

EPIGENOMICS

ANNUAL REPORT 2004

Epigenomics is a technology-pioneer with the potential to establish a new standard in molecular diagnostics.

# Key Figures

2004/2003

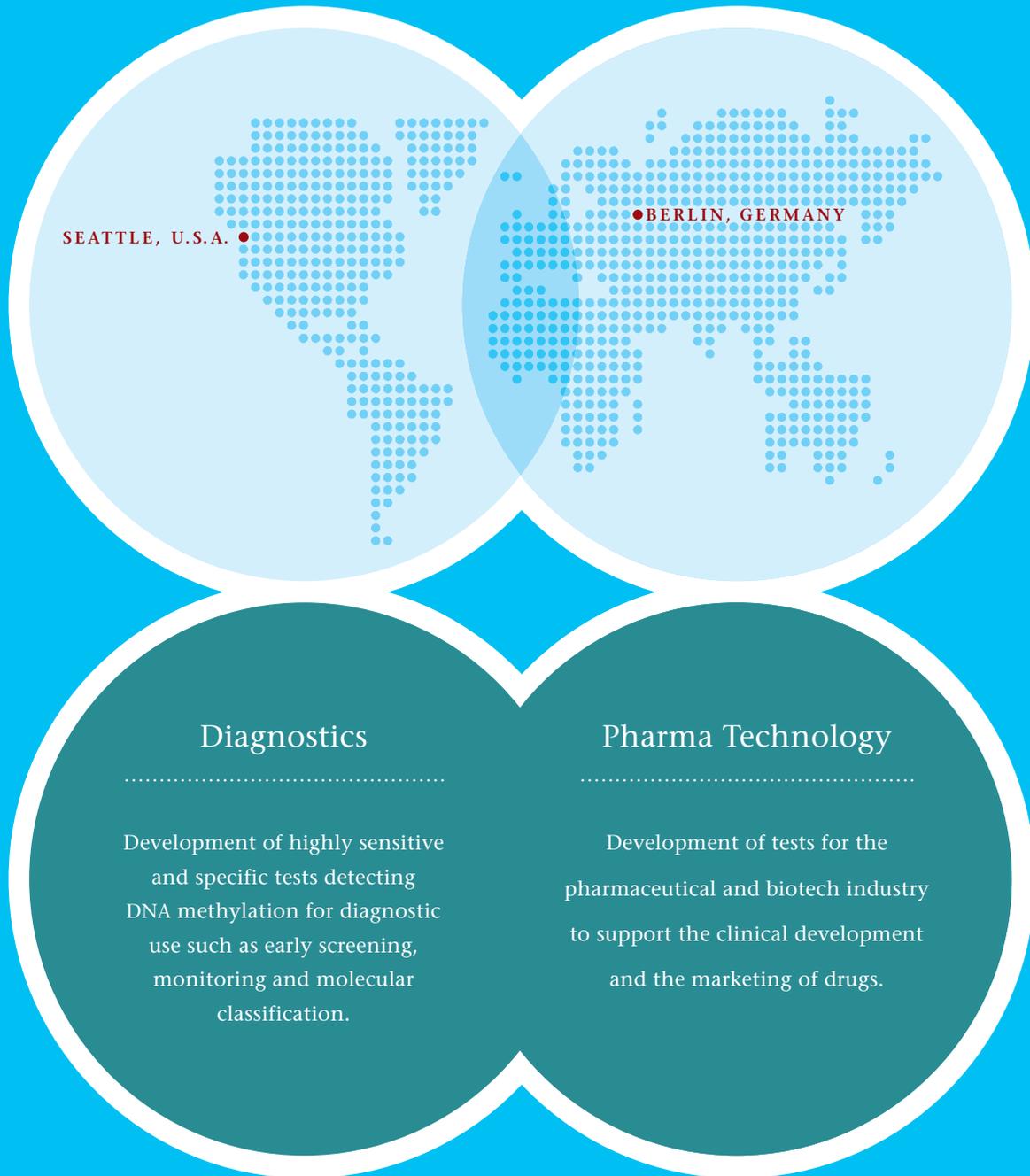
<b>EUR thousand if not indicated otherwise</b>	<b>2004</b>	<b>2003</b>
Revenue	7,931	10,778
Research and development costs	7,789	7,642
Operating result (EBIT)	-9,868	-6,271
EBITDA	-8,424	-4,918
Net loss for the year	-10,493	-6,710
Average number of shares issued (notional par value: EUR 1)	13,783,653	8,443,145
Earnings per share in EUR (basic)	-0.76	-0.79
Cash flow total (incl. currency adjustments)	13,747	11,858

	<b>Dec 31, 2004</b>	<b>Dec 31, 2003</b>
Liquid assets at balance sheet date (incl. marketable securities)	41,039	19,403
Total equity at balance sheet date	47,739	17,713
Equity ratio in %	89.6	56.6
Total assets at balance sheet date	53,284	31,307
Share price at balance sheet date (in EUR)	8.67	n/a
Number of employees at balance sheet date	146	143

# Strategic Business Units

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## Epigenomics Group



EPIGENOMICS

MISSION STATEMENT

Epigenomics seeks to turn its DNA methylation technologies into the leading molecular diagnostic tool, improving the prognosis of cancer and other common diseases.

# Contents

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2	— Letter to Shareholders
4	— Executive Board
6	— Report of the Supervisory Board
9	— Diagnostics
13	— Pharma Technology
16	— Strategy and Business Model
18	— Research & Development
22	— Corporate Governance
26	— Our Stock
30	— Management Report
49	— Consolidated Financial Statements and Notes for Fiscal Year 2004
80	— Auditor's Report
81	— Income Statement 2004 of Epigenomics AG
82	— Balance Sheet of Epigenomics AG
84	— Scientific Advisory Board
Cover	— Contact Corporate Calendar Glossary

# Letter to Shareholders

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Dear shareholders,

Our IPO in July 2004 was an important milestone in the history of our young Company. Therefore, this Epigenomics AG annual report is especially important for us, as it is our first as a listed company.

We had prepared ourselves both organizationally and mentally for the significant increase in responsibility that comes with an IPO. The complex network of requirements that we felt we had to meet was key to all our decisions.

To begin with, we had to achieve important technological breakthroughs. In molecular pathology, i.e. classifying and selecting therapies for tumors, this meant conducting large-scale clinical studies to collect a wide range of significant statistics. They were designed to demonstrate that our DNA methylation-based biomarkers are equal, if not superior, to our competitors' technologies – while simultaneously offering significant advantages as far as reliability and practical applicability in routine diagnostics are concerned. We already had access to this data in November 2003, a time when there was intensive IPO activity in the American biotech sector.

Therefore, we eagerly waited for the first clinical data from our other area of business, Diagnostics, which is involved in early detection of cancer. This was available end of January 2004, and from comprehensive studies, we were able to confirm that tumor identification was possible using blood tests in combination with our technology. It did, however, also become clear that there still was a lot of work to be done for optimization.

On the one hand, we now possessed a technology that offered the potential to develop an incredible number of products that had not been available before, and therefore tap significant markets which were impressively large and promised extraordinary profits. On the other hand, we had already shared all the developmental avenues that we had begun to explore for these markets in our partnership with Roche Diagnostics. As immensely productive as this partnership was and is, we were faced with the strategically important decision of whether to continue to function as contractually bound developers or to start developing our own products independently. We quickly came to the conclusion that developing our own products and commercial identity, and therefore gaining control over the market strategy of our own product portfolio is, in the long term, the best course of action, both for us and our shareholders.

The questions of how to take this step and how to finance it were inextricably linked with this strategic decision. As they had done in our developmental years, our venture capital investors continued to support us. The best route to raise significant funds to fuel the next era of our Company's development was to conduct an IPO. However, this did not mean



“2004 was an important year for Epigenomics, as it marked our first year as a public company. It also was a year of pivotal milestones towards achieving our mission of improving the prognosis of cancer and other common diseases by using our DNA methylation technology.”

that the venture capital investors wanted a quick exit, in fact we would not have been able to undertake this critical step without their full support.

What remained was the crucial question of when best to perform the IPO. At that time, we found ourselves in exactly the situation which, in the U.S., is considered to be the best time for a biotech company to float on the stock market. We had clinical data which showed fundamental proof of the feasibility of a business idea based on a biological principle. This enabled us to move out of basic research with its extremely high risks into the still high-risk but more predictable world of clinical development. This also would offer new investors the chance to profit from successful clinical development.

Many of you gave us your support for our IPO at a very early stage, while others came on board a little later. Together, we can all share in our success. There will always be certain risks, some of which we can only control to a certain extent, but we are conscious that they exist. As Chairman of the Executive Board, I can assure you that we will continue to keep you informed – in a totally transparent manner befitting a partnership like ours – of the risks that we have to take when faced with the extraordinary chances that we are offered.

Above all, it is enthusiasm, optimism, courage and decisiveness which made us successful in the past, and this will continue to be the case in the future. A future, in which we see ourselves as the preferred partner for pharmaceutical and biotech companies in the area of companion diagnostics, and in which we want to develop and sell our own diagnostic products.

My thanks go to you for your trust in us, to our employees for their great commitment, and to our clients and partners for our successful collaboration.

Sincerely,

Alexander Olek  
Chairman of the Executive Board



# Executive Board

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## Alexander Olek, Ph.D. CEO (35)

After his studies in mathematics in Buenos Aires and earning his Bachelor of Science in biochemistry at the University of London, Alexander Olek moved to the Max-Planck-Institute for molecular genetics to do his Ph.D. Having already successfully participated in the establishment of several firms, he founded Epigenomics AG in November 1998 and has been Chief Executive Officer since. Alexander Olek has received several awards for his innovative ideas and his entrepreneurial spirit.

## Aron Braun COO (36)

After his studies in electrical engineering at the EHT Zurich and the Imperial College in London, Aron Braun worked for several years in the semiconductor industry in Switzerland and France. Additionally, he was engaged at the Zuercher Hochschule Winterthur as a lecturer. At the beginning of 1999, he moved from Philips Semiconductors to Epigenomics. Today, being a member of the Executive Board and COO, he is responsible for the high-throughput processes, the project organization as well as for corporate business development.

## Christian Piepenbrock CIO AND HEAD, SBU PHARMA TECHNOLOGY (37)

Christian Piepenbrock graduated with a diploma in bioinformatics from the University of Bielefeld in 1995 and spent one year at Harvard University and the Massachusetts Institute of Technology (MIT) before joining the Technical University of Berlin where he dealt with neural data processing. Being with Epigenomics since November 1998, Christian Piepenbrock heads Epigenomics' bioinformatics efforts as well as the Pharma Technology business unit.



## Dr. Kurt Berlin

CSO (37)

Dr. Kurt Berlin studied chemistry at the University in Bonn, where he also gained his Ph.D. in organic chemistry. Afterwards, he moved to Tufts University in Boston, which he left in 1997 to work at the Max-Planck-Institute for Molecular Genetics. As a member of the Executive Board and CSO, Dr. Kurt Berlin is leading the medical research and development activities as well as all intellectual property-related issues for Epigenomics.

## Gary Schweikhardt, MBA

MS, CEO EPIGENOMICS, INC.

HEAD, SBU DIAGNOSTICS (63)

Gary Schweikhardt received his BS and MS degrees in Mechanical Engineering from the University of Washington and an MBA from Massachusetts Institute of Technology (MIT). From 1982 to 1988, Gary Schweikhardt was the COO of the biotech company ZymoGenetics, Inc. A founder of ORCA Biosciences, Inc. in Seattle U.S.A. in 1997, he has been leading the Diagnostics SBU since the merger with Epigenomics in 2000 and is a member of the Executive Board.

## Oliver Schacht, Ph.D.

CFO (34)

Oliver Schacht earned his diploma in European Business Administration from the European School of Business in Reutlingen and received his Ph.D. in Management Studies from the University of Cambridge (UK). In June 1999, he left Mercer Management Consulting to join Epigenomics AG, where he was appointed to CFO in the Executive Board and has been heading accounting and finance, corporate communications and human resources since.

# Report of the Supervisory Board

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Dear shareholders,

During the financial year 2004, the Epigenomics Supervisory Board fulfilled all its tasks according to the legal requirements and Epigenomics' Articles of Association. The Supervisory Board advised and supported the Executive Board in the management of the company. We performed these functions on the basis of the detailed reports from the Executive Board received at our meetings. We discussed at length the business trends described in the reports from the Executive Board and the prospects for the development of the company and its SBUs. Additionally, the Chairman of the Supervisory Board and the Chairman of the Executive Board maintained a constant exchange of information and ideas. This way, the Supervisory Board was kept continuously informed about the company's business strategy, corporate planning, including financial, investment and human resources planning, as well as the general state of business.

The documents relating to the Executive Board's decisions or actions requiring the approval of the Supervisory Board were inspected by the Supervisory Board at its plenary meetings – usually prepared by its committees – or got approved on the basis of documents circulated to its members.

For the Supervisory Board, a matter of special importance was the IPO of the company that was discussed in great detail with the Executive Board and external advisors. Another major focus of our deliberations was the collaboration with our partner Roche Diagnostics.

The Supervisory Board also discussed and agreed the new corporate governance principles of Epigenomics. Both the Executive Board as well as the Supervisory Board believe that commitment to corporate governance is an important measure for enhancing the confidence of current and future shareholders, corporate partners and employees. Epigenomics signed the German Corporate Governance Code as legally required, and in some cases adopted principles that go beyond the legally required.

During the course of the financial year, five Supervisory Board meetings with the Company's Executive Board took place. The work of the Supervisory Board was supported by its four established committees: the Compensation Committee, the Audit Committee, the Deal-Making Committee and the IPO Committee. As of September 1, 2004, Bruce Carter, member of the Supervisory Board, was appointed to Vice Chairman of the Supervisory Board.



“With the introduction of Epigenomics’ technique to assign methylation profiles, diseases can potentially be diagnosed at an much earlier stage, which is supposed to improve the healing prospects and chances for prevention.”

Already during the preparation of the IPO, John Berriman, Dr. Jörg Neermann and Michael Steinmetz announced their intent to resign from the Supervisory Board at the end of the first annual general shareholders’ meeting after the IPO. Dr. Klaus Stöckemann announced in the scope of the preparation of the IPO to resign with the last day of the lock up period, 180 days after the IPO, and is, as of January 17, 2005, no longer a member of Epigenomics’ Supervisory Board.

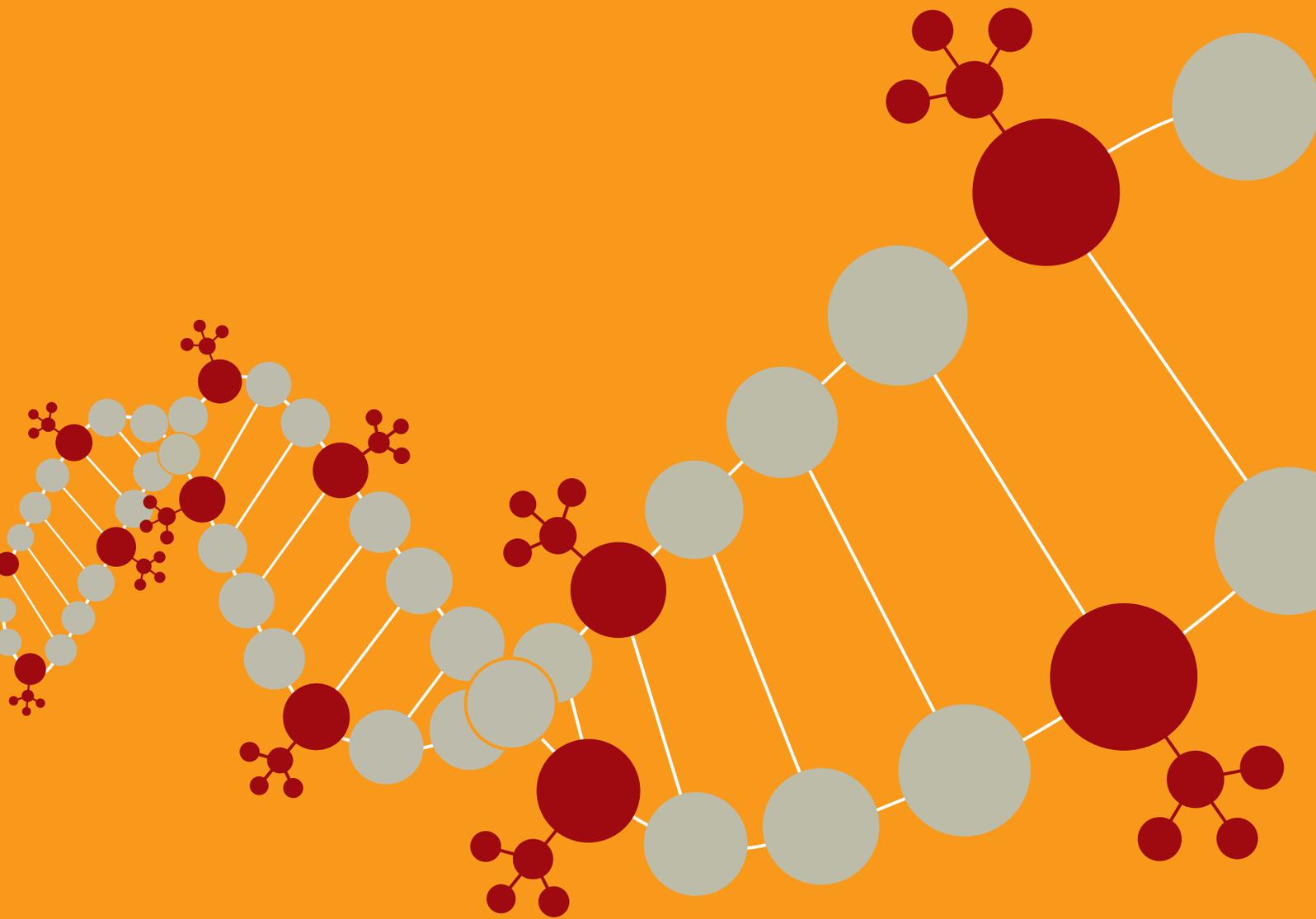
The auditing company UHY Deutschland AG Wirtschaftsprüfungsgesellschaft, Berlin, audited the annual report for 2004, including the management report in compliance with the principles of the German Commercial Code (HGB) as well as the consolidated 2004 report according to the International Financial Reporting Standards (IFRSs). The auditing company did not raise any objections for both reports and granted an unrestricted confirmation note. In the meeting of March 1, 2005, the Supervisory Board has, in the presence of the auditor and according to section 172 of the German Stock Corporation Act (AktG), agreed to the results of the audit and, without exceptions or modifications, approved the annual reports for the financial year as of December 31, 2004, and the consolidated report for the financial year as of December 31, 2004, after having both audited on its own. The annual reports of the Epigenomics AG are thus adopted. Since there are no net earnings for the year, it was not necessary for the Executive Board to make a suggestion about the use of the net earnings.

In regard to Epigenomics’ existing early risk management system, the auditor stated that the Executive Board had met all measures required.

The Supervisory Board would like to express thanks to the Epigenomics Executive Board, the management team as well as all employees for their commitment and efforts in the year 2004.

Berlin, March 2005

Prof. Dr. Dr. h.c. Rolf Krebs  
Chairman of the Supervisory Board



**DNA METHYLATION** occurs on cytosine, one of the four bases of DNA. Cytosine exists in two different versions: either with a methyl group attached (methylated) or without (unmethylated). Leading to activation or inactivation of genes, this phenomenon displays in a specific pattern that can be assigned to a certain tissue or disease.

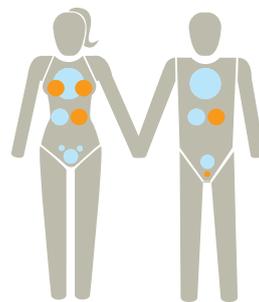
# Diagnostics

In our strategic business unit (SBU) Diagnostics, we address urgent unmet medical needs in cancer. If cancer is detected at the earliest possible stage, use of today's therapeutic measures offers the best chances for survival to patients. Early detection could also help save many lives, avoid unnecessary suffering and reduce costs to healthcare systems for later-stage treatments. Regular monitoring for recurrence of the disease will again ensure best chances for successful treatment. Determining the specific characteristics of a tumor and classifying it most accurately will give physicians the information needed to choose the most promising course of treatment.

**What diagnostic products does Epigenomics develop?** In its Diagnostics SBU, Epigenomics is developing three types of products for the diagnosis of cancer:

- blood<sup>1</sup>-based **early detection tests**,
- blood-based **monitoring tests**,
- tissue-based **molecular classification tests**.

Currently, our product development pipeline consists of early detection tests for each of colon, prostate and breast cancers, as well as a molecular classification test for aggressive versus non-aggressive prostate cancer. All of these tests are being developed in collaboration with our R&D and commercialization partner Roche

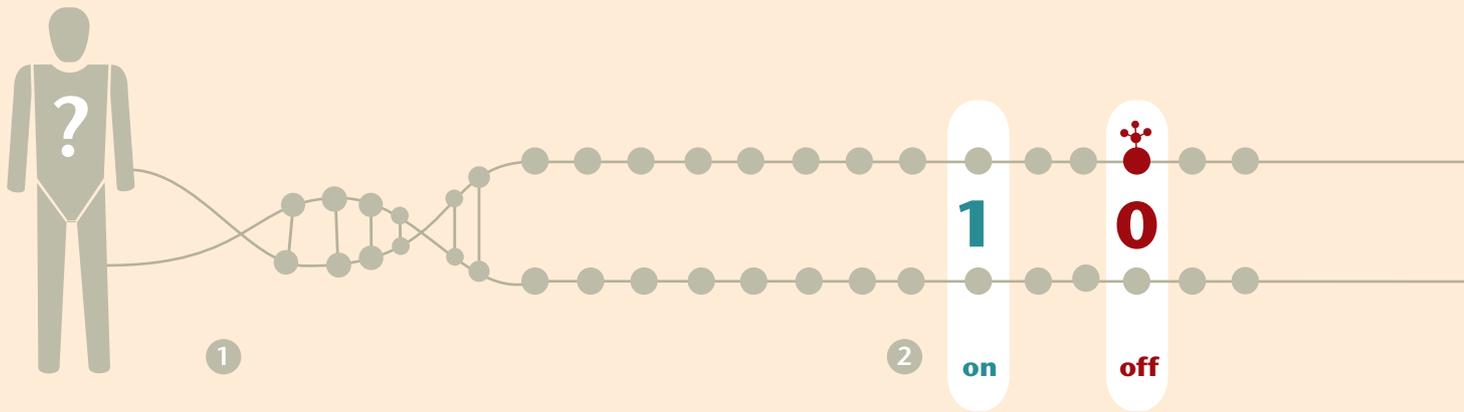


Diagnostics. In addition, Epigenomics has tests under development that so far are not partnered. These address some of the most prevalent types of

cancer and are responsible for hundreds of thousands of deaths each year. Importantly, in all of these diagnostic indication areas there are surgical and drug-based treatment courses today that, if applied early enough, could be life-saving.

For all five Roche programs we have successfully discovered, identified and statistically validated DNA methylation biomarkers. In our colon and prostate cancer screening programs we have made the step to body-fluid-based tests and are currently validating them in large numbers of patient samples. We currently expect the first products to be available from 2008 onwards after clinical trials and

<sup>1</sup> Some tests could use other body fluids such as urine, sputum etc.



regulatory approval, all of which will be managed by Roche.

In the future, we might add other diagnostic test types to our development pipeline in the above cancer indications as well as tests in other cancers such as lung, bladder, liver, ovarian etc.

**What advantages does DNA methylation have in diagnostics?** Our approach to developing these diagnostic products has several unique competitive advantages. Unlike genetic mutations, which mainly tell patients about their predisposition and susceptibility to a disease, DNA methylation allows a diagnosis of what is actually and currently happening in a patient, cell or tissue. Unlike proteins which cannot be amplified and hence may not be detectable if present in only minute quantities, DNA methylation can be detected like a needle in the haystack. Unlike mRNA, which is highly unstable in blood or stored tissue samples and as an analog signal requires counting molecules, methylation sits on robust DNA and is a digital signal. All of these advantages

make DNA methylation uniquely suited to being developed into a standard for molecular diagnostics.

**Who could benefit from these diagnostic tests?** The early detection tests address the asymptomatic population at large, i.e. men and women over the age of fifty<sup>2</sup>, who come in at regular intervals for a medical check-up and early cancer screening. These tests address tens or hundreds of millions of people in the major markets in North America, Europe and Japan.

Monitoring tests are targeted at the millions of people living today with a history of cancer and successful treatment who want to make sure that if the cancer was to recur it would be found at the earliest possible point in time for another treatment.

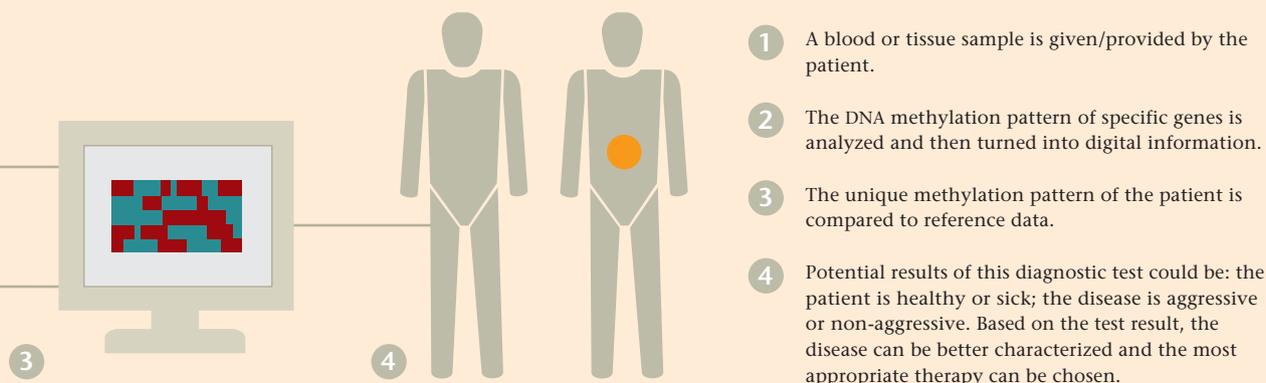
Molecular classification tests are useful in millions of cases each year, where a tumor is newly diagnosed and the physician or pathologist wants to gain the best possible understanding of the characteristics of the cancer to make optimal treatment decisions.

**What would these diagnostic products look like?** The diagnostic test for each person taking it would consist of several elements and components:

1. A patient sample to be taken by a physician (e.g. standard blood draw or tissue biopsy sample),
2. the diagnostic test kit (reagents that allow to test for DNA methylation status of specific genes) and
3. the diagnostic machine (platform that allows running the test in a clinical or reference laboratory by bringing together the patient sample, the test kit and some analysis software and algorithms).

**Who does what in our diagnostics development?** In our R&D and commercialization alliance with Roche Diagnostics, we are responsible for the early phases of product development. These include a genome-wide discovery to find hundreds of potential DNA methylation markers that might answer a diagnostic question, followed by analyzing hundreds of patient samples using several technologies such

<sup>2</sup> Recommended age for early detection may vary by tumor and country.



as sequencing and biochips to identify the best biomarkers. Subsequently, Epigenomics runs large studies involving typically well over a thousand samples using the final test format, e.g. blood to validate the markers statistically in a large population and to come up with a final panel of very few markers that meet certain performance criteria<sup>3</sup>. At that point, Roche will take over the further clinical development, manufacturing of the test kits, regulatory approval, marketing, sales and distribution of the diagnostic products.

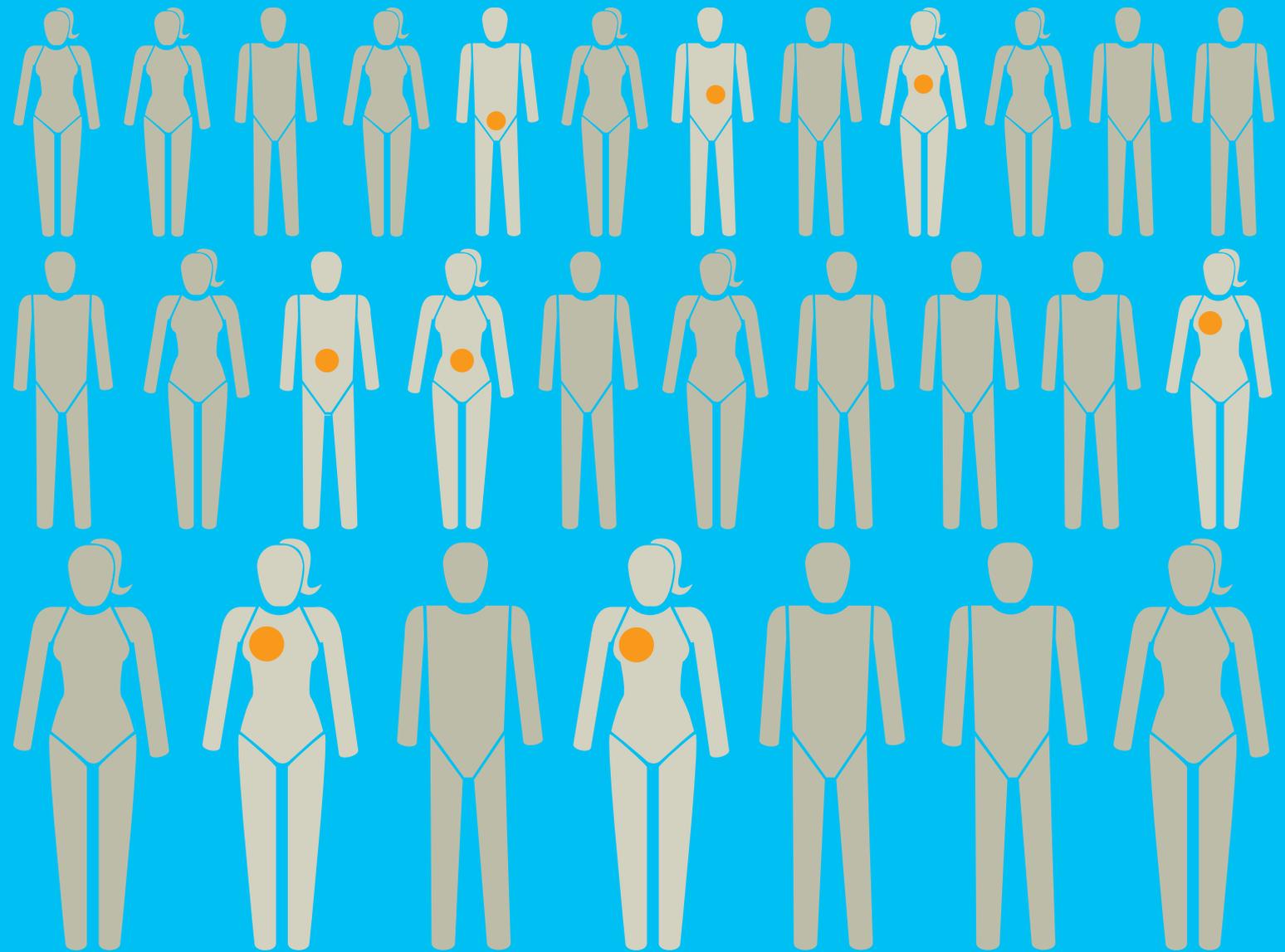
**How is the Roche Diagnostics deal structured?** Roche pays Epigenomics for R&D costs associated with the development of the five initial programs as well as any possible future project. Payment came in the form of a EUR 4 million upfront fee, ongoing annual R&D payments as well as success-dependent milestone payments for each product development program. Some of these milestones are early and under Epigenomics' control, others will occur at later stages and are under Roche's control. In 2004, Epigenomics met several important milestones, e.g. the marker identifi-

cation in our breast cancer early detection and prostate cancer molecular classification programs. Ultimately, Epigenomics will receive a significant royalty on Roche's world-wide product sales of the jointly developed tests.

For the five tests currently included in the agreement and the few that Roche has as options to add to the partnership, world-wide exclusivity will be granted to Roche. However, apart from the specific diagnostic products addressing well-defined diagnostic questions, no further rights have been granted or sold to Roche as of today.

Product Pipeline		Marker Discovery	Marker Identification	Marker Validation	Clinical Development
Screening	Colon Cancer Test	[Progress bar: ~75% complete]			Roche
	Prostate Cancer Test	[Progress bar: ~85% complete]			Roche
	Breast Cancer Test	[Progress bar: ~90% complete]			Roche
Classification	Prostate Cancer Classification Test	[Progress bar: ~80% complete]			Roche
Monitoring	NHL Test	[Progress bar: ~20% complete]			Not yet partnered

<sup>3</sup> Performance criteria for diagnostic tests are typically sensitivity and specificity (100% minus sensitivity/specificity gives the percentage of false negatives and false positives, respectively).



**PHARMACODIAGNOSTIC TESTS** help determine the optimal treatment for various subgroups of patients. This can either be achieved by predicting the efficacy and toxicity of a particular drug in a person or by frequent monitoring of the status of disease.

# Pharma Technology

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In our strategic business unit (SBU) Pharma Technology, we develop pharmacodiagnostic tests that enable physicians to select the most appropriate therapy for each patient. These tests give an indication of a patient's response to a particular therapy. Rather than through trial and error, the best course of treatment can be established upfront. We also work closely with pharmaceutical and biotechnology companies to support their therapeutic clinical evaluation. By targeting their drugs to patient subpopulations, these companies are able to improve efficacy and support the success of clinical trials.

## What pharmacodiagnostic products does Epigenomics develop?

In its Pharma Technology SBU, Epigenomics is developing the following products:

- Breast Cancer (Tamoxifen) Treatment Response Test (as part of the Roche Diagnostics alliance) and
- other cancer treatment response biomarker studies with pharmaceutical companies.

Our most advanced product is the Roche breast cancer treatment response test (Tamoxifen test), which has undergone over two years of extensive discovery, identification and also validation of the biomarkers in



### THE BEST TREATMENT

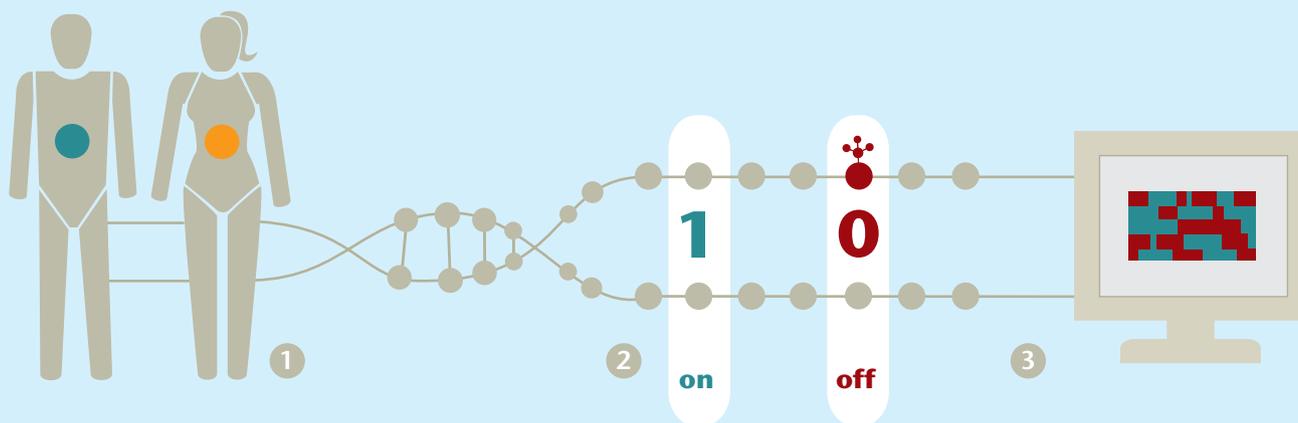
By combining drugs and tests, the most compatible and efficient treatment regime for each patient can be chosen.

well over a thousand paraffin-embedded and retrospective patient samples to date. So far, every milestone has been successfully met in this development. The transfer process to Roche and further independent vali-

dation studies are well underway. Approval and launch of this test could be as early as 2007.

In the future, we might add other pharmacodiagnostic test types to our development pipeline such as developing tests to major marketed cancer drugs on our own, as well as partnered programs with drug developing companies.

**What advantages does DNA methylation have in pharmacodiagnosics?** Our approach to developing these diagnostic products has several unique competitive advantages. Unlike mRNA, which is unstable



in stored tissue samples, methylation sits on robust DNA and is a digital signal. This allows us to make best use of available, historic sample collections, e.g. of paraffin-embedded tissues with all the associated follow-up patient and treatment response outcome data. It not only provides a time advantage but also allows us to work with samples routinely available from our partners. Given the DNA molecule as analyte, we can also combine methylation with the mutation analysis that companies regularly conduct today for predicting drug response. All of these advantages make DNA methylation uniquely suited to being developed into a key component of future pharmacodiagnosics.

### Who could benefit from these pharmacodiagnostic tests?

**Patients and their physicians** would clearly benefit from having the best possible information available for taking potentially life-saving treatment decisions such as

- choosing one drug over another or
- adding chemotherapy to more benign therapy to prevent relapse.

**Drug developing pharmaceutical and biotech companies** would benefit from selecting the right group of patients for any targeted therapy, avoid side effects, maximize efficacy in the subpopulation targeted and avoid failures of clinical trials that might cost huge amounts of money. Also, once on the market, the benefit on the marketing side is better positioning of their drug versus competing drugs and maximizing market share in the specific subpopulation.

The **healthcare systems** would benefit in terms of avoiding unnecessary costs for over- or undertreatment, respectively. Overall, the benefit to **society** would be to bring personalized medicine just one step closer to reality.

### What would these pharmacodiagnostic products look like?

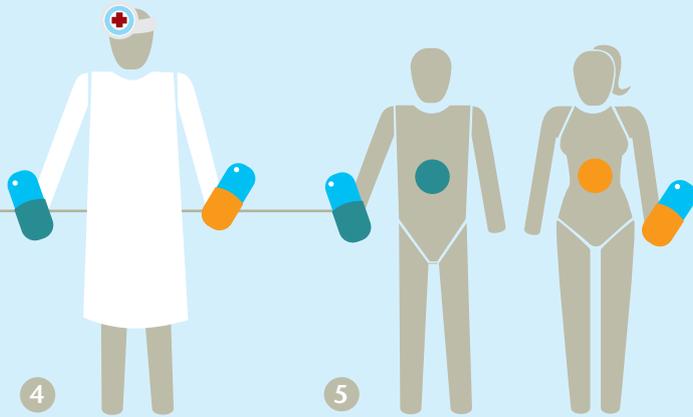
Very similar to diagnostics, each pharmacodiagnostic test for a cancer patient would consist of several elements and components:

1. After initial diagnosis, a patient sample (e.g. tumor tissue biopsy sample) is used for pharmacodiagnostic testing,
2. the pharmacodiagnostic test kit (reagents that allow to test for DNA methylation status of specific genes) and
3. the diagnostic machine (platform that allows running the test in a clinical or reference laboratory by bringing together the patient sample, the test kit and some analysis software and algorithms).

### Who does what in our pharmacodiagnosics development?

The work on our Tamoxifen treatment response test is governed by our Roche alliance (see under SBU Diagnostics).

In all other collaborative studies we typically rely on our partners to provide us with patient samples, e.g. from responders versus non-responders to the particular drug they are interested in finding biomarkers to predict response. In very close interaction with the drug development and biomarker teams at our partners



- 1 After initial diagnosis, a patient sample (e.g. tumor tissue) is used for pharmacodiagnostic testing.
- 2 The unique DNA methylation patterns of specific genes can be analysed with a test kit by looking at activated (“on”) and non-activated (“off”) genes.
- 3 The diagnostics machine acts as a platform for running the test, combining patient samples, test kit and analysis software.
- 4 The result shows whether the patient responds to the therapy or not.
- 5 By looking at the test results the physician can choose the most appropriate treatment for every single patient.

we either go for a de-novo genome-wide discovery at Epigenomics, work with candidate genes that the partners or we may have identified, or a combination of both. Throughout the process, the partners are entirely responsible for the clinical strategy of their drug development program and we synchronize our biomarker and test development efforts with that. Depending on the nature of each partner and project, the strategy for ultimately commercializing the test along-side the drug or on its own may vary.

**How do we view our current pharmacodiagnosics deals?**

Our current pharmacodiagnosics deals fall into different categories:

- The Roche deal relies on the economics of the breast cancer treatment response test to the marketed drug Tamoxifen and as such is not different from the diagnostics deal itself. The same would hold true for any test we would develop for marketed drugs already available.
- All other partnerships such as Astra Zeneca, Wyeth, Pfizer and Biogen Idec are aimed at demonstrating the value of DNA methylation as a rich source of treatment response biomarkers and as a uniquely robust and suitable system to get these tests into the market as quickly and efficiently as possible. In these early agreements the focus is on demonstrating the value of DNA methylation

rather than instigating full-blown test development. The latter could conceivably have economics driven by the value added to a drug by developing and having available a pharmacodiagnosics test.

Product Pipeline	Marker Discovery	Marker Identification	Marker Validation	Clinical Development
Breast Cancer Treatment Response Test	[Progress bar: ~85% complete]			Roche
Treatment Response Test (undisclosed)	[Progress bar: ~40% complete]			Not yet partnered
Cancer Studies	[Progress bar: ~40% complete]			Biogen Idec, Pfizer, Wyeth, AstraZeneca

# Strategy and Business Model

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Molecular diagnostics is a multi-billion euro opportunity expected to grow rapidly, driven by oncology tests. Our current strategy and business model are based on the three pillars of R&D partnerships, own product development, and forward integration.




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Strategy and business model

**1. R&D partnerships.** In our diagnostics business, for all high-volume tests – such as blood-based early detection tests for cancer addressing over a hundred million people of the age of fifty in relevant markets as well as monitoring tests and high-volume molecular classification tests with up to several tens of millions of patients as target population – partnering with an *in-vitro* diagnostics corporation is the strategic aim. Epigenomics currently does not possess the skills and resources required to address large-scale manufacturing, global marketing, sales and distribution, nor do we have access to a diagnostic device (platform).

Also, in the short term for the initial products we are developing with **Roche Diagnostics**, the management of clinical trials and regulatory affairs is partnered. In addition to the five initial tests, Roche exercised two optional products in 2004. We also expect to grow the scope of our collaborative product development portfolio, both in early detection as well as molecular classification testing in oncology.

However, going forward we expect to start building some of the critical components of clinical trial management and getting products further along the development path before partnering their commercialization. Also, for smaller tests in certain indications it may be feasible to find ways of getting them to market without the classical partnering model, e.g. via reference laboratories or specialized sales efforts with a platform partner.

Our partners and customers comprise **AstraZeneca** (EGFR drug program with IRESSA), **Wyeth Pharmaceuticals** (preclinical mouse model and clinical patient sample study), **Biogen Idec** (examining candidate biomarkers to predict drug response in undisclosed oncology program) and **Pfizer** (undisclosed oncology program).

The market potential in cancer alone includes hundreds of clinical trials plus many more preclinical development programs. The value added by pharmacodiagnosics towards more targeted and individualized therapies is seen by many in the hundreds of millions or even billions of euros. Early deals typically involve R&D funding of joint programs with certain intellectual property (IP) rights relating to the diagnostics retained by Epigenomics. Economics in the long run should be driven by sharing such value added with our partners rather than just test sales.

There may, however, also be cases where marketed cancer drugs could benefit from adding a predictive test to identify responders and a pharmacodiagnosics test itself is commercially viable. In that case our business model and partnering strategy could be very similar to the aforementioned diagnostics model.

**2. Own product development.** In order to create higher-value partnerships, e.g. by optimizing for upfront license fees or higher royalties, we have initiated product development programs that are fully funded through internal Epigenomics resources.

A systematic evaluation and selection process has been completed in 2004 and starting in 2005, we will systematically add programs to our product development pipeline in both our business units. Initially, the focus will remain in oncology for both SBUs. Diagnostic questions will likely

involve colon, prostate and breast, as well as other cancers.

Also, a dedicated R&D program for clinical proof of principle studies has been established, aimed at demonstrating the potential and value of DNA methylation in diagnosing diseases other than cancer. An early-stage program in definitive diagnosis of endometriosis, an underdiagnosed disease affecting a significant proportion of all young women and implicated in a high proportion of infertility cases, is underway. In the longer term, such studies could involve indication areas as diverse as autoimmune, metabolic, CNS, cardiovascular etc.

**3. Forward integration.** In line with the first two pillars, the goal is to establish Epigenomics as a molecular diagnostics company with full own product development, clinical trial management, and regulatory affairs capabilities in relevant markets. Also, specialized marketing and sales efforts will be initiated either internally and/or in close collaboration with complementary organizations. The goal is to reduce the operational and financial dependence on strategic partners commercializing our tests and to generate some product sales in addition to only royalties in the medium term, too.

# Research & Development

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Our R&D efforts are focused on improving key areas of our DNA methylation biomarker machine, optimizing remote (body-fluid) sample testing as well as tissue-based testing methods, portfolio management of our intellectual property, and establishing the high-throughput infrastructure for data generation and bioinformatics data management and analysis. The total Epigenomics R&D team comprises 113 of our staff of whom 37 hold Ph.D. degrees or equivalent.

**Methylation marker machine.** The project group “Marker Machine Technology” initiates, coordinates and evaluates technologies for biomarker discovery and evaluation. The aim is a faster, cheaper, and even more robust discovery pipeline for DNA methylation markers. Particular focus in 2004 has been on expanding the portfolio of our genome-wide discovery technologies and subsequent validation of potential methylation marker candidates. This focus is likely to remain key in 2005 along with improved high-throughput processes, including appropriate SOPs and quality controls, for larger clinical studies. Also, we have successfully added capabilities to run Affymetrix mRNA expression discovery studies that could potentially complement our biomarker discovery efforts.

**Remote sample testing.** Major efforts have been geared towards preanalytic steps of efficient isolation and bisulfite treatment of various types of remote samples such as DNA from serum or plasma and urine, ultra-sensitive detection in blood from minute absolute amounts of free-floating DNA, as well as selective amplification against many confounding background molecules using our proprietary HM assay technology.

This R&D effort directly supports all of our Roche product development programs in diagnostics. These R&D projects have also significantly enhanced our understanding of the critical steps in patient sample acquisition for our most advanced programs and concerted efforts are continuously ongoing to establish, enhance and implement standard operating procedures both in-house at Epigenomics, but also at medical partners' facilities with whom we collaborate on our patient sample collection efforts.

**Tissue sample testing.** Significant advances have been made in the use of paraffin-embedded tissue samples, a major competitive advantage of DNA methylation analysis. Relevant workflows and preanalytics of such difficult sample materials were developed, tested and released into routine use for large product development studies such as the Tamoxifen response program.

**Intellectual property portfolio.** At Epigenomics we have developed, built and in-licensed by far the most comprehensive portfolio of DNA methylation-related intellectual property worldwide, including approximately 150 of our own patent filings and around a further 30 in-licensed patents. Overall, more than two dozen important patents have been granted in one or more countries already. The overall maturity of the portfolio has increased substantially over the last year. Further details of our IP portfolio can be found in our IPO prospect.

Our IP covers all aspects and elements of the value chain, starting with exclusive licenses to discovery methods, proprietary bisulfite treatment, amplification and detection technologies on most commercially relevant hardware platforms such as microarrays, real-time PCR, as well as pro-

proprietary DNA methylation biomarkers answering important diagnostic and pharmacodiagnostic questions in many of the relevant cancers such as colon, prostate, breast, lung and many others.

With the progress made to date by the Human Epigenome Project<sup>4</sup>, we also have begun to generate genome-wide information and associated proprietary positions.

**R&D infrastructure.** During 2004, we have continued to expand and improve upon our information technology as well as lab automation and process workflow infrastructure. This has enabled us to successfully run several large studies with hundreds of patient samples in each and even to execute on multiple studies simultaneously. All patient samples as well as all biomarker data are stored in an integrated lab information and management system (LIMS) and enable efficient storage, tracking, quality control and analysis of all data. Various audits were conducted during 2004 on our high-throughput processes with a view to identifying needs for further improvement towards running facilities and processes in line with regulatory requirements in the future.

In Berlin, we successfully negotiated favorable terms for an expansion of our Hackescher Markt facility, which in 2005 we expect to become our sole site in Berlin, combining all R&D facilities and office space for our headquarters.

An integral part of our corporate R&D infrastructure is a global network of academic and medical collaborators many of whom we have been working with over the past several years. Our partners include leading institutes in Germany (e.g. Max Planck Institutes, German Cancer Research Center, University Clinics, Charité and many others), partners across Europe (Wellcome Trust Sanger Institute, Centre National de Génotypage, universities in the U.K., France, Italy, the Netherlands, Hungary), and the U.S.A. (USC, Mayo Clinic, Virginia Mason, AmericasDoctors etc.) as well as collaborators in Argentina and Australia.

<sup>4</sup>The HEP is run in collaboration with the Wellcome Trust Sanger Institute (U.K.) and the Centre National de Génotypage (F).



Mowliid Magare

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RESEARCH ASSOCIATE  
DISCOVERY, SEATTLE

“Knowing that my research at Epigenomics could play an integral part in improving the early detection and treatment of cancer is very gratifying and inspiring.”

# Corporate Governance

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To us as Executive Board members, “Corporate Governance” is the essence of responsible and ethical management of Epigenomics, with very close and regular communication with the Supervisory Board aimed at the generation of long-term value to our shareholders. Openness and transparency in our corporate communications towards all shareholders, employees, the general public, and other stakeholders are the guiding principle.

For Epigenomics, corporate governance has been an important focus for several years and we welcome the publication of the German Corporate Governance Code in its current form. Even as a private company the compliance with the German corporate governance principles was systematically checked and amendments made wherever possible to ensure fair and responsible corporate management according to the new and amended version of the German Corporate Governance Code.

Epigenomics’ corporate governance principles in some instances go beyond the requirements of law and the recommendations of the German Corporate Governance Code. For example, upon successful completion of our initial public offering (IPO), we have established binding internal guidelines on insider trading and have appointed a Corporate Governance Compliance Officer to ensure best practice is adhered to. The Compliance Officer is required to submit regular compliance reports to the Executive Board and these are reported to the Supervisory Board. All reports in 2004 confirmed the Company to be in compliance with corporate governance principles.

There are some notable exceptions where, based on historic contracts and corporate plans put in place as a private company, certain peculiarities lead to deviations from the German Corporate Governance Code. These are detailed below and there is a clear commitment to fully adhere to the Code going forward, e.g. with any future stock option plans and future Supervisory Board compensation plans.

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EXECUTIVE BOARD AND  
SUPERVISORY BOARD

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**Executive Board.** The Executive Board of Epigenomics AG consists of six members and is chaired by the Chief Executive Officer (CEO). The executive board under the German Stock Corporation Act (AktG) is responsible for independently managing and running operations, developing and implementing corporate strategy, financial and budgetary planning, appointing and guiding senior management and overseeing general management of the Company. There is an ongoing regular and very interactive dialog between the Executive Board and the Supervisory Board. In its charter, the Executive Board has a clear set of rules for certain actions and decisions that require Supervisory Board approval, as well as defined reporting and information guidelines.

In line with fair and open disclosure and the requirements of the Prime Standard segment of the Frankfurt Stock Exchange, quarterly financial reports are made available within 60 days of a quarter's end and annual financial statements within 90 days of year-end. All information is available on our webpage simultaneously on <http://www.epigenomics.com>. All material news is announced following the latest guidelines and legal requirements on ad hoc notification.

**Supervisory Board.** Epigenomics' Supervisory Board consists of six members with extensive experience in the pharmaceutical, biotech and financial industries. Its chairman and vice chairman are independent directors, whereas some others are representatives of our major VC shareholders, all of whom, however, have tendered their resignations effective either January 17, 2005, (Klaus Stöckemann) or at the date of the first post-IPO annual general shareholders' meeting, respectively. This will allow the Company's shareholders to elect independent outside members for the Supervisory Board.

The Supervisory Board of Epigenomics AG has formed four committees: first, an Audit Committee assisting the Supervisory Board in approving all financial statements, commissioning the auditors, choosing appropriate topics for main focus of the audit, determining the audit fees, and ensuring the independent status of the auditors. Second, a Compensation Committee dealing with all aspects of Executive Board members' compensation as well as preparing other compensation-related decisions that require Supervisory Board approval. Third, a Deal-Making Committee, which assists with all decisions required for strategic licensing and commercial partnership agreements. Fourth, the IPO Committee, dealing with all aspects of the IPO and therefore only temporarily.

The Supervisory Board, upon discussion with the Executive Board, also sets the strategic, financial and business goals for each fiscal year that form the basis for measuring performance of each member of the Executive Board as pertains to the respective variable compensation component.

**Executive Board compensation.** The appropriateness of compensation for all our Executive Board members is reviewed annually by the Supervisory Board and compared to national and international industry comparables. Compensation is tied to the economic and financial situation, size and complexity of international operations and responsibilities. Each Executive Board member's compensation consists of three elements: a fixed annual salary, a performance-related cash bonus and from time to time, if approved by the annual shareholders' meeting, the possibility of stock option grants. The individual bonuses depend in equal amounts on Company goals and individual goals of the Executive Board member, respectively.

Also, as founders of the Company, all our current Executive Board members hold a significant number of shares that are locked for 12, 18 and 24 months following the date of admission as described in our prospectus.

For the year 2004, the combined total compensation of the Executive Board members amounted to EUR 933 thousand; the individual compensation is shown in the notes on page 75.

**Supervisory Board compensation.** In fiscal 2004, the total compensation paid to our Supervisory Board members was EUR 90 thousand, which was in line with decisions approved unanimously by the annual shareholders' meeting. There were no separate additional consulting arrangements with any of the Supervisory Board members. Individual compensation in 2004 is shown in the notes on page 76.

Given the composition of the Supervisory Board in 2004 with some venture capital-affiliated members and outside directors, there has been an annual cash-only retainer component with no meeting-related fees nor any additional payments for committee work; this amount did not comprise any long-term incentive component. In fact, following a German supreme court decision earlier in 2004, we repurchased all convertible warrants that had been sold to Supervisory and Scientific Advisory Board members in the past. The 2005 annual general shareholders' meeting will decide on a new compensation scheme as well as new members to the Supervisory Board.

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DECLARATION OF COMPLIANCE  
WITH THE GERMAN CORPORATE GOVERNANCE CODE PURSUANT TO  
SECTION 161 OF THE GERMAN STOCK CORPORATION ACT (AKTG)

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The Executive Board and the Supervisory Board of Epigenomics AG hereby declare that Epigenomics complies with the recommendations of the German Corporate Governance Code Commission in the version of May 21, 2003, which were published by the German Federal Ministry of Justice in the official section of the electronic Federal Gazette. Only the following recommendations, partly due to specific corporate particularities, are not complied with:

**Section 3.8 paragraph 2.** The D&O (directors' & officers') liability insurance does include a deductible for the Executive Board and the Supervisory Board members. However, we think a deductible is not a precondition for responsible management; responsible management rather is a self-evident duty of all board members. Therefore, the "adequate" amount of a deductible is not of particular importance. Accordingly, we may not comply with the recommendation regarding an "adequate" deductible.

**Section 4.2.3 paragraph 2.** The stock options granted to Executive Board members in the past do not relate to relevant comparison parameters, with regard to the existing stock option programs a retroactive change of performance targets is not excluded, and for extraordinary, unforeseen developments no limitation possibilities (cap) have been agreed upon. The stock option programs underlying the grant of options have all been established prior to the Company's listing and were disclosed in detail in the offering circular. We think that the responsibility and motivation of Executive Board members are not improved by referring to comparison parameters and that a possibility of limitation (cap) is not necessary due to the structure of the existing stock option programs. The general shareholders' meeting would need to resolve upon a retroactive amendment of the performance targets (which is not intended). Therefore, the aforementioned recommendations pursuant to section 4.2.3 paragraph 2 of the Code will only be implemented with a new stock option plan.

**Section 5.1.2 paragraph 2.** An age limit for members of the Executive Board has not been specified. Such a general limit could restrict the Supervisory Board in its selection of particularly qualified and experienced candidates. From our point of view age is not necessarily an adequate criterion for the disqualification of candidates. Furthermore, the age structure of the Executive Board does not suggest the adoption of an age limit within the foreseeable future.

**Section 5.4.1 sentence 2.** Because of the aforementioned reasons, an age limit for members of the Supervisory Board also has not been specified. An age limit would inappropriately narrow the shareholders' right to elect the members of the Supervisory Board.

**Section 5.4.5 paragraph 1.** The compensation of the Supervisory Board members does not take into account the membership in board committees. Since committee memberships are equally distributed among the Supervisory Board members, a different compensation is not warranted in this respect.

**Section 5.4.5 paragraph 2.** The compensation of the Supervisory Board members does not contain a performance-related component. Given the present composition of the Supervisory Board, a performance-related compensation would not have led to an additional increase in incentive or motivation. The possible adoption of performance-related compensation components shall be the subject of a future decision of the general shareholders' meeting, as the case may be.

Berlin, December 2004

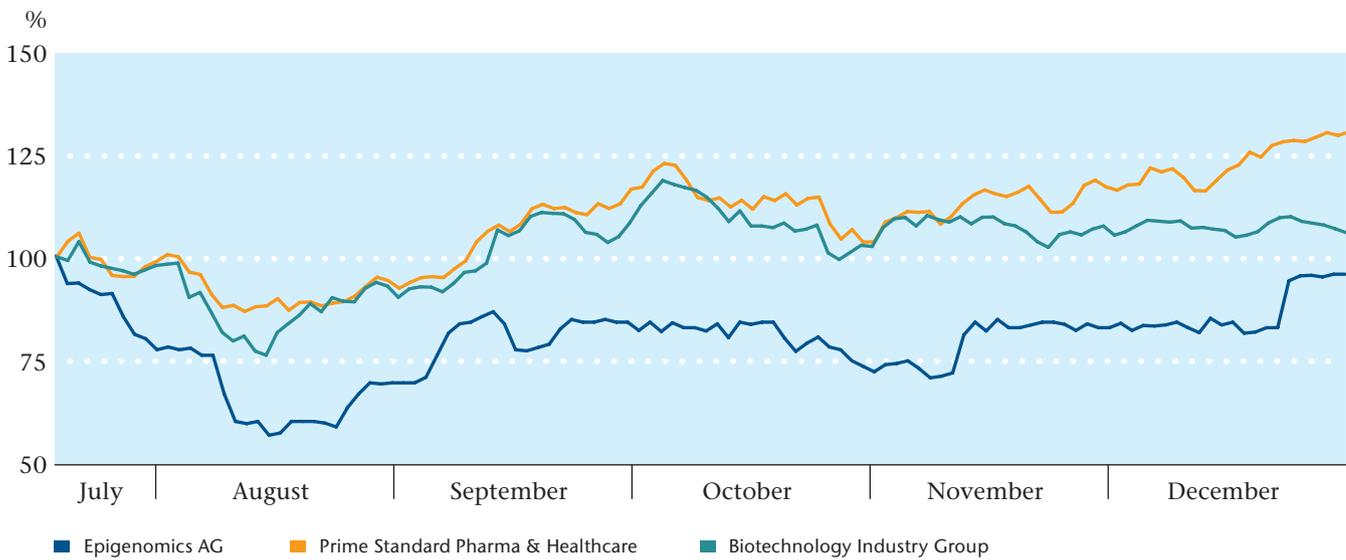


The Supervisory Board



The Executive Board

# Our Stock



Epigenomics stock price development from July 19 to December 30, 2004

The year 2004 was the first in over three years that saw a clear improvement in the public markets for biotech. Following a series of U.S. biotech IPOs and follow-on offerings in late 2003 and early 2004, the European equity capital markets saw the successful completion of two biotech IPOs by summer 2004. After a complete IPO drought for over three years, the German equity capital market witnessed the first few initial public offerings before summer 2004.

## Shares

### MASTER DATA

ISIN:  
DE000A0BVT96

Security Code Number:  
A0BVT9

Against a backdrop of the above as well as a series of Euro-

pean biotech IPOs that were cancelled or postponed at the last minute, Epigenomics did manage to successfully complete its IPO on the Frankfurt Stock Exchange (Prime Standard segment) on July 19, 2004, raising EUR 41.6 million in gross proceeds and thereby significantly strengthening our balance sheet and financial position. The shares were predominantly placed with institutional investors (98.2% of the IPO) and only a relatively small portion went to retail investors (1.8%). Main targets of the marketing effort and ultimate allocation of shares from the IPO were to institutional investors with a clear life science and biotech focus. The German home market quite expectedly saw the strongest demand and overall allocation of around 34%, closely followed by Switzerland and the UK. Some U.S. qualified

institutional buyers also took a sizeable stake in the IPO under rule 144A of the U.S. Securities Act of 1933.

The initial bookbuilding range was lowered due to very difficult market conditions at the time and the 4.6 million shares were successfully sold at EUR 9 per share. Subsequently, despite the complete absence of negative newsflow, the stock experienced significant price pressure throughout the summer and hit a low at EUR 5.75 per share on August 13, 2004, before seeing a substantial recovery all the way up to EUR 8, based on strong newsflow of new deals and meeting critical product development milestones. Since October, the share price has stabilized in a corridor between EUR 7.50 and 8.00 on continuously decreasing trading volumes. On December 30, 2004, the stock closed at EUR 8.67 (Xetra), down 3.7% from its issue price of EUR 9.

Whilst the third quarter 2004 saw a total of 2,325,492 of our shares being traded, that figure dropped for the fourth quarter to a mere 386,633 shares. Given the limited free float of 29% as defined by the Frankfurt Stock Exchange and the continued strong position of the venture capital shareholders, it is too early to draw any firm conclusions on trading volumes with less than six months as reference point and an expected increase of free float going forward.

As of December 31, 2004, a total of 16,334,229 shares were issued and several major shareholder groups each controlled more than 5% of Epigenomics' total share capital:

- DVC 16.2%
- 3i Group 14.8%
- MPM 16.0%
- Abingworth 5.7%
- Management 6.4%
- BB Biotech 6.1%

Following the IPO, three analysts have initiated coverage of Epigenomics' stock to date and have provided regular updates to their views: Morgan Stanley's Dan Mahoney, Lehman Brothers' Sam Williams and DZ Bank's Thomas Höger all maintain a positive outlook on the stock as of the end of 2004. In an environment where analysts are more

and more incentivized via trading volumes, increasing the coverage will be a key challenge going forward.

**Corporate communications.** We continuously strive to provide all our shareholders with timely, accurate and comprehensive information to have the best possible basis for making informed investment decisions in Epigenomics' stock. To that end, we have strengthened our corporate communications team, headed by our Vice President Corporate Affairs, Hong Thieu, to include Corporate Communications Manager Ms. Leila Sad and Corporate Communications Assistant Ms. Yvonne Hartwig. The team reports directly to Epigenomics' CFO Oliver Schacht and works very closely with the entire executive team around CEO Alexander Olek.

The entire team fosters continuous dialog with institutional and private investors, many analysts, the press, and the general public. We use all available communication channels to distribute information about Epigenomics, including email, our corporate webpage, conference calls, personal meetings and a strong presence at industry and trade show meetings. Following the IPO, our webpage now contains company presentations, all published financial reports and links to all ad hoc news and press releases. Also, a corporate calendar including dates of all financial reports, annual press conferences, as well as analyst meetings and annual shareholders' meetings, is provided in a timely and comprehensive manner. Further details can be found on [www.epigenomics.com](http://www.epigenomics.com).

Following the IPO, Epigenomics has presented updates to investors at various conferences in the U.S. as well as in Europe. Also, a series of targeted road shows have been organized to update both current as well as potential future shareholders on the progress of the Company. We expect to further strengthen that effort in 2005 and going forward.



Heike Ziebarth

TECHNICIAN, BERLIN

“I feel that I am part of a brilliant team at Epigenomics that is improving the way cancer and other hereditary diseases are diagnosed. This also means that in the future, patients’ chances of recovery will be assessed much more quickly and efficiently.”

# Management Report

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## 1. ECONOMIC ENVIRONMENT

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Geopolitical uncertainty, the weak U.S.\$ and slow economic growth dominate.

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The year 2004 has been characterized by a continued concern about global terrorism, the ongoing war in Iraq, relatively slow economic growth in major European countries and steep increases in oil prices. They were accompanied by expectations of rising interest rates as well as the November presidential elections in the U.S. Taken together this has led to a much less positive development of the equity capital markets in Europe and Germany in particular than expected.

While the U.S. capital market saw a large number of IPOs and follow-on offerings in many sectors, including over a dozen IPOs in biotech, Europe did not see a similar development with only a handful of biotech IPOs getting completed at all and most of them trading down in the aftermarket.

Also, pressure on big pharmaceutical companies deriving from rising health care costs continued and led to ever-tougher rules on reimbursement in Europe. Together with some high-profile drug failures and uncertainty around the regulatory environment in pharmacodiagnosics, this led to some restraint in R&D spending and the appetite for adding new, external approaches to their portfolios.

The significant weakening of the U.S.\$ vis-à-vis the euro reduced our U.S. cost base in euro terms, but is also creating pricing pressure on our R&D offering to the pharmaceutical and biotech industries, which typically is guided by U.S.\$ benchmarks. Comparatively high unemployment in both, Germany and the U.S., has made the access to highly qualified and motivated personnel relatively easy and swift with overall labor cost increases staying within tight limits in Germany and the U.S.

Overall, the sentiment seems to have improved in the last quarter of 2004 with the U.S. elections out of the equation, signs of economic recovery in the U.S. as well as in Europe and expectations for improving investment and equity financing climate in Europe and Germany in particular. However, as the geopolitical arena sees continued wartime activities in Iraq and concern over the Middle

East, Iran and North Korea remains, the debate about social reforms in Germany is only gradually abating with no self-sustaining economic growth in Germany yet. Therefore, a tough macroeconomic climate for any high-tech business dependent on the capital markets' sentiment will remain.

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**2. GENERAL OVERVIEW OF EPIGENOMICS' BUSINESS**  
 .....

**Epigenomics successfully completes its IPO and strengthens financial position; product development progresses; partnering on track.**

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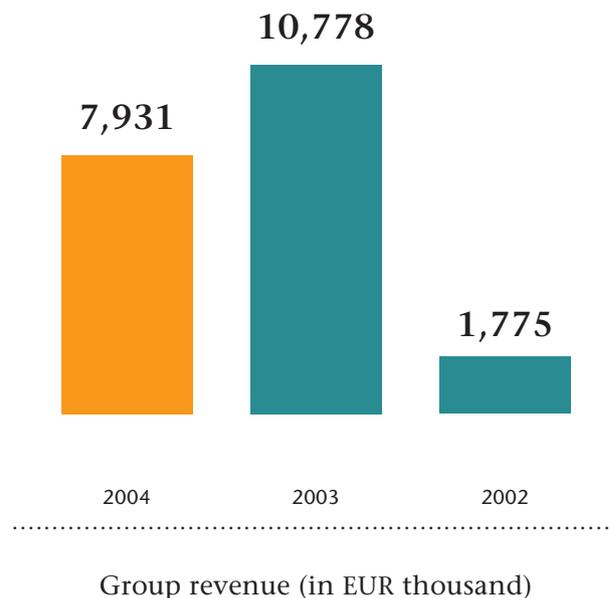
Epigenomics is a molecular diagnostics company active in two strategic business units (SBUs): Diagnostics and Pharma Technology. In both our businesses we are focused on developing novel and proprietary molecular diagnostic tests, i.e. products that shall provide significant benefit to patients in terms of accuracy, convenience and ultimately acceptance of these tests. With our research and development (R&D) and in close collaboration with our commercialization partners we plan to leverage our DNA methylation technologies and set a standard in molecular diagnostics. Initially, we focus primarily on oncology tests but believe that DNA methylation has significantly broader application potential in other indications such as autoimmune disorders, metabolic and cardiovascular as well as central nervous system and possibly inflammatory diseases, too.

Throughout 2004, we have systematically progressed our product development programs in oncology through the various stages of discovery, biomarker identification,

assay development and marker validation. We have continued to meet critical milestones in our Diagnostics and Pharma Technology business units. We delivered study results to our commercial partners and signed up new customers and partners in our pharmacodiagnosics business. With continued improvement of our DNA methylation technologies we strengthened our IP portfolio and contributed to the overall scientific understanding of methylation as a key component of human (epi)genetic information.

Based on the strong performance on fundamentals as well as the unique positioning as a molecular diagnostics player, Epigenomics was able to successfully complete its Initial Public Offering (IPO) on July 19, 2004, and to raise over EUR 41 million in gross proceeds.

In doing so, we became the first biotech company to successfully list on the Frankfurt Stock Exchange in well over three years and one of only a handful of European



biotech IPOs in this period overall. The proceeds from our IPO have allowed us to repay or convert into equity all non-current debt in the form of silent partnerships as well as to strengthen our financial position enabling us to initiate and fund our own product development in 2005 and beyond. This will significantly broaden and deepen our product development pipeline to create a more balanced portfolio of tests and retain more upside for Epigenomics and its shareholders. Overall, our financial position at the end of 2004 has improved significantly over previous years with liquidity of EUR 41.0 million available.

In line with market expectations and guidance given during the IPO, our 2004 revenue was down by 26% to EUR 7.9 million compared to EUR 10.8 million in 2003. This is due to the lump sum payment of milestones and their specific timing in our Roche alliance. Our lead products in colon, prostate and breast cancer indications are expected to reach important clinical milestones in 2005 and 2006 and are expected to contribute to growing our top-line revenue in following years.

Having kept the size and scale of operations virtually constant throughout 2004, the bottom line suffered from the reduced revenue and therefore losses were, although in line with expectations, significantly higher than in 2003. EBIT for 2004 read EUR –9.9 million compared to the previous year's EUR –6.3 million, an increase of 57%. Our 2004 net loss of EUR 10.5 million (previous year: loss of EUR 6.7 million) contained significant one-time effects from our financing.

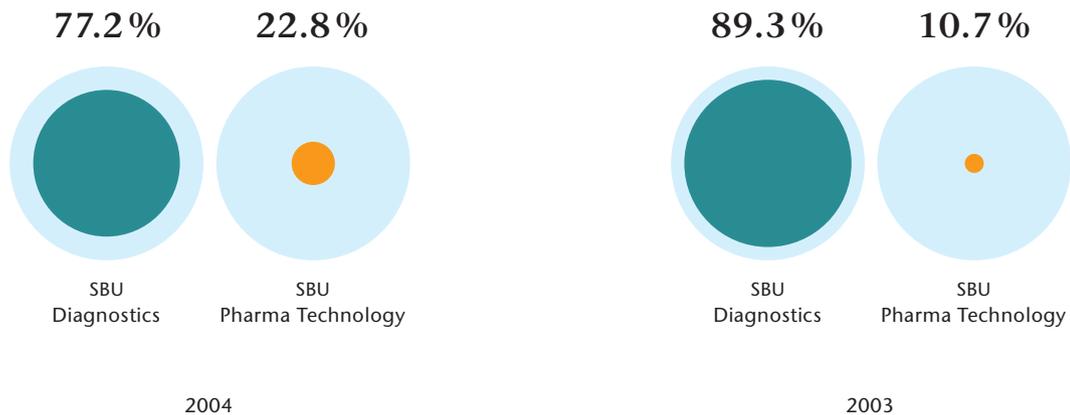
Our total net cash flow for 2004 amounted to EUR 13.7 million compared to 2003's EUR 12.3 million, mainly driven by a negative cash flow from operations and a positive cash flow from financing.

### 3. BUSINESS OVERVIEW BY SEGMENT

#### Execution of Roche programs in Diagnostics; growing importance of Pharma Technology business.

In 2004 as in previous years, Epigenomics continued to be active in two business segments, its Diagnostics and Pharma Technology business units. These two have been structured into independent strategic business units (SBUs) to focus on their respective distinct customer and partnership base. Our Diagnostics SBU develops pure diagnostic tests for the early detection, classification and monitoring of cancer and commercialises these through in-vitro diagnostic partnerships such as the Roche Diagnostics alliance. Pharma Technology focuses on programs that are geared towards developing companion tests for specific cancer drugs and assisting partnering pharmaceutical and biotech companies in their respective drug development programs.

In 2004, the Diagnostics SBU continued to contribute the lion's share of revenue based on successful execution of the Roche programs. However, the relative share of Diagnostics revenue dropped from its 2003 high of 89% to 77% in 2004. All new business deals and commercial agreements in 2004 came from Pharma Technology. The geographic split of our revenue in 2004 was still almost entirely Europe-based with 97% of total revenue coming from European partners and the remaining 3% from U.S. partners.



Group revenue share by SBU (in %)

**a. SBU Diagnostics.** The revenue of EUR 6.1 million in 2004 generated by our Diagnostics SBU was down from EUR 9.6 million in 2003, which is mainly due to the timing of significant one-off milestone payments in our various Roche programs. Several of such lump sum milestones had occurred in 2003, but did not occur again in 2004. With the redefinition and expansion of validation procedures for all our Roche tests, key milestones were pushed into the second half of 2005 and 2006, respectively. Therefore, 2004 revenue was mainly attributable to continued recognition of the upfront payment, R&D funding and reimbursements for all our Roche programs, as well as earlier-stage milestones in some of our product development programs. The following product development projects contributed to the 2004 Diagnostics revenue and are all partnered with Roche:

- Colon cancer early detection test
- Prostate cancer early detection test
- Breast cancer early detection test
- Prostate cancer molecular classification test
- Breast cancer relapse prediction/molecular classification test

Corresponding cost of sales for the execution of our partnered Roche programs were increased in 2004 at EUR 4.7 million (2003: EUR 4.4 million). Therefore, gross profit on sales in our Diagnostics business fell to EUR 1.4 million with the gross margin down at 24% compared to the previous year's EUR 5.2 million and 54%, respectively.

Research and development expenses in 2004 for our Diagnostics business increased significantly to EUR 1.7 million versus EUR 1.1 million the year before. The key drivers were the initiation of our own product development in non-Hodgkin's lymphomas testing as well as continued technology improvements, with specific focus on building a high-throughput system for processing thousands of blood samples for later-stage product development in colon and prostate cancer. Furthermore, continuing effort went into our IT infrastructure (sample databases), assay technologies and sensitive detection of DNA methylation from body fluids in particular. By the end of 2004, the Diagnostics SBU has identified several promising product development projects that will be pursued from 2005 onwards and shall drive future revenue generation through partnerships as well as own commercialization efforts.

Despite significant efforts in Diagnostics business development totaling EUR 0.4 million in 2004 (down from previous year's EUR 0.5 million), there were no deal closings in 2004. Therefore, revenue generation continued to rely on the Roche deal. However, several partnering discussions were ongoing at the end of 2004.

The overall segment earnings contribution from our Diagnostics SBU in 2004 was marginally negative at EUR –0.6 million, compared to a positive contribution of EUR 3.6 million in 2003, which again was almost entirely driven by the drop in top-line revenue.

**b. SBU Pharma Technology.** The revenue of EUR 1.8 million in 2004 generated by our Pharma Technology SBU was up from previous year (EUR 1.1 million). This was mainly due to the increased revenue recognition from our most advanced Roche program, the breast cancer treatment response (Tamoxifen) test, as well as the execution of our partnered projects with AstraZeneca (lung cancer) and Wyeth (Xenograft mouse study). Towards the end of 2004, the newly formed alliances with Pfizer and Biogen Idec added somewhat to the segment unit's top line. 2004 revenue were mainly attributable to the breast cancer treatment response test and the continued recognition of its corresponding portion of the Roche upfront payment as well as R&D funding and reimbursements for all our programs.

Corresponding cost of sales for the execution of our partnered programs were slightly higher in 2004 at EUR 1.1 million (previous year: EUR 0.9 million). Therefore, gross profit on sales in our Pharma Technology business increased to EUR 0.7 million with the gross margin up to 40% compared to last year's EUR 0.2 million and 20%, respectively.

Research and development expenses in 2004 for our Pharma Technology business declined to EUR 1.4 million versus EUR 2.3 million in 2003. Key drivers were the increased focus on commercially partnered programs as well as heavy emphasis on Diagnostics R&D for our lead products there. By the end of 2004, the Pharma Technology SBU has identified several promising product development projects, at least one of which should be pursued from 2005 onwards and shall drive future revenue generation through partnerships as well as own commercialization efforts.

Our very significant efforts in pharmacodiagnostic business development totaling EUR 0.7 million in 2004 (previous year: EUR 0.6 million) started to bear fruit. We initiated two new oncology pharmacodiagnostic partnerships in 2004 and had a healthy pipeline of discussions at the end of 2004 with some potential for growing and further diversifying the revenue generation in 2005.

The overall segment earnings contribution from our Pharma Technology SBU in 2004 was still negative at EUR –1.4 million, yet significantly improved from the 2003 contribution of EUR –2.6 million. This was almost entirely driven by the growth in top-line revenue as well as slightly reduced segment R&D.

4. KEY FIGURES ON  
EPIGENOMICS' BUSINESS

Strengthened financial position and balance sheet; earnings are in line with expectations; R&D streamlined and programs on track; two new alliances closed.

**a. Financial position and investments.** Epigenomics' 2004 cash flow and financial position were mainly affected by the successful completion of our IPO on July 19, 2004, as well as the continued net cash consumption from operations and investments. Overall, the financial position has improved significantly compared to the beginning of the year with cash, cash equivalents and marketable securities amounting to EUR 41.0 million as of December 31, 2004, compared to EUR 19.4 million on January 1, 2004.

Total net cash flow before currency adjustments in 2004 was positive at EUR 13.7 million compared to EUR 12.3 million last year. Cash outflow from operating activities in 2004 amounted to EUR 8.9 million, up from the

previous year's EUR 6.3 million. This increase is primarily a function of the lower cash inflow from our ongoing Roche partnership compared to 2003 due to the timing of milestone payments in 2003, some of which did not occur again in 2004.

In 2004, cash flow from investing activities was strongly influenced by investments in marketable securities and financial assets as part of the treasury function with 2004 total cash outflow from investments at EUR 10.2 million compared to last year's outflow of EUR 1.8 million. However, thereof net cash outflow for investments in tangible and intangible assets totaled EUR 0.8 million in 2004 compared to EUR 1.3 million last year. This reflects our continued cautious investment policy as well as the level of maturity of our facilities and equipment with very little growth in 2004. In the year under review, we put particular emphasis on investments into technical equipment and lab machinery, including the replacement of our self-developed hybridization devices with a second-generation series of devices.

Cash flow from financing activities reflected cash inflows from our IPO, cash outflows for all expenses associated with the IPO including the syndicate's fees as well as repayments of all but one of our silent partnerships including termination premiums and interest. The final silent partnership was converted into equity. Net cash flow from financing activities amounted to EUR 32.8 million in 2004 compared to EUR 20.4 million the year before.

#### Group cash flow

EUR thousand	2004	2003	2002
Cash flow from operating activities	-8,885	-6,338	-6,954
Cash flow from investing activities	-10,214	-1,763	-885
Cash flow from financing activities	32,757	20,446	-172
Currency adjustments	88	-487	-259
<b>Total cash flow</b>	<b>13,746</b>	<b>11,858</b>	<b>-8,270</b>



Yreka Ocampo

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RESEARCH ASSOCIATE,  
DEVELOPMENT, SEATTLE

“Epigenomics truly provides an entrepreneurial environment where I feel enriched professionally and personally. Dialog with my colleagues always consists of an exchange of ideas and concepts to make our work more stimulating.”

**b. Earnings situation.** Compared to 2003, revenue in 2004 was down by 26% to a total of EUR 7.9 million, mainly due to the lack of Roche program milestones falling into the 2004 period to the same extent as in 2003. However, the 2004 revenue base has been broadened to include new partners. Cost of sales for the execution of partnered programs increased by 7.8% to EUR 5.8 million leading to a gross profit of EUR 2.2 million compared to EUR 5.4 million in 2003.

Other income dropped to EUR 1.2 million compared to EUR 1.4 million in 2003, resulting from reduced income from granted projects.

In 2004, EBIT added up to EUR –9.9 million, a drop from previous year's EUR –6.3 million. This was almost entirely the result of the aforementioned revenue and gross profit situation. Costs for R&D increased year over year from EUR 7.6 million to EUR 7.8 million. Marketing and business development costs remained constant at EUR 1.3 million. General and administrative expenses increased from

EUR 3.2 million in 2003 to EUR 3.7 million in 2004, driven by higher post-IPO expenses as a public company.

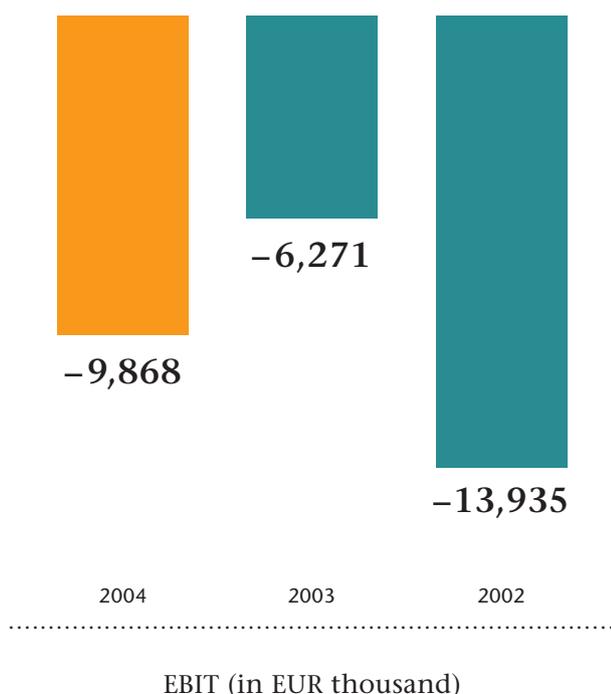
Total operating costs rose moderately in 2004 to EUR 19.0 million from EUR 18.4 million in the year before. This increase was mainly attributable to the extended use of samples in the commercial projects as well as to higher license fees to third parties, higher statutory costs from being public and higher costs for various services. The increase was partly compensated by lower expenditures for external R&D and the significant currency effects from the strength of the euro towards the U.S. \$. Nevertheless, we have proven that we have tightly controlled our costs and avoided unnecessary spending increases even after the IPO inflows.

Key drivers in terms of net interest income were the higher liquid funds on the income side as well as the final interest payments for our silent partnership loans on the expenses side. Other financial expenses of EUR 1.1 million are due to termination premiums for the silent partnerships as well as an accounting charge associated with the conversion into equity of one silent partnership.

Our net loss widened by 56% from last year's EUR 6.7 million to EUR 10.5 million in 2004.

**c. Assets and capital structure.** Epigenomics' balance sheet total increased from EUR 31.3 million as of December 31, 2003, to a total of EUR 53.3 million at year-end 2004.

Total non-current assets increased from the previous year's EUR 8.4 million to EUR 9.7 million at the end of 2004 and contained goodwill of EUR 2.6 million, which did not suffer any impairment upon testing. Tangible assets stayed almost constant at EUR 2.4 million, due to a restrictive investment policy just making up for depreciation. Financial investments in held-to-maturity securities were the main drivers for the increase in non-current assets and were added to the treasury portfolio in early 2004 for interest yield performance purposes.



Current assets dramatically increased from EUR 22.9 million to EUR 43.6 million, due to the cash inflow from our IPO in July 2004.

Upon completion of the IPO, our subscribed capital increased by EUR 5.0 million and capital reserve jumped from EUR 13.1 million as of the end of 2003 to EUR 41.8 million at the end of 2004. Net loss for the year added up to EUR 10.5 million at year-end, leaving the equity ratio of 89.6% at a recent years' record high.

All non-current liabilities were eliminated upon repayment and conversion of all our silent partnership loans, leaving the balance sheet virtually debt-free. The convertible warrants program of previous periods has been closed and repaid as part of the IPO preparation process. Current liabilities added up to EUR 5.5 million at year-end 2004, compared to a total of EUR 7.2 million the year before.

**d. Significant differences in the financial, earnings and/or asset position compared to the annual financial statements of Epigenomics AG according to German GAAP.** The net loss for the year of Epigenomics AG according to German GAAP ("HGB-Einzelabschluss") adds up to EUR 14.7 million as the costs related to the Company's IPO (EUR 4.4 million) had to be expensed extraordinarily instead of offsetting against the capital reserve.

Compared to Group revenue, revenue according to German GAAP was EUR 0.2 million higher due to differences

in revenue recognition. Payments received within our partnership with the Wellcome Trust Sanger Institute were recognized as revenue here, while they had to be accrued according to IFRSs because of expected related expenses of the same amount in 2005.

According to German GAAP, other income amounted to EUR 1.5 million. The difference is mainly due to earnings from the release of a provision for lawsuits, which had been overprovided. Further we had to recognize gains from the capitalization of own services ("Erträge aus aktivierten Eigenleistungen") amounting to EUR 0.2 million.

The balance sheet of Epigenomics AG according to German GAAP shows total assets of EUR 56.7 million, including financial assets of EUR 8.1 million as investments in Epigenomics Inc. but excluding any goodwill from the acquisition of this subsidiary. Total equity here adds up to EUR 51.7 million resulting from historic and current differences in results between IFRSs and German GAAP. Other comprehensive income (mainly used to recognize unrealized gains and losses from securities) is not recorded in the German GAAP statements. Unrealized losses are expensed immediately through profit and loss while unrealized gains lead to hidden assets.

Interest payments for the silent partnerships are shown as cash flow from financing activities according to the IFRS cash flow statement while they are allocated to the operating activities in the cash flow statement according to German GAAP.

## Group balance sheet

EUR thousand	2004	2003	2002
Non-current assets	9,677	8,430	8,783
Current assets	43,607	22,877	8,202
<b>Total assets</b>	<b>53,284</b>	<b>31,307</b>	<b>16,985</b>
Equity	47,739	17,713	3,578
Non-current liabilities	41	6,375	6,041
Current liabilities	5,504	7,218	7,366
<b>Total equity and liabilities</b>	<b>53,284</b>	<b>31,307</b>	<b>16,985</b>

**e. Human resources.** The Epigenomics Group employed a total staff of 146 as of December 31, 2004, a slight increase from the previous year's 143. The average number of employees during 2004 increased to 145 from 143 in the previous year. During 2004, at Epigenomics AG in Berlin we employed an average of 110 people and in our Epigenomics, Inc. subsidiary in Seattle 35 employees (2003: in Berlin 113 and in Seattle 30). Overall staff costs were unchanged compared to the previous year totalling EUR 8.4 million. In 2004, however these costs were significantly impacted by the favorable foreign exchange rate development between the strengthening euro and the softening of the U.S. dollar, thereby reducing our staff costs at Epigenomics, Inc. staff turnover remained very low during 2004 and all open positions could be filled at very short notice.



Group headcount as of December 31

**f. Research & development.** In 2004, Epigenomics continued its strong commitment to building and maintaining its leading position in DNA methylation-based products, science and technology. Consequently, we invested a total of EUR 7.8 million in R&D nearly maintaining its 2003 base of EUR 7.6 million. This amount comprises R&D spending in the Diagnostics SBU of EUR 1.7 million, EUR 1.4 million in the Pharma Technology SBU and other R&D of EUR 4.7 million.

16

NUMBER OF GRANTED PATENTS 2004 (2003:6 | 2002:3)

The other R&D expenses include improvements in our biomarker discovery and development processes, sensitive detection technologies, tissue-based technologies and R&D infrastructure in

bioinformatics and automation. Many of our central R&D programs are undertaken in collaboration with world-leading academic and clinical collaborators.

An indication of the dedicated effort in our R&D towards proprietary technologies and biomarkers is the significant strengthening of our IP portfolio. In 2004, we received a total of 16 patent grants, bringing the total number of own granted patents (in at least one country) up to 32. Several of these manifest key components of our competitive advantage in DNA methylation.

**g. Marketing and business development.** In 2004, both our SBUs marketed their offering of diagnostic and pharmacodiagnostic product development in a business-to-business model entirely driven by strategic R&D and commercialization alliances. To that end, we have strengthened our central, company-wide business development function of experienced biotech business development managers. However, the customer and partnership universe is distinctly different in each of our two SBUs: In Diagnostics we address companies dealing with in-vitro diagnostics and reference labs companies, whose economics are driven by

diagnostic test sales. In Pharma Technology, however, our aim is to add value to drug development programs of our pharmaceutical and biotech industry partners. In both SBUs the primary focus has been on oncology programs in 2004, as had been the case in previous years, too. Total expenses of our business development activities in 2004 added up to EUR 1.3 million (2003: EUR 1.3 million).

In our Diagnostics business we did not succeed at closing an additional strategic partnership during 2004. However, we have ongoing discussions with a variety of in-vitro diagnostics and molecular diagnostics platform companies as well as reference lab companies about a number of our internal product development programs that are as yet un-partnered. Also, there has been a continuous effort at expanding the Roche Diagnostics partnership, which has led to the exercise of two optional products by Roche as well as the significant expansion of Epigenomics' role in the later stages of all clinical validation of our methylation-based assays and biomarkers.

The emphasis in our Pharma Technology business has been two-pronged: On the one hand, we successfully added three pharmaceutical partners during 2004. On the other hand, efforts are underway to assess options for extending and expanding some of the existing project-based partnerships in this area. However, as of the end of 2004, none of the existing partnerships are of a very strategic nature yet and focus is very much on proving that our methylation technology adds pharmacodiagnostic value to each partner's drug project.

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## 5. RISK REPORTING

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### Effective risk management system in place; significant risks remain.

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Epigenomics is a globally operating biotech company and as such subject to many industry and company specific risks. In line with the German "Corporation Sector Supervision and Transparency Act" ("Gesetz zur Kontrolle und Transparenz im Unternehmensbereich" – KonTraG), Epigenomics has established a comprehensive and effective system to identify, assess, communicate and manage risks across its functions and operations. The underlying principles and guidelines have been documented in a Group-wide "Risk Management Policy". The goal of this policy and all related systems is to identify risks systematically at the earliest possible stage, estimate their likelihood of occurrence as well as potential qualitative and quantitative impact, and design and implement countermeasures effectively.

Core principle is a transparency of risks across functions and businesses, interactive evaluation of these risks and a culture of accepting risks as integral part of doing business in biotechnology, but doing so responsibly and seeking an optimal balance of risks and opportunities. Every risk has a clearly identified "Risk Owner" whose responsibility it is to continuously monitor and control it, as well as manage implementation of any countermeasures. At regular intervals, these risk owners report to the corporate "Risk Manager" who in turn communicates these risks to the Executive Board and the Supervisory Board of the Company at least quarterly.

Hence, our management structure, organizational forums for identifying and assessing risks, monthly internal as well as external reporting and controlling systems all serve as integral part of the overall risk management system in a standardized fashion across all functions and locations. All of these tools are regularly monitored for effectiveness and optimized.

As part of our IPO in 2004, a systematic due diligence by several legal advisors to the Company and the underwriters has been completed. A comprehensive review of risk factors that could have a potentially material impact on Epigenomics can be found in our IPO prospectus, which as of the reporting date still adequately reflects these risks. There are, however, a number of major risks that Epigenomics faces, which individually or in combination could severely negatively impact our revenue, earnings and financial situation as well as stock price. These are addressed below:

Despite all of the progress made, a substantial amount of risk remains and pertains to our businesses, products, partnerships, technologies, IP, operations, financials and ultimately our stock. These are described in great detail in our IPO prospectus as well as summarized in this Risk Reporting section. None of our products have yet completed clinical trials nor are they approved by any regulatory authority or marketed and sold. Hence, our top-line revenue in 2004 as well as for the near future depends almost entirely on research and development funding, upfront payments, milestones and certain reimbursements. Also, there is a strong dependency on Roche Diagnostics as a partner with the vast majority of total revenue stemming from that partnership. Whilst new collaboration agreements in our Pharma Technology SBU have allowed us to somewhat diversify our revenue generation basis, all of these partnerships are relatively early-stage and need to demonstrate their commercial potential in the future.

**a. Risks related to our business.** Due to the stage of maturity of our products and technology, a key risk is the ability of DNA methylation assays to achieve the performance necessary for the diagnostic and pharmacodiagnostic tests we develop in cancer or its applicability beyond cancer. This will determine the success of our clinical studies as well as revenue from our partnerships and ultimately product-based revenue such as royalties.

In a space as dynamic and attractive as molecular diagnostics, there is an ever-intensifying degree of competition between small biotech companies as well as groups of large diagnostic players that could reduce or eliminate the competitive edge of our approach.

Lack of success in delivering the clinical sensitivity and specificity of our tests in colon, prostate and breast cancer indications could lead to a termination or reduction in size of our current Roche partnership, which is the main source of current and near-term revenue. Delays or failure to develop these tests, patient sample access, failure to obtain regulatory approval, failure of the underlying drug programs in pharmacodiagnosics, lack of market acceptance and penetration, resistance by the pharma industry against pharmacodiagnosics, payor resistance to reimburse our tests would all have material impact on our revenue, earnings, our financial position and ability to raise further capital. Similar risks exist in all other partnered programs as well and might also make the entering into additional alliances harder or even impossible.

Epigenomics today does not have access to an own hardware or device platform to run commercial diagnostic or pharmacodiagnostic tests and therefore relies heavily on its partner Roche for such a market outlet. Also, Epigenomics as of 2004 does not yet have the full capabilities to run clinical trials, manufacture our tests, obtain regulatory approval or market and sell these products effectively. Again, the above-described partnership-related risks apply.

All of the above we try to manage effectively by keeping close relations and open interactions with all our partners, creating a balanced portfolio of varying types of risks in terms of required technologies, assay systems, clinical

questions, timelines and having a set of partners as well as own in-house product development programs we work on. We also strive towards obtaining access to those components of the value chain we currently do not control through partnering and other commercial arrangements, gradual forward integration and selective investment into such complementary skills and capabilities. Wherever possible and economically viable, we have taken out insurance against loss of data, facilities, downtime, theft, hazards, liabilities etc. and we regularly monitor the appropriateness of the level of our insurance coverage.

Also, to successfully implement our business strategy, we rely on highly skilled, motivated, and loyal employees and the best possible advisors. We have therefore implemented training, incentive and retention programs to ensure the continued success in hiring and keeping the best teams for our businesses. Our internal policies aim at establishing, nurturing and maintaining a culture of risk-awareness and feeling responsible for risk management at every level.

Epigenomics is furthermore subject to significant dependencies on its suppliers of critical patient samples, components of our tests and materials for all its R&D programs. Delays, higher costs, lack of available supplies in a timely and effective manner could seriously hamper individual product development projects and operations inside Epigenomics. To mitigate this risk, we work with second-source suppliers wherever possible, have supplier audits in place for critical components and continuously strive towards optimizing our purchasing efforts. A key risk has been eliminated by agreeing to an out-of-court settlement at favorable terms with a former supplier.

**b. Risks related to our IP.** Our business relies very heavily on commercializing our intellectual property in the form of know-how as well as licenses to patents and patent applications. Therefore, any negative impact on scope, duration, depth and breadth of claims granted, regional coverage, competing IP that we could depend on, difficulties in enforcing the protection, inadvertently infringing other IP, preventing others from infringing our IP, our ability to in-license key IP etc. would negatively impact our cost base, ability to compete, ability to commercialize our products and close alliances, revenue and ultimately earnings and overall commercial success.

**c. Risks related to the regulatory environment.** The regulatory environment in molecular diagnostics and pharmacodiagnosics is evolving rapidly and this could significantly impact the timing, cost and our ability to meet such regulatory standards. In parts, the regulatory frameworks are not fully established or clarified. This in turn could negatively impact our revenue, burden our cost base and earnings, financial position and ability to compete effectively. To mitigate this risk, we have established a corporate function dealing with quality systems as well as regulatory affairs and we do rely on experienced advisors to prepare the organization for any potential issues.

**d. Other risks.** Operating in Germany as well as the U.S. means we are subject to foreign exchange rate risks as well as interest rate risks. In close cooperation with our banks, advisors and internal functions we aim at finding appropriate balance between exposure to these risks, maximizing interest yield and minimizing our U.S. currency exposure.

We continuously monitor all applicable environmental, health and safety, operational as well as other applicable statutory or industrial guidelines and have implemented functions to comply with all of these effectively at each of our business locations.

# HACKESCHER H



Restaurant · Cafe

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Hackescher Markt

Mitte,  
Am Kupfergraben

S-Bhf  
Hackescher Markt

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eat

BVG Fahrinfo SMS.  
So einfach!

eat



Dr. Jürgen Distler

.....  
SENIOR MANAGER,  
ASSAY TECHNOLOGY, BERLIN

“Since 1999, I’ve been interested in the idea of using DNA methylation for molecular biological diagnosis of complex diseases. Today we can use epigenetics to diagnose illnesses in a timely manner, as well as choose the best and least aggressive therapy for the patient. I can therefore say that the last five years have been a total success for me as a scientist.”

To minimize risks from the manifold tax, corporate, employment, competition, IP and other legal frameworks, we base our decision-making and design of our policies and processes on the advice of external as well as internal experts in each of these areas. Wherever appropriate and indicated, we set aside provisions to cover any potential liability.

There are risks specifically associated with our stock: the large holdings of a small number of venture capital (VC) companies in Epigenomics shares even after the lock-up expiry, the comparatively low levels of liquidity in the stock, high volatility based on all of the above-described factors, as well as external influences.

There could potentially be other risks beyond the ones described here that we currently either deem insignificant or are not aware of at the time of this report.

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## 6. OUTLOOK

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**Deliver on milestones; expand partnership base; initiate own product development; grow top-line revenue at slightly higher losses and cash consumption.**

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**a. Economic environment.** We anticipate continuing tough economic circumstances in both Europe as well as the U.S.A. Especially in Germany, economic growth is expected by many to not accelerate as fast as required to have significant impact on labor markets and the local economy. This in turn should lead to only moderate increases in costs for supplies and staff. Inflation is not expected to have a very significant impact on 2005 operating costs either

in Germany or in the U.S.A., although health care costs especially in the U.S. continue rising at high rates.

We expect the U.S. will continue to suffer from a weak U.S.\$, which will in turn benefit Epigenomics' cost of operations in Seattle vis-à-vis costs in Berlin in euro terms. However, pharmaceutical companies are used to purchase R&D collaborative programs in U.S.\$ such that continuing pressure on pricing these deals is anticipated.

Continued geopolitical uncertainty in many regions will have a persistent impact on equity capital markets and we do not currently expect any major rallies in the stock markets in general and in biotech stocks in Germany in particular. Much will depend on the successful completion of other biotech IPOs in Germany and Europe in 2005 to bring back some investor confidence into the sector overall. Also, with political pressure towards reform and job creation unabating, there is some scope for improving the fiscal and legal environment for highly innovative technology companies.

Regulatory pressure on pharma companies worldwide to integrate pharmacodiagnosics into their drug development in order to avoid future cases of serious safety or efficacy concerns is expected to slowly but steadily increase, raising the awareness and perceived need by these companies to integrate pharmacodiagnostic efforts into their programs. Also, with recommendations for reimbursement of early detection especially in cancer by the U.S. government and other bodies and massive popular awareness campaigns, the overall perception of cancer screening for the masses will steadily improve. As pharmacoeconomic arguments continue to be built for saving significant costs by avoiding unnecessary or inappropriate treatments, the contribution of diagnostics towards such end is expected to increase.

**b. Business strategy.** The overriding goal of our corporate and business strategy is to create and grow shareholder value, build and maintain excellent employee and stakeholder relationships, be reliable and valued partners to the diagnostics, pharmaceutical and biotech industries and take an active and involved role in our local communities and our industry as good corporate citizen.

A major part of Epigenomics' business strategy will be to continue the execution of the Diagnostics product development programs in our R&D and commercialization alliance with Roche Diagnostics. Also, in our Pharma Technology business, we expect to deliver results in our partnered programs.

While both SBUs anticipate continuing a drive for more collaborative agreements to develop and commercialize DNA methylation-based molecular diagnostic and pharmacodiagnostic tests, Epigenomics believes a two-pronged approach to gradual forward integration is warranted. On the one hand, both SBUs plan to initiate internally-funded product development programs with a continued focus on oncology tests, but also include some early work on indications outside of oncology to demonstrate the applicability of DNA methylation to their diagnosis.

On the other hand, efforts are undertaken to evaluate opportunities to gain access to testing platforms that might be amenable to adaptation for DNA methylation analysis. Epigenomics considers it necessary to develop and bring in-house certain capabilities with regards to clinical study design, execution, and regulatory affairs expertise, as well as assessing alternatives to a purely partnering-based approach to develop and commercialize our future tests.

Overall, our strategy will remain focused on developing and commercializing innovative molecular diagnostic and pharmacodiagnostic tests in oncology and progressively other disease indications, leverage our leading position in DNA methylation, while complementing the skills and expertise available today with those needed to emerge as a potential leader in the emerging molecular diagnostics space.

**c. Financing strategy.** Our financing strategy is tailored towards a conservative approach with the overriding goal of ensuring sufficient liquidity for our operations based on the available funds today. Apart from cash inflows from alliances, virtually all operations are funded solely through equity capital raised in several venture capital rounds as well as our IPO in July 2004. By the end of 2004, almost all debt has been repaid or converted into equity.

Our investment policy is in line with these goals and ensures we maintain a diversified portfolio of cash, cash equivalents, marketable and held-to-maturity securities. Our aim is to avoid any overexposure to any particular issuer, type of investment, maturity, or other investment risk. A key element in our treasury and investment policies is maintaining relationships with at least two major banks assisting with the investment portfolio management, and a centralized approach and critical review of any individual investment decision.

We continuously monitor the equity capital markets to evaluate opportunities for increasing the free float in Epigenomics' shares by an organized and structured process that allows our venture capital shareholders to begin selling some of their holdings to existing and new investors. We furthermore watch capital markets in terms of their ability to satisfy future financing needs, but, however, have no immediate plans for additional fund raising.

**d. Goals for 2005 and beyond.** Our operating plans are based on a EUR/USD exchange rate in line with recent levels and a largely unchanged macroeconomic and political environment. Thereby we believe to be able to benefit from a contractual revenue base that is almost exclusively in euro and a significant portion of our operational costs in U.S. dollar. Epigenomics expects to achieve its 2005 and 2006 goals with an overall organizational size quite similar to year-end 2004 and a comparable split between its operations in Berlin and Seattle.

In our Diagnostics business we expect completing several important large clinical testing and validation studies in our Roche program. We anticipate announcing some of the results from these from the end of 2005 onwards and others in 2006 and beyond. Both, our body fluid-based early detection products for colon, prostate and breast cancer as well as our tissue-based tests will play an important part in that. Overall, this should help growing the top line in our Diagnostics SBU compared to 2004 over the next two years.

In our Pharma Technology business we aim at adding new initial partnerships with leading pharmaceutical or biotech companies, delivering promising results to our current partners and expanding or extending ongoing relationships towards pharmacodiagnostic product development. Top-line revenue is also expected to grow compared to 2004 over the next two years.

A key strategic goal for 2005 and 2006 is to gain visibility on our own, non-partnered product development programs by broadening and deepening our pipeline of tests under development in both businesses. Initial data would likely become available from 2006 onwards.

Given, that we expect to start investing significant parts of our R&D budget into our own product development as well as facing sizeable costs of being a public company, we expect earnings and cash consumption to remain at similar or somewhat higher levels compared to 2004 for the next two years.

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## 7. IMPORTANT EVENTS AFTER THE END OF THE REPORTING PERIOD

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### **a. Change of composition in Supervisory Board.**

Effective January 17, 2005, Dr. Klaus Stöckemann has resigned from the Supervisory Board of Epigenomics AG. This is in line with communication made throughout the IPO process and constitutes a first step towards enhancing the independence of the Supervisory Board post IPO by adding non-VC (venture capital) members. Epigenomics expects this position to be filled in due course.

### **b. Expiry of lock-up period for VCs.**

Whilst Executive Board members remain locked up for the original 12-18-24-month period agreed in the IPO, the original six-month lock-up period for VC and other non-management shareholders ended after January 14, 2005. On January 20, 2005, Epigenomics issued an ad hoc release stating that we have been informed of an agreement between the vast majority of our VC shareholders and Morgan Stanley, to coordinate all potential selling efforts by these VCs through 2005 – if any. Epigenomics management sees this as a further sign of support by its current VC shareholders into the future and will strive to support this agreement to the extent possible and permissible.

In the run-up to the lock-up expiry, the stock price had come under a little bit of pressure, albeit at very low volumes. Since the announcement we have observed a moderate decline in share price in the days following the lock-up expiry based on slightly enhanced liquidity.

Berlin, February 4, 2005

# Consolidated Financial Statements and Notes for Fiscal Year 2004

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50	— Group Income Statement
51	— Group Balance Sheet
52	— Group Cash Flow Statement
53	— Statement of Changes in Group Equity
54	— Notes to the Consolidated Financial Statements
80	— Auditor's Report

# Group Income Statement

EUR thousand	Notes	2004	2003
<b>Revenue</b>	<b>1</b>	<b>7,931</b>	<b>10,778</b>
Cost of sales	2	-5,758	-5,340
<b>Gross profit</b>	<b>2</b>	<b>2,174</b>	<b>5,438</b>
Other income	3	1,202	1,360
Research and development costs	4	-7,789	-7,642
Marketing and business development costs	5	-1,322	-1,313
General and administrative costs	6	-3,710	-3,205
Other expenses	7	-424	-909
thereof: amortization of goodwill		-56	-223
<b>Operating result (EBIT)</b>	<b>8</b>	<b>-9,868</b>	<b>-6,271</b>
Financial result	9	-569	-399
<b>Net loss before taxes on income</b>		<b>-10,437</b>	<b>-6,670</b>
Taxes on income	10	-55	-40
<b>Net loss for the year</b>		<b>-10,493</b>	<b>-6,710</b>
Earnings per share in EUR (basic)	11	-0.76	-0.79

# Group Balance Sheet

## Assets

EUR thousand	Notes	Dec 31, 2004	Dec 31, 2003
<b>Non-current assets</b>	<b>12</b>		
Intangible assets	12/13	5,534	5,859
thereof: goodwill	12/14	2,625	2,681
Tangible assets	12/15	2,350	2,508
Financial assets	12/16	1,763	32
thereof: shares in associated companies		13	13
Other non-current assets		30	31
<b>Total non-current assets</b>		<b>9,677</b>	<b>8,430</b>
<b>Current assets</b>			
Inventories	17	115	166
Trade and other receivables	18	752	1,940
Marketable securities	19	8,873	984
Cash and cash equivalents	20	32,166	18,419
Other current assets	21	1,702	1,368
<b>Total current assets</b>		<b>43,607</b>	<b>22,877</b>
<b>Total assets</b>		<b>53,284</b>	<b>31,307</b>

## Equity and Liabilities

EUR thousand	Notes	Dec 31, 2004	Dec 31, 2003
<b>Equity</b>	<b>22</b>		
Subscribed capital		16,334	11,353
Capital reserve		41,848	13,077
Net loss for the year		-10,493	-6,710
Other comprehensive income		50	-7
<b>Total equity</b>		<b>47,739</b>	<b>17,713</b>
<b>Non-current liabilities</b>			
Silent partnerships	23	0	6,038
Warrants		0	3
Liabilities from leasing contracts		41	15
Provisions		0	319
<b>Total non-current liabilities</b>		<b>41</b>	<b>6,375</b>
<b>Current liabilities</b>			
Trade payables		1,105	958
Silent partnerships	24	13	0
Liabilities from leasing contracts		43	13
Deferred income	25	3,187	5,152
Other liabilities	26	345	444
Provisions	27	811	651
<b>Total current liabilities</b>		<b>5,504</b>	<b>7,218</b>
<b>Total equity and liabilities</b>		<b>53,284</b>	<b>31,307</b>

# Group Cash Flow Statement

EUR thousand	Notes	2004	2003
Cash and cash equivalents at the beginning of the period	20	18,419	6,561
<b>Operating activities</b>	<b>28</b>		
Net loss before taxes on income		-10,437	-6,670
Corrections for:			
Depreciation on tangible assets		1,092	864
Amortization of intangible assets		352	489
Gains (2003: losses) from the disposal of assets		-7	9
Income from capitalization of own services		0	-11
Write-off of other current assets		125	0
Bad debt losses		74	0
Foreign currency exchange losses		79	69
Other financing expenses		485	319
Interest income		-816	-379
Interest expenses		277	459
Taxes		-55	40
<b>Operating result before changes in net current assets</b>		<b>-8,831</b>	<b>-4,811</b>
Decrease (2003: increase) in trade receivables and other current assets		855	-2,022
Correction item for other current assets		0	-31
Changes in inventories		53	-102
Decrease (2003: increase) in current liabilities		-1,625	130
Increase in non-current provisions		0	319
<b>Liquidity earned from operating activities</b>		<b>-9,548</b>	<b>-6,517</b>
Interest received		663	179
<b>Net cash flow from operating activities</b>		<b>-8,885</b>	<b>-6,338</b>
<b>Investing activities</b>	<b>29</b>		
Payments for investments in tangible assets		-773	-1,023
Proceeds from investment grants		221	519
Payments for investments in intangible assets		-52	-236
Payments for investments in financial assets		-1,750	-32
Proceeds from the sale of marketable securities		2,297	0
Payments for purchase of marketable securities		-10,157	-991
<b>Cash flow from investing activities</b>		<b>-10,214</b>	<b>-1,763</b>
<b>Financing activities</b>	<b>30</b>		
Payments for collection of warrants issued		-3	0
Repayments of silent partnerships		-4,057	0
Interest payments for silent partnerships		-360	-388
Payments for lease financing		-50	-18
Payments for the creation of new shares		-4,370	-150
Proceeds from the issue of shares		41,597	21,002
<b>Cash flow from financing activities</b>		<b>32,757</b>	<b>20,446</b>
<b>Net cash flow</b>		<b>13,658</b>	<b>12,345</b>
Currency adjustments		88	-487
Cash and cash equivalents at the end of the period	20	32,166	18,419

## Statement of Changes in Group Equity

EUR thousand	Subscribed capital	Capital reserve	Retained earnings	Other compreh. income	Losses carried forward	Group equity
<b>December 31, 2002</b>	<b>11,078</b>	<b>6,368</b>	<b>0</b>	<b>0</b>	<b>-13,867</b>	<b>3,578</b>
Income for ordinary capital increase	11,639	0	0	0	0	11,639
Premium from issue of shares	0	9,363	0	0	0	9,363
Income from redemption of shares	-11	11	0	0	0	0
Financing costs	0	-150	0	0	0	-150
Capital decrease	-11,353	0	11,353	0	0	0
Fair value adjustments of securities	0	0	0	-7	0	-7
Deduction of net loss for the year 2002	0	-2,514	-11,353	0	13,867	0
Net loss for the year 2003	0	0	0	0	-6,710	-6,710
<b>December 31, 2003</b>	<b>11,353</b>	<b>13,077</b>	<b>0</b>	<b>-7</b>	<b>-6,710</b>	<b>17,713</b>
Capital increase from issue of shares	4,622	0	0	0	0	4,622
Premium from issue of shares	0	36,975	0	0	0	36,975
Financing costs	0	-4,370	0	0	0	-4,370
Conversion of silent partnership into share capital	359	2,876	0	0	0	3,235
Fair value adjustments of securities	0	0	0	57	0	57
Deduction of net loss for the year 2003	0	-6,710	0	0	6,710	0
Net loss for the year 2004	0	0	0	0	-10,493	-10,493
<b>December 31, 2004</b>	<b>16,334</b>	<b>41,848</b>	<b>0</b>	<b>50</b>	<b>-10,493</b>	<b>47,739</b>

# Notes to the Consolidated Financial Statements

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## BASIC INFORMATION, PRINCIPLES AND METHODS

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**Description of business activity.** Epigenomics AG (the “Company”) was founded in 1998 and has its headquarters in Berlin, Germany. It is registered in the commercial register (“Handelsregister”) Charlottenburg under the number HRB 75861. In 2000, it was converted into a stock corporation and since July 19, 2004, the Company is listed on the Frankfurt Stock Exchange in the “prime standard” segment (ticker symbol: ECX).

In accordance with its Articles of Incorporation, the object of the Company is the development and marketing of procedures and devices for the production of particular epigenetic parameters such as DNA methylation patterns as well as the information technology bases necessary for their procurement and evaluation. The initial focus of the Company lies on the development of novel diagnostic products for cancer.

**General principles.** The consolidated financial statements of Epigenomics AG are prepared according to the International Financial Reporting Standards (IFRSs) of the International Accounting Standards Board (IASB), London, in effect at the closing date. New standards adopted by the IASB apply from the date on which they went into effect. In the reporting period no new standards became mandatory that could affect the Company’s accounting policies. However, the IASB announced a few new standards and interpretations as well as some revisions to existing standards during 2004 that will be mandatory from 2005 on encouraging earlier adoption. The Company decided to adopt the following new or revised standards already from 2004 on:

- New standard IFRS 3 (“Business Combinations”) together with the revisions to IAS 36 (“Impairment of Assets”) and IAS 38 (“Intangible Assets”);
- New standard IFRS 5 (“Non-current Assets Held for Sale and Discontinued Operations”);
- Revisions to IAS 1 (“Presentation of Financial Statements”), IAS 2 (“Inventories”), IAS 8 (“Accounting Policies, Changes in Accounting Estimates and Errors”), IAS 16 (“Property, Plant and Equipment”), IAS 17 (“Leases”), IAS 21 (“The Effects of Changes in Foreign Exchange Rates”), IAS 24 (“Related Party Disclosures”), IAS 27 (“Consolidated and Separate Financial Statements”) and IAS 33 (“Earnings per Share”).

The following new or revised standards that become mandatory from 2005 on and will affect the accounting policies of the Company are not yet adopted in its present 2004 financial statements:

- New standard IFRS 2 (“Share-based Payment”)
- Revisions to IAS 32 (“Financial Instruments: Disclosure and Presentation”) and IAS 39 (“Financial Instruments: Recognition and Measurement”).

The reporting period as defined in these financial statements is the period from January 1, 2004 to December 31, 2004. The reporting currency is the euro.

**Management’s judgement and expectations.** The management of the Company has made several judgements in the process of applying the entity’s accounting policies that have a significant effect on the amounts recognized in the financial statements. Those judgements concern the valuation of goodwill, the capitalization of development costs and the recognition of deferred taxes. The judgements are described for each relevant position in the enumeration of accounting policies.

Management’s expectations on the future are based on a scenario of moderate economic growth in the major countries (G-8 countries and Australia) over the next 3–5 years. The euro currency is expected to remain strong vis-a-vis the U.S. dollar. Dramatic changes in the legislation of the major countries that could significantly affect the biotechnological industries are not assumed. Changes in the tax laws of Germany and the U.S.A. are also not anticipated. All future scenarios assume further an essentially unchanged access to relevant clinical and biological data and resources for the execution of the Company’s commercial projects.

**Consolidation group.** The consolidated Group includes Epigenomics AG as the parent company (principal office: Kleine Präsidentenstrasse 1, 10178 Berlin, Germany), and Epigenomics Inc. (principal office: Suite 300, 1000 Seneca Street, Seattle, WA 98101, U.S.A.), a wholly-owned subsidiary. The two companies have submitted individual financial statements for the reporting year independent of their consolidation.

Epigenomics (France) SARL, which is wholly-owned by Epigenomics AG, was not included in the consolidated Group for materiality reasons. The French company has no employees, so far no significant operations and a nominal capital of only EUR 7,500. Consequently, the French subsidiary remains below the materiality limit on the reporting date. According to French GAAP, Epigenomics (France) SARL had no revenue in 2004 and a net loss for the year of EUR 12 thousand. As of December 31, 2004, total assets of Epigenomics (France) SARL added up to EUR 10 thousand and total liabilities to EUR 15 thousand.

**Principles of consolidation.** In the consolidation of capital, the acquisition values of the investment are balanced with the share of equity capital applicable to them on the date of acquisition or the date on which they were first incorporated into Group accounts. A resulting difference is added to the assets and liabilities in the amount in which its current market value deviates from its book value. An amount in excess is capitalized as goodwill. Intercompany results, revenue, expenses, profits, receivables and payables between the Group companies are eliminated.

**Accounting and valuation principles.** Since the Company has opted for an early adoption of IFRS 3 (“Business Combinations”) in conjunction with the revised standards IAS 36 (“Impairment of Assets”) and IAS 38 (“Intangible Assets”), the regular amortization of capitalized **goodwill** as done in previous periods is discontinued now and replaced by an impairment test of the goodwill to be performed at least once a year. The first-time application of this impairment test was done by the end of 2004, subsequent to the annual budgeting process of the Company. The recorded goodwill has been allocated to the SBU Diagnostics as cash-generating unit (CGU). The impairment test compared the net book value of the assets of the SBU Diagnostics to their value in use. The value in use has been defined as the discounted cash flows of the business unit.

Management’s expectations regarding the future cash flows of the SBU Diagnostics were based on the most recent business plans and are, however, subject to risks and uncertainty. It is expected that the cooperation with Roche, as the key customer of the Diagnostics business, will be continued over the next financial year and that new product developments will be started within this cooperation. An appropriate discount rate of 20% has been applied. (For the generally underlying assumptions to the aforementioned business plans see also “Management’s Judgements and Expectations”). All of those assumptions are key sources of estimation uncertainty and bear a significant risk of causing a material adjustment to the carrying amounts of the capitalized goodwill. However, no impairment of the capitalized goodwill has been determined in 2004.

Other **intangible assets** are valued at acquisition cost less planned amortization on a straight-line basis. Depending on the investment, between three years (software) and twenty years (patents) will be defined as useful life. For patents, the useful life in individual cases always depends on the term of the patent protection. Amortization of intangible assets is allocated to the functional area in which they are used. IAS 38 (“Intangible Assets”) is applied. In accordance with this standard, intangible assets are reported if it is likely that a future financial advantage is associated with the use of such an asset and that the costs of the asset can be reliably determined.

Own **development expenses** are capitalized if they can be clearly identified as such in accordance with IAS 38.57 and it is equally clear that later cash flows have a high likelihood of being directly associated to them. To date, the Company has not capitalized any internal development costs, because management assumes that, due to the risks in the development phase, the “sufficient probability” which would require the capitalization of development costs is not met.

**Tangible assets** are estimated at acquisition or production costs, less planned depreciation caused by usage. Apart from directly calculable costs, pro-rata overhead and depreciation are also included in the production costs of internally produced equipment. Public grants lower acquisition or production costs. Interest on third-party capital is not included in production costs. Repair costs are immediately calculated as an expense. Depreciation for fixtures in buildings is applied on a straight-line basis over the remaining term of the underlying leases. Mobile fixed assets are depreciated in principle on a straight-line basis. The useful life is 3–8 years for technical and electronic equipment and 5–10 years for operational and office equipment.

Fully depreciated fixed assets are shown under acquisition and production costs and accumulated depreciation until the assets in question are decommissioned. The acquisition and production costs as well as the accumulated depreciation are shown as disposal in the case of disposal of assets. Income resulting from disposal of assets (profits less residual book value) is shown in the income statement under other income or expenses.

Investment grants and subsidies received are offset directly against the subsidized assets, i.e. the asset value is reduced. The grant is thus liquidated by a depreciation on the reduced investment over the remaining term.

If the value of the fixed capital assets calculated according to the above principles exceeds the fair value of these assets on the closing date, it will be taken into account with unplanned depreciations. The amount to be adjusted is determined by sale proceeds or – if it is higher – the net present value of future cash flows estimated from value in use of the asset. An impairment test will be done annually for assets or groups of assets for which an unplanned decrease in value is assumed. If there is no longer any reason for unplanned depreciations, an appreciation will take place.

Securities held to maturity are shown under **financial assets** and are recognized at their acquisition costs. If such securities are disposed of or are determined to be impaired, the realized differentials are recognized as income.

Because of the current organization of procedures and the limited storage capacity of the Company, no appreciable amount of **inventories** was held. Exceptions to this are oligonucleotides (samples of synthetically produced DNA) and natural (cell) tissue samples. These are – if not yet opened – assessed at acquisition or recovery costs. Samples that have been opened are deemed to have been fully expensed in the month of their first use in the income statement. However, in most cases, natural tissue samples are not solicited by means of acquisition of property. Rather, these are use rights from collaboration partners. In these cases, remuneration is distributed by means of prepayments and accrued income over the duration of the projects they are based on. All basic low-value consumables are valued at acquisition costs. A standardized consumption pattern is assumed.

**Trade receivables** are recognized at nominal values net of allowances for doubtful accounts.

**Marketable securities** are recognized at fair values. Changes in fair value are recognized in other comprehensive income or in the income statement if they are disposed of, respectively.

A **cash equivalent** is defined as being convertible on a short-term basis to a known amount of cash and carrying a low risk of changes in value. Instruments generally qualify as cash equivalents when they are more closely related to the money markets than to the bond markets and are issued by a debtor rated “investment grade”. Paid premiums on fund shares are expensed immediately through profit and loss.

**Provisions** are recognized if it is likely that a debt exists and a reliable estimate of the amount is possible.

**Deferred income** is recognized for grants and R&D payments received in advance. Grants received in advance that were provided by the government and by comparable central, regional or local authorities, are liquidated with an effect on net income over the subsidized terms of projects according to the progress of the fulfillment of the order. R&D payments received in advance from customers are deducted and liquidated with an effect on revenue over the term of the contract according to the progress of fulfillment. No advance payments were received in the reporting year, which would have to be liquidated within a timeframe of more than 12 months.

**Deferred taxes** are applied to differences between the valuations in the trade and the tax balance sheets of the companies involved, as well as to consolidation proceedings. Deferred tax assets and liabilities are accumulated in the amount of the expected tax credits or liabilities of subsequent fiscal years and will only be offset against each other if they are subject to compensation with regard to identical tax authorities. Deferred tax assets are only recognized if they are guaranteed within reason. According to management’s expectations a realization of those deferred tax assets within the following years can not be deemed “reasonably guaranteed” based on current business plans.

**Revenue** from research and development collaboration agreements is recorded and recognized in accordance with the applicable performance requirements and terms of the respective contracts as contract research costs are incurred, including the percentage of completion basis. Milestone payments are recognized as revenue according to the milestone payment method. Revenue under the milestone payment method is recorded and recognized when acknowledgement of having achieved applicable performance requirements is received from the collaborator. Non-refundable upfront payments are deferred and recognized on a straight-line basis over the maximum research term (i. e. including optional prolongation terms). Revenue from the sale of products and other services is recognized when delivery has taken place, transfer of risk has been completed, the amount of future returns can be reasonably estimated and collection of the receivable is probable.

The preparation of the consolidated financial statements in compliance with International Financial Reporting Standards requires, in the case of several items, that assumptions or estimates be made that affect the valuation in the Group's balance sheet and/or the income statement. This also applies to the listing of contingent assets and liabilities. The actual amounts may vary from these assumptions and estimates. The estimates mainly refer to the assessment of liability reserves and the extent to which positive deferred taxes are realizable.

**Currency translation.** In the individual statements, receivables and liabilities in foreign currencies are valued using the corresponding euro reference rate issued by the European Central Bank on the last business day prior to the closing date. Items that are guaranteed by forward transactions are valued at the forward price. The reporting currency of the U.S.-based Epigenomics Inc. is the euro as well. Therefore, the translation risk from Epigenomics Inc.'s functional currency (U.S. dollar) to the Group's reporting currency (euro) lies completely in the separate financial statements of this subsidiary and not in its consolidation. Rate differences are shown with an impact on earnings in the Group income statement. The exchange rate of the U.S. dollar, the only major foreign currency in the consolidated financial statements, changed during the reporting year as follows:

#### Reporting date rates

	Dec 31, 2004	Dec 31, 2003
EUR/USD	1.3621	1.2630

#### Average rates

	2004	2003
EUR/USD	1.2466	1.1418

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NOTES TO THE GROUP INCOME STATEMENT

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**1. Revenue.** Total revenue in 2004 dropped to EUR 7,931 thousand from EUR 10,778 thousand in the previous year. Service orders not yet fulfilled as of the reporting date account for the major portion of revenue in 2004. The decrease of 26% in revenue was attributable to the SBU Diagnostics, recording approximately 36% less revenue than in 2003 while the SBU Pharma Technology could increase its revenue by 57% in the same period. For the Diagnostics unit it must be mentioned, that several notable bigger one-off effects (mainly milestone revenue) had been recognized in 2003 according to the progress in the Roche collaboration.

**2. Cost of sales/Gross profit.** Cost of sales include the material and personnel expenses and depreciation that can be directly allocated to the sales revenue, as well as pro-rata personnel overheads. The first-time application of a segment reporting in the current financial year led to a changed disclosure of costs. Business units are now charged with indirect costs caused by themselves. The new method of charging overhead costs was technically not possible in former years and is now “providing reliable and more relevant information about the effects of transactions, other events or conditions on the entity’s financial position, financial performance or cash flows”<sup>1</sup>. The effect of the application of this new method is shown in the following table:

Income statement 2003 (restated)

EUR thousand	2003 restated	2003 old	Change
Revenue	10,778	10,778	0
Cost of sales	-5,340	-3,744	-1,596
Gross profit	5,438	7,034	-1,596
Other income	1,360	1,360	0
Research and development costs	-7,642	-9,488	1,846
Marketing and business development costs	-1,313	-988	-325
General and administrative costs	-3,205	-3,280	75
Other expenses	-909	-909	0
thereof: goodwill amortization	-223	-223	0
Operating result (EBIT)	-6,271	-6,271	0

The new cost allocation method leads to higher cost of sales and lower research and development costs as well as slightly reduced general administrative costs simultaneously. At the same time, a new definition of related management cost centers led to a shift from research and development costs to marketing and business development costs.

<sup>1</sup> Extracted from IAS 8, Accounting Policies, Changes in Accounting Estimates and Errors. © IASC Foundation.

The increased utilization of high-value materials – especially tissue samples – was a key driver for higher cost of sales in 2004 compared to 2003 (EUR 5,758 thousand vs. EUR 5,340 thousand). Cost of materials and consumables contained in the cost of sales climbed from EUR 1,500 thousand in 2003 to EUR 1,716 thousand in 2004. Simultaneously, the gross profit dropped sharply to EUR 2,174 thousand (2003: EUR 5,438 thousand) as the lower leverage effect from milestone revenue could not soften the pressure on the gross margin. Especially in the Diagnostics unit the decrease in gross profit directly corresponds to the decrease in revenue. However, the SBU Pharma Technology could improve its gross margin from 20% in 2003 to 40% in the reporting year.

### 3. Other income

EUR thousand	2004	2003
Third-party research grants	849	1,026
Exchange gains from currency conversion	248	24
Income from liquidation of provisions	22	167
Insurance recoveries	54	10
Income from letting	0	35
Refunds from suppliers	0	15
Other	29	83
<b>Total</b>	<b>1,202</b>	<b>1,360</b>

### 4. Research and development costs (R&D costs).

- The following are recorded as research and development costs:
- the direct personnel and material expenses of the R&D divisions;
  - the depreciation of the R&D divisions;
  - the other direct expenses of the R&D divisions;
  - the pro-rata overheads of the R&D divisions.

The R&D costs of EUR 7,789 thousand (2003: EUR 7,862 thousand) include depreciation and amortization of EUR 816 thousand (2003: EUR 549 thousand) and cost of materials and consumables of EUR 1,249 thousand (2003: EUR 769 thousand).

### 5. Marketing and business development costs (M&BD costs).

- The following are recorded as marketing and business development expenses:
- the direct personnel and material expenses of the M&BD divisions;
  - the depreciation of the M&BD divisions;
  - the other direct expenses of the M&BD divisions;
  - the pro-rata overheads of the M&BD divisions.

**6. General and administrative costs.** The following are recorded as general and administrative costs:

- the direct personnel and material expenses of the administrative divisions;
- the depreciation of the administrative divisions;
- the other direct expenses of the administrative divisions;
- the pro-rata overheads of the administrative divisions,

if the costs listed are not carried forward as internal services. The administrative divisions comprise the business departments and systems administration.

The increase in general and administrative costs is mainly attributable to the new status of the Company as a public listed one, which warrants extensive efforts to comply with all the legislative and capital market requirements. The depreciation included in the general and administrative costs dropped from EUR 270 thousand in 2003 to EUR 260 thousand in 2004.

### Personnel costs

EUR thousand if not indicated otherwise	2004	2003
Personnel remuneration	7,296	7,284
Social security expenses	1,100	1,112
Social security expenses in %	15.1	15.3
<b>Total personnel expenses</b>	<b>8,396</b>	<b>8,396</b>
Employees (average)	145	143
Personnel costs/employee	57.9	58.7

The decrease in personnel costs per employee can mainly be explained by the strength of the euro currency towards the U.S. dollar in 2004, reducing overall costs in the U.S.A. (and especially labor costs) significantly on the euro basis.

## 7. Other expenses

EUR thousand	2004	2003
Exchange losses from currency conversion	245	573
Appropriation to provisions	75	100
Amortization of goodwill	56	223
VAT correction expenses	24	0
Final adjustments on granted payments	19	0
Losses from disposal of assets	2	9
Other	3	4
<b>Total</b>	<b>424</b>	<b>909</b>

**8. Operating result (EBIT).** The recorded loss before interest and taxes in the reporting year of EUR 9,868 thousand is by EUR 3,598 thousand higher than the loss before interest and taxes in 2003. Almost 80% of this increase is attributable to the drop in top line revenue.

## 9. Financial result

EUR thousand	2004	2003
Interest and related income	816	379
Interest and related expenses	-277	-459
Other financial expenses	-1,108	-319
<b>Total financial result</b>	<b>-569</b>	<b>-399</b>

The increase in interest and related income from EUR 379 thousand in 2003 to EUR 816 thousand in 2004 was mainly achieved by an intensified cash management and the higher average liquidity balances to control. Interest expenses arose exclusively for the seven loans by silent partners. The termination of six of those silent partnerships subsequent to the Company's IPO led to additional premiums for the partners of EUR 1,281 thousand. A portion of EUR 319 thousand had already been accrued in 2003 while the remaining amount of EUR 962 thousand was recognized as other financial expenses in the reporting year. Cash management fees and premiums on fund investments had to be recognized as well as other financial expenses.

**10. Taxes on income.** The income taxes in the amount of EUR 55 thousand (2003: EUR 40 thousand) resulted from the U.S. subsidiary in Seattle and were imposed by the State of Washington.

Deferred tax revenue in the amount of EUR 249 thousand was calculated for the reporting period. It resulted from valuation differences between IFRSs and German tax law. In this connection, a tax rate of 39% was used as a basis. Deferred tax revenue in the reporting period was calculated from valuation differences between German trade law and German tax law. It amounts to EUR 62 thousand.

From the losses of the German corporation that were carried forward, which at present can very likely be in part allowable against taxes, it was possible to calculate deferred tax revenue in the amount of EUR 7,435 thousand.

Since all the aforementioned matters must be settled with the same tax authority, then in accordance with IAS 12.71 et seq, a balancing of the respective income and expenses has been performed. The deferred tax revenue resulting from this amounts to EUR 7,746 thousand. The current forecasts of the Company with regard to achieving the break-even point are clouded by such uncertainty that the method of deferred tax receivables was dropped.

**11. Earnings per share.** The earnings per share (basic) are calculated by dividing the Group's net loss for the year by the weighted-average number of shares issued.

	2004	2003
Net loss for the year (in EUR thousand)	-10,493	-6,710
Weighted-average number of shares issued	13,783,653	8,443,145
<b>Earnings per share in EUR (basic)</b>	<b>-0.76</b>	<b>-0.79</b>

Because of the net loss to be posted for both 2004 and the previous year, the earnings per share (diluted) are not shown. The number of shares issued as of the balance sheet date amount to 16,334,229.

NOTES TO THE GROUP BALANCE SHEET

12. Non-current assets

EUR thousand	Acquisition costs Jan 1, 2004	Additions 2004	Disposals 2004	Acquisition costs Dec 31, 2004
<b>Intangible assets</b>				
Software	305	28	-24	309
Licenses and patents	3,579	0	0	3,579
Goodwill	3,351	0	0	3,351
<b>Total intangible assets</b>	<b>7,235</b>	<b>28</b>	<b>-24</b>	<b>7,239</b>
<b>Tangible assets</b>				
Fixtures and leasehold improvements	598	28	0	627
Technical equipments	4,680	691	-197	5,175
Other fixed assets	92	1	0	93
Prepayments and assets under construction	11	216	0	227
<b>Total tangible assets</b>	<b>5,382</b>	<b>936</b>	<b>-197</b>	<b>6,121</b>
<b>Financial assets</b>				
Shares in associated companies	13	0	0	13
Investments	19	0	-19	0
Securities held to maturity	0	1,750	0	1,750
<b>Total financial assets</b>	<b>32</b>	<b>1,750</b>	<b>-19</b>	<b>1,763</b>
<b>Total assets</b>	<b>12,649</b>	<b>2,714</b>	<b>-240</b>	<b>15,122</b>

Accumulated depreciation Jan 1, 2004	Additions 2004	Disposals 2004	Accumulated depreciation Dec 31, 2004	Net book value Dec 31, 2004	Net book value Dec 31, 2003
199	73	-23	249	60	106
507	223	0	730	2,849	3,072
670	56	0	726	2,625	2,681
<b>1,377</b>	<b>352</b>	<b>-23</b>	<b>1,705</b>	<b>5,534</b>	<b>5,859</b>
377	97	0	475	152	221
2,450	984	-196	3,238	1,937	2,230
46	12	0	58	34	45
0	0	0	0	227	11
<b>2,874</b>	<b>1,093</b>	<b>-196</b>	<b>3,770</b>	<b>2,350</b>	<b>2,508</b>
0	0	0	0	13	13
0	0	0	0	0	19
0	0	0	0	1,750	0
0	0	0	0	1,763	32
<b>4,250</b>	<b>1,445</b>	<b>-219</b>	<b>5,476</b>	<b>9,647</b>	<b>8,399</b>

**13. Intangible assets.** The value of the capitalized intangible assets dropped by EUR 325 thousand to EUR 5,534 thousand during the reporting period. Reinvestments were overcompensated by depreciation in the reporting period. The licenses listed in the amount of EUR 2,849 thousand represent mainly acquisition costs for acquired patents and exclusive rights of use to patents of third parties. Those acquisition costs were caused usually by upfront payments. The majority of the licenses require the Company to pay additional annual minimum fees that are expensed in the future. The license contracts can usually be cancelled at short notice. However, some of those licenses are vital for the Company's business model.

**14. Goodwill.** The capitalized goodwill was tested for impairment for the first time in 2004 in order to comply with IFRS 3/IAS 36. It had originated in the acquisition of Orca Biosciences Inc. (now: Epigenomics Inc.) in 2001 and is assigned in content to the Diagnostics business unit. No impairment had to be recognized.

**15. Tangible assets.** The net tangible fixed assets were reduced during the reporting period by EUR 158 thousand to a current amount of EUR 2,350 thousand. On the one hand, moderate investment policies are responsible for this decline. On the other hand, investment subsidies received from third parties led to a reduction of the book values, so that the amount of the asset additions is lower than the total amount of the depreciation. In the reporting period, investment subsidies affecting the book values were received by Epigenomics AG in Germany in the amount of EUR 221 thousand (previous year: EUR 533 thousand). This relates to a government investment grant for investments in tangible assets and an investment subsidy that is tied to a project, which is granted proportionately by the EU and the Federal State of Berlin ("GA Funds").

**16. Financial assets.** The financial assets listed refer to a 100% investment in Epigenomics (France) SARL. Due to a lack of materiality, this company was not included in the consolidation. Financial investments in the shape of securities held to maturity of EUR 1,750 thousand were added in 2004 for treasury purposes: a mortgage bond issued by a German mortgage bank in the amount of EUR 750 thousand and a promissory note issued by a German special branch bank in the amount of EUR 1,000 thousand. The Company's stake in Epiontis GmbH was 24.85% as of December 31, 2003 and has been reduced below 20% as of December 31, 2004. The stake is now reported under other current assets.

### Current assets

**17. Inventories.** The stock in trade mainly consists of chemical and biological consumer and consumable materials. It is mainly the stockpiling of tissue samples and oligonucleotides that are significant.

**18. Trade and other receivables.** Trade and other receivables listed in the amount of EUR 752 thousand (previous year: EUR 1,940 thousand) are comprised nearly exclusively of trade receivables towards foreign customers. There are no reasons for value adjustments of individual receivables at balance sheet date.

**19. Marketable securities.** The marketable securities listed in the amount of EUR 8,873 thousand (previous year: EUR 984 thousand) included mainly marketable corporate bonds, mortgage bonds, bond fund shares and debt certificates of various maturities as well as shares in various marketable funds. Under the investment policy of the Company, which was passed in 2004, each investment in securities underlies certain strict criteria. These include amongst others the limitation to securities nominated in euro currency only and an official capital market rating of the issuer or the securities not below “investment grade”. All reported securities are underlying the usual market and interest risks. The interest rate risks are mostly price risks and for some securities there is also an interest rate cash flow risk. Currency risks are minimized by avoiding investments in securities nominated in currencies other than the euro. However, some of the investments are indirectly subject to currency risks as they might be linked or refer partially to non-euro nominations. The fair value of all marketable securities is identified by their stock exchange quotations at each relevant balance sheet date.

EUR thousand	Dec 31, 2004	Dec 31, 2003
Corporate bonds	2,538	292
Bond fund shares	2,015	0
Mortgage bonds	1,299	298
Debt certificates	1,010	0
Preferred securities floater	983	0
Index-linked bonds	628	0
Bearer bonds	400	394
<b>Total</b>	<b>8,873</b>	<b>984</b>

The investment strategy of the Company includes an allocation of the various securities to different remaining maturities.

EUR thousand	Fair value
Time to maturity	
< 1 year	0
1 – 2 years	993
2 – 5 years	2,723
> 5 years	3,142
unlimited	2,015
<b>Total</b>	<b>8,873</b>

**20. Cash and cash equivalents.** Cash and cash equivalents increased to EUR 32,166 thousand at balance sheet date (previous year: EUR 18,419 thousand), which together with the increase in marketable securities mainly reflects the cash inflows from the Company's IPO. More than 95% of those funds were nominated in euro currency at balance sheet date, the rest is nominated in U.S. dollar currency. The total amount is allocated to four different banks.

<b>EUR thousand</b>	<b>Dec 31, 2004</b>	<b>Dec 31, 2003</b>
Open real estate fund shares	12,978	0
Asset-backed securities fund shares	8,110	0
Floating rate notes	3,744	0
Time deposits	3,580	4,399
Short-term bond and money market fund shares	2,517	13,833
Preferred securities bond fund shares	998	0
Bank accounts, petty cash, cheques	239	187
<b>Total</b>	<b>32,166</b>	<b>18,419</b>

The rates of interest of the reported floating rate notes are all based on the 3-month Euribor as reference interest rate. Therefore, these notes are underlying a limited interest rate risk. The reported fund shares are underlying very limited credit risks as well as low market and interest rate risks. The remaining maturities of the time deposits were shorter than three months as of the balance sheet date.

In 2004, the Company paid premiums on the purchase of fund shares amounting to EUR 109 thousand. Those premiums were expensed through the income statement.

## 21. Other current assets

EUR thousand	Dec 31, 2004	Dec 31, 2003
Claims based on granted projects	603	449
Receivables from tax authorities	460	414
Accrued income	291	390
Interest receivables	163	24
Claims based on external research cooperations	75	0
Already delivered equipment	59	72
Claims from sale of financial assets	10	0
Deposits	8	8
Claims against employees	5	0
Other	28	11
<b>Total</b>	<b>1,702</b>	<b>1,368</b>

The total amount of other current assets of EUR 1,702 thousand includes non-marketable securities of EUR 18 thousand with a prospective maturity of more than one year.

## 22. Equity

**Notes to share categories.** As of December 31, 2003, Epigenomics AG's share capital was divided into four classes of shares with a par value of EUR 1 each. During the Company's IPO in July 2004 there were not only 4,621,849 new shares issued but also previously existing differences between the share classes eliminated. The following conversion of a silent partnership by the Technologie-Beteiligungs-Gesellschaft mbH (tbg) created 359,477 additional shares. As of December 31, 2004, the share capital of Epigenomics AG was divided into 16,334,229 common shares with equal rights with a par value of EUR 1 each.

		Preferred shares			Total	
		Common shares	Series A	Series B		Series C
Jan 1, 2004	Opening balance	1,833,504	1,218,900	3,884,143	4,416,356	11,352,903
Jul 19, 2004	Standardization of old shares	9,519,399	-1,218,900	-3,884,143	-4,416,356	0
Jul 19, 2004	Issue of new shares	4,621,849	0	0	0	4,621,849
Oct 13, 2004	Conversion of a silent partnership	359,477	0	0	0	359,477
Dec 31, 2004	Closing balance	16,334,229	0	0	0	16,334,229

Consequently, the capital structure as of December 31, 2004 was as follows:

EUR	Dec 31, 2004
Share capital	16,334,229
Conditional capital I	71,969
Conditional capital II	68,000
Conditional capital III	231,242
Conditional capital IV	758,376
Authorized capital II	140,523
Authorized capital III	6,000,000

**Authorized capital.** As of December 31, 2003, there had been authorized capital amounting to 29,917 shares of a nominal value of EUR 1 each. This authorized capital has been revoked by the annual shareholders' meeting on June 22, 2004, and simultaneously two new tranches have been agreed. Thereof, the authorized capital II of EUR 500 thousand was registered by the commercial register (Handelsregister) Charlottenburg in July 2004 and used by EUR 359,477 for the conversion of a silent partnership into shares. The Executive Board of the Company is no longer authorized to utilize the remainder of EUR 140,523. Another authorized capital (III) of EUR 6 million was registered by the commercial register Charlottenburg in October 2004.

### Non-current liabilities

**23. Silent partnerships.** The liabilities to silent partners, divided into seven different loan contracts as reported in the previous year, have all been terminated in the reporting period. Altogether five loans from the partner tbg (Technologie-Beteiligungs-Gesellschaft mbH) amounting to EUR 2,494 thousand have been contractually paid back immediately after the IPO including their respective final premiums. Another loan by tbg amounting to EUR 2,750 thousand was contractually converted into shares following the IPO. The loan from DtA (Deutsche Ausgleichsbank) was terminated contractually and already paid back by the end of the reporting year.

**Convertible bonds.** The convertible bonds which were issued in previous years have been redeemed completely by the Company before the IPO.

### Current liabilities

**24. Silent partnerships.** The reported liabilities from silent partnerships amounting to EUR 13 thousand are unpaid interest payables on loans terminated before the balance sheet date (see above).

## 25. Deferred income

### Payments received from customers

EUR thousand	Dec 31, 2004	Dec 31, 2003
Payments from commercial cooperations	3,143	5,141
Payments from granted projects	44	11
<b>Total</b>	<b>3,187</b>	<b>5,152</b>

The payments received from commercial cooperations are liquidated in parts over a period from 2005 until 2007 with an impact on earnings. There is no repayment obligation.

## 26. Other liabilities

EUR thousand	Dec 31, 2004	Dec 31, 2003
Payables due to social security institutions	128	113
Payables due to tax authorities	96	142
Liabilities from external research cooperations	75	0
Payables due to silent partners	0	80
Received equipment	0	72
Payables due to staff	6	12
Other	40	25
<b>Total</b>	<b>345</b>	<b>444</b>

## 27. Provisions

EUR thousand	Dec 31, 2004	Dec 31, 2003
Payroll provisions	457	372
Annual shareholders' meeting and supervisory board fees	205	63
Audit services	84	69
Granted projects	37	0
Lawsuits	0	100
Other	28	47
<b>Total</b>	<b>811</b>	<b>651</b>

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## NOTES TO THE GROUP CASH FLOW STATEMENT

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**28. Operating activities.** Cash flow from operations is derived indirectly on the basis of the net loss for the year before taxes on income. The financing expenses reported as correction under cash flow from operating activities are mainly expenses caused by the IPO for the termination of the silent partnerships.

**29. Investing activities.** Cash flow from investing activities is ascertained in respect of payment. For information on the reported proceeds from investment grants please refer to “Tangible Assets”.

**30. Financing activities.** Cash flow from financing activities is ascertained in respect of payment. The repayments of silent partnerships in the amount of EUR 4,057 thousand exclude the loan which was converted into equity following the IPO of the Company.

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SEGMENT REPORTING

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**Segment reporting by business segment.** The Company's business model is set up on two strategic business units (SBUs): Diagnostics and Pharma Technology. The SBU Diagnostics develops pure diagnostic tests for the early detection, classification and monitoring of cancer and commercializes these through in-vitro diagnostic partnerships such as the Roche Diagnostics alliance. The SBU Pharma Technology focuses on programs that are geared towards developing companion tests for specific cancer drugs and assisting partnering pharmaceutical and biotech companies in their respective drug development programs.

The income statements for the SBUs do not contain any intersegment charges.

### Segment results

EUR thousand	Diagnostics		Pharma Technology		Other		Epigenomics Total	
	2004	2003	2004	2003	2004	2003	2004	2003
Revenue	6,125	9,627	1,806	1,151	0	0	7,931	10,778
Cost of sales	-4,679	-4,417	-1,079	-923	0	0	-5,758	-5,340
Gross profit	1,446	5,210	727	228	0	0	2,173	5,438
Gross margin (in %)	24	54	40	20			27	50
Other income	167	147	5	93	1,030	1,119	1,202	1,359
Research and development costs	-1,737	-1,071	-1,425	-2,334	-4,627	-4,238	-7,789	-7,643
Marketing and business development costs	-378	-507	-673	-620	-271	-185	-1,322	-1,312
General and administrative costs	0	0	0	0	-3,710	-3,205	-3,710	-3,205
Other expenses	-132	-223	0	0	-291	-685	-424	-908
Segment result	-633	3,556	-1,366	-2,633	-7,869	-7,194	-9,868	-6,271

### Segment balance sheet data

EUR thousand	Diagnostics		Pharma Technology		Other		Epigenomics Total	
	Dec 31, 2004	Dec 31, 2003	Dec 31, 2004	Dec 31, 2003	Dec 31, 2004	Dec 31, 2003	Dec 31, 2004	Dec 31, 2003
Segment assets	4,945	5,935	682	1,413	47,656	23,959	53,284	31,307
Segment liabilities	277	229	144	168	5,123	13,197	5,545	13,594
Net segment assets	4,668	5,706	538	1,245	42,533	10,762	47,739	17,713
Investments in non-current assets	339	279	65	177	2,310	523	2,714	979
Depreciation and amortization	519	510	147	187	779	656	1,445	1,353

**Segment reporting by geographical segment.** The Company has locations in Germany, the United States of America and France (French operation is dormant). However, it has decided to take the location of its markets and customers as a basis for the segment reporting by geographical segment (according to IAS 14.13 b).

#### Segment results by region

<b>EUR thousand</b>	<b>2004</b>	<b>2003</b>
<b>Total revenues</b>	<b>7,931</b>	<b>10,778</b>
thereof Europe	7,711	10,716
in %	97	99
thereof North America	220	62
in %	3	1

#### Segment assets by region

<b>EUR thousand</b>	<b>Dec 31, 2004</b>	<b>Dec 31, 2003</b>
<b>Net book value of assets</b>	<b>47,739</b>	<b>17,713</b>
thereof Europe	45,991	14,407
in %	96	81
thereof North America	1,748	3,306
in %	4	19
<b>Investments</b>	<b>964</b>	<b>946</b>
thereof Europe	677	640
in %	70	68
thereof North America	287	306
in %	30	32

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OTHER INFORMATION

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### Compensation of the Executive Board and the Supervisory Board

#### Compensation of the Executive Board

	Fixed com- pensation 2004 in EUR	Variable com- pensation 2004 in EUR	Total com- pensation 2004 in EUR	Owned shares as of Dec 31, 2004 (Dec 31, 2003)	Stock options as of Dec 31, 2004 (Dec 31, 2003)	Exercised options in 2004
<b>Alexander Olek, Ph.D.</b>						
Chief Executive Officer Berlin (D)	110,000	76,519	186,519	560,762 (560,762)	86,613 (6,613)	0
<b>Dr. Kurt Berlin</b>						
Chief Scientific Officer Stahnsdorf (D)	110,000	40,919	150,919	114,750 (114,750)	56,613 (6,613)	0
<b>Aron Braun</b>						
Chief Operating Officer Berlin (D)	110,000	38,667	148,667	115,515 (115,515)	56,613 (6,613)	0
<b>Christian Piepenbrock</b>						
Chief Information Officer Berlin (D)	110,000	35,408	145,408	117,300 (117,300)	56,613 (6,613)	0
<b>Oliver Schacht, Ph.D.</b>						
Chief Financial Officer Seattle, WA (U.S.A.)	110,000	43,667	153,667	104,550 (104,550)	69,363 (19,363)	0
<b>R. Gary Schweikhardt</b>						
Chief Executive Officer, Epigenomics Inc. Seattle, WA (U.S.A.)	136,678	10,937	147,615	36,856 (36,856)	106,643 (36,643)	0

## Compensation and mandates of the Supervisory Board

	fees 2004 in EUR
<b>Prof. Dr. Dr. h. c. Rolf Krebs – Chairman</b> former Chairman of the Executive Board of Boehringer Ingelheim GmbH, Ingelheim am Rhein (D) Mandates: Ganymed Pharmaceuticals AG, MG Technologies AG, Vita 34 AG, Air Liquide S.A.	30,000
<b>Bruce Carter, Ph.D. – Deputy Chairman since September 1, 2004</b> President & CEO ZymoGenetics Inc., Seattle, WA (U.S.A.) Mandates: Biolumina A/S, Skele Tech Inc.	13,333
<b>John Berriman</b> Consultant, London (GB) Mandates: Ablynx NV, Alnylam Pharmaceuticals Inc., Algeta AS (Chairman), Micromet AG	10,000
<b>Dr. Jörg Neermann – Deputy Chairman until August 31, 2004</b> Investment Manager, DVC, Munich (D) Mandates: 4SC AG (Chairman), DeveloGen AG, G2M AG, igeneon AG, probiodrug AG, Switch Biotech AG	16,667
<b>Dr. Michael Steinmetz</b> Investment Manager, MPM Capital, Boston, MA (U.S.A.) Mandates: Accelerator Corp. Acorda Therapeutics, Amphora Discovery Corp., Atugen AG, BioXcell SpA (Chairman), Biovitrum AB, Cellular Genomics Inc., Intracel Holdings Corp., MacroGenics Inc., TaiGen Biotechnology Ltd.	10,000
<b>Dr. Klaus Stöckemann – Member until January 17, 2005</b> Investment Manager, 3i Deutschland GmbH, Berlin (D) Mandates: Combinature AG, Elbion AG, Evotec Neuroscience Inc., Jerini AG	10,000

Mandates indicated are memberships in other supervisory boards or comparable boards with supervisory function in Germany or abroad.

As of the balance sheet date, Dr. Jörg Neermann held 1,000 shares of Epigenomics AG.

**Notes to the stock option plans.** As of the balance sheet date, the Epigenomics Group (via Epigenomics AG) had three fixed stock option plans in place. Details on those plans can be found in the Company's IPO prospectus and the consolidated financial statements 2003, respectively.

During the reporting year, 587,905 options authorizing the subscription of one share each have been issued under the 03–07 stock option program. This number includes 350,000 options for members of the Executive Board of the Company. The total number of issued options rose up to 848,906 as shown in the following table:

Option holder	Issued options as of Dec 31, 2003	Issued options 2004 pre IPO	Issued options 2004 post IPO	Lapsed options in 2004	Issued options as of Dec 31, 2004
Alexander Olek, Ph.D.	6,613	80,000	0	0	86,613
Dr. Kurt Berlin	6,613	50,000	0	0	56,613
Aron Braun	6,613	50,000	0	0	56,613
Christian Piepenbrock	6,613	50,000	0	0	56,613
Oliver Schacht, Ph.D.	19,363	50,000	0	0	69,363
R. Gary Schweikhardt	36,643	70,000	0	0	106,643
<b>Total Executive Board</b>	<b>82,458</b>	<b>350,000</b>	<b>0</b>	<b>0</b>	<b>432,458</b>
Employees	186,622	228,405	9,500	8,079	416,448
<b>Options total</b>	<b>269,080</b>	<b>578,405</b>	<b>9,500</b>	<b>8,079</b>	<b>848,906</b>

No stock options have been exercised during the reporting period.

As of the balance sheet date, no share options were held by members of the Supervisory Board. The option rights granted to members of the Executive Board in 2004 will vest in whole or in part upon a resolution by the Supervisory Board. The decision regarding the time and the extent of the vesting lies in the discretion of the Supervisory Board and will take into account the individual performance of each member of the Executive Board holding option rights as well as the development of the Company. Option rights that have not vested before through a declaration by the Supervisory Board will vest at the latest upon expiry of four years following the issuance of the option rights within that tranche. However, the exercise is subject to the expiry of the lock-up periods agreed during the IPO of the Company.<sup>2</sup>

The option rights of all other holders will vest as follows: 25 % of the options will vest on the first anniversary of the grant date, another 25 % on the second anniversary of the grant date, another 25 % upon the third anniversary of the grant date and the remaining 25 % will vest upon the fourth anniversary of the grant date. All vested options may be exercised the earliest from the second anniversary of the grant date. However, the exercise is subject to the expiry of the 6-month lock-up period for those option holders agreed during the IPO of the Company.

<sup>2</sup> The members of the Executive Board have entered into the lock-up undertaking for a period of 12 months from the date of admission of the offered shares to trading at the stock exchange (July 14, 2004). Upon expiry of this 12-month period, a third of their respective shares shall be released from the lock-up and may be freely transferred. 18 months following the admission of the shares to trading at the stock exchange, they may freely transfer a further third of their shares, and upon expiry of a total period of 24 months following the admission of the shares to trading at the stock exchange, all shares of these shareholders shall be released from this lock-up and may be freely transferred.

## Details of stock options granted in 2004

Expiry date	Jan 1, 2011	May 2, 2011	Aug 24, 2011	Total 2011
Number of options	566,826	3,500	9,500	579,826
Exercise price (in EUR)	4.53	4.53	7.15	
Aggregate proceeds if shares are issued (in EUR thousand)	2,568	16	68	2,652

## Terms of the options outstanding at December 31:

Expiry date	Exercise price EUR	2004 Number	2003 Number
2008	1.76	12,750	12,750
	1.94	18,470	18,470
	4.53	66,973	67,613
2009	4.53	59,980	64,544
2010	4.53	105,703	105,703
2011	4.53	575,530	0
	7.15	9,500	0
<b>Total</b>		<b>848,906</b>	<b>269,080</b>

All stock options issued in the past have not been expensed yet in the income statements. The Company will start to expense stock options from 2005 on under the regulations of the new standard IFRS 2 ("Share-based Payment"). It has decided against an earlier adoption in 2004 because of the complexity of this rule and the late availability of first interpretations. Based on the most recent internal estimates, the Company expects for 2005 to account for stock option expenses an amount of less than EUR 350 thousand for options granted in previous years (this number does not include additional costs for options to be granted in 2005). The retrospective application for expenses in 2003 and 2004 that has to be made in 2005 according to IFRS 2.55 is based on these estimates and is anticipated to lead to an adjustment of losses carried forward in the range of EUR 400–500 thousand.

**Other financial obligations.** Other financial obligations arise for Epigenomics AG from a total of three leases at the Berlin and Seattle locations:

- a) For the Berlin location at Kastanienallee there is a fixed-term lease in effect until April 30, 2009. The monthly rent without bills for this property is EUR 3,613.
- b) For the Berlin location at Kleine Präsidentenstrasse there is a fixed-term lease for the rented floors which runs until February 28, 2005. In 2004, this lease agreement has been extended and expanded. The new contract (valid from March 2005 on) runs over a total term of five years ranging from EUR 360 thousand per year in the beginning up to EUR 400 thousand per year at the end of the contractual term.
- c) For the Seattle location there is a fixed-term lease with term expiring on November 30, 2005. The monthly rent without bills for this property is USD 37,017.

In the reporting period as well as in previous years, Epigenomics acquired numerous exclusive licenses to third-party patents. This means that there are some obligations to pay minimum licensing fees in years to come. Additionally, Epigenomics has the obligation to reimburse most of those third parties for costs incurred in connection with the maintenance and the prosecution of the licensed rights. Those costs are mainly charges for patent attorneys or offices and are difficult to forecast regarding their amounts and their timing. The amount due to various licensors stands at approx. EUR 600–700 thousand in 2005 and at approx. EUR 700–800 thousand in 2006. However, most of these agreements can be terminated at short notice by Epigenomics. There is only one case in which Epigenomics is under a fairly long-term binding obligation. However, this obligation will not exceed EUR 25 thousand per year.

If in the future Epigenomics were to generate product revenue with third parties, which was generated with the help of this licensed intellectual property, then in some cases license fees that are above and beyond and which correspond to a percentage of such revenue must be paid to the licensors. Consequently, the potential amount of the obligations is difficult to quantify, since the significant share of the variable license fees is dependent on the type and composition of future revenue.

Following a new collaboration contract with another German biotechnology company, a payment obligation of EUR 75 thousand in 2005 remains for Epigenomics, if the partner delivers his part of the cooperation to specifications.

**Information on transactions with related parties.** At balance sheet date, the Company held a minority stake in Epiontis GmbH, Berlin. Further the Company ordered in the reporting year sample preparation services from Epiontis in a total value of EUR 7 thousand and recognized revenue from services for Epiontis in a total value of EUR 10 thousand. The managing director of Epiontis GmbH is Sven Olek, a brother of Epigenomics' CEO Alexander Olek. In 2004, the Company ordered as well laboratory services amounting to EUR 7 thousand from Prof. Dr. N. Dickgiesser who runs a privately-owned laboratory in Gelsenkirchen, Germany. The equally-entitled partner of Prof. Dickgiesser in running this laboratory is Prof. Dr. Klaus Olek, who is the father of Epigenomics' CEO Alexander Olek.

# Auditor's Report

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We have audited the consolidated financial statements prepared by Epigenomics AG, Berlin, comprising the balance sheet, the income statement and the statement of changes in shareholders' equity and cash flows as well as the notes to the financial statements for the business year from January 1 to December 31, 2004. The preparation and the content of the consolidated financial statements are the responsibility of the Company's executive board. Our responsibility is to express an opinion whether the consolidated financial statements are in accordance with International Financial Reporting Standards (IFRSs) based on our audit.

We conducted our audit of the consolidated financial statements in accordance with German auditing regulations and generally accepted standards 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 such that it can be assessed with reasonable assurance whether the consolidated financial statements are free of material misstatements. Knowledge of the business activity and economic and legal environment of the Group and evaluations of possible misstatements are taken into account in the determination of audit procedures. The evidence supporting the amounts and disclosures in the consolidated financial statements are examined on a test basis within the framework of the audit. The audit includes assessing the accounting principles used and significant estimates made by the executive board 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 the consolidated financial statements of Epigenomics AG give a true and fair view of the net assets, financial position, results of operations and cash flows of the Group for the business year in accordance with IFRSs. Our audit, which also extends to the management report of the Group and of Epigenomics AG (group management report), prepared by the executive board for the business year from January 1 to December 31, 2004, has not led to any reservations. In our opinion, on the whole the group management report together with the other disclosures in the consolidated financial statements provides a suitable understanding of the Group's position and suitably presents the risks of the future development.

In addition we confirm that the consolidated financial statements and the group management report for the financial year from January 1 to December 31, 2004, satisfy the conditions required for the Company's exemption from its obligation to prepare consolidated financial statements and the group management report in accordance with German law.

Berlin, February 7, 2005

UHY Deutschland AG

Wirtschaftsprüfungsgesellschaft



(ppa. Dr. Peters)

Wirtschaftsprüferin

[German Public Auditor]



(Lauer)

Wirtschaftsprüfer

[German Public Auditor]

# Income Statement 2004 of Epigenomics AG

(according to HGB – German GAAP)

	2004 EUR	2003 EUR thousand
<b>Total revenue</b>	<b>10,032,089.17</b>	<b>12,300</b>
Revenue	8,163,265.58	10,778
Changes in inventories	106,444.80	0
Capitalized own services	213,228.03	11
Other operating income	1,549,150.76	1,511
Cost of materials	-4,309,866.77	-3,620
Expenses for raw materials and supplies	-1,740,049.64	-1,177
Expenses for external services	-2,569,817.13	-2,444
Payroll costs	-6,311,660.30	-6,120
Wages and salaries	-5,460,779.12	-5,270
Social security contributions and costs for old-age pensions and public aid	-850,881.18	-851
Depreciation and amortization	-1,103,846.67	-915
on tangible and intangible assets	-1,103,846.67	-915
Other operating expenses	-8,321,655.08	-8,731
Other interest and similar income	1,157,808.27	450
of which from affiliated companies	233,196.54	276
Interest and similar expenses	-1,459,279.73	-777
<b>Result from ordinary business activities</b>	<b>-10,316,411.11</b>	<b>-7,413</b>
Extraordinary expenses	-4,370,336.84	0
<b>Net loss for the year before taxes</b>	<b>-14,686,747.95</b>	<b>-7,413</b>
Income taxes	0.00	0
Other taxes	0.00	0
<b>Net loss for the year</b>	<b>-14,686,747.95</b>	<b>-7,413</b>

# Balance Sheet of Epigenomics AG

(according to HGB – German GAAP) as of December 31, 2004

## Assets

	Dec 31, 2004 EUR	Dec 31, 2003 EUR thousand
<b>Non-current assets</b>	<b>14,502,559.34</b>	<b>12,967</b>
Intangible assets	2,891,467.75	3,154
Licenses, trademarks & other property rights	2,891,467.75	3,154
Tangible assets	1,804,981.22	1,971
Leasehold Improvements	123,270.69	162
Technical equipment and machinery	1,425,277.48	1,757
Other equipment, furniture and fixtures	29,354.72	41
Advances and assets under construction	227,078.33	11
Financial assets	9,806,110.37	7,842
Interests in affiliated companies	599,547.49	600
Loans to affiliated companies	7,456,562.88	7,223
Investments	0.00	19
Non-current securities	1,750,000.00	0
<b>Current assets</b>	<b>42,007,674.55</b>	<b>21,905</b>
Inventories	202,407.96	150
Raw materials and supplies	95,963.16	150
Finished goods	106,444.80	0
Receivables and other assets	2,349,522.20	5,414
Trade accounts receivable	751,530.21	1,939
Receivables due from affiliated companies	186,895.71	2,498
Other current assets	1,411,096.28	977
Securities	37,015,750.35	14,223
Other securities	37,015,750.35	14,223
Cash and cash equivalents	2,439,994.04	2,118
<b>Deferred expenses</b>	<b>190,263.56</b>	<b>264</b>
<b>Total assets</b>	<b>56,700,497.45</b>	<b>35,136</b>

## Equity and liabilities

	Dec 31, 2004 EUR	Dec 31, 2003 EUR thousand
<b>Shareholders' equity</b>	<b>51,740,185.74</b>	<b>21,595</b>
Subscribed capital	16,334,229.00	11,353
Common shares	16,334,229.00	1,834
Preferred shares "Series A"	0.00	1,219
Preferred shares "Series B"	0.00	3,884
Preferred shares "Series C"	0.00	4,416
Capital reserve	41,810,550.39	1,960
Other profit reserves	8,282,154.30	8,282
Net loss for the year (prev. year: balance sheet profit)	-14,686,747.95	0
<b>Accruals and provisions</b>	<b>1,130,572.79</b>	<b>1,490</b>
Accruals for claims of employees	438,060.30	369
Other accruals and provisions	692,512.49	1,121
<b>Payables</b>	<b>643,126.50</b>	<b>6,899</b>
Warrants (convertible)	0.00	3
Trade accounts payable	285,089.80	438
Payables due to silent partners	13,108.12	6,070
Other payables	344,928.58	388
<b>Deferred income</b>	<b>3,186,612.42</b>	<b>5,152</b>
<b>Total equity and liabilities</b>	<b>56,700,497.45</b>	<b>35,136</b>

# Scientific Advisory Board

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**Dr. Stefan Beck**

The Wellcome Trust Sanger Institute,  
Cambridge, U.K.

**Associate Prof. Susan Clark**

Sydney Cancer Centre,  
Sydney, Australia

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# Corporate Calendar

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**March 23, 2005**

Interim report December 31, 2004, and fiscal 2004 results,  
Press conference and Analyst meeting

**May 4, 2005**

Interim report March 31, 2005

**June 28, 2005**

Annual general shareholders' meeting

**August 3, 2005**

Interim report June 30, 2005

**November 2, 2005**

Interim report September 30, 2005

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# Glossary

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## A

### **Amplification**

Duplication.

### **Assay**

Chemical reactions that allow the detection of substances in samples.

### **AstraZeneca**

AstraZeneca UK Ltd., London, United Kingdom.

## B

### **Bases**

Chemical components of DNA: adenine (A), cytosine (C), guanine (G), thymine (T). Bound to the sugar-phosphate-backbone of DNA, they encode the genetic information (also see DNA).

### **Biomarker**

Substances that are normally present in small amounts in the blood or other tissues and which can be used to show the presence of certain diseases.

## C

### **Classification**

The division into medically relevant subtypes, such as aggressive and non-aggressive subclasses of tumors in oncology, once a disease has been positively identified.

## D

### **Diagnostics**

Diagnostics deals with the detection, monitoring and classification of diseases.

### **DKFZ**

The German Cancer Research Center (**D**eutsches **K**rebs-**f**orschungszentrum).

### **DNA (Desoxyribonucleic acid)**

The carrier of genetic information for all complex organisms. DNA consists of four different bases bound to a sugar-phosphate backbone: adenine (A), cytosine (C), guanine (G), thymine (T). The genetic information is encoded in the sequence of the four bases on the sugar-phosphate-backbone.

### **DNA methylation**

DNA can be modified through natural chemical reactions, by which a methyl group binds to the base cytosine (mC). Methylation provides information on gene regulation that is specific for cell types and diseases.

## E

### **EGFR**

Epidermal Growth Factor Receptor.

### **Endometriosis**

Chronic disease affecting women, in which tissue similar to the mucous membrane of the uterus (endometrium) accumulates in the alvus. This tissue can bleed and grow cyclically. Endometriosis may be connected to heavy pains in the preabdomen and is one of the most common causes for infertility. Currently, the only accurate diagnostic method is surgery.

### **Epigenetics**

Analysis of the essential mechanisms which control gene activity. Describes the state and functioning of protein-regulatory factors, secondary modifications of these factors, the regulation of gene activity and the chemical modifications of DNA through methylation.

### **Epigenomics**

The science and commercial exploitation of epigenetics.

### **Expression**

Conversion into the structures present and operating in a cell.

## G

### **Genome**

The genome is the total DNA of a species. Since all the DNA is wrapped up in chromosomes, the number of chromosomes is characteristic for a species, for example, 23 in humans.

### **Genomics**

The science and commercial exploitation of genomes and the functions of genes.

## H

### HEP

Human Epigenome Project.

## I

### Indication

Reason for carrying out a medical examination or therapy.

### In-vitro

In a test tube.

## M

### Molecular diagnostics

Diagnostics based on the knowledge of the human genome.

### Monitoring

The tracing of recurrence or assessment of the progression of a disease.

### mRNA

When a gene is turned on or expressed, it produces a copy in the form of a RNA (ribonucleic acid) sequence called messenger RNA ("mRNA") which is used as a template to direct the production of a protein.

### Methylation

The attachment of a methyl group to DNA in the case of DNA methylation.

### Microarray

Chip.

## O

### Oligonucleotides

Artificially generated sequence of bases.

### Oncology

The study and treatment of tumors in the body.

## P

### Paraffin

A wax-like substance used to preserve tissue samples.

### PCR

Polymerase Chain Reaction. Method to amplify DNA.

### Pharmacodiagnosics

Analysis of the activity of specific genes with regard to drug efficacy and side effects.

### Platform

One or more instruments or devices by means of which a test can be performed and the result analyzed.

## R

### R&D

Research and development.

### Roche Diagnostics

F. Hoffmann-La Roche Ltd., Basel, Switzerland.

## S

### SBU or SBUs

Strategic Business Unit or Units.

### Screening

The systematic and preventive examination of an asymptomatic population for early detection of disease.

### Sensitivity

The measure of a test's ability to accurately detect the presence of disease. For example, a sensitivity of 90% means that out of 100 patients which actually have a disease, on average 90 are correctly diagnosed.

### Specificity

The measure of a test's ability to exclude the possibility of a disease when it is truly not present. For example, a specificity of 90% means that out of 100 healthy people ten are falsely identified as having the disease.

## T

### Tamoxifen

Endocrine therapy drug administered in the case of breast cancer.

### Tamoxifen responder test

Pharmacodiagnostic test to determine the probability of recurrence of breast cancer following Tamoxifen monotherapy.

### Tumor

A mass of excess tissue that results from abnormal cell division.

## V

### Validation

Certain phase of product development during which data is confirmed to a large extent.

## W

### Wyeth

Wyeth Pharmaceuticals.

[www.epigenomics.com](http://www.epigenomics.com)