

## GOALS DEFINED, ROUTE OUTLINED

2009

2010

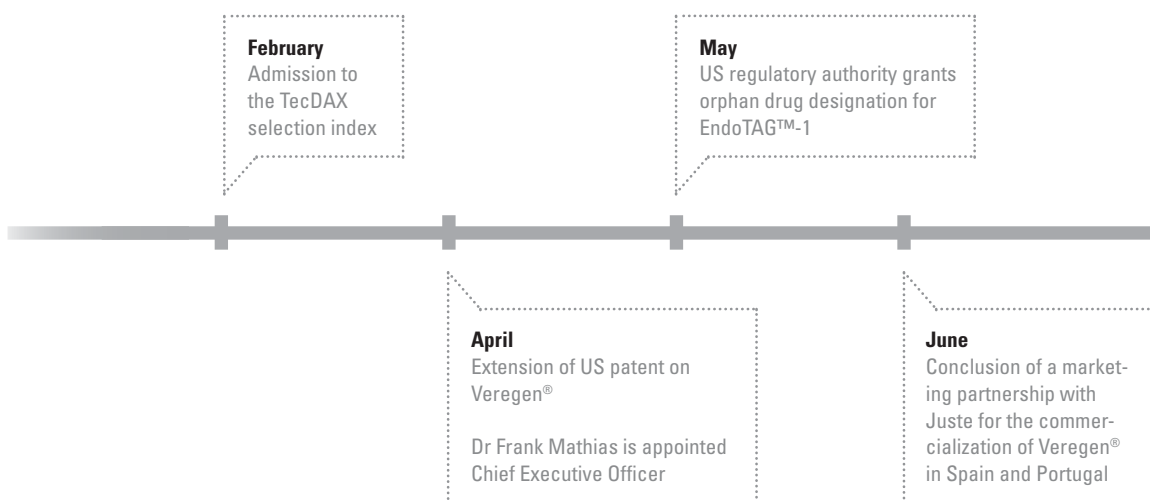
2011–2015

# Key figures

## of MediGene AG

In € thousand	2009	2008	Change
<b>Income statement</b>			
Product sales	37,859	33,507	13%
Other operating income	1,607	6,099	-74%
Total revenue	39,466	39,606	0%
Cost of sales	-31,482	-26,926	17%
Gross profit	7,984	12,680	-37%
Selling, general, and administrative expenses	-9,124	-10,484	-13%
Research and development expenses	-18,499	-27,465	-33%
EBITDA	-18,808	-24,584	-23%
Loss resulting from spin-off	0	-6,431	-%
Operating result	-19,639	-31,700	-38%
Result before income tax	-21,935	-33,146	-34%
Net loss for the year	-21,962	-30,790	-29%
Net loss per share in €	-0.64	-0.91	-30%
Weighted average number of shares	34,231,294	34,008,289	1%
Personnel expenses	-13,043	-16,059	-19%
<b>Cash flow</b>			
Cash flow from operating activities	-18,925	-27,361	-31%
Cash flow from investing activities	226	4,349	-95%
Cash flow from financing activities	5,735	1,734	>200%
<b>Balance sheet data</b>			
Cash and cash equivalents	12,251	25,101	-51%
Balance sheet total	65,723	80,746	-19%
Current liabilities	13,606	15,456	-12%
Non-current liabilities	244	384	-36%
Shareholders' equity	51,873	64,906	-20%
Equity ratio	79%	80%	-1%
<b>Employees as at Dec. 31</b>			
	114	133	-14%
<b>MediGene share</b>			
Total number of shares outstanding as at Dec. 31	35,557,493	34,028,561	4%
Share price (closing price, Xetra)	3.58	4.30	-17%
Dividend in €	0	0	-%

## 2009 milestones



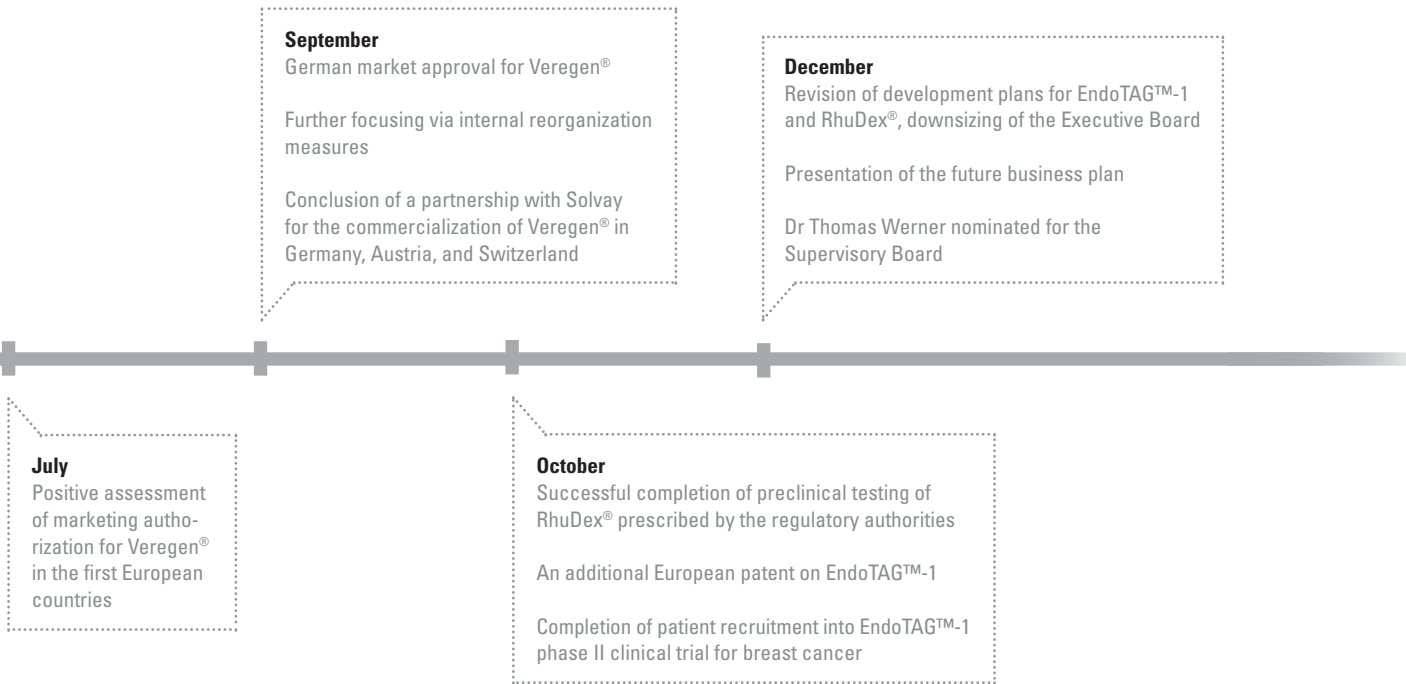
## Clinical drug pipeline

Product	Indication	Clinical phase			Approval	Market
		I	II	III		
<b>Drugs on the market</b>						
Eligard® <sup>1)</sup> <a href="#">see page 12</a>	Prostate cancer	■	■	■	■	■
Veregen® <sup>2)</sup> <a href="#">see page 13</a>	Genital warts	■	■	■	■	■
<b>Drugs in clinical development</b>						
EndoTAG™-1 <a href="#">see page 10</a>	Pancreatic cancer	■	■			
	Hormone-resistant breast cancer	■	■			
RhuDex® <a href="#">see page 11</a>	Rheumatoid arthritis	■	■			
Chance of reaching the market <sup>3)</sup>		10–30%	30–60%	60–80%	80–90%	

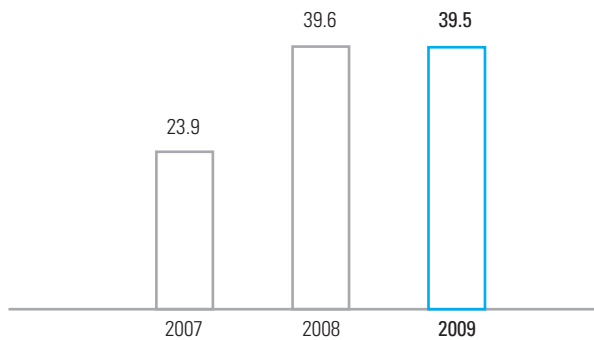
<sup>1)</sup> Licensed from Tolmar Inc., distributed by Astellas Pharma Ltd.

<sup>2)</sup> Marketing partnerships with Nycomed for the US market, with Juste S.A.Q.F. for Spain and Portugal, and with Solvay Arzneimittel GmbH for Germany, Austria, and Switzerland.

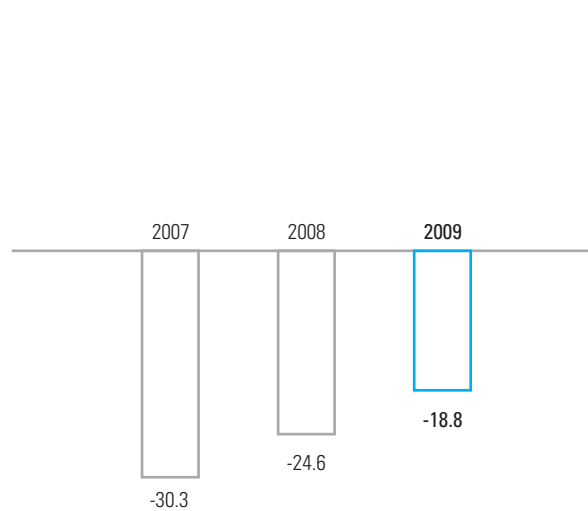
<sup>3)</sup> Industrial average, source: Ernst & Young, 2009.



**Total revenue**  
In € million



**EBITDA**  
In € million



**MediGene strives to contribute to the successful treatment of critically ill cancer patients and to improve their quality of life.**

**In five years, MediGene wants to be a sustainably profitable oncology company which develops innovative drugs and brings them to the market in collaboration with partners.**

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## Management interview

MediGene's Chief Executive Officer Dr Frank Mathias and Chief Financial Officer Dr Thomas Klaue answer questions regarding the business performance in 2009 as well as the future path of MediGene.

### **Dr Mathias, you took over the management of MediGene AG in May of 2009. What have you accomplished since then?**

**Dr Frank Mathias:** We thoroughly analyzed MediGene's assets, chances, and risks, defined the company's core competency, and focused accordingly. The company is leaner today, and concentrates on clinical research as well as the development of cancer drugs with an emphasis on liposome technology. For the time being, our focus there is on the cancer drug EndoTAG™-1. Consequently, we worked out ambitious, yet realistic business and development plans. We have a detailed five-year plan which provides for us to break even in 2015. In 2009, we also made significant progress in our drug development projects.

### **How did these drug candidates progress in 2009?**

**Dr Frank Mathias:** All of our important projects have advanced. EndoTAG™-1, in particular, produced a lot of public interest. Patient recruitment for our phase II clinical trial in the indication breast cancer was successfully completed, and a key US patent was granted. In addition, EndoTAG™-1 obtained orphan drug designation in the USA, which allows benefits in development, approval procedures, and possibly even the commercialization of the product. In the wake of EndoTAG™-1, our drug Veregen® also made considerable progress. The drug obtained market approval in Germany and a positive decision regarding future approval in Austria and Spain. An important European patent was also granted. In addition, we entered into two partnerships for the commercialization of Veregen® in several European countries. For our antirheumatic agent RhuDex®, the laboratory tests prescribed by the regulatory authorities were successfully completed.

### **One major milestone, however, still remains to be achieved, that is the conclusion of a partnership for EndoTAG™-1.**

**Dr Frank Mathias:** As I pointed out from the very beginning, we are not looking for the quickest, but rather the most favorable deal. This also implies that we still have some homework to do. We are, for instance, currently working intensively on optimizing our manufacturing process for EndoTAG™-1 in order to increase its value. We are shifting from freeze-drying to a spray-drying process, which means the future manufacturing cost will be reduced several times over. This will be crucial not only for us, but also for a potential partner. On top of this, we are eagerly awaiting the results of the ongoing clinical trial of EndoTAG™-1 in the indication breast cancer. Following the highly positive results obtained in the phase II trial in pancreatic cancer, we expect this phase II trial to provide a second proof of concept, i.e. further evidence of the therapeutic principle of EndoTAG™-1.

### **When can the shareholders expect the conclusion of an EndoTAG™-1 partnership, and what will a deal like this entail?**

**Dr Frank Mathias:** Our future partner will be expected to bear a large portion of the development expenses for EndoTAG™-1 and, later, be in charge of its commercialization. MediGene may join in on the subsequent sales activities. We are planning to conclude one or more agreements for Europe and the USA in 2010. The expected results of the breast cancer trial will surely add new momentum to our negotiations.

### **What would happen if the results of the breast cancer trial turn out to be negative?**

**Dr Frank Mathias:** This possibility can never be completely ruled out in drug development, but at the moment we do not expect that this will be the case. Besides, our clinical data obtained for



the pancreatic cancer indication is already highly convincing, and the drug candidate offers potential to be developed for the treatment of other types of cancer.

**Dr Klaue, what may we imagine the financial aspect of a partnership for EndoTAG™-1 will look like?**

**Dr Thomas Klaue:** In general, such an agreement is comprised of an upfront payment due immediately upon conclusion, successive milestone payments depending on the achievement of specified development milestones, and royalties on the sales of the marketed drug.

**What does this imply for your financial budgeting?**

**Dr Thomas Klaue:** These sources of revenue may be weighted in different ways. For instance, by waiving large upfront payments upon conclusion of the agreement, we are in a position to secure higher royalties on future sales. This can turn out to be extremely profitable. On the other hand, however, we also need money now which enables us to bear our share in the product development. This means that we are seeking to achieve the best possible balance by concluding an agreement that guarantees a maximum share of the future profit and, at the same time, fulfills our financial requirements over the next few years.

**In 2009, MediGene's result on an EBITDA basis significantly improved, with roughly unchanged revenue. What is your financial forecast for 2010?**

**Dr Thomas Klaue:** The result will largely depend on the planned partnership agreements for EndoTAG™-1. Therefore, we don't think it makes sense to provide a forecast for the total result before we have concluded our negotiations. What we are already assuming today is that the sales of our marketed products will increase significantly.

**Dr Mathias, how do you rate the performance of the MediGene share?**

**Dr Frank Mathias:** Our shareholders are displeased about the negative overall performance of the share over the past few years, and justifiably so. With our consistent plan and its implementation, however, we now want to provide a basis for a more positive performance.

**What are MediGene's most important goals for the next five years?**

**Dr Frank Mathias:** Successful partnering and further development of EndoTAG™-1 up to market launch, step by step focusing on oncology, and the diversification of our oncological drug pipeline.

**What measures are you planning for 2010 in pursuit of these objectives?**

**Dr Frank Mathias:** We will complete the clinical trial of EndoTAG™-1 in the indication breast cancer with hopefully positive results, continue optimizing the manufacturing process for EndoTAG™-1, and expect to close one or more partnership agreements for this product. For our antirheumatic agent RhuDex®, we will conduct additional preclinical tests in 2010, with the resumption of clinical development in mind. Since our focus is on oncology, it is our medium-term goal to out-license the rights to this immunological product. For the same reason, we are also planning to spin off our AAVLP and HSV technologies. For our future revenue generator Veregen®, we expect market launch in Austria at mid-year 2010, following the German market launch which took place in March. We are also preparing market approval applications for other countries as well as the conclusion of additional marketing partnerships.



**Your strategy focuses distinctly on EndoTAG™-1.  
What makes this product so interesting?**

**Dr Frank Mathias:** Up to now, there has been no drug available that provides a significant survival benefit for patients suffering from pancreatic cancer – an extremely severe strain. However, in our phase II clinical trial of EndoTAG™-1, we were able to demonstrate such a benefit compared to existing treatments. This makes us confident about the future development of this product. We hope to achieve equally positive effects in the final stage of clinical development, i.e. in a phase III trial. Moreover, we are considering the possibility of developing this product for additional cancer indications. In particular, the development of EndoTAG™-1 for orphan drug indications seems to be highly promising. These are extremely severe diseases for which only very few treatment options have been developed as only a comparatively small number of patients is affected. In these cases, orphan drug designation may provide excellent opportunities for the long-term protection of a drug.

**Orphan drug designation was already granted for EndoTAG™-1  
in the indication pancreatic cancer.**

**Dr Frank Mathias:** Correct – in both the USA and Europe. Aside from the economic benefits associated with this, the development of orphan drugs also allows us to make a contribution to the treatment of patients who have only very few therapeutic options up to now. This is a special incentive for us.

**What will MediGene's future pipeline look like?  
Will you rely exclusively on EndoTAG™-1?**

**Dr Frank Mathias:** For the time being, EndoTAG™-1 will remain our main project for different types of cancer. In addition, we

are working on the development of new products emerging from our EndoTAG™ technology. We are also open to acquiring other cancer drugs in order to develop them to market approval. For 2015, we are planning to have at least three drugs in clinical development.

**This Annual Report includes an itinerary until 2015.  
Isn't this a bit far-reaching?**

**Dr Frank Mathias:** Without a detailed plan, you will never reach an ambitious goal, unless by accident. We know exactly where we want to go and how to get there. We are aware that an itinerary may also change, just like a GPS navigation device recommends an alternative route in case of roadwork causing a traffic jam. There are also different means of transportation available, and the fastest or most expensive is not always the best. We will be flexible and choose the ways and means that make most sense, both strategically and economically.

**Where will MediGene be in 2015?**

**Dr Frank Mathias:** In 2015, we want to be a sustainably profitable oncology company with at least three innovative drugs on the market, and we want to be ready to start the commercialization of EndoTAG™-1 in cooperation with a partner.

**What sentiment accompanies you into the year 2010?**

**Dr Frank Mathias:** We have a well-thought-out plan, and I look forward to setting off on this journey, along with my competent colleagues and our shareholders.





**Dr Thomas Klaue**

**Chief Financial Officer**

Dr Klaue has been Chief Financial Officer at MediGene AG since June 2007. Before joining MediGene, Dr Klaue was a partner at Fozzati Partners LLC, Frankfurt, a private investment bank. Prior to that, he served as Vice President of Business Development with Infineon Technologies AG for over five years. Before joining Infineon, he held a position as Vice President of M&A at DaimlerChrysler Aerospace (now EADS) for five years. Before that, he was the Director and Head of Department for the pharmaceutical and chemical industry at the Treuhandanstalt, Berlin. Dr Klaue is a chemical engineer and holds a doctorate in business economics. He obtained his management education at the MIT Sloan School and as a Harvard Business School graduate.

**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.

## 2009 MILESTONES

In 2009, MediGene AG focused on its core competencies, set long-term goals, and drew up a strategic roadmap until 2015. The company also made progress with its drug candidates. MediGene's further path is challenging, but we are well prepared and have a rewarding goal.

### COMMERCIALIZATION

#### German market approval for Veregen®

MediGene's first proprietary development obtains market approval for Germany and a statement from the regulatory authorities that the drug will also be approved in Austria and Spain.

### COMMERCIALIZATION

#### European marketing partnerships for Veregen®

MediGene agrees partnerships for the commercialization in Germany, Austria, Switzerland, Spain, and Portugal. An important US patent is extended.

### FINANCE & STRATEGY

#### Exit from early-stage research

MediGene closes down its Early-stage Development department. The freed-up staff and financial resources will be utilized to expand Clinical Development for late-stage drug candidates.

THIS WAY →

2009

### Focus

MediGene's core competency is clinical research and development of innovative cancer drugs up to market approval. The new Executive Board decides to further focus on this core competency, first of all with emphasis on liposome technology, and puts it into practice by means of reorganization measures and revised development plans.

### FINANCE & STRATEGY

#### Progress of EndoTAG™-1

Orphan drug designation in the USA, important European patent granted, and patient recruitment into phase II breast cancer trial successfully completed.

### DEVELOPMENT

#### RhuDex® – revised project plan

MediGene successfully completes the preclinical tests prescribed by the regulatory authorities. In the course of the company refocusing, MediGene decides to prepare the antirheumatic agent for out-licensing.

### DEVELOPMENT

## 2010 ROADMAP

MediGene is accelerating in order to reach its planned milestones for 2010. The conclusion of one or more partnerships for the cancer drug EndoTAG™-1 is of vital strategic and financial importance. With this, MediGene will buy its ticket for an exciting journey leading to new scientific insight, improvements for patients, constructive partnerships, and profitable business.

### COMMERCIALIZATION

**For the first time, Eligard® generates over € 100 million revenue in Europe**

MediGene receives royalties on sales of the product.



THIS WAY →

### COMMERCIALIZATION

**Launch of Veregen® in the first European countries**

In March 2010, MediGene's partner Solvay launched Veregen® on the German market. In Austria, the product obtained market approval and will be launched at mid-year. Further market approval applications are to follow.



**EndoTAG™-1: results of the phase II trial for the indication of breast cancer**

The trial results expected for the first half of the year may provide a second proof of concept.

### DEVELOPMENT

### FINANCE & STRATEGY

**Partnership for EndoTAG™-1**

In 2010, MediGene is planning to conclude one or more partnerships for development and commercialization of the company's most important drug candidate EndoTAG™-1.

### DEVELOPMENT

**More efficient manufacturing process for EndoTAG™-1**

In the fourth quarter of 2010, MediGene is planning to produce the first spray-dried material for the scheduled phase III trial.



**Spin-off of oHSV and AAVLP**

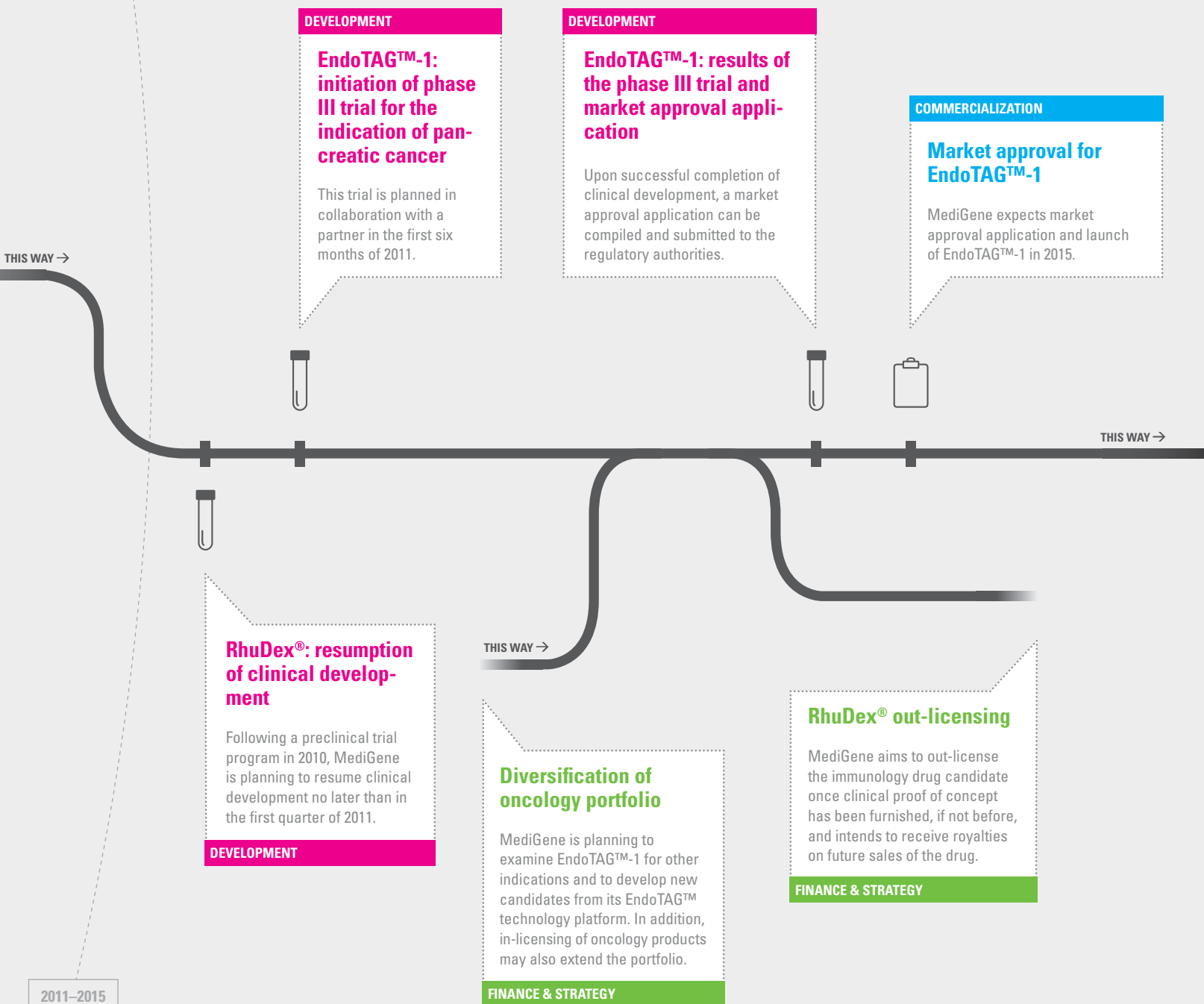
In the course of the company refocusing, MediGene is planning to spin off or out-license the oHSV and AAVLP technologies in 2010 and 2011, respectively.

### FINANCE & STRATEGY

2010

## 2011–2015 ITINERARY

An itinerary becomes more and more sketchy the farther it reaches into the future. We keep our goals in view, but remain flexible enough to bypass the unforeseen, to factor in traffic jams, or to strike new paths. Decisions will have to be made as to whether the fastest, the safest, or the most economical route should be chosen. At the end of this path, MediGene intends to be a sustainably profitable company, and both shareholders and patients should equally benefit from its innovative products.





## OUR GOALS FOR 2015

- **Three drugs on the market:  
Eligard<sup>®</sup>, Veregen<sup>®</sup>, and EndoTAG<sup>™</sup>-1**

COMMERCIALIZATION

- **Other cancer drugs in clinical development:**
  - › e.g. EndoTAG<sup>™</sup>-1 for a new indication
  - › a new product derived from EndoTAG<sup>™</sup> technology
  - › possibly a product from in-licensing or M&A

DEVELOPMENT

- **Break-even point reached for enduring profitability**
- **Company is financed mainly by product sales as well as license and milestone payments received under the terms of partnership agreements**

FINANCE & STRATEGY

### ICON DEFINITIONS



Approval



Strategies and objectives



Partnership



Manufacturing processes



Commercialization



Development progress

**PLEASE FOLD OUT HERE →**

# EndoTAG™-1

## Attack on tumor blood vessels

EndoTAG™-1 adds an innovative variant to the successful therapeutic approach of anti-angiogenesis (inhibition of vascularization in tumors). The drug candidate attaches itself selectively to the newly developed negatively charged tumor blood vessels, thus attacking only these blood vessels and not those in healthy tissue. At the same time, EndoTAG™-1 prevents the formation of new vessels. This should suppress further tumor growth. EndoTAG™-1 is a combination of positively charged liposomes and the therapeutic substance paclitaxel embedded therein. MediGene is assuming that the attack on genetically stable endothelial cells does not lead to any resistance to the therapeutic substance applied.

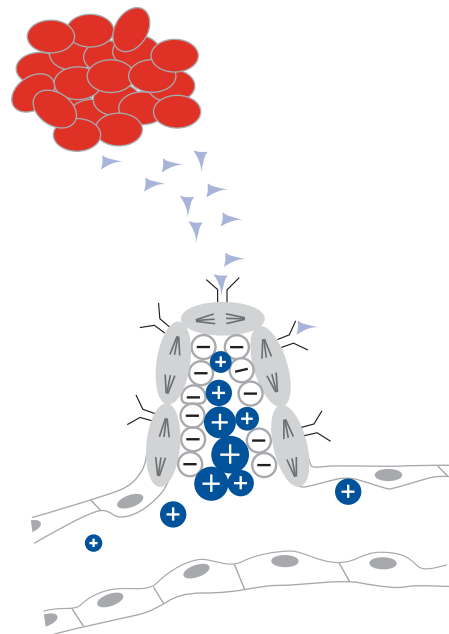
EndoTAG™-1 is MediGene's first product candidate derived from EndoTAG™ platform technology. MediGene obtained positive results with this drug candidate in a controlled phase II clinical trial for the indication of pancreatic cancer. According to this trial, survival time and survival rates improved significantly for those patients treated with EndoTAG™-1 in combination with gemcitabine. At present, MediGene is conducting a phase II trial with the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer (estrogen/gestagen receptor-negative and HER-2 receptor-negative). In Europe and the USA, EndoTAG™-1 has been granted orphan drug designation which provides benefits in drug development and approval.

## Outlook

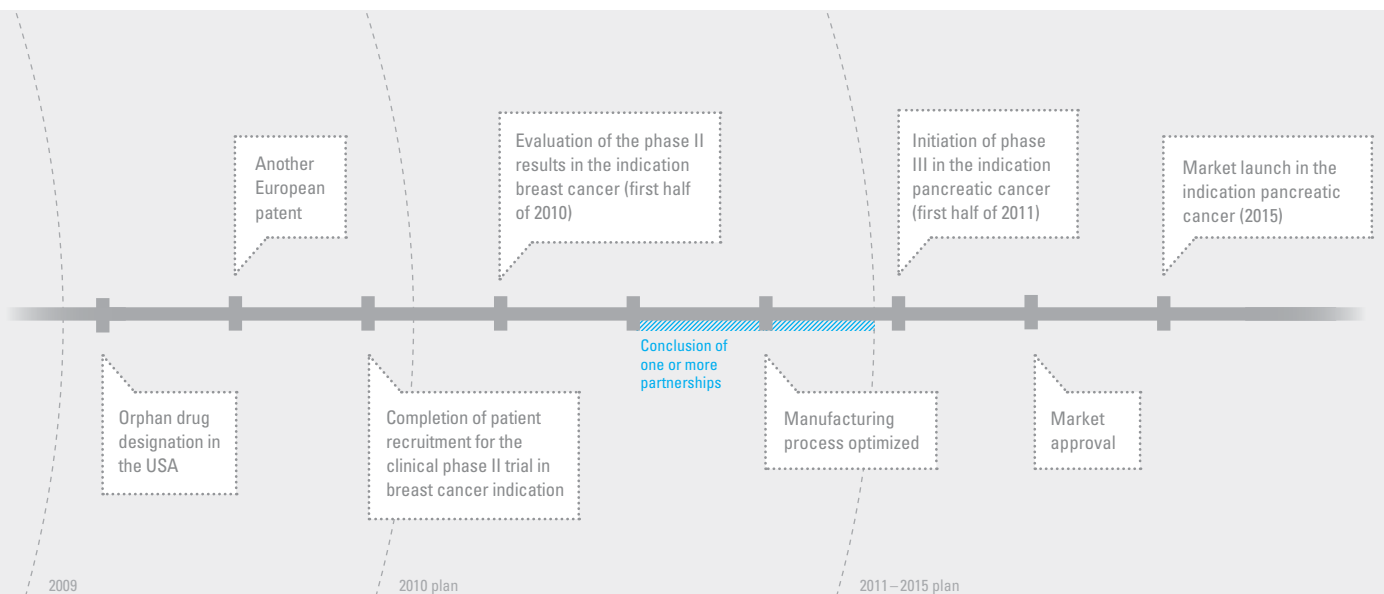
The results of the breast cancer trial with EndoTAG™-1 will be available in the first half of 2010 and are expected to provide a second proof of concept. Moreover, MediGene will shift the manufacturing process from freeze-drying which has been applied up to now to spray-drying, which facilitates a consider-

ably more efficient manufacturing process. MediGene is planning to conclude one or more partnerships for further development and future commercialization of EndoTAG™-1 in 2010. In the first six months of 2011, the initiation of a phase III trial for the indication of pancreatic cancer is planned.

EndoTAG™ attacking endothelial tumor cells



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



# RhuDex®

## Orally available treatment for rheumatoid arthritis

RhuDex® targets one of the most common diseases: rheumatoid arthritis. T-cell activation is pivotal in the onset of rheumatoid arthritis. It is triggered by interaction between specific proteins on immune cell surfaces. The CD80 protein plays a key role in this process. Its interaction with the CD28 protein, a receptor on the surface of T cells, is one of the steps necessary for T-cell activation. RhuDex® can bind to CD80, preventing interaction with CD28, and, thereby, interrupting an important signaling pathway of T-cell activation. Since RhuDex® is an orally available drug candidate of this type, it would be excellently positioned to compete in this billion euro market.

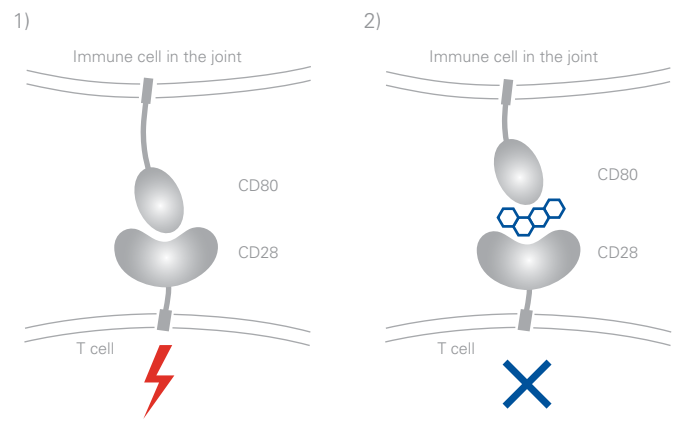
In 2008, MediGene successfully completed a phase IIa pilot trial with twenty-eight patients. Following the unexpected death of a test person in July of 2008, during a phase I clinical trial of RhuDex®, the trial was put on hold to allow an intense search for any possible correlation between the thrombotic event and the administration of RhuDex®. For this purpose, the effect of RhuDex® on the aggregation and activation of platelets, activation of endothelial cells and T cells, and atherosclerotic plaques was examined. These tests were completed in 2009, and there was no indication that RhuDex® might cause any thrombotic events. Consequently, the UK regulatory authority responsible for the clinical trial did not request any further in-vitro tests and has agreed to discuss a protocol for the future clinical development of RhuDex®.

## Outlook


In 2010, MediGene will conduct further preclinical trials with RhuDex®, in order to specify the therapeutic window, thus

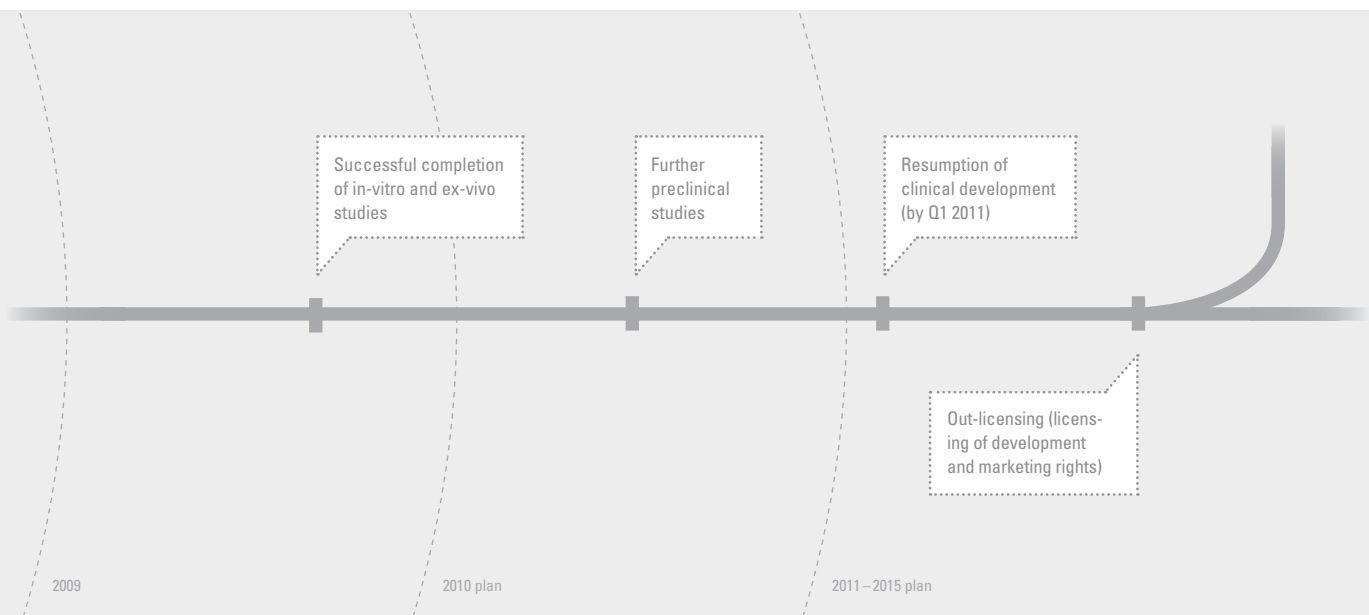
optimizing the clinical development program. MediGene expects to resume clinical development either in the fourth quarter of 2010 or the first quarter of 2011. Within the scope of its strategic focusing, MediGene intends to out-license this immunological drug candidate once clinical proof of concept has been established, if not earlier.

### RhuDex® acting as an anti-inflammatory agent



T cell activation by certain immune cells in the diseased joint is a key step in the onset of rheumatoid arthritis.

- 1) T cell activation requires interaction between the surface proteins CD80 and CD28.
- 2) RhuDex®  prevents the interaction between CD80 and CD28, thus acting as an anti-inflammatory agent.



# Eligard®

## Hormone therapy for prostate cancer with innovative drug delivery system

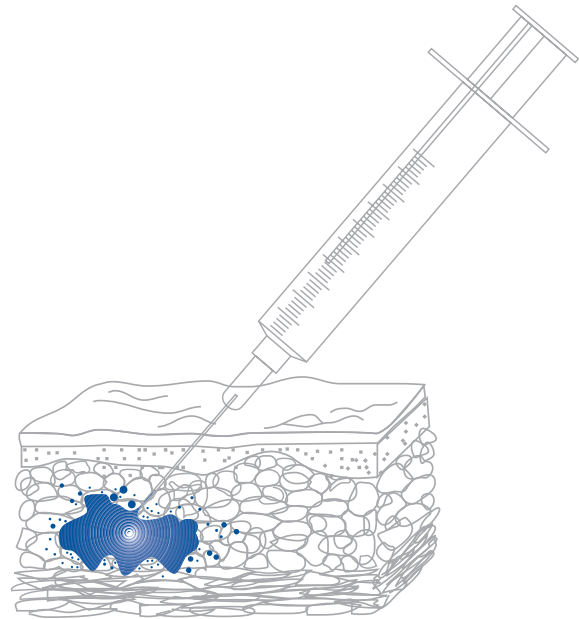
MediGene's first drug on the market, Eligard®, is a hormone compound for the treatment of advanced, hormone-dependent prostate cancer. The active substance (leuprolide acetate) significantly reduces the level of the male sex hormone testosterone, thus, suppressing the testosterone-dependent tumor growth. The established active ingredient is combined with a novel drug delivery system, i.e. Atrigel® depot technology. The liquid drug is injected subcutaneously and forms a gel-like implant that slowly disintegrates. Depending on the dosage administered, the drug is steadily released over a period of one, three, or six months.

MediGene acquired the European marketing rights to Eligard® from Atrix Laboratories, Inc. (now Tolmar Therapeutics Inc.) and successfully guided the drug through the market approval procedure for Germany. The European market launch of Eligard® by MediGene's partner Astellas Pharma started in 2004. Meanwhile, one-month, three-month, and six-month products are available in most European countries. MediGene's revenue from the sales of the drug is comprised of two elements: product sales to Astellas and royalties on Eligard® sales by Astellas. MediGene purchases the product from Tolmar and makes license payments to the company.

## Outlook

Eligard® will remain MediGene's sales mainstay in the coming years.

Administration of Eligard® (skin cross-section, syringe)



For the first time, Eligard® sales generated by MediGene's partner in twenty-five European countries exceed 100 million euros

Market launch in Turkey and Russia

Sales on the European market ensure constant revenue



# Veregen®

## A high-tech product made from green tea

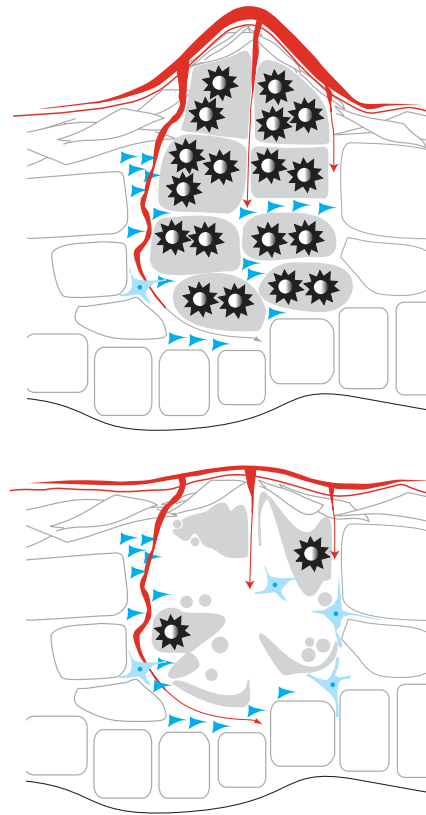
Veregen® constitutes MediGene's second drug on the market. Veregen® for the treatment of external genital warts is already available in the USA and is distributed there by MediGene's partner Nycomed US, Inc. Veregen® makes MediGene the first German biopharmaceutical company with a drug on the US market. In Europe, the national regulatory authorities in Germany, Austria, and Spain reached a positive decision on the application for market approval. Market approval for Germany was granted in September 2009 and for Austria early in 2010. Since March 2010, the drug has been distributed in Germany by Solvay Arzneimittel GmbH (acquired by Abbott on February 15, 2010). In 2009, MediGene signed a license and supply agreement with Solvay for Germany, Austria, and Switzerland. For the commercialization of Veregen® in Spain and Portugal, MediGene entered into a marketing partnership with the Spanish pharmaceutical company Juste S.A.Q.F. in June of 2009. Veregen® is MediGene's first proprietary clinical development.

Veregen® is an extract from green tea leaves manufactured in a highly complex, defined process. Genital warts are benign, but painful and disfiguring skin tumors in the genital and anal areas. This sexually transmitted disease is caused by human papilloma viruses. Genital warts are one of the fastest spreading venereal diseases worldwide.

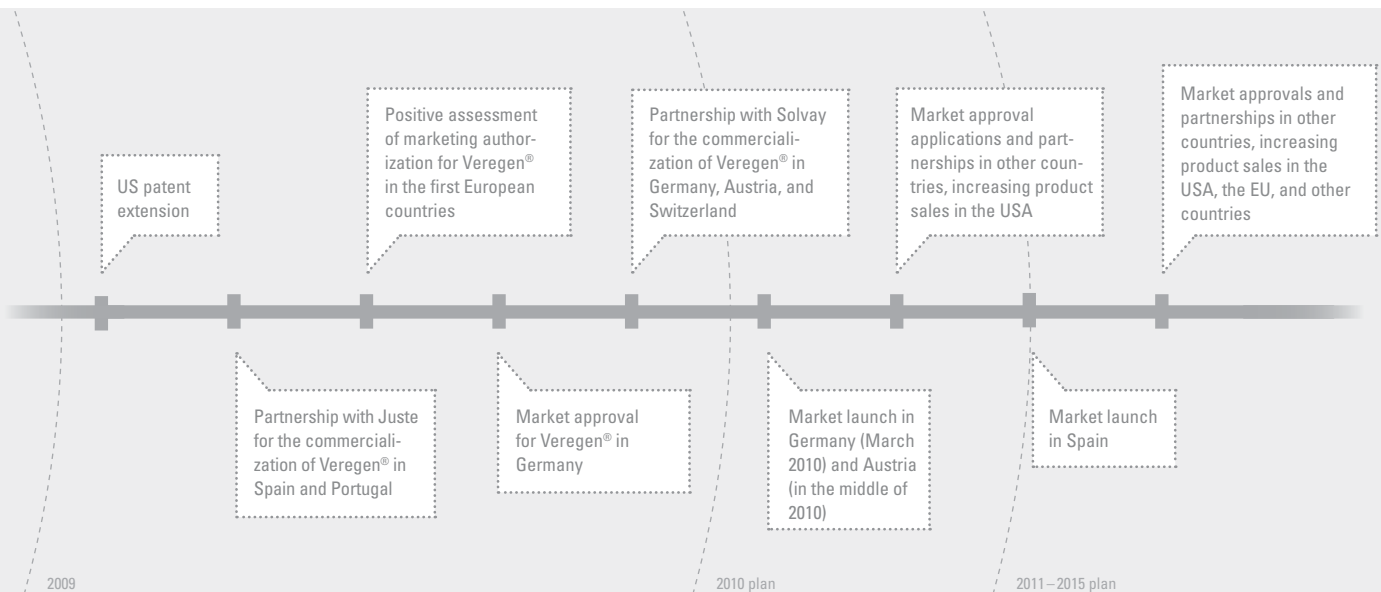
## Outlook

The market approval for the drug granted in Germany, the reference member state in this decentralized procedure, should provide the basis for additional market approval applications submitted in other European countries within the mutual recognition procedure. MediGene intends to conclude additional marketing agreements for the commercialization of Veregen® in further European countries.

Changes in a skin tumor induced by Veregen®



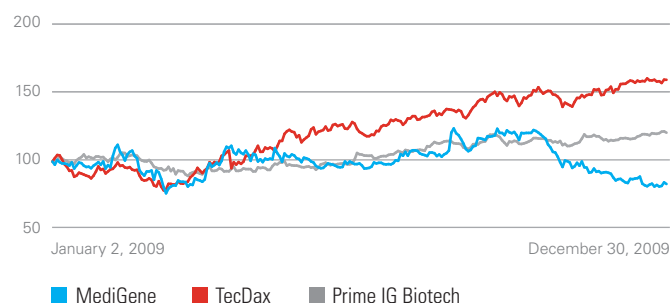
- HPV infection of skin cells induces the formation of warts.
- Veregen® penetrates the skin, unfolds its immuno-modulatory effect, and also directly acts on infected cells.
- Messengers (cytokines, interferons) are released.
- Cells of the immune system invade and destroy infected cells.



# Share performance

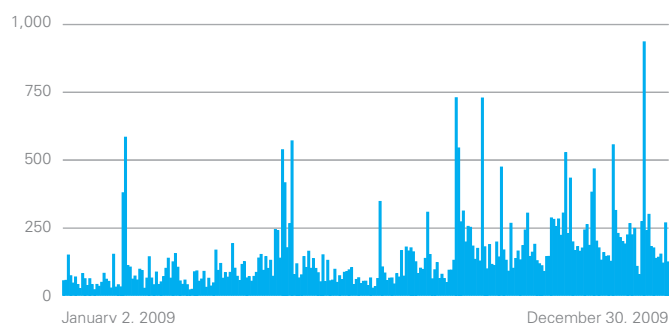
## 2009 share price performance

(Index opening price January 2, 2009, € 4.28 indexed to 100)



## Market volume

In thousands



## Listing on the TecDAX index

The MediGene share has been listed on the TecDAX stock index since February 2009, which makes it one of the most important technology shares in Germany.

## Share price

The opening price of the MediGene share was € 4.28 in 2009. Following admission to the TecDAX selection index, the share price rose significantly to € 4.80 in February. Nearly parallel to the development of the TecDAX, the MediGene share declined to this year's low of € 3.29 in March 2009 and rose to € 4.77 in April, in an improving stock market and after positive news regarding a patent on the drug Veregen®. The unexpected change in leadership at MediGene which took place at the end of April initially caused uncertainty on the capital market, but, following positive news regarding the approval and commercialization of Veregen® in June and July of 2009, the share price rose significantly. Prior to the Shareholders' Meeting in August 2009, the MediGene share reached its yearly high of € 5.31 and remained at this level until mid-October. The subsequent downward trend of the TecDAX had an above-average impact on MediGene. The MediGene share did not profit from the following recovery of the TecDAX, despite the company reporting important progress in its EndoTAG™-1 and RhuDex® development projects during this period. The cautious statements by the company with regard to the date of conclusion of a planned partnership for the drug candidate EndoTAG™-1 may have contributed to this. In December, MediGene AG presented its business plan up to the year 2015. In addition to the company's revised development plans, this business plan also includes the option to conclude the EndoTAG™-1 partnership only after the results from the breast cancer trial expected for the first half of 2010 are available. Toward the end of the year, the downward trend was halted, but the share closing price amounted to only € 3.58, i.e. a loss for the year of approximately 16%.

## Key figures for the MediGene share

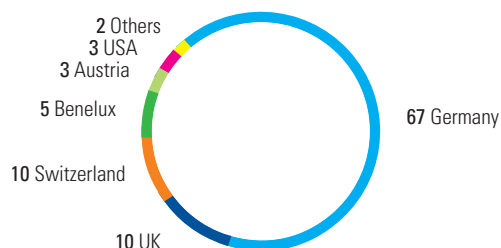
In €	2009	2008
52-week high	5.31	6.62
52-week low	3.29	3.14
Price at the beginning of the year	4.28	5.36
Year-end closing price	3.58	4.30
Average price since beginning of the year	4.30	5.07
Weighted average number of shares	34,231,294	34,008,289
Average daily trading volume (in shares)	144,442	137,987
Average market capitalization (in € million)	147	172
Total number of shares outstanding (Dec. 31)	35,557,493	34,028,561
Dividend per share	0.00	0.00
Nett loss per share	-0.64	-0.91
Shareholders' equity	1.46	1.90

## The following investment banks reported on MediGene in 2009

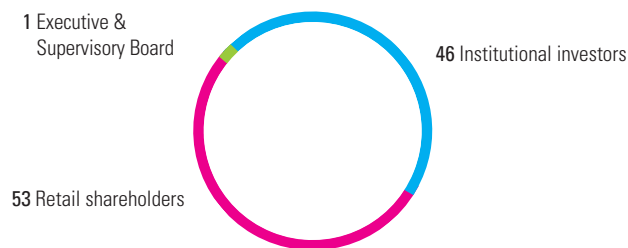
Concord Investment Bank AG	Rüdiger Holzammer
DZ Bank AG	Dr Elmar Kraus
Goldman Sachs International Ltd.	Dr Stephen McGarry, Linden Townson
Landesbank Baden-Württemberg	Dr Hanns Frohnmeier
Nomura Code Securities Ltd.	Samir Devani
Oppenheim Research GmbH	Dr Christian Peter
SNS Securities N.V.	Marcel Wijma
Viscardi AG	Robert Willis, Dr Isabell Friedrichs
WestLB AG	Dr Cornelia Thomas
Piper Jaffray Ltd.	Richard Parkes

**Ownership information by country<sup>1)</sup>**

In %

<sup>1)</sup> as per December 31, 2009, figures rounded, as per MediGene's assessment**Ownership information by type of investor<sup>1)</sup>**

In %

<sup>1)</sup> as per December 31, 2009, figures rounded, as per MediGene's assessment**Positive analysts' coverage**

MediGene is monitored by a number of analysts from renowned investment banks in Germany and abroad. MediGene AG and its products and technologies have been analyzed in detailed reports. As a consequence of the financial crisis, several investment banks reduced the portfolio of companies monitored and discontinued coverage of the MediGene share as well as other securities. On the other hand, other investment banks intensified their interest in MediGene. Early in 2010, five out of seven analysts issued a »buy« recommendation for the MediGene share.

**Intensive investor relations activities**

In 2009, MediGene AG continued its investor relations activities in order to keep the company's investors, the financial analysts, and the business press informed about the development of MediGene. In addition to press and analysts' conferences, MediGene gave interviews to the relevant finance media and had discussions with investors in Germany and abroad. Company presentations at renowned investor conferences underlined MediGene's presence on the international capital market.

**Annual Report receives Platinum Award**

In 2009, MediGene's 2008 Annual Report was honored at the renowned LACP (League of American Communications Professionals) Vision Awards in the USA. On the occasion of this leading international competition for annual reports, MediGene once again won the coveted Platinum Award in the biotechnology category. Thus, MediGene has received another commendation for its transparent reporting to shareholders and the public.

**In 2009, MediGene presented the company at the following international investor conferences**

JP Morgan 27th Annual Healthcare Conference	San Francisco
11th Annual BIO CEO & Investor Conference	New York
Global Biotechnology, Biopharmaceuticals, and Generics Conference, Credit Suisse	London
Kempen & Co. Life Science Conference	London
Deutsche Bank Healthcare Conference	Boston
BIO International Convention	Atlanta
BioEquity	Munich
Jefferies Healthcare Conference	New York
PiperJaffray Europe Conference	London
Sal. Oppenheim Healthcare Conference	Frankfurt
German Healthcare Conference	Zurich
Rodman Renshaw Healthcare Conference	New York
UBS Healthcare Conference	New York
German Equity Forum	Frankfurt

### Flexible access to additional cash

In December of 2008, MediGene closed an equity funding agreement (Standby Equity Distribution Agreement, SEDA) with the investment company YA Global Investments L.P. Under the terms of the agreement, MediGene has the option to call a maximum of € 25 million cash in tranches over a period of up to thirty-six months, making use of YA Global Investments' commitment to subscribe and pay for newly issued MediGene shares from authorized capital totaling up to € 25 million. It remains at the sole discretion of MediGene if and when this option is exercised during the term of the agreement. This agreement grants MediGene flexible access to substantial additional funds. In the fourth quarter of 2009, MediGene issued a total of 1.5 million new shares under the terms of the agreement, generating € 6 million in additional capital.

### Ownership development

The ownership of MediGene AG shifted in favor of private investors in 2009. The portion of their holdings at the end of the year totaled 53% (2008: 44%). The portion of institutional investors decreased accordingly, from 54% to 46%. Directors' holdings since the departure of former Chief Executive Officer, Dr Peter Heinrich amounted to approximately 1% (2008: 3.0%). Most of the shares are still held by investors in Germany (70%), followed by the UK (10%), Switzerland (10%), and the Benelux countries (5%).

### Share data

Stock ID code	MDG
Securities identification number	502 090
ISIN – International Securities Identification Code	DE000 5020903
Common code	1107 3026
CUSIP	993 906 FV5
Reuters symbol	MDGGn
Bloomberg symbol	MDG
Market segment	Prime Standard
Indices	TecDAX, Prime All Share, DAXSubsector Biotechnology
Trading floors	Xetra, Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hanover, Munich, Stuttgart
Designated sponsors	DZ Bank AG, WestLB AG

# Financial information 2009

of MediGene AG

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# Group Management's Discussion and Analysis

of MediGene AG, Planegg/Martinsried, Germany as per December 31, 2009

- **Total revenue: € 39.5 million (2008: € 39.6 million)**
- **Net loss for the year : € 22.0 million (2008: net loss € 30.8 million)**
- **EBITDA: € -18.8 million (2008: € -24.6 million)**
- **Average monthly net cash burn rate: € 1.6 million (2008: € 2.3 million)**
- **Cash and cash equivalents: € 12.3 million (2008: € 25.1 million)**

## Business and overall economic conditions

### Company overview

MediGene AG, Planegg/Martinsried, Germany, is a biopharmaceutical company that specializes in the research, development, and commercialization of innovative drugs, concentrating on indications of great medical necessity and consequently substantial commercial interest. Its research and development activities center upon cancer and autoimmune diseases.

### Organizational and legal structure of the group

MediGene AG was founded in 1994 in Planegg/Martinsried near Munich in Germany. In 1996, the company was transformed into a 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 of 2000 (Deutsche Börse, Regulated Market, Prime Standard; SIN 502090; code MDG). The MediGene AG share is listed in the TecDAX selection index of Deutsche Börse.

In addition to the parent company, MediGene AG in Planegg/Martinsried, Germany, the MediGene group includes two wholly owned subsidiaries, MediGene, Inc., San Diego, California, USA, and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom. The subsidiaries were acquired in 2001 (MediGene, Inc.) and 2006 (MediGene Ltd.), respectively. The subsidiary MediGene Ltd. in turn holds 39.09% of shares in the company Immunocore Ltd. (hereinafter referred to as »Immunocore«), Abingdon, Oxfordshire, United Kingdom. The MediGene group is hereinafter referred to as »MediGene«, the parent company as »MediGene AG«. The group is managed by the Executive Board of the parent company, MediGene AG. The subsidiaries' management entities report directly to the group's Executive Board.

### Segments and major locations

MediGene's business activities are comprised of the two market segments »Marketed Products« (previously »Specialty Pharma«) and »Drug Candidates« (previously »Biopharma«). The regional segmentation differentiates between the regions United Kingdom, USA, and other countries.

### Management structure

MediGene AG's Executive Board is comprised of the Chief Executive Officer, Dr Frank Mathias, and the Chief Financial Officer, Dr Thomas Klaue.

During the year 2009 there were two major changes to the Executive Board. In April, the Chief Executive Officer Dr Peter Heinrich left the company. In December, Dr Axel Mescheder resigned from office. The duties of the two former Executive Board members were assumed by the remaining Executive Board members. Among others, Dr Mathias is responsible for the research and development department, with the support of a newly established executive committee made up of all department heads of the research and development sector.

### Products and key markets

MediGene has two drugs already being marketed: Eligard® for the treatment of prostate cancer and Veregen® for the treatment of genital warts. Both drugs are marketed by partners.

MediGene also has a broad research and development portfolio in the fields of oncology and immunology. In the area of oncology, EndoTAG™-1 and the oncolytic herpes simplex viruses (oHSVs) are in different stages of clinical development. The drug candidate RhuDex® is being clinically tested for the immunological indication of rheumatoid arthritis. MediGene owns the AAVLP technology in the pre-clinical and research stages and has access to mTCR technology via its holdings in Immunocore Ltd. Both are platform technologies for the future development of various drug candidates.

In addition, MediGene is advancing the development of an innovative technology platform for the development of active ingredients, based on EndoTAG™ technology.

### Competitors

The MediGene group operates in a highly competitive market, which is shaped primarily by the results of competitors' research and development activities, patent protection, and, increasingly, by the ability to commercialize products. The company has many competitors on a global level. These include biopharmaceutical, pharmaceutical, and biotechnology companies, as well as universities and other research institutes. From the company's point of view, a large number of organizations are actively involved in the development and marketing of comparable projects and products in the areas of cancer, autoimmune diseases, and dermatology.

## State of the product portfolio and research and development activities

### Eligard®

MediGene owns the European rights to the drug Eligard® for the treatment of hormone-dependent prostate cancer. The drug is distributed via a partner and can be obtained in most European countries.

For the purpose of marketing Eligard® in Europe, a contract has been in existence since January of 2004 with the pharmaceutical group, Astellas Pharma Europe Ltd. (hereinafter referred to as »Astellas Pharma«), Staines, United Kingdom, a leading European company in the field of urology. The validity of the contract reflects the term of the European patents until 2021. Eligard® is available in the form of one-month, three-month, and six-month depot formulations in most European countries. MediGene receives a share of the revenue generated. Sales generated by Eligard® have once again risen significantly in 2009.

### Veregen®

The ointment developed under the name Polyphenon E® has been approved in the USA, Germany, and Austria under the name Veregen®. It is used to treat genital warts and has been available on the US market since December 2007.

A contract for marketing Veregen® in the USA exists with the company Nycomed US, Inc. (hereinafter referred to as »Nycomed«), Melville, New York, USA. The duration of the contract corresponds to the patent term until at least 2022. As of February 2009, Nycomed is actively marketing and selling Veregen® in the US market. MediGene receives successive single payments depending on the achievement of specific milestones and, furthermore, has a share in Veregen® revenue. The milestone payments are linked to progress in the development, approval, and marketing for the indications genital warts and actinic keratosis, and to certain revenue targets being achieved.

MediGene intends to service the European market via regional distribution partnerships. The first such partnerships were entered into for Spain and Portugal with the company Juste S.A.Q.F. (hereinafter referred to as »Juste«), Madrid, Spain and for Germany, Austria, and Switzerland with Solvay Arzneimittel GmbH (hereinafter referred to as »Solvay«), Hanover. The process of assessing the application for market approval submitted to the relevant authorities in Germany, Austria, and Spain in 2007 concluded successfully in July of 2009. Approval has already been granted in Germany and Austria. Approval in Germany should serve as reference for the approval procedures in other European countries as part of a mutual recognition procedure.

### Oracea®

The dermatological drug Oracea® received marketing approval for Europe in the summer of 2008. Marketing rights were subsequently returned to the company Galderma Laboratories Inc. (hereinafter referred to as »Galderma«, formerly CollaGenex Pharmaceuticals, Inc.), Fort Worth, Texas, USA. Galderma committed in turn to an immediate payment of € 8 million to MediGene. Depending on sales achieved by Galderma with Oracea®, MediGene will receive up to € 24 million in the form of milestone payments. There are no additional obligations for either party. In the meantime, Galderma has launched the drug in Germany and additional European markets.

### EndoTAG™-based therapies

The results of a phase II clinical trial with the drug candidate EndoTAG™-1 for the treatment of pancreatic cancer were presented in 2008. The controlled and randomized trial examined the safety and tolerability, as well as the clinical efficacy, of various dosages of EndoTAG™-1 in combination with Gemcitabine, a cytostatic already approved for the treatment of pancreatic cancer. The trial with 200 patients showed significantly longer survival times for patients that had been treated with EndoTAG™-1 in combination with Gemcitabine than for those who received only Gemcitabine. The survival times of the patients treated improved considerably with increasing doses of EndoTAG™-1 and especially with repeated treatment using EndoTAG™-1. Positive results were also recorded for other clinical parameters, such as progression-free survival and safety.

In 2007, MediGene initiated another phase II trial with the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. The objective of the trial is to examine the efficacy of EndoTAG™-1 in treating this highly aggressive form of cancer, as well as to collect additional data on drug safety. The last of the planned number of 135 patients was included in the trial in October of 2009.

The drug candidate EndoTAG™-1 selectively attacks the blood vessels that supply tumors. EndoTAG™-1 is a positively charged lipid complex containing Paclitaxel. It accumulates around the negatively charged cells that line the newly formed tumor vessels. There, the active ingredient in EndoTAG™-1, the cytostatic drug Paclitaxel, is released in order to destroy the blood vessels and, thus, cut off the nutritive supply to the tissue of the tumor.

**RhuDex®**

RhuDex® is an active ingredient for the treatment of rheumatoid arthritis. It is an orally available CD80 antagonist that blocks T-cell activation. The drug candidate RhuDex® works as an immunosuppressive drug with an anti-inflammatory effect. RhuDex® has successfully undergone the preclinical development stages. Tolerability and safety of RhuDex® were analyzed on the basis of a working development in a first clinical trial with healthy test persons. In June of 2008, a phase IIa clinical trial with this working development achieved all trial goals. In addition to positive safety and resorption data as well as good absorption of the drug with oral delivery, the trial showed the first signs of the biological activity of RhuDex®. At the same time, MediGene developed a pill form of the active ingredient with improved galenics.

An ongoing phase I clinical trial with the new formulation of the drug candidate RhuDex® was put on hold in July of 2008. A volunteer in the trial suffered a heart attack a few days after taking RhuDex®. After receiving hospital treatment, he died several days later at home. The autopsy showed that the subject had died of acute myocardial re-infarction as a consequence of coronary thrombosis. According to the investigation, the patient had suffered several small infarctions over a period of many years. From MediGene's point of view, this supports the assessment that a causal correlation between the death of the patient and the administration of the trial medication RhuDex® is unlikely. MediGene conducted a series of additional laboratory tests in coordination with the British Medicines and Healthcare products Regulatory Agency (MHRA) in order to investigate the possibility of harmful interactions of RhuDex® with blood vessels affected by arteriosclerosis. These studies did not show any correlation with RhuDex®.

**Drug candidates based on oncolytic herpes simplex virus (oHSV) technology**

In the past, MediGene investigated the cancer cell-killing virus NV1020 for the treatment of liver metastases in patients with advanced colorectal cancer in a phase I/II trial. The trial was continued in phase II following the conclusion of the phase I clinical portion using the most effective dosage level. MediGene presented results from these trials at key cancer conferences in Europe (ESMO) and the USA (ASCO). These results showed clear indications of efficacy among patients receiving the highest dosage level. Currently, MediGene is evaluating several options to out-license or spin off this project; MediGene does not intend to continue its development alone.

**Technology platforms and preclinical projects**

MediGene is also advancing the development of its innovative proprietary technology platforms for the development of active ingredients, including EndoTAG™ technology. Research into EndoTAG™ technology for the development of further therapeutic molecules was subsidized by public grants through the end of 2009.

Another technology platform is based on AAV-like particles (AAVLP), which MediGene hopes to use for the development of prophylactic and therapeutic vaccines. This promising project covered by broad patent protection is also funded using public grants.

Immunocore, an associate of MediGene, is developing the mTCR technology, which is based on soluble, monoclonal T-cell receptors.

The L1 project, in its preclinical development stage, for the development of a therapeutic monoclonal antibody against ovarian cancer was suspended, since the development candidates to date failed to offer sufficient efficacy.

**General conditions****Regulatory and general economic conditions**

The general regulatory conditions relevant to MediGene remained virtually unchanged in 2009. However, persistent cost pressure on healthcare providers may result in further legislation aimed at reducing the cost of drugs. This could affect the pharmaceutical and biopharmaceutical sectors in Europe and the USA.

Estimates of the daily interest structure on the bond market published by the Deutsche Bundesbank (German Central Bank) show an increase from 3.28% (December 30, 2008) to 3.63% (December 30, 2009) in the interest rate for 10-year (hypothetical) zero bonds with no credit default risk for 2009.

The reference exchange rate of the euro rose from \$ 1.4175 to \$ 1.4405 within the 2009 reporting period. Against the British pound, on the other hand, the euro fell from £ 0.9770 to £ 0.8900 (source: Dresdner Bank reference exchange rates).

**Grants**

Research into EndoTAG™ technology for the treatment of other diseases not involving tumors had been subsidized by public grants totaling € 1.5 million by the end of the period under review. Furthermore, the AAVLP technology was funded by the German Federal Ministry of Education and Research (BMBF) until the end of July 2009 by an amount of € 0.6 million.



## Procurement

Procurement is focused on the approved drugs Eligard®, Veregen®, and 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 and drug candidates

MediGene purchases the drug Eligard® for the European market exclusively from its licensor and manufacturer Tolmar Therapeutics Inc. (hereinafter referred to as »Tolmar«, previously QLT USA, Inc.), Fort Collins, Colorado, USA.

In December of 2006, MediGene entered into a contract with Mitsui Norin Co., Ltd. (hereinafter referred to as »Mitsui Norin«, Tokyo, Japan, for the production and supply of the active pharmaceutical ingredient for Veregen®. The formulation of the ointment is carried out by a contract manufacturer in Germany by order of Nycomed. 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 materials 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 to changes in its development portfolio with the required flexibility. The demands on services of this kind are highly complex and require 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

The management of MediGene uses revenue, EBITDA, gross revenue margin, liquidity cover ratio, and equity ratio as performance indicators for the commercial success of the group's activities. The term EBITDA is used to describe the operating profit/loss before the deduction of interest, taxes, foreign currency exchange gains and/or losses, depreciation of property, plant, and equipment, and amortization of intangible assets.

#### Performance indicators

		2009	2008
Gross margin as a share of total revenue in %	$\frac{\text{Gross profit} \times 100}{\text{Total revenue}}$	20	32
EBITDA in € thousand		-18,808	-24,584

#### Asset and finance indicators

		2009	2008
Liquidity cover ratio in %	$\frac{\text{Cash} \times 100}{\text{Balance sheet total}}$	19	31
Equity ratio in %	$\frac{\text{Equity} \times 100}{\text{Balance sheet total}}$	79	80

### Nonfinancial performance indicators

MediGene's commercial success will essentially depend on the extent to which patent protection will be obtained and maintained for its products and technologies in the respective regional target markets. MediGene's patent situation, therefore, represents the company's pivotal non-financial performance indicator.

#### Patent situation

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)	6	28
USA	4	53

#### Pending patent applications

	Marketed products	Drug candidates
Europe (Germany)	2	32
USA	1	43
International (PCT)	3	67

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

The company's aim is to obtain patent protection for its proprietary products, processes, and technologies. In line with the strategy of obtaining patents for technologies and products in development, MediGene has submitted numerous patent applications for various results of its work on proprietary technologies and products or has exclusively licensed patents for the relevant segments.

## Income position

### Total revenue

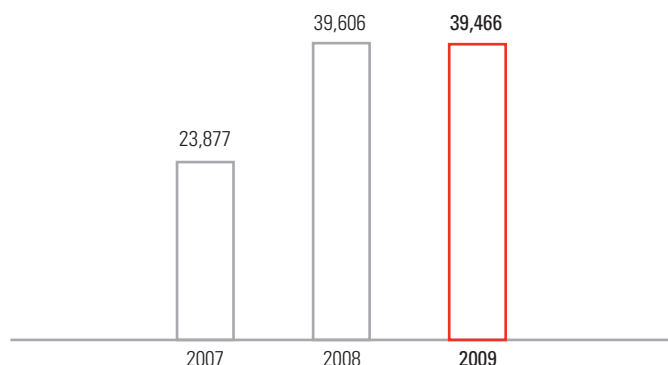
The company generated total revenue of € 39,466 thousand (2008: € 39,606 thousand) during the reporting period. This revenue arises chiefly from the marketing of Eligard® in Europe and to a lesser extent from marketing Veregen® in the USA. Furthermore, MediGene received public grants and payments from cooperation partners. Revenue has been achieved almost exclusively by MediGene AG.

#### Consolidated income statement (abbreviated)

In € thousand	2009	2008	Change
Total revenue	39,466	39,606	0%
Cost of sales	-31,482	-26,926	17%
Gross profit	7,984	12,680	-37%
Selling, general, and administrative expenses	-9,124	-10,484	-13%
Research and development expenses	-18,499	-27,465	-33%
Loss resulting from spin-off	0	-6,431	-%
Operating result	-19,639	-31,700	-38%
Result before income tax	-21,935	-33,146	-34%
Taxes	-27	2,356	-101%
Net loss for the year	-21,962	-30,790	-29%

### Total revenue

In € thousand



While total revenue has remained unchanged in comparison with the previous year, the composition of revenue in 2009 changed in favor of product sales.

As in previous years, the increase in product and license proceeds is due especially from increased Eligard® sales. Furthermore, Veregen® sales achieved in the US markets became noticeable for the first time. All in all, product sales and royalties increased by 23% to € 37,656 thousand (2008: € 30,507 thousand).

Other operating income amounted to € 1,607 thousand (2008: € 6,099 thousand), € 447 thousand (2008: € 914 thousand) stemmed from grants and € 1,160 thousand (2008: € 4,562 thousand) from other income, of which € 1,080 thousand resulted from a compensation agreement. The high level of other income in 2008 was primarily due to a one-time payment in connection with the return of European marketing rights to Oracea®.

Revenue distribution is presented in the Notes to the consolidated financial statements C) item (27), on page 58.

### Cost of sales

Cost of sales was incurred mostly in connection with the commercialization of the drug Eligard® and, to a lesser extent, Veregen®. Costs amounted to € 31,482 thousand (2008: € 26,926 thousand). They relate to the purchase of products and participation of Tolmar in sales revenues.

### Gross profit

Gross profit amounted to € 7,984 thousand in 2009 (2008: € 12,680 thousand). The level of gross profit is determined by the ratio of revenue from product sales to license payments, as well as by any milestone payments. In fiscal year 2008, proceeds from the return of Oracea® rights impacted the gross margin positively, since these one-time receipts were not offset by costs. Gross margins achieved from the drugs Eligard® and Veregen® depend to a degree on the euro-US dollar exchange rate.

### Selling, general, and administrative expenses

Selling, general, and administrative expenses dropped by 13% from € 10,484 thousand (2008) to € 9,124 thousand (2009). This amount was comprised of € 2,192 thousand (2008: € 2,763 thousand) in selling expenses and € 6,932 thousand (2008: € 7,721 thousand) in general and administrative expenses. Higher expenditures in 2008 were incurred primarily due to the registration of shares that had already been issued, and as administrative expenses of the subsidiary MediGene Ltd. Additional expenses during the period under review were incurred due to one-time bonus and severance payments amounting to € 1,203 thousand.

## Research and development expenses

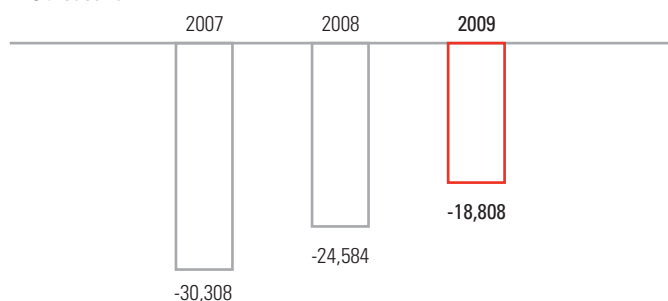
Total expenses for research and development (R&D) decreased by 33% to € 18,499 thousand (2008: € 27,465 thousand). A large part of the expenses for research and development consisted of expenses for clinical trials with the drug candidate EndoTAG™-1 for the indication of triple receptor-negative breast cancer. Other costs arose in connection with additional development projects. The composition of R&D expenses can be found in the Notes to the consolidated financial statements C), item (31), on page 59.

## EBITDA

MediGene uses the term EBITDA to describe the operating profit/loss before the deduction of interest, taxes, foreign currency exchange gains and losses, depreciation of property, plant, and equipment, and amortization of intangible assets (earnings before interest, taxes, depreciation, and amortization), as it gives a good indication of cash flow. Using this indicator instead of the EBIT figure should enable a comparison of the actual operating results before depreciation and amortization in separate periods. In 2009, MediGene reduced the loss based on EBITDA to € 18,808 thousand compared to € 24,584 thousand in 2008.

### EBITDA

In € thousand



### EBITDA

In € thousand	2009	2008	Change
Operating result	-19,639	-31,700	-38%
Depreciation	831	1,173	-29 %
Impairment	0	5,943	-%
<b>Total</b>	<b>-18,808</b>	<b>-24,584</b>	<b>-23%</b>

## Depreciation and impairment

Total depreciation decreased from € 7,116 thousand (2008) to € 831 thousand (2009). Regular depreciation and amortization refers to property, plant, and equipment and intangible assets, including patents and product licenses. During the previous year,

an impairment according to IAS 36 on intangible assets was recorded in the amount of € 5,943 thousand as a result of the transfer of mTCR technology into an independent company.

## Financial result

The financial result, mainly composed of exchange losses and interest income, amounted to € -671 thousand (2008: € -1,190 thousand) in the period under review. The loss due to a derivative financial instrument in accordance with IAS 39, which relates to the product Eligard®, increased compared to the previous year due to the development in value of the US dollar in comparison to the euro. Foreign currency exchange gains/losses arose from the translation of US dollars and British pounds into euro. At the end of the third quarter of 2009, MediGene sold shares held in the Canadian company QLT, Inc., Vancouver, British Columbia, Canada, realizing proceeds of € 689 thousand, leading to income of € 291 thousand.

## Taxes

Tax expense of € 27 thousand (2008: tax income of € 2,356 thousand) was recorded in the period under review. The tax expense arose from the reversion of R&D tax credit that the subsidiary MediGene Ltd. recorded as a liability in 2008.

## Net loss for the year

The net loss for the year dropped from € 30,790 thousand in the previous year to € 21,962 thousand.

## Net loss per share

The net loss per share dropped from € -0.91 in the previous year (weighted average number of shares: 34,008,289) to € -0.64 in fiscal year 2009 (weighted average number of shares: 34,231,294).

The net loss at full dilution as per the reporting date corresponded to the actual loss, as the conversion of ordinary share equivalents would counteract the dilution effect.

## Segments

MediGene's activities are broken down into the segments »Marketed Products« and »Drug Candidates« (refer to page 77 et seq. – »Segments«). The segment »Marketed Products« includes the drugs Eligard® and Veregen®. The »Drug Candidates« segment reports on MediGene's activities related to the drug candidates EndoTAG™-1, RhuDex®, oHSV, and a preclinical drug candidate. In addition, the technology platform EndoTAG™ is classified in this segment.

## Financial position

### Change in cash reserves

Considering foreign exchange differences, cash and cash equivalents showed a total net decrease of € 12,850 thousand in the 2009 reporting year (2008: € 21,410 thousand). The closing balance of cash and cash equivalents in the year under review was € 12,251 thousand (2008: € 25,101 thousand). The liquidity cover ratio, calculated as the proportion of cash and cash equivalents in the balance sheet total, was 19% (2008: 31%) as per the closing date. There were no open credit lines.

#### Changes in cash reserves

In € thousand	2009	2008	Change
<b>Net cash</b>			
used by operating activities	-18,925	-27,361	-31%
from investing activities	226	4,349	-95%
from financing activities	5,735	1,734	>200%
<b>Decrease in cash and cash equivalents</b>	<b>-12,964</b>	<b>-21,278</b>	<b>-39%</b>
Cash and cash equivalents at the beginning of the period	25,101	46,511	-46%
Foreign exchange differences	114	-132	-186%
<b>Cash and cash equivalents at the end of the period</b>	<b>12,251</b>	<b>25,101</b>	<b>-51%</b>

In the period under review, the net cash used by operating activities decreased to € 18,925 thousand (2008: € 27,361 thousand). The largest part of the cash payments was the result of expenses for research and development, which are offset particularly by income from the commercialization of Eligard®. The net cash used by operating activities was derived indirectly from the net loss.

Net cash from investing activities dropped to € 226 thousand in 2009 (2008: € 4,349 thousand). The comparatively high level of cash proceeds in the previous year arose mainly from the return of the European Oracea® rights to Galderma. MediGene realized proceeds of € 689 thousand from the sale of shares held in the Canadian company QLT in 2009.

Investments in property, plant, and equipment and software amounted to € 463 thousand in the period under review (2008: € 358 thousand). These investments consisted primarily of purchases of laboratory equipment and information technology. The group did not enter into any capital lease contracts.

Net cash from financing activities in the reporting period totaled € 5,735 thousand (2008: € 1,734 thousand). € 6,100 thousand was generated from capital increases as part of the SEDA agreement with YA Global Investments L.P. (hereinafter referred to

as »YA Global Investments«), Jersey City, New Jersey, USA, as well as from interest income. This is offset by interest paid, the repayment of convertible bonds, and the costs of the capital increases, the major part of which were incurred one time, at the time the first SEDA tranches were exercised.

### Average monthly cash burn rate from operating activities

The consolidated statement of cash flows for 2009 shows a net cash burn rate from operating activities of € 18,925 thousand (2008: € 27,361 thousand) and an average monthly cash burn rate of € 1,577 thousand (2008: € 2,280 thousand). The net cash used by operating activities is only of limited informative value with regard to future development, as it is significantly influenced by one-off payments arising from partnerships, and by research and development expenses, the amount of which depends on the status of projects.

## Assets position

#### Development of assets and capital structure

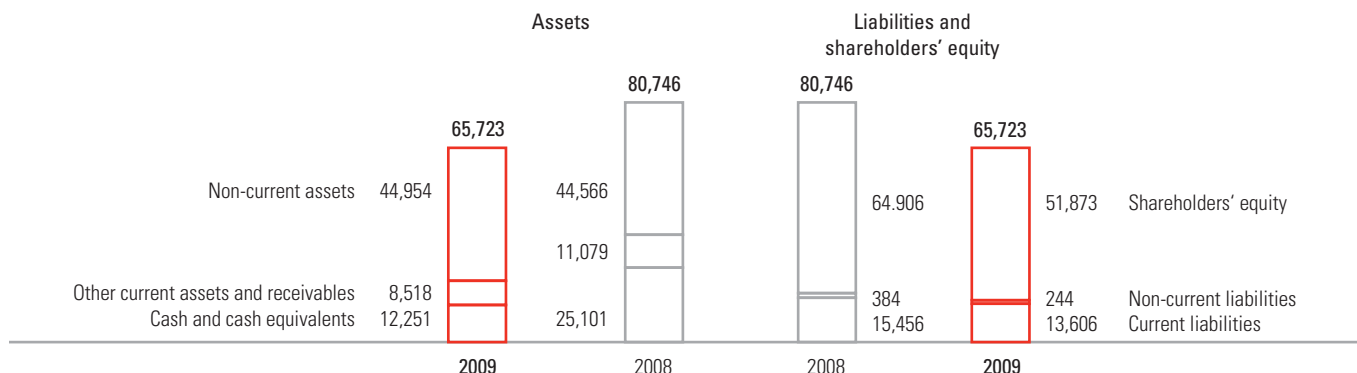
In € thousand	2009	2008	Change
<b>Assets</b>			
Property, plant, and equipment and intangible assets	31,566	29,662	6%
Goodwill	11,272	11,090	2%
Other non-current assets	155	545	-72%
Investment in an associate	1,961	3,269	-40%
Cash and cash equivalents	12,251	25,101	-51%
Inventories and receivables	2,204	5,302	-58%
Other current assets	6,314	5,777	9%
<b>Total assets</b>	<b>65,723</b>	<b>80,746</b>	<b>-19%</b>
<b>Liabilities and shareholders' equity</b>			
Shareholders' equity	51,873	64,906	-20%
Non-current liabilities	244	384	-36%
Current liabilities	13,606	15,456	-12%
<b>Total liabilities and shareholders' equity</b>	<b>65,723</b>	<b>80,746</b>	<b>-19%</b>
<b>Liquidity cover ratio in %</b>	<b>19</b>	<b>31</b>	
<b>Equity ratio in %</b>	<b>79</b>	<b>80</b>	

#### Assets

Compared to the previous year, total assets decreased by 19% to € 65,723 thousand (2008: € 80,746 thousand). This decline can be traced to the decrease in cash and cash equivalents by € 12,850 thousand, impairment of the investment in the associate Immunocore, lower inventories and accounts receivable, and to the sale of the shares of the Canadian company QLT.

**Balance sheet structure**

In € thousand



Despite amortization of licenses, non-current assets rose to € 31,566 thousand (2008: € 29,662 thousand). Property, plant, and equipment amounted to € 1,063 thousand (2008: € 1,151 thousand). Intangible assets rose from € 28,511 thousand to € 30,503 thousand. This rise is primarily due to the increase in intangible assets of the subsidiary MediGene Ltd. related to exchange rates. The RhuDex® project and a further project in the research stage form the basis of these assets denominated in British pounds.

The group holds a 39.09% share in the associate Immunocore as of December 31, 2009. The carrying amount of the holdings acquired on September 30, 2008, dropped to € 1,961 thousand (2008: € 3,269 thousand) at the end of the period under review in line with the share of the loss to be allocated.

Accounts receivable at the end of the period under review amounted to € 749 thousand (2008: € 3,117 thousand). This amount mainly represents receivables from Astellas Pharma.

Inventories totaled € 1,455 thousand (2008: € 2,185 thousand) as per the closing date. They consisted chiefly of Eligard®. The drug is not stockpiled, but resold to the sales partner Astellas Pharma shortly after it is procured.

Other current assets totaled € 6,314 thousand (2008: € 5,777 thousand), of which € 169 thousand (2008: € 637 thousand) were related to public grants, € 1,033 thousand (2008: € 681 thousand) were prepaid expenses for future periods and € 4,683 thousand (2008: € 3,750 thousand) represented deferred product and licensing sales that had not yet been billed. The remaining amount includes other current assets, value-added tax claims, and rent deposits.

**Liabilities and shareholders' equity**

Shareholders' equity decreased to € 51,873 thousand in the period under review (December 31, 2008: € 64,906 thousand). This drop is due primarily to the net loss for 2009, as well as due to a change in other reserves which is offset by receipts from capital increases. Due to the reduction in shareholders' equity, the equity ratio has fallen to 79% (December 31, 2008: 80%).

Current and non-current liabilities decreased by 13% and amounted to € 13,850 thousand (2008: € 15,840 thousand) as per the closing date which constitutes 21% of the balance sheet total. Current liabilities include trade payables totaling € 2,452 thousand (2008: € 10,496 thousand). The level of liabilities in the previous year was due mainly to outstanding payments to QLT USA, Inc. (now »Tolmar«) for the delivery of goods, as well as to license fees and milestones payments amounting to € 8,121 thousand. Furthermore, there are outstanding invoices relating to services used by MediGene.

Working capital, the difference between current assets and current liabilities, has been reduced from € 20,724 thousand (2008) to € 7,163 thousand (2009).

**Capital increases**

Since December of 2008, MediGene has had an agreement (SEDA: Standby Equity Distribution Agreement) with the investment company, YA Global Investments, that assures the company additional equity of up to € 25 million on request. For a period of 36 months after the contract has been entered into, MediGene has the option of drawing down cash in tranches of up to a total of € 25 million and in turn issuing new MediGene shares from authorized capital to YA Global Investments. If and when the company exercises this right during the term of the contract is at MediGene's discretion. During 2009, MediGene drew down five tranches totaling € 6.1 million under this program. A total of 1,528,932 shares were issued in return for these capital increases.

## Employees

### Number of employees in the group

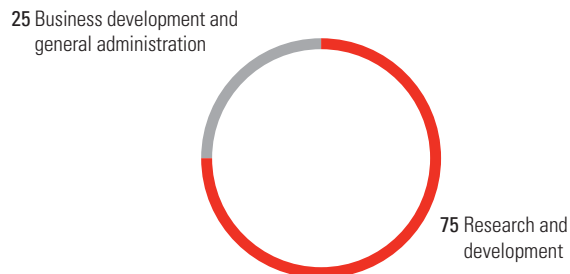
The number of employees (FTEs: full time equivalents) declined to 113 (2008: 150) on average in 2009. This change is due above all to the transfer of almost all employees from the subsidiary MediGene Ltd. to the newly established Immunocore in 2008, and to the reorganization measures implemented during the year 2009. Personnel expenses fell by 19% to € 13,043 thousand (2008: € 16,059 thousand) in the period under review.

#### Employees by region (as at Dec. 31)

	2009	2008	Change
MediGene AG, Planegg/Martinsried, Germany	110	128	-14%
MediGene, Inc., San Diego, USA	4	4	0%
MediGene Ltd., Abingdon, UK	0	1	-%
<b>Total</b>	<b>114</b>	<b>133</b>	<b>-14%</b>

#### Employees according to areas of activity<sup>1)</sup>

In %



<sup>1)</sup> as at December 31, 2009

## Remuneration of Executive Board and Supervisory Board

### Executive Board remuneration

Remuneration of members of the Executive Board in the past fiscal year totaled € 3,077 thousand (2008: € 2,345 thousand) including pension expenses in the amount of € 104 thousand (2008: € 91 thousand) and vehicle leasing costs of € 39 thousand (2008: € 43 thousand). This increase is due mainly to bonus, severance, and continued remuneration in the amount and composition of € 1,722 thousand (2008: € 733 thousand). In addition, stock options with a fair value of € 152 thousand (2008: € 448 thousand) were issued to the Executive Board members. The amount and composition of compensation paid to the individual members of the Executive Board is reported in the Notes to the consolidated financial statements H), item (65) on page 80 et seq.

The Executive Board members' remuneration is comprised of fixed and variable components, as well as performance incentives to enhance shareholder value over the long term. The percentage of corporate objectives achieved is the criterion for the variable component of remuneration. These percentages are established in advance every year. Long-term compensation components consist of stock options. The intention is to create performance incentives geared toward lasting corporate success. The exercise price to be paid for the subscription to a MediGene AG share when exercising the option equals the unweighted average of the closing prices of the company's shares of the last 30 trading days prior to the respective option's allotment date. As a prerequisite for exercising an option, the unweighted average of the closing prices of the company's shares of the last 30 trading days prior to the first day of the respective period in which the option is exercised must equal at least 120% of the exercise price. Options may be exercised only after a waiting period of two years after the allocation date has elapsed, but no later than a period of ten years after the allocation date.

### Supervisory Board remuneration

Supervisory Board remuneration amounted to € 221 thousand in 2009 (2008: € 233 thousand). The total compensation paid to the members of the Supervisory Board is comprised of a fixed portion, as well as meeting attendance fees. Furthermore, expenses are reimbursed. The scope of the duties of the Chairman and Vice Chairman is taken into consideration. Compensation paid to individual members of the Supervisory Board and information on subscription rights of members of the Supervisory and Executive Boards are provided in the Notes to the consolidated financial statements under H), item (66), on page 81 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 will turn out to be hazardous or ineffective, that the products cannot be manufactured in large quantities or marketed profitably, or that they are not sufficiently competitive. Furthermore, proprietary rights held by third parties may pose an obstacle to marketing a product, or other companies may launch drugs that are superior in terms of quality or market price.

### **Risks of unsuccessful drug development**

Prior to commercial use, MediGene's drug candidates have to pass through the preclinical development stage, followed by the individual phases of clinical trials with humans. These trials serve to investigate side effects and efficacy of the drugs. 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 the data presented have been evaluated, the authority decides 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 the execution of a clinical trial or in patient recruitment may increase costs and postpone the market launch. Results of preclinical and clinical trials are unpredictable. Equally, the results of previous trials cannot precisely predict the results of future trials.

Many pharmaceutical and biopharmaceutical 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. Risk diversification is achieved by developing drugs based on a variety of technologies, or by acquiring licenses for products that are in an advanced and lower-risk stage of development.

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. The cancellation of a contract by a service provider might cause a serious delay in the execution of clinical trials and, thus, prolong product development significantly. MediGene places a great deal of importance on consulting only experienced and well-known service providers to undertake clinical trials. It is, nevertheless, possible that a service provider will fail to conduct a trial properly in all respects, which may also cause delays in development.

### **Approval risks**

Even if MediGene is granted market approval for a drug, such approval may be contingent on the fulfillment of certain obligations. This can be detrimental to the product's marketability. Obligations may consist of additional clinical trials or restrictions on the application of a product. Approval may, for instance, be granted only for a sub-group of patients. In addition, the holder of the approval must fulfill a multitude of regulatory duties, such as monitoring the approved drug's safety. Approval – even without additional requirements – obliges MediGene to set up and administer an organization within the company to fulfill these legal requirements. These requirements can be detrimental to the asset, financial, and income position of the company.

Approval of a drug for one particular regional market does not automatically mean that it will be approved for other markets. The individual regional and national markets are subject to different legal requirements that can vary significantly. This also applies to the approval of a drug for treating different diseases. Adherence to approval requirements can delay and/or increase the cost of product commercialization, which could be detrimental to the asset, financial, and income position of the company.

### **Employees**

MediGene 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 growth cannot be ruled out, a fact that could adversely affect MediGene's asset, financial, and income position.

### **Risks of drug commercialization**

#### **Procurement risks**

MediGene purchases the drug Eligard® for the European market exclusively from its licensor and manufacturer Tolmar in the USA. In procuring Eligard® there is, in principle, the risk that the manufacturer will fail to supply the product.

A contract is in place with 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 can adversely affect MediGene's business activities and, therefore, its asset, financial, and income position.

#### **Reimbursement risks**

The commercial success of drug distribution also depends on if, and to what extent, the approved drug is reimbursed by public or private health insurance providers in individual countries. In the European Union and in many other countries, there are price controls and/or other limitations on the reimbursement of drug costs. MediGene may even be forced to reduce the price of a drug in order to be admitted to a reimbursement system at all.

### Risks of low drug sales

The development and marketing of drugs are subject to fierce competition. This applies particularly to the fields of immune-mediated diseases and oncology, the focus of MediGene's activities. Given their commercial potential, these market segments are the focal point of activities on the part of numerous major pharmaceutical and specialized biopharmaceutical companies. MediGene's drug candidates target highly serious and/or still insufficiently treatable diseases. A successful drug would have tremendous market potential for any of these indications. If a competitor became 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 product's profile and sales performance. MediGene's broad-based portfolio strategy is designed to minimize sales risks, although it cannot rule them out entirely.

MediGene's products are currently marketed and sold by partner companies. There is no guarantee that these partners will be 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 asset, financial, and income position.

The ability of MediGene or its marketing partners to sell proprietary drugs on the market can also be adversely affected by competition from generic drugs. Generics are drugs which are launched on the market under the international non-proprietary name or a new trade name after the patent for the original preparation has expired. The marketing of generic drugs that constitute comparable medications can also adversely affect the marketing of MediGene's drugs.

### Risks of dependence on future cooperation agreements

The company has not yet established its own sales and marketing organization. It, therefore, uses the services of cooperation partners for marketing its products. These partners maintain their own sales and marketing organizations. If the company fails to enter into cooperation agreements of this kind under favorable conditions, this could delay or hinder the company's ability to market its products or make such activities unreasonably expensive. This could adversely affect the company's asset, 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 harmful adverse effects from participation in a clinical trial or from taking a prescribed 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 cash flow. 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 could 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 for MediGene

To date, MediGene has not generated any profit, and its future profitability is not assured. Since it was founded in 1994, MediGene has reported operating losses in every fiscal year, as expenses for research and development have exceeded the corresponding revenue and/or gross profit. MediGene still expects to generate losses in the coming fiscal years.

### Planing 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 related to issues such as project progress, the outcome of clinical trials, the conclusion of new licensing agreements and development partnerships, development of product revenue, and general conditions within the relevant pharmaceutical market segments. These assumptions can deviate substantially from actual future developments. Prerequisites for achieving financial targets are an increase in product revenue, the market approval of additional drugs, and the successful outcome of research and development activities. There is no guarantee that MediGene can achieve such product revenue, additional market approvals, and newly concluded partnerships necessary 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 could prove 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. It is possible that MediGene will have 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 from MediGene's research and development activities. MediGene may not always have sufficient funds at its disposal at acceptable conditions when required. Should this be the case, MediGene might be compelled to reduce its spending on research and development, production, or marketing. This could have significant adverse effects on the company's asset, financial, and income position and on its future prospects. So far, MediGene has always been able to raise sufficient capital to ensure the continuous financing of its operations. In order to ensure that such opportunities continue to exist, MediGene is pursuing intensive investor relations and public relations activities.

### Foreign exchange risks

The subsidiary MediGene, Inc. is financed with cash from MediGene AG. If the euro loses value against the US dollar, the cost of operations in the US increases. If the euro rises against the US dollar on the other hand, this impairs the value of MediGene's assets denominated in US dollars. Since the US site is small, the impact of foreign exchange differences from this subsidiary is relatively minor. The same applies to the British subsidiary, MediGene Ltd., the operations of which are denominated in British pounds. There is a significant foreign exchange risk due to a loan within the group granted to MediGene Ltd. by MediGene AG.

MediGene purchases the materials for marketing Eligard® in the USA, and these are invoiced in US dollars. The drug is also sold by MediGene to its European sales partners in US dollars. The gross margin that MediGene achieves is, therefore, also subject to foreign exchange differences.

The development and marketing agreement with Nycomed for Veregen® is transacted in US dollars. The active pharmaceutical ingredients for this drug are also purchased in US dollars. This means that the contractually agreed milestone payments and the margin resulting from product sales are subject to foreign exchange differences.

### Environmental, health, and safety risks

In the United States, the United Kingdom, and Germany, the group must observe a multitude of different laws and standards relating to health, environmental protection, and 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 ordinary business 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 could be highly detrimental to the company's asset, financial, and income position.

### Patent risks and legal risks

#### Patent risks

MediGene's success also depends on its ability to acquire comprehensive patents for its technologies and products, protect its trade secrets, fend off infringements effectively, and assert its own rights without breaching the rights of others. To protect its legally patented technologies and products, MediGene utilizes confidentiality agreements and contractual restrictions in its cooperation with partners, employees, consultants, and other contractual partners.

It cannot be guaranteed 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 continue expanding its technology and product portfolio. In the areas concerned, however, third parties could assert legally protected interests based on industrial property rights or cooperation, research, and license agreements.

#### Legal risks

The risk arising from a legal dispute regarding the commercialization of Eligard® described in the group management's discussion and analysis for 2008 no longer exists since the dispute was settled by the parties involved in July 2009.

In July of 2008, following the death of a volunteer who participated in a trial of the drug candidate RhuDex®, the Public Prosecutor's office in Edinburgh, United Kingdom, initiated a routine investigation, which was concluded in November of 2009. The possibility also exists that a civil action will be initiated on the part of the subject's family. Given the results of the investigation to date, the Executive Board deems the probability of such a suit to be extremely low.

With the exception of the aforementioned legal dispute, no litigation that could have a major influence on the company's financial situation or that of its subsidiaries has been pending in the last twelve months, nor is there currently a threat of any such litigation.

Other legal disputes in the future can not be excluded.

### **Statement regarding risk management according to section 315 (II) (2) and (5) of the German Commercial Code (HGB)**

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

MediGene's corporate strategy is geared toward maximizing shareholder value. This necessitates constant monitoring and improvement of decision-making processes. Corporate success implies taking risks and acting with the appropriate degree of responsibility. With this in mind, MediGene's management utilizes a comprehensive risk management system, which can be flexibly adapted to new situations and is subject to continuous review. Organizational safeguards have been established by segregation of duties. Activities or business transactions that involve risk are never carried out by one employee alone – in all such cases, several individuals are responsible for the decision-making process and for the decision itself. Operating procedures 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 the goal-oriented coordination of planning, information supply, handling, and monitoring. In order to identify any deviations, projects undergo a monthly target-performance comparison, the results of which are discussed regularly with project managers and the Executive Board.

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

MediGene's overall risk with regard to its ongoing existence and success is determined primarily by the individual risks arising in clinical development, product marketing, entering into successful strategic partnerships with the pharmaceutical industry, and in 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 of individual projects failing by maintaining a broad product portfolio based on different technological and scientific approaches which are independent of each other. As some products have already been successfully approved for the market and are consequently generating revenue from products and licenses, these risks are classified as not jeopardizing the company's ongoing existence.

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

MediGene's project portfolio is managed proactively and assessed at regular intervals. The management process includes drawing up development plans for each individual project. These are then adopted by a development committee and compliance with the plan is monitored by the Executive Board. The regular assessment of the individual projects is based on the analysis and evaluation of their opportunities and risks. This analysis and evaluation covers not only the technical risk, but also intellectual property and the 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 respective segment of the drug market.

Results are summarized in a scenario analysis, which 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 platforms and products in order to protect the company against potential competitors. MediGene does not depend on any one technology. It possesses highly diversified technology and product portfolios, both of which are safeguarded by means of far-reaching international patents, pending or granted. In addition, cooperation with external scientific institutes, universities, and other companies provides access to state-of-the-art developments and technologies.

#### **Business planning and forecasting**

At least once a year, MediGene's management prepares a detailed business plan incorporating the results of portfolio management and evaluation. This plan contains numerous assumptions related to issues such as project progress, the outcome of clinical trials, the conclusion of new licensing agreements, development of product revenue, and general conditions within the relevant pharmaceutical market segments. These assumptions can deviate substantially from actual future developments. In order to be able to manage the company despite the resulting uncertainties, a variety of scenarios are developed regarding key assumptions with the aim of securing the company's financing over a period of at least 24 months.

Adherence to the business plan is subject to continuous monitoring. The company is guided based on monthly target-performance comparisons. Furthermore, the business plan is adjusted as soon as there are any changes in the relevant assumptions that have been made.

#### Quality assurance

MediGene's quality assurance system complies with the requirements of the German Pharmaceuticals Act (AMG) and the Good Manufacturing Practice (GMP) guide. GMP contains quality assurance guidelines for production processes and environments in the manufacture of drugs and active ingredients. Following GMP guidelines ensures compliance with defined standards in the development and manufacture of pharmaceutical products, so that proof of the work done and the methods used can be provided at any time. In the quality assurance field, MediGene has a host of standardized workflows at its disposal.

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

As a capital-market-oriented joint stock company as defined in section 264d of the German Commercial Code, the parent company MediGene AG is required pursuant to section 315 (II) (5) of the Code to describe the key features of the internal control and risk management system as it affects the accounting process.

The internal control and risk management system for the accounting process and the group accounting process is not regulated by law. MediGene considers the internal control and risk management system as a comprehensive system and bases its approach on the definitions of the Institute of Public Auditors in Germany (Düsseldorf) regarding accounting-based internal control systems (IDW PS 261, item 19 et seq.) and risk management systems (IDW PS 340, item 4). In accordance with this approach, the principles, procedures, and measures introduced into the company by management that are aimed at the implementation of management decisions in the organization constitute an internal control system:

- to assure the effectiveness and efficiency of business activities (including protection of assets as well as the prevention and detection of losses),
- to ensure proper and reliable internal and external accounting, and
- to comply with the legal provisions applicable to the company.

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

The following structures and processes have been implemented in the group with respect to the accounting processes of the individual companies included, as well as group accounting processes.

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

With regard to the accounting processes of the companies included and the group accounting processes, MediGene considers those features of the internal control and risk management system to be key which can significantly influence the group reporting and overall statement in the consolidated financial statements including the group management's discussion and analysis. 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 process and its results at the divisional and departmental levels, as well as at the companies included in the consolidated financial statements;
- Control measures in group finance and accounting and those companies included in the consolidated financial statements, in units and divisions, that generate fundamental information for the preparation of the consolidated financial statements together with the group management's discussion and analysis, including the separation of functions and the application of predefined approval processes in relevant areas;
- Internal monitoring of the group's accounting-based internal control and risk management system;
- The group has, moreover, implemented a risk management system related to the group-wide accounting process which 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.

## Environmental and health protection

### Safety and environmental protection at a high level

MediGene is committed to safety and environmental protection. The company not only meets stringent statutory requirements, but also strives to keep its laboratory facilities and equipment state of the art. In order to monitor compliance with regulatory requirements, MediGene has appointed in-house officers for biological safety, and waste management, as well as a safety engineer and a project manager for genetic research, all of whom are experienced employees trained specifically for their specialist tasks. MediGene also employs a qualified person for safety trained in accordance with the guidelines of the German chemical industry's employers' liability insurance association.

MediGene's laboratory facilities and equipment are serviced on an ongoing basis and 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 the prevailing requirements. In order to guarantee safety at work for all of our laboratory employees, 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 the fields of environmental and health protection and safety and possesses the pertinent authorizations and permits. The company has passed all random inspections and tests carried out by the various authorities to date without any relevant objections.

### Explanatory management report on the statements in accordance with section 289 (IV) and 315 (IV) of the German Commercial Code (HGB)

The Executive Board has provided statements pursuant to sections 289 (IV) and 315 (IV) of the German Commercial Code (HGB) in the Management's discussion and analysis (MD&A) for MediGene AG and the Group MD&A for the 2009 fiscal year. It has explained these as follows:

#### Number 1: Composition of subscribed capital

The company's share capital amounts to € 35,557,493.00 and is divided into 35,557,493 no-par value registered shares (common shares) with a proportional share in capital of € 1.00. The shareholders of MediGene AG are recorded in the share register. All shares guarantee the same rights. Every share guarantees a vote at the Shareholders' Meeting and the same profit share.

#### Number 2: Restrictions on voting rights or transfer of shares

As far as the Executive Board is aware, there are no restrictions on voting rights or restrictions pertaining to the transfer of shares.

#### Number 3: Investments in capital exceeding 10% of the voting rights

The company was not made aware of any direct or indirect investments in the share capital of MediGene AG that exceed ten of hundred voting rights.

#### Number 4: Shares that grant special control privileges

The company has not issued shares that grant special control privileges.

#### Number 5: Nature of voting rights control if employees have a share in the capital and do not directly exercise their right of control

Employees holding a share in the capital of MediGene AG exercise their right of control directly, the same way as other shareholders do, i.e. in accordance with the law and the Articles of Incorporation. There is no control over voting rights in the event that employees hold a share in the capital and do not directly exercise their right of control.

#### Number 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 is also responsible for revoking such appointment.

Provisions regarding amendments to the Articles of Incorporation are contained in sections 179 and 133 of the German Stock Corporation Act (AktG). Under these provisions, any amendment to the Articles of Incorporation requires a shareholders' resolution for which a simple majority is needed and which at least three quarters of the capital represented at the time of the resolution should 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 should be adopted by a simple majority of the votes cast, unless a larger majority is compulsory under the 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) 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.

### **Number 7: Powers of the Executive Board, especially with regard to the issuance or repurchase of shares**

The Executive Board manages the company on its own authority in accordance with section 76 (I) of the German Stock Corporation Act (AktG) and represents the company in and out of court in accordance with section 78 (I) of the Act.

#### **a) Authorized capital**

The Executive Board was authorized by shareholders' resolution of August 31, 2009 – upon approval by the Supervisory Board – to increase the share capital by a total of up to € 17,026,072 (approximately 47.88% of the share capital) until August 30, 2014, by issuing up to 17,026,072 new registered shares (no-par shares) on one or more occasions against contributions in cash or in kind (2009 authorized capital). The authorization can be used in partial amounts. The Executive Board is authorized to stipulate the further content of share rights and the conditions of issuing shares with the consent of the Supervisory Board. Due to the issue of 1,505,348 new registered shares against cash contribution, a total of 15,520,724 new shares are still available against contribution in cash or in kind of up to € 15,520,724 as at December 31, 2009.

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

The company's share capital was increased conditionally through a number of conditional capital items on December 31, 2009, by up to € 7,018,510 overall, divided into up to 7,018,510 ordinary shares overall (circa 19.74% of share capital).

In detail, the conditional capital items involved: conditional capital I of up to € 136,897 (1997), conditional capital II of up to € 106,429 (1998), conditional capital III of up to € 125, conditional capital IV of up to € 13,770, conditional capital V of up to € 652,329 (2000 and 2001), conditional capital VI of up to € 3,000 (2000), conditional capital VIII of up to € 3,000 (2001), conditional capital X of up to € 3,000 (2002), conditional capital XI of up to € 1,400 (2003), conditional capital XII of up to € 498,560 (2003), conditional capital XVI of up to € 300,000 (2006), conditional capital XVIII of up to € 1,600,000 (2007), and conditional capital XX of up to € 3,700,000 (2009).

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

The purpose of the contingent capital items is:

- a) in the case of conditional capital I, II, V, XII, XVI, and XVIII, exclusively to grant conversion rights to the holders of options for conversion or option 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 exploit the conversion rights stemming from the profit sharing bonds which were issued to Technologie-Beteiligungs-Gesellschaft mbH of the Deutsche Ausgleichsbank;
- c) in the case of conditional capital IV, exclusively to exploit the conversion rights stemming from contracts with IKB Nachrangkapital GmbH and Technologie-Beteiligungs-Gesellschaft mbH of the Deutsche Ausgleichsbank;
- d) in the case of conditional capital VI, VIII, X, and XI, exclusively to grant shares to the holders of convertible bonds which were issued to the 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 XX, exclusively to grant new shares to the holders of conversion rights and options which are issued in accordance with the provisions of the shareholders' resolution of August 31, 2009.

Notes on authorized and conditional capital:

The previously illustrated authorizations of the Executive Board to issue new shares from authorized capital and the previously illustrated conditional capital items in connection with the associated resolution for issuing convertible or warrant-linked bonds put the Executive Board in a position 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, in the cases mentioned in Section 71 (I) of the German Stock Corporation Act (AktG), acquire its own shares in the company. The Executive Board is not currently authorized to repurchase its own shares pursuant to Section 71 (I) (8) of the Act. The company does not hold any treasury shares at the moment.

### **Number 8: Significant agreements of the company which are conditional upon a change of control as a result of a takeover bid**

The contracts governing the appointment to the Executive Board of Board members Dr Thomas Klaue (beginning of term: June 15, 2007), Dr Frank Mathias (beginning of term: April 1, 2008, CEO since April 29, 2009), and Dr Axel Mescheder (beginning of term: May 19, 2008; end of term: December 10, 2009) provide for special termination rights in the event of a change of control, both for the company and for each of the Executive Board members Dr Thomas Klaue, Dr Frank Mathias, and Dr Axel Mescheder. The special termination rights are limited to one year starting from the time of the change in control.

The change in control in the sense of the contractual agreement is said to exist if more than 30% of the voting stock of the company or more than 50% of the voting rights present at the company's Shareholders' Meeting on average in the last three calendar years are acquired by a third party. The point in time at which the control changeover takes place is determined by the entry in the company's share register in accordance with Section 67 (III) of the German Stock Corporation Act (AktG).

The Executive Board members Dr Thomas Klaue, Dr Frank Mathias, and Dr Axel Mescheder are each entitled to special termination rights for the period of one year after the time of the change of control. If this change results in an unacceptable shift in the previous duties and responsibilities of the Executive Board member (budget, number of employees and corporate entities to be supervised), the place of employment is relocated more than 100 km from the Executive Board member's current place of residence without his agreement, the Executive Board member is dismissed, or the company informs the Executive Board member that his appointment will not be extended and denial of such extension is not based on significant cause for which the Executive Board member bears responsibility and which would justify extraordinary termination.

Any details beyond the above have been omitted.

### **Number 9: Compensation agreement with members of the Executive Board or employees in the event of a takeover bid**

If the term of office of the Executive Board members Dr Thomas Klaue, Dr Frank Mathias, and Dr Axel Mescheder comes to an end as a result of the company exercising its special termination right referred to above, the respective Executive Board member shall be entitled to receive severance payment in the amount of the gross remuneration up to the regular end of the Executive Board contract, a pro rata temporis gross bonus (without stock options) on the basis of the average annual bonus up to the regular end of the Executive Board contract term, and a

lump-sum payment amounting to 2.5 times the annual remuneration due (without stock options). This lump-sum payment may exceed neither three times the total annual remuneration and 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.

In the event of a special termination by one of the Executive Board members Dr Thomas Klaue, Dr Frank Mathias, and Dr Axel Mescheder, the respective Executive Board member shall be entitled to receive a compensation payment in the amount of three times the gross monthly sum for every fully completed year of his service on the company's Executive Board. The gross monthly amount is comprised of one twelfth the gross remuneration and one twelfth the average annual bonus at the time of the termination. The severance payment may not exceed either the total of 36 gross monthly salary payments nor 1.5 times the remuneration anticipated for the remaining term of the employment contract.

The intended purpose of the compensation agreements made or to be made with the members of the Executive Board in the event of a takeover bid is to protect the member of the Executive Board and, in the event of a change of control, to maintain his or her independence.

## **Statement on Corporate Governance**

The statement on Corporate Governance in accordance with section 289a of the German Commercial Code (HGB), including the Corporate Governance report according to point 3.10 of the German Corporate Governance Code can be found on pages 92 et seq. of the report at hand.

## **Major events since the end of the period under review**

### **Dr Thomas Werner appointed as new Supervisory Board member**

In February 2010, the Munich Local Court has appointed Dr Thomas Werner as Supervisory Board member, upon request by MediGene AG's Executive Board. This increases the number of Supervisory Board members from five to six.

### **Veregen® – Commercialization is progressing**

MediGene and Teva Pharmaceutical Industries Ltd., Tel Aviv, Israel, in February 2010 entered into a partnership for the registration and commercialization of Veregen® in Israel. This is the first marketing partnership for Veregen® in Asia. On March 1, 2010, MediGene's partner Solvay has initiated the German launch of Veregen®.

## Outlook

The outlook covers the 2010 and 2011 fiscal years.

### General economic conditions

After a global slump in the economy at the beginning of 2009, the European Central Bank perceives a return to growth according to its monthly report for December 2009. While the sustainability of future growth is still highly uncertain, the risks in global economic prospects are considered generally to be well-balanced.

Prospects for the pharmaceutical sector have also improved. IMS Health anticipates a 4–6% growth in the global pharmaceutical market for 2010. This view is substantiated above all by better prospects in the USA. A year ago, the forecast for this pharmaceutical market, the largest in the world, was considerably more subdued. The more distant future is positive as well; IMS assumes an annual worldwide growth of 4–7% until 2013.

### Anticipated developments in the biopharmaceutical industry

Drugs for the treatment of tumor illnesses already account for the largest share of the global drug market. Experts are forecasting that the market volume of cancer drugs will grow continuously over the next few years. Projections put global sales at over \$ 60 billion in 2011. The current market volume is already approximately \$ 50 billion (source: Datamonitor 2007).

The inadequate efficacy of the therapies that are currently available, and the increasing frequency of tumor illnesses will continue to boost demand for innovative drugs. In the process, market growth will additionally be driven by innovative forms of therapy, such as the drug candidate EndoTAG™-1, which, with greater efficacy and milder side effects, may lead to considerable improvements in available therapies.

Continuing cost pressure on healthcare providers could lead to further legislation to reduce the cost of drugs. This could also affect the biopharmaceutical industry in Europe and the USA.

### Further increase in revenue from product sales anticipated

The following developments are expected in the Marketed Products segment:

#### Further sales growth for Eligard®

In 2010, MediGene expects to see another increase in the Eligard®'s market share in Europe and a further boost to the total revenue generated with Eligard®.

#### Veregen® – Product sales in the US via the marketing partner Nycomed

After concentrating its sales activities on the opinion-makers among US doctors in 2009 in order to secure acceptance of the drug in the market, MediGene's sales partner Nycomed plans to expand its sales organization to handle the anticipated size required for marketing Veregen® on a broader scale. As a result, MediGene is expecting increased revenues from the sale of this ointment on the US market in the 2010 fiscal year. In addition to income from the sale of the active ingredient to its partner Nycomed, MediGene receives a share of the net revenue earned on the market.

#### Veregen® – Additional indications

Decisions on the further development of the ointment for additional indications will be made within the framework of the partnerships closed. The successful development of the ointment for an additional indication would open up additional commercial potential.

#### Kick-off of the Veregen® market launch in Europe

MediGene is anticipating the marketing launch in Europe to commence in 2010, starting with Germany. Applications for marketing approval will be submitted for additional European countries.

#### Clinical projects: Partnering for EndoTAG™-1 a key factor

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

#### EndoTAG™-1 – Activities for the conclusion of development and marketing partnerships

MediGene is aiming to enter into one or more development partnerships with pharmaceutical or biopharmaceutical companies for the further development of the drug candidate EndoTAG™-1.

#### EndoTAG™-1 – Continuation of the phase II clinical trial for the treatment of breast cancer

Since April 2007, MediGene has been conducting a phase II trial with the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. The recruitment of patients was completed in October of 2009, so the results of the trial are anticipated in the first half of 2010.

### RhuDex® – Preclinical trials as a basis for resumption of clinical development

After conducting a preclinical trial program in the current year, MediGene plans to resume clinical development no later than the first quarter of 2011.

### Spin-off of research and development projects

MediGene is currently working on spinning off or out-licensing the oHSV and AAVLP programs.

#### Achievement of project goals for 2009

Expectations for 2009		
Marketed Products		
Eligard®	Further increase in product revenue	Achieved
Polyphenon E® Ointment/Veregen®	First decision on the applications for market approval submitted in three European countries	Achieved
	Kick-off of active marketing in the USA	Achieved
	Entering into sales partnerships in Europe	Achieved
Drug Candidates		
EndoTAG™-1	Entering into a development and marketing partnership	Delayed
	Conclusion of patient recruitment for the ongoing phase II clinical trial in the indication of triple receptor-negative breast cancer	Achieved
RhuDex®	Resumption of clinical development and phase I trial	Delayed
oHSV (NV1020)	Publication at a conference of the results from the phase II clinical trial in the indication of liver metastases derived from colorectal cancer	Achieved
	Partnership or spin-off	Delayed

#### R&D projects – Status expected for December 2010

Objectives for 2010	
Marketed Products	
Eligard®	Further increase in product revenue
Veregen®	European market launch
	Conclusion of additional sales partnerships
	Submission of additional applications for market approval in Europe
Drug Candidates	
EndoTAG™-1	Conclusion of a worldwide or several regional development and marketing partnerships for the USA and Europe
	Publication of data from the phase II clinical trial for the indication receptor-negative breast cancer
	Start of production of study medication in spray-drying process
RhuDex®	Preparation of the resumption of clinical development and phase I trial
oHSV	Partnership or spin-off

#### Financial forecast for 2010 and 2011

##### Increase in revenue

MediGene expects to enter into one or more development and marketing partnerships for EndoTAG™-1 in 2010 that will significantly affect net income for the year. However, the financial effects of this are difficult to estimate at the present. Irrespective of any payments from such partnerships, MediGene anticipates increasing revenue of more than € 40 million in 2010, most of which will stem from the product revenue of Eligard® and Veregen®. A key factor in achieving these sales forecasts for 2010 is the continued rise in Eligard® revenue, successful marketing of Veregen® in the USA, and the successful launch of Veregen® in Europe.

MediGene's management anticipates further growth in sales from product marketing during the 2011 fiscal year as well.



A forecast for the year 2010 can be given only after the conclusion of the EndoTAG™-1 partnering process, since both revenue as well as composition and extent of the development expenses will largely depend on the partnership structure.

The future corporate financing will also depend on the structure of the expected partnerships. According to the current plan, financing shall be secured by the revenue from sales of already marketed drugs, as well as payments received under the terms of the partnership for EndoTAG™-1 to be concluded. In addition, the company has closed an equity funding agreement with YA Global Investments, securing additional equity funding. Based on the current business planning and the scenarios deriving thereof, the management assumes that financing of the company is secured beyond the end of the year 2011.

#### **Number of employees to remain relatively constant through 2010**

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

#### **Research and development still the largest cost pool**

A small number of larger single investments in property, plant, and equipment (> € 100 thousand) are planned in 2010 and 2011. The expenses for research and development are still the largest cost pool.

#### **Future procurement**

Regarding procurement, MediGene does not expect developments in 2010 to differ from those in the previous year. In 2010, MediGene will continue to purchase the drug Eligard® from Tolmar for the European market. MediGene will obtain Veregen® for both the US and European markets from contract manufacturers in Japan and Germany.

#### **Dividends**

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

#### **Future legal corporate structure and organization/administration**

No changes in the company's legal structure are planned.

#### **Environmental protection exceeds the required level**

The measures already implemented will continue to be pursued. MediGene will continue to protect the environment beyond the level required by public authorities.

### **The Executive Board**

Planegg/Martinsried, Germany, March 11, 2010  
MediGene AG

#### **Dr Frank Mathias**

Chief Executive Officer

#### **Dr Thomas Klaue**

Chief Financial Officer

# Consolidated income statement

of MediGene AG for the periods from January 1 to December 31, 2009 and 2008

In € thousand	Notes No.	2009	2008
1. Product sales		37,859	33,507
2. Other operating income		1,607	6,099
<b>3. Total revenue</b>	(27)	<b>39,466</b>	<b>39,606</b>
4. Cost of sales	(28)	-31,482	-26,926
<b>5. Gross profit</b>		<b>7,984</b>	<b>12,680</b>
6. Selling expenses	(29)	-2,192	-2,763
7. General and administrative expenses	(30)	-6,932	-7,721
8. Research and development expenses	(31)	-18,499	-27,465
9. Loss resulting from spin-off		0	-6,431
<b>10. Operating result</b>		<b>-19,639</b>	<b>-31,700</b>
11. Interest income	(32)	129	1,452
12. Interest expense	(32)	-5	-2
13. Income/expenses from financial assets	(32)	302	-352
14. Foreign exchange losses	(32)	-519	-2,035
15. Losses from derivative financial instruments	(32)	-578	-253
16. Share of loss of an associate		-1,625	-256
<b>17. Result before income tax</b>		<b>-21,935</b>	<b>-33,146</b>
18. Taxes	(52)	-27	2,356
<b>19. Net loss for the year</b>		<b>-21,962</b>	<b>-30,790</b>
<b>Net loss per share:</b>			
Actual and fully diluted in €		-0.64	-0.91
Weighted average number of shares outstanding		34,231,294	34,008,289

# Consolidated statement of comprehensive income

of MediGene AG for the periods from January 1 to December 31, 2009 and 2008

In € thousand	2009	2008
1. Net loss for the year	-21,962	-30,790
2. Exchange differences on translation of foreign operations <sup>1)</sup>	2,079	-6,949
3. Unrealized gains/losses on hedge of a net investment <sup>1)</sup>	808	-1,837
<b>4. Other comprehensive income for the year, net of tax</b>	<b>2,887</b>	<b>-8,786</b>
<b>5. Total comprehensive income for the year, net of tax</b>	<b>-19,075</b>	<b>-39,576</b>

<sup>1)</sup> no income tax effects were incurred

# Consolidated balance sheet

of MediGene AG as of December 31, 2009 and 2008

## Assets

In € thousand	Notes No.	Dec. 31, 2009	Dec. 31, 2008
<b>A. Non-current assets</b>			
I. Property, plant & equipment	(39)	1,063	1,151
II. Intangible assets	(40)	30,503	28,511
III. Goodwill	(36)	11,272	11,090
IV. Financial assets	(41)	152	540
V. Investment in an associate	(42)	1,961	3,269
VI. Other assets		3	5
<b>Total non-current assets</b>		<b>44,954</b>	<b>44,566</b>
<b>B. Current assets</b>			
I. Inventories	(43)	1,455	2,185
II. Trade accounts receivable	(44)	749	3,117
III. Cash and cash equivalents	(45)	12,251	25,101
IV. Other current assets	(44)	6,314	5,777
<b>Total current assets</b>		<b>20,769</b>	<b>36,180</b>
<b>Total assets</b>		<b>65,723</b>	<b>80,746</b>

## Liabilities and shareholders' equity

In € thousand	Notes No.	Dec. 31, 2009	Dec. 31, 2008
<b>A. Shareholders' equity</b>			
I. Subscribed capital	(46)	35,557	34,029
Number of shares issued and outstanding			
Dec. 31, 2008: 34,028,561			
Dec. 31, 2009: 35,557,493			
II. Additional paid-in capital	(47)	340,487	335,973
III. Accumulated deficit	(48)	-315,229	-293,267
IV. Other reserves	(49)	-8,942	-11,829
<b>Total shareholders' equity</b>		<b>51,873</b>	<b>64,906</b>
<b>B. Non-current liabilities</b>			
I. Financial liabilities	(50)	9	169
II. Pension obligation	(51)	235	215
<b>Total non-current liabilities</b>		<b>244</b>	<b>384</b>
<b>C. Current liabilities</b>			
I. Trade accounts payable	(53)	2,452	10,496
II. Derivative financial instruments	(54)	1,743	1,166
III. Other current liabilities	(53)	8,843	3,339
IV. Accruals	(55)	470	455
V. Deferred income		98	0
<b>Total current liabilities</b>		<b>13,606</b>	<b>15,456</b>
<b>Total liabilities</b>		<b>13,850</b>	<b>15,840</b>
<b>Total liabilities and shareholders' equity</b>		<b>65,723</b>	<b>80,746</b>

# Consolidated statement of cash flow

of MediGene AG for the periods from January 1 to December 31, 2009 and 2008

In € thousand	2009	2008
<b>Cash flow from operating activities</b>		
Net loss for the year (before taxes)	-21,935	-33,146
<b>Adjustments to reconcile net loss before tax to net cash used by operating activities:</b>		
Stock-based compensation	394	1,135
Unrealized exchange loss on foreign currency transaction	0	1,052
Depreciation and impairment	831	7,116
Gains on sale of property, plant & equipment	0	-4,329
Gains on financial assets	-291	352
Interest income	-129	-1,452
Interest expense	5	2
<b>Changes in:</b>		
Inventories	730	-1,617
Other assets and prepaid expenses	1,825	-3,114
Trade accounts payable	-8,044	8,254
Accruals	14	18
Other liabilities and deferred income	6,077	-2,781
Taxes	-27	893
Share of net loss of an associate	1,625	256
<b>Net cash used by operating activities</b>	<b>-18,925</b>	<b>-27,361</b>
<b>Cash flow from investing activities</b>		
Purchase of property, plant & equipment	-463	-358
Return of intangible assets	0	8,000
Disposal of financial assets	689	0
Investment in an associate	0	-3,293
<b>Net cash from investing activities</b>	<b>226</b>	<b>4,349</b>
<b>Cash flow from financing activities</b>		
Proceeds from capital increase	6,100	0
Expenses on capital increase	-452	0
Proceeds from stock options and convertible bonds	0	253
Repayment of convertible bonds	-37	-24
Interest received	129	1,507
Interest paid	-5	-2
<b>Net cash from financing activities</b>	<b>5,735</b>	<b>1,734</b>
<b>Decrease in cash and cash equivalents</b>	<b>-12,964</b>	<b>-21,278</b>
Cash and cash equivalents at beginning of the year	25,101	46,511
Foreign exchange differences	114	-132
<b>Cash and cash equivalents at end of the year</b>	<b>12,251</b>	<b>25,101</b>

# Consolidated statement of changes in shareholders' equity

of MediGene AG for the periods from January 1 to December 31, 2009 and 2008

	Shares	Subscribed capital	Capital reserves	Accumulated deficit	Currency translation	Hedge of net investment	Total shareholders' equity
	No.	€ thousand	€ thousand	€ thousand	€ thousand	€ thousand	€ thousand
<b>Balance at Jan. 1, 2009</b>	34,028,561	34,029	335,973	-293,267	-9,992	-1,837	64,906
Net loss for the year				-21,962			-21,962
Unrealized gains on hedge of a net investment						808	808
Currency translation adjustments					2,079		2,079
<b>Comprehensive income</b>							-19,075
Shares issued	1,528,932	1,528	4,572				6,100
Expenses on shares issued			-452				-452
Stock-based compensation			394				394
<b>Balance at Dec. 31, 2009</b>	<b>35,557,493</b>	<b>35,557</b>	<b>340,487</b>	<b>-315,229</b>	<b>-7,913</b>	<b>-1,029</b>	<b>51,873</b>
<b>Balance at Jan. 1, 2008</b>	33,946,481	33,946	334,667	-262,477	-3,043	0	103,093
Net loss for the year				-30,790			-30,790
Unrealized losses on hedge of a net investment						-1,837	-1,837
Currency translation adjustments					-6,949		-6,949
<b>Comprehensive income</b>							-39,576
Exercise of options/bonds	82,080	83	171				254
Stock-based compensation			1,135				1,135
<b>Balance at Dec. 31, 2008</b>	<b>34,028,561</b>	<b>34,029</b>	<b>335,973</b>	<b>-293,267</b>	<b>-9,992</b>	<b>-1,837</b>	<b>64,906</b>

# Notes to the consolidated financial statements

of MediGene AG, Planegg/Martinsried, Germany, for the fiscal year 2009

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

MediGene AG, Planegg/Martinsried, Germany, is a biopharmaceutical company that specializes in the research, development, and commercialization of innovative drugs, concentrating on indications of great medical necessity and, consequently, substantial commercial interest. Its research and development activities center upon cancer and immune-mediated diseases. The drugs approved to date are sold via sales partners.

The group's main activities are described in Note (G) »Segment Reporting«.

MediGene AG was founded in 1994 in Planegg/Martinsried near Munich, Germany, with share capital of € 26 thousand. In 1996, the company was transformed into a stock corporation. Its headquarters are located at Lochhamer Straße 11, 82152 Planegg/Martinsried, Germany. The company is registered in the Commercial Register of the Munich Local Court under HRB 115761. MediGene AG has been listed since June 2000 (Deutsche Börse, Regulated Market, Prime Standard; SIN 502090; code MDG). Since February 9, 2009, the MediGene AG share has been listed in the TecDAX selection index of Deutsche Börse.

In addition to the parent company, MediGene AG in Planegg/Martinsried, Germany, the MediGene group includes two wholly owned subsidiaries, MediGene, Inc., San Diego, California, USA, and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom. The subsidiaries were acquired in 2001 (MediGene, Inc.) and 2006 (MediGene Ltd.), respectively. Moreover, MediGene has held 39.09% of the shares in the associate Immunocore Ltd., Abingdon, Oxfordshire, United Kingdom, since September 30, 2008. In this report the MediGene group is hereinafter referred to as »MediGene« or »group«.

## B) Accounting and valuation principles

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

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

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

The group, as a capital-market-oriented proprietary company as defined by Article 4 of Regulation (EC) No. 1606/2002, uses the International Financial Reporting Standards (IFRS) in their entirety.

These consolidated financial statements were prepared in compliance with the International Financial Reporting Standards as applicable in the EU. The company's Executive Board is of the opinion that the consolidated financial statements reflect all of the business transactions required to present the asset, financial, and income position as per the end of the periods ending on December 31, 2008 and 2009 respectively. These consolidated financial statements additionally 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, 2009 were approved for publication by a resolution of the Executive Board on March 11, 2010.

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

MediGene has not made any fundamental changes to accounting and valuation methods beyond the application of new and amended accounting standards and new interpretations as illustrated below.

### 1) First-time application of new and revised statutory accounting requirements

In the consolidated financial statements for 2009, the following new and revised International Financial Reporting Standards and Interpretations (IFRIC) were applied for the first time:

IFRS 2	Share-based Payment
IFRS 7	Financial Instruments: Disclosures
IFRS 8	Operating Segments
IAS 1 R	Amendments to Presentation of Financial Statements
Improvements to IFRS in 2008	1. Omnibus edition

The revised standards replace the previous versions of these standards and apply to fiscal years beginning on or after January 1, 2009. The application of new and revised standards impacts the 2009 consolidated annual financial statements of MediGene AG as follows:

#### *Amendment to IFRS 2 (»Share-based Payment«)*

In January 2008, the IASB published an amendment to IFRS 2 in which the definition of vesting conditions was stated more precisely and the balance-sheet treatment of cancelled commitments was adopted. This amendment must be applied for the first time for fiscal years beginning on or after January 1, 2009. The application of this interpretation has no effect on the group's asset, financial, and income position.

In June of 2009, the IASB published an amendment to IFRS 2 for group cash-settled share-based payment transactions. This amendment must be applied for the first time for fiscal years beginning on or after January 1, 2010. This amendment also replaces IFRIC 8 and IFRIC 11. The group has decided not to adopt these amendments prematurely.

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

The amendment was published in March 2009 and must be applied for the first time for fiscal years beginning on or after January 1, 2009. The amended standard defines additional disclosures on determining fair value and liquidity risk and demands a quantitative analysis of the determination of fair values on the basis of a three-level hierarchy for each class of financial instruments recorded at fair value. Additionally, in the valuation of level 3 at fair value a reconciliation between

starting and final balance is prescribed, as is the disclosure of significant reclassifications between levels 1 and 2 of the determination hierarchy. A reconciliation between starting and final balance is prescribed, as is the disclosure of significant reclassifications between levels 1 and 2 of the determination hierarchy. The amendment clarifies the requirements for disclosures of liquidity risks in relation to transactions with derivative financial instruments and of assets used for liquidity management purposes. The information on determining fair values is presented in Note (60). The disclosures concerning the liquidity risk are not changed significantly by the new regulations and are described in Note (59).

#### *IFRS 8 (»Operating Segments«)*

This standard must be applied for the first time for fiscal years beginning on or after January 1, 2009. It requires that a group disclose information on its operating segments. It replaces the requirement to determine primary (business) and secondary (regional) segment reporting formats for the group in question. The revision of the IFRS 8 requirements as far as their application in 2009 is concerned revealed that the previous primary business segments »Specialty Pharma« and »Biopharma« can be transferred to the segments »Marketed Products« and »Drug Candidates«. The two segments are subject to reporting requirements as defined by IFRS 8.

The operating segments in the group which are identified in accordance with IFRS 8 correspond to the operating segments previously identified as per IAS 14 »Segment Reporting«.

A detailed commentary on segment reporting and the implementation of IFRS 8 can be found in Note (26) »Segment Reporting/Business Units«.

#### *IAS 1 R (»Presentation of Financial Statements (revised)«)*

The revised standard was published in September 2007 and must be applied for the first time for fiscal years beginning on or after January 1, 2009. The standard requires separate disclosures for changes in shareholders' equity resulting from transactions with shareholders in their role as equity providers, as well as for other changes in shareholders' equity. The statement of changes in equity includes all details on business transactions with shareholders, while all other changes in equity are presented in one single line. In addition, the standard introduces the disclosure

of comprehensive income in the entire period in which all its reported components are shown either in a single itemized list or in two itemized lists linked to one another. MediGene utilizes the option of continuing to present an income statement in the traditional format, along with a second statement of comprehensive income (SOC1).

#### *Amendments to IFRS 2008 («Omnibus edition«)*

In May 2008, the IASB published an omnibus edition for the amendments to various IFRS standards; these amendments were transposed into EU law on January 23, 2009. They are concerned mainly with eliminating inconsistencies and clarifying

formulations that could lead to misunderstandings. The standard contains a diversity of amendments which are classified in two parts: Part 1 encompasses all the amendments which affect accounting; Part 2 contains terminological or editorial alterations which, in the opinion of the Board, are to be regarded as minor from the user's point of view. The group has decided not to apply these amendments prematurely.

In the following section, MediGene has subjected the accounting-related changes (Part 1) to an initial examination and come to the following conclusions regarding the future effects on the group's asset, financial, and income position:

Standard	Accounting-related amendment	Impact
IFRS 5 »Noncurrent Assets Held for Sale and Discontinued Operations«: Plan to sell the controlling interest in a subsidiary	When a subsidiary is held for sale, all of its assets and liabilities must be classified as held for sale under IFRS 5, even if the company retains a minority interest in the subsidiary after the sale.	No impact
IAS 1 »Presentation of Financial Statements«: Classification of derivatives as current/noncurrent	Assets and liabilities classified as held for trading in accordance with IAS 39 »Financial Instruments: Recognition and Measurement« are not automatically classified as current balance sheet items.	No impact
IAS 16 »Property, Plant, and Equipment«: a) Recoverable amount b) Sale of assets held for rental purposes	a) The term »net selling price« was replaced by the term »fair value less costs to sell« to ensure consistency with IFRS 5 »Noncurrent Assets Held for Sale and Discontinued Operations« and IAS 36 »Impairment of Assets«. b) Items of property, plant, and equipment held for rental purposes that are routinely sold in the ordinary course of business after the rental period expires are transferred to inventory once rental ceases and they are held for sale. Proceeds of such sales are subsequently shown as revenue. IAS 7 »Statement of Cash Flows« has been expanded to include the requirement that payments for the production or acquisition of such assets must be classified as cash flow from operating activities. The cash receipts from rents and the subsequent sale of the assets must also be shown as cash flow from operating activities.	a) No impact b) Not applicable
IAS 19 »Employee Benefits«: a) Plan curtailments and negative past service costs b) Plan administration costs c) Replacement of the term »fall due« d) Guidance on contingent liabilities	a) The definition of »past service costs« was broadened to include reductions in benefits in relation to claims already accrued (»negative past service costs«). At the same time, benefit reductions in relation to future claims that result from alterations to the plan were removed from the definition. Alterations to plans that result in a reduction in benefits related to future claims must be included in the balance sheet as curtailment. b) Plan administration costs that have already been included in the actuarial assumptions for measuring the defined benefit obligation will no longer be considered in the definition of »return on plan assets« in the future. c) The definition of »short-term« and »other long-term« employee benefits has been revised in order to focus more on the point in time when the liability is due to be settled. d) The reference to the recognition of contingent liabilities was removed to ensure consistency with IAS 37 »Provisions, Contingent Liabilities, and Contingent Assets«. IAS 37 stipulates that contingent liabilities may not be included in the balance sheet.	a) No impact b) No impact c) No impact d) No impact
IAS 20 »Accounting for Government Grants and Disclosures of Government Assistance«: Government loans with no interest or a below-market interest rate	Government loans with no interest or a below-market interest rate are not exempt from the requirement to be measured at fair value. The interest rate advantage from government loans with no or low interest rates must also be quantified in the future. This brings the standard into line with IAS 39. The difference between the amount received and the discounted amount must be accounted for as a government grant.	Not applicable
IAS 23 »Borrowing Costs«: Components of borrowing costs	In the future, the definition of borrowing costs will consolidate the types of items that are seen as components of »borrowing costs« under a single item – i.e. the interest expenses calculated using the effective interest method in accordance with the definition in IAS 39. This will underline the interdependency between IAS 23 and IAS 39	At the moment there are no qualifying assets available.



Standard	Accounting-related amendment	Impact
IAS 27 »Consolidated and Separate Financial Statements«: Measurement of a subsidiary held for sale in separate financial statements	When a proprietary entity accounts for a subsidiary at fair value in accordance with IAS 39 in its separate financial statements, this treatment continues when the subsidiary is subsequently classified as held for sale.	Not applicable
IAS 28 »Investments in Associates«: a) Required disclosures when investments in associates are accounted for at fair value through profit and loss b) Impairment of investments in an associate	a) If an associate is accounted for at fair value through profit and loss in accordance with IAS 39 (as it is exempt from the requirements of IAS 28), only the requirement of IAS 28 to disclose the nature and extent of any significant restrictions on the associate's ability to transfer funds to the entity in the form of cash or repayment of loans shall apply. b) An investment in an associate must be considered as a single asset when the existence of potential impairment is being examined. As a result, any impairment is not separately allocated to the goodwill included in the investment balance. The same applies to any reversals of write-downs. In this way, reversals of write-downs overall are recognized as an increase in the investment in an associate.	a) No impact b) No impact
IAS 29 »Financial Reporting in Hyperinflationary Economies«: Description of the measurement basis in financial statements	The reference to the exception from the regulation that assets and liabilities be measured on the basis of historical cost was revised. As a result of the amendment, property, plant, and equipment are shown only as examples and it is no longer implied that the listing of non-monetary items which are being adjusted is exhaustive.	Not applicable
IAS 31 »Interests in Joint Ventures«: Required disclosures when investments in jointly controlled entities are accounted for at fair value through profit and loss	If a joint venture is accounted for at fair value in accordance with IAS 39 (as it is exempt from the requirements of IAS 31), the only disclosure requirements of IAS 31 are those relating to the commitments of the partner company and the joint venture, as well as summarized financial information about the assets, liabilities, income, and expenses.	Not applicable
IAS 36 »Impairment of Assets«: Disclosure of estimates used to determine the recoverable amount	When discounted cash flows are used to estimate »fair value less costs to sell«, the same disclosures are required as when discounted cash flows are used to estimate »value in use«.	Implemented
IAS 38 »Intangible Assets«: a) Advertising and promotional activities b) Production method of amortization	a) Expenditures on advertising and promotional activities are recognized as expenses when the entity either has the right to dispose of the goods or has received the services. Advertising and promotional activities will explicitly include mail-order catalogs in the future. b) IAS 38 previously stated that the use of the production method of amortization was not allowed if it led to a lower cumulative amortization amount than the straight-line method. In the future, the production method of amortization will be allowed if it more accurately reflects the actual terms of use. This will apply even if applying it leads to a lower cumulative write-down amount than the straight-line method.	a) No impact b) No impact
IAS 39 »Financial Instruments: Recognition and Measurement«: a) Reclassification of derivatives into or out of the financial instruments measured at fair value through profit and loss category b) Designation and documentation of hedges at segment level c) Applicable effective interest rate on cessation of fair value hedge accounting	a) The modification makes it clear that changes in circumstances relating to derivatives – especially derivatives designated or no longer designated as hedging instruments after initial recognition – are not reclassifications. A financial derivative can, therefore, be reclassified into or out of the financial instruments measured at fair value through profit and loss category after initial recognition. This is also the case, for example, when financial assets are reclassified as a result of an insurance company changing its accounting and valuation methods in accordance with IFRS 4.45 »Insurance Contracts«. This too is a change in circumstances, not a reclassification. b) The reference to a »segment« in IAS 39 in connection with the determining of whether a financial instrument qualifies as a hedge has been eliminated. c) In the future, use of the revised effective interest rate (rather than the original effective interest rate) must be used when a debt instrument is revalued upon cessation of fair value hedge accounting.	a) No impact b) Not applicable c) Not applicable
IAS 40 »Investment Property«	Property under construction or development for future use as investment property.	Not applicable
IAS 41 »Agriculture«	Discount rate for fair value calculation. Additional biological transformations.	Not applicable

## 2) Amended standards and interpretations with no impact on the group

The following standards and interpretations have been in force since January 1, 2009. These, however, are not applied by the group because they have no impact on either the group's asset, financial, and income position or the presentation of the disclosures in the Notes. This is explained below:

Standard/ Interpretation/ Amendments	Title	Relevant for period under review (as from date)	Incorporation into EU law (endorsement date)
IFRS 1 R/IAS 27	Acquisition cost of an investment in separate financial statements	January 1, 2009	January 23, 2009
IFRS 3 R/ IAS 27 R	Business Combinations Consolidated and Separate Financial Statements	July 1, 2009 July 1, 2009	June 3, 2009 June 3, 2009
IAS 23 R	Changes in Borrowing Costs	January 1, 2009	December 10, 2008
IAS 32/IAS 1R	Classification of puttable financial instruments and obligations arising on liquidation	January 1, 2009	January 21, 2009
IAS 39	Financial Instruments: Recognition and Measurement – Eligible Hedged Items	July 1, 2009	September 15, 2009
IAS 39 IFRIC 9/IAS 39	Reclassification of financial assets: taking effect Amendments – embedded derivatives	July 1, 2009 January 1, 2009	September 9, 2009 November 27, 2009
IFRIC 12	Service Concession Arrangements	January 1, 2008	March 25, 2009
IFRIC 13	Customer Loyalty Programs	July 1, 2008	December 16, 2008
IFRIC 15	Agreements for the Construction of Real Estate	January 1, 2009	July 22, 2009
IFRIC 16	Hedges of a Net Investment in a Foreign Operation	October 1, 2008	June 4, 2009
IFRIC 17	Distribution of Non-cash Assets to Owners	January 1, 2009	November 26, 2009
IFRIC 18	Transfers of Assets from Customers	January 1, 2009	November 27, 2009

## 3) IFRS and IFRIC which have not yet been incorporated into European law

MediGene is waiving the premature application of the following newly-published, but not yet mandatory standards and interpretations (transposition into EU law still unresolved):

Standard/Interpretations/Amendments	Date of coming into effect (IASB)
IFRS 9 Financial Instruments	January 1, 2013
Amendment to IFRIC 14 Prepayments of a minimum funding requirement	January 1, 2011
IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments	July 1, 2010
Improvements to IFRS (2009)	Various, no earlier than January 1, 2009
Amendments to IFRS 2 Group share-based cash-settled payment transactions	January 1, 2010
Amendments to IFRS 1 Exemptions for first-time adopters	January 1, 2010
Revised IAS 24 Related Party Disclosures	January 1, 2011

#### **(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.

##### *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 recognition 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. This mainly concerns the assessment of the circumstances and the period in which tax assets can be realized through the use of existing loss carryforwards. As additional losses continue to be anticipated for the foreseeable future, the management has decided not to recognize these 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, 2009, 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 20 years), the assumptions and forecasts associated with this are subject to a significant degree of uncertainty. Please refer to Note (36) 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 for financial assets and liabilities for which no market prices can be determined are ascertained using valuation methods which include the discounted cash flow method. The input parameters incorporated in the model are based wherever possible on observable market data. If this is not possible, fair values are determined to a certain extent on the basis of discretionary judgments. These discretionary judgments concern input parameters such as liquidity risk, credit risk, and volatility. Changes in the assumptions relating to these factors could affect the fair values reported for the financial instruments. MediGene has measured financial assets and derivative financial instruments at fair value (cf. Note (60)).

**Share-based payment**

The costs of issuing stock options to Executive Board members are valued within the group at the fair values of these equity instruments at the time they are granted. To estimate the fair value of share-based payment it is necessary to determine the most suitable valuation procedure, which depends on the terms under which the payment was granted. In order to make the estimation it will still be necessary to determine suitable input parameters including, in particular, the likely option term and volatility, and then make appropriate assumptions. The assumptions and procedures used to estimate fair value of share-based payment are described in Note (15).

**Defined benefit plans**

The group has concluded agreements on pension plans with employees and members of the company's management. The expenses accrued from defined benefit plans are determined using actuarial calculations. These are based on assumptions with regard to discount rates, expected income from plan assets, future wage and salary increases, mortality rates, and future pension increases. Given the long-term nature of these plans, such estimates are subject to a considerable degree of uncertainty (cf. Note (51)).

**(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 intra-group balances, transactions, income, expenses, and profits and losses arising from intra-group transactions included in the carrying amount of assets have been eliminated in full.

**Reporting entity**

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

**Subsidiaries**

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 proprietary company no longer has control.

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

Consolidated company as at Dec. 31, 2009	MediGene, Inc.	MediGene Ltd.
Registered	San Diego, USA	Abingdon, United Kingdom
Percentage of share in %	100	100
Shareholders' equity in € thousand	-566	-6,717
Net loss for the year in € thousand	-463	-2,111

**(6) Investments in an associate**

The group's investments in an associate are accounted for using the equity method 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 significant influence.

Using the equity method, investments in an associate are recognized in the balance sheet at acquisition cost plus the changes in the group's share of the associate's net assets made after the acquisition. Goodwill relating to the associate is included in the carrying amount of the investment and is neither amortized nor tested for impairment separately.

The income statement reflects the group's share of the associate's profits. The group recognizes its share of any changes shown 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.

### Associate

Effective as per September 30, 2008, MediGene Ltd. founded the company Immunocore Ltd. together with a group of private investors. MediGene Ltd. introduced the monoclonal T-cell receptor technology (mTCR) to Immunocore Ltd. as the core of the new company. Moreover, MediGene Ltd. made a cash contribution of 3 million €, as well as a non-cash contribution (patents and other assets) of 1 million €. The patents mainly pertain to the monoclonal T-cell receptors (mTCR). In return, MediGene Ltd. receives 39.09% of the shares in Immunocore Ltd., making it the new company's largest shareholder. At the moment, Immunocore Ltd. is exclusively a research company which focuses on enhancing the monoclonal T-cell receptor technology platform (mTCR).

The Immunocore Ltd. fiscal year is deviant, starting on October 1 of the respective reporting year. For inclusion in the consolidated financial statement, Immunocore Ltd. has prepared an interim financial statement as per December 31, 2008, in accordance with standard accounting principles.

Associate as at Dec. 31, 2009	Immunocore, Ltd.
Registered	Abingdon, United Kingdom
Percentage of share in %	39.09
Shareholders' equity in € thousand <sup>*)</sup>	4,185
Net loss for the year in € thousand <sup>*)</sup>	-4,157

<sup>\*)</sup> 100%

### (7) Functional currency/foreign currency translation

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

#### Functional currency and reporting currency

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

### Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the time 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 rate on the balance sheet date are recorded in the income statement. An exception is made for differences on foreign currency borrowings accounted for as a hedge of a net investment in a foreign operation. These are reported directly in shareholders' equity until the disposal of the net investment, at which time they are recognized in the income statement. Non-monetary items valued at fair value in a foreign currency are translated using the rate that was in effect as per the time when the fair value was determined. As for receivables and liabilities not carried in the functional currency, the translation is carried out as per the daily exchange rate on the balance sheet date. Purchases and sales in foreign currencies are translated using the daily exchange rate as per the time of the transaction. Any resulting currency differences are included in the income statement.

### Group companies

Every company within the group determines its own functional currency. The items included in the respective company's financial statements are valued using this functional currency. When the foreign subsidiaries MediGene, Inc. and MediGene Ltd. are consolidated, the balance sheet items are basically translated as per the exchange rates on the balance sheet date. The goodwill arising from the acquisition held by MediGene Ltd. and the fair value adjustments to the carrying amounts of assets and liabilities of MediGene Ltd. are reported in the functional currency of the foreign company and translated into euro using the rate as per the balance sheet date. Any resulting exchange rate differences are recognized as a separate component of shareholders' equity.

For the period up to January 1, 2005, the group had exercised the option of treating the goodwill arising in connection with the acquisition of the US subsidiary MediGene, Inc. as a group asset. Accordingly, the goodwill is not subject to foreign currency translation.

Expenses and income are translated into the reporting currency for the purpose of consolidation at the transaction exchange rate. Any differences arising from currency translation in the balance sheet compared with the previous year are recognized directly in shareholders' equity with no effect on income.

The following exchange rates were used in 2009 and as per the balance sheet date December 31, 2009:

	Rate as at closing date		Average rate for the year	
	Dec. 31, 2009	Dec. 31, 2008	2009	2008
1 € in \$	1.4405	1.4175	1.39345	1.47037
1 € in £	0.8900	0.9770	0.89125	0.79638

Source: Dresdner Bank AG, Reference Exchange Rates

### (8) 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 disposals 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 (p. 84 et seq.).

### (9) 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	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 (p. 84 et seq.).

### Technology rights, patents, and licenses

Individually acquired intangible assets with a finite useful life are valued at acquisition cost. Any acquired technology rights, patents, and licenses, 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.

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.

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

**Assets with an indefinite useful life**

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

**Goodwill**

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

**Execution of impairment testing**

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

- represents the lowest level within the company in which the goodwill is monitored for the internal company management, and
- is no larger than a segment based on the primary or secondary reporting format of the group as defined in IFRS 8 »Segment Reporting«.

Insofar as cash flows cannot be identified and assessed separately for the respective intangible assets, they are allocated to the defined CGUs at the lowest level.

The impairment is determined by assessing the recoverable amount of the CGU. The recoverable amount is the greater of the fair value less costs to sell and the value in use. If the carrying amount of the CGU exceeds the recoverable amount, first the allocated goodwill and then the intangible assets allocated to this CGU are written down to this amount. The value in use calculation and the calculation of fair value less costs to sell are based on cash flow forecasts adopted by the management and a discount rate before tax which reflects current market anticipations regarding impact on interest and the specific risks inherent in the asset or the CGU. The planning period under review encompasses the development and approval stages, as well as the period of time commencing with market launch, for which patent terms of slightly over ten years are generally assumed, and the achievement of peak sales five years after market launch.

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 first.

**(11) Financial assets****Initial recognition**

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

Financial assets are initially entered at fair value. The fair value of financial investments traded on organized markets is determined by the market price (bid price) listed as per the balance sheet date. The fair value of financial investments for which there is no active market is determined using valuation methods. These include the use of the most recent business transactions between expert and independent business partners willing to enter into a contract, the comparison with the current fair value of another largely identical financial instrument, the analysis of the discounted cash flow, and the use of other valuation models.

Financial assets not included in the category of »assets at fair value through profit and loss« are initially recognized at fair value plus transaction costs. They are removed from the balance sheet if the rights to payments from the investment have expired and the group has, for the most part, transferred all risks and rewards associated with ownership.

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



### Subsequent measurement

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

#### *a. Assets measured at fair value through profit and loss*

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

#### *b. Held-to-maturity investments*

are non-derivative financial assets with fixed or determinable payments and fixed terms which the management intends and is able to hold until they fall due. In the periods under review, 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 noncurrent 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 noncurrent 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 other reserves. If financial investments are disposed of and/or impaired, the cumulative gain or loss previously recorded in shareholders' equity is transferred to the income statement. Within the framework of pension commitments, for example, capitalized financial assets are allocated to this category.

### Impairment

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

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 impairment determined is recognized through profit and loss.

### Derecognition

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

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

### Hedge accounting

The group has only embedded derivatives. Hedge accounting is not shown in the balance sheet.

**(12) 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.

**(13) 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.

**(14) 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.

**(15) Share-based payment plans: stock options and convertible bonds**

As an incentive to share in the group's long-term success, its employees and the members of its Executive Board receive share-based payment in the form of equity instruments. For this purpose, the group has set up a share-based compensation plan that is fulfilled by issuing new shares. These shareholders' equity instruments such as options and convertible bonds granted to employees are accounted for 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 and 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.

For the convertible bonds issued to employees through 2006, the nominal amount of € 1 paid is accounted for in the balance sheet in accordance with IAS 32/IAS 39. At the same time, the option inherent in the convertible bond is valued in accordance with IFRS 2. Upon conversion, the nominal amount is paid in and reported in such a way that € 1 of the total amount paid in is reported in share capital and the remaining amount – i.e. the difference between the conversion price and the nominal amount – is recognized in the capital reserve.

The dilution effect of the outstanding stock options and convertible bonds is considered in the calculation of net loss per share as additional dilution.

**(16) Financial debt****Initial recognition**

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

**Subsequent measurement**

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

The fair value of the debt component of a convertible bond is determined using the market interest rate for a similar nonconvertible bond. This amount is reported as a liability at amortized acquisition cost until the conversion is carried out or the repayment becomes due. The remaining portion of the revenue constitutes the value of the conversion right. This is included in shareholders' equity after deducting income tax effects.

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

### **(17) 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 on 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. Accruals in foreign currencies are translated as per the closing date.

### **(18) Pension obligation**

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 obligation recognized in the balance sheet for defined benefit plans equals the present value of the defined benefit obligation (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 obligation. 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 obligation 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 obligation 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.

### **(19) 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.

**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, these 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
- in respect of taxable temporary differences associated with investments in subsidiaries, associates, and interests in joint ventures where the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are 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 GAAP 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.

**(20) 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.

**(21) 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 period under review, 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 carried over and the product or active ingredient has been delivered to the buyer. Moreover, MediGene receives license fee payments from the product sales generated by the licensee in the market, which are invoiced on a quarterly basis.

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

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

MediGene receives milestone payments for the official approval 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 delineation 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.

#### **(22) Public grants**

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

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

#### **(24) Net loss per share**

The net loss per share is determined in accordance with IAS 33 »Earnings per Share«.

#### **Basic and actual net loss per share**

The basic net loss per share is calculated by dividing the profit (numerator) due to the equity suppliers by the weighted average number of shares issued during the fiscal year (denominator).

#### **Diluted net loss per share**

The net income for the period is adjusted for all changes in income or expenses that would result from the conversion of the potential ordinary shares with dilution effects. It is assumed that convertible bonds will be exchanged for shares and that the net profit will be adjusted for interest expenses and the tax impact. 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) Cash flow statement**

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/business units**

In contrast to IAS 14, under which a concept based on the presentation of financial information by operating and regional segment, IFRS 8 pursues a »management approach« for identifying and valuing the results generated by operating segments subject to reporting requirements. The distinction between the primary and secondary reporting format was discarded. The internal reporting system is authoritative for which segments are to be reported and which segment data is to be presented in the Notes. As a first step, the company's operating segments were identified. An »operating segment« is a business unit within a company that engages in business activities with which income is generated and expenses can be incurred (including income and expenses in connection with transactions with other business units within the same company), and of which the operating loss is regularly examined by the company's main decision-maker with regard to decisions on the allocation of resources and the assessment of its earning power, and for which relevant financial information is available. Individual operating segments can be consolidated if particular quantitative or qualitative criteria are fulfilled.

For corporate management purposes, the group is organized in business units based on products and services and has two operating segments subject to reporting requirements: »Marketed Products« and »Drug Candidates«. The examination of the requirements of IFRS 8 in respect of the period under review revealed that the group's operating segments newly identified in accordance with IFRS 8 correspond to the operating segments »Biopharma« and »Specialty Pharma« which were previously identified under IAS 14 »Segment Reporting« and can, therefore, be transferred. Financial information that cannot be assigned to either one or the other operating segment is reported under »Reconciliation«.

In addition, the group reports revenue with external customers and noncurrent assets, encompassing property, plant, and equipment, intangible assets, and goodwill, classified by the home country of the entity in which the company has generated revenue and/or holds assets.

The figures for the individual operating segments are presented in the Notes under (G) »Segment Reporting«.

**C) Notes on the income statement**

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

**(27) Total revenue**

The total revenue amounted to € 39,466 thousand in 2009 (2008: € 39,606 thousand). Most of this amount was realized from product sales and royalties from the drug Eligard® in Europe. A small proportion of the revenue generated came from product sales of Veregen® in the USA. The revenue also includes a milestone payment of € 200 thousand for Veregen® from the company's partner Juste S.A.Q.F., Madrid, Spain. In the corresponding period of the previous year, the group received a milestone payment of € 3,000 thousand for reaching the € 75 million annual revenue threshold with Eligard® from its partner Astellas Pharma Europe Ltd. (hereinafter »Astellas Pharma«), Staines, United Kingdom.

Other operating income amounted to € 1,607 thousand (2008: € 6,099 thousand), of which € 447 thousand (2008: € 914 thousand) stemmed from grants and € 1,160 thousand from other income. € 1,080 thousand of other income arose from a compensation agreement. Last year, € 4,402 thousand was posted as other income for the return of the rights to Oracea®.

Total revenue			
In € thousand	2009	2008	Change
Product revenue and royalties	37,656	30,507	23%
Milestones	203	3,000	-93%
<b>Product sales</b>	<b>37,859</b>	<b>33,507</b>	<b>13%</b>
Income from R&D cooperations	0	623	-%
Grants	447	914	-51%
Other income	1,160	4,562	-75%
<b>Total</b>	<b>39,466</b>	<b>39,606</b>	<b>0%</b>

**(28) Cost of sales**

The cost of sales was incurred primarily for the commercialization of the drug Eligard®, and to a lesser extent for Veregen®. These costs amounted to € 31,482 thousand (2008: € 26,926 thousand). Procurement costs are accounted for by the purchase of the products and by the share of Tolmar Therapeutics, Inc. (hereinafter »Tolmar«, formerly QLT USA, Inc.), Fort Collins, Colorado, USA, in the revenue. In the corresponding period of the previous year, MediGene had made a milestone payment of \$ 3.0 million (€ 2.1 million) as Eligard® passed the annual sales threshold of \$ 100 million.

**Cost of sales**

In € thousand	2009	2008	Change
Cost of sales	15,952	13,368	19%
Royalties	15,530	11,442	36%
Milestones	0	2,116	-%
<b>Total</b>	<b>31,482</b>	<b>26,926</b>	<b>17%</b>

**(29) Selling expenses**

Selling expenses consist entirely of expenses for business development. They include personnel expenses, consulting fees, market surveys, advertising material, and other services. No additional selling activities for products were conducted in the period under review.

**Selling expenses**

In € thousand	2009	2008	Change
Personnel expenses	1,195	1,608	-26%
Consultancy fees/market surveys	409	374	9%
Office rent and utilities	91	117	-22%
Marketing	90	107	-16%
Depreciation	2	161	-99%
Other	405	396	2%
<b>Total</b>	<b>2,192</b>	<b>2,763</b>	<b>-21%</b>

**(30) General and administrative expenses**

In the period under review, administrative expenses were 10% lower than in the corresponding period of the previous year. This is attributable primarily to the discontinuation of the administrative expenses for MediGene Ltd. and the costs incurred in the preparation of a prospectus in 2008 for the stock market admission of shares that had already been issued. An increase in costs, however, was incurred in the form of one-off bonus and severance payments of € 1,203 thousand.

**General and administrative expenses**

In € thousand	2009	2008	Change
Personnel expenses	4,082	3,598	13%
Consultancy fees	844	1,985	-57%
Office rent and utilities	316	343	-8%
Depreciation	95	135	-30%
Other	1,595	1,660	-4%
<b>Total</b>	<b>6,932</b>	<b>7,721</b>	<b>-10%</b>

**(31) Research and development expenses**

R&D expenses fell by 33% compared to the previous year. The largest part of R&D expenses pertains to personnel expenses and to external costs for clinical and preclinical development. The decrease in costs compared with the corresponding period in the previous year is attributable primarily by lower expenditure on the RhuDex<sup>®</sup> and mTCR technology projects and the discontinuation of the L1 project. The clinical development of RhuDex<sup>®</sup> was halted in the period under review.

**Research and development expenses**

In € thousand	2009	2008	Change
Personnel expenses	7,766	10,853	-28%
Third party expenses	5,878	10,956	-46%
Patent and license fees	1,246	1,183	5%
Office rent and utilities	979	1,155	-15%
Depreciation	733	877	-16%
Consultancy fees	506	391	29%
Laboratory material costs	434	808	-46%
Other	957	1,242	-23%
<b>Total</b>	<b>18,499</b>	<b>27,465</b>	<b>-33%</b>

**(32) Financial result**

Interest income was generated from the investment of available cash. Interest expenses resulted from the interest on outstanding convertible bonds. All interest payments are recognized as expenses in accordance with IAS 23.

The contract concluded with Astellas Pharma for the marketing of Eligard<sup>®</sup> includes an embedded derivative as it is denominated in US dollars and not in the functional currency of either of the two contracting parties. As a result of an increase in expected and received purchase orders compared with the previous year, and the development in the US dollar's value against the euro during the period under review, a book loss of € 578 thousand (2008: € -253 thousand) from this financial instrument was realized as per the reporting date of December 31, 2009.

Foreign exchange losses resulted from the translation of the US dollar and the British pound into euro.

This can be set against the positive result of € 302 thousand generated mainly by the sale of the company's shares in the publicly listed Canadian company QLT, Inc., Vancouver, British Columbia, Canada, in the third quarter of 2009 (2008: € -352 thousand).

**Financial result**

In € thousand	2009	2008	Change
Interest income	129	1,452	-91%
Interest expense	-5	-2	150%
<b>Subtotal</b>	<b>124</b>	<b>1,450</b>	<b>-91%</b>
Losses from derivative financial instruments	-578	-253	128%
Foreign exchange losses	-519	-2,035	-74%
Income/expenses from financial assets	302	-352	-186%
<b>Total</b>	<b>-671</b>	<b>-1,190</b>	<b>-44%</b>

**(33) Basic and diluted net loss per share**

The following table shows the calculation of the diluted net loss per share:

**Basic net loss per share**

In € thousand	2009	2008	Change
Net loss	-21,962	-30,790	-29%
Interest on convertible bonds	5	2	150%
<b>Result adjusted for effects from convertible bonds</b>	<b>-21,957</b>	<b>-30,788</b>	<b>-29%</b>

**Diluted net loss per share**

In no.	2009	2008	Change
Weighted average number of shares	34,231,294	34,008,289	1%
Effect of dilution:			
Number of stock options	0	125,179	-%
Convertible bonds	0	0	-%
<b>Weighted average number of ordinary shares adjusted for the effect of dilution</b>	<b>34,231,294</b>	<b>34,133,468</b>	<b>0%</b>
<b>Diluted net loss per share</b>	<b>-0.64</b>	<b>-0.91</b>	<b>-30%</b>

The total of 1,389,276 stock options and convertible bonds did not have a dilutive effect, since the exercise price of most of the stock options and convertible bonds was below the average share price of € 4.30 for the year (Deutsche Börse; Xetra closing price).

**(34) Personnel expenses**

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

**Personnel expenses**

In € thousand	2009	2008	Change
Salaries and wages	11,013	12,824	-14%
Social security	1,220	1,577	-23%
Pension expenses			
Defined contribution plans	106	88	20%
Defined benefit plans	165	111	49%
Stock options and convertible bonds issued to executives and employees	394	1,135	-65%
Other	145	324	-55%
<b>Total</b>	<b>13,043</b>	<b>16,059</b>	<b>-19%</b>

**Employees by function**

	Dec. 31, 2009	Dec. 31, 2008	Change
Business development and general administration	28	32	-13%
Research and development	86	101	-15%
<b>Total</b>	<b>114</b>	<b>133</b>	<b>-14%</b>

The average number of employees over the course of the year decreased to 113 (2008: 150). This decrease resulted primarily from the transfer of the employees from the subsidiary MediGene Ltd. to the spun-off company Immunocore Ltd. in 2008. The associate Immunocore Ltd. has 38 employees as per December 31, 2009. Personnel expenses decreased by 19% to € 13,043 thousand (2008: € 16,059 thousand) in the period under review.

**(35) 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 is not shown separately in the income statement. Instead, it is allocated to the general, selling, and administrative expenses, research and development expenses, and/or losses resulting from the spin-off.



**Depreciation and impairment of fixed assets**

In € thousand	2009	2008	Change
Regular depreciation			
of property, plant & equipment	385	570	-32%
of intangible assets	446	603	-26%
<b>Subtotal</b>	<b>831</b>	<b>1,173</b>	<b>-29%</b>
Impairment			
of intangible assets	0	5,014	–%
of goodwill	0	929	–%
<b>Total</b>	<b>831</b>	<b>7,116</b>	<b>-88%</b>

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

The carrying amounts of goodwill and intangible assets not yet available for use as at December 31, 2008 are allocated to the CGUs as follows:

**Carrying amounts of goodwill and intangible assets**

In € thousand	MediGene Ltd.				MediGene, Inc.	
	CGU 1		CGU 2		CGU 3	
	2009	2008	2009	2008	2009	2008
Carrying amount of goodwill	2,046	1,864	0	0	9,226	9,226
Carrying amount of intangible assets	21,971	20,014	3,540	3,225	–	–

The carrying amount of goodwill as per the reporting date December 31, 2009 amounted to € 11,272 thousand (December 31, 2008: € 11,090 thousand), and was allocated to three CGUs altogether. € 2,046 thousand (2008: € 1,864 thousand) of this sum was accounted for by the CGUs 1 and 2 which originate from the acquisition of the British subsidiary MediGene Ltd. in 2006. This component of the goodwill is denominated in British pounds and has increased in value due to the pound's rise against the euro. Goodwill amounting to € 9,226 thousand originates from the acquisition of MediGene, Inc. in 2001 (2008: € 9,226 thousand). This goodwill reported in euro results from CGU 3.

The carrying amount of the intangible assets of the subsidiary MediGene Ltd. denominated in British pounds has increased from € 23,239 thousand to € 25,511 thousand due to a change in exchange rates. These assets are allocated to CGUs 1 and 2.

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

- RhuDex® (CGU 1)
- Early development project (CGU 2)
- oHSV (CGU 3)

**Annual impairment test as per December 31, 2009****Methodology for determining the recoverable amount:**

The recoverable amount for CGUs 1 and 2 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 the research stage which form the basis of CGUs 1 and 2, as the clinical development and subsequent marketing of the drug candidates for a specific indication have been firmly established.

Regarding the oHSV technology which forms the basis of CGU 3, the company's management decided not to invest actively in research and development anymore. Instead the management is seeking to outlicense or spin off the oHSV technology which will lead to varying revenue, depending on the exploitation option chosen. IAS 36 permits the determination of a fair value less costs to sell, even if there is no active market or any binding contractual offerings. The prerequisite of this is the possibility of making a reliable estimate of a future transaction and/or contract value. Since the calculation of a value in use is no longer possible against the background of the varying exploitation options, the company chooses to report a fair value less costs to sell for CGU 3.

The basic assumptions and the project-specific assumptions which form the basis of the calculated values in use and the fair values less costs to sell are explained in more detail below.

**1) Basic assumptions for measuring the value in use**

Approval and marketing of drugs in the three largest pharmaceuticals markets worldwide, i.e. the USA, Europe, and Japan, are assumed for the cash flow models. 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 patent. There are valuation uncertainties regarding the following assumptions that form the basis of the calculation of the fair value of the two CGUs:

- Probabilities of market entry
- Development periods and project progress
- Expected market share and number of patients treated in the relevant submarket

**Probabilities of market entry**

MediGene has made assumptions on the probability of market entry for the individual drug candidates. The necessity to make such assumptions arises from the typical drug development risks. These risks may vary depending on the class of substance and active ingredient, as well as the medical indication. Accordingly, the management has applied the probability of success customary in the industry for its valuation models. In addition, project-specific assumptions were added to these valuations. These risks are taken into consideration when determining the project-specific interest rate.

**Development periods and project progress**

According to pharmaceutical industry statistics, the development of a drug generally takes 10–15 years. This period of time is divided into successive phases. Significant factors which influence the length of the development period are the results regarding effects and side-effects of a drug candidate obtained during the individual development 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 medical indication and class of drugs.

**Expected 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 future patients to be treated, MediGene also reverts to the estimates made by external consulting and assessment specialists.

**Project-specific assumptions**

	MediGene Ltd.	
	CGU 1	CGU 2
Planning period in years	20	18
Project progress discount rate in %	34	82

Based on these assumptions, no need for impairment of CGUs 1 and 2 was determined.

**2) Basic assumptions for the calculation of a fair value less costs to sell**

MediGene considers future revenue from the potential licensing or spin-off of the oHSV technology to different parties interested. These parties vary in the aimed-at therapeutic fields and medical indications.

As there is no active market for the oHSV technology, its potential value is determined on the basis of estimates and assumptions regarding the different exploitation options. For this purpose, one-off payments, royalties, and holdings resulting from spin-offs customary in comparable transactions in the biopharmaceutical industry are estimated for the individual contractual options and scenarios. Costs to sell are estimated accordingly and deducted. The resulting cash flows are discounted on a net present value.

Based on these assumptions, no need for impairment of CGU 3 was determined.

**Sensitivity of assumptions made**

In the basic assumptions made for determining the value in use of CGUs 1 and 2 as well as the fair value of CGU 3, reasonable judgment shows that changes may occur that would cause the carrying amount of the respective CGU to exceed the value in use, thereby inducing depreciation.

The actual value in use of CGU 1 exceeds its carrying amount by approximately € 4.7 million; for CGU 2, this figure is approximately € 2.1 million and for CGU 3 approximately € 0.3 million.

In order to analyze the effects of basic 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:

**CGU 1**

As this CGU possesses the highest value potential, MediGene carried out different sensitivity analyses. The first approach examines the influence of greater risks with regard to the safety and efficacy profile during clinical development. The increased development risks are taken into consideration in a risk factor that measures the probability of obtaining market approval. In case the probability of market approval is lowered by two percentage points, the value in use nearly corresponds to the carrying amount of the CGU.

The second approach examines how the postponement of the planned market entry by one year affects the value. In this scenario, the value in use approximates 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 upfront payments from a partnership are only half as high (50% discount). In that case, the value in use would exceed the CGU's carrying amount.

**CGU 2**

CGU 2 was examined for the extent to which a postponement by two years in development activities, and, consequently, delayed commencement of the partnership, would affect the project's value. These changed assumptions result in the value in use approximating the carrying amount of CGU 2.

**CGU 3**

CGU 3 was examined for the effect of an increase of the discount factor used to determine the fair value less costs to sell. An increase by one percentage point results in the fair value approximating the carrying amount.

**(37) Impairment of intangible assets**

As per the closing date of December 31, 2009, there was no indication of impairment for the EndoTAG™ patents and licenses recorded in the balance sheet. MediGene subjects these assets to regular amortization over the term of the underlying patents.

**(38) Cost of materials and cost of services**

The expenses items in the income statement contain the following costs of materials:

<b>Cost of materials and cost of services</b>			
In € thousand	2009	2008	Change
Cost of sales	31,482	26,926	17%
Expenses for R&D material	434	808	-46%
<b>Subtotal</b>	<b>31,916</b>	<b>27,734</b>	<b>15%</b>
Cost of services	5,878	10,956	-46%
<b>Total</b>	<b>37,794</b>	<b>38,690</b>	<b>-2%</b>

The cost of sales is mainly comprised of procurement expenses for the Eligard® product and, to a lesser extent, the active ingredient for Veregen® as well as royalties to partners. The cost of materials includes expenses for laboratory materials and chemicals amounting to € 434 thousand (2008: € 808 thousand). The services purchased totaling € 5,878 thousand (2008: € 10,956 thousand) are made up of the following items: conducting clinical trials € 2,641 thousand (2008: € 4,955 thousand), production services € 1,704 thousand (2008: € 2,049 thousand), preclinical development services € 1,374 thousand (2008: € 3,450 thousand), and market approval € 159 thousand (2008: € 502 thousand).

**D) Notes on the balance sheet****ASSETS****(39) Property, plant, and equipment**

The detailed composition and development of property, plant, and equipment can be found in the statement of fixed assets (p. 84 et seq.).

**(40) Intangible assets**

The increase in intangible assets from € 28,511 thousand to € 30,503 thousand relates solely to the exchange rate effects as per the balance sheet date. These effects concern the carrying amount of the intangible assets denominated in British pounds which result from the acquisition of the subsidiary MediGene Ltd. and are based on the RhuDex® projects and another project at the research stage. The patents and licenses for the EndoTAG™ products and technologies are also allocated to intangible assets.

MediGene has not capitalized any self-constructed intangible assets.

**(41) Financial assets**

Available-for-sale financial assets are based on a value derived from the share price and consist of the shares of the Canadian partner company QLT, Inc. that were sold in the period under review, and assets resulting from pension agreements which are not to be qualified as plan assets.

**Financial assets**

In € thousand	Dec. 31, 2009	Dec. 31, 2008	Change
Listed shares of QLT, Inc.	0	398	-%
Listed fund shares (pension)	152	142	7%
<b>Total</b>	<b>152</b>	<b>540</b>	<b>-72%</b>

**(42) Investment in an associate**

As per the end of the period under review, the group continues to hold a 39.09% investment in Immunocore Ltd. Immunocore Ltd. has a divergent fiscal year which begins on October 1 each year under review. Immunocore Ltd. prepared corresponding interim financial statements as per December 31, 2009 for inclusion in the consolidated financial statements.

The carrying amount of the shareholding in Immunocore Ltd. fell to € 1,961 thousand (2008: € 3,269 thousand) as per December 31, 2009.

#### Investment in an associate

In € thousand	Dec. 31, 2009	Dec. 31, 2008
Share of the associate's balance sheet:		
Current assets	1,518	2,834
Non-current assets	347	300
Current liabilities	-229	-161
Non-current liabilities	0	0
<b>Pro rata net assets</b>	<b>1,636</b>	<b>2,973</b>
Share of the associate's revenue and result		
Revenue	97	89
Result	-1,625	-256

#### (43) Inventories

Inventories of the Eligard® und Veregen® products totaled € 1,455 thousand (2008: € 2,185 thousand) as per the closing date. There was no impairment of the lower sales price.

#### (44) Other current assets and trade accounts receivables

##### Other current assets and trade accounts receivable

In € thousand	Dec. 31, 2009	Dec. 31, 2008	Change
Accrued royalties	4,683	3,750	25%
Grants incl. R&D tax credit	169	637	-73%
VAT receivables	71	333	-79%
Rent deposit	323	340	-5%
Prepaid expenses with a term <1 year	1,033	681	52%
Other	35	36	-3%
<b>Total other assets</b>	<b>6,314</b>	<b>5,777</b>	<b>9%</b>
<b>Trade accounts receivable</b>	<b>749</b>	<b>3,117</b>	<b>-76%</b>

The accounts receivable and other current assets fall due as follows:

#### Aging analysis of trade accounts receivable and other current assets

In € thousand	impaired	up to 30 days	Maturity				Total
			30-180 days	180-360 days	1-5 years	>5 years	
<b>Balance at Dec. 31, 2009</b>							
Other current assets	0	5,436	240	638	0	0	6,314
Trade accounts receivable	-26	749	0	7	19	0	749
<b>Total</b>	<b>-26</b>	<b>6,185</b>	<b>240</b>	<b>645</b>	<b>19</b>	<b>0</b>	<b>7,063</b>
<b>Balance at Dec. 31, 2008</b>							
Other current assets	0	4,133	970	674	0	0	5,777
Trade accounts receivable	0	3,028	19	70	0	0	3,117
<b>Total</b>	<b>0</b>	<b>7,161</b>	<b>989</b>	<b>744</b>	<b>0</b>	<b>0</b>	<b>8,894</b>

In the period under review, one account receivable was impaired in full on grounds of uncollectibility.

#### Allowance account for bad debts

In € thousand	2009
Balance at Jan. 1, 2009	0
Allowance	26
<b>Balance at Dec. 31, 2009</b>	<b>26</b>

#### (45) Cash and cash equivalents

##### Cash and cash equivalents

In € thousand	Dec. 31, 2009	Dec. 31, 2008	Change
Cash and cash equivalents < 3 months	12,251	25,101	-51%
<b>Total</b>	<b>12,251</b>	<b>25,101</b>	<b>-51%</b>

Cash and cash equivalents were invested in the form of financial investments with terms 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 0.09% to 2.35% in the period under review. The change in cash and cash equivalents from the previous year is shown in the statement of cash flows.

##### Subscribed capital

	Number of shares	Subscribed capital in € thousand	Capital reserves in € thousand	Total in € thousand
<b>Balance at Jan. 1, 2008</b>	<b>33,946,481</b>	<b>33,946</b>	<b>334,667</b>	<b>368,613</b>
Employee stock option plan				
Value of services provided			1,132	1,132
Proceeds from shares issued	78,880	79	161	240
Employee convertible bond plan				
Value of services provided			3	3
Proceeds from shares issued	3,200	4	10	14
<b>Balance at Dec. 31, 2008</b>	<b>34,028,561</b>	<b>34,029</b>	<b>335,973</b>	<b>370,002</b>
Employee stock option plan				
Value of services provided			394	394
Shares issued				
Cash	1,528,932	1,528	4,572	6,100
<b>Balance at Dec. 31, 2009</b>	<b>35,557,493</b>	<b>35,557</b>	<b>340,487</b>	<b>376,044</b>

#### LIABILITIES AND SHAREHOLDER'S EQUITY

##### (46) Shareholders' equity

###### a) Subscribed capital

As per December 31, 2009, the subscribed capital increased from € 34,029 thousand to € 35,557 thousand. This is divided into 35,557,493 no-par-value registered shares, 100% of which were issued and tradable as per the balance sheet date. In the period from June 3 to December 11, 2009, a total of 1,528,932 newly issued shares were admitted in five tranches to trading on the stock exchange. These shares were subscribed to under the terms of the agreement with the investment company YA Global Investments L.P., Jersey City, New Jersey, USA.

**b) Stock options**

Equity instruments such as options and convertible bonds issued to employees are valued and reported in the balance sheet in accordance with IFRS 2.

Stock options are issued to Executive Board members and employees. They are initially issued within one year of the individuals in question joining the company. The exercise price per option on the issue date equals the higher of the market price or the average closing price over the last 60 trading days on the Xetra trading system at Deutsche Börse plus a premium of 20%. Holders of subscription rights cannot exercise their options prior to the expiration of a waiting period of two years starting from the allotment date of the respective subscription right. The options have a contractual term to maturity of ten years. The group is not obliged to repurchase options or compensate them in cash on either a de jure or de facto basis.

In the year under review, 81,350 stock options were issued to Executive Board members from conditional capital XVIII (2008: 550,533 stock options to Executive Board members and employees from conditional capital XVI). MediGene has waived the lapse of these option rights in the case of the resignation of a beneficiary, and expensed these stock options.

The average exercise price for the options issued to Executive Board members was € 3.69. Options were not issued to employees until January 2010.

**Total change in stock options outstanding**

	2009		2008		2007	
	Average exercise price in € per option	Number	Average exercise price in € per option	Number	Average exercise price in € per option	Number
Stock options outstanding, balance at Jan. 1	6.23	1,441,108	7.31	988,026	7.30	801,639
Issued	0	0	4.27	349,371	5.88	242,718
Issued, not accepted in the year under review	3.69	81,350	3.89	201,162	–	–
Exercised	0	0	2.93	-78,880	2.93	-8,944
Forfeited	3.92	-10,976	7.13	-1,371	8.38	-14,675
Lapsed	6.29	-122,206	5.35	-17,200	2.93	-32,712
Stock options outstanding, balance at Dec. 31		1,389,276		1,441,108		988,026
Weighted average exercise price in € per option		6.10		6.23		7.31

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

Valuation parameters for stock option plan			
	2009	2008	2007
Vesting period	2 years	2 years	2 years
Option term	10 years	10 years	10 years
Exercise hurdle rate	120%	120%	120%
Expected volatility	51%	42%/51%	42%
Risk-free interest rate	3.66%	3.36%/3.93%	4.31%

The expected volatility was determined on a historical basis and is based on the floating 250-day average prevailing as per the time when the options are issued. The risk-free interest rate corresponds to the yield of a hypothetical zero coupon bond excluding any risk of default and was 3.66% in the month when the options were issued (source: German Central Bank). The fair value of the stock options issued during the 2009 fiscal year was € 1.87 per option. In 2008, expenses for stock-based payment types totaling € 394 thousand (2008: € 1,132 thousand) were posted in accordance with IFRS. These consist of the following:

Expenses for stock option plan		
In € thousand	2009	2008
Expenses for stock option plan		
2006	0	56
2007	108	286
2008	134	790
2009	152	0
<b>Total</b>	<b>394</b>	<b>1,132</b>

As per December 31, 2009, the stock options outstanding were classified by conversion price, number of options issued, remaining term to maturity, and options that can still be exercised:

Exercise price and term of stock options outstanding			
Exercise price in €	Number of stock options outstanding	Residual term in years	Number of exercisable stock options
6.48	66,521	0	66,521
4.60	45,179	4	45,179
4.68	80,000	4	80,000
7.69	60,237	5	60,237
8.10	40,000	5	40,000
12.37	131,062	6	131,062
10.22	111,341	7	111,341
5.88	234,029	8	234,029
4.34	297,860	9	– <sup>*)</sup>
3.89	241,697	9	– <sup>*)</sup>
3.69	81,350	10	– <sup>*)</sup>
–	<b>1,389,276</b>	–	<b>768,369</b>

<sup>\*)</sup> Stock options issued in 2008 and 2009 could not be exercised as at December 31, 2009.

The weighted average remaining term of stock options in circulation is 7.28 years.

### c) Convertible bonds

Convertible bonds outstanding are reported in the balance sheet as follows: The fair value of the debt component and the equity conversion component are each determined as per the issue date of the convertible bond. The fair value of the debt component included in noncurrent liabilities is calculated using the market interest rates for equivalent non-convertible bonds. The residual value, which shows the value of the equity conversion component, is posted into shareholders' equity under capital reserves.

In the years 2009 and 2008, no convertible bonds were issued.

The number of valid convertible bonds still outstanding as part of the approved investment program came to 9,000 as per December 31, 2009 (2008: 46,210). The weighted average remaining term of convertible bonds outstanding is less than one year.

#### Total change in convertible bonds outstanding

	2009	2008	2007
Convertible bonds outstanding, balance at Jan. 1	46,210	61,831	103,529
Issued	0	0	0
Exercised	0	-3,200	-10,416
Forfeited	0	0	-10,800
Lapsed	-37,210	-12,421	-20,482
Convertible bonds outstanding, balance at Dec. 31	9,000	46,210	61,831
Average conversion price in € per bond	12.37	8.81	7.72

#### Conversion price and term of convertible bonds outstanding

Conversion price in €	Coupon in % p.a.	Number of bonds outstanding	Residual term in years	Number of convertible bonds
12.37	2.5	9,000	1	9,000
		9,000		9,000

#### d) Authorized capital

The Executive Board was authorized, with the approval of the Supervisory Board, by a shareholders' resolution on August 31, 2009 to increase the share capital by a total of up to € 17,026,072 (approximately 47.88% of the share capital) up to August 30, 2014 by issuing up to 17,026,072 new registered shares (no-par shares) on one or more occasions against contributions in cash or in kind (2009 authorized capital). The 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 per December 31, 2009, the company still has 15,520,724 new registered no-par shares from the 2009 authorized capital at its disposal.

#### e) Conditional capital and specification of conditional capital

The company's share capital was increased conditionally by a shareholders' resolution on August 31, 2009 by € 3.700.000 (conditional capital XX). The sole purpose of the conditional capital is to grant new shares to the holders of warrant-linked or convertible bonds that are issued in accordance with the shareholders' resolution on August 31, 2009 under 6 b) by MediGene AG or companies in which it has a direct or majority stake. The shares are issued at the respective standard conversion and option price in accordance with the aforementioned resolution. The conditional capital increase is carried out only insofar as the holders of conversion rights or options exercise these rights or meet the conversion requirements of such bonds. Provided that the shares exist by the start of the company's Annual Shareholders' Meeting they entitle their owners to share in the profits from the beginning of the previous fiscal year, or otherwise from the beginning of fiscal year when they come into being.

#### Classification of conditional capital by stock options and convertible bonds

(No.)	Amount as at Dec. 31, 2009	Usage <sup>1)</sup>
I	136,897	Options
II	106,429	Options
III	125	TBG <sup>2)</sup> loan
IV	13,770	Convertible bonds
V	652,329	Convertible bonds
VI	3,000	Convertible bonds
VIII	3,000	Convertible bonds
X	3,000	Convertible bonds
XI	1,400	Convertible bonds
XII	498,560	Options
XVI	300,000	Options
XVIII	1,600,000	Options
XIX <sup>3)</sup>	0	Convertible bonds and options
XX <sup>4)</sup>	3,700,000	Convertible bonds and options
	<b>7,018,510</b>	

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

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

<sup>3)</sup> Cancelled by a shareholders' resolution of August 31, 2009.

<sup>4)</sup> Newly created by a shareholders' resolution of August 31, 2009.



**(47) Capital reserves**

In 2009, no stock options were exercised (2008: 78,880) and no convertible bonds were converted (2008: 3,200).

**Capital reserves**

In € thousand	Jan. 1, 2008	Change	Dec. 31, 2008	Change	Dec. 31, 2009
Shares issued	345,770	0	345,770	4,572	350,342
Expenses on shares issued	-15,812	0	-15,812	-452	-16,264
Exercise of stock options	729	161	890	0	890
Exercise of convertible bonds	1,445	10	1,455	0	1,455
Expenses on new options/bonds	2,535	1,135	3,670	394	4,064
<b>Total</b>	<b>334,667</b>	<b>1,306</b>	<b>335,973</b>	<b>4,514</b>	<b>340,487</b>

**(48) Accumulated deficit****Accumulated deficit**

In € thousand	Jan. 1, 2008	Change	Dec. 31, 2008	Change	Dec. 31, 2009
Net loss	-262,477	-30,790	-293,267	-21,962	-315,229
<b>Total</b>	<b>-262,477</b>	<b>-30,790</b>	<b>-293,267</b>	<b>-21,962</b>	<b>-315,229</b>

**(49) Other reserves****Other reserves**

In € thousand	Jan. 1, 2008	Change	Dec. 31, 2008	Change	Dec. 31, 2009
Realized losses from QLT, Inc. shares	-243	243	0	0	0
Unrealized gains/losses on hedge of a net investment	0	-1,837	-1,837	808	-1,029
Currency translation adjustments	-3,043	-6,949	-9,992	2,079	-7,913
<b>Total</b>	<b>-3,286</b>	<b>-8,543</b>	<b>-11,829</b>	<b>2,887</b>	<b>-8,942</b>

Monetary items in the form of receivables from foreign subsidiaries are treated as part of a net investment in these foreign business operations. Currency differences are posted directly under shareholders equity. In addition, this balance sheet item shows currency differences for assets and goodwill reported in a foreign currency, as well as foreign currency differences from the translation of foreign subsidiaries' financial statements.

**(50) Non-current financial liabilities**

The noncurrent financial liabilities as per December 31, 2009 included convertible bonds amounting to € 9 thousand. For a description of the structure of the convertible bond program and the balance-sheet accounting, please refer to item (46).

**(51) Pension obligation**

MediGene offers all of its employees in Germany defined benefit plans in the form of a benevolent fund. These pension plans are fully reinsured with contracts. 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 for pension obligations is determined as follows:

<b>Pension obligation</b>		
In € thousand	Dec. 31, 2009	Dec. 31, 2008
Present value of benefit obligation	1,608	1,414
Fair value of plan assets	-1,528	-1,303
<b>Subtotal</b>	<b>80</b>	<b>111</b>
Unrecognized actuarial gains	91	76
Effect of IAS 19.58(b) limit	64	28
<b>Obligation in the balance sheet</b>	<b>235</b>	<b>215</b>

The plan assets are made up of liability insurance policies. As per the closing date of December 31, 2009, the actual income from the liability insurance policies was € 31 thousand. By way of comparison, the actual losses in the previous year totaled € 9 thousand. The following amounts were recorded in personnel expenses in the income statement:

<b>Expenses recognized in the income statement</b>		
In € thousand	2009	2008
Current service cost	109	95
Interest expense	72	59
Expected return on plan assets	-55	-47
Actuarial gains/losses	1	-10
Effect of IAS 19.58(b) limit	38	14
<b>Total included in personnel expenses</b>	<b>165</b>	<b>111</b>

<b>Actuarial assumptions</b>		
In %	2009	2008
Discount rate	6.0	5.7
Expected return on plan assets	4.0	4.0
Future contingent right increases	4.0	4.0
Future pension increases	1.0/2.0	1.0/2.0

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

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

<b>In € thousand</b>	
<b>Benefit obligation at Jan. 1, 2008</b>	<b>1,152</b>
Interest expense	59
Current service cost	95
Plan members contributions	232
Benefits paid	-64
Actuarial losses	-60
<b>Benefit obligation at Dec. 31, 2008</b>	<b>1,414</b>
Interest expense	72
Current service cost	109
Plan members contributions	51
Benefits paid	0
Actuarial losses	-38
<b>Benefit obligation at Dec. 31, 2009</b>	<b>1,608</b>
<b>of which</b>	
<b>funded by plan assets</b>	<b>1,421</b>
<b>not funded by plan assets</b>	<b>187</b>

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

<b>In € thousand</b>	
<b>Fair value of plan assets at Jan. 1, 2008</b>	<b>997</b>
Expected return on plan assets	47
Employer contributions	129
Member contributions	232
Benefits paid	-46
Actuarial losses	-56
<b>Fair value of plan assets at Dec. 31, 2008</b>	<b>1,303</b>
Expected return on plan assets	55
Employer contributions	144
Plan member contributions	51
Benefits paid	0
Actuarial losses	-25
<b>Fair value of plan assets at Dec. 31, 2009</b>	<b>1,528</b>

The figures for the current and previous reporting periods since the pension obligation came into existence are as follows:

In € thousand	2009	2008	2007	2006	2005
Benefit obligation	1,608	1,414	1,152	933	735
Fair value of plan assets	-1,528	-1,303	-997	-840	-576
Deficit	80	111	155	93	159
Unrecognised actuarial gains/losses	91	76	83	-17	-67
Experience adjustments on plan liabilities	-16	-40	-1	-2	-41
Experience adjustments on plan assets	25	57	-4	23	60

## (52) Income taxes

The major components of the income tax expenses for the 2009 and 2008 fiscal years are as follows:

Income taxes			
In € thousand	2009	2008	Change
Actual income taxes:			
R&D tax credit	-27	700	-104%
Deferred taxes	0	1,656	-%
Actual tax income reported in income statement	-27	2,356	-101%

In 2008, the subsidiary MediGene Ltd. received an R&D tax credit amounting to € 700 thousand. In 2009, this tax credit was adjusted downward by € 27 thousand.

Deferred tax as per December 31, 2009 related to the following items:

In € thousand	Consolidated balance sheet		Consolidated income statement	
	Dec. 31, 2009	Dec. 31, 2008	2009	2008
<b>Deferred tax assets</b>				
Deferred taxes on tax loss carry forward				
Germany	42,213	38,915	3,298	4,148
USA	15,778	15,845	188	789
United Kingdom	7,194	6,413	822	-92
	65,185	61,173	4,308	4,845
Non deductible	-57,830	-54,983	-3,779	-5,766
<b>Net</b>	<b>7,355</b>	<b>6,190</b>	<b>529</b>	<b>-921</b>
Different useful lives of tangible assets	59	829	-771	115
Other taxes from grants	1,704	2,374	-642	21
Derivative financial instruments	459	307	152	67
Prepaid expenses	26	0	26	0
Liability pension insurance	166	156	10	73
Valuation of accruals	6	10	-2	1
	2,420	3,676	1,227	277
Non deductible	-1,744	-2,425	652	-11
<b>Net</b>	<b>676</b>	<b>1,251</b>	<b>575</b>	<b>266</b>
<b>Deferred tax liabilities</b>				
Capitalization of acquired licenses	7,868	7,300	68	2,384
Different useful lives of tangible assets	0	0	0	2
Pension accruals	163	141	-22	-75
	8,031	7,441	46	2,311
<b>Deferred tax income/expenses</b>			<b>0</b>	<b>1,656</b>
<b>Deferred tax asset/liabilities (balance)</b>	<b>0</b>	<b>0</b>		

In the years 2009 and 2008, neither tax income nor tax expenses from deferred tax were posted in shareholders' equity.

As additional losses are expected in the foreseeable future, the tax claims from loss carryforwards were not shown to the extent that they exceeded tax liabilities. 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 on January 1, 2008 is based on a combined tax rate of 26.33%. This is composed as follows: 15% corporate income tax rate, 5.5% solidarity surcharge on the corporate income tax, and 10.5% trade tax.

As for the deferred taxes of foreign business segments, the country-specific tax rates were used.

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 table below, in which the tax rate applicable in the respective period was applied.

As the subsidiaries have no distributed profits, no deferred tax liabilities are recognized in that respect.

<b>Income taxes</b>		
In € thousand	2009	2008
Result before income tax	-21,935	-33,146
<b>Expected tax income</b>	<b>5,765</b>	<b>8,727</b>
Tax credit	-27	700
Use of UK tax loss carry forward	0	-813
Increase of unreported deferred taxes on tax loss carry forward	-3,779	-5,766
Adjustment of accumulated losses brought forward from the previous year	-1,517	55
Temporary differences not posted	652	-11
Non-deductible expenses	-529	-533
Changes in UK tax rate	0	-531
Difference from UK tax rate	35	221
Difference from USA tax rate	62	253
Decline in loss carry forward in USA	-647	0
Other	-15	54
<b>Actual tax income</b>	<b>0</b>	<b>2,356</b>

The tax income for the 2008 fiscal year consisted of the effects from the emergence and reversal of temporary differences in a tax credit which was received in the form of an R&D tax credit by the subsidiary MediGene Ltd. in the United Kingdom. This lowers the existing loss carryforwards and the deferred tax assets applied on the basis of these loss carryforwards.

#### **Tax loss carry forward**

In € thousand	Dec. 31, 2009	Dec. 31, 2008
Corporate income taxes Germany	161,196	148,580
Trade taxes Germany	159,086	146,688
State tax USA	38,478	38,630
Federal tax USA	39,804	39,975
Corporate tax UK	25,729	22,558

According to the German Corporate Income Tax Act (KStG), tax losses can in principle be carried forward for an unlimited period of time. The deduction of existing loss carryforwards is ruled out when the company carrying them forward loses its tax identity.

The loss carryforwards of the subsidiary MediGene Ltd. in the United Kingdom may be used for an unlimited period provided that it does not lose its tax identity. In contrast, the loss carryforwards at MediGene, Inc. expire between 2010 and 2026. In the USA, tax loss carryforwards resulting from federal tax can be utilized for 20 years, while those based on state tax expire after 10 years.

#### **(53) Trade accounts payable and other current liabilities**

The trade accounts payable amounting to € 2,452 thousand (2008: € 10,496 thousand) as per the end of the period under review took the form of unpaid invoices which were issued primarily for services utilized by MediGene. For the maturity analysis of the financial liabilities, please refer to Note (59).

The other liabilities amounting to € 8,843 thousand (2008: € 3,339 thousand) consist primarily of royalties due to Tolmar and still to be invoiced amounting to € 5,153 thousand (2008: € 14 thousand), due bonus payments amounting to € 1,040 thousand (2008: € 1,112 thousand), liabilities from wage and church taxes amounting to € 581 thousand (2008: € 559 thousand), and services in the fields of clinical trials and approvals totaling € 344 thousand (2008: € 409 thousand) that have been carried out, but not yet invoiced.

**(54) Derivative financial instruments**

The contract concluded with Astellas Pharma for the marketing of Eligard® includes an embedded derivative as it is denominated in US dollars and not in the functional currency of either of the two contracting parties. Losses (gains) from this derivative arise from currency losses (gains) by the US dollar against the euro, and are posted to income as per the end of the period. The embedded derivative is valued on the basis of Astellas Pharma's orders expected through June 30, 2010.

The license agreement with the Virionics Corporation was cancelled in the year under review. The option it contains for the step-by-step acquisition of an investment of up to 15% in the company remains intact and likewise constitutes a derivative financial instrument. To date, MediGene has not received any shares in Virionics. The management estimates that the fair value of the respective derivative financial instrument is zero.

**(55) Accruals**

In order to comply with the conditions for the market approval of Veregen® imposed by the American Food and Drug Administration, an accrual was formed which amounted to € 470 thousand as per December 31, 2009 (2008: € 455 thousand).

**(56) Contingent liabilities**

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

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

The pro rata financial obligations of Immunocore Ltd. amount to € 58 thousand (2008: € 95 thousand).

As per the balance sheet date, there was a deposit guarantee of € 322 thousand (2008: € 312 thousand) vis-a-vis the landlord and no longer any bank guarantee vis-a-vis the lessor (2008: € 27 thousand).

Expenses of € 1,356 thousand were incurred for operating leases (2008: € 1,461 thousand) in the period under review.

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

In € thousand	Rent and lease payments
2010	1,389
2011	1,309
2012	1,274
2013	1,172
Later	2,941
<b>Minimum lease obligations</b>	<b>8,085</b>

The company leases office and laboratory facilities, office furnishings, laboratory equipment, and vehicles. These constitute operating leases as the contractual agreement does not transfer the risks and rewards to the group. The lease agreements have varying conditions, rental increase clauses, and extension options.

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

**(57) Total amount of unused/open credit lines**

In addition to the cash posted under Note (45), no open credit lines were reported as per December 31, 2009.

**(58) Related parties**

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

Dr Peter Heinrich, former CEO of MediGene AG, was a member of the Board of Directors, the supervisory body at the associate Immunocore Ltd., until the end of April 2009. This function was assumed at the beginning of May 2009 by Dr Thomas Klaue, Chief Financial Officer of MediGene AG. Transactions amounting to € 69 thousand were conducted between MediGene Ltd. and Immunocore Ltd.

The remuneration and shareholdings of the company's Executive and Supervisory Boards are itemized individually for each member of these boards under H) Executive Board and Supervisory Board. In the 2009 fiscal year, there were no further transactions between the group and related parties.

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

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

The group additionally has a derivative financial instrument that is embedded in the contract with Astellas Pharma for marketing the drug. The derivative relates to the handling of product deliveries in US dollars, a non-functional currency.

The group's business activities expose it to various financial risks: market risks (includes foreign exchange risks and fair value interest rate risks), credit risks, liquidity risks, and cash flow interest rate risks.

Below is a description of the financial risk factors and the associated financial risk management of the group. The management does not see the following, currently existing items resulting from financial risks as significant.

#### Market risks

##### Interest rate risk

Fluctuations in market interest rates impact the cash flows of interest-bearing assets and, furthermore, the fair value of convertible bonds and pensions. MediGene's management has deliberately decided to avoid carrying out transactions aimed at hedging interest-based cash flows, as 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
2009	50	78
2008	50	170

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

##### Foreign exchange risk

Foreign exchange risks arise when future business transactions, and assets and liabilities 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 the changes in the rates between the US dollar and the euro or between the British pound and the euro. The subsidiaries of MediGene AG use the US dollar (MediGene, Inc.) and the British pound (MediGene Ltd.) as their functional currencies.

The foreign exchange risk refers to revenue in US dollars from Eligard<sup>®</sup> and Veregen<sup>®</sup> sales, as well as milestone payments for Veregen<sup>®</sup> from the partner company Nycomed. In addition, the costs for purchasing Eligard<sup>®</sup> and the active ingredient in Veregen<sup>®</sup>, as well as the license payments to these products' licensors, depend on exchange rates of foreign currencies. 98% of the overall revenue generated by the group is earned in foreign currency, with 97% of this accruing in US dollars. 95% of the cost of sales is denominated in foreign currency, 100% of which involves US dollars.

The MediGene group reduces the foreign exchange risks resulting from its subsidiaries' operating activities by utilizing the proceeds generated from the products marketed in US dollars to finance the purchase of goods and other activities by the US subsidiary. The following table shows the sensitivity of the group's income before tax and shareholders' equity to changes to the euro's exchange rate against the US dollar. All other variables remain constant.

##### Sensitivity analysis of foreign exchange risk (\$)\*

	Exchange rate development of \$	Effects on results before income taxes in € thousand	Effects on shareholders' equity in € thousand
2009	+5%	232	232
	-5%	-215	-215
2008	+5%	356	356
	-5%	-402	-402

\*1) Referring to the exchange rate as per the due date.

At group level, the operating activities of the subsidiaries and the assets and liabilities classified accordingly result in foreign exchange risks. The change in value of the British pound against the euro has its major impact on the reported assets of MediGene Ltd., the goodwill allocated to this company, and the share in an

associate. In addition, monetary items in the form of an account receivable against foreign subsidiaries (net investment in foreign business operations) are subject to foreign currency fluctuations. The overall resulting changes are posted as other reserves not affecting net income in shareholders' equity.

#### Sensitivity analysis of foreign exchange risk (£)\*1

	Exchange rate development of £	Effects on results before income taxes in € thousand	Effects on shareholders' equity in € thousand
2009	+5%	101	1,917
	-5%	-111	1,974
2008	+5%	215	1,855
	-5%	-238	1,919

\*1 Referring to the exchange rate as per the due date.

#### Securities-related share price risks

The group is not currently exposed to any risk of changes in share prices.

#### Credit risk

The group has no significant concentrations with regard to possible credit risks. There are relationships with two major customers, Astellas Pharma and Nycomed. The creditworthiness of the customers in question is monitored using the publicly accessible management's discussion and analysis reports and the consolidated financial statements.

In terms of the group's other financial assets such as cash and cash equivalents and available-for-sale financial investments, the maximum credit risk upon default by the counterparty equals the carrying amount of these instruments.

#### Liquidity risk

MediGene's liquidity management aims to hold a sufficient degree of cash, cash equivalents, and tradable securities, and to secure the issue of treasury shares on the market in order to overcome any possible liquidity bottlenecks. MediGene is assuming that under the current conditions it can issue tradable securities on the market.

As per December 31, 2009, the group's financial liabilities had the maturities shown below. These are disclosed on the basis of contractual, undiscounted payments.

#### Financial liabilities

In € thousand	Maturity					Total
	up to 30 days	30-90 days	3-12 months	1-5 years	>5 years	
<b>Balance at Dec. 31, 2009</b>						
Trade accounts payable	2,340	112	0	0	0	2,452
Financial liabilities	0	0	9	0	0	9
Other debt	629	7,961	253	0	0	8,843
<b>Total</b>	<b>2,969</b>	<b>8,073</b>	<b>262</b>	<b>0</b>	<b>0</b>	<b>11,304</b>
<b>Balance at Dec. 31, 2008</b>						
Trade accounts payable	9,716	780	0	0	0	10,496
Financial liabilities	0	0	0	169	0	169
Other debt	1,587	1,420	332	0	0	3,339
<b>Total</b>	<b>11,303</b>	<b>2,200</b>	<b>332</b>	<b>169</b>	<b>0</b>	<b>14,004</b>

### 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 proportion of total assets accounted for by cash, cash equivalents, and securities. A sufficiently high equity ratio is needed to make flexible use of the equity and debt financing options on the market.

#### Key figures for capital control

		2009	2008
Liquidity cover ratio in %	Cash x 100		
	Balance sheet total	19	31
Equity ratio in %	Equity x 100		
	Balance sheet total	79	80

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

The following table shows the carrying amounts and fair values of all financial instruments recorded in the consolidated financial statements as per December 31, 2009:

#### Other financial assets and liabilities

In € thousand	Carrying amount		Fair value	
	2009	2008	2009	2008
<b>Financial assets</b>				
Cash and cash equivalents	12,251	25,101	12,251	25,101
Available-for-sale financial assets	152	540	152	540
<b>Financial liabilities</b>				
Financial debt	9	169	9	169
Derivative financial instruments	1,743	1,166	1,743	1,166

### Hierarchy of fair values

The group uses the following hierarchy to determine and show 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 that have a significant effect on the recorded fair value and are not based on observable market data.

The first stage includes the fund shares shown under available-for-sale financial assets which are valued at the stock market price as per the closing date. The fair value of the derivative financial instrument which is determined on the basis of existing Eligard® orders and those forecast by the partner belongs to the second stage. The fair value of convertible bonds is allocated to the third stage. It is determined with the help of the binomial model using market interest rates.

### (61) Major events since the period under review

#### Dr Thomas Werner appointed as new Supervisory Board member

In February 2010, the Munich Local Court has appointed Dr Thomas Werner as Supervisory Board member, upon request by MediGene AG's Executive Board. This increases the number of Supervisory Board members from five to six.

#### Veregen® – Commercialization is progressing

MediGene and Teva Pharmaceutical Industries Ltd., Tel Aviv, Israel, in February 2010 entered into a partnership for the registration and commercialization of Veregen® in Israel. This is the first marketing partnership for Veregen® in Asia.

On March 1, 2010 MediGene's partner Solvay Arzneimittel GmbH, Hannover, Germany, has initiated the German launch of Veregen®.



## E) Consolidated statement of changes in shareholders' equity

The consolidated statement of changes in shareholders' equity for the 2009 and 2008 fiscal years forms a separate part of the consolidated financial statements.

## F) Notes on the statement of cash flow

The statement of cash flows shows the origins and application of the cash flows in the 2009 and 2008 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 loss for the year.

Within the scope of non-cash financing activities, no new lease obligations were entered into in 2009 for laboratory and office equipment.

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.

## G) Segment reporting

### Business units

From a global point of view, the group was organized in two main business units as per December 31, 2009. The business units »Marketed Products« and »Drug Candidates« identified in the group in accordance with IFRS 8 correspond to the business units »Biopharma« and »Specialty Pharma« that were previously identified in accordance with IAS 14 »Segment Reporting« and consist of the following:

### Marketed Products:

- Eligard® for the treatment of hormone-dependent, advanced prostate cancer
- Polyphenon® E Ointment/Veregen® for the treatment of genital warts

### Drug Candidates & technologies:

- EndoTAG™-1 for the treatment of solid tumors
- RhuDex® for the treatment of rheumatoid arthritis
- oHSV for the treatment of various cancer indications
- Anti-L1 antibodies for the treatment of ovarian cancer (discontinued in the first quarter of 2009)
- EndoTAG™ technology
- oHSV technology
- AAVLP technology

The individual segments' revenue is generated by external business relationships.

The transfer prices between the business units and regions are determined on the usual market terms among third parties.

The € 1,961 thousand shareholding in the associate (2008: € 3,269 thousand) has been allocated to »Reconciliation« in the segment assets.

## Segment reporting by business units

In € thousand	Marketed Products	Drug Candidates	Reconciliation <sup>1)</sup>	Consolidation	Total
<b>2009</b>					
Revenue with external customers	37,778	81	0		37,859
Other income	0	1,577	30		1,607
Inter-segment sales <sup>2)</sup>	882	509	0	-1,391	0
<b>Total revenue</b>	<b>38,660</b>	<b>2,167</b>	<b>30</b>	<b>-1,391</b>	<b>39,466</b>
<b>Segment operating result<sup>3)</sup></b>					
Depreciation	-4	-694	-133		-831
Share of loss of an associate	0	0	-1,625		-1,625
<b>Assets</b>					
Investment in an associate	0	0	1,961		1,961
Segment investments <sup>4)</sup>	1	246	216		463
<b>Segment assets<sup>5)</sup></b>	<b>2,204</b>	<b>41,775</b>	<b>21,744</b>		<b>65,723</b>
<b>Segment liabilities<sup>6)</sup></b>	<b>1,841</b>	<b>0</b>	<b>12,009</b>		<b>13,850</b>
<b>2008</b>					
Revenue with external customers	33,492	15	0		33,507
Other income	4,440	1,577	82		6,099
Inter-segment sales <sup>2)</sup>	0	43	0	-43	0
<b>Total revenue</b>	<b>37,932</b>	<b>1,635</b>	<b>82</b>	<b>-43</b>	<b>39,606</b>
<b>Segment operating result<sup>3)</sup></b>					
Depreciation	-162	-6,658	-296		-7,116
Share of loss of an associate	0	0	-256		-256
<b>Assets</b>					
Investment in an associate	0	0	3,269		3,269
Segment investments <sup>4)</sup>	0	159	199		358
<b>Segment assets<sup>5)</sup></b>	<b>5,700</b>	<b>39,601</b>	<b>35,445</b>		<b>80,746</b>
<b>Segment liabilities<sup>6)</sup></b>	<b>1,166</b>	<b>0</b>	<b>14,674</b>		<b>15,840</b>

<sup>1)</sup> Segment »Reconciliation« includes information that can be allocated to neither the »Marketed Products« segment nor the »Drug Candidates« segment, as it does not depict any activities of its own.

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

<sup>3)</sup> Segment operating result does not include any interest income (2009: € 129 thousand; 2008: € 1,452 thousand), any interest expense (2009: € 5 thousand; 2008: € 2 thousand), any foreign exchange losses (2009: € 519 thousand; 2008: € 2,035 thousand), any losses from derivative financial instruments (2009: € 578 thousand; 2008: € 253 thousand), any income or expenses from financial assets (2009: € 302 thousand; 2008: € -352 thousand), or any share of loss of an associate (2009: € 1,625 thousand; 2008: € 256 thousand). Segment operating result does include gains from inter-segment sales (2009: € 1,391 thousand; 2008: € 43 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 (2009: € 3,179 thousand; 2008: € 4,567 thousand), cash and cash equivalents (2009: € 12,251 thousand; 2008: € 25,101 thousand), and other current assets (2009: € 6,314 thousand; 2008: € 5,777 thousand).

<sup>6)</sup> Segment liabilities under »Reconciliation« include non-current liabilities (2009: € 244 thousand; 2008: € 384 thousand), trade accounts payable and other liabilities (2009: € 11,295 thousand; 2008: € 13,835 thousand), and accruals (2009: € 470 thousand; 2008: € 455 thousand).

## Regional segments

The group operates in Germany, the USA, and the United Kingdom.

### Revenue with external customers

In € thousand	2009	2008
UK	36,681	32,997
USA	971	505
Other	207	5
<b>Total</b>	<b>37,859</b>	<b>33,507</b>

The information about the segment revenue is classified by the customers' headquarters. In the »Marketed Products« segment, revenue of € 36,681 thousand was generated with one customer.

### Non-current assets

In € thousand	2009	2008
UK	27,557	25,103
USA	9,231	9,235
Other	6,050	6,414
<b>Total</b>	<b>42,838</b>	<b>40,752</b>

The noncurrent assets shown in the table encompass property, plant, and equipment, intangible assets, and goodwill.

## (62) Legal disputes

The risk arising from a legal dispute regarding the marketing of Eligard® that was described in the 2008 group management's discussion and analysis no longer exists as the dispute was resolved by the parties involved in July 2009.

In July 2008, following the death of a subject who participated in a trial of the drug candidate RhuDex®, the Public Prosecutor's office in Edinburgh, United Kingdom, initiated a routine investigation which was concluded in November 2009. The possibility also exists that a civil action will be initiated on the part of the subject's family. Given the results of the investigation to date, the Executive Board deems the probability of such a suit to be extremely low.

With the exception of the aforementioned legal dispute, no litigation that could have a major influence on the company's financial situation or that of its subsidiaries has been pending in the last twelve months, nor is there currently a threat of any such litigation.

## (63) German Corporate Governance Code

MediGene's Executive Board and Supervisory Board confirmed on December 11, 2009 that MediGene AG complies with most of the recommendations of the German Corporate Governance Code as amended on June 6, 2008, and June 18, 2009. The recommendations of the Code that MediGene AG does not implement are each explained in the Declaration of Compliance in accordance with Section 161 of the German Stock Corporation Act (AktG). This declaration is permanently available in German and English on the company's website ([www.medigene.de/2556-bD1lbg~de~Investor\\_Relations~Corporate\\_Governance~corporategovernance.html](http://www.medigene.de/2556-bD1lbg~de~Investor_Relations~Corporate_Governance~corporategovernance.html)).

## (64) Auditing fees

The auditors and group auditors were paid the following fees for the 2009 fiscal year:

### Auditing fees

In € thousand	2009	2008
Audit	172	120
Other confirmation services	0	19
Tax consulting services	13	0
Other services	92	164
<b>Total</b>	<b>277</b>	<b>303</b>

## H) Executive and Supervisory Boards

### (65) Executive Board

#### Changes to the Executive Board

The CEO of MediGene AG, Dr Peter Heinrich, stepped down from his post as Executive Board member on April 29, 2009 with immediate effect. The Supervisory Board appointed Dr Frank Mathias as his successor.

On December 10, 2009, the Supervisory Board of MediGene AG resolved that the Research and Development business unit will report directly to the CEO, Dr Frank Mathias, in the future. In connection with this decision, the previous Chief Medical Officer & Chief Development Officer, Dr Axel Mescheder, is leaving the company. As a result, the Executive Board of the company has been reduced to two members.

#### Remuneration of the Executive Board

Remuneration of members of the Executive Board in the past fiscal year totaled € 3,077 thousand (2008: € 2,345 thousand) including pensions in the amount of € 104 thousand (2008: € 91 thousand) and vehicle leasing costs of € 39 thousand (2008: € 43 thousand). This increase is due mainly to bonus, severance, and continued remuneration payments in the amount of € 1,722 thousand (2008: € 733 thousand). In addition, stock options with a fair value of € 152 thousand (2008: € 448 thousand) were issued to the Executive Board.

The Executive Board members' remuneration is comprised of fixed and variable components, as well as performance incentives to enhance shareholder value over the long term. The criteria for the variable compensation components are established in advance every year. The stock options represent long-term compensation components. The intention is to create performance incentives geared towards lasting corporate success. The targets that form the basis of these incentives may not be changed subsequently. No advance payments were granted to members of the Supervisory and Executive Boards.

The employment contracts of the Executive Board members Dr Thomas Klaue and Dr Axel Mescheder include provisions according to which the Executive Board member is entitled to a severance payment in case

- a) the employment contract is not extended and the reason for not extending the contract is not based on an important reason for termination for cause the Executive Board member is responsible for, or
- b) the Executive Board member terminates the employment contract for an important reason for which the company is responsible.

#### Executive Board compensation 2009

Executive Board member	Fixed compensation and severance payments <sup>1, 2, 3)</sup> in € thousand	Variable and performance based compensation <sup>4)</sup> in € thousand	Fringe benefit <sup>5)</sup> in € thousand	Variable compensation with long-term incentive effect	
				Number of stock options	Fair value of options in € thousand
Dr Peter Heinrich <sup>1)</sup> , Chief Executive Officer (until April 29, 2009) Biochemist, Todtenweis-Sand, Germany	1,028	308	42	0	0
Dr Frank Mathias Chief Executive Officer (since April 29, 2009), Chief Operating Officer (until April 29, 2009), Pharmacist, Munich, Germany	346	87	36	35,000	66
Dr Thomas Klaue <sup>2)</sup> , Chief Financial Officer Chemical Process Engineer and Business Economist, Pullach, Germany	358	64	31	27,500	51
Dr Axel Mescheder <sup>3)</sup> , Chief Medical Officer & Chief Development Officer (until December 10, 2009) Medical Specialist, Wörthsee, Germany	691	52	34	18,850	35
<b>Total</b>	<b>2,423</b>	<b>511</b>	<b>143</b>	<b>81,350</b>	<b>152</b>

<sup>1)</sup> Severance payment amounting to € 752 thousand.

<sup>2)</sup> Severance payment amounting to € 143 thousand.

<sup>3)</sup> Continued remuneration payment amounting to € 467 thousand.

<sup>4)</sup> On the basis of the accruals for 2009.

<sup>5)</sup> Fringe benefits include pension expenses, and vehicle leasing for the members of the Executive Board.

The severance payment equals one and a half times the gross salary per month for each completed full year of employment of the Executive Board member, but at least six and not exceeding 36 gross amounts per month.

The employment contract of Dr Peter Heinrich included such a provision. In connection with his appointment as Chief Executive Officer of the company, Dr Frank Mathias waived a respective undertaking.

In the 2009 fiscal year, MediGene paid € 6 thousand (2008: € 6 thousand) into the benevolent fund for a pension obligation to a former Executive Board member.

## (66) Supervisory Board

### Remuneration of the Supervisory Board

Supervisory Board remuneration amounted to € 221 thousand in 2009 (2008: € 233 thousand). The Supervisory Board members' total remuneration is comprised of fixed remuneration and fees for attending meetings. Furthermore, expenses are reimbursed. Both the chairmanship and deputy chairmanship of the Supervisory Board are taken into account in the evaluation of the Supervisory Board members' scope of activities. Disclosures on the subscription rights of members of the Supervisory and Executive Boards and employees are shown under Note (67). No advance payments were granted to members of the Supervisory and Executive Boards.

#### Supervisory Board compensation 2009

Supervisory Board member	Fixed compensation in € thousand	Fees for attending meetings in € thousand
Dr Ernst-Ludwig Winnacker Chairman	48	20
Dr Norbert Riedel Deputy Chairman	36	15
Dr Pol Bamelis Member	24	10
Sebastian Freitag Member	24	10
Dr Mathias Albert Boehringer Member	24	10
<b>Total</b>	<b>156</b>	<b>65</b>

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

#### Dr Ernst-Ludwig Winnacker

since November 26, 1996

Chairman

Secretary General of Human Frontier Science Program (HFSP),  
Strasbourg, France

#### Dr Norbert Riedel

since October 27, 2003

Deputy Chairman

Corporate Vice President, Chief Scientific Officer,  
Baxter International, Inc., Glendale, CA, USA

#### Dr Pol Bamelis

since May 23, 2001

Former Executive Board member, Bayer AG, Leverkusen,  
Germany

#### Sebastian Freitag

since June 10, 2005

Investment banker, Frankfurt, Germany

#### Dr Mathias Albert Boehringer

since July 16, 2008

Shareholders' committee member, Boehringer Ingelheim,  
Ingelheim, Germany

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

**Dr Ernst-Ludwig Winnacker**

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

**Dr Norbert Riedel**

- Oscient Pharmaceuticals Inc., USA

**Dr Pol Bamelis**

- Actogenix N.V., Belgium
- PolyTechnos Ltd., Guernsey, United Kingdom
- Recticel, Belgium
- Sioen N.V., Belgium
- Televic N.V., Belgium (until May 31, 2009)

**Sebastian Freitag**

- Wyser-Pratte EuroValue Fund Ltd., Cayman Islands

**Dr Mathias Albert Boehringer**

- Boehringer Ingelheim Gesellschafterausschuss, Ingelheim, Germany
- Phenex Pharmaceutical AG, Ludwigshafen, Germany

**Dr Peter Heinrich (until April 29, 2009)**

- MagForce Nanotechnologies AG, Berlin, Germany
- Immunocore Ltd., United Kingdom (until May 4, 2009)

**Dr Thomas Klaue**

- Immunocore Ltd., United Kingdom (since May 4, 2009)

**(67) Directors' holdings and notes on subscription rights**

Member	Shares Dec. 31, 2009	Shares Dec. 31, 2008	Options Dec. 31, 2009	Options Dec. 31, 2008
Dr Ernst-Ludwig Winnacker Chairman of Supervisory Board, Co-founder	274,476	274,476	0	8,600
Dr Norbert Riedel Vice Chairman of Supervisory Board	3,300	3,300	0	5,590
Dr Pol Bamelis Supervisory Board member	400	400	0	0
Sebastian Freitag Supervisory Board member	2,500	2,500	0	0
Dr Mathias Albert Boehringer Supervisory Board member	0	0	0	0
<b>Total Supervisory Board</b>	<b>280,676</b>	<b>280,676</b>	<b>0</b>	<b>14,190</b>
Dr Peter Heinrich Chief Executive Officer (until April 29, 2009), Co-founder	–*)	505,505	210,000	246,636
Dr Frank Mathias Chief Executive Officer (since April 29, 2009) Chief Operating Officer (until April 29, 2009)	0	0	57,500	22,500
Dr Thomas Klaue Chief Financial Officer	4,500	4,500	65,833	38,333
Dr Axel Mescheder Chief Medical Officer & Chief Development Officer (until December 10, 2009)	6,000	6,000	81,686	62,836
<b>Total Executive Board</b>	<b>10,500</b>	<b>516,005</b>	<b>415,019</b>	<b>370,305</b>

\*) No data as at closing date.

**(68) 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)**

Santo Holding (Deutschland) GmbH, Königstrasse 1 A, 70173 Stuttgart, notified MediGene AG on November 6, 2009 that its voting interest in the company fell below the threshold of 5% as of November 2, 2009, and amounted to 4.95% on that date. This corresponds to 1,706,001 voting rights.

Santo Holding AG, Alte Landstrasse 106, 8702 Zollikon, Switzerland, notified MediGene AG on November 5, 2009 that its voting interest in the company fell below the threshold of 5% as of November 2, 2009, and amounted to 4.95% on that date. This corresponds to 1,706,001 voting rights. Of these, 4.95% of the voting rights (equal to 1,706,001 voting rights) were attributable to Santo Holding AG in accordance with Section 22 (1) (1) (1) of the German Securities Trading Act (WpHG). Attributed votes are held via the following company controlled by Santo Holding AG, whose voting rights in MediGene AG amount to 4.95% (equal to 1,706,001 voting rights): Santo Holding (Deutschland) GmbH, Königstrasse 1 A, 70173 Stuttgart, Germany.

***Disclosures of aggregate voting rights in accordance with Section 26a, German Securities Trading Act (WpHG):***

On the respective closing dates, MediGene AG announced the following aggregate figures for the voting rights: On June 30, 2009 a total of 34,052,145 voting rights, on October 31, 2009 a total of 34,257,483 voting rights, on November 30, 2009 a total of 34,989,312 voting rights, on December 30, 2009 a total of 35,557,493 voting rights.

## **The Executive Board**

Planegg/Martinsried, Germany, March 11, 2010  
MediGene AG

**Dr Frank Mathias**

Chief Executive Officer

**Dr Thomas Klaue**

Chief Financial Officer

## Consolidated statement of changes in fixed assets

### of MediGene AG for the periods January 1 to December 31, 2009

In € thousand	Initial cost				
	Jan. 1, 2009	Currency translation adjustments	Addition	Disposal	Dec. 31, 2009
Property, plant & equipment	6,838	-3	297	-121	7,011
Intangible assets	30,687	2,268	166	0	33,121
Goodwill	13,864	182	0	0	14,046
<b>Total</b>	<b>51,389</b>	<b>2,447</b>	<b>463</b>	<b>-121</b>	<b>54,178</b>

### of MediGene AG for the periods January 1 to December 31, 2008

In € thousand	Initial cost				
	Jan. 1, 2008	Currency translation adjustments	Addition	Disposal	Dec. 31, 2008
Property, plant & equipment	10,111	-840	286	-2,719	6,838
Intangible assets	48,566	-8,139	72	-9,812	30,687
Goodwill	14,555	-691	0	0	13,864
<b>Total</b>	<b>73,232</b>	<b>-9,670</b>	<b>358</b>	<b>-12,531</b>	<b>51,389</b>



Accumulated depreciation					Book value	
Jan. 1, 2009	Currency translation adjustments	Addition	Disposal	Dec. 31, 2009	Dec. 31, 2009	Dec. 31, 2008
5,687	-3	385	-121	5,948	1,063	1,151
2,176	-4	446	0	2,618	30,503	28,511
2,774	0	0	0	2,774	11,272	11,090
10,637	-7	831	-121	11,340	42,838	40,752

Accumulated depreciation					Book value	
Jan. 1, 2008	Currency translation adjustments	Addition	Disposal	Dec. 31, 2008	Dec. 31, 2008	Dec. 31, 2007
8,309	-746	570	-2,446	5,687	1,151	1,802
1,959	9	5,617	-5,409	2,176	28,511	46,607
1,845	0	929	0	2,774	11,090	12,710
12,113	-737	7,116	-7,855	10,637	40,752	61,119

## Auditors' report

We have audited the consolidated financial statements prepared by MediGene AG, Martinsried/Planegg, comprised of the balance sheet, the income statement, the statement of comprehensive income, the statement of changes in equity, the statement of cash flow, and the notes to the consolidated financial statements, together with the group management report for the fiscal year from January 1, 2009 to December 31, 2009. 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«] is the responsibility of the 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 the German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position, and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the group management report are examined

primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used, and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRSs as adopted by the EU, the additional requirements of German commercial law pursuant to Sec. 315 a (1), 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, Germany, March 11, 2010

Ernst & Young GmbH  
Wirtschaftsprüfungsgesellschaft

Dr Napolitano  
German Public Auditor

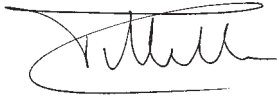
Breyer  
German Public Auditor

## Responsibility statement

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

Planegg/Martinsried, Germany, March 11, 2010

The Executive Board



Dr Frank Mathias  
Chief Executive Officer



Dr Thomas Klaue  
Chief Financial Officer

## Report of the Supervisory Board

During the 2009 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 issues related to this. The Supervisory Board was directly involved in all decisions that were key to the company.

In addition to the reporting during regular Supervisory Board Meetings, the Executive Board routinely issued both written and verbal reports on the current status of research and development projects, the company's economic status and business development position, corporate planning, major business transactions, and fundamental matters of corporate policy, including the company's strategic and organizational direction, cost and earnings trends, investment measures, and financial planning. This was done in a timely and comprehensive manner.

The Supervisory Board continuously observed, monitored, and reviewed the company's risk situation and its risk management in particular and ensured that the company was managed in accordance with the law. Deviations from plans and objectives of business activities were explained to the Supervisory Board in detail, and the Executive Board discussed and agreed the company's strategic direction with the Supervisory Board. All business transactions of importance to the company were explored in detail in the plenary sessions of the Supervisory Board. Information on the risk management system implemented by the company can be found in the risk report of the Annual Report.

### Supervisory Board meetings

The Supervisory Board has fulfilled its obligations on the basis of detailed verbal and written reports by the Executive Board, which contain current and comprehensive information. Five Supervisory Board meetings took place during the 2009 fiscal year (March 5, 2009, May 28, 2009, July 30, 2009, August 31, 2009, and December 11, 2009) and additional conference calls were held. In 2010, during the period until the meeting that approved the financial statements on March 11, 2010, an additional Supervisory Board meeting in the form of a telephone conference took place on February 2, 2010. When required, resolutions were documented in writing. Employees of the company or external experts were brought in to consult on special topics.

The Supervisory Board was also available to the Executive Board for one-on-one discussions. In general, the Chairman of the Supervisory Board spoke with the CEO at least once a week, keeping himself and his Supervisory Board colleagues updated about major business transactions, and offering advice and support.

The Executive Board informed the Supervisory Board immediately of all projects and plans of particular importance for the company outside of meetings as well. The Executive Board presented transactions requiring approval for adopting resolutions in a timely manner.

All business transactions submitted to the Supervisory Board for which either statutory approval or approval according to the terms of the Articles of Incorporation were required have been discussed in depth with the Executive Board. Revenue, earnings, and employment trends were the topics of regular consultations in the plenum. In addition to the economic situation and current business development, the Supervisory Board paid particular attention to the company's strategic reorientation in the 2009 fiscal year. The focus in these discussions was on developing a clear, recognizable core competence for the company, as well as on planning sustainable financing. The departments Clinical Development and CMC (Clinical Manufacturing Controls) were reinforced in connection with the core competence, EndoTAG™, while the research department Early Development was closed. Furthermore, the Supervisory Board supports the company's efforts to spin off the AAVLP technology. In December 2009, the company's future strategic plans to 2015 were presented. Product sales from marketing EndoTAG™-1 should allow the company to have achieved profitability by that point.

In fiscal year 2009, consulting centered on structural and personnel development in corporate management. In April 2009, Dr Peter Heinrich resigned as a member of the Executive Board after many years in office. Thereupon, the Supervisory Board decided to appoint Dr Frank Mathias Chief Executive Officer.

In December 2009, the Supervisory Board furthermore decided in connection with the revision of the development plans for EndoTAG™-1 and RhuDex® to revoke the appointment of Dr Axel Mescheder as Executive Board member and that the research and development department would directly report to Dr Frank Mathias in the future.

At the meeting on March 5, 2009, the Supervisory Board dealt above all with the annual and consolidated financial statements as of December 31, 2008 and corporate planning for the 2009 fiscal year. The objectives for the 2009 fiscal year were also defined at this meeting.

During the meeting on May 28, 2009, the Supervisory Board dealt above all with the strategic approach to the partnering of the drug candidate EndoTAG™-1, as well as financial and development plans for the next ten years.

During the meeting on July 30, 2009, the discussions on the company's financial and development plans continued in depth. The committee concentrated in particular on the MediGene AG project portfolio and future core competences. Furthermore, the Executive Board reported to the Supervisory Board on options for safeguarding the company's liquidity and on the status of each clinical development project. The Shareholders' Meeting was also prepared during this session.

During the meeting on August 31, 2009, the Shareholders' Meeting, which had taken place the same day, took up most of the discussion. In addition, more continuing deliberations on the EndoTAG™-1 project, as well as the company's financing, were on the agenda. The Supervisory Board in particular resolved to continue utilization of the SEDA (Standby Equity Distribution Agreement) with prior approval by the SEDA Committee, following the successful transaction of the test tranche in May. Of its own accord, the Supervisory Board reviewed the Executive Board's intention to shift the manufacturing process for EndoTAG™-1 from freeze-drying to spray drying with immediate effect, and confirmed this plan. The Supervisory Board expects this to strengthen the company's negotiating position in the project partnering process.

During the December 11, 2009 session, budget planning for 2010 was thoroughly discussed, and the budget for the upcoming fiscal year was adopted. Fundamental issues concerning the company's further financing were also discussed. At this meeting, in the absence of the Executive Board, the full plenum of the Supervisory Board explored questions on achievement of objectives for 2009 and the remuneration of the Executive Board. The Executive Board's remuneration was assessed by the full plenum of the Supervisory Board and seen as appropriate. Detailed explanations on the amount and structure of remuneration are included in the remuneration report (see page 80 et seq.) of this report.

Along with the project managers, the Executive Board also provided a detailed presentation of individual portfolio projects and discussed the future strategy of the core projects EndoTAG™ and RhuDex® in depth with the Supervisory Board.

### **Supervisory Board committees**

A Compensation Committee and an Audit Committee existed throughout the 2009 fiscal year. In addition, a SEDA Committee was constituted in May of 2009.

The first two committees each met four times during the course of 2009. The SEDA Committee met five times.

The duties of the Compensation Committee cover employment matters related to Executive Board members. It focuses on entering into and modifying Executive Board members' employment contracts and establishing their remuneration. Key topics for consultation included the resignation of long-standing CEO Dr Peter Heinrich, and assuring his successor, as well as the revocation of Dr Axel Mescheder's appointment as Executive Board member in charge of Research and Development. Due to the importance of these personnel issues, the discussions and decisions in this regard were taken by the full plenum of the Supervisory Board. The Compensation Committee is comprised of Dr Ernst-Ludwig Winnacker (chairman), Dr Pol Bamelis, and Dr Norbert Riedel.

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, establishing audit focal points, and agreeing the audit fee. The Audit Committee obtained the auditor's declaration of impartiality in accordance with point 7.2.1 of the German Corporate Governance Code and monitored this impartiality. The Audit Committee, in the presence of the auditor and the Chief Financial Officer, dealt with the audit of the annual and consolidated financial statements of MediGene AG. The Audit Committee regularly reviewed and discussed the six-month and quarterly reports with the Executive Board prior to publishing them. The Audit Committee is comprised of Sebastian Freitag (chairman and financial expert), Dr Pol Bamelis, and Dr Mathias Boehringer.

The SEDA Committee is a decision-making body, the members of which deal with all decisions arising for the Supervisory Board in connection with the Standby Equity Distribution Agreement entered into with YA Global Investments L.P. for underwriting

new MediGene AG shares. These include, in particular, approvals on the part of the Supervisory Board regarding the issue of new shares, determination of the content of share rights, the conditions of share issue, and subscription rights exclusions, which must be undertaken separately for each tranche. In addition, the SEDA Committee is responsible for the modification of the Articles of Incorporation which is entailed with each share issue under the SEDA program. The SEDA Committee is comprised of Dr Ernst-Ludwig Winnacker, Sebastian Freitag, and Dr Pol Bamelis.

The committees regularly informed the Supervisory Board about their work in the following plenary sessions.

### **Corporate Governance**

In 2009, the Supervisory Board once again addressed the compliance of MediGene AG with the recommendations of the German Corporate Governance Code. The Executive and Supervisory Boards intensively discussed the implementation of the Code at MediGene AG at the Supervisory Board meeting on December 11, 2009 and issued the annual declaration of compliance in accordance with Section 161 of the German Stock Corporation Act (AktG) on the same date. The declaration is permanently available to shareholders on the company's website. The Executive and Supervisory Boards made a commitment to follow the recommendations of the German Corporate Governance Code accordingly.

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

In the 2009 fiscal year, there were no conflicts of interest that the members of the Executive and Supervisory Boards were required to disclose immediately to the Supervisory Board or to report on at the Shareholders' Meeting.

### **Members of the Supervisory Board**

The composition of the Supervisory Board did not change in 2009.

In January 2010, the company applied for the judicial appointment of Dr Thomas Werner for the currently vacant post in the Supervisory Board for the time being until the next Shareholders' Meeting. The Munich Local Court's Registration Court approved this application by resolution dated February 2, 2010. A recommendation will be made at the next Shareholders' Meeting to elect Dr Thomas Werner to the Supervisory Board.

The Supervisory Board regularly evaluates if the panel and accordingly at least one of its members possesses the necessary independence as well as the requested professional qualification and expertise in the field of accounting and audit. This was again the case in 2009. Owing to his education and career, Sebastian Freitag is qualified to be the financial expert on the Board.

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

The auditor chosen by the Shareholders' Meeting and commissioned by the Supervisory Board, Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Munich, Germany, audited the financial statements of MediGene AG as at December 31, 2009, issued by the Executive Board in accordance with the regulations of the German Commercial Code (HGB), as well as the Management's discussion and analysis of MediGene AG for the fiscal year 2009, and granted them an unqualified auditor's opinion. The Audit Committee had commissioned the audit in accordance with the resolution of the Shareholders' Meeting of August 31, 2009. The consolidated financial statements of MediGene AG were prepared on the basis of the international accounting standards as applicable throughout the EU, and the additional requirements pursuant to Section 315 a (I) of the German Commercial Code (HGB). The auditor also issued an unqualified auditors opinion for these consolidated financial statements and the Group management's discussion and analysis.

The Audit Committee along with the auditors established the focal points of the audit for the reporting year.

All Supervisory Board members received all 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 11, 2010, and discussed in the presence of the auditor and the Executive Board, who reported on the results of the audit. The auditor participated in the meeting to approve the annual financial statements and reported on the most important results of his audit, especially on the results of the audit referring to the weaknesses of the internal controlling and risk management system relating to the accounting process. The Executive Board and auditors were available for any supplemental questions and information. All questions were answered to the complete satisfaction of the Supervisory Board.

The Supervisory Board endorsed the auditor's findings after its own examination of the individual and consolidated annual financial statements, the Management's discussion and analysis, and the group management's discussion and analysis. In its meeting on March 11, 2010, it approved the individual and consolidated annual financial statements as at December 31, 2009 in accordance with the recommendation of the Audit Committee. The financial statements are thus adopted.

At the meeting on March 11, 2010, the Audit Committee suggested nominating Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Munich, Germany, as auditors for the 2010 fiscal year for election at the Shareholders' Meeting. The Supervisory Board will heed this suggestion.

The Supervisory Board wishes to thank the Executive Board and all MediGene employees for their successful efforts on behalf of the company in the 2009 fiscal year. Once again, by working together, they achieved a good result.

Planegg/Martinsried, Germany, March 2010

A handwritten signature in black ink, reading "Ernst-Ludwig Winnacker". The signature is written in a cursive style with a large initial "E".

Dr Ernst-Ludwig Winnacker  
Chairman of the Supervisory Board

# Corporate Governance

## Statement on Corporate Governance in accordance with section 289a of the German Commercial Code (HGB)

The content of the statement regarding the methods of operation of the Executive and Supervisory Boards and regarding relevant corporate governance has already been described in the Corporate Governance section on page 92 et seq. MediGene abstains from any further explanation, and refers to this accordingly. In essence, the company perceives this as information regarding internal, practical workflows which have not been described by law or which go beyond legal requirements.

### Supervisory Board committees

A Compensation Committee and an Audit Committee existed throughout the 2009 fiscal year. In addition, a SEDA Committee was constituted in May of 2009.

The duties of the Compensation Committee cover personnel matters related to Executive Board members. It focuses on preparation of Executive Board members' employment contracts and proposals regarding their remuneration. It is the joint Supervisory Board's responsibility to decide on these matters. Members of the Compensation Committee are Dr Ernst-Ludwig Winnacker (Chairman), Dr Pol Bamelis, and Dr Norbert Riedel.

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, establishing audit focal points, and agreeing the audit fee. Members of the Audit Committee are Sebastian Freitag (Chairman and financial expert), Dr Pol Bamelis, and Dr Mathias Boehringer.

The SEDA Committee is a decision-making body, the members of which deal with all decisions that arise for the Supervisory Board in connection with the Standby Equity Distribution Agreement for underwriting new MediGene AG shares entered into with the company YA Global Investments. These include, in particular, approvals on the part of the Supervisory Board regarding the issue of new shares, the content of share rights, the conditions of share issue, and subscription rights exclusions, which must be undertaken separately for each tranche. In addition, the SEDA Committee is responsible for the modification of the Articles of Incorporation which each share issue entails under the SEDA program. Dr Ernst-Ludwig Winnacker, Sebastian Freitag, and Dr Pol Bamelis are members of the SEDA Committee.

## Corporate Governance

In the Corporate Governance Report, the Executive Board reports on corporate governance at MediGene AG, also on behalf of the Supervisory Board, in accordance with point 3.10 of the German Corporate Governance Code and as a part of the report on Corporate Governance according to section 289a (2) of the German Commercial Code (HGB).

MediGene AG's Executive and Supervisory Boards are conscious of their responsibilities toward shareholders, employees, and business partners. Due to its obligation to ensure the continued existence of the company and sustained value creation in harmony with the principles of the social market economy, MediGene AG has broadly implemented the German Corporate Governance Code (in its most recent version dated June 18, 2009). The recommendations and proposals of the Code are made by a commission set up by the German Federal Government and are comprised of internationally and nationally accepted standards of proper and responsible corporate management. The aim of the Executive and Supervisory Boards of MediGene AG is to affirm the trust that investors, financial markets, business partners, employees, and the public have bestowed upon them, and to continuously enhance corporate governance within the group.

Corporate governance ensures the following basic principles:

- defining key shareholder rights,
- indicating clear management principles and the associated responsibilities of corporate bodies,
- governing the cooperation between these bodies,
- fostering open and transparent communication with the public, and
- demanding conscientious as well as reliable accounting and auditing.

### German Corporate Governance Code and Declaration of compliance

MediGene AG has made the Corporate Governance Code universally accessible on the company's website ([www.medigene.com](http://www.medigene.com)). This is also true for the official Declaration of compliance on the part of the Executive and Supervisory Boards in accordance with section 161 of the German Stock Corporation Act (AktG) ([www.medigene.de/E\\_corporate\\_governance\\_erklaerung](http://www.medigene.de/E_corporate_governance_erklaerung)). MediGene AG has, after thorough deliberation, decided not to act in full compliance with the Code with regard to a few individual items. These items are specified in the Declaration. Comments on the reasons for non-compliance are given in this report.



The implementation of corporate governance at MediGene AG includes:

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

MediGene AG respects the rights of its shareholders and guarantees the exercise of these rights to the extent possible within the applicable statutory framework. In particular, these rights include the free purchase and sale of shares, equal voting rights for each share (one share – one vote), participation in the Shareholders' Meeting (including the exercise of voting rights), and appropriately meeting shareholders' information requirements.

### **Communication with the public**

In relaying information to people outside the company, the Executive Board observes the principles of transparency, promptness, openness, comprehensibility, and equal treatment of shareholders. For this purpose, the company provides information such as press releases, financial and conference calendars, annual and quarterly reports, announcements about transactions legally subject to reporting requirements, and corporate governance information on its website [www.medigene.com](http://www.medigene.com) under the headings »News« and »Investor Relations«. MediGene AG regularly reports on the status of research and development programs, as well as other business developments in conference calls, analyst meetings, and at international investor conferences.

The annual Shareholders' Meeting of MediGene AG is prepared with the goal of effectively providing all shareholders with comprehensive information before, during, and after the meeting. Furthermore, MediGene AG aims to assist shareholders in registering for the Meeting and exercising their rights. In advance of the Shareholders' Meeting, shareholders are informed in detail on the fiscal year just elapsed via the Annual Report. The conditions of participation are explained in the invitation to the Meeting. All documents and information pertaining to the Shareholders' Meeting can be found on the MediGene AG website. Members of MediGene AG's Investor Relations department are available to the shareholders to answer any questions either online or by phone prior to the Meeting. Following the Shareholders' Meeting, MediGene AG publishes attendance figures and voting results online. This allows MediGene AG to assure and simplify the exchange of information between MediGene AG and the shareholders in all matters regarding the Meeting.

Shareholders may either exercise their voting right personally at the Shareholders' Meeting or via a delegate of their choice or via one of the company's proxies, who is bound by their instructions.

### **Executive Board**

The Executive Board as a whole, as well as each individual Board member, conducts the company's business with the due care and diligence of proper and conscientious management in accordance with the law, the Articles of Incorporation, and the Executive Board's bylaws. The Executive Board manages the company on its own authority. In doing so, it is obliged to act in the company's best interest and is committed to enhancing shareholder value over the long term. The Executive Board takes into account the interests of the shareholders, employees, and other stakeholders in managing the company. In the composition of the Executive Board, the Supervisory Board places value on a high diversity of expertise and experience.

### **Supervisory Board**

It is the task of the Supervisory Board of MediGene AG to appoint the Executive Board members, advise them regularly, and to monitor and support the management and achievement of MediGene's long-term goals. There are no former members of the Executive Board on the Supervisory Board of MediGene AG. This guarantees that consultation with and supervision of the Executive Board is impartial. When making proposals regarding the composition of the Supervisory Board, the Executive Board places value on a high diversity of expertise and experience.

### **Cooperation between the Executive Board and the Supervisory Board**

The Executive and Supervisory Boards cooperate closely for the benefit of the company. The Chairman of the Supervisory Board maintains regular and intensive contact with the Executive Board, especially with the Chief Executive Officer. The Executive Board coordinates the company's strategic orientation with the Supervisory Board, and, together, they discuss the status of research and development projects, business planning and development, strategy implementation, and the company's risk situation as well as risk management at regular intervals. Deviations of the course of business from the intended plans and objectives are explained and justified during these sessions. The Supervisory Board specifies in the Executive Board's bylaws that transactions of key significance are subject to the consent of the Supervisory Board. This includes, for example, decisions or measures that fundamentally change the company's net assets, financial position, or results of operations.

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

In its version dated June 18, 2009, under point 4.2.5, the German Corporate Governance Code recommends inclusion of a remuneration report as a part of the corporate governance report. The

German Commercial Code (HGB), section 289 (II) (5), however, also stipulates a remuneration report on the Executive Board member's compensation in the Management's discussion and analysis (MD&A). The requirements articulated in the Corporate Governance Code exceed those in the legal provisions, particularly with respect to itemized information. In order to comply both with requirements under the law and under the Corporate Governance Code and to facilitate transparent as well as intelligible presentation, the compensation of the members of the company's management bodies is reported in the »Remuneration report« chapter of the Management's discussion and analysis and the Notes to the consolidated financial statements including the information stipulated under Corporate Governance Code guidelines. Remuneration of Executive and Supervisory Board members is reported on pages 26 and 80 et seq. of the Annual Report and can be accessed on the company's website at [www.medigene.com](http://www.medigene.com). The information is itemized by individual and broken down into its components.

The Supervisory Board members' total compensation is comprised of fixed remuneration and meeting attendance fees. Both the chairmanship and deputy chairmanship of the Supervisory Board are taken into account in assessing the Supervisory Board members' scope of activities.

### **Forward-looking risk management**

A structured risk management system geared to practical requirements helps the company to identify risks at an early stage and take the necessary countermeasures quickly. On page 26 et seq. of the Management's discussion and analysis, we report on MediGene's risk management system and the current business risks.

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

MediGene AG informs shareholders and third parties regularly by means of its consolidated financial statements and the interim reports prepared during the fiscal year. The Supervisory Board discusses the consolidated financial statements as well as the six-month and quarterly reports with the Executive Board prior to their publication. Consolidated reporting complies with the International Financial Reporting Standards (IFRS) as applicable in the EU. Annual financial statements, which also form the basis for taxation, are prepared in accordance with national regulations (German Commercial Code (HGB)) for corporate law purposes (calculation of dividends, creditor protection). The consolidated financial statements and individual financial statements are reviewed by the auditors and the Supervisory Board. The Supervisory Board issues the audit assignment and concludes a fee

agreement with the auditors. The auditors participate in the Supervisory Board's discussions on the annual and consolidated financial statements and report on key audit findings.

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

#### **2007 stock option plan**

Authorization of the Executive Board to grant stock options to employees of affiliated companies at home and abroad did not take place at the Shareholders' Meeting on June 2, 2006. In September of 2006, however, MediGene AG acquired the British company Avidex Ltd. In order to create the opportunity to also grant Avidex's approximately forty employees MediGene AG stock options, the existing 2006 shareholders' resolution was replaced by a new shareholders' resolution during the Shareholders' Meeting on May 25, 2007. This new resolution provides the possibility of granting stock options to employees of affiliated companies at home and abroad. Stock options were issued in March and December of 2008. In contrast to options issued in 2007 and December of 2008, MediGene AG waived its right to forfeit all options under the March 2008 program on the grounds of termination of employment due to personal or conduct-related reasons or as a result of termination of employment by the holder of an option in a case in which the waiting period had not yet expired upon termination of contract. In all remaining items, the 2007 stock option plan corresponds to the 2006 stock option plan (refer to pages 33 and 66 et seq.). 550,533 options were issued in 2008 and 81,350 options were issued in 2009 under this stock option plan.

#### **Earlier employees' incentive programs**

In addition to the 2007 stock option plan, subscription rights still exist for convertible bonds issued to employees and Executive and Supervisory Board members. For more detailed information on MediGene AG's employee incentive programs, please refer to pages 33 and 66 et seq. of this Annual Report.

#### **Directors' dealings**

Under section 15a of the German Securities Trading Act (WpHG), the Executive and Supervisory Board members of MediGene AG, as well as persons who have a close relationship with these members (family members), are required to report any trading in MediGene AG shares. In addition to the purchase and sale of MediGene AG shares, any transactions in securities relating to MediGene AG shares (e.g. the sale or purchase of options on MediGene AG shares) must be reported. The company must be notified of such transactions within five business days and must

publish such transactions immediately. This obligation is not applicable if the total value of trading does not exceed € 5 thousand during one calendar year. During 2009, no securities transactions were carried out that were subject to notification.

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

Any non-compliance with the recommendations of the German Corporate Governance Code according to section 161 of the German Stock Corporation Act (AktG) is outlined below:

#### **Deductible in the case of D&O insurance**

In point 3.8, the German Corporate Governance Code recommends that in the case of Directors and Officers Liability Insurance (D&O insurance), a deductible of at least 10% of the loss up to at least one-and-a-half times the fixed annual remuneration of the Executive Board member be agreed. With regard to the D&O insurance in effect for the Executive and Supervisory Board members of MediGene AG, no deductible has been agreed upon, other than any damages claimed in the USA or in compliance with applicable US law. MediGene AG shall agree a general deductible of at least 10% of the loss up to at least one-and-a-half times the fixed annual remuneration of the respective Executive Board member with its D&O insurance carrier by June 30, 2010. MediGene AG does not intend to agree a general deductible with its D&O insurance carrier for its Supervisory Board members. Both the Executive and Supervisory Boards believe that the motivation and sense of responsibility with which the members of the Supervisory Board of MediGene AG undertake their duties are fully guaranteed without requiring the general deductible recommended under the Code.

#### **Reference to sophisticated, relevant comparative parameters in the course of the issue of stock options**

The German Corporate Governance Code recommends in point 4.2.3 that sophisticated, relevant comparative parameters be referenced for the issue of stock options as part of the remuneration of Executive Board members. This reference recommended by the German Corporate Governance Code is not included in MediGene AG's stock option plans. MediGene AG's 2006 and 2007 stock options plans (agreed upon by the Shareholders' Meetings on June 2, 2006 and May 25, 2007, respectively) stipulate that upon exercising the option, an exercise price must be paid for the purchase of a share. This exercise price equals the unweighted average of the closing prices of the company's shares of the last thirty trading days prior to the relevant option's allotment date. As a prerequisite for exercising an option, the unweighted average of the closing prices of the company's

shares of the last thirty trading days prior to the first day of the respective period in which the option is exercised must equal at least 120% of the exercise price. The stock option plan does not include any comparative parameters beyond this, e.g. a reference to the performance of share indices. The Executive and Supervisory Boards believe that the stock option plan defines sufficiently sophisticated performance hurdles, since both the company itself and its shareholders benefit from an absolute increase in the company's value.

#### **Possibility of limitation (cap) in the case of variable long-term remuneration components**

The German Corporate Governance Code recommends in point 4.2.3 that a limitation (cap) is agreed upon by the Supervisory Board for extraordinary, unforeseen developments in the long-term variable remuneration components of Executive Board members.

MediGene AG's stock option plans do not provide for either a limitation option or a cap. The Supervisory Board believes that it continues to be to the benefit of MediGene AG to fully exploit the legal framework in formulating contracts for Executive Board members, notwithstanding the guidelines of the Code, in order to be able to staff the Executive Board optimally at all times.

#### **Age limits for Executive and Supervisory Board members**

The German Corporate Governance Code recommends in points 5.1.2 (2) and 5.4.1 that age limits be set for Executive Board and Supervisory Board members. There is no age limit for the Executive and Supervisory Board members of MediGene AG. There is no intention to introduce such age limits in future.

Both MediGene AG's Executive and Supervisory Boards consider such age limits to be an inappropriate restriction of the shareholders' right to elect the Supervisory Board members, on the one hand, and, on the other hand, a restriction of the Supervisory Board in the selection of qualified Executive Board members. The age structure in the Supervisory and Executive Boards is well-balanced without any such prescribed age limit.

#### **Formation of a nomination committee**

In point 5.3.3, the German Corporate Governance Code recommends that the Supervisory Board constitute a nomination committee composed exclusively of shareholder representatives. Such a nomination committee has not hitherto been constituted by MediGene AG's Supervisory Board and is not contemplated for the future.

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

#### **Consideration of committee work in the remuneration of Supervisory Board members**

The German Corporate Governance Code recommends in point 5.4.6 (1) that membership in Supervisory Board committees be taken into consideration in the compensation of Supervisory Board members. Membership in Supervisory Board committees is not taken into account in compensating MediGene AG Supervisory Board members nor is this planned for the future. Both the Executive and Supervisory Boards believe that the Supervisory Board members show a high degree of commitment in their committee work without any such arrangement.

#### **Performance-related remuneration of the Supervisory Board members**

The German Corporate Governance Code recommends in point 5.4.6 (2) that the members of the Supervisory Board receive performance-related remuneration in addition to fixed compensation. MediGene AG's Supervisory Board members have hitherto not received performance-related compensation nor is this planned for the future.

The Executive and Supervisory Boards believe that the Supervisory Board's activities are effective and geared toward the greatest possible corporate success regardless of the lack of such performance-related remuneration.

All other recommendations and proposals of the German Corporate Governance Code have been implemented in their entirety. MediGene AG has appointed a Corporate Governance Representative within the company to report amendments to and implementation of the German Corporate Governance Code to the Executive and Supervisory Boards at least once a year. This allows MediGene AG to ensure that these principles are continuously observed within the company. MediGene AG has created the conditions for fair and efficient corporate management through analysis, supervision, and transparency. This shall remain MediGene AG's standard in the future.

# Glossary

## A

### AAVLP

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

### Absorption

Route of a substance into a biological system

### Actinic keratosis

Precursor of malignant spinocellular carcinoma

### AktG

»Aktiengesetz«  
German Stock Corporation Act

### Authorized capital

Value or number of shares authorized in advance by the company's Shareholders' 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

## B

### Biopharmaceutical

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

### Biotechnological

Utilization of natural and modified biological systems and their elements

## C

### Catechins

Natural substances contained in green tea

### CD28 protein, CD80 protein

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

### CD80 antagonist

Prevents the interaction of the surface protein CD80 with specific receptors

### CGU

Cash-generating unit

### Conditional capital

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

### Controlled trial

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

### Cytostatic drugs

Synthetic or natural substances inhibiting cell growth or cell division

## D

### D&O insurance

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

### DBO

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

### Depot formulation

Drug in the form of an implant which slowly disintegrates and releases the active substance over a set period of time

### Dermatology

Branch of medicine that deals with the treatment of skin diseases as well as benign and malignant skin tumors

### Drug candidate

Drug which is still at the development stage

## E

### EBITDA

Earnings before interest, taxes, depreciation, and amortization  
MediGene uses the term EBITDA to describe the operating profit/loss before the deduction of interest, taxes, foreign currency exchange gains and losses, depreciation of property, plant, and equipment, and amortization of intangible assets

### Endothelial cells

Line the interior surface of lymphatic and blood vessels

### Estrogen

Female sex hormone  
*See also »triple receptor-negative breast cancer«*

### Ex vivo

Latin: »out of the living«  
Process in which living biological material is removed from a living organism and cultivated outside the organism for a limited time span

**F****FDA**

Food and Drug Administration  
Government agency of the United States Department of Health and Human Services

**Freeze-drying**

Freeze-drying is a process of gently drying high-value products. The product solution is frozen as rapidly as possible. Afterwards, the solvent (water in most cases) is removed by applying a vacuum. During this process, the ice crystals sublime directly, avoiding the liquid state. This method allows very gentle drying of temperature-sensitive products.

**G****Galenics**

Dosage form of a drug

**Gestagen**

Female sex hormone

See also »triple receptor-negative breast 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

**H****HER2 receptor**

Human Epidermal Growth Factor Receptor 2, a protein found on the surface of many human organs

See also »triple receptor-negative breast cancer«

**HGB**

»Handelsgesetzbuch«  
German Commercial Code

**Human papilloma viruses**

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

**I****IAS**

International Accounting Standards  
Part of the International Financial Reporting Standards

**IFRIC**

International Financial Reporting Interpretations Committee

**IFRS**

International Financial Reporting Standards

**IND**

Investigational New Drug Application  
Application for the execution of a clinical trial submitted to the US regulatory authority, the FDA

**Indication**

Reason for the execution of a medical examination or treatment

**In vitro**

Latin: »in a glass«

Processes/tests that take place outside a living organism

**L****Licensing**

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

**Liposomes**

Minute, hollow globules, composed of fat molecules

**M****M&A**

Mergers and Acquisitions  
A general term for company transactions during which companies either combine or change their owner

**MHRA**

Medicines and Healthcare Products Regulatory Agency, Great Britain

**O****oHSV**

»Oncolytic herpes simplex viruses«

Genetically modified herpes simplex viruses which attack and destroy cancer cells, but are unable to replicate in healthy cells

**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. The designation allows benefits in development, approval procedures, and possibly even the commercialization of the product.

**P****Pancreatic cancer**

Malignant tumor of the pancreas

**PCT**

Patent Cooperation Treaty

International agreement under which a patent application may be filed for currently 142 countries worldwide. For the issue of a patent, this application has to be transferred to a national application at a later date.

**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

**Placebo**

Compound without active pharmaceutical ingredient, thus pharmacologically ineffective

**Platelet activation**

Triggering of platelet aggregation

**Platelet aggregation**

Clumping together of platelets

**Preclinical**

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

**Progression-free survival**

Length of time for which tumor growth has been stopped

**Proof of concept**

Evidence of the fundamental feasibility of a plan

**Prostate cancer**

Malignant tumor of the prostate gland (part of the male sexual organs)

**R****Randomized trial**

Patients are randomly allocated to the groups receiving either the active ingredient or a placebo

**Receptor**

Protein molecule which causes binding of different particles that are transported into a cell

**Resistance**

Ability of an organism to withstand outer influences

**Rheumatoid arthritis**

Inflammatory disease affecting the joints

**S****SEDA**

Standby Equity Distribution Agreement

Method of financing where a company's partner agrees to subscribe to tranches of new shares against capital contribution

**Spray drying**

An especially gentle method of drying sensitive products by atomizing the solution or suspension under pressure into small droplets and drying it with a hot gas

**T****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 that is the basis for the development of different drug candidates

**Thrombosis**

Disease in which a blood clot develops inside blood vessels, mainly in veins

**Triple receptor-negative breast cancer**

Malignant breast tumors that display neither estrogen/gestagen nor HER2 receptors on the cell surface are termed »triple receptor-negative«

# 5-year overview

of MediGene AG

In € thousand	Change 2009/2008	2009	2008	2007	2006	2005
<b>Income statement</b>						
Product sales	13%	37,859	33,507	22,058	30,549	19,555
Other operating income	-74%	1,607	6,099	1,819	675	127
Total revenue	0%	39,466	39,606	23,877	31,224	19,682
Cost of sales	17%	-31,482	-26,926	-18,493	-10,669	-9,077
Gross profit	-37%	7,984	12,680	5,384	20,555	10,605
Selling, general, and administrative expenses	-13%	-9,124	-10,484	-9,026	-7,639	-6,123
Research and development expenses	-33%	-18,499	-27,465	-28,025	-21,275	-15,997
EBITDA	-23%	-18,808	-24,584	-30,308	¹)	¹)
Loss resulting from spin-off	–%	0	-6,431	0	0	0
Operating result	-38%	-19,639	-31,700	-31,667	-8,359	-11,515
Result before income tax	-34%	-21,935	-33,146	-31,345	-7,606	-12,044
Net loss for the year	-29%	-21,962	-30,790	-29,876	-6,891	-12,045
Net loss per share in €	-30%	-0.64	-0.91	0.95	-0.31	-0.65
Weighted average number of shares	1%	34,231,294	34,008,289	31,541,103	22,410,901	18,560,027
Personnel expenses	-19%	-13,043	-16,059	-14,783	-11,801	-9,931
<b>Cash flow</b>						
Cash flow from operating activities	-31%	-18,925	-27,361	-34,037	-2,553	-10,437
Cash flow from investing activities	-95%	226	4,349	-1,296	1,996	-413
Cash flow from financing activities	>200%	5,735	1,734	29,076	15,311	61
<b>Balance sheet data</b>						
Cash and cash equivalents	-51%	12,251	25,101	46,511	52,498	37,625
Balance sheet total	-19%	65,723	80,746	114,929	124,136	57,062
Current liabilities	-12%	13,606	15,456	9,736	14,358	4,973
Non-current liabilities	-36%	244	384	2,100	1,266	312
Shareholders' equity	-20%	51,873	64,906	103,093	108,512	51,777
Equity ratio	-1%	79%	80%	90%	87%	91%
<b>Employees as at Dec. 31</b>	-14%	114	133	172	171	114
<b>MediGene share</b>						
Total number of shares outstanding as at Dec. 31	4%	35,557,493	34,028,561	33,946,481	28,653,630	18,766,172
Share price (closing price, Xetra)	-17%	3.58	4.30	5.35	6.97	8.36
Dividend in €	–%	0	0	0	0	0

¹) not determined



# Financial calendar

## **March 26, 2010**

2009 Annual Report  
Financial press conference and Analysts' teleconference

## **May 07, 2010**

3-month report, Analysts' teleconference

## **May 11, 2010**

Shareholders' Meeting

## **August 06, 2010**

6-month report, Analysts' teleconference

## **November 12, 2010**

9-month report, Analysts' teleconference

# Trademarks

## **Eligard®**

is a trademark of Tolmar Therapeutics, Inc.

## **EndoTAG™**

is a trademark of MediGene AG.

## **MediGene®**

is a trademark of MediGene AG.

## **Oracea®**

is a trademark of CollaGenex  
Pharmaceuticals, Inc.

## **Polyphenon E®**

is a trademark of Mitsui Norin Co., Ltd.

## **RhuDex®**

is a trademark of MediGene Ltd.

## **Veregen®**

is a trademark of MediGene AG.

These trademarks may be held or  
licensed for specific countries.

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## **Concept and text**

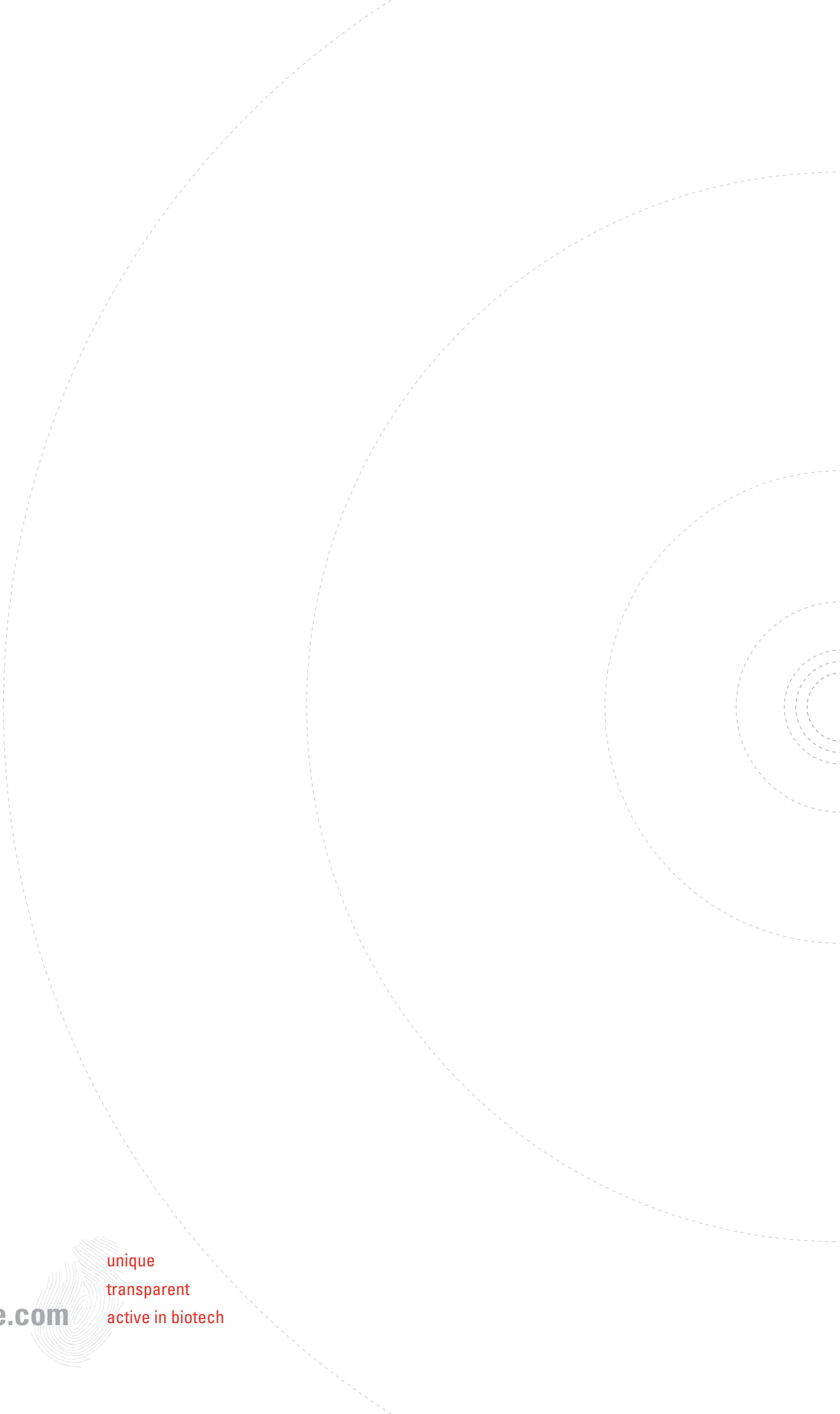
**MediGene AG, Planegg/Martinsried,  
Germany**

## **Concept and design**

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Germany**

## **Production**

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