

## 3-MONTHS REPORT 2009

**We develop innovative therapies.**

MediGene's vision is to expand the potentials of medicine by utilizing biotechnology with a sense of responsibility. We use modern technologies for the development and, finally, their commercialization. MediGene – a leading German biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization.

MediGene's vision is to expand the potentials of medicine by utilizing biotechnology with a sense of responsibility. We use modern technologies to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization.

MediGene's vision is to expand the potentials of medicine by utilizing biotechnology with a sense of responsibility. We use modern technologies to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization.

MediGene's vision is to expand the potentials of medicine by utilizing biotechnology with a sense of responsibility. We use modern technologies to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization. MediGene is the first German biotech company to develop innovative drugs. It is MediGene's strategy to integrate all core domains of an up-to-date biopharmaceuticals company – from research to drug development and, finally, their commercialization.

## MediGene's innovative drug pipeline

Product	Indication	Clinical phase			Approval	Marketed
		I	II	III		
Eligard <sup>® 2)</sup>	Prostate cancer	■	■	■	■	■
Veregen <sup>®</sup> / (Polyphenon E <sup>®</sup> Ointment)	Genital warts	■	■	■	■	■ USA
	Actinic keratosis <sup>5)</sup>	■	■		■ EU	
EndoTAG <sup>™</sup> -1	Pancreatic cancer	■	■			
	Breast cancer	■	■			
	Other solid tumors	■				
RhuDex <sup>™</sup>	Rheumatoid arthritis	■	■			
oHSV	Glioblastoma	■	■			
Chance of reaching the market <sup>6)</sup> :		10 - 30 %	30 - 60 %	60 - 80 %	80 - 90 %	

<sup>1)</sup> Annually; maximum annual sales potential. MediGene will receive royalties on sales of products jointly developed or marketed with other biotech or pharmaceuticals companies.

<sup>2)</sup> Licensed from QLT USA, Inc.

<sup>3)</sup> Marketing partnership with Astellas Pharma Europe Ltd.

<sup>4)</sup> Marketing partnership with Nycomed US, Inc.

<sup>5)</sup> Precursor of a specific type of skin cancer.

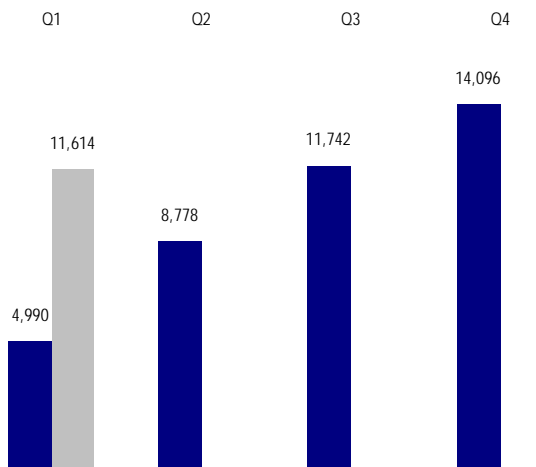
<sup>6)</sup> Industrial average, source: Ernst & Young, 2009.

## MediGene's key figures 3-months report 2009

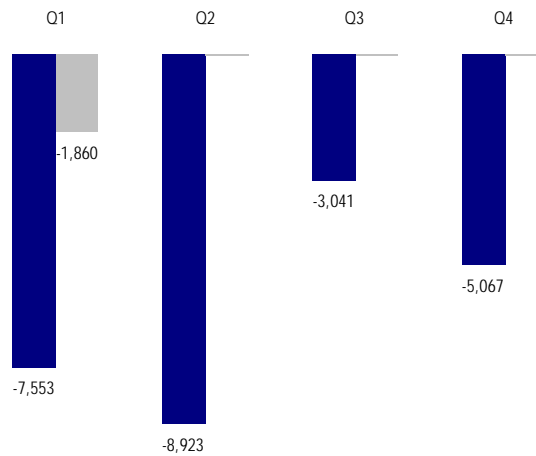
In T€	Q1-2009	Q1-2008	Change
<b>Income statements</b>			
Product sales	10,366	4,447	133%
Other operating income	1,248	543	130%
Total revenue	11,614	4,990	133%
Cost of sales	-7,618	-3,397	124%
Gross profit	3,996	1,593	151%
Selling, general and administrative expenses	-2,036	-2,608	-22%
Research and development expenses	-4,028	-6,866	-41%
EBITDA	-1,860	-7,553	-75%
Operating result	-2,068	-7,881	-74%
Result before income tax	-1,933	-9,461	-80%
Net loss	-1,933	-8,796	-78%
Net loss per share in €	-0.06	-0.26	-78%
Weighted average number of shares outstanding	34,028,561	33,967,496	0%
Personnel expenses	-3,082	-3,832	-20%
<b>Cash flow</b>			
Cash flow from operating activities	-8,375	-9,562	-12%
Cash flow from investing activities	-120	-137	-12%
Cash flow from financing activities	34	602	-94%
<b>Balance sheet data as at March 31, 2009</b>			
Cash and cash equivalents	16,647	37,615	-56%
Balance sheet total	72,813	104,404	-30%
Current liabilities	8,014	11,542	-31%
Non-current liabilities	347	1,403	-75%
Shareholders' equity	64,452	91,459	-30%
Equity ratio in %	89	88	1%
<b>Employees as at March 31, 2009</b>			
	126	172	-27%
<b>MediGene share as at March 31, 2009</b>			
Total number of shares outstanding	34,028,561	30,988,511	10%
Share price (Closing price, XETRA)	3.72	4.41	-16%
Dividend in €	0	0	-

## MediGene's performance 2008 / 2009

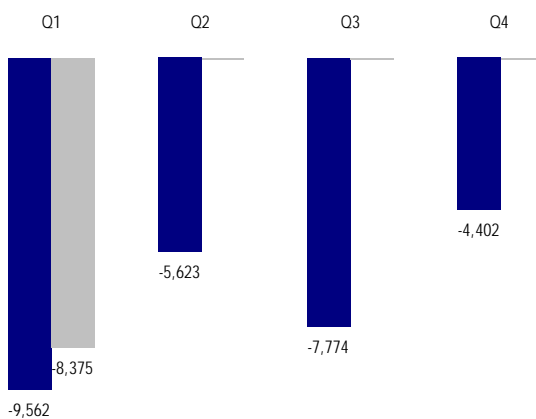
### Total revenue in T€



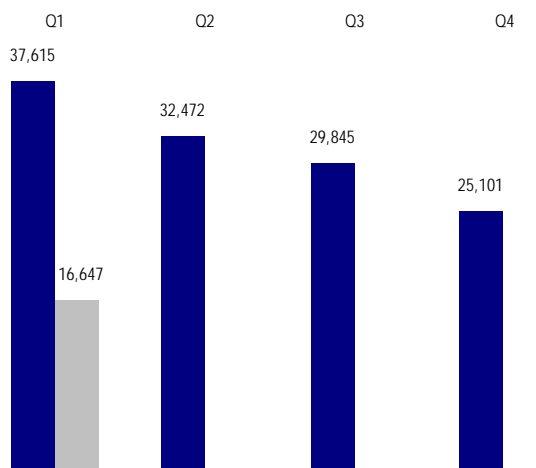
### EBITDA in T€



### Cash flow from operating activities in T€



### Cash and cash equivalents in T€



■ 2008    ■ 2009

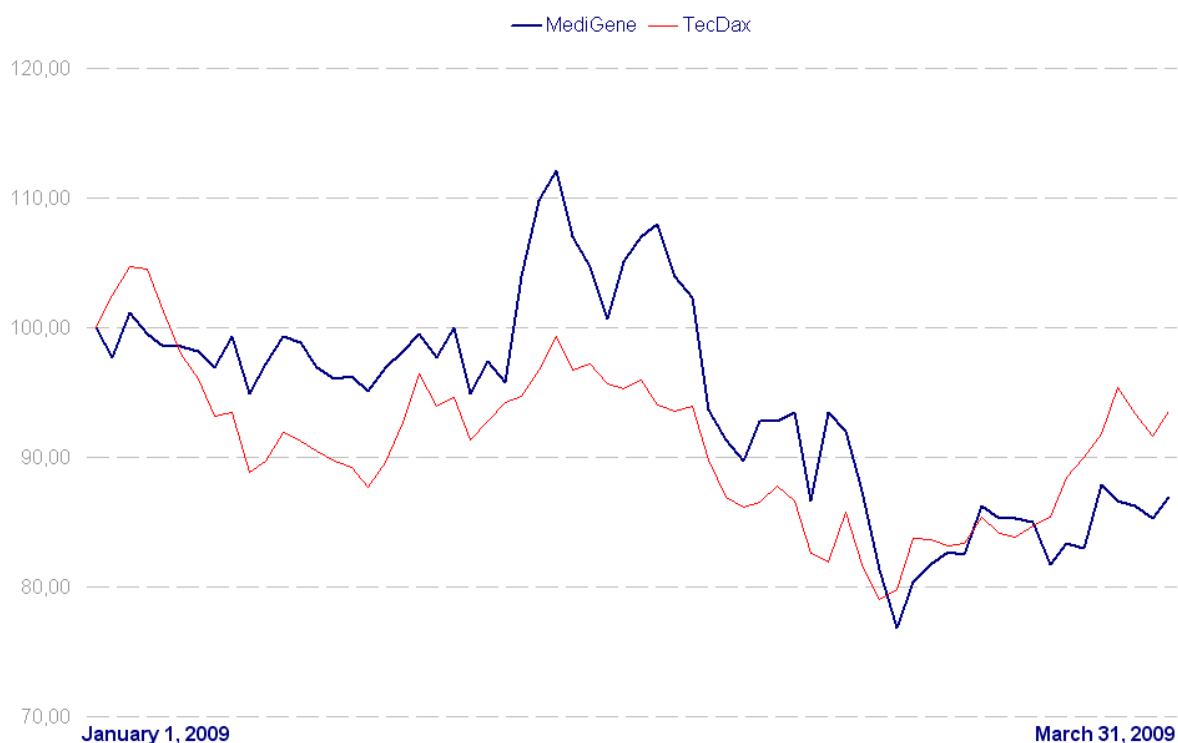
## Contents

Key figures **1** Performance **2** Our share **3** Interim MD&A Q1-2009 **4** Interim financial statements Q1-2009 **12** Notes to the interim consolidated financial statements **16** Financial calendar / imprint **22**

## Our share

### The MediGene share price

(January 2, 2009 4.28 € indexed to 100)



### Key figures for the MediGene share

In €	3M-2009	3M-2008
3-Months high	4.80	5.43
3-Months low	3.29	4.07
Price at beginning of the year	4.28	5.43
Closing price	3.72	4.41
Average price since beginning of the year	4.03	4.48
Weighted average number of shares outstanding	34,028,561	33,967,496
Average market capitalization (million €)	137	152
Average daily trading volume in shares	76,747	67,350
Total number of shares outstanding (March 31, 2008)	34,028,561	33,988,511
Cash flow from operating activities/share*	-0.25	-0.28
Shareholders' equity/share*	1.89	2.69
Free float** (%)	81	75

\* Reference: Total number of shares outstanding \*\* Source: MediGene and Deutsche Börse, March 31, 2009

## Group management's discussion and analysis Q1-2009

### FINANCIAL DEVELOPMENT IN THE FIRST QUARTER 2009

- o Total revenue increased by 133% to 11.6 million € (Q1-2008: 5.0 million €)
- o Improvement of EBITDA by 75% to -1.9 million € (Q1-2008: -7.6 million €)
- o Significant reduction of R&D expenses and selling, general and administrative expenses
- o Cash and cash equivalents at closing date March 31, 2009: 16.6 million €  
(December 31, 2008: 25.1 million €)

### MAJOR EVENTS SINCE THE BEGINNING OF THE YEAR

- o Start of sales promotion and active marketing of Veregen® in the USA through MediGene's partner Nycomed
- o MediGene share listed on the TecDAX index
- o Dr Frank Mathias appointed as new Chief Executive Officer of MediGene AG

## PRELIMINARY NOTES

### MediGene develops drugs to combat cancer and autoimmune diseases

MediGene AG, Planegg/Martinsried, Germany (hereinafter referred to as „MediGene“) is a biopharmaceutical company which focuses on the research, development, and commercialization of innovative drugs, concentrating on indications of great medical necessity and, therefore, substantial commercial interest. Its research and development activities center upon cancer and autoimmune diseases.

### Development state of product portfolio

MediGene has two products already on the market. These two drugs are distributed by partners. In addition, MediGene has a broad research and development portfolio in the fields of oncology and immunology, with several projects at the preclinical and clinical, as well as research stages.

### Eligard®

Meanwhile the one-month, three-month, and six-month dosages of MediGene's drug Eligard® for the treatment of hormone-dependent prostate cancer is successfully marketed by MediGene's partner Astellas Pharma Europe Ltd. (hereinafter referred to as „Astellas Pharma“), Staines, United Kingdom, in most European countries. Just as in every quarter since market launch, the revenue generated with Eligard® significantly increased in the first quarter of 2009 compared to the preceding quarter.

### Veregen®

The ointment developed under the name Polyphenon E® was approved in the USA under the name Veregen® for the treatment of genital warts, and has been promoted and distributed on the US market by MediGene's partner Nycomed US, Inc. (hereinafter referred to as „Nycomed“), Melville, New York, USA, since mid-February 2009. The assessment process for the market approval application submitted to the regulatory authorities in Germany, Austria, and Spain in 2007 shall be concluded within a short time. Approval in these countries shall serve as a reference for approval procedures in other European countries.

### Drugs on the basis of EndoTAG™

In March and in October 2008, MediGene published positive results obtained in a controlled clinical phase II trial of the drug candidate EndoTAG™-1 in the indication pancreatic carcinoma. Apart from safety and tolerability, the trial also investigated the clinical efficacy of different dosages of EndoTAG™-1 in combination with the standard drug gemcitabine, a cytostatic drug already approved for the treatment of pancreatic carcinoma. The trial with 200 patients participating showed substantially extended survival time of those patients treated with EndoTAG™-1 in combination with gemcitabine, compared to those receiving only gemcitabine. The survival time of the patients treated improved significantly coinciding with increased dosage, and particularly with repeated treatment of EndoTAG™-1. In addition, positive results were reported regarding other clinical parameters such as progression-free survival and safety.

In mid-April 2007, MediGene initiated a phase II trial of the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. The objective of the trial is to investigate the efficacy of EndoTAG™-1 in the treatment of this highly aggressive type of cancer for which there is currently no established therapy available, and to collect additional safety data. 135 patients are to be enrolled in this trial which will be conducted by more than 20 centers in several European countries and in India. Patient recruitment is to be concluded in 2009, and the final evaluation of this trial is expected for 2010.

The drug candidate EndoTAG™-1 selectively attacks tumor-supplying blood vessels. EndoTAG™-1 is a positively charged lipid complex which selectively accumulates around the negatively charged cells lining the newly formed tumor blood vessels. There the active ingredient in EndoTAG™-1, the cytostatic drug paclitaxel, is discharged in order to destroy these blood vessels, thus cutting off the nutrient supply for the tumor tissue.

### RhuDex™

RhuDex™, an active ingredient for the treatment of rheumatoid arthritis, is an orally administered CD80 inhibitor which blocks the activation of CD4<sup>+</sup> T cells. RhuDex™ works as an immunosuppressant, and has an anti-inflammatory effect. An ongoing phase I clinical trial with a new formulation of the drug candidate RhuDex™ was put on hold in July 2008. A healthy volunteer participating in the trial suffered a heart attack a few days after receiving the drug. A few days after having received hospital treatment, he collapsed at home. The autopsy revealed that the volunteer had died of acute myocardial re-infarction as a

consequence of coronary thrombosis. These findings clearly prove the pre-existing of a cardiac damage in this patient that had developed over many years. From MediGene's point of view, this supports the assessment that a causal correlation between the volunteer's death and the intake of the trial medication RhuDex™ is unlikely. In cooperation with the British drug regulatory authority MHRA (Medicines and Healthcare Products Regulatory Agency), MediGene is currently conducting a series of in-vitro studies to examine any potential detrimental interaction between RhuDex™ and arteriosclerotic blood vessels.

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

MediGene has recently investigated the cancer-killing virus NV1020 in a phase I/II trial in the indication liver metastases in patients suffering from colorectal cancer. After presentation of the results obtained in an interim analysis of this trial at the most important European (ESMO) and US (ASCO) congresses in oncology, an abstract of the final results was presented at the ASCO GI meeting at the beginning of 2009.

### **Preclinical development projects**

The preclinical L1 project for the development of a therapeutic monoclonal antibody against ovarian cancer was discontinued, since the existing candidates did not show a sufficient efficacy.

### **Technology platforms**

Additionally, MediGene is pushing the development of its proprietary platform technologies for drug development, such as the EndoTAG™ technology which forms the basis for the development of other drug candidates besides EndoTAG™-1. Another platform technology is based on AAV-like particles which MediGene hopes to use for the development of prophylactic and therapeutic vaccines. Both projects are currently funded by public research grants.

## ASSETS POSITION

Cash position 16.6 million €; equity ratio 89%; liquidity cover ratio 23%

Development of the assets and capital structure			
In T€	March 31, 2009 unaudited	Dec. 31, 2008 audited	Change
<b>Assets</b>			
Fixed and intangible assets	30,760	29,662	4%
Goodwill	11,185	11,090	1%
Financial assets	455	545	-17%
Investment in an associate	3,141	3,269	-4%
Cash and cash equivalents	16,647	25,101	-34%
Inventories and trade accounts receivable	3,820	5,302	-28%
Other current assets	6,805	5,777	18%
<b>Total</b>	<b>72,813</b>	<b>80,746</b>	<b>-10%</b>
<b>Liabilities and shareholders' equity</b>			
Shareholders' equity	64,452	64,906	-1%
Non-current liabilities	347	384	-10%
Current liabilities	8,014	15,456	-48%
<b>Total</b>	<b>72,813</b>	<b>80,746</b>	<b>-10%</b>
<b>Liquidity cover ratio in %</b>	<b>23</b>	<b>31</b>	
<b>Equity ratio in %</b>	<b>89</b>	<b>80</b>	

## FINANCIAL POSITION

### Cash flow from operating activities

Cash used by operating activities decreased by 12% to -8,375 T€ in the first quarter of 2009 (Q1-2008: -9,562 T€). The difference between the net loss for the period and the cash used in the first quarter of 2009 is mainly a consequence of the changes in the net working capital.

### Average monthly net cash burn rate from operating activities

The average monthly net cash burn rate from operating activities in the first quarter of 2009 was 2.8 million € (Q1-2008: 3.2 million €). A large portion of this cash burn rate results from the payment of liabilities originating from the previous year, and from a milestone payment made to QLT USA Inc., Vancouver, Canada. When this item is deducted, the monthly cash burn rate in the first three months of 2009 totals 1.1 million €.

### Cash flow from investing activities

During the first quarter of 2009, cash used by investing activities amounted to -120 T€ (Q1-2008: -137 T€).

Development of cash and cash equivalents			
In T€	Q1-2009 unaudited	Q1-2008 unaudited	Change
Net cash			
used by operating activities	-8,375	-9,562	-12%
used by investing activities	-120	-137	-12%
from financing activities	34	602	-94%
<b>Decrease in cash and cash equivalents</b>	<b>-8,461</b>	<b>-9,097</b>	<b>-7%</b>
Cash and cash equivalents at beginning of period	25,101	46,511	-46%
Foreign currency translation	7	201	-97%
<b>Cash and cash equivalents at end of period</b>	<b>16,647</b>	<b>37,615</b>	<b>-56%</b>

As at closing date March 31, 2009, cash and cash equivalents totalled 16,647 T€.



## EARNINGS POSITION

### Total revenue

Total revenue increased to 11,614 T€ in the first quarter of 2009, (Q1-2008: 4,990 T€). It was generated mainly from the commercialization of the drug Eligard® in Europe. Revenue in the reporting period also includes income from royalties on sales of Veregen® in the USA and research grants. In addition, MediGene received a payment of more than one million € from the company TNO, Delft, Netherlands, resulting from a dispute about the quality of preclinical studies within the YourDex™ development program.

#### Consolidated income statement (abbreviated)

In T€	Q1-2009 unaudited	Q1-2008 unaudited	Change
<b>Total revenue</b>	11,614	4,990	133%
Cost of sales	-7,618	-3,397	124%
<b>Gross profit</b>	<b>3,996</b>	<b>1,593</b>	<b>151%</b>
Selling, general and administrative expenses	-2,036	-2,608	-22%
Research and development expenses	-4,028	-6,866	-41%
<b>Operating result</b>	<b>-2,068</b>	<b>-7,881</b>	<b>-74%</b>
<b>Result before income tax</b>	<b>-1,933</b>	<b>-9,461</b>	<b>-80%</b>
<b>Net loss for the period</b>	<b>-1,933</b>	<b>-8,796</b>	<b>-78%</b>

### Cost of sales

Cost of sales arose primarily within the scope of the commercialization of the drug Eligard®, and to a small extent in connection with Veregen®. The cost amounted to 7,618 T€ in the first quarter of 2009 (Q1-2008: 3,397 T€), and is allocated mainly to the purchase of the products and to royalties paid on the sales revenue.

### Gross profit

In the first quarter 2009, gross profit increased to 3,996 T€ (Q1-2008: 1,593 T€). The gross profit amount is determined by milestone payments and the ratio of revenues from product sales to license payments.

### Selling, general and administrative expenses

Compared to last year's reporting period, selling, general and administrative expenses decreased by 22% to 2,036 T€ (Q1-2008: 2,608 T€). This decrease is primarily a consequence of the mTCR technology spin-off.

### Research and development expenses

In the first quarter of 2009, R&D expenses decreased by 41% to 4,028 T€ (Q1-2008: 6,866 T€). The major part of this cost reduction results from the mTCR technology spin-off.

### EBITDA

MediGene uses the term EBITDA as earnings before interest, tax, foreign currency gains/losses, and depreciation of fixed and intangible assets. The loss on EBITDA basis totalled 1,860 T€ in the first quarter of 2009. This represents a 75% reduction compared to last year's reporting period (Q1-2008: 7,553 T€).

### Depreciation

All in all, depreciation decreased by 37% to 208 T€ in the first quarter of 2009 (Q1-2008: 328 T€).

### Financial result

As a result of gains from a derivative financial instrument, the financial result increased to 442 T€ in the reporting period (Q1-2008: -1,580 T€). The contract for the commercialization of Eligard® concluded with Astellas Pharma includes an embedded derivative, since it is processed in US dollars and not in the functional currency of one of the two contracting parties. Foreign currency losses result from the translation of US dollar and British pound into euro.

## Financial result

In T€	Q1-2009 unaudited	Q1-2008 unaudited	Change
Interest income	83	430	-81%
Interest expenses	-5	-1	>200%
<b>Sub-total</b>	<b>78</b>	<b>429</b>	<b>-82%</b>
Gains/Losses from embedded derivatives	856	-1,628	-153%
Foreign currency losses	-492	-381	29%
<b>Total</b>	<b>442</b>	<b>-1,580</b>	<b>-128%</b>

## 3-months result

In the first three months of 2009, the loss for the period decreased by 78% to 1,933 T€ compared to 8,796 T€ in the first quarter 2008. This decrease in loss is primarily due to increased revenue, reduced R&D expenses resulting from the mTCR technology spin-off, and to gains from a derivative financial instrument (see notes D), page 17).

## Result per share

In the first three months 2009, the loss per share decreased to 0.06 € (weighted average number of shares: 34,028,561), compared to 0.26 € loss per share in last year's reporting period (3M-2008: weighted average number of shares: 33,967,496).

## HUMAN RESOURCES

Corporate headcount decreased by 27% to 126 during the first three months of 2009, compared with last year's reporting period. This is a consequence of the mTCR technology spin-off effective from October 1, 2008, and the transfer of the MediGene Ltd. employees into the newly founded company Immunocore Ltd.

	Headcount as at March 31, and Dec. 31			Full-time-equivalent (FTE)		
	Q1-2009	Q1-2008	Y-2008	Q1-2009	Q1-2008	Y-2008
MediGene AG	122	126	128	113	115	117
MediGene, Inc.	4	5	4	4	5	5
MediGene Ltd.	0	41	1	0	40	28
<b>Total</b>	<b>126</b>	<b>172</b>	<b>133</b>	<b>117</b>	<b>160</b>	<b>150</b>

### Personnel expenses

In T€	Q1-2009	Q1 2008	Change
<b>Total</b>	<b>3,082</b>	<b>3,832</b>	<b>-20%</b>

## SEGMENT INFORMATION

Segment information is provided on page 19 f of the appendix.

## RISK REPORT

The inherent risks the MediGene group is subject to are described in the risk report of the published Group Management's Discussion and Analysis (MD&A) 2008. Up to the closing date March 31, 2009, no changes to the state described therein have occurred.

### Legal disputes

Prior to the market launch of Eligard® in 2004, MediGene had filed a suit before the German Federal Patents Court for invalidity of the German portion of a European patent held by its competitors Takeda Chemical Industries, Ltd., Osaka, Japan, and Wako Pure Chemical Industries, Ltd., Osaka, Japan. The patent pertains to more specifically defined high-molecular, biodegradable polymers. After the market launch of Eligard®, Takeda Chemical Industries, Ltd., Takeda Pharma GmbH, Osaka, Japan, and Wako Pure Chemical Industries, Ltd. (Takeda/Wako) sued the partners MediGene and Astellas

Pharma GmbH, Munich, in the summer of 2004 for patent infringement before the Düsseldorf District Court. The lawsuit alleges that the marketing of MediGene's and Astellas Pharma's drug Eligard® infringes the aforementioned patent held by the plaintiffs.

The Third Nullity Board of the German Federal Patents Court decided in verbal negotiations on April 20, 2005 that all claims of the aforementioned patent asserted by Takeda and Wako against MediGene and Astellas Pharma before the Düsseldorf District Court were invalid for the Federal Republic of Germany. Takeda and Wako have appealed this judgment before the Federal Court of Justice. The ruling here is anticipated in 2009. At the same time, the Düsseldorf District Court has suspended the suit for patent infringement until the final legal decision on invalidity is taken. The patent in question expired at the beginning of May 2006.

In the further course of the issue, MediGene filed a claim in April and May 2006 against the issue of European patents EP 1 310 517 B1 and EP 1 330 293 B1 to the companies Wako Pure Chemical Industries, Ltd. and Takeda Pharmaceutical Company Ltd. as well as Takeda Pharmaceutical Company Ltd. Moreover, there was a parallel patent infringement case in the US brought by Takeda Abbott Pharmaceutical Product, Inc., Lake Forest, Illinois, USA, Takeda Chemical Industries, Ltd., and Wako Pure Chemical Industries, Ltd. against MediGene's supplier and licensor QLT USA, Inc. (formerly Atrix Laboratories, Inc.) and the US marketing partner of QLT USA, Inc., Sanofi-Synthelabo, Inc., New York, New York, USA. This lawsuit was settled out of court, according to a press release by QLT USA, Inc. dated February 9, 2007. As the other parties thus far have yet to make any indemnification claims, and the management estimates the likelihood of such a claim at less than 50%, no provision has been formed. Moreover, according to the license agreement signed with QLT USA, Inc., the licensor shall be liable for any indemnification claims.

In July 2008, following the death of a volunteer who participated in a study with the drug candidate RhuDex™, the Procurator Fiscal in Edinburgh, United Kingdom, routinely started investigations which are not yet completed. MediGene expects the investigation to be concluded within the first half of 2009. Additionally, it is possible that the dead volunteer's family will file civil action. Considering the results of the investigation so far, however, the management considers the likelihood of such a claim to be very low.

## **RISK MANAGEMENT SYSTEM**

MediGene's management meets any risks occurring in the group by means of a comprehensive risk management system. For a detailed description of this system we refer to the Group Management's Discussion and Analysis 2008 published on March 31, 2009.

## **MAJOR EVENTS SINCE END OF PERIOD UNDER REVIEW**

### **Dr Frank Mathias new Chief Executive Officer of MediGene**

On April 29, 2009, Dr Peter Heinrich, Chief Executive Officer, resigned from his position as a member of the Executive Board with immediate effect. MediGene's Supervisory Board appointed Dr Mathias as Dr Heinrich's successor.

## **FORECAST**

### **Financial forecast 2009**

For 2009, MediGene expects an increase in revenues and a decrease in loss on EBITDA basis. Based on the current business plan and the scenarios derived from this plan, the management assumes corporate financing to be secured beyond 2010.

### **Continuing increase in Eligard® sales expected**

The six-month depot formulation of Eligard® (Eligard® 45 mg), which was launched in Germany at the beginning of March 2007 and which has been available in 16 other European countries meanwhile, shall be launched by MediGene's partner Astellas Pharma in additional European countries. MediGene anticipates a continuous rise in the Eligard® market share as well as a further increase in sales revenues from Eligard® in Europe.

### **Veregen® (Polyphenon E® Ointment) – increasing sales revenues in the USA**

In February 2009 MediGene's marketing partner Nycomed started active marketing of the drug Veregen® in the USA. Therefore MediGene expects increasing sales revenues from the commercialization of the ointment on the US market.

Following the market approval of Veregen® in Germany, Spain, and Austria which is expected in the next two to three months, MediGene is planning to conclude marketing partnerships for the first European countries.

### **EndoTAG™-1 partnering process ongoing**

In October 2008 MediGene presented the results obtained in a clinical phase II trial of the drug candidate EndoTAG™-1 for the treatment of pancreatic carcinoma. Since April 2007 MediGene has been conducting a phase II trial of the drug candidate EndoTAG™-1 for the treatment of triple receptor-negative breast cancer. Patient recruitment is to be completed in 2009. Final evaluation of the trial is expected in 2010. The negotiations for the conclusion of a global partnership for EndoTAG™-1 have reached an advanced stage.

### **RhuDex™ – in-vitro studies ongoing**

Currently, MediGene is conducting in-vitro tests with RhuDex™, with the goal of ruling out any potential connection between the active ingredient and an increased cardiovascular risk. Upon successful conclusion of these studies and acceptance of the authorities, the clinical development of the drug candidate could be restarted in the second half of 2009.

### **oHSV – spin-off planned**

MediGene is not planning to continue development of oncolytic viruses, and intends to spin off or to sell a license for this technology, similar to the Immunocore model.

## Consolidated income statement

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

In T€	Q1-2009 unaudited	Q1-2008 unaudited
1. Product sales	10,366	4,447
2. Other operating income	1,248	543
<b>3. Total revenue</b>	<b>11,614</b>	<b>4,990</b>
4. Cost of sales	-7,618	-3,397
<b>5. Gross profit</b>	<b>3,996</b>	<b>1,593</b>
6. Selling expenses	-477	-727
7. General and administrative expenses	-1,559	-1,881
8. Research and development expenses	-4,028	-6,866
<b>9. Operating result</b>	<b>-2,068</b>	<b>-7,881</b>
10. Interest income	83	430
11. Interest expenses	-5	-1
12. Foreign exchange losses	-492	-381
13. Gains/Losses from embedded derivatives	856	-1,628
14. Share of loss of an associate	-307	
<b>14. Result before income tax</b>	<b>-1,933</b>	<b>-9,461</b>
15. Taxes	0	665
<b>16. Net loss for the period</b>	<b>-1,933</b>	<b>-8,796</b>
<b>Result per share:</b>		
<b>Actual and fully diluted in €</b>	<b>-0.06</b>	<b>-0.26</b>
Weighted average number of shares outstanding	34,028,561	33,967,496

## Consolidated statement of comprehensive income

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

In T€	Q1-2009 ungeprüft	Q1-2008 ungeprüft
<b>1. Net loss for the period</b>	<b>-1,933</b>	<b>-8,796</b>
2. Exchange differences on translation of foreign operations	1,052	-2,915
3. Net gains/losses on available-for-sale financial assets	415	0
4. Unrealized loss from QLT shares	-87	-178
<b>5. Other comprehensive income for the year, net of tax</b>	<b>1,380</b>	<b>-3,093</b>
<b>6. Total comprehensive income for the period, net of tax</b>	<b>-553</b>	<b>-11,889</b>

## Consolidated balance sheet

of MediGene AG as of March 31, 2009, and December 31, 2008

In T€	March 31, 2009 unaudited	December 31, 2008 audited
<b>Assets</b>		
<b>A. Non-current assets</b>		
I. Property, plant & equipment	1,149	1,151
II. Intangible assets	29,611	28,511
III. Goodwill	11,185	11,090
IV. Financial assets	452	540
V. Investment in an associate	3,141	3,269
VI. Other non-current assets	3	5
<b>Total non-current assets</b>	<b>45,541</b>	<b>44,566</b>
<b>B. Current assets</b>		
I. Inventories	1,186	2,185
II. Trade accounts receivable	2,634	3,117
III. Cash and cash equivalents	16,647	25,101
IV. Other current assets	6,805	5,777
<b>Total current assets</b>	<b>27,272</b>	<b>36,180</b>
<b>Total assets</b>	<b>72,813</b>	<b>80,746</b>
<b>Liabilities and shareholders' equity</b>		
<b>A. Shareholders' equity</b>		
I. Subscribed capital		
Number of shares issued and outstanding:		
December 31, 2008: 34,028,561		
March 31, 2009: 34,028,561	34,029	34,029
II. Additional paid-in capital	336,072	335,973
III. Accumulated deficit	-295,200	-293,267
IV. Other reserves	-10,449	-11,829
<b>Total shareholders' equity</b>	<b>64,452</b>	<b>64,906</b>
<b>B. Non-current liabilities</b>		
I. Financial liabilities	132	169
II. Pension obligations	215	215
<b>Total non-current liabilities</b>	<b>347</b>	<b>384</b>
<b>C. Current liabilities</b>		
I. Trade accounts payable	5,477	10,496
II. Embedded derivatives	309	1,166
III. Other current liabilities	1,773	3,339
IV. Accruals	455	455
<b>Total current liabilities</b>	<b>8,014</b>	<b>15,456</b>
<b>Total liabilities</b>	<b>8,361</b>	<b>15,840</b>
<b>Total liabilities and shareholders' equity</b>	<b>72,813</b>	<b>80,746</b>

## Consolidated cash flow statement

for the periods from January 1 to March 31, 2009, and 2008

In T€	Q1-2009 unaudited	Q1-2008 unaudited
<b>Cash flow from operating activities</b>		
Net loss for the period (before taxes)	-1,933	-9,461
<b>Adjustments to reconcile net loss with cash used in operating activities:</b>		
Stock-based compensation	99	126
Depreciation	208	328
Interest income	-83	-430
Interest expenses	5	1
<b>Changes in:</b>		
Inventories	998	-1,023
Other assets and prepaid expenses	-535	-892
Trade accounts payable	-5,019	829
Accruals	0	-10
Other liabilities and deferred income	-2,422	970
Share of net loss of an associate	307	-
<b>Net cash used by operating activities</b>	<b>-8,375</b>	<b>-9,562</b>
<b>Cash flow from investing activities</b>		
Purchase of property, plant & equipment	-120	-137
<b>Net cash used by investing activities</b>	<b>-120</b>	<b>-137</b>
<b>Cash flow from financing activities</b>		
Proceeds from stock options and convertible bonds	0	129
Repayments of convertible bonds	-37	-15
Interest received	76	489
Interest paid	-5	-1
<b>Net cash from financing activities</b>	<b>34</b>	<b>602</b>
<b>Decrease in cash and cash equivalents</b>	<b>-8,461</b>	<b>-9,097</b>
Cash and cash equivalents at beginning of the period	25,101	46,511
Foreign currency translation	7	201
<b>Cash and cash equivalents at end of the period</b>	<b>16,647</b>	<b>37,615</b>

### Supplementary schedule of non-cash financing activities:

No new leasing obligations for new laboratory and office equipment were incurred during the first three months of 2009, just as in last year's reporting period.

## Consolidated statement of changes in shareholders' equity

for the periods from January 1 to March 31, 2009, and 2008

	Shares	Share capital	Capital reserves	Accumulated losses	Other reserves	Total shareholders' equity
	No.	T€	T€	T€	T€	T€
<b>Balance January 1, 2009, audited</b>	<b>34,028,561</b>	<b>34,029</b>	<b>335,973</b>	<b>-293,267</b>	<b>-11,829</b>	<b>64,906</b>
Net loss for the period				-1,933		-1,933
Net loss on hedge of an investment					415	415
Unrealized loss from QLT shares					-87	-87
Currency translation adjustments					1,052	1,052
<b>Comprehensive income</b>						<b>-553</b>
Exercise of options/bonds						0
Stock-based compensation			99			99
<b>Balance March 31, 2009, unaudited</b>	<b>34,028,561</b>	<b>34,029</b>	<b>336,072</b>	<b>-295,200</b>	<b>-10,449</b>	<b>64,452</b>
<b>Balance January 1, 2008, audited</b>	<b>33,946,481</b>	<b>33,946</b>	<b>334,667</b>	<b>-262,477</b>	<b>-3,043</b>	<b>103,093</b>
Net loss for the period				-8,796		-8,796
Unrealized loss from QLT shares					-178	-178
Currency translation adjustments					-2,915	-2,915
<b>Comprehensive income</b>						<b>-11,889</b>
Exercise of options/bonds	42,030	42	87			129
Stock-based compensation			126			126
<b>Balance March 31, 2008, unaudited</b>	<b>33,988,511</b>	<b>33,988</b>	<b>334,880</b>	<b>-271,273</b>	<b>-6,136</b>	<b>91,459</b>



## Notes to the interim consolidated financial statements

### A) Description of business operations and corporate information

MediGene AG, Planegg/Martinsried (hereinafter referred to as MediGene AG) is a biopharmaceuticals company which focuses on the research, development, and commercialization of innovative drugs, concentrating on indications of great medical necessity and, therefore, substantial commercial interest. The company's research and development activities center upon cancer and autoimmune diseases. The drugs approved thus far are sold through sales partners.

The group's main activities are described in the Notes under H) "Segment Reporting."

MediGene has been a publicly quoted company since June 2000 (German Stock Exchange: Regulated Market; Prime Standard; SIN 502090; code MDG). As of February 9, 2009, MediGene has been listed on the TecDAX, a German Stock Exchange index.

### B) Accounting principles

#### Basic principles for the preparation of interim financial statements

These unaudited interim consolidated financial statements were prepared in compliance with the International Financial Reporting Standards (IAS 34 "Interim Financial Reporting"). It is the Executive Board's conviction that the quarterly financial statements on hand reflect all business transactions required for the portrayal of the assets, financial, and income situation at the end of the periods that expired on March 31, 2008, and 2009.

These quarterly financial statements do not include the full information required to prepare annual financial statements. Therefore these interim reports should be read in connection with the annual financial statements for 2007 and 2008. As a capital market oriented parent company, as defined by article 4 of Regulation (EC) no. 1606/2002, MediGene AG applies the International Financial Reporting Standards in their entirety.

These interim consolidated financial statements were approved for publication by MediGene's Executive Board on May 14, 2009.

#### Changes in accounting and reporting principles

The accounting and reporting principles applied for the interim consolidated financial statements on hand correspond to those applied for the consolidated annual financial statements 2008, with the exception of the application of new or revised accounting standards described in the following.

##### *IFRS 8 ("Operating Segments")*

This standard is to be applied for the first time for financial years starting on or after January 1, 2009, and requires that a group disclose information on its operating segments. It replaces the requirement to set primary (business) and secondary (geographical) segment reporting formats for the group. As a result of the revision of IFRS 8 requirements with regard to 2009, it emerged that the previous primary business segments "Specialty Pharma" and "Biopharma" can be renamed "Marketed Products" and "Drug Candidates." Both segments must be reported in line with IFRS 8.

The group has determined that the operating segments as identified in accordance with IFRS 8 correspond with those previously identified in accordance with IAS 14 "Segment Reporting".

##### *IAS 1R ("Presentation of Financial Statements (Revised)")*

The revised standard was issued in September 2007 and is to be applied for the first time for financial years beginning on or after January 1, 2009. The standard requires separate disclosure 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, whereas all other changes in equity are presented in a single line. In addition, the standard introduces the disclosure of comprehensive income in the entire period in which all components of comprehensive income are shown either in a single itemization or in two itemizations affiliated with one another. MediGene will choose the option to continue to present a "traditional" income statement together with a second statement of comprehensive income (SOCI).

### *IAS 23 R ("Borrowing Costs")*

The revised standard IAS 23 "Borrowing Costs" was issued in March 2007 and is to be applied for the first time for financial years beginning after January 1, 2009. The standard requires capitalization of borrowing costs that can be attributed to a qualifying asset. A qualifying asset is one that takes a substantial period of time to prepare for its intended use or sale. It currently appears that the application of the standard will have no effects on the asset, financial, or income position of the group whatsoever given the absence of qualifying assets.

### *Improvements to IFRS 2008 ("Omnibus edition")*

In May 2008, the IASB issued its first omnibus of amendments to various IFRS standards. They mainly dealt with eliminating inconsistencies and clarifying wordings that could lead to misunderstandings. The standard includes various amendments separated into two parts. Part 1 includes all amendments that have an impact on accounting; part 2 includes terminology or editorial changes that, in the Board's opinion, the user will regard as minor.

Regarding changes relevant to accounting, MediGene refers to the detailed presentation in the Annual Report 2008, page 31 et seq. ("Future changes in accounting and reporting principles").

### **Group companies**

In addition to the parent company, MediGene AG in Planegg/Martinsried, the group (MediGene group) includes two subsidiaries, MediGene, Inc., San Diego, USA, and MediGene Ltd., Abingdon, Oxfordshire, United Kingdom. The subsidiaries were acquired in 2001 (MediGene, Inc., USA) and 2006 (MediGene Ltd., United Kingdom), respectively. Moreover, MediGene holds 39.09% of the shares in the associate Immunocore Ltd., Abingdon, Oxfordshire, United Kingdom, since September 30, 2008.

Apart from that, MediGene held no other shares in affiliated companies, associates, or joint ventures as at March 31, 2009. The financial statements of the companies consolidated have been prepared in accordance with standardized accounting and valuation principles. All intercompany revenues, expenses, and income as well as receivables, payables, and accruals of the companies consolidated were eliminated during consolidation.

### **C) Seasonal dependency of business operations**

MediGene's business operations do not underlie any seasonal fluctuations.

### **D) Notes on the consolidated income statement**

#### **Embedded derivative**

The contract for the commercialization of Eligard® concluded with Astellas Pharma includes an embedded derivative, since it is processed in US dollars and not in the functional currency of one of the two contracting parties. Foreign currency losses (gains) from this derivative result from the translation of US dollar into euro, and are posted affecting net income at the end of the respective reporting period. The valuation of the embedded derivative takes place on the basis of the existing/expected purchase orders from Astellas Pharma.

#### **Associate**

The income statement reflects the group's share (39.09%) 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 corresponding to the share in the associate.

#### **Taxes**

In the first quarter of 2009, the MediGene group did not recognize a tax gain or loss. In last year's reporting period, the MediGene group recognized a tax gain resulting from the release of deferred taxes on the liabilities side affecting net income. The release of deferred taxes affecting net income was effected at the same rate at which the accumulated losses of the subsidiary MediGene Ltd. increased. A tax rate of 30% is applied to this company. In the UK, there is no limitation on the utilization of accumulated losses.

## **E) Notes on the balance sheet**

### **Subscribed capital**

Compared to December 31, 2008, subscribed capital as at March 31, 2009 remained unchanged, i.e. amounted to 34,029 T€.

The subscribed capital is divided into 34,028,561 registered no-par-value common shares, approx. 81% of which were outstanding as at March 31, 2009.

### **Goodwill**

The increase of the reported goodwill compared to December 31, 2008 is due solely to foreign currency translation effects as at closing date. These effects pertain to the carrying amount of goodwill from the acquisition of MediGene Ltd. which is reported in British pounds. This change is posted as "other reserves" in shareholders' equity.

### **Current liabilities**

Compared to December 31, 2008, current liabilities as of March 31, 2009 decreased by 7,442 T€ from 15,456 T€ to 8,014 T€. This decrease is mainly a consequence of a reduction of trade accounts payable and other current liabilities, as well as gains from the derivative financial instrument in the first quarter 2009 (see Notes D), page 17).

## **F) Notes on the cash flow statement**

In the first three months of 2009, cash used by operating activities decreased from 3.2 to 2.8 million € compared to last year's reporting period.

The funds showed in the cash flow statements correspond to the item "cash and cash equivalents" in the balance sheet.

## **G) Earnings per share**

The fully diluted net loss as at reporting date corresponds to the actual loss, as the conversion of common stock equivalents would have an anti-dilutive effect.

## H) Segment reporting

Primary reporting – business units

The group is organized into two primary business units: “Marketed Products” and “Drug Candidates”. The segments are comprised as follows:

### Primary Reporting – Business Units

In T€	Marketed Products	Drug Candidates	Reconciliation <sup>1)</sup>	Total
<b>Q1-2009</b>				
Sales to external customers	10,346	1,246	22	11,614
Intersegment sales <sup>2)</sup>	0	0	0	0
<b>Total revenue</b>	<b>10,346</b>	<b>1,246</b>	<b>22</b>	<b>11,614</b>
<b>Segment result<sup>3)</sup></b>	<b>1,807</b>	<b>-3,897</b>	<b>22</b>	<b>-2,068</b>
Depreciation	-1	-171	-36	-208
Share of loss of an associate	0	0	-307	-307
<b>Assets</b>				
Investment in an associate	0	0	3,141	3,141
Segment investments <sup>4)</sup>	1	61	59	121
<b>Segment assets</b>	<b>4,130</b>	<b>43,936</b>	<b>24,747</b>	<b>72,813</b>
<b>Segment liabilities</b>	<b>310</b>	<b>0</b>	<b>8,051</b>	<b>8,361</b>
<b>Q1-2008</b>				
Sales to external customers	4,447	534	9	4,990
Intersegment sales <sup>2)</sup>	0	0	0	0
<b>Total revenue</b>	<b>4,447</b>	<b>534</b>	<b>9</b>	<b>4,990</b>
<b>Segment result<sup>3)</sup></b>	<b>-12</b>	<b>-7,878</b>	<b>9</b>	<b>-7,881</b>
Depreciation	-60	-177	-91	-328
Share of loss of an associate	0	0	0	0
<b>Assets</b>				
Investment in an associate	0	0	0	0
Segment investments <sup>4)</sup>	0	61	75	136
<b>Segment assets</b>	<b>2,651</b>	<b>56,065</b>	<b>45,688</b>	<b>104,404</b>
<b>Segment liabilities</b>	<b>2,540</b>	<b>94</b>	<b>10,311</b>	<b>12,945</b>

<sup>1)</sup> Reconciliation includes data that cannot be allocated to the segments "Marketed Products" or "Drug Candidates", since they do not represent own activities.

<sup>2)</sup> Intersegment sales are eliminated for consolidation purposes.

<sup>3)</sup> The segment result does not include any interest income (Q1-2009: 83 T€; Q1-2008: 430 T€), interest expenses (Q1-2009: 5 T€; Q1-2008: 1 T€), any foreign exchange losses (Q1-2009: 492 T€; Q1-2008: 381 T€), any gains or losses from embedded derivatives (Q1-2009: 856 T€; Q1-2008: -1,628 T€), or any share of loss of an associate (Q1-2009: 307 T€; Q1-2008: 0 T€).

<sup>4)</sup> Segment investments relate to additions to fixed and intangible assets.

There are no internal service charges of a regular or planned nature between individual market segments or regions. For this reason, there are no details regarding such charges.

The income in the individual segments is generated by external business relationships.

The business units are composed as follows:

#### Marketed products:

- Eligard<sup>®</sup> for the treatment of hormone-dependent, advanced prostate cancer
- Polyphenon E<sup>®</sup> Ointment/Veregen<sup>®</sup> for the treatment of genital warts and actinic keratosis

#### Drug candidates & technologies:

- EndoTAG<sup>™</sup>-1 for the treatment of solid tumors
- RhuDex<sup>™</sup> for the treatment of rheumatoid arthritis
- oHSV for the treatment of various cancer indications
- Preclinical product candidates: YourDex<sup>™</sup>
  
- EndoTAG<sup>™</sup> technology
- oHSV technology

### **J) Other notes**

#### **Contingent liabilities**

There were no accruals for the contingent liabilities listed below, as the risk of their utilization is regarded as improbable.

In the framework of existing license agreements, MediGene has committed to making milestone payments of approximately 9.5 million € to the respective licensor. The management does not believe that any accrual needs to be formed for this, as the corresponding payments will not become due until certain milestones are reached.

The company leases office and laboratory facilities, office furnishings, laboratory equipment, and vehicles. They constitute operating leases given the fact that 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's periods of notice range between one month and ten years for these lease agreements.

## K) Board of Directors and Supervisory Board

### „Directors' Holdings“ and notes on treasury shares and subscription rights

Members	Shares 3M-2009	Shares J-2008	Options 3M-2009	Options J-2008
Prof Dr Ernst-Ludwig Winnacker Supervisory Board Chairman, Co-founder	274,476	274,476	8,600	8,600
Prof Dr Norbert Riedel Supervisory Board Vice Chairman	3,300	3,300	5,590	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>14,190</b>	<b>14,190</b>
Dr Peter Heinrich Chief Executive Officer, Co-founder	505,505	505,505	246,636	246,636
Dr Thomas Klaue Chief Financial Officer	4,500	4,500	38,333	38,333
Dr Frank Mathias Chief Operating Officer	0	0	22,500	22,500
Dr Axel Mescheder Chief Scientific Officer & Chief Development Officer	6,000	6,000	62,836	62,836
<b>Total Executive Board</b>	<b>516,005</b>	<b>516,005</b>	<b>370,305</b>	<b>370,305</b>
<b>Treasury Stock</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

\*) Convertible Bonds

(Status as at March 31, 2009, and December 31, 2008)

## Financial calendar / imprint

**2009**

**July 30**

Annual shareholders' meeting 2009  
Munich

**August 7**

6-Months Report 2009  
Analysts conference call

**November 13**

9-Months Report 2009  
Analysts conference call

### **Publisher**

MediGene AG  
Lochhamer Straße 11  
82152 Planegg/Martinsried  
T +49 (89) 85 65 29 0  
F +49 (89) 85 65 29-20

### **Contact**

#### **Investor Relations**

Dr Georg Doenges  
T +49 (89) 85 65 29-46  
investor@medigene.com

#### **Public Relations**

Julia Hofmann / Dr Nadja Wolf  
T +49 (89) 85 65 33-57  
public.relations@medigene.com

#### **Human Resources**

Angelika Leppert  
T +49 (89) 85 65 33-61  
human.resources@medigene.com

#### **Business Development**

Dr Michael Ruppert  
T +49 (89) 85 65 29-60  
business.development@medigene.com

...we look forward to speaking with you!

