95 INDEXED TO 100)

# 160 140 120 100 80 January 2, 2012 December 31, 2012

#### **MARKET VOLUME**

IN THOUSAND



#### Share price

Medigene shares started trading below €1 in the new stock exchange year, with an opening price of €0.95 on January 2, 2012. In the first half of 2012, the share price developed positively and clearly outperformed the market as a whole. The peak in the first quarter with high trading volumes was associated with the Company's announcement to resume the clinical development of RhuDex® following the launch of a clinical formulation trial. Publication of the annual results for 2011 marked the start of a high price phase for Medigene shares, which ultimately peaked at €1.57 in mid-April. In a positive market environment, the share price remained at a high level on average over the second quarter. Following the announcement of the monetization of its royalty share from Eligard® in June 2012, the share price dropped to €1.09. The European debt crisis and economic problems in the USA shaped a difficult market and consequently the share price remained at a level of just above €1 in May and June. When the Company announced a co-development and commercialization partnership with SynCore for EndoTAG®-1 in July 2012, the share price climbed back up to €1.38 with high trading volumes. Despite a steady news flow of further market authorizations for Veregen® in Europe and the launch in the Swiss market, the share price steadily dropped in the second half of the year. In contrast to a generally improving market climate, the share price still did not improve significantly in

the final quarter of 2012, fluctuating between €1.00 and €1.10. Share price closed at €1.00 on the last trading day (December 28, 2012), which was 5% higher than the year's opening price.

#### Liquidity

The average daily trading volume totaled approximately 61,278 shares in the fiscal year. The highest daily turnover was at the start of the year, with 642,139 shares traded on January 30, 2012. A further peak was recorded on March 27, 2012, when 585,107 shares were traded. This correlated with the announcement of a positive annual result for 2011.

#### Positive analyst coverage

Medigene is monitored by analysts from renowned investment banks in Germany and abroad. The company, as well as its products and drug candidates, have been analyzed in detailed reports. At year-end 2012, three out of four analysts issued a buy recommendation for Medigene shares.

#### Investor relations work

In 2012, Medigene continued its 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

MEDIGENE AG ANNUAL REPORT 2012 THE SHARE 17

#### OWNERSHIP INFORMATION BY COUNTRY

2.8 Benelux USA 0.2

3.8 Austria Others 2.5

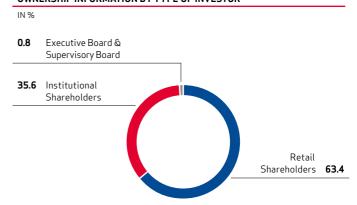
4.5 Switzerland

7.0 UK

Germany 79.2

As at December 31, 2012, figures rounded, data based on Medigene AG assessment

#### OWNERSHIP INFORMATION BY TYPE OF INVESTOR



As at December 31, 2012, figures rounded, data based on Medigene AG assessment

#### MEDIGENE ATTENDED THE FOLLOWING INVESTOR CONFERENCES IN 2012

J.P. Morgan Annual Healthcare Conference	San Francisco
BIO CEO & Investor Conference	New York
BioEquity Europe	Paris
BIO Conference	Boston
German Equity Forum	Frankfurt

#### ANALYSTS' ASSESSMENTS OF MEDIGENE SHARES

Buy	3
Neutral	1
Reduce	0

As at December 2012, basis: 4 analysts' studies

#### IN 2012, THE FOLLOWING INVESTMENT BANKS REPORTED ON MEDIGENE

Close Brothers Seydler Research AG	Igor Kim
DZ Bank AG	Dr. Elmar Kraus
Edison Investment Research Limited	Christian Glennie
Nomura Code Securities Ltd.	Samir Devani
WestLB AG*	Dr. Cornelia Thomas, Mark Belsey

<sup>\*</sup> WestLB discontinued its coverage at the end of June 2012 due to the bank's liquidation.

and analysts' conferences, Medigene gave interviews to the relevant finance media and had discussions with investors in Germany and abroad. Company presentations at investor conferences underlined Medigene's presence on the international capital markets.

#### International awards for the Annual Report

In 2012, Medigene once again won prestigious awards at the biggest international annual report competition: at the Vision Awards of the League of American Communications Professionals (LACP) in the USA, Medigene's Annual Report 2011 received the Gold Award in the biotechnology category and was named one of the Top 50 German Annual Reports. With these awards, Medigene was once again honored for its professional and transparent reporting to shareholders and the public.

#### Ownership development

At year-end 2012, approximately 63% of the shares issued were held by private investors (2011: 64%) and around 36% by institutional investors (2011: 35%). Directors' holdings remained unchanged at 1% in 2012. The majority of shares are held by investors in Germany (79%; 2011: 77%). 7% of the shares were held in the UK and 4% of the shares were held in Austria and Switzerland respectively. Investors in the Benelux countries held 3% of the shares.

#### SHARE DATA

MDG
502090
DE0005020903
1107 3026
993 906 FV5
MDGGn
MDG
Prime Standard
Prime All Share, DAXSubsector Biotechnology
XETRA, Berlin, Bremen, Dusseldorf, Frankfurt, Hamburg, Hanover, Munich, Stuttgart
DZ Bank AG, Close Brothers Seydler Research AG

#### KEY FIGURES OF THE MEDIGENE SHARE

IN€	2012	2011
52-week high	1.57	2.71
52-week low	0.95	0.86
Opening price	0.95	1.99
Year-end closing price	1.00	0.97
Average price since beginning of year	1.18	1.58
Weighted average number of shares (basic, in shares)	37,082,758	37,082,758
Average daily trading volume (in shares)	61,278	142,220
Average market capitalization (in € million)	44	59
Total number of shares outstanding (Dec. 31)	37,082,758	37,082,758
Earnings per share 1) (basic)	-0.27	0.17
Dividend per share <sup>1)</sup>	1.19	1.29
Cash flow per share from operating activities 1)	-0.18	0.19
Freefloat <sup>2)</sup> (in %)	94	94

<sup>1)</sup> Reference amount: Total number of outstanding shares

<sup>&</sup>lt;sup>2)</sup> Sources: Medigene AG, Thomson Reuters

# **CONTENT**

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

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, AS OF DECEMBER 31, 2012

- > Total revenue from continued operations: €6.3 million (2011: €4.7 million)
- > Total revenue from continued and discontinued operations: €11.3 million (2011: €32.5 million)
- > EBITDA from continued operations: €-9.4 million (2011: €-11.0 million)
- > EBITDA total: €-4.4 million (2011: €11.2 million)
- > Net loss for the year: €-9.9 million (2011: €6.3 million)
- → Average monthly operating cash flow: €-0.5 million (2011: €0.6 million), adjusted by one-time effect: €-1.0 million (2011: €-0.8 million)

#### **KEY EVENTS IN 2012**

#### Eligard®:

- → Final milestone payment of €5 million received from Astellas
- → Agreement with Cowen for the transfer of a 2% royalty share

#### Veregen®:

- → Market launch in Spain and Switzerland
- → Market approval in 17 European countries and Israel
- → Partnership agreements for the marketing of Veregen® in Turkey, the Nordic countries as well as Eastern Europe, Russia and the other CIS countries

#### EndoTAG®-1:

- → Development and marketing partnership agreement for Asia concluded with SynCore
- → US patent obtained for the use of EndoTAG\*-1 in combination with taxanes to treat triple-negative breast cancer (TNBC)
- → Investigator Initiated Trial (IIT) in additional breast cancer indication conducted by Prof. Awada from the Jules-Bordet Institute

#### RhuDex®:

- → Clinical formulation trial for optimizing the pharmacokinetic profile of RhuDex® successfully completed
- → Further clinical development plan published: phase II trial in PBC (primary biliary cirrhosis) planned

#### AAVLP:

→ Positive preclinical data presented at the World Vaccine Congress in the USA

#### Change in the Executive Board:

→ Peter Llewellyn-Davies joined the Executive Board of Medigene AG on October 1, 2012

#### **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 and that has one drug on the market.

#### Organizational and legal structure of the Group

Medigene AG was founded in 1994 in Planegg/Martinsried near Munich, Germany. In 1996, the Company was converted into a joint stock corporation. The Company's headquarters are located at Lochhamer Strasse 11, 82152 Planegg/Martinsried, Germany. The Company is registered in the Commercial Register of the Munich Local Court under HRB 115761. Medigene AG has been listed since June 2000 (Deutsche Börse, Regulated Market, Prime Standard, SIN 502090, code MDG).

In addition to the parent company Medigene AG in Planegg/Martinsried, Germany, the Medigene Group (hereinafter referred to as »Medigene«) includes the wholly owned subsidiary Medigene, Inc., San Diego, California, USA, which was acquired in 2001. The former subsidiary Medigene Ltd., Abingdon, Oxfordshire, United Kingdom, was wound up and deconsolidated in 2012, 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 17.45% as of December 31, 2012 were transferred to Medigene AG as part of the winding up process of Medigene Ltd. The subsidiary Medigene, Inc. holds 41.89% of the shares in Catherex, Inc., Philadelphia, Pennsylvania, USA. Medigene is managed by the Executive Board of the parent company, Medigene AG. The subsidiary's management 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 the Chief Executive Officer Dr. Frank Mathias and the Chief Financial Officer Peter Llewellyn-Davies.

#### Products and commercialization

In 2012, Medigene generated revenue from two drugs that are already marketed: Eligard\* for the treatment of prostate cancer and Veregen\* for the treatment of genital warts. Veregen\* is marketed by various partners. In June 2012 and with effect from April 1, 2012, the royalty share of Eligard\* was transferred to US investor Cowen Healthcare Royalty Partners II, L.P. USA (hereinafter referred to as \*Cowen\*).

Medigene 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. For RhuDex\*, which is used to treat autoimmune diseases, Medigene is preparing a clinical phase II

trial in the indication primary biliary cirrhosis (PBC). Medigene's AAVLP technology for the identification and development of potential vaccine candidates is in the research stage.

# Status of the product portfolio and research and development activities

#### **Eligard®**

Eligard\*, a drug developed to treat hormone-dependent prostate cancer, is marketed in most European countries by Astellas Pharma Europe Ltd., Chertsey, UK (hereinafter referred to as »Astellas«). Medigene licensed the European rights in 2001 and transferred them to Astellas in 2011. Since then, Medigene has received a 2% royalty share from Eligard\* net sales. With effect from April 1, 2012, Medigene transferred this royalty share to Cowen in return for payment of €14.1 million (US\$17.68 million). The related proceeds from Eligard\* are realized pro rata over the Eligard\* patent term of approx. ten years and used for the amortization of the related financial liability. The transaction has considerably strengthened Medigene's financial position.

#### Veregen®

Veregen\*, a drug used to treat genital warts, was developed by Medigene AG. It is currently available in the US, German and Austrian markets as well as in Spain (since June 2012) and Switzerland (since October 2012). In addition, Veregen\* is approved for marketing in the following countries: Poland, Sweden and Norway (since April 2012), Serbia (since May 2012), France, Denmark, Slovakia and Israel (since July 2012) as well as Finland, the Netherlands, Belgium, Hungary, Slovenia, Romania, Bulgaria, Cyprus and Luxembourg (August to November 2012), as well as in the Czech Republic (early 2013).

In the USA, Veregen\* is marketed by Fougera Pharmaceuticals, Inc., Melville, NY, USA (hereinafter referred to as »Fougera«), while the drug is marketed by regional sales companies of the Abbott Group in Germany, Austria and Switzerland. In Spain, Veregen\* is marketed by pharmaceutical company Bial Industrial Farmaceutica, S.A. (formerly Juste S.A.Q.F.), which also owns the marketing rights for Portugal. Additional partnership agreements are in place for France (Laboratoires Expanscience), the Benelux countries (L.F. Will-Pharma & Cie), Greece, Cyprus, Romania and Bulgaria (Meditrina Pharmaceuticals, Ltd.), Serbia, Bosnia & Herzegovina, Montenegro, Macedonia, Croatia, Slovenia and Albania (Pharmanova d.o.o.), Israel (Teva Pharmaceutical

Industries Ltd.), Canada (Triton Pharma), Mexico, Central America, Venezuela and Colombia (Pierre Fabre Medicament SAS), China (GC-RISE Pharmaceutical Ltd.), Taiwan (SynCore Biotechnology Co., Ltd.) and South Korea (Kolon Pharmaceuticals Inc.). In 2012, Medigene also signed partnership agreements for marketing Veregen\* in Turkey (EIP Eczacibasi Ilac Pazarlama A.S.), the Nordic countries including Denmark, Sweden, Norway, Finland and Iceland (Azanta A/S) as well as Eastern Europe, Russia and the other CIS countries (Nordic Pharma). Medigene receives successive single payments from these partners depending on the achievement of specific milestones and also has a share in Veregen\* revenue. Medigene earns further revenue from selling the active pharmaceutical ingredient and finished product to the sales partners.

Veregen\* is an innovative drug formulation based on a defined extract from green tea leaves, which is obtained in a complex and specifically developed production process. In its current treatment guidelines for sexually transmitted diseases, the US Center for Disease Control and Prevention recommends Sinecatechins 15% ointment (Veregen\*) as a possible option for treating genital warts. In addition, the »2012 European Guideline for the Management of Anogenital Warts« includes Sinecatechins 10% & 15% ointment (Veregen\*) as a recommended treatment option for genital warts.

#### EndoTAG°-1

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

Medigene has successfully completed two clinical phase II trials of EndoTAG\*-1 in the indications pancreatic cancer and triple-negative breast cancer (TNBC). In 2012, the principal investigator of the TNBC trial, Prof. Dr. Ahmad Awada from the Jules Bordet Institute in Brussels, Belgium, successfully conducted an exploratory IIT (investigator initiated trial) for early stage HER2-negative breast cancer in a neoadjuvant setting. The final results are expected in the first half of 2013.

In May 2012, Medigene was granted a US patent which protects the use of EndoTAG\*-1 in combination with taxanes to treat TNBC. The patent term runs until 2029.

In July 2012, Medigene signed a development and marketing partner-ship agreement for EndoTAG\*-1 with SynCore Biotechnology Co., Ltd. (hereinafter referred to as »SynCore«), a member of the Sinphar Pharmaceutical Group. Medigene granted an exclusive license to SynCore for the joint development as well as marketing EndoTAG\*-1 in Asia, Australia and New Zealand. In return, Medigene received an advance payment and is entitled to further payments from SynCore when specific development and approval milestones are achieved as well as royalties. SynCore has additionally undertaken to finance the Asian part of a global phase III trial, which is expected to comprise around 50% of all patients to be included in the trial.

#### RhuDex®

RhuDex\* is being developed by Medigene as an oral, disease modifying agent to treat autoimmune diseases. It is a CD8o antagonist that blocks undesired T-cell activation and production and thus has an immunomodulating and anti-inflammatory effect. This drug candidate can be classified with the group of Disease-Modifying Antirheumatic Drugs (DMARDs). Medigene has successfully completed a pilot phase lla trial in the indication rheumatoid arthritis.

In the first half of 2012, Medigene conducted a clinical formulation trial to develop an optimized oral formulation of RhuDex\* for the treatment of chronic diseases. In this trial, the formulation developed showed an optimized pharmacokinetic profile, excellent tolerability and reduced dosage units compared to previous formulations investigated. Medigene is currently preparing for a clinical phase II trial with RhuDex\* in the autoimmune disease primary biliary cirrhosis (PBC).

#### **AAVLP** technology

Within the AAVLP program, Medigene is developing an innovative technology platform for producing prophylactic and therapeutic vaccines designed to permanently protect against infectious diseases. For this purpose, virus-like particles derived from adeno-associated viruses (AAVLP) are employed in the development of innovative vaccines. Medigene is currently conducting research into the use of the AAVLP technology to treat infectious diseases and cancer, and into the suitability of AAV libraries to identify suitable novel vaccine candidates systematically. At the 2012 World Vaccine Congress in Washington, USA, Medigene presented positive preclinical data generated during collaboration with renowned researchers of The Johns Hopkins University School of Medicine, USA.

#### **GENERAL CONDITIONS**

#### **Procurement**

As part of its business activities, Medigene AG is responsible for the procurement of supplies for the marketed drug Veregen\* 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

Medigene has a contract with Mitsui Norin Co., Ltd., Tokyo, Japan (hereinafter referred to as »Mitsui Norin«), for the production and supply of the active pharmaceutical ingredient for Veregen\*. The formulation of the ointment is carried out by a contract manufacturer in Germany by order of Fougera for the US market and 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 and flexibility.

#### 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 as well as other expenses e.g. in 2012 from the deconsolidation of Medigene Ltd.

#### PERFORMANCE INDICATORS

		2012	2011
Gross margin as a share of total revenue from continued and discontinued operations	Gross profit x 100 Total revenue	89%	81%
EBITDA total		€-4,409 thousand	€11,180 thousand

#### ASSET AND FINANCE INDICATORS

		2012	2011
Liquidity cover ratio	<u>Cash x 100</u> Balance sheet total	33%	24%
Equity ratio	<u>Equity x 100</u> Balance sheet total	72%	90%

#### 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)	3	14
USA	4	26

#### ANHÄNGIGE PATENTANMELDUNGEN

	MARKETED PRODUCTS	DRUG CANDIDATES
Europe (Germany)	3	17
USA	2	17
International (PCT)	2	25

# Consistent patent strategy provides the basis for commercial success

The Company aims to obtain patent protection for its proprietary products, processes and technologies. In line with the strategy of obtaining patents for technologies and products in development, Medigene has submitted numerous 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 2012, Medigene increased total revenue by 35% to  $\epsilon$ 6,284 thousand (2011:  $\epsilon$ 4,656 thousand) and achieved revenue from discontinued operations totaling  $\epsilon$ 5,032 thousand (2011:  $\epsilon$ 27,828 thousand).

Revenue from continued operations was generated from the commercialization of Veregen\* in the USA, Germany, Austria, Switzerland and Spain amounting to  $\epsilon$ 2,774 thousand (2011:  $\epsilon$ 2,050 thousand), as well as from milestone payments for Veregen\* of  $\epsilon$ 610 thousand (2011:  $\epsilon$ 250 thousand). Other operating income amounted to  $\epsilon$ 2,900 thousand (2011:  $\epsilon$ 2,356 thousand). This income essentially comprises the 2% royalty share from Eligard\* net sales from Astellas totaling  $\epsilon$ 613 thousand for the first quarter of 2012 and since April 1, 2012, from the transfer of the future cash flows from this revenue share to Cowen, which amounts to  $\epsilon$ 208 thousand per month. This revenue is a non-cash item and will be recognized as income pro rata over the term of the patent of approx. ten years. The related financial liability will be amortized, taking into account the non-cash interest expense. In the first quarter of 2012, Medigene additionally received a compensation payment from a service provider for costs incurred amounting to  $\epsilon$ 300 thousand.

Revenue from discontinued operations mainly comprised the final milestone payment of €5,000 thousand (2011: €20,000 thousand) for the sale of the Eligard\* rights to Astellas. In the previous year's period, alongside the milestone payments received, the Eligard\* product sales achieved and license payments received up to the end of February 2011 were also reported under this item.

25

Revenue distribution is presented in the → Notes to the consolidated financial statements D) note (27) on page 67.

#### CONSOLIDATED INCOME STATEMENT (ABBREVIATED)

(1.551.511.511.511.511.511.511.511.511.5			
2012	2011	CHANGE	
6,284	4,656	35%	
3,387	2,305	47%	
-1,250	-953	31%	
5,034	3,703	36%	
-7,909	-8,103	-2%	
-7,399	-11,254	-34%	
-6,166	0	-	
-16,440	-15,654	5%	
-14,795	-15,474	-4%	
-82	1,241	-	
-14,877	-14,233	5%	
5,032	27,828	-82%	
5,018	20,514	-76%	
-9,859	6,281	-	
	6,284 3,387 -1,250 5,034 -7,909 -7,399 -6,166 -16,440 -14,795 -82 -14,877 5,032 5,018	6,284 4,656 3,387 2,305 -1,250 -953 5,034 3,703 -7,909 -8,103 -7,399 -11,254 -6,166 0 -16,440 -15,654 -14,795 -15,474 -82 1,241 -14,877 -14,233 5,032 27,828 5,018 20,514	

#### Cost of sales

The cost of sales from continued operations amounted to €1,250 thousand in the reporting year compared with €953 thousand in the previous year. In the previous year, cost of sales were also incurred from discontinued operations for the commercialization of the drug Eligard®, which amounted to €5,326 thousand.

#### **Gross profit**

Gross profit from continued operations totaled €5,034 thousand in 2012 (2011: €3,703 thousand) and gross profit from discontinued operations totaled €5,032 thousand (2011: €22,502 thousand). The gross margin achieved from the drug Veregen® depends 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 €8,103 thousand (2011) to €7,909 thousand (2012). This amount consists of €2,271 thousand (2011: €2,272 thousand) in selling expenses and €5,638 thousand (2011: €5,831 thousand) in general administrative expenses. Selling expenses from discontinued operations totaled €14 thousand in the reporting period (2011: €343 thousand).

#### Research & development expenses

Total expenses for research and development (R&D) were down 34% to €7,399 thousand (2011: €11,254 thousand). A large part of the cost for research and development consisted of expenses for clinical and preclinical development as well as regulatory expenses and consultancy fees. At the same time, personnel expenses and rent were down. In the previous year's period, the write-down of an early-stage research project which Medigene no longer pursued, amounting to €3,827 thousand, was posted as an expense. The composition of research and development expenses can be found in the  $\rightarrow$  Notes to the consolidated financial statements D) note (31) on page 68.

#### Other expenses

Other expenses of €6,166 thousand were incurred in connection with the deconsolidation of Medigene Ltd. As part of this, other reserves included under shareholders' equity were largely written back → see Notes to the consolidated financial statements E) note (52) on page 77. Although this posting with no effect on shareholders' equity is reported in the income statement, it is a non-cash item and has no impact on EBITDA  $\rightarrow$  as defined by Medigene, see below and p. 23.

#### **EBITDA**

Medigene AG's EBITDA is derived from net profit/loss for the year excluding taxes, the financial result, depreciation, amortization and impairment as well as other expenses e.g. in 2012 from the deconsolidation of Medigene Ltd. In 2012, Medigene's loss based on EBITDA amounted to €-4,409 thousand (2011: EBITDA profit of €11,180 thousand). The loss from continued operations amounted to €-9,427 thousand in the reporting period ended (2011: €-10,979 thousand).

-12,756

# EBITDA IN € THOUSAND 11,180 2010 2012 2011 -4,409

#### EBITDA

IN € THOUSAND	2012	2011	CHANGE
INETHOUSAND	2012	2011	CHANGE
Net result for the year	-9,859	6,281	-
Taxes	82	630	-87%
Financial result	516	586	-12%
Share of result of associates	59	-766	-
Income from revaluation of investment	-2,220	0	-
Derivative financial instrument	0	-226	-
Depreciation and amortization	847	4,675	-82%
Other expenses (deconsolidation)	6,166	0	-
Total	-4,409	11,180	-
From continued operations	-9,427	-10,979	-14%

#### Depreciation and amortization

In total, depreciation and amortization decreased from  $\epsilon$ 4,675 thousand (2011) to  $\epsilon$ 847 thousand (2012). Scheduled amortization relates to intangible assets, including patents and product licenses. Scheduled depreciation relates to property, plant and equipment. During the previous year's period, a project at the early research stage which Medigene is no longer pursuing was written down in full and derecognized ( $\epsilon$ 3,827 thousand).

#### Financial result

The financial result, consisting mainly of net interest income and foreign exchange gains/losses, amounted to  $\epsilon$ -516 thousand in the reporting period (2011:  $\epsilon$ -586 thousand). The financial result also

includes non-cash interest expense of €1,244 thousand from the financial liability to Cowen under the Eligard® transaction. In the previous year's reporting period, the financial result from discontinued operations comprised a gain from the financial derivative as per IAS 39 of €226 thousand, which related to the product Eligard®. Following the transfer of the Eligard® rights to Astellas, this derivative no longer exists.

#### Result of associates

The result from investments in associates amounted to  $\epsilon$ -59 thousand in 2012 (2011:  $\epsilon$ 766 thousand) and is related to the associate Catherex, Inc. As of December 31, 2012, the Group held 41.89% of the shares in Catherex. Inc.

#### Income from revaluation of investments

As a consequence of the reduction of the share in Immunocore Ltd. below 20%, this investment was reclassified in the balance sheet and, accordingly, a revaluation pursuant to IAS 28.18 at fair value. The revaluation associated with it resulted in a non-cash income of  $\epsilon_{2,220}$  thousand  $\Rightarrow$  see Notes to the consolidated financial statements E) note (44) on page 72.

#### Taxes

In the reporting period, a tax expense of  $\epsilon_{13}$  thousand was posted, which relates to the previous year. 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, a tax expense of  $\epsilon_{63}$ 0 thousand was posted. In addition, other taxes (withholding tax) of  $\epsilon_{69}$  thousand arose.

#### Net result for the year

In the reporting period, the net loss for the year amounted to  $\epsilon$ 9,859 thousand compared with a profit for the year of  $\epsilon$ 6,281 thousand in the previous year. The result for the year from continued operations totaled  $\epsilon$ -14,877 thousand (2011:  $\epsilon$ -14,233 thousand) and the result from discontinued operations  $\epsilon$ 5,018 thousand (2011:  $\epsilon$ 20,514 thousand).

#### Earnings per share

In 2012, the loss per share amounted to  $\epsilon$ 0.27 (basic weighted average number of shares: 37,082,758, diluted: 37,372,649) compared with earnings of  $\epsilon$ 0.17 in the previous year (basic weighted average number of shares: 37,082,758, diluted: 37,200,471). 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 Notes to the consolidated financial statements H) »Business units« on page 86 et seg. 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	2012	2011	CHANGE
Net cash			
from/used by operating activities	-6,507	6,864	-
from/used by investing activities	-255	1,423	-
from financing activities	14,094	0	-
Increase in cash and cash equivalents	7,332	8,287	-12%
Cash and cash equivalents at the beginning of the period	12,811	4,770	169%
Foreign exchange differences	-30	-246	-88%
Cash and cash equivalents at the end of the period	20,113	12,811	57%

#### Change in cash reserves

Net cash used by operating activities amounted to  $\epsilon$ -6,507 thousand in the reporting period (2011: net cash inflow of  $\epsilon$ 6,864 thousand) and comprised the final milestone payment of  $\epsilon$ 5 million (2011:  $\epsilon$ 15 million) from the sale of the Eligard\* rights to Astellas. Net of this non-recurring item, net cash used by operating activities amounted to  $\epsilon$ -11,507 thousand (2011:  $\epsilon$ -9,910 thousand). The major portion of net cash used related to expenses for research and development.

The net cash outflow for investing activities in 2012 totaled  $\epsilon$ -255 thousand (2011: net cash inflow of  $\epsilon$ 1,423 thousand). In the previous year, Medigene earned  $\epsilon$ 1,774 thousand from the sale of shares in Immunocore Ltd.

Investments in property, plant and equipment as well as software amounted to €270 thousand in the reporting period (2011: €406 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.

The net cash inflow from financing activities amounted to  $\epsilon$ 14,094 thousand in the reporting period (2011:  $\epsilon$ 0). This item comprises the payments received in respect of the financial liability to Cowen relating to the transfer of the 2% share of revenue from Eligard\* net sales.

In total, cash and cash equivalents were up by  $\[ \epsilon 7,332 \]$  thousand in the 2012 reporting year (2011:  $\[ \epsilon 8,287 \]$  thousand). The closing balance of cash and cash equivalents in the year under review was  $\[ \epsilon 20,113 \]$  thousand (2011:  $\[ \epsilon 12,811 \]$  thousand). The liquidity cover ratio, calculated as the proportion of cash and cash equivalents in total assets/liabilities, was 33% as of the reporting date (2011: 24%). There were no open credit lines.

#### Average monthly cash flow from operating activities

The consolidated statement of cash flows for 2012 shows an average monthly net cash burn rate for operating activities of  $\epsilon$ -542 thousand (2011: net cash inflow of  $\epsilon$ 572 thousand). Net of the above-mentioned non-recurring items, the monthly cash burn rate for 2012 was an average of  $\epsilon$ -959 thousand (2011:  $\epsilon$ -826 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 CAPITAL STRUCTURE AS OF DEC. 31

DEVELOPMENT OF ASSETS AND CAPITAL STRUCTURE AS OF DEC. 31			
IN € THOUSAND	2012	2011	CHANGE
Assets			
Property, plant and equipment and intangible assets	27,973	28,554	-2%
Goodwill	2,212	2,212	0%
Financial and other non-current assets	3,896	263	>200%
Investment in associates	2,727	4,183	-35%
Cash and cash equivalents	20,113	12,811	57%
Inventories and receivables	3,344	4,100	-18%
Other current assets	990	1,169	-15%
Total assets	61,255	53,292	15%
Liabilities and shareholders' equity			
Shareholders' equity	44,215	47,932	-8%
Non-current liabilities	12,723	536	>200%
Current liabilities	4,317	4,824	-11%
Total liabilities and shareholders' equity	61,255	53,292	15%
Liquidity cover ratio in %	33	24	
Equity ratio in %	72	90	

#### Assets

Compared with the previous year, total assets rose by 15% to €61,255 thousand (2011: €53,292 thousand). This increase was mainly due to the rise in cash and cash equivalents resulting from the transfer of the future cash flows from the 2% Eligard\* sales share to Cowen.

Property, plant and equipment and intangible assets decreased to €27,973 thousand in the reporting period (2011: €28,554 thousand). Property, plant and equipment accounted for €604 thousand (2011: €829 thousand). Intangible assets were down from €27,725 thousand to €27,369 thousand as a result of scheduled amortization. Goodwill remained unchanged on the previous year's figure and amounted to €2.212 thousand.

In the reporting period, the carrying amount of investments in associates fell from  $\epsilon_{4,1}83$  thousand (2011) to  $\epsilon_{2,727}$  thousand (2012) and related to associate Catherex, Inc. Following the issue of new Immunocore Ltd. shares, Medigene's shareholding in this company fell below 20%. In accordance with IAS 28.6, this investment is no longer valued according to the equity method but at fair value, pursuant to IAS 28.18 respectively IAS 39, and recognized as financial asset. This item rose to  $\epsilon_{3,895}$  thousand in the reporting period (2011:  $\epsilon_{2}62$  thousand). As of December 31, 2012, the Group held a share of  $\epsilon_{1,89}$  in Catherex, Inc.

#### **BALANCE SHEET STRUCTURE**

IN € THOUSAND



Accounts receivable as of the end of the reporting period amounted to €1,139 thousand (2011: €1,897 thousand). This amount essentially represents receivables from Fougera.

Inventories of Veregen\* totaled  $\epsilon_{2,205}$  thousand as of the reporting date (2011:  $\epsilon_{2,203}$  thousand).

Other current assets amounted to  $\epsilon$ 990 thousand (2011:  $\epsilon$ 1,169 thousand), of which  $\epsilon$ 592 thousand (2011:  $\epsilon$ 670 thousand) were expenses incurred for future periods. The remaining amount includes other current assets and rent deposits.

#### Liabilities and shareholders' equity

In the reporting period, shareholders' equity decreased to a total of €44,215 thousand (December 31, 2011: €47,932 thousand). The reduction was due to the net loss for 2012. As a result, the equity ratio was also down to 72% (December 31, 2011: 90%).

Current and non-current liabilities totaled  $\epsilon_{17}$ , 040 thousand as of the reporting date (2011:  $\epsilon_{5,3}$ 60 thousand). This constitutes 28% of total liabilities. Current liabilities mainly include trade payables amounting to  $\epsilon_{719}$  thousand (2011:  $\epsilon_{1,773}$  thousand), other liabilities totaling  $\epsilon_{2,8}$ 88 thousand (2011:  $\epsilon_{2,3}$ 44 thousand), which comprise the short-term share of the liability arising in connection with the transfer of the future cash flows from the 2% Eligard\* sales share to Cowen totaling  $\epsilon_{927}$  thousand, tax liabilities of  $\epsilon_{642}$  thousand (2011:  $\epsilon_{630}$ 0 thousand) and deferred income of  $\epsilon_{68}$ 0 thousand (2011:  $\epsilon_{77}$ 1 thousand). The liabilities arise from outstanding invoices and services utilized by Medigene. Non-current liabilities comprise the long-term share of the above-mentioned royalty share transferred to Cowen of  $\epsilon_{11,906}$ 0 thousand, other liabilities totaling  $\epsilon_{258}$ 1 thousand (2011:  $\epsilon_{255}$ 1 thousand), pension obligations amounting to  $\epsilon_{255}$ 1 thousand (2011:  $\epsilon_{255}$ 1 thousand) and deferred income of  $\epsilon_{304}$ 4 thousand (2011:  $\epsilon_{01}$ 201:  $\epsilon_{02}$ 3 thousand) and deferred income of  $\epsilon_{304}$ 4 thousand (2011:  $\epsilon_{01}$ 3 thousand) and deferred income of  $\epsilon_{304}$ 4 thousand (2011:  $\epsilon_{01}$ 3 thousand) and deferred income of  $\epsilon_{304}$ 4 thousand (2011:  $\epsilon_{01}$ 3 thousand) and deferred income of  $\epsilon_{304}$ 4 thousand (2011:  $\epsilon_{01}$ 3 thousand)

Working capital, the difference between current assets and current liabilities, was up from  $\epsilon_{13,256}$  thousand (2011) to  $\epsilon_{20,130}$  thousand (2012), primarily as a result of the rise in cash and cash equivalents.

#### Overall statement

In the 2012 fiscal year, Medigene achieved an increase in revenue from continued operations to  $\epsilon 6.3$  million and reported an EBITDA-based loss of  $\epsilon 4.4$  million. The Company therefore respectively achieved and exceeded the targets it published at the start of 2012 (revenue from continued operations in excess of  $\epsilon 5$  million and an EBITDA-based loss in the mid single-digit million range). Based on the upward trend in Veregen\* sales, the Company again has a positive outlook in 2013.

#### **EMPLOYEES**

#### Number of employees in the Group

As of December 31, 2012, the number of employees was 53 (2011: 52). The average number of employees (full-time equivalents) was down to 49 in 2012 (2011: 52). Personnel expenses fell by 5% in the reporting period to  $\epsilon$ 5,818 thousand (2011:  $\epsilon$ 6,145 thousand).

#### **EMPLOYEES BY REGION AS OF DEC. 31**

	2012	2011	CHANGE
Medigene AG, Planegg/Martinsried	50	49	2%
Medigene, Inc., San Diego	3	3	0%
Total	53	52	2%

#### **EMPLOYEES BY AREA OF ACTIVITY**

22 Selling

R&D 48

30 G&A

as of Dec. 31, 2012

# REMUNERATION OF THE EXECUTIVE BOARD AND SUPERVISORY BOARD

#### **Executive Board remuneration**

Remuneration of members of the Executive Board in the past fiscal year totaled  $\epsilon_1$ ,035 thousand (2011:  $\epsilon_944$  thousand), including pension expenses of  $\epsilon_{52}$  thousand (2011:  $\epsilon_48$  thousand) and vehicle leasing costs for company cars of  $\epsilon_{31}$  thousand (2011:  $\epsilon_{26}$  thousand). In addition, stock options with a fair value of  $\epsilon_{34}$  thousand (2011:  $\epsilon_{33}$  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  $\Rightarrow$  *Notes to the consolidated financial statements I*) note (67) page 89 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.

#### Supervisory Board remuneration

Supervisory Board remuneration amounted to €255 thousand in 2012 (2011: €229 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. The greater scope of activities of the Supervisory Board Chairman and his Deputy are taken into account and reflected accordingly by higher remuneration. The amount of remuneration paid to individual members of the Supervisory Board and disclosures regarding subscription rights of the members of the Supervisory and Executive Boards are provided in the → Notes to the consolidated financial statements I) notes (68). and (69), page 93 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 not all the financing required to develop product candidates can be raised, that the products cannot be manufactured in large quantities or marketed profitably, or that they are not sufficiently competitive. Furthermore, proprietary rights held by third parties may pose an obstacle to marketing a product, or other companies may launch drugs that are superior in terms of quality or market price.

#### Risks of unsuccessful drug development

Prior to commercial use, Medigene's drug candidates have to pass through the preclinical development stages, followed by the individual phases of clinical trials with human subjects. In these trials, the effectiveness of the drugs and side effects 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

For the reasons mentioned, there is a risk of Medigene not being granted market approval for its drug candidates. However, even if market approval is granted, such approval may be contingent on the fulfillment of certain obligations which may be detrimental to the marketability of the product or products. Obligations may consist of additional clinical trials or restrictions on the application of a product. Approval may, for instance, be granted only for a sub-group of patients. In addition, the holder of the approval must 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.

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.

Finally, there is the possibility of losing previously granted market approval for drugs in whole or in part if serious quality shortcomings or safety risks are subsequently ascertained. The risks mentioned may have a negative impact on the 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 Japanese company Mitsui Norin for the production and supply of the active pharmaceutical ingredient for Veregen\*. The raw material, which consists of green tea leaves, is obtained from Chinese tea 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. Companies may even be forced to reduce the price of a drug in order to be included in such a reimbursement system. This risk affects Medigene indirectly, since the drug Veregen\* is marketed by sales partners, and Medigene receives royalties on the drug sales.

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

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

#### Risks of dependence on future cooperation agreements

The Company uses the services of cooperation partners for marketing its products. These partners maintain their own sales and marketing organizations. Medigene also pursues cooperation with partner companies for developing drug candidates. 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 develop and 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 has reported operating losses in almost every fiscal year, as expenses for research and development in the relevant years exceeded the corresponding revenue or gross profit. The future achievement of profitability depends on progress in terms of operations as well as Medigene's strategic decisions and is not yet secured.

#### Planning risks

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

#### Financing risks

Medigene's present shareholders' equity and operating cash flow may possibly be insufficient to cover the expected investment expenses and working capital that will be required in the foreseeable future, covering 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 risk may threaten the existence of Medigene AG. However, on the basis of current liquidity planning, the company assumes that it will remain fully financed. Regarding the planned development in the coming fiscal years, we refer to the  $\Rightarrow$  financial forecast on page 41.

#### Accounting risks

As a company, Medigene is not yet profitable. In most of the past fiscal years, Medigene generated a negative result. In view of the extensive research and development expenses, these losses accumulate over time and produce a high amount of loss carried forward. Although based on the current level of shareholders' equity reported in the relevant annual financial statements prepared under the applicable provisions of German commercial law it is unlikely, a halving of share capital subject to disclosure cannot be ruled out. In accordance with Section 92 (I) of the German Stock Corporation Act (AktG), this requires the immediate convening of an extraordinary General Meeting. Medigene would incur organizational and financial expenses as a result of conducting such an extraordinary General Meeting, and this may impact negatively on the share price.

#### Foreign exchange risks

The Group's subsidiary in the US exposes it to certain exchange rate fluctuations in terms of the euro to US dollar exchange rate. 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® is transacted in US dollars. The active pharmaceutical ingredient for this drug is also purchased in US dollars, but is pegged to the yen. 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® 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

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 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 opponent filed a notice of appeal against the decision of the European Patent Office. A decision in this appeal procedure is not expected until 2014. Medigene continues to assume that the patent will be upheld with a scope that remains to protect the EndoTAG\*-1 product.

#### 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 subsidiary 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-theart. 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

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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, 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;
- $\Rightarrow$  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, Medigene'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 target-oriented coordination of planning, information supply, handling and monitoring. In order to identify any deviations, projects undergo a monthly targetperformance 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 essentially determined by the individual risks arising in clinical development and product marketing, as well as entering into

successful strategic partnerships with the pharmaceutical industry and corporate financing. The commercial success and future existence of the Company therefore depend primarily on successful drug development and 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 cover 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 diversified portfolio, which is safeguarded by means of far-reaching international patents that are either pending or have been granted. In addition, cooperation with external scientific institutes, universities and other companies provides access to state-of-the-art developments and technologies.

#### Business planning and forecasting

Medigene's management regularly prepares a detailed business plan, at least once a year, incorporating the results of portfolio management and evaluation. This plan contains numerous assumptions relating to issues such as project progress, the outcome of clinical trials, the conclusion of new 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 as of December 31.

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

#### Quality assurance

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

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#### 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 consolidated companies and the Group accounting processes. They include, in particular, the following elements:

- → Identification of key risk zones and controlling areas relevant to the Group-wide accounting process;
- → Checks to monitor the Group-wide reporting system and its findings at the divisional and departmental levels and at the companies included in the 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  $\epsilon_{37,082,758}$ .oo and is divided into 37,082,758 registered no-par shares representing a proportional share of the capital of  $\epsilon_{1.00}$  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 does 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 guarters 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 and 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 July 10, 2012 to increase the share capital by a total of up to €18,541,379.00 (50% of the share capital at the date of the shareholders' resolution) until July 9, 2017 by issuing up to 18,541,379 new registered ordinary shares (no-par shares) on one or more occasions against payment in cash or in kind (2012 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. This authorization has not been utilized to date.

#### b) Conditional capital

The Company's share capital was increased conditionally through a number of conditional capital items on December 31, 2012 by up to €16,318,510.00 overall, divided into up to 16,318,510 ordinary shares (approx. 44% of the share capital).

This concerns the following individual conditional capital items: conditional capital I of up to  $\epsilon_{13}6,897.00$  (1997), conditional capital II of up to  $\epsilon_{10}6,429.00$  (1998), conditional capital III of up to  $\epsilon_{12}5.00$  (2000), conditional capital IV of up to  $\epsilon_{13}.770.00$  (2000), conditional capital V of up to  $\epsilon_{52}.329.00$  (2000 and 2001), conditional capital VI of up to  $\epsilon_{3}.000.00$  (2000), conditional capital VIII of up to  $\epsilon_{3}.000.00$  (2001), conditional capital X of up to  $\epsilon_{3}.000.00$  (2002), conditional capital XI of up to  $\epsilon_{1.4}00.00$  (2003), conditional capital XII of up to  $\epsilon_{49}8.560.00$  (2003), conditional capital XVIII of up to  $\epsilon_{3}.000.00$  (2006), conditional capital XVIII of up to  $\epsilon_{1.2}00.000.00$  (2007), conditional capital XXIII of up to  $\epsilon_{1.2}00.000.00$  (2012) and conditional capital XXIII of up to  $\epsilon_{2.4}00.000.00$  (2012).

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, XVIII and XXIII, 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 mhH·
- 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 XXII, exclusively to issue new shares to the holders of conversion and option rights to be granted in accordance with the provisions of the shareholders' resolution of July 10, 2012.

#### 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 Dr. Frank Mathias, who has been an Executive Board member since April 1, 2008 and Chief Executive Officer since April 29, 2009, and the contract of employment for Peter Llewellyn-Davies, who has been an Executive Board member since October 1, 2012, include special termination rights for both the Company and the respective Executive Board members, applicable in the event of a change in control. For more detailed information see > Notes to the consolidated financial statements I) note (67) on page 89 et seq.

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

The corporate governance report and statement on corporate governance pursuant to Section 289a of the German Commercial Code (HGB) are publicly available on the Company's website at 

http://www.mediqene.com/media-investors/corporate-qovernance.

## MAJOR EVENTS SINCE THE END OF THE REPORTING PERIOD

The following major events in terms of corporate development have occurred in 2013 to date:

# Expansion of the trial plan and new timelines for the development of RhuDex\* in PBC

In February 2013, Medigene announced the expansion of the clinical development plan for RhuDex\* in the indication primary biliary cirrhosis (PBC). The planned phase II trial is to be expanded by a control arm to comprise four trial arms, and the planned treatment period for patients will be extended from three to six months. The aim is to increase the informative value of the trial data collected, in order to confirm the mode of action of RhuDex\* in autoimmune diseases and facilitate the future approval of RhuDex\* for PBC. Subject to successful completion of the work still required to prepare the trial and approval of the trial by the competent authorities, the schedule provides for a start of this expanded phase II trial no later than in the first half of 2014. It replaces the phase IIa trial with RhuDex\* originally planned for 2013. As a result, the major financial expenses relating to the phase II trial will be deferred to 2014 and thereafter.

# Inclusion of Veregen° into the European Guideline for the Management of Anogenital Warts

In February 2013, Medigene announced that Veregen® was included into the »2012 European Guideline for the Management of Anogenital Warts«. This internationally accepted treatment guideline, developed by clinical experts, recommends Veregen® (Sinecatechins 10% & 15% ointment) as a treatment option for genital warts.

#### OPPORTUNITIES AND OUTLOOK

This outlook comprises the 2013 and 2014 fiscal years.

#### Products on the market

The following objectives are planned for the Marketed Products segment:

#### Veregen®

Medigene expects market approval and market launch of Veregen® in numerous countries. For the global commercialization of Veregen®, Medigene is planning to conclude additional partnership agreements. In 2013, Medigene also expects further growth of Veregen® sales revenue in the significant double-digit percent range.

#### **Eligard®**

Due to the transfer of future royalty payments for Eligard\*, Medigene will post other revenue of €208 thousand per month in the future, as well as monthly interest expenses. Both are non-cash items.

#### **Development projects**

The following developments are planned for the Drug Candidates segment:

#### EndoTAG°-1

The final data of the IIT are expected in the first half of 2013 and are targeted to be presented at a scientific conference in the course of the year.

Medigene plans a pivotal global phase III trial of EndoTAG\*-1 in triplenegative breast cancer (TNBC), with the aim to achieve market approvals worldwide. Under the terms of the exclusive license agreement for the rights to EndoTAG\*-1 in Asia, Australia, and New Zealand which was concluded in 2012, SynCore will bear a significant portion of the costs of the planned phase III trial. For the remaining part of the trial expenses, Medigene is seeking further partners.

#### RhuDex®

Medigene plans to conduct a phase II clinical trial in primary biliary cirrhosis (PBC), in order to confirm the mode of action and the overall clinical profile of RhuDex® in autoimmune diseases. Subject to the successful completion of the necessary preparatory work and the approval of the trial by the regulatory authorities, the start of this phase II trial is scheduled to start not later than in the first half of 2014.

#### AAVLP technology

Further preclinical studies will be conducted in Medigene's proprietary AAVLP vaccine technology. The project is available for partnerships and licensing.

#### **OBJECTIVES ACHIEVED IN 2012:**

OBJECTIVES		STATUS AT THE END OF 2012
Marketed pro	ducts	
Eligard®	Transfer of rights for non-EU countries to Astellas	Achieved
Veregen*	Market launch in additional countries	Achieved
	Market approval in additional countries	Achieved
	Conclusion of additional marketing partnerships	Achieved
Drug Candida	tes	
EndoTAG®-1	Conclusion of one or more develop- ment and marketing partnerships	Achieved
RhuDex*	Initiation and completion of a clinical formulation study	Achieved
	Continuation of clinical development	Phase II trial in preparation
AAVLP technology	Further validation through preclinical trials	Achieved

#### **FORECAST**

	OBJECTIVES	SCHEDULED DATE
Marketed pro	ducts	
Veregen*	Market launch in additional countries	2013
	Market approval in additional countries	2013
	Conclusion of additional marketing partnerships	2013
Drug Candida	tes	
EndoTAG*-1	Conclusion of one or more develop- ment and marketing partnerships	Date not specified
RhuDex*	Preparation of phase II trial	2013
	Initiation of phase II trial	First half of 2014
AAVLP- Technologie	Further validation through preclinical trials	2013

#### Financial outlook for 2013 and 2014

In 2013 Medigene expects increasing total revenue to about  $\epsilon_7$  – 8 million, compared to  $\epsilon_6$  million in 2012. The projected income in 2013 essentially includes Veregen\* revenue as well as non-cash income totaling  $\epsilon_{2.5}$  million (2012:  $\epsilon_{1.9}$  million) from the Eligard\* deal concluded in 2012.

At the same time Medigene expects increasing R&D expenses for 2013, as well as a loss on EBITDA basis between €9 − 11 million, compared to €9 million from continued operations in 2012. Since discontinued operations of Medigene were ceased at the end of 2012, the company will starting 2013 only report continued operations.

As a result of the expected expansion in the commercialization of Veregen\*, Medigene expects continued significantly increased revenue in 2014.

In the event of changes in Medigene's drug pipeline, the financial forecast will be adjusted accordingly.

Based on current business planning and the respective scenarios, Medigene's management anticipates that the funding of the company is secured at least until the end of 2014.

At present, no major individual investments in property, plant and equipment (> €100 thousand) are planned in 2013 and 2014. The expenses for research and development will continue to be the largest cost area.

#### Future procurement

In 2013, Medigene will continue to obtain the drug Veregen® from contract manufacturers in Japan and Germany.

#### **Dividends**

In view of the current income position, Medigene will not distribute any dividends. 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 13, 2013 Medigene AG

Dr. Frank Mathias Chief Executive Officer

Peter Llewellyn-Davies Chief Financial Officer

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## **CONSOLIDATED INCOME STATEMENT**

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2012 AND 2011

IN€THOUSAND	NOTE	2012	2011
Product sales		3,384	2,300
Other operating income		2,900	2,356
Total revenue	(27)	6,284	4,656
Cost of sales	(28)	-1,250	-953
Gross profit		5,034	3,703
Selling expenses	(29)	-2,271	-2,272
General and administrative expenses	(30)	-5,638	-5,831
Research and development expenses	(31)	-7,399	-11,254
Other expenses	(32)	-6,166	0
Operating result		-16,440	-15,654
Interest income	(33)	55	131
Interest expense	(33)	-1,260	0
Foreign exchange gains/losses	(33)	689	-717
Share of result of associates	(36)	-59	766
Income from revaluation of investment	(37)	2,220	0
Result from continued operations before tax		-14,795	-15,474
Taxes	(55)	-82	1,241
Result from continued operations		-14,877	-14,233
Revenue from discontinued operations	(27)	5,032	27,828
Cost of sales from discontinued operations	(28)	0	-5,326
Selling expenses from discontinued operations	(29)	-14	-343
Gains from derivative financial instruments from discontinued operations	(33)	0	226
Taxes from discontinued operations	(55)	0	-1,871
Result from discontinued operations		5,018	20,514
Net result for the year		-9,859	6,281
Basic and diluted earnings per share from continued operations in €	(34)	-0.40	-0.38
Basic and diluted earnings per share from discontinued operations in €	(34)	0.13	0.55
Basic and diluted gain/loss per share after tax in €	(34)	-0.27	0.33
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## **CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2012 AND 2011

IN € THOUSAND	NOTE	2012	2011
Net result for the year		-9,859	6,281
Exchange differences on translation of foreign operations <sup>1)</sup>	(52)	-111	713
Derecognition of deconsolidation <sup>1)</sup>	(52)	6,166	0
Available-for-sale financial assets <sup>1)</sup>	(52)	-3	-4
Other comprehensive income for the year, net of tax		6,052	709
Total comprehensive income for the year, net of tax		-3,807	6,990

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

## **CONSOLIDATED BALANCE SHEET**

OF MEDIGENE AG AS OF DECEMBER 31, 2012 AND 2011

#### **ASSETS**

NOTE	DEC. 31, 2012	DEC. 31, 2011
(42)	604	829
(43)	27,369	27,725
(39)	2,212	2,212
(44)	3,895	262
(45)	2,727	4,183
	1	1
	36,808	35,212
(46)	2,205	2,203
(47)	1,139	1,897
(48)	20,113	12,811
(47)	990	1,169
	24,447	18,080
	61.255	53,292
	(42) (43) (39) (44) (45) (46) (47) (48)	(42)     604       (43)     27,369       (39)     2,212       (44)     3,895       (45)     2,727       1     36,808       (46)     2,205       (47)     1,139       (48)     20,113       (47)     990

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#### LIABILITIES AND SHAREHOLDERS' EQUITY

IN € THOUSAND	NOTE	DEC. 31, 2012	DEC. 31, 2011
A. Shareholders' equity			
I. Subscribed capital	(49)	37,082	37,082
II. Additional paid-in capital	(50)	343,938	343,848
III. Accumulated deficit	(51)	-336,676	-326,817
IV. Other reserves	(52)	-129	-6,181
Total shareholders' equity		44,215	47,932
B. Non-current liabilities			
I. Financial liabilities	(53)	11,906	0
II. Pension obligations	(54)	255	255
III. Other financial liabilities	(61)	258	281
IV. Deferred income	(57)	304	0
Total non-current liabilities		12,723	536
C. Current liabilities			
I. Trade accounts payable	(56)	719	1,773
II. Other current liabilities	(56)	2,888	2,344
III. Deferred income	(57)	68	77
IV. Tax liabilities	(55)	642	630
Total current liabilities		4,317	4,824
Total liabilities		17,040	5,360
Total liabilities and shareholders' equity		61,255	53,292

## **CONSOLIDATED STATEMENT OF CASH FLOWS**

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2012 AND 2011

IN € THOUSAND	2012	2011
Cash flows from operating activities		
Net result for the year (before tax)	-9,777	6,911
Non-cash adjustments to reconcile net result before tax to net cash flows:		
Share-based compensation	90	144
Effect from foreign currency translation	6,166	822
Other non-cash income	-1,870	0
Depreciation and impairment	847	4,675
Gain on disposal of property, plant and equipment	-12	-32
Interest income	-55	-131
Interest expense	1,260	0
Changes in:		
Inventories	-2	-510
Other assets and accounts receivable	-1,372	8,289
Trade accounts payable	-1,054	-581
Other liabilities and deferred income	-756	-12,090
Income tax expense	-69	0
Share of result of associates	59	-766
Subtotal	-6,545	6,731
Interest received	45	133
Interest paid	-7	0
Net cash from/used by operating activities	-6,507	6,864
Cash flows from investing activities		
Purchase of property, plant and equipment	-270	-406
Proceeds from sale of property, plant and equipment	15	55
Disposal of financial assets	0	1,774
Net cash from/used by investing activities	-255	1,423
Cash flows from financing activities		
Proceeds from financial liabilities	14,094	0
Net cash from financing activities	14,094	0
Increase in cash and cash equivalents	7,332	8,287
Cash and cash equivalents at the beginning of the year	12,811	4,770
Foreign exchange differences	-30	-246
Cash and cash equivalents at the end of the year	20,113	12,811

# CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

OF MEDIGENE AG FOR THE PERIODS FROM JANUARY 1 TO DECEMBER 31, 2012 AND 2011

IN€THOUSAND	SUBSCRIBED CAPITAL	CAPITAL RESERVE	ACCUMULATED DEFICIT	CURRENCY TRANSLATION	FINANCIAL ASSETS	TOTAL SHAREHOLDERS' EQUITY
Balance at Jan. 1, 2011	37,082	343,704	-333,098	-6,891	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
Share-based compensation		144				144
Balance at Dec. 31, 2011	37,082	343,848	-326,817	-6,178	-3	47,932
Balance at Jan. 1, 2012	37,082	343,848	-326,817	-6,178	-3	47,932
Net loss for the year			-9,859			-9,859
Net loss on available-for-sale financial assets					-3	-3
Currency translation adjustments				6,055		6,055
Comprehensive income						-3,807
Share-based compensation		90				90
Balance at Dec. 31, 2012	37,082	343,938	-336,676	-123	-6	44,215

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

OF MEDIGENE AG, PLANEGG/MARTINSRIED, GERMANY, FOR THE FISCAL YEAR 2012

## 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 and has one drug on the market.

The Group's main activities are described in <u>→ note (H)</u> »Segment reporting« of these notes to the consolidated financial statements.

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 (hereinafter referred to as »Medigene«) includes the wholly owned subsidiary Medigene, Inc., San Diego, California, USA, which was acquired in 2001. The former subsidiary Medigene Ltd., Abingdon, Oxfordshire, United Kingdom, was wound up and deconsolidated in 2012, 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 17.45% as of December 31, 2012 were transferred to Medigene AG as part of the winding up process of Medigene Ltd. The subsidiary Medigene, Inc. holds 41.89% of the shares in Catherex, Inc., Philadelphia, Pennsylvania, USA. Medigene is managed by the Executive Board of the parent company, Medigene AG. The subsidiary's management report directly to the Group's Executive Board.

#### **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, 2011 and 2012 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, 2012 were approved for publication by a resolution of the Executive Board on March 13, 2013.

#### (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 2012, the following new and revised International Financial Reporting Standards, Interpretations and amendments to these were applied for the first time:

Amendments to IFRS 7	Financial Instruments: Disclosures – Enhanced Derecognition Disclosure Requirements
Amendments to IAS 12	Income Taxes: Recovery of Underlying Assets

The revised standards replace the previous versions of these standards and apply to fiscal years beginning on or after January 1, 2012. The application of these standards has no impact on the assets, financial and income position of the Group or its disclosures.

#### Amendments to IFRS 7

In October 2010, the IASB published supplements to IFRS 7 »Financial Instruments: Disclosures«, which resulted in additional disclosures being required when financial assets are transferred. Since the Group has no assets with these features, they have no impact on the consolidated financial statement and, thus, on the Group's asset, financial, and income position.

#### Amendments to IAS 12

This amendment includes a clarification regarding the calculation of deferred taxes on real property valued at fair value, introducing the refutable assumption that in principle a realization of the carrying amount by sale is pivotal for the calculation of deferred taxes on real property which is valued at fair value, according to IAS 40. This amendment had no impact on the Group's asset, financial and income position or its disclosures.

2) Future changes in accounting and valuation methods
Starting 2013 and the following years, the application of the following newly published and revised standards and interpretations will be mandatory. Medigene evaluated the impact of the new standards. The impact of IAS 19 is described in > note (54). The remaining standards

do not have any major impact, and are applied for the reporting periods starting on or after January 1, 2013. Medigene waives the early application for the following reason:

STANDARDS/INTERPRETATIONS/AMENDMENTS	DATE OF COMING INTO EFFECT (IASB)
Amendments to IFRS 7 Offsetting Financial Assets and Financial Liabilities	January 1, 2013
Improvements to IFRSs 2009-2011 (Reapplication of IFRS 1, IAS 1, IAS 16, IAS 32 and IAS 34)	January 1, 2013
Amendments to IAS 1 Presentation of Items of Other Comprehensive Income	January 1, 2013
Amendments to IAS 19 Employee Benefits (revised 2011)	January 1, 2013
Amendments to IAS 27 Separate Financial Statements (revised in 2011)	January 1, 2014
Amendments to IAS 28 Investments in Associates and Joint Ventures (revised in 2011)	January 1, 2014
Amendments to IAS 32 Offsetting Financial Assets and Financial Liabilities	January 1, 2014
IFRS 9 Financial Instruments: Classification and Measurement (revised in 2009, 2010 and 2011)	January 1, 2015
IFRS 10 Consolidated Financial Statements	January 1, 2014
IFRS 11 Joint Arrangements	January 1, 2014
IFRS 12 Disclosure of Interests in Other Entities	January 1, 2014
Amendments to IFRS 10, IFRS 11 and IFRS 12 Transition Guidance	January 1, 2013
IFRS 13 Fair Value Measurement	January 1, 2013
Amendments to IFRS 10, IFRS 12 und IAS 27 Investment Entities	January 1, 2014

## (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 existing marketing partner Astellas Pharma Europe Ltd., Chertsey, United Kingdom (hereinafter referred to as »Astellas«). The Eligard\* rights for the EU countries were transferred effective from March 1, 2011 and those for the countries outside the EU at the beginning of May 2012. 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 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, 2012, 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 cash-generating units. As the projects are not yet available for use, they are tested for impairment once a year. In order to estimate the value in use, 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 17 years), the assumptions and forecasts associated with this are subject to a significant degree of uncertainty. Please refer to  $\frac{1}{2}$  note (39) 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 liabilities at fair value  $\Rightarrow$  see note (62).

#### Share-based compensation

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 compensation it is necessary to determine the most suitable valuation procedure which depends on the terms under which the compensation 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 compensation are described in hote (16).

#### 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 discounted 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  $\Rightarrow cf.$  note (54).

In establishing the appropriate discount rate, the management uses the interest rates on corporate bonds in the relevant currency with a minimum rating of AA as guidelines, adjusting these to the expected term of the defined benefit obligation on the basis of extrapolation. Furthermore, the quality of the underlying bonds is checked. Bonds with excessively high credit spreads are removed from the bond portfolio on the basis of which the discount rate is derived, since such bonds are not first-ranking bonds.

In the Eurozone, the portfolio was expanded in the course of the fiscal year following market changes in respect of the high-quality corporate bonds which are used as a basis for establishing the interest rate. Bonds that are AA rated by at least one of the rating agencies are now included. The minimum volume for consideration was additionally reduced to €50 million and information about corporate bonds with a rating of A (after deduction of the spread between AA and A) was also taken into account. Had the previous data basis been applied at the end of the fiscal year, the defined benefit obligations would marginal deviated from the balanced value.

#### (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

Compared with the previous year, the wholly-owned subsidiary Medigene Ltd. was wound up and deconsolidated in the reporting period ended.

#### **SUBSIDIARY**

CONSOLIDATED COMPANY AS AT DEC. 31, 2012	MEDIGENE, INC.
Registered office	San Diego, USA
Percentage of share in%	100
Shareholders' equity in € thousand	1,706
Net income for the year in € thousand	-149

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 the financial statements of the parent company, Medigene AG, Planegg/Martinsried, Germany, the consolidated financial statements comprise the financial statements of whollyowned subsidiary Medigene, Inc., San Diego, California, USA, which was acquired in 2001. The former wholly-owned subsidiary Medigene Ltd., Abingdon, Oxfordshire, United Kingdom, was wound up and deconsolidated in 2012, since its operations ceased upon transfer of all patents to Medigene AG.

#### (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

Using the equity method the Group determines whether it is necessary to recognize an impairing loss for its shares in an associate. At each balance sheet date, the Group determines whether there are any objective indications of impairment of a share in an associate. If so, the impairment amount is determined as the difference between the recoverable amount of the share in an associate and the carrying amount, and the loss is recognized through profit and loss as »share of result of associates«.

#### **ASSOCIATE**

ASSOCIATE AS AT DEC. 31, 2012	CATHEREX, INC.
Registered office	Philadelphia, USA
Percentage of share in%	41.89
Shareholders' equity in € thousand <sup>1)</sup>	2,296
Net loss for the year in € thousand <sup>i)</sup>	-141

<sup>1) 100 %</sup> 

#### 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\* are shown separately from income and expenses from continuing business operations and are stated separately in the consolidated statement of comprehensive income as income and expenses 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 currency of the parent company and reporting currency of the Group. Each company within the Group determines its own functional currency. The items included in the annual financial statements of the relevant company are measured on the basis of this functional currency. The functional currency of Medigene, Inc. is the US dollar (\$).

#### Transactions and balances

Transactions in foreign currencies are translated into the functional currency at the exchange rates that applied on the date of the transaction. Gains and losses resulting from the settlement of such transactions and from 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 measured at fair value in a foreign currency are translated using the exchange 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

When foreign subsidiaries are consolidated, in principle, the balance sheet items are translated as per the exchange rates on the balance sheet date. The translation of income and expenses for the purposes of consolidation is carried out at the relevant transaction exchange rate on the date of the transaction. The resulting differences arising from currency translation are recognized directly in shareholders' equity (under other income) with no effect on income. The amount included in other income is reclassified in the income statement upon the disposal or deconsolidation of foreign subsidiaries  $\Rightarrow$  cf. note (32).

The following exchange rates were used in 2012 and as per the balance sheet date December 31, 2012:

#### **EXCHANGE RATES**

	RATE AS AT CLOSING DATE		AVERAGE RATE FOR THE YEAR	
	DEC. 31, 2012	DEC. 31, 2011	2012	2011
1 € in \$	1.31560	1.29020	1.28263	1.39064
1€in£	0.81380	0.83470	0.80943	0.86658

 $Source: Commerzbank\ AG,\ Reference\ Exchange\ Rates$ 

#### (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 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  $\Rightarrow$  page (96) 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  $\Rightarrow$  page (96) et seq.

**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 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 not approved 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 good-will 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 development and approval, as well as the period of time commencing with market launch, for which patent terms of slightly over ten years are generally assumed.

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. In the reporting periods, the Group did not hold any investments of this category.

#### 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 which are not qualified as plan 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.

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.

#### (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 compensation: 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 compensation 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 liabilities

#### Initial recognition

Financial liabilities within the scope of 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, net of directly attributable transaction costs in the case of loans.

#### Subsequent measurement

Financial liabilities classified as loans are 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.

#### Derecognition

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

#### (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 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) 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, third party expenses, laboratory material costs, patent and license fees, consultancy fees and other costs such as rent and electricity, as well as depreciation. 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.

#### (24) 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.

#### (25) 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.

#### (26) 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\* rights to Astellas at the beginning of March 2011. All revenue and expenses attributable to Eligard\* up to this date are stated under this heading.

Medigene sold the exclusive European marketing and distribution rights to the cancer drug Eligard\* to Astellas by means of an agreement signed in July 2010 and received the first milestone payment of €5 million in return. The second payment amounting to €15 million was made after the transfer of the rights for EU countries on March 3, 2011. Medigene received the final payment of €5 million upon transfer of the rights for non-EU countries at the beginning of May 2012.

Since March 1, 2011, Medigene has received a 2% share in net revenue from European Eligard® sales. With effect from April 1, 2012, Medigene transferred future cash flows in connection with this share in net revenue to Cowen Healthcare Partners II, L.P., USA (hereinafter referred to as »Cowen«) in return for payment of €14.1 million. The relevant income (monthly €208 thousand) is a non-cash item and will be recognized as income pro rata over the term of the Eligard® patent of approx. ten years and the financial liability associated with the transfer will be amortized, taking into account the non-cash interest expense.

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

#### **KEY FIGURES FROM CONTINUED AND DISCONTINUED OPERATIONS**

IN€THOUSAND		2012			2011	
	CONTINUED	DISCONTINUED	TOTAL	CONTINUED	DISCONTINUED	TOTAL
Product sales	3,384	5,000	8,384	2,300	27,668	29,968
Other operating income	2,900	32	2,932	2,356	160	2,516
Total revenue	6,284	5,032	11,316	4,656	27,828	32,484
Cost of sales	-1,250	0	-1,250	-953	-5,326	-6,279
Gross profit	5,034	5,032	10,066	3,703	22,502	26,205
Selling expenses	-2,271	-14	-2,285	-2,272	-343	-2,615
General and administrative expenses	-5,638	0	-5,638	-5,831	0	-5,831
Research and development expenses	-7,399	0	-7,399	-11,254	0	-11,254
Other expenses (deconsolidation)	-6,166	0	-6,166	0	0	0
Operating result	-16,440	5,018	-11,422	-15,654	22,159	6,505
Interest income	55	0	55	131	0	131
Interest expense	-1,260	0	-1,260	0	0	0
Foreign exchange gains/losses	689	0	689	-717	0	-717
Gains from derivative financial instruments	0	0	0	0	226	226
Share of result of associates	-59	0	-59	766	0	766
Income from revaluation of investment	2,220	0	2,220	0	0	0
Result from continued operations before tax	-14,795	5,018	-9,777	-15,474	22,385	6,911
Taxes	-82	0	-82	1,241	-1,871	-630
Result from continued operations	-14,877			-14,233		
Result from discontinued operations		5,018			20,514	
Net result for the year			-9,859			6,281

Revenue from discontinued operations consists of product sales (2012:  $\epsilon$ 0; 2011:  $\epsilon$ 5,380 thousand), royalties (2012:  $\epsilon$ 0; 2011:  $\epsilon$ 2,287 thousand) and milestone payments (2012:  $\epsilon$ 5,000 thousand; 2011:  $\epsilon$ 20,000 thousand) for Eligard\* in Europe as well as other operating income (2012:  $\epsilon$ 32 thousand; 2011:  $\epsilon$ 160 thousand).

The cash inflow from operating activities allocated to discontinued operations amounted to €3,877 thousand in the past fiscal year (2011: €20,572 thousand). There was no cash from/used by financing and investing activities for discontinued operations.

#### D) NOTES TO THE INCOME STATEMENT

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

#### (27) Total revenue

Total revenue amounted to  $\epsilon$ 6,284 thousand in fiscal year 2012 (2011:  $\epsilon$ 4,656 thousand). This revenue originates from product sales and license fees for the drug Veregen\* in the USA, Germany, Austria, Switzerland and Spain amounting to  $\epsilon$ 2,774 thousand (2011:  $\epsilon$ 2,050 thousand) and also includes milestone payments totaling  $\epsilon$ 610 thousand (2011:  $\epsilon$ 250 thousand) for Veregen\* from partner companies.

Other operating income amounted to €2,900 thousand (2011: €2,356 thousand). It essentially comprises the 2% share in revenue from Eligard® net sales from Astellas of €613 thousand for the first quarter of 2012, and since April 1, 2012 from the transfer of future cash flows relating to this share in revenue to Cowen, which amounts to €208 thousand per month. This income is a non-cash item and will be recognized as income pro rata over the term of the patent of approx. ten years. The financial liability associated with the transfer will be amortized, taking into account the non-cash interest expense. In the first quarter of 2012, Medigene additionally received a compensation payment from a service provider for costs incurred amounting to €390 thousand.

Revenue from discontinued operations essentially consists of the final milestone payment of  $\epsilon_{5,000}$  thousand (2011:  $\epsilon_{20,000}$  thousand) for the sale of the Eligard\* rights to Astellas. In the previous year, alongside the milestone payments, this item included the product sales and license fees achieved with Eligard\* up to the end of February 2011.

#### **TOTAL REVENUE**

IN€THOUSAND	2012	2011	CHANGE
Product revenue and royalties	2,774	2,050	35%
Milestones	610	250	144%
Product sales	3,384	2,300	47%
Other	2,900	2,356	23%
Total from continued operations	6,284	4,656	35%
Discontinued operations	5,032	27,828	-82%

#### (28) Cost of sales

The cost of sales amounting to  $\epsilon_{1,250}$  thousand (2011:  $\epsilon_{953}$  thousand) includes procurement costs for the product Veregen® and a share in sales revenue in the form of license payments. For the commercialization of Eligard®, no procurement costs from discontinued operations were incurred (2011:  $\epsilon_{5,32}$ 6 thousand).

#### **COST OF SALES**

IN€THOUSAND	2012	2011	CHANGE
Cost of sales	709	549	29%
Royalties	541	404	34%
Total from continued operations	1,250	953	31%
Discontinued operations	0	5,326	_

#### (29) Selling expenses

Expenses for business development and marketing are reported under selling expenses. These include personnel expenses, marketing and regulatory costs (incl. FDA fees), 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	2012	2011	CHANGE
Personnel expenses	1,135	1,098	3%
Marketing/regulatory fees	612	554	10%
Office rent and utilities	164	227	-28%
Consultancy fees/market surveys	112	152	-26%
Depreciation	1	1	0%
Other	247	240	3%
Total from continued operations	2,271	2,272	0%
Discontinued operations	14	343	-96%

#### (30) General and administrative expenses

In the reporting period, administrative expenses were down compared with the previous year. This was mainly due to downsizing the space rented for business premises.

#### **GENERAL AND ADMINISTRATIVE EXPENSES**

IN€THOUSAND	2012	2011	CHANGE
Personnel expenses	2,497	2,448	2%
Consultancy fees	1,317	1,070	23%
Office rent and utilities	351	886	-60%
Depreciation	115	91	26%
Other	1,358	1,336	2%
Total	5,638	5,831	-3%

#### (31) Research and development expenses

R&D expenses fell by 34% compared with the previous year. The major portion of R&D expenses is attributable to services in connection with clinical and preclinical development as well as regulatory expenses and personnel expenses. In the previous year, the write-down of a project at the early research stage that Medigene is no longer pursuing was realized, which amounted to  $\mathfrak{e}_3,827$  thousand.

#### RESEARCH AND DEVELOPMENT EXPENSES

IN € THOUSAND	2012	2011	CHANGE
Third party expenses	2,473	2,031	22%
Personnel expenses	2,174	2,405	-10%
Depreciation	731	4,583	-84%
Office rent and utilities	509	667	-24%
Patent and license fees	492	726	-32%
Consultancy fees	420	161	161%
Laboratory material costs	154	183	-16%
Other	446	498	-10%
Total	7,399	11,254	-34%

#### (32) Other expenses (deconsolidation)

Other expenses totaling €6,166 thousand were incurred in connection with the deconsolidation of Medigene Ltd. As part of this, other reserves under shareholders' equity were largely written back. The derecognition of other reserves is recorded in the income statement.

#### (33) Financial result

The financial result, which essentially comprises net interest income and foreign exchange gains and losses, amounted to  $\epsilon$ -516 thousand in the fiscal year ended (2011:  $\epsilon$ -586 thousand). Foreign exchange gains arose in connection with the translation of US dollars into euro amounts. The financial result also includes non-cash interest expenses of  $\epsilon$ 1,244 thousand relating to the financial liability to Cowen as part of the Eligard\* transaction.

Interest income was generated from the investment of available cash.

In the previous year's reporting period, the financial result from discontinued operations comprised a profit of €226 thousand from a derivative instrument in accordance with IAS 39, which related to the product Eligard\*. Following the transfer of the Eligard\* rights to Astellas, this derivative no longer exists.

#### **FINANCIAL RESULT**

IN € THOUSAND	2012	2011	CHANGE
Interest income	55	131	-58%
Interest expense	-1,260	0	-
Subtotal	-1,205	131	-
Foreign exchange gains/losses	689	-717	-
Total	-516	-586	-12%
Discontinued operations (derivative financial instrument)	0	226	-

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

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

#### **BASIC AND DILUTED EARNINGS PER SHARE**

IN NO.	2012	2011	CHANGE
Weighted average number of shares	37,082,758	37,082,758	0%
Effect of dilution: Number of stock options	289,891	117,713	146%
Weighted average number of ordinary shares adjusted for the effect of dilution	37,372,649	37,200,471	0%
Basic and diluted earnings per share in €	-0.27	0.17	-
Basic and diluted earnings per share from continued operations in €	-0.40	-0.38	5%
Basic and diluted earnings per share from discontinued operations in €	0.13	0.55	-76%

Of the total 1,868,094 stock options, 1,538,835 had no dilutive effect in 2012, since the exercise price of most of the stock options was above the average share price of €1.18 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	2012	2011	CHANGE
Salaries and wages	4,960	5,219	-5%
Social security	594	590	1%
Pension expenses			
defined contribution plans	64	37	73%
defined benefit plans	64	84	-24%
Stock options issued to executives and employees	90	144	-38%
Other	46	71	-35%
Total	5,818	6,145	-5%

#### **EMPLOYEES BY FUNCTION**

	DEC. 31, 2012	DEC. 31, 2011	CHANGE
General administration	16	21	-24%
Business development	12	9	33%
Research and development	25	22	14%
Total	53	52	2%

The average number of employees in 2012 fell to 49 (2011: 52). Personnel expenses decreased by 5% in the reporting period to  $\epsilon$ 5,818 thousand (2011:  $\epsilon$ 6,145 thousand).

#### (36) Share of result of associates

The profit from investments in associates amounted to  $\epsilon$ -59 thousand in the reporting period ended (2011:  $\epsilon$ 766 thousand). As of December 31, 2012, the Group held a 41.89% stake in Catherex, Inc. In the previous year, the profit also comprised the shareholding in associate Immunocore Ltd. Since the beginning of 2012, Immunocore Ltd. has no longer been reported as an associate. In accordance with IAS 28.6, this investment is therefore no longer valued at equity, but stated under financial assets  $\Rightarrow$  see note (44).

#### (37) Income from revaluation of investment

As a consequence of the reduction of the share in Immunocore Ltd. below 20%, this investment was reclassified in the balance sheet and, accordingly, a revaluation pursuant to IAS 28.18 at fair value. The revaluation associated with it resulted in a non-cash income of  $\epsilon$ 2,220 thousand  $\Rightarrow$  see note (44).

#### (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 as well as research and development expenses.

#### **DEPRECIATION AND IMPAIRMENT OF FIXED ASSETS**

IN € THOUSAND	2012	2011	CHANGE
Regular depreciation			
of property, plant & equipment	388	402	-3%
of intangible assets	459	446	3%
Subtotal	847	848	0%
Impairment/Write-off			
of intangible assets	0	3,827	-
Total	847	4,675	-82%

## (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 are allocated to CGU RhuDex and comprised the following as of December 31, 2012:

#### CARRYING AMOUNTS OF GOODWILL AND INTANGIBLE ASSETS

IN € THOUSAND	2012	2011
Carrying amount of goodwill	2,212	2,212
Carrying amount of intangible assets not yet available for use	23,750	23,750

#### Annual impairment test as of December 31, 2012

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 project-specific interest rate.

#### Development periods and project progress

According to pharmaceuticals industry statistics, the development of a drug generally takes 10 to 15 years. This period of time is divided into successive phases. Significant factors which influence the length of the development period are the results for efficacy and side effects of a drug candidate, which are obtained during the individual phases. The assumptions made by Medigene's management for each 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	17
Risk adjusted project-specific discount rate in %	27

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 9%, the value-in-use would approach the carrying amount of the CGU.

The second approach examines how postponing the planned market entry by eight 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 will fall 18 % below the carrying amount of the CGU.

#### (40) Impairment of other intangible assets

As of the reporting date of December 31, 2012, there was no indication of any impairment of the EndoTAG\* 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	2012	2011	CHANGE
Cost of sales	1,250	953	31%
Expenses for R&D material	154	183	-16%
Subtotal	1,404	1,136	24%
Cost of services	2,473	2,031	22%
Total from continued operations	3,877	3,167	22%
Discontinued operations	0	5,326	_

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  $\epsilon$ 154 thousand (2011:  $\epsilon$ 183 thousand). The cost of services totaling  $\epsilon$ 2,473 thousand (2011:  $\epsilon$ 2,031 thousand) comprises the following items: Implementation of clinical trials amounting to  $\epsilon$ 1,041 thousand (2011:  $\epsilon$ 1,149 thousand), production services of  $\epsilon$ 511 thousand (2011:  $\epsilon$ 197 thousand), preclinical development services of  $\epsilon$ 679 thousand (2011:  $\epsilon$ 500 thousand) and approval costs of  $\epsilon$ 242 thousand (2011:  $\epsilon$ 185 thousand). In the previous year, cost of sales for the purchase of the drug Eligard\* and license payments to the partner were 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  $\Rightarrow$  page (96) et seq.

#### (43) Intangible assets

The decrease in intangible assets from  $\epsilon$ 27,725 thousand to  $\epsilon$ 27,369 thousand is accounted for by scheduled amortization. The patents and licenses for RhuDex\* and EndoTAG\* as well as software are stated as intangible assets.

Medigene has not capitalized any internally generated intangible assets.

#### (44) Financial assets

Financial assets comprise the following items:

#### FINANCIAL ASSETS

Total	3,895	262	>200%
Investment in Immunocore Ltd.	3,533	0	-
Loan to Catherex, Inc.	216	114	89%
Available-for-sale financial assets (pension)	146	148	-1%
IN€THOUSAND	DEC. 31, 2012	DEC. 31, 2011	CHANGE

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. Any gains and losses resulting from this category are recognized in the statement of comprehensive income with no effect on income.

The loan to associate Catherex, Inc. is a fixed-interest loan. It was increased to  $\epsilon$ 216 thousand in the reporting year ended and has a loan term up to December 31, 2013. The management of Medigene currently assumes that this loan will be extended beyond the agreed loan term.

Following the issue of new Immunocore Ltd. shares, Medigene's stake in this company fell below 20%. Since the beginning of 2012, Immunocore Ltd. has no longer been reported as an associate. In accordance with IAS 28.6, this investment is no longer valued according to the equity method but at fair value, pursuant to IAS 28.18 respectively IAS 39, and recognized as financial asset. After discontinuation of a significant influence over an associate, the share in Immunocore Ltd. was valued at fair value and totaled  $\mathfrak{E}_{3,533}$  thousand at closing date.

#### (45) Investment in associates

As of the end of the reporting period, the Group held 41.89% of the shares in Catherex. Inc.

The carrying amount of the shares in associates as of December 31, 2012 decreased to  $\epsilon$ 2,727 thousand (2011:  $\epsilon$ 4,183 thousand). This reduction in the carrying amount is attributable to the loss relating to the Catherex shareholding of  $\epsilon$ 59 thousand, the reclassification of the Immunocore shareholding of  $\epsilon$ 1,343 thousand to financial assets  $\Rightarrow$  cf. note (44) and foreign exchange losses of  $\epsilon$ 54 thousand.

#### **INVESTMENT IN ASSOCIATES**

IN € THOUSAND	DEC. 31, 2012	DEC. 31, 2011
Share of the associates' balance sheet:		
Current assets	20	979
Non-current assets	1,274	1,657
Current liabilities	-77	-307
Non-current liabilities	-255	-219
Pro rata net assets	962	2,110
Share of the associates' revenue and result:		
Revenue	0	91
Result	-59	-1,476

#### (46) Inventories

Inventories in respect of Veregen® amounted to  $\epsilon$ 2,205 thousand as of the reporting date (2011:  $\epsilon$ 2,203 thousand). 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, 2012	DEC. 31, 2011	CHANGE
Described to the state of the s	F03	C70	-12%
Prepaid expenses with a term <1 year	592	670	-12%
Rent deposit	375	323	16%
VAT receivables	0	145	_
Other	23	31	-26%
Total other assets	990	1,169	-15%
Trade accounts receivable	1,139	1,897	-40%

Other assets totaled  $\epsilon$ 990 thousand in the reporting period ended (2011:  $\epsilon$ 1,169 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  $\epsilon$ 592 thousand (2011:  $\epsilon$ 670 thousand).

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

#### AGING ANALYSIS OF TRADE ACCOUNTS RECEIVABLE AND OTHER CURRENT ASSETS

IN€THOUSAND			MATURITY			
_	UP TO 30 DAYS	30-180 DAYS	180-360 DAYS	1-5 YEARS	>5 YEARS	TOTAL
Balance at Dec. 31, 2012						
Other current assets	615	374	1	1	0	991
Trade accounts receivable	1,139	0	0	0	0	1,139
Total	1,754	374	1	1	0	2,130
Balance at Dec. 31, 2011						
Other current assets	585	467	117	0	0	1,169
Trade accounts receivable	1,896	0	1	0	0	1,897
Total	2,481	467	118	0	0	3,066

In the reporting period ended, no significant value adjustments were made. Other assets mainly consist of rental deposits which do not require any value adjustments.

#### (48) Cash and cash equivalents

#### **CASH AND CASH EQUIVALENTS**

IN€THOUSAND	DEC. 31, 2012	DEC. 31, 2011	CHANGE
Cash and cash equivalents < 3 months	20,113	12,811	57%
Total	20,113	12,811	57%

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 0.06% to 1.20% in the reporting period. The change in cash and cash equivalents compared with the previous year is shown in the statement of cash flows.

#### LIABILITIES AND SHAREHOLDERS' EQUITY

#### (49) Shareholders' equity

#### a) Subscribed capital

As of December 31, 2012, 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.

#### 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 68,750 stock options were issued to Executive Board members as per the shareholders' resolution dated July 10, 2012 (conditional capital XXIII), (2011: 65,000 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 the stock options as an expense.

#### SUBSCRIBED CAPITAL

Balance at Dec. 31, 2012	37,082,758	37,082	343,938	381,020
Value of services provided			90	90
Executives and employees stock option plan				
Balance at Dec. 31, 2011	37,082,758	37,082	343,848	380,930
Value of services provided			144	144
Executives and employees stock option plan				
Balance at Jan. 1, 2011	37,082,758	37,082	343,704	380,786
	NUMBER OF SHARES	SUBSCRIBED CAPITAL IN € THOUSAND	CAPITAL RESERVE IN € THOUSAND	TOTAL IN € THOUSAND

In December 2012, a further 88,823 stock options were issued to employees from conditional capital XXIII as per the shareholders' resolution dated July 10, 2012 (2011: 115,570 stock options).

If an employee's contract of employment is terminated on grounds of personal capability or conduct, or if the option holder hands in his/her notice of resignation before the end of the relevant 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 2012 was €1.05.

#### TOTAL CHANGE IN STOCK OPTIONS OUTSTANDING

	2012	2012		2011		2010	
	AVERAGE EXERCISE PRICE IN €	NUMBER	AVERAGE EXERCISE PRICE IN €	NUMBER	AVERAGE EXERCISE PRICE IN €	NUMBER	
Stock options outstanding, balance at Jan. 1	5.09	1,722,955	5.52	1,567,719	6.10	1,389,276	
Issued	1.05	157,573	1.03	180,570	2.63	263,574	
Exercised	0	0	0	0	0	0	
Forfeited	1.27	-12,434	2.77	-25,334	3.80	-18,610	
Lapsed	0	0	0	0	6.48	-66,521	
Stock options outstanding, balance at Dec. 31		1,868,094		1,722,955		1,567,719	
Weighted average exercise price in € per option		4.78		5.09		5.52	

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

#### **VALUATION PARAMETERS FOR STOCK OPTION PLAN**

	2012	2011	2010
Vesting period	2/4 years	2/4 years	2 years
Option term	10 years	10 years	10 years
Exercise hurdle rate	120%	120%	120%
Expected volatility	48%	50%	51%/50%
Risk-free interest rate	1.49%	2.08%	3.66%/ 3.18%

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 1.49% (source: German central bank). The fair value of the stock options issued in December 2012 amounted to  $\epsilon$ 0.49 per stock option (2011:  $\epsilon$ 0.50). For 2012, an expense for share-based compensation totaling  $\epsilon$ 90 thousand (2011:  $\epsilon$ 144 thousand) was reported in accordance with IFRS.

The breakdown of these payments is as follows:

#### **EXPENSES FOR STOCK OPTIONS**

IN€THOUSAND	2012	2011
Expenses for stock options		
2009	0	0
2010	31	112
2011	25	32
2012	34	0
Total	90	144

As of December 31, 2012, 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:

#### **EXERCISE PRICE AND TERM OF STOCK OPTIONS OUTSTANDING**

EXERCISE FRICE AND TERM OF STOCK OF HONS OUTSTANDING						
EXERCISE PRICE IN €	NUMBER OF STOCK OPTIONS OUTSTANDING	RESIDUAL TERM IN YEARS	NUMBER OF EXER- CISABLE STOCK OPTIONS			
4.60	45,179	1	45,179			
4.68	80,000	1	80,000			
7.69	60,237	2	60,237			
8.10	40,000	2	40,000			
12.37	131,062	3	131,062			
10.22	111,341	4	111,341			
5.88	234,029	5	234,029			
4.34	297,860	6	297,860			
3.89	231,547	6	231,547			
3.69	81,350	7	81,350			
3.69	89,316	8	89,316			
1.87	140,464	8	136,914			
1.03	180,570	9	_1)			
1.05	145,139	10	_1)			
	1,868,094		1,538,835			

<sup>1)</sup> Stock options issued in 2011 and 2012 could not be exercised as at December 31, 2012.

The weighted average remaining term of stock options in circulation is 4.24 years.

#### c) Authorized capital

The Executive Board was authorized by a shareholders' resolution dated July 10, 2012 to increase the share capital, with the approval of the Supervisory Board, by a total of up to €18,541,379.00 (approx. 50% of the share capital on the date of the shareholders' resolution) until July 9, 2017 by issuing a total of up to 18,541,379 new registered ordinary shares (no-par shares) on one or more occasions against payment in cash or in kind (authorized capital 2012). 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, 2012, the Company still had 18,541,379 new registered no-par shares available from authorized capital 2012.

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

As of December 31, 2012, the Company's share capital had been increased conditionally through a number of conditional capital items by up to €16,318,510.00, divided into a total of up to 16,318,510 ordinary shares (approx. 44% 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, 2012	USAGE: TO PROVIDE FOR
<u> </u>	136,897	Options
II	106,429	Options
III	125	TBG <sup>1)</sup> loan
IV	13,770	Convertible bonds
V	652,329	Convertible bonds
VI	3,000	Convertible bonds
VIII	3,000	Convertible bonds
Х	3,000	Convertible bonds
XI	1,400	Convertible bonds
XII	498,560	Options
XVI	300,000	Options
XVIII <sup>2)</sup>	1,200,000	Options
XXI <sup>2)</sup>	0	Convertible bonds and options
XXII3)	11,000,000	Convertible bonds and options
XXIII <sub>3)</sub>	2,400,000	Options
	16,318,510	

<sup>&</sup>lt;sup>1)</sup> Technologie-Beteiligungs-GmbH

<sup>&</sup>lt;sup>2)</sup> Cancelled by a shareholders' resolution of July 10, 2012

<sup>3)</sup> Newly created by a shareholders' resolution of July 10, 2012

#### (50) Capital reserve

No stock options were exercised in 2012 and 2011.

#### **CAPITAL RESERVE**

IN € THOUSAND	JAN. 1, 2011	CHANGE	DEC. 31, 2011	CHANGE	DEC. 31, 2012
Shares issued	353,317	0	353,317	0	353,317
Expenses on shares issued	-16,286	0	-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	4,328	144	4,472	90	4,562
Total	343,704	144	343,848	90	343,938

#### (51) Accumulated deficit

#### **ACCUMULATED DEFICIT**

IN € THOUSAND	JAN. 1, 2011	CHANGE	DEC. 31, 2011	CHANGE	DEC. 31, 2012
Net gain/loss	-333,098	6,281	-326,817	-9,859	-336,676
Total	-333,098	6,281	-326,817	-9,859	-336,676

#### (52) Other reserves

#### OTHER RESERVES

IN € THOUSAND	JAN. 1, 2011	CHANGE	DEC. 31, 2011	CHANGE	DEC. 31, 2012
Net gain/loss on available-for-sale financial assets	1	-4	-3	-3	-6
Currency translation adjustments	-6,891	713	-6,178	6,055	-123
Total	-6,890	709	-6,181	6,052	-129

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. As a result of Medigene Ltd. being wound up in the 2012 fiscal year, an expense of €6,166 thousand relating to the deconsolidation was realized and consequently, other reserves under shareholders' equity were largely written back.

#### (53) Financial liabilities

Financial liabilities include the long-term portion of the liability relating to the transfer of future cash flows from the 2% royalty share in Eligard® revenue to Cowen, according to IAS 32 and 39. This item totaled  $\epsilon$ 11,906 thousand at closing date, and will be amortized over the Eligard® patent term of approx. ten years  $\Rightarrow$  see notes (27), (33), (61) and (62).

#### (54) 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, 2012	DEC. 31, 2011
Present value of benefit obligations	2,115	1,835
Fair value of plan assets	-1,812	-1,601
Subtotal	303	234
Unrecognized actuarial gains/losses	-48	21
Obligations in the balance sheet	255	255

The plan assets comprise reinsurance policies. As of the reporting date December 31, 2012, the actual income from the reinsurance policies amounted to €69 thousand (2011: €59 thousand). The following amounts were recognized under personnel expenses in the income statement:

#### **EXPENSES RECOGNIZED IN THE INCOME STATEMENT**

IN€THOUSAND	2012	2011
Current service cost	45	54
Interest expense	90	91
Expected return on plan assets	-65	-61
Total included in personnel expenses	70	84

#### **ACTUARIAL ASSUMPTIONS**

IN %	2012	2011
Discount rate	3.6	4.9
Expected rate of return on plan assets	3.6	4.0
Future salary increases	3.6	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 rollows:		
IN € THOUSAND		

Benefit obligations at Jan. 1, 2011	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
Interest expense	90
Current service cost	45
Plan members contributions	9
Assumption of contract	64
Actuarial gains	72
Benefit obligations at Dec. 31, 2012	2,115
of which	
funded by plan assets	1,812
not funded by plan assets	303

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

IN € THOUSAND	
Fair value of plan assets at Jan. 1, 2011	1,491
Expected return on plan assets	61
Employer contributions	75
Member contributions	13
Benefits paid	-37
Actuarial losses	-2
Fair value of plan assets at Dec. 31, 2011	1,601
Expected return on plan assets	65
Employer contributions	69
Plan member contributions	9
Assumption of contract	64
Actuarial gains	4
Fair value of plan assets at Dec. 31, 2012	1.812

The figures for the current and previous reporting periods since the pension obligations first arose are as follows:

IN€THOUSAND	2012	2011	2010	2009	2008
Benefit obligations	2,115	1,835	1,687	1,608	1,414
Fair value of plan assets	-1,812	-1,601	-1,491	-1,528	-1,303
Deficit	303	234	196	80	111
Actuarial gains	-48	21	49	91	76
Experience adjustments on plan liabilities	42	-1	50	-16	-40
Experience adjustments on plan assets	-4	3	23	25	57

Explanation of the effect of IAS 19 (revised in 2011), starting January 1, 2013

At December 31, 2012, a so-called unrecognized actuarial loss of €48 thousand existed. This amount has to be posted at January 1, 2013

from shareholders' equity to accruals, with no effect on income. The full deficit (obligations in the balance sheet) of  $\[ \in \]$  303 thousand is considered in the balance sheet at January 1, 2013. According to IAS 19 (revised in 2011), the interest rate of the plan assets in the pension expenses 2013 is determined with a discount rate of 3.6%. For 2013, this results in an assumed return of  $\[ \in \]$  67 thousand. Following the previous IAS 19, an expected return based on an assumed interest rate on the plan asset of 4.0% would add up to  $\[ \in \]$  74 thousand. This would result in  $\[ \in \]$  7 thousand less pension expenses in 2013, according to the previous IAS 19. Currently there is no unrecognized passed service cost.

Applying IAS 19 (revised in 2011), the unrecognized loss of  $\le$  48 thousand at December 31, 2012 is to be considered in the balance sheet at January 1, 2013, with no effect on income, and expenses in 2013 are  $\le$ 7 thousand higher.

#### (55) Taxes

The major components of the income tax expenses for the 2012 and 2011 fiscal years are as follows:

#### **INCOME TAXES**

Income tax expense reported in income statement	-82	-630
Deferred taxes:	0	0
Adjustments in respect of current income tax of previous year	-13	0
Current income tax expense	-69	-630
Current income taxes:		
IN€THOUSAND	2012	2011

In the reporting period, a tax expense of €82 thousand was posted in the income statement. It essentially resulted from foreign withholding tax on license fees received by Medigene AG. In the previous year, the Group reported a tax expense of €630 thousand as a result of the positive net income for the year at Medigene AG.

Deferred taxes as of December 31, 2012 related to the following items:

#### **DEFERRED TAXES**

IN € THOUSAND CONSOLIDATED BALANCE SHEET			CONSOLIDATED INCOME STATEMENT	
-	DEC. 31, 2012	DEC. 31, 2011	2012	2011
Deferred tax assets				
Deferred taxes on tax loss carryforwards				
Germany	47,233	45,412	1,821	58
USA	17,664	18,004	-340	1,970
United Kingdom	0	1,911	-1,911	0
	64,897	65,327	-430	2,028
non deductible	-61,985	-62,847	862	-2,007
Net	2,912	2,480	432	21
Different useful lives of tangible assets	13	20	-7	-30
Other taxes from grants	1,834	1,870	-36	194
Derivative financial instruments	0	0	0	-59
Share of result of associates	134	112	22	112
Other assets	4	0	4	0
Other liabilities	7	0	7	0
Prepaid expenses	0	20	-20	-3
Liability pension insurance	321	293	28	25
Valuation of accruals	6	12	-6	-23
	2,319	2,327	-8	216
non deductible	-1,975	-1,990	15	-249
Net	344	337	7	-33
B.C. Lie Lie Lieber				
Deferred tax liabilities				
Capitalization of acquired licenses	2,899	2,634	-265	31
Pension accruals	210	183	-27	-19
Other accruals	147	0	-147	0
	3,256	2,817	-439	12
Deferred tax income/ expenses			0	0
Deferred tax asset/liabilities (balance)	0	0		

In 2012 and 2011, 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, 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.

The change of the unrecognized deferred tax assets is the balance of changes of tax losses carried forward and effects of the current year.

#### INCOME TAXES

IN € THOUSAND	2012	2011
Result before income tax from continued operations	-14,795	-15,474
Result before income tax from discontinued operations	5,018	22,385
Result before income tax	-9,777	6,911
Expected tax income/expense	2,574	-1,819
Use of German tax loss carryforwards	0	2,040
Increase in unrecognized deferred tax assets	-1,508	-1,198
Winding-up OCI (derecognition investment UK)	-1,623	0
Non-deductible expenses	-59	-31
Difference from German trade tax	-7	-17
Difference from UK tax rate	-37	-21
Difference from US tax rate	25	48
Tax-free revenue	622	351
Other	-69	17
Income tax expense	-82	-630
thereof from continued operations	-82	1,241
thereof from discontinued operations	0	-1,871
Effective tax rate in%	1	9

The breakdown of tax loss carryforwards is as follows:

#### TAX LOSS CARRYFORWARDS

IN€THOUSAND	DEC. 31, 2012	DEC. 31, 2011
Corporate income tax Germany	180,293	173,352
Trade tax Germany	178,110	171,228
State tax USA	42,326	43,066
Federal tax USA	40,947	41,754
Corporate tax UK	0	6,826

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.

It was possible to use the loss carryforwards of the subsidiary Medigene Ltd. in the United Kingdom without restriction for as

long as the company's tax identity remained in place. In view of the winding up and deconsolidation of Medigene Ltd., the relevant loss carryforwards lapsed 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.

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

The trade accounts payable of  $\[ \]$ 779 thousand as of the end of the reporting period (2011:  $\[ \]$ 773 thousand) consisted in unpaid invoices issued primarily for services utilized by Medigene. For the maturity analysis of the financial liabilities, please refer to  $\[ \]$ 7 note (61).

Other financial liabilities amounting to  $\epsilon$ 2,888 thousand (2011:  $\epsilon$ 2,344 thousand) include the short-term portion of the liability relating to the transfer of future cash flows from the 2% share in Eligard\* revenue to Cowen totaling  $\epsilon$ 927 thousand (2011:  $\epsilon$ 0), bonus payments due of  $\epsilon$ 626 thousand (2011:  $\epsilon$ 725 thousand), holiday entitlements amounting to  $\epsilon$ 191 thousand (2011:  $\epsilon$ 175 thousand) and license payments not yet billed of  $\epsilon$ 150 thousand (2011:  $\epsilon$ 891 thousand).

#### (57) Deferred income

Deferred income totaled €372 thousand in the reporting period. It mainly resulted from short-term deferred income of €68 thousand (2011: €77 thousand) and long-term deferred income of €304 thousand (2011: €0). Medigene received the long-term deferred income as an advance payment upon signing the contract relating to the development and marketing partnership for EndoTAG\*-1 agreed with SynCore Biotechnology Co., Ltd. (hereinafter referred to as »SynCore«) in July 2012.

#### (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.

In 2004, Medigene concluded an agreement with the insolvency administrator of MBT, under which payments by Medigene to the insolvency administrator were agreed in the event of certain milestones being achieved, including a milestone payment upon commencement of a clinical phase III trial. In connection with signing the SynCore agreement in July 2012, the Company has now come to an agreement with the insolvency administrator, which provides for Medigene not making any further milestone payments, but only having to transfer a low percentage amount of the income achieved with EndoTAG\*-1. According to the agreement, the total amount is limited to €11 million. The management does not believe that accruals need to be formed for this, since the relevant payments will not become due until specific events occur.

As of the balance sheet date, deposit guarantees of €375 thousand (2011: €397 thousand) had been granted to property lessors.

Expenses of  $\epsilon_{1,100}$  thousand (2011:  $\epsilon_{1,747}$  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
2013	976
2014	961
2015	903
2016	514
Later	1
Minimum lease obligations	3,355

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 five 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  $\rightarrow$  note (48), no open credit lines were available as of December 31, 2012.

#### (60) Related parties

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

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. In the previous year, Medigene, Inc. granted a fixed-rate loan to Catherex, Inc. amounting to €114 thousand, which was increased to €216 thousand in the reporting period → 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 > I) Executive Board and Supervisory Board. 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 are trade accounts payable, other financial liabilities and borrowings. 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's business activities expose it to various financial risks: market risks (including interest rate risks and foreign exchange 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 interest-based 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
2012	50	91
2011	50	69

#### 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, yen and euro. The subsidiary Medigene Inc. uses the US dollar as its functional currency. Following the winding-up and deconsolidation of Medigene Ltd. in the reporting period ended, a foreign exchange risk between the British pound and euro no longer exists for the Group.

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, 19% is generated in US dollars. In total, 86% of procurements costs were incurred in US dollars.

The Medigene Group reduces the foreign exchange risks resulting from its subsidiary's 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 (\$)1)

			` '
	EXCHANGE RATE DEVELOPMENT OF \$	EFFECTS ON RESULTS BEFORE INCOME TAXES IN€THOUSAND	EFFECTS ON SHARE- HOLDERS'EQUITY IN € THOUSAND
2012	+5%	-74	-74
	-5%	63	63
2011	+5%	-41	-41
	-5%	31	31

<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.

#### SENSITIVITY ANALYSIS OF FOREIGN EXCHANGE RISK (£)1)

	EXCHANGE RATE DEVELOPMENT OF £	EFFECTS ON RESULTS BEFORE INCOME TAXES IN € THOUSAND	EFFECTS ON SHARE- HOLDERS'EQUITY IN € THOUSAND
2012	+5%	0	0
	-5%	0	0
2011	+5%	-12	-12
	-5%	13	13

<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  $\Rightarrow$  see note (44).

#### Credit risk

The Group has no significant concentration in terms of potential credit risks. A business relationship exists with a major customer, Fougera Pharmaceuticals, Inc., Melville, New York, USA. The creditworthiness of the customer 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, 2012, the Group's financial liabilities were due as shown below. The amounts disclosed are based on contractual payments discounted at a rate of 3.93%.

#### 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**

		2012	2011
Liquidity cover ratio in%	<u>Cash x 100</u> Balance sheet total	33	24
Equity ratio in %	<u>Equity x 100</u> Balance sheet total	72	90

#### **FINANCIAL LIABILITIES**

IN€THOUSAND			MATUR	ITY		
	UP TO 30 DAYS	30-90 DAYS	3-12 MONTHS	1-5 YEARS	>5 YEARS	TOTAL
Balance at Dec. 31, 2012						
Trade accounts payable	719	0	0	0	0	719
Financial liabilities	0	0	0	5,042	6,864	11,906
Other current liabilities	798	875	1,215	258	0	3,146
Total	1,517	875	1,215	5,300	6,864	15,771
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
Total	2,413	1,433	271	281	0	4,398

# (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, 2012:

#### OTHER FINANCIAL ASSETS AND LIABILITIES

IN € THOUSAND	CARRYING	AMOUNT	FAIR VALUE		
	2012	2011	2012	2011	
Financial assets					
Cash and cash equivalents	20,113	12,811	20,113	12,811	
Trade accounts receivable	1,139	1,897	1,139	1,897	
Available-for-sale financial					
assets	146	148	146	148	
Loans and receivables	216	114	216	114	
Investment in					
Immunocore Ltd.	3,533	0	3,533	0	
Financial liabilities					
Financial liabilities	11,906	0	11,906	0	
Other non-current liabilities	258	281	258	281	
Trade accounts payable	719	1,773	719	1,773	
Other current liabilities	2,888	2,344	2,888	2,344	

The financial liabilities totaling €11,906 thousand are stated at fair value through profit or loss, which are non-cash items. The fair value is calculated on the basis of the estimated future revenue from royalties. Income and interest 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 (for pensions) units reported under available-for-sale financial assets which are valued at the stock market price as of the reporting date. Loans and receivables are allocated to the second stage. The financial liability relating to the transfer of future cash flows in connection with the 2% share in Eligard\* sales to Cowen is recorded under the third category (>> see notes (27) and (33).

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

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

Expansion of the trial plan and new timelines for the development of RhuDex® in PBC

In February 2013, Medigene announced the expansion of the clinical development plan for RhuDex\* in the indication primary biliary cirrhosis (PBC). The planned phase IIa trial is to be expanded by a control arm to comprise four trial arms, and the planned treatment period for patients will be extended from three to six months. The aim is to increase the informative value of the trial data collected, in order to confirm the mode of action of RhuDex\* in autoimmune diseases and facilitate the future approval of RhuDex\* for PBC. Subject to successful completion of the work still required to prepare the trial and approval of the trial by the competent authorities, the schedule provides for a start of this expanded phase II trial no later than in the first half of 2014. It replaces the phase IIa trial with RhuDex\* originally planned for 2013. As a result, the major financial expenses relating to the phase II trial will be deferred to 2014 and thereafter.

# Inclusion of Veregen° into the European Guideline for the Management of Anogenital Warts

In February 2013, Medigene announced that Veregen® was included into the 2012 European Guideline for the Management of Anogenital Warts. This internationally accepted treatment guideline, developed by clinical experts, recommends Veregen® (Sinecatechins 10 % & 15% ointment) as a treatment option for genital warts.

# F) CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

The consolidated statement of changes in shareholders' equity for the 2012 and 2011 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 2012 and 2011 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 2012.

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, 2012. The business units »Marketed Products« and »Drug Candidates« identified within the Group in accordance with IFRS 8 consist of the following:

#### **Marketed Products**

- → Eligard® for the treatment of prostate cancer (discontinued operations)
- → Veregen® for the treatment of genital warts

#### Drug Candidates & technologies

- → EndoTAG®-1 for the treatment of solid tumors
- → RhuDex® for the treatment of autoimmune diseases
- → 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 €2,727 thousand (2011: €4,183 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
2012						
Revenue with external customers	8,384	0	8,384	0	-5,000	3,384
Other income	2,518	5	2,523	409	-32	2,900
Inter-segment sales <sup>2)</sup>	336	0	336	-336	0	0
Total revenue	11,238	5	11,243	73	-5,032	6,284
Segment operating result <sup>3)</sup>	5,718	-17,156	-11,438	16	-5,018	-16,440
Depreciation and impairment	0	-693	-693	-154		-847
Share of result of associates	0	0	0	-59		-59
Assets						
Investment in associates	0	0	0	2,727		2,727
Segment investments <sup>4)</sup>	6	55	61	209		270
Segment assets <sup>5)</sup>	3,344	29,581	32,925	28,330		61,255
Segment liabilities <sup>6)</sup>	68	0	68	16,972		17,040
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

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

³) Segment operating result does not include any interest income (2012: €55 thousand; 2011: €131 thousand), any interest expense (2012: €1,260 thousand; 2011: €0), foreign exchange gains or losses (2012: €689 thousand; 2011: €-717 thousand), or any share of result of associates (2012: €-59 thousand; 2011: €766 thousand). Segment operating result includes gains from inter-segment sales (2012: €336 thousand; 2011: €238 thousand).

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

<sup>5|</sup> Segment assets under »Reconciliation« include in part non-current assets (2012: €7,227 thousand; 2011: €5,275 thousand), cash and cash equivalents (2012: €20,113 thousand; 2011: €1,169 thousand), and other current assets (2012: €990 thousand; 2011: €1,169 thousand).

<sup>6)</sup> Segment liabilities under »Reconciliation« include non-current liabilities (2012: €12,723 thousand; 2011: €536 thousand), trade accounts payable and other liabilities (2012: €3,607 thousand; 2011: €4,117 thousand), and tax liabilities (2012: €642 thousand; 2011: €630 thousand).

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

#### **REVENUE WITH EXTERNAL CUSTOMERS**

IN € THOUSAND	2012	2011
UK	5,000	27,668
USA	2,115	1,744
Other	1,269	556
Total	8,384	29,968

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  $\epsilon_5$ ,000 thousand.

The major portion of non-current assets is held in Germany. In addition, a shareholding is held in an associate in 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 opponent filed a notice of appeal against the decision of the European Patent Office. A decision in this appeal procedure is not expected until 2014. Medigene continues to assume that the patent will be upheld with a scope that remains to protect the EndoTAG\*-1 product.

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 in their declaration of compliance of December 6, 2012 that Medigene AG complies with the recommendations of the German Corporate Governance Code in the versions dated May 26, 2010 and May 15, 2012, with the exceptions mentioned in the declaration of compliance. The recommendations of the Code which Medigene AG does not implement are explained in detail and justified in the declaration 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  $\Rightarrow$  http://www.medigene.com/media-investors/corporate-governance.

#### (66) Auditing fees

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

#### **AUDITING FEES**

IN € THOUSAND 2012	2011
Auditing services 143	136
Other services 28	30
Total 171	166

#### I) EXECUTIVE BOARD AND SUPERVISORY BOARD

#### (67) Executive Board

#### Changes in the Executive Board

With effect from October 1, 2012, the Supervisory Board appointed Peter Llewellyn-Davies as member of the Executive Board of Medigene AG. He succeeded Arnd Christ as Chief Financial Officer, who stepped down from the Company's Executive Board on September 19, 2012.

#### Remuneration of the Executive Board

Remuneration of the members of the Executive Board totaled  $\[earset{\epsilon}_1,035\]$  thousand in the fiscal year ended (2011:  $\[earset{\epsilon}_944\]$  thousand), including pension expenses of  $\[earset{\epsilon}_52\]$  thousand (2011:  $\[earset{\epsilon}_48\]$  thousand) and vehicle leasing costs for company cars of  $\[earset{\epsilon}_31\]$  thousand (2011:  $\[earset{\epsilon}_26\]$  thousand). In addition, stock options with a fair value of  $\[earset{\epsilon}_34\]$  thousand (2011:  $\[earset{\epsilon}_33\]$  thousand) were issued to the Executive Board.

In fiscal year 2012, Medigene made a payment of €6 thousand (2011: €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 to approve the remuneration system for Executive Board members. The resolution approving the current remuneration system was passed at the Annual General Meeting on May 11, 2010. A majority of 96% of the share capital represented adopted the remuneration system for Executive Board members.

## 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. At the Annual General Meeting 2010, the Executive and Supervisory Boards presented the current

remuneration system for Executive Board members. It was adopted by a majority of 96% of the share capital represented. The remuneration system has been implemented in all current employment contracts for Executive Board members. It is described as follows:

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 performance-related remuneration

- → 65% of the annual performance-related payment granted is paid after the Company's financial statements for the relevant fiscal year have been adopted. Payment of the remaining 35% of the annual performance-related remuneration granted in a specific fiscal year is deferred for a period of three years.
- → At the end of this three-year period, the Supervisory Board decides whether and to what extent sustained corporate growth can be affirmed. Based on this decision, the Supervisory Board resolves whether and to what extent the remaining 35% of the relevant annual performance-based remuneration will be paid to the respective Executive 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 30 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. 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

- $\Rightarrow$  a company car,
- → reimbursement of business travel expenses,
- → accident insurance cover and payment of the relevant insurance premiums,
- $\Rightarrow$  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 contracts of employment for Executive Board members Dr. Frank Mathias and Peter Llewellyn-Davies include special termination rights for both the Company and the Executive Board members in the event of a change in control.

A change in control within the meaning of the contractual agreement valid for Dr. Frank Mathias exists in the event of direct or indirect purchase of Company shares by a third party, which results in the third party directly or indirectly holding 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.

A change in control within the meaning of the contractual agreement valid for Peter Llewellyn-Davies 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).

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

The above-mentioned Executive Board members each have a special termination right for a period of one year after the date of the change in control if this change results in an unacceptable shift in the previous duties and responsibilities of the relevant Executive Board member (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 relevant 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 a 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 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 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).

If the term of office of Executive Board member Peter Llewellyn-Davies comes to an end as a result of the Company exercising its special termination right referred to above, he will be entitled to receive a severance payment in the amount of the gross remuneration up to the regular end of his contract, a pro rata temporis gross bonus (without stock options) up to the regular end of 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 €390 thousand (caps).

In the event that Executive Board member Peter Llewellyn-Davies resigns under the special termination conditions listed above, he will be entitled to receive a severance payment in the amount of three times the gross monthly sum for every completed year of his membership of the Company's Executive 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 (caps). The minimum severance payment amounts to six gross monthly salary payments (lower limit).

#### **EXECUTIVE BOARD COMPENSATION 2012**

EXECUTIVE BOARD MEMBER	FIXED COMPENSATION	VARIABLE AND PER- FORMANCE BASED	FRINGE BENEFIT <sup>2)</sup>	VARIABLE COMPONENTS IN THE FORM OF STOCK OPTIONS	
		COMPONENTS <sup>1)</sup>	-	NUMBER OF STOCK	FAIR VALUE OF OPTIONS
	IN€THOUSAND	IN€THOUSAND	IN€THOUSAND	OPTIONS	IN€THOUSAND
Dr. Frank Mathias Chief Executive Officer	375	187	40	35,000	17
Arnd Christ Chief Financial Officer (until September 19, 2012)	195	97	34	26,250	13
Peter Llewellyn-Davies Chief Financial Officer (since October 1, 2012)	65	33	9	7,500	4
Total	635	317	83	68,750	34

<sup>&</sup>lt;sup>1)</sup> On the basis of the accruals for 2012 (without discounting) in the event of 100% payment.

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

#### Dr. Frank Mathias

External positions

German supervisory board positions:

→ Faller KG, Waldkirchen

Positions outside Germany:

→ Catherex, Inc., USA

#### Arnd Christ (until September 19, 2012)

External positions

German supervisory board positions:

→ DNS Beteiligungsgesellschaft mbH, Bessenbach

Positions outside Germany:

→ Immunocore Ltd., United Kingdom (until September 18, 2012)

#### Peter Llewellyn-Davies (since October 1, 2012)

External positions

Positions outside Germany:

→ Immunocore Ltd., United Kingdom (since October 1, 2012)

<sup>&</sup>lt;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 €255 thousand in 2012 (2011: €229 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. The greater scope of activities of the Supervisory Board Chairman and his Deputy are taken into account and reflected accordingly by higher remuneration. Details regarding the subscription rights of members of the Supervisory Board and Executive Board are provided in ≥note (69). No advances were paid to members of the Supervisory Board and Executive Board.

#### **SUPERVISORY BOARD REMUNERATION 2012**

***************************************		
SUPERVISORY BOARD MEMBER	FIXED COMPENSATION	FEES FOR ATTENDING MEETINGS
	IN € THOUSAND	IN€THOUSAND
Prof. Dr. Ernst-Ludwig Winnacker Chairman	48	20
Prof. Dr. Norbert Riedel Deputy Chairman	36	15
Dr. Pol Bamelis Member	24	10
Dr. Mathias Albert Boehringer Member	24	10
Dr. Thomas Werner Member	24	10
Klaus Kühn Member	24	10
Total	180	75

Supervisory Board members of Medigene AG:

#### Prof. Dr. Ernst-Ludwig Winnacker

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

External positions

German supervisory board positions:

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

#### 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

#### External positions

Positions outside Germany:

→ ARIAD Pharmaceuticals, Inc., Cambridge, MA, USA

#### Dr. Pol Bamelis

since May 23, 2001

former Executive Board member, Bayer AG, Leverkusen, Germany

#### External positions

German supervisory board positions:

→ Hemacon GmbH, Düsseldorf

Positions outside Germany:

- → Actogenix N.V., Belgium
- → PolyTechnos Ltd., Guernsey, United Kingdom

#### Dr. Mathias Albert Boehringer

since July 16, 2008

Diploma in business administration, Ingelheim, Germany

External positions

German supervisory board positions:

- → Boehringer Ingelheim Gesellschafterausschuss, Ingelheim
- → Phenex Pharmaceutical AG, Ludwigshafen
- → Phorms Management AG, Berlin

#### Dr. Thomas Werner

since February 2, 2010

Freelance management consultant, Utting am Ammersee, Germany

#### External positions

German supervisory board positions:

- → 4SC AG, Planegg/Martinsried
- → SuppreMol GmbH, Planegg/Martinsried
- ⇒ BSN Medical GmbH, Hamburg (since September 2012)
- → Blackfield AG, Köln (since September 2012)

Positions outside Germany:

- → SkyePharma plc., United Kingdom
- → Basilea Pharmaceutical Ltd., Switzerland

#### Klaus Kühn

since August 4, 2011

former Executive Board member, Bayer AG, Leverkusen, Germany

#### External positions

German supervisory board positions:

- → Flossbach von Storch AG, Köln
- → Hella KGaA Hueck & Co., Lippstadt
- → 4SC AG, Planegg/Martinsried (since July 2012)

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

MEMBER	SHA	RES	OPTIONS	
	DEC. 31, 2012	DEC. 31, 2011	DEC. 31, 2012	DEC. 31, 2011
Prof. Dr. Ernst-Ludwig Winnacker Chairman of Supervisory Board, Co-founder	274,476	274,476	0	0
Prof. Dr. Norbert Riedel Deputy Chairman of Supervisory Board	3,300	3,300	0	0
Dr. Pol Bamelis Supervisory Board member	400	400	0	0
Dr. Mathias Albert Boehringer Supervisory Board member	0	0	0	0
Dr. Thomas Werner Supervisory Board member	0	0	0	0
Klaus Kühn Supervisory Board member	0	0	0	0
Total Supervisory Board	278,176	278,176	0	0
Dr. Frank Mathias Chief Executive Officer	6,000	6,000	162,500	127,500
Arnd Christ Chief Financial Officer (until September 19, 2012)	5,000	5,000	70,528	44,278
Peter Llewellyn-Davies Chief Financial Officer (since October 1, 2012)	6,000	-	7,500	-
Total Executive Board	17,000	11,000	240,528	171,778

### (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)

No notifications 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) have been received by the Company for fiscal year 2012. In respect of previous fiscal years, 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 25, 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 25, 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 has not touched any further threshold since December 11, 2006 and amounted to 6.7598%. This corresponded to 2.403.610 votes at that time. Of these, 2.403.610 votes – corresponding to 6.7598% 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 25, 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).

The MLawGroup, Munich, Germany notified Medigene AG on March 25, 2010 on behalf of its client Advent Management III Ltd., Edinburgh, United Kingdom that Advent Management III Ltd. Partnership's shareholding in Medigene AG has not touched any further threshold since December 11, 2006 and amounted to 6.7598%. This corresponded to 2.403.610 votes at that time. Of these, 2.403.610 votes – corresponding to 6.7598% 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).

Santo Holding (Deutschland) GmbH, Königstrasse 1 A, 70173 Stuttgart, Germany notified Medigene AG on November 6, 2009 that its share-holding 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 1A, 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 13, 2013 Medigene AG

**Dr. Frank Mathias**Chief Executive Officer

**Peter Llewellyn-Davies** Chief Financial Officer

## **CONSOLIDATED STATEMENT OF CHANGES IN FIXED ASSETS**

OF MEDIGENE AG FOR THE PERIOD JANUARY 1 TO DECEMBER 31, 2012 AND 2011

Total	40,861	-3	270	-161	40,967	
				-		
Goodwill	3,141	0	0	0	3,141	
Intangible assets	30,993	-1	104	0	31,096	
Property, plant and equipment	6,727	-2	166	-161	6,730	
	JAN. 1, 2012	TRANSLATION ADJUSTMENTS	ADDITION	DISTOSAL	BEC. 31, 2012	
	JAN. 1, 2012	CURRENCY	ADDITION	DISPOSAL	DEC. 31, 2012	
IN € THOUSAND			INITIAL COST			

Total	45,142	13	406	-4,700	40,861	
Goodwill	3,141	0	0	0	3,141	
Intangible assets	34,968	9	112	-4,096	30,993	
		<u> </u>		<u> </u>		
Property, plant and equipment	7,033	4	294	-604	6,727	-
	JAN. 1, 2011	CURRENCY TRANSLATION ADJUSTMENTS	ADDITION	DISPOSAL	DEC. 31, 2011	
				BIGBOOM		
IN € THOUSAND			INITIAL COST			

ACCUMULATED DEPRECIATION					CARRYING AMOUNT	
JAN. 1, 2012	CURRENCY TRANSLATION ADJUSTMENTS	ADDITION	DISPOSAL	DEC. 31, 2012	DEC. 31, 2012	DEC. 31, 2011
5,898	-2	388	-158	6,126	604	829
3,268	0	459	0	3,727	27,369	27,725
929	0	0	0	929	2,212	2,212
10,095	-2	847	-158	10,782	30,185	30,766

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

### **AUDITORS' REPORT**

»We have audited the consolidated financial statements prepared by Medigene AG, Martinsried/Planegg, comprising the statement of financial position, the income statement, the statement of comprehensive income, the statement of changes in equity, the statement of cash flows and the notes to the consolidated financial statements, together with the group management report for the fiscal year from January 1, 2012 to December 31, 2012. 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. 315 a (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 IFRS as adopted by the EU, the additional requirements of German commercial law pursuant to Sec. 315 a (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 13, 2013

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Dr. Napolitano Weides

German Public Auditor German Public Auditor

MEDIGENE AG ANNUAL REPORT 2012 RESPONSIBILITY STATEMENT

## **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 13, 2013

The Executive Board

Dr. Frank Mathias Peter Llewellyn-Davies

### REPORT OF THE SUPERVISORY BOARD

During the 2012 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 deviation 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 2012 fiscal year, five meetings (March 15, 2012, May 23, 2012, July 3, 2012, September 26, 2012 and December 5, 2012) were held. None of the members of the Supervisory Board participated in less than half of the meetings. In 2013, prior to the meeting that approved the financial statements on March 13, 2013, the full Supervisory Board held one meeting (January 29, 2013) and one conference call (February 4, 2013) and the Audit Committee held one conference call (March 6, 2013) and one meeting (March 11, 2013). 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 was also available to discuss matters one-on-one with the Executive Board. The Chairman of the Supervisory Board regularly spoke with the CEO, 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 project trends were the topics of regular plenary discussions. In fiscal year 2012, the Supervisory Board directed its particular attention to the financial position and the current business trend as well as to the obtaining comprehensive information about the EndoTAG\*-1 and RhuDex\* projects, activities relating to new partnerships for EndoTAG\*-1, the monetization of the 2% share of net sales revenue from the drug Eligard\* and approval and commercialization activities in connection with the Veregen\* project.

Furthermore, the Supervisory Board also took personnel decisions concerning the Executive Board in the 2012 fiscal year. Based on the resolution dated September 18, 2012, the Supervisory Board appointed Peter Llewellyn-Davies as member of the Executive Board of Medigene AG for a period of two years with effect from October 1, 2012.

MEDIGENE AG ANNUAL REPORT 2012 REPORT OF THE SUPERVISORY BOARD

During the meeting on March 15, 2012, the Supervisory Board examined the annual and consolidated financial statements as at December 31, 2011 in detail in the presence of the auditors. The Executive Board gave a presentation to the Supervisory Board on a concept for the further development of RhuDex\*. Moreover, the Executive Board and Supervisory Board discussed the business plan for 2012. The Supervisory Board members discussed the targets for fiscal year 2012 amongst themselves, and also with the Executive Board, and adopted them.

On May 23, 2012, the Supervisory Board dealt in detail with the development projects, in particular the further development strategy for RhuDex\* and preparing for the decisions regarding the Company's two key strategic transactions in fiscal year 2012. The discussion centered on the ongoing contractual negotiations with Syncore Biotechnology Co. Ltd., Taiwan, regarding the conclusion of a development and marketing partnership agreement for EndoTAG\*-1. In addition, the Executive Board reported in detail on progress with the negotiations regarding the monetization of the remaining 2% share of net sales revenue from the drug Eligard\*. The Supervisory Board studied the content of the two envisaged transactions in depth and weighed up all relevant considerations relating to the decision-making process. Finally, the Supervisory Board prepared the 2012 Annual General Meeting on the occasion of this meeting and reviewed the efficiency of its own activities.

As part of a separate written decision-making procedure, the Supervisory Board subsequently approved the conclusion of an agreement for selling the share of Eligard\* net sales revenue on June 6, 2012.

The Supervisory Board approved the agreement with Syncore Biotechnology Co. Ltd. for the further partnership-based development of EndoTAG\*-1 in a separate written resolution on July 4, 2012. This resolution was preceded by a Supervisory Board meeting in the form of a conference call, as part of which the Supervisory Board members obtained detailed information about the content of the agreement to be concluded and deliberated extensively on whether the agreement should be signed.

In its meeting on September 26, 2012, the Supervisory Board dealt in detail with the development of Veregen\* and was informed by the Executive Board about the market trend for Veregen\* in particular.

The Executive Board also reported on the status of the RhuDex\* and EndoTAG\*-1 development projects and these were discussed.

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During the meeting on December 5, 2012, the Supervisory Board heard a report on the status of the clinical development of RhuDex\*. It was also informed by the Executive Board on the further partnership activities relating to EndoTAG\*-1. The Executive Board provided explanations on the Company's financial position. The Supervisory Board adopted the 2013 budget presented by the Executive Board. In this meeting, the Supervisory Board also obtained information about amendments to 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.

During its meeting on January 29, 2013, and the conference call on February 4, 2013, the Supervisory Board addressed the expansion of the clinical development plan for RhuDex®, as well as the budget planning and adjustments associated with it.

#### **Supervisory Board Committees**

A Compensation Committee and an Audit Committee existed throughout the 2012 fiscal year.

The Compensation Committee held two meetings in the course of 2012 and the Audit Committee held five meetings, four of which were conference calls.

The duties of the Compensation Committee cover matters related to the employment of Executive Board members. Its main tasks are the conclusion and amendment of 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 appointment of Peter Llewellyn-Davies as member of the Company's Executive Board as well as the associated conclusion of the relevant service contract. Due to the importance of these personnel issues, the discussions and decisions in this regard were taken by the entire Supervisory Board.

#### SUPERVISORY BOARD COMMITTEES

COMMITTEE	MEMBERS		
Compensation Committee	Prof. Dr. Ernst-Ludwig Winnacker (Chairman) Dr. Pol Bamelis Prof. Dr. Norbert Riedel		
Audit Committee	Klaus Kühn (Chairman) Dr. Mathias Boehringer Dr. Thomas Werner		

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. Furthermore, the Audit Committee regularly discussed the half-yearly and quarterly reports with the Executive Board prior to their publication. Moreover, it monitored the accounting process, the efficacy of the internal monitoring system, the risk management system and the internal audit.

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

#### Corporate Governance

In 2012, 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 5, 2012 and issued the annual declaration of compliance pursuant to section 161 of the German Stock Corporation Act (AktG). 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 2012 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

In 2012, no changes occurred in terms of the composition of the Supervisory Board.

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 2012 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, 2012 and the management's discussion and analysis of Medigene AG for the 2012 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 July 10, 2012. 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.

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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 13, 2013 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 where approved and reported in detail on the most important results of his audit, especially the 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.

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 13, 2013, the Supervisory Board approved the individual and consolidated financial statements as of December 31, 2012 in accordance with the recommendation of the Audit Committee. The financial statements have therefore been adopted.

The Supervisory Board wishes to thank the Executive Board and all Medigene employees for their successful efforts on behalf of the Company in the 2012 fiscal year. Due to their collective efforts, they achieved excellent results in the fiscal year ended in a difficult sector environment.

Planegg/Martinsried, March 2013

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

Ernt-lider Wilman

### **GLOSSARY**

#### Α

#### **AAVLP**

»Adeno-Associated Virus-Like Particle«
Adeno-associated virus-like particle, AAV-like particle

#### **Antibody**

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

#### Antigen

Substance recognized as being foreign by the immune system

#### 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**

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

#### C

#### CD28 protein, CD80 protein

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

#### CD80 antagonist

#### **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

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#### 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, impairment and other expenses

#### Endothelial cells

Line the interior surface of lymphatic and blood vessels

#### **Exploratory trials**

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

#### F

#### **FDA**

»Food and Drug Administration«

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

#### **Formulation**

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

#### G

#### Gemcitabine

Agent used in chemotherapy for e.g. pancreatic cancer

#### 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

#### **GMP**

»Good Manufacturing Practice«

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

#### Н

#### **HER2** receptor

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

#### **HGB**

»Handelsgesetzbuch« German Commercial Code

#### Human papillomaviruses (HPV)

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

#### 1

#### IAS

»International Accounting Standards«
Part of the International Financial Reporting Standards

#### **IFRIC**

»International Financial Reporting Interpretations Committee«

#### **IFRS**

»International Financial Reporting Standards«

#### IIT

»Investigator Initiated Trial«

Clinical trial of a drug candidate that is instigated, organized and financed by the medical profession. They focus on enhancing a specific therapy for patients

#### Indication

Disease; 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

#### N

#### Neoadjuvant setting

Therapy used to shrink a tumor before surgical removal of the tumor

#### 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

#### **Paclitaxel**

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

#### Primary biliary cirrhosis (PBC)

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

#### Pancreatic cancer

Malignant tumor of the pancreas

#### PCT

#### »Patent Cooperation Treaty«

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

MEDIGENE AG ANNUAL REPORT 2012 GLOSSARY 107

#### **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

#### 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

#### Т

#### 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

#### **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

### **TRADEMARKS**

March 22, 2013
Annual Report 2012
Press and Analyst conference call

May 16, 2013 3-Month Report 2013 Analyst conference call

July 16, 2013 Annual General Meeting

August 09, 2013 6-Month Report 2013 Analyst conference call

November 14, 2013 9-Month Report 2013 Analyst conference call Eligard®

is a trademark of Tolmar Therapeutics, Inc.

**EndoTAG®** 

is a trademark of Medigene AG

Medigene®

is a trademark of Medigene AG

Polyphenon E°

is a trademark of Mitsui Norin Co. Ltd.

RhuDex®

is a trademark of Medigene AG

Veregen®

is a trademark of Medigene AG

These trademarks may be held or licensed for specific countries.

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Medigene AG, Planegg/Martinsried

#### Concept, design and realization

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#### **Photographs**

Matthias Tunger, München

#### **Production**

Druckerei Kriechbaumer, München

#### Disclaimer

This annual report contains forward-looking statements that are based on certain assumptions and expectations made by the management of Medigene AG at the time of its publication. These forward-looking statements are therefore subject to unpredictable risks and uncertainties, so there is no guarantee that these assumptions and expectations will turn out to be accurate. Many of those risks and uncertainties are determined by factors that are beyond the control of Medigene AG and cannot be gauged with any certainty at this point in time. This includes future market conditions and economic developments, the behavior of other market participants, the achievement of targeted synergy effects as well as legal and political decisions. Medigene AG cannot preclude that actual results may differ substantially from those expectations expressed in or implied by the forward-looking statements. Medigene AG does not intend or assume any obligation to update any forward-looking statements to reflect events or circumstances after the date of this annual report.

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