

### Annual report 2005

Revenues Increased by 50% Due to First Drug Second Drug Undergoing Approval Procedure Pipeline of Novel Anti Cancer Drugs



Key figures MediGene AG

### MediGene Group, IFRS

# **Key figures**

In T€	2005	2004	Change
Income statements			
Revenues	19,555	12,501	56%
Other operating income	127	637	-80%
Cost of goods sold	9,077	5,930	53%
Selling, general and administrative expenses	6,123	6,294	-3%
Research and development expenses	15,997	15,627	2%
Operating result (EBIT)	-11,515	-14,713	22%
Result before income tax	-12,044	-12,665	5%
Net result	-12,045	-12,666	5%
Personnel expenses	9,639	8.427	14%
Balance sheet data			
Cash and cash equivalents	37,625	48,460	-22%
Balance sheet total	57,062	72,894	-22%
Current liabilities	4,973	9,302	-47%
Long-term liabilities	312	1,880	-83%
Shareholders' equity	51,777	61,712	-16%
Equity ratio	91%	85%	7%
Cash flow			
Cash flow from operating activities	-10,437	-12,096	-14%
Cash flow from investing activities	-413	4,785	-109%
Cash flow from financing activities	61	34,341	-100%
Employees as at Dec. 31	114	114	0%
MediGene share			
Number of shares issued as at December 31	18,766,172	18,522,684	1%
Weighted average number of shares	18,560,027	13,996,440	33%
Result per share in €	-0.65	-0.90	28%
Share price in € as at December 30 (closing price)	8.36	8.50	-1%
Dividend in €	0	0	-

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Pipeline MediGene AG

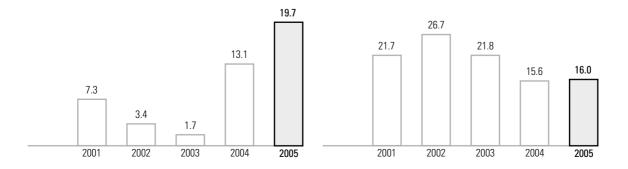
# **Comprehensive product pipeline**

Product	Indication	Clinical Phase			Approval	Marketed	Peak Sales Potential <sup>1)</sup>	
		1	II		Ш			(in million €)
Eligard® 2) see page 12	Prostate Cancer						<b>✓</b>	> 100 <sup>3)</sup>
Polyphenon® E Ointment see page 13	Genital Warts							> 1504)
	Actinic Keratosis <sup>5)</sup>							> 200
EndoTAG-1 see page 14	Pancreatic Cancer							> 200
	Additional solid tumors							> 1,000
HSV (NV1020) see page 15	Colon Liver Metastases							> 300
HSV (G207) see page 15	Glioblastoma							> 200
Chance of reaching	the market	10 – 30%	30 – 60%	60 —	80%	80 – 90%		

<sup>&</sup>lt;sup>1)</sup> Per year, peak sales. MediGene will receive royalties from sales of products, which are jointly developed or marketed with biotech or pharmaceuticals companies.

Total revenues in million €

Research & development expenses in million €



<sup>&</sup>lt;sup>2)</sup> European marketing rights acquired from QLT USA Inc. (formerly Atrix)

<sup>&</sup>lt;sup>3)</sup> Marketing partnership with Astellas Pharma

<sup>&</sup>lt;sup>4)</sup> Marketing partnership with Bradley Pharmaceuticals

<sup>&</sup>lt;sup>5)</sup> Precursors of a specific kind of skin cancer

MediGene AG Annual Survey 2005

# **Annual Survey 2005**

	February	November
	MediGene's preliminary net result for 2004 ahead of forecast.	MediGene AG announces nine-months result and confirms forecast for the year.
see page 12	March	MediGene's drug Eligard® launched in Spain and fur-
see page 16	MediGene to be listed on TecDAX index.  MediGene reduced net loss 2004 by 60%.	ther European countries.  December  US regulatory authority FDA accepts of new drug
	May	application Polyphenon® E Ointment for filing.
see page 2	Again MediGene AG significantly improves quarterly result.	MediGene receives one-time payment for license agreement with Glaxo Group.
	June	January 2006
see page 15 see page 2, 7, 13	Clinical phase I trial of cancer-killing virus G207 for the treatment of malignant glioma started.	MediGene and Bradley Pharmaceuticals enter marketing and development partnership for Polyphenon®
see page 13	MediGene announces phase II trial results of Polyphenon® E for the treatment of actinic keratosis.	E Ointment.  February
	August	MediGene AG announces financial results for 2005 and forecast for 2006.
see page 14	MediGene AG initiates clinical phase II trial with EndoTAG-1 for the treatment of pancreatic cancer.	Eligard® launched in France and other European countries.
	September	
see page 17	MediGene is awarded international prize for annual report 2004.	
see page 2, 13	MediGene AG submits new drug application for its second drug, Polyphenon® E Ointment.	
	October	
see page 3	MediGene honored with European Biotechnica Award.	

ediGene AG Mission 1

MediGene's strategic goal is to integrate all the core areas of the modern drug development business, from research on novel therapeutic concepts to the development and marketing of drugs. In this way we will participate in all steps of the value chain. Major components of this strategy are already in place: MediGene is the first German biotechnology company with a drug on the market. The marketing authorization application for the second drug has been submitted. In addition, MediGene has several drug candidates in various phases of clinical development. MediGene possesses proprietary technologies for drug development that not only feed our own product pipeline, but are also made available for collaborative partnerships. The revenues from drug sales as well as from marketing and development partnerships help us to finance further research and development projects.

2 Letter to the shareholders MediGene AG

# Dear Shanholders, Ladies and Gentlemen,

In 2005 MediGene grew considerably and made significant progress.

### Increase of revenues by 50%

Our revenues increased by 50% to 20 million €. This means that we achieved the very ambitious results that we had forecast. Our success was a consequence of the increasing sales of our first drug, Eligard®, in Germany, and of the launch of Eligard® in nine other European countries. Additional income was generated by a license agreement closed with the Glaxo Group in 2005, giving them the right to exploit a MediGene-developed technology for producing specific vaccines.

# Marketing Authorization Application for second drug

We also made significant progress regarding our second drug, Polyphenon® E Ointment. In September 2005, MediGene submitted the marketing authorization application for it to the US regulatory authority FDA, as scheduled. In November, the FDA accepted our application for further review, the first positive signal within the approval procedure. The marketing authorization application is based on MediGene's successful clinical phase III trials during which more than 1,000 patients in 15 countries were treated with Polyphenon® E Ointment. The trials yielded excellent results with Polyphenon® E Ointment for the treatment of genital warts.

Our first phase II trial of the Polyphenon® E Ointment for the treatment of the skin disease actinic keratosis, however, was a disappointment. This clinical trial on about 60 patients, completed in June 2005, showed unsatisfactory results regarding the ointment's efficacy in this indication. We are currently analyzing the reasons for these results and are scrutinizing the opportunities for a continuation of the development in the indication actinic keratosis under changed conditions.

The trial results in the indication actinic keratosis have no impact on the approval procedure of the Polyphenon® E Ointment for the treatment of genital warts. Consequently we expect a positive result of the approval procedure, and anticipate market launch of the ointment for genital warts in 2007.

### **US-Marketing partnership**

MediGene's new partner Bradley Pharmaceuticals, one of the major US specialty pharmaceuticals companies, will take on the commercialization of Polyphenon® E Ointment in the USA. I am very proud that MediGene was able to close this marketing partnership in January 2006. With more than 100 sales representatives working in the field of dermatology, Bradley has a powerful and competent sales force excellently qualified to tap the full economic potential of our Polyphenon® E Ointment on the US market. In addition to Eligard®, which has been available since 2004, MediGene now has a second drug whose market launch is within reach!

### **Progress in clinical projects**

In 2005 we also took some important steps with regard to our early-stage, innovative drug development projects. MediGene initiated a clinical phase II trial of the drug candidate EndoTAG-1 for the treatment of pancreatic cancer. The trial investigates tolerability, dosage and efficacy trends of the drug candidate in about 200 patients. It is assumed that due to its specific mode of action, EndoTAG could be applied in the treatment of numerous types of cancer, and we are already working on the design of further clinical trial programs.

In addition, MediGene also pushed the development of cancer-killing viruses, so-called oncolytic viruses, in 2005. The clinical phase II trial of the drug candidate NV1020, initiated in 2004, was continued, and a second phase I trial of another oncolytic virus, G207, was also begun. Oncolytic viruses represent one of the most innovative approaches in the development of novel cancer therapies. If MediGene experiences long-term success in this area, it will be a tremendous achievement. However, the road there is very long and several obstacles need to be overcome.

### Well-balanced drug pipeline

This is one of the reasons why MediGene pursues the strategy of keeping its drug pipeline well-balanced, comprising both drugs close to market and early-stage, highly innovative drug candidates. In 2005 we successfully maintained and stabilized this balance by making progress in each of our drug development projects.

Clinical development comprises three phases

All the drug candidates under development, product portfolio

MediGene AG Letter to the shareholders 3

These achievements were honored with the European Biotechnica Award, which is regarded as the most important award in the European biotech industry.

### Share price slightly decreased

The MediGene share price reflected the successful development of the company in the first six months of the year, with an increase by approximately 30% until midyear, thereby surpassing the comparative index TecDAX by 25%. After announcing the results of the trial of Polyphenon® E Ointment in the indication actinic keratosis in June 2005, however, we had to note a significant price drop. In December, a clear upward trend began. The year-end closing price of the MediGene share was 4% below the preceding year's closing price. This is not satisfactory. MediGene will do its utmost to lay the foundations for a significant rise in the share price in 2006. The substantial upward trend at the beginning of 2006 marks a promising start.

Earnings before interests and taxes (EBIT)

### Financial result improved by 20%

In 2005, MediGene improved its operating result by more than 20% to 11.5 million €. Adding a write-off on QLT shares the annual loss is 12 million €.

### Financial goals for 2006

For the financial year 2006 we are planning to increase revenues by an additional 50%, and to reach breakeven on the operational level. To achieve this result, however, we need to achieve several objectives which not only depends on MediGene alone. One of these objectives is a significant increase in revenues from the sales of Eligard®, as well as marketing authorization of the Polyphenon® E Ointment before the end of 2006. Sales revenues for Eligard® need to be boosted by our marketing partner Astellas Pharma, and should increase as a result of conquering an additional market share, and of the market launch in 14 other countries. The US regulatory authority FDA will decide about marketing authorization of the Polyphenon® E Ointment. If this authorization is granted before the end of 2006, MediGene will receive milestone payments from the marketing partner Bradley, which will have a significant effect on our annual result.

### **Project goals for 2006**

We have also set ourselves ambitious goals regarding our other drug development projects. We are planning to submit marketing authorization applications for our Polyphenon® E Ointment in several European countries. For the ongoing clinical phase II trials of EndoTAG-1 and NV1020 we intend to publish interim results at the end of the year 2006. Moreover we are preparing the initiation of two clinical phase II trials of EndoTAG-1 in other cancer indications, with one of them starting this year. The clinical phase I trial of G207 is continued parallel to that.

During the current financial year we will continue to analyze our drug development projects and keep reviewing our decision about their further development. This also applies to the development of our Polyphenon® E Ointment for the treatment of actinic keratosis and other indications which will be determined jointly with our marketing partner Bradley. We will also review whether MediGene can be further strengthened by company or product acquisitions. It will be crucial for our decision whether the product candidates represent a reasonable supplement to our product portfolio, and whether their therapeutic concept has been proven.

MediGene enjoyed a very successful financial year 2005. With its attractive product portfolio, its qualified employees and trustworthy business partners, the company possesses an excellent basis for future growth. I would be very happy if you decided to join us!

Thank you for the confidence you put in MediGene.

Sincerely,

Dr Peter Heinrich Chief Executive Officer

Peter Hernich



MediGene AG Executive Board 5

### **Executive Board**

of the MediGene AG

# Chief Executive Officer, Co-Founder (at the right)

Dr Peter Heinrich is a co-founder of MediGene AG and has been Chief Executive Officer of the company since 1995. Prior to this position, he was responsible for the formation of a biotechnology division at Wacker Chemie. During his nearly eight years' occupation with Wacker he further held various positions in the fields of biopharmaceutical/biochemical research and international alliance management. Dr Peter Heinrich studied biology and chemistry at Munich University where he received a PhD in biochemistry. After that he worked as a scientist at Harvard University.

Dr Peter Heinrich is President of the European Emerging Biopharmaceutical Enterprises (EBE), a specialized group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels. In addition, he is co-founder and spokesman of the Board of the BIO Deutschland, an independent association of the German biotech industry, with offices in Berlin. Besides that, Dr Heinrich is a member of the advisory committee at the VCI (Verband der Chemischen Industrie e.V. = German chemical industry association), and a committee member at Bayern Innovativ GmbH. Among other things, Dr Heinrich is involved as a member with the German Economic Affairs Council (federal expert commission growth & innovation), and as a mentor and tutor at the Bayarian Elite Academy.

# Chief Operating Officer (middle)

Dr Ulrich Delvos, MD, PhD, joined MediGene as Executive Board Member for Research and Development in October 2004. Ulrich Delvos is a physician with deep experience in drug development and possesses 18 years of management experience in major pharmaceuticals companies as well as biotech companies in Germany and in the USA. Before joining MediGene he was an Executive Committee Member and Managing Director at Aventis Behring GmbH, Marburg, and Senior Vice President and Chief Scientific Officer at Aventis Behring LLC in the USA. During his career, he was in charge of licensing, drug approvals, the set-up or reorganization of R&D organizations and the conclusion of financing activities.

# Chief Financial Officer (at the left)

Alexander Dexne Since May 2002, Alexander Dexne has been Chief Financial Officer of MediGene AG heading the Finance and Business Development activities. Alexander Dexne attended the University of Göttingen and holds a master's degree in economics as well as an MBA degree from Massey University, New Zealand. After graduation, he gained ten years of experience in international finance management. He worked as a management consultant for Pricewaterhouse, and afterwards he was Finance Director of Olympus Diagnostica GmbH. Later on he was promoted to General Manager Finance & Controlling at the European headquarters of the Olympus Optical Group. Before joining MediGene AG, he was a member of the Executive Board at the software company Kiwilogic AG, in charge of finance and operations.

MediGene's revenues increased by 50% in 2005. This increase results particularly from MediGene's first drug on the market, Eligard® for the treatment of prostate cancer. Eligard® was launched in Germany by MediGene's partner Astellas Pharma (formerly Yamanouchi) in 2004, 2005 launches in nine other European countries ensued. By the end of 2006 Eligard® should be available in 14 more countries, which will further increase MediGene's revenues. With Eligard®, we are reaping the fruit of an idea from the early days. In 2001, MediGene had acquired the license for the pan-European commercialization of Eligard® and taken the drug through the approval procedures for Germany.

In 2006 MediGene's revenues are expected to increase by another 50%. The second drug beside Eligard®, Polyphenon® E Ointment, will also contribute to the company's growth. The new partner Bradley Pharmaceuticals already made the first payments for this product to MediGene upon conclusion of a partnership in January 2006. Bradley will take on commercia-

lization of our drug in the US; MediGene will receive milestone payments and royalties on the sales of the drug. MediGene expects market launch and the first revenues from the sale of the Polyphenon® E Ointment in 2007.

Growth

Growth targets at profitability. Regarding business operations, MediGene wants to break even in 2006. This, however, requires marketing authorization for Polyphenon<sup>®</sup> E being granted by the end of 2006, and Astellas significantly developing sales of Eligard<sup>®</sup>. MediGene plans to have several drugs on the market in ten years, marketed either by partners or our own distribution channels. Some of MediGene's future drugs should emanate from our research work; the majority of them, however, should be licensed products, such as our successful product Eligard<sup>®</sup>.

Only progress allows us to look over other peoples' heads and see the horizon.

# Progress

MediGene's first drug is on the market. In 2005, we made significant progress with our second drug. MediGene submitted a marketing authorization application for the Polyphenon® E Ointment for the treatment of genital warts to the US regulatory authority FDA. After preliminary examination, the FDA accepted the application for further review. Also, at the beginning of 2006, MediGene successfully entered into a marketing and development partnership for the Polyphenon® E Ointment, important steps on the way to approval and market launch of our second drug. Moreover, MediGene initiated two clinical trials of the drug candidates EndoTAG-1 and G207 in 2005.

Progress in medicine is often accompanied by setbacks. A clinical trial in 2005 to investigate the applicability of Polyphenon® E in the treatment of another skin disease did not yield the expected results, which is not unusual in drug development and does not necessarily mean that further development will be unsuccessful. Nevertheless MediGene and the marketing partner will carefully examine whether or not we should make any future investments in the development of this drug for other indications. Not every branch yields rewards. But it may still be worthwhile in the long term to pursue ideas that enhance the potential of our products.

Further goals for 2006: In the current financial year, MediGene intends to submit a marketing authorization application for the Polyphenon<sup>6</sup> E Ointment for the treatment of genital warts in several European countries. We will also continue to push the development of our other drug candidates. The initiation of a new clinical trial of EndoTAG-1 is projected, and for the ongoing clinical trials of EndoTAG-1 and NV1020 we are planning to publish interim results obtained.



For tomorrow's success we are already working on the development of new drugs. For this purpose we are breaking new ground, utilizing new technologies based on novel principles, and with innovative drug candidates emerging from these technologies. Several product candidates are already undergoing clinical development: EndoTAG uses the therapeutic approach of cutting off the blood supply from the tumor cells, thus \*starving them out\*; MediGene's oncolytic viruses infect tumor cells and act as cancer killers. Due to their novel mode of action these products possess an outstanding potential. The drug candidates are already undergoing phase II trials, that is the second stage of the three-stage clinical development process. The

# Innovation

ongoing trials investigate tolerability and dosage, as well as an indication of the drug candidates efficacy in patients suffering from various types of cancer.

MediGene will continue to keep its drug pipeline filled. The statistical probability of a drug development project reaching the market rises with its progressing development. The probability of success is 10 to 30% for a drug undergoing clinical phase I testing, rises to 40 to 60% in phase II, and reaches 60 to 80% in phase III. During the marketing authorization procedure, the probability of success is 90%. From the very beginning, MediGene has put emphasis on a well-balanced drug pipeline comprising projects in both an advanced and an early development stage. This allows us to pursue our visions while keeping our feet firmly on the ground. MediGene will keep this balance in the future as well and, whenever possible, license or acquire additional drug development projects provided that they represent a reasonable supplement to our portfolio. We have proven in the past that MediGene has the capability of developing ideas and projects, and of making products a success.

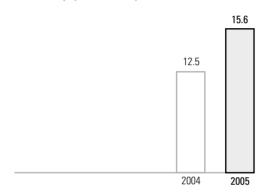
12 Products MediGene AC

### **Specialty Pharma Segment**

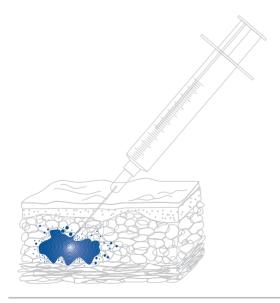
# **Eligard**®

Indication		Clinical Phas	е	Approval	Marketed	Peak Sales Potential <sup>1)</sup>	
	1	II	III			(in million €)	
Prostate Cancer					✓	> 100	

MediGene's Eligard® revenues 2004 and 2005 (Milestone payments and royalties)



Administration of Eligard®



# Hormone therapy 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) permits a significant reduction in the level of the male sex hormone testosterone, thus suppressing tumor growth. The established substance is combined with a drug delivery system, our 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, four or six months. The one-month and three-month products have now been approved and launched in Europe.

Since MediGene's partner Astellas Pharma (previously Yamanouchi) launched Eligard® in Germany in 2004, MediGene's revenues from the sale of the drug have increased to 15.6 million € in 2005. These revenues are made up of two elements: royalties on the sales of Eligard®, as well as milestone payments transferred from Astellas to MediGene on achievement of defined targets. This includes approval and market launch in specific European countries. MediGene, on the other hand, makes license fee payments for Eligard® to QLT (previously Atrix Laboratories). MediGene had acquired the pan-European marketing rights for Eligard® from Atrix and successfully took the product through the approval procedures for Germany and Europe. Meanwhile Eligard® has been approved in 24 European countries and was launched in ten countries by the end of 2005.

### **Outlook**

Eligard® will remain MediGene's mainstay of sales in the coming years. Revenues will continuously increase as a result of the market launch of the drug in another 14 countries in 2006. LHRH-Agonist

Per year. MediGene will receive royalties from sales of product.

Products 13

**Specialty Pharma Segment** 

# **Polyphenon® E Ointment**

Indication	Clinical Phase		9	Approval	Marketed	Peak Sales Potential <sup>1)</sup>
	1	II	III			(in million €)
Genital Warts						> 150
Actinic Keratosis						> 200

### **Immune modulation using catechines**

The Polyphenon® E Ointment is the second drug from MediGene to have passed clinical development. In 2005, MediGene submitted the marketing authorization application to the US regulatory authority FDA. MediGene's marketing partner Bradley Pharmaceuticals will take on promotion and commercialization of the product in the USA.

Polyphenon® E Ointment contains a concentrate of catechines with a defined composition. These natural substances are extracted from green tea leaves in a specific procedure. During clinical development, Polyphenon® E Ointment tested in the treatment of genital warts showed high and sustained efficacy with very few adverse events. The results come from an international phase III development program, during which more than 1,000 patients in 15 countries were medicated with Polyphenon® E Ointment.

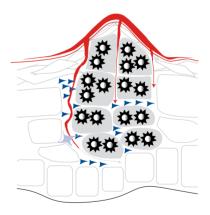
Genital warts are benign but painful and disfiguring skin tumors in the genital and anal areas. The sexually transmitted disease is caused by human papilloma viruses. Approximately 30 million people worldwide are infected by these viruses (HPV type 6 or 11) that cause genital warts. Genital warts are one of the fastest spreading venereal diseases worldwide.

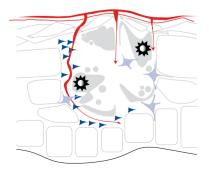
MediGene's recent findings indicate that Polyphenon® E Ointment activates the body's defenses. Moreover, MediGene was able to prove that Polyphenon® E Ointment inhibits major functions of the papilloma virus and counteracts specific changes in tumor cells. This presents two targets for efficient combat against

### Outlook

In 2006, MediGene is planning to submit marketing authorization applications for Polyphenon® E Ointment for the treatment of genital warts in several European countries. The decision whether or not the product will be developed for the treatment of other skin diseases will be made jointly by MediGene and the marketing partner. MediGene assumes that the current approval procedure for the ointment for genital warts will be completed successfully, and expects US market launch of the Polyphenon® E Ointment in 2007.

Changes in a skin tumor, as induced by Polyphenon® E Ointment

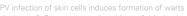




growth inhibition

immune modulation









the tumor, which may open up new therapeutic approaches for other skin diseases. An initial clinical trial (phase II) in the indication actinic keratosis conducted in 2005, however, did not yield the desired results.

royalties from sales of product.

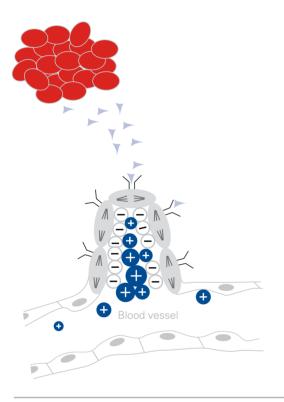
14 Products MediGene AC

### **Biopharma Segment**

### **EndoTAG-1**

Indication		Clinical Phase		Approval	Marketed	Peak Sales Potential <sup>1)</sup>		
	1	П	III			(in million €)		
Pancreatic Cancer						> 200		
Additional solid tumors						> 1,000		

**EndoTAG-1 Destroys Tumor Vessels** 



- Tumor cells
- Tumor releases signals inducing growth of blood vessels
- EndoTAG attacks activated endothelial cells and destroys blood vessel. Thereby the blood supply of the tumor is impaired

### Starving out cancer cells

EndoTAG-1 directly attacks specific blood vessels needed for the growth of a tumor. If these blood vessels, the so-called endothelial cells, are destroyed, the cancer cell does not receive sufficient oxygen and nutrients: the tumor is »starved out«.

The drug candidate is based on lipids – i.e. fat molecules which also exist inside the cell membrane – and a therapeutic substance. In EndoTAG, these components exist as so-called lipid complexes or liposomes which can be pictured as minute, hollow globules (ten thousand times smaller than a milli-

meter). The therapeutic substance is embedded in these globules. In the case of EndoTAG-1 this substance is Taxol®, one of the most effective substances in anti-cancer therapy. The EndoTAG liposomes are positively charged, enabling them to attach selectively to the negatively charged, newly developing endothelial tumor cells (neovascular targeting) and to destroy them. This process is intended to suppress nutrient supply and to inhibit further tumor growth.

In this way, EndoTAG links to the successful new anti-angiogenesis therapy (inhibition of vascularization), and yet provides an innovative variation thanks to its novel mechanism of action. Moreover, EndoTAG offers a therapeutic approach that can be used as an alternative to conventional chemotherapy. MediGene expects that direct destruction of the endothelial cells does not lead to any resistance to the therapeutic substance applied. This would solve a common problem inherent to existing therapies. In addition, the EndoTAG concept is expected to provide a wide range of applications, and could even be suitable for the treatment of all types of solid tumors showing their own vascularization. Phase I trials have already been conducted in several indications. There is also a clear indication that the combination of EndoTAG and chemotherapeutic drugs will have a synergistic effect. MediGene is currently investigating this in the indication pancreatic cancer: in a phase II trial initiated in 2005, EndoTAG-1 is being used in combination with the drug Gemcitabin®.

EndoTAG-1 ist MediGene's first product derived from the technology platform EndoTAG.

### **Outlook**

By the end of 2006, interim results from the ongoing phase II trials should be available. Completion of this trial is scheduled for 2007. Beside that, MediGene is also planning trial programs of EndoTAG for other cancer indications. A phase II trial is scheduled to start in 2006.

neovascular targeting

vascular disrupting

<sup>&</sup>quot;Per year. MediGene will receive royalties from sales of product.

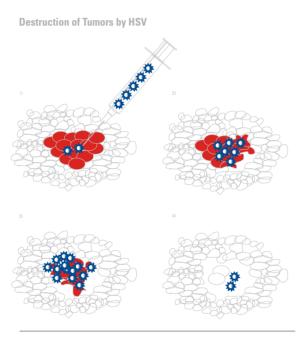
MediGene AG Products 15

### **Biopharma Segment**

# **Oncolytic herpes simplex viruses (HSVs)**



VV1020 G207



- <sup>1)</sup> Oncolytic virus is applied to the tumor.
- <sup>2)</sup> Tumor cells support virus replication
- 3) Tumor mass is selectively destroyed (»oncolysis«).
- 4) Complete destruction of the tumo

A technology that can be used for a variety of research or application purposes

### **Cancer-killing viruses**

MediGene is developing cancer-killing viruses, socalled oncolytic viruses, for the treatment of various forms of cancer. These viruses are specific herpes simplex viruses, or HSVs, generally known as the cause of cold sores. MediGene uses these viruses, however, in a modified and »disarmed« form in order to make them utilizable as a therapeutic agent in humans. This was achieved by switching off certain genes that normally enable the virus to multiply in healthy cells, which would destroy these cells. As a result of this genetic modification, the HSVs are able to reproduce in tumor cells solely, since only these offer an environment that compensates for the loss of the removed viral genes. Consequently, the virus is able to replicate in the tumor cells, selectively destroying them without harming healthy tissue.

If this hypothesis is confirmed, oncolytic HSVs will act more selectively and efficiently than conventional cancer therapies do, yet without leading to severe adverse events. They could also provide a therapeutic alternative for the treatment of tumors that are inoperable or have developed a resistance to chemotherapy or radiotherapy. There may even be a synergistic effect in combining oncolytic HSV and standard therapies.

Preliminary clinical phase I trials with cancer patients have already yielded encouraging results: since 2004, MediGene has investigated the virus NV1020 in a continuative phase I/II trial in the indication liver metastases developing from colorectal carcinoma. In this trial, NV1020 is combined with standard chemotherapy. In 2005, a phase I trial of another HSV, i.e. G207 for the treatment of malignant brain tumors was initiated. This trial is conducted in cooperation between the University of Alabama at Birmingham, and MediGene, and is substantially supported by a SPORE grant (Specialized Program of Research Excellence) awarded by the National Cancer Institute.

NV1020 and G207 are derived from MediGene's technology platform HSV.

### **Outlook**

MediGene is planning to complete the clinical trial of NV1020 in 2007. Interim results should be published at the end of 2006. The clinical trial of G207 is continuing according to schedule.

Per year. MediGene will receive royalties from sales of product.

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### The share

### **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	TecDAX30, Prime All Share, Prime IG Biotechnology
Trading floors	XETRA, Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hannover, Munich, Stuttgart
Designated sponsors	Concord Effekten AG, West-LB
No. of shares	18,766,172

### Member of the TecDax30 index

MediGene is listed on the Prime Standard market segment and is a member of the TecDAX30 index. This makes MediGene one of the primary technology shares in Germany.

### Share price declined slightly

The MediGene share had an opening price of 8.70 € in 2004 and performed excellently during the first six months of the year. With a rise of 34% the share price reached its yearly high of 11.66 € in February, outperforming the comparative index TecDAX by 32%. Despite interim downward trends, this high level was almost maintained throughout the year. In July 2005, MediGene noted a substantial price drop, since an initial clinical phase II trial of Polyphenon® E for the treatment of actinic keratosis had yielded unsatisfactory results. Despite the positive news following shortly afterwards, the downward trend of the share continued until November. The yearly low was reached at 6.85 €. The US regulatory authority FDA's acceptance for further review of the marketing authorization application for the Polyphenon® E Ointment early in December turned this development. The year-end closing price of the MediGene share was 8.36 €, i.e. with a decline of 3.9% (TecDAX30: +13%). The year 2006 started with a rise in the MediGene share price.

### Intense investor relations activities

In 2005 we continued our extensive activities by keeping investors, financial analysts and the business press informed about MediGene's development. In addition to our press and analyst conferences, we had numerous interviews with investors and journalists at home and abroad, and presented the company at the following renowned investors conferences.

### **Broad coverage by analysts**

Being one of the major biopharmaceutical companies in Europe, MediGene is actively accompanied by a large number of financial analysts from renowned investment banks at home and abroad. In numerous reports they thoroughly analyzed our company and its products and technologies. Independent analyses are an important element in addressing potential investors successfully.

MediGene AG The share 17

### In 2005, the following investment banks reported on MediGene:

Code Securities	Dr Samir Devani
Concord Effecten AG	Dr Roger Becker
DZ Bank	Dr Patrick Fuchs
Equinet Institutional Services	Dr Martin Possienke
Goldman Sachs International	Dr Stephen McGarry
Landesbank Baden- Wuerttemberg	Dr Hanns Frohnmeyer
Metzler Equity Research	Dr Karl-Heinz Scheunemann
Morgan Stanley Dean Witter	Dr Daniel Mahony
Oppenheim Research GmbH	Dr Ruediger Weseloh
SES Research GmbH	Henner Rueschmeier
Viscardi Securities GmbH	Robert Willis/ Isabell Friedrichs Dr Liming Ge
Vontobel Securities AG	Dr Markus Metzger
WestLB AG	Oliver Kaemmerer/ Andreas Theisen

# Award for annual report and investor relations activities

In June 2005, MediGene was honored with the ARC Award »The World's Best Annual Reports« in New York City for its Annual Report 2004. The ARC Awards is the world's largest annual report competition. MediGene received the »bronze award« in the category biotechnology. The jury appraised lucidity, information content, and layout of 1,900 reports in 12 categories. With this award, MediGene was once again honored for its reporting towards both the shareholders and the public. The business magazine Capital also rated MediGene very positively on the occasion of its 2005 investor relations contest: in a survey with 5,500 investment professionals from about 300 European financial institutions, MediGene took sixth place in the category TecDAX. The companies' investor relations activities were assessed by the following criteria: credibility, quality, promptness and corporate governance.

### **Development of shareholder structure**

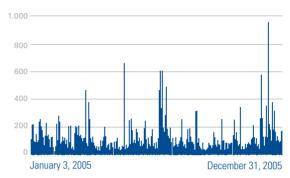
As in the preceding year, the portion of institutional investors was approximately 34%, whereas the portion of private investors stayed at 61% (2004: 62%). Directors' holdings decreased slightly to 4.8% (2004: 5.1%). At the end of the year, Techno Venture Management was the only investor holding more than 5% of the share capital (5.5%). The portion of shares held in Germany increased to 73.8%, compared to the preceding year (2004: 65.4%). 94.5% of the MediGene shares are free-floating.

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### Share price 2005 (January 3, 2005 € 8.70 indexed to 100)



### Volume In thousands



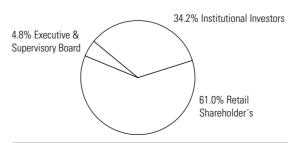
### Key figures per share

Key ligares per share		
In T€	2005	2004
52 weeks high	11.66	9.20
52 low high	6.85	5.70
Opening price	8.70	6.06
Year end/closing price	8.36	8.50
Mean share price	9.20	7.21
Weighted average number of shares outstanding	18,560,027	13,996,440
Average trading volume in shares	138,787	72,486
Average market capitalization in million	171	101
Total numbers of shares outstanding as at Dec. 31	18,766,172	18,522,684
Dividend per share	0.00	0.00
Cashflow per share from operating activities	-0.64	-0.86
Equity per share	2.79	4.42

### Shareholder structure by country<sup>1)</sup>



### Shareholder structure by investor type<sup>1)</sup>



<sup>1)</sup> as per December 31, 2005

<sup>1)</sup> as per December 31, 2005

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# **Corporate Governance**

MediGene's Executive and Supervisory Boards are aware of the company's responsibility towards its shareholders, employees and business partners. For the purpose of a value-oriented corporate management, MediGene has therefore implemented the German Corporate Governance Code to a wide extent, thereby surpassing legal provisions. The recommendations and proposals made by a commission set up by the German Federal Government comprise internationally and nationally accepted standards regarding good and responsible management of companies.

Corporate Governance principles provide regulations for the following areas:

- · they describe the major rights of the shareholders,
- they define clear management principles and the respective responsibilities for the individual company bodies,
- they regulate the interaction between these bodies,
- they demand straightforward and transparent communication with the public, and
- they require conscientious, reliable accounting and auditing.

# Corporate Governance Code and Compliance Declaration

MediGene's Corporate Governance Code is accessible on our website at www.medigene.de/englisch/corporate\_governance). This also applies to the official Compliance Declaration of MediGene's Executive and Supervisory Boards. With regard to a few individual items MediGene has, after thorough deliberation, decided not to comply with the code. These items are specified in the declaration. Reasons for non-compliance are stated in the report (see p. 21 et sqq.). The implementation of Corporate Governance at MediGene means amonast others:

### **Relations with its shareholders**

MediGene AG respects the rights of shareholders and guarantees the exercise of these rights to the best of its ability within the statutory framework. In particular, these rights include free purchase and free sale of shares, equal voting rights for each share (one share – one vote), participation in the general meeting and exercise of the right to vote and appropriate satisfaction of information requirements.

### Communication with the public

In relaying information to people outside the enterprise, the Management Board observes the principles of transparency, promptness, openness, comprehensibility and due equal treatment of shareholders.

### **Executive Board**

The Executive Board as a whole as well as each individual board member will conduct the enterprise's business with the due care and diligence of a precise and conscientious executive officer in accordance with the law, the Articles of Association and the Executive Board Terms of Reference. The Executive Board manages the enterprise on their own responsibility. In doing so, it is obliged to act in the enterprise's best interests and undertakes to increase sustainable enterprise value.

### **Supervisory Board**

It is the task of the Supervisory Board of MediGene AG to appoint the Executive Board and to advise it regularly, as well as to supervise and support the management and the achievement of MediGene's long-term goals.

# Cooperation between the Executive Board and the Supervisory Board

The Executive Board and the Supervisory Board cooperate closely to the benefit of the enterprise. The Chair of the Supervisory Board keeps in regular contact with the Executive Board, especially with its Chair. The Executive Board coordinates the enterprise's strategic alignment with the Supervisory Board and discusses with it at regular intervals the current state of strategy implementation, as well as risk management. For transactions of fundamental importance, the Supervisory Board specifies provisions in the Terms of Reference for the Executive Board requiring the Supervisory Board's approval. Such transactions include decisions or measures that fundamentally change the asset, financial or earnings situation of the enterprise.

# Remuneration of Executive and Supervisory Board members

Remuneration of Executive and Supervisory Board members is reported on pages 84 and 85 of the annual report, and is accessible at the company's web site www.medigene.com. The information is individualized and itemized. The compensation paid to the Executive Board members comprises fixed and variable

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components, as well as performance incentives to increase the value of the company in the long term. The criteria for the variable compensation components are laid down in advance each year. The long-term compensation components consist of stock options. The intention of this is to create performance incentives geared towards lasting corporate success. The results targets that form the basis of these incentives may not be changed subsequently.

The Supervisory Board members' total compensation comprises a fixed cash amount and fees for attending meetings. The consideration of the scope of the members' activities takes the duties of the Chairman and Deputy Chairman into account.

### Reporting and audit of annual financial statements

MediGene informs shareholders and third parties regularly by means of Consolidated Financial Statements and by means of interim reports during the financial year. Group reporting is in accordance with the International Financial Accounting Standards (IFRS). For corporate law purposes (calculation of dividend, shareholder protection), Annual Financial Statements are prepared according to national regulations (German Commercial Code), which also form the basis for taxation. The Consolidated Financial Statements are examined by the auditor and by the Supervisory Board. The Supervisory Board commissions the auditor to carry out the audit and concludes an agreement on the latter's fee. The auditor takes part in the Supervisory Board's deliberations on the Annual Financial Statements and Consolidated Financial Statements and reports on the essential results of its audit.

# Stock option plan and similar securities-based incentive systems

### Current Stock Option Plan

The current stock option plan of 2003 provides for the issuance of option rights to the company's Executive Board and employees. The strike price to be paid for the subscription to a MediGene share upon exercise of the option right amounts to 120% of the basic value. This basic value corresponds to either the average closing price of the MediGene share of the past 60 trading days prior to the date of issuance of the respective options ("allotment date") or the opening price of the MediGene share on the allotment date, whichever is higher. The holders of subscription rights

cannot exercise the option rights before expiration of a waiting period of two years starting from the allotment date of the respective subscription right. The option rights have a term of ten years from the allotment date. The corporation is neither legally nor factually obliged to repurchase any options or compensate in cash. For further details on the stock option plan 2003, please see page 71 et sqq. of the annual report.

### Earlier employees'stock ownership programs

In addition to the 2003 stock option plan, subscription rights from the years 1997 and 1998 exist for convertible bonds issued to employees as well as executive and supervisory board members. For further details on MediGene's employees' stock ownership program, please see page 71 et sqq. of the annual report.

### **Director's Dealings**

Under section 15a of the Securities Trading Act (Wertpapierhandelsgesetz), the Members of the Management and Supervisory Board of MediGene AG, as well as by persons who have a »close relationship« with such members, are obligated to report trading in MediGene stock. In addition to the buying and selling of MediGene stocks, transactions in securities relating to MediGene stocks (e.g. the sale or purchase of warrants for MediGene shares) must be reported. The transactions have to be published within five working days on the issuer's home page for a minimum period of one month, unless the total value of these tradings executed by such person within one calendar year does not exceed € 5,000.

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Director's Dealings in 2005

DGAP- Notification	Name of the Board Member	Function	Classifica- tion of the share	ISIN	Trans- action	Place of Trans- action	Date of Transaction	Price per Share	Number of Shares	Deal Volume
							in €	in €		in €
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Nov. 10, 2004	8.01	16,570	132,710.00
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Nov. 12, 2004	7.53	9,030	68,025.00
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Dec. 14, 2004	8.15	4,400	35,838.00
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Dec. 16, 2004	8.15	2,159	17,595.85
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Jan. 4, 2005	9.00	5,000	45,000.00
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Jan. 31, 2005	10.04	2,841	28,511.01
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Feb. 1, 2005	10.36	30,000	310,757.24
Feb. 4, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Feb. 2, 2005	10.14	10,000	101,430.70
Feb. 11, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	Feb. 10, 2005	11.50	10,000	115,000.00
July 26, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	June 24, 2005	11.26	5,000	56,300.00
July 26, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Sale	XETRA	June 30, 2005	11.26	3,500	39,410.00
July 26, 2005	Dr Manfred Scholz	Supervisory Board Member	Share	DE00 0502 09038	Purchase	XETRA	July 1, 2005	9.26	5,000	46,300.00

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

The following specifies the items in which we do not comply with the recommentations of the German Corporate Governance Code:

### Deductible in the case of D&O insurances

With regard to the D&O insurance effected for the Executive and Supervisory Board members of MediGene AG, no deductible has been agreed. Both the Executive and Supervisory Boards believe that the sense of responsibility applied in fulfillment of their duties is fully guaranteed without any such deductible.

### 2Age limits for Executive and Supervisory Board members

No age limit exists for the Executive and Supervisory Board members of MediGene AG. Both the Executive and Supervisory Boards consider such age limits to be an inappropriate constraint of the shareholders' right to elect the Supervisory Board members, and also a considerable restriction on the Supervisory Board with regard to the choice of qualified Executive Board members.

# Consideration of committee work in the compensation of Supervisory Board members

The membership in Supervisory Board committees is not taken into consideration for the remuneration of Supervisory Board members of MediGene AG. 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 regulation.

# Possibility of limitation (cap) regarding variable long-term remuneration components

No such caps have been agreed with the Executive Board members of MediGene AG. The Supervisory Board believes that such an agreement would lead to 22 Corporate Governance MediGene AC

an unacceptable degree of insecurity for the Executive Board members and for the corporation, since it is impossible to predict in which cases the criteria of an extraordinary, unforeseen development would be fulfilled.

### Performance-related remuneration of the Supervisory Board members

The Supervisory Board members of MediGene AG do not receive performance-related remuneration. Due to recent developments in legislation, MediGene abstains from continuing the performance-related remuneration for Supervisory Board members in the form of convertible bonds.

### Publications on the web site of MediGene AG

Unless required by law, MediGene AG does not disclose any details about capital increases on its web site before the end of the subscription period. In this way the company intends to comply with the conditions of the US capital market legislation.

All other recommendations and proposals of the German Corporate Governance Code have been implemented in their entirety. MediGene 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. In this way we ensure the continuous observance of these principles in our company. By means of analysis, supervision and transparency MediGene lays the foundations for fair and efficient corporate management. This will remain our standard in the future as well.

# **Financial information**

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# **Report of the Executive Board**

The preparation of these Consolidated Financial Statements and the information contained in the Management's Discussion & Analysis (MD&A) are the responsibility of the Executive Board of MediGene AG. The consolidated accounts are for the first time drawn up on the basis of the International Financial Reporting Standards (IFRS), as applicable throughout the EU. The Executive Board of the company believes that these Consolidated Financial Statements reflect all of the adjustments that are necessary for the portrayal of the assets, financial and income position at the end of the periods ending in December 2004 and 2005. These Consolidated Financial Statements certain estimates and assumptions by the Executive Board that influence the figures specified in the Financial Statements. These estimates and assumptions were made with the utmost care and are based on all of the knowledge that was available at the time. The Consolidated Financial Statements and the MD&A were supplemented with information that is required by the German Commercial Code (HGB).

With the help of an effective internal risk management system, the deployment of reliable software and standardized operating systems, we ensure that all activities within the company are performed in compliance with existing authorizations and that all business transactions are documented and processed with maximum care and attention. This integrated system is supplemented by written guidelines and work instructions, an appropriate selection and training of qualified employees. The result of all this is a secure basis that guarantees that the course of business is represented in a way that corresponds to the actual situation.

In accordance with the decision of the Shareholders' Meeting, PricewaterhouseCoopers GmbH, Wirtschaftsprüfungsgesellschaft, Munich, an independent auditing company, has audited the Consolidated Financial Statements – in compliance with IFRS – and the group MD&A. The Supervisory Board discussed the

Consolidated Financial Statements, the group MD&A and the audit report thoroughly in the presence of the auditor. The results of this audit can be found in the Supervisory Board Report (see p. 92 of this annual report).

Martinsried, March 2006

MediGene AG
The Executive Board

Dr Peter Heinrich Chief Executive Officer

Peter Humih

Dr Ulrich Delvos Chief Operating Officer

Alexander Dexne Chief Financial Officer MediGene AG Auditor's report 25

# Auditor's report

We have audited the consolidated financial statements prepared by the MediGene AG, comprising the balance sheet, the income statement, statement of changes in equity, cash flow statement and the notes to the consolidated financial statements, together with the group management report for the business year from January 1 to December 31, 2005. The preparation of the consolidated financial statements and the group management report in accordance with the IFRSs, as adopted by the EU, and the additional requirements of German commercial law pursuant to § (Article) 315a Abs. (paragraph) 1 HGB (»Handelsgesetzbuch«: German Commercial Code) articles of incorporation are the responsibility of the parent Company's Board of Managing Directors. Our responsibility is to express an opinion on the consolidated financial statements and on the group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with § 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer (Institute of Public Auditors in Germany) (IDW) (where appropriate: and additionally observed the International Standards on Auditing (ISA)). 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 the entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by the Company's Board of Managing Directors 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 the IFRSs as adopted by the EU, the additional requirements of German commercial law pursuant to § 315a Abs. 1 HGB articles of incorporation 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 and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development.

1/ Teluce

Munich, February 3, 2006

McMahon Menne Auditor Auditor

MM

PricewaterhouseCoopers GmbH Wirtschaftsprüfungsgesellschaft

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# Management's Discussion and Analysis (MD&A)

as at December 31, 2005

- Total revenues amount to 19.7 million € (2004: 13.1 million €)
- Net loss of 12.0 million € (2004: 12.7 million €)
- Average monthly net cash burn rate of 0.9 million €
   (2004: 1.2 million €)
- Cash and cash equivalents amount to 37.6 million €
   (2004: 48.5 million €)

### **Preliminary remarks**

MediGene develops anti-cancer and anti-tumor drugs

MediGene's core field of competence lies in the research and development of innovative approaches to the treatment of various cancer and tumor diseases. MediGene focuses its activities on indications in fields of great medical need and commercial potential. In addition to the drug Eligard®, which has already been authorized for commercialization purposes, further potential sources of income are payments from cooperation agreements for the joint development and marketing of products, payments from R&D and technology contracts, and the marketing of products by MediGene itself.

### Major milestones achieved in 2005

In the past financial year, MediGene has made significant progress in the following areas of its product and development portfolio:

- Eligard®, MediGene's first authorized drug, was launched on several more European markets.
- Second drug in the approval process: the application for the approval of Polyphenon® E Ointment was accepted by the US regulatory authority FDA.
- The clinical development program for the drug candidate EndoTAG-1 in the pancreatic carcinoma indication was initiated.
- A clinical phase I trial for the drug candidate G207 was started in the USA.

The financial targets that were set for the financial year 2005 have largely been reached:

- Total revenues were increased by 50% to almost 20 million € thanks to an increase in Eligard® sales and the conclusion of a licensing agreement with the Glaxo Group Limited.
- The net loss for the year was reduced from 12.7 million € to approx. 10.5 million € excluding non-recurring depreciation.

State of development in the product portfolio

MediGene's first drug **Eligard®** is marketed in Germany and other European countries, including Spain, Portugal, Switzerland and the Netherlands. Further market launches in additional European countries are being planned. Eligard® is used for the treatment of advanced prostate cancer.

In December 2004, the approval process of mutual recognition for Eligard® was successfully completed in 22 other European countries and Switzerland. As expected, the first national authorities issued the national approvals during the financial year 2005, with the result that the marketing of Eligard® began in the other European countries. All of the planned market launches in Europe are scheduled for completion in the financial year 2006. The drug will then be marketed in a total of 24 European countries (incl. Germany) by MediGene's partner Astellas Pharma Europe Ltd., Staines, UK (»Astellas Pharma; «formerly Yamanouchi Ltd.).

In the second quarter of 2005, MediGene applied for the approval of the second drug, Polyphenon® E Ointment for treating genital warts. The application was submitted to the US regulatory authority FDA (Food and Drug Administration), which formally accepted the application in December 2005 and began the review process. As the minimum trial and testing period is one year, the market launch of Polyphenon® E Ointment can be expected in 2007. MediGene holds the global marketing rights for the drug and plans to apply for approval in Europe as well in 2006.

At the end of the second quarter of 2005, MediGene had presented the results of a phase II concept trial with Polyphenon® E Ointment for the treatment of actinic keratosis, a precursor of skin cancer. The primary objective of the trial, statistically significant evidence of efficacy, was not achieved.

In August 2005, MediGene began a clinical phase II trial with the drug candidate EndoTAG-1 for treating pancreatic carcinomas. EndoTAG-1 is a combination of the established active substance Taxol® with a carrier system that selectively brings the substance to newly formed blood vessels in the tumor. The destruction of the tumor's blood vessels aims at cutting off the inflow of nutrients and thereby starve the tumor. In addition to the safety and tolerability of the drug, the current trial is concentrating mainly on the clinical efficacy of various dosages of EndoTAG-1 in combina-

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tion with Gemcitabin®, a cytostatic that has already been approved for pancreatic carcinoma therapy. It is planned that around 200 patients in some 20 centers in four European countries will take part in the trial. The recruitment of patients for the project is going according to plan. An interim analysis is planned for the end of 2006.

In addition, the efficacy of the **oncolytic herpes simplex virus NV1020** for treating liver metastases derived from colon cancer is being investigated. A clinical phase I/II trial that was begun in September 2004 is still ongoing. Interim results are planned by the end of 2006. MediGene expects the complete data from the trial to be available in 2007.

In early June 2005, MediGene announced that a clinical phase I trial for the **oncolytic herpes simplex virus G207** for treating malignant brain tumors had begun at the University of Alabama at Birmingham, USA. G207 is a herpes simplex virus that was genetically modified to destroy tumor cells selectively without damaging healthy tissue. The trial is investigating the safety, tolerability and efficacy trends of G207, as well as a possible synergetic effect in conjunction with radiotherapy.

### **Cooperation and license agreements**

# Marketing of Eligard® is the focal point of the partnership with Astellas Pharma Europe Limited

In January 2004, MediGene concluded a partnership with the pharmaceuticals group Astellas Pharma Europe Ltd., Staines, UK, for the marketing of the cancer drug Eligard® in Europe. Astellas Pharma, Europe's third-biggest pharmaceuticals company in the urology field, promotes and markets Eligard® in Europe. In return, MediGene receives stage-by-stage milestone payments up to a total of 21.5 million €, including an upfront payment of 4 million € that MediGene received when the contract was signed, plus royalties from the sales revenues generated by Eligard®.

# MediGene and the Glaxo Group Limited sign non-exclusive license agreement

In December 2005, MediGene granted the Glaxo Group Limited, Brentford, UK, a non-exclusive license for patents that ensued from MediGene's program for the development of a therapeutic tumor vaccine. In return, MediGene received a one-off payment from the Glaxo Group Limited.

### **General conditions**

### Consolidation process within the industry continues

The consolidation process within the pharmaceuticals and biopharmaceuticals industry made further advances in the period under review. Acquisitions and mergers are leading to the restructuring and adjustment of the technology and product portfolios of the new corporate entities that are emerging from this process. Consequently, during the past year, increased numbers of transactions affecting technologies, individual products and entire product segments were concluded. Experts believe that this consolidation process will continue.

# Favorable conditions for partnerships between pharmaceuticals and biotech companies

MediGene AG's technology and product portfolio is opening up promising potential for the company to conclude strategic partnerships. The pharmaceuticals and specialty pharmaceuticals industry, in particular, needs innovative technologies and products in order to maintain its past growth rates. In this area there is a dearth of promising drugs with new modes of action, and a similar lack of new technologies. This deficiency within the pharmaceuticals industry is opening up new cooperation alternatives for the innovative biotech industry.

MediGene is striving on the one hand to conclude partnerships by issuing licenses to others (out-licensing), and on the other to supplement its own development portfolio usefully by acquiring licenses for new technologies and attractive products. For that reason, MediGene is continuously screening the market for new biopharmaceutical developments and examining individual products and technologies as part of its own in-licensing activities. The persistent consolidation and restructuring process in the pharmaceuticals and biopharmaceuticals industry is creating additional potential for putting this strategy into practice.

# No change in the general political and economic conditions

The general political and economic conditions with relevance for MediGene remained largely unchanged in 2005. As far as the future is concerned, the company is assuming that Germany's political leaders will continue to regard biotechnology as a key industry for the country and encourage the development of this industrial segment.

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On the other hand, the persistent cost pressure on service providers in the medical sector may well lead to further legislation to reduce drug costs, which could also affect the pharmaceuticals and biopharmaceuticals industry in Europe and the USA.

The European Central bank did not increase money market interest rates in January 2006. In the short term too, the general expectation in the euro zone is that money market interest rates will remain stable. Within the period under review, the euro's reference exchange rate fell by approx. 13% from 1.3621 to 1.1825 US dollars (source: Dresdner Bank reference exchange rate).

### **Earnings position**

For explanatory comments on these consolidated financial statements, please see the notes (see p. 54). With the exception of the adjustments occasioned by the first-time transition to IFRS, the accounting and valuation methods applied do not contain any significant content-related divergences from the consolidated financial statements prepared in accordance with US-GAAP.

Income statement (abbreviated)

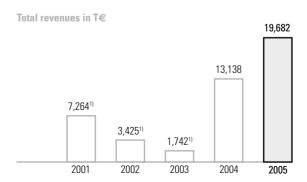
micomic statement (appreviated)			
In T€	2005	2004	Change
Total revenues	19,682	13,138	50%
Cost of sales	9,077	5,930	53%
Gross profit	10,605	7,208	47%
General administration and selling expenses	6,123	6,294	-3%
Research and development expenses	15,997	15,627	2%
EBIT	-11,515	-14,713	22%
Net loss from continued operations	-12,044	-12,665	5%
Result from discontinued operations	-1	-1	0%
Net loss	-12,045	-12,666	5%

### **Total revenues increase significantly**

In the period under review, total revenues increased by 50%, from 13,138 T€ (2004) to 19,682 T€. These revenues were generated mainly with the commercialization of the drug Eligard® and the conclusion of a license agreement with the Glaxo Group Limited.

Revenues were generated by product sales and royalties (10,794 T€) as well as by milestone, upfront and one-off payments (8,761 T€). Other operating income amounted to 127 T€ (2004: 357 T€). In 2005 MediGene received no public grants (2004: 55 T€). All revenues were earned in Germany.

Compared with the previous year, this has led to an increase in revenues based on both rising product sales in Germany and further market launches in Europe.



1) US-GAAF

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The milestone payments had become due with the market approval and market launch of the Eligard® three-month product in other European countries. As a result of the newly granted market approvals, MediGene has partially recognized a deferred revenue item that had been set up when the marketing contract had been concluded with Astellas Pharma.

In December 2005, MediGene received a one-off payment from the Glaxo Group Limited in return for granting it a non-exclusive license for patents that had resulted from MediGene's program for developing a therapeutic tumor vaccine.

The revenues were generated in the individual segments as follows (see Segment Reports, p. 31 ff.):

Revenues by segments

In T€	2005	2004	Change
Specialty Pharma	15,591	12,694	23%
Biopharma	4,030	226	> 200%
Other	61	218	-72%
Total from continued operations	19,682	13,138	50%
Discontinued operations	6	32	-81%
Total	19,688	13,170	49%

### **Cost of sales**

In the course of the marketing of Eligard®, cost of sales of 9,077 T€ were posted (2004: 5,930 T€). These include not only the costs of purchasing Eligard®, but also royalties paid to QLT Inc.

### Higher gross profit

The gross profit in 2005 amounted to 10,605 T€ (2004: 7,208 T€).

### **General administration and selling expenses**

Compared with the previous year, general administration and selling expenses decreased slightly from 6,294 T€ in 2004 to 6,123 T€ in 2005. This amount consisted of 1,100 T€ in selling expenses (2004: 1,164 T€) and 5,023 T€ in general and administrative expenses (2004: 5,130 T€).

Selling expenses were incurred mainly in connection with business development activities. This business unit is concerned with, among other things, the commercialization of MediGene's product candidates and technologies within the framework of partnerships.

### **R&D** expenses increase slightly

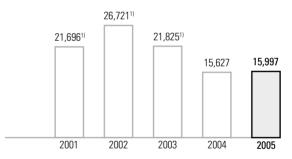
Total R&D expenses increased slightly by 2% to 16,004 T€ (2004: 15,660 T€). The progress made within the development portfolio is responsible for the slight increase in the expenses.

**R&D** expenses by segments

In T€	2005	2004	Change
Specialty Pharma	4,815	6,907	-30%
Biopharma	11,182	8,720	28%
Total from continued operations	15,997	15,627	2%
Discontinued operations	7	33	-79%
Total	16,004	15,660	2%

The total R&D expenses include patent expenses for discontinued operations.

R&D expenses in T€



1) US-GAAP

### Amortization and depreciation unchanged

Total depreciation and amortization remained almost unchanged at 1,348 T€ (2004: 1,362 T€). The amortization of intangible assets refers to the patents and licenses of the former Munich Biotech AG that were acquired in August 2004.

In 2004, depreciation on discontinued operations was accrued in the course of the liquidation of LARNAX GmbH, MediGene's former cardiology segment (see Discontinued Operations, p. 31).

With regard to the goodwill of 9,226 T€ reported in the balance sheet, the impairment test as at November 30, 2005 did not result in any need for amortization.

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### Depreciation

In T€	2005	2004	Change
Fixed assets	671	744	-10%
Intangible assets	510	207	146%
Capital lease	167	182	-8%
Total from continued operations	1,348	1,133	19%
Discontinued operations	0	229	-100%
Total	1,348	1,362	-1%

The amortization and depreciation are reported in the income statement under general administration and selling expenses (107 T $\in$ ) and research and development expenses (1,241 T $\in$ ).

### **EBIT** improves

The loss before income and taxes (EBIT) from continued operations was reduced by 22% from 14,713  $T \in$  to 11,515  $T \in$ .

**EBIT** by segments

In T€	2005	2004	Change
Specialty Pharma	1,390	-295	> 200%
Biopharma	-7,152	-8,494	16%
Other	-5,753	-5,924	3%
Total	-11,515	-14,713	22%

### **Financial result decreases**

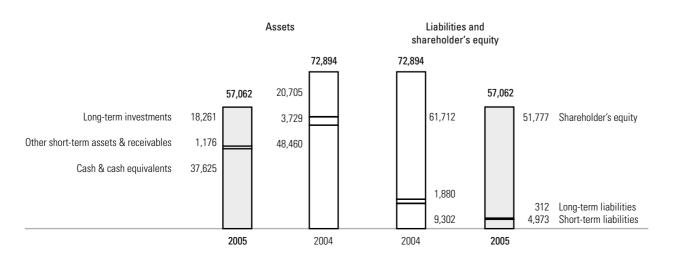
The overall financial result decreased by 126% to -529 T€ (2004: 2,048 T€), primarily as a result of expenses incurred for securities. In the financial year 2005, MediGene carried out a valuation allowance for shares held in QLT Inc. In the course of the valuation allowance, expenses of 1,512 T€ were recorded. In the previous year, MediGene had reported a profit of 1,581 T€ that had resulted from the swapping of Atrix Laboratories Inc. shares with QLT Inc. shares. In November 2004, the Canadian company QLT Inc. had acquired the US corporation Atrix Laboratories Inc. and exchanged each Atrix share in one QLT Inc. share plus 14.61 US \$ in cash.

Interest income increased in 2005 as a result of a higher sum invested. Interest expenses accrued mainly from the lease of fixed assets. There were also exchange rate gains resulting from cash that QLT Inc. paid to MediGene within the course of the acquisition of Atrix Laboratories Inc.

Financial result

In T€	2005	2004	Change
Interest income	827	647	28%
Interest expense	149	90	66%
Sub-total	678	557	22%
Expenses/Income from securities	-1,512	1,581	-196%
Foreign currency gains/losses	305	-90	> 200%
Total	-529	2,048	-126%

### Balance sheet structure in T€



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### Net loss for the year decreases

Compared with the same period in the previous year, MediGene reduced its net loss from continued operations by 5%, from 12,665 T€ to 12,044 T€. This reduction in the loss can be attributed to the increase in revenues and the accompanying improvement in gross profit. At the same time, expenses in the general administration, selling and R&D areas remained almost constant compared with the previous year.

The net result in both periods was significantly influenced by expenses and income resulting from the shares in Atrix Laboratories Inc. and QLT Inc. held by MediGene. While a valuation allowance was carried out on these shares in 2005, MediGene had realized income of 1,581 T€ in the corresponding period of the previous year (cf. assets position, page 34).

The annual result posted by MediGene AG according to HGB (German Commercial Code) amounted to -16,489 T€ (2004: -12,888 T€).

### Loss per share significantly reduced

In the financial year 2005, the net loss per share decreased by 28%, from  $-0.90 \in$  (average weighted number of shares 13,996,440) to  $-0.65 \in$  (average weighted number of shares 18,560,027). This improvement in the loss per share was a consequence of both the reduction in the net loss for the year and the increase in the average number of shares.

The fully diluted net loss per share is the same as the actual loss since the conversion of common stock equivalents would have an anti-dilutive effect.

### **Discontinued operations**

The cardiology segment, corresponding to LARNAX GmbH, which was liquidated in 2003 is reported under discontinued operations. In 2005, a loss of 1 T€ was incurred for discontinued operations. LARNAX GmbH discontinued its operating activities as at the end of 2003. In accordance with its announcement of July 8, 2005, MediGene AG acquired by means of a merger the assets of the wholly owned subsidiary LARNAX GmbH, with head office in the Martinsried district of Planegg, Munich administrative district, entered in the commercial register of Munich Local Court (AG) under HRB 115761, in its entirety without its liquidation pursuant to section 2 no. 1, sections 62, 68 subsection 1 no. 1 in conjunction with sections 46 ff UmwG (German Law Regulating Transformation

of Companies). The LARNAX GmbH shareholders' meeting gave its consent to the merger agreement on August 11, 2005.

### **Segment reports**

Within the reporting period 2005, MediGene's business operations were geared towards the development of anti-cancer and anti-tumor drugs. These activities were divided up into the »Specialty Pharma« and »Biopharma« segments (see p. 31 ff.).

The »Other« segment brings together those items that cannot be allocated clearly to one individual segment.

### **Specialty Pharma**

The Specialty Pharma segment comprises the drug Eligard® and the product candidate Polyphenon® E Ointment.

In the last financial year, important milestones were reached with the marketing of the one-month and three-month Eligard® products for the treatment of advanced prostate cancer: after the approval process of mutual recognition for Eligard® had been completed successfully in 22 other European countries in December 2004, the first national authorities granted the country-specific approvals during the financial year 2005. In addition, approval was granted in Switzerland. Accordingly, the drug's marketing has now commenced in several more European countries, including Spain, Portugal, Switzerland and the Netherlands. Eligard® has been marketed in Germany since May 2004. All of the planned market launches are scheduled for completion in the financial year 2006. The drug is being marketed in Europe for the treatment of advanced prostate cancer by MediGene's partner Astellas Pharma.

At the end of September, as planned, MediGene submitted its application for approval to market Polyphenon® E Ointment for the treatment of genital warts to the US regulatory authority FDA (Food and Drug Administration). The FDA accepted the application for the approval of Polyphenon® E Ointment in December 2005 and began its review. As the minimum period is one year, the market launch of Polyphenon® E Ointment can be expected in 2007. MediGene holds the global marketing

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rights for the drug and plans to apply for approval in Europe in 2006. At the end of the second quarter of 2005, MediGene had completed a phase II clinical trial with Polyphenon® E Ointment for the treatment of actinic keratosis, a precursor of skin cancer. The primary objective of the trial, statistically significant proof of efficacy, was not achieved. Altogether, 62 patients participated in the trial, of whom 42 were treated with Polyphenon® E Ointment and 20 exclusively with ointment basis (»placebo«) over a period of four months.

### **Specialty Pharma**

In T€	2005	2004	Change
Total revenues	15,591	12,694	23%
Cost of sales	9,077	5,930	53%
Gross profit	6,514	6,764	-4%
Selling expenses	309	152	103%
R&D expenses	4,815	6,907	-30%
EBIT	1,390	-295	> 200%
Average number of employees	21	18	17%

### **Total revenues Specialty Pharma**

In T€	2005	2004	Change
Product revenues and royalties	10,774	4,501	139%
Milestone and upfront payments	4,761	8,000	-40%
R&D payments from partners	0	0	_
Research grants	0	0	_
Other income	56	193	-71%
Total	15,591	12,694	23%

Total revenues of 15,591 T€ recorded for the Specialty Pharma segment were generated solely by the marketing of Eligard®. The cost of these sales amounted to 9,077 T€ and contain not only the cost of purchasing Eligard®, but also a milestone payment to the licensor QLT Inc. R&D expenses within this segment decreased by 30% to 4,815 T€ (2004: 6,907 T€) as a result of the completion of the clinical trial for Polyphenon® E Ointment in the indication genital warts. There were no significant R&D costs for the marketed drug Eligard®. Costs were incurred in the pre-clinical development of Polyphenon® E Ointment and the implementation of a phase II trial in the actinic keratosis indication. Further R&D expenses were incurred in connection with the preparation, drafting and

submission of the marketing authorization application of Polyphenon® E Ointment in the USA.

### **Biopharma**

MediGene's activities for the product candidate EndoTAG-1 and the technology platform EndoTAG are reported in the Biopharma segment. The technology of oncolytic herpes simplex viruses (HSV) and the product candidates NV1020 and G207 are also allocated to this segment.

In August, MediGene began a clinical phase II trial with the drug candidate EndoTAG-1 for the treatment of advanced pancreatic carcinomas. EndoTAG-1 is a combination of the established active substance Taxol with a carrier system that selectively brings the substance to newly formed blood vessels in the tumor. The destruction of the tumor's blood vessels aims at reducing the inflow of nutrients and thereby starve the tumor. In addition to the safety and tolerability of the drug, the trial that has now begun is concentrating mainly on the clinical efficacy of various dosages of EndoTAG-1 in combination with Gemcitabin®, a cytostatic that has already been approved for pancreatic carcinoma therapy. It is planned that around 200 patients in some 20 centers in four European countries will take part in the trial. The recruitment of patients for the project is going according to plan. An interim analysis is planned for the end of 2006.

In the field of oncolytic herpes simplex viruses, MediGene is presently conducting two clinical development programs. Since September 2004, the virus strain NV1020 has been undergoing tests in a clinical phase I/II trial for the treatment of liver metastases derived from colon cancer. The trial will investigate the safety, tolerability and efficacy of treatment with NV1020 and their synergies with chemotherapy. Some 30 patients in up to seven clinical centers in the USA are to be treated during the trial. An interim analysis is planned by the end of 2006, and MediGene expects to receive the complete trial data during 2007.

Since June, another virus strain, G207, has been undergoing a clinical phase I trial at the University of Alabama at Birmingham, USA. G207 is being examined for its suitability to treat malignant brain tumors. This herpes simplex virus was genetically modified to destroy tumor cells selectively without damaging healthy tissue. The trial is investigating the safety, tolerability and efficacy trends of G207, as well as

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a potential synergetic effect in conjunction with radiotherapy.

## Biopharma

Біорііатіна			
In T€	2005	2004	Change
Total revenues	4,030	226	> 200%
Cost of sales	0	0	_
Gross profit	4,030	226	> 200%
Selling expenses	0	0	_
R&D expenses	11,182	8,720	28%
EBIT	-7,152	-8,494	-16%
Average number of employees	57	57	0%

#### **Total revenues Biopharma**

<u>-</u>			
In T€	2005	2004	Change
Product revenues and royalties	0	0	_
Milestone, upfront and one-off payments	4,000	0	_
R&D payments from partners	0	225	-100%
Research grants	0	0	-
Other income	30	1	> 200%
Total	4,030	226	> 200%

In the Biopharma segment, MediGene realized a license payment in 2005 that it had received on conclusion on a non-exclusive licensing agreement with the Glaxo Group Limited. In the Biopharma segment there are currently no partnerships from which R&D payments were received.

R&D expenses increased by 28% to 11,182 T€ (2004: 8,720 T€) in 2005. This can be attributed not only to the resumption of the EndoTAG program

and the start of the trial for the product candidate EndoTAG-1, but also the progress in the clinical development of NV1020. The development of G207 is receiving significant support from the University of Alabama and the National Cancer Institute in the USA.

## Intellectual property

In compliance with the corporation's strategy of obtaining patent protection for technologies and products in development, numerous patent applications for various work results from these technologies and products were filed, or exclusive licenses have been acquired for relevant fields. As the proprietor or licensee, the MediGene group currently holds rights to the following patents and patents pending:

Patents granted or allowed

	Specialty Pharma	Biopharma
Germany/Europe	5	17
USA	2	42

## Patents pending

	Specialty Pharma	Biopharma
Germany/Europe	2	34
USA	4	40
International	7	50

## Rigorous patent strategy as foundation of commercial success

The commercial success of MediGene will significantly depend on its success in obtaining and maintaining patent protection for the products and technologies on the relevant geographical target markets. For this reason the company is striving to secure its own products, processes and technologies with patents. In MediGene's opinion, its patent applications cover innovative technologies with potential commercial significance. The company is assuming that it will be able to benefit from its previous patent applications. Due to the long period of time required to examine patent applications, many of MediGene's applications are still pending.

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MediGene is planning to extend its technology and product portfolio in the future too, by concluding licensing and/or cooperation agreements for products, technologies, processes and other inventions to which third parties hold or claim to hold rights.

### License agreement signed with Glaxo Group Limited

In December 2005, MediGene, in return for a one-off payment, granted the Glaxo Group Limited a non-exclusive license for patents that emerged from MediGene's program for the development of a therapeutic tumor vaccine.

#### Investments

#### Investments in fixed assets decrease

During the year under review, investments decreased by 25%. Investments in fixed assets, including software, amounted to 452 T€ (2004: 605 T€) and were spent primarily on laboratory equipment and information technology. No investments were made via capital lease contracts in the year under review (2004: 325 T€).

Of the aforementioned 452 T€, 3 T€ were allocated to the Specialty Pharma segment and 243 T€ to the Biopharma segment. The investments in the Biopharma segment were accounted for mainly by the procurement of laboratory equipment.

Investments amounting to 206 T€ were reported under »Other«. The investments recorded in this segment were incurred in the expansion of the infrastructure in the information technology field and the marketing and quality assurance divisions.

All in all, the investments were spread out over a multitude of devices and facilities. There were no individual investments of note (> 100 T€) in the period under review.

## **Assets position**

Cash position 37.6 million €; equity ratio 91%

Compared with the previous year, the balance sheet total decreased by 22% to 57,062 T€ (31.12.2004: 72,894 T€). The overall equity ratio increased from 85% in 2004 to 91% in the financial year 2005.

The cash position declined to 37,625 T€ (2004: 48,460 T€) as at December 31, 2005.

Total fixed assets – excluding goodwill and financial assets – decreased by 11% to 7,680 T€ (2004: 8,585 T€), of which 1,137 T€ (2004: 1,565 T€) were accounted for by tangible fixed assets. Intangible assets were written down from 7,020 T€ to 6,543 T€, as planned. These largely comprise the patents and licenses for the EndoTAG® products and technology that were acquired in 2004.

The book value of the capitalized lease assets as part of fixed assets decreased by 56%, from 408 T€ to 180 T€ as at December 31, 2005. The decrease results from expired lease contracts and the consequential transfer of the leased objects to fixed assets, as well as depreciation of capitalized lease items.

The goodwill of 9,226 T€ did not change as at the closing date December 31, 2005. The goodwill was capitalized in the course of the acquisition of the subsidiary MediGene, Inc. The impairment test for the goodwill was based on the two projects G207 and NV1020. The fair value established for the two projects using the discounted cash flow method exceeds the book value (cf. note F) (41), see p. 67).

The long-term investments contain 233,918 shares in the Canadian company QLT Inc. MediGene did not sell any shares in 2005. As at the closing date December 31, 2005, however, the item was depreciated with the result that the value of MediGene's QLT shares then amounted to 1,258 T€ (2004: 2,761 T€). Accordingly, a loss of 1,512 T€ was realized in the period under review. The valuation is based on the exchange rate of 1 € to 1.1825 US\$ that prevailed on the closing date.

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The decrease in current assets can be attributed mainly to the use of cash and cash equivalents. No stocks of Eligard® were available as at the closing date. Eligard® is not bought for stocking-up purposes, but for reselling to the marketing partner soon after purchase. Research and development materials are not reported as inventories; instead, they are expensed as they occur.

There were no receivables of note at the end of the period under review (2005: 2 T€; 2004: 115 T€).

The other current assets amount to 1,174 T€, of which 861 T€ are attributable to deferrals of license income from the cooperation with Astellas Pharma.

Equity decreased in the period under review, primarily as a result of the deficit for the period. In the financial year 2005, 43,840 shares were issued against cash as part of the exercise of stock options and convertible bonds. An additional 199,648 shares were created by the conversion of an outstanding convertible bond.

Borrowed capital (long-term and short-term liabilities) decreased by 53% altogether and amounted to 9% of the balance sheet total as at the closing date (5,285 T€).

Long-term liabilities decreased from 1,880 T€ to 312 T€. The bulk of this decrease (1,314 T€) was accounted for by the conversion of bonds into shares.

Development of the assets and capital structure

In T€	2005	2004	Change
Assets			
Long-term investments	1,355	2,894	-53%
Goodwill	9,226	9,226	0%
Fixed and intangible assets	7,680	8,585	-11%
Liquid assets	37,625	48,460	-22%
Other assets	1,176	3,729	-68%
Total assets	57,062	72,894	-22%
Liabilities			
Shareholders' equity	51,777	61,712	-16%
Long-term liabilities	312	1,880	-83%
Current liabilities	4,973	9,302	-47%
Total liabilities and equity	57,062	72,894	-22%
Liquidity cover ratio	66%	66%	
Equity ratio	91%	85%	

The 47% decrease in current liabilities, from 9,302 T€ to 4,973 T€, results from the full repayment of a loan granted by Aventis as part of a R&D-cooperation (2,106 T€), the redemption of an obligation to the receiver of the former Munich Biotech AG (1,000 T€) and the pro-rata redemption of a deferred revenue item in connection with further approvals of the drug Eligard® in Europe (1,333 T€).

As at December 31, 2005, other current liabilities included, among other things, outstanding license payments to QLT Inc., liabilities for taxes and social benefits and for bonuses, clinical trials and the production of the trial materials.

MediGene has trade payables amounting to 845 T€ in the form of unsettled invoices sent to the company, primarily for services used.

The deferred revenue item of 667 T€ results from the partial recognition of an upfront payment of 4 million € that MediGene had received in January 2004 on conclusion of the marketing partnership with Astellas Pharma Europe Ltd. The deferred revenue item will be released pro rata to income when Eligard® receives market approval in another European country.

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The liquidity cover ratio, calculated as the proportion of cash and cash equivalents in the balance sheet total, was 66% as at the closing date (2004: 66%).

Working capital, i.e. the difference from current assets and liabilities, decreased by 21%, from 42,887 T€ to 33,828 T€, primarily as a result of the decrease in cash and cash equivalents. Current assets include cash and cash equivalents as well as other investment assets

As at December 31, 2005 there was a rental security and bank guarantee amounting to 260 T€ (2004: 206 T€). The increase in the rental guarantees results from the rental of new office premises at the German site. No contingencies were entered into for the benefit of members of the company's management bodies.

As part of the acquisition of the assets of the former Munich Biotech AG, MediGene undertook to make milestone payments to the receiver. Depending on the clinical success of EndoTAG-1, the first payments will become due when the clinical phase III begins and will total 9.5 million €.

A total of 121 T€ will become due for capitalized leased items next year, and a total of 3,815 T€ will become due for operational lease contracts in the next five years.

## **Financial position**

Cash used in operating activities decreases further

The cash used in operating activities is derived indirectly from the net loss for the year. The 14% decrease in cash used by operating activities, from 12,096 T€ (2004) to 10,437 T€ (2005) results from the reduction in the net loss caused by higher revenues on the one hand and reduced R&D expenses on the other

In contrast to the previous year's net cash inflow from investing activities of 4,785 T€, a cash outflow of 413 T€ was reported in 2005. In 2004, a net inflow of 5,047 T€ resulting from the acquisition of the assets of Munich Biotech AG was reported. At the same time, additional investment in fixed assets increased from 280 T€ (2004) to 452 T€ in the year under review.

The cash inflow from financing activities amounted to 61 T€ in the period under review (2004: 34,341 T€). In the previous year, MediGene received approx. 35.3 million € from cash capital increases.

In August 2005, the repayment of a loan granted by Aventis was completed. In 2005 a total of 2,106 T€ was repaid and the corresponding current liability was released.

Incoming payments of 260 T $\in$  (2004: 61 T $\in$ ) resulting from the exercise of options and convertible bonds were posted. The cash outflow from financing lease obligations decreased from 313 T $\in$  (2004) to 267 T $\in$ .

In the year under review, cash and cash equivalents posted a net decrease of 10,835 T€, including exchange rate fluctuations amounting to -46 T€. Cash and cash equivalents at the end of the financial year amounted to 37,625 T€, representing 66% of the balance sheet total (2004: 66%).

As at the closing date, in addition to the financing lease obligations, there remained liabilities of 250 T€ for the settlement of employee claims. There were no open credit lines. The level of cash and cash equivalents corresponds to the net cash position.

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## Change in the cash position in the period under review

In the financial year 2005, the change in the liquid funds and securities reported in the balance sheet (cf. page 49 »Consolidated balance sheet«) led to a net cash burn rate of 10,835 T€, including cash inflows of 68 T€ resulting from the exercise of options. In the comparable period of the previous year, a net cash inflow of 27,016 T€ was posted. This figure includes 35,340 T€ and was accounted for by net income from capital increases and incoming payments from the exercise of options and convertible bonds. In addition, a cash inflow of 5,047 T€ from the acquisition of MediGene Oncology GmbH was posted in the third quarter 2004.

#### Development of cash and cash equivalents

In T€	2005	2004	Change
Net cash used			
in operating activities	-10,437	-12,096	14%
in investing activities	-413	4,785	-109%
in financing activities	61	34,341	-100%
Currency translations	-46	-14	>200%
Decrease/increase in cash and cash equivalents	-10,835	27,016	-140%
Cash and cash equivalents at beginning of period	48,460	21,444	126%
Cash and cash equivalents at end of period	37,625	48,460	-22%
in % of balance sheet total	66	66	

## Monthly net cash burn rate from operating activities

According to the consolidated cash flow statements, the net cash burn rate from operating activities in the financial year 2005 amounted to 10,437 T $\in$  (2004: 12,096 T $\in$ ), giving an average monthly rate of 870 T $\in$  (2004: 1,008 T $\in$ ).

#### **Human Resources**

## Number of group employees unchanged

As at the end of 2005, the number of MediGene's employees totaled 114, comprising 107 in Martinsried (2004: 105 employees) and seven at MediGene, Inc. in the USA (2004: nine employees). The subsidiary MediGene, Inc. is presently being continued with the departments »Clinical Development« and »Regulatory Affairs«. Personnel expenses amounted to 9,628 T€ in the period under review (2004: 8,389 T€).

**Employees by function (as at Dec. 31)** 

	2005	2004	Change
Business development and general administration	34	35	-2%
Research and development	80	79	1%
Total	114	114	0%

Employees by region (as at Dec. 31)

	2005	2004	Change
MediGene AG, Martinsried	107	105	2%
MediGene, Inc., San Diego	7	9	-22%
Total	114	114	0%

## Employees by function1)

30% Business development and general administration

70% Research and

development

<sup>1)</sup> as at December 31, 200

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## **Executive Board compensation 2005**

			Other variable compensation with a long-term incentive	
Executive Board member	Fixed compensation	Variable compensation	Number of stock options	Value of Options
	in T€	in T€	no	in T€
Dr Peter Heinrich, Chief Executive officer	237	110	20,000	95
Alexander Dexne, Chief Financial Officer	185	84	20,000	95
Dr Ulrich Delvos, Chief Operating Officer	216	72	5,000	24
Total	638	266	45,000	214

In addition, 70 T€ were expensed for pension of Executive Board Members.

## **Supervisory Board compensation 2005**

Supervisory Board member	Fixed compensation	Variable compensation	Variable compensation with a long- term incentive (no. of convertible bonds or stock	Compensation for individually performed services
	in T€	in T€	options)	in T€
Prof. Dr Ernst-Ludwig Winnacker Chairman	48	25	0	0
Dr Norbert Riedel Deputy Chairman	36	19	0	0
Dr Pol Bamelis Member	24	12	0	0
Sebastian Freitag Member (since June 10, 2005)	12	5	0	0
Dr Alexandra Goll Member (until June 10, 2005)	12	5	0	0
Dr Manfred Scholz Member	24	8	0	0
Michael Tarnow Member	24	12	0	0
Total	180	86	0	0

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## **Executive Board and Supervisory Board compensation**

### **Executive Board compensation**

The total compensation paid to the members of the Executive Board in the last financial year amounted to 974 T€ (2004: 736 T€). The compensation paid to the Executive Board members comprises fixed and variable components, as well as performance incentives to increase the value of the company in the long term. The criteria for the variable compensation components are laid down in advance each year. The long-term compensation components consist of stock options. The intention of this 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 made to the Board's members.

### **Supervisory Board compensation**

The compensation paid to members of the Supervisory Board in 2005 amounted to 266 T€ (2004: 197 T€). The Supervisory Board members' total compensation comprises a fixed cash amount and fees for attending meetings. The consideration of the scope of the members' activities takes the duties of the Chairman and Deputy Chairman into account. Information about subscription rights of members of the management bodies is provided under item p. 84). No advance payments were made to the board.

#### **Procurement**

Procurement is focused on the drug Eligard®, as well as services, chemicals and laboratory supply for research and development. MediGene concerns itself intensively with the development and optimization of the future drugs production processes so that the procurement of their required substances can then be organized efficiently.

## **Procurement of Eligard®**

MediGene purchases the drug Eligard® for the European market exclusively from its licensor and manufacturer QLT Inc. in the USA. The costs thereby incurred are posted as cost of sales. These include milestone payments to the licensor as well as royalties and costs for the purchase of the product.

## **Procurement management for R&D supplies**

MediGene is not restricted to specific raw materials suppliers for its R&D work, instead soliciting quotations from various suppliers as a matter of principle and placing the purchase orders with the most favorably priced supplier, taking all quality considerations into account. The procurement is organized in such a way that MediGene is able to secure supply at the best despite any possible supply bottlenecks or quality problems while optimizing its purchase prices. The cost of purchasing laboratory supplies makes up only a small proportion of total expenses. As long as prices develop within the usual range, procurement costs play only a subordinate part in MediGene's cost structure.

#### Complex demands on service providers

MediGene avails itself of extensive services mainly in the fields of large-scale production and the formulation of therapeutic substances, as well as for the execution of pharmacological, toxicological and clinical trials. The outsourcing of these activities ensures that we will be able to respond to changes in our development portfolio with the required flexibility. The demands made on such services are highly complex and require the purchaser to have a great deal of expertise and experience. The partner selection criteria in such projects, besides quality and efficiency, are punctuality of delivery, reliability and flexibility.

## **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 the stringent statutory requirements, but also strives to keep its laboratory facilities and equipment state-of-the-art. In order to monitor compliance with the regulatory requirements, MediGene has appointed in-house radiation safety, biological safety and waste management officers, a safety engineer and a project manager for genetic research, all of whom are experienced employees trained specifically for their specialist tasks. The safety engineer was also given additional training in accordance with the guidelines of the chemical industry's employers' liability insurance association.

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MediGene provides for the thorough servicing and the continuous maintenance and expansion of its laboratory facilities and equipment. With the help of external service companies, MediGene ensures that all of the accumulated waste materials are properly separated and professionally disposed of or recycled in accordance with the specific requirements. In order to guarantee workplace safety for all of our employees in the laboratories, the safety engineer analyzes the hazards and holds training sessions. In addition, preventive medical checkups are carried out at regular intervals. MediGene complies with all of the significant requirements in the fields of environmental and health protection and safety, and possesses the required permits and authorizations. All of the random inspections and tests carried out by various authorities to date have been passed without any relevant objections.

## Comprehensive risk management system in the interests of shareholder value

## Principles, administration and controlling

MediGene's corporate strategy is geared towards maximizing shareholder value. This necessitates the continuous monitoring and improvement of the decision-making processes. Corporate success implies taking risks and acting accordingly with a sense of responsibility. With this in mind, MediGene's management implements a comprehensive risk management system that is adapted flexibly to new situations and monitored continuously. Organizational safeguarding measures have been established by separating functions. Any activities or business transactions that carry potential risks are never carried out by one employee alone - in every such case, a committee assumes responsibility for the decision-making process and for the decision itself. Work instructions and flows are standardized to ensure the consistent execution of each individual operation. EDP risks are minimized by means of access restrictions and regulations for system development and program maintenance. Forms, worksheets and laboratory journals are used to record and document all of the data obtained. MediGene's controlling function is responsible for the goal-oriented coordination of the planning, information supply, steering and monitoring. In order to reveal any deviations, the company's projects undergo a monthly target-performance comparison whose results are discussed regularly with the project managers and the Executive Board.

## Portfolio steering and evaluation

MediGene's project portfolio is steered actively and evaluated at regular intervals. The steering function includes the drawing up of development plans for each individual project; these are then adopted by a development committee and their observance is monitored by the Executive Board. The regular evaluation of the individual projects is based on the analysis and assessment of their opportunities and risks. The analysis and assessment covers not only the technical risk, but also the patent position and the scientific assumptions of potential competitors. Other areas covered by the evaluation are clinical development considerations, the market approval terms, process development and the portfolio strategy. Another significant element is the analysis of the current and future development of the respective segments on the drug market.

The results are summarized in a feasibility study and a profitability evaluation. This provides the basis for any decision relating to MediGene's overall portfolio and future strategic orientation. MediGene's international scientific advisors critically examine the company's research and development activities from a technical point of view and provide advice based on the latest insights from research and clinical applications.

Particular attention is devoted to intellectual property. MediGene is striving for comprehensive patent protection for both platform technologies and product candidates in order to protect the company against potential competitors. MediGene does not depend on any one single technology; it possesses highly diversified technological and product portfolios, both of which are protected by far-reaching international patents, both pending and granted. Moreover, cooperations with external scientific institutes, universities and other companies provide access to state-of-the-art technologies.

## **Quality assurance**

MediGene's quality assurance system complies with the requirements of the German Pharmaceuticals Act and the »Good Manufacturing Practice (GMP) « guidelines. GMP contains guidelines for the quality assurance of production processes and environments in the manufacturing of drugs and active substances. The observance of GMP guidelines ensures compliance with defined standards in the development and manufacture of pharmaceutical products, with the

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result that evidence of the working methods used can be provided at any time. In the quality assurance field, MediGene has a host of standardized workflows at its disposal.

## Risik report

#### **Procurement risks**

MediGene purchases the drug Eligard® for the European market exclusively from its licensor and manufacturer QLT Inc. in the USA. In principle, there is the risk that the manufacturer will fail to deliver the product. In cooperation with QLT Inc., MediGene has taken precautions that enable it to resort to alternative manufacturers. In individual cases, however, these precautions might not be sufficient to prevent supply bottlenecks.

### **Industry and market risks**

MediGene is subject to the typical industry and market risks that are inherent in the development of pharmaceutical products using innovative technologies. Experience shows that the development of a drug takes 10 to 15 years. In principle, there is a risk that some or all of MediGene's products may not be developed or marketed successfully. There is also the possibility that some product candidates will fail to obtain the regulatory authorities' approval that is 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 insufficiently competitive. Furthermore, third-party proprietary rights may be an obstacle to the products' marketing or other companies could launch drugs that are superior in terms of quality or price on the market.

## **Reimbursement risks**

The commercial success of a drug also depends on whether and to what extent the approved drug is reimbursed by the state-run or private health insurance schemes in the individual countries. In all of the European Union's member states and in many other countries there are price controls and/or other limitations on reimbursements for drugs. MediGene might even be forced to reduce the price of a drug to be admitted to the reimbursement system.

## **Financing risks**

MediGene's currently available equity and its operating cash flow might possibly be insufficient to cover the investment outlays expected and the working capital required in the foreseeable future. It is possible that MediGene will have to raise further funds from external sources. Success in raising additional capital depends on financial, economic and other factors which, in the majority of cases, cannot be influenced by the company's management. It is possible that MediGene will not always have sufficient funds on acceptable terms at its disposal. In such cases, 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 commercial, financial and revenue position and on its future prospects. In the past, however, MediGene has always been able to raise sufficient capital for the future financing of the company's operations. In order to ensure this, also in the future, MediGene is actively pursuing its investor relations and public relations activities.

## Risks arising from development and product liability

MediGene is exposed to the risk of substantial indemnification claims if a patient suffers adverse side-effects while participating in a clinical trial or taking a prescribed drug developed by MediGene. In particular, such claims for indemnification in the event of adverse side-effects could exceed MediGene's insurance coverage and consequently have a negative impact on the company's financial and revenue position as well as its cash flow. Although the procedures used in the clinical trials are designed in such a way that potential adverse effects are identified and evaluated, the possibility can never be ruled out that a drug may cause unexpected adverse side-effects even after obtaining official approval. Such adverse effects could impair the drug's safety profile and be so severe that the drug has to be withdrawn from the market.

## **Employees**

The company is dependent on highly qualified employees in the field of research and development. Companies are engaged in intense competition to recruit employees with practical expertise in the industry. MediGene's commercial success will continue to depend on its success in recruiting suitably qualified and skilled employees for these areas.

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## Portfolio strategy to reduce overall risk

MediGene's overall risk is defined primarily by the individual risks arising in the fields of clinical development, product marketing and corporate finance. MediGene's commercial success and its future existence both depend crucially on successful drug development and commercialization, as well as the conditions on the capital market. MediGene counters the generally very high risk that some individual projects will fail by maintaining a broad product portfolio based on various technologies and scientific approaches that are independent of one another. This reduces but does not completely rule out the risk of individual product failures endangering the company and its survival.

#### Legal risks and patent risks

MediGene's success also depends on its ability to achieve a maximum of patent protection for its technologies and products, to protect its trade secrets, to fend off infringements of these efficiently and to enforce its own rights without breaching the rights of others. MediGene applies confidentiality agreements and contractual use restrictions when cooperating with partners, employees, consultants and other contracting partners.

It cannot be guaranteed that patents will not be challenged, declared invalid or circumvented, or that they will be commercially beneficial for the company. The company intends to take appropriate action against any infringements and to further extend its technology and product portfolio. In the affected areas, however, third parties could assert legally protected interests based on industrial property rights or cooperation, research and license agreements. Further legal disputes cannot be ruled out in the future (see also »Legal disputes« p. 43).

## Risks of unsuccessful drug development

Before their commercialization, MediGene's product candidates have to undergo the pre-clinical development stage, followed by the individual phases of the clinical trials in humans. These trials investigate adverse effects and the efficacy of the substance in question before the application for market approval can be submitted to the respective regulatory authority. After the evaluation of the application and data that were submitted, the authority decides whether to grant market approval. There is a possibility that approval will be denied, or granted only under certain conditions, or that additional data will be required before a final

decision on whether to grant approval can be made. Delays arising in the execution of clinical trials or in patient recruitment may cause increased costs and lead to the postponement of the market launch. The results of pre-clinical and clinical trials are not predictable, and the results obtained in previous trials do not permit any forecasts regarding future trials.

Numerous biotech companies, including MediGene, have experienced setbacks in clinical trials, even after 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.

The company commissions specialist service providers to conduct the required clinical trials. Some of the contracts in question provide for a cancellation right for the respective service provider. The cancellation of a contract by a service provider might cause a serious delay in the execution of a clinical trial, thereby significantly prolonging the development of the drug.

## Risks of low drug sales

The development and marketing of drugs are subject to fierce competition. This applies particularly to the anti-cancer drugs market on which MediGene's activities are focused. Thanks to its commercial potential, this market segment is at the epicenter of many major pharmaceuticals and specialized biotech companies' activities. MediGene's drug candidates target very serious and/or still insufficiently treatable diseases. In each of these indications, a successful drug would have tremendous market potential. If a competitor is the first company to launch a product successfully, MediGene's drug could be less competitive or even in an inferior position, depending on the product's profile and sales performance. MediGene's portfolio strategy is designed to minimize the sales risks.

## Foreign currency risks

MediGene has a subsidiary based in San Diego, USA that is financed by funds from MediGene. In the event of the euro losing value against the US dollar, the cost of operations in the USA will increase. On the other hand, a rise in the value of the euro against the US dollar will require a valuation allowance for MediGene's assets in the USA or denominated in US dollars. Since the US site is small, the impact of foreign currency fluctuations is relatively minor.

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MediGene purchases the materials for marketing the drug Eligard® in the USA, and these are invoiced in US dollars. MediGene sells the drug on the European market, also against US dollars. This reduces the foreign currency risk significantly, as it is related solely to the sales margin realized by MediGene.

In the balance sheet to December 31, 2005, MediGene has reported shares in the Canadian company QLT, Inc. (NASDAQ: QLTI) with a value of 1,258 T€. The value of these shares is also subject to changes in the value of the US dollar against the euro.

## Legal disputes

Prior to the market launch of Eligard®, MediGene had already filed a suit before the German Federal Patents Court for the invalidity of a patent on specifically defined high-molecular, biodegradable polymers of its competitors Takeda Chemical Industries, Ltd., Osaka, Japan and Wako Pure Chemical Industries, Ltd., Osaka, Japan. In the summer of 2004, after the market launch of Eligard®, Takeda Chemical Industries, Takeda Pharma GmbH, Aachen, Germany, and Wako Pure Chemical Industries (Takeda and Wako) sued the partners MediGene and Astellas Pharma GmbH (formerly Yamanouchi Pharma GmbH) for alleged patent infringement before Düsseldorf District Court. In their lawsuit, they argue that the commercialization of MediGene's and Astella's drug Eligard® infringes the aforementioned plaintiffs' patent.

On April 20, 2005, the Third Nullity Board at the German Federal Patents Court decided in an oral hearing that all of the claims from the aforementioned patent that Takeda and Wako were asserting against MediGene and Astellas before Düsseldorf District Court were invalid within the Federal Republic of Germany. Takeda and Wako have appealed against this judgment before the Federal Supreme Court (BGH), whose judgment can be expected by 2007 at the earliest. At the same time, Düsseldorf District Court has suspended the German part of the suit for patent infringement until the final and absolute decision on the suit for invalidity.

There is also a parallel court case regarding patent infringement in the USA, in which MediGene's supplier and licensor QLT USA Inc., Fort Collins, USA, (formerly Atrix Laboratories Inc.) and the US market-

ing partner of QLT USA Inc., Sanofi-Synthelabo Inc., New York, USA, are being sued on grounds of patent infringement by Takeda Abbott Pharmaceutical Product Inc., Takeda Chemical Industries, Ltd. and Wako Pure Chemical Industries, Ltd. Based on the current status of the case, it can be assumed that this legal dispute will not have any impact whatsoever on the selling of Eligard® in Europe.

In May 2004, in order to eleminate any legal uncertainties, the company opposed European patent no. EP 0 814 823 B1 of Indena S.p.A., Milan, which covers specific polyphenol fractions in tea. In June 2004, Indena S.p.A. thereupon restricted the patent to a scope which is of no significance for MediGene. In December 2005, the Opposition Division of the European Patent Office repealed the patent in its entirety. At present it is uncertain whether Indena will appeal this decision.

## Major events since the closing date

MediGene and Bradley Pharmaceuticals conclude marketing and development partnership for Polyphenon® E Ointment

Effective from January 30, 2006, MediGene initiated a marketing and development partnership with Bradley Pharmaceuticals for the marketing of Polyphenon® E Ointment in the USA. The period of validity of the contract covers at least the duration of the underlying patents. Bradley Pharmaceuticals, a US-based specialty pharmaceuticals company that focuses mainly on dermatology, will promote and market the drug for treating genital warts in the USA. In addition, MediGene and Bradley have agreed on a development partnership for the purpose of testing the application of Polyphenon® E Ointment for other skin diseases.

Depending on the achievement of specified milestones, MediGene will receive stage-by-stage payments totaling up to 69 million US\$, including a one-off payment of 5 million US\$ when the contract is signed. In addition, MediGene will receive royalties on revenues generated by Polyphenon® E Ointment. The milestone payments are bound to the progress made in the development, approval and marketing of Polyphenon® E Ointment in the genital warts and actinic keratosis indications and to particular revenue targets.

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Within the framework of the agreed development partnership, Bradley will assume the bulk of the costs that are incurred if the Polyphenon® E Ointment is developed for further dermatological indications. MediGene has the right to commercialize all of the development results outside of the USA. Within the United States, Bradley holds the marketing rights for Polyphenon® E Ointment in the treatment of all skin diseases.

No further changes influencing the business situation had occurred by February 1, 2006.

### **Outlook** and forecast

The forecasts refer to the financial years 2006 and 2007.

#### **General economic conditions**

The economic indicators at the start of 2006 are indicating that the economy in the euro zone will continue with its moderate course of growth. In addition, money market interest rates are expected to remain stable at a relatively low level.

## **Expected development of the biopharmaceuticals industry**

Drugs for the treatment of tumor diseases are already accounting for the largest proportion of the global drugs market. The experts are forecasting the market volume for cancer drugs to grow continuously over the next few years. It is being forecast that global revenues will total more than 60 billion US\$ in 2009; the current market volume is already approx. 50 billion US\$ (source: Datamonitor 2005).

The inadequate efficacy of therapies that are currently available and the increasing frequency of tumor diseases will continue to boost demand for innovative drugs. In the process, market growth will be driven additionally by innovative forms of therapy which, with high efficacy and slight side-effects, can bring about significant improvements in the therapy provided. In the future, these could include MediGene's EndoTAG® technology and the oncolytic herpes simplex viruses.

In view of the continuing increase in the cost pressure on the service providers in the field of medical care, there is a possibility of legislation to reduce drugs costs; these could also affect the biopharmaceuticals industry in Europe and the USA.

### Focus on drugs for the treatment of tumor diseases

## Market launches of Eligard® in Europe scheduled for completion in 2006

The one-month and three-month sustained release forms of Eligard®, an LH-RH agonist for the treatment of advanced prostate cancer, are now being marketed by MediGene's partner Astellas Pharma not only in Germany, but also in other European countries including Spain, Portugal, Switzerland and the Netherlands. The market launch process in Europe is scheduled for completion in 2006, with the result that Eligard® will then be marketed in a total of 24 European countries. In 2006 MediGene is expecting milestone payments from Astellas Pharma for one outstanding national approval and further market launches. MediGene is also expecting that the marketing of the drug in additional countries will lead to a further increase in sales revenues from Eligard®.

## Four-month and six-month sustained release Eligard® products offer additional potential

In addition to the licenses for the one-month and three-month sustained release products, MediGene had acquired additional options on European marketing licenses for the four-month and six-month products in 2001. These sustained release products are also covered by the contract concluded with Astellas Pharma. Both products, for which there are no approved rival preparations in Europe, provide additional opportunities to increase the value of the product. These formulations can be launched on the market in 2007 at the earliest. Both sustained release products have already been approved and launched on the market in the USA.

## Polyphenon® E Ointment – application for market approval in the USA is being processed by the FDA

Polyphenon® E Ointment is being developed for the treatment of benign tumors in the genital area, such as genital warts.

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In the third quarter of 2005, MediGene submitted its marketing authorization application for Polyphenon® E Ointment in this indication to the FDA. The FDA accepted the application for the approval of Polyphenon® E Ointment in December 2005 and began with its review. The minimum review period is one year. If Polyphenon® E Ointment is approved, its market launch can be expected in 2007. MediGene concluded a marketing and development partnership with Bradley Pharmaceuticals for the marketing of Polyphenon® E Ointment in the USA (see Major Events Since Closing Date, p. 43).

## Polyphenon® E Ointment – application for market approval in Europe planned

MediGene is planning to submit a marketing authorization application in Europe during the financial year 2006. The relevant preparations are already being made.

## Polyphenon® E Ointment – further indications

Decisions regarding further development of the Polyphenon® E Ointment for additional indications, such as actinic keratosis, will be made within the framework of the partnership with Bradley Pharmaceuticals. The successful development of the ointment in an additional indication would open up further commercial potential.

# EndoTAG-1 – interim analysis of the ongoing clinical phase II trial expected at the end of 2006

In August 2005, MediGene started a clinical phase II trial with the drug candidate EndoTAG-1 for the treatment of pancreatic carcinomas. In addition to the safety and tolerability of the drug, the trial concentrating mainly on the clinical efficacy of various dosages of EndoTAG-1 in combination with Gemcitabin®, a cytostatic that has already been approved for pancreatic carcinoma therapy. It is planned that around 200 patients in some 20 centers in four European countries will take part in the trial. An interim analysis is planned for the end of the financial year 2006. Clearly positive results from this trial in respect of the efficacy and side-effects of EndoTAG-1 can significantly increase both the project value and the value of the company.

## EndoTAG-1 – expansion of the clinical development program into other indication fields planned

MediGene is currently preparing to expand the clinical development program for the drug candidate EndoTAG-1. Appropriate trials are being prepared in the treatment of solid tumors. The first additional trial is scheduled to begin in 2006.

## NV1020 – the first results from the ongoing clinical phase I/II trial expected for end of 2006

In September 2004, MediGene initiated a clinical phase I/II trial of the oncolytic virus NV1020 in the indication liver metastases deriving from colon cancer. The goal of this trial is to investigate the safety, tolerability and efficacy of treatment with NV1020 and to analyze possible synergies with chemotherapy. Some 30 patients in up to seven clinical centers in the USA are to be treated during the trial. Interim data are expected by the end of 2006. MediGene is expecting to receive the full data from the trial during 2007. Positive trial results can increase the value of the project while simultaneously facilitating the conclusion of a development partnership with a biotech or pharma company. The maximum annual sales potential of NV1020 upon successful completion of its clinical development is estimated at more than 200 million €.

### G207 – clinical phase I trial continues

At the beginning of June 2005, MediGene announced the start of a clinical phase I trial for the drug candidate G207 for the treatment of malignant brain tumors. The trial is investigating the safety, tolerability and efficacy trends of G207, as well as a potential synergetic impact in conjunction with radiotherapy. MediGene is assuming that the trial will continue throughout 2006. The trial is not expected to finish until 2007 at the earliest.

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#### R&D projects – goals achieved in 2005:

#### Expectations for 2005

Specialty Pharma		
Eligard®	Market launch in other European countries.	Achieved
Polyphenon® E Oint- ment	Submission of market authorization application for the USA and preparation for European market approval.	Achieved
	Conclusion of a development and marketing partnership for the USA.	Not achieved
Biopharma		
EndoTAG-1	Resumption of clinical development program phase II.	Achieved
NV1020	Continuation of clinical phase I/II trial.	Achieved

## R&D projects - status expected for December 2006:

## Goals for 2006

Specialty Pharma		
Eligard®	Market launch of Eligard® in other European countries.	
Polyphenon® E Oint- ment	Conclusion of a development and marketing partnership in the USA. Achieved in January 2006.	
	Preparation and submission of marketing authorisation application in Europe.	
Biopharma		
EndoTAG-1	Interim analysis of the ongoing phase II trial.	
NV1020	Interim data by the end of 2006. Publication of full trial data in 2007.	
G207	Continuation of the clinical phase I trial.	

## Expansion of technology and product portfolios remains strategic goal

The licensing of products such as Eligard® continues to play an important part in MediGene's strategy. In the future, MediGene intends to expand its technology and product portfolios in order to enhance its chances of achieving sustained growth. For that reason, licensing, mergers and acquisitions are important strategic options for extending and strengthening MediGene's product portfolio.

#### **Financial forecast**

Revenues of 30 million € and achievement of breakeven planned For 2006, MediGene is expecting to generate revenues of approx. 30 million € and reach breakeven in EBIT terms. The decisive factor in the achievement of the planned financial targets is the approval of Polyphenon® E Ointment in the USA before the end of the financial year 2006. Further assumptions for the fulfillment of the financial plan for 2006 are that the market launches of Eligard® in Europe go according to plan and that this leads to a further increase in product revenues.

On the basis of the revenue and results forecast, the cash position is expected to be at 37 million  $\in$ .

For 2007 MediGene is planning to further increase revenues. Key assumptions include the successful launch of the Polyphenon® E Ointment in the US market in the first half of 2007 and further increasing revenues from Eligard®. Compared to the forecast 2006 MediGene's Management expects lower revenues from milestone payments in 2007 resulting in a reduced gross margin. Therefore, EBIT 2007 is expected to be below the EBIT forecast 2006.

#### R&D remains focal point

No major investments in fixed assets are planned for 2006 and 2007. Research and development remains the largest cost pool.

## Total number of employees to increase in financial year 2006

The company is planning to strengthen the clinical development and quality assurance areas with selective hiring. The total number of employees will therefore increase slightly in 2006. In order to further improve our employees' professional and personal skills, we will continue to provide in-house and external ongoing training. The group expects to have 135 employees on its payroll by the end of 2006.

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#### Investments

No major investments (> 100 T€) are planned for 2006 and 2007.

### **Future procurement**

As far as procurement is concerned, MediGene does not expect developments in 2006 to deviate from those in 2005. In 2006, MediGene will purchase the drug Eligard® from QLT Inc. for the European market.

## Residual dividend policy

MediGene pursues the concept of residual dividend distribution: this stipulates that dividends should be paid each time the company's financial resources cannot be reinvested in such a way that they will yield at least the same risk-equivalent return that shareholders could achieve on the capital market. This means that the residual amount of the financial resources that cannot be used in the interests of shareholders, in consideration of the given number of product developments and the company's known profitability criteria, should be distributed. Consequently, the dividend that MediGene may distribute at some point in the future will not be an indication of the company's revenue potential. In the medium term, MediGene will invest the 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 to the legal corporate structure are planned.

**Environmental protection exceeds the level required** 

The measures already implemented will continue to be pursued. MediGene will continue to provide environmental protection above the level required by the authorities.

#### **Executive Board**

Martinsried, February 1, 2006 MediGene AG

**Dr Peter Heinrich**Chief Executive Officer

Alexander Dexne
Chief Financial Officer

**Dr Ulrich Delvos**Chief Operating Officer

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## **Consolidated income statements**

of MediGene AG for the periods from January 1 to December 31, 2005 and 2004

In T€		Notes No.	2005	2004
1.	Product sales		19,555	12,501
2.	Other operating income		127	637
3.	Total revenues	(32)	19,682	13,138
4.	Cost of goods	(33)	9,077	5,930
5.	Gross profit		10,605	7,208
6.	Selling expenses	(34)	1,100	1,164
7.	General and administrative expenses	(35)	5,023	5,130
8.	Research and development expenses	(36)	15,997	15,627
9.	Operating loss		-11,515	-14,713
10.	Interest income and expenditures	(37)	678	557
11.	Expenses/Income from securities	(37)	-1,512	1,581
12.	Foreign currency exchange gains/losses	(37)	305	-90
13.	Result before income tax		-12,044	-12,665
14.	Net loss from continued operations		-12,044	-12,665
15.	Result from discontinued operations	(38)	-1	-1
16.	Net loss		-12,045	-12,666
	Earnings per share in €:			
	- basic	(44)	-0,65	-0,90
	Weighted average number of shares outstanding		18,560,027	13,996,440

#### IFRS

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## **Consolidated balance sheet**

of MediGene AG as of December 31, 2005 and 2004

Assets	Λ	_	_	_	+-
	А	S	S	е	LS

In T€		Notes No.	Dec. 31, 2005	Dec. 31, 2004
A. Loi	ng-term assets			
I.	Property, plant & equipment	(46)	1,137	1,565
II.	Intangible assets	(47)	6,543	7,020
III.	Goodwill	(41)	9,226	9,226
IV.	Investments	(48)	1,258	2,761
V.	Other assets		97	133
Total	long-term assets		18,261	20,705
B. Cu	rrent assets			
I.	Accounts receivable	(49)	2	115
II.	Cash and cash equivalents	(50)	37,625	48,460
III.	Other current assets	(49)	1,174	3,614
Total	current assets		38,801	52,189
Total	assets		57,062	72,894

Total liabilities and shareholders' equity

	ties and shareholders' equity		1	
In T€		Notes No.	Dec. 31, 2005	Dec. 31, 2004
A. Sh	areholders' equity			
I.	Share capital	(51)	18,766	18,523
	Number of shares issued and outstanding			
	December 31, 2004: 18,522,684			
	December 31, 2005: 18,766,172			
II.	Additional paid-in capital	(52)	258,776	256,882
III.	Accumulated deficit	(53)	-225,710	-213,665
IV.	Net income recognized directly in equity	(54)	-55	-28
Total	shareholders' equity		51,777	61,712
B. Loi	ng-term liabilities			
I.	Long-term debt less current portion	(57)	115	1,674
II.	Other long-term liabilties	(56)	100	55
III.	Capital lease obligation less current portion	(57)	0	115
IV.	Pension accrual	(55)	97	36
Total	ong-term liabilities		312	1,880
C. Cu	rent liabilities			
I.	Trade accounts payable	(56)	845	618
II.	Other current liabilties	(56)	3,343	6,415
III.	Current portion of capital lease obligation	(57)	118	269
IV.	Deferred income	(56)	667	2,000
Total	current liabilities		4,973	9,302

57,062

72,894

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## **Consolidated cash flow statements**

of MediGene AG for the periods from January 1 to December 31, 2005 and 2004

InT€	2005	2004
Cash flow from operating activities		
Net loss	-12,045	-12,665
Adjustments to reconcile net loss to cash used in operating activities:		
Stockbased compensations options/bonds	501	363
Other non-cash income	-1,333	C
Depreciation	1,348	1,362
Gains/losses on sales of property, plant & equipment	-18	30
Unrealized gains/losses from investments	1,512	-1,581
Changes in:		
Other assets	2,588	-372
Trade accounts payable	227	-3,079
Other liabilities and deferred revenue	-3,217	3,846
Net cash used by operating activities	-10,437	-12,096
Cash flow from investing activities		
Purchases of property, plant & equipment	-452	-280
Sales of property, plant & equipment	39	18
Net cash from acquisition of MediGene Oncology GmbH	0	5,047
Net cash from investing activities	-413	4,785
Cash flow from financing activities		
Proceeds from capital increase	0	36,641
Expenses capital increase	0	-2,801
Proceeds from stock options	260	61
Repayments of/Proceeds from loans	68	-747
Proceeds fron convertible bonds	0	1,500
Principal payments under finance lease obligations	-267	-313
Net cash from financing activities	61	34,341
Currency translation	-46	-14
Decrease in cash and cash equivalents	-10,835	27,016
Cash and cash equivalents at beginning of period	48,460	21,444
Cash and cash equivalents at end of period	37,625	48,460

IFRS

## **Consolidated changes in shareholders' equity**

of MediGene AG for the periods from January 1 to December 31, 2005 and 2004

	Shares	Share capital	Capital reserves	Accumulated losses	Net income directly recognized in equity	Total share- holders' equity
	No.	T€	T€	T€	T€	T€
Balance January 1, 2004 (US-GAAP)	11,206,205	11,206	218,177	-199,943	-220	29,220
IFRS Adjustment	0	0	111	-1,056	975	30
Balance January 1, 2004 unaudited (IFRS)	11,206,205	11,206	218,288	-200.999	755	29,250
Net loss 2004				-12,666		-12,666
Realized gains from disposal of Atrix shares					-756	-756
Non realized profit from QLT shares					-8	-8
Currency translation adjustments					-19	-19
Comprehensive income						-13,449
Capital increase	7,293,722	7,294	40,764			48,058
Expenses capital increase			-2,801			-2,801
Exercised options/bonds	22,757	23	268			291
Expenses on new options/bonds			363			363
Balance December 31, 2004	18,522,684	18,523	256,882	-213,665	-28	61,712
Balance January 1, 2005 (US-GAAP)	18,522,684	18,523	256,411	-212,248	-1,003	61,683
IFRS Adjustment	0	0	471	-1,417	975	29
Balance January 1, 2005 unaudited (IFRS)	18,522,684	18,523	256,882	-213,665	-28	61,712
Net loss 2005				-12,045		-12,045
Non realized profit from QLT shares					8	8
Currency translation adjustments					-35	-35
Comprehensive income						-12,072
Capital increase						0
Expenses capital increase						0
Exercised options/bonds	243,488	243	1,393			1,636
Expenses on new options/bonds			501			501
Balance December 31, 2005 audited	18,766,172	18,766	258,776	-225,710	-55	51,777

IFRS

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## **Consolidated changes in fixed assets**

of MediGene AG for the periods from January 1 to December 31, 2005

In T€			Initial C	ost		
	January 1, 2005	Currency translation adjustments	Addition	Disposal	Reduction from market valuation	December 31, 2005
Fixed assets						
Property, plant & equipment <sup>1)</sup>	6,556	63	452	-371		6,700
Software	197	5	67	0		269
Technical and laboratory equipment	6,359	58	385	-371		6,431
Intangible assets	7,385	39	0	0		7,424
Technology licenses	7,385	39				7,424
	13,941	102	452	-371	0	14,124
Goodwill	11,071	0				11,071
Investments	2,761	0	0	0		2,761
Total	27,773	102	452	-371	0	27,956
1)thereof Leasing	734		0	-95	-314	325

IFRS

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	Depreciation						Value
January 1, 2005	Currency translation adjustments	Addition	Disposal	Reduction from market valuation	December 31, 2005	December 31, 2005	December 31, 2004
4,991	58	865	-351		5,563	1,137	1,565
162	5	28	0		195	74	35
4,829	53	837	-351		5,368	1,063	1,530
365	33	483	0		881	6,543	7,020
365	33	483	0		881	6,543	7,020
5,356	91	1,348	-351	0	6,444	7,680	8,585
1,845					1,845	9,226	9,226
0		1,503			1,503	1,258	2,761
7,201	91	2,851	-351	0	9,792	18,164	20,572
326		167	-95	-253	145	180	408

## Notes on the consolidated financial statements 2005

MediGene AG. Martinsried

## A) Business operations

The MediGene Group consists of MediGene AG and its wholly owned subsidiary, MediGene, Inc. based in San Diego, California, USA. The purpose of the group is the research, development and commercialization of, in particular, technologies applied in molecular biology, processes and products in the field of drugs, pharmaceutical substances and intermediate products, and the rendering of services related to these areas. MediGene AG is a listed company since June 2000 (German Stock Exchange: Prime Standard; ISIN 502090; code MDG).

MediGene AG was founded in 1994 in Martinsried near Munich (Germany) with share capital of 26 T€. In 1996, the company was transformed into a stock corporation. The company's headquarters are located at Lochhamer Straße 11, 82152 Martinsried, Germany. MediGene is entered in the commercial register of Munich Local Court under HRB 115761. MediGene, Inc., the company's only subsidiary at present, was acquired in 2001.

## B) Accounting principles

**Application of international accounting principles** 

As MediGene AG is a capital market-oriented parent company as defined by Article 4 of EU Regulation No. 1606/2002, the application of the International Financial Reporting Standards is mandatory under the aforementioned regulation for the financial year ending on December 31, 2005.

In principle, IFRS requires that all of the standards and interpretations applicable on the balance-sheet closing date of the group's first IFRS financial statements are also applied retrospectively to the previous period.

These consolidated financial statements were for the first time prepared in compliance with the International Financial Reporting Standards (IFRS), as applicable throughout the EU. The Executive Board of the company believes that these consolidated financial statements reflect all of the adjustments that are necessary for the portrayal of the assets, financial and income position at the end of the periods ending in December 2004 and 2005.

Exemption from preparing a management report and consolidated financial statements in accordance with the German Commercial Code

The prerequisites stipulated in section 315a HGB (German Commercial Code) to release companies from the obligation to prepare consolidated financial statements under German commercial law are satisfied.

The companies in the reporting entity have applied standardized accounting and valuation principles.

The individual financial statements of MediGene AG were prepared in compliance with the statutory provisions on the rendering of accounts and the principles of proper accounting that supplement those provisions. In this annual report, the MediGene AG financial statements should be seen merely as information supplementing the consolidated annual report. Full individual financial statements for MediGene AG in accordance with HGB are being prepared separately and will be deposited with the commercial register.

## **General remarks**

The preparation of the consolidated financial statements according to generally accepted accounting principles requires estimates and assumptions by the Executive Board which at the time of accounting influence the revenues, expenses, assets, liabilities and contingencies that are posted. The actual figures may differ from the estimates that the Board makes to the best of its knowledge (cf. paragraph E), (29) »Critical accounting estimates and assumptions«).

## C) Changes in accounting, valuation and reporting principles

(1) First-time adoption of International Financial Reporting Standards (IFRS)

The consolidated financial statements of MediGene as at December 31, 2005 were prepared in accordance with the regulations of the International Financial Reporting Standards for the first time. The transition of the accounting principles from US-GAAP to IFRS was carried out in compliance with the »First-time Adoption of IFRS « regulations in IFRS 1.

In these consolidated financial statements, accordingly, MediGene is applying the standards that are mandatory from December 31, 2005 in their entirety.

MediGene's consolidated financial statements were prepared for the last time using US-GAAP as at December 31, 2004. In those areas where the accounting, valuation and consolidation principles applied under US-GAAP and IFRS diverged, the accounts prepared under US-GAAP for the comparative period were adjusted as appropriate to the IFRS regulations. This applies to both the period under review and the comparative period.

The transitional calculations required under IFRS 1 and the explanations of the effects of the transition to IFRS on the consolidated equity and the consolidated financial statements are contained in paragraph J) (see p. 78) and paragraph O) (see p. 88-90) of the notes.

The adaptation of the accounting and valuation as at January 1, 2004 to IFRS was carried out in compliance with IFRS 1, neutral to results and in favor or at the expense of retained earnings, as though the accounts had always been prepared in accordance with IFRS.

## (2) Relief options in IFRS 1 as per the transition date January 1, 2004 are being used as follows:

## **Business Combinations**

MediGene AG acquired a company in 2001. Medi-Gene's management decided that it would make use of the relief option for corporate mergers provided for under IFRS 1 and that, consequently, the previous accounting principles for corporate mergers carried out before the transition date (January 1, 2004) would not be adapted to the new principles.

### Foreign currency translation

IFRS 1 allows companies to apply the standard IAS 21 (»The Effects of Changes in Foreign Exchange Rates«) prospectively. This means that it is assumed that all of the accumulated currency exchange gains and losses reported according to US-GAAP before the transition date are valued at zero as at the date of transition to IFRS, and that currency exchange differences which arise after the transition date must be reported separately in the balance sheet for each foreign subsidiary.

The differences that emerge are set at zero as at the date of transition from US-GAAP to IFRS in the item »Net income/expenses recorded directly in equity« and the retained earnings are reduced accordingly.

The retained earnings are reported in the balance sheet under the item »Accumulated Deficit«.

#### Compound Financial Instruments

A compound financial instrument is divided into an equity and a borrowings component only if the borrowings component still exists as at the transition date (January 1, 2004). These compound financial instruments are portrayed in accordance with IAS 32 or IAS 39. The equity component is produced by the difference between the issue proceeds and the fair value of the future payment obligations (borrowings component).

#### Share-based compensation

Share-based instruments, such as options and convertible bonds issued to employees are reported in the balance sheet in accordance with IFRS 2. Under this regulation, the reporting of share-based instruments that were issued before November 7, 2002 is waived.

The instruments are valued with the help of a binomial model that takes account of, among other things, blocking periods, hurdle rates, volatility in the underlying instrument and interest rates.

## Other options

No further options in addition to the above are used for the transition from US-GAAP to the new accounting standard.

#### Mandatory exemptions

The application of the mandatory exemptions in IFRS 1 did not give rise to any adjustments.

With the exception of the aforementioned adjustments resulting from the first-time transition to IFRS, deviations of the IFRS regulations from the consolidated financial statements as at December 31, 2004 prepared under US-GAAP had no material impact for MediGene.

## (3) Early application of new standards and interpretations

The following standards and interpretations that were already published but have not yet come into effect were not applied early: IFRS 6, Amendment to IAS 39 (Fair Value-Option and Cash Flow-Hedge Accounting), Amendment to IAS 19, IFRIC 4 and IFRIC 5. Their early and future application has, and will have, no material impact on MediGene's consolidated financial statements.

## D) Consolidation methods, consolidated entity

### (4) Consolidation of subsidiaries

Subsidiaries are companies in which the group has the capacity to determine the financial and business policy; this regularly involves a share of more than 50% in the voting rights. The evaluation of whether a controlling influence prevails takes into account OR considers the existence and impact of potential voting rights that can currently be exercised or converted.

Subsidiaries are reported in the consolidated financial statements (full consolidation) from the point at which the possibility of control has passed to the group. They are removed from the reporting entity on the date when the possibility of control ceases to apply.

The capital is consolidated using the purchase accounting method. This means that the acquisition cost of the purchased shares are offset against the share of the equity attributable to the parent company as at the date of acquisition. Any difference is allocated, in accordance with the proportion of the shares, to the assets and liabilities of the subsidiary up to the proportionate fair value. Any remaining difference is capitalized as goodwill. All of the intercompany receivables and liabilities, revenues, expenses and income, as well as intermediate results within the reporting entity, are eliminated as part of the consolidation process.

The surplus of the acquisition cost of the purchase over the group's share of the net assets calculated at fair value is reported as goodwill, which is subject to an annual impairment test. If the acquisition costs are lower than the net assets of the acquired subsidiary at fair value, the difference is reported directly in the income statement.

The consolidated financial statements include not only the financial statements of MediGene AG, Martinsried, but also the financial statements of the wholly owned subsidiary MediGene, Inc., San Diego. Apart from that, MediGene AG held no other shares in any affiliated companies, associated companies or joint ventures as at December 31, 2005.

The financial statements of the companies reported in the consolidated financial statements have been prepared in accordance with standardized accounting and valuation principles.

Consolidated company	MediGene, Inc.
Head office	San Diego, USA
Percentage stake %	100
Equity as at Dec. 31, 2005 in T€	-413
Net loss for 2005 in T€	-2,837

## (5) Changes in the reporting entity

## LARNAX GmbH

On August 25, 2005, MediGene AG acquired through merger the assets of the wholly owned subsidiary LARNAX GmbH, based in the Martinsried district of Planegg, Munich administrative district, entered in the commercial register of Munich Local Court under HRB 115761, in its entirety without its liquidation pursuant to section 2 no. 1, sections 62, 68, subsection 1 no. 1 in conjunction with sections 46 ff UmwG (German Law Regulating Transformation of Companies). The LARNAX GmbH shareholders' meeting gave its consent to the merger agreement on August 11, 2005. The relevant entry in the commercial register was made on August 25, 2005.

LARNAX GmbH had discontinued its business operations as at December 31, 2003. In March 2003, Larnax GmbH came out of OR was created from MediGene's former cardiology research program.

#### MediGene Oncology GmbH

MediGene also acquired through merger the assets of the wholly owned subsidiary MediGene Oncology GmbH, based in the Martinsried district of Planegg, Munich administrative district, entered in the commercial register of Munich Local Court under HRB 153259, in its entirety without its liquidation pursuant to section 2 no. 1, sections 62, 68, subsection 1 no. 1 in conjunction with sections 46 ff UmwG (German Law Regulating Transformation of Companies). The LARNAX GmbH shareholders' meeting gave its consent to the merger agreement on August 11, 2005. The relevant entry in the commercial register was made on August 25, 2005.

MediGene had acquired all of the shares in MediGene Oncology GmbH, the owner of Munich Biotech AG's assets, on August 13, 2004.

## E) Fundamental principles of accounting and valuation

## (6) Realization of income

In the period under review, MediGene posted income from product sales, milestone and license payments and research and development payments from partners, research grants and other income.

## Income from product sales and recurring license payments

Eligard® has been marketed since May 2004 in Germany as MediGene's first drug. This means that revenues were generated from a drug's commercialization for the first time. In January 2004, MediGene had concluded a partnership for the commercialization of Eligard® with Astellas Pharma Europe Ltd. (formerly Yamanouchi Ltd. hereinafter referred to as Astellas Pharma). MediGene's partner is responsible for the marketing activities in Germany and the rest of Europe. The income from product sales is recognized when the product is delivered to Astellas Pharma. MediGene also receives license payments from the product sales generated by Astellas Pharma. MediGene recognizes license payments in line with the sales revenues posted by Astellas Pharma in each quarter.

## Income from upfront, milestone and non-recurring license payments

In accordance with IAS 18, so-called "upfront" payments (non-recurring advance payments) that MediGene receives from pharmaceutical partners on conclusion of a new contract are collected when specific milestones are reached. When the upfront payment has been received the cash flow increases by the full amount of that payment, and at the same time a deferred revenue item is created. This item is reversed proportionately when a milestone is achieved and is reported in the consolidated income statement as revenue from product sales.

MediGene receives milestone payments when research and development goals defined as part of the cooperation agreements have been attained. Accordingly, these payments are collected and posted to income immediately without any deferral being necessary.

In accordance with IAS 18, non-recurring license payments are basically accrued proportionally over the contractual period. If all risks and potential rewards pass to the licensee, on the other hand, the income is recognized immediately.

R&D payments from partners, research grants and other income Income from research cooperations is posted to net income, in accordance with IAS 20, when the contractually agreed objectives or milestones have been achieved. Contractually agreed payments and scheduled payments not linked to a future performance are posted as income when the cooperation partner confirms that the contractual agreements were fulfilled. MediGene receives pro rata grants when expenses are incurred. The grants are posted to net income when the expenses are reported.

## (7) Research and development expenses

Research and development expenses include personnel expenses, consultancy fees, material and laboratory expenses, services, legal fees and charges and other allocated costs such as rent and electricity, as well as depreciation on laboratory equipment. They are reported immediately with effect on net income.

Development costs are reported in the balance sheet in accordance with IAS 38, paragraph 57. In MediGene's estimation, a development project for pharmaceutical products does not have sufficient certainty to hold out the promise of future benefits until official market approval has been granted. For that reason, these costs are posted to expenses.

#### (8) Earnings per share

Earnings per share are calculated according to IAS 33 »Earnings per Share«.

### Undiluted, or actual, earnings per share

The undiluted earnings per share are calculated by dividing the profit due to the equity suppliers by the weighted average number of issued shares during the financial year.

## Diluted earnings per share

The diluted earnings per share are calculated by increasing the weighted average number of shares in circulation by all of the conversion and option rights. It is assumed that convertible bonds will be exchanged for shares and the net profit adjusted for interest expenses and fiscal impact. For 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 calculated is compared with the number that would have resulted had the stock options been exercised.

## (9) Discontinued operations

The balance sheet reporting of discontinued operations is treated in accordance with IFRS 5 »Non-current Assets Held for Sale and Discontinued Operations«. Discontinued operations are reported in compliance with the obligation to report separately those company operations that are sold or made available for sale. Accordingly, the company reports a separate amount in the income statement containing the after-tax result of the discontinued business segment. The net cash flows that are attributable to operating activities and the discontinued operations' investment and financing activity are reported in the same way. There are assets and liabilities from discontinued operations.

## (10) Foreign currency translation

#### Functional and presentation currency

The consolidated financial statements are presented in euros, the company's functional and reporting currency. The items contained in the financial statements of the US-based subsidiary MediGene, Inc. are valued using the currency of the primary economic environment in which the company operates (the »functional currency«).

#### Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at yearend exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement. Translation differences on nonmonetary items, such as »available-for-sale« investments held at fair value through profit or loss, must be reported as part of their fair value gain or loss. On the other hand, translation differences on non-monetary items, such as »available-for-sale« investments, are included in the fair value reserve in equity. The company has made use of the relief option in IFRS 1 for its currency translation.

### Group companies

IAS 21 »The Effects of Changes in Foreign Exchange Rates« is applied. In the consolidation of the US based subsidiary MediGene, Inc., which prepares its balance sheet in US dollars, the balance sheet items are translated at the rates prevailing on the closing date (closing date rate method). The only exception is equity, which is reported on the basis of the historical exchange rate. Expenses and income are translated into the reporting currency for consolidation purposes at the respective average exchange rate over the course of the year. Translation differences in the balance sheet compared with the previous year's translation are reported without affecting net income. Instead they are directly recognized in equity (»Net income/expense copied directly in equity«).

Receivables and liabilities in currencies other than the functional currency are translated at the daily rate prevailing on the closing date. Purchases and sales in foreign currencies are translated at the daily rate prevailing on the date of the transaction. Foreign currency gains and losses are included explicitly as such in the income statement. The following exchange rates were applied in 2005:

Foreign currency exchange rates 2005 € in US\$

	Rate as at closing date		Average rate for the year
Dec. 31, 2005	1.1825	2005	1.24480
Dec. 31, 2004	1.3621	2004	1.24329

Source: Dresdner Bank AG, reference exchange rates

#### **Assets**

## (11) Property, plant and equipment

Property, plant and equipment are valued at acquisition cost and are subject to regular depreciation using the straight-line method. Property, plant and equipment are depreciated over the expected service life, or in the case of improvements to leased properties over a possibly shorter lease contract period.

Software	3 – 4 years
Technical equipment and laboratory facilities	3-8 years
Improvements to leased properties	8 – 10 years

Subsequent acquisition costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that their future economic benefits will flow to the group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred. If property, plant and equipment are disposed of, the acquisition costs as well as the resultant accumulated depreciation are deleted from the accounts in the year of the disposal. Gains and losses on disposals are posted to results in other income and expenses. The purchase and disposal of property, plant and equipment within the group are eliminated during consolidation.

For details on the development of fixed assets, please see the statement of fixed assets (see p. 52).

## (12) Intangible assets

Intangible assets acquired against payment that have a limited service life are valued at acquisition cost less regular depreciation using the straight-line method. The amortization of intangible assets is based on the following service life which is based on the estimated useful lifespan:

Patents/Licenses for technologies and products	3 - 16 years
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For details on the development of fixed assets, please see the statement of fixed assets.

## (13) Impairment of property, plant and equipment and intangible assets

#### Assets with limited useful life

Assets are subjected to regular depreciation/amortization. They undergo an impairment test if there are any indications that their book value might no longer be realizable. An impairment loss is reported as the amount by which the book value exceeds the asset's realizable value. The attainable amount is the fair value of the asset less disposal costs or the rental value, whichever is higher. For the impairment test, assets are combined at the lowest level for which cash flows can be identified and estimated separately (cash generating units, CGUs). If the book value exceeds the amount of the discounted cash flows, the fair value is measured and, if necessary, the asset is written off at the value.

## Assets with an indefinite useful life

Assets that have an indefinite useful life are not subject to depreciation/amortization and are tested annually for impairment. As at the closing date there were no intangible assets with an indefinite useful life.

The possible impairment of goodwill is tested as part of the annual project evaluation. This evaluation is carried out every year, or during the course of the year if there are any signs of impairment. If an evaluation of this kind reveals an impairment, non-scheduled amortization is required. This calculation is based on forecast cash flows derived from plans for the business unit that were approved by management. The planning period in question encompasses the development and approval phase and the period following

the market launch for which average patent terms of 10 years are assumed, as well as the achievement of maximum revenues 5 years after this point. The current book value is then compared with the result of the project evaluation. The goodwill is allocated to the identified cash generating units in the group in accordance with country of operation and business segment.

#### (14) Inventories

Inventories are stated at acquisition cost. In principle, these acquisition costs are measured on the basis of direct costs including incidental acquisition costs. Inventories are stated at the lower of acquisition cost and net realizable value. Inventories come into being as part of the commercialization of Eligard® and contain the costs incurred in purchasing the goods from QLT Inc.

#### (15) Investments

The group classifies its financial assets in the following four categories:

- Financial assets at fair value through profit or loss
- Loans and receivables
- Held-to-maturity investments
- Available-for-sale financial assets

The classification depends on the purpose for which the investments were acquired. The management determines the classification of its investments at initial recognition and re-evaluates this designation at every closing date.

## a) Financial assets at fair value through profit and loss Did not exist in the year under review or in the pr

Did not exist in the year under review or in the previous year.

## b) Loans and receivables

Are non-derivative financial assets with fixed or determinable payments that are not listed on an active market. They come into being when the group provides a debtor directly with money, goods or services with no intention of trading these receivables. They are included in current assets, except for those with maturities greater than 12 months after the balance sheet date. These are classified as long-term assets. Loans and receivables are reported in the balance sheet under trade receivables and other assets.

#### c) Held-to-maturity investments

Are non-derivative financial assets with fixed or determinable payments and fixed maturities that the group's management has the positive intention and the ability to hold to maturity. The group did not hold any investments in this category during the year.

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

Are non-derivatives that are either designated in this category or not classified in any of the other categories. They are included in long-term assets unless management intends to dispose of the investment within 12 months of the balance sheet date. The shares in the company QLT Inc. USA, are included in this category.

#### e) Valuation of the above categories

All purchases and sales of investments are recognized on the trading date – the date on which the group undertakes to purchase or sell the asset. Investments that are not financial assets carried at fair value through profit or loss are initially recognized at fair value plus transaction costs. Investments are derecognized when the rights to receive cash flows from the investments have expired and the group has essentially transferred all of the risks and potential rewards associated with their ownership.

Unrealized gains and losses arising from changes in the fair value of non-monetary securities classified as available for sale are recognized in equity. When securities classified as »available-for-sale« are sold or impaired, the accumulated fair value adjustments are included in the income statement as gains and losses from investment securities.

The fair values of listed investments are based on current market prices.

If there is no active market for financial assets or if the assets are not listed, the group determines fair value by using suitable valuation techniques.

Loans and receivables and held-to-maturity investments are reported in the balance sheet at net book value using the effective interest method. At each closing date it is assessed whether there is objective evidence that a financial asset or a group of financial assets is impaired. In the case of equity securities classified as »available-for-sale«, a significant or prolonged decline in the fair value of the security below its cost is considered in determining whether the securities are impaired. If any such evidence exists for »available-for-sale« financial assets, the cumulative loss - measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that financial asset previously recognized in profit or loss - is removed from equity and recognized in the income statement. Impairment losses recognized in the income statement on equity instruments are not reversed through the income statement.

#### (16) Trade receivables

Trade receivables are initially recognized at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment. A provision for the impairment of trade receivables is set up when there is objective evidence that the group will not be able to collect all of the amounts due. The amount of the provision is the difference between the book value of the receivable and the present value of the estimated future cash flows, discounted at the effective interest rate. The amount of the provision is recognized in the income statement.

## (17) Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and checks with original maturities of three months or less. They are reported in the balance sheet at nominal value.

## (18) Leases

Lease agreements for property, plant and equipment where the group is the lessee and essentially has all of the risks and potential rewards of ownership are classified under IAS 17 as finance leases. Finance leases are capitalized on commencement of the lease at the fair value of the leased property or the present value of the minimum lease payments, whichever is lower. The lease obligations are carried as liabilities. Each lease payment is allocated between the liability and finance charges in order to achieve a constant interest rate on the finance balance outstanding. The

rental obligations, net of finance charges, are included in other liabilities. The interest element of the finance cost is charged to the income statement. The property, plant and equipment held under finance leases are depreciated over the asset's estimated useful life or the lease term, whichever is shorter.

Leases where the group is the lessee and the major proportion of the risks and potential rewards associated with the ownership of the leased property are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the income statement using the straight-line method over the period of the lease.

## (19) Borrowings

Borrowings are initially recognized at fair value, net of any transaction costs incurred. They are subsequently stated at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method. The group's borrowings consist of research and development loans, finance lease obligations and convertible bonds.

The borrowings are classified as current liabilities unless the group has an unconditional right to defer settlement of the liability for at least 12 months after the balance sheet date.

The fair value of the debt component of a convertible bond is determined using the market interest rate for a similar non-convertible bond. This amount is reported as a liability at amortized cost until the conversion is carried out or the redemption becomes due. The remaining part of the proceeds constitutes the value of the conversion right. This is included in equity, net of income tax effects.

## (20) Shareholders' Equity

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

Costs that are directly attributable to the issuance of new shares or those that are directly connected with the acquisition of a company are contained in the costs of the acquisition in question as part of the consideration for the acquisition.

### (21) Stock options and convertible bonds

The group has set up a share-based remuneration program that is fulfilled by issuing new shares. The fair value of the options that MediGene grants in return for employees' work performances are reported as expenses. The instruments are valued with the help of the binomial model instead of the Black Scholes method that was used in the previous years. The latter cannot be used under IFRS because it does not portray the fair value correctly. The binomial model takes account of, among other things, vesting periods, hurdle rates, volatility of the underlying value and interest rates. The total expenses to be reported over the vesting period of the options comprise the fair value of the options. Equity instruments, such as options and convertible bonds granted to employees are reported in the balance sheet in accordance with IFRS 2. Their reporting waives the inclusion of equity instruments that were issued before November 7, 2002.

On every balance sheet date, the estimate of the number of options expected to be exercisable is re-examined. The effects of any relevant changes to the original estimates are included in the income statement and by making an appropriate adjustment in equity over the remainder of the vesting period.

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

When convertible bonds are issued to employees, the paid-in nominal amount of 1 € is reported in the balance sheet in accordance with IAS 32/39. At the same time, the option right inherent in the convertible bond is valued in accordance with IFRS 2.

When the bonds are converted, the nominal amount is paid in and reported in such a way that  $1 \in$  of the total amount paid in is reported in share capital and the remaining amount, the difference between the conversion price and the nominal amount, in the capital reserve.

In the case of convertible bonds that are divided up into bonds, the conversion price is paid upon issuance. These are also reported in the form of equity and borrowings components. In this case the conversion into share capital requires no additional payment. At the same time, the bond terms include a fixed conversion ratio for the bonds. After their exercise, the equity and borrowings components are liquidated, with  $1 \in \text{per}$  created share instead being reported in share capital and the remaining amount, the conversion price less the share capital component, in the capital reserve.

#### (22) Provisions

Other provisions are formed in accordance with IAS 37 if there is a current obligation to a third party that arose from a past event, that will probably lead to an outflow of resources in the future and whose amount can be estimated reliably. Provisions for obligations that are unlikely to lead to a charge on property in the subsequent year are formed at the current value of the expected outflow of assets. The valuation of the provisions is examined on every closing date. Provisions in foreign currencies are translated as at the closing date.

## (23) Pension accruals

In the group there are various pension schemes. The group has both defined benefit and defined contribution plans. A defined benefit plan is a pension plan that defines an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and salary. A defined contribution plan is a pension plan under which the group pays fixed contributions into a separate entity (fund). The group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all of the employees the benefits relating to employee service in current and previous financial years.

The contributions are recognized as employee benefit expenses when they fall due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available.

The liability recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the balance sheet date less the fair value of plan assets, together with adjustments for unrecognized actuarial gains or losses and past service costs.

As at December 31, 2004, no actuarial gains or losses were reported due to the use made of the relief option in accordance with IFRS 1. The defined benefit obligation (DBO) is calculated annually by an independent actuary using the projected unit credit method. The present value of the DBO is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension liability.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are posted to income over the employees' expected average remaining working lives.

Past service costs are recognized immediately in income, unless the changes to the pension plan are conditional on the employees remaining in service for a specified period of time (the vesting period). In this case, the past service costs are amortized using the straight-line method over the vesting period.

## (24) Termination benefits

Termination benefits are payable when employment is terminated before the normal retirement date, or when an employee accepts voluntary redundancy in exchange for these benefits. The group recognizes termination benefits when it demonstrably has to pay termination benefits as a result of an offer made to encourage voluntary redundancy. Benefits falling due more than 12 months after the balance sheet date are discounted to their present value.

#### (25) Bonus plans

The group recognizes a liability and an expense for bonus payments. This is based on the underlying contractual agreements.

#### (26) Deferred taxes

Deferred taxes are recognized, in accordance with IAS 12, using the liability method for all time differences between the tax base of the assets/liabilities and their book values in the IFRS financial statements. Deferred taxes are valued using the tax rates (and tax regulations) that apply on the balance sheet date or have been passed and are expected to be legally effective when the deferred tax receivable is recognized or the deferred tax liability is settled. Deferred tax receivables are reported to the extent that a taxable profit is likely to be available, against which the time difference can be used (OR applied). Deferred tax assets on loss carryforwards are recognized only if a realization is guaranteed with sufficient certainty.

#### (27) Cash flow statement

The cash flow statement was prepared in compliance with IAS 7 »Cash Flow Statements«. In determining the cash flow from ordinary activities, the company applied the indirect method and classification by business activity, investment activity and financing activity.

#### (28) Financial risk management

#### Financial risk factors

The group's activities expose it to a variety of financial risks: market risk (including foreign exchange risk and fair-value interest rate risk), credit risk, liquidity risk and cash-flow interest rate risk.

#### **Market risks**

#### Foreign exchange risk

A foreign exchange risk arises when future business transactions, assets reported in the balance sheet and liabilities are denominated in a currency other then the company's functional currency. The group operates internationally and is consequently exposed to foreign exchange risk arising from changes in the exchange rate between the US dollar and the euro. The foreign exchange risk concerns income realized with the sale of Eligard®. Foreign exchange risks also arise from expected future transactions assets reported in the balance sheet and liabilities.

## Price risk

The group is exposed to an equity securities price risk because of its shareholdings, since a shareholding held by the group was classified in the consolidated balance sheet as "available-for-sale".

## **Credit risk**

The group has no significant concentrations of possible credit risks. Its business relationships are solely with large-scale customers. The liquidity of the customers in question is monitored with the help of publicly available annual reports and consolidated financial statements.

### **Liquidity risk**

Prudent liquidity management implies the maintenance of sufficient cash and marketable securities and the ability to issue securities on the market. Under the present conditions, MediGene assumes that it is able to issue marketable securities on the market.

#### Cash flow and fair value interest rate risk

Although the group holds substantial interest-bearing assets, the consolidated profit and the operating cash flow are dependent only to a slight extent on changes in the market rate of interest. The fixed-interest lease obligations give rise to a fair-value interest rate risk.

### (29) Critical accounting estimates and assumptions

The group makes estimates and assumptions concerning the future. The resultant accounting estimates will, by definition, seldom correspond to the actual results. All of the estimates and assumptions are reassessed on a continuous basis. The estimates and assumptions that carry a significant risk of causing a material adjustment to the book values of assets and liabilities within the next financial year are discussed in this note.

The group carries out an annual assessment, in compliance with the accounting and valuation method described in note (13), as to whether goodwill has suffered any impairment. The recoverable amounts of cash generating units (CGUs) have been determined on the basis of value-in-use calculations. These calculations are based on specific assumptions.

As part of the impairment test for goodwill, the influence of the valuation parameters gross margin, discount factor and maximum market share on the underlying projects G207 and NV1020 is analyzed. If the projects make further progress, for example by completing clinical trials successfully, the management accepts an increase in the "probability of success" factor. For that reason, the variation in this parameter does not influence the consideration of the worst-case scenarios (cf. basic assumptions, Note (41)).

The base-case scenario does not require any impairment of the goodwill, whereas the worst-case scenario would necessitate a complete write-off. For each of the two drug candidates G207 and NV1020, the worst-case scenario assumes the simultaneous change in the parameters as follows: reduction of gross margin to 85%, decrease in maximum attainable market share to 15% and increase in discount factor to 20%.

#### (30) Estimate of fair value

The fair value of "available-for-sale" securities is based on the quoted market price on the balance sheet date. The quoted market price used for financial assets is the current bid price; the appropriate quoted market price for financial liabilities the current ask price.

The fair value of financial instruments that are not traded on an active market is determined by using the binomial model. The group does this by making assumptions based on the market conditions prevailing on the balance sheet date ((cf. Note (51) b), Stock option plan).

In the case of trade and other receivables, it is assumed that the nominal values less valuation allowances correspond to their fair values. The fair values of financial liabilities shown in the notes are determined by discounting the future contractual cash flows at the current market interest rate that is available to the group for comparable financial instruments.

## (31) Segment reporting/Business units

According to IAS 14, "Segment Reporting" segment reporting must be carried out in accordance with the group's internal organizational and reporting structure. A business segment is a group of assets and operations engaged in providing products or services carrying risks and potential rewards that differ from those of other business segments. A geographical segment is engaged within a particular commercial environment in providing products involving risks and potential rewards that differ from those of segments operating in other commercial environments.

## F) Notes on the consolidated income statements

The income statements were prepared in accordance with the cost of sales method.

#### (32) Total revenues

MediGene's revenues were generated mainly from the commercialization of the drug Eligard® and comprise product revenues and royalties and milestone payments that MediGene receives from its marketing partner Astellas Pharma. When Eligard® was granted market approval in particular European countries, an existing deferred revenue item that had been formed on conclusion of the marketing contract with Astellas was partially recognized.

**Total revenues** 

In T€	2005	2004	Change
Product revenues and royalties	10,794	4,501	139%
Milestone, upfront and one off-payments	8,761	8,000	10%
Product sales	19,555	12,501	56%
R&D funding	0	225	-100%
Research grants	0	55	-100%
Other income	127	357	-64%
Total	19,682	13,138	50%

## (33) Cost of sales

Cost of sales result from the commercialization of Eligard® and comprise, apart from milestone payments to the licensor QLT Inc. (formerly Atrix Laboratories, Inc.), purchasing costs for the product and royalties on sales revenues paid to QLT Inc. The total cost of sales for Eligard® amounted to 9,077 T€ (2004: 5,930 T€).

### **Cost of sales**

In T€	2005	2004	Change
Milestone payments	846	2,494	-66%
Royalty payments	2,026	864	134%
Cost of goods sold	6,205	2,572	141%
Total	9,077	5,930	53%

## (34) Selling expenses

The selling expenses are reported solely in the field of business development. They comprise personnel expenses, consultancy fees, market surveys, cost of materials and other services. At present there are not yet any selling activities for approved drugs.

### **Selling expenses**

In T€	2005	2004	Change
Labor expenses	536	772	-31%
Consultancy	243	61	>200%
Office rent and utilities	47	60	-22%
Cost of material and services	41	89	-54%
Depreciation	12	10	20%
Other expenses	221	172	28%
Total	1,100	1,164	-5%

## (35) General and administrative expenses

The general and administrative expenses consist of the following:

## **General and administrative expenses**

In T€	2005	2004	Change
Labor expenses	2,708	2,349	16%
Consultancy	847	1,213	-30%
Office rent and utilities	299	213	40%
Cost of material and services	85	96	-11%
Depreciation	95	197	-52%
Other expenses	989	1,062	-7%
Total	5,023	5,130	-2%

## (36) Research and development expenses

The research and development expenses including discontinued operations consist of the following items:

## **Research and development expenses**

In T€	2005	2004	Change
Labor expenses	6,687	5,905	13%
Office rent and utilities	853	739	15%
Laboratory material costs	397	387	3%
Third party expenses	4,412	5,364	-18%
Depreciation	1,241	1,155	7%
Other expenses	2,414	2,110	14%
Total	16,004	15,660	2%

#### (37) Financial results

Interest income was generated through the interest on available cash deposits in the form of call money. Interest expenses were incurred mainly through the interest on convertible bonds outstanding (132  $T \in$ ) and through finance leases for the procurement of property, plant and equipment (17  $T \in$ ).

## **Financial results**

In T€	2005	2004	Change
Interest income	827	647	28%
Interest expenses	149	72	66%
Sub-total	678	557	22%
Expense/Income from securities	-1,512	1,581	-196%
Foreign currency gains/losses	305	-90	>200%
Total	-529	2,048	-126%

## (38) Discontinued operations

The discontinued operations essentially comprise costs that were incurred in MediGene AG's former cardiology segment. They include costs (7 T€) that are basically attributed to maintaining patents that belonged the former subsidiary LARNAX GmbH. LARNAX GmbH was merged with its parent company, MediGene AG, in August 2005. The result from discontinued operations totaled -1 T€ (2004: -1 T€).

#### **Result from discontinued operations**

	Dec. 31, 2005	Dec. 31, 2004	Change
Other Income	6	32	-81%
R&D expenses	7	33	-79%
Result discontinued operations	-1	-1	0%

The group has reported no assets and liabilities from discontinued activities.

## (39) Employee benefit expenses

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

**Employee benefit expenses** 

In T€	2005	2004	Change
Salaries and wages	7,776	7,132	9%
Social security costs	1,112	1,095	1%
Pension costs			
Defined contributions plans	138	117	18%
Defined benefit plans	101	1	> 200%
Stock options granted to directors and employees	501	386	30%
Total from continued operations	9,628	8,731	10%
Discontinued operations	0	38	-100%
Total	9,628	8,769	9%

## Employee benefit expenses by segments

In T€	2005	2004	Change
Specialty Pharma	2,028	1,451	40%
Biopharma	4,477	4,252	5%
Other	3,123	3,027	3%
Total from continued operations	9,628	8,731	10%
Discontinued operations	0	38	-100%
Total	9,628	8,769	10%

## **Employees by function**

	Dec. 31, 2005	Dec. 31, 2004	Change
Business development and general administration	34	35	-2%
Research and development	80	79	1%
Total from continued operations	114	114	0%

The average number of employees in the group in 2005 was 105, including seven at MediGene, Inc. This represents an increase of 1% over the previous year, when the workforce totaled 104.

## (40) Depreciation of fixed assets

In compliance with the cost of sales method, the amortization of intangible assets and depreciation of property, plant and equipment are not reported separately; instead, they are allocated to the general selling and administrative expenses and research and development expenses respectively.

### **Depreciation of fixed assets**

In T€	2005	2004	Change
Fixed assets incl. intangibles	1,181	951	24%
Capital lease	167	182	-8%
Total from continued operations	1,348	1,133	19%
Discontinued operations	0	229	-100%
Total	1,348	1,362	-1%

## (41) Amortization of goodwill

In the year under review, as in the previous year, no amortization of goodwill was required. The goodwill of 9,226 T€ refers to MediGene, Inc. (formerly NeuroVir Therapeutics Inc.), which was acquired by MediGene AG in 2001. The goodwill reported in the balance sheet results from MediGene, Inc.'s development projects G207 and NV1020. The two projects are being regarded as cash generating units (CGU). The possible impairment of the goodwill is assessed annually as part of the evaluation of the clinical development projects G207 and NV1020. MediGene is assuming a certain degree of probability that both projects will reach the market and generate revenues there. Should one or both projects not come successfully to fruition, a valuation allowance up to full goodwill amortization could become necessary (cf. page 64, note (29)). The valuation is carried out on November 30 of each financial year.

The impairment test for goodwill, which is based on a comparison of the current book value with the result of the project valuation in the form of a net present value calculation, revealed no need for a write-down. The realizable amount of the CGU was determined by calculating its use value. This calculation was based on forecast cash flows derived from plans that management adopted for this unit. The planning period in question is 16 to 17 years. The estimate is based on the assumption of correspondingly long patent terms and the estimated achievement of maximum revenues for products 5 years after their market launch. A residual value is still being calculated.

The valuation was influenced by the following factors in the year under review:

Project	G207	NV1020
Gross margin	93%	93%
Project duration	2006 – 2022	2006 – 2023
Max. market share five years after launch	33%	35%
Interest rate	15%	15%
Growth rate	1.0%	0.5%
Probability of success	37%	37%

The management determined the budgeted gross margin on the basis of developments in the past and expectations for future market trends. The weighted average growth rates are based on assumptions customary in the industry for the revenue development of newly launched products. The discount rates used are pre-tax interest rates and reflect the specific risks of the segments concerned. The success coefficient is based on average values customary in the industry (source: Scrip, July 2004).

#### (42) Amortization of investments

As at the closing date December 31, 2005, MediGene carried out a valuation allowance amounting to 1,503 T€ on shares held in the company QLT Inc. Taking net expenses of 8 T€ included in equity into account, expenses of 1,512 T€ were reported in connection with the valuation allowance.

#### (43) Material costs and cost of services

The expenses items in the income statement contain the following material costs:

#### Material costs

2005	2004	Change
9,077	5,930	53%
397	382	4%
9,474	6,312	50%
4,412	5,380	-18%
13,886	11,692	19%
0	12	-100%
13,886	11,680	19%
	9,077 397 9,474 4,412 13,886	9,077 5,930 397 382 9,474 6,312 4,412 5,380 13,886 11,692 0 12

The costs of purchasing the product Eligard® are reported under expenses for purchased goods. The material costs include costs of 397 T€ (2004: 382 T€) for laboratory materials and chemicals. The purchased services comprise the following: conducting clinical trials 2,366 T€ (2004: 4,044 T€), market approval 85 T€ (2004: 81 T€), production services 908 T€ (2004: 684 T€) and pre-clinical development services 1,053 T€ (2004: 554 T€).

## G) Notes on earnings per share

## (44) Undiluted earnings per share

The following table shows the calculation of the actual, undiluted net loss per share:

#### Undiluted earnings per share

Onditatou cariffigo per onai	0		
In T€	2005	2004	Change
Net loss from continued operations	-12,044	-12,665	2%
Undiluted loss per share from continued operations in $\in$	-0.65	-0.90	28%
Loss from discontinued operations	-1	-1	0%
Net loss incl. discontinued operations	-12,045	-12,666	2%
Undiluted loss per share from continued and discontinued operations in €	-0.65	-0.90	28%
Weighted average number of shares	18,560,027	13,996,440	33%

# (45) Diluted earnings per share

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

#### H) Notes on the balance sheet

#### **Assets**

For the detailed composition and development of the property, plant and equipment see the statement of fixed assets.

# (46) Property, plant and equipment/Leasing

### Property, plant and equipment/Leasing

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Initial cost	325	734	-56%
Accumulated depreciation	-145	-326	56%
Net book value	180	408	-56%

No revaluation of the property, plant and equipment in accordance with the option granted by IAS 16 »Property, Plant and Equipment« was carried out.

The lease obligations are specified under (57) loans and other capital lease obligations.

### (47) Intangible assets

The other assets essentially comprise licenses and patent rights that originate from the acquisition of Munich Biotech AG's assets in 2004. These are being amortized over the patent's term of 16 years.

#### (48) Investments

»Available-for-sale« investments consist solely of shares in the Canadian partner company QLT Inc. (1,258 T€). These shares originate from the swap of Atrix shares for QLT shares plus cash, a process that began in 2004 and was completed in the spring of 2005.

#### Investments

In T€	2005	2004	Change
Beginning of the year	2,761	4,452	-38%
Exchange differences	116	2,045	-85%
Disposal	0	-2,509	100%
Reduction from market valuation	-1,619	0	_
Transfer to »Net income recognized directly in equity«	0	-1,227	+100%
End of the year	1,258	2,761	-54%

#### (49) Other current assets and trade receivables

No valuation allowances on trade receivables had to be carried out in the reporting year 2005 or in 2004.

The other current assets of 1,174  $T \in$  consist mainly of tax claims from capital yields (48  $T \in$ ) and deferrals of royalties from the cooperation with Astellas Pharma (861  $T \in$ ).

#### Other current assets and trade receivables

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Other assets with a term < 1 year			
Tax refund from capital income	48	14	> 200%
VAT refund	2	401	-100%
Receivables from royalties	861	435	98%
Interest	2	16	-88%
Receivable QLT Inc from conversion of shares	0	2,509	-100%
Rent deposit	28	33	-15%
Other	1	2	-50%
Sub-total	942	3,410	-72%
Prepaid expenses with a term < 1 year			
Insurance	90	63	43%
Maintenance	29	21	38%
Conference fee and travel	28	20	40%
Consultancy fee	0	58	-100%
Licenses	55	16	> 200%
Other	30	26	15%
Sub-total	232	204	14%
Other current assets	1,174	3,614	-68%
Trade receivables	2	115	-98%

At the closing date all prepaid expenses were due within one year. All of the receivables and other assets fall due within three months.

#### (50) Cash and cash equivalents

#### Cash and cash equivalents

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Cash and cash equiva- lents < 3 Months	37,625	48,460	-22%
Total	37,625	48,460	-22%

The cash and cash equivalents are invested so that they fall due in less than two months. The effective interest rate for short-term bank deposits was 1.75 - 2.50%.

Cash in bank of 345 T€ serves as security for all capital lease obligations.

# Liabilities and shareholders' equity

# (51) Shareholders' equity

### a) Ordinary shares

As at December 31, 2005, the subscribed capital had increased by 243 T€, from 18,523 T€ to 18,766 T€. It is divided up into 18,766,172 no-par-value ordinary shares of which 100% were in circulation. One shareholder, Techno Venture Management GmbH, Munich, holds 5.55% of the shares, exceeding the 5% limit established by the German Securities Trading Act (WpHG) beyond which shareholdings have to be reported. Each share entitles its owner to an arithmetical share of 1 € in the subscribed capital.

#### **Ordinary shares**

	Number of shares	Share capital	Capital reserves	Total
	no. and €	in T€	in T€	in T€
Balance January 1, 2004	11,206,205	11,206	218,288	229,494
Employee stock option plan				
Value of services provided			344	344
Proceeds from shares issued	21,000	21	40	61
Employee convertible bond plan				
Value of services provided				
Proceeds from shares issued	1,757	2	247	249
Capital increase				
Cash	5,332,784	5,333	28,747	34,080
Non-cash acquisitions	1,960,938	1,961	9,216	11,177
Balance December 31, 2004	18,522,684	18,523	256,882	275,405
Employee stock option plan				
Value of services provided			495	495
Proceeds from shares issued	40,062	40	211	251
Employee convertible bond plan				
Value of services provided			6	6
Proceeds from shares issued	3,778	3	9	12
Capital increase				
Mandatory conversion of convertible bond	199,648	200	1,173	1,373
Balance December 31, 2005	18,766,172	18,766	258,776	277,542

The Executive Board was authorized by a resolution of the general shareholders' meeting of June 10, 2005 to increase the share capital by a total of up to 9,261,342 € up to June 9, 2010 by issuing a total of up to 9,261,342 new bearer ordinary shares (no-par-value shares) on one or more occasions against contributions in cash or kind (Authorized Capital I/2005). The authorization can be used in partial amounts. The Executive Board is authorized, with the agreement of the Supervisory Board, to lay down the further content of the share rights and the terms of the share issue.

#### b) Stock options

Equity instruments, such as options and convertible bonds granted to employees are valued in accodance with IFRS 2.

Stock options are issued to managers and employees. They are first issued within one year of the manager or employee joining the company. The exercise price for each option corresponds to the higher of the following two prices on the day of issue: either the quoted

price or the average price from the previous 60 days in the German stock exchange's XETRA trading system, plus a premium of 20%. The options can be exercised on expiration of the second year after the granting date. The options have a contractual maturity term of 10 years. The group has no legal or de facto obligation of any kind to repurchase the options, in cash or otherwise.

146,691 stock options were issued in 2005 (2004: 112,955 stock options). In accordance with the shareholders' resolution of June 4, 2003, 439,673 stock options from Conditional Capital XII are still available for issue. The issue is restricted as follows: 40,000 to members of the executive boards and management bodies of affiliated companies, 75,000 to the group's Executive Board and 174,062 to employees.

The average exercise price for the options issued in 2005 is 12.37  $\in$ , compared with 7.84  $\in$  in the previous year.

#### Total changes in stock options

	2005	2005		2004		2003	
	Average exercise price € per share	No.	Average exercise price € per share	No.	Average exercise price € per share	No.	
Beginning balance January 1	6.80	604,379	6.25	516,344	6.80	385,052	
Granted	12.37	146,691	7.84	112,955	4.65	131,292	
Exercised	6.26	-40,062	2.93	-21,000	0	0	
Forfeited	9.18	-9,579	7.69	-3,920	0	0	
Lapsed		0		0	0	0	
Ending balance December 31		701,429		604,379		516,344	
Average exercise price € per share		6.88		5.50		4.90	

Stock options were exercised regularly during the period under review. The weighted average price of MediGene's shares in the period under review was 6.26 €. This value was calculated from the XETRA closing price on the date of exercise, multiplied by the number of stock options exercised, divided by the total number of options exercised during the reporting period.

This year, the instruments are being valued using a binomial model for the first time. In 2003 and 2004 the valuation was carried out using the Black-Scholes model. The following parameters are being taken into account:

### Valuation parameters stock option plan

	2005	2004	2003
Vesting period	2 years	2 years	2 years
Option duration	10 years	10 years	10 years
Hurdle rate	120%	120%	120%
Volatility	40%	106%	81%
Risk-free interest rate	3.24%	5.65%	5.65%

The volatility was calculated on a historical basis.

For 2005, in accordance with IFRS, expenses for share-based forms of remuneration totaling 495 T  $\in$  were reported (2004: 344 T  $\in$ ). 64 T  $\in$  (2004: 127 T  $\in$ ) of these originate from the 2003 stock option program, 214 T  $\in$  (2004: 217 T  $\in$ ) from the 2004 option program and 217 T  $\in$  from the 2005 option program.

#### **Expenses stock option plan IFRS**

In T€	2005	2004
Expenses stock option plan		
2003	64	127
2004	214	217
2005	217	0
Total	495	344

As at December 31, 2005, the stock options outstanding are classified by conversion price, number of issued options, remaining contractual life and number of options still exercisable as follows:

Conversion price and contractual life of issued stock option plan

Conversion price in €	Number of stock options	Remaining contractual life	Number of exercisable stock options
2.93	120,461	2	120,461
4.60	47,819	8	47,819
4.68	80,000	8	80,000
5.35	17,200	2	17,200
5.53	9,460	3	9,460
6.48	180,342	5	180,342
7.69	62,496	9	_1)
8.10	40,000	9	_1)
12.37	143,651	10	_1)
_	701,429	-	455,282

<sup>&</sup>lt;sup>1)</sup> Stock options granted in 2004 and 2005 were not exercisable as of December 31, 2005.

#### c) Convertible bonds

In 2005, 9,000 convertible bonds were issued to employees of the group's subsidiary MediGene, Inc. (2004: 12,277 convertible bonds). The average conversion price for the convertible bonds issued in 2005 is 12.37 €, compared with 7.69 € in the previous year.

In March 2004. MediGene had issued convertible bonds with an interest rate of 4% p.a. and a life of four years, together with an obligation to convert when requested by the company, in a total nominal amount of 1,500,000 €, divided up into 1,500,000 bonds each with a nominal value of 1 €. The holders are entitled to interest up to the end of the day that precedes the day when the conversion right is exercised. As stated in an ad-hoc announcement of December 15, 2005, MediGene had, in accordance with the bond terms, decided that all of the convertible bonds issued in March 2004 and the 4% of convertible bonds still outstanding at that point in time should be converted compulsorily into bearer no-par-value shares. The conversion will reduce the company's liabilities by approx. 1.5 million € and lead to a reduction in future interest expenses. After a cash capital increase that was

completed in November 2004, the conversion price was, in accordance with the bond terms, adjusted from 7.50 € to 7.4783 €. Any differences that arose during the course of the conversion were settled in cash. The conversion gave rise to a total of 199,648 new shares that were issued to the bond creditors against the redemption of the convertible bonds.

The convertible bonds are reported in the balance sheet as follows: the fair value of the liability component and the equity conversion component is determined as at the convertible bonds' issue date. The fair value of the liability component, which is included in long-term liabilities, is calculated with market interest rates for equivalent non-convertible bonds. The residual value that shows the value of the equity conversion component is reported in equity under other reserves.

The number of convertible bonds valid and still outstanding within the scope of the equity participation program was 126,772 as at December 31, 2005 (2004: 332,168).

Total changes in convertible bonds

	2005	2004	2003
Opening balance January 1	332,168	107,523	337,903
Granted	9,000	243,277	47,273
Exercised	-203,426	-1,757	0
Forfeited	-9,970	-16,875	-277,653
Lapsed	1,000	0	0
Closing balance December 31	126,772	332,168	107,523
Average exercise price € per share	12.66	9.55	15.26

#### Conversion price and life of issued convertible bonds

Conversion price and the or issued convertible bonds				
Conver- sion price in €	Coupon in % p.a.	Number of issued bonds	Remain- ing con- tractual life	Number of exer- cisable bonds
23.57	2.5%	1,600	1	1,600
31.63	2.5%	21,235	1	21,235
64.16	2.5%	30	1	30
11.72	2.5%	22,325	2	22,325
26.40	2.5%	1,957	2	1,957
9.90	2.5%	1,600	2	1,600
3.80	2.5%	10,300	3	10,300
4.83	2.5%	14,915	3	14,915
4.97	2.5%	1,600	3	1,600
7.69	2.5%	17,210	4	8,6051)
8.08	2.5%	25,000	4	12,500 <sup>1)</sup>
12.37	2.5%	9,000	5	_1)
		126,772		96,667

<sup>&</sup>lt;sup>1)</sup>Convertible bonds granted in 2004 and 2005 were not exercisable as of December 31, 2005

# d) Contingent capital

The company's share capital was increased conditionally by up to 5,000,000 new no-par-value shares (Conditional Capital 2005/I) by a shareholders' meeting resolution of June 10, 2005. The sole purpose of the conditional capital is to grant new shares to the holders of warrant-linked bonds or convertible bonds that are issued in accordance with the regular shareholders' meeting resolution of June 10, 2005 by the company or by companies in which the company has a direct or indirect majority stake. If the shares come into being before the company's regular shareholders' meeting commences, they entitle their owners to a share in the company's profits from the beginning of the previous financial year; or if this is not the case, from the beginning of the financial year in which they come into being.

# e) Allocation of options and convertible bonds to contingent capital

As at the closing date December 31, 2005, the total number of shares outstanding was 18,766,172 and the number of »fully diluted« shares was 19,594,373. The changes in equity are specified in the consolidated changes in shareholders' equity.

**Specification of contingent capital** 

Usage	Amount Dec. 31, 2005	(No.)
Options	225,721	1
Options	106,429	II
TBG <sup>1)</sup> Ioan	125	III
Convertible bonds	13,770	IV
Convertible bonds	664,865	V
Convertible bonds	3,000	VI
Convertible bonds	1,300,352	VII
Convertible bonds	3,000	VIII
Convertible bonds	3,000	Х
Convertible bonds	2,600	XI
Options	676,527	XII
Convertible bonds	200,000	XIII
Convertible bonds	0	XIV <sup>2)</sup>
Convertible bonds	5,000,000	XV <sup>3)</sup>
	8,199,389	

<sup>1)</sup> Technology participation company

#### (52) Other capital reserves

40,062 stock options and 203,426 convertible bonds were converted in 2005. The equity component of the convertible bonds is  $11.3 \text{ T} \in$ .

<sup>&</sup>lt;sup>2)</sup> Cancelled by shareholders' resolution of June 10, 2005.

<sup>3)</sup> Newly created by shareholders' resolution of June 10, 2005

#### Other capital reserves

In T€	at Jan. 1, 2004	Change	at Dec. 31, 2004	Change	at Dec. 31, 2005
Shares issued	227,884	40,764	268,648	0	268,648
Expenses capital increase	-10,759	-2,802	-13,561	0	-13,561
Exercised stock options	443	41	484	211	695
Exercised convertible bonds	0	228	228	1,182	1,410
Expenses new options/bonds	720	3,634	1,083	501	1,584
Total	218,288	38,594	256,882	1,894	258,776

#### (53) Accumulated deficit

#### **Accumulated deficit**

In T€	at Jan. 1, 2004	Change	at Dec. 31, 2004	Change	at Dec. 31, 2005
Retained earnings	-200,999	-12,666	-213,665	-12,045	-225,710
Total	-200,999	-12,666	-213,665	-12,045	-225,710

# (54) Net income directly recognized in equity

# Net income directly recognized in equity

In T€	at Jan. 1, 2004	Change	at Dec. 31, 2004	Change	at Dec. 31, 2005
Realized profit from Atrix shares	764	-764	0	0	0
Unrealized gain/profit from market valuation QLT shares	-8	0	8	8	0
Currency translations adjustments	-1	-19	-20	-35	-55
Total	755	-783	-28	-35	-55

The company, in accordance with IFRS 1, applies the standard IAS 21 ("The Effects of Changes in Foreign Exchange Rates") prospectively. This means that all of the cumulative currency translation gains and losses posted under US-GAAP before the transition date are reclassified and that only translation differences arising after the transition date have to be posted separately.

#### (55) Pension accruals

The accrual amount in the balance sheet was calculated as follows:

#### Pension accruals

In T€	Dec. 31, 2005	Dec. 31, 2004
Present value of funded obligations	735	36
Fair value of plan assets	575	0
Unrecognized actuarial losses	-63	0
Liability in the balance sheet	97	36

In 2005 the company made a pension commitment to employees in the form of a company wide relief fund. The pension obligation is reported at the asset value of the associated employer's pension liability insurance.

The plan assets comprise employer's pension liability insurance policies. The following amounts were reported in the income statement as personnel expenses:

#### Expenses recognized in the income statement

In T€	2005	2004
Current service cost	90	0
Interest cost	29	1
Expected return on plan assets	-22	_
Actuarial losses recognized in the year	4	_
Past service cost	_	_
Losses on curtailment	_	_
Total included in personnel expenses	101	1

15 T€ of the total amount was included in research and development expenses and 86 T€ in the general and administrative expenses.

**Principal actuarial assumptions** 

	2005	2004
Discount rate	4.0	4.75
Expected return on plan assets	4.0	4.75
Future salary increases	4.0	4.75
Future pension increases	2.0	2.0

The 2005 guideline tables devised by Professor Klaus Heubeck (2004: 1998 guideline tables) were used as the biometric basis for calculation. Probabilities of fluctuation were not taken into account.

The amounts shown in the accrual reported in the balance sheet developed as follows:

Pension accrual

In T€	Dec. 31, 2005	Dec. 31, 2004
Beginning of year	36	35
Adjustments due to better knowledge	-40	0
Personnel expenses recognized in income statement	101	1
End of year	97	36

Several pension commitments were reported in the balance sheet for the first time in 2005 due to better knowledge. Since it neither concerns a significant error nor a marginal error brought about intentionally, no retroactive correction took place, pursuant to IAS 8.

(56) Trade account and other payables

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Current liabilities			
Trade accounts payables	845	618	37%
Other current liabilities	3,343	6,415	-48%
Current portion of capital lease obligations	118	269	-56%
Deferred income	667	2,000	-67%
	4,973	9,302	-47%
Long-term liabilities			
Liabilities from options consultancy	100	55	82%
	100	55	82%

The deferred revenue item amounting to 667 T€ (2004: 2,000 T€) refers to the still unrealized part of the upfront payment that MediGene had received on conclusion of the Eligard® marketing partnership with Astellas Pharma. Other current liabilities essentially correspond to services already used but not yet invoiced, such as those for the carrying out of clinical trials and the submission of the application for the approval of Polyphenon® E Ointment.

The other current liabilities shown in the table are classified as follows:

#### Other current liabilities

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Interest convertible bonds	0	45	-100%
Wage and church tax liabilities	141	131	8%
Social insurance li- abilities	133	133	0%
Liabilities from relief fund and direct insurance	5	16	-69%
Withholding tax	261	31	> 200%
Remaining purchase price of assets of Munich Biotech AG	0	1,000	-100%
Liabilities Aventis	0	2,105	-100%
Liabilities QLT	725	373	94%
Vacation and overtime	244	237	3%
Bonuses	555	351	58%
Severance	10	43	-77%
Annual report audit	87	70	24%
Licenses	90	32	181%
Annual report costs	58	100	-42%
Clinical trials and approval	353	1,096	-68%
Production and pre- clinical trials	304	139	119%
Legal	60	131	-54%
Consultants	9	274	-97%
Treasury fund	250	0	_
Other	58	108	-46%
Total	3,343	6,415	-48%

# Liabilities against Aventis

Within the framewoth of the cooperation with Aventis, MediGene had received a loan of 3,222 T€, which had been repaid to Aventis in twelve equal monthly installments of 269 T€, starting in August 2004. The loan had completely been repaid by December 31, 2005.

#### (57) Loans and capital lease obligations

Loans and capital lease obligations represent financial debt.

Loans

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Long-term debt less current portion	115	1,674	-93%
Total	115	1,674	-93%

As per December 31, 2005, the long-term debt includes convertible bonds. At last year's closing date, the item »long-term debt « mainly included a convertible bond issued by MediGene in March 2004, bearing 4% interest annually, with a maturity term of four years and an obligation to conversion upon demand by the company. The convertible bond at a total nominal value of 1,500,000 € was divided into 1,500,000 bonds at a nominal value of 1 € each. In December 2005, the convertible bond was fully converted into shares, in accordance with the terms (see notes to the consolidated financial statements H), note (51c)).

#### Capital lease obligation

In T€	Dec. 31, 2005	Dec. 31, 2004	Change
Capital lease obligation less current portion	0	118	-100%
Current portion of capital lease obligation	121	287	-58%
Total	121	405	70%

#### Capital lease obligation

The future minimum payments for capitalized lease items and the future annual minimum lease installments for finance leases are as follows:

#### Present value liabilities finance lease

In T€	Dec. 31, 2005	
< 1 year	118	269
Between 1 and 5 years	0	115
Over 5 years	0	0
Total	118	384

The present value of the liabilities from finance leases was determined by means of an annual interest rate of 6.8%.

# I) Changes in consolidated shareholders' equity

The changes in consolidated shareholders' equity for the financial years from January 1 to December 31, 2005 and 2004 are shown on page 51 of the notes.

# J) IFRS adjustment and other notes on the balance sheet

#### **Capital reserves**

As at December 31, 2003, the capital reserve according to US-GAAP amounted to 218,177 T€. As at January 1, 2004, calculation according to IFRS produced a figure of 218,288 T€, i.e. 111 T€ higher.

As at December 31, 2004, the capital reserve according to US.GAAP amounted to 256,411 T€. The application of IFRS increased the capital reserve by 471 T€ to 256,882 T€.

The differences specified above result from the inclusion of personnel expenses for stock options and interest expenses for convertible bonds.

#### **Retained earnings**

As at December 31, 2003, the net loss for the year according to US-GAAP was 199,943 T€. The application of IFRS increased the loss as at the closing date January 1, 2004 by 1,057 T€ to 201,000 T€.

The net loss according to US-GAAP amounted to 212,248 T€ as at December 31, 2004. Under IFRS regulations the net loss increased by 1,417 T€ to 213.665 T€.

The increase in the net loss as at the individual balance sheet dates results essentially from the reclassification of currency translation gains and losses amounting to 975 T€, which for foreign subsidiaries will not have to be posted separately until the date of transition. It also includes personnel expenses for stock options and interest expenses for convertible bonds.

#### Net income/expenses directly recognized in equity

The net expenses directly recognized in equity as at December 31, 2003 amounted to -221 T€ under US GAAP. The presentation in accordance with IFRS reduces the amount by 975 T€ to 754 T€. The decrease results from the inclusion of currency translation gains and losses amounting to 975 T€.

As at December 31, 2003, the net income directly recognized in equity according to US-GAAP amounted to -1,003 T€. The calculation according to IFRS reduces this amount by 975 T€ to -28 T€ due to the reclassification of currency translation gains and losses amounting to 975 T€.

#### Accruals adjusted to other current liabilities

Pursuant to IAS 37, the accruals of 3,342 T€ as per January 1, 2004, and of 2,953 T€ as per December 31, 2004, respectively were adjusted to other current liabilities.

### K) Notes on the cash flow statement

The cash flow statements show the origin and use of the cash flows in the financial years 2005 and 2004. They therefore have a pivotal significance for the assessment of the company's financial situation.

Cash flow from investing activities as well as cash flow from financing activities are determined on the basis of payments and receipts. Cash flow from operating activities, on the other hand, is derived indirectly from the net loss for the year.

Within the non-cash financing activities, no finance lease obligations were entered into for laboratory and office equipment in 2005 (2004: 325 T€).

The repayments for a loan granted by Aventis as part of a research and development partnership are posted under repayments/proceeds from loans.

The cash equivalents at the end of the period under review comprised cash on hand, credit balances with banks and checks with an original maturity of < 3 months. In this respect, they correspond to the balance sheet item »Cash and cash equivalents«.

# L) Segment reporting

#### Primary reporting – business units

As at December 31, 2005, the group is organized in two primary business units in global terms: **"Specialty Pharma"** and **"Biopharma"**. The Specialty Pharma segment encompasses the drug Eligard<sup>®</sup> and the product candidate Polyphenon<sup>®</sup> E Ointment; the Biopharma segment consists of MediGene's EndoTAG and oncolytic herpes simplex virus technology, as well as the product candidates EndoTAG-1, NV1020 and G207 that are derived from the above.

### Specialty Pharma products & product candidates:

- Eligard® for the treatment of hormone-dependent advanced prostate cancer
- Polyphenon® E Ointment for the treatment of genital warts and actinic keratosis

#### Biopharma products & technologies:

- EndoTAG-1 for the treatment of solid tumors (since August 2004)
- NV1020 for the treatment of liver metastases
- G207 for the treatment of brain tumors
- EndoTAG technology
- HSV technology

There are no internal charges of a regular or planned nature between the market segments and regions. For that reason there are no details regarding such charges. The income in the individual segments is generated by external business relationships.

# Secondary reporting – geographical segments/ segments by region

The company operates in Germany and the USA. The segment reporting by regions consists only of the continuing activities. The discontinued activities concerned only the site in Germany.

The segment assets consist primarily of property, plant and equipment, intangible assets, inventories, receivables and cash and cash equivalents used for operating purposes. They exclude deferred taxes. The segment liabilities consist of operating liabilities. The segment investments consist of additions to property, plant and equipment intangible assets and finance lease investments.

### Segment reporting by geographical segments/segments by region

In T€	Germany 2005	USA 2005	Germany 2004	USA 2004
Total revenues	19,682	0	13,131	7
Cost of sales	9,077	0	5,930	0
R&D expenses	14,766	1,231	13,258	2,369
Selling expenses and general and administrative expenses	5,882	241	5,973	114
EBIT	-10,045	-1,470	-11,719	-2,995
Segment investments	452	0	603	2
Cash flow from operating activities	8,984	1,453	8,857	3,239
Assets	56,840	222	72,696	198
Liabilities	4,779	506	10,833	349
Average number of employees	98	7	93	12

# Segment reporting by market segments

In T€	Specialty Pharma	Biopharma	Other	Not allocated	Total
2005					
Total revenues	15,591	4,030	61	_	19,682
Cost of sales	9,077	0	0	_	9,077
Gross profit	6,514	4,030	61	_	10,605
Selling expenses	309	0	791	_	1,100
General and administrative expenses	0	0	5,023	_	5,023
R&D expenses	4,815	11,182	0	_	15,997
Operational result continued operations (EBIT)	1,390	-7,152	-5,763	_	-11,515
Finance result					-529
Net loss from continued operations					-12,044
Result from discontinued operations					-1
Net loss					-12,045
Segment assets	1,258	15,769	_	40,035	57,062
Segment liabilities	667	506	_	4,112	5,285
Depreciation	2	1,166	_	179	1,347
Average number of employees	21	57	30	_	108
Investments <sup>1)</sup>	3	243	206	_	452
2004					
Total revenues	12,694	226	218	_	13,138
Cost of sales	5,930	0	0	_	5,930
Gross profit	6,764	226	218	-	7,208
Selling expenses	152	0	1,012	-	1,164
General and administrative expenses	0	0	5,130	-	5,130
R&D expenses	6,907	8,720	0	_	15,627
Operational result continued operations (EBIT)	-295	-8,494	-5,924	-	-14,713
Finance result					2,048
Net loss from continued operations					-12,665
Result from discontinued operations					-1
Net loss					-12,666
Segment assets	2,761	16,246	_	53,887	72,894
Segment liabilities	2,000	506	_	8,677	11,183
Depreciation	119	806	_	208	1,133
Average number of employees	18	57	30	_	105
Investments <sup>1)</sup>	2	545	59		606

<sup>1)</sup> Investments also include finance lease investments.

#### M) Other notes

# (58) Income Taxes

Due to the operating losses posted, no taxes on income were incurred in the financial years 2005 and 2004 with the exception of the items described below.

Deferred taxes on income for the period ending December 31, 2005 refer to the following items:

#### **Deferred income tax**

In T€	Dec. 31, 2005	Dec. 31, 2004
Deferred tax assets		
Deferred taxes on carry forward tax losses	56,696	49,855
Other taxes from grants	2,847	2,961
Difference from useful life of assets	84	78
Convertible bonds	40	20
Capital lease	42	138
Milestone payments	240	720
Other assets	59	0
Different valuation accruals	12	26
	60,020	53,798
Valuation allowance	-58,537	-52,061
Deferred tax liabilities		
Capitalization acquired licenses	1,362	1,455
Difference from useful life of assets	32	60
Capital lease	65	147
Pension accruals	24	0
Convertible bonds	0	75
	1,483	1,737
Deferred taxes net	0	0

Since further losses can be expected for the foreseeable future, the tax claims were not reported to the extent that they exceed the tax liabilities. Deferred taxes on the assets and liabilities sides were balanced against each other, as they are reported to the same tax authorities and refer to congruent periods. The calculation of the deferred taxes is based on a mixed tax rate of 35.98% consisting of a corporate income tax rate of 25%, a solidarity surcharge of 5.5% and trade tax of 13.04%. The deductibility of the trade tax was taken into account when the mixed tax rate was determined.

The reported tax expenses diverge from the expected tax expenses that had been calculated by applying the nominal tax rate (35.98%) to revenues in accordance with IFRS. A transition of the differential effects is shown in the table below.

#### **Deferred taxes**

In T€	Dec. 31, 2005
Earnings before tax	-12,045
Expected tax income	-4,334
Non capitalization of deferred taxes on losses of the period	6,841
Temporary differences	1,856
Non-deductible expenses/other	366
Effect of tax rate differences	170
Result before taxes	115
Actual tax expense	0

#### **Carried forward losses in Germany**

In T€	Dec. 31, 2005	Dec. 31, 2004
Corporate taxes	115,323	104,830
Trade taxes	113,646	103,177

Under the German Corporate Income Tax Act (KStG), tax losses can be carried forward for an unlimited number of years. The deduction of existing loss carryforwards is excluded when the company carrying those losses forward loses its fiscal identity. The loss of such a corporate fiscal identity is assumed when the following two criteria are cumulatively fulfilled: (i) more than 50% of the company's shares were transferred and (ii) the company is continuing its business operations or resuming them afresh with predominantly new assets. The legally restricted deductibility of operating losses applies to both corporate income tax and trade tax. It is possible that the company lost part of its loss carryforwards as a result of the capital increase within the framework of the IPO.

#### Carried forward losses in USA

In T€	Dec. 31, 2005	Dec. 31, 2004
State Tax	44,194	40,679
Federal Tax	46,054	42,505

#### (59) Cooperation agreements

#### Astellas Pharma Europe Ltd.

On January 12, 2004 the company had concluded a cooperation, sublicensing and supply agreement with the pharmaceuticals group Astellas Pharma Europe Ltd., Staines, UK (formerly Yamanouchi Europe Ltd.) for the marketing of Eligard® in Europe. The company granted Astellas the exclusive sublicense for the marketing of Eligard® in four sustained releases with the right to acquire further sublicenses. In Europe, Astellas is the third-largest pharmaceuticals company in the field of urology. Since May 2004, Astellas has been marketing the one-month and three-month sustained release forms of Eligard® for the treatment of prostate cancer in Germany. As part of the contract, MediGene receives stage-by-stage milestone payments up to a total of 21.5 million €, including a one-off payment of 4 million € when the contract was signed and royalties from the sales of Eligard®.

#### QLT Inc.

In 2001, MediGene acquired the European marketing rights for the prostate cancer drug Eligard® (formerly Leuprogel from the US-based company Atrix Laboratories, Inc., Fort Collins, Colorado, USA (now QLT Inc., Fort Collins, Colorado, USA). This agreement gave MediGene the exclusive European marketing rights for various dosages of the product. In 2004, Atrix Laboratories Inc. was acquired by the Canadian company QLT Inc. The licensor QLT Inc. received not only milestone payments in return for market approval and revenue targets, but also payments from MediGene on purchase of the goods and a royalty on the ongoing sales revenues. As part of the marketing contract, MediGene acquired shares in Atrix Laboratories, Inc. These shares were swapped for QLT shares in the course of the company's acquisition.

#### Glaxo Group Limited

In December 2005, MediGene granted the Glaxo Group Limited, Brentford, UK, a non-exclusive license for patents that emerged from MediGene's program for the development of a therapeutic tumor vaccine. MediGene received a one-off payment from the Glaxo Group Limited in return.

#### (60) Legal disputes

Prior to the market launch of Eligard®, MediGene had already filed a suit before the German Federal Patents Court for the invalidity of a patent on specifically defined high-molecular, biodegradable polymers of its competitors Takeda Chemical Industries, Ltd., Osaka, Japan and Wako Pure Chemical Industries, Ltd., Osaka, Japan. In the summer of 2004, after the market launch of Eligard®, Takeda Chemical Industries, Takeda Pharma GmbH, Aachen, Germany, and Wako Pure Chemical Industries (Takeda and Wako) sued the partners MediGene and Astellas Pharma GmbH (formerly Yamanouchi Pharma GmbH) for alleged patent infringement before Düsseldorf District Court. In their lawsuit, they argue that the commercialization of MediGene's and Astella's drug Eligard® infringes the aforementioned plaintiffs' patent.

On April 20, 2005, the Third Nullity Board at the German Federal Patents Court decided in an oral hearing that all of the claims from the aforementioned patent that Takeda and Wako were asserting against MediGene and Astellas before Düsseldorf District Court Court were invalid within the Federal Republic of Germany. Takeda and Wako have appealed against this judgement before the Federal Supreme Court (BGH), whose judgement can be expected by 2007 at the earliest. At the same time, Düsseldorf District Court has suspended the German part of the suit for patent infringement until the final and absolute decision on the suit for invalidity.

There is also a parallel court case regarding patent infringement in the USA, in which MediGene's supplier and licensor QLT USA Inc. (formerly Atrix Laboratories, Inc.) and the US marketing partner of QLT USA Inc., Sanofi-Synthelabo Inc., are being sued on grounds of patent infringement by Takeda Abbott Pharmaceutical Product Inc., Takeda Chemical Industries, Ltd. and Wako Pure Chemical Industries, Ltd. Ltd. Based on

the current status of the case, it can be assumed that this legal dispute will not have any impact whatsoever on the sales of Eligard® in Europe.

In May 2003, in order to remove any legal uncertainties regarding Polyphenon® E, the company filed an objection to the European patent EP 0 814 823 B1 held by the company Indena S.p.A., Milan, which concerns special polyphenol fractions in tea. Then, in June 2004, Indena S.p.A. limited the patent to such an extent that it has no significance for the company. In December 2005, the objections division of the European Patent Office revoked the patent completely. At present it is not clear whether Indena is going to file a complaint against this decision.

#### (61) Contingencies and other financial obligations

For the contingencies listed below there were no accruals, as the risk of their utilization is regarded as improbable:

- As at the balance sheet date there was a rent security guarantee (233 T€) and a bank guarantee (27 T€) vis-à-vis the respective lessors.
- When it acquired the assets of the former Munich Biotech AG, MediGene committed itself to make milestone payments to the receiver. Depending on the clinical success of EndoTAG-1, the payments in question will fall due with clinical phase III and amount to 9.5 million € in total. No provision had to be set up because, due to the product's current state of development, the probability of the payments becoming necessary is seen as lower than 50%.
- The future minimum payments for capitalized leased items and the future annual minimum lease installments for operating leases are as follows:

Contingencies and other financial obligations

In T€	Operating lease
2006	1,160
2007	1,055
2008	929
2009	668
Thereafter	3
Minimum lease obligations	3,815

The company also leases office and laboratory premises, office furnishings and fittings, laboratory equipment and motor vehicles which constitute operating leases since due to the contractual agreement, the group does not carry the risks and potential rewards. The lease agreements have different terms, rental increase clauses and prolongation options. The group has notice periods of one month to five years for these lease agreements.

#### (62) Total unused/open credit lines

In addition to the cash and cash equivalents reported in note (50), there were no open credit lines as at December 31, 2005.

#### (63) Major events since end of year under review

MediGene and Bradley Pharmaceuticals, Inc. conclude marketing and development partnership for Polyphenon® E Ointment
As of January 30, 2006 MediGene has entered into a partnership agreement with Bradley Pharmaceuticals Inc. to commercialize Polyphenon® E Ointment in the US. Bradley Pharmaceuticals, a US specialty pharmaceutical company that markets to niche physician specialties, will take on US promotion and commercialization of the drug for the treatment of genital warts. MediGene and Bradley also agreed upon a development partnership to examine the application of Polyphenon® E Ointment for the treatment of other skin diseases.

Under the terms of the agreement, MediGene could receive successive milestone payments up to 69 million US\$, including a payment of 5 million US\$ due upon signing of the contract. In addition, MediGene will receive royalties on sales of Polyphenon® E Ointment in the US. Milestone payments are dependent upon specific achievements in development, approval, and commercialization of Polyphenon® E Ointment in the genital warts and actinic keratosis indications, and are linked to specific sales targets reached in any indication.

Bradley Pharmaceuticals will take over the majority of the development costs for Polyphenon® E Ointment if it is developed in dermatological indications other than genital warts. MediGene holds the right to commercialize all of these developments outside the US, whereas Bradley holds the right to market Polyphenon® E Ointment in all dermatological indications within the US.

#### (64) Major concentrations of risks

MediGene's sales revenues are generated mainly by the marketing of Eligard® by its partner Astellas Pharma Europe Ltd.

#### (65) German Corporate Governance Code

On November 28, 2005, MediGene AG's Executive Board and Supervisory Board confirmed that MediGene AG complies with most of the recommendations of the German Corporate Governance Code, version of July 12, 2005. The recommendations that are not implemented by MediGene AG are explained in the Declaration of Compliance in accordance with § 161, German Stock Corporation Act (AktG). This declaration is permanently accessible in German and English on the company's website (http://www.medigene.de/englisch/corporate\_governance.php).

#### (66) Auditing fees

Auditors and group auditors were paid the following fees in the financial year under review:

# **Auditing fees**

In T€	MediGene AG 2005
Audit	56
Other certification or valuation services	10
Tax consulting services	29
Other services	51
Total	146

### N) Executive Board and Supervisory Board

#### (67) Changes on the Executive Board

There were no changes on the Executive Board in 2005.

### Executive Board compensation

The total compensation paid to the members of the Executive Board in the last financial year amounted to 974 T€ (2004: 736 T€). The compensation paid to the Executive Board members comprises fixed and variable components, as well as performance incentives to increase the value of the company in the long term. The criteria for the variable compensation

# **Executive Board Compensation in fiscal year 2005**

Executive Board member			Other variable compensation with a long-term incentive		
	Fixed compensation	Variable compensation	Number of stock options	Value of options	
	in T€	in T€	no	in T€	
Dr Peter Heinrich, Chief Executive Officer	237	110	20,000	95	
Alexander Dexne, Chief Financial Officer	185	84	20,000	95	
Dr Ulrich Delvos, Chief Operating Officer	216	72	5,000	24	
Total	638	266	45,000	214	

components are laid down in advance each year. The long-term compensation components consist of stock options. The intention of this is to create performance incentives geared towards lasting corporate success. The results targets that form the basis of these incentives may not be changed subsequently. No advance payments were made to the Board's members.

In addition, 70 T€ were expensed for pension of Executive Board Members.

#### (68) Changes on the Supervisory Board

A new addition to the Supervisory Board in the year under review was the previous alternate member Mr Sebastian Freitag, Investment Banker, Frankfurt am Main. Mr Freitag replaces the departing member Dr Alexandra Goll.

#### Supervisory Board compensation

The compensation paid to members of the Supervisory Board in 2005 amounted to 266 T€ (2004: 197 T€). The Supervisory Board members' total compensation comprises a fixed cash amount and fees for attending meetings. The consideration of the scope of the members' activities takes the duties of the Chairman and Deputy Chairman into account. Information about subscription rights of members of the management bodies and employees is provided in this section. No advance payments were made to the Board's members.

Supervisory Board compensation in fiscal year 2005

Supervisory Board member	Fixed compensation	Variable compensation	Variable compensa- tion with a long-term incentive (No. of convertible bonds or	Compensation for individually performed services
	in T€	in T€	stock options)	in T€
Prof. Dr Ernst-Ludwig Winnacker, Chairman	48	25	0	0
Dr Norbert Riedel,				
Deputy Chairman	36	19	0	0
Dr Pol Bamelis, Member	24	13	0	0
Sebastian Freitag, Member (since June 10, 2005)	12	5	0	0
Dr Alexandra Goll,				
Member (until June 10, 2005)	12	5	0	0
Dr Manfred Scholz, Member	24	8	0	0
Michael Tarnow, Member	24	13	0	0
Total	180	88	0	0

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

**Prof Dr Ernst-Ludwig Winnacker** 

since November 26, 1996

Chairman

President of the German Research Foundation, Bonn, Germany

#### **Prof 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 at Bayer AG, Knokke, Belgium

#### **Sebastian Freitag**

since June 10, 2005

Investment Banker, Frankfurt, Germany

#### **Dr Manfred Scholz**

since June 2, 2004

Managing Director, Augsburg Airways GmbH & Co. KG, Augsburg, Germany

### **Michael Tarnow**

since May 23, 2001

Consultant, Boston MA, USA

The members of the Executive and Supervisory Boards also hold positions on the following Supervisory Boards and/or similar bodies:

#### **Prof Dr Ernst-Ludwig Winnacker**

- Bayer AG, Leverkusen
- KWS Saat AG, Einbeck
- Wacker Chemie AG, Munich

#### **Prof Dr Norbert Riedel**

• Oscient Pharmaceuticals Inc., USA

#### **Dr Pol Bamelis**

- Bekaert N.V., Belgium
- Crop Design N.V., Belgium
- Evotec OAI AG, Hamburg
- Innogenetics N.V., Gent
- Oleon N.V., Belgium
- PolyTechnos Ltd., Guernsey, UK
- Recticel, Belgium

#### **Sebastian Freitag**

No other board memberships.

#### **Dr Manfred Scholz**

- ASSTEL Lebensversicherung, Cologne
- CINVEN, London/Frankfurt, UK/Germany
- Citigroup Global Markets Deutschland AG & Co KGaA, Frankfurt
- Droege & Comp., Düsseldorf, Germany
- Gothaer Finanzholding AG, Cologne
- Pfleiderer AG, Neumarkt
- Württembergische Hypothekenbank AG, Stuttgart

#### **Michael Tarnow**

- AXCAN Pharma Inc., Canada
- Caprion Pharmaceuticals, Inc., Canada
- Ferghana Partners Group, USA
- Entremed, USA
- Xenon Genetics, Inc., Canada

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

Members	Shares 2005	Shares 2004	Options 2005	Options 2004	CB <sup>1)</sup> 2005	CB <sup>1)</sup> 2004
Prof Dr Ernst-Ludwig Winnacker Supervisory Board Chairman, Co-founder	292,676	292,676	38,700	38,700	3,200	3,200
Dr Norbert Riedel Deputy Supervisory Board Chairman	3,300	3,300	5,590	5,590	0	0
Dr Pol Bamelis, Supervisory Board Member	1,000	1,000	0	0	1,200	1,200
Sebastian Freitag, Supervisory Board Member	0	0	0	0	0	0
Dr Manfred Scholz, Supervisory Board Member	86,500	142,841	0	0	0	0
Michael Tarnow, Supervisory Board Member	6,337	6,337	0	0	36,200	36,200
Total Supervisory Board	389,813	446,154	44,290	44,290	40,600	40,600
Dr Peter Heinrich Chief Executive Officer, Co-founder	503,505	503,505	96,636	76,636	0	0
Dr Ulrich Delvos, Chief Operating Officer	1,000	360	5,000	0	0	0
Alexander Dexne, Chief Financial Officer	0	0	80,000	60,000	0	0
Total Executive Board	504,505	503,865	181,636	136,636	0	0
Treasury Stock	0	0	0	0	0	0

<sup>1)</sup> Convertible bonds

# (70) Notification according to § 21 Securities Trade Act, and announcement according to § 25 Securities Trade Act (WpHG)

In August 2005, MediGene announced in accordance with § 25 of the Securites Trade Act that TVM V Life Science Management GmbH & Co. KG, Munich, disclosed that their voting interest in MediGene exceeded the 5% threshold on March 12, 2004, and amounted to 6.93% at that time. Subsequently the voting interest decreased on Nomvember 16, 2004 and amounted to 5.55% at that time. These voting rights are to be allocated to TVM V Life Science Management GmbH & Co. KG, Munich, in accordance with § 22, clause 1, no. 1 of the Securities Trade Act. As of closing date December 31, 2005, no new or additional notification according to § 21 of the Securities Trade Act existed.

(71) Individuals and undertakings close to the company Individuals and undertakings close to the company are deemed to be undertakings and/or individuals that can be materially influenced by the company or exert a material influence upon the company. Individuals closely associated with the company are the members of the Executive Board and Supervisory Board of the company.

The compensation of the company's Executive and Supervisory Board members and their shareholdings are listed individually under N) Executive Board and Supervisory Board. In the last financial year there were no transactions other than these between the group and the individuals close to the company.

These consolidated financial statements for the financial period from January 1, 2005 to December 31, 2005 were prepared in accordance with the International Financial Reporting Standards, as applicable throughout the EU, and approved for publication by the Executive Board on February 1, 2006.

MediGene AG Adjustment US-GAAP to IFRS 89

# 0) Adjustments US-GAAP to IFRS

# **Adjustment consolidated income statements**

for the periods from January 1 to December 31, 2004

In T€		Notes No.	2004 US-GAAP	2004 Adjustment	2004 IFRS
1.	Product sales		12,501	0	12,501
2.	Other operating income		637	0	637
3.	Total revenues	(32)	13,138	0	13,138
4.	Cost of goods	(33)	5,930	0	5,930
5.	Gross profit		7,208	0	7,208
6.	Selling expenses	(34)	1,164	0	1,164
7.	General and administrative expenses	(35)	4,788	342	5,130
8.	Research and development expenses	(36)	15,627	0	15,627
9.	Operating loss		-14,371	-342	-14,713
10.	Interest income and expenditures	(37)	575	-18	557
11.	Income from securities	(37)	1,581	0	1,581
12.	Foreign currency exchange gains/losses	(37)	-90	0	-90
13.	Result before income tax		-12,305	-360	-12,665
14.	Net loss from continued operations		-12,305	-360	-12,665
15.	Result from discontinued operations	(38)	-1	0	-1
16.	Net loss		-12,306	-360	-12,666
	Earnings per share in €:				
	- basic	(46)	-0.88	-0.02	-0.90
	Weighted average number of shares outstanding		13,996,440	0	13,996,440

IFRS

The accompanying notes are an intergral part of the consolidated financial statements. Totals may vary due to rounding.

90 Adjustment US-GAAP to IFRS MediGene AG

# **Adjustment consolidated balance sheet**

as of January 1, 2004

#### Assets

In T€		Notes No.	Jan. 1, 2004 US-GAAP	Adjustment	Jan. 1, 2004 IFRS
A. Lor	ng-term assets				
I.	Property, plant & equipment	(46)	2,189	0	2,189
II.	Intangible assets	(47)	76	0	76
III.	Goodwill	(41)	9,226	0	9,226
IV.	Investments	(48)	4,452	0	4,452
V.	Other assets		42	0	42
Total	long-term assets		15,985	0	15,985
B. Cu	rrent assets				
I.	Accounts receivable	(49)	79	0	79
II.	Cash and cash equivalents	(50)	21,444	0	21,444
III.	Other current assets	(49)	859	0	859
Total	current assets		22,382	0	22,382
Total	assets		38,367	0	38,367

# Liabilities and shareholders' equity

In T€		Notes No.	Jan. 1, 2004 US-GAAP	Adjustment	Jan. 1, 2004 IFRS
A. Sh	areholders' equity				
I.	Share capital	(51)	11,206	0	11,206
	Number of shares issued and outstanding				
	December 31, 2003: 11,206,205				
II.	Additional paid-in capital	(52)	218,177	111	218,288
III.	Accumulated deficit	(53)	-199,943	-1,057	-201,000
IV.	Net income recognized directly in equity	(54)	-220	975	755
Total shareholders' equity			29,220	29	29,249
B. Loi	ng-term liabilities				
I.	Long-term debt less current portion	(57)	108	-29	79
II.	Other long-term liabilties	(56)	34	0	34
III.	Capital lease obligation less current portion	(57)	108	0	108
IV.	Pension accrual	(55)	35	0	35
Total	long-term liabilities		285	-29	256
C. Cu	rrent liabilities				
I.	Trade accounts payable	(56)	1,764	0	1,764
II.	Other current liabilties	(56)	268	3,342	3,610
III.	Current portion of capital lease obligation	(57)	265	0	265
IV.	Accruals		3,342	-3,342	0
V.	Deferred income	(56)	3,222	0	3,222
Total	current liabilities		8,862	0	8,862
Total	liabilities and shareholders' equity		38,367	0	38,367

IFRS

The accompanying notes are an integral part of the consolidated financial statements. Totals may vary due to rounding. MediGene AG Adjustment US-GAAP to IFRS 91

# **Adjustment consolidated balance sheet**

as of January 1, 2005

#### Assets

In T€		Notes No.	Jan. 1, 2005 US-GAAP	Adjustment	Jan. 1, 2005 IFRS
A. Lor	ng-term assets				
l.	Property, plant & equipment	(46)	1,565	0	1,565
II.	Intangible assets	(47)	7,020	0	7,020
III.	Goodwill	(41)	9,226	0	9,226
IV.	Investments	(48)	2,761	0	2,761
V.	Other assets		133	0	133
Total	ong-term assets		20,705	0	20,705
B. Cu	rrent assets				
l.	Accounts receivable	(49)	115	0	115
II.	Cash and cash equivalents	(50)	48,460	0	48,460
III.	Other current assets	(49)	3,614	0	3,614
Total	current assets		52,189	0	52,189
Total	assets		72,894	0	72,894

# Liabilities and shareholders' equity

In T€		Notes No.	Jan. 1, 2005 US-GAAP	Adjustment	Jan. 1, 2005 IFRS
A. Sh	areholders' equity				
I.	Share capital	(51)	18,523	0	18,523
	Number of shares issued and outstanding				
	December 31, 2004: 18,522,684				
II.	Additional paid-in capital	(52)	256,411	471	256,882
III.	Accumulated deficit	(53)	-212,248	-1,416	-213,664
IV.	Net income recognized directly in equity	(54)	-1,003	975	-28
Total	Total shareholders' equity		61,683	29	61,712
B. Lo	ng-term liabilities				
I.	Long-term debt less current portion	(57)	1,703	-29	1,674
II.	Other long-term liabilties	(56)	55	0	55
III.	Capital lease obligation less current portion	(57)	115	0	115
IV.	Pension accrual	(55)	36	0	36
Total	long-term liabilities		1,909	-29	1,880
C. Cu	rrent liabilities				
I.	Trade accounts payable	(56)	618	0	618
II.	Other current liabilties	(56)	3,462	2,953	6,415
III.	Current portion of capital lease obligation	(57)	269	0	269
IV.	Accruals	(56)	2,953	-2,953	0
V.	Deferred income	(59)	2,000	0	2,000
Total	current liabilities		9,302	0	9,302
Total	liabilities and shareholders' equity		72,894	0	72,894

The accompanying notes are an integral part of the consolidated financial statements. Totals may vary due to rounding.

92 MediGene AG income statements

MediGene AG

# MediGene AG individual financial statements

# **Income statements in accordance with HGB**

MediGene AG individual financial statements for the periods from January 1 to December 31, 2005 and 2004

In T€	2005	2004
1. Revenues	18,222	14,709
2. Other operating income	463	2,080
	18,686	16,790
3. Cost of materials		
a) Cost of raw, auxiliary, operating materials and cost of goods	9,475	6,316
b) Cost of services bought	6,284	8,21
	15,759	14,52
4. Gross profit	2,926	2,26
5. Personnel expenses		
a) Wages and salaries	6,849	5,88
b) Social insurance contributions and expenditures for retirements benefits thereof for retirements: 143 T€ (2004: 82 T€)	1,145	1,01
	7,995	6,90
6. Depreciation of intangible and tangible assets	761	61
7. Other operating expenses	5,566	8.18
8. Operating loss	-11,395	-13,43
9. Other interest and related costs	827	61
10. Depreciation of financials assets	-1,512	-1
11. Interest and related expenses	-59	-4
12. Result from ordinary operations	-12,139	-12,88
13. Ordinairy expenses	4,350	
14. Net loss for the year	-16,489	-12,88
15. Net loss carried forward	-103,724	-90,83
16. Accumulated deficit	-120,213	-103,72

Totals may vary due to riunding

790

1,564

134,646

2.441

4,618

152,678

# **Balance sheet in accordance with HGB**

MediGene AG individual financial statements as of December 31, 2005 and December 31, 2004

3. Other liabilities

thereof with a term < 1 year: 790 T€; (2004: 2,441 T€)

thereof social insurance: 133 T€; (2004: 133 T€)

thereof with a term < 1 year: 0 T€; (2004: 0 T€)

thereof taxes: 402 T€; (2003: 140 T€)

3. Related parties liabilities

In T€		2005	2004
A. Fixed a	ssets		
I.	Intangible assets		
	1. Licenses	2,750	(
	2. Software	78	3!
II.	Tangible assets		
	1. Plant and equipment	765	897
III.	Financial assets		
	1. Investments in related parties	90,862	102,156
	2. Securities	1,258	2,770
		95,713	105,859
B. Curren	t assets		
I.	Receivables and other assets		
	Other assets thereof with a term > 1 year: 163 T€; (2002: 36 T€)	1,170	3,665
II.	Cash and cash equivalents	37,558	42,978
		38,728	46,644
C. Accure	d and deferred items	204	175
		134,646	152,678
Liabilities	and Shareholder's equity		
In T€		2005	2004
A. Shareh	older's equity		
I.	Share capital	18,766	18,523
II.	Additional paid-in capital	232,186	230,668
III.	Accumulated deficit	-120,213	-103,724
		130,739	145,467
B. Accrua	ils		
	1. Pension accrual	163	30
	2. Other accruals	2,179	2,55
		2,343	2,593
C. Liabiliti	es	=,0	_,,,,
	1. Loan thereof convertible: 127 T€; (2004: 1.632 T€)	127	1,63
	2. Trade liabilities thereof with a term < 1 year: 647 T€; (2004: 545 T€)	647	54

94 Report from the Supervisory Board MediGene A

# **Report from the Supervisory Board**

In fiscal year 2005, the Supervisory Board performed in full its statutory duties and the duties specified in the Articles of Incorporation. On the basis of verbal and written reports by the Executive Board, the Supervisory Board kept the corporation's management under continuous surveillance.

The Executive Board regularly reported on the corporation's economic status and business development position, corporate planning, major business transactions and fundamental matters of corporate policy, including the strategic and organizational alignment, cost and earnings trends, investment measures and financial planning.

The Supervisory Board performed its duties during four meetings (April 1, 2005, June 10, 2005, August 29, 2005 and November 28, 2005), in a meeting held on February 25, 2005 via conference call, and in further telephone discussions. On specific issues employees of the company were consulted. 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 Chairman of the Executive Board at least once a week, keeping himself and his Supervisory Board colleagues updated about major business transactions, and offering advice and support.

### **Focal Points of Discussion**

All business submitted to the Supervisory Board for which either statutory approval or approval according to the terms of the Articles of Incorporation were required was discussed in depth with the Executive Board. Besides current business development, the Supervisory Board paid particular attention to the corporation's strategic orientation.

Aside from existing development projects, the key points of discussion were the submission of the market approval application in the U.S.A for the drug Polyphenon® E-Ointment for the treatment of external genital warts and the negotiations for a marketing partnership for this product. In addition, the Supervi-

sory Board requested and received comprehensive reports about the budget for 2006, which the Supervisory Board approved after detailed consultation. Furthermore, the Supervisory Board also satisfied itself that the Executive Board was performing its duties in compliance with the terms of the German Corporate Control and Transparency Act, and that the risk management system implemented was functioning as intended.

#### **Supervisory Board Committees**

In the entire fiscal year 2005, there were an Audit Committee and a Compensation Committee.

The duties of the Compensation Committee include the personnel affairs of the Executive Board members. Focal points are the conclusion and alteration of the employment contracts with the Executive Board members and the fixing of their remuneration.

The members of the Audit Committee deal with issues relating to accounting and risk management, the required independence of the auditor, the awarding of the audit assignment to the auditor, the determination of audit focal points and the fee agreement .

# **Corporate Governance**

In 2005, the Supervisory Board also dealt with MediGene's fulfillment of the recommendations of the German Corporate Governance Codex. In November 2005, the Executive Board and the Supervisory Board issued the annual declaration of compliance in accordance with §161 Stock Corporation Act. The Executive Board and the Supervisory Board have committed themselves to follow the recommendations of the German Corporate Governance Codex accordingly. In 2005, no conflicts of interest of members of the Supervisory Board have occurred.

### Members of the Supervisory Board

With effect as of the end of the annual general meeting of MediGene on June 10, 2005, Dr Alexandra Goll resigned from her office as member of the Supervisory Board. As a result of the resignation, the

supplementary member elected by the annual general meeting on June 2, 2004, Mr Sebastian Freitag, automatically succeeded Dr Goll as member of the supervisory Board.

# Annual Report And Consolidated Financial Statements

The auditor chosen by the Shareholders' Meeting and commissioned by the Supervisory Board, PricewaterhouseCoopers Gesellschaft mit beschränkter Haftung Wirtschaftsprüfungsgesellschaft, Munich Branch, audited the Financial Statements of MediGene AG, the Consolidated Financial Statements for the fiscal year 2005, and the MD&As of MediGene AG and the group, and granted them the unqualified audit certificate. The Consolidated Financial Statements in accordance with IFRS were supplemented by a Consolidated MD&A and other explanatory notes in accordance with § 315 HGB. These IFRS Consolidated Financial Statements exempt the company from submitting a report based on German law.

The Supervisory Board received all balance sheet and income statements and the auditor's reports in time for its balance sheet meeting. They were discussed in full detail during the balance sheet meeting of the Supervisory Board held on March 1, 2006. The auditor participated in the balance sheet meeting, reporting on the most important results of his audit, and answered queries.

The Supervisory Board has endorsed the auditor's findings. It has examined the Consolidated Financial Statements and the Consolidated MD&A and the Financial Statements and MD&A of MediGene AG within the remit of the statutory requirements and raises no objections.

At its meeting on March 1, 2006, the Supervisory Board approved the Financial Statements of MediGene AG drawn up by the Executive Board and the Consolidated Financial Statements for the fiscal year 2005, which are thus adopted.

The Supervisory Board would like to thank the Executive Board and members of staff for their successful efforts for the company during the fiscal year 2005.

Munich, March 1, 2006

Prof. Ernst-Ludwig Winnacker Supervisory Board Chairman 96 Glossary MediGene AG

# **Glossary**

Actinic keratosis

Precursor of malignant spinocellular carcinoma

**Biopharma** 

The Biopharma segment consists of MediGene's EndoTAG and oncolytic herpes simplex virus technology, as well as the product candidates EndoTAG-1, NV1020 and G207 that are derived from the above

**Biopharmaceutical** 

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

**Biotechnological** 

Utilization of natural and modified biological systems and their components

**Catechines** 

Natural substances contained in green tea

Depot formulation, technology

Drug in the form of an implant which slowly disintegrates and releases the active substance over a set period of time

**Drug candidate** 

Drug under development

**Drug pipeline** 

All drug candidates in development

**EBIT** 

Earnings before interest and taxes

Genetic engineering, genetically modified

Methods of analysis, targeted modification and recombination of genetic information

Genital tumors, genital warts

Benign tumors of the skin in the genital region, caused by infection with specific human papilloma viruses

Herpes simplex virus (HSV)

Virus that may cause cold sores, for instance. Infection frequently does not lead to apparent symptoms

Hormone

Biochemical transmitter substance which controls and coordinates biochemical and physiological processes

**Human papilloma virus (HPV)** 

Virus that may cause genital warts

**IFRS** 

International Financial Reporting Standards

**Indications** 

Reason for the execution of a medical examination or treatment

Licensing

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

Liver metastasis

Secondary tumor of the liver

Liposomes

Minute, hollow globules, composed of fat molecules

Malignant melanoma

Most severe type of skin cancer

Net cash burn rate

Net consumption of cash, calculated from the changes in the balance sheet

Oncology

Science of tumors and tumor-related diseases

**Oncolysis** 

Tumor dissolution (Greek: oncos, tumor; and lyo, (dis-)solve)

**Pharmacology** 

Science of the interaction between drug and organism

**Pipeline** 

All the drug candidates that are under development

Placebo

Drug dummy, pharmacologically ineffective

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# **Prostate cancer**

Malignant tumors of the prostate gland (part of the male crotch)

# R&D

Research and development

# **Speciality Pharma**

The Specialty Pharma segment encompasses Medigene's drug Eligard® and the product candidate Polyphenon® E Ointment

# **Technology platform**

A technology that can be used for a variety of research or application purposes

#### **Toxicology**

Science of the harmful effects of substances on health

# Urology

Science of the urinary organs and their diseases

#### **US-GAAP**

United States Generally Accepted Accounting Principles

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# Multi-year overview MediGene Group

in T€	Change 2005/2004 in %	20054)	20044)	2003 5)	20025)	20011)5)	20005)	1999 <sup>5)</sup>	19985)
Income statements									
Revenues	56%	19,555	12,501	0	0	0	0	0	174
Other operating income	-80%	127	637	1,742	3,425	7,264	6,081	5,544	1,707
Cost of sales	53%	9,077	5,930	0	0	0	0	0	
Research and development expenses	2%	15,997	15,627	21,825	26,721	21,696	11,213	1,439	3,066
Selling, general and administrative expenses	-3%	6,123	6,294	7,926	7,177	5,736	2,528	0	876
Amortization of goodwill	-	0	0	0	0	1,845	0	0	0
Depreciation <sup>2)</sup>	_	_	-	1,031	1,085	768	323	216	123
Operating result before write-off »IPR&D³¹«	-22%	-11,515	-14,713	-29,040	-31,558	-22,782	-7,982	-2,709	-2,184
Result before income tax	-5%	-12,044	-12,665	-28,333	-30,231	-104,583	-6,905	-2,861	-2,246
Net result from continued operations	-5%	-12,045	-12,666	-31,060	-38,870	-110,490	-9,264	-3,745	-2,853
Write-off »IPR&D <sup>3</sup> )«	_	0	0	0	0	86,543	0	0	0
Personnel expenses	10%	9,628	8,769	10,973	11,245	7,938	4,089	2,316	1,393
	_								
Balance sheet data	_								
Cash and securities	-22%	37,625	48,460	21,444	47,762	86,843	115,226	18,059	17,261
Balance sheet total	-22%	57,062	72,894	38,367	67,079	108,383	127,790	21,268	18,674
Shareholders' equity	- 16%	51,777	61,712	29,220	59,435	100,406	118,793	9,360	13,284
Long-term liabilities	_	312	1,880	285	2,993	2,402	1,362	5,984	4,278
Equity ratio	7%	91%	85%	76%	89%	93%	93%	44%	71%
	_								
Cash flow	_								
Cash flow from operating activities	-14%	-10,437	-12,096	-26,544	-38,635	-22,015	-6,560	-2,977	-1,990
Cash flow from investing activities	-109%	-413	4,785	-12	5,296	9,031	-21,494	-8,412	-615
Cash flow from financing activities	-100%	61	34,341	267	312	930	110,807	4,278	17,265
	-								
Employees as at December 31	0%	114	114	121	182	158	88	48	34
	-								
MediGene share	-								
Shares outstanding as at Dec. 31	1%	18,766,172	18,522,684	11,206,205	11.206.205	11,198,637	10,106,722	6,728,124	6,728,124
Weighted average number of shares	33%	18,560,027	13,996,440	11,206,205	11.204.990	11,003,245	8,417,423	6,728,124	4,936,701
Net result per share	-28%	-0.65	-0.90	-2.53	-3.47	-10.04	-1.10	-0.56	-0.58
Net result per share adjusted for write-off »IPR&D«	- 28%	-0.65	-0.90	-2.53	-3.47	-2.18	-1.10	-0.56	-0.58
Sharesprice at the end of the year	-2%	8.36	8.50	5.90	4.00	21.20	73.50	-	_
Dividend	_	0	0	0	0	0	0	0	0

<sup>&</sup>lt;sup>1)</sup> Acquisition and Consolidation of MediGene, Inc. From March 1, 2001

<sup>&</sup>lt;sup>2</sup> Due to the first-time adoption of International Financial Reporting Standards (IFRS) as of 2004, depreciation is included in R&D expenses, business development and general administration.

IPR&D = In Process Research and Development
 According to IFRS
 According to US-GAAP

# **Financial calendar**

#### March 22

Annual report 2005

# May 3

3-months report
Press and analysts conference call

#### June 2

Annual shareholder's meeting

# August 2

6-months report
Press and analysts conference call

# **November 8**

9-months report
Press and analysts conference call

# 2007

# March 28

Annual report 2005 Press and analysts conference

# **Trademarks**

# Eligard®

is a trademark of QLT USA, Inc.

# Polyphenon® E

is a trademark of Mitsui Norin

# EndoTAG™

is a trademark of MediGene AG.

#### MediGene™

is a trademark of MediGene AG

... we are looking forward to speaking with you

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