ANNUAL REPORT 2011

Epi proColon®

ADDRESSING THE LARGEST DIAGNOSTIC MARKET IN THE WORLD



## Dear shareholders!

We would like to take this opportunity to thank you for your positive feedback and continuous interest in our annual reports over the past years!

2011 was a year of many changes for Epigenomics. Among other things, we have also dealt intensively with costs and benefits as well as with the environmental aspects of our annual report. From this fiscal year onwards, we will only provide the legally required portion of the report in printed form. You will find everything else in our new »online« annual report on http://www.epigenomics.com/en/annual-report-2011.html

Moreover, all current information about the company and our products can be found as usual on our website at www.epigenomics.com

With this change we are making an important contribution to reducing the use of resources. This is not only environmentally appropriate but also in the best interest of our shareholders, as it represents a contribution to cost reduction.

Thank you for your understanding and we remain available for your feedback and suggestions.

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## FOREWORD BY THE CHIEF EXECUTIVE OFFICER

#### **DEAR SHAREHOLDERS,**

We started off last year with high expectations for the clinical development and commercial success for our lead products Epi proColon<sup>®</sup> in Europe and the U.S. as well as Epi proLung<sup>®</sup> for the European market. We succeeded on some fronts but faced a few hurdles along the way. Overall, it has been a challenging albeit productive year for Epigenomics which leads us into the Company's most decisive time as we currently approach the most critical steps of our regulatory pathway for Epi proColon<sup>®</sup> in the U.S.A.

→ OUR PRIMARY OBJECTIVE IN 2011 was to successfully complete the development as well as EU and U.S. regulatory submissions of our second-generation bloodbased test, Epi proColon<sup>®</sup> 2.0, the first world-wide patient friendly blood test for the early detection of colorectal cancer. Colorectal cancer remains one of the most frequent and unnecessary causes of cancer-related deaths if not diagnosed early.

→ IN EARLY 2011, our development team made significant improvements to our first version Epi proColon® assay by reducing the number of technical components and handling steps, thereby making it easier to perform the test. We also made the assay automatable on a wide range of commercial automation platforms which over time will make the test accessible to low-, medium- and high-volume laboratories across the world. Furthermore, Epi proColon® 2.0 now can be optimized to either high cancer detection rate (high sensitivity) or low false positive rate (high specificity) which makes it possible to adapt the test to individual preferences in the different national healthcare systems. Importantly, the Epi proColon® 2.0 assay consistently showed marked improvement in detecting methylated Septin9 in patient samples based on several case-controlled studies.

➤ EPIGENOMICS COMPLETED A CLINICAL VALIDATION STUDY in Europe and a separate study in the United States for this second-generation test. The results of the European study, which were based on retrospectively collected patient samples (blood samples taken from patients diagnosed with colorectal cancer by colonos-copy), demonstrated a very significant improvement over the performance of the Company's first-generation product. The test accurately identified 95% of the cancer cases in the study with a 15% false positive rate when optimized for cancer detection rate and found 81% of the cancer cases with only 99% false positive rate when optimized for specificity. The Company presented the results at the United European Gastroenterology Week in Stockholm in October 2011 and based on the very positive clinical results we launched our second-generation product Epi proColon® 2.0 in the high specificity setting as a CE marked product in Europe.

The successfully completed validation study in Europe enabled the start of a prospectively designed clinical validation study in the United States which was performed as part of the required data package to seek U.S. Food and Drug Administration (FDA) regulatory approval of the product. The testing was conducted at three external laboratories that analyzed a subset of blood samples from approximately 8,000 subjects who underwent a blood draw prior to undergoing colonoscopy. In a prospective setting blood samples are taken prior to colonoscopy from patients participating in a screening program and therefore it is expected to see a lower point estimate of sensitivity when comparing to case control studies. In December, we announced the results of the study showing that Epi proColon<sup>®</sup> 2.0 detected 68% of the colorectal cancer cases (sensitivity) while correctly identifying 80% of study subjects free of disease (specificity).

The Company was fortunate to meet with FDA shortly after our announcement to discuss the potential path forward for Epi proColon<sup>®</sup>. We were encouraged that the FDA confirmed that the data from our U.S. clinical validation study could be assessed as part of a modular Premarket Approval (PMA) review process. Nonetheless, in addition to the clinical validation study data, Epigenomics was requested to perform a head-to-head comparative study for colorectal cancer detection through comparison with fecal immunochemical testing (FIT) for the purpose of demonstrating non-inferiority of Epi proColon<sup>®</sup> to FIT.



Geert W. Nygaard, Chief Executive Officer

This study will become an integral part of the PMA submission to the FDA and is anticipated to be completed in 2012. We submitted the first module of our PMA submission at the end of last year. Additional modules will be submitted in the first and second quarter of 2012 while the final module will be included for submission in the second half of 2012 and will include the entire clinical package.

Although we remain committed to making Epi proColon® 2.0 commercially available as an FDA-approved in vitro diagnostic (IVD) kit in the U.S.A., our partners, Quest Diagnostics and ARUP Laboratories, continue to make their laboratory-developed Septin9 tests (LDT) available. Earlier in 2011, Quest received approval of their test version, ColoVantage™, by the New York State Department of Health. Quest has also demonstrated very encouraging sales volume growth since it started actively promoting its test in Q1/2011. Their emphasis around the launch and the initial traction of ColoVantage™ in our opinion has been validating that Septin9 testing as a blood-based test could play a major role in the early detection of colorectal cancer in the U.S. market. Our second US-based LDT partner ARUP has been marketing their Septin9 LDT since July 2010 and presented the results of a recent clinical study using their version of the assay, Septin9 LDT, at the Association of Molecular Pathology Meeting in November. ARUP's Septin9 LDT assay detected 90% of the colorectal cancer cases at a specificity of 88% which is consistent with the case-controlled clinical validation data we announced with our Epi proColon® 2.0 assay.

→ IN FEBRUARY 2011, Qiagen signed an option agreement to develop and commercialize a colorectal cancer blood test based on our Septin9 biomarker and certain DNA methylation analysis technologies. We now have three potential IVD collaborators including Abbott Molecular and Sysmex for the Japanese market. Given existing contractual arrangements with these partners, we still have the opportunity to offer license rights to develop and commercialize an IVD product based on Septin9 outside of Japan to a fourth and last cooperation partner.

→ ALONGSIDE SOME OF OUR PARTNERS we have performed several surveys during 2011 that highlight the great potential for the broad acceptance of a blood test for colorectal cancer screening. Focusing specifically on the U.S. healthcare environment, a cost effectiveness analysis was presented at the *Digestive Disease Week* conference in May, confirming that Septin9 screening was medically beneficial and cost effective if more people complied with screening recommendations through this method.

→ WE ARE WORKING ON INCREASING AWARENESS OF OUR SECOND TEST, EPI PROLUNG®, throughout the European expert community, particularly in Germany. To this end, Epigenomics is sponsoring investigator-driven studies directed at demonstrating the benefits of Epi proLung® in clinical practice. Results from these studies will be published in 2012.

→ MID 2011, WE IMPLEMENTED SIGNIFICANT RESTRUCTURING MEASURES to allow us to control our expenses more effectively across all operating segments of the business and to be better positioned into 2012 and beyond. Regrettably, we had to make headcount reductions as part of our effort to conserve cash resources. Since product sales generated from Epi proColon® in Europe were lower than expected as a result of slow self-payer adoption, we also readjusted our European commercial strategy in connection with the implementation of the restructuring plan. With less and more focused internal resources, we now target payers and large institutional customers deeply entrenched in the healthcare system as well as distributors in selected European countries. We expect that this will result in the generation of more sustainable revenues in the mid to long term. Furthermore, as result of the restructuring, we have halted most of our research and development activities in areas in which commercial product revenues are only achievable in the long term. Nevertheless, we will keep our broad and attractive portfolio of intellectual property rights in the area of methylation technologies and biomarkers as well as the ability to enter into selected cooperations in the area of personalized medicine.

→ **DESPITE THE DRAMATIC LOSS IN SHARE PRICE** and the challenges faced throughout 2011, we remain committed to realize the value of our products to the benefit of our shareholders in view of the progress achieved so far. We know that 2012 will be a decisive year and we will work hard to secure the necessary resources to allow us pursue our important goals.

→ LOOKING AHEAD, OUR GOAL IS to complete the FIT comparative study and to subsequently file the last module of our PMA-application to the FDA before end of the year. It remains the company's ultimate goal to introduce our test to the largest commercial market for molecular diagnostic products. We will continue to work hard towards establishing our products globally in the market and to support our partners in driving adoption of Septin9-based tests for early detection of colorectal cancer. We at Epigenomics firmly believe that our blood-based test can increase compliance to colorectal cancer screening, which will ultimately help to save lives. The thought of being able to reduce the mortality from cancer is a big motivation in our daily work.

Also in 2012, we look forward to updating you regularly on the results of our efforts and progress of our partners. As we manage to work through the tasks ahead of us, I'm grateful to have the support of our shareholders, employees, customers and collaboration partners.

Yours sincerely,

Geert Walther Nygaard Chief Executive Officer

## REPORT OF THE SUPERVISORY BOARD

#### **DEAR SHAREHOLDERS,**

Throughout 2011, the Supervisory Board was continuously kept informed about the operational progress and the key challenges as well as about the financial situation and the risk management assessments as prepared by the Executive Board of the company. All corporate planning, including financial, capital expenditure and human resources planning, as well as the general performance of the business was reported on a regular basis. To the extent that German corporate law or the existing Rules of Procedure of the Executive Board required approval for certain decisions or actions to be taken by the Executive Board, such approvals were given by the Supervisory Board after detailed examination of the documentation provided and intensive discussions. Mid 2011 wide-ranging restructuring measures were discussed thoroughly and subsequently implemented. Among the important issues discussed regularly, the Premarket Approval (PMA) review process in the United States for the company's key product Epi proColon®, the launch of Epi proColon<sup>®</sup> 2.0 CE in Europe as well as the completion of a prospectively designed clinical validation study in the United States were overarching topics of ongoing discussion.

#### WORK OF THE SUPERVISORY BOARD

As in previous years, the Supervisory Board fulfilled all its duties assigned to it by law, the Articles of Association and the Rules of Procedure in 2011. The Supervisory Board advised and monitored the Executive Board in managing the company. On the basis of detailed written and oral reports of the Executive Board, the Supervisory Board discussed all relevant issues concerning financial and operational business aspects as well as the company's business strategy during its meetings. The Supervisory Board thereby always took into account the interests of Epigenomics' shareholders. In addition to the very close dialogue between all members of the Supervisory and the Executive Boards in joint meetings, multiple conference calls as well as individual discussions were held. During 2011, five ordinary plenary meetings of the Supervisory Board with the company's Executive Board took place on March 30, June 27, June 28, September 27, and November 25. These meetings were all held in Berlin. Important topics of the Supervisory Board meetings in 2011 included all relevant aspects of the PMA review process, the development of Epi proColon<sup>®</sup> 2.0, the implementation of restructuring measures and the decrease of the company's share capital as well as the approval of the annual financial statements, the execution of the non-exclusive licensing strategy, the company's business development issues as far as approvals for terms and conditions of new collaboration contracts were required and several strategic opportunities presented to the company. Thus, the Supervisory Board was kept up to date on the company's current business



Professor Dr. Dr. h. c. Rolf Krebs, Chairman of the Supervisory Board

situation and key events. At its meeting on November 25, 2011, the Supervisory Board considered in detail the operational budgets, financial planning and human resource allocation plan for the fiscal year 2012.

For each Supervisory Board meeting, all members of the Supervisory Board received extensive written reports well in advance of the individual meetings, prepared by the Executive Board with the input of the respective senior managers of all functional areas. These documents were sufficiently detailed and comprehensive to analyze and discuss all relevant topics of the respective agenda of the Supervisory Board meetings and to pass all required resolutions. Written minutes of these meetings were prepared. Between meetings, the Supervisory Board was informed in detail by means of written and oral reports about all ongoing projects and plans of particular importance to the company. Whenever necessary, resolutions were also passed by written vote in accordance with the company's Articles of Association.

#### COMMITTEES

The work of the Supervisory Board was continuously supported by its two committees: the Audit and Corporate Governance Committee chaired by Prof. Dr. Günther Reiter as well as the Personnel and Compensation Committee chaired by Prof. Dr. Dr. h. c. Rolf Krebs. Both committees held several meetings or telephone conferences in 2011. The Audit and Corporate Governance Committee convened together with representatives of the company and its auditors four times in 2011 and dealt with the quarterly as well as the annual financial statements. Furthermore the committee dealt with important accounting issues and other topics within the scope of responsibility of the committee. The Audit and Corporate Governance Committee further advised and monitored the Executive Board in all aspects relating to the company's risk management and ensured compliance with the German Corporate Governance Code with the purpose to continuously build and reinforce trust of the shareholders in the management of the company.

The Personnel and Compensation Committee held several meetings and conference calls in 2011 in order to discuss matters related to the compensation of the Executive Board as well as strategic personnel issues. In addition, the committee also dealt with the question of possible candidates for the Supervisory Board in light of the upcoming re-election of its members at the Annual General Meeting in 2012. Reports of the meetings of the committees were presented at the plenary sessions of the Supervisory Board.

#### **CORPORATE GOVERNANCE**

The Supervisory Board and the Audit and Corporate Governance Committee continuously reviewed all issues of legal compliance. Due to the continued challenging global economic environment and the increasingly tight financial situation of the company, these bodies also dealt intensively with the adequacy of the risk management system. Executive and the Supervisory Boards regard the commitment to good corporate governance as exceedingly important to strengthen the confidence of current and future shareholders, corporate partners and employees in the company. In December 2011, the Executive Board and the Supervisory Board issued a new Declaration of Compliance with the German Corporate Governance Code pursuant to Section 161 of the German Stock Corporation Act (AktG), which is included in this annual report and is also permanently available on Epigenomics' website. In its declaration, the company has committed itself to adherence to the German Corporate Governance Code, and only deviates in explicitly mentioned, company-specific cases from its recommendations.

#### **AUDIT OF THE ANNUAL FINANCIAL STATEMENTS**

The independent auditing company UHY Deutschland AG Wirtschaftsprüfungsgesellschaft, Berlin (UHY), has audited the annual financial statements and the related management report of Epigenomics AG for fiscal 2011 in compliance with the principles of the German Commercial Code (HGB) as well as the consolidated financial statements and the consolidated management report for fiscal 2011 according to International Financial Reporting Standards (IFRSs). UHY did not raise any objections for either of the financial statements and approved them with unqualified audit opinions. However, UHY highlighted that the Group is dependent on the supply of additional financial resources no later than Q2/2013, since according to the current plans and financial prognosis the cash consumption for the next 24 months exceeds existing liquid assets of EUR 14.0 million as of December 31, 2011. The consolidated financial statements and the consolidated management report were prepared in accordance with Section 315a HGB using international accounting standards IFRSs. UHY's audit was conducted in accordance with German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer in Deutschland e. V. (IDW, Institute of Public Auditors in Germany). The above-mentioned documents were submitted to the Supervisory Board by the Executive Board in a timely manner.

The Audit and Corporate Governance Committee discussed these documents in detail. The UHY audit reports were presented to all members of the Supervisory Board and were discussed in depth at the plenary meeting on March 16, 2012, in the presence of the external auditor, who reported on the main findings of its audit. At this meeting, the Executive Board explained the annual financial statements 2011 and consolidated financial statements 2011 as well as the company's risk management system. UHY also provided a report on the scope and focal points of the audit. As a result of the findings and examination by the Audit and Corporate Governance Committee and the entire Supervisory Board, the Supervisory Board raised no objections, but accepted and confirmed the results of the audit. In its meeting on March 16, 2012, the Supervisory Board in the presence of the external auditor formally approved the annual financial statements and the consolidated financial statements as of December 31, 2011 without exception and modification. By the Supervisory Board's approval, the annual financial statements 2011 of Epigenomics AG are thus adopted as submitted in accordance with Section 172 AktG.

With respect to the existing internal control and risk management systems as the company's early warning system, the auditor stated to the Supervisory Board that in its opinion this system is suitable to meet all legally intended requirements. Both the Audit and Corporate Governance Committee and the entire Supervisory Board ensured that appropriate risk management measures were implemented during 2011.

The Supervisory Board would like to thank the Executive Board, the senior management as well as all employees for their efforts, commitment and dedication throughout the challenging year 2011.

Berlin, March 2012

For the Supervisory Board

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

# OUR STOCK

DISAPPOINTING SHARE PRICE DEVELOPMENT AMID A CHALLENGING CAPITAL MARKET ENVIRONMENT

#### **SHARE PRICE DEVELOPMENT IN 2011**

Epigenomics experienced a significant decrease of about 87% in its stock price during the course of 2011 compared to the Xetra closing price of 2010. At year-end 2011, our stock closed at a low for the year of EUR 1.30 (Xetra). Especially the share capital reduction and reverse share split decided upon during our AGM on June 28, 2011, and the publication of the data from the clinical validation study necessary for the U.S. approval of our product had a negative impact on the share price. Epigenomics' share price declined by 28% between June 28, 2011, and the implementation of the reduction of the share capital on August 8, 2011. In the period between the publication of the clinical validation data on December 9, 2011, and year-end the share price fell sharply by 67%.

With ongoing significant volatility, trading volumes in Epigenomics' stock (Ticker symbol: ECX) decreased from almost 18,900 shares per day on average on Xetra in the first quarter of 2011 to just around 13,600 shares per day on Xetra in the fourth quarter of 2011. Due to the 5:1 reverse split in August 2011, the share capital in 2011 decreased from EUR 44,092,085.00 to now EUR 8,818,417.00. As of December 31, 2011, a total number of 8,818,417 shares were issued. The following major shareholder groups () on page 11) controlled more than 3% each of Epigenomics' total shares outstanding.

#### **UNCHANGED INVESTOR INTEREST**

Three analysts, Edison's Jacob Plieth (from June, 2011), equinet's Edouard Aubery, and independent analyst Thomas Schiessle (via Vara Research) covered Epigenomics' stock during 2011 providing updates on their views and recommendations. Due to the development of the Company in 2011, some analysts adjusted their ratings during the year. These currently stand at "buy" and "hold" recommendations for our shares. The published price targets are significantly above year-end trading prices of the share. During this year, the main interest in Epigenomics from investors in Germany and abroad laid on our colorectal cancer screening test, Epi proColon<sup>®</sup>, which now represents the main focus of our internal efforts after the restructuring of our business activities in summer 2011. The approval process at the U.S. Food and Drug Administration (FDA) and the launch of the second generation of the product remained the main objectives.

#### TRANSPARENT DIALOGUE WITH SHAREHOLDERS

We are committed to maintain an ongoing and active dialogue with the investment community and always remained available to answer questions about Epigenomics and its products.

In order to also provide timely, accurate and comprehensive information to our shareholders in 2011 and to give them the best possible information for making informed investment decisions in Epigenomics' stock, additionally conference calls took place on important Company updates in which investors could participate.

In addition, we invited to an annual press conference and an analyst meeting on April 7, 2011, in Frankfurt am Main, as well as to our Annual General Shareholders' Meeting in Berlin on June 28, 2011. At the Annual General Shareholders' Meeting, all proposals of the Company were agreed with vast majorities with a representation of approximately 50.8% of the share capital present or represented. Throughout the year, we also presented at several investor meetings and published updates on our clinical data at major scientific conferences in the United States and in Europe. Furthermore, we continued to provide opportunities for close dialogue with shareholders and interested investors at numerous road show meetings in Germany, Austria, the Benelux, Switzerland, France as well as in the United Kingdom and the United States.





🛢 Epigenomics AG 🔹 Prime Pharma Performance Index 🔳 Prime Biotech Performance Index 🔳 TecDax Performance Index

Voting rights threshold
> 15%
> 5%
> 3%

\* (total held, controlled or advised)

Key data on Epigenomics' stock

ISIN	DE000A1K0516
Security code number	A1K051
Security code number	AIROJI
Stock exchange abbreviation	ECX
Reuters	ECXG.DE
Stock exchange	Frankfurt Stock Exchange
	Regulated Market (Prime Standard)
1 <sup>st</sup> day of trading	July 19, 2004
Designated Sponsor	ICF Kursmakler AG Wertpapierhandelsbank
	equinet AG
Number of shares (Dec 30, 2011)	8,818,417
Free float (Dec 30, 2011)	75.30%
Market capitalization (Dec 30, 2011)	EUR 11,463,942
Year-end closing price	EUR 1.30
Highest price in 2011	EUR 9.95
Lowest price in 2011	EUR 1.30

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## CONSOLIDATED MANAGEMENT REPORT

## ECONOMIC ENVIRONMENT 2011 AND OUTLOOK 2012

2011 was characterized by a growing uncertainty in the global economic environment, mainly driven by the sovereign debt crisis of certain European countries and its effects on the stability of the European currency. The discussions about possible defaults in sovereign debt by Greece and other European countries have left investors very nervous and have led to a major shift in asset allocation into perceived lower-risk asset classes.

Stock markets have been very volatile throughout 2011, showing a significant downturn in the third quarter and a gradual improvement thereafter, moving towards levels comparable to the beginning of the year. While major European equity markets yielded net losses in the range of 10% to 20% in 2011, the U.S. stock markets remained mainly flat throughout 2011. A series of downgrades of credit ratings even for high-credit-score debtors has led to a growing nervousness in the market which was manifested by investors seeking high-liquidity short-term investments. This difficult investment climate has been challenging for our stock as well.

The exchange rate between the euro and the U.S. dollar started at the beginning of 2011 with a rate of EUR/USD 1.34, peaked at a high of EUR/USD 1.48 in Q2 at the time of the U.S. government potentially not being able to secure its budget and closed at year-end below EUR/USD 1.30 amid the uncertainty about the future of the common European currency. Forecasts for 2012 are quite diverse and tend towards an ongoing high volatility without visibility of a clear trend.

While the economic outlook for Germany and some emerging countries remains cautiously optimistic, certain other countries are facing significant challenges with respect to economic growth estimates in 2012. This will pose some challenges to the capital markets and it is expected that volatility will remain high next year.

Access to the capital markets to strengthen our financial position going forward remains of paramount importance to Epigenomics and is a critical success factor for our Company as long as we are not able to sustain the Company on the basis of profits generated by own product sales. The above mentioned factors like market uncertainty and risk averseness by investors for low-liquidity stocks also have the potential to harm the Company by means of inability to secure a stable and committed shareholder base.

Traditionally, the healthcare and life sciences industry has been viewed by investors as a "defensive sector" with less dependency on strong ups and downs of the economic development as demand for its goods and services is typically not dependent of the prevailing economic environment. However, there are increasing signs among major companies in the field that growing economic pressure is excreted by payers on overall healthcare spending, taking influence on the earnings situation among these companies.

More importantly, there are going to be implications on healthcare in general and diagnostics in particular under the U.S. healthcare reform. Over time, it is likely that the high profitability of healthcare businesses cannot be maintained and pricing will come under increasing pressure in the globally largest single healthcare market. Our industry should also be able to benefit from an increased focus on prevention and early detection of disease in several important markets. Colorectal cancer (CRC) screening continues to be high on many healthcare systems' agendas as an area of attention and future growth.

The molecular diagnostics segment of the life sciences industry continues to be one of the most attractive and soughtafter investment opportunities in spite of the increasing cost pressure on companies in the field. An accelerating trend in M&A activity has led to a heightened interest in this sector throughout of 2011. Growth rates in the molecular diagnostics industry are substantially higher than in the diagnostics industry overall. The application area of oncology, in which we predominantly operate, is expected to be a major contributor to future growth of the molecular diagnostics space. With 300 million people in North America, Europe, and Japan over the age of 50 being potentially eligible for a CRC blood test, that market opportunity alone is in excess of USD 3 billion p.a. to the diagnostics industry. About 320 thousand new cases of CRC per year in the EU and about 143 thousand new CRC cases in the United States every year are diagnosed and still more than 60% of all CRC being detected at symptomatic stages when survival rates are much lower than in early stages. Thus, the overall market potential for a test like Epi proColon<sup>®</sup> remains unchanged.

In the chapters "Opportunities and Risks" and "Prognosis Report" of this management report, reference is made to the individual implications that the global situation could have on our business and our Group if applicable.

### BUSINESS ACTIVITIES, STRATEGY AND ORGANIZATION

#### **GROUP STRUCTURE AND BUSINESS ACTIVITIES**

Epigenomics AG is headquartered in Berlin, Germany, and operates a wholly owned subsidiary, Epigenomics, Inc. in Seattle, WA, U.S.A.

We are a molecular diagnostics company developing and commercializing a pipeline of proprietary products for the screening and diagnosis of cancer based on DNA methylation detection. All of our late-stage research and development (R&D) activities as well as our commercialization and business development efforts are geared towards fulfilling this mission. With our lead product Epi proColon® for the early detection of colorectal cancer, which has been re-launched as a secondgeneration product outside the United States in 2011, we are now well underway to fulfill this commitment. Septin9-based blood tests for CRC detection are also available through some of our partners like Abbott Molecular Diagnostics, Inc. ("Abbott"), Quest Diagnostics, Inc. ("Quest"), ARUP Laboratories, Inc. ("ARUP") and Warnex, Inc. ("Warnex") on the basis of licenses granted to these partners by Epigenomics. Following a dual-business model, we develop and commercialize cancer diagnostic tests in colorectal cancer and in lung cancer; both via direct marketing and sales efforts of in vitro diagnostic (IVD) kits and through non-exclusive licensing partnerships for the biomarkers constituting the basis for these products. In this model, we are directly addressing certain market segments through our own products, while other markets are or will be served by our partners through the licenses granted to them. All our cancer molecular diagnostic products target substantial market opportunities and address significant unmet medical needs with a view to providing patients and physicians with benefits from more convenient and superior diagnostic tests.

#### **CORPORATE GOALS, STRATEGY AND MANAGEMENT**

We take a very focused and goal-oriented approach to managing and monitoring progress when executing our strategy. Every year, the Supervisory Board and the Executive Board of the Company define milestones and deliverables in terms of revenue, operating results, partnering and dealmaking targets as well as product development and clinical studies against which performance of the Company and its employees is measured.

For 2011, the most important corporate goal was to progress development of our key value driver Epi proColon®, the leading blood-based test for CRC detection. As planned, we advanced significantly in the development of the secondgeneration product in spite of major challenges along the way. Our development team could demonstrate high performance of this test in a prototype, develop it as a commercial product in Europe and initiate the Premarket Approval (PMA) submission for the product to the U.S. Food and Drug Administration (FDA). Clinical data published at major conferences by us and our partners and ultimately the results of a large prospective study completed in December highlighted the unique clinical and biological potential of methylated Septin9 as biomarker for CRC detection. Hereby, we were able to detect up to 95% of cancer cases in several case-control studies and 68% in a challenging cohort of a prospective study. Taken together, we feel that such performance in blood-based CRC detection represents a robust foundation for the development of a successful commercial product.

While we also had high expectations for the commercial deployment of Epi proColon<sup>®</sup> in Europe, it became apparent to us in 2011 that in the absence of reimbursement established in our home markets, direct commercialization of the product to private payers was an effort we underestimated. Therefore, revenue goals from product sales were not met. This situation was aggravated even more by the later implementation of our restructuring measures, by which we significantly reduced our marketing and sales efforts in Germany. Nevertheless, the introduction of the second-generation product and a more targeted commercialization approach towards key stakeholders in the healthcare system in Europe gives us an opportunity to realize the significant revenue potential here.

Throughout the year, we remained focused on attracting additional business partners to Epigenomics. In February 2011, we were fortunate to attract Qiagen GmbH ("Qiagen") to acquire an option to one of the remaining IVD product licenses available from us.

We have repeatedly demonstrated our ability to operate under highest regulatory standards, successfully undergoing audits of our ISO-certified quality management system covering requirements for IVD development, manufacturing and commercialization for both our sites, including individual requirements for the Canadian market.

Finally, we also keep providing high-value-added biomarker research services and solutions to customers in the pharmaceutical and life sciences industry and retained this ability to a certain extent in spite of ceasing most of our research operations in the course of the implemented restructuring. We remain convinced that these efforts in the area of personalized medicine and our deep understanding of the field will set us apart from our competitors and establish us as one of the leaders in this emerging area of our industry.

We clearly focused our strategy on the key value driver of the Company and through the implemented restructuring, we created a more efficient operation by ceasing activities in non-core areas.

#### **OVERVIEW OF OUR BUSINESS IN 2011**

During 2011, we continued to follow the strategy on further establishing our Company as a marketing and sales operation as well as to increase the public perception of Epigenomics as a commercially-driven cancer molecular diagnostics company. Furthermore, we were focused on driving market acceptance and sales of our Epi proColon<sup>®</sup> test for the early CRC detection and for our partners' Septin9-targeted CRC tests.

At the beginning of the year, we took a major step to broaden the availability of our CRC blood-based test targeted on the Septin9 marker to the important U.S. market. We completed the pre-development phase of our improved second-generation test and began the development and verification phase of the Epi proColon<sup>®</sup> 2.0 product, which was developed simultaneously for the specific requirements of the U.S. market and as a second-generation product for the European market and other markets.

In February 2011, we announced the signing of a collaboration agreement for the development of an IVD test for CRC with Qiagen, adding to the existing IVD licenses with Abbott and an option agreement with Japan's Sysmex Corporation ("Sysmex"). Under the terms of the agreement, Qiagen received an option on a worldwide non-exclusive commercial license to our technology for the development of an IVD test for the detection of methylated Septin9 in blood. Qiagen can exercise the option within a period of two years. Furthermore, we have granted Qiagen a research license to the Septin9 biomarker and related technologies.

Throughout 2011, we also continued to work intensively with our partners in assisting them with commercialization efforts for their own Septin9-based CRC tests. In particular, our partner Quest continues to see substantial uptake of its laboratory-developed Septin9 test ColoVantage<sup>™</sup>. In March 2011, Quest received approval for ColoVantage<sup>™</sup> by the New York State's Department of Health. The New York State is the only state in the United States where laboratorydeveloped tests require explicit approval for patient testing. With this approval, ColoVantage<sup>™</sup> is now available in the entire United States. Starting in Q1 2011 with virtually no sales, Quest meanwhile has reached a situation of highvolume growth, currently performing thousands of tests per month based on our license. Effective March 31, 2011, Epigenomics' co-founder Oliver Schacht Ph.D., until this day Chief Financial Officer of Epigenomics AG and Chief Executive Officer of Epigenomics, Inc., resigned from his Executive Board position and left the Company to pursue other career opportunities. Dr. Thomas Taapken succeeded Oliver Schacht Ph.D. on the Company's Executive Board as Chief Financial Officer effective April 1, 2011.

Furthermore, we engaged in preparations to strengthen our commercial presence in the United States. In May 2011, we hired Mr. Noel Doheny as new CEO of our U.S. subsidiary Epigenomics, Inc. Mr. Doheny brings more than 30 years of experience in the field of diagnostics to the Company. His main goal is the development and implementation of the commercial strategy as well as the preparation of a successful launch of Epi proColon<sup>®</sup> 2.0 after potential approval by the FDA.

The third quarter of 2011 was a turbulent time for our Company. The incidence of a new worldwide crisis on the capital markets sent stock prices across the board to the lowest levels for more than two years and also had a severe impact on Epigenomics' share price. Furthermore, our announcement of a restructuring plan in connection with the publication of mid-year results in August and the implementation of the previously announced reverse stock split aggravated this negative trend.

As product sales in the European self-payer segment were ramping up slower than expected, we adapted our marketing and sales strategy in Europe to a key account approach. Directly and increasingly through distributors, we are now mainly targeting payers and large institutional customers (e.g. health maintenance organizations) with deep reach into the healthcare system in selected markets in Europe and beyond.

In this context, we also decided that our R&D efforts will be shifted towards existing and near-term product opportunities, while putting longer-term opportunities on hold for the time being. The restructuring measures have further sharpened the focus of the organization. The restructuring led to a reduction in our total workforce from 84 employees at the end of the first half of 2011 to approximately 45 employees by the end of Q1/2012. We implemented the aforementioned commercialization approach of targeting key accounts for Epi proColon<sup>®</sup> and Epi proLung<sup>®</sup> and furthermore scaled down our direct marketing and sales efforts in the European self-payer segment, discontinued all early-stage research projects and technology research activities and announced the planned relocation of our U.S. headquarters from Seattle, WA, to the U.S. East Coast from 2012 onwards. One-time restructuring costs added up to EUR 2.9 million. Thus, we expect to realize annual savings on a comparable operational cost basis of approximately EUR 3.5 million to EUR 4.0 million from 2012 onwards.

In September 2011, we released encouraging data from a clinical validation study for this second-generation CRC test (Epi proColon<sup>®</sup> 2.0), confirming if not surpassing the performance observed in the prototype data published earlier in the year. In a cohort of 247 patients, the test accurately identified 95% of the cancer cases (i.e. 95% sensitivity) at a specificity of 85%. Most importantly, for stage I and II cancers, for which therapeutic interventions have the greatest likelihood of curing the patient from the disease, the combined sensitivity was 91%. These results demonstrate a very significant improvement over the performance of the first-generation Epi proColon<sup>®</sup> test. This study provided the clinical evidence as required for a CE-marking of Epi proColon<sup>®</sup> 2.0 as subsequently launched in the European market.

The new test version, optimized for maximum specificity for CRC, demonstrates an accuracy of detecting CRC that is unmatched by any other non-invasive method of CRC detection. In particular, the positive predictive value (PPV) of the test - a commonly used measure for the likelihood of actually having cancer when a test is positive - was found to be 45% in a large study evaluating its performance when compared to the PPV of only 10% reported for the most widely used stool tests for CRC screening. To specifically meet market requirements in many European countries, the new product minimizes the number of false positive results while maintaining excellent sensitivity in CRC detection. Thus, Epi proColon® 2.0 - configured as highly specific test - detects more than 80% of all CRCs at 99% specificity. With this high level of performance, the new test provides a reliable and convenient alternative to conventional methods of CRC screening such as stool tests.

Also in September 2011, we started our second validation study as required for a submission of the test to the FDA. This pivotal clinical trial was conducted at three external laboratories, which tested blood samples from a subset of a prospectively collected cohort of 7,940 study subjects. The study was designed to measure the clinical performance of Epi proColon<sup>®</sup> for CRC detection in comparison to colonoscopy and was completed at the beginning of December 2011. In this setting, Epi proColon<sup>®</sup> detected 68% of the CRC cases (sensitivity) while correctly identifying 80% of the patients free of disease (specificity). While the results of the study represent the lower end of the expected performance data, the findings of the study confirm the results obtained in a previously conducted clinical study with our first-generation test in the same cohort of patients.

After consultation with the FDA, we confirmed that the clinical data would be assessed as part of the regular PMA review process. We began the regulatory process with the FDA by submitting the first module of its PMA in late December, as originally expected.

On the financial side, we clearly missed our revenue targets in 2011, ending the year with revenue of EUR 1.4 million. Especially product sales in our home markets (Germany, Austria, and Switzerland) couldn't fulfill our expectations. Like in the years before, we kept our operating costs under control but the lack of revenue led to a widening of our net loss to EUR 15.6 million in fiscal 2011, whereby an amount of EUR 5.5 million was attributable to the restructuring and the amortization of the goodwill (thereof EUR 4.6 million non-cash effect).

The aforementioned restructuring also was a response to this negative trend observed which led to a reduction of our liquidity faster than originally expected. We recorded restructuring costs of EUR 2.9 million to establish new structures which should sustainably help us to reduce our cash consumption in the following years. At year-end 2011, our financial position including marketable securities showed a total liquidity amounting to EUR 14.0 million, which should take us well into 2013.

As approved by the Annual General Shareholders' Meeting (AGM) in June 2011, a 5:1 reverse split of our share capital has been implemented in August 2011. Five old Epigenomics shares were replaced by one new Epigenomics share. Therefore, our share capital was reduced from the previous total of EUR 44.1 million to now EUR 8.8 million, allocated to 8,818,417 shares outstanding.

We experienced a significant and in our view unfortunate decrease of about 87% in our stock price during the course of 2011. At year-end 2011, our stock closed at a low for the year of EUR 1.30 (Xetra). Between June 28, 2011, and the implementation of the reduction of the share capital on August 8, 2011, Epigenomics' share price declined by 28%. In the period between the publication of the clinical validation data on December 9, 2011, and year-end, the share price fell sharply by a further 67%.

## COMMERCIALIZATION AND BUSINESS DEVELOPMENT

In mid 2011, after a thorough analysis of our business and strategic situation, we took the decision to focus the organization and its commercial activities to the key market for our product, the United States. This led to a significant reduction in headcount and costs for marketing and sales activities in Europe. At the same time, we initiated our efforts to build the commercial expertise in the U.S. market by hiring a CEO to our U.S. subsidiary who brought a significant level of commercial execution expertise into the organization.

In the absence of regulatory approval to sell our product in the United States, we have granted a number of licenses to certified laboratories in North America in order to enable them to offer their own laboratory-developed tests (LDTs) targeted on Septin9 as a service and an aid in the diagnosis of CRC. These partners include ARUP and Quest in the U.S.A. and Warnex in Canada.

Especially our partner Quest has invested considerably into the training of their sales and laboratory personnel, which led to a remarkable step-up of services rendered by them from the second quarter of 2011 onwards. Until the end of 2011, a total of more than 26,000 tests to patients have been performed throughout the United States. While right now, we are only entitled to a moderate royalty on their product sales, we expect our LDT partners needing to purchase regulated IVD test kits once the test is approved by the FDA and commercially available in the United States.

Apart from Quest, our partner ARUP is commercially offering the testing service to its customers. Albeit the number of tests performed is lower than Quest's, ARUP has proven to be an excellent partner in helping us to gain the reputation in the U.S. market which will be needed to commercially succeed. Highly successful studies showing the potential of bloodbased Septin9 testing have been carried out and published by them.

Our business development efforts in the United States are currently focused towards securing additional LDT partners for Septin9. Such partners are all expected to become future customers once and if Epi proColon<sup>®</sup> is approved by the FDA. Furthermore, in 2011, we took an additional remarkable step in executing our commercial strategy by entering into an option agreement for a global commercialization license to Septin9 with Qiagen. For a period of up to two years, Qiagen has the right to implement the test on their proprietary instrumentation platform with the goal of developing its own version of the test. If technically successful, Qiagen has the right to exercise its option by making a one-time payment and thus getting the right to sell its own product. It is our goal to commercialize Septin9 testing as Epigenomics directly as well as together with up to three non-exclusive IVD partners (including Abbott and potentially Qiagen and Sysmex) in the medium term.

After a disappointing development of product sales for our first-generation test since its introduction to the market in Europe, we took drastic measures in 2011 to reduce our cost basis in the marketing and sales area and implemented a new commercialization strategy. Furthermore, we expect that the introduction of our second-generation product, Epi proColon<sup>®</sup> 2.0, will also lead to an increased market acceptance on the basis of better performance, more convenience for the testing laboratory and a lowered price to the end-customer.

As part of the restructuring measures, our commercialization focus shifted from addressing generalists and end-customers to a more targeted key account approach, aimed at key players in the healthcare system and payers. We have a small and very skilled team of individuals, which are perceived as competent and professional experts in the dialogs we have with our various current and prospective business partners.

A significant number of laboratories have meanwhile been educated and trained on the use of the Epi proColon<sup>®</sup> test throughout Europe and are now in the process of being re-qualified to use the second generation of our test.

In addition, our commercial team has supported our IVD licensing partners like Abbott, Qiagen or Sysmex as well as our North American LDT partners like Quest, ARUP and Warnex with the goal to ensure a coherent positioning and branding of their respective blood-based CRC tests targeted on the methylated Septin9 biomarker.

### RESEARCH AND DEVELOPMENT (R&D)

In spite of the major restructuring of our operations in the summer of 2011 which severely affected our R&D team, our development and manufacturing team has made significant progress in advancing our key products in their development and has provided assistance in the commercial establishment of the products.

#### **COLORECTAL CANCER (SEPTIN9)**

In 2011, we completed the development of our secondgeneration CRC product, Epi proColon<sup>®</sup> 2.0, transferred manufacturing to a well-established contract manufacturing organization in the United States, validated the product in a pivotal trial in three independent U.S. laboratories and submitted the first module of our PMA submission to the FDA. In addition, Epi proColon<sup>®</sup> 2.0 was validated for the European market and launched as a CE-marked product shortly after year-end.

The development of the Epi proColon® 2.0 prototype assay was successfully completed in early 2011. The clinical performance of the second-generation prototype clearly outperformed the clinical sensitivity of the first-generation product in a final case-control study in March. Following a positive management review board decision, the project was moved under design control and verification/validation as well as design transfer activities were started. The design was finally validated in a pivotal trial in the fall of 2011 using our tissue samples from the prospective PRESEPT study conducted in 2008 and 2009. Those samples were collected from an average-risk asymptomatic population eligible for screening. Testing was done at three external laboratories in the United States using validation lots manufactured by our contract manufacturing organization under current Good Manufacturing Practice (cGMP). The product demonstrated very robust and reproducible performance and top-line results of this study were published early December.

While the pivotal trial was ongoing, the first PMA submission module was prepared, reviewed and approved and finally submitted to the FDA at the end of reporting year. This work was supported by two regulatory consultant agencies in the United States.

The Epi proColon<sup>®</sup> 2.0 product – primarily developed for the U.S. market – was simultaneously adapted to the specific requirements of the European market and the corresponding validation studies were conducted. Key requirements were

the adaptation to the Roche LightCycler 480 and the validation of Sarstedt CPDA blood collection tubes allowing room temperature storage of blood for up to 72 hours which will enable to ship blood even from remote locations to test laboratories.

In addition to the achievements above, we continued to adapt the second-generation product on Stratec's InviGenius robot and thus will be able to provide an automated solution in the near future.

#### LUNG CANCER

We continue working towards establishing our second product, Epi proLung<sup>®</sup>, in the market as an aid in the diagnosis of lung cancer. To this end, we have sponsored investigatordriven studies in 2011 directed at demonstrating the benefits of Epi proLung<sup>®</sup> in clinical practice. These studies are a key prerequisite for generating meaningful revenue from this product in the years to come.

#### **PROSTATE CANCER**

As part of a company-wide restructuring program around mid 2011, our prostate cancer molecular diagnostic tests targeted on PITX2 (a tissue-based prognostic test following radical prostatectomy) and GSTP1 (a biopsy- or urine-based assay to help diagnosing prostate cancer) have been put on hold.

Earlier already, we have successfully out-licensed our GSTP1 biomarker and DNA methylation technologies non-exclusively for U.S. LDT rights to Quest and Predictive Biosciences, Inc. ("Predictive"). We continue to look for additional commercial partners for our prostate cancer programs.

## QUALITY MANAGEMENT

We have a well-established comprehensive guality management system for the design, development, manufacturing and distribution of IVD products, compliant with the requirements of 21 CFR 820 and ISO 13485. The 21 Code of Federal Regulations (CFR) 820, Quality System Regulation, covers the U.S. American current good manufacturing practice requirements for medical device manufacturers. ISO 13485 is an internationally recognized guality management standard developed for medical devices by the International Organization for Standardization (ISO), a worldwide federation of national standards bodies. 21 CFR 820 and ISO 13485 specify requirements for a quality management system, which demonstrates the organization's ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. The implementation of a quality management system compliant to 21 CFR 820 and ISO 13485 demonstrates our commitment to develop safe and effective diagnostic products.

In 2011, we have successfully undergone surveillance audits for our ISO 13485 and ISO 13485 CMDCAS (Canadian Medical Devices Conformity Assessment System) certification of our quality management system for the design, development, manufacture and distribution of IVD products at both our headquarters in Berlin and our subsidiary in Seattle.

This demonstrates the continued commitment to and the use of a quality management system that conforms to the international quality management standards for medical devices including IVD products such as our tests for colorectal and lung cancer.

The quality management function in the Company is headed by a designated quality manager reporting directly to the CEO. We have continued to build a quality management system that is a solid foundation for regulatory approval of our products on a global basis.

## FINANCIALS

#### **RESULTS OF OPERATIONS**

In 2011, total revenue decreased by 19.6% from EUR 1.8 million in the previous year to EUR 1.4 million. Revenue was generated from product sales of our Epi proColon<sup>®</sup> kits as well as from continued and newly signed collaborations and licensing agreements in the form of R&D payments, licensing fees and royalty income.

After a product revenue growth below expectations in the first half of 2011, we announced a comprehensive restructuring of the organization including a shift to a key account approach on the European market. Therefore, product revenue for the second half of 2011 was influenced by these measures and we could not catch up with previous year's numbers. Despite increasing income from licensing partners (e.g. Quest Diagnostics), total royalty income dropped as well due to one-off effects in 2010 without corresponding events in the reporting year.

Cost of sales decreased from EUR 0.5 million to EUR 0.4 million. Gross profit amounted to EUR 1.1 million, a decrease of 17.7% compared to EUR 1.3 million in 2010 while our gross margin slightly improved from 73% in 2010 to now 75%.

Other income decreased to EUR 0.4 million in 2011 from EUR 1.0 million in the year before. The decrease is mainly attributable to less income from third-party research grants and lower income from the reversal of provisions compared to 2010. Additionally, foreign currency exchange gains were somewhat smaller.

In 2011, research and development costs ("R&D") decreased significantly from EUR 7.2 million in 2010 to EUR 4.9 million, whereby this decrease can completely be explained by the capitalization of our development activities in the amount of EUR 2.8 million (2010: EUR 0.4 million). The included sharp increase in the expenses for materials and consumables was attributable to the massive use of tissue samples for our studies. As large parts of these samples have been collected already in previous reporting periods, there was no related cash outflow in 2011 for those costs. Personnel costs included in R&D costs were down to EUR 3.2 million in 2011 from EUR 3.8 million in the year before – signalizing the reduction in our headcount over the reporting year.

Selling, general and administrative costs (SG&A costs) increased from EUR 5.8 million in 2010 to EUR 5.9 million in 2011 as a result of our marketing, sales and supporting activities for our Epi proColon<sup>®</sup> test on the one hand as well as some initial U.S. market preparation activities in this connection on the other.

Other expenses increased from EUR 0.8 million in 2010 to EUR 5.9 million in 2011 mainly due to the restructuring of the Company in the second half of the reporting year. On the one hand, direct restructuring costs amounted to EUR 2.9 million. As our strategic focus has been explicitly sharpened, large parts of our intellectual property portfolio and our technical equipment have become impaired. Therefore, EUR 1.0 million alone for unscheduled depreciation and amortization had to be recorded. Due to our decision to relocate our U.S. headquarters from the West to the East Coast, our rent agreement for the offices in Seattle has become onerous as well as some office space in Berlin; a provision of EUR 0.9 million has been set up in this context. Redundancy payments for our staff added up to EUR 0.8 million. On the other hand, an impairment charge in the full amount of EUR 2.6 million had to be recorded for capitalized goodwill as a collateral effect of the restructuring.

In 2011, operating loss (EBIT) increased by 33.9% from EUR 11.4 million in 2010 to EUR 15.2 million, strongly driven by the restructuring measures and the goodwill amortization amounting to EUR 5.5 million in total. Apart from these extraordinary effects, our overall operating costs increased only slightly by 3.1% year on year. However, it must be considered, that development activities were capitalized in an amount of EUR 2.8 million (2010: EUR 0.4 million), whereby pressure of such volume has been taken off of the operating result. Then again, the restructuring took place in the third quarter of the reporting year and the expected cost reduction effects could not yet materialize in the reporting year.

In 2011, our net loss finally amounted to EUR 15.6 million and was therefore 35.7% higher than in the previous year (EUR 11.5 million).

#### FINANCIAL POSITION AND CASH FLOW

At the end of the reporting year, our cash and cash equivalents added up to EUR 14.0 million. Total net cash outflow in 2011 amounted to EUR 12.0 million compared to a net cash inflow of EUR 20.6 million in 2010, which was admittedly strongly influenced by a large capital increase in that period. A more meaningful comparison shows an increase in cash consumption from EUR 10.3 million in 2010 to EUR 12.2 million in 2011. The aforementioned restructuring had only a small impact on the cash consumption, as it partly had no cash flow effect at all (depreciation and amortization including goodwill of EUR 3.6 million) or will have its impact on the cash flow not before 2012 (mainly rent- and facility-related restructuring costs but as well some staff redundancy payments). In fact, the increase in cash consumption in 2011 was mainly attributable to the absence of significant cash

Cash outflow from operating activities amounted to EUR 9.1 million and was lower than the corresponding cash outflow in 2010 (EUR 9.5 million). However, our net cash outflow from investing activities rocketed to EUR 2.8 million in 2011 (2010: EUR 0.3 million), mainly due to our capitalized development activities for the Epi proColon<sup>®</sup> test. Cash outflows for the purchase of tangible and other intangible assets amounted to not more than EUR 0.4 million, more or less unchanged to 2010.

Less than EUR 0.1 million cash outflow from financing activities were recognized in the reporting year and were attributable to the execution of the reverse stock split in the third quarter; whereas the capital increase 2010 led to a corresponding net inflow of EUR 30.4 million.

#### **NET ASSET POSITION**

inflows.

Our balance sheet total decreased significantly from EUR 33.8 million at the end of 2010 to EUR 19.5 million at year-end 2011 mainly due to the ongoing cash consumption for our operating and investing activities and the goodwill amortization.

Non-current assets decreased from EUR 5.5 million at yearend 2010 to EUR 4.0 million at the reporting year's end. Mainly two measures in connection with the restructuring of the Company are causative for this sharp decrease. On the one hand, unscheduled depreciation and amortization charges for technical equipment and in-licensed property rights in the amount of EUR 1.0 million had to be recorded. On the other hand, capitalized goodwill in the amount of EUR 2.6 million has been determined as impaired and therefore been written off in the full amount.

However, the impairment of the goodwill has also to be associated with the capitalization of the development costs for our Epi proColon<sup>®</sup> 2.0 test. In the past, the value of the capitalized goodwill was determined by the commercial potential of the blood-based colorectal cancer test targeted on the Septin9 biomarker. As now the product development plans for Epi proColon<sup>®</sup> 2.0 have further been implemented and materialized individually in the balance sheet as capitalized development costs, the future cash flow projections for this developed product can no longer serve for the impairment test of the goodwill which had now been allocated to the cancer screening business of the Company apart from the Epi proColon<sup>®</sup> sales as the underlying cash-generating unit. The overall projections for this remaining cancer screening business were of course impacted by the restructuring and the included downsizing of the Company resulting not at least in a cutback of its development capacities.

In consideration of these consequences and the Company's limited liquidity, due to its decreasing market capitalization especially towards the end of the reporting year and hence the uncertainty regarding the future availability of sufficient financial resources to exploit the commercial potential of this cancer screening business beyond the Epi proColon® test, the Company has reduced the future expectations for the commercialization to a very prudent approach. Therefore, the value of the capitalized goodwill could not be construed anymore as a recoverable amount and the management of Epigenomics has recognized an impairment of the capitalized goodwill, resulting in an impairment charge in the full amount of EUR 2.6 million.

Current assets decreased from EUR 28.4 million to EUR 15.4 million, to a large extent driven by the aforementioned cash consumption; notwithstanding the additional decrease in receivables and other current assets.

As approved by the Annual General Shareholders' Meeting in June 2011, a 5:1 reverse split of our share capital has been implemented during the third quarter of the year. As of August 8, 2011, five old Epigenomics shares (security code number A0BVT9) were replaced by one new Epigenomics share (security code number A1K051). Therefore, the share capital was reduced from the previous total of EUR 44,092,085.00 to now EUR 8,818,417.00, allocated to 8,818,417 shares outstanding. The main purpose of this share capital reduction was to improve our capital market situation, most notably with a view to future financing opportunities. The released capital in the amount of EUR 35.3 million has been used in full to offset the retained losses in our consolidated balance sheet. Other comprehensive income improved by EUR 0.3 million due to the premature repayment of securities available for sale, because accumulated losses of these securities had to be realized through profit or loss now.

Current liabilities increased from EUR 2.5 million at year-end 2010 to EUR 3.3 million. While trade payables of EUR 1.2 million remained nearly at an identical level as 12 months before, deferred income of EUR 0.2 million at December 31, 2010, has been fully recognized as revenue in 2011. Simultaneously, other liabilities and provisions increased from

EUR 0.9 million and EUR 0.3 million at the end of the previous year to EUR 1.0 million each at December 31, 2011. Main reasons for the significant increase in provisions are onerous rental contracts with potential repayment obligations as a consequence of the restructuring program.

### **EMPLOYEES**

	Berlin	Seattle	Total
Number of employees as at Dec 31, 2011	51	10	61
Number of employees as at Dec 31, 2010	69	13	82
Employees on average 2011	66	13	79
Employees on average 2010	67	16	83

The restructuring of the Company as announced and started in August 2011 led to a significant reduction in our headcount number. The number of employees decreased from 84 at the end of the first half year 2011 to 61 at the end of the reporting year with an expected further drop to 45 at the end of the first quarter 2012.

The number of 61 employees as of year-end 2011 comprises 35 employees directly involved in R&D activities. The remaining number of 26 includes both Executive Board members, 12 employees in sales and marketing functions and another 12 in general administration functions.

Overall personnel costs totaled EUR 6.9 million in 2011, compared to the previous year's EUR 6.7 million, an increase of 3.0%. This increase was partly attributable to one-off payments in connection with the implementation of the restructuring plan.

### SUPPLEMENTARY REPORT

No significant events took place after the end of the reporting year.

## OPPORTUNITIES AND RISKS

#### **OPPORTUNITIES AND RISK MANAGEMENT SYSTEM**

Epigenomics is a globally operating cancer molecular diagnostics company and as such subject to many industryand company-specific opportunities and risks. In line with the German "Corporation Sector Supervision and Transparency Act" ("Gesetz zur Kontrolle und Transparenz im Unternehmensbereich" - KonTraG), Epigenomics has an established, comprehensive and effective system to identify early, assess, communicate and manage opportunities and risks across all of 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 instruments 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 effective countermeasures. The risk management has been regularly discussed and is being developed further at product development team level, senior management level and at the Executive Board and the Supervisory Board levels. A core principle is transparency of risks and opportunities across all functions and businesses, interactive evaluation of these and a culture of seizing opportunities and accepting risks as integral part of doing business in cancer molecular diagnostics, but doing so responsibly and seeking an optimal balance of opportunities and risks.

FINANCIALS EMPLOYEES SUPPLEMENTARY REPORT OPPORTUNITIES AND RISKS

Every risk has a clearly identified "Risk Owner" whose responsibility it is to continuously monitor and control risks as well as manage the implementation of any countermeasures. At quarterly intervals, these risk owners report to the corporate "Risk Manager" who in turn communicates the risks to the Executive Board and the latter to the Supervisory Board. In case of any material risk, this risk is immediately brought to the attention of the corporate "Risk Manager" and discussed at the appropriate board levels. Important risks and the risk management system itself have also been discussed in broader management groups as well as between the Company's auditors and the Audit and Corporate Governance Committee of the Supervisory Board throughout the year.

Hence, our management structure, our organizational forums for identifying and assessing opportunities and risks, the monthly internal and external reporting as well as our controlling systems, all form an 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 well as reviewed by our auditors and the Audit and Corporate Governance Committee.

There are a number of important risks Epigenomics is faced with, which individually or in combination could severely impact our revenue, earnings and financial situation as well as our stock price. These are described below.

#### **BUSINESS-RELATED OPPORTUNITIES AND RISKS**

After the launch of our first IVD product, the CRC screening test Epi proColon<sup>®</sup>, in October 2009, we launched our second IVD product Epi proLung® in July 2010. Furthermore, we introduced the second generation of the CRC screening test Epi proColon<sup>®</sup> at the UEWG conference in Stockholm during the fourth quarter of 2011. However, product revenue so far have not met our expectations and our ability to grow revenue from our CRC screening test, and our lung cancer diagnostic test will depend, among other things, on the successful marketing and commercialization of both tests with key stakeholders in the healthcare industry. Such marketing and commercialization require the acceptance by the medical community and third-party payers in each country. Because of the critical importance of reimbursement of the tests by third parties we have - together with our partners - to convince important private health organizations and guidelineissuing bodies to include our tests in their cancer screening guidelines.

Furthermore, we will only be able to generate revenue from own product sales in the United States if our CRC screening test is approved by the FDA. In order to achieve that, we have initiated our regulatory approval process of Epi proColon<sup>®</sup> in the United States. In order to achieve this goal, we have retained some of the leading regulatory consulting groups with proven track record of successful client submissions of molecular diagnostics and oncology products to support our efforts. Throughout the year, we have had a series of interactions with the FDA in order to provide them with the necessary background and to enhance the chances of a successful submission with the ultimate goal of product approval. We initiated the approval process by submitting the first module of our PMA application late last year. While in light of the recently published data of our clinical validation study in the United States significant regulatory risks remain, we still have the expectation of ultimately being able to achieve the desired product approval in the United States. The FDA has requested us to perform an additional study with the goal of directly demonstrating non-inferiority of our test to already approved stool-based FIT tests in the market. The outcome of this study is of critical importance to our chances of being successful with our application.

As part of our dual-business model we are dependent on large diagnostic companies and reference laboratories, to develop, commercialize, sell and distribute our products and licensed products based on our biomarkers and technologies. To ensure that our partners devote their best efforts to commercialize these licensed products, we will continue to support our partners with all the expertise and know-how needed in order to see them succeed in the market. Our dependence from the commercial success of our partners remains a risk factor, especially when strategic decisions of our partners lead to a change in their focus areas, which can only be mitigated by diversification of our partner base.

Partnering and licensing is one way we already generate revenue in the form of royalty income. Qiagen has entered into an option agreement for a global commercial license with us, thereby obtaining the right to develop and commercialize its own Septin9-based IVD product. Development work at Qiagen has started and we are guite encouraged to see the progress they are making on that front. In order to achieve additional revenue from this business relation, Qiagen would need to exercise their option and start commercializing their test in the global markets. Upon the launch of a Septin9-based test in Europe and the Asia/Pacific region by our collaboration partner Abbott in 2009, product launches by our other partners followed thereafter. In order to be able to offer their product commercially in the United States, too, our IVD partners Abbott and Qiagen would also need to get regulatory approval by the FDA.

In the absence of an FDA-cleared product in the United States at this point in time, we have also entered into licensing agreements with selected reference laboratories in the U.S.A., which have introduced their own versions of Septin9-based laboratory-developed tests (LDT). In the course of 2011, Quest intensively promoted its LDT (ColoVantage<sup>™</sup>) for aiding the detection of CRC in the United States, demonstrating encouraging market adoption as showed in numbers of tests sold in 2011. Our partner ARUP has also introduced an LDT product based on our Septin9 technology in the U.S.A. and has been very active in providing additional scientific proof of its utility in the aid of detecting CRC. Our ability to receive significant royalty income from these relationships nevertheless depends on our LDT partners' ability to secure adequate reimbursement for their test offerings. Changes in the regulatory environment and uncertainties in the reimbursement landscape pose an inherent risk to royalty income we might be able to achieve. Furthermore, we do expect that due to contractual agreements with these partners and regulatory requirements, these partners would convert their product offerings from self-developed LDT tests to commercially available tests like Epi proColon® or other products from our partners Abbott and/or Qiagen, once these have been approved by the FDA. There is a remaining risk that such a conversion might not occur in a timely manner or even at all.

We still intend to close additional non-exclusive licensing and partnering deals for Septin9 (IVD and LDT) in order to fully leverage multiple platforms in all key markets around the world and to address the broadest possible market potential. Although we are currently in discussion with additional potential partners, there can be no assurance that these negotiations will be successful and that we will obtain sufficiently favorable terms. If our existing partners do not market or do not market sufficiently our products or are not successful in marketing them at all, we may not find additional partners or the planned royalty income will not be achieved.

The CRC screening field has seen intensive competition over the past years. Some competitors have made progress in developing other non-invasive CRC screening tests. It is important that we and our partners defend the lead we have in terms of clinical validation with the only prospectively validated CRC blood test that is today available as an IVD test kit. Epigenomics' future success partly relies on the experience and the know-how of the management and personnel, which represents a decisive competitive advantage of the Company. Our ability to retain the current level of expertise through key employees in the Company and to be able to recruit such expertise as it might become necessary remains a critical success factor and might have an effect on the future results of operations and financial condition. After the implementation of wide-ranging restructuring measures in mid 2011, the management has implemented a retention plan with the goal to secure the commitment of key employees.

#### **IP-RELATED OPPORTUNITIES AND RISKS**

Our business relies heavily on commercializing our intellectual property in the form of know-how, licenses to third-party patents and own patent applications. Therefore, any negative impact on scope, duration, depth and breadth of each single claim granted, on 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, our ability to compete as well as to commercialize our products and to close alliances, our revenue and ultimately our earnings and overall commercial success.

Seeing that, we face the risk of a challenge of the validity, ownership or enforceability of our patents in court. It may happen that a competitor successfully challenges our patents or that a challenge will result in limiting the coverage of our patents. As a result, we may lose important patent protection relating to our technologies and we could lose our ability to prevent others from utilizing these technologies without compensating us. Litigation could result in substantial costs, a delay in commercialization of our products and divert our management's attention and resources. We have faced continued opposition proceedings with regard to the Methy-Light Patent (EP 1185695) which we in-licensed from the University of Southern California and which had been granted in July 2006. In these proceedings, the Opposition Division of the European Patent Office agreed with the arguments provided by the opponent and interlocutorily revoked the patent. As we still believe, that the MethyLight technology is patentable, we filed an appeal against the decision of the Opposition Division. This appeal extends the effectiveness of the MethyLight patent until a final decision is reached. The next communication from the European Patent Office regarding our appeal is expected in the course of 2012 at the earliest.

Since we have moved our business from only developing new products to also marketing and selling our existing products launched in Europe in October 2009 and July 2010, patent protection is now even more important to prevent competitors from launching competitive products based on our biomarkers. To that end, we have conducted extensive freedom to operate analyses also for our future U.S. product, resulting in satisfactory results, at least for the time being. As a precautionary measure, we constantly monitor the status of patent applications deemed to be relevant and work closely with our IP lawyers to ensure the best possible protection of our IP rights in light of ongoing developments in this field.

At the same time, the progress made in expanding our IP portfolio and getting several key patents for cancer testing granted (such as our "SEPT9, "PITX2 and "GSTP1 biomarkers) puts Epigenomics in a unique position to provide attractive licensing opportunities for the growing number of commercial players active in DNA methylation. This opportunity has been underscored by numerous licensing deals in the past several years.

#### OPPORTUNITIES AND RISKS RELATED TO THE REGULATORY ENVIRONMENT

The regulatory environment in cancer molecular diagnostics has become more challenging especially with regard to LDTs/ homebrew assays. This could impact the timing and cost as well as our ability to meet such regulatory standards. In parts, the regulatory frameworks are not fully established or clarified as evidenced by a number of warning letters sent by the FDA to a number of diagnostics companies and large reference laboratories. This in turn could negatively impact on revenue generation and put a burden on 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. We seek advice from experienced advisors to prepare the organization for any potential issues. For example, for the preparation of FDA approval we have retained the services of the leading regulatory affairs consulting groups in the United States with a successful track record of guiding companies through the FDA approval process for cancer molecular diagnostic products. Strict management of our interactions with reference laboratories as well as seeking an ongoing dialog with the FDA as evidenced by several meetings held with the agency throughout 2011 are an integral part of our risk management policies.

#### FINANCIAL OPPORTUNITIES AND RISKS

As of December 31, 2011, our available liquidity (cash, cash equivalents and marketable securities) amounted to EUR 14.0 million. Based on the current plans and income projections of the Company, this liquidity is not sufficient to sustain the Company's operations over the following 24 months. Management is aware of the risk to have limited liquid assets to sustain the operations of the business as they are today potentially not beyond Q2 2013. Should we not succeed in raising fresh funds by that time, we are facing the risk of insolvency. However, having to raise additional funds in sufficient amounts by the issuance of new shares could become a challenge after the drastic decline of our share price at the end of the reporting year. The ongoing activities regarding our application for FDA approval for the Epi proColon<sup>®</sup> test, including potential additional studies could face unforeseeable obstacles and therefore lead to an accelerated cash outflow, thus jeopardizing the existence of the Company even at an earlier time.

As we are based in Germany and as well have operations in the United States and as we are operating on a global basis, we are subject to foreign exchange rate risks even though it is currently predominantly limited to the euro/U.S. dollar relation. In the future, our partners' and distributors' net sales may also be subject to foreign exchange risks and therefore our expected royalties may indirectly be exposed to additional exchange rate risks. We monitor these risks on a regular basis and evaluate on a case by case basis whether the exposure due to a particular single risk or a risk bundle can be reduced by hedging transactions. Additionally, it should be mentioned that foreign-currency-related transactions might entail opportunities as well.

Our portfolio of securities faces price risks in the form of interest rate, issuer and market related impairment risks. All past investments in marketable securities still contained in our portfolio have been made under the Company's investment policy, which was and is approved by the Supervisory Board. This policy stipulates to open only positions with an "investment grade" rating. However, to minimize those risks, we have not made any new investments in securities for more than six years. In close cooperation with our banks, advisors and the Supervisory Board, we continuously aim at finding an appropriate balance between exposure to these opportunities and risks. This has been a continuing area of focus in 2011 due to the aftermath of the global financial crisis. The financial crisis has made it harder to liquidate any security at short notice no matter how good the rating of the issuer is. Wherever possible, we have sold or redeemed these securities and as part of our risk mitigation strategy have exclusively been investing in money market instruments on euro or U.S. dollar basis to maximize availability of the liquidity by simultaneously accepting the rather poor returns that could be earned in global money markets at the still historically low interest rates.

In 2012 and going forward, we continue to maintain as much of our liquid assets in the form of cash and the most secure cash equivalents as possible.

#### **OTHER OPPORTUNITIES AND RISKS**

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. To minimize the potential impact from 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 internal experts in each of these areas and if necessary of external advisors. Wherever appropriate and indicated, we set aside provisions to cover any potential liability. There are risks particularly associated with our stock: the large holdings of a small number of institutional shareholders in Epigenomics shares, comparatively low levels of liquidity in the stock, very high volatility based on all of the above-described factors, as well as external influences and negative perceptions by others of any share sale. However, at the same time, the existing shareholdings in Epigenomics' stock provide the opportunity to have a very interactive dialog with key shareholders on a regular basis.

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

#### **OVERALL RISK SITUATION OF THE EPIGENOMICS GROUP**

Faced with the increased challenge of now entering the final steps towards completion of our regulatory pathway for Epi proColon<sup>®</sup> in the United States, our overall risk profile has certainly increased over the course of 2011. Failure to obtain regulatory approval, failure to secure adequate reimbursement for our products as well as lack of market acceptance and penetration would all have material impact on our revenue, earnings, financial position and our ability to raise

further capital and can lead to a total loss of value in our stock. Financial resources of EUR 14.0 million in liquid assets at year-end 2011 limit our ability to cope with potential additional hurdles along the regulatory track or in our commercial efforts. While the introduction of our second-generation product Epi proColon® 2.0 in Europe has the potential to somewhat increase our commercial traction in Europe, we are cautious not to expect a significant uptake of the product in the absence of widely available reimbursement to the end user. While initial commercial success from our U.S. LDT partners and the prospects of being able to sign up additional partners in 2012 demonstrate the interest from the market for a product like ours, we are also convinced that wide adoption of the product in the United States remains dependent on regulatory approval, inclusion in screening guidelines and secured reimbursement. Ultimately, our ability to access additional capital to reach our commercial goals remains the key risk for the Company.

## PROGNOSIS REPORT

#### PLANNED AND STRATEGIC DIRECTION OF EPIGENOMICS IN THE NEXT TWO YEARS

Over the next two years, we plan to further establish Epigenomics as a late-stage development and commercial operation as well as to increase the public perception of Epigenomics as a commercially-driven cancer molecular diagnostics company. The key success factor will be to master the PMA approval process with the FDA for our main product, Epi proColon<sup>®</sup>. To that end, our operational execution in 2012 will focus heavily on finalizing any clinical trials necessary for the completion of the submission documents in order to finalize the filing process, which is planned before the end of the year.

We will continue working with our partners by assisting Abbott in their commercialization efforts and Qiagen in assisting them in completing their development efforts required to commercialize their own version of a Septin9-IVD kit for the U.S. and European markets. While we are seeing encouraging adoption of our test in the United States as an LDT through our partners Quest, ARUP, and Warnex, we have in collaboration with our partners initiated the activities to ensure appropriate reimbursement for the U.S. market in collaboration with our partners. We will strive to broaden the number of laboratories where Septin9 testing is offered in Europe and the United States as well as in other countries where Septin9 testing is offered. One important element to the successful implementation of our corporate strategy for broad market penetration will be to close additional non-exclusive licensing deals for Septin9-based CRC screening in 2012 and beyond.

This will be a cornerstone of our business development efforts going forward whilst, simultaneously, we will take great care to optimize the value of Septin9 through careful timing of such deals.

After having implemented far-reaching restructuring measures last year, we have reduced our direct marketing and sales efforts in our home markets and have focused our commercialization efforts in Europe by selectively targeting key players in the healthcare system, which can act as multiplicators of our marketing messages. At the same time, we are also expanding the geographic coverage via agents and distributors to start selling in other major European and significant non-European markets.

The goal remains to establish Epigenomics as a leading cancer molecular diagnostics company with proprietary products in the markets, directly, through partners and through distributors.

According to our current plans, our limited R&D activities shall exclusively concentrate on the current product pipeline in colorectal and lung cancer diseases to develop successive generations of products with even higher performance and line extensions to broaden the scope of our proprietary biomarkers to related clinical applications. We aim to maintain our leadership in DNA methylation technologies and provide selected partners access to our know-how, expertise and IP in this field via licenses and/or services.

## EXPECTED ECONOMIC CONDITIONS IN THE NEXT TWO YEARS

We expect overall economic conditions and the capital market environment to continue to be challenging. Ongoing uncertainty in the capital markets will prevail for the near to midterm future, due to the overall macroeconomic circumstances. Nevertheless, we also assume that despite any possible set-backs, life sciences companies should still be able to raise equity capital based on solid fundamental performance in 2012 and beyond. However, as companies on the customer and partner side contract and cut budgets and R&D spending, it may become harder to close business deals that are front-loaded and provide us with cash inflows in advance as needed according to our mid-term business plans.

With currency movements remaining volatile between the U.S. dollar and the euro in the past 12 months and prognoses over the next 12 months anywhere from EUR/USD 1.20 to EUR/USD 1.50, we have decided to lock-in our budget rate for 2012 at EUR/USD 1.3773.

#### **OUTLOOK ON EARNINGS SITUATION**

Prior to securing the approval of Epi proColon<sup>®</sup> as an IVD diagnostic product in the U.S. markets, our revenue estimate remains cautious. We do expect revenue from our partnering activities in diagnostics at comparable or slightly increasing levels than 2011 for the following year. Any increase should be mainly driven by the gradual adoption of Septin9 targeted LDTs in the United States. Another contributor could be potential future licensing income, especially if we succeed to secure additional partners for Septin9 licensing agreements in 2012 and 2013. A major increase in revenue can only be expected once we are able to sell Epi proColon® directly in the U.S. market. At the same time, revenue growth from our Epi proColon® IVD kit sales in Europe will be moderate as long as we do not secure major agreements with key accounts or reimbursement through healthcare insurers. After initial difficulties encountered in the market, we recognized the self-payer market in Europe as being a very challenging one and thus have reacted by adapting our commercial strategy in 2011. These changes are expected to lead to more sustainable revenue, although it might take longer to reach that point.

We expect EBIT and net loss for 2012 to be at significantly lower levels than in 2011, since the implemented restructuring measures start to show their full effect. Estimated savings of EUR 3.5 million on a comparable operational basis should lead to a net loss in the range of EUR 9.5 to 11.0 million, depending on the additional costs for necessary studies in connection with our PMA submission.

Despite the expected decrease in operational cost, we will need to sponsor the required clinical trials for our own planned FDA-approved version of Epi proColon<sup>®</sup> and to make investments in automation development for higher throughput CRC testing, as well as in R&D activities towards next-generation products.

#### **OUTLOOK ON THE FINANCIAL SITUATION**

Cash consumption for the fiscal year 2012 should be at a lower level compared to 2011, i.e. around EUR 9.5 to 11.0 million and should decrease once the FDA approval activities have been finalized and revenue growth after product approval is expected to lead to a ramp-up in cash inflows. Coming from EUR 14.0 million in liquid resources (cash, cash equivalents and marketable securities) at year-end 2011 and this projected cash consumption in 2012, current financial resources are not sufficient to support the Company's operations for the next two years. Since at the present time it is not anticipated that we will be able to generate sufficient cash from licensing income or from product sales in the short term, we will diligently explore all strategic options available to the Company. These options include a capital market transaction. Given the volatility of the financial markets and the development of the Company's share price, we will furthermore explore other strategic options for the further development of the Company and the Group.

#### **OPPORTUNITIES OVER THE NEXT TWO YEARS**

The next 24 months hold the opportunity to provide the commercial proof of concept for our DNA-methylation-based cancer diagnostics. The products developed by us and our partners for blood-based CRC testing have matured significantly and are now being introduced for commercialization in the global markets. Potential future FDA approvals for Septin9 tests like Epi proColon<sup>®</sup> offer the opportunity to address the largest and most attractive global IVD market: the United States.

Lung cancer raises many clinical questions implicating huge medical needs for better diagnostics based on molecular tests. Our SHOX2 biomarker and the Epi proLung<sup>®</sup> IVD kit present an opportunity to address such market needs and provide clear benefits to patients and physicians in fighting this dreadful disease.

There are clear opportunities beyond CRC and lung cancer testing with other methylation biomarkers developed by Epigenomics. While we do not currently pursue these opportunities internally, they do represent further potential partnering and licensing opportunities.

For our shareholders there is the opportunity to see the increased enterprise value from catalytic events such as additional licensing partnerships, successful clinical trials for FDA approval of our Epi proColon<sup>®</sup> as well the publication of clinical data from different studies sponsored by us.

#### **OVERALL PROGNOSIS FOR THE EPIGENOMICS GROUP**

The transformation of Epigenomics into a commercially driven molecular diagnostics company with growing revenue derived from product sales remains the goal for the medium and long term.

The most significant milestone for us over the next 24 months is to ensure that we can get the approval for our product by the FDA to be able to start the commercialization of Epi proColon<sup>®</sup> in the most relevant market of the world: the United States. The future value of the Company and its financial situation is heavily dependent on this.

In order to be able to protect the continuity of our business operations, sufficient liquidity has to be maintained or secured. We aim to have liquidity to finance at least one year's operations at all times. We rely on capital markets to raise equity and debt financing from time to time and are expected to do so again in the next twelve months. In order not having to rely exclusively on a capital market financing of our business while remaining in control of the situation, in parallel we will also evaluate other reasonable strategic options for the further development of the Company and the Group.

## CORPORATE GOVERNANCE

To the Executive Board and the Supervisory Board, corporate governance lies at the heart of responsible and ethical management at Epigenomics. The very interactive dialog and regular communication between the Executive Board and the Supervisory Board and its committees aimed at generating long-term value to our shareholders are central to good corporate governance. Openness and transparency in our corporate communications with all shareholder groups, employees, the general public, and other stakeholders are the overarching principle.

Again, corporate governance was important for Epigenomics in 2011. We welcome the German Corporate Governance Code (the "Code") and we systematically and regularly monitor compliance with the German Corporate Governance principles making amendments wherever possible to ensure fair and responsible corporate management to the most recent version of the German Corporate Governance Code. Epigenomics' corporate governance principles in certain aspects go well beyond legal requirements and recommendations of the German Corporate Governance Code. For example, we have established binding internal guidelines on insider trading and made these part of all employment agreements. We have appointed our Manager Legal Affairs as Corporate Governance Compliance Officer to ensure adherence to the corporate governance principles. The Compliance Officer is required to submit regular compliance reports to the Executive Board, which are then passed on to the Supervisory Board.

There are a few notable exceptions based on certain Company specifics and peculiarities we chose to deviate from the German Corporate Governance Code. These exceptions are detailed below. There is a clear commitment to adhere to the Code going forward to the greatest extent possible.

#### DECLARATION OF COMPLIANCE 2011 WITH THE GERMAN CORPORATE GOVERNANCE CODE PURSUANT TO SECTION 161 OF THE GERMAN STOCK CORPORATION ACT (AKTG)\*

The governmental committee "Regierungskommission Deutscher Corporate Governance Kodex" appointed by the German Ministry of Justice in September 2001 has approved the German Corporate Governance Code on February 26, 2002, as well as its latest amendments on May 26, 2010. contains The Code recommendations (so-called "Soll-Vorschriften") and suggestions (so-called "Sollte-" or "Kann-Vorschriften") for the management and supervision of German listed companies and is based on international and national recognized standards of good and responsible management. The Code also includes recommendations and suggestions on corporate governance with respect to shareholders, general meetings, executive board and supervisory board, as well as transparency, accounting and auditing. Compliance with the Code is not mandatory.

Pursuant to Section 161 of the German Stock Corporation Act (Aktiengesetz – AktG), the Executive Board and the Supervisory Board of Epigenomics as a listed company have to explain each year, which recommendations of the German Corporate Governance Code were or were not complied with. This statement is made permanently accessible to the general public in German and English language on the Company's website under *www.epigenomics.com/en/news-investors/investors/corporate-governance.* 

The Executive Board and the Supervisory Board of Epigenomics AG hereby declare that, since the last declaration of compliance in March 2011, Epigenomics AG has complied, and complies, with the recommendations of the German Government Commission on the German Corporate Governance Code in the version of May 26, 2010 (hereinafter also "Code"), in each case with the exceptions set forth below.

#### Section 2.3.2

In the past, the Company did not send notification of the convening of the Annual General Shareholders' Meeting with the convention documents to all domestic and foreign financial services providers, shareholders and shareholders' associations by electronic means. The transmission by electronic means requires the consent of the Annual General Shareholders' Meeting. Such consent has been granted by the Annual General Shareholders' Meeting only by resolution of 28 June 2011. Starting with the Annual General Shareholders' Meeting 2012, the Company intends to send notification of the convening of the Annual General Shareholders' Meeting, including all pertaining documents, to the shareholders by electronic means, to the extent that the consent of the individual shareholders also has been granted.

#### Section 4.1.5

When filling managerial positions in the Company, the Executive Board considers company-specific situations and seeks to achieve an appropriate diversity. This applies both to the internationality of the managerial staff and to the appropriate consideration of women. However, it is ultimately in the corporate interest to fill managerial positions with the most suitable male or female candidate. Therefore, in our opinion, sweeping requirements inadequately restrict the Executive Board in its decision on the filling of managerial positions.

#### Section 4.2.3 Paragraph 2 and 3

The service contracts of the Executive Board members do not and did not provide that both positive and negative developments are taken into account when determining variable compensation components. Therefore, the granting of stock options to Executive Board members in the past did not relate to demanding, relevant comparison parameters. The existing deviation from the Code in this respect is due to the fact that we believe that relating to comparison parameters does not improve the sense of responsibility and the motivation of the Executive Board members and that a possibility of limitation (cap) is not necessary due to the structure of our existing stock option programs.

The service contracts of the Executive Board members include a compensation structure which is oriented toward sustainable growth of the Company. Due to the current business model, the service contracts of the Executive Board members do not, however, provide for variable compensation elements on a multi-year assessment basis. However, there is no deviation from recommendations of the Code in this respect. As a result of the German Act on the Appropriateness of Executive Board Compensation (VorstAG), Section 87 paragraph 1 of the German Stock Corporation Act has been amended and the Code has been adjusted accordingly. Instead of the former recommendation that variable compensation components should also include components with long-term incentives containing risk elements, the Code reflects the amended statutory provisions and no longer contains any recommendation in this respect. When concluding or amending service contracts of Executive Board members, the Supervisory Board, as a matter of course, observes the applicable statutory requirements for the structuring of the compensation of the Executive Board members and will decide in each case also in the future whether or not the Code recommendations regarding variable compensation components are complied with.

#### Section 4.2.3 Paragraph 4 and 5

The service contracts with Executive Board members of Epigenomics AG do not include a severance payment cap in case of a premature extraordinary termination due to a change of control pursuant to Section 4.2.3 paragraphs 4 and 5. In case of such an extraordinary termination, the payout of the basic compensation for the remaining contractual period is provided. An agreement of a severance payment cap would be contradictory to the nature of a service contract for Executive Board members, which is regularly concluded for the term of appointment and could potentially not accommodate sufficiently for the concrete circumstances in a change of control case. Accordingly, we did not and will not comply with the recommendation in Section 4.2.3 paragraph 5.

## Section 5.1.2 Paragraph 1 and 2 and Section 5.4.1 Paragraph 2 and 3

In the past, when filling the positions in its bodies, the Executive Board and the Supervisory Board considered the company-specific situation, and also made allowances for potential conflicts of interest as well as the international activities of the Company through an appropriate diversity of their members. Deviating from the recommendations in Section 5.1.2 paragraph 2 and in Section 5.4.1 paragraph 2, we consider the commitment to institute special age limits for members of the Executive Board and the Supervisory Board as an inadequate limitation of the voting rights of our shareholders. In addition, we are convinced that sweeping requirements for the composition of the Executive Board as requested in Section 5.1.2 paragraph 1 constrain the Supervisory Board inadequately in its selection of suitable members of the Executive Board. The same applies accordingly to the specification of sweeping objectives regarding the composition of the Supervisory Board, as required in Section 5.4.1 paragraph 2 and assumed in Section 5.4.1 paragraph 3. We use our best efforts to achieve an appropriate diversity in the Executive Board and the Supervisory Board, especially with respect to the internationality and the participation of women. However, it is ultimately in the corporate interest to appoint as members of the Executive Board and the Supervisory Board the most suitable male or female candidates. We therefore believe that sweeping requirements constitute an inadequate limitation of the individual selection of suitable candidates for the Executive Board or the Supervisory Board. Furthermore, a target requirement regarding the composition of the Supervisory Board also inadequately impairs our shareholders' right to elect the Supervisory Board members. Accordingly, we did not and will not comply with these recommendations of the Code.

#### Section 5.3.3

The Supervisory Board took and takes the view that the requirement to form a nomination committee composed exclusively of shareholder representatives which proposes suitable candidates to the Supervisory Board for recommendation to the Annual General Shareholders' Meeting is not necessary with regard to the size of the Company. Instead, this task is also performed in the Supervisory Board by the Personnel and Compensation Committee.

#### Section 5.4.3 Sentence 3

As of yet, we have not complied with the recommendation to announce proposed candidates for the Supervisory Board chair to the shareholders, as, pursuant to Section 10 paragraph 4 of the Company's Articles of Association, the newly composed Supervisory Board elects a chairperson from among its members and such Supervisory Board does not necessarily need to consist of the same persons as the Supervisory Board which is in office prior to the Annual General Shareholders' Meeting and thus at the time when candidates are proposed for the Supervisory Board chair. Against this background, the announcement of the proposed candidates did not appear reasonable. Accordingly, Epigenomics AG has so far not complied with the recommendation in Section 5.4.3 sentence 3. However, in connection with the upcoming new election of the Supervisory Board members in 2012, it is planned to comply with the recommendation.

#### Section 5.4.5 Sentence 2

The Supervisory Board cannot comply with the recommendation in Section 5.4.5 sentence 2 of the Code 2009, that a Supervisory Board member who is the member of the executive board of a listed company, shall not accept more than a total of three supervisory board mandates in non-group listed companies or in supervisory bodies of companies with similar requirements. The Supervisory Board considers a corresponding limitation of the number of mandates as not necessary, as long as each Supervisory Board member has sufficient time to pursue the duties of his/her mandates. Accordingly, Epigenomics AG did not and will not comply with the recommendation in Section 5.4.5 sentence 2, as long as it is ensured that all Supervisory Board members have sufficient time to pursue the duties of their mandates.

#### Section 5.4.6 Paragraph 1 Sentence 3

The compensation of the Supervisory Board members for their committee activities is structured such that there is a separate compensation for the committee chairmanship but not for the mere membership in a committee. Since the committee activities are evenly distributed among the members of the Supervisory Board, a separate compensation for the mere membership in committees does not appear necessary. Accordingly, we did not and will not comply with the recommendation in Section 5.4.6 paragraph 1 sentence 3.

#### Section 5.4.6 Paragraph 2

The compensation of the Supervisory Board members does not include a performance-related component. In our opinion, a performance-related compensation would not lead to an additional incentive or an increase in motivation. Accordingly, we did not and will not comply with the recommendation in Section 5.4.6 paragraph 2. The adoption of performance-related compensation components in the future shall be subject of a future decision of the Annual General Shareholders' Meeting, as the case may be.

#### Section 7.1.2 Sentence 4

Due to the change in the Executive Board as of April 1, 2011, Epigenomics AG did not publish its Consolidated Financial Statements for the financial year 2010 until April 7, 2011. Accordingly, we did not comply with the recommendation in Section 7.1.2 sentence 4 that the Consolidated Financial Statements shall be publicly accessible within 90 days of the end of the financial year. In the future, i.e. as from the publication of the Consolidated Financial Statements for the financial year 2011, we will again comply with the recommendation set forth in Section 7.1.2 sentence 4.

Berlin, December 2011

On behalf of the Supervisory Board

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

On behalf of the Executive Board

Geert Walther Nygaard	Dr. Thomas Taapken
(CEO)	(CFO)

#### **DECLARATION OF GOVERNANCE**

According to Section 289a of the German Commercial Code (HGB), the Declaration of Governance was made permanently accessible to the general public in German and English language on Epigenomics AG's website under *www.epigenomics.com/en/news-investors/investors/corporate-governance.* 

#### KEY FEATURES OF THE INTERNAL CONTROL AND RISK MANAGEMENT SYSTEM RELATED TO THE GROUP ACCOUNTING PROCEDURES OF THE COMPANY

The internal control and risk management system (ICR) of Epigenomics has been set up by the Company's top management who also takes responsibility for it. The ICR is not defined as a comprehensive standardized system across the entire enterprise but rather scope of control and intensity are adjusted according to the respective risk. In addition, control options are used at all Company levels and supervision by the management is established. Epigenomics has developed an individual top-down approach for Company-wide controls and supervision including a proof of effectiveness. A flexible setup of the reporting system – supported by established tools and adjusted to the Company's needs – ensures transparency and targeted supervision by the internal control system. Financial and non-financial indicators are taken into account. The supervision of the ICR takes place continuously by the Supervisory Board and the Executive Board. Apart from truth and fairness of the financial reporting it also includes the securing of efficiency and cost-effectiveness of the daily business as well as compliance with relevant regulations and internal guidelines. The supervision of the accounting procedures goes hand in hand with the supervision of the ICR.

Within the organization of the Company there are various departments and employees involved in the setup, the coordination and the supervision of control measures. The risk management function and the controlling as well as quality departments are of major importance here. Due to the size of the Group, the Company has not yet established an internal audit function.

Assessment of the adequacy and the effectiveness of the ICR are continuously ensured by discussions with relevant employees, by benchmarking with other organizations and also by way of a regular dialog with the Company's auditors and consultations of the Company's lawyers as required.

Basically, the Epigenomics Group has established the principle of separation of functions as far as reasonable in a commercial organization with a given number of employees. This principle is supplemented by the four-eyes principle. Neither Executive Board members nor any employees are authorized to represent and sign on behalf of the Company alone.

For internal routine activities, instructions and regulations are provided if possible. Those instructions and regulations can be found within so-called "standard operating procedures" (SOPs) as well as in guidelines like e.g. an employee's manual, detailed job descriptions, a travel policy or an accounting manual. The guidelines are constantly accessible to all employees of the Company via the intranet. All guidelines are checked continuously and get amended if necessary. Legal advice from experts is taken as needed to ensure conformity of the internal regulations with the applicable legal requirements.

The Company's controlling system is primarily based on miscellaneous planning, monitoring and reporting tools. Qualitative information derives from a self-developed project documentation database, and quantitative information is processed in both Group entities by Navision<sup>™</sup>, a widely used enterprise resource planning software. Our accounting and controlling departments provide all relevant controlling information to the Executive Board on a monthly basis. An ongoing education of the team members is ensured. For internal control purposes, we set up an annual budget based on the current five-year strategic business plan of the Company and a corresponding set of goals. The budget is developed bottom-up from all cost centers and R&D projects. All budgets are extensively reviewed internally by the senior management team and the Executive Board, and a final approval of the annual budget by our Supervisory Board is mandatory. Primary focus of our regular internal management reporting lies in comparing actual versus budgeted values for a comprehensive set of metrics. From these, we compile the external quarterly reports. Each quarterly report is accompanied by an internal forecast, which provides us with an updated estimate of expected full-year results and performance vis-à-vis target numbers and public guidance. Actual versus budget comparisons of financial performance indicators are also drawn on a regular basis within the framework of the internal reporting system and are reported monthly to the top management of the Company. The focus is on cost and liquidity control. Deviations versus budget or historical values are analyzed on a short-term basis and supplemented by a presentation of alternative options. The reporting is supplemented as needed with additional data requested by the Supervisory Board or the Executive Board as well as the controlling team.

Impairment tests on the Company's assets are done on a regular basis according to the appropriate accounting standards or, if necessary, when any staff members reports a reasonable suspicion of a possible impairment.

#### DIRECTORS' DEALINGS AND DIRECTORS' SHARE OWNERSHIP\*

According to Section 15a of the German Securities Trading Act (Wertpapierhandelsgesetz) and Section 6.6 paragraph 1 of the German Corporate Governance Code, persons discharging managerial responsibilities within an issuer of financial instruments are required to disclose their personal transactions in shares of the issuer and financial instruments based on them, especially derivatives, to the issuer and to the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht – BaFin). The duty to disclose applies to the members of the Executive Board and the Supervisory Board. Moreover, the duty of disclosure also applies to persons who have regular access to insider information about the Company and are empowered to make significant managerial decisions. The duty to disclosure also applies to persons and certain legal entities closely associated with a person discharging managerial duties at the Company. The duty to disclose does not apply if the purchase or sale transactions do not exceed EUR 5 thousand in a calendar year.

The following declared securities transactions took place during 2011:

Members of the Executive Board	Date	Туре	Number of shares	Transaction value in EUR
Geert Walther Nygaard, CEO	April 7, 2011	Purchase	10,000 <sup>1</sup>	17,100
Dr. Thomas Taapken, CFO	Sept 26, 2011	Purchase	1,000	3,990
Dr. Thomas Taapken, CFO	Sept 29, 2011	Purchase	800	3,271

<sup>1</sup> Number of shares is not adjusted (i.e. Mr. Nygaard purchased 10,000 shares with the old security code number A0BVT9, which have been converted by the reverse stock split in August 2011 to 2,000 shares with the new security code number A1K051).

## REMUNERATION REPORT

#### COMPOSITION AND COMPENSATION OF THE EXECUTIVE BOARD

The Executive Board of Epigenomics AG is responsible for independently managing and running operations, developing and implementing corporate strategy and budgetary planning, appointing and guiding senior management and overseeing general management of the Company. There is a continuous and intensive dialog between the Executive Board and the Supervisory Board and their respective members. In its charter, the Executive Board has been given a clear set of rules and procedures for certain actions and decisions that require Supervisory Board approval.

The Executive Board of Epigenomics AG consisted in the reporting period of three members:

- Geert Walther Nygaard, Chief Executive Officer, Jan 1, 2011 – Dec 31, 2011
- Oliver Schacht, Ph.D., Chief Financial Officer, Jan 1, 2011 – Mar 31, 2011
- Dr. Thomas Taapken, Chief Financial Officer, Apr 1, 2011 – Dec 31, 2011

Effective March 31, 2011, Mr. Oliver Schacht, Ph.D., co-founder of Epigenomics AG, Chief Financial Officer (CFO) of Epigenomics AG and Chief Executive Officer (CEO) of Epigenomics, Inc. resigned from his Executive Board position and left Epigenomics to pursue other career opportunities. Dr. Thomas Taapken succeeded Mr. Oliver Schacht, Ph.D., at the position as Executive Board member and CFO effective April 1, 2011. The service agreement with Dr. Taapken has a term of three years (April 2011 – March 2014).

The compensation of the members of the Company's Executive Board is composed of a fixed and a variable component. The variable amount is determined on the basis of a variety of criteria, including the achievement of individual performance goals and Company performance goals, which are set by the Supervisory Board on a yearly basis. Total compensation – which is reviewed by the Supervisory Board annually – is compared to national and international benchmarks. Compensation takes into account the economic and financial situation of the Company as well as size and complexity of international operations and responsibilities. Apart from the fixed and the variable component, there is a third compensation in the form of stock option grants.

The service agreements of Mr. Nygaard and Dr. Taapken contain post-contractual non-compete provisions for a period of two years after the respective service agreement has ended. During such period, Mr. Nygaard and Dr. Taapken are entitled to 100% of their last basic salary as a non-competition payment.

In case of a change of control, Mr. Nygaard and Dr. Taapken are entitled to terminate their respective service agreements and would in such case be entitled to receive payment of the fixed compensation amount for the time remaining until their service agreement would have anyhow expired. In 2011, the aggregate compensation of the members of the Executive Board amounted to EUR 0.7 million. It consisted of EUR 0.6 million in fixed salary and the remainder of EUR 0.1 million in variable and other salary components.

Until Mr. Schacht's resignation, the Company paid rent in monthly installments for his apartment in Berlin and reimbursed incidental apartment expenses – due to his simultaneous activity as CEO for Epigenomics, Inc. in Seattle.

The individual compensation is shown below, whereby "other compensation" consists of payments for vacation days not taken and the aforementioned reimbursements for rent and incidental expenses.

in EUR		2011 (2010)			
	Fixed	Variable	Other	Total	
Members of the Executive Board in 2011	compensation	compensation	compensation	compensation	
Geert Walther Nygaard					
Chief Executive Officer	390,000	0	0	390,000	
Berlin (D)	(390,000)	(160,470)	(0)	(550,470)	
Oliver Schacht, Ph.D. (until March 31, 2011)					
Chief Financial Officer,	60,775	28,390	14,602	103,767	
Seattle, WA (U.S.A.)	(230,430)	(139,580)	(10,093)	(380,103)	
Dr. Thomas Taapken (since April 1, 2011)					
Chief Financial Officer,	168,750	0	0	168,750	
Berlin (D)	(0)	(0)	(0)	(0)	
Total compensation	619,525	28,390	14,602	662,517	
	(620,430)	(300,050)	(10,093)	(930,573)	

Due to the disappointing development of Epigenomics' share price during 2011, Mr. Nygaard and Dr. Taapken have voluntarily decided to waive their entitlement to any bonus payments for the reporting year.

In accordance with Section 6.6 paragraph 2 of the German Corporate Governance Code, the ownership of shares in the Company or related financial instruments by the Executive Board and the Supervisory Board will be reported if these directly or indirectly exceed 1% of the shares issued by the Company. As of December 31, 2011, Mr. Nygaard owned 12,000 shares of the Company (Dec 31, 2010: 10,000) and Dr. Taapken owned 2,000 shares of the Company (Dec 31, 2010: 0).

	as	as of Dec 31, 2011 (Dec 31, 2010)				
Members of the Executive Board	Stock options held	Weighted average exercise price in EUR	Vested options	Weighted average exercise price in EUR	Exercised options	
Geert Walther Nygaard	77,000	16.10	45,332	20.59	0	
	(57,000)	(19.35)	(38,333)	(21.80)	(0)	
Dr. Thomas Taapken	20,000	9.60	0	n/a	0	
	(0)	n/a	(0)	n/a	(0)	

In 2011, a total of 40,000 stock options was granted to and no stock options were exercised by the members of the Executive Board.

## COMPOSITION AND COMPENSATION OF THE SUPERVISORY BOARD

Epigenomics AG's Supervisory Board consists of six members with broad experience in the pharmaceutical, diagnostics or financial industries. No changes in the Supervisory Board took place during the reporting year. The current mandates of all six members expire on May 2, 2012, after the Company's Annual General Shareholders' Meeting 2012. The Supervisory Board has established two committees: an Audit and Corporate Governance Committee as well as a Personnel and Compensation Committee (for further details please refer to our Declaration of Governance permanently accessible on Epigenomics' website under www.epigenomics.com/en/ news-investors/investors/corporate-governance).

Members of the Supervisory Board	Member since	Audit and Corporate Governance Committee	Personnel and Compensation Committee	Memberships at Dec 31, 2011, in - (1) other supervisory boards, - (2) comparable domestic or international control boards, acc. to Section 125 para. 1 sent. 5 Stock Corp. Act
Chairman	Feb 2001	no	yes	(1) Ganymed Pharmaceuticals AG (D), (Chairman)
Prof. Dr. Dr. h. c. Rolf Krebs			<i>y</i> ==	(1) Merck KGaA (D), (Chairman)
Mainz (D)				(1) Merz GmbH & Co. KGaA (D)
Retired physician				(1) Merz Pharmaceuticals GmbH (D)
				(1) Senator GmbH & Co. KGaA (D)
				(2) E. Merck KG (D), (Board of partners)
				(2) Air Liquide S.A. (F)
Deputy Chairman	May 2005	yes	no	(1) Definiens AG (D)
Prof. Dr. Dr. Dr. h. c. Uwe Bicker				(1) Future Capital AG (D)
Bensheim-Auerbach (D)				(1) Siemens Healthcare Diagnostics
Dean of the Medical Faculty				Holding GmbH (D), (Chairman)
Mannheim/Heidelberg				(2) Sanofi Aventis S.A. (F)
Joseph Anderson, Ph.D.	June 2010	no	yes	(2) Abingworth BioEquities Fund Ltd. (GB)
Oxted, Surrey (GB)				(2) Algeta ASA (N)
Abingworth LLP, London,				(2) Amarin Corporation plc (EIR)
Partner				
Günter Frankenne	July 2006	yes	no	(1) 4SC AG (D)
Berg/Neumarkt (D)				(1) Concentro Management AG (D), (Chairman)
Owner of StratCon				(1) Curadis GmbH (D), (Chairman)
Strategy Consulting company				(1) iMTM GmbH (D)
				(1) November AG (D), (Chairman)
				(1) Verbena AG (D)
				(1) ViroLogik GmbH (D), (dormant)
Ann Clare Kessler, Ph.D.	June 2005	no	yes	(2) Althea Dx, Inc. (USA)
Rancho Santa Fe, CA (USA)				(2) GenProbe, Inc. (USA)
Independent consultant				(2) GenScript, Inc. (USA)
				(2) MedGenesis Therapeutix, Inc. (CAN)
Prof. Dr. Günther Reiter	June 2005	yes	no	(1) Deltoton GmbH (D)
Pfullingen (D)				
Professor at the ESB Business				
School, Reutlingen				

The compensation structure for the Supervisory Board previously approved by the Annual General Shareholders' Meeting in 2005 has been left unchanged in 2011 and is based on an annual cash retainer ("fixed compensation"), meeting-related fees ("variable compensation") plus additional payments for committee chairing work ("other compensation"). The compensation does not comprise any performancerelated elements or long-term incentive components.

Compensation of the members of the Supervisory Board in 2011:

		Fixed compensation		Variable compensation		Other compensation		Total compensation
	2010	2011	2010	2011	2010	2011	2010	2011
Prof. Dr. Dr. h. c. Rolf Krebs	30,000	30,000	5,000	5,000	5,000	5,000	40,000	40,000
Prof. Dr. Dr. Dr. h. c. Uwe Bicker	20,000	20,000	10,000	8,000	0	0	30,000	28,000
Joseph Anderson, Ph.D.	5,833	10,000	8,000	10,000	0	0	13,833	20,000
Günter Frankenne	10,000	10,000	10,000	10,000	5,000	0	25,000	20,000
Ann Clare Kessler, Ph.D.	10,000	10,000	10,000	10,000	0	0	20,000	20,000
Prof. Dr. Günther Reiter	10,000	10,000	10,000	10,000	0	5,000	20,000	25,000
Total	85,833	90,000	53,000	53,000	10,000	10,000	148,833	153,000

In addition, the members of the Supervisory Board were reimbursed for expenses totaling EUR 23 thousand in 2011 (2010: EUR 27 thousand).

During the reporting year, the members of the Supervisory Board held neither stock options nor any other convertible instrument nor any other equity-linked compensation entitlement of the Company. As of December 31, 2011, the only Supervisory Board member that held any shares in Epigenomics AG is Mrs. Kessler, Ph.D., who owned 2,800 shares of the Company together with her husband, an unchanged number compared to December 31, 2010.

#### FINANCIAL MARKET REPORTING

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 two months after quarter's end and annual financial statements within four months after year-end. All information is made available simultaneously on our website *www.epigenomics.com*. All material news is announced following the latest guidelines and legal requirements on ad hoc notification.

## ADDITIONAL MANDATORY DISCLOSURES FOR LISTED COMPANIES PURSUANT TO SEC-TION 315 PARAGRAPH 4 OF THE GERMAN COMMERCIAL CODE (HGB)

According to Section 315 paragraph 4 of the German Commercial Code (HGB), the Company is required to report on certain structures governed by company law and other legal relationships, in order to provide a better overview of the Company and disclose any impediments to a takeover.

#### SHAREHOLDERS WITH DIRECT OR INDIRECT SHAREHOLD-INGS OF MORE THAN 10% OF THE VOTING RIGHTS

Shareholder	Notification date	Shareholdings in %
Abingworth LLP, London, U.K.	April 1, 2010	19.58

#### **COMPOSITION OF SHARE CAPITAL**

As of December 31, 2011, the share capital of Epigenomics AG comprised exclusively common shares with equal rights and a par value of EUR 1.00 each.

As approved by the Annual General Shareholders' Meeting in June 2011, a 5:1 reverse split of our share capital has been implemented during the third quarter of the year. As of August 8, 2011, five old Epigenomics shares (security code number A0BVT9) were replaced by one new Epigenomics share (security code number A1K051). Therefore, the total number of outstanding shares was reduced from 44,092,085 to now 8,818,417.

Under certain conditions, shareholders may not be entitled to vote according to Section 136 of the German Stock Corporation Act (AktG). We are not aware of any contractual restrictions related to voting rights or the transfer of shares.

#### LEGISLATION AND PROVISIONS OF THE ARTICLES OF ASSOCIATION APPLICABLE TO THE APPOINTMENT AND WITHDRAWAL OF MEMBERS OF THE EXECUTIVE BOARD AND GOVERNING AMENDMENTS TO THE ARTICLES OF ASSOCIATION

The appointment and withdrawal of members of the Executive Board is subject to the provisions of Sections 84 and 85 of the German Stock Corporation Act (AktG). The Supervisory Board shall appoint members of the Executive Board for a maximum period of five years. It is permissible to appoint members to the Executive Board on more than one occasion or to extend their period of office, on each occasion for a maximum of five years.

The Executive Board may consist of one or more persons. The number of members of the Executive Board shall be determined by the Supervisory Board in accordance with the statutory provisions. The Supervisory Board may appoint a member of the Executive Board as its chairperson and one or more members of the Executive Board as his/her deputy(ies). Deputy members of the Executive Board may be appointed. The statutory provisions regarding the amendment of the Articles of Association are governed in Sections 179 to 181 of the German Stock Corporation Act (AktG).

Pursuant to Section 14 of the Articles of Association, the Supervisory Board is entitled to adopt amendments and completions to the statutes which only involve the version thereof.

#### AUTHORITY OF THE EXECUTIVE BOARD TO ISSUE SHARES

The Executive Board is authorized until June 27, 2016, to increase, with the consent of the Supervisory Board, the share capital of the Company once or several times by up to EUR 881,841.00 against contribution in cash and/or in kind by issuing new non-par value bearer shares (Authorized Capital 2011/I). The subscription rights shall be granted to the shareholders. The new shares can be subscribed by a financial institution or a syndicate of financial institutions under the obligation to offer the shares to the shareholders for subscription (indirect subscription right).

The Executive Board is authorized until June 27, 2016, to increase, with the consent of the Supervisory Board, the share capital of the Company once or several times by up to EUR 3,527,366.00 against contribution in cash and/or in kind by issuing new non-par value bearer shares (Authorized Capital 2011/II). The subscription rights shall be granted to the shareholders. The new shares can be subscribed by a financial institution or a syndicate of financial institutions under the obligation to offer the shares to the shareholders for subscription (indirect subscription right).

ADDITIONAL MANDATORY DISCLOSURES FOR LISTED COMPANIES PURSUANT TO SECTION 315 PARAGRAPH 4 OF THE GERMAN COMMERCIAL CODE (HGB)

The share capital is increased conditionally by up to EUR 123,485.00 by issuance of up to 123,485 new non-par value bearer shares with a nominal par value of EUR 1.00 per share (Conditional Capital IV). The conditional capital increase can only be carried out to the extent that option rights were issued on the basis of the stock option program 03-07 of the Company, and the holders of these share options exercise their right to subscribe to shares of the Company and the Company does not transfer its own shares in fulfillment of these option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. Conditional Capital IV cannot be used anymore to grant stock options as the underlying authorization for a granting time frame has expired. However, 21,968 new shares can still be created upon exercise of granted options from the underlying program.

The share capital is further conditionally increased by up to EUR 129,535.00 by issuance of up to 129,535 new non-par value bearer shares with a nominal par value of EUR 1.00 per share (Conditional Capital V). The conditional capital increase can only be carried out to the extent that option rights were issued on the basis of the stock option program 06-10 of the Company and the holders of these share options exercise their right to subscribe to shares of the Company and the Company does not transfer its own shares in fulfillment of these option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. Conditional Capital V cannot be used anymore to grant stock options as the underlying authorization for a granting time frame has expired. However, 111,861 new shares can still be created upon exercise of granted options from the underlying program.

The share capital is further conditionally increased by up to EUR 304,246.00 by issuance of up to 304,246 new non-par value bearer shares with a nominal par value of EUR 1.00 per share (Conditional Capital VII). The conditional capital increase can only be carried out to the extent that option rights were issued on the basis of the stock option program 09-13 of the Company and the holders of these share options exercise their right to subscribe to shares of the Company and the Company does not transfer its own shares in fulfillment of these option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. 164,130 new shares can still be created upon exercise of already granted options from the underlying program. Another 137,451 options can still be granted to beneficiaries from the underlying program.

The share capital is further conditionally increased by up to EUR 296,648.00 by issuance of up to 296,648 new non-par value bearer shares with a nominal par value of EUR 1.00 per share (Conditional Capital VIII). The conditional capital increase can only be carried out to the extent that option rights were issued on the basis of the stock option program 11-15 of the Company and the holders of these share options exercise their right to subscribe to shares of the Company and the Company and the stock option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. 20,000 new shares can still be created upon exercise of already granted options from the underlying program. Another 276,648 options can still be granted to beneficiaries from the underlying program.

## FIVE-YEAR OVERVIEW

## - according to the consolidated financial statements -

EUR thousand (unless stated otherwise)	2007	2008	2009	2010	2011
Income statement					
Revenue	2,567	2,586	4,260	1,787	1,437
Gross profit	1,693	888	1,462	1,313	1,080
EBIT	-13,504	-12,750	-10,218	-11,449	-15,245
EBITDA	-12,259	-10,242	-9,442	-10,307	-10,939
Net loss for the year	-13,151	-12,271	-10,223	-11,476	-15,575
Balance sheet					
Non-current assets	9,070	5,857	5,716	5,463	4,042
Investments in non-current assets <sup>1</sup>	65	258	324	439	388
Current assets	13,844	14,426	10,638	28,375	15,421
Non-current liabilities	0	38	9	0	0
Current liabilities	5,093	3,677	4,261	2,543	3,277
Equity	17,821	16,568	12,084	31,295	16,186
Equity ratio in %	77.8	81.7	73.9	92.5	83.2
Total assets	22,914	20,283	16,354	33,838	19,463
Cash flow statement					
Cash flow from operating activities	-11,516	-9,800	-10,629	-9,479	-9,111
Cash flow from investing activities	1,049	1,468	-195	-315	-2,842
Cash flow from financing activities	4,547	11,500	4,964	30,394	-44
Net cash flow	-5,920	3,168	-5,860	20,600	-11,997
Cash consumption	-11,488	-9,957	-11,324	-10,294	-12,241
Cash and cash equivalents at year-end	6,646	9,814	3,954	24,554	12,557
Stock <sup>2</sup>					
Weighted-average number of shares issued	3,561,452	5,201,422	5,834,427	8,083,549	8,818,417
Earnings per share (basic and diluted) in EUR	-3.70	-2.35	-1.75	-1.40	-1.77
Share price (in EUR) at year-end	9.75	10.00	17.60	10.25	1.30
Number of employees at year-end	112	90	86	82	61

Excluding capitalized development costs
 In order to ensure the comparability, the figures for 2007–2010 have been adjusted retroactively.

# CONSOLIDATED FINANCIAL STATEMENTS AND NOTES

- according to International Financial Reporting Standards (IFRSs) -

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### GROUP INCOME STATEMENT FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31, 2011

EUR thousand	Notes	2010	2011
Revenue	1	1,787	1,437
Cost of sales	3	-474	-357
Gross profit		1,313	1,080
Gross margin in %		73.4	75.1
Other income	2	1,012	452
Research and development costs	3	-7,222	-4,946
Selling, general and administrative costs	3	-5,779	-5,938
Other expenses	5	-773	-5,893
Operating result (EBIT)	6	-11,449	-15,245
Interest income	7	165	219
Other financial result	7	-152	-292
Net loss for the year before taxes on income		-11,436	-15,318
Taxes on income	8	-40	-257
Net loss for the year		-11,476	-15,575
Earnings per share (basic and diluted) in EUR <sup>1</sup>	9	-1.40	-1.77

<sup>1</sup> In order to ensure the comparability the number for 2010 has been adjusted retroactively following the consolidation of shares in 2011.

# STATEMENT OF INCOME AND EXPENSES RECOGNIZED IN GROUP EQUITY

EUR thousand	Notes	2010	2011
Net loss for the year		-11,476	-15,575
Fair value adjustments of securities	22	139	333
Total income and expenses recognized in Group equity		139	333
Total comprehensive income		-11,337	-15,242

## GROUP BALANCE SHEET AS OF DECEMBER 31, 2011

ASSETS EUR thousand	Notes	Dec 31, 2010	Dec 31, 2011
Non-current assets			
Intangible assets	10, 12	4,498	3,322
thereof: goodwill	10	2,625	0
Tangible assets	11, 12	544	506
Deferred taxes	13	421	214
Total non-current assets		5,463	4,042
Current assets			
Inventories	14	162	283
Trade receivables	15	476	211
Marketable securities	16	1,815	1,428
Cash and cash equivalents	17	24,554	12,557
Other current assets	18	1,368	942
Total current assets		28,375	15,421
Total assets		33,838	19,463

EQUITY AND LIABILITIES EUR thousand	Notes	Dec 31, 2010	Dec 31, 2011
Equity			
Subscribed capital	19	44,092	8,818
Capital reserve	20	22,078	22,212
Retained earnings	21	-22,494	1,303
Net loss for the year	21	-11,476	-15,575
Other comprehensive income	22	-905	-572
Total equity		31,295	16,186
Current liabilities			
Trade payables	24	1,134	1,228
Liabilities from leasing contracts		9	0
Deferred income	25	240	0
Other liabilities	26	890	1,013
Provisions	27	270	1,036
Total current liabilities		2,543	3,277
Total equity and liabilities		33,838	19,463

## GROUP CASH FLOW STATEMENT FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31, 2011

EUR thousand	Notes	2010	2011
Cash and cash equivalents at the beginning of the year	17	3,954	24,554
Operating activities	29		
Net loss for the year before taxes on income		-11,436	-15,318
Corrections for:			, ,
Depreciation on tangible assets	11	265	349
Amortization of intangible assets	10	877	3,957
Losses from the disposal of assets		6	37
Stock option expenses	4	290	134
Foreign currency exchange losses		-31	-6
Interest income	7	-165	-219
Realized losses from the sale of available-for-sale securities	7	0	432
Taxes	8	-81	-46
Operating result before changes in net current assets		-10,275	-10,680
Changes in trade receivables and other current assets		2,313	682
Changes in inventories		-2	-122
Changes in current liabilities from operating activities		-1,701	782
Liquidity earned from operating activities		-9,665	-9,338
Interest received		186	227
Cash flow from operating activities		-9,479	-9,111
Investing activities	30		
Payments for investments in tangible assets		-205	-326
Proceeds from the sale of non-current assets		0	5
Payments for investments in intangible assets		-234	-35
Additions to capitalized development costs	3, 10	-376	-2,774
Proceeds from the sale of available-for-sale securities		500	288
Cash flow from investing activities		-315	-2,842
Financing activities	31		
Payments for the creation of new shares	31	-2,648	-36
Proceeds from the issue of new shares		33,069	0
Payments for lease financing		-27	-8
Cash flow from financing activities		30,394	-44
Cash flow		20,600	-11,997
Cash and cash equivalents at the end of the year		24,554	12,557

### STATEMENT OF CHANGES IN GROUP EQUITY AS OF DECEMBER 31, 2011

Other Capital Subscribed Retained Net loss for compreh. Group EUR thousand Notes capital reserve earnings the year income equity Dec 31, 2009 29,395 12,084 6,227 -22,494 0 -1,044 Total comprehensive income -11,476 0 0 0 139 -11,337 Capital increase from the issue of shares 14,697 0 0 0 0 14,697 Premium from the issue of shares 0 18,372 0 0 0 18,372 0 -2,811 0 0 0 -2,811 Financing costs Stock option expenses 4 0 290 0 0 0 290 Dec 31, 2010 44,092 22,078 -22,494 -11,476 -905 31,295 Total comprehensive income 0 0 0 -15,575 333 -15,242 Transfer of net loss for the year 2010 0 0 -11,476 11,476 0 0 to retained earnings Reverse stock split (5:1) -35,274 35,274 0 19, 21 0 0 0 Stock option expenses 134 0 0 0 134 0 4 Dec 31, 2011 8,818 22,212 1,303 -15,575 -572 16,186

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## BASIC INFORMATION, PRINCIPLES AND METHODS

#### **DESCRIPTION OF BUSINESS ACTIVITY**

Epigenomics ("Epigenomics" or the "Company") was founded as a limited liability company (GmbH) in 1998 and has its headquarters in Berlin, Germany. In 2000, the Company was converted into a stock corporation (AG) and entered into the commercial register ("Handelsregister") Charlottenburg under HRB 75861. Since July 19, 2004, it is listed in the Prime Standard segment of the Frankfurt Stock Exchange (ticker symbol: ECX).

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

#### **GENERAL PRINCIPLES**

The consolidated financial statements of Epigenomics AG have been prepared according to Section 315a of the German Commercial Code ("HGB") under regulations according to the German Accounting Law Modernisation Act ("Bilanzrechtsmodernisierungsgesetz – BilMoG") and the International Financial Reporting Standards (IFRSs) of the International Accounting Standards Board (IASB), London, in effect at the closing date December 31, 2011, as mandatory and applicable in the European Union. Further, these statements are in accordance with the German Accounting Standards (GASs).

The "going concern" principle according to IAS 1.25 *Presentation of Financial Statements* has been considered.

The reporting period as defined in these consolidated financial statements is the period from January 1, 2011, to December 31, 2011. The reporting currency is the euro.

The income statement has been prepared using the cost of sales method.

## NEW AND REVISED STANDARDS AND INTERPRETATIONS EFFECTIVE IN THE REPORTING PERIOD

The following new and revised standards and interpretations issued by the IASB have been considered in these consolidated financial statements. Their adoption has either not had any significant impact or has not had any impact at all on the amounts reported in these financial statements but may affect the accounting for future transactions or arrangements:

- IAS 1 Presentation of Financial Statements: Amendments to IAS 1 as part of Improvements to IFRSs 2010,
- IAS 24 Related Party Disclosures: Revised 2009,
- IAS 27 Consolidated and Separate Financial Statements: Amendments to IAS 27 (2008),
- IAS 32 Financial Instruments Presentation: Classification of Rights Issues,
- IAS 34 Interim Financial Reporting: Amendments to IAS 34,
- IFRS 1 First-time Adoption of International Financial Reporting Standards: Amendments to IFRS 1; Limited Exemption from Comparative IFRS 7 Disclosure,
- IFRS 3 Business Combinations: Amendments to IFRS 3 as part of Improvements to IFRSs 2010,
- IFRS 7 Financial Instruments Disclosures: Amendments to IFRS 7,
- IFRIC 13 Customer Loyalty Programmes: Amendments to IFRIC 13,
- IFRIC 14 IAS 19 The Limit of a Defined Benefit Asset, Minimum Funding Requirements and their Interactions: Voluntary Prepayments of Minimum Funding Requirements
- IFRIC 19 Extinguishing Financial Liabilities with Equity Instruments.

The Group has not yet adopted the following new and revised standards and interpretations, issued in 2011, for which a mandatory adoption is planned after the indicated business years. These standards are partly not yet endorsed by the EU.

Mandatory adoption...

...at or after July 1, 2011:

- IFRS 1 First-time Adoption of International Financial Reporting Standards: Removal of Fixed Dates for First-time Adopters,
- IFRS 7 Financial Instruments Disclosures: Transfer of Financial Assets,

...at or after January 1, 2012:

IAS 12 Income Taxes: Amendments to IAS 12,

...at or after July 1, 2012:

IAS 1 Presentation of Financial Statements: Amendments to IAS 1,

...at or after January 1, 2013:

- IAS 19 Employee Benefits: Amendments to IAS 19,
- IAS 27 Consolidated and Separate Financial Statements: Separate Financial Statements,
- IAS 28 Investments in Associates: Investments in Associates and Joint Ventures,
- IFRS 10 Consolidated Financial Statements,
- IFRS 11 Joint Arrangements,
- IFRS 12 Disclosure of Interests in Other Entities,
- IFRS 13 Fair Value Measurement,
- ...at or after January 1, 2015:
- IFRS 9 Financial Instruments.

The Company intends to adopt most of these new and/ or revised standards, interpretations and amendments as soon as their adoption is mandatory and they are endorsed by the EU. The Company does not expect a potential material impact of the adoption of these amendments on its financial statements.

#### **MANAGEMENT'S JUDGMENT AND EXPECTATIONS**

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

Management's expectations on the future are usually based on the current economic outlook according to the consensus prognoses by leading economic and financial research institutions and independent analysts. After the turbulences on the financial and capital markets over the past years, there is disagreement within these groups whether the global situation will improve in 2012 or another year of unsteadiness must be expected. The plans of the Group's management do not expect Epigenomics to be very dependent on the overall economic situation in the short term. The Group's operating activities are not very dependent on the availability or the price development for commodities or industrial supplies but rather on the individual situation of the Company and its opportunities to continue its operations by further financing transactions.

In the medium term, the euro currency is expected to remain stable vis-à-vis the U.S. dollar. Management plans are based on an average exchange rate of EUR/USD 1.30 - 1.40 throughout 2012. It also took note of the predictions of financial experts and banks, which are usually diverging with regard to this relation.

Material changes in the legislation of those major countries that could significantly affect the diagnostics industry are not assumed. Changes in the tax laws of Germany and the U.S.A. that would in any material way affect our financial situation in the foreseeable future are also not anticipated. In the medium to long term, the reform project for the local healthcare system planned by the Obama administration may influence activities of all life sciences companies. At the present time, however, it is uncertain, when, to which extent and whether this reform project will be implemented. All future scenarios furthermore assume an essentially unchanged access to relevant clinical and biological samples, corresponding clinical data and sufficient resources for the execution of the Company's commercial projects.

#### **CONSOLIDATION GROUP**

The consolidated Group comprises Epigenomics AG as the parent company (principal office: Kleine Präsidentenstrasse 1, 10178 Berlin, Germany) and Epigenomics, Inc. (principal office: Suite 3800, 901 Fifth Avenue, Seattle, WA 98164-2044, U.S.A.), its wholly owned subsidiary.

For the reporting year, the two companies have submitted individual, audited financial statements independent of their consolidation.

#### **PRINCIPLES OF CONSOLIDATION**

In the consolidation of capital, the acquisition values of the investment are balanced with the share of equity capital of the subsidiary applicable to them on the date of acquisition. A resulting difference is added to the assets and liabilities in the amount in which their market value deviates from their carrying value at the time of the initial consolidation. An amount in excess is capitalized as goodwill.

All intercompany transaction results, revenue, expenses, profits, receivables and payables are eliminated in full on consolidation.

#### **ACCOUNTING AND VALUATION PRINCIPLES**

#### Goodwill

Goodwill arising upon an acquisition is initially recognized as an asset at cost and subsequently measured at cost less any accumulated impairment losses. Therefore, the goodwill has to undergo an impairment test at least once a year according to IFRS 3 *Business Combinations* in connection with IAS 36 *Impairment of Assets*. The regular application of this impairment test is scheduled for the end of each calendar year, subsequent to the annual budgeting process of the Company. The goodwill as recognized in former reporting years had been allocated to the Group's cancer screening business as cash-generating unit (CGU). The impairment test compared the net carrying value of the assets of the cancer screening business to their recoverable amount. The recoverable amount had been defined as the discounted future cash flows of this business.

Management's expectations regarding the future cash flows of the cancer screening business were based on the most recent business plans as well as on the current financial situation of the Company and are, however, subject to risks and uncertainties.

#### Intangible assets

Other intangible assets than goodwill and capitalized development costs are valued at acquisition or production cost less scheduled amortization on a straight-line basis. Depending on the investment, useful life will be defined between three years (software) and twenty years (patents). For patents, the useful life in individual cases depends on the term of the patent protection. Amortization of intangible assets is allocated in the income statement to the functional area in which they are used. IAS 38 *Intangible Assets* is applied. In accordance with this standard, an intangible asset is reported if it is likely that a future financial advantage is associated with the use of such asset and that its cost can be reliably determined. An impairment test will be done annually for assets or groups of assets for which an unplanned decrease in value is assumed. If the carrying amount of an intangible asset exceeds the recoverable amount of this asset at the closing date, it will be taken into account by means of an unplanned amortization determined by the result of the impairment test. If there is no longer any reason for an impairment loss, an appreciation will take place up to the amortized acquisition costs as a maximum.

#### Capitalized development costs

Expenditure on research activities is recognized as an expense in the period in which it is incurred. An internally generated intangible asset arising from internal development is recognized if, and only if, all of the following requirements according to IAS 38.57 *Intangible Assets* have been fulfilled:

- proof of the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- proof of the intention to complete the intangible asset to use or sell it;
- proof of the ability to use or sell the intangible asset;
- proof how the intangible asset will generate probable future economic benefits;
- proof of the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset;
- demonstration of the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for the capitalization of development costs is the sum of expenditure incurred from the date when the intangible assets first met the aforementioned recognition criteria. Where no internally generated intangible asset can be recognized, development expenditure is charged to profit or loss in the period in which it is incurred. Subsequent to initial recognition, capitalized development costs are reported at cost less accumulated amortization and impairment losses, on the same basis as intangible assets acquired separately. The useful life of such capitalized development costs is assumed under consideration of the business plan and amounts to up to five years for the currently capitalized assets. Depreciation is recorded on a straight-line basis.

#### Tangible assets

Tangible assets are measured at acquisition or production cost less scheduled depreciation caused by usage. Apart from directly attributable costs, pro rata overhead cost and depreciation are also included in the production costs of internally produced equipment. Public and governmental investment grants lower the acquisition or production costs. Repair costs are immediately calculated as an expense. Depreciation for leasehold improvements 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 three to eight years for technical and electronic equipment and five to ten years for operational and office equipment.

In the "Assets schedule" (notes item 12), fully depreciated tangible assets are shown under acquisition/ production cost and accumulated depreciation until the assets in question are decommissioned. In the case of disposal, assets and related depreciation are eliminated from the accounts. Income or expense resulting from the disposal of assets (proceeds less residual carrying value) is shown in the income statement under other income/other expenses.

If the carrying value of the tangible assets calculated according to the above principles exceeds the recoverable amount of these assets at the closing date, it will be taken into account by means of an unscheduled depreciation. The amount to be adjusted is determined by sale proceeds or – if higher – the net present value of future cash flows estimated from the 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 unscheduled depreciation, an appreciation will take place up to the amortized acquisition costs as a maximum.

#### Leasing contracts

A leasing contract qualifies as a finance lease, if the contractual conditions of the contract transfer all risks and opportunities in connection with the ownership to the lessee. All other leasing contracts are recognized as operating leases.

#### Deferred taxes

Deferred taxes are calculated according to the rules of IAS 12 *Income Taxes* and are recognized for temporary differences between the carrying amount of assets and liabilities in the financial statements multiplied by the weighted tax rates and the corresponding tax balance sheets of the companies involved. Further, deferred tax assets are recognized from tax loss carryforwards to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and that they are expected to reverse in the foreseeable future. If such a realization is not probable, a valuation allowance is recognized against the tax loss carryforwards.

Deferred tax assets and liabilities are measured at the local tax rates enacted or the rates, which are expected to apply at the time of realization. Deferred tax assets and liabilities are offset only if they are subject to compensation with regard to the same tax authority and if the Group intends to settle its current tax assets and liabilities on a net basis.

#### Inventories

Inventories comprise finished goods, raw materials, low-value consumables as well as other production supplies. They are valued at the lower of acquisition or manufacturing cost and net realizable value. The manufacturing costs of the finished goods include directly attributable unit costs, depreciation, amortization of capitalized development costs and overheads attributable to the production process. For the balance sheet date, a physical inventory of all materials, consumables and finished goods was taken.

#### **Financial instruments**

Purchase and sale of financial assets is recognized using trading date accounting.

#### Primary financial instruments

The reported primary financial instruments comprise cash and cash equivalents, marketable securities, trade receivables, trade payables and other liabilities. Those instruments are initially recognized at acquisition costs or at fair value and then at amortized acquisition costs or at their fair value.

#### Marketable securities

According to the definitions of IAS 39.9 *Financial Instruments: Recognition and Measurement*, the Company's marketable securities are classified either as "financial assets at fair value through profit or loss" (FVTPL) or as "available-for-sale financial assets" (AFS). The Group does not hold financial assets for trading purposes. Irrespective of this classification, financial assets are recognized at fair value. Changes in fair value are recognized through profit or loss or – if the securities classify for AFS – in other comprehensive income until the securities are disposed of or are determined to be permanently impaired. Impairment losses recognized in profit or loss are subsequently reversed if an increase in the fair value of the instrument can be objectively determined.

#### Derivative financial instruments

Derivative financial instruments are carried at fair value. As a matter of principle, the fair values of derivative financial instruments correspond to their market values. For unlisted derivatives the fair values are determined by individual settlement quotes from the Company's house banks. Changes in the fair value of derivative financial instruments are recognized as financial result.

#### Impairment of financial assets

At the balance sheet date, a financial asset, other than those measured at fair value, is measured whenever there is an indication that the asset might be impaired. A financial asset is impaired when there is objective evidence that, as a result of one or more events that occurred after the initial recognition of the financial asset, the estimated future cash flows of the investment have been impacted.

The carrying amount of a financial asset is reduced by the impairment amount directly for all financial assets with the exception of trade receivables, where the carrying amount is reduced through the use of an allowance account. When a trade receivable is considered to be no longer collectible, it is written off against the allowance account. Subsequent recoveries of amounts previously written off are credited against the allowance account. Changes in the carrying amount of the allowance account are recognized in profit or loss.

#### Cash equivalents

A cash equivalent is defined as a financial instrument being readily convertible on a short-term basis to a known amount of cash and carrying an insignificant risk of changes in value (IAS 7.6 *Statements of Cash Flows*). Financial 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". All such cash equivalents must be convertible into primary cash at any time.

#### Prepaid expenses

Payments before the balance sheet date, which will be expenses for a specific period after that date, are deferred and reported as prepaid expenses in other current assets.

#### **Current liabilities**

Liabilities are classified as current when certain criteria in accordance with IAS 1.60 *Presentation of Financial Statements* are met. Basically, the Company's normal operating cycle according to this definition is 12 months. In the licensing business the operating cycle is even more than 12 months. Liabilities are measured at amortized costs, which are basically equivalent to their fair values.

#### Trade payables

Trade payables are initially recognized at the fair value of the received goods and services. After initial recognition they are measured at amortized costs. Foreign currency liabilities are converted at market currency exchange rates at the reporting date. Trade payables are derecognized if the obligation on which this liability is based is fulfilled, cancelled or expired.

#### Deferred income

Deferred income is recognized for grants and for research and development payments ("R&D payments") received in advance. Grants received in advance which were provided by governmental or comparable central, regional or local authorities are recognized through profit or loss as other income over the subsidized terms of each project according to its progress of fulfillment. Payments received in advance from customers for R&D services to render or for licenses are deducted and recognized through profit or loss over the term of the contract according to the progress of fulfillment.

#### Provisions

In accordance with IAS 37 *Provisions, Contingent Liabilities and Contingent Assets,* a provision is recognized if a present obligation as a result of a past event exists, if it is probable that an outflow of resources embodying benefits will be required to settle this obligation and if a reliable estimate of the amount of the obligation can be made. The amount recognized as a provision is the best estimate of the expenditure required to settle the present obligation at the balance sheet date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows expected to be required to settle the present obligation, its carrying amount is the present value of these cash flows.

#### **Revenue recognition**

Revenue from the sale of products and the rendering of 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.

Revenue from research and development collaboration agreements is recorded and recognized using the percentage of completion method, when costs are incurred in connection with the contractual obligations in accordance with the applicable performance requirements and terms of the respective contracts.

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 partner.

Nonrefundable upfront payments are deferred and recognized on a straight-line basis over the contractual collaboration term. Optional prolongation terms are considered individually according to the underlying exercise conditions and anticipated likelihood of their exercise.

Royalty revenue is recognized on an accrual basis in accordance with the substance of the relevant contract. Royalties determined on a time basis are recognized on a straight-line basis over the contracted period. Royalty arrangements that are based on sales and other measures are recognized by reference to the underlying contract.

#### Cost of sales

Cost of sales include expenses for material used in sold products, changes in inventories, services received in connection with product sales or other types of revenue, royalties to be paid to third parties and triggered by product sales or other types of revenue. In addition, cost of sales include directly allocable portions of personnel expenses, IP costs, depreciation and amortization as well as pro rata overheads.

#### Government grants

In individual cases cost contributions from public authorities are granted for research projects. These grants are partially paid in advance and then reported as deferred income (see above). To some extent, grants will only be paid after the work has been performed and proven. In such cases, another current asset is capitalized through profit or loss.

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

Government grants usually come with certain requirements, which have been met so far by the Company and are expected to be met going forward. If the requirements were not met anymore in the future, repayment claims could arise which have not been recognized yet.

#### Research and development costs

Research and development costs (R&D costs) include the personnel expenses for the R&D staff, material expenses, scheduled depreciation and amortization, service fees, licensing fees and other direct expenses in connection with the Company's research and/or development activities (including clinical studies) which cannot be classified as revenue-generating activities. In addition, R&D costs include pro rata overhead costs charged to the R&D departments.

#### Selling, general and administrative costs

Selling, general and administrative costs (SG&A costs) include:

- all direct personnel and material expenses of the corresponding departments,
- scheduled depreciation and amortization of the corresponding departments,
- other direct expenses of the corresponding departments, and
- the pro rata overheads of the corresponding departments as well as the Company's statutory costs.

#### Stock option expenses

The fair value of granted stock options is calculated using the Black-Scholes option pricing model and is expensed over the expected option term of up to four years against the capital reserve. According to IFRS 2.11 *Share-based Payment,* the valuation date is the grant date.

#### MANAGEMENT'S JUDGMENTS IN THE APPLICATION OF ACCOUNTING POLICIES/ ASSUMPTIONS AND ESTIMATES

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 consolidated balance sheet and/or income statement. This also applies to the listing of contingent assets and liabilities. The actual amounts may vary from these assumptions and estimates.

#### In particular, assumptions and estimates are required for:

- determining, if the criteria for the capitalization of development costs and the recoverability of internally generated intangible assets are met;
- testing a potential impairment of assets (especially regarding intangible assets like goodwill and licenses);
- determining the terms of in-licensed intellectual property rights;
- determining the useful lives of tangible and intangible non-current assets in particular of capitalized development costs;
- determining, if deferred taxes are realizable;
- determining, if securities classify as "available for sale" or "at fair value through profit or loss";
- determining the fair value of financial instruments;
- setting the parameters regarding the valuation of stock option grants; and
- accounting for provisions (especially the determination of the likelihood of occurrence).

#### **Currency translation**

In the individual financial statements, receivables and liabilities in foreign currencies are valued using the corresponding euro reference rate published by the European Central Bank and applicable at the closing date. Items that are hedged by forward transactions are valued at their forward prices.

For consolidation purposes, the reporting currency of the U.S.-based Epigenomics, Inc. is the euro as well.

Transactions in foreign currencies are translated with the exchange rates at the transaction date. Exchange rate differences resulting from such transactions and from the translation with the reporting date rates are recognized through profit or loss.

Applied foreign currency exchange rates in the reporting period:

Reporting date rates	Dec 31, 2010	Dec 31, 2011
EUR/USD	1.3362	1.2939
EUR/GBP	0.86075	0.83530
EUR/CAD	1.3322	1.3215

Average rates	2010	2011
EUR/USD	1.3207	1.4000
EUR/GBP	0.85601	0.87124
EUR/CAD	1.3660	1.3805

## NOTES TO THE GROUP INCOME STATEMENT

## REVENUE

Revenue source by revenue type:

	2010		2011	
	EUR thousand	% of total	EUR thousand	% of total
Licensing and royalty income	1,202	67.3	845	58.8
Product sales (own and third-party)	252	14.1	347	24.1
R&D payments	131	7.3	170	11.8
Reimbursements	202	11.3	75	5.3
Total revenue	1,787	100.0	1,437	100.0

Revenue source by geographical market:

	2010	2010		
	EUR thousand	% of total	EUR thousand	% of total
Europe	993	55.6	1,023	71.2
North America	729	40.8	320	22.2
Rest of the world	65	3.6	94	6.6
Total revenue	1,787	100.0	1,437	100.0

Of total revenue, 67% was generated by the three largest customers (2010: 63%).

## OTHER INCOME

EUR thousand	2010	2011
Foreign currency exchange gains	300	164
Income from the reversal of provisions	235	138
Third-party research grants	320	80
– thereof: from public authorities	287	80
Recoveries and refunds	7	30
Income from the disposal of assets	18	23
Income from option exercises	67	8
Corrections of invoices of previous periods	60	7
Other	5	2
Total other income	1,012	452

## COST ANALYSIS

2010	Cost of	R&D	SG&A	
EUR thousand	sales	costs	costs	Total
Materials and consumables	116	674	36	826
Depreciation and amortization	50	483	73	606
Personnel costs	100	3,868	2,743	6,711
Other costs	208	2,522	2,978	5,708
Capitalized development costs	0	-325	-51	-376
Total	474	7,222	5,779	13,475

2011	Cost of	R&D	SG&A	
EUR thousand	sales	costs	costs	Total
Materials and consumables	134	1,403	45	1,582
Depreciation and amortization	21	519	128	668
Personnel costs	60	3,223	2,800	6,083
Other costs	142	2,575	2,965	5,682
Capitalized development costs	0	-2,774	0	-2,774
Total	357	4,946	5,938	11,241

## **4 PERSONNEL COSTS**

EUR thousand	2010	2011
Personnel remuneration	5,607	6,003
Stock option expenses	290	134
Social security expenses	814	773
– thereof:		
employer's contribution to the national pension fund (Germany)	274	279
employer's contribution to a 401(k) savings plan (U.S.A.)	58	40
Total personnel costs	6,711	6,910
Average number of employees:		
Employees in operating departments	55	49
Employees in sales, marketing and administrative departments	28	30
Total employees	83	79
Personnel costs/employee (in EUR thousand)	81	87

## **5** OTHER EXPENSES

EUR thousand	2010	2011
Restructuring expenses	0	2,938
– thereof:		
depreciation and amortization	0	1,013
rent and additional property expenses	0	945
personnel costs	0	828
consulting and other services	0	110
materials and consumables	0	32
other	0	10
Goodwill amortization	0	2,625
Foreign exchange rate losses	229	293
– thereof:		
due to the translation of deferred tax assets	-31	4
Losses from the disposal of assets	6	36
Extraordinary amortization on intangible assets	537	0
Other	1	1
Total other expenses	773	5,893

#### 6 EARNINGS BEFORE INTEREST AND TAXES (EBIT) AND EBIT BEFORE DEPRECIATION AND AMORTIZATION (EBITDA)

EUR thousand	2010	2011	Variance in %
EBIT	-11,449	-15,245	-33.2
Depreciation	265	349	31.7
Amortization	877	3,957	351.2
EBITDA	-10,307	-10,939	-6.1

#### **7** FINANCIAL RESULT

EUR thousand	2010	2011
Interest from cash and cash equivalents	101	188
Interest from available-for-sale financial assets	64	31
Interest and related income	165	219
Fair value adjustment for derivative instruments	0	142
Other financial income	0	142
Total financial income	165	360
Fair value adjustment for derivative instruments	-144	0
Adjustment from disposal of available-for-sale financial assets	-6	-432
Other finance costs	-2	-1
Total financial expenses	-152	-433
Total financial result	13	-73

Other financial income of EUR 142 thousand in 2011 (2010: financial expenses of EUR 144 thousand) is attributable to valuation adjustments for a U.S. dollar-based currency forward contract with a remaining term until December 2012.

In the reporting year, a net gain of EUR 142 thousand for derivative instruments has been recognized (2010: net loss of EUR 144 thousand). For the net gains and losses of all other financial instruments reference is made to the overview above.

## 8 TAXES ON INCOME

The reported income taxes in the amount of EUR 257 thousand (2010: EUR 40 thousand) comprise exclusively taxes recorded by the Company's U.S. subsidiary in Seattle.

EUR thousand	2010	2011
Current tax expenses	40	46
Deferred tax expenses due to loss carryforwards	0	211
Total taxes on income	40	257

For the calculation of deferred taxes of the U.S. subsidiary, a local tax rate of 34% was applied. Calculation of the applicable tax rate in Germany for the purpose of deferred taxes:

in %	2010	2011
Corporate tax rate	15.0	15.0
Solidarity charge	5.5	5.5
Trade tax charge	14.0	14.0
underlying trade tax rate of assessment	410	410
Total applicable tax rate in Germany		
for the purpose of deferred taxes	29.8	29.8

#### Tax reconciliation:

EUR thousand	2010	2011
Net loss for the year before taxes on income	-11,436	-15,318
Weighted-average tax rate for the Group	29.7%	<b>29.6</b> %
Expected tax expense	-3,401	-4,537
loss carryforwards not capitalizable	3,895	4,788
goodwill amortization	0	782
capitalization of development costs (net)	0	-679
unscheduled amortization on non-current financial assets	0	-298
fair value recognition of securities	0	99
stock option expenses	86	40
effect from foreign tax rates	-13	33
tax effect from non-deductible operating expenses	26	24
provision for onerous contracts	0	12
capital-increase-related expenses	-586	0
other temporary effects	33	-7
Effective tax expense	40	257
Effective tax rate	-0.3%	-1.7%

The expected tax expense for the reporting year has been calculated by applying the expected weighted-average tax rate for the Group to the consolidated net loss before taxes on income.

## **9** EARNINGS PER SHARE

The earnings per share (basic) are calculated by dividing the net loss for the year by the weighted-average number of shares issued. In order to ensure the comparability after the reverse stock split in August 2011, the number of shares issued has been adjusted retroactively with a corresponding effect on the historical earnings per share numbers.

	2010	2011
Net loss for the year (in EUR thousand)	-11,476	-15,575
Weighted-average number of shares issued	8,083,549	8,818,417
Earnings per share (basic and diluted) in EUR	-1.40	-1.77

The outstanding stock options granted by the Company are antidilutive according to IAS 33.41 and 33.43 *Earnings per Share*. Therefore, the earnings per share (diluted) equal the earnings per share (basic). The number of shares issued as of the balance sheet date amounted to 8,818,417.

## NOTES TO THE GROUP BALANCE SHEET

#### NON-CURRENT ASSETS

## **10** INTANGIBLE ASSETS

EUR thousand		Software	Licenses/ patents	Goodwill	Devel- opment costs	Total intangible assets
Jan 1, 2010	Acquisition costs	686	4,871	3,351	459	9,367
	Additions	158	139	0	325	622
	Disposals	0	-1,068	0	0	-1,068
Dec 31, 2010	Acquisition costs	844	3,942	3,351	784	8,921
	Additions	32	0	0	2,775	2,807
	Disposals	-60	-1,643	-3,351	0	-5,054
Dec 31, 2011	Acquisition costs	816	2,299	0	3,559	6,674
Jan 1, 2010	Accumulated amortization	607	3,203	726	78	4,614
	Additions	34	709	0	134	877
	Disposals	0	-1,068	0	0	-1,068
Dec 31, 2010	Accumulated amortization	641	2,844	726	212	4,423
	Additions	62	776	2,625	494	3,957
	Disposals	-60	-1,617	-3,351	0	-5,028
Dec 31, 2011	Accumulated amortization	643	2,003	0	706	3,352
Dec 31, 2010	Carrying values	203	1,098	2,625	572	4,498
Dec 31, 2011	Carrying values	173	296	0	2,853	3,322

In former years, the underlying assumptions and expectations for the impairment test of the capitalized goodwill had been based on the commercialization potential of the blood-based colorectal cancer test targeted on the Septin9 biomarker. In the reporting year, the product development plans for the Epi proColon<sup>®</sup> 2.0 product have further been implemented and materialized now in the balance sheet as capitalized development costs. The cash flow projections from the Company's most recent business plans regarding the Epi proColon<sup>®</sup> test were therefore reallocated to determine the recoverability of this development asset. As a consequence, these future cash flows could no longer serve for the impairment test of the goodwill which had been allocated to the cancer screening business of the Company apart from the Epi proColon<sup>®</sup> sales as the underlying cash-generating unit. The overall projections for this cancer screening business were of course impacted by the restructuring of the Company in the reporting year, as this restructuring included a downsizing of the Company, i.e. a cutback of its development capacities.

In December 2011, the capitalized goodwill was tested for impairment in order to comply with IFRS 3 *Business Combinations* and IAS 36 *Impairment of Assets*. The Company's current business plan projections for the cancer screening business were used for the test taking into account the aforementioned considerations. According to this plan, future cash inflows will be generated in a partnering model from direct

product sales as well as from milestone payments, R&D payments, and royalty income by third parties. The plans are based on the existing and future collaboration contracts with the Company's partners. Growth rates were anticipated in line with industry comparables. Due to the business model, the expected product life cycle and the underlying terms of the patents, cash flows were planned for a period of ten years. All future cash flows are measured by the net present value method. The appropriate discount rate, which has been applied in the reporting year, was 25%.

The value of the capitalized goodwill could not be construed anymore as a recoverable amount and the management of Epigenomics has recognized an impairment of the capitalized goodwill, resulting in an impairment charge in the full amount of EUR 2,625 thousand.

Total amortization added up to EUR 3,957 thousand in 2011. Included here is – apart from the aforementioned goodwill amortization – further unscheduled amortization of EUR 988 thousand. This amount was recorded in connection with the restructuring of the Company in the reporting year and was affected by the impairment of some in-licensend technologies (EUR 657 thousand) and capitalized development costs for Epi proLung<sup>®</sup> (EUR 331 thousand). In all cases the previously reported book values could not be confirmed anymore by the expected recoverable amounts derived from future utilization.

## TANGIBLE ASSETS

EUR thousand		Fixtures/ leasehold improve- ments	Technical equipment	Other fixed assets	Total tangible assets
Jan 1, 2010	Acquisition costs	541	4,082	92	4,715
	Additions	0	233	11	244
	Disposals	0	-452	-6	-458
Dec 31, 2010	Acquisition costs	541	3,863	97	4,501
	Additions	0	353	4	357
	Disposals	-12	-1,204	-3	-1,219
Dec 31, 2011	Acquisition costs	529	3,012	98	3,639
Jan 1, 2010	Accumulated depreciation	524	3,561	58	4,143
	Additions	8	251	6	265
	Disposals	0	-445	-6	-451
Dec 31, 2010	Accumulated depreciation	532	3,367	58	3,957
	Additions	1	342	6	349
	Disposals	-11	-1,159	-3	-1,173
Dec 31, 2011	Accumulated depreciation	522	2,550	61	3,133
Dec 31, 2010	Carrying values	9	496	39	544
Dec 31, 2011	Carrying values	7	462	37	506

Total depreciation added up to EUR 349 thousand in 2011. Included here is unscheduled depreciation of EUR 25 thousand. This amount was recorded in connection with the restructuring of the Company in the reporting year. In all cases the previously reported book values could not be confirmed anymore by the expected recoverable amounts derived from future utilization.

## **12** ASSETS SCHEDULE

EUR thousand		Intangible assets	Tangible assets	Total assets
Jan 1, 2010	Acquisition costs	9,367	4,715	14,082
	Additions	622	244	866
	Disposals	-1,068	-458	-1,526
Dec 31, 2010	Acquisition costs	8,921	4,501	13,422
	Additions	2,807	357	3,164
	Disposals	-5,054	-1,219	-6,273
Dec 31, 2011	Acquisition costs	6,674	3,639	10,313
Jan 1, 2010	Accumulated depreciation/amortization	4,614	4,143	8,757
	Additions	877	265	1,142
	Disposals	-1,068	-451	-1,519
Dec 31, 2010	Accumulated depreciation/amortization	4,423	3,957	8,380
	Additions	3,957	349	4,306
	Disposals	-5,028	-1,173	-6,201
Dec 31, 2011	Accumulated depreciation/amortization	3,352	3,133	6,485
Dec 31, 2010	Carrying values	4,498	544	5,042
Dec 31, 2011	Carrying values	3,322	506	3,828

#### **13** DEFERRED TAX ASSETS

	Deferred tax assets		Deferred tax liabilities	
EUR thousand	Dec 31, 2010	Dec 31, 2011	Dec 31, 2010	Dec 31, 2011
Intangible and tangible assets	217	208	177	856
Current assets	2	0	2	0
Current liabilities	40	55	0	0
Total	259	263	179	856

For the Group, deferred taxes arise furthermore as described in the following table:

Since all the aforementioned matters must be settled with the same fiscal authority, in accordance with IAS 12.71 et seqq. *Income Taxes,* a balancing of the respective tax income and expenses has been performed. According to the table above, a deferred tax liability of EUR 593 thousand (net) was determined.

Since its inception through December 31, 2010, the Company's tax loss carryforwards in Germany amounted to approximately EUR 123 million for corporate taxation and to approximately EUR 122 million for trade taxation. In addition, the Company expects to increase its cumulated tax losses for both types of taxes by around EUR 16 million with the filing of its tax returns for 2011. According to German tax law, such tax losses have an unlimited carryforward period. As the deductibility of the tax loss carryforwards has been partially challenged by the German tax authorities in the past, it is not certain to which extent these carryforwards will lead to deferred tax income in the future. However, the undisputable part of the tax loss carryforwards amounts to more than EUR 20 million. The resulting deferred tax asset is therefore sufficient to offset the aforementioned deferred tax liability of EUR 593 thousand. Due to the current financial situation of the Company, without sufficient liquidity to achieve the break-even point, valuation allowances have been recognized for the calculated exceeding amount of deferred tax assets.

In former years, deferred tax assets had been capitalized due to tax loss carryforwards of Epigenomics, Inc. and temporary differences between IFRSs and U.S. tax law (see also notes item 8 "Taxes on income"). Deferred tax assets have been capitalized based on the taxable profits generated in connection with the existing transfer price agreement between Epigenomics, Inc. and Epigenomics AG. The usage of a cost plus method according to this agreement leads to a guaranteed annual profit for Epigenomics, Inc., so that a utilization of its tax loss carryforwards in the foreseeable future is sufficiently probable.

At the balance sheet date, these deferred tax assets were valued at EUR 214 thousand. A capitalization of even larger claims against the U.S. tax authorities was waived insofar as such claims are currently not accepted yet and the possibility of a later utilization is uncertain, respectively. The tax loss carryforwards of Epigenomics, Inc. add up to USD 1.4 million and can be utilized for up to 20 years.

Changes in capitalized deferred tax assets in the reporting year:

EUR thousand	2010	2011
January 1	391	421
Deferred tax expenses	0	-211
Foreign currency adjustment	30	4
December 31	421	214

CURRENT ASSETS

## **14** INVENTORIES

EUR thousand	Dec 31, 2010	Dec 31, 2011
Consumables, raw materials, supplies	111	64
Finished goods	51	219
Total inventories	162	283

## **15** TRADE RECEIVABLES

Trade receivables primarily include receivables from development partners, customers and licensees. These receivables do not bear interest and are therefore not exposed to any interest rate risk. The carrying amounts of the receivables correspond to their fair values. The maximum default risk corresponded to the carrying value as of the balance sheet date.

EUR thousand	Dec 31, 2010	Dec 31, 2011
Trade receivables, gross	482	211
Allowance for bad debt	-6	0
Trade receivables, net	476	211

At the balance sheet date, trade receivables in the amount of EUR 58 thousand were not due (Dec 31, 2010: EUR 274 thousand). Further trade receivables in the amount of EUR 134 thousand were not yet invoiced at the balance sheet date (Dec 31, 2010: EUR 157 thousand).

Receivables past due at the balance sheet date:

EUR thousand	Dec 31, 2010	Dec 31, 2011
Trade receivables past due up to 30 days	13	0
Trade receivables past due 31-60 days	0	0
Trade receivables past due 61-90 days	23	0
Trade receivables past due more than 90 days	9	0
Trade receivables, net	45	0

### **16** MARKETABLE SECURITIES

All marketable securities in the amount of EUR 1,428 thousand as of December 31, 2011 (Dec 31, 2010: EUR 1,815 thousand) are recognized as financial instruments "available for sale" according to IAS 39.9 *Financial Instruments: Recognition and Measurement.* 

Under the investment policy of the Company, each investment in securities is subject to 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". However, the Company has not invested in any marketable securities during the last six years.

All reported securities are subject to the usual market and interest risks. The interest rate risks are price risks and interest rate cash flow risks. Currency risks are minimized by avoiding investments in securities nominated in currencies other than the euro.

The fair value of all marketable securities is identified by their stock exchange quotations at each relevant balance sheet date. All securities have been traded on active markets in the reporting year.

EUR thousand	Dec 31, 2010	Dec 31, 2011
Corporate bonds	1,534	1,428
Debt certificates	281	0
Total marketable securities	1,815	1,428

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

	Dec 31, 2010		Dec 31, 2011	
Time to maturity of marketable securities	Fair value EUR thousand	in %	Fair value EUR thousand	in %
less than 12 months	0	0.0	986	69.0
13-24 months	972	53.5	0	0.0
25-60 months	562	31.0	442	31.0
unlimited	281	15.5	0	0.0
Total marketable securities	1,815	100.0	1,428	100.0

## **17** CASH AND CASH EQUIVALENTS

Cash and cash equivalents decreased to EUR 12,557 thousand at the balance sheet date (Dec 31, 2010: EUR 24,554 thousand). Approximately 97.5% of those funds were denominated in euro at the balance sheet date. The remainder is predominantly denominated in U.S. dollar. The total amount is allocated to three different banks.

EUR thousand	Dec 31, 2010	Dec 31, 2011
Time deposits	23,936	12,089
Bank accounts, petty cash, cheques	618	468
Total cash and cash equivalents	24,554	12,557

## **18** OTHER CURRENT ASSETS

EUR thousand	Dec 31, 2010	Dec 31, 2011
Prepaid expenses	901	576
Receivables from tax authorities	233	205
Claims based on granted projects	89	84
– thereof: claims against public authorities	89	84
Interest receivables	38	27
Excess payments	13	0
Advance payments	9	8
Other	85	42
- thereof: with a prospective maturity > 1 year	38	38
Total other current assets	1,368	942

EQUITY

### **19** SHARE CATEGORIES AND CAPITAL STRUCTURE

As of December 31, 2011, the share capital of Epigenomics AG comprised exclusively common shares with equal rights and a par value of EUR 1.00 each. As approved by the Company's Annual General Shareholders' Meeting (AGM) on June 28, 2011, a 5:1 reverse split of the Company's share capital has been implemented during the reporting year. On August 8, 2011, 5 (five) old Epigenomics shares (security code number: A0BVT9) were exchanged by 1 (one) new Epigenomics share (security code number: A1K051). Hereby, the share capital was reduced from the previous total of EUR 44,092,085 to EUR 8,818,417, allocated to 8,818,417 shares outstanding. No new shares have been created by the exercise of stock options during the reporting period.

EUR	Dec 31, 2010	Dec 31, 2010 pro forma	Dec 31, 2011
Share Capital	44,092,085	8,818,417	8,818,417
Conditional Capital	2,925,964	585,191	853,914
Conditional Capital III	139,625	27,925	0
Conditional Capital IV	617,426	123,485	123,485
Conditional Capital V	647,679	129,535	129,535
Conditional Capital VII	1,521,234	304,246	304,246
Conditional Capital VIII	0	0	296,648
Authorized Capital	0	0	4,409,207
Authorized Capital 2011/I	0	0	881,841
Authorized Capital 2011/II	0	0	3,527,366

The following table shows the equity structure of the Company as of December 31 with an extra pro forma column to demonstrate the effect of the capital decrease during the reporting year.

Conditional Capital IV and V cannot be used anymore to grant stock options as the underlying authorization for a granting time frame has expired. However, new shares can still be created upon exercise of options from these older programs.

Conditional Capital VII allows the creation of new shares upon the exercise of stock options granted under the stock option program (09-13). During the reporting year, a total number of 81,800 stock options has been granted to members of the Company's Executive Board and to its employees from this stock option program.

Conditional Capital VIII allows the creation of new shares upon the exercise of stock options granted under the stock option program (11-15) as approved by the AGM on June 28, 2011. During the reporting year, a total number of 20,000 stock options has been granted to employees of the Company from this stock option program.

In the AGM on June 28, 2011, the shareholders of the Company resolved upon creating two authorized capitals ("Authorized Capital 2011/I" and "Authorized Capital 2011/II") and the corresponding addition of Section 5 paragraph 9 and 10 to the Company's Articles of Association. Under the Authorized Capital 2011/I, the Executive Board is authorized to increase, with the consent of the Supervisory Board, the share capital of the Company at any time or from time to time on or before June 27, 2016, by up to EUR 881,841.00 by issuing up to 881,841 new no-par value bearer shares in return for contributions in cash and/or in kind, whereby, in case of a capital increase against contribution in cash, shareholders have, in principle, a pre-emptive right. Under the Authorized Capital 2011/II, the Executive Board is authorized to increase, with the consent of the Company at any time or from time to time on or before June 27, 2016, by up to a capital increase against contribution in cash, shareholders have, in principle, a pre-emptive right. Under the Authorized Capital 2011/II, the Executive Board is authorized to increase, with the consent of the Supervisory Board, the share capital of the Company at any time or from time to time on or before June 27, 2016, by up to EUR 3,527,366.00 by issuing up to 3,527,366 new no-par value bearer shares in return for contributions in cash and/or in kind, whereby, in case of a capital increase against contribution in cash, shareholders have, in principle, a pre-emptive right. The Authorized Capital 2011/II and the Authorized Capital 2011/II as well as the corresponding amendment of the Articles of Association were registered with the commercial register on August 3, 2011.

## **20** CAPITAL RESERVE

In the reporting year, the capital reserve increased from EUR 22,078 thousand at December 31, 2010, to EUR 22,212 thousand at December 31, 2011, exclusively due to stock option expenses.

## **21** RETAINED EARNINGS

Retained earnings increased from EUR -22,494 thousand at the end of the previous year to EUR 1,303 thousand at December 31, 2011. This improvement was attributable to the aforementioned capital decrease. The reduction in share capital of EUR 35,274 thousand was utilized in the full amount for settlement of all accumulated losses, including the net loss of 2010.

## **22** OTHER COMPREHENSIVE INCOME

The other comprehensive income arises from the revaluation of financial assets available for sale not affecting net income. The effective sale of revaluated financial assets available for sale leads to a recognition of the cumulated differences through profit or loss.

EUR thousand	2010	2011
January 1	1,044	905
Adjustments from the sale of marketable securities	-20	-461
Revaluation of marketable securities	-119	128
December 31	905	572

## **23** CAPITAL MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximizing the long-term return to stakeholders. An optimization of the debt/equity ratio is always considered.

The balance sheet structure of the Group consists of current liabilities, cash and cash equivalents, instruments available for sale and equity attributable to equity holders, comprising subscribed capital, capital reserve (including offset retained earnings) and other comprehensive income.

In 2011, the Group's equity ratio decreased from 92.5% as of December 31, 2010, to 83.2% as of December 31, 2011.

The Company is not subject to any statutory capital requirements. However, the Company is obliged to issue new shares in connection with its existing stock option programs.

CURRENT LIABILITIES

## **24** TRADE PAYABLES

The reported trade payables are all non-interest-bearing and are generally due within 30 days.

## **25** DEFERRED INCOME

Payments received in advance for services to be rendered by Epigenomics AG in the future are recorded as deferred income. The payments received for commercial collaborations are recognized as revenue over the respective contractual terms. The payments received for granted projects are recognized as other income according to the percentage of completion method. There is no repayment obligation for Epigenomics.

EUR thousand	Dec 31, 2010	Dec 31, 2011
Payments for commercial collaborations	214	0
Payments for granted projects	26	0
Total deferred income	240	0

## **26** OTHER LIABILITIES

EUR thousand	Dec 31, 2010	Dec 31, 2011
Payables due to staff	384	390
Payables for onerous rental agreements	0	251
Payables due to tax authorities	196	218
Accrued audit fees	107	105
Down payments received	3	35
Accrued Supervisory Board fees	17	4
Payables due to social security institutions	26	2
Liabilities from derivative instruments	144	2
Other	13	6
Total other liabilities	890	1,013

Payables for onerous rental agreements of EUR 251 thousand were recognized for the Company's office space in Seattle in connection with the restructuring of the Company and the planned relocation of the U.S. subsidiary.

## 27 **PROVISIONS**

As of December 31, 2011, the provisions of the Company added up to EUR 1,036 thousand (Dec 31, 2010: EUR 270 thousand). Substantially, they were recognized for:

- possible obligations from onerous rental agreements following the Company's restructuring in 2011;
- possible obligations from licensing contracts, depending on outstanding decisions from patent courts;
- possible obligations against employees due to the German employee invention act and from potential redundancy claims;
- expenses in connection with the Annual General Shareholders' Meeting and
- other operating obligations which were uncertain at the reporting date regarding their exact amounts or the point in time when they will incur.

While a utilization of the other provisions is largely expected within the next 12 months, a utilization of the contract-related and the payroll provisions could lie in more than 12 months' time.

Statement of changes in current provisions:

	Contract-			
	related	Payroll	Other	
EUR thousand	provisions	provisions	provisions	Total
January 1, 2010	188	311	72	571
Utilization	0	-80	-56	-136
Reversal	0	-227	-6	-233
Additions	0	0	68	68
December 31, 2010	188	4	78	270
Utilization	0	0	-69	-69
Reversal	0	0	-9	-9
Additions	704	93	47	844
December 31, 2011	892	97	47	1,036

### 28 **FINANCIAL INSTRUMENTS**

 AC
 = Amortized Cost

 FV Rec. Eq.
 = Fair Value Recognized in Equity

 FV Rec. PL
 = Fair Value Recognized in Profit or Loss

Primary financial instruments		Dec 31, 2	2010	Dec 31,	2011
EUR thousand	Valuation principle	Carrying amount	Fair value	Carrying amount	Fair value
Assets					
Loans and receivables	AC	693	693	362	362
Trade receivables		476	476	211	211
Other current assets		217	217	151	151
Financial assets available for sale	FV Rec. Eq.	1,815	1,815	1,428	1,428
Marketable securities		1,815	1,815	1,428	1,428
Cash and cash equivalents	n/a	24,554	24,554	12,557	12,557
Liabilities					
Financial liabilities measured					
at amortized cost	AC	1,531	1,531	1,895	1,895
Trade liabilities		1,134	1,134	1,228	1,228
Liabilities from leasing contracts		9	9	0	0
Other current liabilities		388	388	667	667

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Derivative financial instruments		Dec 31, 20	10	Dec 31, 20	11
EUR thousand	Valuation principle	Carrying amount	Fair value	Carrying amount	Fair value
Liabilities					
Financial liabilities held for trading	FV Rec. PL	144	144	2	2
Currency forward contracts		144	144	2	2

## NOTES TO THE GROUP CASH FLOW STATEMENT

## **29** OPERATING ACTIVITIES

Cash flow from operating activities is derived indirectly on the basis of the net loss for the year before taxes on income. Cash comprises bank deposit and cash in hand. Cash equivalents are defined as instruments being convertible on a short-term basis to a known amount of cash, highly liquid financial instrument, which carry a very low risk of changes in value.

## **30** INVESTING ACTIVITIES

Cash flow from investing activities is ascertained in respect of payment.

## **31** FINANCING ACTIVITIES

Cash flow from financing activities is ascertained in respect of payment.

Payments for the creation of new shares in the reporting year of EUR 36 thousand were related fully to the Company's capital decrease in August 2011.

## **32** CASH CONSUMPTION

The total of cash flow from operating activities and cash flow from investing activities less transactions in securities is monitored by the Company as "cash consumption" key figure.

EUR thousand	2010	2011
Cash flow from operating activities	-9,479	-9,111
Cash flow from investing activities	-315	-2,842
Net proceeds from transactions in securities	-500	-288
Cash consumption	-10,294	-12,241

## RISKS AND RISK MANAGEMENT

## **33** GENERAL

For a comprehensive overview of the risks the Company is facing reference is made to the "Opportunities and Risks" section of the Group management report 2011 as well as in particular to the prospectus prepared for the capital increase executed in March 2010. This document is available on the Company's website (*www.epigenomics.com*).

## **34** LIQUIDITY RISK

The liquidity risk of Epigenomics results from the Group's potential inability to meet its financial liabilities, i.e. not paying its suppliers, creditors or lenders. It is therefore the task of the cash and liquidity management to assure the individual Group companies' liquidity at any time. The expected cash inflows and outflows are constantly monitored to ensure short-term liquidity. These activities are supported by internal cash forecasts and a corresponding strategy of managing time deposits with the Company's house banks.

Furthermore, Epigenomics constantly monitors the capital markets and undertakes if required all necessary efforts to raise fresh capital in order to avoid illiquidity.

Epigenomics has a strict cost management in place to avoid unnecessary spending. On the procurement side the Company always tries to reduce purchase prices by closing favorable contracts and negotiating all relevant conditions and takes advantage of granted terms of payment.

## **35** FOREIGN CURRENCY EXCHANGE RISK

The Group constantly faces a foreign currency exchange risk through the fluctuations between the euro and the U.S. dollar as well as to a limited extent the British pound sterling. The risk mainly originates from the need to purchase goods and services partially in U.S. dollar. Also, certain services of the Group are sold in U.S. dollar. The Group constantly tries to mitigate or to eliminate this risk as far as possible. Wherever possible, the Group exerts its influence in negotiations to avoid this risk and mainly uses derivative financial instruments in the shape of forward contracts to minimize this risk. These instruments are recognized at fair value on the consolidated balance sheet as current assets or short-term liabilities.

At the balance sheet date, a so-called "Target Profit Forward" contract has been in place to secure the Group's requirements for U.S. dollars throughout the following business year. According to this contract, the Group has the right [the obligation] to buy USD 300 thousand [USD 450 thousand] at a fixed exchange rate of EUR/USD 1.3750 at the end of each calendar month if the actual exchange rate of this currency pair at these points in time is below EUR/USD 1.3750 [is above EUR/USD 1.4200]. The right to buy USD 300 thousand at the end of each calendar month at EUR/USD 1.3750 while the actual rate is below EUR/USD 1.3750 is limited up to a cumulative difference of EUR/USD 0.25. Once this cumulative difference is exceeded, the contract will be terminated.

Due to the limited volume of positions denominated in foreign currencies at the reporting date, an increase or a decrease of the euro to the U.S. dollar by 10% each, provided that all other assumptions were to remain unchanged, would (as in the previous year) not have led to substantial changes in the net result of the Group or in its equity.

## **36** CREDIT RISK

The Company's overall credit risk is low. Securities have only been acquired under careful observation of the Company's investment policy, i.e. a strict selection by the credit ratings of the issuers has been conducted. However, the worldwide financial market crisis over the last years has shown that even top-rated issuers can suddenly face a threatening situation or even collapse. Additionally, it has become clear that there is a pending risk of illiquid markets.

Trade receivables basically concern renowned commercial partners with acceptable ratings. Whenever possible, payments are collected upfront. In all cases, the maximum amount at risk can be derived from the carrying values.

## **37** INTEREST RATE RISK

The Group holds interest-bearing financial instruments in the form of cash and cash equivalents (daily and time deposits) and of selected securities.

As the Group's time deposits have usually maturities of up to a maximum of 360 days, the interest rate risk of these financial instruments can be considered negligible. Being free of long-term financial debt, the Group faces no interest rate risk on the borrowing side at all.

However, the securities held by the Group with maturities of more than one year are subject to an interest rate risk as the terms and conditions for interest payments depend on the development of the long-term interest rates on the capital markets. In a worst-case scenario, the Group would receive no interest payments at all from the issuers of these securities but in no case will it have a negative interest income (i.e. it will not pay interest).

INFORMATION ON STOCK OPTION PROGRAMS<sup>2</sup>

### **38** STOCK OPTION PROGRAMS IN PLACE

As of the balance sheet date, the Epigenomics Group (via Epigenomics AG) had four fixed stock option programs (SOPs) in place. Details of the three programs 03-07, 06-10 and 09-13 can be found in the Company's prospectus for the capital increase dated March 12, 2010. This document is available on the Company's website. The two programs 03-07 and 06-10 have expired as of the balance sheet date, i.e. no stock options can be granted from those programs in the future.

In general, the rights under all four programs are such that option holders can obtain shares in the Company by exercising their options once all exercise hurdles have been surpassed. In order for options to be exercisable, the stock price must have appreciated by at least 10% versus the applicable share price at grant date and the legally required waiting period as well as vesting must have been completed. If employees leave the Company before the options are vested these forfeit without compensation.

Stock options can only be granted from the SOPs 09-13 and 11-15. SOP 11-15 was introduced in 2011 and approved by the Annual General Shareholders' Meeting (AGM) on June 28, 2011. The Company's share capital was therefore conditionally increased by up to 3.36% of the share capital registered before the capital increase, i.e. by up to EUR 296,648.00 by issuance of up to 296,648 bearer shares of common stock with an accounting par value of EUR 1.00 each (Conditional Capital VIII). The Executive Board of the Company is authorized until December 31, 2015, to issue subscription rights with respect to shares out of the stock option program 11-15 in one or more annual tranches in favor of beneficiaries according to the conditions of this program. In case of Executive Board members being beneficiaries, only the Supervisory Board can grant such options.

Each individual subscription right entitles the beneficiary to subscribe to one bearer share of common stock of the Company with a par value of EUR 1.00 each against payment of the exercise price. Beneficiaries of the program are the Company's Executive Board members ("group 1"; a maximum of 60% of the total volume) and the employees of the Company and of affiliated companies, but excluding the members of the Management Board of affiliated companies ("group 2"; a maximum of 40% of the total volume).

The subscription rights in every tranche shall vest for the group-2-beneficiaries as follows: one-third of the subscription rights issued in one tranche shall vest one year after the issuance of the subscription rights of such tranche; a further one-third of the subscription rights issued in one tranche shall vest two years after the issuance of the subscription rights of such tranche; the final one-third of the subscription rights issued in one tranche shall vest three years after the issuance of the subscription rights of such tranche; the final one-third of the subscription rights issued in one tranche shall vest three years after the issuance of the subscription rights of such tranche.

<sup>2</sup> All numbers, share prices and values are based on the Company's capital structure after the capital decrease in August 2011. In order to ensure the comparability, the concerned figures for 2010 have been adjusted retroactively.

The subscription rights of every tranche shall vest completely or partially for group-1-beneficiaries, if and to the extent that the Supervisory Board of the Company declares such vesting of subscription rights vis-à-vis a group-1-beneficiary in compliance with the rules set out hereafter.

Subscription rights of each tranche can be exercised for the first time after their vesting as described before and after expiration of the waiting period. The waiting period starts with the issuance of the subscription rights of a tranche and ends four years after the issuance of these subscription rights.

The term of the subscription rights of every tranche begins with the issuance of the subscription rights of such tranche and ends with the expiration of seven years after the issuance of these rights.

The subscription rights can only be exercised against payment of the exercise price to the Company. For the calculation of the exercise price, the average stock exchange closing price on the 20 stock exchange trading days preceding the issuance of the subscription rights in the Exchange Electronic Trading (XETRA system) will be compared with the most recently available stock exchange closing price of the share on the day before the subscription rights were issued. The exercise price is defined as the higher of these two values increased by 10%. Furthermore, the subscription rights can only be exercised in case the average price of the Company's share has reached or surpassed the payable exercise price at least once within the period between the issuance of the subscription rights and the exercise of these rights (performance target).

Any subscription rights of a beneficiary that have not yet vested expire without compensation in any case upon termination of the employment or work contract with the beneficiary, irrespective of the reason for such termination. The expiration date is the day on which the employment or work contract ends.

The subscription rights granted to the beneficiaries under the stock option program 11-15 are non-transferable. In case subscription rights are not or cannot be exercised until the end of their term, they expire without compensation.

The new shares shall participate in the profit from the beginning of the fiscal year in which they are issued.

### **39** INFORMATION ON STOCK OPTIONS IN THE REPORTING YEAR

In the reporting year, 81,800 stock options were granted under the SOP 09-13 to Executive Board members and employees of the Company. Additionally, 20,000 stock options were granted to employees of the Company under the SOP 11-15. Each option right entitles the holder to subscribe to one bearer share of common stock with a par value of EUR 1.00 each in return for payment of the exercise price. The exercise price equals the higher of the average closing price of the underlying share in the Exchange Electronic Trading (XETRA system) on the 20 stock exchange trading days preceding the issuance of the subscription rights and the XETRA closing price of the share on the day the subscription rights were issued, increased by 10%.

Total

Expiry date	Jan 1, 2018	Apr 1, 2018	July 1, 2018	Oct 4, 2018	2018
Number of granted stock options	38,000	20,000	23,800	20,000	101,800
Applicable share price at					
grant date (in EUR)	10.05	8.73	6.28	4.26	
Exercise price (in EUR)	11.05	9.60	6.91	4.69	
Historical volatility at grant					
date (in %)	58.1	59.0	56.4	57.5	
Risk-free interest rate (in %)	1.24	2.15	1.83	0.81	
Aggregate proceeds if shares					
are issued (in EUR)	419,900	192,000	164,384	93,800	870,084

# A total of 414,099 stock options can still be granted to the Company's employees and Executive Board members from the SOPs 09-13 (137,451) and 11-15 (276,648).

	Options issued as of	Issued	Forfeited	Cancelled	Exercised	Options issued as of	Options exercisable as of
	Dec 31, 2010		in 2011 Dec 31, 201		2011		
Option holder							
Geert W. Nygaard	57,000	20,000	0	0	0	77,000	4,666
Dr. Thomas Taapken	0	20,000	0	0	0	20,000	0
Total Executive Board	57,000	40,000	0	0	o	97,000	4,666
Oliver Schacht, Ph.D.	49,000	0	10,000	11,667	0	220.050	52 157
Other option holders	177,990	61,800	18,293	27,871	0	220,959	53,157
All option holders	283,990	101,800	28,293	39,538	0	317,959	57,823
Average exercise price (in EUR)	19.19	8.55	22.05	15.09	n/a	16.08	14.35

Terms of outstanding stock options:

	Weighted-average	Stock options	Weighted-average	Stock options
	exercise price	issued and	exercise price	issued and
	in EUR	outstanding	in EUR	outstanding
	as of	as of	as of	as of
Term	Dec 31, 20	010	Dec 31, 20	011
2011	22.65	24,340	22.65	0
2012	40.65	68	40.65	68
2013	27.30	21,588	27.30	20,300
2014	22.50	83,599	22.50	83,595
2015	10.53	6,000	10.53	6,000
2016	13.40	67,000	13.41	56,331
2017	18.00	81,400	18.00	63,265
2018	n/a	0	8.25	88,400
Total		283,995		317,959

## OTHER INFORMATION

### 40 INFORMATION ON THE EXECUTIVE BOARD AND THE SUPERVISORY BOARD OF THE COMPANY AND THEIR REMUNERATION

Members of the Executive Board of the Company during the reporting year were:

- Geert Walther Nygaard, Berlin (D), Chief Executive Officer,
- Dr. Thomas Taapken, Berlin (D), Chief Financial Officer (since April 1, 2011),
- Oliver Schacht, Ph.D., Seattle, WA (U.S.A.), Chief Financial Officer; Chief Executive Officer of Epigenomics, Inc. (until March 31, 2011).

In 2011, the total remuneration of the members of the Executive Board amounted to EUR 663 thousand (2010: EUR 931 thousand), comprising EUR 620 thousand in fixed compensation (2010: EUR 621 thousand), EUR 28 thousand in bonus payments (2010: EUR 300 thousand) and EUR 15 thousand in other compensation payments (2010: EUR 10 thousand). A total of 40,000 stock options with a fair value at grant date of EUR 87 thousand have been granted to the members of the Executive Board in 2011 (2010: 28,000 stock options with a fair value at grant date of EUR 130 thousand).

In case of a change of control, Mr. Nygaard and Dr. Taapken are entitled to terminate their service agreements and would in such case be entitled to receive payment of the fixed compensation amounts for the time remaining until their service agreements would have anyhow terminated.

Members of the Supervisory Board of the Company during the reporting year were:

- Prof. Dr. Dr. h. c. Rolf Krebs, Mainz (D), Chairman
- Prof. Dr. Dr. Dr. h. c. Uwe Bicker, Bensheim-Auerbach (D), Deputy Chairman
- Joseph Anderson, Ph.D., Oxted, Surrey (GB)
- Günter Frankenne, Berg/ Neumarkt (D)
- Ann Clare Kessler, Ph.D., Rancho Santa Fe, CA (U.S.A.)
- Prof. Dr. Günther Reiter, Pfullingen (D)

In 2011, total remuneration of the members of the Supervisory Board amounted to EUR 153 thousand (2010: EUR 149 thousand) plus out-of-pocket expenses amounting to EUR 23 thousand (2010: EUR 27 thousand).

Further details to the composition of the Executive Board and the Supervisory Board and the compensation of their members in the reporting year can be found in the "Compensation Report" section of the Group management report 2011.

## **4 OTHER FINANCIAL OBLIGATIONS**

For the Epigenomics Group, other financial obligations arise from a total of two leases at the Berlin and Seattle locations:

- a) For the Berlin location at Kleine Präsidentenstrasse 1, there is a fixed-term lease with a term expiring on August 31, 2014. Until this date, a total rent of approximately EUR 960 thousand (undiscounted) has to be paid.
- b) For the Seattle location, there is a fixed-term lease with a term expiring on June 30, 2017. Until this date, a total rent of approximately USD 1.8 million (undiscounted) has to be paid. This contract includes an option for early termination as of November 30, 2012. In connection with such an early termination, Epigenomics would have to pay a total rent of USD 202 thousand for the period from January 1, 2012, to November 30, 2012, and early termination fees currently estimated at USD 673 thousand to the landlord.

In the previous years, Epigenomics acquired numerous exclusive licenses to third-party intellectual property. This means that there are some obligations to pay minimum license 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 office actions and are difficult to forecast regarding their amounts and timing. The expected amount due to various licensors stands at approximately EUR 400 thousand for the years 2012 and 2013.

Due to contracts with third parties, at the balance sheet date, Epigenomics had payment obligations of approximately EUR 244 thousand for goods and services to be received in 2012. However, as delivery dates and effective delivery quantities are to some extent uncertain, the future payments resulting from those contracts could also be lower.

Resulting from the "Target Profit Forward" currency contract (as described under notes item 35 "Foreign currency exchange risk" and under the conditions valid at the balance sheet date), the Company faces the obligation to buy up to a total of USD 5.4 million in 2012 by paying a fixed euro amount up to a total of approximately EUR 3.9 million in twelve equal tranches at the end of each calendar month. Each transaction will have to be settled if the exchange rate at the end of the month is above EUR/USD 1.4200 and will in each case result in an immediate currency exchange rate loss of at least EUR 10 thousand. This contract has been amended in favor of the Company after the balance sheet date to reflect the increase of the U.S. dollar vis-à-vis the euro towards the end of the reporting year. However, throughout 2012, the potential obligations for the Company remained on a level comparable to the previous year.

#### INFORMATION ON THE AUDITORS OF THE COMPANY 42

As in the previous years, UHY Deutschland AG had been chosen as the Company's auditing firm for the financial year 2011. During the reporting year, a total amount of EUR 149 thousand (2010: EUR 199 thousand) has been expensed for miscellaneous services of this auditing firm for Epigenomics AG. Details are shown in the following table:

EUR thousand	2010	2011
Costs for audit services	104	96
Costs for other confirmation services	95	51
Costs for other services	0	2
Total	199	149

The costs disclosed for the annual audits are related to the audits on the individual financial statements of Epigenomics AG according to German GAAP as well as on the consolidated financial statements for the Epigenomics Group according to IFRSs. Other confirmation services occurred for critical reviews of the quarterly reports.

### 43 STATEMENT OF THE EXECUTIVE BOARD AND THE SUPERVISORY BOARD OF EPIGENOMICS AG PURSUANT TO SECTION 161 OF THE GERMAN STOCK CORPORATION ACT (AKTIENGESETZ) WITH RESPECT TO THE **GERMAN CORPORATE GOVERNANCE CODE**

In December 2011, the Executive Board and the Supervisory Board of the Company issued the declaration of conformity in accordance with Section 161 of the German Stock Corporation Act (Aktiengesetz). The declaration has been published on the Company's website

(www.epigenomics.com/en/news-investors/investors/corporate-governance).

#### INFORMATION ON OTHER TRANSACTIONS WITH RELATED PARTIES 44

At the reporting date, the Company's payables due to members of its Executive Board amounted to EUR 2 thousand (Dec 31, 2010: EUR 189 thousand) and the liabilities due to members of its Supervisory Board amounted to EUR 89 thousand (Dec 31, 2010: EUR 38 thousand).

#### 45 **CLEARED FOR PUBLICATION**

These consolidated financial statements have been approved and cleared for publication by the Executive Board of the Company on February 29, 2012.

Berlin, February 29, 2012

The Executive Board

# **RESPONSIBILITY STATEMENT**

To the best of our knowledge, and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the Group, and the Group management report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group.

Berlin, February 29, 2012

The Executive Board

## AUDITOR'S REPORT

"We have audited the consolidated financial statements prepared by Epigenomics AG, Berlin, comprising the Group balance sheet, the Group statement of comprehensive income (Group income statement and statement of income and expenses recognized in Group equity), statement of changes in Group equity, Group cash flow statement and the notes to the consolidated financial statements, together with the Group management report for the business year from January 1 to December 31, 2011. The preparation of the consolidated financial statements and the Group management report in accordance with IFRS, as adopted by the European Union (EU), and the additional requirements of German commercial law pursuant to § 315a Abs. (paragraph) 1 HGB (Handelsgesetzbuch: German Commercial Code) and supplementary provisions of the articles of association are the responsibility of the parent company's management. Our responsibility is to express an opinion on the consolidated financial statements and on the Group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with § 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer (Institute of Public Auditors in Germany - IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the Group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the Group management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and Group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRS, as adopted by the EU, the additional requirements of German commercial law pursuant to § 315a Abs. (paragraph) 1 HGB and supplementary provisions of the articles of association and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The Group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development.

Furthermore, not intended to qualify our opinion, we point out that the financial statements are prepared on a going concern basis of the Group. However, based on the current plans and income projections the available liquidity of EUR 14.0 million at balance sheet date is not sufficient to sustain the Group's operations over the following 24 months. According to the Company's plans, to avoid illiquidity, fresh funds must be raised no later than in the second quarter 2013.

In case this required fund raising would not be realised by that time, it might be necessary for the Epigenomics AG to file for insolvency as early as in the second quarter of 2013. In this regard, we refer to the explanations regarding financial risks in the consolidated management report, in particular to the sections "Financial Opportunities and Risks" and "Outlook on the financial situation"."

Berlin, February 29, 2012

UHY Deutschland AG Wirtschaftsprüfungsgesellschaft

(Lauer) Wirtschaftsprüfer [German Public Auditor] (ppa. Kulla) Wirtschaftsprüferin [German Public Auditor]

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This publication expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Epigenomics AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Epigenomics AG is providing this statement as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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# CORPORATE CALENDAR

Report on Business 2011 – Annual press conference and analyst meeting in Frankfurt am Main	Friday, March 23, 2012
Annual General Shareholders' Meeting 2012 in Berlin	Wednesday, May 02, 2012
3-Month Report 2012 January 01–March 31, 2012	Wednesday, May 09, 2012
6-Month Report 2012 January 01–June 30, 2012	Wednesday, August 08, 2012
9-Month Report 2012 January 01–September 30, 2012	Wednesday, November 07, 2012



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