Annual report 2003

A leading German biotech company

First drug approved and on the verge of market launch

Novel cancer drug candidates

Reaching the Market

MediGene

Comprehensive product pipeline

Products	Diseases	Pre-clinical	Clinical phases 1	2	3	Approval	Max. sales[1] (million €)
Eligard®	Prostate cancer						> 50[2]
Polyphenon® E Ointment	Genital tumors						> 100
	Actinic keratosis[3]						> 200
	Basal cell carcinoma						> 50
Oncolytic HSV	Liver metastases		[4]				> 200
	Brain tumors (Glioblastom)		[5]				> 300
	Prostate cancer						> 500
	Hepatocellular carcinoma						
rAAV tumor vaccine	Malignant melanoma						> 200[6]
Chance of reaching the market		0 – 10%	10 – 30%	40 – 60%	60 – 80%	90%	

[1] Per year, peak sales. MediGene will receive royalties from sales of products, which are jointly developed or marketed with biotech or pharmaceuticals companies.

[2] Marketing partnership with Yamanouchi
[3] Precursors of a specific kind of skin cancer
[4] Phase 1/2 in preparation
[5] Project plan under review
[6] Development partnership with Aventis

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Key figures

MediGene Group, US-GAAP

in T€	2002	2003	Change
Income statements[1)]			
Other operating income	3,425	1,742	-49%
Research and development expenses (R&D)	26,721	21,825	-18%
Business development and general administration expenses	7,177	7,926	10%
EBITDA	-30,473	-28,009	8%
Depreciation	1,085	1,031	-5%
EBIT	-31,558	-29,040	8%
Result before income tax	-30,231	-28,333	6%
Net loss from continued operations	-30,231	-28,333	6%
Net loss[2)]	-38,870	-31,060	20%
Personnel expenses	11,245	10,973	-2%
Balance sheet data			
Balance sheet total	67,079	38,367	-43%
Shareholders' equity	59,435	29,220	-51%
Cash and securities	47,762	21,444	-55%
Cash and cash equivalents	47,762	21,444	-55%
Long-term liabilities	2,993	285	-90%
Equity ratio	89%	76%	-14%
Cash flow			
Cash flow from operating activities	-38,635	-26,544	31%
Cash flow from investing activities	5,296	-12	-100%
Cash flow from financing activities	312	267	-14%
Employees as at Dec. 31 from continued operations	**157**	**112**	**-29%**
MediGene share			
Shares outstanding as at Dec. 31 in €	11,206,205	11,206,205	0%
Weighted average number of shares in €	11,204,990	11,206,205	0%
Net loss per share from continued operations in €	-2.70	-2.53	6%
Net loss per share in €	-3.47	-2.77	20%
Shareprice at the end of the year in €	4.0	5.9	49%
Dividend in €	0	0	–

[1)] From continued operations (discontinued operations see p. 85)
[2)] Including discontinued operations (see p. 85)

2003 at a glance

January
- MediGene reaches a settlement in its legal dispute with Loyola University and MedImmune.

March
- MediGene and Schering halt development of the CVLP tumor vaccine.
- Spin-off of MediGene's cardiology unit.

April
- The U.S. Patent and Trademark Office grants MediGene a further patent for its rAAV technology.

May
- MediGene successfully completes patient admission for the European part of its phase 3 trials of Polyphenon® E Ointment six weeks ahead of schedule.

June
- MediGene relocates the entire research unit of its U.S. subsidiary MediGene, Inc. to Germany.

August
- MediGene halts phase 1/2 trial of G207. Further project plan is under review.

September
- Chief Research and Development Officer Dr Johanna Holldack leaves MediGene AG. Dr K. Jon Kowal takes over the duties of Dr Holldack as new Senior Vice President for Research & Development.
- MediGene acquires patents for the Polyphenon® E Ointment for application in further indications.

October
- MediGene acquires further patents for the drug candidates NV1020 and G207, as well as for the HSV technology.

November
- The U.S. Patent and Trademark Office grants MediGene a core patent for the manufacture of therapeutic viruses.

December
- The German Federal Institute for Pharmaceuticals and Medical Products (German acronym: BfArM) grants MediGene German market approval for the one-month dosage of the cancer drug Eligard® (former name Leuprogel®).

January 2004
- MediGene and Yamanouchi conclude a marketing and development partnership for Eligard®.
- MediGene receives German market approval for the three-months dosage of Eligard®.

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

MediGene is the first German biotech company with an approved drug on the verge of market launch. 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 partnerships will help us to finance the development of additional therapeutics and to reach break-even.

MediGene – a leading German biopharmaceuticals company.

Dear Shareholders, Ladies and Gentlemen,

»Peter Heinrich has a reason to smile again,« the German business weekly Wirtschaftwoche wrote in December 2003 on the occasion of the first marketing authorization of one of MediGene's drugs. This comment was certainly meant less to illuminate my personal frame of mind as Chief Executive Officer than to describe the situation at MediGene AG. After a difficult year characterized by deep cuts and restructuring, as well as by a low market value for MediGene shares, things were turning positive by the end of 2003.

MediGene became Germany's first biotech company to obtain approval for one of its drugs, in MediGene's case Eligard® (earlier known under the name Leuprogel®) to fight prostate cancer. Moreover, MediGene is now one of the few European biotech companies to carry out large-scale phase 3 trials for another drug, the final step in clinical drug development. The signing of a marketing agreement in January 2004 has also made MediGene the first company in the German biotechnology industry to initiate the market launch of one of its drugs.

Our company also made progress in other decisive fields in 2003: We concentrated on the most promising projects with the greatest value-added component and parted company with projects and sectors with fewer prospects for success. Restructuring has made our company leaner and increased our financial room for maneuver. We were able to cut our losses for the year by 20% in comparison to the preceding year and still reach most of the financial goals we had set for ourselves at the beginning of the year.

You had to wait longer for some of these steps, in particular the marketing partnership for Eligard®, than I had told you at the beginning of the year. This had a negative impact on the price of MediGene shares. Still, in the final analysis, we were



able to reach the basic goals we had announced during the year. And this has been reflected in the price of MediGene shares, which went up by almost 50% in the course of the last fiscal year.

The MediGene AG you see today is a new and stronger company than that you knew one or two years ago. We positioned ourselves more clearly in 2003, specializing in the development of tumor drugs. We are now more concentrated: by focusing on fewer, but more valuable and feasible drug development projects. And we have reached a new stage in our development as a company: from being a mere drug developer towards being a company with an approved product on the market. We have indeed reached the market, and thus almost completely realized our strategy of covering all process steps in a biopharmaceutical company, from research to development and finally marketing of drugs.

It has not been an easy road, and one fraught with painful cuts in fiscal 2003. By spinning off our cardiology unit and bundling all our laboratory activities at our German location, MediGene cut almost 40% of its workforce, while still being able to strengthen its German location at the same time. We have also discontinued or put on hold two of our drug development projects: The development of the tumor vaccine CVLP was discontinued after the initial clinical development phase because the active agent did not meet the demanding criteria placed on a competitive product. We also halted the development of the drug candidate G207 during the clinical phase 1/2 for financial reasons to ease the strain on our company's resources.

These steps were necessary to turn MediGene into the company it is today, a lean, clearly focused company with an appropriate and financially viable number of value-added projects. Our product portfolio – also known as our drug pipeline – is attractive in many different ways. It is far advanced in development, includes highly innovative drug candidates, and holds opportunities for expanding the range of medical indications, i.e. for the treatment of other diseases. I would like to cite two examples of this: MediGene's NV1020 agent is a virus we have genetically modified to treat colorectal liver metastases. Should NV1020 be successfully developed to marketability, MediGene could perhaps become the first company to succeed in developing a genetically modified virus as a drug. This would be an outstanding innovation with a potential not yet foreseeable. And should the mode of action of a therapeutic virus be verified, it would be highly probable that NV1020 might also be suited for the treatment of other forms of cancer. The value of this drug would then multiply by leaps and bounds. Also our Polyphenon® E Ointment for the treatment of benign genital warts which we are presently developing, could under certain circumstances be further developed as a form of therapy for other tumor-related conditions in the dermatology field. To examine this, however, further testing and trials, starting on a pre-clinical level will be necessary.

In fiscal year 2004, we still have a number of important steps ahead of us. Our marketing partner Yamanouchi, one of the top companies in the European urology market, will launch our first drug Eligard® on the German market and thus provide regular revenues. MediGene will support Yamanouchi in the further approval process for Eligard® in other European countries. At the same time, we will also continue to push the development of our other drug candidates. In doing so, we will put special emphasis on starting the clinical phase 2 trial of the NV1020 agent, and on a successful conclusion of the phase 3 trials of our Polyphenon® E Ointment.

Our financial goals for the fiscal year are ambitious. We are planning to cut our loss by more than 50% to around 15 million € in 2004. By lowering our cash burn rate far below prior year levels and our capital increase measures initiated in March 2004, with private and institutional investors who invested approximately 16 million € in MediGene, we are expecting cash on hand to be 25 million € by the end of the year. For medium-term financing of our company, other partnerships will be of significance in addition to the revenues generated by the existing one with Eligard®. We will therefore

speak intensively with pharmaceuticals and biotech companies about cooperation for the joint development and marketing of our Polyphenon® E Ointment. We are planning to do the same for one of our virology projects. Agreements arising from this are likely to be expected in 2005.

Dear shareholders, in the 21st century, cancer still remains a disease that we do not fully understand and are only inadequately capable of treating. Cancer is still a closed book for both scientists and physicians. Biotechnology, and with it companies such as MediGene, are looking for ways to read this book. The search is time-consuming, extremely expensive, and punctuated by repeated failures. Besides the opportunities described above, you should also be aware of the risks involved. It is especially important for me to draw your – our shareholders' and investors' – attention to this subject.

On the opposite to the risks, however, are the opportunities that our products offer, the competency of our highly qualified staff, and the experience we have been able to gather during the almost ten years of our company's business. MediGene has undergone an interesting development, characterized by both, success and failure. MediGene's management and staff have learned a lot from past incidents. In Germany, there is no other biotechnology company as experienced in the field of drug development and the processes involved as your company, MediGene AG.

I would like to take this opportunity to express my heartfelt thanks to our entire staff, all of whom have always worked tirelessly for the benefit of MediGene, even in difficult times. I would also like to thank our business associates, analysts and journalists for their interest and their good cooperation. But most of all I would like to thank you, our shareholders, for your confidence and commitment to our company.

It is true: I have good reason to be optimistic about our company's future. Now I would also like to pass this optimism on to you.

Yours faithfully,

Dr Peter Heinrich
Chief Executive Officer

Dr Peter Heinrich, co-founder of the company, has been Chief Executive Officer of MediGene AG since 1995. Prior to that he was in charge of developing the biotechnology division at Wacker Chemie, a subsidiary of former Hoechst AG (now Aventis). During his seven years with Wacker he held various research as well as management positions. Dr Heinrich had studied biology and chemistry at the University of Munich and earned his PhD in biochemistry. Afterwards he worked as a scientist at Harvard University.

Dr Heinrich is president of the Emerging Biopharmaceuticals Enterprises (EBE), Brussels. Moreover, he is co-founder and vice-chairman of the Association of German Biotechnology Corporations (VBU) and a board member of the Society for Chemical Engineering and Biotechnology e.V. (DECHEMA).

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 Price Waterhouse, 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.

Dr K. Jon Kowal leads as Senior Vice President the international Research & Development activities of MediGene since October 2003. At the same time, he incorporates the function of Managing Director of the U.S. subsidiary MediGene, Inc. which he joined in September 2001. Dr Kowal possesses more than 20 years of expertise in the management of development and manufacture of biological substances, and has been significantly involved in the development of MediGene's HSV technology. Before, Dr Kowal has been General Manager of Chiron Corporation's Center for Gene Therapy. Previously, he held various positions at the Lederle Laboratories Division of Wyeth (formerly American Cyanamid Company). Dr Kowal holds a PhD degree in microbiology from the University of Pittsburgh, School of Medicine.

Dr Peter Heinrich
Chief Executive Officer,
Co-Founder

Alexander Dexne
Chief Financial Officer

Dr K. Jon Kowal
Senior Vice President
Research and Development

Management of MediGene AG

»The present MediGene portfolio is the best we have ever had.«

Interview with CFO
Alexander Dexne

Will the market launch of Eligard® be MediGene's breakthrough?

In many ways, it truly is a breakthrough when a young biotechnology company can take the difficult hurdle of product approval and earn its first revenues from the sales of a drug. By doing so, we have shown that we have built up the know-how necessary to bring products to market and earn income from them. We consider this to be an important indicator for continuing to successfully commercialize on our drugs in the future as well.

How much money will MediGene be earning with Eligard®?

Revenues from Eligard® for MediGene come in two parts: First, there are the milestone payments we will be receiving from our marketing partner Yamanouchi when specific hurdles are taken. These payments are essentially tied to approvals and market launches of Eligard® on the largest European markets and will amount to up to 23.5 million €. The second component consists of a share in the sales of Eligard®. Although the milestone payments will make an important contribution to financing our company over the next two years, the revenues from royalties on sales will be flowing throughout the entire period under agreement and therefore over many years. Revenues from sales will thus be playing a significant role in reaching our break-even point.

What factors will be important for the further development of MediGene sales?

The central component for the short-term development of MediGene sales is, of course, the success of Eligard® sales in Europe. We are convinced that Yamanouchi, with its outstanding strength in the field of urology, can exploit the market potential of Eligard® extremely well. Should Yamanouchi decide to launch the four – or even the six-month depots of Eligard® in Europe – it would also pose increased additional sales potentials for MediGene.

If very good efficacy against genital tumors can be evidenced in the ongoing clinical trials for Polyphenon® E Ointment, I see this project as the next significant building block for lasting sales growth. With Polyphenon® E Ointment, we have one of the world's very few exciting dermatology projects in phase 3 of clinical development. A successful partnering for Polyphenon® E will generate additional revenue streams for MediGene and thus continue to strengthen the company's financial position. We assume that we will continue to earn revenue on the successful sales of Polyphenon® E Ointment by taking a share in the sales of this drug after its market launch.

At the same time, we are focussed on increasing the value and the marketability of our HSV technology (cancer-destroying herpes simplex viruses). I see the results of the phase 2 trials for NV1020 beginning in 2004 as an important milestone in this. If the trials go successfully, NV1020 offers a significant medium-term revenue potential for our company.

Many speak of consolidation in the industry. Are you planning to acquire or merge with other companies?

That could be an interesting opportunity for accelerating the growth of our company, under the prerequisite, however, that the potential partners are well-suited, i.e. they complement each other and both can benefit from the other. Only then such a step would generate superior growth in the value of our company, and this is why MediGene carefully assesses potential opportunities that arise. However, we place great emphasis on not diluting the current focus of MediGene through any such potential transaction, and on keeping operations manageable.

The MediGene product pipeline has been reduced in the past two years from seven to four current projects today. Hasn't this precipitated a fall in their value and, at the same time, a rise in the risk they pose for MediGene?

On the contrary. The present MediGene portfolio is the best we have ever had. I am convinced that risk falls as focus sharpens. And also, our projects have, in the meantime, been developed further and reached significant clinical milestones which have further increased the value of the products and their chances of reaching the market. One project – Eligard® – has already obtained market approval and is now on the verge of market launch. After the partnerships for Eligard®, we are now concentrating specifically on two parts of our pipeline: On the one hand, our Polyphenon® E Ointment, for which we are presently evaluating the opportunity for line extensions, that is for use in other indications and, on the other, our highly innovative HSV technology which has an even greater potential for future sales. In both areas, we have obtained a leading global position through our proven expertise, our widespread network of scientific and clinical cooperations and our strong patent position.

What are your financial goals for 2004?

We are striving for a quadrupling of sales to 8 million € and a halving of our losses to 15 million €. The marketing of Eligard® and the cost-cutting measures taken in 2003 will both contribute to this clear improvement in our results. Eligard®, as a sales-maker with consistent growth, will be making a significant contribution to MediGene's results in the coming years as well. Cash reserves will probably be 25 million € by the end of 2004. This forecast includes the capital increase measures announced in March 2004 which will increase our cash available by approximately 16 million €.

What do you think makes MediGene more attractive than other biotech companies?

We have a mature and attractive pipeline with products with high sales and earnings potential, and we also have the power to develop this pipeline successfully. We possess extraordinary scientific know-how in the research and development of biological substances, but also many years of experience in clinical development from the more than 10 international clinical studies we have carried out. We have been able to build up excellent contacts with regulatory authorities in the U.S. and Europe and have shown how to get a drug approved and commercialize it in the best way possible. In short, MediGene fulfills all the prerequisites to position itself as a successful and innovative biotechnology company over the long term.

MediGene's drug pipeline

Eligard®

MediGene's cancer drug Eligard® to treat advanced prostate cancer was approved for the German market in December 2003. The hormone therapy (active agent: leuprolide acetate) combines a standard hormone therapy with a novel, effective and patient-friendly form of administration, the Atrigel® sustained release technology. Liquid Eligard® is injected under the patient's skin and forms a solid depot. The biodegradable implant slowly disintegrates in the body, continuously releasing the active ingredient over an extended period of time. Eligard® is an LHRH agonist (LHRH = Luteinizing Hormone Releasing Hormone) which reduces the testosterone level in the body during the treatment period sufficiently to suppress tumor growth in patients with hormone-dependent prostate cancer. The clinical studies have shown that Eligard® is safe, well tolerated and efficient.

MediGene had licensed the one- and three-month versions of Eligard® (formerly Leuprogel®) from the U.S. company Atrix Laboratories, Inc. in April 2001, and taken them through the approval process in Germany. In preparation for the approval procedure, the experimental clinical data provided by Atrix were edited and processed in order to meet the requirements relevant to approval by the German authorities. In addition to this, further pre-clinical trials were carried out, such as pharmacological and toxicological studies, since the demands made by the European authorities on applications for approval significantly vary from those made by the U.S. FDA. MediGene also acquired options on the four- and six-month release products of Eligard®, and received German market approval for the drug in December 2003 (one-month dosage) and January 2004 (three-months dosage). In order to market Eligard® in Europe, MediGene concluded a partnership with the pharmaceuticals company Yamanouchi in January 2004. The two companies are planning to obtain the approval for Eligard® in other important European markets. In 2003, sales of around 580 million € were realized with LHRH agonists in the five largest European countries. MediGene expects that Yamanouchi, as the second largest pharmaceuticals company in the European urology field, will be able to take a significant share of this market with Eligard®.

Polyphenon® E Ointment

MediGene's Polyphenon® E Ointment to treat benign genital tumors (genital warts) is presently undergoing phase 3 clinical trials, the final step in clinical development. Genital warts are caused by an infection with certain human papillome viruses (HPV) transmitted through sexual contact. Polyphenon® E Ointment is based on a defined blend of agents isolated from green tea. Pre-clinical and clinical trials indicate that the polyphenols in green tea extract inhibit HPV replication, counteract specific pathologic cellular changes, and activate the patient's immune system.

MediGene is testing Polyphenon® E Ointment to treat genital warts on around 1,000 patients in two international phase 3 trials, the final results of which will be crucial for the marketing approval of the drug. The European phase 3 trial is already completed, results are expected for the end of March 2003. The U.S. trial is scheduled to be completed and evaluated by the end of 2004. If the final results are positive, MediGene will probably submit the application for approval of Polyphenon® E Ointment to the U.S. authorities. MediGene estimates the peak sales potential for Polyphenon® E Ointment to fight genital tumors at more than 100 million € annually.

MediGene's Polyphenon® E Ointment may also be suitable for treating other dermatological disorders. Pre-clinical data indicate that actinic keratosis, a precursor of skin cancer, and basal cell carcinoma, the most common form of malignant skin cancer, could also perhaps be treated using Polyphenon® E Ointment. MediGene is carrying out pre-clinical trials to determine whether the ointment can be further developed in clinical trials for these skin disorders. If this turns out to be the case, the market potential for Polyphenon® E Ointment could triple, provided that the clinical trial results are sufficiently positive.

Oncolytic herpes simplex viruses

MediGene is developing oncolytic (cancer-killing) viruses to treat various types of cancer. They are specific herpes simplex viruses (HSV) genetically modified for the selective destruction of tumor cells without causing damage to healthy tissue. HSV have been specifically engineered to replicate only within tumor cells where they cause cellular death (oncolysis) of the tumor. The technology is based on the hypothesis that HSV act in a more targeted and efficient manner than conventional tumor therapies do, yet without any serious side effects. They could offer a therapeutic alternative for treating tumors which cannot be surgically removed, or which have become resistant to chemotherapy or radiotherapy.

The oncolytic herpes simplex virus NV1020 to treat colorectal carcinoma metastasized to the liver has successfully passed its clinical phase 1/2 trial. In 2004, a further phase 1/2 trial on this highly innovative agent will be initiated. Analysts estimate the sales potential of NV1020 for this disease to be more than 200 million € annually (peak sales). Positive phase 1 data is already available on another HSV, that is G207 to treat malignant brain tumors (glioblastoma). Plans for further clinical development of G207 to treat glioblastoma are presently under review.

MediGene's oncolytic viruses also offer a potential for further development as a drug to treat other cancers such as prostate or liver cell cancer, as pre-clinical data suggest. The economic potential of MediGene's HSV technology will rise considerably with these options.

rAAV tumor vaccine

In cooperation with the pharmaceuticals group Aventis, MediGene is currently developing genetically modified adeno-associated viruses (rAAVs) to treat malignant melanoma. rAAVs bearing immune-stimulating genes are introduced into previously removed tumor cells. These cells are then injected back into the patient in order to stimulate his or her body's own cancer-killing system. This tumor vaccine is currently undergoing a clinical phase 1/2 trial scheduled for completion in the middle of 2004.

Comprehensive product pipeline

Products	Diseases	Pre-clinical	Clinical phases			Approval	Max. sales[1] (million €)
			1	2	3		
Eligard®	Prostate cancer						> 50[2]
Polyphenon® E Ointment	Genital tumors						> 100
	Actinic keratosis[3]						> 200
	Basal cell carcinoma						> 50
Oncolytic HSV	Liver metastases		[4]				> 200
	Brain tumors (Glioblastom)		[5]				> 300
	Prostate cancer Hepatocellular carcinoma						> 500
rAAV tumor vaccine	Malignant melanoma						> 200[6]
Chance of reaching the market		0 – 10%	10 – 30%	40 – 60%	60 – 80%	90%	

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[3] Precursors of a specific kind of skin cancer
[4] Phase 1/2 in preparation
[5] Project plan under review

[6] Development partnership with Aventis

The door to the market

How MediGene's first drug will be marketed:

The marketing partnership

»We are proud to present Yamanouchi, one of the top companies in the European urology market, as our partner for Eligard®,« MediGene's Chief Executive Officer Dr Peter Heinrich announced during a hastily called telephone press conference. That was on January 14, 2004, the day that marked the conclusion of more than a year of challenging negotiations. MediGene had already launched talks in 2002 with a number of pharmaceuticals companies that were considered to be potential partners for marketing of the prostate cancer drug Eligard®. Protracted negotiations, simultaneously with a number of interested parties followed, finally leading to the partnership with MediGene's preferred partner, the Japanese pharmaceuticals company Yamanouchi, the second largest pharmaceuticals company in Europe in the field of urology, which is the market segment relevant for Eligard®. Under the agreement, Yamanouchi will take on promotion and sale of Eligard® in Europe, and MediGene will deliver the finished product.

That was on January 14, 2004, the day that marked the conclusion of more than a year of challenging negotiations. MediGene had already launched talks in 2002 with a number of pharmaceuticals companies that were considered to be potential partners for marketing of the prostate cancer drug Eligard®.

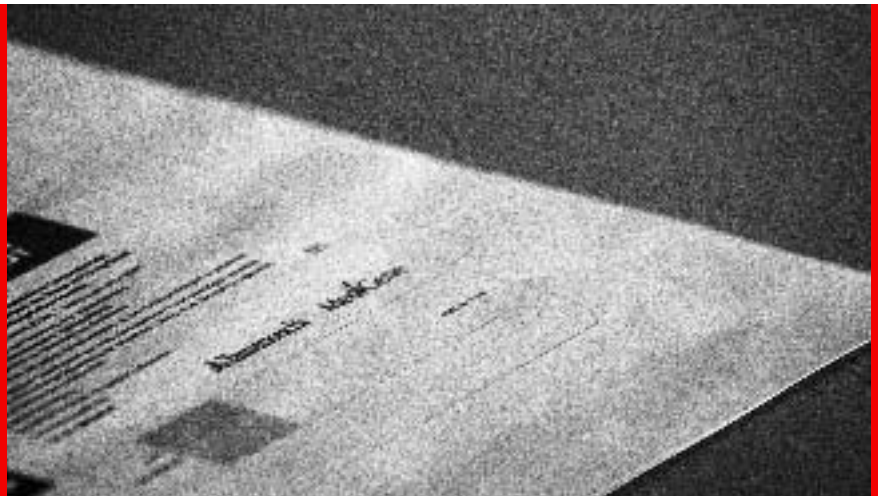
»With Yamanouchi, on the other hand, the prospects are excellent.«

But why won't MediGene market the drug by itself? In his office, Chief Financial Officer Alexander Dexne pulls out a chart. It shows the sales expected for Eligard® in two different circumstances: One curve marks the sales figures expected in case MediGene promotes and sells the drug by itself, and the second curve, significantly above the other one shows the sales performance achieved with a strong partner like Yamanouchi. The reasons for the difference in the prospects for success are obvious: »Up to now, a new company like MediGene possesses neither the recognition nor the experience, nor the marketing structures or resources needed for successful sale of a product on the highly competitive urology market,« Dexne explains. »With Yamanouchi, on the other hand, the prospects are excellent,« he adds, underscoring this prediction with figures: More than 800 Yamanouchi sales rep-

resentatives ensure excellent customer relations throughout Europe. Proven sales experience and adequate marketing budgets facilitate intense promotion of the products on offer. In 2002 alone, Yamanouchi posted 500 million € in sales of its drugs in Europe, a large portion of this with urology products. Eligard®, says European Yamanouchi Head, Kazuyoshi Hatanaka, in MediGene's press release, is perfectly suited for Yamanouchi's ambition to significantly expand its strong position in the urology market.

The price of this valuable partnership: MediGene grants Yamanouchi the marketing rights for Eligard® and receives in return a specified royalty rate on future sales of the drug realized by the partner. In addition, Yamanouchi has agreed to make specified milestone payments to MediGene when certain non sales-based milestones are reached. Milestones will be certain approvals of Eligard® in significant European markets, followed by the respective market launch. These milestone payments may total up to 23.5 million € in the coming years. Included in this sum is a signing fee of 4 million € that MediGene has already received, and a further payment amounting to millions was due upon German approval of the three-months Eligard®; both achieved in January 2004.

MediGene had acquired the license for Eligard® (previously named Leuprogel®) from the U.S. company Atrix Laboratories, Inc. in April 2001, and with it the exclusive European rights to the product. MediGene also committed to take the drug through the European approval process. This means, of course, that there is a third party on board. MediGene will forward a portion of the royalties for Eligard® to Atrix, who is also entitled to a small share of the milestone payments by Yamanouchi to MediGene. »The three-party constellation has made negotiations very complex,« says Falk Nürnberger, MediGene's Legal Counsel, responsible for the legal elaboration of the agreements. »However, we jointly managed to find the ideal balance of the different interests of each party involved. For this purpose, the MediGene team frequently traveled to the U.S. and to the London Yamanouchi office for negotiations, or received partner delegations at Martinsried. Chief Financial Officer Alexander Dexne is highly satisfied with the re-



sults of these negotiations, saying »The Eligard® partnership is strategically important and financially very attractive for MediGene. I am very happy about this agreement.«

German marketing authorization for the one- and three-month sustained release products of Eligard®, obtained in December 2003 and January 2004, respectively, formed a prelude to the future pan-European commercialization of the drug. MediGene and Yamanouchi have announced that they will also apply for approval of Eligard® in other European countries. As a part of the so-called »mutual recognition process,« the German approval will serve as a reference. In this procedure, national approval processes take a maximum of six months each.

In the future, Yamanouchi will bear responsibility for further approval procedures and, if required, for further product development by means of additional trials. MediGene will provide support to the partner by contributing expertise and, if necessary, by carrying out the clinical trials. Yamanouchi will bear the respective expenses. MediGene is responsible for the supply of the product which is manufactured by Atrix in the U.S., including professional import and product qualilty assurance. MediGene obtained the import permit from the German authorities in November 2003. Marketing planning and all marketing activities are in the hands of Yamanouchi. MediGene is, however, represented in the marketing committee and thus has the opportunity »to look over its partner's shoulder and learn from them,« Alexander Dexne explains – an interesting opportunity indeed for a company with the long-term goal of marketing its products by itself some day.

A colored printout lies on the desk of CEO Dr Heinrich, an initial, tentative draft of the Eligard® wrapping. He points at the MediGene logo positioned on one side of the package. »Soon drugs bearing our company logo will be available at pharmacies,« he proudly says. »This means that we will be present where we want to be: that is, on the market.«

»The Eligard® partnership is strategically important and financially very attractive for MediGene. I am very happy about this agreement.«

Working for that one enchanted moment

The long journey from development of a drug candidate to receipt of marketing authorization for a medicinal product: the approval process

»Granting approval for a drug means that regulatory authorities are assuming enormous responsibility, and therefore it is only correct that they take it seriously,« says Dr Gander, »It is not easy to convey so much confidence in a medicinal product to those responsible that they will say, yes, we can expose our citizens to this drug without any concern.«

It doesn't look like much: a bundle of cheap white paper with plain typing on it. No seal, no watermark, no trace of glory or splendor. And still, this is a document of great importance for MediGene: the marketing authorization for Eligard® (formerly known as Leuprogel®), MediGene's first medicinal product approved for marketing by a European regulatory authority. This makes MediGene Germany's first biotechnology company to obtain marketing authorization for one of its drugs and arrange for market access. »This is that one enchanted moment«, Dr Irene Gander, the Director of Regulatory Affairs at MediGene, says succinctly. MediGene and

While the marketing authorization application was being drafted, the regulatory staff at MediGene initiated an intensive dialogue with the regulatory authorities in different European countries.

its shareholders had been waiting for this moment for almost two years, and it finally became reality when the marketing authorization was received on December 1, 2003.

This moment was preceded by a long-lasting marketing authorization application process for the drug, for which MediGene had acquired the European marketing rights from the U.S. company Atrix Laboratories, Inc. in April 2001. By doing so, MediGene had taken over the task of convincing the regulatory authorities in key European markets that patients in Europe should have access to Eligard® and that Eligard® should therefore be approved by those authorities. »Granting approval for a drug means that regulatory authorities are assuming enormous responsibility, and therefore it is only correct that they take it seriously,« says Dr Gander, »It is not easy to convey so much confi-

»Before the authorities actually review the documents, no one can precisely predict whether they will request further data or not. This is where experience and a keen sense of the process are needed in order to decide whether and, if so, what supplementary experiments have to be carried out proactively. If you just wait and watch until the authorities ask for further information, you can possibly lose valuable time. However, if you start up a lot of additional experiments, it can be a drain on valuable resources. For a young company like MediGene, it is therefore especially important to balance this in a professional way«.

dence in a medicinal product to those responsible that they will say, yes, we can expose our citizens to this drug without any concern.« To do this, a vast amount of data is necessary to prove the product is both safe and effective. The dossier encompassed almost 60 large files that MediGene had put together to apply for the marketing authorization for Eligard® at the German regulatory authority. The results from studies carried out by MediGene's partner Atrix in the U.S., and the remainder of the U.S. marketing authorization dossier formed the basis for the German application dossier. However, European authorities have a different way of working and, in some areas, different evaluation criteria. Therefore, even though the U.S. documentation served MediGene as a basis, it had to be reworked and supplemented in many areas.

While the marketing authorization application was being drafted, the regulatory staff at MediGene initiated an intensive dialogue with the regulatory authorities in different European countries. After comprehensive preparation and correspondence, a MediGene team finally traveled to the regions in question, in order to personally meet with the representatives of the authorities responsible for the approval process. Assisted by their partner Atrix and external consultants, MediGene representatives from regulatory affairs, clinical development, toxicology and project management discussed with experts from the regulatory authorities in order to identify the requirements of the Eligard® approval documentation. »After these discussions, we were able to generally assess which critical points the authorities saw, what data still had to be requested from Atrix and whether additional experiments would need to be carried out,« says Dr Gander.

After all these considerations and deliberations had been included in the drafting of the dossier, MediGene submitted the marketing authorization application for the one-month product of Eligard® to the German authorities in November 2001. The application for the three-month product followed in April 2002. While dossier evaluation was ongoing, MediGene carried out further pre-clinical trials to generate further data and compile information on specific issues. In this regard it was always of great importance to find the right balance of time and resources on one hand and possible requirements on the other, Gander explains: »Before the authorities actually review the documents, no one can precisely predict whether they will request further data or not. This is where experience and a

keen sense of the process are needed in order to decide whether and, if so, what supplementary experiments have to be carried out proactively. If you just wait and watch until the authorities ask for further information, you can possibly lose valuable time. However, if you start up a lot of additional experiments, it can be a drain on valuable resources. For a young company like MediGene, it is therefore especially important to balance this in a professional way«.

In the course of 2003, MediGene received the official reaction to the documents it had submitted – and as it turned out, MediGene had done an excellent job. The authorities only requested further data in areas the MediGene team had foreseen. This enabled MediGene to answer the extensive questions within just a few weeks. But would the answers satisfy the officials?

»Another period of waiting ensued, during which we once again checked through the documents we had submitted with a critical eye as to whether or in which areas we might still have to go back to the drawing board,« Elke Piller, who conducted the Eligard® marketing authorization application process at MediGene, explains. But the answers were comprehensive and convincing so that only very few, very small detailed inquiries followed, which the company was able to answer quickly. After yet another phase of waiting, the authorities at the Federal Institute did react, this time with the marketing authorization. »Because the first phase of the process had taken so long, we just couldn't believe the positive news at first,« Elke Piller says, and admits that there was a bit of »jumping for joy« within the department.

MediGene had underestimated the length of time the authorities would require to review the application documentation, and had assumed a possible approval as early as spring 2003. But still, MediGene is convinced that it was worth waiting, because the German regulatory authorities enjoy an excellent reputation. »The German authorities are deemed to be especially thorough. This will help in future approval processes in other European countries because, in the so-called ›mutual recognition process,‹ Germany is now acting as the reference member state,« Dr Gander explains and adds, »Furthermore, Germany is also the largest market for pharmaceuticals in Europe – another reason for launching the approval process here.«

Eligard® will be marketed in Europe by MediGene's partner Yamanouchi. In future approval processes, MediGene will support its partner company. After the successful approvals in Germany – in January 2004, the three-month Eligard® product was also approved – the further processes will be much easier and shorter. National approval processes are limited to 180 days under the »mutual recognition process.« But it still applies here as well: Each country has its own requirements, each country demands the drafting of its own marketing authorization application documentation.

In other areas as well, MediGene's regulatory team will continue to face significant challenges. With its Polyphenon® E Ointment, the company has another product in its pipeline which is close to market. To prepare for the current phase 3 trial, MediGene has already been in intensive contact with the various regulatory authorities. The same is true for the preparations for phase 2 trials on NV1020, which are scheduled to begin in 2004. The clinical development of Polyphenon® E Ointment is supposed to be finalized at the end of 2004. The approval process, the final spurt to the market, could thus begin in 2005.

Here begins the hour of truth

Clinical trials with patients are used to determine whether a product under development can become a drug: the clinical development

There is a humming in the foyer of the U.S. congress center. More than 120 people are leaving the lecture hall discussing what they have just heard. Medical specialists have come together here, dermatologists, gynecologists and urologists who want to find out as many details as they can about a large-scale clinical trial being conducted on a new drug. They will also take part in the study as investigators. A new clinical trial is about to begin.

»Clinical trials are used to study novel, less researched and not yet approved compounds and their effects on humans. This means that every error counts at once. All those involved have to know exactly what they're doing,« says Axel Mescheder, M.D., Vice President Clinical Research and Development at MediGene. »Comprehensive preparation of the investigators tak-

»Clinical trials are used to study novel, less researched and not yet approved compounds and their effects on humans. This means that every error counts at once. All those involved have to know exactly what they're doing.«

»Once a trial has started, the concept for such a trial already in progress cannot be changed unconditionally. Therefore, we have to make the proper judgments in advance in order to achieve a sound result for treatment and the highest degree of safety for patients.«

ing part in the study is therefore of fundamental importance. The physicians have to know the background behind the development of this drug, be accurately informed about the indications for the drug and understand the study protocol.«

The study protocol is the key to the success of any clinical development phase. This document includes critical basic data: Which patients may be included in the trials? How often and in which dosages should a drug be administered? What measurements have to be taken to best study the effects and side effects of the drug? »Once a trial has started, the concept for such a trial already in progress cannot be changed unconditionally. Therefore, we have to make the proper judgments in advance in order to achieve a sound result for treatment and the highest degree of safety for patients,« Dr Mescheder explains. To

do so, he and his clinical development team make use of all their knowledge and experience, but also include the advice of independent experts as well as the know-how of the investigators who will be taking part in the planned trials. They base their work on the results from the pre-clinical research and development phase. »Results from pre-clinical trials are, however, never transferable to humans 1:1,« says Dr Mescheder. »Our job is to translate the existing data to the clinical treatment situation of patients. Not until the clinical trials does it become evident whether a drug truly meets expectations: Will it work? Does it cause any side effects? How are the patients doing with it? Here begins the hour of truth.«

This »acid test« of a new drug has three phases to it: In clinical trials they are the phases 1-3 which begin with a few patients and end in comprehensive trial schedules. In phase 1, the tolerability and safety of a drug on humans is tested first. In phase 2, the focus is on the dosage, and in phase 3 tolerability, safety and efficacy are all extensively verified. Only when all phases of the clinical development, which can also be mixed, have been successfully concluded, can an application for market approval of the product be submitted to the authorities.

The drafting of the study protocol, its approval by the health authorities and the meeting of the study investigators must be completed prior to each of these trial phases, and before the first patient can even be recruited or treated in the trial itself. An important interim goal is the conclusion of patient recruitment, i.e. the moment when the number of patients called for in the trial schedule is reached. This is not always easy because treatment using little researched drugs does have its risks and the eligibility criteria often require a highly specific patient profile. When this milestone is reached, however, the actual time frame can be clearly traced up to the point that the trials are concluded, i.e. the point in time when the last patient has been treated and monitored during the follow-up period. The preparation and execution of this phase of the trial requires not only a high degree of scientific and medical knowledge, but also organizational skills.

Therefore, Prof Dr Hoda Tawfik is constantly on the go. She is responsible for the operative portion of the clinical trials at MediGene worldwide and visits, along with her staff, clinics, trial physicians and experts throughout the world. In 2003 alone, the team traveled tens of thousands of miles to obtain the opinions of experts, discuss study protocols and examine the quality of the clinical trials being done. In their work, these trained scientists and trial specialists never treat patients themselves, that is left to the investigators and their health care professionals. »There is a clear separation prescribed between company and patient, and this is a good thing,« says Prof Tawfik. »It is the only way to reliably protect patient data.« Furthermore, high-grade clinical trials, such as the phase 3 trials currently being carried out by MediGene, include several protective mechanisms intended to

The European and U.S. phase 3 trials on Polyphenon E ® Ointment on a timeline:

Spring 2002
Contact with experts for dermatology and HPV infection as well as with important approval authorities in Europe and the U.S. to discuss the trial schedule.

August 2002
Completion of the trial schedule; Submission of study protocol to the relevant approval authorities in Europe and the U.S.

September 2002
Submission of the study protocol (European part) to the relevant Ethics Commissions; Approval of trial schedule by the Ethics Commissions Study initiation: recruitment of the 1st patient in the trial and first treatment.

November 2002
European investigators' meeting in Rome with more than 120 physicians: MediGene presents the trial schedule for the trial and trains the investigators, together with external experts, in the correct way to conduct the trial.

May 2003
Conclusion of patient recruitment after the required number of patients is randomized.

June 2003
Submission of the trial schedule to the approval authorities and the Ethics Commissions/Institutional Review Boards in the U.S. and Latin American countries; U.S. investigators' meeting in San Diego with more than 120 physicians.

July 2003
Trial begins in the U.S.: Treatment of the 1st patient.

prevent a company or investigator from manipulating the results. For instance, in a »randomized« study, decisions are made by chance as to which patients are treated with which dosages of the drug. If trials are »double blind,« the random list remains sealed until completion of the trials, so that neither the company nor the investigators, not even the patients themselves know which patient is being treated with which dosage or whether the patient is receiving a placebo instead of the active agent. »This ensures that the results of the treatments will be unadulterated,« Prof Dr Tawfik explains.

In spite of the »iron curtain« in front of the hospital bed, the general responsibility for the clinical trial lies with MediGene, the so-called sponsor. The company has to ensure that the trials are carried out properly and in accordance with the legal provisions for them, and also see to it that the patients taking part in the trials are treated as prescribed. Particularly in large-scale, international trials such as MediGene's current phase 3 program on its Polyphenon E® Ointment, in which more than 1,000 patients in over 100 clinics in 14 countries are being treated, this can be an enormous task. In doing so, MediGene works together with specialized companies, so-called CROs (Clinical Research Organizations) which supervise the treatment of the patients and the course of the trials on site. The MediGene team maintains the closest possible contact with the CROs and monitors their work meticulously and regularly. As an external control mechanism, independent auditors are also on hand to monitor, on behalf of MediGene, the execution of the trials, the supervision of which is prescribed by law. »And of course, our own visits on site are irreplaceable«, says Prof Tawfik and explains: »In direct contact with the clinics, we are able to judge and solve possible problems and weak points more quickly and more directly. In personal talks we also learn a great deal about the working conditions in the various clinics and countries which can differ significantly in specific cases. Personal visits or group meetings with the investigators in a particular region breathe life into the relationship we have with our partners and improve the cooperation among the experts. Both are important for the success of a trial and for the further development of the drug.«

The focus of MediGene's worldwide clinical development work in 2003 lay on the execution of two phase 3 trials for Polyphenon® E Ointment to treat genital tumors. The European trials already started in September 2002, the U.S. trials began in July 2003. Together, the two trials are the largest clinical study ever carried out by a German biotechnology company. The start of another central trial is planned for 2004: a phase 2 clinical trial for the cancer drug NV1020 to treat liver metastases from colorectal cancer is planned for the U.S. The overall results from the two Polyphenon® E trials are expected for the end of 2004. Then, with the end of the »hour of truth,« the decision will be made as to whether this product has passed the test which can make it a marketable drug. For MediGene, this could then be the second product mature for the market.

August 2003
MediGene visits Russian trial physicians. Goal: monitor quality of the trials being done, discuss audit results and solve possible problems.

Oct.–Dec. 2003
MediGene visits all U.S. clinical centers as well as selected physicians in Chile, Peru, Columbia, Mexico. Goal: comprehensive monitoring of execution and course of the trial, discussion of audit results and solutions to possible problems.

November 2003
Regional investigators' meeting in Buenos Aires.

Dezember 2003
Conclusion of patient treatment in the European trials.

Spring 2004
Evaluation of the European trial is concluded.

By end 2004
Conclusion of the U.S. trial and general evaluation of the two trials is expected.

This stuff has to get under the skin

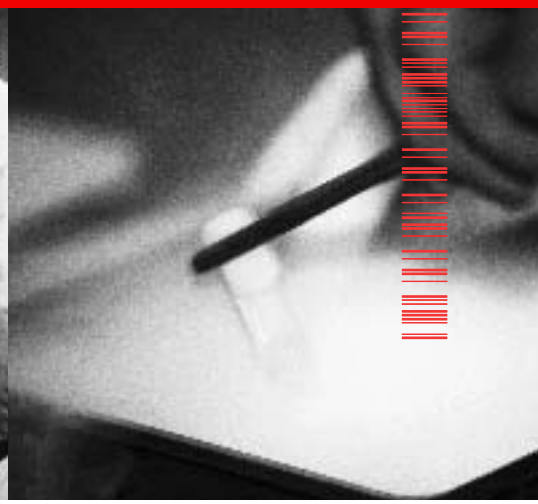
How an active agent becomes a product: the manufacturing process

»We also have to find a feasible way to manufacture it and also ›pack‹ it in a manner it can be sensibly administered. Only then can a substance become a product.«

Yellow signs on the door warn »Virus,« »Bio Safety Level 2.« From the entrance, you can see the entire laboratory: white lab coats hanging on a line of hooks, bubbling aluminum pipes, the scent of disinfectants in the air. Lined along the hall are lab rooms with sterile workbenches, incubators and microscopes. This is the site of MediGene's Process Development: »It's not enough just to discover a substance,« Dr Josef Gabelsberger, Director of Process Development at MediGene, explains. »We also have to find a feasible way to manufacture it and also ›pack‹ it in a manner it can be sensibly administered. Only then can a substance become a product. Only then can clinical trials begin.«

He gives an example: MediGene's active agent Polyphenon® E against genital warts is based on green tea extracts, in its natural state a brown,

»The stuff has to get under the skin to display its effect.«



slightly bitter tasting powder, as the scientist shows. The agents contained in Polyphenon® E are believed to make genital warts, benign skin tumors in the genital area, recede. However, in its natural state, the substance remains ineffectual: »The stuff has to get under the skin to display its effect,« Dr Gabelsberger explains. Therefore, MediGene has developed an ointment that can transport the agent in Polyphenon® E under the skin without causing adverse skin reactions. At the same time, the shelf life of the product was tested in stability studies. The result is that MediGene is presently testing Polyphenon® E Ointment on almost 1,000 patients in an international clinical phase 3 trial. To make the ointment, an extract is isolated from several tons of green tea leaves and processed into an ointment through a number of precisely defined steps. MediGene developed the method for

manufacturing the ointment. Large-scale production is outsourced to specialty manufacturing companies where the drug is made and tested in accordance with the strict instructions and under the constant supervision by MediGene.

»The significance of the manufacturing process is sometimes underestimated,« says Dr Gabelsberger. »The history of modern drug development shows, however, that a large number of projects fail because the agent in them cannot be manufactured properly or at an acceptable price.« Effects and side effects are therefore not the only criteria deciding on the success or failure of drug-making projects.

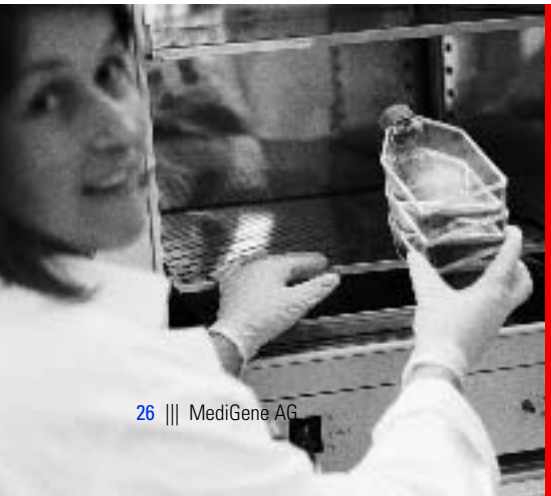
»Viruses are simply not that easy to produce and can't be copied like a car,« Dr Rainer Müller explains. »Viruses are tricky.«

»Process development becomes really exciting when it comes to classes of agents that have never existed in this or any similar form – such as our oncolytic viruses HSV,« Gabelsberger continues. HSV stands for herpes simplex virus, the name for a pathogen known to many people as the cause of cold sores. Oncolytic means destroying or dissolving cancer and is the name of an entirely new therapeutic principle.

With the production of therapeutic viruses, MediGene is treading new scientific territory.

MediGene's oncolytic viruses are HSV which have been genetically modified to selectively infect cancer cells, reproduce within them and thus destroy them. Healthy cells are not destroyed in the process. This is the hypothesis and the goal. Whether this approach will work in the way desired is the objective of a number of extensive trials MediGene is presently running. Initial studies with patients (clinical phases 1 and 1/2) have already provided promising data on this.

However, the scientific accomplishment in this innovation cannot be found only in genetic alteration. The »prototype« of the MediGene cancer-killing virus going by the name of NV1020 was already developed about five years ago. Since then, however, the challenge has been to reproduce this prototype exactly, the only way to enable the treatment of large patient groups. »Viruses are simply not that easy to produce and can't be copied like a car,« Dr Rainer Müller, Group Director in the Department of Process Development, explains. »Viruses are tricky.«



With biological agents, it is particularly difficult to maintain the level of purity, stability and reproducibility required for medicine production: Every virus produced has to be clean, i.e. free from such residues as bacteria, every virus has to comply with precisely defined criteria for stability, and every virus has to be exactly like the prototype in both, form and effectiveness. This is an enormous challenge and requires new scientific methods.

»One possible method is to produce viruses in eggs, but this is a rather greasy, grimy affair and not a state-of-the-art approach,« Dr Müller explains. MediGene uses cell cultures to breed viruses. They can be controlled, are cleaner and more stable. The cell lines used by MediGene are based on specified animal cells, which have been collected once so as to be reproduced over and over again. MediGene scientists breed these cells in so-called cell culture vessels. These plastic containers are similar to milk bottles and act like little greenhouses in which the cells are seeded and then can divide and proliferate. When a sufficiently large cell colony has formed, a liquid is added which then ends up holding a small amount of the desired viruses. The cells are the culture medium for virus reproduction, they release the new viruses. »Now it's harvest time,« Dr Müller adds and explains how the viruses are separated from their host cells: using extremely fine-mesh filters, the contents of the cell culture vessels are passed through. The viruses harvested in this way can, however, still contain impurities, which is why they are processed further by ever more refined purification steps. The result is the desired viruses in their purest form, which are then frozen until they can be used therapeutically.

MediGene has developed the process for manufacturing oncolytic viruses on a large scale. The production itself is carried out by specialized service companies. The most important issue is to adhere to the official regulations in the so-called Good Manufacturing Practices, abbreviated GMP, in every stage of production. »Some scientists claim that this abbreviation actually stands for ›Generate More Paper‹,« Dr Gabelsberger jokes, and indeed the GMP do require an enormous amount of documentation. Furthermore, they incorporate a huge number of safety and control regulations to ensure the greatest possible safety and security for both scientists and patients – an important aspect, especially for novel agents such as viruses.

With the production of therapeutic viruses, MediGene is treading new scientific territory. »There are many companies working on the development of therapeutic viruses,« Dr Gabelsberger says, »but not one drug which is a virus has yet come to market.« In this race, MediGene could be the first company in the world to bring such a drug to market.

Faces of MediGene

MediGene's guiding principles

Performance

Our corporation's performance depends on our employees' enthusiasm. We will reach our goals only if all of us give their best performance. Each employee's contribution is of vital importance for our success.

We encourage our employees to do their best by clearly assigning responsibility and authority and by providing feedback to them in regular intervals. We want our emploees to enjoy their work and give them the opportunity to grow with their responsibility.

Competitiveness

In order to survive on the pharmaceuticals market, we are developing a comprehensive, innovative product portfolio protected by extensive patents.

In order to remain competitive in this tough environment, MediGene develops its drugs in pursuance with the requirements of a global market.

In order to reach our goals we need employees who are both, highly qualified as well as highly dedicated.

Team spirit
All MediGene employees work to reach our joint goals. We consider ourselves to be one team.

To us, team spirit means fair interaction with each other, to be helpful and to show mutual recognition. All employees from each department and each location enjoy the same high appreciation. Each employee is given the opportunity to make full use of his/her skills and to unfold his/her personality.

Innovation
Apart from established principles, MediGene, a future-oriented corporation, also pursues novel concepts and goals.

It is our objective to identify new developments and opportunities on the market and to create quick and efficient decision-making paths.

We expect our employees to be open-minded, creative, prepared to take risks and flexible, ready to scrutinize our work and performance. Every employee is requested to keep his knowledge up-to-date and to utilize it proactively within the corporation.

Internationality
MediGene is a globally oriented enterprise.

Locations in Germany and the USA guarantee access to European and U.S. university and clinic networks as well as to local regulatory authorities.

We are seeking for worldwide utilization of synergies by means of continuous exchange of information with experts, institutions and authorities.

The photographer came across these 36 out of 112 MediGene employees, as he walked down the corridors on February 24, 2004.

They are biologists, chemists and physicians, engineers, financial experts and attorneys, IT specialists and technical or administrative assistants. They are working on the drugs of tomorrow, and they are driving the development of our company. They are investing their expertise and energy into a company that cannot offer them the job security a well-entrenched company would. Instead, they count on MediGene's potential, and their competence, ideas and commitment are the company's major capital.

At the end of 2003, MediGene employed a staff of 112. All of them are excellently trained and often contribute job experience gained in other companies or research institutes. More than half of the staff have university degrees, and more than half of those with a university degree have doctorate degrees. To foster the employees' professional and personal skills, MediGene supports their participation in advanced vocational training measures as well as renowned professional congresses and conferences.

MediGene has the most experienced drug development team in the German biotechnology industry. No other German biotech company has carried out a comparable number of clinical trials, nor as advanced trials. And no other, or hardly any other German biotech company has all the departments a biopharmaceutical company needs, from research and pre-clinical development to process development, clinical development, quality assurance and regulatory affairs. MediGene possesses many years of experience in all these fields. This expertise is further expanded by the developmental experience a large number of employees have gathered in large pharmaceuticals corporations prior to joining MediGene. Even in a comparison with other companies worldwide, MediGene is exceptionally well-positioned in this field.

MediGene is a clearly structured company with short decision-making processes, providing ample scope for the individual employees. Within a clearly defined set of goals, MediGene employees bear responsibility for the effi-

Efficiency

To us, efficiency stands for responsible utilization of resources.

This means that all resources shall be used in such a way that they contribute to a long-term sustained company value.

Independence

All MediGene employees are encouraged to act independently and on their own responsibility. This is supported by an assigning an appropriate scope of action and showing tolerance towards mistakes.

Advanced vocational training will broaden the employees' knowledge and personal competence. MediGene wants to motivate all employees to accept new challenges.

cient execution of their tasks and the goals laid down for the entire company. Individual initiative and new suggestions are explicitly welcome, versatility is required. Bonus systems promote individual motivation. A friendly working atmosphere is reflected in a particularly constructive collaboration between teams that are often made up of members from different countries.

In 2003, MediGene's management and employees jointly developed and implemented a corporate model to define corporate goals, values and guidelines. It is intended to facilitate the execution of corporate tasks and enhance the employees' identification with their company. Corporate values are of equal importance as supporting personal skills as well as the ethics of scientific work.

In 2003, MediGene cut back on staff from 185 to 112 as part of its restructuring program. On the one hand, this affected around 30 employees in the cardiology unit who left MediGene AG as a consequence of the spin-off of this unit. On the other hand, almost 30 jobs were cut step by step at the U.S. subsidiary in San Diego, as all research activities were moved to the German headquarters in Martinsried in the course of the year. In some cases, vacancies were not filled. By year's end, MediGene employed a staff of 92 in Martinsried and 20 in San Diego. According to current planning, this headcount shall remain relatively unchanged through 2004.

MediGene's vision is the expansion of medical opportunities by utilizing scientific methodology with a sense of responsibility. MediGene's employees have shown extraordinary commitment in doing so. Their creativity, knowledge and experience form the foundation upon which we will be able to realize this vision.

Credibility
Credibility results from competence, honesty and reliability.

By means of lucid and prompt inward and outward communication we want to build confidence, being a reliable partner for shareholders, employees and partners. In order to achieve this, we need to scrutinize all projects in regular intervals.

Initiative
Each individual MediGene employee is expected to accept personal responsibility and initiative.

We interpret initiative as independent problem analysis and solving. In certain exceptional circumstances it may be more important to solve a problem quickly and efficiently rather than involving all hierarchical levels in the company.

Ethics
We carry an obligation to take care of the welfare of all humans and animals involved in clinical trials.

In order to do so, we set the highest ethical standards for all our clinical trials.

Shares

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 (until 9/22/2003), Prime All Share, Prime IG Biotechnology
Trading floors	XETRA, Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hanover, Munich, Stuttgart
Designated sponsors	Bank Vontobel, Morgan Stanley
No. of shares (12/31/2003)	11,206,205

Share price up by around 50%

Despite interim lows during the year, the MediGene share price rose by almost 50% in 2003. This means that the shares performed better than the benchmark TecDAX30 Index and Prime Biotechnology Index did. Although the entire biotech sector posted positive performance on capital markets from the beginning of 2003, MediGene shares did not start their rise until several months later. At the beginning of 2003, MediGene shares first lost a great deal of their value. The news about the discontinuation of our CVLP drug project certainly contributed significantly to this downturn. From midyear, however, MediGene shares were able to post a far above-average performance, an important contribution to this presumably as a consequence of the cost-cutting and restructuring steps implemented by the management. In addition, the approval of our first drug Leuprogel®/Eligard®, apparently anticipated by the market, had a positive and lasting impact on MediGene shares in September. The announcement of the approval itself actually did not have any effect. It was not until the marketing partnership with the Japanese pharmaceutical company Yamanouchi was announced in early 2004 that the share price began to rise again.

MediGene shares ended 2003 at a price of € 5.97. A 12-month high of € 9.23 was reached in September. The launch of Eligard® on the German market this year will enable us to post revenue from product sales for the first time. We expect positive effects for our company from this as well as from product approval in other European countries, resulting in a positive impact on the MediGene share.

Numerous reports published about MediGene AG

As one of Europe's leading biotechnology companies, MediGene is actively monitored by a large number of analysts from major investment banks in Germany and around the world. Our company and its products and technology have been comprehensively analyzed in a number of reports. Reports by independent analysts are a significant element in successfully addressing potential investors. Furthermore, we also maintain our contacts to a number of other investment banking institutions as well as to leading business and industry media.

The following investment banks have accompanied MediGene with reports in 2003:

Code Securities	Dr Samir Devani
DZ Bank	Dr Thomas Höger/Dr Patrick Fuchs
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
Vontobel Securities AG	Dr Markus Metzger

Participation in major international investor conferences

MediGene's management continued its investor relations activities in 2003 by attending the following international investor conferences: »JP Morgan Healthcare Conference,« »BIO CEO & Investors Conference« and »BIO 2003« in the U.S. In Europe, MediGene also participated in the »6th German Corporate Conference« hosted by the Deutsche Bank, in the »5th Biotech & Finance Forum« and in the »Biopharmaceutical Conference in Europe.« The strategy and future development of the company was presented to and discussed with analysts and investors in many talks with them during the year. We started 2004 with a significant increase of our investor relations efforts, and this will continue throughout the year with participation in investor conferences and international road shows. We see ourselves as exceptionally well-positioned to win new investors for our company, as we are the first German biotechnology company with an approved product and revenues from its commercialization.

Transparency, continuity and real-time – core elements of our investor relations work

The objectives of our investor relations efforts are to present, in a clear and concise manner, our corporate strategy to analysts as well as to current and future shareholders, to clearly underscore that we are value-driven, and to report to them on important developments within our company. In doing so, we also desire to attain an appropriate valuation and a stable price for our shares. We want to reach these goals by winning domestic and foreign investors and shareholders with a long-term investment horizon. The past has shown that confidence is the prerequisite for an investment. Transparency, continuity and real-time reporting thus form the foundation of our investor relations strategy.

Competent communications: MediGene's reports once again win awards

In August, MediGene received its second award for some of the best financial and quarterly reporting in Germany. The »Manager Magazin« hosted the business reporting competition, and their jury awarded third place in the TecDAX index of the market to MediGene. According to »Manager Magazin,« the award-winning reports display a high degree of transparency and content quality.

Re-entry into the TecDAX30 Index is the goal

MediGene shares are traded in the Prime Standard of the Deutsche Börse (Frankfurt Stock Exchange). From March to September 2003, MediGene was a member of the TecDAX30 index. The Deutsche Börse reshuffled this stock market index during the third quarter of the year, and dropped the shares of MediGene AG from the TecDAX30 index effective September 22, 2003. The reason for exclusion from this index was the low valuation of our company in comparison to other technology companies. Valuation equals the number of outstanding shares multiplied by the stock price, and a number of technology companies which had not belonged to the TecDAX30 until then had improved their valuation. Re-entry into the TecDAX30 index is one of our top-priority goals. The composition of this index of the market is reshuffled every three months, and MediGene already met the share volume criteria in the December 2003 rankings published by the Deutsche Börse (rank 18). In market capitalization, MediGene ranked 39th. Re-entry into the TecDAX30 is possible with a ranking above 35th place.

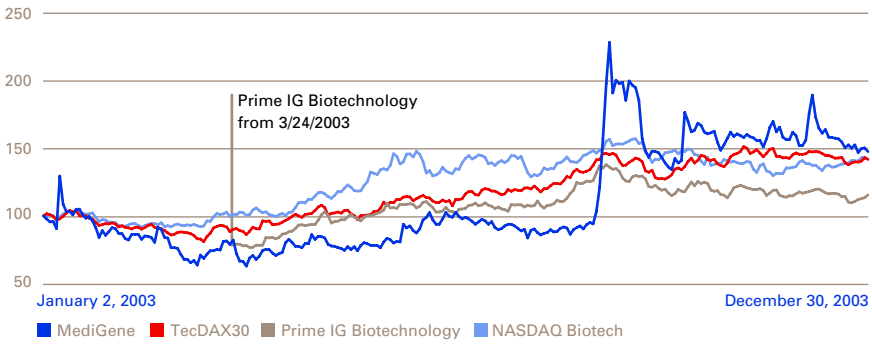
Changes in the shareholder structure

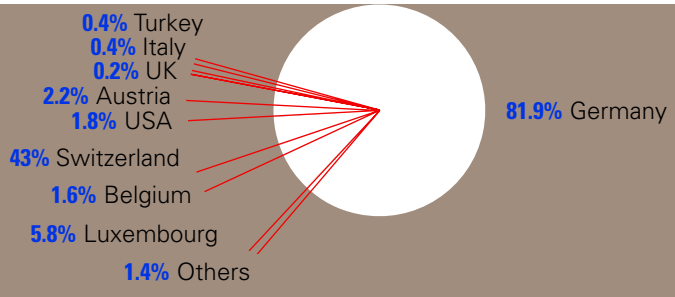
As in previous years, the share of institutional investors has not changed significantly, the percentage of private shareholders has grown slightly to 81.5% (2002: 78%). With the resignation of Prof Dr Michael Hallek (10/31/2003) and Dr Helmut Schühsler (12/31/2003) from the Supervisory Board, the number of shares held by the members of this body has declined from 10% to 7.5%.

Due to the approval of Eligard® and the friendly sentiment towards biotechnology shares globally, we expect a further increase in investor interest in 2004. As a re-

Share price 2003

(January 2, 2003 € 4.05 indexed to 100)





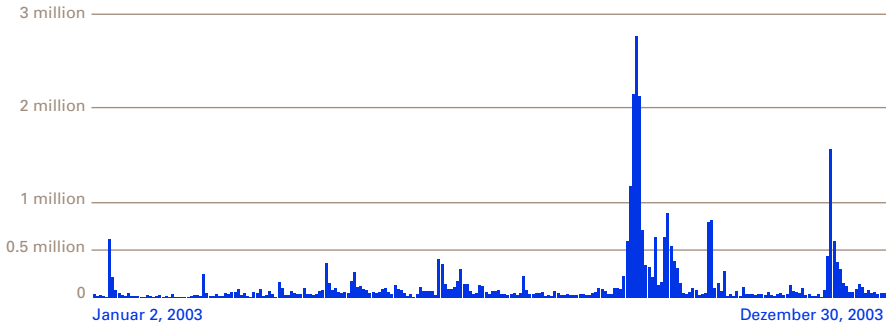
Shareholder structure by country*)

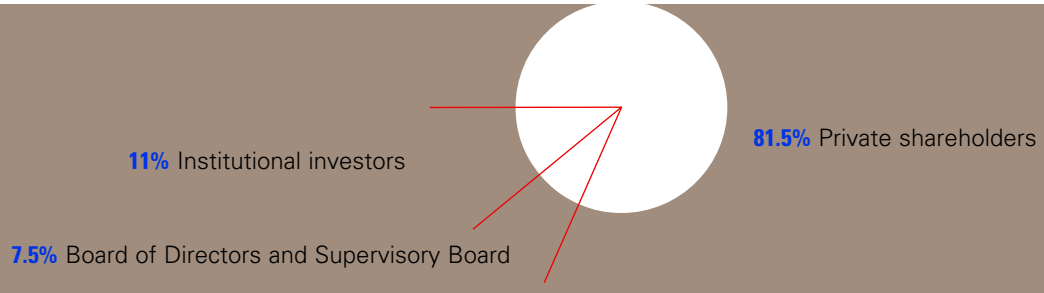
Key figures per share	2002	2003
52 weeks high €	24.89	9.23
52 weeks low €	2.71	2.55
Opening price €	19.9	4.05
Year end closing shares €	3.95	5.97
Mean share price of the year 2003 €	8.81	4.48
Number of shares	11,206,205	11,206,205
Average number of shares	11,204,990	11,206,205
Average market capitalization in million €	99	50,2
Average daily trading volume	71,073	115,357
Dividend per share €	0	0
Cash flow per share €	-3.4	-2.35
Equity per share €	5.3	2.61

sult of this, MediGene's management will continue its efforts in 2004 to win more institutional investors.

In terms of the geographic distribution of share ownership, the number of shares held outside Germany fell from 26% to 18% compared to the previous year. No investor held more than 5% of the company's share capital on the reporting date, the portion of freely floated shares to total capital (the free float) was 100%.

Volume
in million





*) As per 12/31/2003

Shareholder structure by investor type*)

Corporate Governance

Corporate governance refers to the system of responsible, value-oriented and transparent management and control of companies.

This system consists of several elements:

- clearly definded management principles and the responsibility for company organs that these involve,
- cooperation among these organs,
- open and transparent communication with the public and
- conscientious, reliable accounting and auditing.

MediGene AG is conscious of its accountability as a corporate body to its shareholders, staff and business associates. This is why the company committed itself once again in December 2003 to adhere to the fundamental recommendations and suggestions in the German Corporate Governance Codex, version dated May 21, 2003. For cases in which we have decided, after careful deliberation, not to adhere to individual recommendations in the Codex, we have explained such decisions in our Compliance Declaration as stipulated in § 161 of the German Stock Corporation Act (see p. 39f).

In addition to this, MediGene has also developed its own specific Corporate Governance Principles that, as part of our voluntary commitment, go above and beyond the legal provisions. In order to create maximum degree of transparency, we have posted these Principles together with our Compliance Declaration pursuant to § 161 of the German Stock Corporation Act on our website at www.medigene.de.

The MediGene AG Executive Board has also appointed a Corporate Governance Representative within the company to reports to the Executive Board and the Supervisory Board on amendments to and implementation of our Corporate Governance Principles at least once a year. This enables us to ensure a continuous further development of our Principles and surveillance of compliance with them.

Extracts from our Corporate Governance Principles:

Relations with its Shareholders

»MediGene AG respects the rights of shareholders and guarantees the exercise of these rights to the best of its ability within the statutory framework.

In particular, these rights include:

- free purchase and free sale of shares
- equal voting rights for each share (one share – one vote)
- participation in the general meeting and exercise of the right to vote
- appropriate satisfaction of information requirements
- a share in corporate profit...«.

Executive Board

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

Supervisory Board

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

Cooperation between the Executive Board and the Supervisory Board

»The Executive Board and the Supervisory Board cooperate closely to the benefit of the enterprise. The Chair of the Supervisory Board keeps in regular contact with the Executive Board, especially with its Chair. The Executive Board coordinates the enterprise's strategic alignment with the Supervisory Board and discusses with it at regular intervals the current state of strategy implementation, as well as risk management.

For transactions of fundamental importance, the Supervisory Board specifies provisions in the Terms of Reference for the Executive Board requiring the Supervisory Board's approval. Such transactions include decisions or measures that fundamentally change the asset, financial or earnings situation of the enterprise...«

Reporting

»MediGene informs shareholders and third parties regularly by means of Consolidated Financial Statements and by means of interim reports during the financial year. Group reporting (Consolidated Financial Statements and quarterly reports) is in accordance with the U.S. Generally Accepted Accounting Principles (GAAP), so it complies with internationally recognized accounting principles.

For corporate law purposes (calculation of dividend, shareholder protection), Annual Financial Statements are prepared according to national regulations (German Commercial Code), which also form the basis for taxation.

MediGene AG makes its Consolidated Financial Statements publicly available within 90 days of the end of the financial year, and interim reports within 45 days of the end of the reporting period.

In the Consolidated Financial Statements, MediGene provides specific details of:

- stock option and convertible bond schemes of the company,
- third party companies in which it has a shareholding that is not of minor importance for the enterprise (name and head office of the company, size of shareholding, amount of equity capital and performance in the last financial year),
- relationships with shareholders to be considered as ›related parties‹ pursuant to the applicable accounting regulations.«

Audit of Annual Financial Statements

»The Consolidated Financial Statements are examined by the auditor and by the Supervisory Board.

The audit of the Consolidated Financial Statements by the auditor elected by the General Meeting and commissioned by the Supervisory Board is conducted in accordance with the relevant audit regulations.

Prior to submitting a proposal for election, the Supervisory Board or, respectively, the Audit Committee of MediGene obtains a statement from the proposed auditor stating whether and, where applicable, what professional, financial and other relationships exist between the auditor and its executive bodies and head auditors on

the one hand, and the enterprise and the members of its executive bodies on the other hand, that could call the auditor's independence into question. This statement includes the extent to which other services were performed for the enterprise in the past financial year, especially in the field of consultancy, or are contracted for the following year.

The Supervisory Board agrees with the auditor that the Chair of the Supervisory Board or, respectively, of the Audit Committee, will be informed immediately of any grounds for disqualification or impartiality arising during the audit, unless such grounds are eliminated. It further arranges for the auditor to report without delay on all facts and events of importance for the tasks of the Supervisory Board that occur during performance of the audit.

The Supervisory Board further arranges for the auditor to inform it and/or note in the Auditor's report if, during the performance of the audit, the auditor comes across facts which show a misstatement by the Management Board and Supervisory Board of MediGene AG on the German Corporate Governance Code.

The Supervisory Board commissions the auditor to carry out the audit and concludes an agreement on the latter's fees.

The auditor takes part in the Supervisory Board's deliberations on the Annual Financial Statements and Consolidated Financial Statements and reports on the essential results of its audit.«

Communication with the Public

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

Extract from legal transactions requiring approval*)

The Executive Board, notwithstanding its management powers and duties, shall require the prior approval of the Supervisory Board for, among other things, the following business transactions:

- decisions or measures that fundamentally change the assets, financial or income position of the company;
- the conclusion and cancellation of significant patent, licensing, know-how and cooperation contracts and the disposal of industrial property rights that are of major significance for the company;
- the conclusion and cancellation of significant distribution contracts;
- all instances of recourse to loans, provided that these do not merely involve current commercial credit;
- all significant transactions with Executive Board members and related persons or undertakings;
- annual plans, particularly the budget plans for the subsequent fiscal year;
- the establishment and termination of companies or enterprises, the purchase and sale of participating interests in other companies, the conclusion, alteration and termination of company lease and management contracts and contracts between business enterprises;
- the establishment, acquisition, closure and sale of enterprises, parts of enterprises or branches.

*) This list is not comprehensive and merely provides an insight into the rules of procedure for the Executive Board of MediGene AG.

Declaration by the Management Board and Supervisory Board of MediGene AG pursuant to § 161 German Stock Corporation Act on the German Corporate Governance Code's Recommendations

I. Declaration regarding the past

Since the last declaration pursuant to § 161 German Stock Corporation Act as of December 2, 2002 until now, MediGene AG has fulfilled all recommendations of the German Corporate Governance Code (in the version as of November 7, 2002) with the following exceptions:

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 should be agreed. The Management Board and Supervisory Board of MediGene AG are of the opinion that the motivation and sense of responsibility with which members of the MediGene Management Board and Supervisory Board perform their tasks is fully assured even without a deductible of this kind.

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. The Management Board and Supervisory Board of MediGene AG see a specification of this kind as, for one, an inappropriate restriction of shareholders' right to elect the members of the Supervisory Board and, for another, as a marked restriction of the Supervisory Board in its choice of suitable Management Board members.

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 membership of Supervisory Board committees. The Management Board and Supervisory Board of MediGene AG are of the opinion that even without an arrangement of this kind a very high level of commitment of Supervisory Board members to committee work is taken for granted.

II. Declaration regarding the present and future

MediGene AG fulfils all recommendations of the German Corporate Governance Code (in the version as of May 21, 2003) with the following exceptions:

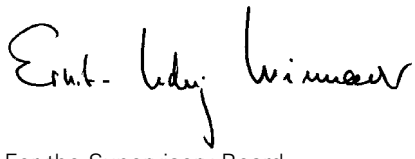
1. **Possibility of limitation (Cap) regarding variable long-term compensation components** The German Corporate Governance Codex recommends that for extraordinary, unforeseen developments regarding the variable long-term components of the Management Board compensation, a possibility of limitation (cap) shall be agreed for by the Supervisory Board. The Supervisory Board of MediGene AG is of the opinion that such agreement would result in an unacceptable level of uncertainty for the Management Board members and for the company, since it is not possible to determine in advance in which cases the criterion of an extraordinary, unforeseen development would be fulfilled.

2. **Deductible in the Case of D&O insurances/Age Limits for Management Board and Supervisory Board Members/Consideration of Committee Work in the Compensation of Members of the Supervisory Board** The recommendations of the German Corporate Governance Codex listed above under I, Sections 1. to 3., which have not been amended in the version of the Codex as of May 21, 2003, will not be fulfilled further on (see I. Sections 1. to 3.).

It is also pointed out for clarification that the current stock option plans and convertible bonds which were issued prior to the amendment of the Codex as of May 21, 2003, and in which the Management Board also participate, are not – contrary to the recommendations of the Codex version 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 Codex under the version as of May 21, 2003.

Martinsried, December 1, 2003

For the Management Board
Dr Peter Heinrich



For the Supervisory Board
Prof Dr Ernst-Ludwig Winnacker

Supervisory Board

Prof Dr Ernst-Ludwig Winnacker
from November 26, 1996
Chairman, President of the German Research Association
Membership of other Supervisory Boards:
- Bayer AG, Leverkusen
- EleGene AG, Martinsried
- Therascope AG, Heidelberg

Dr Helmut Schühsler
until December 31, 2003
Deputy Chairman,
Managing Partner of the Techno Venture Managment
Membership of other Supervisory Boards:
- Ascenion GmbH, Neuherberg
- Atomika Instruments GmbH, Oberschleißheim
- Garching Innovation GmbH, Munich
- GPC Biotech AG, Martinsried
- Ingenium Pharmaceuticals AG, Martinsried
- Intercell Biomedical Forschungs- und Entwicklungs AG, Austria
- Peptor Ltd., Israel
- selectX Inc., USA
- Sequenom Inc., USA
- VitaResc Biotech AG, Martinsried

Prof Dr Dr Ernst-Günter Afting
from November 26, 1996
Chief Executive Officer, GSF
Membership of other Supervisory Boards:
- Bio^{M} AG, Martinsried
- Enanta Pharmaceuticals, Inc., USA
- Intercell Biomedical Forschungs- und Entwicklungs AG, Austria
- Sequenom Inc., USA
- VitaResc Biotech AG, Munich
- Xerion Pharmaceuticals GmbH, Martinsried

Dr Pol Bamelis
from May 23, 2001
Former Management Board member of Bayer AG, Leverkusen
Membership of other Supervisory Boards:
- Agfa-Gevaert AG, Leverkusen
- Agfa-Gevaert N. V., Belgium
- Crop Design N. V., Belgium
- Evotec OAI AG, Hamburg
- N.V. Bekaert S.A., Belgium
- Oleon N.V., Belgium
- PolyTechnos (GP) II Ltd., Guernsey

Prof Dr Michael Hallek
until October 27, 2003
Co-founder
Chief Physician for Internal Medicine at the Großhadern Clinic of the University of Munich
Membership of other Supervisory Boards:
- Sireen AG, Munich

Prof Dr Norbert Riedel
from October 27, 2003
Senior Vice President, Chief Scientific Officer, Baxter International, Inc.
Membership of other Supervisory Boards:
- Genencor International, Inc., USA
- Genome Therapeutics Corp., USA
- Nanomateria, Inc., USA

Michael Tarnow
from May 23, 2001
Consultant of the Biopharmaceutical Industry, Boston, USA
Membership of other Supervisory Boards:
- AXCAN Pharma Inc., Canada
- Caprion Pharmaceuticals, Inc., Canada
- Ferghana Partners, UK
- Nanopharma Inc., USA
- Paladin Labs, Inc., Canada
- Tao Biosciences, USA
- Xenon Genetics, Inc., Canada

The Scientific Advisory Board

An international team of renowned and highly qualified experts supplements the classic organs of the corporate management.

A top-class advisory board staffed with experienced, internationally leading scientists meets at least once a year to discuss our research and development programs. The members of the board make recommendations and suggestive on strategically relevant developments and represent a kind of scientific conscience to the company.

Members of the Scientific Advisory Board:

Prof Dr Brian Seed,
Professor of Molecular Genetics at the Harvard Medical School and member of the Department of Molecular Biology at the Massachusetts General Hospital in Boston, Mass., USA Professor Seed studied mathematics and biology at the California Institute of Technology in Pasadena and is considered to be a leading immunologist and molecular biologist. He has developed new techniques in molecular biology with a view to identifying transmission routes for biological signals within the immune system. He is a co-founder of three U.S. biotech corporations and a member of the scientific advisory council of seven firms in the United States and Europe, including Aventis.

Prof Dr Lutz Gissmann,
Head of the Department of Genome Modification and Cancer Origination at the German Cancer Research Center Professor Gissmann headed research and development at MediGene AG from 1997 to 1999. From 1993 to 1996 he was head of viral oncology at the department of gynecology and obstetrics at Chicago's Loyola University. He is considered to be one of the leading experts in HPV research. Prof Gissmann has received several awards for his work.

Prof Dr Robert Kotin,
Head of Molecular Hematology at the National Heart, Lung and Blood Institute of the National Institute of Health (NIH) in Washington, D.C. Professor Kotin's work on Adeno-Associated Viruses (AAV) form the basis for the use of AAV in genetherapy. He is considered to be a leading expert in the field of AAV virology and genetherapy.

Prof Dr Cornelis J. M. Melief,
Professor of Internal Medicine and Head of the Department of Immunohematology and Blood Banks at Leiden University Hospital in the Netherlands Professor Melief's research is focused on tumor immunology and immunotherapy. He is a member of the Royal Netherlands Academy of Sciences, an Advisory Body for Universities and the Dutch government.

Prof Dr Bernard Roizman,
Distinguished Service Professor at the Departments of Molecular Genetics and Cell Biology and the Biochemistry and Molecular Biology of the University of Chicago Professor Roizman is considered to be a leading international expert on herpes simplex viruses, a subject on which he has worked for more than 40 years. He has won many awards for his work and is a member of the National Academy of Sciences, USA and the American Academy of Arts and Sciences.

Prof Dr Robert Martuza,
Professor of Neurosurgery at the Harvard Medical School and Chief of the Neurosurgery Service of the Massachusetts General Hospital in Boston Professor Martuza's scientific interest is focused on the treatment of various forms of brain tumors. He plays a leading role in the clinical development of oncolytic Herpes Simplex technology and is the author of numerous scientific publications.

Financial information

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Report of the Executive Management Board

The preparation of these Consolidated Financial Statements and the information contained in the MD&A are the responsibility of the Executive Board of MediGene AG. The consolidated accounts are drawn up on the basis of U.S. 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, and in particular the Auditing Committee of 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. 100 of this Annual report).

Martinsried, March 2004

MediGene AG
The Executive Management Board

Dr Peter Heinrich
Chief Executive Officer

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, 2003, and the related consolidated statement of income, statement of changes in equity and statement of cash flows as well as the notes (consolidated finanical 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, 2003 and of its result of operations and its cash flow for the fiscal year from January 1 to December 31, 2003, 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, 2003 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, 2003 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, March 5, 2004

Reitmeier
Auditor

McMahon
Auditor

PricewaterhouseCoopers GmbH
Wirtschaftsprüfungsgesellschaft

Management's Discussion and Analysis (MD&A)

as per December 31, 2003 – in accordance with US-GAAP

- **Cash reserves of 21.4 million € for the continued financing of Research & Development**
- **Income from operations from cooperation agreements with pharmaceutical companies: 1.7 million €**
- **Cost-cutting measures reduce R&D expenses by 18% to 21.8 million €**
- **Average monthly net cash burn rate fell by 33% to 2.2 million €**
- **Eligard® (formerly known as Leuprogel®) is the first drug approved from a German biotechnology company**
- **Partnership with pharmaceutical company Yamanouchi signed**

Framework data

Signs of a global economic recovery

In 2003, global economic development remained far behind expectations, not lastly due to the Iraq war. By mid-year, however, indicators were increasingly pointing to growth in the economies of both the U.S. and Japan. In Europe, a significant improvement in sentiment was also seen, and by the same token there are now first signs of a notable economic recovery. Although real growth in gross domestic product in the U.S. was 2.5% (2002: 2.4%) in 2003 despite an increase in unemployment, economic weakness continued in Germany and in the euro area. In Europe a significant economic upswing is expected for 2004.

In spite of the relatively better economic development in the U.S., the increase in the U.S. trade deficit caused a significant fall in the value of the U.S. currency in the second half of the year as compared to the euro. The reference rate of the euro rose by 17% from 1.0819 to 1.2630 US$, and the upward trend in the common currency continued in early 2004.

The bottom of money market rates has been reached

Inflation fell in the various economic areas. Experts expect that the lows in money market interest rates during this economic cycle have been reached. Due to the recovery in the economy, stable or slightly higher interest rates are expected by the end of 2004.

Much improved sentiment on the capital markets

Stock markets recovered greatly during 2003. This trend is expected to continue in 2004. Further rises in corporate profits and a jump-start to the economy could be additional positive impulses for world stock markets.

The growth story in the biopharmaceutical industry is still intact

It has primarily been biotechnology shares that benefited from the improved sentiment of the stock markets during the second half of the year. Special demand was seen for the shares of drug developers: In 2003 number of biopharmaceutical companies met and even at times exceeded high expectations during the year with positive product news and approvals. Particularly in the field of cancer, reports were of highly innovative products which open up new therapeutic opportunities for diseases which have, until now, only been insufficiently treatable. Among these are antibodies like Avastin but also novel agents such as Velcade. At the end of 2003, MediGene became the first German biotech company to succeed in obtaining the approval of a product.

All in all, the excellent news flow, together with the growth perspectives resulting from it, also rekindled interest in biotechnology stocks in Germany. The stock price for many biotech companies quoted on the German Stock Exchange rose to many times their original value in a brief time, among them MediGene AG.

Higher stock prices in biotechnology improved corporate financing

The global improvement in capital market sentiment also had a positive effect on the financial position of biotechnology companies. Many companies in the U.S. have used this fact to improve their own liquidity position. In Europe, a similar development, albeit less pronounced, can also be seen. For the first time, financing rounds are being held again. Such funds primarily serve to finance promising new projects.

Consolidation phase in the German biotech industry expected for 2004

In line with 2002 expectations, the worldwide consolidation in the industry continued during the year just ended. Besides numerous mergers and acquisitions reported from the U.S. and Europe, many companies have also taken steps to restructure their operations. In spite of the general improvement in conditions for biopharmaceutical companies resulting from this, experts are still expecting continued consolidation for 2004. This will particularly affect the German biotech industry. The possible winners in this situation are companies which have already successfully restructured and have a promising position with products on the market.

Favorable conditions for partnerships among pharmaceutical and biotechnology companies

The pharmaceutical industry needs innovative technologies and products to maintain their historical growth rates over the medium and long term. The industry is particularly lacking in promising drugs in early and later phases of development that work on new and different principals of effect. This shortcoming within the pharmaceutical industry offers the innovative biotech industry new opportunities for cooperation.

Whereas fewer and fewer partnerships between pharmaceutical and biotech companies have been concluded over the past few years, this trend turned around in 2003. The willingness in the pharmaceutical industry and among large biotechnology companies to invest in innovative products and technologies has increased considerably. This trend is expected to continue in 2004. With its Polyphenon® E Ointment and its oncolytic herpes simplex virus technology, MediGene has outstanding opportunities for concluding further strategic partnerships.

Group overview

MediGene focuses on drugs to fight tumor diseases

MediGene tightened its corporate activities during 2003 and continued to direct its efforts towards developing drugs for treating tumor diseases. In the wake of this restructuring, far-reaching cost-cutting and savings measures were taken. At present, our activities encompass pre-clinical and clinical development, manufacturing process development and as well the commercialization of drugs.

Over the short term, the development of MediGene's revenues will depend primarily on the sales of its drug Eligard® (formerly known as Leuprogel®) in Germany and its approval in other European countries. In coming years, we expect revenues from product sales of Eligard® to continue to gain significance for MediGene. To this end, successful marketing by our partner Yamanouchi Pharmaceutical Co., Ltd., which will be distributing Eligard® in Europe, is decisive. Above and beyond the marketing and approval of Eligard®, the conclusion of new strategic partnerships for further candidate drugs – Polyphenon® E Ointment and projects in HSV technology – is of crucial importance. Positive results of the clinical trials in both programs are the basic prerequisite for this.

Cost-cutting steps implemented

As part of focusing its activities, MediGene's management initiated three major steps in 2003 to lower costs and save on future expenses. Besides the downsizing of the U.S. subsidiary, MediGene, Inc., carried out in 2003, the spin-off of the cardiology research program completed in March 2003 will also lead to cost savings. The third step MediGene took during the year was to halt the clinical development of the drug candidate G207 to treat brain tumors. Any further development of G207 to planned readiness for approval would have resulted in costs of around 40 million €. The project is currently under review. All the measures taken throughout 2003 already had positive effects during the year. Starting in fiscal 2004, annual savings of up to 9 million € can be expected.

Spin-off of the cardiology unit

In March 2003, MediGene announced that it was spinning off its cardiology research program. Together with the Bio^{M} AG holding company, MediGene established LARNAX GmbH. The core of LARNAX was MediGene's entire cardiology research program with activities aimed at discovering and developing new agents to treat cardiac and metabolic disorders. MediGene last held a 67% stake in LARNAX. LARNAX discontinued its business activities as of December 31, 2003. MediGene will thus now be reporting the R&D activities reported in previous years in the cardiology segment as »Discontinued operations.« Since March 2003, LARNAX has been treated during the year as a »Variable interest entity« pursuant to FIN 46 due to a loan granted to it and included in the consolidated entity.

MediGene Group receives approval to market its first drug, Eligard® (formerly known as Leuprogel®)

MediGene's first drug, Eligard® (formerly: Leuprogel®) to treat advanced prostate cancer was approved for marketing in Germany by the Federal German Institute for Pharmaceuticals and Medical Products (in German: Bundesinstitut für Arzneimittel und Medizinprodukte, acronym BfArM). The approval of the one-month formulation was granted in December 2003, approval for the three-month sustained-release formula followed in January 2004. MediGene had licensed the European marketing rights of the one- and three-month versions of Eligard® from the U.S. company Atrix Laboratories, Inc. in April 2001, and taken them through the approval process in Germany. In preparation for the approval procedure, the experimental clinical data provided by Atrix were edited and processed in order to meet the requirements relevant to approval by the German authorities. In addition to this, further pre-clinical trials were carried out, such as pharmacological and toxicological studies, since the demands made by the European authorities on applications for approval significantly vary from those made by the U.S. FDA.

In January 2004, MediGene concluded a Europe-wide partnership with the Japanese pharmaceutical company Yamanouchi Pharmaceutical Co., Ltd. (Yamanouchi) to market Eligard®. MediGene is receiving an advance of 4 million € as well as milestone payments totaling an additional 19.5 million €. MediGene will also be receiving royalties on product sales. This means that, starting in 2004, MediGene will, for the first time, be benefiting directly from sales of a medical product. The total amount of these revenues will depend primarily on the marketing success attained by our partner Yamanouchi.

Cooperation and licensing agreements with Schering and Aventis

For 2003, we are reporting on other revenues from operations only when they stem primarily from our cooperation agreements with Schering (CVLP tumor vaccine, HPV-indications segment) and Aventis (rAAV tumor vaccine, oncology segment).

The focus is on R&D activities

During the year under review, our business activities were concentrated on R&D for innovative candidate drugs und technologies in the field of tumor diseases. Our present activities are intended to build a foundation for subsequent drug sales.

MediGene obtained income from its strategic alliances with Schering and Aventis in the segments HPV-indications and oncology during the period covered by this report. This included milestone payments and reimbursements for research and development costs, but also licensing revenues which have been booked as »other operating income.« The amount of R&D payments made by the partners depends on the amount of costs MediGene incurs for each of the projects it works on with the partner in question, i.e. the greater the costs, the higher the »other operating income« will lie.

Partnership with Aventis to develop a vaccine against skin cancer

In 2000, we concluded a partnership with the pharmaceutical company Aventis to develop a therapeutic vaccine to treat malignant melanoma. The term of the contract is open. The agreement states that Aventis shall be granted an exclusive license to develop and market the tumor vaccine. The total value of the agreement can add up to 37 million €, including milestone payments and the mutually agreed R&D budget that MediGene is jointly financing until confirmation of the therapy concept. MediGene will also receive a small percentage in royalties on all product sales. At present, the therapeutic concept is being studied in a clinical phase 1/2 trial. Both companies are taking part in conducting this trial.

Development of the CVLP tumor vaccine completed

In March 2003, MediGene announced a halt to the further development of the CVLP tumor vaccine to treat cervical cancer it was working on together with Schering. A clinical phase 1/2 trial on the vaccine concluded prior to the announcement had delivered positive data on tolerability

and indicators of effectiveness. The trial results did not, however, meet the criteria defined prior to the study, something which would have been necessary to justify continuing the project under aspects of economic viability. For MediGene, the discontinuation of its cooperation with Schering meant lower costs but also, by the same token, lower income in 2003. The agreement stipulated that MediGene was responsible for research and the pre-clinical trials. The clinical phase 1/2 trial was carried out by both partners together, subsequent clinical trials as well as approval and marketing were the duty of Schering. In return, Schering was granted the exclusive global license.

Statement of accounts

Explanations on the annual balance sheets for 2002 and 2003 can be found in the notes (see p. 76).

Income statement (abbreviated)

in T€	2002	2003	Change
Other operating income	3,425	1,742	-49%
R&D expenses	26,721	21,825	-18%
Business development and general administration	7,177	7,926	10%
EBITDA	**-30,473**	**-28,009**	**-8%**
Depreciation on intangible and fixed assets	1,085	1,031	-5%
EBITA	**-31,558**	**-29,040**	**-8%**
EBIT	**-31,558**	**-29,040**	**-8%**
Loss from continued operations	**31,558**	**29,040**	**-8%**
Minority interest in discontinued operations	0	261	–
Result from discontinued operations	-8,639	-2,988	-65%
Net loss	**-38,870**	**-31,060**	**-20%**

Other operating income declined

Income from strategic alliances with Aventis and Schering

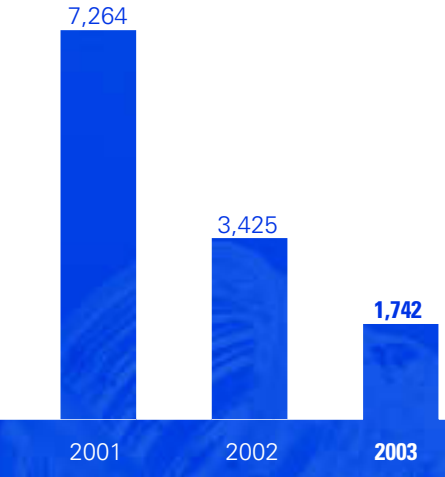
Other operating income booked by MediGene in the year under review fell by 49% to 1,742 T€ (2002: 3,425 T€). This decline is explained by the reduction in income within the segments of HPV-indications and oncology (see segment reporting). These revenues are made up of reimbursements for research and development costs as well as licensing income from the partners Schering (CVLP vaccine project, HPV-indications segment) and Aventis (rAAV tumor vaccine project, oncology segment) and have been booked accordingly in those segments. Due to the status of the joint

Other operating income

in T€	2002	2003	Change
HPV-indications	1,713	703	-59%
Oncology	1,640	944	-42%
Intersegment	72	95	32%
Total from continued operations	**3,425**	**1,742**	**-49%**
Result from discontinued operations	112	153	37%
Total	**3,537**	**1,895**	**-46%**

Other operating income

in T€



projects, MediGene had lower R&D expenses in the period under review and thus fewer costs to be reimbursed by the partners.

The revenues from operations are mainly based on activities at the parent company and were made in Germany.

R&D expenses lowered

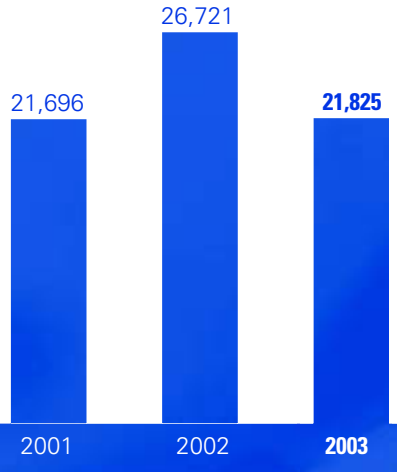
Due to the restructuring steps taken in the course of the year and due to changes within the product portfolio, total R&D expenses in continuing operations fell by 18% to 21,825 T€ (2002: 26,721 T€). The main reason for this are the much lower expenses in the oncology segment.

R&D expenses by segment

in T€	2002	2003	Change
HPV-indications	8,868	8,982	1%
Oncology	14,344	8,621	-40%
Intersegment	3,509	4,222	20%
Total from continued operations	**26,721**	**21,825**	**-18%**
Discontinued operations	8,524	2,901	-66%
Total	**35,245**	**24,726**	**-30%**

R&D expenses

in T€



Intersegment includes all R&D expenses not clearly attributable to any other segment. The cost increase of 20% within this segment is due among other factors to the expansion in the areas of pharmacology and toxicology. The work areas of pharmacology and toxicology encompass research on medicinal effects in pre-clinical and clinical trials. These trials are an essential part of later applications for marketing approval.

Increase in SG&A costs

Total costs for selling – consisting of costs for business development and marketing – and for general administration in continuing operations grew slightly by 10% to 7,926 T€ (2002: 7,177 T€). This includes one-time restructuring expenses amounting to ca. 1,000 T€ which were incurred by shrinking the U.S. location.

The two areas of business development and marketing serve the commercialization of our technologies and products. The area of business development also encompasses licensing of products and technologies and also patent protection for our own products and technologies. In the period under review, the rights protecting our intellectual property were expanded through further patent applications, newly granted patents and additionally acquired licenses (see p. 55, Intellectual property). The protection of technologies and products is a basic prerequisite for MediGene's future success.

The operational costs posted in the profit and loss statements include expenses for preparative steps to market the drug Eligard®. These comprise participation in urology specialist congresses and the organization of meetings to serve to present the product to relevant medical professionals.

EBITDA loss decreases

The loss prior to interest, taxes and depreciation (EBITDA) fell in continued operations from 30,473 T€ (2002) to 28,009 T€. This decline was due to the lower R&D expenses in the oncology segment.

EBITDA by segment

in T€	2002	2003	Change
HPV-indications	-7,176	-8,296	-16%
Oncology	-12,926	-7,860	39%
Intersegment	-10,371	-11,852	-14%
Total from continued operations	**-30,473**	**-28,009**	**8%**
Discontinued operations	-8,412	-2,748	67%
Total	**-38,885**	**-30,757**	**21%**

Lower depreciations

Depreciations on continuing operations fell by 5% to 1,031 T€. Depreciations were booked in the segments oncology (498 T€; +5%), Intersegment (503 T€; +52%) and HPV-indications (152 T€; -45%) and attributed to fixed assets and immaterial assets.

Depreciation

in T€	2002	2003	Change
of goodwill	0	0	–
of fixed asset incl. intangibles	804	760	-5%
of capitalized leased items	281	271	-4%
Total from continued operations	**1,085**	**1,031**	**-5%**
Discontinued operations	227	240	6%
Total	**1,312**	**1,271**	**-3%**

The impairment test did not lead to any change in goodwill in 2003.

EBIT improved

In continuing operations, the loss prior to interest and taxes (EBIT) fell from 31,558 T€ to 29,040 T€.

EBIT by segments

in T€	2002	2003	Change
HPV-indications	-7,453	-8,448	-13%
Oncology	-13,401	-8,359	38%
Intersegment	-10,704	-12,233	-14%
Total from continued operations	**-31,558**	**-29,040**	**8%**
Discontinued operations	-8,639	-2,988	65%
Total	**-40,197**	**-32,028**	**20%**

Lower financial result

In comparison to the prior year, financial result fell by 47% to 707 T€. The decrease in interest receipts resulted essentially from a much lower amount invested. Interest costs were incurred through the acquisition of fixed assets on leasing. Due to a lower level of cash reserves in U.S. dollars, currency fluctuations to be booked fell consistently.

Financial result

in T€	2002	2003	Change
Interest income	2,179	778	-64%
Interest expense	98	77	-21%
Disposal of investments	0	0	–
Foreign currency exchange gains/losses	-753	6	-101%
Total	**1,328**	**707**	**-47%**

Annual loss decreased

In comparison to the prior year period, MediGene was able to lower its annual loss from continuing operations by 6% to 28,333 T€. Including discontinued operations and minority shareholdings, the loss fell even more sharply by 20% to 31,060 T€. This fall was primarily caused by lower R&D expenses resulting from our restructuring measures in the segments of cardiology and oncology.

The annual results for MediGene AG based on the German Commercial Code (acronym: HGB) were -22,591 T€ (2002: -25,562 T€).

Reduced loss per share

The net loss per share fell by 6% in 2003 from 2.70 € (weighted average number of shares of 11,204,990) to 2.53 € (weighted average number of shares of 11,206,205). The improvement in results per share reflects the first successes achieved in the cost-cutting and savings initiated during the year. Discontinued operations are not included in this figure. If they were included, however, the loss per share fell by 20% from 3.47 € to 2.77 €.

The net loss when completely diluted matched the actual loss as per date of this report as the conversion of equivalents to common stock counteracts any effect from such dilution.

Segment reports

During the 2003 period under review, MediGene's business activities were directed towards the oncology and HPV-indications segments (see p. 92f – »Definition of segments«) of the drugs market. The activities in the cardiology segment were spun off from MediGene AG effective March 31, 2003 and are reported as discontinued operations.

In the intersegment, positions are listed which are not clearly attributable to any one segment. These include, among others, the areas of pharmacology, toxicology, clinical project management and quality assurance.

The following developments were posted in the oncology segment in 2003: At year's end, MediGene received marketing approval for the one-month sustained release formulation of the drug Eligard® in Germany.

In June, MediGene initiated a move of the research activities at its U.S. subsidiary to its headquarters in Martinsried as part of the steps it took to reduce R&D expenses. By year's end, the number of employees working at the U.S. subsidiary had been cut back to 20, in the first half of 2004, this number will be further reduced to a total of ca. 10 employees. The U.S. location of MediGene, Inc. will remain with its activities the departments »Clinical development« and »Regulatory affairs.« Development of the candidate drug G207 is under review since August 2003. From 2004 on, annual cost cuts of around 5 million € should be implemented in the oncology segment.

In the HPV-indications segment, a clinical phase 3 trial for Polyphenon® E Ointment has been ongoing in Europe since the third quarter of 2002. The ointment has been developed to treat benign genital tumors caused by HPV infection. In May, the planned number of 480 patients in the first part of the trial had been recruited. A second part of the phase 3 trial began in the third quarter of 2003. In this trial, which will be focusing on the U.S. and Latin America, the number of 480 patients had been recruited by February 2004 as planned. The clinical development of the CVLP tumor vaccine being carried out together with Schering was discontinued in the first half of 2003.

On March 31, 2003, MediGene completed the spin-off of its cardiology research program. LARNAX GmbH, which resulted from this spin-off, was consolidated due to a loan granted during the year as per April 1, 2003 as a »Variable interest entity« in the cardiology segment. At the end of December, MediGene held a 67% stake in LARNAX GmbH. The operative business activities of LARNAX were discontinued as per December 31, 2003. Since March 2003, LARNAX has been treated during the year as a »Variable interest entity« pursuant to FIN 46 due to a loan granted to it and included in the consolidated entity. In this report, the MediGene cardiology research program linked to it is reported under »Discontinued operations.«

HPV-indications

The HPV-indications segment includes the CVLP technology and the clinical development projects on Polyphenon® E Ointment and the CVLP tumor vaccine. The other operating income in the HPV-indications segment arises from the strategic alliance with Schering. The subject of the cooperation agreement was the joint development of a tumor vaccine to treat cervical cancer and its precursors. The project was discontinued as per June 30, 2003.

HPV-indications

in T€	2002	2003	Change
Other operating income	1,713	703	-59%
Selling expenses	21	17	-19%
R&D expenses	8,868	8,982	1%
EBITDA	**-7,176**	**-8,296**	**-16%**
Depreciation	277	152	-45%
EBIT	**-7,453**	**-8,448**	**-13%**

Other operating income
HPV-indications

in T€	2002	2003	Change
R&D payments received from partners	1,609	663	-59%
Milestone and license fee payments	0	0	–
Research grants	0	40	–
Other revenue	104	0	–
Total	**1,713**	**703**	**-59%**

R&D expenses in the HPV-indications segment remained virtually unchanged during the period under review. In total, the increase in costs resulting from the final Polyphenon® E trials slightly overcompensated for the savings linked to the end of the CVLP project.

Polyphenon® E Ointment has been developed to treat benign tumors of the genital tract, so-called genital warts. The ointment is administered to patients in three different dosages (10%, 15% and placebo) three times daily for up to 16 weeks. The treatment is followed by a twelve-week follow-up period.

A total of ca. 1,000 patients were recruited for the phase 3 trial relevant for marketing authorization, which is carried out in two portions, namely in Europe and South Africa, and in North and South America, respectively. To obtain informative statements, the trial is randomized and double blinded. This means that the patients are allotted randomly to the various different treatment groupings, and that both patients and physicians involved are not informed if placebo or drug is administered to the patient, in order to ensure an impartial evaluation. The criteria for the proof of efficacy and tolerability of the Ointment that apply to the design of both parts of the trial have been predetermined by the positive results obtained in a phase 2/3 trial that was completed in December 2001. To obtain market authorization for the ointment in the USA and Europe, a positive overall result of both parts of the trial is required. The results of the part of the trial carried out in Europe are expected by the end of the first quarter of 2004, and the results of the second part of the trial should be available by the end of the year.

The results of the first clinical phase 1/2 trial on the CVLP tumor vaccine to treat cervical cancer and its precursors did not fulfill the criteria required to continue development. The joint project with Schering was thus terminated as per June 30, 2003.

Oncology

In the oncology segment, MediGene's activities are reported for the two technologies of oncolytic herpes simplex viruses (HSV) and recombinant adeno-associated viruses (rAAV) as well as for the drug candidates Eligard®, G207, NV1020 and the rAAV tumor vaccine.

In this segment, there is other revenue from operations as part of the joint project with Aventis. In this project, a tumor vaccine to treat so-called malignant melanoma is developed The vaccine is presently in phase 1/2 clinical trials, the results of which are expected for mid-2004.

Oncology

in T€	2002	2003	Change
Other operating income	1,640	944	-42%
Selling expenses	222	183	-18%
R&D expenses	14,344	8,621	-40%
EBITDA	**-12,926**	**-7,860**	**39%**
Depreciation	476	498	5%
EBIT	**-13,401**	**-8,359**	**38%**

Other operating income
Oncology

in T€	2002	2003	Change
R&D payments from partners	1,455	811	-44%
Milestone and license fee payments	102	102	0%
Research grants	0	0	–
Other revenue	83	31	-63%
Total	**1,640**	**944**	**-42%**

The R&D expenses in the oncology segment fell by 40% in 2003. Both the downsizing of our U.S. location and changes in the status of various development projects have contributed to this. In addition, the lower value of the U.S. dollar compared to the euro led to a reduction in the costs incurred at our U.S. site and thus the costs converted into our report currency.

In June 2003, MediGene initiated the relocation of the research activities of the U.S. subsidiary MediGene, Inc. to Germany. The U.S. location of MediGene, Inc. will remain with the departments »Clinical Development« and »Regulatory affairs.« In the wake of this move, the number of employees working at the U.S. location fell to 20 at year's end.

No clinical trials were carried out for NV1020 in 2003, although in the first nine months of 2002 a clinical phase 1 trial for this candidate drug was still running. At present, we are preparing a new clinical trial for NV1020 expected to begin in mid-2004 at the earliest. Furthermore, the development of G207 is under review as part of our cost-cutting measures led to further savings. G207 has been developed by MediGene to treat malignant brain tumors. The further development of this project should not continue without external financing.

Management expects to implement annual cost cuts in the oncology segment amounting to 5 million € after all measures have been completed.

In December 2003, MediGene received marketing approval for the one-month sustained release formula of Eligard® in Germany, the approval for the three-month version followed in January 2004. To market Eligard®, MediGene concluded a marketing partnership with the Japanese pharmaceuticals company Yamanouchi in early 2004. In April 2001, MediGene had acquired the European marketing rights for Eligard® from the U.S. biotechnology company Atrix Laboratories, Inc. Eligard® is already approved in the U.S. and is marketed there by Atrix's U.S. marketing partner. On the basis of trial data from Atrix, MediGene submitted the application for the marketing approval for the one-month and the three-month form to the European authorities.

Discontinued operations

Discontinued operations include the cardiology segment posted during the interim period under review. In the cardiology segment, MediGene was researching the causes for cardiac diseases and identifying targets for developing new drugs to treat such diseases. On March 31, 2003, MediGene established LARNAX GmbH together with the seed financing company Bio^{M} AG. The core of this new company was MediGene's cardiology research program. Since March 2003, LARNAX has been treated during the year as a »Variable interest entity« pursuant to FIN 46 due to a loan granted to it and included in the consolidated entity. As per September 30, MediGene held a 67% stake in the company. LARNAX GmbH discontinued operations on December 31, 2003.

Discontinued operations

in T€	2002	2003	Change
Other operating income	112	153	37%
Selling expenses	0	0	–
R&D expenses	8,524	2,901	-66%
EBITDA	**-8,412**	**-2,748**	**67%**
Depreciation	227	240	6%
EBIT	**-8,639**	**-2,988**	**65%**

Other operating income

Discontinued operations

in T€	2002	2003	Change
R&D payments from partners	0	0	–
Milestone and license fee payments	0	0	–
Research grants	106	148	40%
Other revenue	6	5	-17%
Gesamt	**112**	**153**	**37%**

Other operating income in this area are public funds for basic research.

Intellectual property

Patents granted or allowed

	HPV-indications	Oncology
Germany	1	9
USA	6	26

Patents pending

	HPV-indications	Oncology
Germany	5	9
USA	12	28
International	7	33

The development of MediGene's patent portfolio reflects the company's focus on the field of tumor drugs. In the HPV-indications and oncology segments, the patent position improved in comparison to the same prior period. The patent portfolio was streamlined in the area of HPV-indications, due to the discontinuation of the development of the CVLP tumor vaccine and the settlement reached in early 2003 in the lawsuit with Loyola University in Chicago and MedImmune, Inc. In the settlement, several patents were surrendered and certain property rights to the technology for chimeric virus-similar particles (CVLP) were transferred to Loyola (HPV-indications: Germany -3, USA -2). The development of the CVLP tumor vaccine was halted in June 2003 (see Segment Reporting: HPV-indications). MediGene possesses patents to protect parts of the CVLP technology which are unaffected by this. In addition, the company has a number of patents for further therapeutic and diagnostic applications in the area of cervical cancer.

Investments

Fixed asset investments decline

Investments in the year under report fell by 67%. Investments in fixed assets including software were 235 T€ (2002: 721 T€) and primarily served the acquisition of lab equipment and informational technology. Of this sum, 54% were carried out in a liquidity saving manner by means of so-called capital leasing contracts.

Of this total, 12% of the fixed asset investments were attributable to MediGene, Inc.

Of the 235 T€, 38 T€ (-84%) were attributable to the oncology segment and 195 T€ (-56%) to the intersegment. In the HPV-indications segment, on the other hand, no investments were made (2002: 40 T€). The total investment amount of 235 T€ also includes investments made in discontinued operations amounting to 1 T€.

The investments booked in the intersegment came from the expansion of our informational technology infrastructure and from the units for marketing and quality assurance. The total amount of investment was distributed among many different pieces of plant and equipment. Notable individual investments were not made.

Assets positions

Cash reserves of 21.4 million €, equity ratio at 76%

In comparison to the prior year, the balance sheet came to 38,367 T€, 43% less than the 67,079 T€ on the cut-off date December 31, 2002. This move in the balance sheet total is primarily the result of the use of company equity. The company's equity ratio fell in 2003 from 89% to 76%, cash reserves amounted to 21,444 T€ on December 31, 2003.

Total fixed assets – not including goodwill and financial assets – fell by 41% from 3,821 T€ to 2,265 T€. This reflects the decrease in fixed assets of 40% to 2,189 T€ and the reduction in immaterial assets by 44% to 76 T€. The considerable fall in fixed asset levels is primarily traceable to the downsizing of the U.S. subsidiary. At the same time, the conversion of some of the fixed assets from U.S. dollars to euros led to a reduction of 202 T€. The reduction in immaterial assets is the result of scheduled depreciation and currency effects.

The book value of capitalized leased assets as a portion of tangible assets as per December 31, 2003 fell by 42% from 944 T€ to 552 T€. This reduction was caused by expired leasing contracts and the transfer of the leased objects to fixed assets linked to this, but also the depreciation of capitalized leased assets.

On the cut-off date of December 31, 2003, the impairment test did not lead to any change in the value of goodwill, which amounted to 9,226 T€. Goodwill was capitalized as a result of the acquisition of the subsidiary MediGene, Inc. (formerly NeuroVir Therapeutics) and concerned the valuation of the two projects G207 and NV1020. The value assumed for the two projects remains unchanged and exceeded goodwill.

Long-term assets are primarily the shares of the U.S. company Atrix Laboratories, Inc. acquired under the licensing agreement for Eligard®. Due to the improved situation on the stock markets, the value of the Atrix shares held by MediGene on the cut-off date rose 29% to 4,452 T€ (2002: 3,443 T€). This valuation is based on the currency rate on the cut-off date of 1 € to 1.2630 US$.

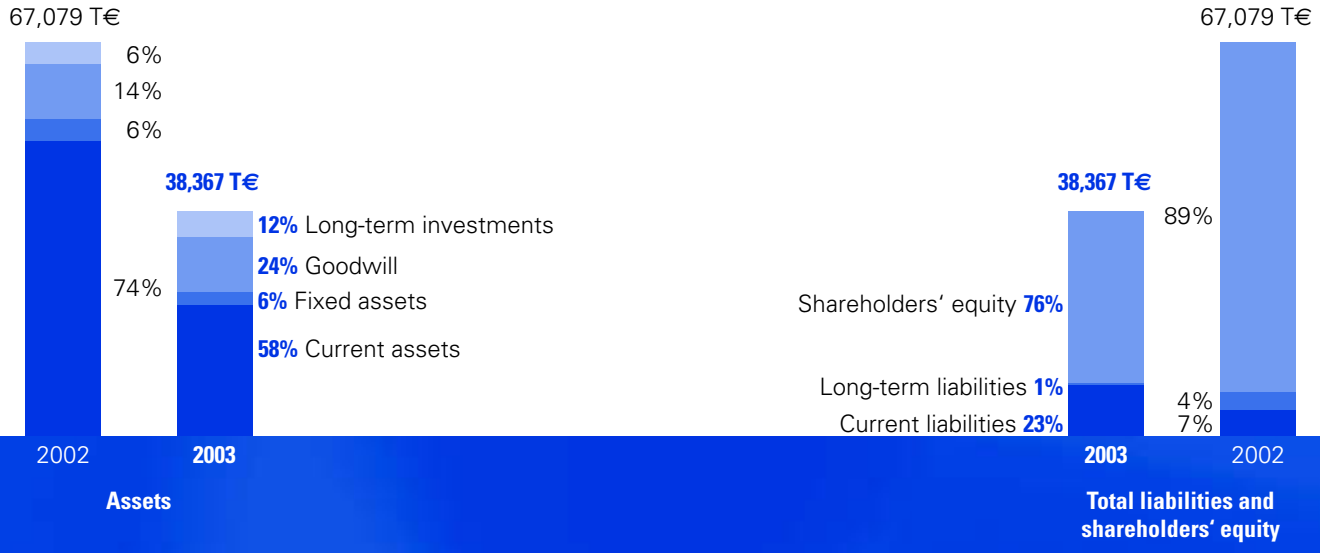
The decrease in current assets is largely explained by the decline in liquid funds which were used to finance R&D activities. At the same time, inventories fell from 492 T€ (2002) to 0 T€. The reason for this is the adjustment in our interpretation of the US-GAAP, according to which the balance sheet usually views inventories in connection with sales activities. MediGene had no sales of its own in 2003 and thus no inventories. In 2002, reagents and other materials used for research purposes were attributable here. Receivables fell 92% to 79 T€ (2002: 1,027 T€). In 2002 there was an invoice sent to Aventis for reimbursement of R&D expenses.

In the period under review, the company's net equity fell by 51%. MediGene financed product development primarily with its own equity capital that the company received in its IPO in 2000.

Total liabilities (long- and short-term liabilities) increased by 20%. By the same token, it also increased in proportion to the balance sheet total.

Long-term liabilities fell 90% in comparison to the prior year's period to 285 T€, during which time short-term liabilities grew by 91% to 8,861 T€. The reason for these two changes is a change in the way a loan in the amount of 3,222 T€ is treated in the balance sheet. The loan was granted from

Balance sheet structure



Aventis as part of the rAAV joint project. MediGene is obliged to pay back the loan as soon as the drug candidate is proved effective and the cooperation is continued. If Aventis ends the cooperation, even though the test of effectiveness ends up positive, MediGene can then redeem the loan affecting other operating income. In all other cases, MediGene is required to pay back the loan. On December 31, 2003, a repayment date had not yet been fixed. However, clinical data are expected for the current joint project by mid-year so that a repayment of the loan could become possible sometime during 2004. Also, there are short-term liabilities in the form of open invoices billed to MediGene in connection with the execution of clinical trials.

The degree of liquidity coverage, calculated as the portion liquid funds and securities in the total balance sheet, was 56% (2002: 71%) on the cut-off date.

Working capital fell by 70% from 45,579 T€ to 13,521 T€ caused by cash burn.

As per December 31, 2003, there were no liability relationships other than guarantees for rental deposits amounting to 783 T€.

For activated leased assets, sums will become payable in the next three years totaling 373 T€ and for operative leasing agreements in the next four years totaling 2,015 T€.

Changes in assets and capital structure

in T€	Dec. 31, 2002	Dec. 31, 2003	Change
Assets			
Long-term investments	3,802	4,494	18%
Goodwill	9,226	9,226	0%
Fixed assets	3,821	2,265	-41%
Current assets	50,230	22,382	-55%
Total assets	**67,079**	**38,367**	**-43%**
Liabilities and shareholders' equity			
Shareholders' equity	59,435	29,220	-51%
Long-term liabilities	2,993	285	-90%
Current liabilities	4,651	8,862	91%
Total liabilities	**67,079**	**38,367**	**-43%**
Liquidity cover ratio	**71%**	**56%**	
Equity ratio	**89%**	**76%**	

Financial position

Cash outflow decreased significantly

Cash outflow from current business is indirectly derived from the annual loss. The lower cash outflow from current business, which fell by 31% from 38,635 T€ in 2002 to 26,544 T€ in 2003, resulted primarily from the restructuring steps initiated in 2003 and from the lower cash burn linked to them.

In comparison to the cash outflow from investment activity in the prior year (2002: 5,296 T€), a cash outflow in 2003 amounting to 12 T€ was posted, caused by the net acquisition of tangible assets. In 2003, MediGene invested much less in tangible assets, 108 T€, than in the prior year (2002: 705 T€). Cash inflow from investment activity in 2002 resulted from the sale of fixed interest securities amounting to 6,000 T€.

Cash inflow from financing activities fell by -14% in comparison to the prior year. This decline resulted from lower payments made by Aventis to cover the costs MediGene incurred executing on the joint rAAV project, 680 T€ (2003)

as opposed to 729 T€ (2002). These payments were made by Aventis in the form of a loan and thus not booked as other operating income. In addition, no incoming payments were booked in connection with the exercising of options (2002: 46 T€). Cash outflow through finance lease obligations fell slightly to 431 T€ as opposed to 463 T€ in 2002.

For the year under review, there was a net decline in cash and cash equivalents of 26,318 T€, the role played by currency fluctuations being -29 T€. The final amount of liquid funds was 21,444 T€ and thus made up 56% of the balance sheet amount (2002: 71%).

On the cut-off date of the balance sheet, there were no financial liabilities or open lines of credit other than the research loan posted and the finance lease obligations. The amount of liquid funds available matches the net liquidity.

Monthly net cash burn

There was a net cash burn rate during the period under review, the year 2003, of 26,318 T€ (2002: 39,081 T€) and an average monthly value of 2,193 T€ (2002: 3,257 T€) as a result of the change in the cash and cash equivalents posted in the balance sheet.

The gross cash burn rate – the sum of all operative expenses and depreciation – was 30,782 T€ during the period under review. This corresponds to an average monthly value of 2,565 T€. MediGene is presently using the funds available to it to develop its own products.

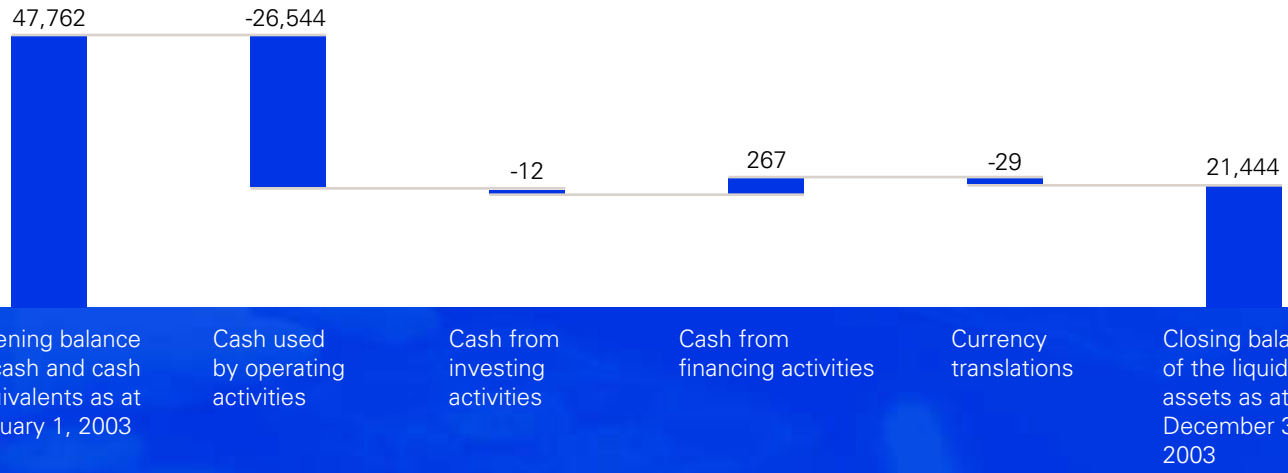
Human resources

Reduction in Group workforce

At year-end 2003, MediGene employed a total of 112 persons in its continuing operations – 92 of them in Martinsried (2002: 105 staff) and 20 at MediGene, Inc. in the U.S. (2002: 52 staff). There were also 12 persons employed in discontinued operations (LARNAX GmbH) up until December 31, 2003. All in all, the number of employees in continuing operations throughout the Group fell by 29%; taking account of LARNAX by 33%.

Development of cash and cash equivalents

in T€



As part of the restructuring of the MediGene Group, personnel expenses in continuing operations fell by 2% to 10,973 T€. Including discontinued operations, these costs were cut by 5% to 12,036 T€. A significant portion of personnel expenses savings will become effective beginning at 2004.

On the balance sheet date, 152 T€ were accrued for severance payments. The appropriate reserve will most likely be closed out in the first quarter of 2004.

Employees by function

	2002	2003	Change
Business development and general administration	102	53	-48%
Research and development	55	59	7%
Total from continued operations	**157**	**112**	**-29%**
Discontinued operations	28	12	-57%
Total	**185**	**124**	**-33%**

Personnel expenses

in T€	2002	2003	Change
Wages and salaries	9,436	9,510	1%
Social insurance	1,809	1,463	-19%
of which for pension	*135*	*186*	*38%*
Total from continued operations	**11,245**	**10,973**	**-2%**
Discontinued operations	1,430	1,063	-26%
Total	**12,675**	**12,036**	**-5%**

Downsizing of the U.S. subsidiary, MediGene, Inc.

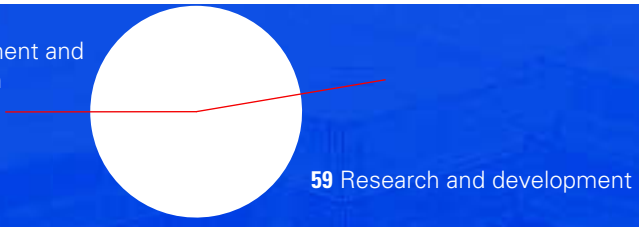
Between June and December 2003, MediGene relocated the research activities of the U.S. subsidiary MediGene, Inc. completely to its German headquarters in Martinsried. In the wake of these restructuring steps, the jobs of the almost 30 persons working at the San Diego, California site were gradually cut through to the end of the year. On December 31, 2003, 20 persons were still employed at MediGene, Inc.

In the course of the first half of 2004, this location will be further downsized to ca. 10 employees.

Employees by region

	2002	2003	Change
MediGene AG, Martinsried	105	92	-12%
MediGene, Inc., San Diego	52	20	-62%
Total from continued operations	**157**	**112**	**-29%**
Discontinued operations	28	12	-57%
Total	**185**	**124**	**-33%**

MediGene, Inc. will be continued with the departments »Clinical development« and »Regulatory affairs«. The many clinical and academic cooperation agreements in the area of HSV technology in the U.S. will remain in existence in their full extent.



Employees by function

Procurement

Focus on process development: cost effective production processes

Procurement is concentrated on services, chemicals and lab materials for the R&D area. As long as costs and prices stay within their usual parameters, procurement costs only play a subordinate role in the MediGene cost structure. On the other hand, the development of cost-effective production processes for our candidate drugs are of great importance for efficiently designing later procurement of our ingredient agents. MediGene is working intensively on the development and improvement of production processes for its future drugs.

For the drug Eligard® the supply of individual dosages is assured.

Complex demands on service providers

The procurement of a wide range of services can mainly occur in such outsourced areas as the large-scale production and formulation of therapeutic agents, the execution of pharmacological and toxicological trials and the execution of clinical trials. The outsourcing of these activities assures the flexibility we need to reach quickly to changes in our development portfolio. The demands made on such services are highly complex and require great expert knowledge and experience on the part of the purchaser. Criteria for the choice of partners in such projects are not only the quality of the service but also delivery loyalty, reliability and flexibility.

Procurement management for materials

MediGene is not committed to any specific raw material suppliers for its R&D work. Instead, it always gathers different bids and places orders with the most favorably priced supplier in consideration of all quality aspects. Our procurement is organized in such a way that we can assure the required certainty in cases of supply bottlenecks or quality problems and still obtain the best purchasing prices. The procurement costs for lab materials only bear a slight portion of our entire costs.

Environmental and health protection

A top priority

MediGene is committed to safety and environmental protection. We not only meet the high statutory requirements and abide by the regulations, we also go beyond them with efforts to keep our lab equipment at the latest state of technology. To monitor compliance with official requirements, we have filed the internal positions of Radiation Representative, Deputy for Biological Safety, Safety Engineer, Waste Management Representative and Project Manager for Gene Research only with experienced persons trained specifically for these functions. The Safety Engineer was also trained in accordance with the guidelines of the German Occupational Insurers for the Chemical Industry (»Berufsgenossenschaft«).

Our lab systems are carefully cared for and continuously serviced and expanded on. With the aid of external service companies, MediGene sees to it that any waste generated is cleanly separated and expertly disposed of and/or reprocessed in accordance with the requirements specific to it. To ensure the occupational safety of all those working in our labs, our Safety Engineer carries out hazard analysis studies and training sessions, and our physicians see to regular medical check-ups. MediGene fulfills all the essential requirements of environmental and health protection and safety, and also has the required permits and approvals as evidence of this. The random-sample appraisals and inspections made at various intervals by a wide variety of authorities have gone through without any relevant objections.

MediGene sees the development of innovative drugs as a social mission of high ethical character. This is why we are concentrating our resources primarily on this area.

Risk report

Industry and market risks

MediGene is subject to the risks typical to the industry and market inherent in the development of biopharmaceutical products using the latest technologies. Experience has shown a drug can take 10 to 15 years to develop. The fundamental risk is that several or even all the products from MediGene may not be successfully developed or marketed. It is possible that drug candidates may not obtain the marketing authorization from the authorities necessary to market or further develop them, that one or all the candidate products may turn out to be either risky or without the desired effect, that it may not be possible to manufacture MediGene's products in large amounts or that they may not be economically marketable or not sufficiently competitive. Furthermore, third party property rights might hinder the marketing of the products or third parties might market superior or more cost-effective products.

Procurement risks

MediGene purchases the drug Eligard® for the European market from the licensor and manufacturer Atrix Laboratories Inc., in the U.S. When procuring Eligard®, it is possible that deliveries will be broken off by Atrix Laboratories Inc. In cooperation with its partners Atrix Laboratories Inc. and Yamanouchi Pharmaceutical Co., Ltd., MediGene has taken precautions so that it can fall back on alternative manufacturers.

Legal risks/patent risks

MediGene also depends on its ability to obtain the most extensive possible patent protection for its own technologies and products, to protect its trade secrets, to effectively defend itself against breaches of its legal rights and to enforce its rights properly without violating the rights of any third party. To protect the legal rights to our technologies and products, we make use of additional non-disclosure agreements and contractual limitations to use by our cooperation partners, staff, consultants and our other contractual parties.

A warranty can not be accepted that patents will not be disputed, declared invalid or evaded, and that they will create a commercial advantage for the company. By the same token, the company will take all means available to it to defend itself against infringements upon its rights. The company intends to expand its technology and product portfolio. In the areas concerned, third parties could, however, assert legally protected interests on grounds of cooperation, research and licensing agreements. For the future, legal disputes cannot be ruled out.

In early 2003, MediGene reached a settlement in a lawsuit with Loyola University of Chicago, its consultants Sigma Technologies, Inc., one natural person and MedImmune, Inc. According to the agreement, all claims for damages by Loyola and MedImmune against MediGene were dropped, MediGene's appeal was stopped and the disputed property rights were transferred to Loyola. MediGene was involved in the lawsuit since 1998. Object of the suit filed by MediGene, Loyola University and MedImmune was the ownership of patents and rights to patent applications for the CVLP technology.

Risks of unsuccessful drug development

MediGene's drug candidates have to undergo the pre-clinical development phase and a number of phases of clinical trials on patients before they can be commercially viable. In these trials, the side effects and the effectiveness of a drug are examined before the application for marketing approval can be submitted to the relevant authorities. After the application the data submitted are evaluated and the authorities decide on marketing approval. Besides approval, there is also a possibility that the product will not be approved on the basis of the data submitted or that further data will be required before the product can be approved. Delays in the clinical trials or in patient recruitment can lead to increased costs and a delay in market entry. Results of pre-clinical and clinical trials are not predictable. In addition, the results of previous trials allow for no precise forecasts as to future trial results. Analysts estimate the probability of a regulatory approval for a new drug at the different project development stages as follows:

- in registration phase 90%
- in clinical phase 3 60 – 80%
- in clinical phase 2 40 – 60%
- in clinical phase 1 10 – 30%
- in pre-clinical trials 0 – 10%

Apart from MediGene, a number of biotech companies have experienced significant setbacks in advanced clinical trials – even after promising results in earlier phases. To minimize the risk of setbacks during development, we carry out every step in the development process in accordance with the highest standards. In addition, we maintain close relationships with the regulatory authorities and subject all our projects to an annual risk assessment. We achieve risk diversification by developing drugs based on a variety of different technologies. At present, we have four candidate drugs in clinical development based on three different technological approaches. They are at different stages in development, as well. If MediGene does not succeed in keeping to the intended development plan, or not successfully conclude the clinical trials, this could have significant detrimental consequences for the company's business, financial and earnings situation.

Risks of low drug sales

The development and marketing of drugs faces keen competition. This is especially true for the market for tumor therapies, the focus of MediGene's activities. Due to the potentials this market segment offers, it is the focus of the activities of many large pharmaceutical corporations and specialized biotech companies. The drugs under development at MediGene are designed to treat extremely serious diseases, most of which have only been insufficiently treatable until now. A successful drug for each of these indications would have a significant market potential. Should one of the competitors succeed in being first to market with a similar product, MediGene's development could, depending on the profile and the marketing success of the product, be less competitive or even inferior. Our portfolio strategy serves to minimize development and sales risks.

Financing risks

Existing company capital and cash flows from operating activities at MediGene's may not, under certain circumstances, suffice to cover the expected investment spend and the operational capital needed for the foreseeable future. There is a possibility that MediGene will have to procure further financial funds from external sources. The ability to raise these additional funds depends on a series of financial, economic and other factors over which the management does not have a great deal of control. If needed, it can happen that MediGene does not always have sufficient means available to it at acceptable conditions. In such cases, MediGene would perhaps have to lower R&D, production or marketing spend. This could incur significant disadvantages for the business, financial and revenue situation, but also for the future prospects of the company. To date, MediGene has always managed to raise sufficient capital to finance the company's further activities. To keep chances for this good in the future, MediGene implements intensive investor relations and public relations activities.

As part of the rAAV joint project, Aventis granted MediGene a loan of 3,222 T€. MediGene is required to pay this loan back as soon as the effectiveness of the drug candidate has been proven and the cooperation continues. In case Aventis terminates the cooperation agreement even though the test for effectiveness has gone positively, MediGene may cancel the loan positively affecting net income. In all other cases, however, MediGene must repay the loan. As of December 31, 2003, no date for repayment was fixed. However, clinical data from the current joint project are expected for mid-year so that a possibility of repayment in 2004 does exist.

On the cut-off date December 31, 2003, no derivative financial instruments were on the balance sheet.

Risks related to commercialization

MediGene's current business plan is based on the commercialization of the Polyphenon® E Ointment and the HSV technology. Successful commercialization largely depends on the results of the clinical development programs, as well as MediGene's ability to attract an adequate cooperation partner (see Risks related to unsuccessful drug development; Industry and market risks.)

Currency risks

MediGene runs a subsidiary in San Diego, California, USA. It is financed with funds from MediGene AG. The costs for our activities in the U.S. rise when the euro loses value in comparison to the U.S. dollar. On the other hand, a rise in the value of the euro in comparison to the U.S. dollar means that existing assets in U.S. dollar have to be revalued. As a result of the considerable downsizing of U.S. operations, the effect of currency fluctuations will diminish.

In 2004, the selling of Eligard® will begin. MediGene procures the drug from the U.S., invoicing will be done in U.S. dollar. The costs for procuring these goods will rise with a detrimental move in the currency rate between U.S. dollar and euro. The drug will, however, be sold by MediGene in Europe in U.S. dollar, meaning that the currency fluctuation risk will be much reduced and will thus only affect the sales margin achieved by MediGene. MediGene posted in its balance sheet dated December 31, 2003 shares of the U.S. company Atrix Laboratories Inc. (NASDAQ: ATRX) valued at 4,452 T€. The value of the shares is also subject to changes in the currency rate between U.S. dollar and the euro.

Portfolio management strategy for reducing total risk

The total risk for MediGene is essentially comprised of the individual risks facing the company in the areas of clinical development, product marketing and financing for the company. Both the success of the company and the further existence of MediGene thus depend essentially on successful drug development and product marketing, but also on capital market conditions. MediGene counteracts the risk of the failure of individual projects, which is, in principal high, by maintaining a broad product portfolio based on a variety of different, mutually independent technological and scientific approaches. This reduces the risk posed by individual product failures, or even the risk for the continued existence of the company, though such risks cannot be completely ruled out.

Comprehensive risk management system for greater shareholder value

Principles, administration and controlling

Our corporate strategy is geared towards maximizing shareholder value. This necessitates a constant monitoring and improvement in our decision-making mechanisms. Entrepreneurial success means taking risks and dealing responsibly with them. MediGene's management thus employs a comprehensive risk management system that can adapt flexibly to new situations and be continuously improved. Organizational safety measures have been taken by separating certain functions. Any actions or business transactions that might involve a risk are never carried out by one staff member alone – committees are always responsible for decision-making and for the decisions themselves. Standardized work instructions and work flows ensure that each work step is carried out in a uniform manner. IT risks are limited by the use of access restrictions, rules on system development and care. Forms, worksheets and lab books serve to record and document all data completely. MediGene's controlling system is responsible for a goal oriented coordination of planning, information supply, steerage and control. Projects go through a monthly plan/actual comparison to discover any deviations from plan which are then discussed regularly with project heads and the Executive Board.

Portfolio management and evaluation

MediGene's project portfolio is actively managed and regularly evaluated. This management includes the drafting of development plans for individual projects which are then passed by development committees. Adherence to them is regularly monitored by the Executive Board. A regular evaluation of each individual project in terms of its chances and risks focuses primarily on the technical risk. It also includes an analysis of the patent position, the scientific hypotheses of possible competitors and a consideration of clinical development, approval conditions, process development and portfolio strategy. The results are summarized in a feasibility study and an economic evaluation. Using this as a basis, a decision is made on MediGene's entire portfolio and on our further strategic direction. MediGene's international scientific advisory committee critically examines our research and development activities from a technical point of view and advises us using the latest knowledge from research and clinical application.

Special emphasis is given to our patent work. We attempt to broadly secure both our technology platforms and our products under patent law in order to protect ourselves from possible competition. MediGene is not dependent on any single technology, instead it possesses a broad range of technologies and a diversified product portfolio – both are protected under far-reaching international patent applications and patents themselves. In addition, our cooperation agreements with external scientific institutes, universities and other companies grant us access to the latest technologies.

Quality assurance

MediGene's quality assurance system fulfills the requirements of pharmaceutical law and »Good Manufacturing Practice« guidelines. It ensures that the development and manufacture of pharmaceutical products meet defined standards and that proof can be provided at any time of the work being done. In our quality assurance area, we have a number of standardized workflows.

The risk management system was evaluated by our auditors as part of their assessment of general statements made by the consolidated annual statements.

Major events since the cut-off date for this report

No changes have occurred to the general conditions facing the company through to February 29, 2004.

MediGene and Yamanouchi conclude marketing and development partnership for cancer drug Eligard®

On January 14, 2004, MediGene concluded a partnership with the pharmaceuticals group Yamanouchi for the commercialization in Europe of the cancer drug Eligard®, previously known as Leuprogel®. Yamanouchi, the second largest pharmaceuticals company in Europe in the field of urology, will take on pan-European promotion and sale of the drug for treatment of prostate cancer. In return, MediGene will receive successive milestone payments totaling up to 23.5 million € including a signing fee of 4 million € and royalties on the sale of Eligard®.

MediGene receives approval for three-month dosage of Eligard®

On January 26, 2004, MediGene received marketing authorization for Germany from the »Bundesinstitut für Arzneimittel und Medizinprodukte« (Federal Institute for Pharmaceuticals and Medical Devices, German acronym BfArM) for the three-month sustained release product of Eligard® to treat advanced prostate cancer. The corresponding one-month sustained release product of this drug had received marketing authorization at the beginning of December 2003. The three-month sustained release product offers additional applications for Eligard® thus enhancing its competitiveness. As announced on January 14, 2004, MediGene's partner Yamanouchi will take on the market launch and sale of Eligard®. As part of the agreement with Yamanouchi, MediGene will receive a milestone payment for this approval of the three-month sustained release product.

Patient recruitment for final phase 3 clinical trial of Polyphenon® E Ointment completed as scheduled

In February MediGene has successfully completed patient recruitment for the final clinical trial (phase 3) of the Polyphenon® E Ointment as scheduled. The admission of 480 patients needed for the American arm of the trial will allow a timely completion of the trial by the end of this year, as planned.

In May 2003, MediGene had already successfully completed the European part of the phase 3 trial, with more than 500 patients. MediGene will report the results of the European part at the end of the first quarter of 2004. The overall results of both arms of the study are expected by the end of 2004. With approximately 1,000 patients in 100 centers and 14 countries, this programme is the most extensive clinical trial ever conducted by a German biotech company.

MediGene intends to raise 16 million € in a share capital increase

On March 4 MediGene has finalized a three-step corporate action to increase cash available by approx. 16 million €. The first step will be a share capital increase by 10% through a private placement under participation of Techno Venture Management (TVM) without subscription rights for shareholders. Approx. 1.1 million new shares will be issued at the average market price of the past five trading days, that is 6.80 € per share. In a second capital increase of 10%, MediGene will submit an offer to current shareholders for again approx. 1.1 million new shares at 6.80 € each. In addition, MediGene will offer convertible bonds at the amount of 1.5 million €, which can be subscribed to by shareholders for 1 € each. The conversion price is 7.50 € per share. The convertible bonds bear 4% interest annually during the four years to maturity. Conversion is possible after a period of twelve months. MediGene can ask for conversion under certain circumstances. Subscription period wil be March 6 – 19, 2004. According company´s statements the capital increase measures will extend the financial scope for MediGene AG and increase the current amount of cash to about 40 million €. Due to these measures, the number of MediGene shares will rise from 11,228,362 to 13,474,032. The capital increase measures will be carried out with authorized and conditional capital. No further shareholder´s resolution is needed.

Prospects & prognoses

At the end of 2003, economic indicators showed that the global economy will also continue down the path of growth in 2004. By the same token, it appears that the lows in money market interest rates in the U.S. and the euro zone have been reached for this economic cycle. By the end of 2004, expectations are for the same or slightly rising interest rates in both economic areas due to the world economic recovery. For the end of 2004, experts expect the euro to trade around the 1.20 US$ mark.

Expected situation of the entire economy and developments in the biopharmaceutical industry

In their January report, the European Central Bank (ECB) is expecting a further expansion in growth of the global economy in 2004. For the euro zone, the latest data on production and business confidence is pointing to a sustained economic recovery, and the dynamics of growth should strengthen in the course of 2004. The latest data and information provide evidence that a recovery began in the second half of 2003. All in all, existing economic indicators lead us to believe that the growth in real GDP posted during the third quarter of the past year continued into the final quarter of 2003. All available prognoses and projections are speaking for a continued strengthening in the dynamics of growth during 2004. The ECB is expecting economic growth in the euro zone of 1.1 to 2.1% in 2004. In 2005, growth is then expected to accelerate to 1.9 to 2.9%. For the U.S., experts are expecting GDP growth in the area of 3.0 to 3.5%.

Drugs to treat tumor diseases already pose the largest part of worldwide drug sales today, and the market for biopharmaceutical products will continue to grow. For the coming decade, experts predict continuous growth in the market volume for anti-cancer drugs. In 2010, this market is estimated at 50 billion US$ globally, today the market volume of sales in this market is already around 20 billion US$. The low effectiveness of presently available therapies and the increasing frequency of tumor diseases will make the demand for innovative drugs grow. Market growth will be primarily driven forward by new and novel forms of therapy which can offer a clear improvement in patient treatment with greater effectiveness and fewer side effects. These include the oncolytic herpes simplex viruses developed by MediGene, among others.

MediGene focuses on drugs to treat tumor diseases

In 2003, MediGene continued to focus its business activities on the development and marketing of tumor therapies. As part of this, extensive cost-cutting and savings have been initiated.

Eligard® (formerly Leuprogel®) approved for marketing

Eligard®, an LH-RH agonist to treat advanced prostate cancer, is MediGene's first drug approved for the market. In December 2003 (one-month sustained release product) and January 2004 (three-month sustained release product), MediGene received German marketing authorization from the »Bundesamt für Arzneimittel und Medizinprodukte« (Federal Institute for Pharmaceuticals and Medical Devices, German acronym BfArM). Germany serves as the reference country for further European approvals of Eligard® as part of the European mutual recognition process.

To market Eligard® in Europe, MediGene formed a marketing partnership with the Japanese pharmaceuticals company Yamanouchi in early January 2004. Besides a signing fee and milestone payments amounting to a total of 23.5 T€, MediGene will also receive royalties on Eligard®.

MediGene is expecting a market launch of the approved sustained release forms of Eligard® by its partner Yamanouchi by mid-2004. At the same time, approval of the one- and three-month sustained release formulas should be applied for in other European countries.

Four- and six-month formulas of Eligard® offer additional potential

Besides the licenses for the one- and three-month sustained release formulas, MediGene also has options on European marketing licenses for four- and six-month sustained release formulations. These sustained release products are also objects of the agreement made with Yamanouchi. MediGene will have no notable additional costs if it decides to exercise its options. Both sustained release forms, for which there are no similar approved competitor products in Europe, offer an interesting opportunity to further increase the value of the product. The partners have not yet made any decision on the development for these two sustained release versions. The four-month version is already approved in the U.S., for the six-month product a final clinical trial by Atrix Laboratories Inc. has been concluded with good results. The application for marketing approval is presently being prepared in the U.S. by Atrix.

Polyphenon® E Ointment – conclusion of the clinical trial expected in 2004

Polyphenon® E Ointment has been developed to treat benign tumors of the genital tract, so-called genital warts. The ointment is administered to patients in three different dosages (10%, 15% and placebo) three times daily for up to 16 weeks. The treatment is followed by a twelve-week monitoring period.

A total of ca. 1,000 patients were recruited for the phase 3 trial relevant for marketing authorization, which is carried out in two portions, namely in Europe and South Africa, and in North and South America, respectively. To obtain informative statements, the trial is randomized and double blinded. This means that the patients are allotted randomly to the various different treatment groupings, and that both patients and physicians involved are not informed if placebo or drug is administered to the patient, in order to ensure an impartial evaluation. The criteria for the proof of efficacy and tolerability of the Ointment that apply to the design of both parts of the trial have been predetermined by the positive results obtained in a phase 2/3 trial that was completed in December 2001. To obtain market authorization for the ointment in the USA and Europe, a positive overall result of both parts of the trial is required. The results of the part of the trial carried out in Europe are expected by the end of the first quarter of 2004, and the results of the second part of the trial should be available by the end of the year.

By 2005, the conclusion of a marketing partnership is planned for Polyphenon® E Ointment.

Polyphenon® E Ointment – Potential in further indications being investigated

At present, MediGene is examining the potential for Polyphenon® E Ointment in further indications in the fields of dermatology/oncology. Especially in the indications actinic keratosis (i.e. a certain kind of skin tumor in the face and on the back of the hands) and basal cell carcinoma (i.e. a prevalent, benign skin tumor). This examination includes both the economic evaluation as well as the first pre-clinical trials. Depending on the results of this examination, a decision is slated to be made during the year on the initiation of appropriate development projects. The opening up of new indications for Polyphenon® E Ointment offers additional potential to increase the value of this product for our company.

NV1020 – Next clinical trial to begin in 2004

In 2004, a new clinical trial is scheduled to begin for the candidate drug NV1020 for the treatment of colorectal tumors which have metastasized into the liver. This trial is presently in preparation and is planned as a proof of concept study.

G207 – Continuation only with external financing

The further development of G207 is currently being evaluated. Until recently G207 was examined in an clinical phase 1/2 study.

rAAV tumor vaccine

In the joint project carried out together with our partner Aventis to develop an rAAV tumor vaccine to treat malignant melanoma, data from a current clinical trial are scheduled to be available by mid-2004.

Supplementing the technology and product portfolio continues to be the strategic goal

In-licensing, especially for products, such as Eligard®, are of particular importance within MediGene's strategy, and this also applies to the future. We want to continue to supplement our technology and product portfolios in order to increase our chances for sustainable growth. New license agreements, mergers and acquisitions are important strategic means for complementing our development pipeline.

Decline of the loss – cash reserves of 25 million € by the end of 2004

For 2004, we are expecting a fourfold increase in sales to 8 million €. The annual loss should fall by half to 15 million €. Cash reserves will probably be 25 million € by year's end. This includes the completion of the capital measure announced in March 2004.

R&D projects: goals reached in 2003

HPV-indications		
Polyphenon® E Ointment	Second phase 3 trial started	Achieved
CVLP tumor vaccine	Results from phase 1/2 trial available	Achieved
Oncology		
Eligard® (formerly Leuprogel®)	Approval and market launch in Germany	Approval obtained; Market launch delayed
G207	Phase 1b/2 trial in progress	Project put on hold for financial reasons
NV1020	Initiation of next clinical trial	Delayed
rAAV tumor vaccine	Results from clinical phase 1/2 trial	Delayed

R&D projects: status expected for December 2004

HPV-indications	
Polyphenon® E Ointment	Results from first part of ongoing phase 3 trial in Q1-2004
	Results from second part of oingoing phase 3 trial in Q4-2004
Oncology	
Eligard® (formerly Leuprogel®)	Market launch in Germany
NV1020	Initiation of next clinical trial
rAAV tumor vaccine	Results from clinical phase 1/2 trial

R&D remains the focus

Larger investments in tangible assets are not planned for 2004. Largest cost item will remain research and development spend.

Total staff number remains constant

The total staff number will not change appreciably in 2004. To further enhance the specialist and social competency of our staff, we will continue to offer internal and external further education opportunities in the future as well. Staffing numbers in the Group will be around 110 at year's end, ten of those at the U.S. site in San Diego.

Future procurement

In procurement, we are not expecting any appreciable change in 2004 as appeared to the prior year. MediGene will be purchasing the drug Eligard® from Atrix Laboratories Inc. for the European market during 2004. MediGene will therefore be buying the goods from the U.S., billing will be done in U.S. dollar. The drug is sold by MediGene in Europe in U.S. dollar. This will appreciably lower the exchange rate risk and only affect the sales margin MediGene makes.

Future legal corporate structure and organization/ administration

No changes are planned in the legal structure of the company. The cardiology unit was spun off from the company effective March 31, 2003.

Environmental protection in excess of what is required

The steps already taken will be continued. MediGene will also protect the environment in future to any extent above and beyond what is legally required.

Distributing residuals

MediGene pursues the concept of distributing residual dividends. Dividends should always be paid when financial resources cannot be reinvested in the company in such a way as to earn at least the risk-equivalent yield shareholders could expect to receive on the capital market. Accordingly, this distribution involves the amount of financial resources that, given the number of products under development and the known profitability criteria, cannot be put to use of in the company in the interest of the shareholders. This means that any dividend MediGene distributes in the future does not constitute a signal to the revenue potential of the company. In the medium term, MediGene will probably continue to make a loss and thus invest available funds in the development of potential drugs. The distribution of dividends can thus not be expected for the foreseeable future.

Consolidated income statements

of MediGene AG for the periods from January 1 to December 31, 2003 and 2002

in T€		Notes No.	2002	2003
1.	**Total other operating income**	(21)	3,425	1,742
2.	Selling expenses	(22)	1,677	1,448
3.	General and administrative expenses	(23)	5,500	6,478
4.	Research and development expenses		26,721	21,825
5.	Depreciation		1,085	1,031
6.	**Operating loss**		-31,558	-29,040
7.	Interest income and expenditures		2,081	701
8.	Foreign currency exchange gains/losses		-753	6
9.	**Result before income tax**		-30,231	-28,333
10.	Tax	(28)	0	0
11.	**Net loss from continued operations**		-30,231	-28,333
12.	Minority interest in discontinued operations		0	261
13.	Result from discontinued operations	(29)	-8,639	-2,988
14.	**Net loss**		-38,870	-31,060
Per share data in €:				
Result from continued operations (»actual« and »fully diluted«)			-2,70	-2,53
Result incl. discontinued operations			-3,47	-2,77
Weighted average number of shares outstanding			11,204,990	11,206,205

The number of shares used in calculating the diluted net loss per share is the same as 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 722,955 in 2002 and 623,867 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, 2003 and 2002

Assets in T€	Notes No.	2002	2003
A. Current assets			
I. Cash and cash equivalents	(30)	47,762	21,444
II. Short-term investments/marketable securities	(31)	1,027	79
III. Accounts receivable	(32)	492	0
IV. Prepaid expenses and other current assets	(33)	949	859
Total current assets		**50,230**	**22,382**
B. Long-term assets			
I. Property, plant & equipment	(34)	3,686	2,189
II. Intangible assets	(34)	135	76
III. Goodwill		9,226	9,226
IV. Investments	(35)	3,443	4,452
V. Loans		187	0
VI. Other assets		172	42
Total fixed assets		**16,849**	**15,985**
Total assets		**67,079**	**38,367**

Liabilities and shareholders' equity in T€	Notes No.	2002	2003
A. Current liabilities	(36)		
I. Current portion of capital lease obligation		401	265
II. Short-term debt and current portion of long-term debt		0	3,222
III. Trade accounts payable		1,128	1,764
IV. Accruals	(37)	2,526	3,342
V. Deferred income		103	0
VI. Other current liabilities		493	268
Total current liabilities		**4,651**	**8,862**
B. Long-term liabilities	(36)		
I. Long-term debt less current portion		2,650	108
II. Capital lease obligation less current portion		277	108
III. Pension accrual		32	35
IV. Other long-term liabilities		34	34
Total long-term liabilities		**2,993**	**285**
C. Shareholders' equity	(38)		
I. Share capital		11,206	11,206
Number of shares issued and outstanding			
December 31, 2002: 11,206,205			
December 31, 2003: 11,206,205			
II. Additional paid-in capital		218,142	218,177
III. Accumulated deficit		-168,882	-199,943
IV. Accumulated other comprehensive income		-1,031	-220
Total shareholders' equity		**59,435**	**29,220**
Total liabilities and shareholders' equity		**67,079**	**38,367**

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, 2003 and 2002

in T€	2002	2003
Cash flow from operating activities		
Net loss	-38,870	-31,060
Adjustments to reconcile net loss to cash used in operating activities:		
APB 25 expense on new options/bonds	108	35
Minority interest		242
Net loss minority interest		-261
Depreciation	1,312	1,271
Losses on sales of property, plant & equipment	18	220
Changes in:		
Inventories	83	492
Other assets and prepaid expenses	-487	1,355
Trade accounts payable	-1,372	636
Accruals	575	849
Other liabilities and deferred income	-2	-324
Net cash used by operating activities	**-38,635**	**-26,544**
Cash flow from investing activities		
Purchases of property, plant & equipment	-705	-108
Sales of property, plant & equipment	1	96
Disposal of securities	6,000	0
Net cash from investing activities	**5,296**	**-12**
Cash flow from financing activities		
Proceeds from stock options	46	0
Proceeds from minority interest	0	19
Repayments of/Proceeds from loans	729	680
Principal payments under finance lease obligations	-463	-431
Net cash from financing activities	**312**	**267**
Currency translation	-55	-29
Decrease in cash and cash equivalents	**-33,081**	**-26,318**
Cash and cash equivalents at beginning of period	80,843	47,762
Cash and cash equivalents at end of period	**47,762**	**21,444**

Supplementary schedule of non-cash financing activities:

Capital lease obligations of 127 T€ incurred in 2003 (2002: 255 T€) when the company entered into leases for new equipment.

Consolidated changes in shareholders' equity

of MediGene AG for the periods from January 1 to December 31, 2003 and 2002

	Shares	Share capital	Capital reserves	Accumulated losses	Other comprehensive income	Total shareholders' equity
	No.	T€	T€	T€	T€	T€
Balance January 1, 2002	**11,198,637**	**11,199**	**217,995**	**-130,012**	**1,224**	**100,406**
Net loss 2002				-38,870		-38,870
Unrealized profit from Atrix shares					-2,022	-2,022
Currency translation adjustments					-233	-233
Comprehensive income						**-41,125**
Exercised options	7,568	7	39			46
APB No. 25 Expenses on new options/bonds			108			108
Balance December 31, 2002	**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
Comprehensive income						**-30,250**
Exercised options						0
APB No. 25 Expenses on new options/bonds			35			35
Balance December 31, 2003	**11,206,205**	**11,206**	**218,177**	**-199,942**	**-221**	**29,220**

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, 2003

in T€					Sales value	
	January 1, 2003	Currency translation adjustments	Addition	Disposal	Reduction from market valutaion	Take over leasing
Fixed assets						
Property, plant & equipment*	7,297	-424	235	-935		
Improvement of leased objects, technical and laboratory equipment	*7,135*	*-416*	*215*	*-926*		
Software	*162*	*-8*	*20*	*-9*		
Intangible assets	333	-58	0	0		
Technology licenses	*333*	*-58*				
	7,630	**-482**	**235**	**-935**	**0**	**0**
Goodwill	**11,071**	**0**				
Investments	**3,443**	**0**			**1,009**	
Total	**22,144**	**-482**	**235**	**-935**	**1,009**	**0**
** thereof leasing*	*1,409*		*127*			*-622*

	Depreciation						Book value	
December 31, 2003	January 1, 2003	Currency translation adjustments	Addition	Disposal	Take over leasing	December 31, 2003	December 31, 2003	December 31, 2002
6,173	3,611	-242	1,234	-618		3,985	2,188	3,686
6,008	*3,491*	*-236*	*1,202*	*-611*		*3,846*	*2,162*	*3,644*
165	*120*	*-6*	*32*	*-7*		*139*	*26*	*42*
275	198	-38	38	0		198	77	135
274	*198*	*-38*	*42*	*0*		*202*	*72*	*135*
6,448	**3,809**	**-280**	**1,272**	**-618**	**0**	**4,183**	**2,265**	**3,821**
11,071	**1,845**					**1,845**	**9,226**	**9,226**
4,452	**0**					**0**	**4,452**	**3,443**
21,971	**5,654**	**-280**	**1,272**	**-618**	**0**	**6,028**	**15,943**	**16,490**
914	*465*		*270*		*-374*	*361*	*553*	*944*

US-GAAP
The accompanying notes are an intregal part of the consolidated financial statements.
Totals may vary due to rounding

Notes to the consolidated financial statements

of MediGene AG as of December 31, 2003

A) Description of business activity

MediGene AG was founded in 1994 in Martinsried near Munich, Germany with equity capital of 26 T€. In 1996, the company was converted into a stock corporation. The company's headquarters are at Lochhamer Straße 11, 82152 Martinsried, Germany. MediGene is registered in the commercial register at Munich Local Court (Amtsgericht) under the number HRB 115761. The company has one fully-owned subsidiary, MediGene, Inc. based in San Diego, California, USA. The purpose of the company is to research, develop and market in particular molecular biological technologies, processes and products in the fields of pharmaceuticals, pharmaceutical agents and the corresponding interim products, as well as the execution of the services concomitant to them. MediGene is publicly quoted on the German stock exchange since June 2000 (Prime Standard, ISIN: MDG).

B) Statutory accounting requirements

These consolidated annual financial statements were drafted in accordance with the U.S. Generally Accepted Accounting Principles (GAAP). The company has taken advantage of the provisions of § 292a of the German Commercial Code (HGB) for these consolidated annual financial statements. For this reason, this report was supplemented to include statements exempting the company from the German statutory requirement to present consolidated financial statements and a consolidated management report. The companies that comprise the consolidated entity have used uniform accounting and valuation methods.

The individual financial statements for MediGene AG, in contrast, were drafted in accordance with the accounting principles laid down in the German Commercial Code (HGB). For the purposes of this report, these financial statements should be regarded as nothing more than informational in nature to supplement these consolidated financial statements. Individual financial statements for MediGene AG will be drafted separately and filed in accordance with the German HGB. This report will be deposited at the commercial register.

The currency used in the 2003 financial statements is the euro (€) or EUR '000 (T€), originally from the German manner of writing, T€ for '000 €. The functional currency of MediGene, Inc. was the U.S. dollar (US$).

In drawing up the consolidated annual financial statements in accordance with the Generally Accepted Accounting Principles, the Executive Board must make assessments and assumptions that affect revenues, expenses, assets, liabilities and contingent liabilities listed in the financial statements at the time the accounts were drafted. The actual figures may differ from the estimates which were made to the best of our knowledge and belief.

C) Changes in accounting, valuation and recording principles

Starting January 1, 2003 FASB[1] requires the application of the following rules:

- SFAS[2] No. 143 »Accounting for obligations associated with the retirement of long-lived assets«,
- SFAS No. 146 »Accounting for costs associated with exit or disposal activities«,
- SFAS No. 148 »Accounting for stock-based compensation – transition and disclosure – an amendment of SFAS 123«,
- FIN[3] 45 »Guarantor's accounting and disclosure requirements for guarantees, including indirect guarantees of indebtedness of others« and
- FIN 46 »Consolidation of variable interest entities« as well as FIN 46 Revised.

[1] Financial Accounting Standards Board
[2] Statements of Financial Accounting Standards
[3] FASB Interpretation

SFAS No. 148 had no impact on the financial statements 2003 of MediGene.

FIN 45 stipulates that a guarantor must take as a liability a guarantee given to the amount of the present value for the obligation he has taken on by granting the guarantee. According to detailed disclosure requirements these guarantees have to be reported in detail within the notes.

D) Consolidation principles

In addition to the financial statements of MediGene AG Martinsried group accounts include the statements of the wholly-owned subsidiary MediGene, Inc., San Diego and since March 31, 2003 of LARNAX GmbH, Martinsried. MediGene last held a 67% stake in LARNAX GmbH. As per December 31, 2003, LARNAX GmbH discontinued its business operations. As per December 31, 2003, MediGene AG owned no other stakes in affiliated companies, affiliated companies or partnerships.

In case control of affiliated companies by the parent company by means of direct or indirect majority of voting rights is possible, these affiliated companies have to be fully consolidated. Furthermore, corporations are fully consolidated if the company does not hold the majority of voting rights according to FIN 46, but is the primary beneficiary from this variable interest entity.

Capital consolidation was carried out using the so-called »Purchase accounting«-method. The purchasing expense for the stakes acquired is set off against the share of the equity capital at the time of purchase attributable to the parent company. Any difference is attributable to the assets and liabilities of the subsidiary in proportion to the share of the stake purchased up to the amount of the apportioned present values. Any remaining capitalized difference is seen as equity.

All internal Group receivables and payables, sales, expenses and revenues, but also interim results in the consolidated entity, have been eliminated as part of the consolidation.

Consolidated company

	MediGene, Inc.	LARNAX GmbH
Registered office	San Diego, USA	Martinsried, Germany
Shareholding in %	100	67.5
Equity at Dec. 31, 2003 in T€	-59	-405
Net loss for the year 2003 in T€	**-7,958**	**-1,257**

E) Essential principles of accounting and valuation

(1) Foreign currency translation

SFAS No. 52 »Foreign currency translation« was applied in consolidating the U.S. subsidiary, which prepares its accounts in U.S. dollar, balance sheet items always being converted at the rate of exchange on the balance sheet date, with the sole exception of shareholder equity which is converted at its historic exchange rate. For consolidation purposes, income and expenses are translated into the reporting currency at the average annual rate of exchange. Differences between the foreign currency translation in the balance sheet and the translation from the previous year are also reported neutral to income under other comprehensive income. This balance sheet item for 2003 was -220 T€ (2002: -1,031 T€). Receivables and payables not denominated in the functional currency are converted at the rate of exchange on the balance sheet date. Items bought and sold in foreign currencies are converted at the rate of exchange on the date of transaction. Foreign currency exchange gains and losses are listed as such in the profit and loss statement. The following exchange rates applied in 2003:

US$/€ exchange rates in 2003

Cut-off date rate			Annual average rates
December 31	1.2630	2003	1.1308

At the cut-off date 2003 the rise in the euro versus the U.S. dollar led to currency-based corrections in the value of fixed assets amounting to -202 T€ (2002: -282 T€). Effects from currency translation are reported on the balance sheet as »Accumulated other operating income«.

(2) Statement of revenues

Income from research cooperations is booked when the contractually agreed targets or milestones have been reached. Contractually agreed payments and fixed-date payments that do not depend on future performance are recognized as income when the cooperation partner confirms that the contractual obligations have been fulfilled. Payments for research and development are recognized on the basis of the progress made in the work. So-called »Upfront payments« (one-off) made by a pharmaceuticals partner when a new contract is signed are, as per US-GAAP, spread over the entire estimated contracted period. Cash flow increases by the full amount received in payment. Payments itemized in the balance sheet are recognized pro-rata over the product development period and/or the term of the contract and booked in the profit and loss statement as other operating income. In 2003, no new contracts were signed to which this provision would have applied. Payments made for unsuccessful research work are not refunded. Grants received are posted as other operating income.

(3) Research and development expenses

Research and development expenses include all costs generated by research and development activities: personnel expenses, consultant fees, material costs, services, laboratory costs, legal costs and other allocated costs such as rent and electricity. They are expensed when incurred.

(4) Earnings per share

Earnings per share are calculated according to SFAS No. 128 »Earnings per share«. The actual earnings per share from continued operations are -2.53 € and are derived by dividing the annual net loss from continued operations into the average number of shares outstanding (2003: 11,206,205 shares). Earnings per share from continued operations on a fully diluted basis (2003: -2.40 €) are calculated by dividing the annual net loss into the average number of shares outstanding plus all potentially dilutive shares created by exercising options and convertible bonds granted. This may result in a dilution of the earnings per share in the future (2003: 11,830,072 potential shares).

(5) Cash and cash equivalents

Cash and cash equivalents comprise cash in hand and at banks, also checks with an original maturity of up to three months. They are booked at par value.

(6) Financial investments and securities held as current assets

There are no major holdings over which any decisive control can be exerted. All other holdings and securities held as fixed or current assets are classified as available-for-sale in accordance with SFAS No. 115 »Accounting for certain investments in debt and equity securities«. Securities held as fixed and current assets can be sold at any time and are valued at their market price. Resulting unrealized gains or losses are posted under other comprehensive revenue without consideration for deferred taxes and neutral to revenues as part of shareholder equity impermanent in nature. If there is permanent value impairment for an available-for-sale security, depreciation would be incurred with an effect on results.

(7) Receivables

Receivables from deliveries and services are posted at par value. Neither any specific bad debt nor any lump-sum allowances were necessary.

(8) Intangible assets

Intangible assets acquired for cash and with a limited period of use are posted at cost and depreciated regularly using the linear method. No extraordinary write-downs

resulting from a permanent decline in value were necessary. Depreciation of intangible assets is based on the following useful lives calculated on the basis of the estimated working life:

Software	3 – 4 years
Licenses for technologies and products	3 – 5 years

The goodwill amounted to 9,226 T€. The goodwill is related to MediGene, Inc. and is reported in the oncology segment.

Since January 1, 2002, SFAS No. 141 »Business combinations« and SFAS No. 142 »Goodwill and other intangible assets« have been applied. The scheduled amortizations of acquired goodwill over the estimated useful life of the asset therefore no longer applied. Instead, the value of goodwill was examined within the framework of the annual project evaluation process. This evaluation is carried out annually, also during the course of the year when there are signs of a decline in value. If such an examination reveals a decline in value, an unscheduled amortization must be carried out. The impairment test is based on a comparison of the current book value with the result of the project valuation in the form of a net present value (NPV). In this process, the net present value (capital value) of an investment is ascertained on the basis of a discount factor for a series of periodic payments. In 2003 depreciation of goodwill was not required.

Further details on the development of the assets can be found in the fixed asset statement.

(9) Property, plant and equipment

Property, plant and equipment are valued at cost and depreciated at regular intervals using the linear method. Unscheduled extraordinary depreciations due to a permanent decline in value were not necessary. We have not yet manufactured any assets ourselves. Property, plant and equipment are depreciated over their expected useful life, improvements to leased assets also over the term of the contract, whichever is shorter.

Improvements to leased assets	8 – 10 years
Technical equipment and lab fixtures and fittings	3 – 5 years

Significant renovations and improvements are capitalized insofar as they increase the value of the plant and equipment. All other expenditures for maintenance and repairs are booked as expenses at the time they are incurred. When property, plant or equipment is sold, their purchase price and resultant accrued depreciation are eliminated from the accounts in the year of sale. The resultant gain or loss is posted under other revenue and expenses the thereby affecting net income. The purchase and sale of fixed assets within the Group are eliminated in the course of consolidation.

Fixed assets with purchase prices up to 410 € are classified as of insignificant value. These assets are not allocated to fixed assets but are instead reported in their entirety under other operational expenses. Details on changes to the company's fixed asset position can be found in the fixed asset statement.

(10) Unscheduled depreciations and amortizations on intangible assets with limited service lives and on tangible assets

Whenever signs indicate that a decline in value could occur, an impairment test in assets with planned depreciation schedules is made. In such cases, assessed future cash flow is compared to remaining book value of the asset. Should it be the case that the residual book value of the asset exceeds the amount of undiscounted cash flow, the current value will be calculated and the asset depreciated to this amount.

An unscheduled depreciation must be considered to the extent that the book value exceeds the specified market value.

(11) Leasing

The company has concluded long-term leasing agreements for certain operating and office equipment. These agreements fulfill at least one of the SFAS No. 13 requirements for classification as capital leases and are thus capitalized at the same time as the matching leasing liability. Assets activated in this way are reported at cost of purchase and like other tangible assets in the company, written off using the linearly over the estimated economic life. In addition,

the company rents office and laboratory space, office equipment, laboratory apparatus and vehicles that are considered operative leasing. These operating leasing payments are booked as expenses when they occur. Leasing agreements for office furnishings are made for 60 months and those for office and business equipment for 36 months. Main lessors are HVB Leasing and GE Capital Ltd. MediGene's role is strictly that of a lessee.

(12) Liabilities

Trade payables are valued at their redemption cost. Financial liabilities consist primarily of research and development loans as well as capital leasing liabilities.

(13) Accruals

Pension and other accruals were made. In 1988, the company made a pension commitment to Dr Heinrich as part of a salary conversion. This consisted of a one-off payment of 26 T€.

This liability is valued at its present value. Other accruals consist mainly of services received but yet to be billed. They are considered at a level which takes suitable account of all recognizable risks. For these accruals, no significant estimate parameters, price increases or calculations on a partial or full cost basis were necessary. No options on accounting were taken up.

(14) Stock options and convertible bonds

US-GAAP Accounting Principles Board No. 25 specifies that stock options and convertible bonds issued to employees and members of the Executive and Supervisory Boards are to be shown under »expenses« as the difference between current market value and total conversion price spread over the vesting period. Following HGB guidelines, options are not reported on issuance. They are only reported in capital reserves when they have been converted.

(15) Comprehensive income

SFAS No. 130 »Reporting comprehensive income« requires the disclosure and description of total earnings. In other comprehensive income, unrealized gains or losses from the market valuation of securities are booked as a change in equity capital without any effect on operational results. Differences resulting from foreign currency translation are also listed under other comprehensive income.

(16) Deferred taxes

Deferred taxation is based on temporary differences. They result from time differences in the reporting of results under commercial and tax law and the different values assigned in the commercial and then in the tax balance sheet. Taxes to be deferred are calculated using the liability method. The future tax rate based on present legal provisions is applied when the only temporary difference will probably be compensated for again in the near future. The effect of changes in tax law will be posted and affect results in the period they take effect. For tax deferral made up to December 31, 2003, the tax rate was 37.9%. Deferred taxes may be revalued. Capitalized deferred taxes are only posted in so far as it is probable that the tax advantages linked to them might actually be realized.

(17) Cash flow statement

The cash flow statement is drawn up according to SFAS No. 95 »Statement of cash flows«. For its calculation the company applied an indirect method and broke down cash flows according to operating, investing and financing activities.

(18) Discontinued operations according to SFAS No. 144

Discontinued operations are accounted according to SFAS No. 144 »Accounting for the impairment or disposal of long-lived assets«. Company entities, which are planned for sale or to be discontinued, have to be reported separately »Discontinued operations«. Significant assets and liabilities of the respective entities have to be shown in a separate balance sheet item. As a result of the discontinuation of the operational activities of LARNAX GmbH its balance sheet did not include any major items as per December 31, 2003. Earnings and losses from sale as well as earnings and losses from common business activities of corresponding entities will be reported in the profit and loss statement as »Discontinued operations«. Prior periods will be adapted accordingly.

(19) Important differences between HGB and US-GAAP

These consolidated financial statements were drafted on the basis of US-GAAP. US-GAAP differs from the German Commercial Code HGB in a variety of points. Differences in accounting principles between US-GAAP and HGB relevant to these consolidated financial statements are as follows:

IPO costs

US-GAAP requires costs incurred in going public to be listed as reduction in capital reserves. HGB posts them as extraordinary expenses.

Intangible assets

US-GAAP requires purchased intangible assets – including goodwill – to be posted in the balance sheet. HGB leaves the option open as to whether to capitalize goodwill. According to US-GAAP goodwill is not depreciated linearly, whereas HGB requires depreciations to be spread over the planned useful economic life.

Tangible assets

US-GAAP requires scheduled depreciation to reflect wear-and-tear. Newly acquired property, plant and equipment with an estimated useful life that extends beyond the fiscal year is depreciated over its estimated useful life. US-GAAP strictly rules out any special depreciation made purely for taxation reasons. When writing off their assets companies that file HGB-based accounts frequently tend to be guided by the amortization tables used as a basis for taxation purposes. They may opt in such cases for applying the linear or the declining-rate amortization method.

Leasing

US-GAAP makes a fundamental distinction between two forms of leasing: capital and operating. Operating lease corresponds to a rental-type agreement under which the lessor must include it in his balance sheet. Capital lease, however, requires capitalization by the lessee. The German Commercial Code (HGB) does not specify how to handle leasing transactions in the balance sheet. The commercial approach would indicate that the leased item should be included in the accounts of the »economic owner« at the given time.

The economic owner could be either the lessee or the lessor. A number of criteria need to be considered in clarifying once and for all who should report a leasing contract in his balance sheet. In practice, leasing agreements are generally drawn up in such a way that the leased items are allocated to the lessor for tax advantage reasons.

Deferred taxes

US-GAAP requires the mandatory capitalization of deferred tax assets, regardless of their origins, and the mandatory accrual of deferred tax liabilities. Deferred tax assets are checked for the likelihood of being realized and, if required, are then valued fairly. German principles do not allow deferred tax assets based on net losses and then carried forward in the books to be posted in the accounts. Only deferred tax assets resulting from difference in valuation between commercial and taxation law may be posted, while deferred tax liabilities have to be accrued.

Foreign currency translation

US-GAAP requires payables and receivables denominated in foreign currencies to be converted at the rate of exchange on the balance sheet date. Gains and losses not only temporarily unrealized must be posted so as to affect operating results. According to German commercial law, assets and liabilities must be valued individually on the date of the balance sheet. Valuation must be conservative with earnings only being posted if they are realized by the closing date. For consolidation purposes, both US-GAAP and HGB apply the principle of functional currency.

Revenue recognition

Revenue recognition is subject to much stricter criteria in the US-GAAP than in the German HGB. The main consideration is the time revenues are booked. This can lead to differences within the accounting period.

Unrealized increases and decreases in the value of securities

US-GAAP allows unrealized fluctuations in the value of securities available for sale to be entered as »Other comprehensive income« under shareholder equity. This applies only to temporary fluctuations. Unrealized losses which are not solely temporary must be posted so as to affect profit and loss results. In the German HGB, a strict lowest-cost-to-market principle is applied to securities held as current assets. According to this principle, unrealized losses must be stated in the profit and loss statement in a manner affecting operating results whereas profits may only be shown once they are realized.

Calculating the purchase price of acquisitions

US-GAAP requires the purchase price of an acquisition to be stated at the market value of the shares offered in payment. The market value is the market price quoted on the date the transfer terms of the stock-swap acquisition were published. German principles require the price to be set after the date on which the commitment can no longer be reversed (date of no return).

Stock options and convertible bonds

US-GAAP Accounting Principles Board No. 25 requires that stock options and convertible bonds issued to employees and members of the Executive and Supervisory Boards be expensed as the difference between current market value and total price of conversion of such shares over the entire vestment period. The HGB does not require options to be reported on issuance, not until they have been converted and then they are reported as accrued capital reserves.

Variable interest entities

According to US-GAAP (FIN 46) so-called »Variable interest entities» have to be fully consolidated by the holder of the majority interest. This independent from the share-ownership ratio. Equivalent rules do not exist in the German Commercial Code HGB.

Content and presentation of the annual balance sheet

US-GAAP classifies balance sheet items as either »current« or »long-term« depending on how easily they can be converted into cash. The profit and loss statement is drafted on the basis of the cost-of-sale accounting formula and makes a distinction between operating and non-operating expenses. HGB does not classify balance sheet items in this way. The profit and loss statement here must be based on either the total cost or the cost-of-sale accounting formula. In the latter case, additional details must be provided. The differences in balance sheet accounting between US-GAAP and HGB for the consolidated MediGene financial statements have not been quantified because the only consolidated subsidiary, MediGene, Inc., reports solely according to US-GAAP. HGB-based reporting by a U.S. corporation, which has formed a part of the reporting entity since March 2001, and an audit of the report do not make economic sense for MediGene.

(20) New accounting principles

According to FIN 46, assets, liabilities and operating results of corporations in which the company holds a majority interest (»Variable interest entity«) have to be consolidated. FIN 46 applies to corporations being founded later than January 31, 2003. For corporations being founded prior to Febuary 1, 2003, the respective regulations have to be applied for the periods ending after December 15, 2003. FIN 45 Revised is applied by the company since the first fiscal quarter 2003. Due to a loan of 472 T€, LARNAX GmbH is considered as a variable interest entity in accordance with FIN 46, and therefore consolidated into MediGene's figures as »Discontinued operations». This includes the associated cardiological research program of MediGene.

F) Notes on the income statement

(21) Other operating income

Other operating income

in T€	2002	2003	Change
R&D funding from partnerships	3,064	1,474	-52%
Milestone and license fee payments from partnerships	102	102	0%
Grants	55	95	73%
Other	204	71	-65%
Total from continued operations	**3,425**	**1,742**	**-49%**
Discontinued operations	112	153	37%
Total	**3,537**	**1,895**	**-46%**

(22) Selling expenses

No sales activities are yet in progress so that selling expenses include only spendings for business development and pre-marketing, among such expenses being personnel expenses, consultant fees, market studies, material costs and other services.

(23) General and administrative expenses

This item primarily includes personnel expenses, capital market communication spend and press work, also administration-related and general services. Other operating expenses are not included. Expenses for rent, rental overheads, telecommunications services, security and the like are attributed to the various segments. Assets are directly attributed to the various segments so that depreciation as

well as profits and losses from the disposal of assets are booked directly. The same applies to the acquisition and disposal of accruals, foreign exchange profits or losses, which are posted separately in the profit and loss account.

(24) Personnel expenses

The following personnel expenses are posted as expense items in the profit and loss statement:

Personnel expenses

in T€	2002	2003	Change
Wages and salaries	9,436	9,510	1%
Social insurance	1,809	1,463	-19%
of which for pension	*135*	*186*	*38%*
Total from continued operations	**11,245**	**10,973**	**-2%**
Discontinued operations	1,430	1,063	-26%
Gesamt	**12,675**	**12,036**	**-5 %**

Personnel expenses by segment

in T€	2002	2003	Change
HPV-indications	1,333	814	-39%
Oncology	4,044	3,360	-17%
Intersegment	5,867	6,799	16%
Total from continued operations	**11,245**	**10,973**	**-2%**
Discontinued operations	1,430	1,063	-26%
Total	**12,675**	**12,036**	**-5%**

Employees by function

	Dec. 31, 2002	Dec. 31, 2003	Change
Business development and general administration	102	53	-48%
Research and development	55	48	-7%
Total from continued operations	**157**	**112**	**-29%**
Discontinued operations	28	12	-57%
Total	**185**	**124**	**-33%**

The decline in personnel expenses can be attributed to the cost-cutting and savings programs introduced in 2003. An average workforce of 157 was employed at the MediGene Group in 2003, 35 at MediGene, Inc. und 23 in discontinued operations. This corresponds to a reduction of 11% in comparison to the number of 176 for the prior year. All employees are salaried staff.

Members of the Supervisory Board and the Executive Board are listed in Note (48). Total income of Executive Board members in the last fiscal year was 663 T€ (2002: 569 T€). Remuneration to Executive Board members contains fixed and variable components as well as adequate provisions for performance-based incentives to assure long-term growth in the value of the company. The criteria for variable remuneration are determined in advance each year. Long-term remuneration includes stock options which are intended to serve as incentives to secure the lasting success of the company. For such incentives, no subsequent change in the earnings goals may be made. Total remuneration for Super-

in T€	Fixed salary	Variable, performance related components	Variable components with a long-term incentive (No. of stock options)
Dr Peter Heinrich, Chief Executive Officer	248	20	20,000
Alexander Dexne, Chief Financial Officer	177	20	40,000
Dr Johanna Holldack, Chief Operating Officer (until October 1, 2003)	178	20	20,000

visory Board members in 2003 was 89 T€ (2002: 90 T€). Supervisory Board remuneration includes a fixed cash amount and a stake in the MediGene AG convertible bond program. Consideration of the scope of work of the Supervisory Board members included the Chairman and his Deputy. For details of the subscription rights held by members of the two Boards and the employees see »Directors' Holdings«, Note (38). No advance payments were made to the members of these bodies.

(25) Material costs

The following material costs have been booked in the profit and loss statement:

Material costs

in T€	2002	2003	Change
Cost of raw, auxiliary and operating materials	1,185	845	-29%
Cost of services	11,507	10,648	-7%
Total from continued operations	**12,691**	**11,493**	**-9%**
Discontinued operations	5,727	926	-84%
Total	**18,418**	**12,419**	**-33%**

The costs for raw, auxiliary and operating materials mainly comprise laboratory materials and chemicals. Services purchased, without consideration of discontinued operations, are made up of the execution of clinical trials (7,120 T€), Regulatory affairs (368 T€), production services (2,015 T€) and pre-clinical development services (1,145 T€).

(26) Amortization of goodwill

Since January 1, 2002, SFAS No. 141 »Business combinations« and SFAS No. 142 »Goodwill and other intangible assets« have been applied. The application of these provisions meant that an impairment test was carried out. It was based on the net present value (NPV) calculation formula applied to development projects carried out by MediGene, Inc. The result was a markedly higher amount than the goodwill reported on the balance sheet which meant that an unscheduled extraordinary write-off on goodwill was not necessary.

(27) Financial results

Financial results

in T€	2002	2003	Change
Interest income	2,179	778	-64%
Interest expenditure	-98	-77	-21%
Foreign currency exchange gains/losses	-753	6	-101%
Total	**1,328**	**707**	**-47%**

(28) Income tax

Deferred tax assets are as follows:

Income tax

in T€	MediGene AG Germany 2002	MediGene, Inc. USA 2002	MediGene AG Germany 2003	MediGene, Inc. USA 2003
Deferred tax assets on net losses	24,743	13,942	35,454	15,574
Deferred tax assets/liabilities on temporary timing differences	21	-155	-193	-25
Valuation allowance	-24,764	-13,787	-35,261	-15,549
Deferred tax assets, net	**0**	**0**	**0**	**0**

As the company's medium-term budget projections do not anticipate any profit, deferred tax assets were written down to zero. This present assessment may have to be modified if the future earnings situation changes, necessitating lower valuation allowances. Under German tax law, losses can be carried forward for an unlimited time. Under U.S. tax law, however, there is a time limit on accrued losses carried forward. MediGene, Inc.'s losses carried forward shall therefore expire between 2004 and 2023 depending on when they were incurred. In Germany the corporate tax rate decreased 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 (as per March 31, 2003), was classified a discontinued operation. Since March 31, 2003, LARNAX was included as a consolidated entity and reported on during the year in the cardiology segment. MediGene last held a 67% stake in LARNAX GmbH. As per December 31, 2003, LARNAX GmbH discontinued its operations. The LARNAX loss amounted to 1,125 T€. The loss from discontinued operations amounted in total to 2,988 T€.

Accounting of discontinued operations according to SFAS No. 144

In October 2001 the FASB issued SFAS No. 144 »Accounting for the impairment or disposal of long-lived assets«. SFAS No. 144 deals with accounting and explanatory duties related to the impairment of long-lived assets and discontinued activities. According to SFAS No. 144 the obligation to report discontinued operations applied to business segments is extended to include components of entities, which are being sold, planned for sale, discontinued or have been separated in the course of split-up or spin-off. Concerning the operations discontinued, SFAS No. 144 intends to provide useful informations to creditors and investors. MediGene reports the cardiology segment including LARNAX GmbH as discontinued operations.

Except for the newly applied rules, all other methods of accounting have been continued.

G) Notes on earnings per share

The following table indicates the calculation of actual and diluted loss per share:

Notes on earnings per share

in T€	2002	2003
Operating loss	30,231	28,333
Net loss from continued operations	**30,231**	**28,333**
Net loss per share from continued operations in €	2,70	2,53
Minority interest	0	261
Loss from discontinued operations	8,639	2,988
Net loss	**38,870**	**31,060**
Net loss per share in €	3,47	2,77
Weighted average number of shares	11,204,990	11,206,205

The fully diluted net loss was equivalent to the actual loss as the conversion of common stock equivalents would have had an anti-dilutive effect.

H) Notes on the balance sheet

Assets

(30) Cash

Cash

in T€	2002	2003	Change
Cash and cash equivalents < 3 months	47,762	21,444	-55%
Total	**47,762**	**21,444**	**-55%**

The decline in the cash position was the result of cash burn for research and development activities at the company.

(31) Receivables

As in 2002, no allowance for questionable accounts receivable were made in 2003. All receivables are due within three months.

(32) Inventories

In 2003, inventories were devalued from 492 T€ (2002) to 0 T€. The reason for this was an adjusted interpretation of US-GAAP according to which inventories are usually posted in the balance sheet in connection with sales activities. MediGene had no sales of its own in 2003 and thus maintained no inventories. In 2002, test tubes and materials for research purposes had been capitalized.

(33) Prepaid expenses and other current assets

Other assets

with a term < 1 year

in T€	2002	2003	Change
Tax refund claims	68	32	-53%
VAT refund claims	117	424	262%
Grants	55	44	-20%
Cooperation agreements	2	29	1,350%
Interest	72	18	-75%
Advances	124	0	-100%
Rent deposit	0	105	–
Other	0	1	–
Total	**438**	**653**	**49%**

Prepaid expenses

with a term < 1 year

in T€	2002	2003	Change
Insurance services	23	38	62%
Use of software and data	7	0	-100%
Research services	154	1	-99%
Maintenance	78	22	-72%
Conference fees and travel	45	11	-76%
Fees designated sponsors	20	58	190%
Licenses	59	0	-100%
Other	125	76	-39%
Total	**511**	**206**	**-60%**
Balance sheet item	**949**	**859**	**-10%**

(34) Intangible assets and property, plant and equipment

A detailed listing of and the developments in intangible assets and property, plant and equipment can be found in the fixed asset statement.

(35) Investments

Financial assets as per December 31, 2003 were as follows:

Investments

in T€	Acquisition costs	Market value Dec. 31, 2003	Unrealized acc. profit Dec. 31, 2003
Atrix Laboratories, Inc.	3.698	4.452	754

A detailed listing of and developments in financial assets can be found in the fixed asset statement.

Liabilities and shareholders' equity

(36) Liabilities

The pension accruals have a term of more than five years. The remaining long term liabilities are all due within five years and are not secured. In 2003 trade accounts payable increased mainly because of outstanding accounts related to the conduction of the clinical trials of the Polyphenon® E Ointment.

Research and development loans

Since 2000, the company has received a development loan from a cooperation partner to cover the costs incurred by the company to carry out a joint project. On the balance sheet date of December 31, 2003, the amount of the loan was 3,222 T€. The company is obliged to repay the loan as soon as the proof of concept has been obtained for the candidate and the partner has decided to continue the cooperation. If the partner pulls out of the cooperation project even though the proof of concept was positive, the company will not have to repay the loan. In all other cases, MediGene must repay the loan. MediGene is expecting the proof of concept study to be completed in 2004. This will result in a potential repayment date in 2004 meaning that the loan will then enter the balance sheet as a current liability. As a result, long-term loan debt decreased accordingly and the current amount increased.

Liabilities

in T€	2002	2003	Change in T€	Change
Current liabilities				
Current portion of capital lease obligations	401	265	-136	-34%
Trade accounts payable	1,128	1,764	636	56%
Debt	0	3,222	3,222	–
Accruals	2,526	3,342	816	32%
Deferred income	103	0	-103	-100%
Other current liabilities	493	268	-225	-46%
	4,651	**8,862**	**4,211**	**91%**
Long term liabilities				
Long-term debt	2,650	108	-2,542	-96%
Capital lease obligations	277	108	-169	-61%
Other liabilities	34	34	1	3%
with a term > 5 years: Pension accrual	*32*	*35*	*2*	*6%*
	2,993	**285**	**-2,708**	**-90%**

Other liabilities as per December 31, 2003, comprised the following items:

Other liabilities

in T€	2002	2003	Change
Other current liabilities			
Grant-related liabilities	73	0	-100%
Liabilities from cooperation agreements	41	0	-100%
Wage- and church-tax liabilities	158	130	-18%
Social insurance	151	132	-13%
Liabilities from benevolent fund and direct insurance	42	4	-90%
Liabilities from withholding tax	28	2	-93%
	493	**268**	**-46%**
Other long-term liabilities			
Convertible bond liabilities	34	34	0%
	34	**34**	**0%**

The reduction in other current liabilities can be attributed to the reduction in liabilities arising from grants (73 T€) and co-operation agreements (41 T€) as well as from benefit insurance funds and direct insurance (38 T€).

(37) Accruals

As part of the downsizing at the U.S. subsidiary, accruals were made for severance pay and restructuring costs.

In addition to other accruals, we have a pension reserve. In 1998, the company, as part of a salary conversion, agreed to grant Dr Heinrich a pension commitment in the form of a one-off payment of 26 T€. The commitment was booked at its cash value of 35 T€. This calculation was based on the tabular guidelines set up by Dr Klaus Heubeck with an interest rate of 6%.

Accruals

in T€	Dec. 31, 2002	Uses/ reversed	Set up	Dec. 31, 2003
Vacation entitlements and overtime	324	324	224	224
Bonuses	77	77	349	349
Compensation	0	0	152	152
Taxes	4	4	0	0
Rent payments	115	115	71	71
Costs of annual financial statement and audit	104	104	117	117
Employers' liability insurance	59	59	50	50
License payments	44	44	36	36
Other annual financial statement costs	68	68	77	77
Clinical trials and approval	1,050	1,050	1,111	1,111
Production and pre-clinical trials	412	379	322	355
Other	114	114	43	43
Legal costs	23	23	74	74
Consultants	131	131	114	114
Restructuring expenses	0	0	569	569
	2,526	**2,493**	**3,309**	**3,342**

(38) Shareholders' equity

As per December 31, 2003, shareholders' equity remained unchanged in comparison to the prior year. Total number of common shares outstanding with no par value was 11,206,205 which have all been issued and are all in circulation as per balance sheet date. In arithmetic terms, each share of subscribed capital represents a stake of 1 € in the company.

Changes in the Executive Board

Effective October 1, 2003, Dr Johanna Holldack, Chief Operating Officer, left MediGene AG at her own wish. The Executive Board is thus now made up of Dr Peter Heinrich, Chief Executive Officer, and Alexander Dexne, Chief Financial Officer.

The leadership of research and development in the MediGene Group has now been taken over by Dr K. Jon (Kerry) Kowal, Senior Vice President. Dr Kowal, until now Managing Director and head of research and development at our U.S. subsidiary MediGene, Inc., will, in future, report directly to Dr Peter Heinrich, Chief Executive Officer.

Changes in the Supervisory Board

Effective October 27, 2003, Prof Dr Norbert Riedel, the substitute member selected in the regular General Meeting from May 23, 2001, replaced the departing member Prof Dr Michael Hallek in the Supervisory Board. The studied biologist Prof Riedel is Senior Vice President and Chief Scientific Officer of Baxter International Inc., one of the world's leading U.S. pharmaceuticals company. In 1998, he was named Director of the unit there for Recombinant Therapeutic Proteins at Baxter BioScience. Before this, he had been Global Director for Biotechnology and Global Director for Central Research at Hoechst Marion Roussel. Prof Riedel studied at the University of Frankfurt, went on to study at Harvard and taught at the Massachusetts Institute of Technology and the Boston University School of Medicine where he is still an Associate Professor today.

Prof Hallek has headed up the well-known Clinic for Hematology and Oncology at the University of Cologne since November 2003 and, as a result of this change in his career, is laying down his position in the MediGene Supervisory Board. He will, however, continue to act as a scientific and clinical consultant to MediGene AG. The change in the Executive Board was announced in the electronic Bundesanzeiger (www.gbi.de, Germany) from December 1, 2003.

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

Members	No. of share 2002	No. of share 2003	No. of options 2002	No. of options 2003	No. of CB* 2002	No. of CB* 2003
Prof Dr Ernst-Ludwig Winnacker Supervisory Board Chairman, Co-founder	292,676	292,676	38,700	38,700	2,400	3,200
Dr Helmut Schühsler (until Dec. 31, 2003) Supervisory Board Deputy Chairman	25,940	25,940	6,880	6,880	1,800	2,400
Prof Dr Dr Ernst-Günter Afting Supervisory Board member	11,217	11,217	15,370	15,370	1,200	1,600
Dr Pol Bamelis Supervisory Board member	330	1,000	0	0	800	1,200
Prof Dr Norbert Riedel (as of Oct. 21, 2003) Supervisory Board member	–	2,330	–	5,590	–	–
Michael Tarnow Supervisory Board member	6,337	6,337	0	0	25,800	31,200
Total Supervisory Board	**336,170**	**339,500**	**60,950**	**66,540**	**32,000**	**39,600**
Dr Peter Heinrich Chief Executive Officer, Co-founder	499,500	503,505	36,636	56,636	41,000	0
Alexander Dexne Chief Financial Officer	0	0	0	40,000	0	0
Total Executive Board	**499,500**	**503,505**	**36,636**	**96,636**	**41,000**	**0**
Shareholders' equity	**0**	**0**	**0**	**0**	**0**	**0**

* Convertible bonds
(status as per December 31, 2002 and December 31, 2003)

On January 1, 2004, Dr Schühsler left the Supervisory Board to concentrate on his work as Managing Partner at venture capital company TVM and on his Supervisory Board mandates at other private companies. The change was announced in the electronic Bundesanzeiger (www.gbi.de, Germany) from January 15, 2004.

(39) Stock option plan

In July 2003, the annual shareholders' meeting decided to issue 680,000 options to the Executive Board, the employees and the consultants of the company, of which up to 240,000 can be issued to the Executive Board, 400,000 to the staff and 440,000 to the members of affiliated companies in Germany and abroad. These options can be issued until June 3, 2008 and mature within ten years after issue. The options issued can be converted at staggered intervals during the maturity period, beginning after a waiting period of two years. In 2003 131,292 stock options were granted. The issue of the remaining number of 548,708 stock options was restricted as follows: 40,000 to members of the management bodies of affiliated companies, 160,000 go to the Executive Board and 348,708 to the staff. Strike price per option is based on the day's market high on the day of issue or on the average stock price over the past 60 days of trading on the XETRA trading platform of the German Stock Exchange in addition to a premium over quote of 20%. The strike price for the options issued in 2003 was 4.60 €.

Stock option plan

in T€	2002	2003	Change in T€	Change
Expenses for stock options according to APB 25	0	0	0	0%
Expenses for convertible bonds	108	35	-73	-68%
	108	**35**	**-73**	**-68%**

On December 31, 2003, the total number of shares outstanding was 11,206,205 and the number of shares on a fully diluted basis was 11,830,072. The changes in shareholder equity are listed in the consolidated change list of shareholders' equity.

The annual shareholders' meetings of July 1997 and July 1999 adopted stock option plans. These granted options to employees and members of the Executive and Supervisory Boards as well as to the Scientific Advisory Board. The number of options is restricted to 593,056. The number of options on offer depends in part on the individual's length of service with the company and position attained. The options must be exercised within a period of ten years from the date of issue. They may be exercised at any time after option rights are granted in consideration of a waiting period of six months (for options issued in 1997 and 1998) or two years (for options issued in 1999 and 2000). Holders of options are entitled to exercise their rights under their options and, during the term, buy new company stock in return for payment of an exercise price per share. The following options were issued and/or exercised from 1997 to 2003:

The strike price for the options issued in 1997 and 1998 was 2.93 €, for those in 1999 and 2000 6.48 €. The company applies the Accounting Principles Board Opinion No. 25 »Accounting for stock issued to employees«. As a result, no personnel expenses are recognized for options issued to staff and members of the Executive and Supervisory Boards before December 31, 1999. In 2001, expenses totaling 138 T€ (in 2000: 138 T€) were recognized based on a fair value of 10 € per option. The value of the options issued to members of the Scientific Advisory Board is expensed at the date of the options granted.

Had the company prepared its accounts in accordance with SFAS No. 123 »Accounting for stock based compensation« on the basis of which the company would have had to include the value of the options in the balance sheet at their fair value on the date of issue, there would have been no effects on the company's annual results in 2003. The last options with a term of two years were issued in 2000. Therefore, the term of maturity for these options would

Stock options

No.	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
Total options issued	**657,913**	**63,640**	**721,553**
Options converted into shares in 2000	100,465	0	100,465
of which under the 1997 stock option plan	*100,465*	*0*	*0*
of which under the 1999 stock option plan	*0*	*0*	*0*
Options converted into shares in 2001	92,704	2,580	95,284
of which under the 1997 stock option plan	*85,046*	*2,580*	*87,626*
of which under the 1999 stock option plan	*7,658*	*0*	*7,658*
Options converted into shares in 2002	7,568	0	7,568
of which under the 1997 stock option plan	*860*	*0*	*860*
of which under the 1999 stock option plan	*6,708*	*0*	*0*
Options converted into shares in 2003	0	0	0
Total options converted	**200,737**	**2,580**	**203,317**
Withdrawn options rendered invalid 2001	731	0	731
Withdrawn options rendered invalid 2002	1,161	0	1,161
Total remaining convertible options as at Dec. 31, 2003	**455,284**	**61,060**	**516,344**

have expired in 2002. In 2003, the pro-forma impact of the application of SFAS No. 123 would have been:

Net loss

in T€	2003
As reported	31,060
Pro forma according to SFAS No. 123	53
Pro forma-net loss	31,113
Pro forma-net loss per share in €	**2.78**

The value of the options was worked out using the Black Scholes Option Pricing Method. To do this, the following assumptions were made:

Risk-free interest rate	5.65%
Expected volatility	1.0
Expected dividend	0.0

(40) Convertible bonds

A new convertible bond plan was adopted at the extraordinary shareholders' meeting in May 2000. Under this plan, employees, advisers and members of the Executive Board receive convertible bonds at a par value of 1 €. The number of convertible bonds granted to employees and members of the Executive Board is restricted to 670,000. The number of convertible bonds granted to members of the Supervisory Board is restricted to 3,000. The number of convertible bonds offered depends, among other things, on how long an individual has worked for the company and the position he or she holds. These convertible bonds expire five years after the date they were granted. They can be exercised at graduated intervals during this period after a vestment period of two to four years. Holders of convertible bonds are paid interest of 2.5% of the par value they paid for their bonds.

At the ordinary shareholders' meeting in May 2001, the resolution passed in 2000 was amended. The convertible bonds issued from June 2001 can be converted at staggered intervals during the redemption period after a vestment period of one to three years. It was agreed that the issue of the remaining 659,830 convertible bonds be restricted as follows: 150,000 to members of the Executive Board and management bodies of affiliated companies, of there 100,000 to the Executive Board of MediGene, 439,830 to the staff and 70,000 to consultants. The conversion price per convertible bond is based on the market price at the time of issue +20%.

At the ordinary shareholders' meeting in May 2001, it was also agreed that a further 3,000 convertible bonds be issued to members of the Supervisory Board.

At the ordinary shareholders' meeting in May 2002, the Executive Board was authorized to issue a further 195,000 convertible bonds subject to the conditions prevailing in 2001. The issue is restricted as follows: 75,000 to members of the Executive Board and the management bodies of affiliated companies and 120,000 to the staff. If bonds are to be issued to members of the Executive Board of the company, only the Supervisory Board is entitled to issue them. At this ordinary shareholders' meeting in May 2002, it was also decided to issue 3,000 convertible bonds to the members of the Supervisory Board.

In accordance with the 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 (50.40 € in 2000) of the convertible bonds was expensed over the vestment period. The total expense was, in 2003, 35 T€, in 2002 108 T€.

Convertible bonds issued in 2003

	No.	Fair value	Total conversion price
February	33,553	*	4.83 €
June	3,000	*	4.97 €
July	10,720	*	3.80 €
	47,273		

* Fair value below conversion price

Convertible bonds issued in 2002

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

* Fair value below conversion price

Convertible bonds issued in 2001

	No.	Fair value	Total conversion price
January	540	*	64.16 €
June	3,000	*	24.57 €
June/July	156,065	*	31.63 €
	159,605		

* Fair value below conversion price

Convertible bonds issued in 2000

	No.	Fair value	Total conversion price
July	3,000	64.90 €	50.40 €
September	9,630	106.50 €	50.40 €
	12,630		

Altogether, 414,804 convertible bonds have been issued so far within the framework of the participation programs that have been adopted. 1,200 convertible bonds were withdrawn from former employees in 2001 and are thus invalid. In 2002, this figure was 28,428. The number of withdrawn and returned convertible bonds was 307,281 in 2003. As a result, the number of valid issued convertible bonds fell to 107,523 as per December 31, 2003.

I) Notes on the cash flow statement

The cash flow statement shows origin and use of cash flows in fiscal 2003 and 2002. It is therefore of vital importance for the assessment of the financial position of the company.

Cash flow from investing activities and cash flow from financing activities are both ascertained in respect of payment. Cash flow from operations, on the other hand, is derived indirectly on the basis of the net loss for the year.

Within the scope of non-cash financing activities, leasing liabilities amounting to 127 T€ (2002: 255 T€) were entered into for laboratory and office supplies in 2003.

Proceeds from minority shareholders were booked as part of the establishment of LARNAX GmbH.

Proceeds from research and development loans and due convertible bonds issued have been reported as »Proceeds from loans« under cash inflow from financing activity.

The final amount of cash and cash equivalents includes cash in hand, bank balances and checks with an original term of up to three months. It thus conforms to the corresponding item in the consolidated balance sheet in this respect. The amount reported was subject to a restraint on disposal as per December 31, 2003 due to a rent deposit guarantee amounting to 783 T€, 577 T€ of that for the U.S. facility. This guarantee will be disposed of on April 30, 2004.

J) Segment reporting

In accordance with SFAS No. 131 »Disclosures about segments of an enterprise and related information« segment reporting follows in conformity with the internal organizational and report structure of the Group.

The company is active in the market segments of HPV-indications and oncology. In these segments, drugs are being developed using a variety of different technologies classified as follows:

HPV-indications: CVLP technology
Drugs:
- Polyphenon® E to treat genital warts
- CVLP tumor vaccine – vaccine against cervical cancer and its precursor stages (until June 2003)

Oncology: rAAV technology, HSV technology
Drugs:
- Eligard® (formerly known as Leuprogel®) to treat advanced prostate cancer
- rAAV vaccine – vaccine against malignant melanoma
- G207 to treat brain tumors (since August 2003 under review)
- NV1020 to treat liver metastases

Intersegment income in 2003 consist primarily of state grants and subsidies from the Federal Ministry of Education and Research (German acronym: BMBF) for a competency development project (55 T€). There are no regular or planned charges for services between the market segments and regions. For this reason, no disclosures can be made about internal pricing. Internal revenues in 2003 totaled 1,238 T€

Segment reporting by market segment

in T€	HPV-indications	Oncology	Intersegment	Total
2003				
Other operating income	703	944	95	**1,742**
Selling expenses	17	183	1,248	**1,448**
General and administrative expenses	0	0	6,478	**6,478**
R&D expenses	8,982	8,621	4,222	**21,825**
Depreciation	152	498	381	**1,031**
Operating loss	8,448	8,359	12,233	**29,040**
Investments[1)]	0	38	195	**235**
Average number of employees	13	44	76	**133**
2002				
Other operating income	1,713	1,640	72	3,425
Selling expenses	21	222	1,434	1,677
General and administrative expenses	0	0	5,500	5,500
R&D expenses	8,868	14,344	3,509	26,721
Depreciation	277	476	332	1,085
Operating loss	7,453	13,401	10,704	31,558
Investments[1)]	40	242	439	721
Average number of employees	23	52	74	149

[1)] Investments also include capital leasing investments.

(2002: 16 T€). This increase is due to the spin-off of the cardiology unit, the move of U.S. subsidiary activities to our German facilities and the execution of a clinical Polyphenon® E trial in the USA. Those revenues were eliminated during consolidation.

Segment reporting by regions:

The company is active in Germany and the U.S. Segment reporting by region only includes continued operations. Discontinued operations were only located at the site in Germany (29).

Segment reporting by regions

in T€	Germany 2002	USA 2002	Germany 2003	USA 2003
Other operating income	3,425	0	1,718	24
R&D expenses	16,085	10,636	16,325	5,500
Depreciation	578	507	626	405
EBIT	-18,261	-13,297	-20,831	-8,209
Investments[1)]	332	389	207	28
Cash flow (from operating activities)	25,341	13,385	19,571	6,973
Assets	64,350	2,729	37,555	812
Liabilities and shareholders' equity	6,606	1,038	8,033	1,114
Average number of employees	100	49	98	35

[1)] Investments also include capital leasing investments.

K) Other notes

(41) Cooperation agreements

Aventis

In February 2000, MediGene AG entered into a licensing and cooperation agreement with Aventis Pharma Germany GmbH. The object of this agreement was the joint development of an rAAV tumor vaccine to treat malignant melanoma. Under this agreement, Aventis will have an exclusive license to develop and market the vaccine in 37 countries (including the EU, the U.S. and Japan). The total value of the agreement is up to 37 million €, plus licensing fees on sales revenues. MediGene owns the marketing rights for most Eastern European countries as well as a number of countries in South America, the Middle East and East Asia. The two companies will conduct all studies jointly, up to and including clinical phase 1/2 trials. Aventis will manufacture the vaccine, conduct the phase 3 trial and register the vaccine. The tumor vaccine is currently in clinical phase 1/2 trials. Results are expected for mid-2004.

Schering

In September 1999, MediGene AG signed a licensing and cooperation agreement with Schering AG for the clinical development and marketing of the vaccine developed by MediGene to treat cervical carcinoma and its precursor stages caused by human papilloma viruses. In June 2003, the project to develop the CVLP tumor vaccine against cervical cancer was stopped. A first clinical phase 1/2 trial on the vaccine did provide positive data on tolerance as well as several details on effectiveness. The results of the trial, however, did not meet the high level of effectiveness criteria set down for it beforehand that would have been necessary to continue the project.

(42) Legal disputes

The company places great emphasis on furnishing its own innovations with immediate protection by registering patents, obtaining the required third party licenses to develop its own products and by defending its own patent rights.

In January 2003, MediGene recognized that it had reached a settlement in its lawsuit for certain property rights on CVLP technology with Loyola University of Chicago and MedImmune Inc. As part of the agreement, all claims for damages by Loyola and MedImmune on MediGene were dropped, MediGene's appeal was ended and the disputed property rights were transferred to Loyola.

In the 2003 reporting period, there were no other court or arbitration procedures that would or could have or have had substantial impact on the company's commercial position, and no such suit is presently pending or threatened.

(43) Contingencies and other financial obligations

On the balance sheet date, there was a rent deposit guarantee totaling 783 T€, 577 T€ of which to be disposed of on April 30, 2004.

No commitments were assumed on behalf of Board members.

Future minimum payments for capitalized leased items and future annual leasing installments on operating leases are as follows:

Contingencies and other financial obligations

in T€	Capital lease	Operating lease
2004	284	1,209
2005	111	709
2006	0	97
2007	0	11
after	0	7
Minimum leasing obligations	**395**	**2,033**
Less interest amount	-22	
Capital lease obligations	**373**	
Short-term obligations	265	
Long-term obligations	108	

(44) Total unused/open credit lines

No open credit lines existed as per December 31, 2003 besides the cash positions reported under Note (30).

(45) Financial instruments

SFAS No. 107 »Disclosures concerning the fair value of financial instruments« requires the disclosure of the fair values of financial instruments regardless of whether they are reflected in the balance sheet. Due to their short-term maturities, the book values of financial instruments such as cash, receivables, liabilities and accruals correspond approximately to their fair values. MediGene's financial instruments currently consist exclusively of these original financial instruments. The book values of these instruments correspond to their market values.

(46) Major events since the cut-off date for this report

On January 14, 2004, MediGene concluded a partnership with the pharmaceuticals group Yamanouchi for the commercialization in Europe of the cancer drug Eligard®, previously known as Leuprogel®. Yamanouchi, the second largest pharmaceuticals company in Europe in the field of urology, will take on pan-European promotion and sale of the drug for treatment of prostate cancer. In return, MediGene will receive successive milestone payments totaling up to 23.5 million € including a signing fee of 4 million € and royalties on the sale of Eligard®.

On January 26, 2004, MediGene received marketing authorization for Germany from the »Bundesinstitut für Arzneimittel und Medizinprodukte« (Federal Institute for Pharmaceuticals and Medical Devices, German acronym BfArM) for the three-month sustained release product of the anti-cancer drug Eligard® to treat advanced prostate cancer. The corresponding one-month sustained release product of this drug had received marketing authorization at the beginning of December 2003. The three-month sustained release product offers additional applications for Eligard® thus enhancing its competitiveness. As announced on January 14, 2004, MediGene's partner Yamanouchi will take on the market launch and sale of Eligard®. As part of the agreement with Yamanouchi, MediGene will receive a milestone payment for this approval of the three-month sustained release product.

In February MediGene has successfully completed patient recruitment for the final clinical trial (phase 3) of the Polyphenon® E Ointment as scheduled. The admission of 480 patients needed for the American arm of the trial will allow a timely completion of the trial by the end of this year, as planned.

In May 2003, MediGene had already successfully completed the European part of the phase 3 trial, with more than 500 patients. MediGene will report the results of the European part at the end of the first quarter of 2004. The overall results of both arms of the study are expected by the end of 2004. With approximately 1,000 patients in 100 centers and 14 countries, this programme is the most extensive clinical trial ever conducted by a German biotech company.

On March 4, MediGene has finalized a three-step corporate action to increase cash available by approx. 16 million €. The first step will be a share capital increase by 10% through a private placement under participation of Techno Venture Management (TVM) without subscription rights for shareholders. Approx. 1.1 million new shares will be issued at the average market price of the past five trading days, that is 6.80 € per share. In a second capital increase of 10%, MediGene will submit an offer to current shareholders for again approx. 1.1 million new shares at 6.80 € each. In addition, MediGene will offer convertible bonds at the amount of 1.5 million €, which can be subscribed to by shareholders for 1 € each. The conversion price is 7.50 € per share. The convertible bonds bear 4% interest annually during the four years to maturity. Conversion is possible after a period of 12 months. MediGene can ask for conversion under certain circumstances. Subscription period wil be March 6 – 19, 2004. According company´s statements the capital increase measures will extend the financial scope for MediGene AG and increase the current amount of cash to about 40 million €. Due to these measures, the number of MediGene shares will rise from 11,228,362 to 13,474,032. The capital increase measures will be carried out with authorized and conditional capital. No further shareholder´s resolution is needed.

(47) German Corporate Governance Code

In December 2003, the Executive Board and the Supervisory Board of MediGene AG confirmed that MediGene AG adhered to most of the recommendations of the German Corporate Governance Code in the version of May 21, 2003. The recommendations in the Code that MediGene AG is not implementing are explained in its Compliance Declaration pursuant to Sec. 161 of the German Companies Act. This declaration is permanently accessible on the company website (http://www.medigene.de/deutsch/corporate_governance.php) in both German and English.

(48) Members of the Board of Directors and the Supervisory Board

Executive Board

Dr Peter Heinrich
Chief Executive Officer

Dr Johanna Holldack (until September 30, 2003)
Chief Operating Officer

Alexander Dexne
Chief Financial Officer

Supervisory Board

Prof Dr Ernst-Ludwig Winnacker
Chairman
President of the German Research Association

Dr Helmut Schühsler (until December 31, 2003)
Deputy Chairman
Managing Partner, TVM

Prof Dr Ernst-Günter Afting
Chief Executive Officer, GSF

Dr Pol Bamelis
Former Management Board member of Bayer AG, Leverkusen

Prof Dr Michael Hallek (until October 27, 2003)
Co-founder
Chief Physician for Internal Medicine at the Großhadern Clinic of the University of Munich

Prof Dr Norbert Riedel (from October 27, 2003)
Senior Vice President, Chief Scientific Officer, Baxter International, Inc.

Michael Tarnow
Consultant of the Biopharmaceutical Industry, Boston, USA

The members of the Board of Director and the Supervisory Board are also active in the following Supervisory Boards and/or similar bodies:

Prof Dr Ernst-Ludwig Winnacker
- Bayer AG, Leverkusen
- EleGene AG, Martinsried
- Therascope AG, Heidelberg

Dr Helmut Schühsler (until December 31, 2003)
- Ascenion GmbH, Neuherberg
- Atomika Instruments GmbH, Oberschleißheim
- Garching Innovation GmbH, Munich
- GPC Biotech AG, Martinsried
- Ingenium Pharmaceuticals AG, Martinsried
- Intercell Biomedical Forschungs- und Entwicklungs AG, Austria
- Peptor Ltd., Israel
- selectX Inc., USA
- Sequenom Inc., USA
- VitaResc Biotech AG, Martinsried

Prof Dr Ernst-Günter Afting
- Bio^{M} AG, Martinsried
- Enanta Pharmaceuticals, Inc., USA
- Intercell Biomedical Forschungs- und Entwicklungs AG, Austria
- Sequenom Inc., USA
- VitaResc Biotech AG, Munich
- Xerion Pharmaceuticals GmbH, Martinsried

Dr Pol Bamelis
- Agfa-Gevaert AG, Leverkusen
- Agfa-Gevaert N.V., Belgium
- Crop Design N.V., Belgium
- Evotec OAI AG, Hamburg
- N.V. Bekaert S.A., Belgium
- Oleon N.V., Belgium
- PolyTechnos (GP) II Ltd., Guernsey

Prof Dr Michael Hallek (until October 27, 2003)
- Sireen AG, Munich

Prof Dr Norbert Riedel (from October 27, 2003)
- Genencor International, Inc., USA
- Genome Therapeutics Corp., USA
- Nanomateria, Inc., USA

Michael Tarnow
- AXCAN Pharma Inc., Canada
- Caprion Pharmaceuticals, Inc., Canada
- Ferghana Partners, UK
- Nanopharma Inc., USA
- Paladin Labs, Inc., Canada
- Tao Biosciences, 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, 2003 and 2002

in T€		2002	2003
1.	Revenues	0	0
2.	Other operating income	3,752	2,228
		3,752	**2,228**
3.	Cost of materials		
	a) Cost of raw, auxiliary and operating materials	981	756
	b) Cost of services bought	12,683	10,351
		-13,664	**-11,107**
4.	**Gross profit**	**-9,913**	**-8,879**
5.	Personnel expenses		
	a) Wages and salaries	6,803	6,268
	b) Social insurance contributions and expenditures for retirements benefits	1,212	1,112
	thereof for retirements: 107 T€ (2002: 50 T€)		
		-8,015	**-7,380**
6.	Depreciation of intangible and tangible assets	539	415
		-539	**-415**
7.	Other operating expenses	9,236	6,069
8.	**Operating loss**	**-27,703**	**-22,743**
9.	Other interest and related costs	2,177	785
10.	Depreciation of financial assets	0	-601
11.	Interest and related expenses	-36	-32
12.	**Result from ordinary operations**	**-25,562**	**-22,591**
13.	Taxes	0	0
14.	**Net loss for the year**	**-25,562**	**-22,591**
15.	Net loss carried forward	-42,683	-68,246
16.	**Accumulated deficit**	**-68,245**	**-90,837**

Totals may vary due to rounding

Balance sheet in accordance with HGB

MediGene AG individual financial statements as of December 31, 2003 and 2002

Assets in T€		2002	2003
A.	**Fixed assets**		
I.	Intangible assets		
	Software	26	12
II.	Tangible assets		
	Plant and equipment	1,198	715
	Prepaid/in construction	0	389
III.	Financial assets		
	1. Investments in related parties	84,439	90,862
	2. Investments	3,698	3,698
		89,361	**95,676**
B.	**Current assets**		
I.	Inventories		
	Raw materials and supplies	443	0
II.	Receivables and other assets		
	Other assets	1,351	507
	thereof with a term > 1 year: 35 T€; (2002: 32 T€)		
III.	Cash and cash equivalents	47,151	21,287
		48,946	**21,794**
C.	**Prepaid items**	**406**	**238**
Total assets		**138,712**	**117,708**

Liabilities and shareholders' equity in T€		2002	2003
A.	**Shareholders' equity**		
I.	Share capital	11,206	11,206
II.	Additional paid-in capital	189,857	189,857
III.	Accumulated deficit	-68,245	-90,837
		132,817	**110,226**
B.	**Accruals**		
1.	Pension accrual	32	35
2.	Other accruals	1,724	2,059
		1,755	**2,094**
C.	**Liabilities**		
1.	Loan	338	108
	thereof convertible: 108 T€; (2002: 338 T€)		
2.	Trade liabilities	894	1,590
	thereof with a term < 1 year: 1.590 T€; (2002: 894 T€)		
3.	Intercompany liabilities	0	221
	thereof with a term < 1 year: 221 T€; (2002: 0 €)		
4.	Other liabilities	2,805	3,469
	thereof with a term < 1 year: 3.469 T€; (2002: 493 T€)		
	thereof social insurance: 120 T€; (2002: 151 T€)		
	thereof taxes: 124 T€; (2002: 185 T€)		
		4,037	**5,387**
D.	**Accrued and deferred items**	**103**	**0**
Total liabilities and shareholders' equity		**138,712**	**117,708**

Report from the Supervisory Board

In fiscal year 2003, 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 seven meetings (March 5, 2003, April 14, 2003, April 28, 2003, June 4, 2003, August 5, 2003, and November 13, 2003) and numerous telephone discussions. Other employees were consulted on specific issues. 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. For this purpose, strategic focus of research and development projects on the tumor diseases segment were discussed with particular intensity.

Aside from existing projects, the focus of discussion was on approval and marketing of the drug Eligard® (formerly Leuprogel®) for the treatment of prostate cancer, the initiation and execution of clinical trials, as well as the corporate financial position. In addition, the Supervisory Board requested and received comprehensive reports about the restructuring of the company and the budget for 2004. Following detailed consultation, the Supervisory Board approved the respective plans of the Executive Board, which are assessed as sustainable and future-oriented. 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 early warning system implemented was functioning as intended.

Supervisory Board committees

In the fiscal year 2003, there were an Audit Committee, a Compensation Committee, and a Commitee responsible for the approval of Executive Board business that required approval.

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.

Enhancements of Corporate Governance

In 2003, the Supervisory Board also dealt in detail with the further development of corporate governance at MediGene. The specific Corporate Governance Principles were adjusted to the altered German Corporate Governance Code. The Executive Board and the Supervisory Board have committed themselves to the implementation of MediGene's Corporate Governance Principles.

In December 2003, the Executive Board and the Supervisory Board issued the annual declaration of compliance in accordance with § 161, Stock Corporation Act.

Members of the Supervisory Board

After the resignation of Supervisory Board member Prof Dr Michael Hallek as of October 27, 2003, the former substitute member Prof Dr Norbert Riedel succeeded to his position in the Supervisory Board.

Dr Helmut Schühsler resigned from the Supervisory Board as of December 31, 2003. There has been no substitute member for this position.

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 2003, 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.

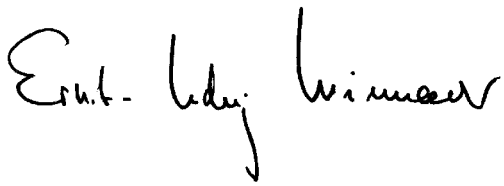
The Supervisory Board received all balance sheet and income statements and the auditor's reports in time for its balance sheet meeting. They were discussed in full detail during the balance sheet meeting of the Supervisory Board held on March 5, 2004. The auditor participated in the balance sheet meeting, reporting on the most important results of his audit, and answered queries.

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

At its meeting on March 5, 2004, 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 2003, which are thus adopted.

The Supervisory Board would like to thank the Executive Board and members of staff for their valuable efforts for the company during the difficult fiscal year 2003.

Munich, March 5, 2004



Prof Ernst-Ludwig Winnacker
Supervisory Board Chairman

Glossary

Actinic keratosis
Precursor of malignant spinocellular carcinoma

Adeno-associated virus (AAV)
A widespread virus, according to present-day knowledge safe for humans

Basal cell carcinoma
Common malignant skin tumor

Biopharmaceuticals
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

Depot formulation, depot product
Drug in the form of an implant which slowly disintegrates and releases the active substance over a set period of time

Dermatology
The science of skin and its diseases

Drug candidate
Drug which is still in a development stage

EBIT
Earnings before interest and taxes

EBITDA
Earnings before interest, taxes, depreciation and amortization

Gene
DNA section that includes the genetic information for a specific protein

Genetic engineering
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)
A virus that may cause genital warts or cervical cancer and its precursors

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

Line extension
Extension of the application range of a drug to other diseases

Liver cell cancer
Malignant tumors developing from liver cells

Liver metastasis
Secondary tumor of the liver

Malignant melanoma
Most severe type of skin cancer

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

Oncology
Science of tumors and tumor-related diseases

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

Pharmacology
Science of the interaction between drug and organism

Pipeline
All drug candidates in development

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

Regulatory affairs
Drug approval department

Royalties
Defined participation in sales

Testosterone
Male sex hormone

Therapeutic viruses
Viruses genetically modified for the treatment of diseases

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

6-year overview

MediGene Group, US-GAAP

T€	1998	1999	2000	2001*	2002	2003	Change 2003/2002
Income statements							
Revenues	174	0	0	0	0	0	–
Other operating income	1,707	5,544	6,081	7,264	3,425	1,742	-49%
Research and development expenses (R&D)	3,066	6,598	11,213	21,696	26,721	21,825	-18%
Business development and general administration expenses	876	1,439	2,528	5,736	7,177	7,926	10%
Amortization of goodwill	0	0	0	1,845	0	0	–
Depreciation	123	216	323	768	1,085	1,031	-5%
Operating result	-2,184	-2,709	-7,982	-22,782	-31,558	-29,040	8%
Write-off »IPR&D«	0	0	0	86,543	0	0	–
Result before income tax	-2,246	-2,861	-6,905	-104,583	-30,231	-28,333	6%
Net result	-2,853	-3,745	-9,264	-110,490	-38,870	-31,060	20%
Personnel expenses	1,393	2,316	4,089	7,938	11,245	10,973	-2%
Balance sheet data							
Balance sheet total	18,674	21,268	127,790	108,383	67,079	38,367	-43%
Shareholders' equity	13,284	9,360	118,793	100,406	59,435	29,220	-51%
Cash and securities	17,261	18,059	115,226	86,843	47,762	21,444	-55%
Cash and cash equivalents	17,261	10,149	92,903	80,843	47,762	21,444	-55%
Long-term liabilities	4,278	5,984	1,362	2,402	2,993	285	-90%
Equity ratio	71%	44%	93%	93%	89%	76%	-14%
Cash flow							
Cash flow from operating activities	-1,990	-2,977	-6,560	-22,015	-38,635	-26,544	31%
Cash flow from investing activities	-615	-8,412	-21,494	9,031	5,296	-12	-100%
Cash flow from financing activities	17,265	4,278	110,807	930	312	267	-14%
Employees as at Dec. 31	**35**	**50**	**90**	**160**	**185**	**124**	**-33%**
MediGene share							
Shares outstanding as at Dec. 31 in €	6,728,124	6,728,124	10,106,722	11,198,637	11,206,205	11,206,205	0%
Weighted average number of shares in €	4,936,701	6,728,124	8,417,423	11,003,245	11,204,990	11,206,205	0%
Net loss per share from continued operations in €	0.58	0.56	1.10	10.04	2.70	2.53	6%
Net loss per share adjusted for write-off »IPR&D« in €	0.58	0.56	1.10	2.18	3.47	2.77	20%
Shareprice at the end of the year in €	–	–	73.5	21.2	4.0	5.9	49%
Dividend in €	0	0	0	0	0	0	–

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

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Press and analysts conference

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3-months report
Press and analysts phone conference call

June, 2
Annual shareholders' meeting

August, 4
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Press and analysts phone conference call

November, 10
9-months report

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March, 23
Annual report 2004
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. . . we are looking forward to speaking with you

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