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Annual report 2004

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commercialization. MediGene is the first German biotech company with an approved drug on the market. Some of our drug candidates are currently in clinical development, and we possess our own technologies for the development of active substances. The revenues from drug sales as well as from marketing and development of additional substances, thus helping to reach break-even. MediGene is a leading German biopharmaceuticals company, expanding its activities into new markets. Some of our drug candidates are currently in clinical development, and we possess our own technologies for the development of active substances. The revenues from drug sales as well as from marketing and development of additional substances, thus helping to reach break-even. MediGene is a leading German biopharmaceuticals company, expanding its activities into new markets. Some of our drug candidates are currently in clinical development, and we possess our own technologies for the development of active substances. The revenues from drug sales as well as from marketing and development of additional substances, thus helping to reach break-even. MediGene is a leading German biopharmaceuticals company, expanding its activities into new markets.

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### Financial report and MD&A

Separate report in the sleeve on the back

Glossary see page 54 of the financial report

# Portfolio of Novel Cancer Therapeutics

Products	Indication	Clinical phases			Approval	Market launch	Sales potential <sup>1)</sup> (million €)
		I	II	III			
Eligard <sup>®2)</sup>	Prostate cancer	■	■	■	✓	✓	> 100 <sup>3)</sup>
Polyphenon <sup>®</sup> E Ointment	Genital warts	■	■	■			> 100
	Actinic keratosis <sup>4)</sup>	■	■				> 200
EndoTAG-1	Pancreatic cancer	■					> 200
	Prostate cancer	■					> 200
Oncolytic HSV	Liver metastases	■	■				> 200
	Glioblastom	■					> 300
Chance of reaching the market		10 – 30%	40 – 60%	60 – 80%	90%		

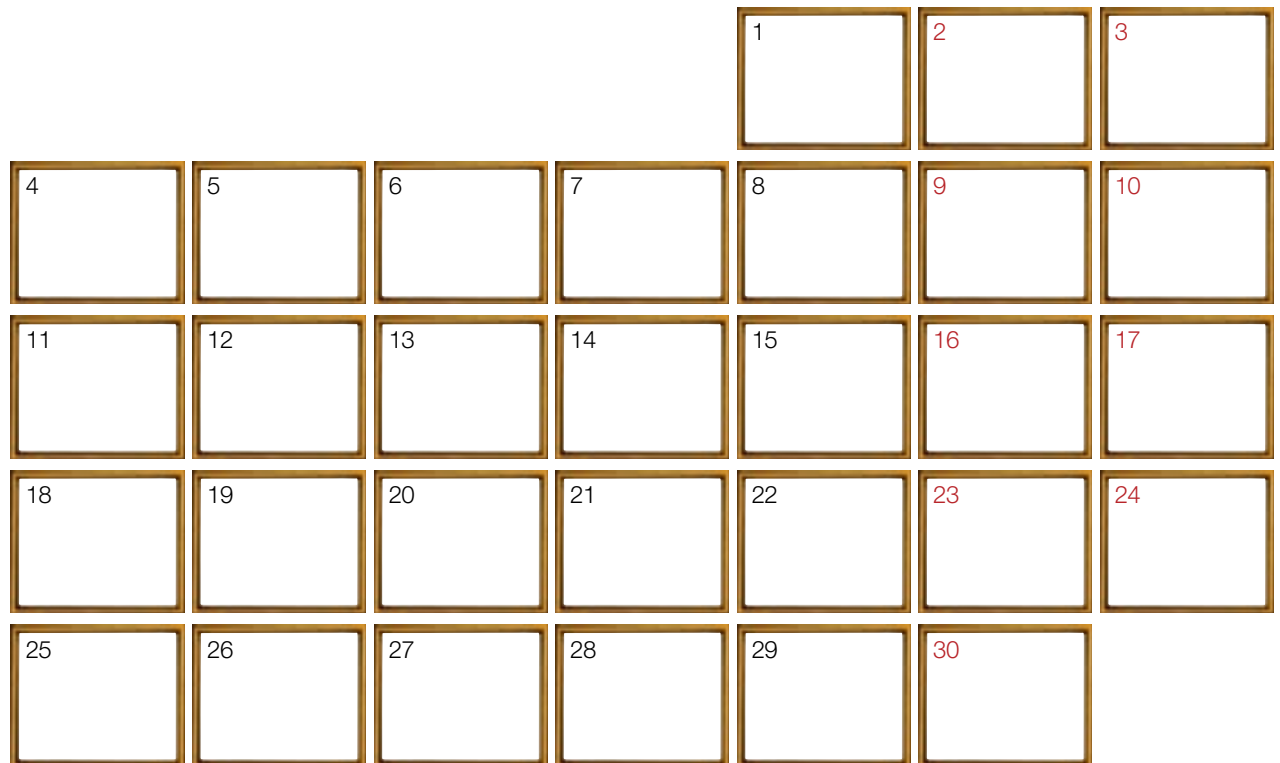
<sup>1)</sup> Per year, peak sales. MediGene will receive royalties from sales of products, which are jointly developed or marketed with biotech or pharmaceuticals companies.

<sup>2)</sup> In-licensed from QLT USA, Inc. (formerly Atrix)

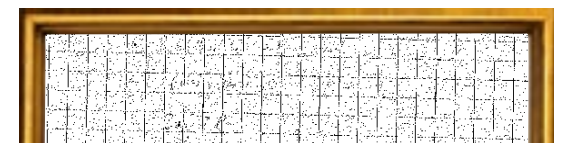
<sup>3)</sup> Marketing partnership with Yamanouchi

<sup>4)</sup> Precursors of a specific kind of skin cancer

# april 05



April 13 – 15, 2005: BioSquare Conference, Lyon, presentation MediGene





**1994** Formation

**1996** Established three research programs and service business



**1998** Shifted focus to drug development, Sold service business

**1999** License acquired for active ingredient for Polyphenon® E



**2000** IPO

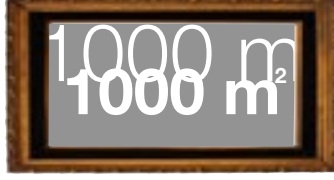
Initiated first clinical trial (CVLP product)

1,000 m<sup>2</sup> laboratory space in use



**2001** Acquisition of subsidiary MediGene, Inc., USA

MediGene's 100<sup>th</sup> employee hired



Acquired license for Eligard®

**2002** MediGene ceases development of the cardiac drug candidate Etomoxir

**2003** Shifted focus to anti-cancer drugs, Cardiology program divested



Discontinued CVLP project

MediGene became first German biopharmaceuticals company to obtain drug approval



**2004** Marketing partnership with Yamanouchi

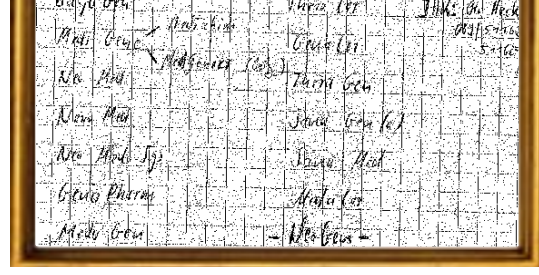
Discontinued AAV project

MediGene became first German biopharmaceuticals company to successfully complete clinical phase III trial (Polyphenon® E Ointment)



MediGene launched its first drug: Eligard®!

**1994** Naming MediGene, excerpt from the notebook of Dr Peter Heinrich



# MediGene – Yesterday, Today, Tomorrow

**Dear Shareholders,** 2004 marked the tenth year in the history of our company. Since our IPO in 2000, the year 2004 also proved to be MediGene's most successful.

The approval and market launch of our first anti-cancer drug Eligard® was in itself a dramatic and groundbreaking success not only for MediGene, but also for the German biopharmaceuticals industry as a whole. In 2004, Eligard® became the first drug ever to be launched by a German biopharmaceuticals company. Starting midyear in 2005, the drug is to be sold in other European countries as well. The respective approvals for 23 countries have already been granted. For the commercialization of Eligard®, we gained an extremely powerful marketing partner with the pharmaceuticals group Yamanouchi.

And our next drug is practically waiting in the wings: in 2004, MediGene completed the clinical phase III of Polyphenon® E Ointment for the treatment of genital warts with excellent results (each clinical development procedure comprises three phases). We are now preparing the marketing authorization application and expect market launch in 2007. The planned closure of a marketing partnership should already generate revenues from milestone payments in 2005.

We have also laid the foundations for further growth in another respect. In 2004, MediGene acquired the products of Munich Biotech AG, thus enhancing MediGene's product portfolio and adding another technology platform. We have particularly high expectations for the drug candidate EndoTAG-1, which has already passed preliminary clinical trials in various cancer indications. For 2005, MediGene is planning to conduct a continuative clinical phase II trial. The EndoTAG product candidates which are intended to »starve out« cancer cells are very exciting in both scientific and economic respects. These products show impressive prospects for the future.

Moreover, we have been able to extend clinical development of our Polyphenon® E Ointment to the indication actinic keratosis, a precursor of skin cancer (phase II initiated). This multiplies the sales potential of the product. Clinical development of another drug candidate, NV1020 for the treatment of liver metastases, is also being continued (phase I/II initiated). In addition, we managed to further extend MediGene's strong patent portfolio by new patents and licenses.

The financial development of our company was one of our major achievements in 2004. We were able to increase revenues from almost two million € to approximately 13 million €, as well as reduce our net loss by 60% to approximately twelve million €. We are planning to further improve this result in the current fiscal

year 2005. We have made provision for a sound financing of our company over the next few years: despite a very restrained stock market environment, we successfully closed two capital increases and brought in 38 million € for the company by issuing new shares. This will provide sufficient scope to finance both our current projects as well as future growth. I would like to thank you, our shareholders, for making this possible.

With a 40% increase, the MediGene share price has developed far above average as a consequence of our successes. The significant raise in market capitalization is equally important. The raise in share price and the increased number of shares resulted in a 130% increase to 157 million € at the end of the year. Not least because of that, MediGene was admitted to the important German stock index TecDAX30.

2004 represents a clear mark of success in an exciting decade for MediGene. I would like to express my sincere thanks to all employees, business partners and shareholders for your trusting cooperation. I look forward to the coming ten years for MediGene AG – may they be even more successful.

Sincerely,

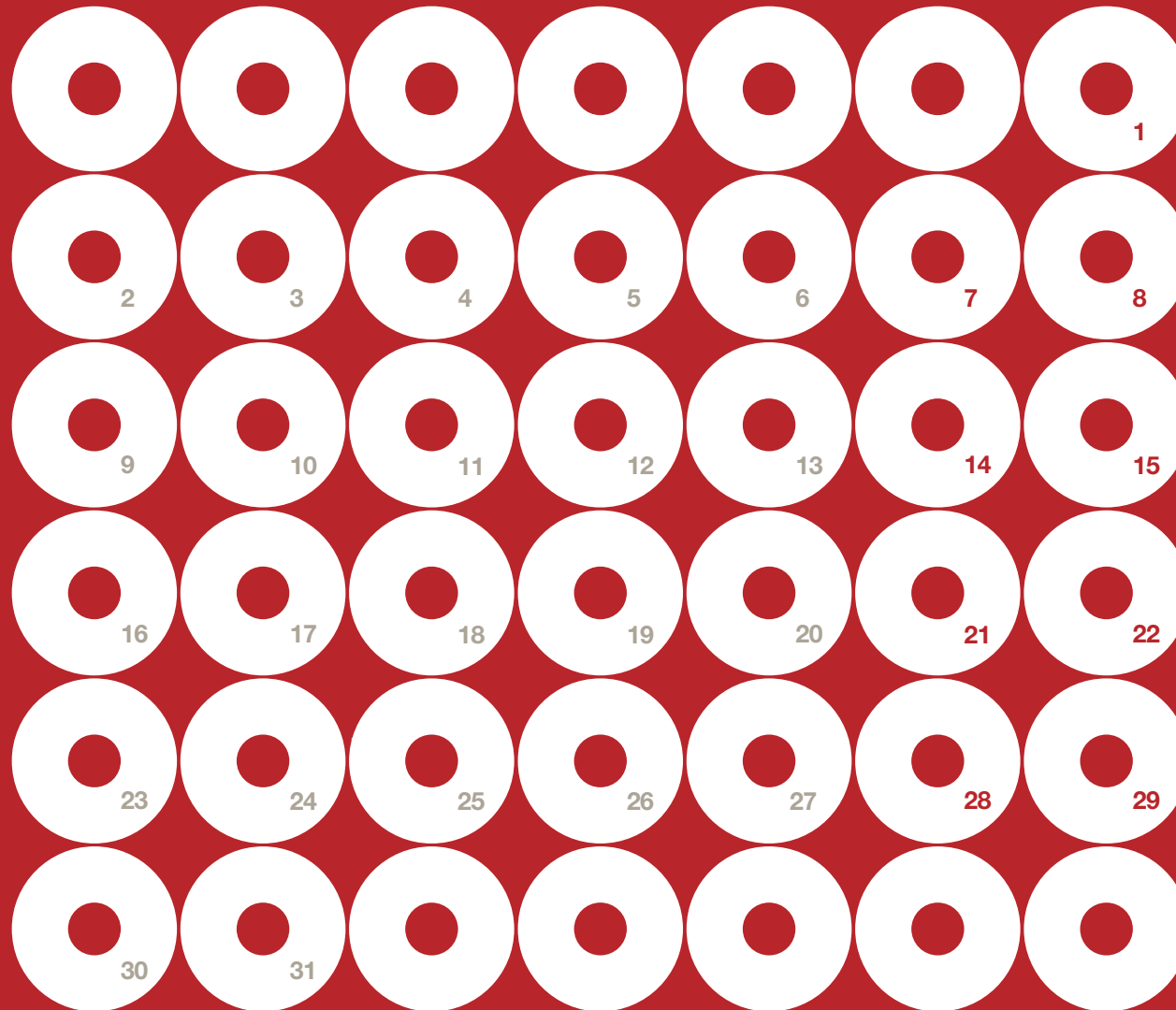


Dr Peter Heinrich, Chief Executive Officer

## MediGene 10 Years from Now – Our Vision:

- We aim to have several drugs on the market.
- Some of them will be marketed by partners, others by our own sales force.
- Some of our drugs will emerge from our own research and development, the majority of them, however, should be licensed products.
- MediGene will have strengthened its position as one of the leading biopharmaceutical companies in Europe.

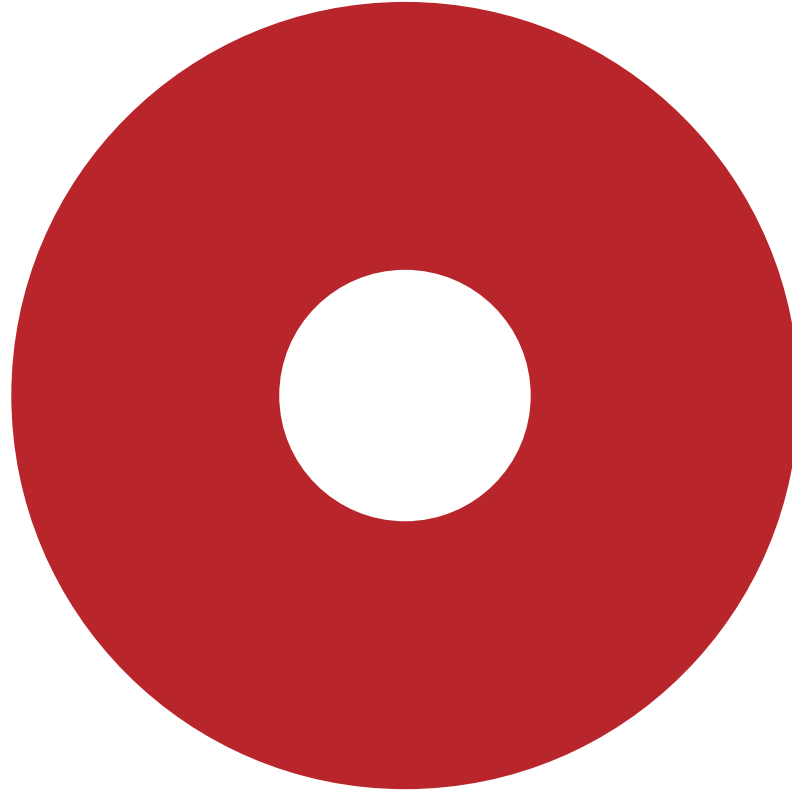
# may 05



May 2 – 6, 2005: International Papillomavirus Conference. presentation MediGene

May 4, 2005: Publication of the 3-months report 2005

May 9 – 11, 2005: IPMC-Biotech/Healthcare Conference, Frankfurt, presentation MediGene



4. 01

MediGene acquires pan-European marketing rights for Eligard® (one-month, three-months, four-months and six-months sustained release products) from Atrix (today's QLT USA, Inc.).

12. 02

MediGene submits marketing authorization application for the one-month product to the German regulatory authorities.

4. 02

MediGene submits marketing authorization application for the three-months product.

12. 03

MediGene obtains German marketing authorization for the one-month product.

1. 04

German marketing authorization for the three-months product. Marketing partnership with Yamanouchi.

5. 04

Eligard® launched on the German market.

12. 04

EU approval process for 23 additional countries successfully completed.



# Time for the Debut

MediGene Becomes First German Biopharmaceutical Company to Launch Its Premiere Drug

On May 4, 2004, MediGene made history when its first drug Eligard® became available in German pharmacies for the first time. The medical representatives of MediGene's marketing partner Yamanouchi, one of Europe's leading companies in the urology market, swarmed out to the urologists to promote this new drug for the treatment of prostate cancer. Very successfully: by the end of 2004, Eligard® had already reached more than a 7% share in the market – an outstanding result, which should even be surpassed in 2005 and in the years to come.

Thus MediGene is now reaping the fruit of an idea from the early days. MediGene had already lined up for IPO in 2000 with the strategy of pursuing its own scientific approaches as well as acquiring other companies' product candidates in a further advanced development stage, in order to complete their development to the point of market launch. By doing so, MediGene planned to bridge the gap between early developments and product candidates close to the market, and to generate revenues from drug sales as quickly as possible. This plan succeeded.

In 2001, MediGene acquired the license for the pan-European commercialization of Eligard® from the U.S. company Atrix Laboratories, Inc. (today's QLT USA, Inc.). Clinical development of Eligard® was complete, but the drug had not obtained marketing authorization at that time. MediGene assumed the task of taking the drug through approval procedures for Europe, starting with Germany. For this purpose, the clinical data collected by Atrix was adapted to German requirements, and the resulting dossier was submitted to the German regulatory authorities. In addition, MediGene conducted supplementary pre-clinical trials. Thanks to our comprehensive preparatory work, we were able to reply quickly to all queries from regulatory authorities, providing them with substantiated arguments and evidence. At the turn of the years 2003/04, after having gone through two years of a very intense procedure, MediGene finally obtained the valuable German marketing authorizations for the one-month and three-months sustained release products of Eligard®. As a result, MediGene is now the first German biopharmaceutical company with an approved drug on the market.

Early in 2004, MediGene managed to gain the pharmaceuticals heavyweight Yamanouchi as a marketing partner for the pan-European commercialization of

Eligard®. MediGene is responsible for the supply of the product which is manufactured by QLT in the United States, for the professional import of the drug to Europe and for the quality of the product. According to the terms of the agreement, MediGene receives royalties on sales of Eligard® as well as milestone payments for the approval and market launch of the drug in major European countries. At the end of 2004, the »mutual recognition procedure« for 23 additional EU member states (e.g. France, Italy, and Spain) was successfully completed with European regulatory authorities.

Eligard® is a hormone compound for the treatment of advanced, hormone-dependent prostate cancer. The active substance (leuprolide acetate) permits a significant reduction of the male sex hormone level, thus suppressing tumor growth. The established substance is combined with a novel drug delivery system, the Atrigel® depot technology: the liquid drug is injected subcutaneously into the patient where it forms a gel-like depot that slowly disintegrates while steadily releasing the drug over a period of one month or three months, depending on the dosage administered. Up to now, no application for approval in Europe of two other dosages of Eligard®, i.e. the four-months and six-months products, has been submitted. It is up to Yamanouchi to decide on that.

**MediGene will remain a pioneer in the German biopharmaceutical industry in the future as well.**

Another premiere awaits the company and its shareholders in 2005: the launch of Eligard® in other European countries. Like in Germany, the drug will be marketed by MediGene's partner Yamanouchi. The four-months and six-months products may even increase the sales potential of Eligard®.

MediGene's second drug follows hard on the first one: in 2005, we intend to submit the marketing authorization application for Polyphenon® E Ointment. This drug for the treatment of various skin tumors has been MediGene's first proprietary clinical development and has already successfully undergone all three stages in clinical development.



# june 05



June 10, 2005: Annual shareholder's meeting, Munich  
June 12 - 15, 2005: LES International Conference, Munich  
June 19 - 22, 2005: BIO 2005 Conference, Philadelphia. Booth and presentation MediGene





# Green Tea Time

MediGene's Second Drug Completes Last Stage of Clinical Development: Active Substance in Green Tea to Treat Skin Tumors

For centuries, green tea has been considered to be good for your health. Only recently have chemical and biochemical techniques made it possible for researchers to examine green tea components for their therapeutic potential. For the first time, the appropriate methods are available to isolate these substances and combine them in order to multiply their effect, for systematic application as a drug in humans.

MediGene has developed a drug based on green tea extracts, which is intended for the treatment of various skin tumors. The last stage of clinical development of Polyphenon® E Ointment for the treatment of the sexually transmitted skin disease genital warts was successfully passed through at the end of 2004 (completion of clinical phase III). A clinical phase II trial is currently in progress to test this drug candidate in another tumor disease, i.e. actinic keratosis, a precursor of malignant acanthocyte skin cancer. The onset of both diseases is attributed to infection by certain viruses, i.e. the human papilloma viruses. MediGene's Polyphenon® E Ointment contains a high dose of specific catechines, extracted from green tea leaves. They are supposed to inhibit major functions of the papilloma viruses, counteract specific changes in tumor cells and, moreover, activate the patient's immune system. The result: in clinical trials, the Polyphenon® E Ointment showed excellent efficacy and very slight adverse events.

Polyphenon® E Ointment is MediGene's second drug in the pipeline and already very close to the market. MediGene acquired the license for this substance from the company Epitome Pharmaceuticals Ltd. in 1999, and since then has continued the substance's development in nine additional clinical phase I – III trials. This was a tremendous accomplishment for a company

of MediGene's size. With more than 1,000 patients in 15 countries, the pivotal phase III trial alone required immense professional and organizational know-how. The clinical trials were accompanied by pre-clinical trials investigating mode of action and safety of the drug in vitro or in animal experiments. This challenging task was also executed by MediGene and in cooperation with external partners. This also applies to the Polyphenon® E Ointment production process developed on MediGene's behalf. Our employees transferred this production process to large-scale manufacturers who produce bulk quantities of the drug. All in-house and external operations are supervised by our quality assurance experts. That way, we can ensure compliance with the regulatory authorities' stringent requirements in the field of drug development.

## We are pursuing very ambitious plans concerning our Polyphenon® E Ointment:

- In 2005, we will submit the marketing authorization application in the United States for the indication genital warts, followed by the application for Europe approximately six months later. We expect to launch the drug in the United States, the primary market for this drug, in 2007.
- By midyear 2005, we also expect to receive the results of the phase II trial of Polyphenon® E Ointment in the indication actinic keratosis.
- The conclusion of a marketing partnership will be one of the major achievements in 2005. This partner will promote and sell our Polyphenon® E Ointment. MediGene will receive milestone payments as well as royalties on the sales of this drug. We are currently negotiating with a number of potential partners. The contract should be closed this year, generating proceeds from milestone payments.

july 05

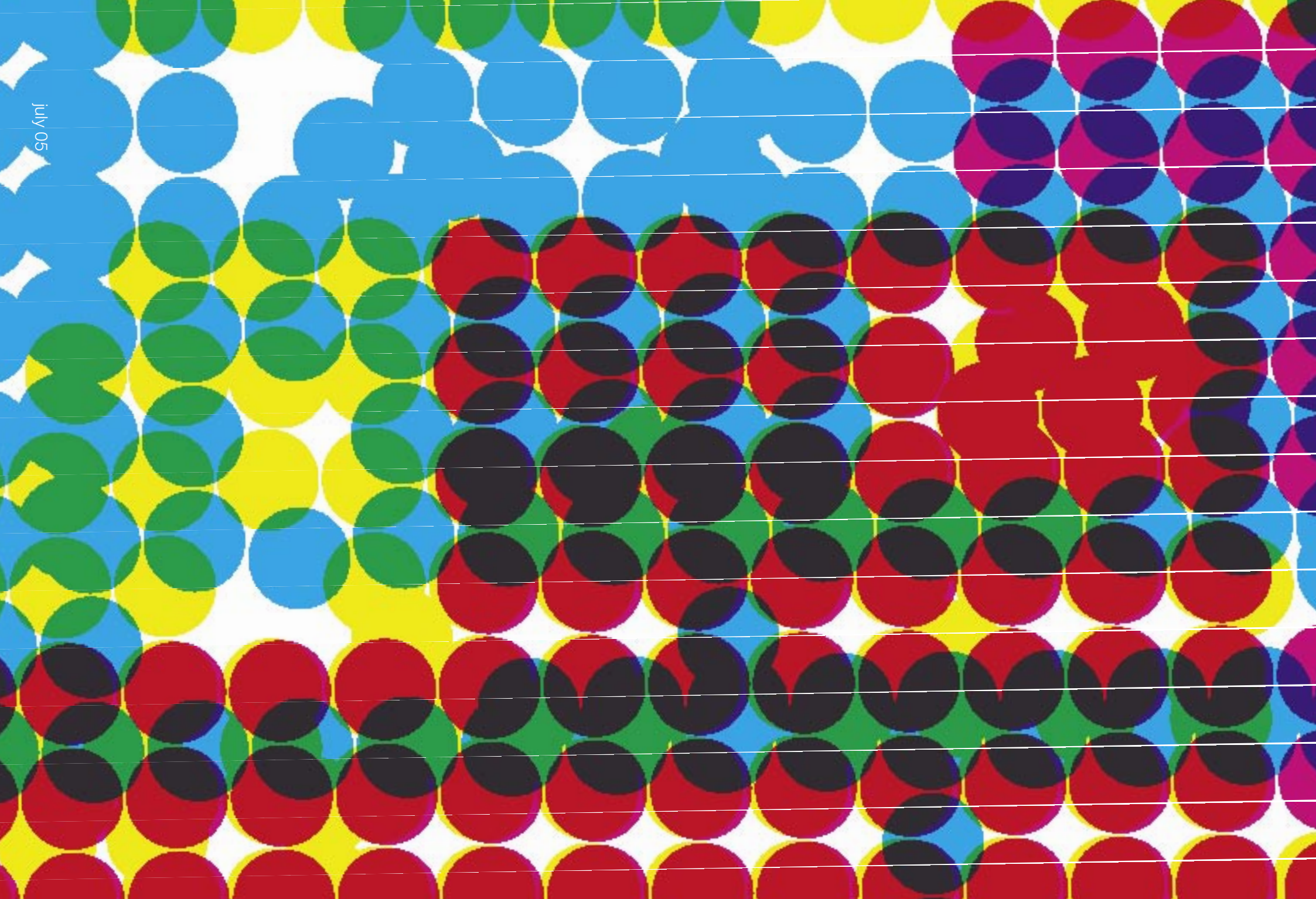
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# Time for Two

MediGene Extends Drug Pipeline by Acquiring Munich Biotech AG

**For MediGene, 2004 was a year of partnerships and acquisitions:** In January, we signed an extensive marketing contract with the pharmaceuticals group Yamanouchi for the anti-cancer drug Eligard®. In September, MediGene acquired the major assets of Munich Biotech AG (MBT), in particular its products, which are drug candidates in clinical development as well as the underlying platform technology. The respective patents and licenses were also assigned to MediGene. Moreover, MediGene hired a number of MBT's key employees in order to secure the expertise needed for further development of the products and technology. Apart from the EndoTAG technology platform, the drug candidate EndoTAG-1 in particular is the focus of attention in MediGene's development plans. This cutting-edge product candidate has already passed through several clinical phase I trials in various cancer indications and, according to expert opinion, it possesses blockbuster potential. MediGene paid a syndicate of existing MBT investors a purchase price for MBT's assets amounting to 11.3 million € in the form of shares. In turn, this syndicate invested four million € in cash to cover further development expenses. In addition, MediGene committed itself to make milestone payments, starting with the clinical phase III of EndoTAG-1 and depending on its success during these trials.

The acquisition of Munich Biotech significantly strengthened MediGene's drug pipeline. With Eligard® for the treatment of prostate cancer, Polyphenon® E against genital warts and actinic keratosis, our oncolytic viruses for the treatment of liver metastases and brain tumors, and our new EndoTAG-1 for the treatment of various cancer diseases, we have a broad product portfolio with attractive market potential. The combination of product candidates within this portfolio is also very well-

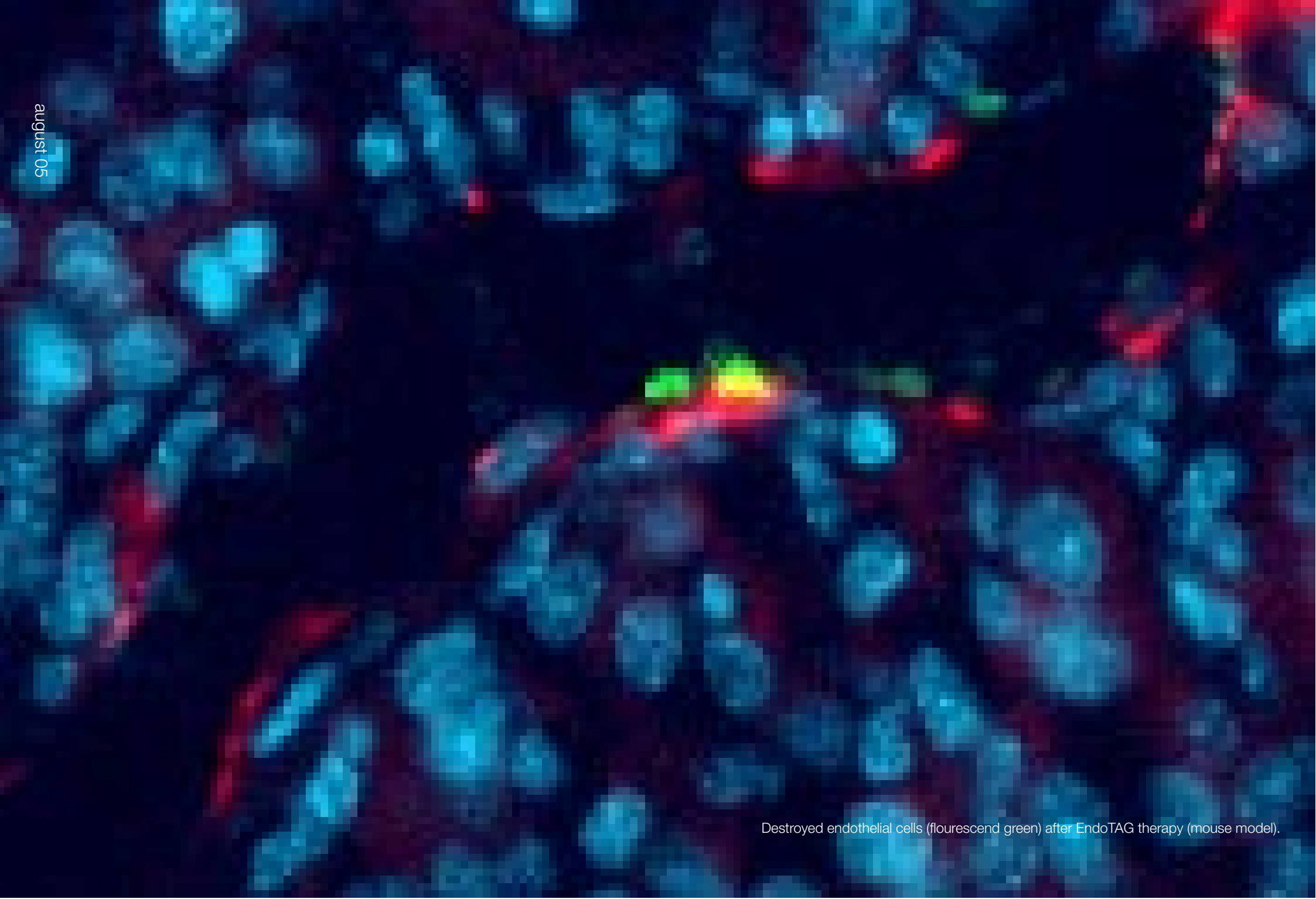
balanced: apart from one drug on the market and a second on the verge of approval procedure, we also have product candidates currently undergoing clinical phase I and II trials, thus providing »new blood« for MediGene. As drug development statistics indicate, not all of our product candidates will make it to the market. Many drug development projects worldwide are terminated prematurely because they do not show the expected efficacy, they lead to severe adverse events, or their realization is not profitable. For this reason, MediGene's product portfolio comprises on the one hand substances that are very likely to reach the market because they are based on established principles or have reached an advanced development stage. On the other hand, we also have genuine »bio-high-tech« product candidates which are highly innovative, although they involve corresponding development risks. Keeping this balanced will remain one of our major objectives in the future.

**A broad drug pipeline with a well-balanced risk profile requires continuous review and the courage to induce change.** If a project yields unsatisfactory results or proves to be unprofitable, we will terminate it. To guarantee continuous growth, we are reviewing all opportunities of further extending our pipeline with new products. In the long run, these drugs may be developed from our technology platforms, but this is a process lasting many years. In order to access product candidates faster, new partners are an interesting alternative: other biopharmaceutical companies could sell us a license for a product, like Eligard®. A merger or an acquisition, similar to that of Munich Biotech, would also be a possible strategy. We are reviewing these options carefully. If they are suited to increase MediGene's potential, we will realize them.

august 05

1	2	3	4	5	6	7
8	9	10	11	12	13	14
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22	23	24	25	26	27	28
29	30	31				





Destroyed endothelial cells (flouescend green) after EndoTAG therapy (mouse model).

# Start from the Beginning

MediGene's EndoTAG Products Starve Out Cancer Cells by Targeting Tumor Growth Early On

In many cases, extirpation is the most efficient method of combat. This is exactly what MediGene's EndoTAG products aim to achieve. They directly attack specific blood vessels needed for the growth of a tumor. If these blood vessels are destroyed, the cancer cells do not receive sufficient oxygen and nutrients: the tumor is »starved out«.

How does this work? EndoTAG 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 millimeter). The therapeutic substance is embedded in these globules. In the case of EndoTAG-1 this substance is Paclitaxel®, one of the most effective substances in chemotherapy. The EndoTAG liposomes are positively charged, enabling them to attach very easily to the negatively charged, newly developing tumor blood vessels (endothelial cells), and to merge with the cells of the vascular walls (»neovascular targeting«). This way the therapeutic substance can be transported selectively into those blood vessels that are responsible for increasing nutrient supply of tumors. By destruction of the endothelial cells, further growth of the existing tumor is suppressed. This represents a novel, alternative therapeutic approach compared to both conventional chemotherapy and classical anti-angiogenesis therapy (inhibition of vascularization). The EndoTAG concept offers a wide range of applications, and could even be suited for the treatment of any solid tumors.

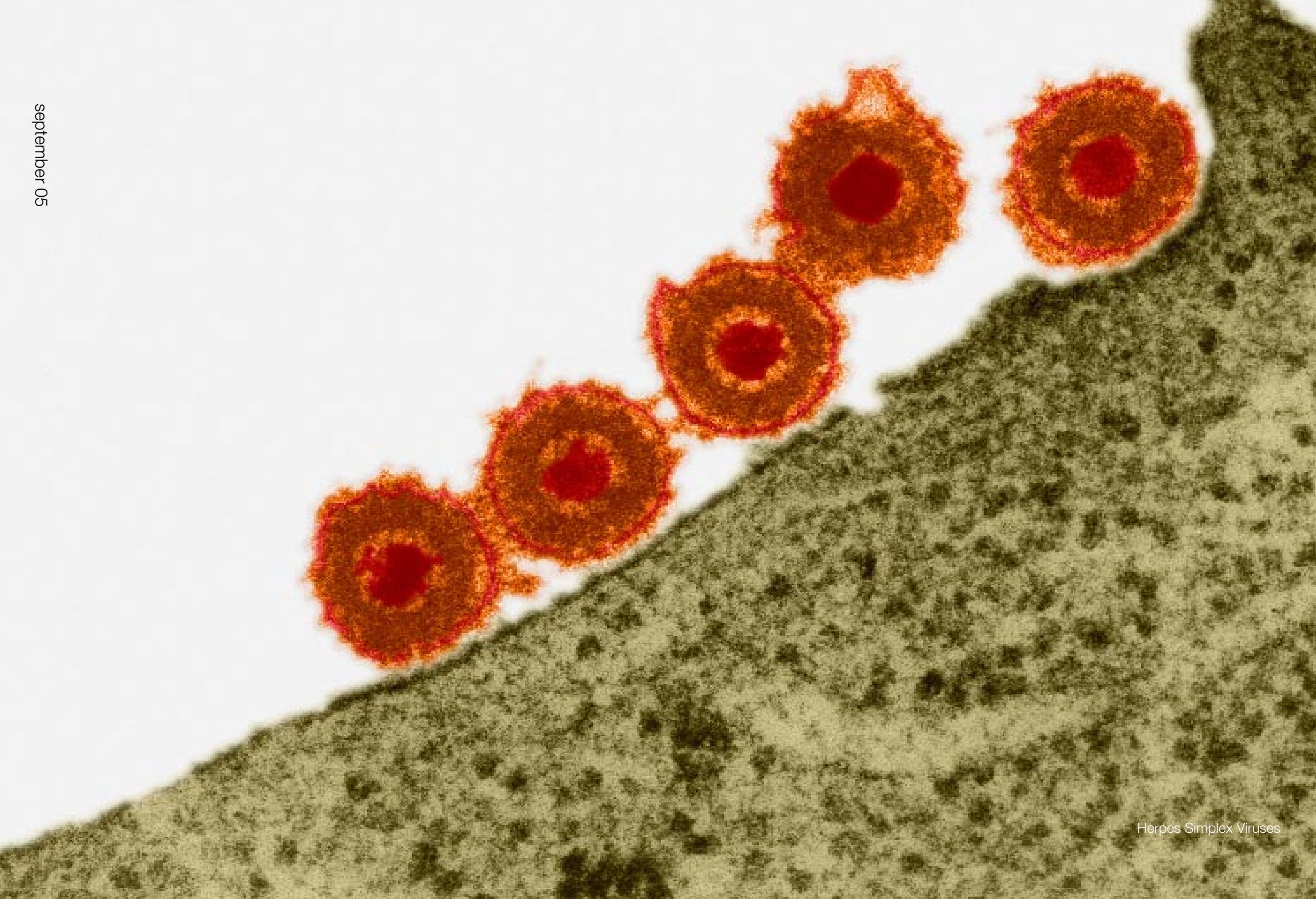
In addition, MediGene's scientists believe that the endothelial cells of a tumor do not develop resistances to the substance, whereas cancer cells may evade treatment with conventional therapies due to continuous metabolic changes.

EndoTAG provides a good combination of new and established therapies: the application of liposomes in medicine has been researched in depth already, and chemotherapy is standard cancer treatment. Even the approach to cut off nutrient supply from the tumor cells was also recently established as a therapy. The drug Avastin® is the most prominent example there. The principle of targeting the tumor vascular system directly, thus intervening in tumor development at a very early stage, is the cutting-edge characteristic of EndoTAG. Combining Paclitaxel® with the liposome carrier system is also innovative. Both innovations could make a very interesting contribution to the future development in cancer therapy. The field of anti-angiogenesis drugs already represents a very promising market.

With EndoTAG, MediGene owns a platform technology from which a multitude of drugs based on liposomes could be developed. For the time being, MediGene is focusing its development plan on the drug candidate EndoTAG-1. This drug candidate has already undergone several clinical phase I trials in different cancer indications. Soon it will be tested to treat pancreatic and prostate cancer. **MediGene will start with a continuative phase II trial in 2005.**

# september 05





# Think Future

MediGene Develops Viruses to Combat Cancer – Today's Dreams or Tomorrow's Reality?

**Viruses against cancer** – this concept seems to replace one evil with another. Of all things, these dreaded pathogens are supposed to fight the severest diseases?

This idea came up for the first time about 80 years ago, when some individual cancer patients showed receding tumors after a severe viral infection. However, it was not possible at that time to direct viruses in such a way that they target their destructive potential specifically at cancer cells. Today, this seems technically feasible.

MediGene is developing cancer-killing, so-called »oncolytic« viruses for the treatment of various cancer diseases. These viruses are specific herpes simplex viruses, abbreviated HSV, known to many people as the cause of cold sores. MediGene, however, is not utilizing these viruses as they occur in nature, but is modifying them genetically instead. The viruses are »disarmed« and modified to make them therapeutically utilizable for humans. The trick is to switch off certain genes that normally enable the virus to multiply in healthy cells, which would destroy these cells. For reproduction, the modified virus now has to switch to tumor cells. The cancer cells 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. Healthy tissue remains uninjured.

If this hypothesis is confirmed, oncolytic HSV will act more selectively and efficiently than conventional cancer therapies do, yet without leading to severe

adverse events. They could provide a therapeutic alternative against 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 trials with cancer patients have already yielded positive results. MediGene successfully completed several phase I trials of HSV against liver metastases and brain tumors. In September 2004, we initiated a continuative phase I/II trial in the indication liver metastases developing from colorectal carcinoma. In this trial, HSV is combined with chemotherapy. Clinical development of oncolytic viruses is an extremely challenging project. Since this project implies the administration of viruses to humans, regulatory conditions and provisions imposed are extraordinarily stringent.

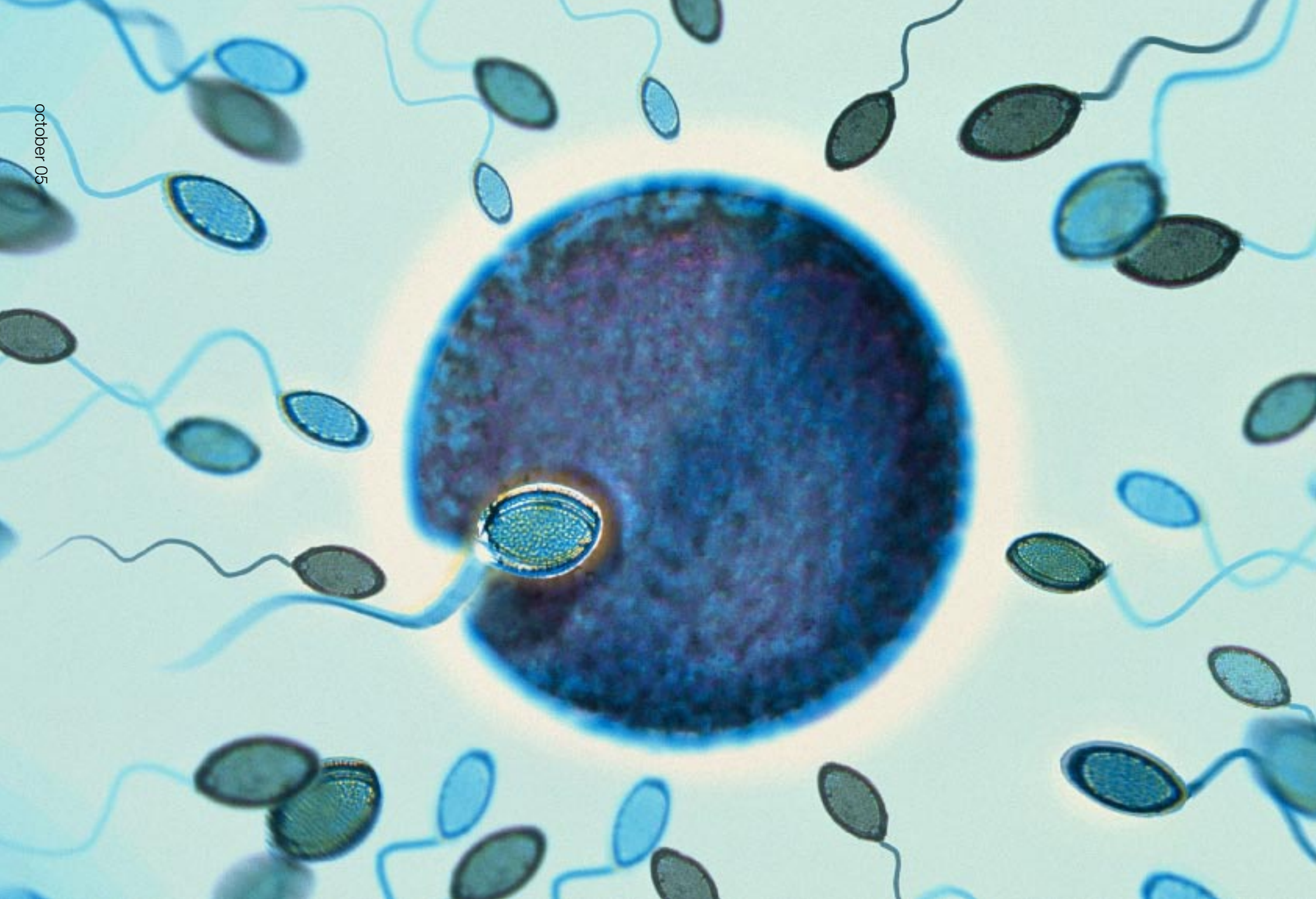
**MediGene is planning to complete the ongoing phase I/II trial of HSV in 2006.** To what extent MediGene will further invest in this highly innovative technology will be determined depending on the progress and results of this trial. MediGene strongly believes that oncolytic viruses may play a major role in future cancer therapy. Due to existing obstacles to the application of viruses, however, clinical development requires an especially long time and high investment. MediGene is doing pioneer work here. The coming months and years will show whether viruses against cancer are still just dreams or tomorrow's reality.

october 05

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Halloween





# Seize the Moment

In 2004, MediGene Achieved Two Capital Increases Thanks to Perfect Timing and Active Investor Relations Work

In the stock market, they say you should trade as long as time permits. The time span available for realizing capital market measures is usually very short and difficult to predict. 2004 was not a very successful year for the German stock exchange. Major indexes developed very moderately (DAX: +6%) or even dropped slightly (TecDAX: -6%). A number of planned IPOs failed or had to be effected at reduced prices. Very few companies were able to place new shares on the market successfully.

MediGene dared to take this chance twice – and was successful. Early in March, the company offered 2.2 million new shares as well as convertible bonds for subscription. The demand exceeded the supply. MediGene was able to place all securities with institutional investors and MediGene shareholders at home and abroad. Proceeds from this capital increase amounted to 16.7 million €.

In October 2004, MediGene raised about 21 million € by issue of approximately 3 million new shares. All existing MediGene shareholders were invited to subscribe. These new shares were also sold completely, and, like in the first capital increase, without a reduction of the respective market price.

Altogether, MediGene's capital stock increased by 65% compared to 2003, due to the above-mentioned measures and the issue of approximately two million shares during the acquisition of MBT. Total proceeds from the capital increases amounted to 38 million €, which substantially filled the company's cashbox.

The excellent results achieved over the year have been the basis of our success, as well as our investor relations policy pursued intensely, and our courage to consistently implement the appropriate measures at the right time. The first capital increase in 2004 was announced after having successfully completed the Eligard® project, i.e. obtained approval and concluded a marketing partnership. Other results, however, were still outstanding. Even before completion of the

crucial phase III trial of Polyphenon® E, our investors showed such high confidence that we dared to issue new shares. At the same time we took advantage of the occasionally friendly stock market climate appearing on the horizon in February 2004. In October we also acted at the right moment – realizing our capital increase on the surge of positive news and a brightening stock market climate, although the pivotal American phase III trial of Polyphenon® E was not completed then. We were able to meet our shareholders' high expectations, since the trials yielded positive results, and the share price increased significantly by 40%.

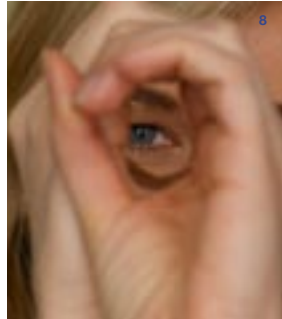
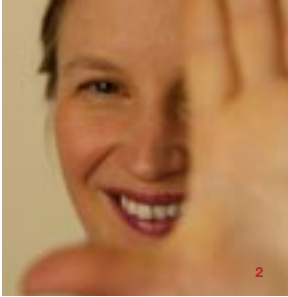
During the course of the year, but in particular in the run-up to our capital increases, we communicated our achievements to investors, financial analysts and journalists, illustrating them in detail on the occasion of numerous conferences as well as one-on-one interviews. In addition to MediGene's own roadshows, the company participated in the following renowned conferences for investors in 2004: BIO CEO & Investor Conference (New York), IPMC Healthcare Conference of the DVFA (Frankfurt), BioEquity (Edinburgh), Rodman & Renshaw Conference (New York) and the German Equity Capital Forum (Frankfurt). Moreover, we held numerous roadshows in Germany, Europe and in the United States. In the course of these roadshows we visited several major investors and financial analysts. In doing so, we were able to attract a number of renowned institutional investors at home and abroad.

With the capital increases in 2004, MediGene has established a very sound financial position. Our cash position of 48.5 million € at the end of the year will provide sufficient financial scope beyond currently ongoing projects. In case of another acquisition or license agreement closed, capital increases will be an important financing option in the future as well. In the future, we will continue to pursue our investor relations activities, keeping our shareholders and potential investors informed in detail, thereby fostering their trust in MediGene.



# november 05





**Some of us:** 1 Dr Matthias Karrasch, Clinical Research and Development 2 Dr Sandra von Meier, Business Development 3 Jürgen Seifried, Process Development 4 Dr Ulrich Moebius, Preclinical Research and Development 5 Jessica Kern, Human Resources and Organization 6 Julia Hofmann, Corporate Communications 7 Annette Krames, Intellectual Property 8 Ines Arlt, Research 9 Dr Peter Vorstheim, Business Development 10 Dr Axel Mescheder, Clinical Research and Development

# Ready for Busy Times

MediGene's Employees Stand for High Efficiency with Their Expertise, Flexibility and Commitment

To MediGene, being in business **for ten years** means a fast-paced history, full of ever-changing developments. Our colleagues and employees form the backbone of our success. They have helped to build up and develop MediGene through many changes. Their high flexibility and commitment are the prerequisites for our dynamic business development. The outstanding expertise and professional know-how of each individual forms the basis of our performance.

At the end of fiscal year 2004, MediGene had 117 employees, a 4% increase compared with 2003. Our company has a well-balanced mix of talented young specialists and professionals with many years of experience. They are excellently trained, and most of them gained professional experience in other companies before joining MediGene. More than 50% of our employees are university graduates, and over half of those hold a doctorate. In order to help employees develop their professional and personal skills, MediGene supports their participation in specific advanced trainings as well as renowned congresses and conferences.

MediGene is a lean company with short decision-making processes. It is our objective to provide our employees with sufficient room to maneuver. In return, each employee is expected to be proactive and to show great sense of responsibility. Working on one's own initiative is a sign of creativity and innovation, but it also requires accuracy, efficiency and cost effectiveness for the company. All employees are invited to have a stake in the company by participating in special stock option ownership programs.

When selecting employees for MediGene, we pay special attention to personal qualities – apart from professional skills – such as team spirit and openness. The willingness and ability to become acquainted with new fields of work

very quickly permit the integration of new employees and projects, e.g. after the acquisition of assets from Munich Biotech AG.

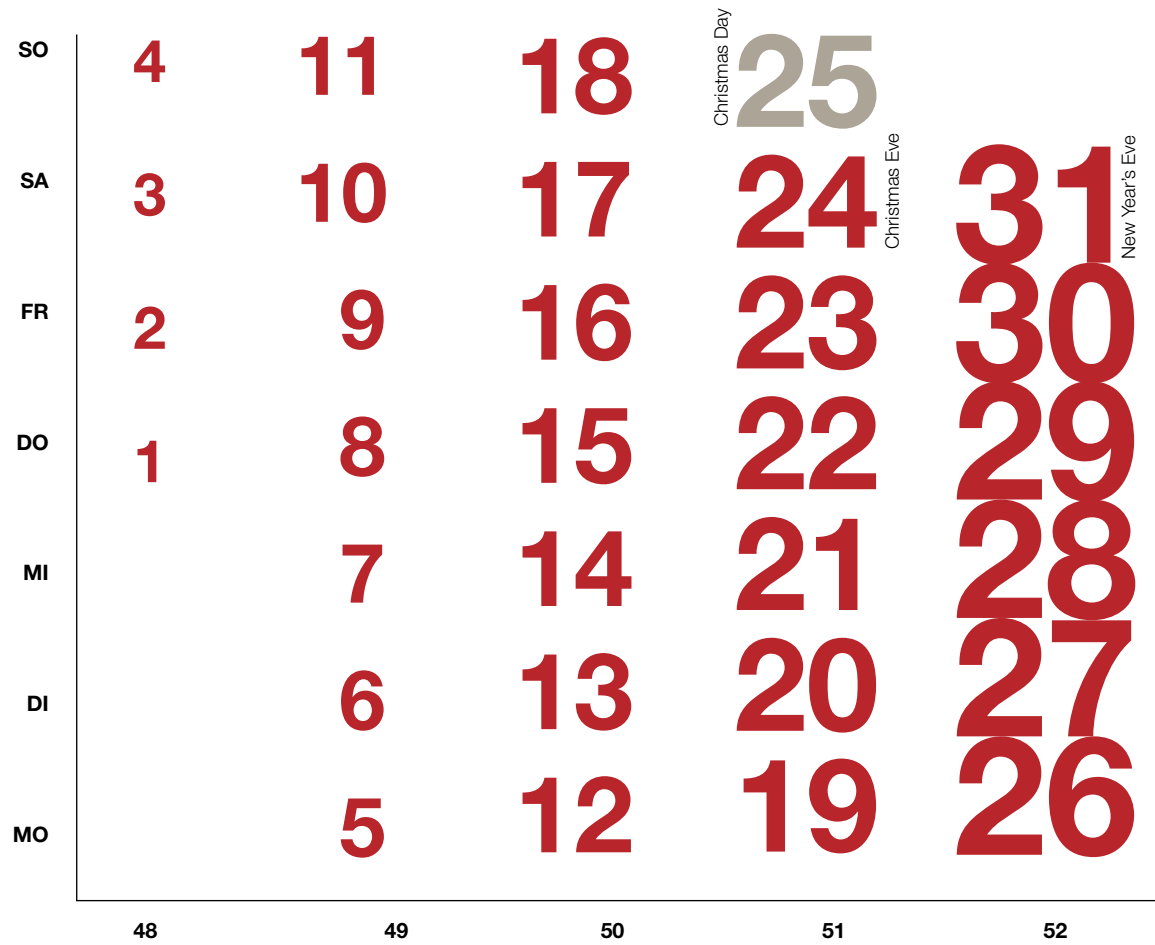
During this acquisition in August 2004, MediGene hired 15 former Munich Biotech AG employees. In this connection, the research and process development departments in particular were further expanded.

In addition, MediGene has further increased its management in 2004 by some top-class specialists. For instance, MediGene was able to attract Dr Ulrich Delvos as Executive Board Member for Research and Development. Delvos, a physician with postdoctoral lecture qualification and deep experience in drug development, was an Executive Board Member of the pharmaceuticals company Aventis Behring. He also has more than 18 years of international managerial experience in pharmaceuticals and biopharmaceutical companies in Germany and the United States. He will be significantly involved in MediGene's future development as a biopharmaceuticals company.

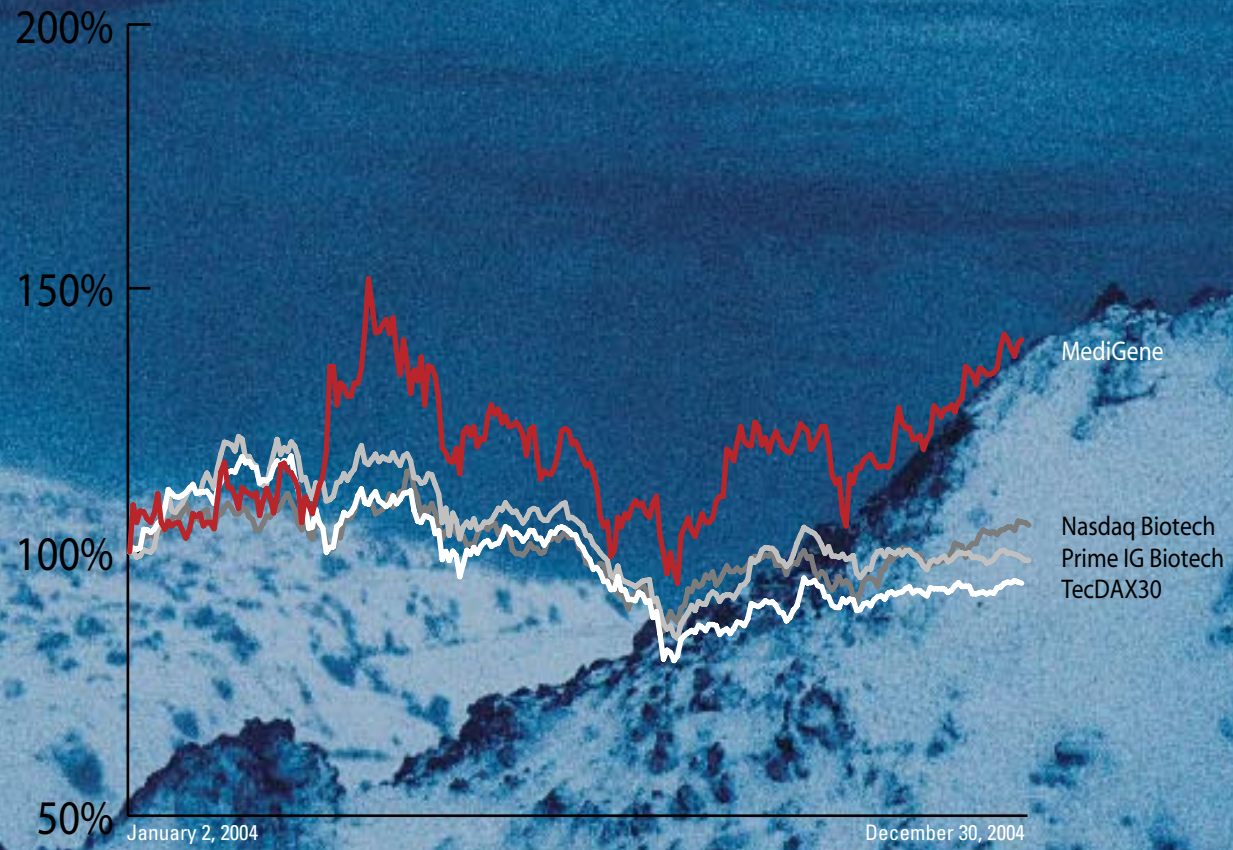
MediGene's identity and success will continue to be shaped by our employees in the future. MediGene counts on their productivity in order to realize the company's ambitious goals. During the current fiscal year, we do not expect any major changes to the number of employees. We have remarkable people on our team. For future vacancies or newly created positions, we will continue to recruit candidates of the highest caliber.

MediGene has great plans. **Are you ready?**

# december 05









# Climbing High Again

The MediGene Share Has Risen Again – with 40% Stock Price Gain, It Surpassed All Comparable Indexes

After high increases in 2003, the MediGene share price rose by almost 40% during the 2004 fiscal year. This positive trend is a consequence of the extremely favorable development of our company as well as our intense investor relations activities. Our share has developed several times better than the relevant indexes, which are TecDAX30 (-6%), Prime IG Biotechnology (-2%), and Nasdaq Biotech (+6%).

The year 2004 opening price of the MediGene share was 6.06 €, and the year-end closing price was 8.50 €. A new twelve months' high of 9.20 € was reached in April. This was probably a result of the expectations linked with the market launch of our first drug Eligard® early in May 2004. The twelve months' low of 5.70 € on August 13<sup>th</sup> resulted from a weak market environment and was overcome very quickly by the lasting upward trend of the MediGene share. The acquisition of the Munich Biotech product candidates, among other things, gave fresh impetus to the share price. This positive development has continued up to the year 2005.

Apart from the share price, the market value of MediGene AG has also significantly increased in 2004. It is calculated from the share price multiplied by the number of shares. The positive performance as well as the issue of new shares led to a market capitalization increase by more than 130%: at the end of 2004, MediGene's market capitalization was 157 million €, with 18.5 million outstanding shares. Market capitalization is an important criterion for international investors' interest in the company, and it is a crucial factor for the admission to the stock exchange index TecDAX30.

In 2004, we were able to attract a number of leading institutional investors both in Europe and in the United States. Consequently, the shareholders' composition was changed considerably. The portion of institutional investors

rose by 11% to 34%, whereas the portion of private investors declined to 62% (2003: 81.5%). Approximately 35% of the MediGene shares was held abroad at the end of 2004, which is roughly 16% more than the previous year. At the end of 2004, 9.1% of the shares were held in the United States (2003: 1.8%). Directors' holdings dropped to 4% (2003: 7.5%) due to the increased total number of shares. At reporting date, Techno Venture Management GmbH was the only investor holding more than 5% of the share capital (5.55%). The portion of free-floating shares compared to share capital is approximately 84%.

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 technology. Reports were set up by international investment banks such as Goldman Sachs International, Morgan Stanley Dean Witter and Sal. Oppenheim, as well as Metzler Equity Research, DZ Bank, Landesbank Baden-Württemberg, Vontobel Securities, Equinet Institutional Services and Concord Effecten. Reports by independent analysts form an important element in addressing potential investors successfully.

The substantial upward trend of the MediGene share and the increased market capitalization reflect MediGene's successes in 2004. We are continuing our efforts to move MediGene forward in 2005 as well. In March 2005, MediGene was selected for inclusion on the TecDAX30 index of German Stock Exchange. Thus MediGene is one of Germany's most important mid-cap technology companies which may have a very positive influence on the development of our share.

# january 06

1  
New Year's Day

2 3 4 5 6 7 8  
9 10 11 12 13 14 15  
16 17 18 19 20 21 22  
23 24 25 26 27 28 29  
30 31



January 06





# Continuous Observation

MediGene Ensures Value-Oriented Corporate Management through Analysis, Supervision, and Transparency

**One company: many people are working on complex processes.** These processes as a whole require guidance and supervision and are difficult to see through from outside. It is in the interest of our shareholders, employees, partners, and the public that we have implemented the »German Corporate Governance Code« to a great extent, thus going beyond legal provisions. The recommendations and proposals by a commission set up by the German Federal Government comprise nationally and internationally accepted standards regarding good and responsible management of companies. They have been set up to make processes in publicly listed companies transparent and comprehensible.

Corporate Governance principles rest on several pillars:

- 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.

MediGene's Corporate Governance Code is accessible on our website at [www.medigene.com](http://www.medigene.com). 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. For the Compliance Declaration and further explanations on the Corporate Governance policy, please see the financial information on page 4 of this annual report.

MediGene developed an early-warning system for in-house risk monitoring, which inquires, identifies and quantifies potential perils in all company divisions. Employees in charge are appointed to monitor the individual risks and possible approaches are developed accordingly.

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.

The contents of our risk management system are updated at regular intervals and presented to the Executive Board at least twice a year.

A responsible management is MediGene's objective, and sustained increase of the company's value is our commitment. **This is what we always keep in view.**

# february 06

Valentine's Day

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28



Catherine Jones, bank clerk, 43 years old, married, three daughters

# Today's Needs

MediGene's Drugs Target High Medical Need – and Thus Have High Economic Potential

Nearly five million<sup>1)</sup> people worldwide are diagnosed with cancer, a diagnosis which changes their lives entirely. Malignant tumors are often incurable, even with today's state-of-the-art medicine. Scientific progress, however, makes many of these diseases a little more controllable. We are gaining insight into some causes of cancer and are searching for methods to combat its growth and alleviate the consequences. MediGene's drugs are intended to make a contribution to this.

Eligard®, MediGene's first drug on the market, was developed for the treatment of advanced, hormone-dependent prostate cancer. 600,000 men in Europe are suffering from this disease, with additional 500 newly diagnosed cases daily.<sup>1)</sup>

MediGene's Polyphenon® E Ointment has successfully undergone clinical development (phases I – III) in the indication genital warts. Genital warts are benign yet painful and disfiguring skin tumors in the genital area. Genital warts are caused by certain human papilloma viruses (types six and eleven) and are sexually transmitted. With an annual growth rate of 1%<sup>2)</sup>, this is one of the most common and fastest spreading venereal diseases worldwide. Approximately 30 million people are infected by human papilloma viruses.<sup>3)</sup>

Polyphenon® E Ointment is also developed for the treatment of actinic keratosis (phase II). Actinic keratosis is a hornification disorder and forms a precursor of skin cancer. It may be caused by excessive exposure of the skin to the sun or by infection with human papilloma viruses and often develops into malignant acanthocyte skin cancer. In the northern hemisphere countries alone, 45 million people are suffering from this type of cancer, with an upward tendency.<sup>4)</sup>

Our drug candidate EndoTAG-1 is going to be tested for the treatment of hormone-resistant prostate cancer (phase II in preparation). Hormone compounds such as Eligard® have no effect on this disease pattern. 100,000 people are affected, and the number of patients rises by approximately 1.2% annually. The development of EndoTAG-1 will likely be continued in the indication pancreatic cancer as well (phase II in preparation). 100,000 people worldwide suffer from this malignant disease, and the growth rate here is 1.6%.<sup>5)</sup>

MediGene's cancer-destroying herpes simplex viruses are currently in development against liver metastases from colorectal carcinoma (phase I/II). This type of metastases occurs in 165,000 people worldwide and leads to a very pessimistic prognosis.<sup>6)</sup>

In the indication malignant brain tumors (glioblastoma), MediGene has also carried out several tests with herpes simplex viruses (phase I completed). Glioblastoma rank among the most aggressive types of cancer and are extremely difficult to treat.

The sales potential of our drug candidates is very high. We estimate that our marketing partner for Eligard® will generate sales of up to 100 million € annually if peak sales are achieved. MediGene will receive a share of these revenues. Regarding Polyphenon® E Ointment we estimate the annual peak sales potential to be 100 million € for the indication genital warts, and at least 200 million € for the indication actinic keratosis. If EndoTAG-1 reaches the market, the sales potential for the indications pancreatic cancer and prostate cancer could amount to far above 200 million € annually. Line extension of this product to other cancer diseases may be possible. Experts estimate the annual sales potential of herpes simplex viruses for the treatment of liver metastases and brain tumors at 200 million € and 300 million €, respectively.

<sup>1)</sup> Source: Globocan <sup>2)</sup> Source: Decision Resources 2004 <sup>3)</sup> Source: Eurotech <sup>4)</sup> Source: MediGene's estimate, American Society of Dermatology <sup>5)</sup> Source: Datamonitor 2002 <sup>6)</sup> Source: Globocan, MediGene's estimate

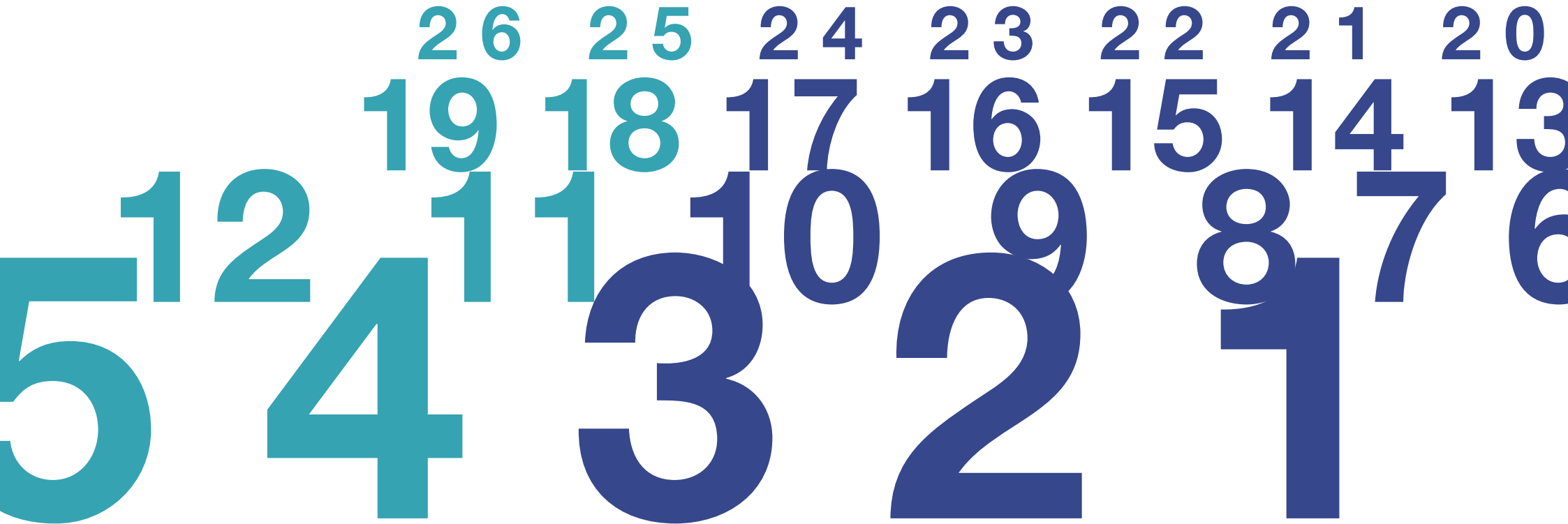
We have developed an extensive pipeline of drug candidates against cancer and tumor diseases, and are continuously working to further expand it. The further advanced in clinical development, the higher the chances are that a product candidate will reach the market in order to help people who are suffering from serious diseases.

Apart from the challenge this means for MediGene in scientific and medical respects, it is the company's objective to generate revenues from drug sales and partnerships. These revenues shall provide future financing for the development of additional drugs and make our company profitable.

march 06

March 22, 2006: Publication of the annual report 2005

31 30 29 28 27





2006



# Tomorrow's Goals

To Continue Its Own Strategy MediGene Has Set Itself Ambitious Objectives

MediGene's vision is to expand the opportunities of medicine by means of a responsible utilization of biotechnology, chemistry and biochemistry. We apply the latest technologies to develop innovative anti-cancer drugs.

It is our strategy to integrate all core areas of a modern biopharmaceutical company – from research and development of drugs to their commercialization.

In 2004, we achieved several major milestones in the pursuit of our strategy:

- Our first drug Eligard® obtained marketing authorization for Germany and 23 other European countries. Moreover, we gained a powerful marketing partner for Eligard® who launched the drug on the German market. This makes MediGene the first German biopharmaceutical company with a drug on the market.
- We successfully completed clinical development of our second drug, Polyphenon® E.
- We extended our product pipeline by acquiring Munich Biotech's products, and we made further progress with our existing drug development projects.
- Due to a rapid increase in our revenues (from 1.7 million € to 13.1 million €) and declining expenses, we were able to reduce our net loss by 60% to 12.3 million €.
- MediGene's cash position was significantly improved to 48.5 million €.

All research and development areas of a biopharmaceuticals company are integrated in our company, including process development and regulatory affairs. With our marketing partner Yamanouchi we have established our first contact with the market.

In 2004, MediGene laid the foundations for future growth. We will consistently pursue this path, and we have set ourselves the following goals for 2005:

- Market launch of Eligard® in other European countries
- Completion of the clinical phase II trial of Polyphenon® E for the treatment of actinic keratosis
- Submission of marketing authorization application to the U.S. regulatory authority FDA for Polyphenon® E Ointment against genital warts
- Initiation of the phase II trial of EndoTAG-1 for the treatment of pancreatic cancer
- Conclusion of a marketing partnership for Polyphenon® E
- Further increase in revenues by approximately 50% to approximately 20 million € through Eligard® as well as revenues from the planned Polyphenon® E partnership
- Further improvement of the annual result: net loss below ten million €

**We're ready for takeoff... join us on our journey!**

**We wish you all the best for the  
continuing year 2006!**

MediGene



## Financial information

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# Key figures

## MediGene Group, US-GAAP

in T€	2004	2003	Change
<b>Income statements<sup>1)</sup></b>			
Product sales	12,501	0	–
Other operating income	637	1,742	-63%
Research and development expenses (R&D)	14,701	21,825	-33%
Selling and general administration expenses	5,745	7,926	-28%
EBITDA	-13,238	-28,009	53%
Depreciation	1,133	1,031	10%
EBIT	-14,371	-29,040	51%
Result before income tax	-12,305	-28,333	57%
Net loss from continued operations	-12,305	-28,333	57%
Net loss <sup>2)</sup>	-12,306	-31,060	60%
Personnel expenses	8,383	10,973	-24%
<b>Balance sheet data</b>			
Balance sheet total	72,894	38,367	90%
Shareholders' equity	61,683	29,220	111%
Cash and securities	48,460	21,444	126%
Cash and cash equivalents	48,460	21,444	126%
Long-term liabilities	1,909	285	> 200%
Equity ratio	85%	76%	11%
<b>Cash flow</b>			
Cash flow from operating activities	-12,097	-26,544	-54%
Cash flow from investing activities	4,785	-12	> 200%
Cash flow from financing activities	34,342	267	> 200%
<b>Employees as at Dec. 31 from continued operations</b>			
	117	112	4%
<b>MediGene share</b>			
Shares outstanding as at Dec. 31	18,522,684	11,206,205	65%
Weighted average number of shares	13,996,440	11,206,205	25%
Net loss per share from continued operations in €	0.88	2.53	-65%
Net loss per share in €	0.88	2.77	-68%
Share price at the end of the year in €	8.5	5.9	44%
Dividend in €	0	0	–

<sup>1)</sup> From continued operations (discontinued operations see p. 34)

<sup>2)</sup> Including discontinued operations (see p. 34)

## Share data

Share price increased by 40%

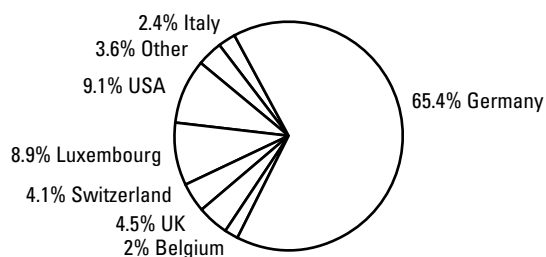
### Share data

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 (since March 18, 2005), Prime All Share, Prime IG Biotechnology
Trading floors	XETRA, Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hanover, Munich, Stuttgart
Designated sponsors	Concord Effekten AG, West-LB (since Feb. 2005)
No. of shares (12/31/2004)	18,522,684

### The following investment banks have accompanied MediGene with reports in 2004:

Code Securities	Dr Samir Devani
Concord Effekten AG	Dr Roger Becker
DZ Bank	Dr Patrick Fuchs/Dr Thomas Höger
Equinet Institutional Services	Dr Martin Possienke
Goldman Sachs International	Dr Stephen McGarry
Landesbank Baden-Württemberg	Dr Hanns Frohnmeyer
Metzler Equity Research	Dr Karl-Heinz Scheunemann
MM Warburg & Co.	Thomas Richter
Morgan Stanley Dean Witter	Dr Daniel Mahony/Anja Seyfried
Oppenheim Beseard GmbH	Dr Rüdiger Weseloh
Vontobel Securities AG	Dr Markus Metzger

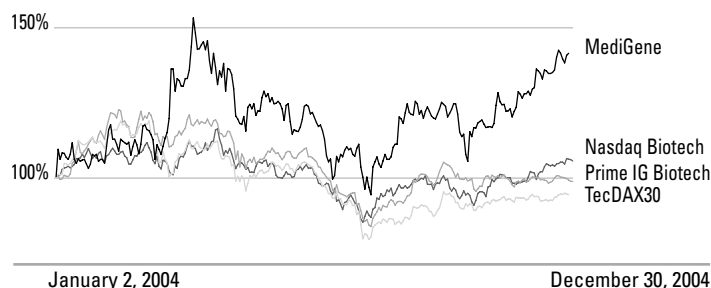
### Shareholder structure by country<sup>\*)</sup>



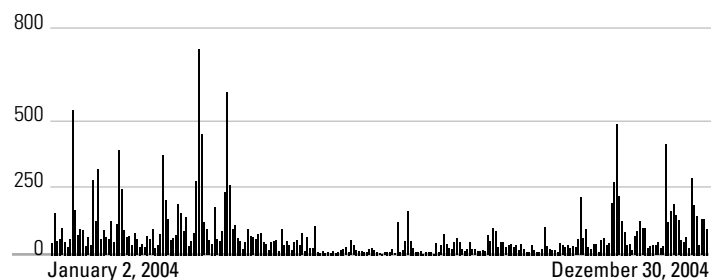
### Key figures per share

	2004	2003
53 weeks high €	9.20	9.23
53 weeks low €	5.70	2.55
Opening price €	6.06	4.05
Mean share price of the year 2004 €	7.21	3.83
Year end closing shares €	8.50	5.97
Number of shares	18,522,684	11,206,205
Average number of shares	13,996,440	11,206,205
Average market capitalization in million €	100.91	50.2
Dividend per share €	0	0
Cashflow from Operating Activities/Share €	-0.86	-2.97
Equity per share €	4.42	2.61
Average trading volume	72,486	115,357

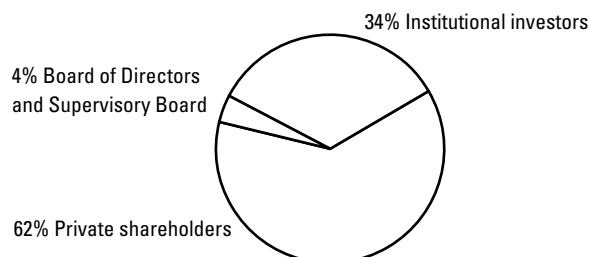
### Share price 2004 (January 2, 2004 € 6.06 indexed to 100)



### Volume in thousand



### Shareholder structure by investor type<sup>\*)</sup>



<sup>\*)</sup> As per 12/31/2004

## Executive Board of the MediGene AG



### **Dr Peter Heinrich**

Chief Executive Officer, Co-Founder

Dr Peter Heinrich is a co-founder of MediGene AG and has been chairman of the Executive Board of the company since 1995. He was previously in charge of developing the biotechnology division at Wacker Chemie. In his seven years with Wacker he held various positions in research and management, including responsibility for cooperation with Japanese and U.S. biotech corporations. After studying biology and chemistry at the University of Munich and receiving a PhD in biochemistry 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 sector.



### **Dr Ulrich Delvos**

Executive Board Member for  
Research and Development

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.



### **Alexander Dexne**

Chief Financial Officer

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.

# Supervisory Board

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

from November 26, 1996

Chairman

President of the German Research Foundation

### **Membership of other Supervisory Boards:**

- Bayer AG, Germany
- KWS Saat AG, Germany

## **Prof Dr Norbert Riedel**

from October 27, 2003

Deputy Chairman

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

### **Membership of other Supervisory Boards:**

- Genencor International Inc., USA
- Oscient Pharmaceuticals Inc., USA

## **Prof Dr Dr Ernst-Günter Afting**

from November 26, 1996 until June 2, 2004

Director GSF-Forschungszentrum für Umwelt und Gesellschaft  
(National Research Center for Environment and Health)

### **Membership of other Supervisory Boards:**

- Bio<sup>M</sup> AG, Germany
- Enanta Pharmaceuticals Inc., USA
- Intercell Biomedical Forschungs- und Entwicklungs AG, Austria
- Sequenom Inc., USA
- VitaResc Biotech AG, Germany
- Xerion Pharmaceuticals GmbH, Germany

## **Dr Pol Bamelis**

from May 23, 2001

former Executive Board member at Bayer AG, Knokke, Belgium

### **Membership of other Supervisory Boards:**

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

## **Dr Alexandra Goll**

from April 1, 2004

General Partner Techno Venture Management GmbH, Germany

### **Membership of other Supervisory Boards:**

- Addex Pharmaceuticals SA, Switzerland
- Axxima Pharmaceuticals AG, Germany
- Biovertis AG, Austria
- Pharmasset Ltd., USA
- Arrow Therapeutics Ltd., UK

## **Dr Manfred Scholz**

from June 2, 2004

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

### **Membership of other Supervisory Boards:**

- ASSTEL Lebensversicherung, Germany
- Citigroup Global Markets Deutschland AG & Co KGaA, Germany
- Gothaer Finanzholding AG, Germany
- Pfeleiderer AG, Germany
- Württembergische Hypothekenbank AG, Germany

## **Michael Tarnow**

from May 23, 2001

Consultant, Boston, MA, USA

### **Membership of other Supervisory Boards:**

- AXCAN Pharma Inc., Canada
- Caprion Pharmaceuticals Inc., Canada
- Ferghana LLC, USA
- Nanopharma Inc., USA
- Entremed, USA
- Xenon Genetics Inc., Canada

# Corporate Governance at MediGene

MediGene's Executive and Supervisory Boards are aware of the company's responsibility towards its shareholders, employees and business partners. Therefore they have again committed themselves in 2004 to comply to a wide extent with the recommendations of the German Corporate Governance Code. Corporate Governance describes the system of responsible, value-oriented and transparent management and supervision of companies.

The 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.

In accordance with paragraph 3.10 of the German Corporate Governance Code, we report as follows about Corporate Governance at MediGene:

The Executive and Supervisory Boards of MediGene cooperate closely for the company's benefit and are committed to the sustained enhancement of the company's value, as well as the principle of a responsible business management.

## **Declaration of Compliance**

On October 25, 2004, the Executive and Supervisory Boards executed the annual declaration of compliance pursuant to § 161 German Stock Corporation Act (see p. 6). In accordance with this declaration, MediGene complies to a wide extent with the recommendations of the German Corporate Governance Code. MediGene decided not to comply with the following recommendations which are also explicitly listed in the declaration of compliance.

### **1. 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.

### **2. Age 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 on the one hand, and a significant restriction on the Supervisory Board with regard to the choice of qualified Executive Board members.

### **3. 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.

### **4. 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 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.

### **5. Performance-related remuneration of the Supervisory Board members**

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

### **6. 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.

**Internet support for our shareholders**

Our shareholders are informed about major events on a regular basis, by means of a financial calendar published in the annual report (see last cover page), in the quarterly reports, as well as on the company's web site. On the occasion of the annual shareholders' meeting they have the opportunity to exercise their voting rights either by themselves, or by proxy, or by an authorized representative of the corporation bound by instructions. It was possible to give these instructions by means of electronic media prior to the annual shareholders' meeting. This possibility will also be available for the upcoming annual shareholders' meeting which will be held on June 10, 2005.

**Close cooperation between the Executive and Supervisory Boards**

The Executive Board members report to the Supervisory Board at regular intervals, promptly, and comprehensively all relevant issues regarding corporate planning and strategic development, business operations and the group's situation. Reservation of approval of the Supervisory Board for major business operations is laid down in the Executive Board bylaws.

**Remuneration of Executive and Supervisory Board members**

Remuneration of Executive and Supervisory Board members is reported on pages 37 and 42 of the annual report, and is accessible at the company's web site [www.medigene.com](http://www.medigene.com). The information is individualized and itemized.

**Corporate Governance Representative**

MediGene has appointed an employee Corporate Governance representative who reports adjustments and implementation of the German Corporate Governance Code to the Executive and Supervisory Boards at least once a year. Thus we ensure continuous compliance with these principles in the company.



# Declaration of MediGene AG regarding the German Corporate Governance Code pursuant to § 161 German Stock Corporation Act

## Management Board and Supervisory Board of MediGene AG herewith declare:

MediGene AG has complied and complies with the recommendations of the »Government Commission German Corporate Governance Code« which were published by the Ministry of Justice in the official part of the Federal Gazette on July 4, 2003 with the exception of the following recommendations:

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

The German Corporate Governance Code recommends that if a company takes out a directors' and officers' liability (D&O) insurance for the members of its Management Board and Supervisory Board, a suitable deductible shall be agreed. With regard to the D&O insurance for the Management Board and Supervisory Board members of MediGene AG, no such deductible has been agreed.

### 2. Age limits for Management Board and Supervisory Board members

The German Corporate Governance Code recommends specifying age limits for Management Board and Supervisory Board members. No such age limits exist for the Management Board and the Supervisory Board members of MediGene AG.

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

The German Corporate Governance Code recommends that remuneration of Supervisory Board members should take into consideration the membership in Supervisory Board committees. The membership in Supervisory Board committees is not taken into consideration for the remuneration of Supervisory Board members of MediGene AG.

### 4. Possibility of limitation (cap) regarding variable long-term compensation components

The German Corporate Governance Code recommends that for extraordinary, unforeseen developments regarding the variable long-term components of the Management Board members' compensation, a possibility of limitation (cap) shall be agreed for by the Supervisory Board. No such caps have been agreed with the members of the Management Board of MediGene AG.

### 5. Performance-related compensation of the Supervisory Board members

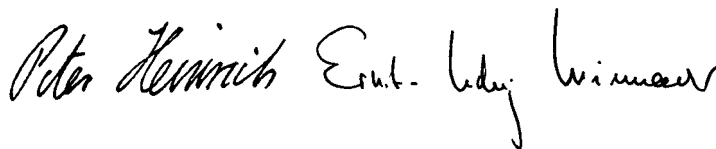
The German Corporate Governance Code recommends that the members of the Supervisory Board shall receive both fixed as well as performance-related compensation. The Supervisory Board members of MediGene AG do not receive a performance-related compensation.

### 6. Publications on the Internet site of MediGene AG

The German Corporate Governance Code recommends that information on the enterprise which the company publishes shall also be accessible via the company's Internet site. MediGene AG does not make information about capital increases before the end of the subscription period accessible on its Internet site as far as this is not required by law.

It is also pointed out for clarification that the current stock option plans and convertible bonds which were implemented prior to the amendment of the German Corporate Governance Code on May 21, 2003 and in which the Management Board members also participate, are not – contrary to the recommendations of the German Corporate Governance Code as of May 21, 2003 – related to relevant comparison parameters and do not contain any possibilities of limitation by the Supervisory Board. The Management Board and the Supervisory Board of MediGene AG are of the opinion that the current stock option plans and convertible bonds are conform to the German Corporate Governance Code as of May 21, 2003.

Martinsried, October 25, 2004



For the Management Board  
Dr Peter Heinrich

For the Supervisory Board  
Prof Dr Ernst-Ludwig Winnacker

## 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 drawn up on the basis of US Generally Accepted Accounting Principles (GAAP) and contain 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 US-GAAP – 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. 52 of this annual report).

Martinsried, March 2005

MediGene AG  
The Executive Management Board



Dr Peter Heinrich  
Chief Executive Officer



Dr Ulrich Delvos  
Member of the Board for R&D



Alexander Dexne  
Chief Financial Officer

## Independent Auditor's Report

We have audited the accompanying consolidated balance sheet prepared by MediGene AG for the fiscal year from January 1 to December 31, 2004, and the related consolidated statement of income, statement of changes in equity and statement of cash flows as well as the notes (consolidated financial statements). These consolidated financial statements prepared in accordance with United States Generally Accepted Accounting Principles are the responsibility of the company's Board of Managing Directors. Our responsibility is to express an opinion on these consolidated financial statements based on our audit, as to whether the consolidated financial statements comply with US-GAAP.

We conducted our audit of the consolidated financial statements in accordance with German auditing regulations for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer in Deutschland (IDW). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. Any knowledge of the company's business activities and of the corporate group's economic and legal environment as well as the expectations of possible errors are taken into consideration when determining the audit procedures. The audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. The audit also includes assessing the accounting principles used and significant estimates made by the Board of Managing Directors, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

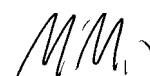
In our opinion, based on our audit, the consolidated financial statements referred to above present fairly, in all material respect, the net assets and financial position of MediGene AG as of December 31, 2004 and of its result of operations and its cash flow for the fiscal year from January 1 to December 31, 2004, in compliance with United States Generally Accepted Accounting Principles.

Our audit, which according to German auditing regulations also extends to the group management report prepared by the Board of Managing Directors for the fiscal year from January 1 to December 31, 2004 has not led to any reservations. In our opinion, on the whole the group management report, in combination with the rest of the details in the consolidated financial statements, provides a suitable understanding of the Group's position and suitably presents the risks of future development. In addition, we confirm that the consolidated financial statements and the group management report for the fiscal year from January 1 to December 31, 2004 satisfy the conditions required for the Company's exemption from its duty to prepare consolidated financial statements and the group management report in accordance with German accounting law.

Munich, February 25, 2005



Reitmeier  
Auditor



McMahon  
Auditor

PricewaterhouseCoopers GmbH  
Wirtschaftsprüfungsgesellschaft

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

## as per December 31, 2004

- **Eligard® is the first drug of a German biotechnology company launched on the market**
- **Total revenues amounting to 13.1 million € (2003: 1.7 million €)**
- **Cost-cutting measures lead to 33% reduction of R&D expenditure to 14.7 million €**
- **Net loss reduced by 60% to 12.3 million €**
- **Average monthly net cash burn rate from operating activities reduced by 45% to 1.2 million €**
- **Cash position 48.5 million € for future R&D financing (2003: 21.4 million €)**

### Framework Data

#### Moderate growth in the euro zone, weak US dollar

In 2004, economic growth in the euro zone continued to be almost 2%; in the USA, economic growth during the same period was approximately 4%. Despite this comparatively better economic development in the USA, the increase in trade deficit led to a further loss in the value of the US currency against the euro. The conditions for further growth within the euro zone are sound, and world economic growth remains robust, which should have a positive effect especially on exports from the euro zone. The euro reference rate rose by 8% from 1.2630 to nearly 1.3621 US dollars.

Short-term inflation risks have slightly declined, and therefore the European Central Bank decided in January 2005 to leave the money market interest rates at their historic bottom. Most recent indicators do not suggest any short-term inflationary pressure build-up in the euro zone, which is the reason why money market interest rates are expected to remain persistently stable.

#### Upswing possible, consolidation to continue

The upward trend of the MediGene share as well as the comparative indexes that has started in August 2004, has also continued in January 2005. This trend is expected to continue in 2005. The comparable indexes at the German Stock Exchange which are relevant for MediGene moved sideways in 2004: TecDAX30 (approx. -6%), Prime IG Biotechnology Performance Index (approx. -2%), whereas the MediGene share showed an increase in closing price of approx. 40% for the same period.

At the same time, the capital market continued to be very difficult for private or not publicly listed biotech companies. In 2004, the first companies filed for insolvency, including Munich Biotech AG. This company's assets including product candidates and technology were acquired by MediGene AG in August 2004. Apparently this consolidation process is going to continue in 2005, and mature, publicly listed companies in particular may benefit.

#### Favorable conditions for partnerships between pharmaceuticals and biotech companies

The pharmaceuticals industry requires innovative technologies and products in order to maintain its past growth rates in the medium and long term. There is a particular lack of promising drugs with new modes of action in both early and late development stages. This lack within the pharmaceuticals industry opens up new alternatives for cooperation to the innovative biotech industry.

This also applies to MediGene AG and its Polyphenon® E Ointment, which represents a very promising opportunity for conclusion of an additional strategic partnership.

### Preliminary notes

#### MediGene develops anti-tumor drugs

MediGene is a biopharmaceuticals company focusing on tumor diseases. Thus MediGene focuses on indications of high medical need and economic potential. R&D and technology contracts, payments from cooperation agreements for joint product development as well as the commercialization of proprietary drugs are potential sources of revenue.

In addition to the approved drug Eligard®, MediGene's product portfolio includes several drug candidates in different development stages.

Eligard® was approved for the treatment of hormone-dependent prostate cancer and was launched on the German market in May 2004. In December 2004, the EU approval process was successfully completed in 23 other European countries. This drug is sold by the Japanese company Yamanouchi Ltd. under the terms of a marketing partnership.

Regarding another drug candidate, Polyphenon® E Ointment for the treatment of genital warts, MediGene published positive results from two independent clinical phase III trials in the indication genital warts. Moreover, the potential of the ointment is investigated in a clinical phase II trial for the treatment of actinic keratosis (precursor of skin cancer).

Furthermore, MediGene is developing oncolytic herpes simplex viruses (drug candidate NV1020) for the treatment of liver metastases from colorectal carcinoma. A clinical phase I/II trial was initiated in September 2004, and is expected to be completed in 2006.

For the product candidate EndoTAG-1 which was acquired in August 2004, clinical phase II trials in the indications pancreatic cancer and hormone-resistant prostate cancer are currently in preparation. These trials shall be initiated in 2005.

#### Major milestones achieved in 2004

In the past financial year, MediGene has made substantial progress in its development:

- Eligard® was the first drug to obtain marketing authorization in 24 European countries, including Germany
- Conclusion of a marketing partnership for Eligard® with Yamanouchi Ltd.

- Market launch of Eligard® in Germany
- Positive results for Polyphenon® E Ointment from two independent clinical phase III trials
- Development pipeline extended by acquisition of product candidates and assets of former Munich Biotech AG
- Financial position improved and new institutional investors won by means of two capital increases

On the other hand, the joint development project with Aventis for a rAAV tumor vaccine was terminated.

#### **First revenues from the commercialization of Eligard®**

Since early May 2004, Eligard® is MediGene's first drug available on the German market. Thus we are generating revenues from drug sales for the first time. Until now, sales revenues have developed very positively. In January 2004, MediGene had already concluded a partnership for the commercialization of Eligard® with Yamanouchi Ltd. MediGene's partner will be responsible for sale in Germany as well as in all other European countries. Meanwhile the approval process within the mutual recognition procedure was successfully completed in 23 other European countries. Beginning in mid 2005, further market launches are planned. MediGene had acquired the pan-European license rights for Eligard® from the US company Atrix Laboratories, Inc., today's QLT Inc., in 2001 and taken the drug through the approval procedure.

#### **Clinical development of Polyphenon® E Ointment in the indication genital warts completed with positive results**

A total of more than 1,000 patients participated in two independent clinical phase III trials with main emphasis in Europe and America. The statistically significant trials proved that the drug showed clear efficacy with good tolerability, compared to placebo. This fulfills the clinical requirements for submitting a marketing authorization application. MediGene is planning to submit this application for Polyphenon® E Ointment to the American regulatory authorities in 2005, and afterwards to the European authorities.

#### **Acquisition of drug candidates and platform technology of former Munich Biotech AG**

A syndicate of existing Munich Biotech AG-investors led by Global Life Science, HypoVereinsbank (HVB Life Science) and DEWB, which also includes SET and MPC amongst other investors, founded MediGene Oncology GmbH. The newly founded company acquired the intangible assets of Munich Biotech AG. Following that, MediGene AG acquired all assets of MediGene Oncology GmbH including 4 million € cash from the syndicate of existing Munich Biotech AG investors. For this purpose 1,960,938 MediGene shares worth 11.3 million € were issued. The newly issued shares are subject to a twelve months lock-up period. Depending on clinical achievements with EndoTAG-1, MediGene will make milestone payments to the receiver of, starting with clinical phase

III. The assets acquired by MediGene include the patents, rights and licenses of the Munich Biotech AG technology and products. To secure the know-how and to guarantee a smooth transfer, MediGene has employed 15 Munich Biotech AG key employees. MediGene has not assumed any liabilities of the former Munich Biotech AG.

#### **Discontinuation of the joint development project with Aventis for the rAAV vaccine**

MediGene and Aventis decided to terminate development of a vaccine based on recombinant adeno-associated viruses (rAAV) for the treatment of malignant melanoma. Under this partnership, a clinical phase I/IIa trial in the indication malignant melanoma was conducted in some selected European countries. In the opinion of both companies, this initial trial did not show results that would justify further development. The reasons for discontinuation were especially due to the manufacturing of the drug product.

#### **Financial position strengthened**

In the past financial year, MediGene improved its financial position by means of two successful capital increases. Total proceeds from the issue of 5,332,784 new shares and 1.5 million convertible bonds amounted to approx. 38 million €. Cash position at the end of the reporting period was 48.5 million €.

#### **Annual result improved – segment reporting adjusted**

In addition to the revenues from the commercialization of Eligard®, the reorganization and cost-cutting measures implemented in 2003 have contributed to a significant improvement of our result.

Through these measures and the acquisition of the product candidates from Munich Biotech AG, the composition of our product portfolio has changed significantly. Consequently our market segment reporting was adjusted in comparison with last year's reporting period: the segments HPV indications and oncology (see annual report 2003) have been replaced by the specialty pharmaceutical product («specialty pharma») and biopharmaceutical product («biopharma») segments. Specialty pharma comprises products that have been launched on the market or completed clinical development. Biopharma comprises MediGene's clinical and pre-clinical development activities in the field of EndoTAG and oncolytic herpes simplex viruses technologies.

## Cooperation and license agreements with Yamanouchi Ltd. and Aventis

### Commercialization of Eligard® is in the focus of the partnership with Yamanouchi Ltd.

Early January, MediGene concluded a partnership with the pharmaceuticals group Yamanouchi Ltd. for the commercialization of the anti-cancer drug Eligard®. Yamanouchi, the second largest pharmaceuticals company in the field of urology in Europe, promotes and sells Eligard® in Europe. In return MediGene receives successive milestone payments totaling up to 21.5 million €, including an upfront payment fee of 4 million € as well as royalties on sales of Eligard®. Eligard® has been available on the German market since early May 2004. In the meantime the EU approval process was successfully completed in 23 other European countries. Further market launches are expected as of mid 2005.

### Partnership with Aventis for the development of a vaccine against malignant melanoma was terminated

MediGene and Aventis terminated their partnership for the development of a vaccine for the treatment of malignant melanoma. Within this partnership, a clinical phase I trial was conducted in some selected European countries. In the opinion of both companies, this initial trial did not show results that would justify further development. The manufacturing process of this vaccine specifically for each individual patient had turned out to be extremely difficult. In 2000, MediGene had obtained a loan to cover the expenses accruing from the joint project. As of closing date July 31, 2004, this loan amounted to 3,312 T€. In August 2004, MediGene started repayment of the loan in twelve equal monthly instalments.

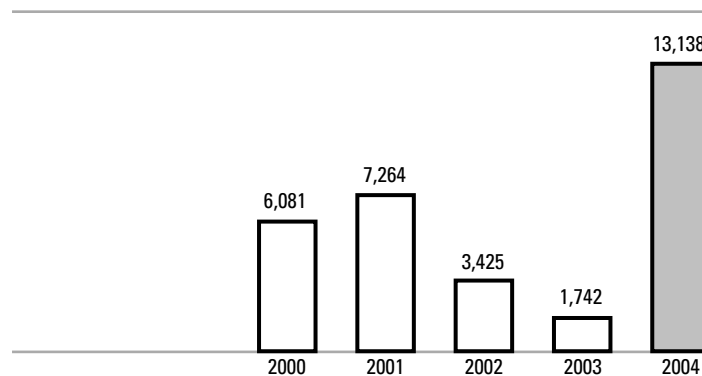
## Statement of accounts

For comments on the annual financial statements 2003 and 2004, please see the notes (see p. 36).

### Income statement (abbreviated)

in T€	2004	2003	Change
<b>Total revenues</b>	<b>13,138</b>	<b>1,742</b>	<b>654%</b>
Cost of sales	5,930	0	-
<b>Gross profit</b>	<b>7,208</b>	<b>1,742</b>	<b>314%</b>
General administration and selling	5,745	7,926	-28%
Research and development expenses	14,701	21,825	-33%
<b>EBITDA</b>	<b>-13,238</b>	<b>-28,009</b>	<b>-53%</b>
Depreciation on intangible and fixed assets	1,133	1,031	10%
<b>EBIT</b>	<b>-14,371</b>	<b>-29,040</b>	<b>-51%</b>
<b>Net loss from continued operations</b>	<b>-12,305</b>	<b>-28,333</b>	<b>-57%</b>
Result from discontinued operations	-1	-2,988	-
<b>Net loss</b>	<b>-12,306</b>	<b>-31,060</b>	<b>-60%</b>

### Total revenues in € million



### Total revenues significantly increased

In the reporting period, total revenues increased from 1,742 T€ to 13,138 T€. These revenues were mainly generated within the partnership concluded with the Japanese pharmaceuticals group Yamanouchi Ltd. for the commercialization of Eligard®. MediGene's partner Yamanouchi Ltd. has been selling Eligard® in Germany since May 2004. In addition to upfront and milestone payments totaling 8,000 T€, additional 4,501 T€ were received from product sales and license fees. Milestone payments have become due upon approval of the three-months product and the market launch of Eligard® in Germany.

Additional 637 T€ consist of R&D-payments from Aventis (225 T€), research grants (55 T€) and other income (357 T€). All revenues were earned in Germany.

### Revenue by segments

in T€	2004	2003	Change
Specialty pharma	12,694	31	-
Biopharma	226	1,616	-86%
Intersegment	218	95	129%
<b>Total from continued operations</b>	<b>13,138</b>	<b>1,742</b>	<b>654%</b>
Discontinued operations	32	153	-79%
<b>Total</b>	<b>13,170</b>	<b>1,895</b>	<b>595%</b>

### Cost of sales

In the course of the commercialization of Eligard® which had started in 2004, cost of sales were posted. These amounted to 5,930 T€ in the reporting period. Cost of sales include a milestone payment made to the licensor QLT Inc., as well as the cost of purchase of Eligard® and corresponding royalties in the sales revenues paid to QLT Inc.

### Gross profit

Gross result in 2004 was 7,208 T€ (2003: 1,742 T€).

### Selling and general administration expenses reduced

In the reporting period, selling and general administration expenses were reduced by 28% from 7,926 T€ to 5,745 T€. This amount includes 1,154 T€ selling expenses (2003: 1,448 T€) and 4,591 T€ cost of general administration (2003: 6,478 T€). The disproportionate reduction in cost of general administration is mainly a consequence of the cost-cutting measures implemented in 2003 (downsizing of US subsidiary and spin-off of the cardiology department).

Selling expenses arose from business development activities. This business unit is concerned with the commercialization of MediGene's product candidates in the framework of partnerships.

### R&D expenses declined

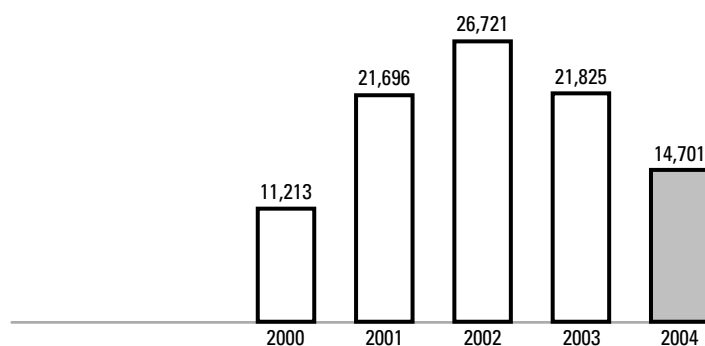
Total R&D expenses in continued operations were reduced by 33% to 14,701 T€ (2003: 21,825 T€). This reduction is a result of the changes in composition and status of the company's development portfolio.

#### R&D expenses by segments

in T€	2004	2003	Change
Specialty pharma	6,680	9,721	-31%
Biopharma	7,994	11,826	-32%
Intersegment	27	278	-90%
<b>Total from continued operations</b>	<b>14,701</b>	<b>21,825</b>	<b>-33%</b>
Discontinued operations	-196	2,901	-107%
<b>Total</b>	<b>14,505</b>	<b>24,726</b>	<b>-41%</b>

In 2004, MediGene's product portfolio comprised five drug candidates: Eligard® (formerly known as Leuproge®) for the treatment of advanced, hormone-dependent prostate cancer, Polyphenon® E Ointment for the treatment of benign genital tumors and actinic keratosis, NV1020 for the treatment of liver metastases from colorectal carcinoma, EndoTAG-1 for the treatment of solid tumors, and an rAAV vaccine against malignant melanoma. Eligard® and Polyphenon® E Ointment are allocated to the specialty pharma segment, and NV1020, EndoTAG-1 as well as the rAAV vaccine are allocated to the biopharmaceuticals segment.

#### R&D expenses in € million



### Specialty pharma segment

After having obtained approval for the German market for the one-month and three-months products of Eligard®, the drug has been sold in Germany by MediGene's partner Yamanouchi since early May 2004.

For Polyphenon® E Ointment, two independent clinical phase III trials in the indication genital warts were completed in 2004, with positive results. A total of more than 1,000 patients participated in these statistically significant trials. In addition, MediGene initiated a phase II trial of Polyphenon® E Ointment in the indication actinic keratosis (precursor of skin cancer) in 2004. Patient recruitment for this trial was completed in the year under review, 2004. The results are expected for the second quarter of 2005.

### Biopharma segment

In September 2004, MediGene initiated a clinical phase I/II trial in the USA of the drug candidate NV1020 for the treatment of liver metastases from colorectal carcinoma. Approximately 30 patients are going to participate in this trial. NV1020 is based on MediGene's technology of oncolytic herpes simplex viruses. These viruses have been genetically modified for the selective destruction of tumor cells (oncolysis).

In August 2004, MediGene acquired the anti-cancer drug candidate EndoTAG-1 as well as the underlying EndoTAG technology from the former Munich Biotech AG. MediGene is currently preparing clinical phase II trials in the indications pancreatic cancer and advanced, hormone-resistant prostate cancer. These trials are to be initiated in 2005. Pre-clinical trials and research projects will accompany this project.

Until mid 2004, MediGene and Aventis were conducting a joint project for the development of a tumor vaccine for the treatment of malignant melanoma. The two companies decided to terminate their partnership, since a clinical phase I/IIa trial in this indication had not shown results that would justify further development.

### Intersegment

Intersegment includes selling and general administrative expenses which cannot be allocated explicitly to any of the other segments.

### EBITDA loss declining

Loss before interest, taxes, depreciation and amortization (EBITDA) from continued operations decreased by 53% from 28,009 T€ to 13,238 T€. This significant improvement is a consequence of the increase in revenues, with a decrease in administrative as well as R&D expenses at the same time.

## EBITDA by segments

in T€	2004	2003	Change
Specialty pharma	-68	-9,890	99%
Biopharma	-7,768	-10,210	24%
Intersegment	-5,402	-7,909	32%
<b>Total from continued operations</b>	<b>-13,238</b>	<b>-28,009</b>	<b>53%</b>
Discontinued operations	228	-2,748	-
<b>Total</b>	<b>-13,010</b>	<b>-30,757</b>	<b>58%</b>

## Depreciation

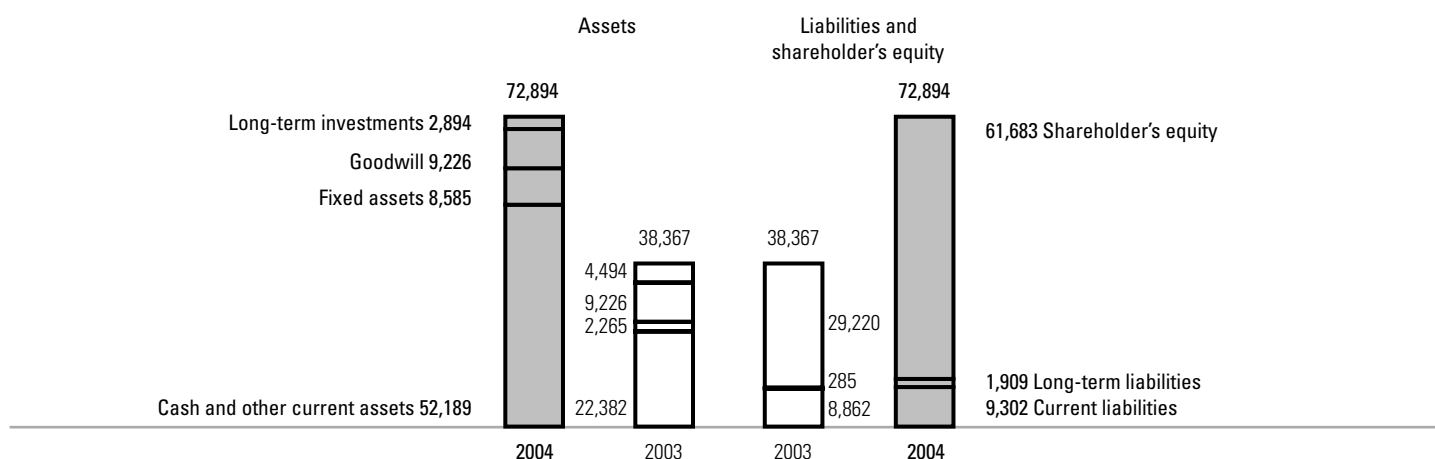
Depreciation of fixed assets including intangibles slightly increased compared to 2003, by 7% from 1,271 T€ to 1,362 T€. The corresponding depreciation was posted in the specialty pharma (119 T€) and biopharma (806 T€) segments, as well as intersegment (208 T€), made to fixed assets including intangibles (see segment reports).

In the course of liquidation of the cardiology segment («discontinued operations»), depreciation amounting to 229 T€ accrued. With regard to goodwill reported in the balance sheet, the impairment test at the end of the year under review did not lead to any changes compared to the preceding year.

## Depreciation

in T€	2004	2003	Change
Fixed assets incl. intangibles	951	881	8%
Capital lease	182	150	21%
<b>Total from continued operations</b>	<b>1,133</b>	<b>1,031</b>	<b>10%</b>
Discontinued operations	229	240	-5%
<b>Total</b>	<b>1,362</b>	<b>1,271</b>	<b>7%</b>

## Balance sheet structure in T€



## EBIT improved

Loss before interest and taxes (EBIT) from continued operations was reduced by 51% from 29,040 T€ to 14,371 T€.

## EBIT by segments

in T€	2004	2003	Change
Specialty pharma	-187	-9,908	98%
Biopharma	-8,574	-10,974	22%
Intersegment	-5,610	-8,157	31%
<b>Total from continued operations</b>	<b>-14,371</b>	<b>-29,040</b>	<b>51%</b>
Discontinued operations	-1	-2,988	-
<b>Total</b>	<b>-14,372</b>	<b>-32,028</b>	<b>55%</b>

## Financial result increased

Compared to 2003, the financial result rose by 192% to 2,066 T€. This increase is mainly due to a profit realized in connection with the exchange of Atrix Laboratories Inc. shares for QLT Inc. shares. In November 2004, the Canadian company QLT Inc. had acquired the US stock corporation Atrix Laboratories, Inc. Atrix shareholders received a QLT Inc. share for each Atrix share, plus 14.61 US dollars cash per share. MediGene's gain from the exchange of shares was 1,581 T€. In 2001, MediGene had acquired 233,918 shares from the licensor Atrix as a part of the Eligard® contract.

Although MediGene's cash position had significantly increased at the cut-off date, interest income decreased due to a lower average annual amount invested. Interest expenses accrued from lease of fixed assets. The increase in foreign currency exchange losses resulted from the purchase and sale of Eligard® from QLT Inc. and to Yamanouchi Ltd., respectively.



## Financial result

in T€	2004	2003	Change
Interest income	647	778	-17%
Interest expense	72	77	-6%
<b>Sub-total</b>	<b>575</b>	<b>701</b>	<b>-18%</b>
Income from securities	1,581	0	-
Foreign currency exchange gains/losses	-90	6	-
<b>Total</b>	<b>2,066</b>	<b>707</b>	<b>192%</b>

## Annual loss decreased

Compared to the preceding year under review, MediGene was able to reduce the net loss from continued operations by 57% to 12,306 T€. This reduction was a consequence of increased revenues, reduced expenses in all company divisions as well as the extraordinary increase in the financial result.

The annual result of MediGene AG according to HGB (German Commercial Code) amounted to -12,888 T€ (2003: -22,591 T€).

## Loss per share reduced significantly

In 2004, net loss per share was reduced by 68% from 2.77 € (weighted average number of shares 11,206,205) to 0.88 € (weighted average number of shares 13,996,440). This improvement was a consequence of both the reduction in net loss for the year as well as the increase in average number of shares.

The net loss from full dilution at closing date was equivalent to the actual loss, as the conversion of common stock equivalents would have an anti-dilutive effect.

## Segment reports

During the reporting period 2004, MediGene's business activities were focused on the development of anti-cancer and anti-tumor drugs. These activities are divided into the segments specialty pharma and biopharma products as well as intersegment (see p. 46 – segment definition). The adjustment of segment reporting reflects the developments and changes in MediGene's product portfolio in 2004.

The specialty pharma segment includes the drug Eligard® and the drug candidate Polyphenon® E Ointment. The segment biopharma comprises MediGene's EndoTAG as well as the oncolytic herpes simplex technology, and the product candidates EndoTAG-1, NV1020 and G207 emanating from these technologies.

Intersegment comprises items that cannot be clearly allocated to one individual segment.

## Specialty pharma

In 2004, the following developments were registered in the specialty pharma segment: at the beginning of the year, MediGene concluded a marketing partnership for pan-European commercialization of Eligard® with Yamanouchi Ltd. In addition to a signing fee and milestone payments totaling up to 21.5 million €, MediGene receives royalties on the

sales of the drug. Eligard® has been available on the German market since early May 2004. In December 2004, MediGene obtained approval for Eligard® in 23 other European countries.

For Polyphenon® E Ointment, MediGene reported positive results in 2004 from two independent clinical phase III trials for the treatment of genital warts. The statistically significant trials with more than 1,000 patients showed the significant efficacy of the drug with good tolerability compared to placebo. The ointment was administered to the patients in three different dosages (10%, 15% and placebo) three times daily for a maximum period of 16 weeks. Following the treatment, the patients were observed for twelve weeks. Both trials were randomized and double-blind. This means that the patients were randomly assigned to one of the individual groups, and the data obtained are not accessible to anyone during treatment with the exception of an independent monitoring committee. For 2005, MediGene is planning submission of the marketing authorization application for the drug to the American regulatory authorities, followed by the European authorities.

In addition, a clinical phase II trial for the treatment of actinic keratosis (precursor of skin cancer) was initiated end of April 2004. Patient recruitment for this trial was completed end of October.

## Specialty pharma segment

in T€	2004	2003
Total revenues	12,694	31
Cost of sales	5,930	0
<b>Gross profit</b>	<b>6,764</b>	<b>31</b>
Selling expenses	152	200
R&D expenses	6,680	9,721
<b>EBITDA</b>	<b>-68</b>	<b>-9,890</b>
Depreciation	119	19
<b>EBIT</b>	<b>-187</b>	<b>-9,908</b>
Average number of employees	17	14

## Total revenues Specialty pharma

in T€	2004	2003
Revenues and license fees	4,501	0
Milestone and upfront payments	8,000	0
Research grants	0	0
Other income	193	31
<b>Total</b>	<b>12,694</b>	<b>31</b>

Revenues of 12,694 T€ posted in the specialty pharma segment were generated solely from the commercialization of Eligard®. The respective cost of sales amounted to 5,930 T€ and include, apart from the cost of purchase for Eligard®, a milestone payment to the manufacturer due upon approval of Eligard® in Germany. R&D expenses within this segment dropped by 31% to 6,680 T€ in the reporting period. For the

drug Eligard® which is already available on the market, no significant R&D expenses accrued, whereas expenses were posted for clinical and pre-clinical development of Polyphenon® E Ointment, especially for the execution of two phase III trials in the indication genital warts and a phase II trial in the indication actinic keratosis.

### Biopharma

The biopharma segment comprises MediGene's activities in the fields of oncolytic herpes simplex viruses (HSV), recombinant adeno-associated viruses (rAAV), and for the product candidates G207, NV1020 and the rAAV tumor vaccine. In addition, the activities regarding the product candidate EndoTAG-1 and the platform technology EndoTAG of the former Munich Biotech AG since August 2004 are reported in this segment. At present, clinical phase II trials of EndoTAG-1 in the indications pancreatic cancer and hormone-resistant prostate cancer are in preparation and discussed with the regulatory authorities in the USA and Europe. The trials are to be initiated in 2005. Further development of the rAAV technology was discontinued in August 2004.

The restructuring measures in the US subsidiary MediGene, Inc. were completed in the first half of 2004. Research and development in the field of HSV technology were relocated to the headquarters in Martinsried. The US subsidiary MediGene, Inc. with nine employees (2003: 20) now comprises the clinical development and regulatory affairs departments. At present, MediGene is investigating the oncolytic herpes simplex virus NV1020 for the treatment of liver metastases from colorectal carcinoma in a clinical phase I/II trial which was initiated in September 2004. This trial examines safety, tolerability and efficacy of a treatment with NV1020, as well as possible synergies of this drug combined with chemotherapy. Approximately 30 patients in up to seven clinical centers in the USA are to be treated during this trial.

### Biopharma

in T€	2004	2003	Change
Total revenues	226	1,616	-86%
Cost of sales	0	0	-
Gross profit	226	1,616	-86%
Selling expenses	0	0	-
R&D expenses	7,994	11,826	-32%
EBITDA	-7,768	-10,210	24%
Depreciation	806	764	5%
EBIT	-8,574	-10,974	-22%
Average number of employees	58	79	-27%

### Total revenues Biopharma

in T€	2004	2003	Change
Revenues and license fees	25	1,474	-98%
Milestone and upfront payments	200	102	96%
Research grants	0	40	-100%
Other income	1	0	-
<b>Total</b>	<b>226</b>	<b>1,616</b>	<b>-86%</b>

In the biopharma segment, other operating income posted was generated within the framework of the partnership with Aventis (see p. 10, »cooperation agreements«). As a consequence of the discontinuation of the joint development project, other operating income decreased to 226 T€.

R&D expenses in 2004 were reduced by 32% to 7,994 T€ (2003: 11,826 T€). Both the downsizing of our US subsidiary as well as the changes in the status of our development projects have contributed to this reduction. At the same time, the loss in the value of the US dollar against the euro has led to a decrease in the costs accrued for the US subsidiary which were converted into the reporting currency, the euro.

The development of G207 which had been put on hold in 2003 has not been resumed up to now. MediGene has developed G207 for the treatment of malignant brain tumors. Further development of this project will not be continued without external financing.

### Discontinued operations

In discontinued operations, the cardiology segment which had been terminated in 2003, or LARNAX GmbH are reported. The loss from discontinued operations in 2004 amounted to 1 T€. On March 2003, MediGene and the seed financing company Bio<sup>M</sup> AG jointly founded LARNAX GmbH. MediGene's former cardiological research program formed the core of this new company. LARNAX GmbH ceased operations at the end of 2003.

### Intellectual property

In compliance with the corporation's strategy to obtain 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, MediGene currently holds rights to the following patents/patents pending:

## Patents granted or allowed

	Specialty pharma	Biopharma
Germany	4	11
USA	2	35

## Patents pending

	Specialty pharma	Biopharma
Germany	4	30
USA	3	45
International	7	49

The economic success of MediGene will also depend on whether it will be successful in obtaining patent protection for the products and technologies in the corresponding geographical target markets. For this reason the company is striving to secure its products, processes and technologies by patents. In the company's opinion, the patent applications cover novel technologies with potential economic significance. The company acts on the assumption that it will be able to benefit from its previous patent applications. Due to the long period of time required for the examination of patent applications, a large number of the MediGene's applications are still pending.

MediGene is planning to extend the technology and product portfolio in the future as well, by means of concluding license and/or license agreements for products, technologies or other inventions to which third part parties have or claim to have any rights.

## Investments

### Investments in fixed assets increased

During the year under review, investments increased by 157%. Investments in fixed assets including software amounted to 605 T€ (2003: 235 T€) and were primarily spent on laboratory equipment and information technology. In order to save cash resources, 46% of this sum were spent by means of so-called capital lease contracts.

Investments at the US subsidiary MediGene, Inc. amounted to 2 T€ (2003: 28 T€).

2 T€ of the above mentioned 605 T€ were spent within the specialty pharma segment, and 545 T€ in the biopharma segment; in intersegment, investments of 58 T€ were made. Investments in the biopharma segment mainly accrued from the purchase of laboratory equipment.

Investments posted in intersegment accrued by the extension of infrastructure in the fields of information technology, and the marketing and quality assurance departments. Altogether the investments were divided up for a multitude of equipment and facilities. Any noteworthy individual investments (> 100 T€) were not made.

## Assets position

### Cash position 48.5 million €; equity ratio 85%

Compared to the preceding year, the balance sheet total increased by 90% to 72,894 T€ (December 31, 2003: 38,367 T€). The equity ratio improved to 85%. Cash position as at December 31, 2004 increased to 48,460 T€. In addition to the net cash inflow from capital increases amounting to 14,2 million € (March 2004) and 19,8 million € (October 2004), revenues from the commercialization of Eligard® also contributed to this. Within the acquisition of the assets from the former Munich Biotech AG, cash amounting to 5.0 million € was received.

Total fixed assets – not including goodwill and financial assets – increased by 279% from 2,265 T€ to 8,585 T€. Whereas fixed assets declined by 28% to 1,565 T€, intangibles rose from 77 T€ to 7,020 T€ through the acquisition of Munich Biotech AG's assets. This included patents and licenses on the EndoTAG products and technology.

The book value of capitalized leased items as a part of fixed assets decreased by 26% from 553 T€ to 408 T€ as at December 31, 2004. This decrease is a result of expired lease contracts and the consequential transfer of the leased objects to fixed assets, as well as depreciation of capitalized leased items.

At the closing date December 31, 2004, the impairment test did not lead to any changes in the goodwill of 9,226 T€. Goodwill was capitalized in the course of the acquisition of the subsidiary MediGene, Inc. and refers to the valuation of the two projects G207 and NV1020. The value assumed for both projects exceeds goodwill.

Long-term investments correspond to 233,918 shares of the Canadian company QLT Inc. As at closing date, the value of the QLT shares held by MediGene amounted to 2,761 T€. This valuation is based on the exchange rate on the closing date of 1 euro against 1.3621 US dollar. As a former holder of 233,918 shares of the US company Atrix Laboratories, Inc. MediGene received a cash premium of approx. 2,5 million € and 233,918 shares of QLT Inc. This exchange of shares is a consequence of the acquisition of Atrix Laboratories, Inc. by QLT Inc. which was passed in November 2004. No shares were sold during this transaction.

The increase in current assets is mainly a consequence of the increase in cash and cash equivalents realized in particular during the capital increases. At the cut-off date, no Eligard® inventories existed. Eligard® is not purchased on inventory, instead it is immediately resold to the marketing partner after purchase. Laboratory and chemical supplies are not treated as inventories, but are expensed as they occur.

Receivables increased by 46% to 115 T€ (2003: 79 T€).

In the year under review, equity increased by 111%. In the past financial year, MediGene issued a total of 7,293,722 shares against cash and non-cash capital contribution.

Long-term as well as short-term liabilities increased by 26%, whereas their share in the balance sheet total has decreased from 24% to 16%.

Long-term liabilities rose from 285 T€ to 1,909 T€. This is a consequence of the issue of convertible bonds issued during the capital increase in March 2004. The convertible bonds have a maturity term of four years and bear 4% interest annually. The conversion price is 7.50 € each. Conditional capital is available to secure the conversion rights arising from issue of a bond.

Current liabilities rose by 5% to 9,302 T€. These liabilities exist in the form of outstanding invoices to MediGene for the execution of clinical trials, as well as some other items explained in the following: the deferred income of 2 million € results from the pro-rata posting of a 4 million € payment which MediGene received upon signature of the marketing partnership with Yamanouchi Ltd. in January 2004. This deferred income will be recorded as income on a pro-rata basis upon market approvals and launches of the drug Eligard® in other European countries (see balance sheet, p. 25, A.V. »Deferred Income«). Other current liabilities of 3,462 T€ gross include the residual debt of 2,106 T€ gross from a loan granted to MediGene by Aventis within the framework of their partnership. Upon announcement of the termination of this cooperation in August 2004, MediGene is now committed to repay the loan in twelve equal monthly instalments, starting in August 2004. In the opinion of both companies, an initial clinical trial of the tumor vaccine in the indication malignant melanoma had not shown results that would have justified further development.

Liquidity ratio, calculated as the portion of cash and cash equivalents and securities in the balance sheet total, was 72% as at closing date (2003: 56%).

Working capital rose by 217% from 13,520 T€ to 42,887 T€ due to the rise in cash and cash equivalents.

### Changes in assets and capital structure

in T€	2004	2003	Change
<b>Assets</b>			
Long-term investments	2,894	4,494	-36%
Goodwill	9,226	9,226	0%
Fixed assets	8,585	2,265	279%
Current assets	52,189	22,382	133%
<b>Total assets</b>	<b>72,894</b>	<b>38,367</b>	<b>90%</b>
<b>Liabilities and shareholders' equity</b>			
Shareholders' equity	61,683	29,220	111%
Long-term liabilities	1,909	285	570%
Current liabilities	9,302	8,862	5%
<b>Total liabilities and shareholders' equity</b>	<b>72,894</b>	<b>38,367</b>	<b>90%</b>
Liquidity cover ratio	72%	56%	
Equity ratio	85%	76%	

As at December 31, 2004, there were no other contingencies than a rental guarantee of 206 T€ (2003: 783 T€). The decline in rental guarantee is a consequence of the downsizing in our US subsidiary.

Within the acquisition of Munich Biotech AG MediGene committed to milestone payments to the receiver. The payments depend on the clinical development success of EndoTAG-1 and become due upon start of clinical phase III trial. These payments can amount of up to 9.5 million €.

For capitalized leased items, a total of 405 T€ will become due in the next two years, and for operational lease contracts, a total of 4,463 T€ will become due in the next five years.

### Financial position

#### Cash used by operating activities decreased significantly

Cash used by operating activities is indirectly derived from the annual loss. The decrease of cash used by operating activities by 54% from 26,544 T€ to 12,097 T€ results mainly from the first revenues generated by the commercialization of Eligard®, the savings through the reorganization measures implemented in 2003, the reduced expenses in all sectors of the company.

Compared to the cash outflow from investing activities in the preceding year (12 T€), a cash inflow of 4,785 T€ was realized in 2004. This includes the net inflow of 5,047 T€ from the acquisition of MediGene Oncology GmbH (see p. 31, notes on the consolidated financial statements). In 2004, MediGene made significantly higher investments in fixed assets than in the preceding year, that is 280 T€ (2003: 108 T€).

Cash inflow from financing activities amounted to 34,342 T€. This increase results mainly from the following net income from cash and non-cash capital increases in 2004: 15.7 million € from a three-step capital increase in March 2004, 19.8 million € from a capital increase in October 2004.

In August 2004, the company started repayment of a loan granted by Aventis in twelve equal monthly instalments, after the cooperation between the two companies had been terminated. Of the total 3,312 T€ loan, the net amount of 1,297 T€ was repaid since September. Apart from that, incoming payments amounting to 62 T€ from the exercise of options were posted (2003: 0 T€). Cash outflow from finance leasing obligations decreased from 431 T€ to 313 T€.

The net increase in cash and cash equivalents in the year under review totaled 27,016 T€, including exchange rate fluctuations amounting to -14 T€. Cash and cash equivalents at the end of the year was 48,460 T€, which represents 66% of the balance sheet total (2003: 56%).

As at closing date, there were no other financial liabilities or open lines of credit than the convertible bonds as well as the finance lease obligations posted. The amount of cash and cash equivalents conforms to the net cash position.

#### Development of cash and cash equivalents

in T€	2004	2003	Change
<b>Net cash used</b>			
by operating activities	-12,097	-26,544	-54%
from investing activities	4,785	-12	-
from financing activities	34,342	267	-
Currency translations	-14	-29	-52%
<b>Decrease/increase in cash and cash equivalents</b>	<b>27,016</b>	<b>-26,318</b>	<b>-203%</b>
Cash and cash equivalents at beginning of period	21,444	47,762	-55%
Cash and cash equivalents at end of period	48,460	21,444	126%
in % of balance sheet total	66	56	

#### Monthly net cash burn rate from operating activities

From the consolidated cash flow statements, the net cash burn rate from operating activities for the year 2004 (net cash used during the reporting period) amounts to 14,733 T€ (2003: -26,337 T€), and a monthly average rate of 1,203 T€ (2003: 2,195 T€).

The gross cash burn rate – the sum of operating expenses and depreciation – amounted to 13,238 T€. This corresponds to a monthly average of 1,103 T€. MediGene is using the cash and cash equivalents for the development of its own products.

## Human resources

### Number of group employees reduced

At year-end 2004, the number of MediGene's employees totalled 117, with 108 in Martinsried (2003: 92 employees), and nine at the US-sub-sidiary MediGene, Inc. (2003: 20 employees). Altogether the headcount in continued operations rose from 112 (2003) by 4% to 117. As a consequence of the group reorganization measures implemented, personnel expenses decreased by 30% to 8,345 T€.

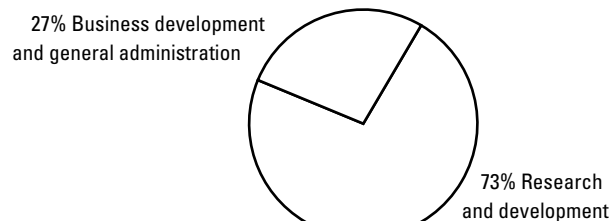
### Employees by function (as at Dec. 31)

	2004	2003	Change
Business development and general administration	32	36	-10%
Research and development	85	77	11%
<b>Total from continued operations</b>	<b>117</b>	<b>112</b>	<b>4%</b>
Discontinued operations	0	12	-100%
<b>Total</b>	<b>117</b>	<b>124</b>	<b>-6%</b>

### Downsizing of the US site MediGene, Inc.

In 2004, MediGene completed the relocation of the research department from the US subsidiary MediGene, Inc. to the German headquarters in Martinsried. In the course of this relocation, the number of employees at the US site in San Diego was reduced to nine by the end of the year.

### Employees by function





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

	2004	2003	Change
MediGene AG, Martinsried	108	92	17%
MediGene, Inc., San Diego	9	20	-55%
<b>Total from continued operations</b>	<b>117</b>	<b>112</b>	<b>4%</b>
Discontinued operations	0	12	-100%
<b>Total</b>	<b>117</b>	<b>124</b>	<b>-6%</b>

At present, MediGene, Inc. continues operations with the clinical development and regulatory affairs departments.

**Procurement**

Procurement is focused on the drug Eligard® as well as chemicals and laboratory supply for R&D. MediGene concentrates on developing and optimizing the production processes to organize efficient future procurement of the substances needed.

**Procurement of Eligard®**

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

**Procurement management for R&D supplies**

MediGene is not restricted to specific raw material suppliers for R&D, but as a matter of principle solicits quotations from different suppliers, placing the purchase orders with the most favorably priced supplier, taking into consideration all relevant quality aspects. The procurement is organized in such a way that MediGene is able to guarantee supply despite possible delivery bottlenecks or quality problems, and at the most favorable purchase prices. The cost of purchase of laboratory supplies constitutes only a small portion of our total expenses. As long as prices develop within the usual scope, procurement costs play only a minor role in MediGene's cost structure.

**Complex demands on service providers**

MediGene calls for extensive services mainly for large-scale production and formulation of therapeutic substances, as well as for the execution of pharmacological, toxicological and clinical trials. Outsourcing of these activities ensures that we will be able to respond to changes in our development portfolio with the appropriate flexibility. The demands on these services are very complex and require high expertise and

experience of the purchaser. The criteria for partner selection in such projects are quality, efficiency, but also things like deadline effectiveness, reliability and flexibility.

**Environmental and health protection****A top priority**

MediGene is committed to safety and environmental protection. The company not only meets the statutory requirements, but also strives to keep its laboratory facilities and equipment state-of-the-art. In order to monitor the observance of the regulatory requirements, MediGene has appointed in-house radiation safety, biological safety, and waste management officers, a safety engineer as well as a project manager for genetic research, all of whom are experienced employees with specific training for this purpose. Moreover, the safety engineer has been especially trained in accordance with the guidelines of the employers' liability insurance association for the chemical industry (»Berufsgenossenschaft«).

MediGene provides for thorough servicing and for continuous maintenance and expansion of our laboratory facilities and equipment. External service companies assist MediGene in having all accumulating waste materials thoroughly separated and professionally disposed of or recycled, in compliance with the specific requirements. In order to guarantee workplace safety to all employees in our laboratories, our safety engineer analyzes the hazards and carries out safety trainings. In addition, preventive medical checkups are made at regular intervals. MediGene meets all major requirements regarding environmental and health protection as well as safety, and holds the necessary permits and approvals. All random inspections and tests made by various authorities so far passed without any noteworthy objections.

In MediGene's opinion, the development of innovative drugs is a social mission of high ethical pretension. For this reason, the company focuses its own resources mainly on this area.

**Comprehensive risk management system in terms of shareholder value****Principles, administration and controlling**

Our corporate strategy is geared to maximizing the shareholder value. This necessitates continuous monitoring and improvement of our decision-making processes. Corporate success implies taking risks and dealing with them with a sense of responsibility. For this purpose MediGene has implemented a comprehensive risk management system which is continuously improved and can be flexibly adjusted to new situations arising. Organizational protective measures through separation of functions have been established. Any activities or business transactions that

carry potential risks are never executed by one employee alone – in each case it is a committee that assumes responsibility for decision-making and the decision itself. Work instructions and flows are standardized to ensure consistent execution of each individual operation. EDP risks are minimized by access restrictions and regulations for system development and program maintenance. Forms, worksheets and laboratory journals are used to record and document all data obtained. MediGene's controlling accounts for goal-oriented coordination of planning, steering and supervision. The company's projects undergo a monthly target-performance comparison to reveal any deviations which are then discussed with the project leaders and the executive board at regular intervals.

### **Portfolio steering and evaluation**

MediGene's project portfolio is steered actively and evaluated at regular intervals. Steering includes the drawing up of development plans for each individual project which are passed by a development committee. The executive board keeps the observance of these development plans supervised. Regular evaluation of the individual projects, i.e. opportunities and risks involved, applies especially to the technical risk. This includes analysis of the relevant patent position, scientific assumptions of potential competitors, considerations with regard to clinical development, marketing authorization conditions, process development, and portfolio strategy. The results are summarized in a feasibility study and a profitability evaluation. This provides the basis for any decision regarding MediGene's overall portfolio, and the future strategic orientation. MediGene's international scientific advisory board critically examines the research and development activities from a technical point of view and provides advice based on latest insights from research and clinical applications.

Special emphasis is put on intellectual property. MediGene is striving for a broad patent protection for both platform technologies as well as product candidates, in order to safeguard MediGene against potential competitors. MediGene does not depend on one single technology, but possess highly diversified technology and product portfolios – both protected by extensive patents pending and granted. Moreover, cooperations with external scientific institutes, universities and other companies grant 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« guidelines. It guarantees observance of the defined standards in the development and manufacture of pharmaceutical products, and that evidence of the working methods can be provided at any time. In the field of quality assurance, MediGene possesses a multitude of standardized workflows.

The risk management system was evaluated by our auditors as a part of the appraisal of the consolidated annual financial statements.

## **Risk report**

### **Industry and market risks**

MediGene is subject to the typical industry and market risks inherent to the development of pharmaceutical products utilizing novel technologies. Experience shows that the development of a drug requires 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 fail to obtain the regulatory authorities' approval required for commercialization or further development, that one or some product candidates turn out to be hazardous or inefficient, that large-scale production of the drugs is impossible, or that they are not profitable or sufficiently competitive. Moreover, third parties' proprietary rights may oppose commercialization, or other companies may launch drugs that are superior in quality or more favorably priced.

### **Procurement risks**

MediGene purchases the drug Eligard® for the European market exclusively from the licensor and manufacturer QLT Inc. in the USA. In principle there is the risk that the manufacturer fails to deliver the product. In cooperation with QLT Inc., MediGene has taken precautions against this, by being able to resort to alternative manufacturers. In particular cases, however, these precautions may not be sufficient to avoid supply problems.

### **Legal risks/patent risks**

MediGene's success also depends on its capability of achieving a maximum of patent protection for its technologies and products, protecting its business secrets, fending off any infringements efficiently, and of enforcing its own rights without breach of others' rights. In order to guarantee the legal protection of its technologies and product, MediGene applies confidentiality agreements and contractual use restrictions in the cooperation with partners, employees, consultants and other contractual partners.

There is no guarantee that patents are not challenged, declared invalid, or evaded, 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 areas, third parties might, however, assert legally protected interests based on industrial property rights or cooperation, research and license agreements. Future litigations cannot be ruled out (see also p. 47 »legal disputes«).

## **Risks of unsuccessful drug development**

Before commercialization, MediGene's drug candidates have to undergo the pre-clinical development stage, followed by the individual clinical trials in humans. These trials investigate adverse effects and efficacy of the substance before the marketing authorization application can be submitted to the respective regulatory authorities. After evaluation of the application and the data submitted, the authorities decide upon marketing authorization. There is a possibility that approval is denied, or that additional data are required before a final decision on the approval can be made. Delays arising in the execution of the clinical trials or in patient recruitment may cause increased costs and 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 prognosis about future trials.

Numerous biotech companies, including MediGene, have experienced severe setbacks in clinical trials, even after having obtained promising results in earlier stages. MediGene cultivates close relations with the regulatory authorities and performs an annual risk assessment of each project. Risk diversification is achieved by developing drugs based on a variety of technologies.

Specialized service providers are assigned to conduct the necessary clinical trials. Some of the respective contracts provide for a cancellation right of the particular service provider. Cancellation of a contract by the service provider might cause a severe delay in the execution of a clinical trial, thus protracting drug development significantly.

## **Risks of low drug sales**

Drug development and commercialization face keen competition. This applies especially to MediGene's focus, i.e. the anti-cancer drug market. Due to its commercial potential, this market segment is in the epicenter of the activities of numerous major pharmaceutical and specialized biotech companies. MediGene's drug candidates target very severe or insufficiently curable diseases. In each of these indications, an efficient drug would have a tremendous market potential. If a competitor is the first to successfully launch a product, MediGene's drug could be less competitive or even in an inferior position, depending on the product profile or sales performance. MediGene's portfolio strategy should minimize the sales risks.

## **Risks arising from development and product liability**

MediGene is exposed to the risk of considerable claims for indemnification in case a patient suffers adverse events while participating in a clinical trial or taking a prescribed drug developed by MediGene. Such claims for indemnification of adverse events could in particular exceed MediGene's insurance coverage, and consequently have a negative impact on the company's financial and revenues position as well as its

cash flow. Although the proceedings used in clinical trials are designed in such a way that potential adverse events are identified and evaluated, the possibility can never be ruled out that a drug may cause unexpected adverse events even after having obtained approval. Such adverse events could impair the drug's safety profile and be so severe that the drug has to be withdrawn from the market.

## **Financing risks**

MediGene's equity available and operating cash flow may possibly not be sufficient to cover expected investment expenses and working capital required in the foreseeable future. There is the possibility that MediGene has to raise capital 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 may occur that MediGene does not have sufficient funds at acceptable terms. In that case MediGene could be impelled to reduce research and development, production or marketing expenses. In the past, however, MediGene has always been able to raise sufficient capital for future financing of the company's operations. In order to ensure this in the future as well, MediGene is actively pursuing its investor and public relations activities.

## **Risks related to reimbursement**

The sales performance of a drug also depends on whether and to which amount the approved drug is reimbursed by state-run or private health insurance carriers in the individual countries. In all European Union member states and in many other countries, prices are controlled, and/or other limitations are imposed on drug reimbursement. MediGene might even be forced to reduce the price of a drug in order to be admitted to the reimbursement system.

## **Foreign currency risks**

MediGene runs a subsidiary in San Diego, USA which is financed by MediGene capital. In case of a loss in the value of the euro against the US dollar, the operating expenses in the USA will rise. On the other hand, a rise in the value of the euro against the US dollar will require value adjustment of MediGene's assets in the USA. Due to the significant downsizing of the US site, the impact of foreign currency fluctuations has decreased.

MediGene purchases the drug Eligard® in the USA. The product is invoiced in US dollars. MediGene sells the drug on the European market, also against US dollars. Thus the foreign currency risk is reduced significantly, as it refers exclusively to the sales margin realized by MediGene.

On the balance sheet of December 31, 2004, MediGene has posted shares of the Canadian company QLT Inc. (NASDAQ: QLTI), amounting

to 2,761 T€. The price of these shares is also subject to changes in the value of the US dollar against the euro.

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

MediGene's overall risk is primarily defined by the individual risks arising in the fields of clinical development, product marketing and corporate financing. Both MediGene's business success and survival decisively depend on successful drug development and commercialization as well as capital market conditions. With its broad product portfolio based on different independent technological and scientific approaches, MediGene meets the usually very high risk that some individual projects fail to succeed. This reduces but does not completely rule out the risk that individual product failures would endanger the company and its survival.

### **Employees**

The company depends on highly qualified employees in the field of research and development. Companies are competing vigorously for employees with expertise specific to the industry. MediGene's economic success will continue to depend on successful recruitment of qualified and abiding employees.

### **Major events since closing date**

No major changes to the state of business have occurred up to February 25, 2005.

### **MediGene to be Listed on TecDAX30 Index**

The German Stock Exchange announced on March 3, 2005 that MediGene has been selected for inclusion on the TecDAX30, the index including Germany's most important mid-cap technology companies. According to the decision MediGene has fulfilled the admission criteria for the TecDAX30 and will be included there as of March 18, 2005. The TecDAX30 follows the blue chip DAX index and comprises 30 companies admitted to the stock market »Prime Standard« segment. In addition to compliance with comprehensive international transparency requirements, the admission criteria include an above-average market capitalization (share price multiplied by the number of company shares), and a high trading volume (number of shares traded daily). According to the decision made by the German Stock Exchange on March 3, 2005, MediGene has fulfilled the admission criteria for the TecDAX30 and will be included there as of March 18, 2005.

### **Outlook and forecast**

At the beginning of 2005, economy indicators suggest that the moderate economic growth in the euro zone is going to continue. At the same time the money market interest rates appear to persist on a low level.

The German biotech industry will probably be shaped by a continuing consolidation process in 2005 as well. Simultaneously new guidelines regarding clinical trials and the health care reform in Germany will have an influence on the sentiment towards biotechnology shares.

### **Expected development of the biopharmaceutical industry**

At this stage, anti-tumor drugs constitute the bigger part of the international drug market: for the next decade experts predict a continuous growth of the anti-cancer drug market volume. In 2010, worldwide sales are estimated at approx. 50 billion US dollars. Today's market volume is already approx. 20 billion US dollars. The insufficient efficacy of available therapies and the rising incidence of tumor diseases will lead to a growing demand for cutting-edge drugs. Market growth will be driven by novel therapies that may provide more efficacy accompanied by fewer adverse events, i.e. significantly improved treatment for the patient. MediGene's EndoTAG technology as well as the oncolytic herpes simplex viruses could be examples of this.

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

In 2004, MediGene has extended its own product portfolio by the acquisition of the assets from Munich Biotech AG, i.e. the drug candidate EndoTAG-1 and the EndoTAG technology.

### **Further market launches of Eligard® in Europe planned**

The one-month and three-months sustained release products of Eligard®, an LH-RH agonist for the treatment of advanced prostate cancer, were on the German market by MediGene's partner Yamanouchi Ltd. in May 2004. In December 2004, the mutual recognition procedure for drug approval in 23 other European countries was completed. MediGene expects successive launches on these markets as from mid 2005.

In this connection MediGene anticipates further milestone payments from Yamanouchi Ltd. as well as more revenues from the sale of Eligard® in these markets.

### **Four-months and six-months sustained release products of Eligard® provide additional potential**

In addition to the licenses for the one-month and three-months products, MediGene had acquired options on European marketing licenses for the four-months and six-months products. These sustained release products are also subject matter of the contract concluded with Yamanouchi Ltd. By exercise of these options, no substantial additional cost for MediGene will arise. Both products, for which there are no approved competitive products on the European market, provide an interesting opportunity to further increase the value of this drug. It is up to Yamanouchi Ltd. to decide on the development of the two sustained release products, which are already approved and have been launched in the USA.

## **Polyphenon® E Ointment – submission of marketing authorization application in the USA planned**

Polyphenon® E Ointment is developed for the treatment of benign tumors of the genital area, so-called genital warts.

In March and December 2004, two clinical phase III trials, each with a total of more than 500 patients participating in the USA and in Europe, were completed with positive results.

At present MediGene is preparing marketing authorization application for this drug and plans submission to the American regulatory authorities in 2005, followed by submission in Europe.

In addition, a marketing partner for Polyphenon® E Ointment shall be announced by the end of 2005.

## **Polyphenon® E Ointment – completion of clinical phase II trial in actinic keratosis expected**

End of October 2004, MediGene reported completion of patient recruitment for a clinical phase II trial of Polyphenon® E Ointment for the treatment of the skin disease actinic keratosis (precursor of skin cancer). A total of more than 60 patients were admitted to participate in the trial which investigates efficacy and tolerability of Polyphenon® E Ointment applied against actinic keratosis. The sales potential of Polyphenon® E Ointment in this application is estimated at at least 200 million € annually, provided that the multistage development and marketing authorization procedures are successfully completed.

## **EndoTAG-1 – Resumption of clinical development program phase II**

At present, clinical phase II trials of EndoTAG-1 in the indications pancreatic cancer and hormone-resistant prostate cancer are in preparation and discussed with the regulatory authorities in the USA and Europe. The first trial is to be initiated in 2005. The market potential is expected to reach more than 200 million € each.

## **NV1020 – clinical phase I/II trial ongoing**

In September 2004, MediGene initiated a new clinical phase I/II trial of the oncolytic virus NV1020 in the indication liver metastases from colorectal carcinoma. This trial is continuing and is intended to investigate safety, tolerability and efficacy of treatment with NV1020 as well as potential synergies from a combination with chemotherapy. About 30 patients in up to seven clinical centers in the USA shall be treated during this trial. Positive results obtained in a clinical phase I trial of NV1020 form the basis of this trial. The results of the phase I/II trial are expected in 2006. The sales potential of NV1020 upon successful completion of clinical development is estimated at more than 200 million €.

## **Expansion of technology and product portfolios remains strategic goal**

Licensing of products such as Eligard® continues to play an important role in MediGene's strategy. MediGene intends to expand its technology and product portfolios in order to enhance its opportunities for sustained growth. Therefore licensing, mergers and acquisitions represent important strategic options in the expansion of MediGene's product portfolio.

## **Reduction of loss – cash position at the end of 2005 to be 30 million €**

In 2005, MediGene plans to increase revenues to approx. 20 million €. At the same time MediGene plans to further improve results. The annual loss is planned to be less than 10 million €. Cash position at the end of 2005 is expected to be approx. 30 million €.

## **R&D remains focus**

No major investments in fixed assets are planned for 2005. Research and development expenses remain largest cost pool.

## **Total number of employees constant in 2005**

The clinical development and quality assurance departments shall be enforced by selective new hires. The total number of employees is not going to change significantly in 2005. In order to further improve professional and personal skills of our employees, we will continue to provide in-house as well as external vocational training. The number of corporate employees at year-end 2005 shall be approx. 120, with ten employees at our US subsidiary in San Diego.

## **Future procurement**

Regarding procurement, we do not expect any deviations in 2005, compared to last year. In 2005, MediGene will purchase the drug Eligard® for the European market from QLT Inc. The product is purchased in the USA and invoiced in US dollars. MediGene sells the drug on the European market, also against US dollars. Thus the foreign currency risk is reduced significantly, as it refers exclusively to the sales margin realized by MediGene.



## R&D projects: goals achieved in 2004

### Prospects in 2004

#### HPV indications

Polyphenon® E Ointment	Results from first portion of ongoing phase III trial in the first quarter	Achieved
	Results from second portion of ongoing phase III trial in the fourth quarter	Achieved

#### Oncology

Eligard® (previously Leuproge®)	Approval and market launch in Germany	Achieved
	Successful completion of mutual recognition process in 23 European countries	Achieved
NV1020	Next clinical phase I/II trial ongoing	Achieved
rAAV tumor vaccine	Results from clinical I/II trial available	Project discontinued

## R&D projects: status expected for December 2005

#### Specialty pharma

Eligard®	Market launch of Eligard® in other European countries
Polyphenon® E Ointment	Submission of marketing authorization application to US regulatory authorities
	Conclusion of a development and marketing partnership for the USA

#### Biopharma

EndoTAG-1	Resumption of clinical development program phase II
NV1020	Continuation of clinical phase I/II trial

## Future legal corporate structure and organization/administration

No changes to the legal corporate structure are planned.

## Environmental protection beyond the extent required

The measures implemented already will remain to be in effect. MediGene will continue to provide for environmental protection beyond the extent required by the authorities.

## Residual dividend policy

MediGene pursues the concept of residual dividend distribution: dividends are to be paid each time the company's financial funds cannot be reinvested in such a way that they will yield at least the same rate of return the shareholders could obtain on the capital market. This means that the residual amount of the financial funds is to be distributed which cannot be used in the interest of the shareholders, considering the given number of product developments and known yardsticks of profitability. Consequently the dividend which MediGene may distribute at some time in the future will not represent an indication of the company's income

potential. In the medium term MediGene is very likely to generate losses and to invest the funds available in drug development. Thus a dividend distribution cannot be expected for the time being.

## Investments

No major investments (> 100 T€) are planned for 2005.

Martinsried, February 25, 2005  
MediGene AG

Dr Peter Heinrich  
Chief Executive Officer

Dr Ulrich Delves  
Executive Board Member for Research and Development

Alexander Dexne  
Chief Financial Officer

# Consolidated Income Statements

of MediGene AG for the periods from January 1 to December 31, 2004 and 2003

in T€	Notes No.	2004	2003
1. Product sales	(2)	12,501	0
2. Other operating income	(2)	637	1,742
<b>3. Total revenues</b>	(20)	<b>13,138</b>	<b>1,742</b>
4. Cost of goods sold	(21)	5,930	0
<b>5. Gross profit</b>		<b>7,208</b>	<b>1,742</b>
6. Selling expenses	(22)	1,154	1,448
7. General and administrative expenses	(23)	4,591	6,478
8. Research and development expenses	(3)	14,701	21,825
9. Depreciation		1,133	1,031
<b>10. Operating loss</b>		<b>-14,371</b>	<b>-29,040</b>
11. Interest income and expenditures	(27)	575	701
12. Income from securities		1,581	0
13. Foreign currency exchange gains/losses	(1)	-90	6
<b>14. Result before income tax</b>		<b>-12,305</b>	<b>-28,333</b>
15. Tax	(28)	0	0
<b>16. Net loss from continued operations</b>		<b>-12,305</b>	<b>-28,333</b>
17. Result from discontinued operations		0	261
18. Minority interest in discontinued operations	(29)	-1	-2,988
<b>19. Net loss for the period</b>		<b>-12,306</b>	<b>-31,060</b>
<b>Per share data in €</b>			
Result from continued operations (»actual« and »fully diluted«)		-0.88	-2.53
Result incl. discontinued operations (»actual« and »fully diluted«)		-0.88	-2.77
Weighted average number of shares outstanding		13,996,440	11,206,205

The number of shares used in calculating the diluted net loss per share is the same as used in calculating the basic net loss per share since conversion of common stock equivalents would have an anti-dilutive effect. The number of potentially dilutive shares related to options and convertible debt that could dilute basic earnings per share in the future was 936.547 in 2004 and 722.955 in 2003.

US-GAAP

The accompanying notes are an integral part of the consolidated financial statements.

Totals may vary due to rounding

**Consolidated balance sheet**  
**of MediGene AG as of December 31, 2004 und 2003**

<b>Assets in T€</b>	<b>Notes No.</b>	<b>2004</b>	<b>2003</b>
<b>A. Current assets</b>			
I. Cash and cash equivalents	(30)	48,460	21,444
II. Accounts receivable	(31)	115	79
III. Inventories	(31)	0	0
IV. Prepaid expenses and other current assets	(33)	3,614	859
<b>Total current assets</b>		<b>52,189</b>	<b>22,382</b>
<b>B. Long-term assets</b>			
I. Property, plant & equipment	(34)	1,565	2,189
II. Intangible assets	(34)	7,020	76
III. Goodwill	(26)	9,226	9,226
IV. Investments	(35)	2,761	4,452
V. Other assets		133	42
<b>Total long-term assets</b>		<b>20,705</b>	<b>15,985</b>
<b>Total assets</b>		<b>72,894</b>	<b>38,367</b>

<b>Liabilities and shareholders' equity in T€</b>	<b>Notes No.</b>	<b>2004</b>	<b>2003</b>
<b>A. Current liabilities</b>			
I. Current portion of capital lease obligation	(36)	269	265
II. Short-term debt and current portion of long-term debt		0	3,222
III. Trade accounts payable		618	1,764
IV. Accruals	(37)	2,953	3,342
V. Deferred income		2,000	0
VI. Other current liabilities		3,462	268
<b>Total current liabilities</b>		<b>9,302</b>	<b>8,862</b>
<b>B. Long-term liabilities</b>			
I. Long-term debt less current portion	(36)	1,703	108
II. Capital lease obligation less current portion		115	108
III. Pension accrual		36	35
IV. Other long-term liabilities		55	34
<b>Total long-term liabilities</b>		<b>1,909</b>	<b>285</b>
<b>C. Shareholders' equity</b>			
I. Share capital	(38)	18,523	11,206
Number of shares issued and outstanding			
December 31, 2004: 18,522,684			
December 31, 2003: 11,206,205			
II. Additional paid-in capital		256,411	218,177
III. Accumulated deficit		-212,248	-199,943
IV. Accumulated other comprehensive income	(41)	-1,003	-220
<b>Total shareholders' equity</b>		<b>61,683</b>	<b>29,220</b>
<b>Total liabilities and shareholders' equity</b>		<b>72,894</b>	<b>38,367</b>

US-GAAP

The accompanying notes are an integral part of the consolidated financial statements.

Totals may vary due to rounding

# Consolidated cash flow statements

of MediGene AG for the periods from January 1 to December 31, 2004 and 2003

in T€	2004	2003
<b>Cash flow from operating activities:</b>		
Net loss	-12,306	-31,060
<b>Adjustments to reconcile net loss to cash used in operating activities:</b>		
APB No. 25 expense on new options/bonds	3	35
Minority interest	0	242
Net loss minority interest	0	-261
Depreciation	1,362	1,271
Losses on sales of property, plant & equipment	30	220
Realized gains from investments	-1,581	0
<b>Changes in:</b>		
Inventories	0	492
Other assets and prepaid expenses	-372	1,355
Trade accounts payable	-3,079	-636
Accruals	-390	849
Other liabilities and deferred income	4,236	-324
<b>Net cash used by operating activities</b>	<b>-12,097</b>	<b>-26,544</b>
<b>Cash flow from investing activities:</b>		
Purchases of property, plant & equipment	-280	-108
Sales of property, plant & equipment	18	96
Net cash from acquisition of MediGene Oncology GmbH	5,047	0
<b>Net cash from investing activities</b>	<b>4,785</b>	<b>-12</b>
<b>Cash flow from financing activities:</b>		
Proceeds from capital increase	36,641	0
Expenses for capital increase	-2,801	0
Proceeds from stock options	61	0
Proceeds from minority interest	0	19
Repayments of/Proceeds from loans	-746	680
Proceeds from convertible bonds	1,500	
Principal payments under finance lease obligations	-313	-431
<b>Net cash from financing activities</b>	<b>34,342</b>	<b>267</b>
Currency translation	-14	-29
<b>Increase/Decrease in cash and cash equivalents</b>	<b>27,016</b>	<b>-26,318</b>
Cash and cash equivalents at beginning of period	21,444	47,762
<b>Cash and cash equivalents at end of period</b>	<b>48,460</b>	<b>21,444</b>

**Additional overview of non-cash financing activities:** In 2004, 1,960,938 shares worth 11,177 T€ were issued for the acquisition of MediGene Oncology GmbH. Capital lease obligations of 325 T€ (2003: 127 T€) for laboratory and office equipment were incurred in 2004. Cash paid for interest in 2004 71 T€ and 87 T€ in 2003.

US-GAAP

The accompanying notes are an integral part of the consolidated financial statements.

Totals may vary due to rounding

**Consolidated changes in shareholders' equity  
of MediGene AG for the periods from January 1 to December 31, 2004 and 2003**

	<b>Shares</b>	<b>Share capital</b>	<b>Capital reserves</b>	<b>Accumulated losses</b>	<b>Other comprehensive income</b>	<b>Total shareholders' equity</b>
	<b>No.</b>	<b>T€</b>	<b>T€</b>	<b>T€</b>	<b>T€</b>	<b>T€</b>
<b>Balance January 1, 2003</b>	11,206,205	11,206	218,142	-168,882	-1,031	59,435
Net loss 2003				-31,060		-31,060
Unrealized profit from Atrix shares					1,009	1,009
Currency translation adjustments					-199	-199
<b>Comprehensive income</b>						<b>-30,250</b>
Exercised options						0
APB No. 25 Expenses on new options/bonds			35			35
<b>Balance December 31, 2003</b>	11,206,205	11,206	218,177	-199,942	-221	29,220
Net loss 2004				-12,306		-12,306
Unrealized profit from Atrix shares					-763	-763
Currency translation adjustments					-19	-19
<b>Comprehensive income</b>						<b>-13,088</b>
Capital increase	7,293,722	7,294	40,764			48,058
Expenses capital increase			-2,801			-2,801
Exercised options	22,757	23	268			291
APB No. 25 Expenses on new options/bonds			3			3
<b>Balance December 31, 2004</b>	18,522,684	18,523	256,411	-212,248	-1,003	61,683

US-GAAP

The accompanying notes are an integral part of the consolidated financial statements.

Totals may vary due to rounding



**Consolidated changes in fixed assets  
of MediGene AG for the period from January 1 to December 31, 2004**

in T€	Sales value						
	January 1, 2004	Changes from consolidations	Currency translation adjustments	Addition	Disposal	Reduction from market valuation	Take over leasing
<b>Fixed assets</b>							
Property, plant, and equipment*	6,173	0	-32	605	-190		
<i>Improvement of leased objects, technical and laboratory equipment</i>	<i>6,008</i>		<i>-30</i>	<i>571</i>	<i>-190</i>		
<i>Software</i>	<i>165</i>		<i>-2</i>	<i>34</i>	<i>0</i>		
Intangible assets	275	7,130	-20	0	0		
<i>Technology licenses</i>	<i>275</i>	<i>7,130</i>	<i>-20</i>				
	<b>6,448</b>	<b>7,130</b>	<b>-52</b>	<b>605</b>	<b>-190</b>	<b>0</b>	<b>0</b>
<b>Goodwill</b>	<b>11,071</b>	<b>0</b>	<b>0</b>				
<b>Investments</b>	<b>4,452</b>	<b>0</b>	<b>0</b>	<b>2,769</b>	<b>-4,452</b>	<b>-8</b>	
<b>Total</b>	<b>21,971</b>	<b>7,130</b>	<b>-52</b>	<b>3,374</b>	<b>-4,642</b>	<b>-8</b>	<b>0</b>
* thereof leasing	914			325			-505

US-GAAP

The accompanying notes are an integral part of the consolidated financial statements.

Totals may vary due to rounding

Depreciation							Book value		
December 31, 2004	January 1, 2004	Changes from consolidations	Currency translation adjustments	Addition	Disposal	Take over leasing	December 31, 2004	December 31, 2004	December 31, 2003
6,556	3,985	0	-32	1,180	-142		4,991	1,565	2,188
6,359	3,846		-30	1,155	-142		4,829	1,530	2,162
197	139		-2	25			162	35	26
7,385	198	0	-15	182	0		365	7,020	77
7,385	198		-15	182	0		365	7,020	77
13,941	4,183	0	-47	1,362	-142	0	5,356	8,585	2,265
11,071	1,845						1,845	9,226	9,226
0									
2,761	0						0	2,761	4,452
0									
27,773	6,028	0	-47	1,362	-142	0	7,201	20,572	15,943
734	361			346		-381	326	408	553

# Notes on the consolidated financial statements

## A) Business operations

MediGene was founded in 1994 in Martinsried near Munich (Germany), with share capital of 26 T€. In 1996, the company was converted into a stock corporation. The company's headquarters are located at Lochhamer Str. 11, 82152 Martinsried, Germany. MediGene is entered on the Commercial Register of the Munich Local Court, HRB no. 115761. The company owns two other enterprises in Germany, as well as a wholly owned subsidiary in the USA, that is MediGene, Inc. in San Diego. The purpose of the company is research, development and commercialization in particular of technologies applied in molecular biology, of processes and products in the field of drugs and pharmaceutical substances, and the execution of services related to these areas. MediGene AG has been publicly quoted since June 2000 (German Stock Exchange: Prime Standard; security identification code: 502090; MDG).

## B) Accounting principles

These consolidated annual financial statements were drawn up in compliance with the US Generally Accepted Accounting Principles (US-GAAP). The company calls upon § 292a of the German Commercial Code (HGB) for these consolidated financial statements which were not drawn up in compliance with HGB. For this reason, this annual report was supplemented by the details necessary to be exempted from the liability to prepare consolidated annual financial statements and management's discussion and analysis in accordance with German law. The companies included in the consolidation have applied uniform accounting and valuation methods. The MediGene AG individual financial statements, however, were drawn up in accordance with the statutory provisions for accounting and the supplementary principles of proper bookkeeping. These financial statements are to be considered merely as information supplementary to the consolidated annual report. Regular individual financial statements of MediGene AG in accordance with HGB will be drawn up and filed with the Commercial Register.

The currency used in the report for 2004 is the euro (€), and thousand euros (T€) respectively, according to German notation of numbers. The functional currency at MediGene, Inc. was the US dollar (US\$).

The compilation of the consolidated annual financial statements according to generally accepted accounting principles requires estimates and assumptions by the Executive Board which at the time of accounting affect revenues, expenses, assets, liabilities and contingencies posted. The actual figures may differ from the estimates made to the best of knowledge.

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

With SFAS<sup>1)</sup> 151, »Inventory Cost, an Amendment of ARB<sup>2)</sup> No. 43, Chapter 4« (SFAS 151), the FASB<sup>3)</sup> has published new regulations regarding inventories valuation in November 2004. The standard substantiates the requirement that unusually high expenses for vacancies, rejects,

freight and handling are constituents of the manufacturing costs which cannot be capitalized but have to be posted directly affecting net income in the period they accrue. Accordingly, the allocation of fixed costs has to take place on the basis of a normal production capacity in the future. The company is committed to apply SFAS 151 to financial years starting after December 15, 2004. The company expects no major effects of the first application of SFAS 151 on its assets, finances and earnings.

In December 2004, the FASB published SFAS No. 153, »Exchanges of Nonmonetary Assets an Amendment of APB<sup>4)</sup> Opinion No. 29« (SFAS 153). According to this, the underlying fair value has to be used in principle as the basis for valuation of exchange of nonmonetary assets. The company is committed to apply the regulations to financial years starting after June 15, 2005. The company expects no major effects of the first application of SFAS 153 on its assets, finances and earnings.

Moreover, the FASB published the revised version of SFAS 123, »Share-Based Payment« (SFAS 123 (R)) in December 2004. With this revision, the voting right for the application of APB Opinion No. 25, »Accounting for Stock Issued to Employees« in the reporting of share-based remuneration was abolished. These transactions are now, with very few exceptions, to be valued at their fair value at the time of granting and to be recognized as expenses within the income statement. The amended regulations within SFAS 123(R) have to be applied for the first time by publicly quoted companies to financial years starting after June 15, 2005. The management is currently evaluating the effects of the conversion to the changed regulations of SFAS 123(R).

## D) Consolidation principles

The consolidated financial statements include the financial statements of MediGene AG, Martinsried, the financial statements of the wholly owned subsidiary MediGene, Inc., San Diego, of LARNAX GmbH, Martinsried, and MediGene Oncology GmbH, Martinsried. LARNAX GmbH discontinued business operations as per December 31, 2003. Apart from that, MediGene does not hold any stake in affiliated companies, associated companies or joint ventures. Those subsidiaries which may be controlled by the parent company by means of indirect or direct majority of voting rights are consolidated in full.

Capital consolidation is carried out using the method of purchase accounting. This means that the acquisition cost of the stake acquired is set off against the parent company's share of the shareholders' equity at the time of acquisition. Any difference is allocated to the assets and liabilities of the subsidiary, according to its portion of stake and up to the share in fair value. Any remaining active difference is capitalized as goodwill.

All intercompany receivables and payables, revenues, expenses and income as well as interim results of the companies consolidated were eliminated during consolidation.

<sup>1)</sup> Statements of Financial Accounting Standards

<sup>2)</sup> Accounting Research Bulletins

<sup>3)</sup> Financial Accounting Standards Board

<sup>4)</sup> Accounting Principles Board

Consolidated company	MediGene		
	MediGene, Inc.	LARNAX GmbH	Oncology GmbH
Registered offices	San Diego, USA	Martinsried, Germany	Martinsried, Germany
Shareholding in %	100	100	100
Shareholders' equity as per Dec. 31, 2004 in T€	-150	-403	6,986
Annual net loss/profit 2004 in T€	-2,999	2	-179

### Acquisition of MediGene Oncology GmbH

On August 13, 2004, MediGene acquired MediGene Oncology GmbH, which since then is consolidated as wholly owned subsidiary of MediGene AG.

### Structure of the acquisition

A syndicate of existing investors of the insolvent Munich Biotech AG contributed major assets of Munich Biotech AG to MediGene Oncology GmbH, and invested additional cash for further development of products and technology. In return, this syndicate led by Global Life Science, HypoVereinsbank (HVB Life Science) and DEWB, which also includes SET and MPC amongst other investors, received MediGene shares amounting to 11.3 million €. After the transaction, the 1,960,938 new shares issued for this purpose from authorized capital correspond to 12.7% share in MediGene AG. The newly issued shares are subject to a 12 months lock-up period. Depending on clinical achievements with EndoTAG-1, MediGene will make milestone payments to the receiver of Munich Biotech AG, starting with clinical phase III. The assets acquired by MediGene include the patents, rights and licenses of the Munich Biotech AG technology and products. To secure the scientific know-how and to guarantee a smooth transfer, MediGene hired 15 key Munich Biotech AG employees.

### EndoTAG-1 and the EndoTAG technology

The Munich Biotech AG drug candidates such as EndoTAG-1 are based on the EndoTAG technology which aims at a novel method of cancer therapy by »starving out« tumors. They utilize the already approved and applied therapeutic principle of anti-angiogenesis (suppressing tumor vascularization), while adding another and unique alternative: the cutting-edge liposome carrier system facilitates a novel application method of established cytostatic drugs (e.g. Taxane), intended to cause specific attachment to and destruction of the newly developed tumor vascular system (»neovascular targeting«). Thus this treatment starts off at a very early stage of angiogenesis which is vital for both tumor as well as metastases growth, which could permit a particularly reliable efficacy. Moreover, the development of typical resistance to cytostatic drugs becomes unlikely, since the toxic substance does not damage the tumor cells directly. These two specific factors may increase the efficiency of conventional therapies and alleviate their adverse effects. The EndoTAG technology is protected by extensive patents and provides a basis for the development of various cancer therapies. Immediately after consulting

with the international regulatory authorities, MediGene will continue clinical development of the drug candidate EndoTAG-1.

### Cost of the acquisition

In accordance with US-GAAP the transaction was posted applying the »Purchase Method«:

Issue of 1,960,938 MediGene shares at 5.70 € each	11,177,347 €
Fees and other expenses for the purchase	117,135 €
<b>Total purchase price</b>	<b>11,294,482 €</b>

Within the transaction, the assets acquired were valued in order to allocate the purchase price in compliance with SFAS No. 141, »Accounting for Business Combinations«. The total purchase price of 11,294,482 is split up as follows:

Cash	7,164,005 €
Liability from the acquisition of Munich Biotech AG assets	-3,000,000 €
<b>Net cash</b>	<b>4,164,005 €</b>
Amortization of intangible assets	7,130,477 €
<b>Total purchase price</b>	<b>11,294,482 €</b>

As per December 31, 2004, liabilities of 1 million € from the acquisition of the assets are posted under other liabilities.

The purchase price of MediGene Oncology GmbH was based on the share price at the date of acquisition disclosure. Accordingly, the purchase price including cost of the transaction amounted to 11,294,482 €.

Intangible assets (patents and licenses) solely were acquired which are depreciated over the patent term of 16 years. In 2004, depreciation of intangible assets was 148.6 T€.

Pro forma information is not provided, since MediGene Oncology GmbH was not founded until 2004. The results of MediGene Oncology GmbH are included in the consolidated financial statements as from September 1, 2004.

# Consolidated financial statements

## E) Fundamental principles of accounting and valuation

### (1) Foreign currency translation

SFAS No. 52, »Foreign Currency Translation«, was applied in consolidating the American subsidiary MediGene, Inc. which accounts in US dollars. All balance sheet items are converted at the exchange rate on the cutoff date (cutoff date conversion method), with the exception of shareholders' equity which is converted at the historical cutoff date exchange rate. For consolidation, expenses and revenues are converted into the reporting currency at the respective annual average exchange rate. Differences resulting from foreign currency translation in the balance sheet compared with the translation for the previous year are reported not affecting operating result under accumulated other comprehensive income. This balance sheet item amounted to -1,003 T€ in 2004 (2003: -220 T€). Receivables and payables not posted in the functional currency are converted at the exchange rate of the balance sheet date. Cost of goods purchased and sold in foreign currencies are converted at the current exchange rate on the date of transaction. Foreign currency translation gains and losses are explicitly posted as such in the consolidated income statements. The following exchange rates were applied in 2004:

#### Foreign currency exchange rates 2004 € in US\$

	Rate at cut-off date	Annual average exchange rate	
December 31, 2004	1.3621	2004	1.24329
December 31, 2003	1.2630	2003	1.13080

Fluctuations in exchange rates led to adjustments of fixed assets amounting to -6 T€ (2003: -202 T€). The adjustments caused by exchange rate fluctuations are reported in the balance sheet under »accumulated other comprehensive income«.

### (2) Realization of income

During the year under review, MediGene posted income from product sales, milestone and license payments, R&D payments from partners, research grants and other income.

#### Income from product sales

Since early May 2004, Eligard® has been MediGene's first drug to be sold on the German market. For the first time revenues from the commercialization of a drug are generated. In January 2004, MediGene concluded a marketing partnership with Yamanouchi Ltd. for the commercialization of Eligard®. MediGene's partner takes on sale of the drug in Germany and the other European countries. Income from product sales is realized upon delivery.

#### Income from advance, milestone and license payments

In accordance with US-GAAP, so-called »upfront« payments (non-recurring advance payments), to be paid by pharmaceuticals partners upon conclusion of a new contract are collected over the entire estimated contract period. Thereby cash flow increases by the full amount of incoming payment. The deferred income is resolved over the product development period or contract period, and reported as product sales in the consolidated income statements. These rules are in particular applied to the new contract closed with Yamanouchi Ltd. in January 2004. License payments are collected for product sales of Eligard® by Yamanouchi Ltd.

#### R&D payments from partners, research grants and other income

Income from research cooperations is recognized affecting net income when the contracted objectives or milestones have been achieved. Contractual payments and scheduled payments not linked to a future achievement are posted as income when the cooperation partner confirms fulfillment of the contractual agreements. Payments for research and development are received according to the progress of the research and development work. Grants received are posted as other operating income.

### (3) Research and development expenses

Research and development expenses include all costs arising from research and development activities, such as personnel expenses, consultancy fees, material and laboratory expenses, services, legal fees and charges, as well as other allocated costs such as rent and electricity. They are recorded immediately, affecting net income.

### (4) Earnings per share

Earnings per share are calculated according to SFAS No. 128, »Earnings per Share«. The actual result per share is -0.88 €, resulting from dividing the net loss by the weighted average number of shares in the year under review (2004: 13,996,440 shares). Consideration of the number of possible shares resulting from the exercise of options and convertible bonds would have an anti-dilutive effect in the calculation of the net loss per share. Therefore the fully diluted loss per share (2004: -0.63 €) is lower than the actual loss (2004: -0.88 €).

The corresponding diluted net loss is calculated by dividing the net loss by the weighted average number of shares plus potentially diluted shares from the conversion of options and convertible bonds that could dilute earnings per share in the future (2004: 19,459,231 shares fully diluted).



#### **(5) Cash and cash equivalents**

Cash and cash equivalents include cash on hand as well as credit balances with banks, and checks with an original maturity of up to three months. They are reported at nominal value.

#### **(6) Investments**

Any major holdings that would permit execution of significant influence do not exist. All other investments and securities included in fixed and current assets are allocated to the category available-for-sale securities, according to SFAS No. 115, »Accounting for Certain Investments in Debt and Equity Securities«. These securities can be sold at any time and are valued at their market price. The resulting gains and losses not realized are recognized directly under accumulated other comprehensive income in shareholders' equity. They are of a non-permanent nature. In case permanent impairment of marketable available-for-sale securities occurs, they are written off affecting net income.

#### **(7) Accounts receivable**

Trade accounts receivable are posted at nominal value. Individual or lump-sum value adjustments were not required.

#### **(8) Intangible fixed assets**

Intangible fixed assets purchased bearing a limited service life are valued at acquisition cost and are subject to regular depreciation on a straight-line basis. Permanent impairment did not occur. Depreciation of intangible fixed assets is based on the following service life, resulting from an estimated useful life :

Licenses for technologies and products	3 – 16 years
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Goodwill amounting to 9,226 T€ refers to MediGene, Inc., and is allocated to the biopharma segment.

As from January 1, 2002, SFAS No. 141, »Business Combinations« and SFAS No. 142, »Goodwill and Other Intangible Assets« have been applied. Therefore regular depreciation of acquired goodwill over an estimated service life was omitted. Instead the impairment test of goodwill was executed within the framework of the annual project evaluation. This evaluation is made annually, and, upon indication of impairment, during the year as well. If this evaluation reveals impairment, a non-scheduled depreciation is required. The impairment test is based on a comparison of the actual book value with the result of the project evaluation, carried out in the form of a »Net Present Value« (NPV) calculation. This means that the net present value (capitalized value) of an investment is determined, based on a discount rate for a number of periodical payments.

For details on the fixed assets development, please see the statement of fixed assets.

#### **(9) Property, plant, and equipment**

Property, plant, and equipment are valued at acquisition costs and are subject to regular depreciation on a straight-line basis. Up to now, no property, plant, and equipment was manufactured by MediGene AG. Depreciation of property, plant, and equipment is made over the expected service life, whereas improvements to leased objects may also be depreciated over a possibly shorter lease contract period.

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

Major renovation work or improvements are capitalized as far as they increase the value of property, plant, and equipment. All other expenses for maintenance and repairs are posted as expenses at the time they accrue. In case of sale of property, plant, and equipment, the acquisition costs as well as the accumulated depreciation resulting are deleted from the accounts in the year of sale. Gains and losses from the sale are posted affecting net income in other income and expenses. Purchase and sale of property, plant, and equipment within the group are eliminated during consolidation.

Property, plant, and equipment with a purchase price of up to 410 € are rated as low-value items. They are not allocated to fixed assets but are recognized to their full amount in other operating expenses. For details on the development of fixed assets, please see the statement of fixed assets.

#### **(10) Non-scheduled depreciation of intangible assets with limited service life and of property, plant, and equipment**

Upon indication of possible impairment, an impairment test is executed of the fixed assets that are usually subject to regular depreciation. In that case, the estimated future cash flow is compared to the residual value of the asset. If the residual value exceeds the amount of undiscounted cash flow, the fair value is determined and, if necessary, the asset is written off at that value.

Non-scheduled depreciation is to be recognized to the extent to which the book value exceeds the corresponding fair value.

# Consolidated financial statements

## (11) Leasing

The company has concluded long-term lease contracts for specific office and laboratory facilities. These contracts fulfill at least one requirement as stipulated in SFAS No. 13 for the classification as finance leases, and are capitalized with simultaneous accrual of the leasing obligation. Contracts capitalized in this way are recognized at acquisition cost and amortized on a straight-line basis over the estimated service life, like other property, plant, and equipment in the company. In addition, the company rents office and laboratory space, office and laboratory equipment as well as vehicles, all of which representing operational leasing. These operational leasing payments are posted affecting expenses when accruing. The lease contract period for office furniture is 60 months, and for office and laboratory facilities 36 months. The main lessor is HVB Leasing. The company acts merely as a lessee.

## (12) Liabilities

Trade accounts payable are recognized at their redemption cost. Debt comprises mainly a research and development loan, as well as capital lease obligations.

## (13) Accruals

Pension and other accruals were formed. In 1998, the company made a pension commitment to Dr Heinrich in the form of a non-recurring payment of 26 T€, by means of salary transformation. The liability was valued at present value.

Other accruals comprise mainly services received but not yet invoiced. In regard to their assessment, they adequately and sufficiently allow for all recognizable risks. Any major appraisal parameters, observance of price increases or determination on partial or full cost basis were not required. Any voting rights for accounting were not called upon.

## (14) Stock options and convertible bonds

According to US-GAAP, Accounting Principles Board No. 25, options and convertible bonds issued to employees and members of the Executive and Supervisory Boards are recorded as expenses. The difference between the common stock fair value and the exercise or conversion price distributed over the waiting period is posted.

## (15) Accumulated other comprehensive income

SFAS No. 130, »Reporting Comprehensive Income«, requires disposal and description of the total income. In accumulated other comprehensive income, gains and losses from the fair value measurement of securities are recognized directly as changes in shareholders' equity. The difference accruing from foreign currency translation is also included in accumulated other comprehensive income.

## (16) Deferred taxes

Deferred taxes are based on temporary differences caused by time differences in income statements according to fiscal and commercial law, and different valuation in the tax and commercial balance sheets. The calculation of the deferred taxes is made according to the liability method. The tax rates applied are those that will, according to governing law, be applicable at the time when the temporary differences are likely to level out. The effects of changes in fiscal legislation on deferred tax assets and liabilities are posted affecting net income in the reporting period of inception. The tax rate applied to determine deferral as at December 31, 2004 was 37.9%. Adjustments of the deferred taxes calculated are possible. Deferred tax assets are recognized only in so far as coherent tax advantages are likely to be realized.

## (17) Cash flow statements

The cash flow statements were prepared in compliance with SFAS No. 95, »Statement of Cash Flow«. The company has applied the indirect method, and split up cash flow for operating, investing and financing activities.

## (18) Discontinued operations according to SFAS No. 144

Discontinued operations are reported according to SFAS No. 144, »Accounting for the Impairment or Disposal of Long-Lived Assets«. The company is committed to report separately business units to be divested or sold (»discontinued operations«). Any major assets and liabilities of these business units have to be posted in a separate balance sheet item. As per December 31, 2004, no major items were posted in the balance sheet of LARNAX GmbH, since the company had discontinued operating activities. Gains and losses from the divestiture, as well as gains and losses from operating activities of these business units are posted separately under »discontinued operations« in the consolidated income statements.

## (19) Major differences HGB vs. US-GAAP

These consolidated financial statements were drawn up in accordance with the US Generally Accepted Accounting Principles (US-GAAP). US-GAAP differs in several items from the German principles stipulated in the Commercial Code (HGB). The differences between accounting in compliance with US-GAAP vs. HGB relevant for these consolidated financial statements are highlighted in the following:

### Cost of IPO

According to US-GAAP, the costs accruing from IPO and further capital increases are posted as decrease in additional paid-in capital, whereas according to HGB they are posted as extraordinary expenses.

### Intangible assets

US-GAAP requires intangible assets purchased, including goodwill, to be capitalized. According to HGB capitalization of purchased intangible assets is optional. Goodwill recognized according to US-GAAP is not subject to regular depreciation, whereas according to HGB regular depreciation over the service life is mandatory.

**Property, plant, and equipment**

US-GAAP requires regular depreciation to reflect wear. Newly acquired assets with an estimated service life exceeding the individual financial year are depreciated over their estimated service life. US-GAAP rules out special depreciation of assets merely for tax purposes. In their assessment of depreciation of property, plant, and equipment, many companies accounting according to HGB are guided by the depreciation rates applicable for tax purposes. Both the straight-line as well as the declining balance methods of depreciation are allowed.

**Leasing**

US-GAAP draws a distinction between two types of leasing, i.e. capital and operational leases. Operational lease corresponds to a rental agreement that has to be reported in the lessor's financial statements. Capital leases, however, are to be capitalized by the lessee. Accounting of leasing transactions is not addressed by HGB. Following an economic approach, leased objects have to be accounted for by the respective »economic owner«.

Both the lessee as well as the lessor may be the economic owner. A multitude of criteria has to be scrutinized in order to make a clear allocation for reporting. In practice most lease agreements are drawn up in such a way that the leased objects are allocated to the lessor, due to the tax advantages involved.

**Deferred taxes**

According to US-GAAP deferred tax assets have to be capitalized regardless of their origin, and deferred tax liabilities have to be accrued. Deferred tax assets are reviewed for probability of their realization, and, if necessary, adequately depreciated. Following German principles, deferred tax assets based on a tax loss brought forward are not recognized. Only those deferred tax assets resulting from valuation differences between commercial and tax legislation may be recognized. Accruals for deferred tax liabilities have to be made.

**Foreign currency translation**

According to US-GAAP, foreign currency translation of accounts receivable and payable has to be made at the exchange rate of the balance sheet date. Unrealized gains and losses which are not of a temporary nature have to be posted affecting net income. According to the German principles, assets and liabilities have to be valued individually as of balance sheet date. Valuation has to be conservative, i.e. gains are to be recognized only if realized at the balance sheet date. Both US-GAAP as well as HGB require application of the functional currency method.

**Revenue recognition**

US-GAAP applies much more stringent criteria for the accounting of revenues than HGB does. The main focus is on the date of revenue accounting, which may result in differences within a period under review.

**Unrealized securities value gains and losses**

According to US-GAAP, unrealized fluctuations in the value of available-for-sale securities may be recognized as »other comprehensive income« in shareholders' equity. This applies, however, only to temporary fluctuations. Unrealized gains and losses which are not of a temporary nature have to be posted affecting net income. HGB applies the stringent principle of the lower of cost or market to securities held as current assets. According to this principle, unrealized losses must be posted affecting expenses in the income statements, whereas gains must not be posted before realization.

**Purchase price calculation for acquisition**

According to US-GAAP, the purchase price of an acquisition is determined at the fair value of the shares transferred as payment. The fair value corresponds to the share price on the date of disclosure of the conditions of the acquisition by means of exchange of shares. According to the German principles, the price valid at the date at which the liability becomes irrevocable has to be posted.

**Stock options and convertible bonds**

According to US-GAAP Accounting Principles Board No. 25, stock options and convertible bonds issued to employees and members of the Executive and Supervisory Boards are posted under expenses. The difference between the fair value of common stock and the exercise or conversion price over the waiting period is entered. According to HGB, stock options are not reported upon issue, but are recognized under additional paid-in capital upon conversion.

**Contents and presentation of the annual financial statements**

According to US-GAAP the balance sheet items are split up into »current« and »long-term«, depending on the possibility of liquidation. The income statements are drawn up in the cost of sales format and distinguish between operating and non-operating expenses. A balance sheet drawn up in compliance with HGB is not divided up that way. The income statements are drawn up either in the total cost format, or the cost of sales format. Application of the cost of sales format requires additional details. We abstain from quantifying the differences in accounting according to US-GAAP and HGB for the consolidated annual report of MediGene, since the consolidated subsidiary, i.e. MediGene, Inc., accounts solely according to US-GAAP. Reporting in line with HGB and auditing of the American subsidiary, consolidated since March 2001, is not economical for MediGene.

# Consolidated financial statements

## F) Notes on the consolidated income statements

### (20) Total revenues

#### Total revenues

in T€	2004	2003	Change
Revenues and license fees	4,501	0	–
Milestone and upfront payments	8,000	0	–
<b>Product sales</b>	<b>12,501</b>	<b>0</b>	<b>–</b>
R&D funding from partnerships	225	1,576	-86%
Research grants	55	95	-42%
Other income	357	71	403%
<b>Total revenues</b>	<b>13,138</b>	<b>1,742</b>	<b>654%</b>

### (21) Cost of sales

Cost of sales accrues in the commercialization of Eligard®, and comprises, apart from milestone payments to the licensor QLT Inc. (previously Atrix Laboratories, Inc.), purchasing costs for the product and royalties on sales revenues paid to QLT Inc. The manufacturing costs for Eligard® totalled 5,930 T€ (2003: 0 T€).

### (22) Selling expenses

So far there are no sales activities for approved drugs ongoing. Selling expenses comprise exclusively business development and pre-marketing expenses, including personnel expenses, consultancy fees, market research, material costs and other services.

### (23) General and administrative expenses

This item comprises mainly personnel expenses, expenses accruing in communication with the capital market and public relations as well as administrative and other services. Other operating expenses are not included. Expenses for rentals, incidental rental expenses, telecommunication services, safety etc. are allocated to the individual segments. In 2004, rental expenses for office and laboratory space amounted to 913 T€ (2003: 1,648 T€). Fixed assets are directly allocated to the individual segments, for direct posting of depreciation as well as gains and losses from the disposal of assets. This also applies to the forming and liquidation of accruals. Foreign currency translation gains and losses are separately posted in the income statements.

### (24) Personnel expenses

The following personnel expenses are posted in the expense items of the income statements:

#### Personnel expenses

in T€	2004	2003	Change
Wages and salaries	7,132	9,510	-25%
Social insurance	1,213	1,463	-17%
<i>of which for pension</i>	<i>137</i>	<i>186</i>	<i>-26%</i>
<b>Total from continued operations</b>	<b>8,345</b>	<b>10,973</b>	<b>-24%</b>
Discontinued operations	38	1,063	–
<b>Total</b>	<b>8,383</b>	<b>12,036</b>	<b>-30%</b>

#### Personnel expenses by segments

in T€	2004	2003	Change
Specialty pharma	1,213	1,046	16%
Biopharma	4,491	5,898	-24%
Intersegment	2,641	4,028	-34%
<b>Total from continued operations</b>	<b>8,345</b>	<b>10,973</b>	<b>-24%</b>
Discontinued operations	38	1,063	–
<b>Total</b>	<b>8,383</b>	<b>12,036</b>	<b>-30%</b>

#### Employees by function

	Dec. 31, 2004	Dec. 31, 2003	Change
Business development and general administration	32	36	-10%
Research and development	85	76	11%
<b>Total from continued operations</b>	<b>117</b>	<b>112</b>	<b>4%</b>
Discontinued operations	0	12	-100%
<b>Total</b>	<b>117</b>	<b>124</b>	<b>-6%</b>

The decline in personnel expenses is a result of the cost-cutting and savings measures completed in 2004. The average number of employees in the group in 2004 was 106, with 12 employees at MediGene, Inc. This corresponds to a 32% reduction compared to 157 employees in 2003. All employees are salaried employees.

	Fixed salary in T€	Variable, performance related components in T€	Variable components with a long-term incentive (No. of stock options)
Dr Peter Heinrich, Chief Executive Officer	263	120	20,000
Alexander Dexne, Chief Financial Officer	193	91	20,000
Dr Ulrich Deltos, Member of the Board for R&D (as of October 1, 2004)	54	15	0

The members of the Supervisory and Executive Boards are listed under (50). Total remuneration for Executive Board members in the past financial year was 736 T€ (2003: 663 T€). Remuneration for the Executive Board members comprises both fixed and variable components, as well as sufficient performance-related incentives for long-term growth in company value. The criteria for the variable components are established annually in advance. The long-term remuneration components are stock options, intended to create an incentive targeted at the sustainability of the company performance. A retrospective change of the objectives to be achieved is impossible. No company body member received any advance payment.

#### (25) Material costs

The expenses items in the income statements include the following material costs:

##### Material costs

in T€	2004	2003	Change
Cost of raw, auxiliary and operating materials and goods	6,312	845	647%
Cost of services	5,380	10,648	-49%
<b>Total from continued operations</b>	<b>11,692</b>	<b>11,493</b>	<b>2%</b>
Discontinued operations	-12	926	-101%
<b>Total</b>	<b>11,680</b>	<b>12,419</b>	<b>-6%</b>

##### Income tax

in T€	MediGene AG Germany 2004	MediGene, Inc. USA 2004	MediGene AG Germany 2003	MediGene, Inc. USA 2003
Deferred tax assets on net losses	35,371	15,415	35,454	15,574
Deferred tax assets/liabilities on temporary timing differences	-496	0	-193	-25
Valuation allowance	-34,875	-15,415	-35,261	-15,549
<b>Deferred tax assets, net</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

Expenses for raw materials and supplies comprise laboratory materials and chemicals totalling 387 T€. Services received not including discontinued operations comprise: execution of clinical trials 4,044 T€ (2003: 7,120 T€), regulatory affairs 81 T€ (2003: 368 T€), production services 684 T€ (2003: 2,015 T€), as well as pre-clinical development services 554 T€ (2003: 1,145 T€).

#### (26) Amortization of goodwill

As from January 1, 2003, SFAS No. 141, »Business Combinations«, and SFAS No. 142, »Goodwill and Other Intangible Assets«, have been applied. Accordingly, an impairment test was carried out, based on a »Net present Value« (NPV) calculation of the development projects at MediGene, Inc. The result exceeded the reported goodwill, which means that extraordinary amortization of goodwill was not necessary.

#### (27) Financial results

##### Financial result

in T€	2004	2003	Change
Interest income	647	778	-17%
Interest expense	-72	-77	-6%
<b>Sub-total</b>	<b>575</b>	<b>701</b>	<b>-18%</b>
Income from securities	1,581	-	-
Foreign currency exchange gains/losses	-90	6	-
<b>Total</b>	<b>2,066</b>	<b>707</b>	<b>192%</b>

#### (28) Income taxes

Deferred taxes are as follows:

## Consolidated financial statements

Since the company's medium-term forecast does not provide for any annual profit, deferred tax assets were reduced to zero. Today's estimate, however, may change depending on the company's future earnings situations, leading to lower adjustments. According to German tax legislation, losses can be carried forward without any time constraint. US tax legislation imposes a time limit for any loss carried forward. Consequently losses carried forward by MediGene, Inc. lapse between 2005 and 2023, depending on the year when they were incurred. The German corporate tax rate was reduced from 26.5% in 2003 to 25.0% in 2004.

### (29) Discontinued operations

As per December 31, 2003, the cardiology segment, including LARNAX GmbH, Martinsried, was classified as discontinued operations. LARNAX was included in the consolidation as from March 31, 2003, and reported in the cardiology segment during the period. At last MediGene held a 100% stake in LARNAX GmbH. As per December 31, 2003, LARNAX GmbH discontinued business operations. The result from discontinued operations was -1 T€ (2003: -2,988 T€). Discontinued operations were treated in accordance with SFAS No. 144.

## G) Notes on earnings per share

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

in T€	2004	2003
Pre-tax operating loss	12,305	28,333
<b>Net loss from continued operations</b>	<b>12,305</b>	<b>28,333</b>
Net loss per share from continued operations in €	0.88	2.53
Minority interest	0	261
Loss from discontinued operations	1	2,988
<b>Net loss</b>	<b>12,306</b>	<b>31,060</b>
Net loss per share in €	0.88	2.77
Weighted average number of shares	13,996,440	11,206,205

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.

## H) Notes on the balance sheet

### Assets

#### (30) Cash and cash equivalents

##### Cash and cash equivalents

in T€	2004	2003	Change
Cash and cash equivalents < 3 months	48,460	21,444	126%
<b>Total</b>	<b>48,460</b>	<b>21,444</b>	<b>126%</b>

The increase in cash and cash equivalents resulted mainly from the capital increases closed in 2004. In addition to the net cash inflow amounting to 15.7 million € from the three-step capital increase carried out in March 2004, and the net cash inflow amounting to 19.8 million € from the capital increase in October 2004, MediGene received 5.0 million € net from the acquisition of Munich Biotech AG.

#### (31) Accounts receivable

In both years under review, 2004 as well as 2003, no adjustments to accounts receivable were made. All accounts receivable are due within a period of three months.

#### (32) Inventories

There were no inventories as per December 31, 2004 and as per December 31, 2003.

#### (33) Prepaid expenses and other current assets

##### Other assets

with a term < 1 year

in T€	2004	2003	Change
Tax refund	14	32	-56%
VAT refund	401	424	-5%
Grants	0	44	-100%
Cooperations	435	29	–
Interest	16	18	-11%
Receivable QLT Inc. from conversion of shares	2,509	0	–
Rent deposit	33	105	-69%
Other	2	1	100%
<b>Total</b>	<b>3,410</b>	<b>653</b>	<b>422%</b>



### Prepaid expenses

with a term < 1 year

in T€	2004	2003	Change
Insurance	63	38	66%
Research services	0	1	-100%
Maintenance	21	22	-5%
Conference fee and travel	20	11	82%
Consultancy fee	58	58	0%
Licenses	16	0	–
Other	26	76	-66%
<b>Total</b>	<b>204</b>	<b>206</b>	<b>-1%</b>
<b>Balance sheet item</b>	<b>3,614</b>	<b>859</b>	<b>321%</b>

### (34) Intangible assets and property, plant, and equipment

The detailed composition and development of intangible assets as well as property, plant, and equipment is included in the assets statements. During the first consolidation of MediGene Oncology, GmbH, the amount of intangible assets increased by 7,130 T€. The estimated annual expenses for depreciation amount to 446 T€.

### (35) Investments

Long-term investments correspond to 233,918 shares of the Canadian company QLT Inc. MediGene received these shares plus 2.5 million € in exchange for 233,918 shares of the company Atrix Laboratories, Inc. The exchange of shares is a result of the acquisition of Atrix Laboratories by QLT Inc., approved in November 2004. The year-end value of the QLT shares held by MediGene amounted to 2,761 T€. This amount is based on the year-end exchange rate of 1 € against 1.3621 US dollar.

For the detailed composition and development of investments, please see the assets statement.

### Liabilities and shareholders' equity

#### (36) Liabilities

In August 2004, MediGene announced the termination of the partnership with the pharmaceuticals company Aventis. Within the framework of this cooperation, MediGene had received a loan of 3,312 T€, which is repaid to Aventis in twelve equal monthly installments, starting in August 2004. As per closing date December 31, 2004, the remaining amount to be repaid was 2,105 T€. This amount is posted under current trade accounts payable.

Deferred revenues refer to the still unrealized share of the upfront payment MediGene had received upon closure of the Eligard® marketing partnership with Yamanouchi Ltd.

Pension accruals have a maturity term of more than five years. All other long-term liabilities are due within five years and are not secured.

### Liabilities

in T€	2004	2003	Change	Change
<b>Current liabilities</b>				
Current portion of capital lease obligations	269	265	4	2%
Debt	0	3,222	-3,222	-100%
Trade accounts payable	618	1,764	-1,146	-65%
Accruals	2,953	3,342	-389	-12%
Deferred income	2,000	0	2,000	–
Other current liabilities	3,462	268	3,194	–
	<b>9,302</b>	<b>8,862</b>	<b>440</b>	<b>5%</b>
<b>Long-term liabilities</b>				
Long-term debt	1,703	108	1,595	–
Capital lease obligations	115	108	7	6%
Pensions accrual with a term > 5 years	36	35	1	3%
Other liabilities	55	34	21	62%
<b>Total</b>	<b>1,909</b>	<b>285</b>	<b>1,624</b>	<b>570%</b>

Other liabilities as per December 31, 2004 comprise the following items:

#### Other liabilities

in T€	2004	2003	Change
<b>Other current liabilities</b>			
Interest convertible bonds	45	0	100%
Wage- and church-tax liabilities	131	130	1%
Social insurance	133	132	1%
Liabilities from benevolent fund and direct insurance	16	4	300%
Liabilities from withholding tax	31	2	–
Remaining sales price assets Munich Biotech AG	1,000	0	–
Liabilities Aventis	2,105	0	–
	<b>3,462</b>	<b>268</b>	<b>–</b>
<b>Other long-term liabilities</b>			
Convertible bonds	55	34	62%
	<b>55</b>	<b>34</b>	<b>62%</b>

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The increase in other current liabilities results mainly from remaining sales price of 1,000 T€ assumed during the acquisition of assets from Munich Biotech AG. In addition, the residual liabilities towards Aventis, amounting to 2,105 T€ are now posted under other liabilities (previously short-term loans).

### (37) Accruals

Other accruals as per December 31, 2004 comprise the following items:

#### Accruals

in T€	Dec. 31, 2003	Used/ reversed	Accrued	Dec. 31, 2004
Vacation and overtime	224	224	237	237
Bonuses	349	309	311	351
Severance	152	109	0	43
Taxes	0	0	0	0
Office rent	71	71	0	0
Annual report audit	117	112	65	70
Workers compensation	50	50	42	42
Licenses	36	0	369	405
Annual report printing costs	77	77	100	100
Clinical trials and approval	1,111	1,062	1,047	1,096
Production and pre-clinical trials	355	348	132	139
Other	43	33	55	65
Legal	74	74	131	131
Consultants	114	114	274	274
Restructuring	569	569	0	0
	<b>3,342</b>	<b>3,152</b>	<b>2,763</b>	<b>2,953</b>

In addition to other accruals, there is a pension accrual. In 1998, the company made a pension commitment to Dr Heinrich in the form of a non-recurring payment of 26 T€, by means of salary transformation. The liability was valued at present value and amounts to 36 T€.

### (38) Shareholders' Equity

As per December 31, 2004, share capital rose by 7,317 T€ to 18,523 T€ compared with the previous year, divided into 18,522,684 no-par-value shares of which 89.4% have been floating as per closing date. The remaining 10.6% are subject to a 12 months lock-up period expiring on August 13, 2005. Each share bears a calculated portion of 1 € of the share capital.

In March 2004, MediGene carried out a three-step capital increase. At first, 1,122,835 shares at 6.80 € each were issued twice. As a third

step, MediGene offered convertible bonds in the total nominal amount of 1.5 million €, to be converted into 200,000 shares at a conversion price of 7.50 € each. The convertible bonds bear 4% interest annually during the four years to maturity. To ensure conversion rights, conditional capital is available, raised by means of shareholders' resolution.

On August 13, 2004, MediGene acquired the anti-cancer drug candidates and platform technology from the former Munich Biotech AG. During the transaction, existing investors had founded MediGene Oncology GmbH and, in addition to a cash investment, introduced Munich Biotech AG drug candidates and EndoTAG technology into the newly founded company. Afterwards MediGene AG acquired MediGene Oncology GmbH by issue of 1,960,938 new shares to the owners. This corresponds to an acquisition price of approx. 11.3 million €. MediGene Oncology GmbH is consolidated as a wholly owned subsidiary of MediGene AG.

In October 2004, MediGene closed a second capital increase. During this transaction, MediGene successfully placed 3,087,114 newly issued shares at 7.00 € each with existing shareholders of the company as well as new institutional investors.

In addition, 21,000 stock options and 1,757 convertible bonds were converted.

### Allocation of Options and Convertible Bonds

#### Contingent Capital No.

	Amount Dec. 31, 2004	Usage
I	226,366	Options
II	142,373	Options
III	125	TBG <sup>3)</sup> -Debt
IV	13,770	Convertible bonds
V	668,643	Convertible bonds
VI	3,000	Convertible bonds
VII	1,500,000	Convertible bonds
VIII	3,000	Convertible bonds
IX <sup>1)</sup>	0	–
X	3,000	Convertible bonds
XI	2,600	Convertible bonds
XII	680,000	Options
XIII <sup>2)</sup>	200,000	Convertible bonds
XIV <sup>2)</sup>	3,000,000	Convertible bonds
	<b>6,442,877</b>	

<sup>1)</sup> cancelled by shareholders' resolution of June 2, 2004

<sup>2)</sup> newly created by shareholders' resolution of June 2, 2004

<sup>3)</sup> Technologie-Beteiligungsgesellschaft

## »Directors' Holdings« and notes on company-owned shares and warrants

Members	No. of shares 2003	No. of shares 2004	No. of options 2003	No. of options 2004	No. of CB <sup>1)</sup> 2003	No. of CB <sup>1)</sup> 2004
<b>Prof Dr Ernst-Ludwig Winnacker</b> Supervisory Board Chairman, Co-founder	292,676	292,676	38,700	38,700	3,200	3,200
<b>Dr Norbert Riedel</b> Deputy Supervisory Board Chairman	2,300	3,300	5,590	5,590	0	0
<b>Dr Pol Bamelis</b> Supervisory Board Member	1,000	1,000	0	0	1,200	1,200
<b>Dr Alexandra Goll</b> Supervisory Board Member	0	0	0	0	0	0
<b>Dr Manfred Scholz</b> Supervisory Board Member	0	142,841	0	0	0	0
<b>Michael Tarnow</b> Supervisory Board Member	6,337	6,337	0	0	31,200	36,200
<b>Total Supervisory Board</b>	<b>302,313</b>	<b>446,154</b>	<b>44,290</b>	<b>44,290</b>	<b>35,600</b>	<b>40,600</b>
<b>Dr Peter Heinrich</b> Chief Executive Officer, Co-founder	503,505	503,505	56,636	76,636	0	0
<b>Dr Ulrich Delves</b> Chief Operating Officer	–	360	–	0	–	0
<b>Alexander Dexne</b> Chief Financial Officer	0	0	40,000	60,000	0	0
<b>Total Executive Board</b>	<b>503,505</b>	<b>503,865</b>	<b>96,636</b>	<b>136,636</b>	<b>0</b>	<b>0</b>
<b>Treasury stock</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

<sup>1)</sup> Convertible bonds (Status as per December 31, 2004 and December 31, 2003)

### Changes on the Executive Board

As from October 1, 2004, MediGene appointed Dr Ulrich Delves Executive Board Member for Research and Development. The physician, qualified as a university lecturer, formerly held the positions of an Executive Board member and Managing Director at Aventis Behring GmbH, Marburg, and simultaneously Senior Vice President and Chief Scientific Officer at Aventis Behring LLC, USA.

### Changes on the Supervisory Board

MediGene's annual shareholders' meeting was held on June 2, 2004. The following Supervisory Board members were elected: Prof Dr Ernst-Ludwig Winnacker, President of the German Research Foundation (Deutsche Forschungsgemeinschaft), was confirmed in his office as Chairman of the Supervisory Board. Prof Dr Norbert Riedel, Executive Board Member at Baxter International, was appointed Deputy Chairman of the Supervisory Board. Dr Manfred Scholz, Managing Director at Augs-

burg Airways GmbH & Co. KG, Augsburg, was elected new Supervisory Board member. Dr Scholz replaces Prof Dr Dr Afting who has resigned from office. Sebastian Freitag, Investment Banker, Frankfurt/Main was elected substitute member. Apart from that, the annual shareholders' meeting approved all items on the agenda by its majority.

### Supervisory Board remuneration

In 2004, Supervisory Board remuneration totalled 197 T€ (2003: 89 T€). Total Supervisory Board remuneration consists of a fixed amount in cash as well as attendance fees. Upon consideration of the Supervisory Board members' scope of activities, chairmanship as well as deputy chairmanship are incorporated. For details regarding subscription rights of board members and employees, please see item (39). No advance payments to board members have been made.

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## Supervisory Board remuneration

	Fixed Payment in T€	Payment for Participa- tion in Plenary Meetings in T€	Variable components with a long-term incen- tive (No. of convertible bonds or stock options)	Payment for individually performed services
Prof Dr Ernst-Ludwig Winnacker Chairman	40,000	15,000	15,000	0
Dr Norbert Riedel Deputy Chairman	28,000	11,250	0	0
Prof Dr Dr Ernst-Günter Afting Supervisory Board Member (until June 2, 2004)	6,000	0	0	0
Dr Pol Bamelis, Supervisory Board Member	20,000	7,500	0	0
Dr Alexandra Goll, Supervisory Board Member (from April 1, 2004)	16,000	7,500	0	0
Dr Manfred Scholz, Supervisory Board Member (from June 2, 2004)	14,000	5,000	0	0
Michael Tarnow, Supervisory Board Member	20,000	5,000	0	5,000 CB <sup>1)</sup>

<sup>1)</sup> Convertible bonds

### (39) Stock option plan

In June 2003, the annual shareholders' meeting approved the issue of 680,000 option rights to the Executive Board and employees. Of this total number, up to 240,000 may be issued to Executive Board members, 400,000 to employees, and 40,000 to members in affiliated companies at home and abroad. These stock options can be issued until June 3, 2008, and have a maturity term of ten years after issue. The options issued may be exercised in graded quantities during the maturity term, starting after a waiting period of one to three years. In 2004, 109,035 stock options were issued (2003: 131,292 stock options). The following restrictions were imposed on the issue of the remaining number of 439,673 stock options: 40,000 to Executive Board members and management of affiliated companies, 160,000 to the corporate Executive Board, and 239,673 to the employees. The exercise price per stock option is based on the higher value: either on the market price on the day of issue, or the average market price of the past 60 trading days at the German stock exchange XETRA trading system plus a 20% premium. The exercise price of the options issued in 2004 is 7.69 €, compared to 4.60 € in 2003.

As per December 31, 2004, the total number of shares outstanding was 18,522,684, and the number of fully diluted shares was 19,459,231. The changes in shareholders' equity are listed in »Consolidated Changes in Shareholders' Equity«.

### Stock option plan

in T€	2004	2003	Change	Change
Expenses for stock options according APB No. 25	0	0	0	0
Expenses for convertible bonds	3	35	-32	-91%
	3	35	-32	-91%

In July 1997 and 1999, the company's annual shareholders' meeting decided upon stock option plans. As a result, stock options were granted to the employees, and to the members of the Executive, Supervisory, and Scientific Advisory Boards. The number of options is limited to 593,056. Among other things, the number of stock options offered depends on the individual duration of employment, and the position held within the company. The options have a maturity term of ten years after the date of granting. They may be exercised at any time during the maturity term, starting after a waiting period of six months (options from 1997 and 1998), or two years (options from 1999 and 2000) after granting. The option holders are entitled to exercise their option right during maturity term, purchasing new shares of the company against payment of an exercise price per share. During the years 1997 until 2004, the following options were issued and/or exercised:

## Stock options

in T€	Employees, Executive Board and Supervisory Board	Scientific Advisory Board	Total
Options issued in 1997	256,452	24,080	280,532
Options issued in 1998	51,600	17,200	68,800
Options issued in 1999	139,879	22,360	162,239
Options issued in 2000	78,690	0	78,690
Options issued in 2003	131,292	0	131,292
Options issued in 2004	109,035	0	109,035
<b>Total options issued</b>	<b>766,948</b>	<b>63,640</b>	<b>830,588</b>
Options converted into shares in 2000	100,465	0	100,465
<i>of which under the 1997 stock option plan</i>	<i>100,465</i>	<i>0</i>	<i>100,465</i>
<i>of which under the 1999 stock option plan</i>	<i>0</i>	<i>0</i>	<i>0</i>
Options converted into shares in 2001	92,704	2,580	95,284
<i>of which under the 1997 stock option plan</i>	<i>85,046</i>	<i>2,580</i>	<i>87,626</i>
<i>of which under the 1999 stock option plan</i>	<i>7,658</i>	<i>0</i>	<i>7,658</i>
Options converted into shares in 2002	7,568	0	7,568
<i>of which under the 1997 stock option plan</i>	<i>860</i>	<i>0</i>	<i>860</i>
<i>of which under the 1999 stock option plan</i>	<i>6,708</i>	<i>0</i>	<i>6,708</i>
Options converted into shares in 2003	0	0	0
Options converted into shares in 2004	21,000	0	21,000
<i>of which under the 1997 stock option plan</i>	<i>21,000</i>	<i>0</i>	<i>21,000</i>
<b>Total options converted</b>	<b>221,737</b>	<b>2,580</b>	<b>224,317</b>
Withdrawn options rendered invalid 2001	731	0	731
Withdrawn options rendered invalid 2002	1,161	0	1,161
<b>Total remaining convertible options as at Dec. 31, 2004</b>	<b>543,319</b>	<b>61,060</b>	<b>604,379</b>

The exercise price for the options issued in 1997 and 1998 is 2.93 € each, and for those issued in 1999 and 2000, it is 6.48 € each. The company applies Accounting Principles Board Opinion No. 25, »Accounting for Stock Issued to Employees«. This stipulates that no personnel expenses are to be recognized for options issued to employees as well as members of the Executive and Supervisory Boards up to December 31, 1999. In 2001, expenses totaled 138 T€ (2000: 138 T€), based on a fair value of 10 € per option. The value of options issued to Scientific Advisory Board members is recognized as expense at the date of granting.

In case the company had accounted in accordance with SFAS No. 123, »Accounting for Stock Based Compensation«, stipulating that the company include the value of the options into the balance sheet at the time of granting at their fair value, pro forma personnel expenses of 268 T€ would have accrued in 2004.

### Net loss

in T€	2004	2003
As reported	12,306	31,060
Pro forma personnel expenses according SFAS No. 123	268	53
Pro forma net loss	12,574	31,113
<b>Pro forma net loss per share in €</b>	<b>0,90</b>	<b>2,78</b>

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The value of stock options is determined applying the Black Scholes Option Pricing Method. The following assumptions were made for calculation:

Risk-free interest rate	5.65%
Expected volatility	106% in 2003, and 81% in 2004
Expected dividend	0.0

### (40) Convertible bonds

In June 2004, the company's annual shareholders' meeting decided to revoke the shareholders' resolution of May 22, 2002 regarding the creation of conditional capital for the issue of conversion rights to Executive Board members and management bodies of subordinated affiliated companies at home and abroad, as well as the management and employees of the group and subordinated companies. At the same time, conditional capital was authorized, and the Executive Board was authorized to issue convertible bonds. Since the authorization of May 15, 2000/May 23, 2001 will expire on May 15, 2005, and, due to the acceptance of the stock option plan launched in 2003, the demand for convertible bonds as an instrument of employees' stock ownership has changed, the authorization dated May 22, 2002, of which up to then nobody had made any use, was revoked and replaced by another authorization adapted to the changed requirements. The Executive Board was authorized to issue up to 200,000 bonds with conversion rights (convertible bonds) with a maximum maturity term of five years and at a nominal value of 1 € each, once, several times or – in case of expiration of rights granted due to termination or other reasons – repeatedly up until June 1, 2009, to members of the management, employees and consultants of the company and subordinated affiliated companies at home and abroad (optionees). The total nominal value of the bonds must not exceed 200 T€. Thereby members of the management and employees may receive bonds at a maximum nominal value of 100 T€, and consultants may receive bonds at a maximum nominal value of 100 T€. Each convertible bond entitles the holder to conversion into a registered, no-par-value common (individual) share of the company, under observance of the following regulations. The convertible bonds are issued at nominal value. Any subscription right of shareholders to convertible bonds is barred. The companies may issue convertible bonds in one or more tranches during the period from February 1 until November 30 of each year for which the authorization was granted.

In compliance with Accounting Principles Board Opinion No. 25, »Accounting for Stock Issued to Employees«, the difference between the higher fair value (in July 2000 64.90 €; in September 2000 106.50 €) and the total conversion price (2000: 50.40 €) is posted as expenses during the waiting period. Total expenses amounted to 44T€ in 2004 and to 35 T€ in 2003.

### Convertible bonds issued in 2004

	No.	Fair value	Conversion price
February	18,277	*	7.69 €
February	25,000	*	8.08 €
March	200,000**	*	7.50 €
	<b>243,277</b>		

\* Fair value below conversion price

\*\* In March 2004, MediGene issued convertible bonds bearing 4% interest annually, with a maturity term of four years and an obligation to conversion upon demand by the company, at a total nominal value of 1,500,000, divided into 1,500,00 convertible bonds at a nominal value of 1.00 € each. At the end of the maturity term, the convertible bonds are automatically converted into MediGene shares at the ratio of 7.5 : 1 if the MediGene share price equals or exceeds the conversion price on the trading day before the end of maturity term. As from April 15, 2005, MediGene is entitled to demand premature conversion if the MediGene share price equals or exceeds the conversion price on the trading day before the conversion date. In case of conversion, the holder of the bonds is entitled to receive the interest accruing up to the end of the day preceding the day of exercise of conversion rights. In addition, the holders of the convertible bonds are entitled to convert their convertible bonds into MediGene shares at the ratio of 7.5 : 1 as per April 15, 2005 for the first time, and then as per June 30 and December 15. Fractional amounts are reimbursed in cash. No extra payments upon conversion are to be made.

### Convertible bonds issued in 2003

	No.	Fair value	Conversion price
February	33,553	*	4.83 €
June	3,000	*	4.97 €
July	10,720	*	3.80 €
	<b>47,273</b>		

\* Fair value below conversion price



### Convertible bonds issued in 2002

	No.	Fair value	Conversion price
February	102,140	*	26.40 €
May/June	3,000	*	9.90 €
July	90,156	*	11.72 €
	<b>195,296</b>		

\* Fair value below conversion price

### Convertible bonds issued in 2001

	No.	Fair value	Conversion price
January	540	*	64.16 €
June	3,000	*	24.57 €
June/July	156,065	*	31.63 €
	<b>159,605</b>		

\* Fair value below conversion price

### Convertible bonds issued in 2000

	No.	Fair value	Conversion price
July	3,000	64.90 €	50.40 €
September	9,630	106.50 €	50.40 €
	<b>12,630</b>		

Within the stock ownership plans decided, a total of 658,081 convertible bonds have been issued up to now. The number of convertible bonds called in and returned amounted to 324,156 up to 2004. 1,757 convertible bonds were converted into shares. Thus the number of valid convertible bonds issued rose to 332,168 as per December 31, 2004 (2003: 107,523).

### (41) Accumulated other comprehensive income

in T€	2004
Unrealized gain from market valuation of QLT shares	-8
Currency translation	-995
<b>Total as at Dec. 31, 2004</b>	<b>-1,003</b>

## I) Notes on the consolidated cash flow statements

The cash flow statements show origin and use of the cash flows in the financial years 2004 and 2003. Therefore they have a pivotal significance for the assessment of the company's financial condition.

Cash flow from investing as well as cash flow from financing activities are determined based on payments and receipts, whereas cash flow from operating activities is indirectly derived from the annual net loss.

Within the non-cash financing activities, finance lease obligations for laboratory and office equipment totalled 325 T€ (2003: 127 T€).

In 2003, proceeds from minority interest for the establishment of LARNAX GmbH were posted.

Under repayments/proceeds from loans, the repayments for a loan granted by Aventis within a research and development partnership are posted.

Cash and cash equivalents at the end of the period comprise cash on hand, as well as credit balances with banks, and checks with an original maturity of < 3 months. In this respect the amount equals the corresponding balance sheet item. As per December 2004, this amount posted was subject to a restraint on disposal as a consequence of a rental guaranty amounting to 206 T€, fully allocated to the Martinsried headquarters.

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## J) Segment reporting

According to SFAS 131, »Disclosure about Segments of an Enterprise and Related Information«, segment reporting has to comply with the company's in-house organizational and reporting structure.

As a consequence of the reorganization measures implemented in 2003, and the acquisition of the product candidates from Munich Biotech AG, the composition of the company's product portfolio has changed significantly. Therefore segment reporting has been adjusted, in contrast to the previous year under review: The HPV indications and oncology segments have been replaced by the special pharmaceutical products (»Specialty pharma«) and biopharmaceutical products (»Biopharma«) segments. The specialty pharma segment includes the drug Eligard® and the drug candidate Polyphenon® E Ointment; in the biopharma products segment, MediGene's EndoTAG and the oncolytic herpes simplex virus (HSV) technologies are reported, as well as the drug candidates emerging from these technologies, that is EndoTAG-1, NV1020 and G207.

### Specialty pharma products:

Drugs/drug candidates:

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

### Biopharma products: EndoTAG technology, HSV technology

Drug candidates:

- EndoTAG-1 for the treatment of solid tumors (since August 2004)
- rAAV vaccine for the treatment of malignant melanoma (until August 2004)
- NV1020 for the treatment of liver metastases
- G207 for the treatment of brain tumors (put on hold in August 2003)

## Segment reporting by market segments

in T€	Specialty pharma	Biopharma	Inter-segment	Total
<b>2004</b>				
Total revenues	12,694	226	218	13,138
Cost of goods sold	5,930	0	0	5,930
Gross profit	6,764	226	218	7,208
Selling expenses	152	0	1,002	1,154
General and administrative expenses	0	0	4,591	4,591
R&D expenses	6,680	7,994	27	14,701
Depreciation	119	806	208	1,133
Loss from continued operations	187	8,574	5,610	14,371
Investments <sup>1)</sup>	2	545	58	605
Employees ø	17	58	30	105
<b>2003</b>				
Total revenues	31	1,616	95	1,742
Cost of goods sold	0	0	0	0
Gross profit	31	1,616	95	1,742
Selling expenses	200	0	1,248	1,448
General and administrative expenses	0	0	6,478	6,478
R&D expenses	9,721	11,826	278	21,825
Depreciation	19	764	248	1,031
Loss from continued operations	9,908	10,974	8,157	29,040
Investments <sup>1)</sup>	1	40	194	235
Employees ø	14	79	40	133

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

Intersegment income in 2004 mainly consists of government grants by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF). There are no in-house charges resulting from services of a regular or scheduled nature between market segments or regions. Therefore no details on these charges are available.

### Segment reporting by regions

The company's business operations take place in Germany and in the USA. Segment reporting by regions comprise only continued operations. Discontinued operations were based exclusively in Germany.

### Segment reporting by regions

in T€	Germany 2004	USA 2004	Germany 2003	USA 2003
Total revenues	13,131	7	1,718	24
Cost of sales	5,930	0		
R&D expenses	12,306	2,369	16,325	5,500
Depreciation	1,018	114	626	405
EBIT	-11,349	-2,995	-20,831	-8,209
Investments <sup>1)</sup>	603	2	207	28
Cash flow from operating activities	11,274	3,239	19,571	6,973
Assets	72,696	198	37,555	812
Liabilities	10,862	349	8,033	1,114
Employees ø	93	12	98	35

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

## K) Other notes

### (42) Cooperation agreements

#### Aventis/rAAV tumor vaccine

MediGene and Aventis discontinued their partnership for the development of a tumor vaccine for the treatment of malignant melanoma. Under the terms of this partnership, a clinical phase I/IIa trial in the indication malignant melanoma was conducted in some selected European countries. In the opinion of both companies, however, this initial trial did not yield results that would justify further development. In particular the production of the specific vaccine for each individual patient turned out to be very difficult. In 2000, MediGene had received a loan in order to cover the expenses accruing within the joint project. As per closing date July 31, 2004, this loan amounted to 3,312 T€. MediGene is committed to repayment of the loan in twelve equal monthly installments, starting in August 2004.

#### Yamanouchi Ltd.

On January 12, 2004, the company closed a cooperation, sublicense and supply contract with the pharmaceuticals group Yamanouchi for pan-European commercialization of Eligard®. The company granted Yamanouchi a sublicense for the sale of four formulations of Eligard®, including the right to further sublicenses. Yamanouchi is the second largest pharmaceuticals company in Europe in the field of urology. In May 2004, Yamanouchi launched the one-month and three-months sustained release products of Eligard® for the treatment of prostate cancer on the German market. Under the terms of the agreement, MediGene receives successive milestone payments totalling up to 21.5 million €, including a signing fee of 4 million €, as well as royalties on sales of Eligard®.

### (43) Legal disputes

Prior to the launch of Eligard®, MediGene had already filed a suit for invalidity of a patent on defined, high-molecular, biodegradable polymers of their competitors Takeda Chemical Industries, Ltd., and Wako Pure Chemical Industries, Ltd, before the Federal Patent Tribunal. In summer 2004, after the launch of Eligard®, Takeda Chemical Industries, Takeda Pharma GmbH, and Wako Pure Chemical Industries (Takeda/Wako) have sued the partners MediGene and Yamanouchi Pharma GmbH for alleged patent infringement before the Düsseldorf district court. In this suit they argue that the commercialization of MediGene's and Yamanouchi's drug Eligard® infringes the above mentioned plaintiffs' patent. The company expects a decision in this matter in 2005. Action for an injunction in this matter was already dismissed by the Hamburg district court. Based on their assessment of the known facts, both MediGene and Yamanouchi are convinced that the commercialization of Eligard® does not represent a patent infringement, and for this reason they do not expect any legal restrictions on the sale of Eligard® in Germany and in Europe. In parallel, patent infringement proceedings are ongoing in the USA between Takeda Abbot Pharmaceutical Inc., Takeda Chemical Industries, Ltd., and Wako Pure Chemical Industries, Ltd. as litigators, and MediGene's supplier and licensor, QLT Inc., as well as their US marketing partner, Sanofi-Synthelabo, Inc. as respondents.

In May 2003, the company has opposed European patent no. EP 0 814 823 B1 of Indena S.p.A., Milan, which covers specific polyphenol fractions in tea, in order to eliminate any legal uncertainties. Thereupon Indena S.p.A. restricted the patent to a scope which is of no significance for MediGene.

With the exception of the litigations mentioned, no legal disputes that might have a significant influence on the economic situation of the company or its subsidiaries have been pending during the past three financial years, nor are currently imminent.

## Consolidated financial statements

### (44) Contingencies and other financial obligations

As per balance sheet date, a rental guarantee of 206 T€ existed.

No contingencies for the benefit of board members were assumed.

Within the framework of the acquisition of the assets from the former Munich Biotech AG, MediGene has committed itself to make milestone payments to the receiver, depending on clinical achievements with EndoTAG-1. These payments will become due with clinical phase III and amount to a total of 9.5 million €.

Future minimum payments for capitalized leased items and future annual minimum lease payments for operational leasing are as follows:

in T€	Capital lease	Operating lease
2005	287	1,126
2006	118	938
2007	0	823
2008	0	798
Thereafter	0	778
Minimum leasing obligations	405	4,463
Less interest	-21	
Capital lease obligation	384	
Short-term obligations	269	
Long-term obligation	115	

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

No other open credit lines existed as per December 31, 2004, in addition to cash and cash equivalents reported under (30).

### (46) Financial instruments

SFAS No. 107, »Disclosure of the Fair Value of Financial Instruments«, requires the disclosure of fair value of financial instruments, irrespective of whether it is reflected on the balance sheet. The book value of financial instruments such as cash and cash equivalents, accounts receivable and payable, and accruals corresponds approximately to their fair value, due to their short-term maturities. At present, MediGene's financial instruments consist exclusively of these actual financial instruments. Their book value corresponds to their fair value.

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

After year-end closing date, no major events that might affect the company's business or financial situation have occurred.

### (48) Major concentration of risks

MediGene's sales revenues are generated mainly by the commercialization of Eligard® by the company's partner Yamanouchi.

### (49) German Corporate Governance Code

In December 2004, MediGene's Executive and Supervisory Boards confirmed that the company complies with most recommendations of the German Corporate Governance Code, version of May 21, 2003. Those recommendations not implemented by MediGene AG are listed in the Declaration of Compliance according to § 161 German Stock Corporation Act. This declaration is permanently accessible in German and in English at the company's website [http://www.medigene.com/englisch/corporate\\_governance.php](http://www.medigene.com/englisch/corporate_governance.php)

## **(50) Members of the Executive and Supervisory Boards**

### **Executive Board**

**Dr Peter Heinrich**  
Chief Executive Officer

**Dr Ulrich Delvos, MD PhD**  
since October 1, 2004  
Executive Board Member for Research and Development

**Alexander Dexne**  
Chief Financial Officer

### **Supervisory Board**

**Prof Dr Ernst-Ludwig Winnacker**  
since November 26, 1996  
Chairman  
President of the German Research Foundation

**Prof Dr Norbert Riedel**  
since October 27, 2003  
Deputy Chairman  
Corporate Vice President, Chief Scientific Officer, Baxter International, Inc., Glendale, CA, USA

**Prof Dr Dr Ernst-Günter Afting**  
from November 26, 1996 until June 2, 2004  
Director GSF-Forschungszentrum für Umwelt und Gesellschaft  
(National Research Center for Environment and Health)

**Dr Pol Bamelis**  
since May 23, 2001  
former Executive Board member at Bayer AG, Knokke, Belgium

**Dr Alexandra Goll**  
since April 1, 2004  
General Partner Techno Venture Management GmbH, Germany

**Dr Manfred Scholz**  
since June 2, 2004  
Managing Director of Augsburg Airways GmbH & Co. KG, Germany

**Michael Tarnow**  
since May 23, 2001  
Consultant, Boston, MA, USA

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

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

- Bayer AG, Germany
- KWS Saat AG, Germany

### **Prof Dr Norbert Riedel**

- Genencor International Inc., USA
- Oscient Pharmaceuticals Inc., USA

### **Dr Pol Bamelis**

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

### **Dr Alexandra Goll**

- Addex Pharmaceuticals SA, Switzerland
- Axxima Pharmaceuticals AG, Germany
- Biovertis AG, Austria
- Pharmasset Ltd., USA
- Arrow Therapeutics Ltd., UK

### **Dr Manfred Scholz**

- ASSTEL Lebensversicherung, Germany
- Citigroup Global Markets Deutschland AG & Co KGaA, Germany
- Gothaer Finanzholding, Cologne
- Pfeleiderer AG, Germany
- Württembergische Hypothekenbank AG, Germany

### **Michael Tarnow**

- AXCAN Pharma Inc., Canada
- Caprion Pharmaceuticals Inc., Canada
- Ferghana LLC, USA
- Nanopharma Inc., USA
- Entremed, USA
- Xenon Genetics Inc., Canada

# Income statements in accordance with HGB

MediGene AG individual financial statements for the periods from January 1 to December 31, 2004 and 2003

in T€	2004	2003
1. Revenues	14,709	0
2. Other operating income	2,080	2,228
	<b>16,790</b>	<b>2,228</b>
3. Cost of materials		
a) Cost of raw, auxiliary, operating materials and cost of goods	6,316	756
b) Cost of services bought	8,211	10,351
	<b>14,528</b>	<b>11,107</b>
<b>4. Gross profit</b>	<b>2,262</b>	<b>-8,879</b>
5. Personnel expenses		
a) Wages and salaries	5,888	6,268
b) Social insurance contributions and expenditures for retirement benefits thereof for retirements: 81 T€ (2003: 107 T€)	1,014	1,112
	<b>6,902</b>	<b>7,380</b>
6. Depreciation of intangible and tangible assets	613	415
7. Other operating expenses	8,183	6,069
<b>8. Operating loss</b>	<b>-13,436</b>	<b>-22,743</b>
9. Other interest and related costs	613	785
10. Depreciation of financial assets	-19	-601
11. Interest and related expenses	-46	-32
<b>12. Result from ordinary operations</b>	<b>-12,888</b>	<b>-22,591</b>
<b>13. Net loss for the year</b>	<b>-12,888</b>	<b>-22,591</b>
14. Net loss carried forward	-90,837	-68,246
<b>15. Accumulated deficit</b>	<b>-103,724</b>	<b>-90,837</b>

Totals may vary due to rounding.



# Balance Sheet in accordance with HGB

MediGene AG individual financial statements as of December 31, 2004 and December 31, 2003

Assets in T€	2004	2003
<b>A. Fixed assets</b>		
I. Intangible assets		
Software	35	12
II. Tangible assets		
Plant and equipment	897	715
Prepaid/in construction	0	389
III. Financial assets		
1. Investments in related parties	102,156	90,862
2. Securities	2,770	3,698
	<b>105,859</b>	<b>95,676</b>
<b>B. Current assets</b>		
I. Receivables and other assets		
Other assets thereof with a term > 1 year: 36 T€ (2003: 35 T€)	3,665	507
II. Cash and cash equivalents	42,978	21,287
	<b>46,644</b>	<b>21,794</b>
<b>C. Accrued and deferred items</b>	175	238
<b>Total assets</b>	<b>152,678</b>	<b>117,708</b>

Liabilities and shareholders' equity in T€	2004	2003
<b>A. Shareholders' equity</b>		
I. Share capital	18,523	11,206
II. Additional paid-in capital	230,668	189,857
III. Accumulated deficit	-103,724	-90,837
	<b>145,467</b>	<b>110,226</b>
<b>B. Accruals</b>		
I. 1. Pension accrual	36	35
2. Other accruals	2,557	2,059
	<b>2,593</b>	<b>2,094</b>
<b>C. Liabilities</b>		
1. Loan thereof convertible: 1,632 T€ (2003: 108 T€)	1,632	108
2. Trade liabilities thereof with a term < 1 year: 545 T€ (2003: 1,590 T€)	545	1,590
3. Related parties liabilities thereof with a term < 1 year: 0 T€ (2003: 221 T€)	0	221
4. Other liabilities thereof with a term < 1 year: 2,441 T€ (2003: 3,469 T€) thereof social insurance: 133 T€ (2003: 120 T€) thereof taxes: 140 T€ (2003: 124 T€)	2,441	3,469
	<b>4,618</b>	<b>5,387</b>
<b>Total liabilities and shareholders' equity</b>	<b>152,678</b>	<b>117,708</b>

Totals may vary due to rounding.

# Report of the Supervisory Board

In fiscal year 2004, 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 five meetings (March 5, 2004, March 12, 2004, June 2, 2004, August 3, 2004 and December 13, 2004), and 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 projects, the focus of discussion was on approval and marketing of the drug Eligard® for the treatment of prostate cancer, the conduct of capital increases, as well as the acquisition of new tech-

nologies and development projects. In addition, the Supervisory Board requested and received comprehensive reports about the budget for 2005, 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 2004, 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.

Until the new election of the supervisory board members by the annual general meeting on June 2, 2004 there also existed a Committee responsible for the approval of Executive Board business that required approval.

## **Corporate Governance**

In 2004, the Supervisory Board also dealt with MediGene's fulfillment of the recommendations of the German Corporate Governance Codex. In October 2004, 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.

#### **Election of the Supervisory Board**

On June 02, 2004, the Annual General meeting elected Dr. Pol Bamelis, Dr. Alexandra Goll, Prof. Norbert Riedel, Michael Tarnow, Dr. Manfred Scholz and Prof. Dr. Ernst-Ludwig Winnacker as members of the Supervisory Board until the end of the Shareholders' Meeting which resolves on the approval of the performance of the duties for the second fiscal year following the beginning of the term of office; the fiscal year, in which the term of office begins, not counting. Sebastian Freitag, investment banker, Frankfurt am Main was elected as supplementary member.

#### **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 2004, and the MD&As of MediGene AG and the group, and granted them the unqualified audit certificate. The Consolidated Financial Statements in accordance with US-GAAP were supplemented by a Consolidated MD&A and other explanatory notes in accordance with § 292a HGB. These US-GAAP Consolidated Financial Statements exempt the company from submitting a report based on German law.

The balance sheet and income statements were discussed in full detail during the balance sheet meeting of the Supervisory Board held

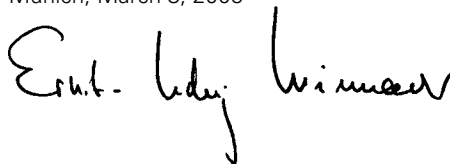
on February 25, 2005. The auditor participated in the balance sheet meeting, reporting on the most important results of his audit, and answered queries.

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.

By resolution on March 4, 2005, 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 2004, 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 2004.

Munich, March 8, 2005



Prof Ernst-Ludwig Winnacker  
Supervisory Board Chairman

# Glossary

**Actinic keratosis**

Precursor of malignant spinocellular carcinoma

**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 pipeline**

All drug candidates in development

**EBIT**

Earnings before interest and taxes

**EBITDA**

Earnings before interest, taxes, depreciation and amortization

**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

**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

**Placebo**

Drug dummy, pharmacologically ineffective

**Prostate cancer**

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

**Randomization**

Random administration of drug

**R&D**

Research and development

**Recombinant**

Genetically modified

**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

# Multi-year overview

## MediGene Group, US-GAAP

in T€	2004	2003	2002	2001*	2000	1999	1998	Change 2004-2003
<b>Income statements</b>								
Product sales	12,501	0	0	0	0	0	174	–
Other operating income	637	1,742	3,425	7,264	6,081	5,544	1,707	-63%
Research and development expenses (R&D)	14,701	21,825	26,721	21,696	11,213	6,598	3,066	-33%
Selling and general administration expenses	5,745	7,926	7,177	5,736	2,528	1,439	876	-28%
Amortization of goodwill	0	0	0	1,845	0	0	0	0%
Depreciation	1,133	1,031	1,085	768	323	216	123	10%
Operating result	-14,371	-29,040	-31,558	-22,782	-7,982	-2,709	-2,184	51%
Write-off »IPR&D«	0	0	0	86,543	0	0	0	0%
Result before income tax	-12,305	-28,333	-30,231	-104,583	-6,905	-2,861	-2,246	57%
Net result	-12,306	-31,060	-38,870	-110,490	-9,264	-3,745	-2,853	60%
Personnel expenses	8,383	10,973	11,245	7,938	4,089	2,316	1,393	-24%
<b>Balance sheet data</b>								
Balance sheet total	72,894	38,367	67,079	108,383	127,790	21,268	18,674	90%
Shareholders' equity	61,683	29,220	59,435	100,406	118,793	9,360	13,284	111%
Cash and securities	48,460	21,444	47,762	86,843	115,226	18,059	17,261	126%
Cash and cash equivalents	48,460	21,444	47,762	80,843	92,903	10,149	17,261	126%
Long-term liabilities	1,909	285	2,993	2,402	1,362	5,984	4,278	> 200%
Equity ratio	85%	76%	89%	93%	93%	44%	71%	11%
<b>Cash flow</b>								
Cash flow from operating activities	-12,097	-26,544	-38,635	-22,015	-6,560	-2,977	-1,990	-54%
Cash flow from investing activities	4,785	-12	5,296	9,031	-21,494	-8,412	-615	> 200%
Cash flow from financing activities	34,342	267	312	930	110,807	4,278	17,265	> 200%
<b>Employees as at December 31</b>								
	117	124	185	160	90	50	35	4%
<b>MediGene share</b>								
Shares outstanding as at December 31	18,522,684	11,206,205	11,206,205	11,198,637	10,106,722	6,728,124	6,728,124	65%
Weighted average number of shares	13,996,440	11,206,205	11,204,990	11,003,245	8,417,423	6,728,124	4,936,701	25%
Net loss per share from continued operations in €	0.88	2.53	2.70	10.04	1.10	0.56	0.58	-65%
Net loss per share adjusted for write-off »IPR&D« in €	0.88	2.77	3.47	2.18	1.10	0.56	0.58	-68%
Share price at the end of the year in €	8.5	5.9	4.0	21.2	73.5	–	–	44%
Dividend in €	0	0	0	0	0	0	0	–

\* Consolidation of MediGene, Inc. from March 1, 2001



## Financial calendar

### **March, 23**

Annual report 2004  
Press and analysts conference

### **May, 4**

3-months report  
Press and analysts phone conference call

### **June, 10**

Annual shareholders' meeting

### **August, 3**

6-months report  
Press and analysts phone conference call

### **November, 2**

9-months report  
Press and analysts phone conference call

## **2006**

### **March, 22**

Annual report 2005  
Press and analysts conference

. . . we are looking forward to speaking with you

## Imprint

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