

epigenomics

ANNUAL REPORT 2012

Epi proColon®

2012

ADDRESSING THE LARGEST  
DIAGNOSTIC MARKET IN THE WORLD



## CONTENTS

Foreword by Dr. Thomas Taapken .....	<b>01</b>
Report of the Supervisory Board .....	<b>06</b>
Our stock .....	<b>12</b>
Consolidated Management Report .....	<b>15</b>
Consolidated Financial Statements .....	<b>45</b>
Notes to the Consolidated Financial Statements .....	<b>50</b>
Auditor's Report .....	<b>86</b>
Imprint .....	<b>88</b>

# FOREWORD

BY

**DR. THOMAS TAAPKEN**

CFO AND ACTING CEO

## **DEAR SHAREHOLDERS,**

By the close of 2012 we had completed a very busy year with significant further progress in our regulatory approval in the U.S. and commercialization plans for our blood-based colorectal cancer (CRC) screening assay, Epi proColon®.

➤ **OUR PRIMARY OBJECTIVE IN 2012** was to complete the development of our key value driver Epi proColon® and to ensure its success in the United States, the world's largest commercial market for molecular diagnostics, without losing sight of the European market. By completing submission of our Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) we achieved this important goal by the end of 2012.

2012 was also a critical year to ensure the future of Epigenomics since the scarcity of funds posed a threat to the execution of our plans. To allow greater operational efficiency we completed far-reaching restructuring measures as already announced in 2011 and implemented changes in our Supervisory and Executive Boards. These changes have already proven effective and allowed us to successfully complete a financing round in early 2013.

➤ **SUCCESSFUL COMPLETION OF FINAL REGULATORY CLINICAL TRIAL – SUBMISSION OF PMA APPLICATION.** In order to gain commercialization approval of Epi proColon® in the U.S., we had initiated the PMA process with the FDA early in the year. The first three data modules were submitted in the course of the year and we completed the application with submission of the fourth module, including all clinical data, by the end of 2012. At the request of the FDA, in addition to already existing data, we performed a head-to-head comparative study with the goal of demonstrating the non-inferiority of Epi proColon® to fecal immunochemical testing (FIT) in the detection of CRC. This clinical trial started in Q2 2012, after having agreed on the study protocol with the FDA, and was successfully completed before year-end.

In summary, Epi proColon® met the critically important endpoint of non-inferiority with respect to sensitivity compared to FIT. The sensitivity – or cancer detection rate – amounted to 71%. The FIT comparator used in the study showed a sensitivity of 67% and detected less cancer cases than Epi proColon®.

The difference in specificity of both methods – or the rate of correctly assessed non-cancer cases – was 81% for Epi proColon® and at 98% for FIT and is in line with previous studies performed with Epi proColon® and published data for FIT. The difference in specificity was anticipated and in our opinion is less vital, since patients will undergo a colonoscopy – the currently recommended screening procedure in the U.S. – as a result of a positive test result.

The results from this important study represent a decisive milestone for Epigenomics. Based on the achieved non-inferiority, we believe that Epi proColon® has demonstrated its value to be a patient friendly test for CRC detection. This could significantly drive awareness for colorectal cancer screening among those individuals that would otherwise be noncompliant. We are now in a productive dialog with the FDA regarding next steps towards potential product approval.

➔ **THE FINAL STEPS TO MARKET ARE NOW.** Important prerequisites in being commercially successful in the U.S. are the inclusion of our test in screening guidelines and the availability of reimbursement by insurance carriers. Also in this respect we made solid progress, although the decisive steps will only be possible once the FDA approval for Epi proColon® has been granted. In the meantime, we keep up our dedicated efforts to secure far-reaching support in the medical and laboratory customer communities and we further extended our existing network in the medical expert community during 2012. To this end, a major accomplishment has been the inclusion of Septin9 testing into the 2013 Current Procedural Terminology (CPT) coding document issued by the American Medical Association which is the basis for reimbursement by healthcare providers. Septin9 testing is now explicitly mentioned with its own code for possible future reimbursement.



Dr. Thomas Taapken, CFO and acting CEO

In parallel, we signed an additional non-exclusive licensing agreement for a laboratory-developed test (LDT) version of our Septin9 biomarker with Companion Dx Reference Lab. This is in line with our strategy to familiarize future potential customers with our test in order to prepare the market launch before the potential FDA approval of Epi proColon®. The agreement with Companion Dx complements our existing LDT arrangements with Quest, ARUP and Gamma Dynacare in North America. While so far we are only entitled to modest royalties on their test services provided, we expect these partners turning into Epigenomics customers once Epi proColon® is FDA approved. We are pleased to observe an encouraging market acceptance for Septin9 tests in North America with more than 45,000 tests performed in 2012 by our license partners compared to 26,000 tests in 2011.

Also in Europe, we had positive news to report despite our reduced sales and marketing efforts. Swiss Life, one of the largest private health insurance companies, decided to recommend the blood-based Septin9 test for the early detection of CRC to its customers in France as part of a preventive health program. This decision clearly confirms our focused commercialization approach by working closely with key players in the healthcare systems throughout Europe.

Overall, we are making solid progress on the commercial front. Patients obviously prefer blood-based tests over other established screening methods. This was confirmed in two independent studies and strengthens our view that providing Septin9-based testing will help physicians to detect CRC early and clearly improve patient health outcomes. With this in mind, we remain fully committed to the launch and distribution of Epi proColon® in the U.S., throughout Europe and other markets worldwide.

→ **MARKET ESTABLISHMENT OF EPI PROLUNG®, OUR SECOND TEST.** Our Epi proLung® BL Assay is an aid for the physician in the diagnosis of lung cancer. In 2012, results from an independent clinical study conducted by Professor Dr. Manfred Dietel of the Charité University Hospital in Berlin, Germany, impressively demonstrated the diagnostic performance of Epi proLung®. The combination of both cytological analysis and Epi proLung® resulted in a combined sensitivity of 98% at a specificity of 92%. Only one of the 54 confirmed lung carcinoma cases in the study was missed in the combined analysis. Based on these results, Charité has announced that the assay will be introduced into its clinical practice as a routine aid in the diagnosis of lung cancer in patients with negative or suspicious cytological results.

→ **EXTERNAL VALIDATION OF OUR APPROACH.** In 2012, additional positive results and data obtained from several studies with external academic collaborators were published. Among others, Professor Dr. Béla Molnár from the Semmelweis University in Budapest, Hungary, showed that our Septin9 biomarker detects CRC equally well on both sides of the colon, whereas other methods like colonoscopy and fecal testing typically fall behind in the detection for right-side cancerous lesions.

Another high-profile publication by Prof. Dr. Ebert from the University of Heidelberg, Germany, in the prestigious "The New England Journal of Medicine" reported the ability of our proprietary TFAP2E biomarker to predict CRC drug resistance against the widely used chemotherapy agent 5-fluorouracil (5-FU).

These two studies, as well as several others, further highlight the great potential of our DNA-methylation-based approach in cancer diagnostics and personalized medicine. Thanks to our broad patent portfolio and know-how in this field, Epigenomics continues to make significant contributions today and for many years to come.

➤ **FOCUS ON NEXT STEPS.** In 2012, Mr. Heino von Prondzynski was elected to our Supervisory Board and has assumed the role of Chairman. He is an internationally recognized expert and accomplished business leader in the field of molecular diagnostics. At the same time the shareholders voted in favor of a reduction of the size of the Supervisory Board to three members. The existing Supervisory Board members, Ms. Ann Clare Kessler, Ph.D., and Prof. Dr. Günther Reiter, were confirmed for a further term until the Annual General Meeting of shareholders in 2015, while our former Chairman Prof. Dr. Dr. h. c. Rolf Krebs; Mr. Joseph Anderson, Ph.D.; Prof. Dr. Dr. Dr. Uwe Bicker; and Mr. Günther Frankenre retired from their Supervisory Board positions. I would like to take the opportunity to thank them all for their valuable contributions over the many years of their Supervisory Board tenure.

In the third quarter, we announced my appointment to serve as acting CEO in addition to my responsibilities as CFO after the retirement of Geert W. Nygaard, a position which I gladly accepted. In connection with this, Dr. Uwe Staub was promoted to the newly created position of Chief Operating Officer.

The implemented structural changes in the Company and, consecutively, its governing bodies provide a higher overall efficiency and cost effectiveness, thus preparing us for the next important steps in the development of our company towards a commercially successful provider of molecular diagnostic products.

➤ **LOOKING AHEAD,** it remains our primary goal to bring the advantages of this convenient blood-based test to the benefit of patients. In order to achieve this, we successfully completed a financing round of EUR 5.0 million in early January 2013, which has extended the cash runway of the Company into Q4 2013. This financing brings the Company closer to a potential FDA approval for Epi proColon® and possible initial U.S. product revenues. Through the potential FDA approval and the successful commercialization of Epi proColon®, we will also create sustainable value for our shareholders.

As we go through 2013 we look forward to updating you regularly on the results of our work and the progress of our business activities, especially on major milestones in relation to the FDA regulatory process for Epi proColon®.

We will also continue to review all strategic options for the Company, including the possibility of a further capital increase in order to accelerate the commercialization of our cancer diagnostics. 2013 will be an exciting and pivotal year for Epigenomics and I am truly grateful to have the full support of our shareholders, employees, customers and partners.

Yours sincerely,

**Dr. Thomas Taapken**  
CFO and acting CEO

# REPORT

OF THE

## SUPERVISORY BOARD

### DEAR SHAREHOLDERS,

Your Company experienced profound changes in 2012 which were substantially derived from the restructuring measures already announced in 2011. Additionally, the uncertainties regarding the Company's future led to some employees feeling compelled to look for new challenges outside Epigenomics in 2012. However, we now assume that we have established the necessary degree of stability on a consolidated level, which shall enable us to achieve our ambitious goals in the future. The strategy was adapted to fit the financial circumstances, which should and must lead to a significantly lower burn rate. Today, the Company is focusing on two key elements: FDA approval for Epi proColon® and further development of the assay portfolio. Various strategic options were reviewed by the Supervisory Board in 2012 and with the same commitment it will be a focus of our work through 2013. Continuous evaluation of options and securing the Company's mid-term financial position will be key areas of ongoing activity for the Management and will be closely coordinated with the Supervisory Board at regular intervals. We are convinced the Company is on a solid path to successfully develop through the critical year 2013.

### WORK OF THE SUPERVISORY BOARD

Throughout 2012, the Supervisory Board fulfilled all its duties assigned to it by law, the Articles of Association and the Rules of Procedure. The Supervisory Board advised and monitored the Executive Board in managing the Company. The Supervisory Board was continuously informed about operational progress and key challenges, as well as the overall financial situation and findings from the risk management system of the Company. All corporate planning, including financial, capital expenditure and human resources as well as general business performance was reported on a regular basis by the Executive Board. To the extent that German corporate law or the existing Rules of Procedure required consent for certain decisions or actions of the Executive Board, such approvals were granted by the Supervisory Board after thorough deliberation and careful examination of oral reports and written documentation, which were provided.





Heino von Prondzynski, Chairman of the Supervisory Board

On the basis of detailed written and oral reports of the Executive Board, the Supervisory Board discussed all relevant issues during its meetings and telephone conferences. Among the important issues discussed regularly at the Supervisory Board meetings in 2012, the progress and subsequently the results of the head-to-head comparison study between Epi proColon® and FIT, the PMA application for the colorectal cancer screening test in the United States, human resources issues, and the overall financial situation of the Company were overarching topics of ongoing discussion. Furthermore, a regular assessment of possible strategic options for the Company in the fields of financing and business transactions was a matter of review and discussion throughout the year. Also, the approval of the annual and consolidated financial statements and the Company's business development issues concerning approvals for terms and conditions of new collaboration contracts were discussed. The Supervisory Board always took into account the interests of Epigenomics' shareholders.

During 2012, six ordinary plenary meetings of the Supervisory Board with the Company's Executive Board took place on January 17, March 16, May 2, June 11, September 3 and November 26. These meetings were held in Berlin, Frankfurt and once in Switzerland. All current members of the Supervisory Board at the respective time attended all the meetings.

In addition to the very close dialogue between all members of the Supervisory and the Executive Board in joint plenary meetings, multiple telephone conference calls and individual discussions were held. Thus, the Supervisory Board was continually kept up to date on the Company's current business situation and key events throughout the year. At its meeting on November 26, 2012 and a telephone conference on December 14, 2012 the Supervisory Board considered in detail the operational budgets, financial planning and human resource allocation plan for the fiscal year 2013.

For each meeting, all members of the Supervisory Board received comprehensive written reports in advance, prepared by the Executive Board with the input of the respective functional managers of the Company. 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 all official meetings and telephone conferences were always 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.

#### **ORGANIZATIONAL CHANGES IN THE BOARD IN 2012**

At the Company's Annual General Meeting (AGM) on May 2, 2012, the shareholders voted in favor of a reduction of the Supervisory Board from six to three members and elected Mr. Heino von Prondzynski as new member to the Supervisory Board. The former Board members Ms. Ann Clare Kessler, Ph.D., and Prof. Dr. Günther Reiter were confirmed for a further term until the AGM in 2015. In the initial meeting the newly elected Supervisory Board subsequently appointed Mr. Heino von Prondzynski as its new Chairman and Ms. Ann Clare Kessler, Ph.D. as Vice-Chairwoman.

Epigenomics' former CEO Geert W. Nygaard agreed with the Supervisory Board of the Company to retire from the Executive Board and to leave the Company effective September 30, 2012. Simultaneously, the Supervisory Board appointed the Company's CFO, Dr. Thomas Taapken, to serve as acting CEO in addition to his responsibilities as CFO, effective October 1, 2012. Epigenomics' Executive Board was therefore reduced to one person. The Supervisory Board concomitantly widened the responsibilities of Dr. Uwe Staub, previously Senior Vice President Research & Development, and promoted him to the newly created function of COO. His former duties were expanded by the responsibility for Medical and Regulatory Affairs as well as Customer Support.

## COMMITTEES

Until the AGM on May 2, 2012 the work of the Supervisory Board was supported by its two committees: the Audit and Corporate Governance Committee chaired by Prof. Dr. Günther Reiter and the Personnel and Compensation Committee chaired by Prof. Dr. Dr. h. c. Rolf Krebs.

During the first four months of 2012, the Audit and Corporate Governance Committee convened together with representatives of the Company and its auditors once and held telephone conference. These discussions focused on the quarterly as well as the annual and consolidated financial statements, 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 risk management and ensured compliance with the German Corporate Governance Code in order to continuously build and reinforce trust of the shareholders in the management of the Company.

The Personnel and Compensation Committee held one plenary meeting and several conference calls in the first four months of 2012. The committee discussed 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 election of its members at the AGM in 2012.

Reports of the meetings of the committees were presented and discussed at the plenary sessions of the Supervisory Board.

As a consequence of the reduction of the number of Supervisory Board members from six to three at the AGM in May of 2012, the Supervisory Board does not consider the formation of committees to be adequate. In lieu of the Audit Committee, the Supervisory Board designated Prof. Dr. Günther Reiter as the main expert for Financial Reporting and Audit Matters. In this role, he regularly met with the Executive Board and Senior Vice President Finance, Accounting and Controlling as well as with the Auditors of the Company, in order to provide advice on the preparation of financial reports, audits and quarterly reviews. He provides regular reports and highlights any findings and observations in this area to the entire Supervisory Board. At the same time, in lieu of the Personnel and Compensation Committee, the Supervisory Board designated Ms. Ann Clare Kessler, Ph.D., as the main expert on compensation and nomination matters. Mr. Heino von Prondzynski was designated the main expert regarding corporate governance.

## CORPORATE GOVERNANCE

The Supervisory Board continuously reviewed all issues of legal and regulatory compliance by the Company. Due to the continued challenging global economic environment and the financial position of the Company, it also dealt intensively with the adequacy of the risk management system. Both the Executive Board and the Supervisory Board regard the commitment to good corporate governance as exceedingly important to strengthen the confidence of current and future shareholders, corporate partners and employees of the Company. In October 2012, 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 ([www.epigenomics.com/en/news-investors/investors/corporate-governance.html](http://www.epigenomics.com/en/news-investors/investors/corporate-governance.html)). 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 audit company UHY Deutschland AG Wirtschaftsprüfungsgesellschaft (UHY), Berlin, has audited the annual financial statements and the related management report of Epigenomics AG for fiscal 2012 in accordance with the principles of the German Commercial Code (HGB), as well as the consolidated financial statements and the consolidated management report for fiscal 2012 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 Q1/2014 to avoid illiquidity according to the Company's plans. 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 at the latest in the first quarter of 2014.

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 audit reports and the audit certificates were submitted to the Supervisory Board by the Executive Board in a timely manner.

The UHY audit reports were presented to all members of the Supervisory Board and were discussed in depth at the plenary meeting on March 19, 2013, 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 2012 and consolidated financial statements 2012, 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 its findings and examination, the Supervisory Board raised no objections and accepted and confirmed the results of the audit. 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, 2012, without exception and modification. By the Supervisory Board's approval, the annual financial statements 2012 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 well as the Company's early warning system, the auditor stated to the Supervisory Board that in its opinion these systems are suitable to meet all legally intended requirements. The entire Supervisory Board worked towards the implementation of appropriate risk management measures during 2012.

The Supervisory Board would like to thank the Executive Board, the senior management as well as all employees of Epigenomics for their commitment and dedication throughout the challenging year 2012.

The Supervisory Board would also like to thank its previous Chairman Prof. Dr. Dr. h. c. Rolf Krebs as well as former Supervisory Board members Mr. Joseph Anderson, Ph.D., Prof. Dr. Dr. Uwe Bicker, and Mr. Günter Frankenne for their valuable contributions. The Supervisory Board also thanks its former CEO Geert W. Nygaard for his dedication to the Company over the past years. Under Mr. Nygaard's leadership, Epigenomics significantly advanced into a commercially focused company.

Berlin, March 2013

On behalf of the Supervisory Board

**Heino von Prondzynski**

# OUR STOCK

SHARE PRICE DRIVEN BY UPCOMING FDA DECISION –

DEVELOPMENT REFLECTS TIGHTENING FINANCIAL SITUATION TOWARDS YEAR-END

## SHARE PRICE DEVELOPMENT IN 2012

Epigenomics shares (Ticker symbol: ECX) closed the year 2011 at EUR 1.30 (XETRA). In February 2012 – within less than three weeks and in the absence of any reported event or news – the stock rapidly climbed from EUR 1.38 to EUR 3.55. Thereafter, it steadily declined in value to EUR 0.86 in October 2012. This trend was not driven by any negative Company news or clinical data, but was a consequence of the tightening financial situation towards year-end. The scarcity of funds posed a serious threat to the execution of Epigenomics' plans. Following the announcement of the encouraging comparison study data of Epi proColon® to FIT on December 4, 2012, the share price traded up from EUR 1.00 to EUR 2.10 at year-end. In summary, driven by the upcoming FDA decision, Epigenomics' stock price increased by 61.5% over the entire reporting year, outperforming most of the relevant stock market indices.

With ongoing significant volatility, trading volumes in Epigenomics' stock on XETRA increased from about 32,900 shares traded per day on average in the first quarter of 2012 to about 55,200 shares traded per day in the fourth quarter of 2012. As of December 31, 2012, a total of 8,818,417 shares were issued. The following major shareholder groups (■ on page 13) controlled more than 3% each of Epigenomics' total shares outstanding.

## UNCHANGED INVESTOR INTEREST

Two analysts, Edison Investment Research's Wang Chong, and equinet Bank's Edouard Aubery, covered Epigenomics' stock during 2012 providing updates on their views and recommendations. Most recently, equinet issued a "buy" rating for our shares. The published price target is significantly above the year-end trading price of our stock.

During this year, investors in Epigenomics primarily focused on our colorectal cancer screening test, Epi proColon®, and its head-to-head comparison study with FIT. The PMA approval process at the U.S. Food and Drug Administration and the overall financial situation of the Company remained the main points of interest.

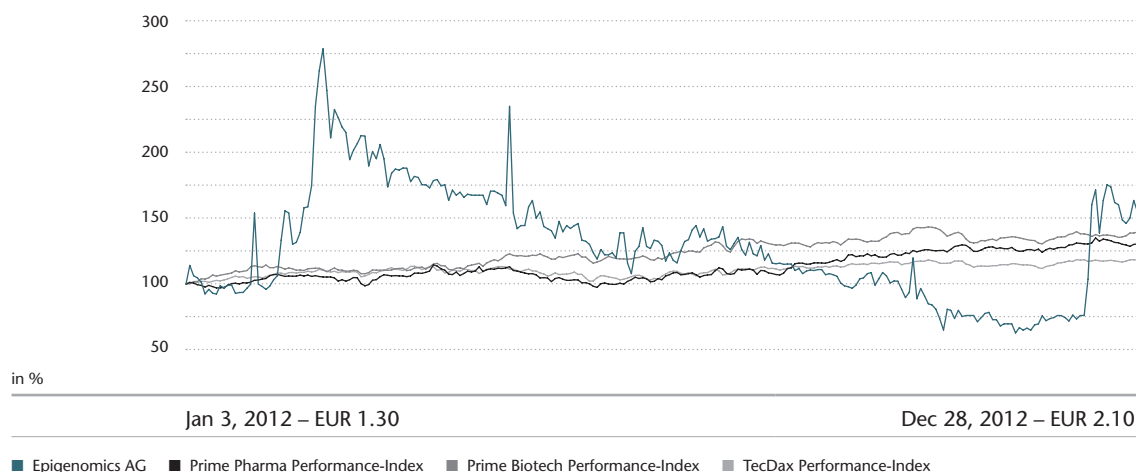
## TRANSPARENT DIALOGUE WITH SHAREHOLDERS

Epigenomics is committed to maintain an ongoing and active dialogue with the investment community in order to regularly provide timely, accurate and comprehensive information about Epigenomics and its products and to give our shareholders the best possible information for making informed investment decisions regarding Epigenomics' stock.

Throughout 2012, conference calls, in which investors could participate, took place on important Company updates. We also presented at several investor meetings and published updates on our clinical data at major scientific conferences in the United States and Europe. Furthermore, we continued to provide opportunities for a close dialogue with shareholders and interested investors at numerous road show meetings in Germany, Switzerland, France as well as in the United Kingdom and the United States.

In addition, we invited to an annual press conference and an analyst meeting on March 30, 2012, in Frankfurt am Main, as well as to our Annual General Meeting (AGM) of shareholders in Berlin on May 2, 2012. At the AGM, all proposals of the Company were agreed by vast majorities with a representation of approximately 44.7% of the share capital present or represented.

## EPIGENOMICS STOCK PERFORMANCE



Shareholder	Voting rights threshold
Abingworth LLP *	> 10%
Mr. Gilbert Gerber	> 5%
VCG Venture Capital Gesellschaft *	> 3%
Omega Fund II L.P. *	> 3%

\* (total held, controlled or advised)

## Key data on Epigenomics' stock

ISIN	DE000A1K0516
Security code number	A1K051
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	equinet AG
Number of shares (Dec 28, 2012)	8,818,417
Free float (Dec 28, 2012)	80.42%
Market capitalization (Dec 28, 2012)	EUR 18,518,675
Year-end closing price	EUR 2.10
Highest price in 2012	EUR 3.26
Lowest price in 2012	EUR 0.77

## CONTENTS CONSOLIDATED MANAGEMENT REPORT

Economic Environment in 2012 and Outlook 2013 .....	15
Business Activities, Strategy and Organization .....	17
Overview of our Business in 2012 .....	19
Commercialization and Business Development .....	22
Research and Development .....	22
Quality Management .....	25
Financials .....	25
Employees .....	26
Supplementary Report .....	27
Opportunities and Risks .....	27
Prognosis Report .....	32
Corporate Governance .....	34
Remuneration Report .....	39
Additional Mandatory Disclosures for Listed Companies Pursuant to Section 315 Paragraph 4 of the German Commercial Code (HGB) .....	42
Five-year Overview .....	44



# CONSOLIDATED MANAGEMENT REPORT

## ECONOMIC ENVIRONMENT IN 2012 AND OUTLOOK 2013

The worldwide economic growth has been weaker than expected in 2012, according to the United Nations "World Economic Situation and Prospects 2013" report. The authors observed that more and more developed countries have fallen into a double-dip recession caused by "high unemployment, weak aggregate demand compounded by fiscal authority, high public debt burdens, and financial sector fragility".

Especially in Europe, the year 2012 was again characterized by the sovereign debt crisis and ongoing discussions on the stability of the European currency. While the much-disputed haircut for Greek sovereign debt was taken in March 2012, it became increasingly obvious that other EU countries – foremost Spain – might not be able to solve their tremendous economic problems unassisted. With increasing nervousness in the financial markets, the European Central Bank gave a guarantee for the euro and offered to repurchase bonds issued by crisis-shaken countries without limitation. Although the situation has somewhat calmed down at the end of the year, it remains fragile and carries significant anxiety and uncertainty going into 2013.

In Germany, the economy again seemed to be positively disconnected from the pan-European turbulences. The country recovered better than most others from the 2009 global financial crisis. The inflation rate decreased, the unemployment rate remained at low levels, and the national debt is a significantly smaller issue than in most other European countries. However, economic experts question the sustainability of this positive development and are expecting a negative impact on Germany too from the suffering economies of other countries.

A recovery of the economy could also be observed in 2012 in the United States, especially in the second half of the year. The main topic here has been the uncertainty prior to the presidential election in November when the Obama administration was confirmed, even though its economic and fiscal course has been heavily disputed. The year 2012 ended with a spectacular showdown, when the most powerful global economy was endangered by political budget discussions. Finally, the U.S. Senate passed legislation on New Year's Day 2013 and avoided a fiscal cliff disaster for the economy for the time being.

Stock markets have developed very well in 2012. On a risk-weighted basis, the MSCI World index climbed by more than 14% after a 3% decrease the year before. This increase was significantly driven by the European stock markets and especially the development in Germany, where the DAX index climbed by almost 30% in the 12-month period.

The healthcare sector basically performed accordingly well in the United States and in Europe, but overall, the industry is facing decreasing profitability. Increasing pressure on prices for medical products, and a challenging regulatory environment resulting in growing approval and reimbursement hurdles in the developed countries are main reasons for this situation, although research and development expenses are continuing to grow year over year. It is expected that M&A activity will accelerate and that large players will increase their focus on emerging markets. This puts additional pressure on future business prospects for small and mid-sized companies in this sector, especially in high developed countries like Germany. It is not surprising that 2012 was not a good year for the German biotech industry, which is historically suffering from weak political support and a domestic capital market environment with diminishing attractiveness for international investors.

The exchange rate between the euro and the U.S. dollar started at the beginning of 2012 with a rate of EUR/USD 1.29 and remained more or less stable over 2012 with a slight weakness phase of the euro between May and August and a regained strength at year-end with a EUR/USD 1.32 quote. Overall, it was a year of low volatility for this currency pair.

The outlook for the worldwide economic recovery “remains fragile and uncertain” as laid out in the “Global Economic Prospects” by the World Bank (January 2013) with low growth rates for the high-developed countries. Global GDP is expected to grow by 2.4%, but only at a rate of 1.3% for the high-income regions – including 0.1% expected growth for the euro area. A cautiously optimistic outlook for the German economy is shared by most of the experts worldwide. A modest growth of the economy can be expected. The German government predicts a 0.5% growth of the domestic economy in 2013. For the euro area – and in particular in countries affected by the debt crisis – it will become another challenging year and the economic development will again strongly depend on major political decisions and on regaining confidence by all parties.

The German biotech industry shares a rather skeptical view and does not expect a significant growth in employment or capital expenditures in 2013 compared to 2012.

It is doubtful whether the stock markets will show another strong year, even if the interest rate levels in the developed countries will remain at the current low levels. The sentiment in the capital markets in general will to a large extent depend on the development of the debt crisis in Europe and the United States.

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 unable to sustain the Company on the basis of profits generated through our business activities including product sales. The above-mentioned factors like market uncertainty and risk averseness by investors, especially for stocks with low liquidity, could harm the Company’s stable and committed shareholder base.

Traditionally, the healthcare and life sciences industry has been viewed by investors as a “defensive sector” because demand for its goods and services is typically not dependent on the prevailing economic environment or cyclical developments. However, the mounting pressure on general healthcare spending due to budgetary restrictions exerted through growing economic and political restrictions is expected to affect earnings of most life sciences companies.

More importantly, the U.S. healthcare reform will likely have implications on healthcare spending in general and diagnostics in particular. Over time, an erosion of historically high profit margins of healthcare businesses is likely since pricing will come under increasing pressure in the world’s largest single healthcare market. Our industry segment – life sciences and diagnostics – should be able to benefit from an increased focus on prevention and early detection of disease. Colorectal cancer screening looks set to be a high priority for the United States and many national healthcare bodies.

The molecular diagnostics subsegment of the life sciences industry continues to be one of the most attractive and sought-after investment opportunities in spite of the increasing margin and cost pressure on companies. An accelerating trend in M&A activity has led to a heightened interest in this sector since 2011. Analyst reports suggest that this will be sustained throughout 2014 and 2015. Growth rates in the molecular diagnostics industry are substantially higher than in the diagnostics industry overall. In particular, oncology diagnosis, 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 colorectal cancer (CRC) blood test, this market opportunity alone could exceed revenue of USD 3 billion p.a. to the diagnostics industry. About 320,000 new cases of CRC per year are diagnosed in the EU and about 143,000 in the United States. Still today, over 60% of all CRC cases are detected in symptomatic stages when survival rates are much lower compared to earlier-stage detection. Thus, the overall market potential for a test such as Epi proColon® is very significant.

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

## 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. Our business activities are mainly targeting at the important international markets of Europe, North America and Asia. Epigenomics AG, as the parent company, oversees the Group's central business functions (e.g. accounting, human resources and intellectual property). The Group's research and development (R&D) activities are also conducted from the Berlin location. Epigenomics, Inc. is mainly active in developing our business and commercial activities in North America and beyond.

We are a molecular diagnostics company focusing on developing and commercializing of in vitro diagnostic (IVD) tests for the screening and diagnosis of cancer. Our products are based on a unique and proprietary technology platform, which relies on a fundamental biological phenomenon called DNA methylation as a source for the discovery of highly informative and disease-specific biomarkers which are at the core of every diagnostic test we have developed so far.

Following a dual-business model, we develop and commercialize cancer diagnostic tests in CRC and in lung cancer; both via direct marketing and sales efforts of 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 others 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 diagnostic needs with a view to providing patients and physicians with benefits from more convenient and superior diagnostic tests.

Our lead product is Epi proColon®, a blood-based test for the early detection of CRC which relies on our proprietary DNA methylation biomarker, Septin9. The majority of our activities are focused on the introduction of Epi proColon® as an IVD kit in the United States, the world's largest commercial market for molecular diagnostic products. In 2012, we completed the Premarket Approval (PMA) application and are expecting an approval decision from the U.S. Food and Drug Administration (FDA) before the end of 2013. Already now, ahead of regulatory approval of Epi proColon® in the United States, blood-based tests using the Septin9 biomarker are available worldwide through our partners, including Abbott Molecular Diagnostics, Inc. ("Abbott"), Quest Diagnostics, Inc. ("Quest"), ARUP Laboratories, Inc. ("ARUP"), Gamma Dynacare ("Gamma Dynacare") and Companion Dx Reference Lab ("Companion Dx"). These product and diagnostic service offerings are performed on the basis of licenses granted to these partners by Epigenomics.

### CORPORATE STRATEGY

After pioneering DNA methylation technology development and biomarker discovery, it soon became obvious to us that interaction with patients and medical professionals is essential for the acceptance and market penetration of innovative products that address urgent unmet challenges in cancer diagnosis and personalized medicine. Today, as a company, we cover all steps necessary to provide commercially successful molecular diagnostic tests from addressing relevant clinical challenges for development and validation of biomarkers, IVD test kit development through to marketing and sales of our products to laboratories, physicians and patients.

We are convinced to be the best advocates of our own products and that we have to spearhead driving their medical adoption. Nevertheless, we also realize that the opportunity in cancer molecular diagnostics is too vast to leverage the potential of our products just by ourselves. Therefore, we have adopted a dual-business strategy: We market our own products in the home markets of Germany, Austria, and Switzerland and through a steadily increasing network of distributors in the rest of Europe and other designated areas. At the same time, we have entered into partnerships with some of the most distinguished companies in clinical diagnostics through licensing our Septin9 biomarker for early detection of colorectal cancer. Thereby, we typically participate in the commercial success of our partners through upfront and milestone payments, but most importantly through royalties on the sales they generate with their diagnostic products and services based on our biomarker and technologies.

Besides cancer early detection and diagnosis, personalized medicine and companion diagnostics are widely recognized drivers of growth, both in the pharmaceutical and diagnostics markets. Our experience in developing concepts and biomarkers for drug response prediction goes back to the early days of personalized medicine, and we leverage this experience and know-how in multiple partnerships with pharmaceutical companies. In these partnerships, we discover and validate drug response biomarkers for our partners and develop high-quality clinical assays with the potential to fuel our future product pipeline.

## MANAGEMENT

Epigenomics is managed by a team characterized by a unique mix of seasoned diagnostics industry experience, science and management expertise, and the entrepreneurial commitment to build a world-leading cancer molecular diagnostics company.

Being a stock corporation under German law, the Company is led by an Executive Board and controlled by a Supervisory Board elected by our shareholders. Currently, Dr. Thomas Taapken is acting as sole member of the Executive Board. He joined Epigenomics on April 1, 2011, as Chief Financial Officer (CFO) and additionally took over the Chief Executive Officer (CEO) position after the retirement of Geert W. Nygaard effective September 30, 2012. The Supervisory Board of Epigenomics comprises three members, all with relevant experience and expertise in their respective fields.

For further details on the members of the Boards, reference is made to the "Corporate Governance" section of this management report.

Epigenomics operates under a quality management system certified according to ISO 13485 for the design, development, manufacturing and distribution of IVD products. We have repeatedly demonstrated our ability to operate under highest regulatory standards, successfully undergoing audits of our ISO-certified quality management system covering all necessary requirements for IVD development, manufacturing and commercialization for both our sites in Germany and the United States.

## CORPORATE GOALS

We take a very focused and goal-oriented approach to managing and monitoring operational progress when executing our strategy. The Supervisory Board and the Executive Board of the Company regularly define company goals related to financial indicators, technology and product development targets as well as clinical and regulatory milestones against which performance of the Company and its employees is monitored.

In 2012, the most important corporate goal was to progress the development of our key value driver Epi proColon® and to ensure its success in the United States without losing sight of the European market. At the very end of 2011, we had initiated the FDA registration process for this product. In 2012, we subsequently started a head-to-head comparative study with the goal to demonstrate non-inferiority of Epi proColon® to fecal immunochemical testing (FIT) as requested by the FDA after having agreed to the clinical trial protocol with the agency. As we had anticipated, we were able to complete this clinical trial successfully before year-end 2012. This allowed us to finalize our application by submitting the fourth and final module of our PMA application at the end of the reporting year.

In order to gain support for our product with key opinion leaders in the field, during 2012, we further extended our network in the medical expert community and have started our preparations for a potential advisory panel meeting, which we expect to become part of the review process by the FDA.

Further important elements in being commercially successful are the inclusion of our test in relevant screening guidelines and the availability of reimbursement by insurance carriers. In this respect, we have made and continue making significant progress in creating acceptance from our medical and laboratory customers and in securing their support for our efforts.

While most of our resources were dedicated to the progress of Epi proColon®, 2012 was also a critical year to ensure the future of Epigenomics since the scarcity of funds posed a threat to the execution of our plans. To allow greater operational efficiency we completed far-ranging restructuring measures as announced in 2011 and subsequently implemented changes in our Executive Board and in our Supervisory Board. These changes have already proven effective. It was also of utmost importance to raise further capital to extend our financial runway closer to market launch of our lead product in the United States and we successfully completed a financing round in early 2013 after the end of the reporting period.

Finally, we also keep providing high-value-added biomarker research services and solutions to customers in the pharmaceutical and life sciences industry and to a certain extent retained this ability in spite of ceasing most of our research operations as a consequence 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.

In summary, we strongly focused our strategy on the key value driver of the Company throughout the reporting year and ultimately created a leaner but nevertheless more efficient organization.

### PERFORMANCE INDICATORS

Epigenomics' goal is to increase shareholder value by consequently following our mission and strategy. We are using financial and non-financial performance indicators on an ongoing basis to control and monitor the success of our endeavors.

The financial indicators used to control our operations include key financial figures which are well established and recognized by the international investor community. These include revenue, EBIT, EBITDA and operating results or earnings per share. All of these indicators are monitored closely on a monthly basis and published on a quarterly basis in our financial reports. They are regularly compared against planned and forecasted values and against external benchmarks if appropriate. Not having yet achieved to become profitable, our cash flow and our cash consumption are amongst the most important financial indicators and are therefore monitored extremely close and regularly reported.

Non-financial performance indicators that are important for conducting our business are mainly derived from our R&D and commercial activities. The set of indicators comprises of the number of (granted) patents, sensitivity and specificity numbers for our products as obtained from scientific studies or as well publications of study results in renowned scientific journals. The progress in our current PMA approval process with the FDA, the successful passing of audits of our quality system and reaching yardsticks and milestones in our development activities are further important indicators to measure target achievement and to assist us in guiding internal efforts and external communication.

## OVERVIEW OF OUR BUSINESS IN 2012

Our operational efforts in 2012 were highly focused and to a large extent targeted towards the head-to-head comparison study between Epi proColon® and FIT as well as towards the completion of the PMA application with the FDA for our colorectal cancer screening test.

### NON-INFERIORITY DEMONSTRATION OF EPI PROCOLON® AGAINST FIT

The comparison study, which was started in the first quarter of 2012, aimed at demonstrating the non-inferiority of Epi proColon® in detection of CRC compared to FIT, and was defined to be an integral part of our PMA submission. On December 4, 2012, we announced to have met the critically important endpoint of non-inferiority with respect to sensitivity of Epi proColon® to FIT which provides the potential to detect CRC in patients more accurately than with any other available non-invasive test.

In the reported trial, Epi proColon® detected 73 in a total of 103 evaluable samples from patients with CRC, which represents a sensitivity – or cancer detection rate – of 71%. The FIT comparator used in the study, one of the most commonly used FIT products in the U.S. market, detected 66 out of 98 cancer cases for which stool samples were provided, translating into a sensitivity of 67%.

The double-blinded study was performed at 70 clinical trial sites across the United States and comprised two arms. The first arm included a total of 103 asymptomatic, average-risk individuals without family history or previous incidences of CRC, who were diagnosed and confirmed as having colorectal cancer during a screening colonoscopy. Matched blood and stool samples from these patients were collected at least ten days after colonoscopy but before surgical intervention.

The second arm of the study included 198 individuals selected according to the same criteria, but whose blood and stool samples were collected before the colonoscopy. This study arm included three cancer cases as well as individuals with advanced adenomas, polyps or no evidence of disease. Based on all non-CRC samples from the second arm, specificity for Epi proColon® – or the rate of correctly assessed non-cancer cases – was determined at 81% and at 98% for FIT. These findings are in line both with previous studies on Epi proColon® and with published data for FIT.



The difference in specificity was anticipated and in the Company's opinion is less vital, since patients will undergo a colonoscopy – the currently recommended screening procedure – as a result of a positive test result. In addition to this it is noteworthy that the Company's CE-marked version of our product, optimized for specificity and launched in Europe earlier in 2012, has a specificity for CRC detection of 99%. This opens additional possibilities to address the U.S. market in the future.

More details on this study can be found in the "Research and Development" section of this report.

### **COMPLETION OF PMA APPLICATION FOR EPI PROCOLON®**

We initiated the process of gaining U.S. regulatory approval for Epi proColon® in late 2011 by submitting the first module of our modular PMA approval submission to the FDA. The first submission module included all required documentation on the manufacturing and quality controls section in relation to the product. The second module was delivered in March 2012, including the sections in relation to hardware and software validation of the instrumentation needed to run the test, followed by the third module of the submission in June 2012. This module described the analytical performance of Epi proColon® in terms of accuracy, precision and stability. Reproducibility and validation of the analytical performance were assessed through testing at three external laboratories. The submission was finally completed at the end of the year by module four which contained all clinical data generated with the test, including the results of the aforementioned FIT comparison study. Through the submission of the fourth module, we formally completed our PMA application, which has now officially been filed with the FDA and will be subject to review by the authorities in 2013.

### **ENCOURAGING RESULTS BEYOND REGULATORY STUDIES**

During 2012, we were able to announce further positive results and data obtained in studies involving Septin9 and CRC screening as well as regarding the clinical performance of our Epi proLung® BL assay and our proprietary TFAP2E biomarker.

Prof. Béla Molnár and his team from the Semmelweis University, Budapest, Hungary, showed that our Septin9 biomarker detects CRC equally well in both sides of the colon.

A survey conducted in the United States indicated that a large majority of previously unscreened participants eligible for CRC screening would prefer a Septin9 blood test to other screening methods. These study results were further confirmed by an adherence study performed by us in Berlin. The offering of alternative screening methods to study participants which refused to undergo colonoscopy showed a definite preference for blood-based testing compared to stool tests.

Another study conducted 2012 in Berlin at the Charité University Hospital demonstrated that our Epi proLung® BL assay is a valuable tool in the diagnosis of lung cancer when combined with a cytological analysis. Furthermore, a high-profile study published in "The New England Journal of Medicine" proved the value of our TFAP2E biomarker as a CRC drug resistance predictor.

For details on all these studies reference is made to the "Research and Development" section of this report.

### **NEW LDT PARTNERSHIP IN THE UNITED STATES**

In June 2012, we signed another non-exclusive licensing agreement for our Septin9 biomarker with Companion Dx Reference Lab ("Companion Dx"), a molecular diagnostic reference laboratory and innovative leader in personalized medicine, based in Houston, TX, U.S.A. Under the terms of the agreement, Companion Dx has obtained rights to establish and commercialize a blood-based LDT using methylated Septin9 as biomarker for CRC detection. Epigenomics is entitled to double-digit royalties on sales. The agreement with Companion Dx complements our LDT agreements with Quest, ARUP, and Gamma Dynacare in North America. Regionally focused Companion Dx is a strong partner to effectively serve the Texan cancer-testing market ahead of FDA approval and commercial launch of Epi proColon®.

### **SWISS LIFE TO REIMBURSE FOR SEPTIN9 TESTING IN FRANCE**

Swiss Life, one of the largest private health insurance companies in France with nearly two million policyholders, in July 2012 announced to start providing the Septin9 blood-based test for the early CRC detection as part of a preventive health program. As the first French insurance company to promote the Septin9 test, Swiss Life is offering up to 50% reimbursement. French Social Security does not currently cover the Septin9 test. With this decision, Swiss Life France is demonstrating its strong commitment to the improved prevention of CRC for its policyholders. Furthermore, the decision underpins its pioneering approach to disease prevention. Epi proColon®, as our version of the Septin9 test, had previously become commercially available in France.

## ORGANIZATIONAL CHANGES

At the Company's Annual General Meeting (AGM) in May 2012, the shareholders voted with vast majority in favor of a reduction of the Supervisory Board from six to three members and elected Heino von Prondzynski as new member to the Supervisory Board. Initially, the former Supervisory Board members Ann Clare Kessler, Ph.D., and Prof. Dr. Günther Reiter were confirmed for a further term until the AGM in 2015. In the initial meeting, the newly elected and confirmed Supervisory Board subsequently elected Heino von Prondzynski as its new Chairman and Anne Clare Kessler as Vice-Chairwoman.

Epigenomics' former CEO Geert W. Nygaard agreed with the Supervisory Board of the Company to retire from the Executive Board and to leave the Company effective September 30, 2012. Simultaneously, the Supervisory Board appointed the Company's CFO, Dr. Thomas Taapken, to serve as acting CEO in addition to his responsibilities as CFO, effective October 1, 2012. Epigenomics' Executive Board was therefore reduced to one person, marking a significant step in reducing the Company's cost basis. The Supervisory Board concomitantly widened the responsibilities of Dr. Uwe Staub, previously Senior Vice President Research & Development, and promoted him to the newly created function of Chief Operating Officer (COO). His former duties were expanded by the responsibility for Medical and Regulatory Affairs and Customer Support.

## FINANCIAL RESULTS

Our revenue amounted to EUR 1.0 million in the reporting year, down from EUR 1.4 million in the year before. This shortfall has to be seen in the light of the restructuring process in 2011. Despite of this, we recognized moderately increased product revenue, mainly through our established LDT agreements and R&D services revenue at previous year's level. The decline in total revenue is mostly attributable to one-off payments received from licensing partners in 2011 with no comparable effects in 2012 to compensate for. Nevertheless, recorded revenue overall remained well below our expectations as new business opportunities have not yet unfolded.

On the cost side, the implemented and now completed restructuring showed the intended results. Personnel costs were reduced from EUR 6.9 million in 2011 down to EUR 4.8 million in 2012 and significant decreases could also be observed in other cost categories (e.g. rent, travel costs, licensing fees, external R&D services and marketing expenses). Total operating expenses decreased by EUR 3.0 million in 2012 compared to the previous year (EUR 14.1 million vs. EUR 17.1 million). However, it must be considered that this comparison is distorted by the capitalization of development costs in the amount of EUR 2.8 million in 2011. This effect diminished last year's comparable figure, while the amount in the reporting year additionally included the amortization of EUR 0.5 million resulting from the capitalization. This brings year-on-year cost savings up to an amount of EUR 5.8 million. Moreover, operating costs in 2012 were significantly burdened by the one-time effect attributable to the FIT comparison study, which was requested by the FDA for our product approval process. In summary – on a comparable operational basis –, it can be said, that we have reduced the Company's cost basis in 2012 dramatically compared to 2011 and to previous years.

The aforementioned study also distorts the presentation of our reduced cash consumption in 2012, which still amounted to EUR 10.9 million (2011: EUR 12.2 million). This figure was decisively influenced by cash outflows of up to EUR 2.3 million directly attributable to the study. The cash consumption further included payments related to the 2011 restructuring as well as to the retirement of Geert Nygaard in the total amount of EUR 1.4 million. At year-end 2012, our liquidity had decreased to EUR 2.7 million, leading to an urgent need for a cash infusion to secure the future operations of the Company. We eventually succeeded in raising gross proceeds of EUR 5.0 million by a rights issue in January 2013 after the end of the reporting period.

## SHARE PRICE DEVELOPMENT

Epigenomics share had been traded at EUR 1.30 (XETRA) at the end of 2011. In February 2012 – within less than three weeks and in the absence of any reported events or news – the stock rapidly climbed from EUR 1.38 to EUR 3.55 per share. A subsequent steady decline in value to EUR 0.86 in October 2012 took place in the absence of any major commercial news or additional clinical study data. Following the announcement of the FIT comparison study data, a pronounced share price increase from EUR 1.00 on December 3, 2012, to EUR 2.10 at year-end took place. Over the entire reporting year, our share price increased by 61.5%, outperforming most of the relevant stock market indices.

## COMMERCIALIZATION AND BUSINESS DEVELOPMENT

Throughout 2012, we continued to follow the adjustments to our strategy originally initiated in 2011. At that time, we had taken the decision to focus the organization and its commercial activities to the key market for our lead product, the United States. Meanwhile, we made good progress in our primary goal to introduce our lead product Epi proColon® into the U.S. market.

In early 2012, we began the head-to-head clinical trial to prove the non-inferiority of blood-based Epi proColon® against FIT in CRC detection. The trial, which was reported in December, completed the last PMA application step to finalize the FDA registration process. We submitted the fourth and final module to complete the PMA process subsequently and are now in a productive dialog with the agency regarding next steps. We anticipate a decision on approval by the FDA in the second half of 2013.

Another major accomplishment in 2012 has been the inclusion of Septin9 testing with its own defined code into the Current Procedural Terminology (CPT) coding document issued by the American Medical Association, which is the basis for reimbursement of laboratory tests by payors in the United States.

Ahead of the pursued regulatory approval to sell our product in North America, we have granted a number of licenses to certified laboratories in order to enable them to offer their LDTs targeted on Septin9 as a service and an aid in the diagnosis of CRC. These partners include Quest, ARUP and Companion Dx in the United States and Gamma Dynacare in Canada.

Encouragingly, we are seeing a growing market acceptance for our test in North America with an expectation of more than 45,000 Septin9 tests being performed in 2012 by our license partners compared to 26,000 tests in 2011. While right now, we are entitled to royalties on their service revenues, we expect our laboratory partners needing to purchase regulated IVD test kits once our test is approved by the FDA and commercially available in North America.

Throughout the year, our commercial team has continued to support our IVD licensing partners as well as our North American LDT partners with the goal to ensure a coherent positioning and branding of their respective blood-based CRC tests using Septin9 as a biomarker.

As part of the realignment of our business, our commercialization focus in Europe 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 are seeing increasing acceptance from healthcare bodies, which have begun to adopt the patient-friendly blood test for the early detection of CRC. Swiss Life, one of the largest private health insurance companies in France, decided in July 2012 to recommend and reimburse up to 50% of the costs of Septin9 testing to its insured persons as part of a preventive health program. This decision by Swiss Life clearly confirms our European commercialization approach. Since Epi proColon® is commercially available in France, we are now able to expand into the French market.

In brief, we are making solid progress on the commercial side. Together with our partners, we share the view that providing Septin9 testing will help physicians to improve patient health outcomes and decrease the rising costs associated with CRC treatment. With this in mind, we continue to build support for Epi proColon® in the United States, throughout Europe and on worldwide markets.

## RESEARCH AND DEVELOPMENT

In light of our focused strategy, activities of our R&D team were geared towards advancing our key products in their development and assisting in their commercial establishment.

### COLORECTAL CANCER MARKER (SEPTIN9)

#### *Non-inferiority demonstration of Epi proColon® against FIT*

The comparison study was started in the first quarter of 2012 to demonstrate the non-inferiority of Epi proColon® in detection of CRC compared to FIT, and as an integral part of our PMA submission to the FDA. On December 4, 2012, we announced that Epigenomics met the critically important endpoint of non-inferiority with respect to sensitivity of Epi proColon® to FIT, which provides the potential to discover more CRC patients.



In the reported trial, Epi proColon® detected 73 in a total of 103 evaluable samples from patients with CRC, which represents a sensitivity of 71%. The FIT comparator used in the study, one of the most commonly used FIT products in the U.S. market, detected 66 out of 98 cancer cases for which stool samples were provided, translating into a sensitivity of 67%.

The double-blinded study was performed at 70 clinical trial sites across the U.S.A. and comprised two arms. The first arm included a total of 103 asymptomatic, average-risk individuals without family history or previous incidences of CRC, who were diagnosed and confirmed as having colorectal cancer during a screening colonoscopy. Matched blood and stool samples from these patients were collected at least ten days after colonoscopy but before surgical intervention.

The second arm of the study included 198 individuals selected according to the same criteria, but whose blood and stool samples were collected before colonoscopy. This study arm included three cancer cases as well as advanced adenomas, polyps and individuals with no evidence of disease. Based on all non-CRC samples from the second arm, specificity for Epi proColon® was determined at 81% and for FIT at 98%. These findings are in line both with previous studies on Epi proColon® and published data for FIT.

While the point estimate of 81% specificity for Epi proColon® was still above the pre-defined non-inferiority margin, this result was statistically non-significant. The difference in specificity is less vital in the Company's opinion, as patients will undergo a colonoscopy – the currently recommended screening procedure – as a result of a positive test result. In addition to this it is noteworthy that the Company's CE-marked version of our product, optimized for specificity and launched in Europe earlier in 2012, has a specificity for CRC detection of 99%. This opens additional possibilities to address the U.S. market in the future.

Testing of all samples was performed strictly according to the instructions for use by the respective manufacturers of both tests at an independent third-party testing laboratory in the United States, which was blinded to the samples analyzed.

Further analysis of the data showed that Epi proColon® was able to demonstrate 61% sensitivity for 23 cases in stages 0 and 1 (FIT: 61%), 75% for 16 cases in stage 2 (FIT: 75%), 70% for 20 cases in stage 3 (FIT: 85%) and 92% in 12 stage 4 cases (FIT: 64%). In the 32 cases of unknown clinical staging, the sensitivity was 69% (FIT: 57%). The correspondence of the blood- and stool-based test methods was 62%, whereby Epi proColon® was able to identify 20 cases that could not be identified by FIT, while FIT identified 17 CRC cases, which were not found through Epi proColon®.

Among the 198 average risk individuals of the second arm of the study, three CRC cases were identified by colonoscopy. Both, Epi proColon® and FIT were able to find two out of these three CRC cases. At the same time, of the 24 advanced adenomas included in the second arm, neither method detected a significant number of these. The adenoma detection for Epi proColon®, as shown in previous studies, was low. Surprisingly, the finding was the same for FIT, although it was previously believed to be a distinct advantage of this method.

With the announcement of having met the critically important endpoint of non-inferiority with respect to sensitivity of Epi proColon® to FIT, we demonstrated the potential to detect CRC in patients more accurately than with any other available non-invasive test.

#### *Septin9 biomarker detects CRC equally in both sides of the colon*

According to a study conducted in collaboration with Prof. Béla Molnar and his team from the Semmelweis University, Budapest, Hungary, our Septin9 biomarker detects CRC equally well in both sides of the colon. The complete study data was presented during the Digestive Disease Week 2012 conference in San Diego, CA, U.S.A.

In a blinded case control study of a total of 184 study participants, plasma from 92 CRC cases (56 left-, 36 right-sided cases) was analyzed and methylated Septin9 was detected in a total of 88 cancer cases, representing 96% sensitivity for overall CRC detection. The control arm consisted of 92 samples of individuals with no evidence of disease as verified by colonoscopy and the reported specificity was 85%. Sensitivity for detection of left- and right-sided cases was 96% and 94% respectively, thus showing no significant difference between cancer detection in either side of the colon.

In a subset of 39 subjects that received a fecal occult blood test (FOBT, Hemoccult II stool test) in addition to a Septin9 test, the sensitivities for FOBT for the detection of twelve left-sided cases was 83% and 50% for the ten right-sided cases in this study. Overall, sensitivity for FOBT was 68% and specificity was 71%.

These results are in line with previously reported performance evaluations for CRC detection in case control studies performed by Epigenomics and others. They reflect the value and the superiority of blood-based testing of methylated Septin9 for early detection of colorectal cancer, independently of the localization of the cancerous lesion.

### *Blood-based Septin9 biomarker tests preferred for reasons of convenience, cost and accuracy*

Beyond the ability to accurately detect cancer, another crucial aspect in cancer screening is compliance to screening methods, a factor which is still less than satisfactory for CRC screening programs. As presented at the United European Gastroenterology Week in October 2012, results from an adherence study – conducted by Epigenomics in Berlin with about 200 patients – demonstrate that even when recommended by their doctors, 62% of the patients refused to undergo colonoscopy, the currently recommended screening method in Germany. When offering alternative screening methods to the participants refusing colonoscopy, 87% of them opted for blood-based testing compared to 9% that chose a stool test.

Those initial data confirm earlier findings in the United States from a former CRC screening preference survey conducted by Jennifer Taber and her team (Huntsman Cancer Institute at the University of Utah and our partner ARUP Laboratories). We announced the survey results at the Annual Meeting of the American Society for Preventive Oncology 2012 in Washington, D.C., U.S.A. The survey indicated that given the performance of the ARUP Septin9 test (90% sensitivity, 89% specificity) and its cost of approximately USD 180, two thirds of previously unscreened subjects would prefer a Septin9 blood test to other screening methods. Among the positive aspects of the test, participants noted its convenience (62%), cost (52%) and accuracy (55%).

These studies show that blood-based Septin9 tests are obviously preferred by patients. The convenience of a blood-based test should lead to a greater acceptance and thus a higher compliance to CRC screening. It underlines the value that blood-based Septin9 tests can potentially bring as alternative for CRC detection based on patient preference for blood-based testing compared to stool tests.

### **LUNG CANCER MARKER (SHOX2)**

We also continued working towards establishing our second product, Epi proLung®, in the market as an aid in the diagnosis of lung cancer. At the annual meeting of the German Association of Pathologists in May 2012 in Berlin, the results from a clinical study conducted by Professor Dr. Manfred Dietel and his team of the Charité University Hospital in Berlin, Germany, were presented. The study evaluated the clinical performance of the Epi proLung® BL assay (based on Epigenomics' proprietary biomarker detecting methylated SHOX2) in bronchial washings from patients suspected of having lung carcinoma.

In the prospective study conducted between March 2011 and November 2011, a total of 228 bronchial washing specimens were submitted to cytological analysis according to established clinical routine. In addition, the Epi proLung® BL assay was performed on all patient samples. Final clinical status indicated that 54 of the 228 subjects were definitively diagnosed with lung carcinoma. Of the 54 confirmed lung carcinoma subjects, 29 were detected by both tests, twelve were detected by the Epi proLung® BL assay only, and twelve were detected by cytological analysis only. The combination of both cytological analysis and the Epi proLung® BL assay resulted in a final sensitivity of 98% at a specificity of 92%. Only one confirmed lung cancer case was missed with the combined analysis.

Based on these results, which independently confirm the clinical utility of the Epi proLung® BL assay, Charité has announced that the assay will be introduced into its clinical practice as a routine aid in the diagnosis of lung cancer in patients with negative or suspicious cytological results.

### **STUDIES WITH OTHER BIOMARKERS**

In January 2012, we announced that our proprietary TFAP2E biomarker predicts CRC drug resistance according to a study authored by Prof. Dr. Matthias Ebert at the University of Heidelberg, Germany, entitled "TFAP2E-DKK4 and Chemo-resistance in Colorectal Cancer" published in the January 2012 edition of The New England Journal of Medicine.

In this study involving more than 200 patients in four independent cohorts, Prof. Dr. Ebert and his team demonstrated that hypermethylation of the TFAP2E gene was correlated with non-responsiveness to the commonly used chemotherapeutic agent 5-fluorouracil (5-FU). Furthermore, using a combination of data from cancer cell lines and patient samples, the authors demonstrated that this effect was potentially mediated through up-regulation of the DKK4 gene, previously implicated in 5-FU resistance. Resistance to treatment was observed with 5-FU-based chemotherapy or 5-FU chemotherapy combined with radiation, indicating that the methylated TFAP2E gene may be a valuable biomarker for response prediction in either setting.

This further demonstrates the growing importance of DNA-methylation-based tests in cancer diagnostics and personalized medicine.

## QUALITY MANAGEMENT

We have a well-established comprehensive quality 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 US-American current good manufacturing practice requirements for medical device manufacturers. ISO 13485 is an internationally recognized quality 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 ongoing commitment to develop safe and effective diagnostic products such as our tests for colorectal and lung cancer.

We are continuously improving our quality management system to be a solid foundation for regulatory approval of our products on a global basis.

## FINANCIALS

### RESULTS OF OPERATIONS

Total revenue for the year amounted to EUR 1.0 million and was below previous year's figure of EUR 1.4 million. Thereof, product revenue from kit sales (own and third parties) of EUR 0.4 million was lower than planned as our international distributors were not yet meeting our sales expectations. Our own sales and marketing resources were significantly diminished due to implemented restructuring measures in 2011 and could therefore not compensate for this shortfall. On the other hand, our R&D service business (EUR 0.2 million) suffered from smaller collaborations than expected and from missing new business opportunities. Licensing income from established partnerships finally met our expectations on the revenue side with a contribution of EUR 0.4 million, down from EUR 0.8 million in 2011, when a significant part of this revenue component was attributable to one-off effects.

Cost of sales decreased in line with negative revenue development from EUR 0.4 million to EUR 0.3 million. Gross profit and gross margin decreased accordingly from EUR 1.1 million and 75.1% in 2011 to EUR 0.7 million and 72.0% in 2012.

Other income increased significantly to EUR 1.0 million in 2012, after EUR 0.5 million in the year before. The increase was driven by the reversal of provisions (EUR 0.6 million), mainly related to the restructuring of the Company in 2011 and by foreign currency exchange gains. Further sources were income from the sale of assets and from research grants as well as recoveries and refunds, all above previous year's levels.

Research and development ("R&D") costs increased significantly from EUR 4.9 million in 2011 to EUR 8.0 million in the reporting year. This increase was attributable to the execution of the FIT comparison study. On the other hand, it has to be considered, that the capitalization of development expenses for the Epi proColon® test in 2011 had significantly reduced the R&D expenses in that period, which does not allow for a direct comparison. As the product development for Epi proColon® had been completed in the previous year, no further capitalization effect was recorded in 2012. R&D costs comprised to a large extent of consulting and service fees for external providers and the clinical sites involved in the aforementioned study.

Selling, general and administrative ("SG&A") costs dropped from EUR 5.9 million in 2011 to EUR 5.5 million in 2012, mirroring the effect of our reduced market activities in Europe after the restructuring in 2011. This effect was partly compensated by an increase in legal and consulting costs with regard to the extensive evaluation of strategic alternatives in financing the Company towards the end of 2012.

Other expenses amounted to EUR 0.3 million in 2012 – significantly below previous year's EUR 5.9 million, which were to a large extent driven by the restructuring of the Company and the amortization of the goodwill. The 2012 figure mainly comprised foreign exchange rate losses, extraordinary amortization of development costs and late costs in conjunction with the 2011 restructuring.

Total operating costs added up to EUR 14.1 million after EUR 17.1 million in the year before.

In the reporting year, operating loss (EBIT) improved by 20.5% from EUR 15.2 million in 2011 to EUR 12.1 million. The decline in revenue and the sharp increase in R&D costs as mentioned above were thereby considerably overcompensated by reduced SG&A costs and the absence of extraordinary effects (i.e. restructuring and goodwill amortization).

In 2012, our net loss finally amounted to EUR 12.2 million – a 21.7% improvement compared to the previous year (EUR 15.6 million). This equals a loss per share of EUR 1.38 (2011: EUR 1.77).

## FINANCIAL POSITION AND CASH FLOW

Our cash consumption amounted to EUR 10.9 million in 2012 and was lower than in 2011 (EUR 12.2 million), but still higher than originally anticipated. We missed our revenue target for 2012, since we generated less cash inflows from product sales, R&D collaborations and licensing activities than originally planned. On the other hand, we had to conduct the large FIT comparison study. Cash outflow in relation to this study amounted to approximately EUR 2.3 million in the reporting year and is expected to amount to another EUR 0.7 million in 2013. Cash consumption 2012, excluding the FIT comparison study, therefore amounted to EUR 8.6 million, corresponding to our expectations of reductions in annual cash consumption in the range of EUR 3 million as a consequence of our restructuring in Q3 2011. Above all it has to be considered that cash outflows of more than EUR 0.8 million in 2012 were still late one-off payments attributable to this restructuring in the form of an early termination fee with regard to our office rental agreement in Seattle and redundancy payments for retired employees.

Cash inflow from investment activities was generated in the amount of EUR 0.9 million mainly due to the repayment of available-for-sale securities at maturity. Capital expenditures for tangible and intangible assets of less than EUR 0.1 million were in line with internal budgets. In the previous year, a cash outflow from investing activities in the amount of EUR 2.8 million had been reported when development expenses for Epi proColon® were capitalized.

Cash outflow of EUR 0.4 million was attributable to financing activities, i.e. the evaluation of various strategic options throughout the reporting year. A part of these expenses occurred eventually in connection with the preparation of the capital increase accomplished in January 2013 (see below).

## NET ASSET POSITION

Due to our ongoing losses from operations, the equity ratio of the Group decreased to 60.5% at December 31, 2012, down from 83.2% at the beginning of the reporting period. Accumulated losses (including the net loss of 2012) amounted to EUR 26.5 million, thus reducing total equity to EUR 4.2 million. Total liabilities amounted to EUR 2.7 million at the balance sheet date (Dec 31, 2011: EUR 3.3 million) and were completely classified as current liabilities. Trade payables increased from EUR 1.2 million at the beginning of the year to EUR 1.7 million at year-end, mainly attributable to costs recorded in December in connection with our FIT comparison study, which were due for payment in January 2013.

Total liquidity at December 31, 2012, was down to EUR 2.7 million. This decrease in liquidity was the main reason for the reduction of our current assets from EUR 15.4 million to EUR 3.8 million in the course of 2012. The reduction was moreover pronounced by a decrease in inventories from EUR 0.3 million to EUR 31 thousand year over year which can be explained by cut-off-date effects.

Non-current assets dropped from EUR 4.0 million at the beginning of 2012 to EUR 3.1 million at year-end, mainly attributable to regular amortization and depreciation on intangible and tangible assets as well as to unscheduled amortization of development costs, only insignificantly compensated by capital expenditures of slightly more than EUR 0.1 million.

To reinforce the Group's equity ratio and to improve the threatening cash situation at balance sheet date, we had started dedicated financing activities in late 2012, which finally materialized in a capital increase by a public rights issue announced in December 2012 and successfully completed in January 2013. Hence, we received a gross cash inflow of EUR 5.0 million by issuing a total of 3.1 million additional shares. While this additional liquidity will fund the Company's operations at least until the end of 2013 according to our business projections, it is intended to secure the further financing of Epigenomics by additional activities in the months to come.

## EMPLOYEES

Mainly as a consequence of the Company's restructuring initiated in 2011, the total number of employees decreased from 61 at December 31, 2011, to 39 at December 31, 2012, with an average number of 45 throughout the reporting year (2011: 79). Seven of the 39 employees at year-end were located in Seattle, U.S.A.

The number of 39 employees as of year-end 2012 comprised 23 employees directly involved in R&D activities. The other 16 comprised seven employees in sales, marketing and business development functions and nine in general administration functions.

Overall personnel costs in 2012 totaled EUR 4.8 million, 30% below previous year's amount of EUR 6.9 million, even including a one-off payment in connection with the retirement of the Company's former CEO Geert Nygaard in the amount of EUR 0.6 million. This decrease is predominantly attributable to the aforementioned reduction in headcount.



## SUPPLEMENTARY REPORT

### SUCCESSFUL CAPITAL INCREASE

On January 25, 2013, we announced that our Executive Board, with the approval of the Supervisory Board, had taken the decision to implement a capital increase from authorized capital for 3,149,430 new ordinary bearer shares, generating gross proceeds of EUR 4,976,099.

Of these new ordinary bearer shares, 2,811,707 were taken up by existing shareholders at a subscription price of EUR 1.58 per new share during the subscription period which ended on January 24, 2013. The remaining 337,723 unsubscribed new shares were sold at the same price per new share in a private placement to institutional investors. The private placement was significantly oversubscribed.

On January 29, 2013, the implementation of the capital increase was registered with the commercial register ("Handelsregister"). Therefore, our total issued share capital increased from EUR 8,818,417.00 to EUR 11,967,847.00. The new shares were admitted to trading to the Frankfurt Stock Exchange on January 30, 2013.

We intend to use the net proceeds from the capital increase to finance our current operations.

### INVITATION TO AN EXTRAORDINARY GENERAL SHAREHOLDERS' MEETING

On January 25, 2013, we invited our shareholders in due time and form to an extraordinary General Shareholders' Meeting (EGM) on March 8, 2013. An EGM was required after we had announced on December 21, 2013, according to Section 92 Para. 1 of the German Stock Corporation Act, that Epigenomics AG as the Group's parent company had suffered a loss amounting to half of its share capital (according to German GAAP).

### NOTIFICATION OF ACCEPTANCE FOR FILING OF THE PMA APPLICATION FOR EPI PROCOLON® BY FDA

On February 21, 2013, we announced that the FDA gave us notification of acceptance of our PMA application for Epi proColon®. The agency concluded that all information needed for the substantive review is included and has granted priority review status to the application.

## OPPORTUNITIES AND RISKS

### OPPORTUNITIES AND RISK MANAGEMENT SYSTEM

Epigenomics is a globally operating cancer molecular diagnostics company and as such subject to many industry- and 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.

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 auditor and 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 auditor and the Supervisory Board.

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 share price. These are described below.

## BUSINESS-RELATED OPPORTUNITIES AND RISKS

We launched our first IVD product, the CRC screening test Epi proColon®, in October 2009 and our second IVD product Epi proLung® in July 2010. Furthermore, we introduced the second generation of Epi proColon® in early 2012. However, product revenue so far has not met our expectations. Following our decision to focus the organization and its commercial activities to the key market for our lead product Epi proColon®, the United States, FDA approval is most important for Epigenomics to be able to generate revenue from own product sales there.

The upcoming FDA decision on the approval of Epi proColon® is both opportunity and risk. Having proved the non-inferiority of blood-based Epi proColon® against FIT in the detection of CRC, we have removed one major risk and have now completed the full PMA for U.S. market approval. However, there is still a significant risk that FDA will not approve Epi proColon® for commercialization in the U.S.A. At this current time, we have no reason to believe this will be case. So far we have had a constructive dialog with the FDA, which we expect to continue. In order to achieve our 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.

Beyond U.S. market approval, our ability to grow revenue from our products will depend, among other factors, on the successful marketing and commercialization of our 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. During 2012, we continued to make all efforts to generate support in the medical and laboratory customer communities. We extended our network in the medical expert community in order to gain support for our product with key opinion leaders in the field and have started our preparations for a potential advisory panel meeting, which we expect to become part of the review process by the FDA.

Important elements in being commercially successful are the inclusion of the test in screening guidelines and the availability of reimbursement by insurance carriers. This is now looking more positive with the inclusion of Septin9 testing with its own defined code into the Current Procedural Terminology (CPT) coding document issued by the American Medical Association, which is the basis for reimbursement of laboratory tests by payers in the United States. Nevertheless, there is still a significant risk that despite the inclusion of Epi proColon® in the CPT coding list, major payors in the healthcare system might refuse reimbursement of the test.

Also in Europe we made progress with Swiss Life, one of France's largest private health insurance companies, deciding to recommend and reimburse up to 50% of the costs of the Septin9 blood-based test for the early detection of CRC to its insured persons as part of a preventive health program. This decision by Swiss Life clearly confirms our commercialization approach in Europe – working closely with key players in the healthcare systems throughout Europe. Nevertheless, considering the fragmented reimbursement landscape in Europe, there is still a major risk that the lack of broad positive reimbursement availability might continue hindering broad commercial acceptance of our main product in the different European markets. Also, the described difficult macroeconomic situation in several European countries might pose an additional obstacle in obtaining favorable reimbursement decisions and thus could also hinder market acceptance of our products.

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 these 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. Upon the launch of a Septin9-based test in Europe and the Asia/Pacific region by our collaboration partner Abbott in 2009, product sales by Abbott have fallen significantly behind our expectations. There is a risk that our licensing partners will not commit sufficient resources to successfully introduce and commercialize their versions of the test in major markets. In order to be able to offer their product commercially in the United States too, our IVD partners Abbott and potentially Qiagen would also need to get regulatory approval by the FDA, which bears additional risks.

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 North America, which have introduced their own versions of Septin9-based LDTs. In June, we added an additional non-exclusive licensing agreement with Companion Dx. Regionally focused Companion Dx will establish and commercialize a LDT in the Texan cancer-testing market and plans to launch the test early in 2013. In 2012, Quest intensively promoted its LDT (ColoVantage™) for aiding the detection of CRC in the United States, demonstrating encouraging market adoption as showed in numbers of tests sold. Our partner ARUP, which also markets

an LDT product based on our Septin9 technology in the United States, has been very active in providing additional scientific and commercial 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 the 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 LDTs to commercially available tests like Epi proColon® or Septin9 products from our partners, 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 instrumentation 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 sufficiently market our products or are not successful in marketing them at all, we may not find additional partners or the planned royalty income may 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. The management has implemented a retention plan with the goal to secure the ongoing 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 MethyLight 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 2013 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. Further freedom to operate analyses will be conducted as soon as new products or changes to existing products are planned and such analyses become appropriate. 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 Septin9, 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. The regulatory frameworks continue to be not fully established or clarified. 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 FDA approval of Epi proColon® we have retained the services of a leading regulatory affairs consulting group in the U.S.A. with a successful track record of guiding companies through the FDA approval process for (cancer) molecular diagnostic products. Furthermore, during 2012, we further extended our network in the medical expert community in order to gain support for our product with key opinion leaders and have started our preparations for a potential advisory panel meeting, which we expect to become part of the review process by the FDA. Strict management of our interactions with reference laboratories as well as seeking an ongoing dialog with the FDA as evidenced by meetings held with the agency throughout 2012 are an integral part of our risk management policies.

#### **FINANCIAL OPPORTUNITIES AND RISKS**

As of December 31, 2012, our available liquidity (cash, cash equivalents and marketable securities) amounted to EUR 2.7 million. Management is aware of the risk to have limited liquid assets to sustain the operations of the business. Therefore, we have announced a capital increase by way of a rights issue in January 2013. With this capital increase we generated gross proceeds of almost EUR 5.0 million which should extend our cash runway at least until year-end 2013. However, based on the current plans and income projections of the Company, this liquidity is still not sufficient to sustain the Company's operations over more than twelve months. Thus, in order to mitigate the risk of insolvency, we will have to secure additional funds in the near future to remain operational beyond 2013. Since it is not anticipated that we will be able to generate sufficient cash flows from licensing income or from product sales in the short term, we will continue to evaluate all strategic options including the option to raise additional capital in the markets before the end of 2013.

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.



We have reduced our portfolio of available-for-sale securities over the last years to only one remaining position. The historical investment in this remaining position has been made under the Company's investment policy, which was approved by the Supervisory Board. This policy stipulates to open only positions with an "investment grade" rating. Though, such ratings underwent intense critical discussions worldwide over the last years and were challenged regarding their expressiveness. Our security portfolio faces price risks – in the form of interest rate, issuer and market-related impairment risks – and liquidity risks. Under specific market conditions it could be difficult or impossible to liquidate the securities on short term at their fair value – irrespective of a good rating of the issuer. We have not made any investments in securities over the last years and as part of our risk mitigation strategy have exclusively been investing in money market instruments (i.e. time deposits) on euro or U.S. dollar basis to maximize availability of the liquidity. Simultaneously, we are accepting the rather poor returns that could be earned in the money market at the continuously low interest rates.

In 2013 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

The critical FDA decision on the approval of our lead product Epi proColon® in the United States is getting closer rapidly and is both a significant opportunity and risk. Having proved the non-inferiority of Epi proColon® against FIT in the detection of CRC, we have removed one major hurdle and have now completed the full PMA for U.S. market approval. However, there is still a significant risk that FDA will not approve Epi proColon® for commercialization in the United States, although at this current time, we have no reason to believe this will be case. While initial commercial success from our LDT partners in North America 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 relevant screening guidelines and secured reimbursement. Failure to obtain regulatory approval and reimbursement as well as lack of market acceptance and penetration in the United States would all have material impact on our revenue, earnings, financial position and our ability to raise further capital and can ultimately lead to a total loss of value in our stock. While initial positive commercial signs from key players in the healthcare systems in Europe, such as the reimbursement decision by Swiss Life, are encouraging, we are cautious not to expect such a significant uptake of the product in Europe that could balance a failure in the U.S. market in the absence of widely available reimbursement to the end user. 2013 will be a pivotal year for Epigenomics as financial resources of EUR 2.7 million in liquid assets at year-end 2012 plus the gross proceeds of EUR 5.0 million raised in early 2013 limit our ability to cope with potential additional hurdles along the regulatory track or in our commercial efforts. Ultimately, our ability to access additional capital to reach our commercial goals remains the key risk for the Company.

## PROGNOSIS REPORT

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

Over the next years, we plan to further establish the public perception of Epigenomics as a commercially-driven development operation for molecular diagnostic tests. The key success factor will be gaining U.S. market approval for our main product, Epi proColon®, by the FDA. To this end, our operational execution in 2013 will focus heavily on achieving FDA market approval and building the U.S. market for Epi proColon® without losing sight of the European market and our second product, Epi proLung®. Alongside these endeavors, we will continue to support our partner Abbott in its commercialization activities in completing the development of its own version of a Septin9 IVD kit for the U.S. and the European markets.

Throughout 2012, we continued to see encouraging adoption of our test in the United States as an LDT through our partners Quest, ARUP, and Gamma Dynacare. Adding Companion Dx to that list will further our reach into the North American market. Together with our partners we have taken a major step in having Septin9 testing reimbursable by inclusion of this test into the Current Procedural Terminology (CPT) coding document issued by the American Medical Association in 2012. Having now its own code for possible future reimbursement is a major step.

After a far-reaching restructuring of our direct marketing and sales efforts in our home markets we have focused our commercialization activities in Europe on targeting selectively key players in the healthcare systems. As a measure of our initial success in these steps, Swiss Life, one of France's largest private health insurance companies, has decided to recommend and reimburse up to 50% of the costs of the Septin9 test. This decision by Swiss Life clearly confirms and rewards our commercialization approach in Europe – working closely with key players in the healthcare systems throughout Europe – and we will continue on this path.

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 to provide selected partners access to our know-how, expertise and IP in this field via licenses and/or services.

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. With the anticipated FDA approval of Epi proColon® and the growing acceptance of Septin9 testing, we strongly believe that our shift from a R&D company to a commercial, revenue-generating company will successfully be accomplished.

### EXPECTED ECONOMIC CONDITIONS IN THE NEXT YEARS

We expect overall economic conditions and the capital market environment to continue to be challenging. Despite the recent, somewhat more positive sentiment, we feel that uncertainty in the capital markets will prevail for the near to mid-term 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. However, as companies on the customer and on the partner side reduce and cut budgets and R&D spending, it may become harder to close front-loaded business deals providing us with cash inflows in advance as required according to our mid-term business plans.

With currency movements remaining volatile between the U.S. dollar and the euro and prognoses over the next 12 months anywhere in the range from EUR/USD 1.20 to EUR/USD 1.50, we have decided to lock-in our budget rate for 2013 at EUR/USD 1.30.

## OUTLOOK ON THE EARNINGS SITUATION

Prior to securing the approval of Epi proColon® as an IVD diagnostic product in the U.S. market, our revenue estimate remains cautious. We expect revenue from our activities with diagnostic partners at comparable or slightly increasing levels compared to 2012 for the following year. Any increase until potential FDA approval is expected to be mainly driven by the growing adoption of Septin9-targeted LDTs in the U.S.A. Another contributor can be potential future licensing income, especially if we succeed to gain additional partners for Septin9 licensing agreements in 2013 and 2014. A major increase in product 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 markets, we recognized the self-payer segment in Europe as being a very challenging one and thus have adapted our commercial strategy. These changes are expected to lead to more sustainable revenue growth, although it might take longer to reach that point.

We expect EBIT and net loss for 2013 to be at significantly lower levels than in 2012. Following completion of the head-to-head comparative study of Epi proColon® against FIT and the concentration of our R&D activities on the most important value driver, R&D expenses are expected to be just half of the amount of 2012. In addition, the significant reduction in headcount, sales and marketing costs, and the implemented restructuring measures in the past will continue to reduce our cost base. On this basis, net loss is expected to range between EUR 6.5 to 7.5 million in 2013, assuming regulatory approval for Epi proColon® in the United States will be granted according to our expectations.

Despite the expected decrease in operating costs, we will still need to sponsor a limited number of clinical trials to drive commercial adoption and to invest in automation development for higher-throughput CRC testing as well as in R&D activities towards next-generation products.

## OUTLOOK ON THE FINANCIAL SITUATION

In line with the reduced net loss, cash consumption for the fiscal year 2013 is projected at a significantly lower level compared to 2012, i.e. around EUR 6.5 to 7.5 million. It is expected to further decrease only once revenue growth helps to create a ramp-up in cash inflows. Coming from EUR 2.7 million in liquid resources (cash, cash equivalents and marketable securities) at year-end 2012 plus the gross proceeds of EUR 5.0 million raised at the beginning of 2013, current financial resources are not sufficient at this projected cash consumption to support the Company's operations beyond 2013. 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 continue to diligently explore all strategic options available to the Company. These options explicitly include capital market transactions. Given the volatility of the financial markets and the development of the Company's share price, we continue to further explore other strategic options for the further development of Epigenomics.

## MID-TERM OPPORTUNITIES

Coming from a company history in pioneering DNA methylation technology and biomarker discovery and development, the opportunity for breakthrough commercial success in the key markets with our DNA-methylation-based cancer diagnostic products is finally becoming more visible. While there is still a phase of investment ahead of us in the mid-term, the decreasing development and regulatory risks around our products and in our key markets are encouraging facts. Furthermore, the increasing acceptance of early cancer diagnosis as a way of fighting disease as well as concerns about performance and acceptance of the available testing methods to date create a fertile ground for our business in the medium term.

The products developed by us and our partners for blood-based CRC testing have matured significantly and were introduced for commercialization in the global markets. The expected FDA approval for our Septin9 test Epi proColon® offers a significant near-term opportunity to address the largest and most attractive global IVD market: the United States of America.

Lung cancer raises many clinical questions implicating huge medical needs for better diagnostics based on molecular tests. Our SHOX2 biomarker and the Epi proLung® IVD kit present an opportunity to address such market needs and provide clear benefits to patients and physicians in fighting this dreadful disease. Having now further proved the utility of our test, we anticipate being able to attract some interest from third parties with whom we might be able to commercialize this product in the global markets.

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 enterprise value increase from catalytic events, primarily the market approval of Epi proColon® in the United States and also additional licensing partnerships.

#### 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 months to come is the expected approval for our product by the FDA to be able to start the commercialization of Epi proColon® in the most relevant market of the world – the United States of America. The future value of the Company and its financial situation are heavily dependent on this milestone.

In order to be able to protect the continuity of our business operations, sufficient liquidity has to be available. We continuously rely on the capital markets to raise equity and debt financing as needed and we expect having to make use of this option again in the near future. In order to not having to rely exclusively on a capital market financing of our business while remaining in control of the situation, we will continue to evaluate other reasonable strategic options for our further development.

## CORPORATE GOVERNANCE

To the Executive Board and the Supervisory Board of Epigenomics, corporate governance lies at the heart of responsible and ethical management. The very interactive dialog and regular communication between the Executive Board and the Supervisory Board throughout 2012 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.

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 Code.

Epigenomics' corporate governance principles in certain aspects go well beyond legal requirements and recommendations of the 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 where we chose to deviate from the Code. There is a clear commitment to adhere to the Code going forward to the greatest extent possible.

**DECLARATION OF COMPLIANCE 2012 WITH  
THE GERMAN CORPORATE GOVERNANCE CODE  
PURSUANT TO SECTION 161 OF THE  
GERMAN STOCK CORPORATION ACT (AKTG)\***

Pursuant to Section 161 of the German Stock Corporation Act (Aktiengesetz – AktG), the Executive Board and the Supervisory Board of Epigenomics AG as a listed company have to explain each year, which recommendations of the German Corporate Governance Code were or were not complied with.

The Executive Board and the Supervisory Board of Epigenomics AG hereby declare that, since the last declaration of compliance in December 2011 and until June 15, 2012, Epigenomics AG has complied with the recommendations of the German Government Commission on the German Corporate Governance Code in the version of May 26, 2010, and has since June 15, 2012, complied, and complies, with the recommendations of the Code in the version of May 15, 2012 (published by the Ministry of Justice in the official part of the Federal Gazette on June 15, 2012), in each case with the exceptions set forth below.

**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 4.2.1**

In view of the size and financial situation of the Company, the Supervisory Board is of the opinion that the current composition of the Executive Board with only one member is adequate. The Supervisory Board is convinced that Dr. Taapken has the necessary expertise and personality to manage the Company. The Supervisory Board will supervise the fulfilment of all requirements for a successful management of the Company together with the Executive Board and, if deemed necessary, take adequate personnel decisions. Based on the fact that the Executive Board has only one member, no chairman or spokesman of the Executive Board is appointed. Accordingly, the by-laws governing the work of the Executive Board do not contain provisions recommended in Section 4.2.1 to the extent they refer to Executive Boards composed of several persons.

**Section 4.2.3 Paragraphs 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 referring to comparison parameters does not improve the sense of responsibility and the motivation of the Executive Board members and that the possibility of a limitation (cap) is not necessary due to the structure of our existing stock option programs.

**Section 4.2.3 Paragraphs 4 and 5**

The service contracts with Executive Board members of Epigenomics AG did not and do not include severance payment caps 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 particular circumstances in case of a change of control. Accordingly, we did not and will not comply with the recommendation in Section 4.2.3 Paragraph 5.

\* This declaration is not part of the audited consolidated management report.



*Section 5.1.2 Paragraphs 1 and 2 and  
Section 5.4.1 Paragraphs 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 as well as the appointment of an adequate number of independent Supervisory Board members. In deviation 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 strive to achieve an appropriate diversity in the Executive Board and the Supervisory Board, especially with respect to the internationality and the participation of women, and to ensure that an adequate number of independent Supervisory Board members is elected. 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 5.3.1, 5.3.2 and 5.3.3*

As a consequence to the reduction of the number of Supervisory Board members from six to three resolved upon in the Annual General Shareholders' Meeting on May 2, 2012, the Supervisory Board considers the formation of committees no longer to be adequate. An increase of the efficiency of the Supervisory Board's work would not be achieved. Committees comprising less than three members and therefore less than the full Supervisory Board could not be delegated powers to take decisions. Therefore, the Supervisory Board has not formed committees.

In addition, prior to the reduction of the number of Supervisory Board members, the Supervisory Board did, in view of the Company's size, not consider the formation of a nomination committee (Section 5.3.3) necessary. In the past, these issues were handled by the personnel and remuneration committee.

*Section 5.4.5 Sentence 2*

The Supervisory Board cannot comply with the recommendation in Section 5.4.5 Sentence 2, 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 Paragraphs 1 Sentence 3*

In the past, the compensation of the Supervisory Board members for their committee activities was structured such that there was a separate compensation for the committee chairmanship but not for the mere membership in a committee. The committee activities were evenly distributed among the members of the Supervisory Board. A separate compensation for the mere membership in committees did not appear necessary. Accordingly, we did not comply with the recommendation in Section 5.4.6 Paragraph 1 Sentence 3.

As a consequence of the reduction of the number of the Supervisory Board members resolved upon in the Annual General Shareholders' Meeting on May 2, 2012, committees do no longer exist. Accordingly, a separate compensation is neither stipulated for the chairmanship nor the mere membership in committees. Therefore, we continue to 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 comply with the recommendation in Section 5.4.6 Paragraph 2 of the Code in the version of May 26, 2010. In the version of the Code of May 15, 2012, the recommendation to implement a performance-related compensation is repealed; therefore, as from the applicability of this version of the Code on June 15, 2012, no deviation from the Code is to be declared.

Berlin, October 2012

On behalf of the Supervisory Board

**Heino von Prondzynski**  
(Chairman of the Supervisory Board)

On behalf of the Executive Board

**Dr. Thomas Taapken**  
(CEO/CFO)

This statement is also made permanently accessible to the general public on the Company's website under [www.epigenomics.com/en/news-investors/investors/corporate-governance](http://www.epigenomics.com/en/news-investors/investors/corporate-governance).

#### **DECLARATION OF GOVERNANCE**

According to Section 289a of the German Commercial Code (HGB), the Declaration of Governance has been made permanently accessible to the general public on Epigenomics AG's website under [www.epigenomics.com/en/news-investors/investors/corporate-governance](http://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 which 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 auditor and consultations of the Company's lawyers as required.

Basically, the Epigenomics Group has established the principle of segregation of duties as far as reasonable in a commercial organization of this size. This principle is supplemented by the four-eyes principle. Neither the Executive Board nor any employees are authorized to represent and sign exclusively on behalf of the Company according to internal regulations.

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 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™, 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 reasonable suspicion of a possible impairment arises.

## DIRECTORS' DEALINGS\*

The following declared securities transactions took place during 2012:

Date	Executive Board member	Transaction type	Number of shares	Share price (in EUR)	Transaction value (in EUR)
April 4, 2012	Dr. Thomas Taapken	Purchase	2,000	2.25	4,500
April 16, 2012	Dr. Thomas Taapken	Purchase	1,000	2.18	2,180

\* This declaration is not part of the audited consolidated management report.



## REMUNERATION REPORT

### COMPOSITION AND REMUNERATION 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.

Dr. Thomas Taapken had been the Company's CFO in the reporting year. Effective October 1, 2012, he was appointed additionally as the Company's acting CEO after Geert W. Nygaard, the former CEO of Epigenomics, had left the Executive Board and the Company on September 30, 2012. The service agreement with Dr. Taapken has a term until March 2014.

The remuneration 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 remuneration – which is reviewed by the Supervisory Board annually – is compared to national and international benchmarks. Remuneration 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 remuneration component: a long-term performance-based remuneration in the form of stock option grants.

The service agreement of Dr. Taapken contains a post-contractual non-compete provision for a period of two years after the service agreement has ended. During such period, Dr. Taapken is entitled to 100% of his last basic salary as a non-competition payment. In case of a change of control, Dr. Taapken is entitled to terminate his service agreement and would in such case be entitled to receive payment of the fixed remuneration amount for the time remaining until his service agreement would have expired.

The individual remuneration of the Executive Board members in 2012 is shown below, whereby "other compensation" comprises exclusively a one-off payment to Mr. Nygaard in connection with his retirement.

in EUR	<b>2012</b> (2011)			
	Fixed compensation	Variable compensation	Other compensation	Total compensation
Members of the Executive Board in 2012				
<b>Dr. Thomas Taapken</b> <i>(since April 1, 2011)</i>	225,000	0	0	225,000
Berlin (GER)	(168,750)	(0)	(0)	(168,750)
<b>Geert Walther Nygaard</b> <i>(until September 30, 2012)</i>	292,500	0	580,000	872,500
Berlin (GER)	(390,000)	(0)	(0)	(390,000)
<b>Total remuneration</b>	<b>517,500</b>	<b>0</b>	<b>580,000</b>	<b>1,097,500</b>
	(558,750)	(0)	(0)	(558,750)

In accordance with Section 6.6 Sentence 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 has to be reported if these directly or indirectly exceed 1% of the shares issued by the Company.

As of December 31, 2012, Dr. Taapken owned 5,000 shares of the Company (Dec 31, 2011: 2,000). He was granted 60,000 stock options in the reporting year.

Mr. Nygaard held 137,000 stock options of the Company before his retirement on September 30, 2012, of which 78,001 were cancelled then. As of December 31, 2012, his remaining 58,999 stock options were fully vested and had a weighted-average exercise price of EUR 18.25.

Member of the Executive Board	Stock options held	as of Dec 31, 2012 (Dec 31, 2011)		2012 (2011)	
		Weighted-average exercise price in EUR	Vested options	Weighted-average exercise price in EUR	Exercised options
Dr. Thomas Taapken	80,000	4.67	0	n/a	0
	(20,000)	(9.60)	(0)	n/a	(0)

## COMPOSITION AND REMUNERATION OF THE SUPERVISORY BOARD

Epigenomics AG's Supervisory Board consists of three members with broad experience in the pharmaceutical, diagnostics or financial industries. According to a resolution of the Company's Annual General Shareholders' Meeting 2012, the number of Supervisory Board seats has been reduced from six to three. As a consequence to this reduction, the formation of committees was no longer considered to be adequate (for further details please refer to our Declaration of Governance permanently accessible on the Company's website).

The Supervisory Board members of the Company as of December 31, 2012, were:

- **Heino von Prondzynski** – Einsiedeln (CH) – Chairman (since May 2, 2012)  
*Independent consultant and former member of the group management of F. Hoffmann-La Roche Ltd. (CEO of the Division Roche Diagnostics at F. Hoffmann-La Roche Ltd., Basel, CH)*  
Supervisory Board member from May 2007 until March 2010 and since May 2012.  
Mr. Heino von Prondzynski is not a member of other mandatory supervisory boards. He is a member of comparable boards with supervisory function of the following German and foreign undertakings:  
– Hospira, Inc., Lake Forest, IL (U.S.A.)  
– HTL-Strefa S.A., Warsaw (POL) – (Chairman)  
– Koninklijke Philips Electronics N.V. (Royal Philips Electronics), Eindhoven (NL)  
– Qiagen N.V., Venlo (NL)

- **Ann Clare Kessler, Ph.D.** – Rancho Santa Fe, CA (U.S.A.)  
*Independent consultant and former Head of Global Project Management at F. Hoffmann-La Roche Ltd., Basel (CH) and former Head of the Division of Exploratory Research at F. Hoffmann-La Roche Inc. (U.S.A.)*

Supervisory Board member since June 2005.

Ms. Kessler, Ph.D., is not a member of other mandatory supervisory boards. She is a member of comparable boards with supervisory function of the following German and foreign undertakings:

- Althea Dx Inc., San Diego, CA (U.S.A.)
- MedGenesis Therapeutix, Inc., Victoria, BC (CAN)

- **Prof. Dr. Günther Reiter** – Pfullingen (GER)  
*Professor at the ESB Business School in Reutlingen (GER)*

Supervisory Board member since June 2005.

Prof. Dr. Reiter is not a member of other mandatory supervisory boards. He is a member of comparable boards with supervisory function of the following German and foreign undertakings:

- Deltoton GmbH, Würzburg (GER)
- CSA Verwaltungs GmbH, Würzburg (GER)

The following members retired from the Supervisory Board on May 2, 2012:

- **Prof. Dr. Dr. h.c. Rolf Krebs** – Mainz (GER) – Chairman until May 2, 2012  
*Physician*
- **Prof. Dr. Dr. Dr. h.c. Uwe Bicker** – Bensheim-Auerbach (GER) – Deputy chairman until May 2, 2012  
*Dean of the Medical Faculty of Mannheim/Heidelberg University (GER)*
- **Joseph Anderson, Ph.D.** – Oxted, Surrey (GB)  
*Partner at Abingworth LLP, London (GB)*
- **Günter Frankenne** – Berg/Neumarkt (GER)  
*Independent Strategy Consultant*

A new remuneration structure for the Supervisory Board has been approved by the Annual General Shareholders' Meeting on May 2, 2012, and is based on an annual cash retainer ("fixed remuneration") and meeting-related payments ("variable remuneration"). The previous remuneration structure (valid until May 2, 2012) had additionally been based on further payments for the chairpersons of the formed committees ("other remuneration").

The remuneration does not comprise any performance-related elements or long-term incentive components.

Remuneration of the members of the Supervisory Board in 2012:

in EUR	Fixed compensation		Variable compensation		Other compensation		Total compensation	
	2011	2012	2011	2012	2011	2012	2011	2012
Heino von Prondzynski	0	39,839	0	8,000	0	0	0	47,839
Ann Clare Kessler, Ph.D.	10,000	29,919	10,000	12,000	0	0	20,000	41,919
Prof. Dr. Günther Reiter	10,000	16,640	10,000	12,000	5,000	1,680	25,000	30,320
Prof. Dr. Dr. h.c. Rolf Krebs	30,000	10,161	5,000	2,000	5,000	1,694	40,000	13,855
Prof. Dr. Dr. Dr. h.c. Uwe Bicker	20,000	6,774	8,000	4,000	0	0	28,000	10,774
Joseph Anderson, Ph.D.	10,000	3,387	10,000	4,000	0	0	20,000	7,387
Günter Frankenne	10,000	3,387	10,000	4,000	0	0	20,000	7,387
<b>Total</b>	<b>90,000</b>	<b>110,107</b>	<b>53,000</b>	<b>46,000</b>	<b>10,000</b>	<b>3,374</b>	<b>153,000</b>	<b>159,481</b>

In addition, the members of the Supervisory Board were reimbursed for expenses totaling EUR 42 thousand in 2012 (2011: EUR 23 thousand).

Holding of shares in the Company by the members of the Supervisory Board at December 31:

in EUR	Shares held	
	2011	2012
Heino von Prondzynski	n/a	12,100
Ann Clare Kessler, Ph.D.	2,800	2,800
Prof. Dr. Günther Reiter	0	0
Prof. Dr. Dr. h.c. Rolf Krebs	0	n/a
Prof. Dr. Dr. Dr. h.c. Uwe Bicker	0	n/a
Joseph Anderson, Ph.D.	0	n/a
Günter Frankenne	0	n/a
<b>Total</b>	<b>2,800</b>	<b>14,900</b>

## 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](http://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 SECTION 315 PARAGRAPH 4 OF THE GERMAN COMMERCIAL CODE (HGB)

According to Section 315 Paragraph 4 of the German Commercial Code, 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 SHAREHOLDINGS OF MORE THAN 10% OF THE VOTING RIGHTS

Shareholder	Notification date	Shareholdings in %
Abingworth LLP, London (GB)	April 1, 2010	19.58

## COMPOSITION OF SHARE CAPITAL

As of December 31, 2012, the share capital of Epigenomics AG comprised exclusively common shares with equal rights and a par value of EUR 1.00 each. The total number of outstanding shares as of December 31, 2012, was 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 AktG.

Pursuant to Section 14 of the Articles of Association, the Supervisory Board is entitled to adopt amendments and completions to the Articles of Association 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).

The share capital is conditionally increased 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, 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, 11,400 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, 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, 102,195 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, 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. 200,430 new shares can be created upon exercise of already granted options from the underlying program. Another 103,816 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, 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. 83,696 new shares can be created upon exercise of already granted options from the underlying program. Another 212,952 options can still be granted to beneficiaries from the underlying program.

The share capital is further conditionally increased by up to EUR 3,527,366.00 by issuance of up to 3,527,366 new non-par value bearer shares with a nominal par value of EUR 1.00 per share (Conditional Capital IX). The conditional capital increase serves the purpose of granting shares to holders or creditors of bonds or participation rights issued by the Company or a subsidiary on the basis of the authorization resolution dated May 2, 2012, until May 1, 2017, if option or conversion rights are exercised, option or conversion obligations are performed or the Company exercises an election right to entirely or partially grant non-par value shares of the Company instead of payment of the due cash amount. The issuance of the new shares occurs at the respective option or conversion price or the lower issue price, in each case as further to be determined and specified in accordance with the aforementioned authorization resolution. The conditional capital increase is only to be implemented if bonds or participation rights are issued in accordance with the authorization resolution of the General Shareholders' Meeting dated May 2, 2012, and only to the extent that

- option or conversion rights are exercised or
- holders or creditors of bonds or participation rights who are under an obligation to exercise an option or to convert perform their obligation to exercise the option or to convert or
- the Company exercises an election right to grant non-par value shares of the Company instead of paying a due cash amount

and to the extent that no cash settlement is granted or treasury shares or shares of another listed company are delivered.

## FIVE-YEAR OVERVIEW

– according to the consolidated financial statements –

EUR thousand (unless stated otherwise)	2008	2009	2010	2011	2012
<b>Statement of Profit or Loss</b>					
Revenue	2,586	4,260	1,787	1,437	1,039
Gross profit	888	1,462	1,313	1,080	747
EBIT	-12,750	-10,218	-11,449	-15,245	-12,123
EBITDA	-10,242	-9,442	-10,307	-10,939	-11,200
Net loss for the year	-12,271	-10,223	-11,476	-15,575	-12,197
<b>Balance sheet</b>					
Non-current assets	5,857	5,716	5,463	4,042	3,053
Investments in non-current assets <sup>1</sup>	258	324	439	388	87
Current assets	14,426	10,638	28,375	15,421	3,825
Non-current liabilities	38	9	0	0	0
Current liabilities	3,677	4,261	2,543	3,277	2,720
Equity	16,568	12,084	31,295	16,186	4,158
Equity ratio in %	81.7	73.9	92.5	83.2	60.5
Total assets	20,283	16,354	33,838	19,463	6,878
<b>Cash flow statement</b>					
Cash flow from operating activities	-9,800	-10,629	-9,479	-9,111	-10,884
Cash flow from investing activities	1,468	-195	-315	-2,842	954
Cash flow from financing activities	11,500	4,964	30,394	-44	-422
Net cash flow	3,168	-5,860	20,600	-11,997	-10,352
Cash consumption	-9,957	-11,324	-10,294	-12,241	-10,930
Cash and cash equivalents at year-end	9,814	3,954	24,554	12,557	2,205
<b>Stock<sup>2</sup></b>					
Weighted-average number of shares issued	5,201,422	5,834,427	8,083,549	8,818,417	8,818,417
Earnings per share (basic and diluted) in EUR	-2.35	-1.75	-1.40	-1.77	-1.38
Share price (in EUR) at year-end	10.00	17.60	10.25	1.30	2.10
<b>Number of employees at year-end</b>					
	90	86	82	61	39

<sup>1</sup> Excluding capitalized development costs<sup>2</sup> In order to ensure comparability following the reverse stock split, the figures for 2008–2010 have been adjusted retroactive.

# CONSOLIDATED FINANCIAL STATEMENTS AND NOTES

– according to International Financial Reporting Standards (IFRSs) –

## CONTENTS

Group Statement of Profit or Loss and Other Comprehensive Income .....	46
Group Balance Sheet .....	47
Group Cash Flow Statement .....	48
Statement of Changes in Group Equity .....	49
Notes to the Consolidated Financial Statements .....	50
<i>Basic Information, Principles and Methods</i> .....	50
<i>Notes to the Group Statement of Profit or Loss     and other Comprehensive Income</i> .....	59
<i>Notes to the Group Balance Sheet</i> .....	66
<i>Notes to the Group Cash Flow Statement</i> .....	78
<i>Risks and Risk Management</i> .....	79
<i>Information on Stock Option Programs</i> .....	81
<i>Other Information</i> .....	83



GROUP STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME  
FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31

EUR thousand	Notes	2011	2012
Revenue	1	1,437	1,039
Cost of sales	3	-357	-292
<b>Gross profit</b>		<b>1,080</b>	<b>747</b>
<i>Gross margin in %</i>		<i>75.1</i>	<i>72.0</i>
Other income	2	452	979
Research and development costs	3	-4,946	-8,016
Selling, general and administrative costs	3	-5,938	-5,520
Other expenses	3, 6	-5,893	-313
<b>Operating result (EBIT)</b>	7	<b>-15,245</b>	<b>-12,123</b>
Interest income	8	219	104
Other financial result	8	-292	-24
<b>Net loss for the year before taxes on income</b>		<b>-15,318</b>	<b>-12,043</b>
Taxes on income	9	-257	-154
<b>Net loss for the year</b>	10	<b>-15,575</b>	<b>-12,197</b>
<i>Items that may be reclassified subsequently to profit or loss:</i>			
Fair value adjustments of available-for-sale securities	23	333	81
<b>Other comprehensive income for the year</b>		<b>333</b>	<b>81</b>
<b>Total comprehensive income for the year</b>		<b>-15,242</b>	<b>-12,116</b>
<b>Earnings per share (basic and diluted) in EUR</b>	10	<b>-1.77</b>	<b>-1.38</b>

## GROUP BALANCE SHEET

<b>ASSETS</b> EUR thousand	Notes	<b>Dec 31, 2011</b>	<b>Dec 31, 2012</b>
<i>Non-current assets</i>			
Intangible assets	11, 13	3,322	2,589
Tangible assets	12, 13	506	358
Deferred taxes	14	214	106
<b>Total non-current assets</b>		<b>4,042</b>	<b>3,053</b>
<i>Current assets</i>			
Inventories	15	283	31
Trade receivables	16	211	314
Marketable securities	17	1,428	509
Cash and cash equivalents	18	12,557	2,205
Other current assets	19	942	766
<b>Total current assets</b>		<b>15,421</b>	<b>3,825</b>
<b>Total assets</b>		<b>19,463</b>	<b>6,878</b>

<b>EQUITY AND LIABILITIES</b> EUR thousand	Notes	<b>Dec 31, 2011</b>	<b>Dec 31, 2012</b>
<i>Equity</i>			
Subscribed capital	20	8,818	8,818
Capital reserve	20	22,212	22,299
Retained earnings	22	1,303	-14,272
Net loss for the year	10	-15,575	-12,197
Other comprehensive income	23	-572	-491
<b>Total equity</b>		<b>16,186</b>	<b>4,158</b>
<i>Current liabilities</i>			
Trade payables	25	1,228	1,681
Deferred income	26	0	306
Other liabilities	27	1,013	357
Provisions	28	1,036	376
<b>Total current liabilities</b>		<b>3,277</b>	<b>2,720</b>
<b>Total equity and liabilities</b>		<b>19,463</b>	<b>6,878</b>

# GROUP CASH FLOW STATEMENT

## FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31

EUR thousand	Notes	2011	2012
<b>Cash and cash equivalents at the beginning of the year</b>	18	<b>24,554</b>	<b>12,557</b>
<i>Operating activities</i>	30		
<b>Net loss for the year before taxes on income</b>		<b>-15,318</b>	<b>-12,043</b>
Corrections for:			
Depreciation on tangible assets	5, 7, 12	349	172
Amortization of intangible assets	5, 7, 11	3,957	751
Losses from the disposal of assets		37	34
Stock option expenses	4	134	87
Net foreign exchange rate result		-6	3
Interest income	8	-219	-104
Realized losses from the disposal of available-for-sale securities	8	432	0
Taxes		-46	-50
<b>Operating result before changes in net current assets</b>		<b>-10,680</b>	<b>-11,150</b>
Changes in trade receivables and other current assets		682	56
Changes in inventories		-122	252
Changes in current liabilities from operating activities		782	-164
<b>Liquidity earned from operating activities</b>		<b>-9,338</b>	<b>-11,006</b>
Interest received		227	122
<b>Cash flow from operating activities</b>		<b>-9,111</b>	<b>-10,884</b>
<i>Investing activities</i>	31		
Payments for investments in tangible assets		-326	-41
Proceeds from the sale of non-current assets		5	13
Payments for investments in intangible assets		-35	-18
Additions to capitalized development costs		-2,774	0
Proceeds from the disposal of available-for-sale securities	31	288	1,000
<b>Cash flow from investing activities</b>		<b>-2,842</b>	<b>954</b>
<i>Financing activities</i>	32		
Payments for the creation of new shares	32	-36	-422
Payments for lease financing		-8	0
<b>Cash flow from financing activities</b>		<b>-44</b>	<b>-422</b>
<b>Net cash flow</b>		<b>-11,997</b>	<b>-10,352</b>
<b>Cash and cash equivalents at the end of the year</b>	18	<b>12,557</b>	<b>2,205</b>

STATEMENT OF CHANGES IN GROUP EQUITY  
AS OF DECEMBER 31

EUR thousand	Notes	Subscribed capital	Capital reserve	Retained earnings	Net loss for the year	Other comprehensive income	Group equity
<b>December 31, 2010</b>		<b>44,092</b>	<b>22,078</b>	<b>-22,494</b>	<b>-11,476</b>	<b>-905</b>	<b>31,295</b>
<b>Total comprehensive income</b>	10, 23	<b>0</b>	<b>0</b>	<b>0</b>	<b>-15,575</b>	<b>333</b>	<b>-15,242</b>
Transfer of net loss for the year 2010 to retained earnings		0	0	-11,476	11,476	0	0
Reverse stock split (5:1)		-35,274	0	35,274	0	0	0
Stock option expenses	4	0	134	0	0	0	134
<b>December 31, 2011</b>		<b>8,818</b>	<b>22,212</b>	<b>1,303</b>	<b>-15,575</b>	<b>-572</b>	<b>16,186</b>
<b>Total comprehensive income</b>	10, 23	<b>0</b>	<b>0</b>	<b>0</b>	<b>-12,197</b>	<b>81</b>	<b>-12,116</b>
Transfer of net loss for the year 2011 to retained earnings		0	0	-15,575	15,575	0	0
Stock option expenses	4	0	87	0	0	0	87
<b>December 31, 2012</b>		<b>8,818</b>	<b>22,299</b>	<b>-14,272</b>	<b>-12,197</b>	<b>-491</b>	<b>4,158</b>

# 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") and in application of the International Financial Reporting Standards (IFRSs) of the International Accounting Standards Board (IASB), London, in effect at the closing date December 31, 2012, as mandatory 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 statement of profit or loss has been prepared using the cost of sales method.

### REPORTING PERIOD AND REPORTING CURRENCY

The reporting period (comparison period) as defined in these consolidated financial statements is the period from January 1 to December 31, 2012 (2011). The reporting currency is the euro.

### 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 4100, 800 Fifth Avenue, Seattle, WA 98104, U.S.A.), its wholly owned subsidiary.

For the reporting year and the previous year, the two companies have submitted individual financial statements which were either audited or critically reviewed, 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, income and expenses, profits and losses, receivables and payables are eliminated in full on consolidation.

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

The Group has applied the amendments to IAS 1 *Presentation of Items of Other Comprehensive Income* in advance of the new effective date (annual reporting periods beginning on or after July 1, 2012). According to these amendments to IAS 1, the “income statement” is renamed “statement of profit or loss”. Simultaneously, the Group has elected for the first time the option of IAS 1.10A to present profit or loss and other comprehensive income in a single statement instead of two separate statements as in previous years. The application of these amendments to IAS 1 does not lead to any impact on profit or loss and comprehensive income. In accordance with IAS 1.10, the Group continues to use the term “balance sheet” instead of “statement of financial position”.

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 the Annual Improvements to IFRS 2009–2011,
- *IAS 12 Income Taxes* –  
Amendments to IAS 12 – *Deferred Tax: Recovery of Underlying Assets*.

The Group has not applied the following new and revised IFRSs which have been issued but are not yet effective:

		Mandatorily applicable beginning on or after
Amendments to IFRSs	Annual Improvements to IFRSs 2009–2011 Cycle except for the amendments to IAS 1	January 1, 2013
Amendments to IFRS 7	Disclosures – Offsetting Financial Assets and Financial Liabilities	
IFRS 10	Consolidated Financial Statements	
IFRS 11	Joint Arrangements	
IFRS 12	Disclosure of Interests in Other Entities	
Amendments to IFRS 10, IFRS 11 and IFRS 12	Transition Guidance	
IFRS 13	Fair Value Measurement	
IAS 19 (as revised in 2011)	Employee Benefits	
IAS 27 (as revised in 2011)	Separate Financial Statements	
IAS 28 (as revised in 2011)	Investments in Associates and Joint Ventures	
IFRIC 20	Stripping Costs in the Production Phase of a Surface Mine	January 1, 2014
Amendments to IAS 32	Offsetting Financial Assets and Financial Liabilities	
IFRS 9	Financial Instruments	January 1, 2015
Amendments to IFRS 7 and IFRS 9	Mandatory Effective Date of IFRS 9 and Transition Disclosures	

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

## MANAGEMENT'S JUDGMENT, ASSUMPTIONS 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 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. The global economic situation is not expected to improve significantly in 2013, but rather to remain stable as long as the sovereign debt crisis does not deteriorate again. 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 of 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 1.28–1.38 throughout 2013. 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.

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 the consolidated statement of profit or loss. 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);
- 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).



## ACCOUNTING AND VALUATION PRINCIPLES

### *Intangible assets*

Intangible assets other 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 statement of profit or loss 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 of 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", 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 statement of profit or loss 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 the net 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 stated 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 finished products the principle of separate valuation applies.

### ***Financial instruments***

Financial assets and liabilities are initially measured at fair value. 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 cost or at fair value and then at amortized acquisition cost 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 initially recognized at fair value at the date the derivative contracts are entered into and are subsequently remeasured to their fair values at the end of each reporting period. The result is recognized as financial result through profit or loss.

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 Group's contractual partner of the underlying agreement.

### ***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 *Statement 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 twelve months. In the licensing business the operating cycle is even more than twelve months. Liabilities are measured at amortized cost, 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 cost. 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 supranational, regional or local authorities are recognized through profit or loss as other income over the subsidized terms of each granted project according to its progress of fulfillment. Payments received in advance from customers for R&D services to render or for licenses are deferred 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. When 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 goods and the rendering of other services is recognized when

- delivery of the goods to the buyer has taken place,
- transfer of risks and rewards in connection with the goods has been completed,
- the amount of revenue and the costs incurred related to the transaction can be measured reasonably 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.

Non-refundable 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.

### *Other expenses*

Other expenses comprise of all operating expenses which do not classify as cost of sales, R&D costs or SG&A costs as defined above. This includes in particular but not exclusively

- foreign currency exchange rate losses,
- losses from the disposal of assets and
- expenses due to extraordinary effects or measures like restructuring expenses or impairment losses of non-current assets (e.g. goodwill amortization).

### *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

### *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, 2011	Dec 31, 2012
EUR/USD	1.2939	1.3194
EUR/GBP	0.83530	0.81610
EUR/CAD	1.3215	1.3137

Average rates	2011	2012
EUR/USD	1.4000	1.2932
EUR/GBP	0.87124	0.81193
EUR/CAD	1.3805	1.2906

## NOTES TO THE GROUP STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

### 1 REVENUE

Revenue source by revenue type:

	2011		2012	
	EUR thousand	% of total	EUR thousand	% of total
Product sales (own and third-party)	347	24.1	406	39.0
Licensing income	845	58.8	386	37.2
R&D income and reimbursements	245	17.1	247	23.8
<b>Total revenue</b>	<b>1,437</b>	<b>100.0</b>	<b>1,039</b>	<b>100.0</b>

Licensing income is generated by out-licensing of own intellectual property (e.g. technologies, bio-markers) to third parties. Revenue from product sales is generated by the sale of the Group's products through own sales channels, through distribution partners or by the rendering of services based on the Company's products by third parties. R&D income and reimbursements are generated by rendering services in connection with contract research and by charging pass-through costs to third parties.

Revenue source by geographical market:

	2011		2012	
	EUR thousand	% of total	EUR thousand	% of total
Europe	1,023	71.2	712	68.6
North America	320	22.2	284	27.3
Rest of the world	94	6.6	43	4.1
<b>Total revenue</b>	<b>1,437</b>	<b>100.0</b>	<b>1,039</b>	<b>100.0</b>

Of total revenue, 56% (2011: 67%) was generated by the three largest customers of the Company.



## 2 OTHER INCOME

EUR thousand	2011	2012
Correction of liabilities	0	445
Income from the reversal of provisions	138	159
Foreign exchange rate gains	164	140
Third-party research grants from public authorities	80	92
Income from the disposal of assets	23	79
Recoveries and refunds	30	46
Income from option exercises	8	18
Corrections of invoices of previous periods	7	0
Other	2	0
<b>Total other income</b>	<b>452</b>	<b>979</b>

## 3 COST ALLOCATION BY FUNCTION

2011 EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	134	1,403	45	0	1,582
Depreciation and amortization	21	519	128	3,638	4,306
Personnel costs	60	3,223	2,800	828	6,911
Other costs	142	2,575	2,965	1,427	7,109
Capitalized development costs	0	-2,774	0	0	-2,774
<b>Total</b>	<b>357</b>	<b>4,946</b>	<b>5,938</b>	<b>5,893</b>	<b>17,134</b>

2012 EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	116	908	49	0	1,073
Depreciation and amortization	3	739	101	80	923
Personnel costs	94	1,923	2,794	5	4,816
Other costs	79	4,446	2,576	228	7,329
Capitalized development costs	0	0	0	0	0
<b>Total</b>	<b>292</b>	<b>8,016</b>	<b>5,520</b>	<b>313</b>	<b>14,141</b>

## 4 PERSONNEL COSTS

EUR thousand	2011	2012
Personnel remuneration	6,003	4,259
Stock option expenses	134	87
Social security expenses	773	470
– thereof:		
<i>employer's contribution to a national pension fund (Germany)</i>	279	154
<i>employer's contribution to a 401(k) savings plan (U.S.A.)</i>	40	24
<b>Total personnel costs</b>	<b>6,910</b>	<b>4,816</b>

## 5 DEPRECIATION AND AMORTIZATION

EUR thousand	2011	2012
Scheduled depreciation of tangible assets	324	171
Unscheduled depreciation of tangible assets	25	1
Scheduled amortization of intangible assets except for goodwill	344	673
Unscheduled amortization of intangible assets except for goodwill	988	78
Amortization of goodwill	2,625	0
<b>Total depreciation and amortization</b>	<b>4,306</b>	<b>923</b>

## 6 OTHER EXPENSES

EUR thousand	2011	2012
Foreign exchange rate losses	293	102
– thereof: due to the translation of deferred tax assets	4	-4
Extraordinary amortization of intangible assets	0	78
Restructuring expenses	2,938	66
– thereof:		
depreciation and amortization	1,103	2
rent and additional property expenses	945	41
personnel costs	828	5
consulting and other services	110	14
materials and consumables	32	0
other	10	4
Losses from the disposal of assets	36	34
Corrections for previous years	0	33
Goodwill amortization	2,625	0
Other	1	0
<b>Total other expenses</b>	<b>5,893</b>	<b>313</b>

## 7 OPERATING RESULT (EBIT) AND EBITDA

EUR thousand	2011	2012
<b>Operating result/earnings before interest and taxes (EBIT)</b>	<b>-15,245</b>	<b>-12,123</b>
Depreciation on tangible assets	349	172
Amortization on intangible assets	3,957	751
<b>EBIT before depreciation and amortization (EBITDA)</b>	<b>-10,939</b>	<b>-11,200</b>

## 8 FINANCIAL RESULT

EUR thousand	2011	2012
Interest from cash and cash equivalents	188	78
Interest from available-for-sale securities	31	26
<b>Interest and related income</b>	<b>219</b>	<b>104</b>
Fair value adjustment for derivative instruments	142	2
<b>Other financial income</b>	<b>142</b>	<b>2</b>
<b>Total financial income</b>	<b>360</b>	<b>106</b>
Fair value adjustment for derivative instruments	0	-25
Other finance costs	-1	-1
Adjustment from the disposal of available-for-sale securities	-432	0
<b>Total financial expenses</b>	<b>-433</b>	<b>-26</b>
<b>Total financial result</b>	<b>-73</b>	<b>80</b>

Other financial income of EUR 2 thousand in 2012 (2011: EUR 142 thousand) is attributable to valuation adjustments for a U.S. dollar-based currency forward contract with a remaining term until May 2013.

In the reporting year, a net loss of EUR 23 thousand for derivative instruments has been recognized (2011: net gain of EUR 142 thousand). For the net gains and losses of all other financial instruments reference is made to the overview above.

## 9 TAXES ON INCOME

The reported taxes on income in the amount of EUR 154 thousand (2011: EUR 257 thousand) comprise exclusively taxes recorded by the Company's U.S. subsidiary in Seattle.

EUR thousand	2011	2012
Current tax expenses	46	50
Deferred tax expenses due to loss carryforwards	211	104
<b>Total taxes on income</b>	<b>257</b>	<b>154</b>

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 %	2011	2012
Corporate tax rate	15.0	15.0
Solidarity charge	5.5	5.5
Trade tax charge	14.0	14.0
<i>underlying trade tax rate of assessment</i>	<i>410</i>	<i>410</i>
<b>Total applicable tax rate in Germany for the purpose of deferred taxes</b>	<b>29.8</b>	<b>29.8</b>

Tax reconciliation:

EUR thousand	2011	2012
<b>Net loss for the year before taxes on income</b>	<b>-15,318</b>	<b>-12,043</b>
<b>Weighted-average tax rate for the Group</b>	<b>29.6%</b>	<b>30.6%</b>
<b>Expected tax expense</b>	<b>-4,537</b>	<b>-3,688</b>
<i>loss carryforwards not capitalizable</i>	4,788	2,085
<i>goodwill amortization</i>	782	0
<i>capitalization of development costs (net)</i>	-679	189
<i>unscheduled amortization of non-current financial assets</i>	-298	684
<i>non-deductible waiver</i>	0	884
<i>fair value recognition of securities</i>	99	24
<i>stock option expenses</i>	40	26
<i>effect from other foreign taxes</i>	33	48
<i>tax effect from non-deductible operating expenses</i>	24	25
<i>provision for onerous contracts</i>	12	-55
<i>capital-increase-related expenses</i>	0	-41
<i>other temporary effects</i>	-7	-27
<b>Effective tax expense</b>	<b>257</b>	<b>154</b>
<b>Effective tax rate</b>	<b>-1.7%</b>	<b>-1.3%</b>

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

## 10 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

	2011	2012
Net loss for the year (in EUR thousand)	-15,575	-12,197
Weighted-average number of shares issued	8,818,417	8,818,417
Earnings per share (basic and diluted) in EUR	-1.77	-1.38

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

**11 INTANGIBLE ASSETS**

EUR thousand		Software	Licenses/ patents	Goodwill	Development costs	Total intangible assets
Jan 1, 2011	<b>Acquisition costs</b>	<b>844</b>	<b>3,942</b>	<b>3,351</b>	<b>784</b>	<b>8,921</b>
	Additions	32	0	0	2,775	2,807
	Disposals	-60	-1,643	-3,351	0	-5,054
Dec 31, 2011	<b>Acquisition costs</b>	<b>816</b>	<b>2,299</b>	<b>0</b>	<b>3,559</b>	<b>6,674</b>
	Additions	18	0	0	0	18
	Disposals	-7	-15	0	0	-22
<b>Dec 31, 2012</b>	<b>Acquisition costs</b>	<b>827</b>	<b>2,284</b>	<b>0</b>	<b>3,559</b>	<b>6,670</b>
Jan 1, 2011	<b>Accumulated amortization</b>	<b>641</b>	<b>2,844</b>	<b>726</b>	<b>212</b>	<b>4,423</b>
	Additions	62	776	2,625	494	3,957
	Disposals	-60	-1,617	-3,351	0	-5,028
Dec 31, 2011	<b>Accumulated amortization</b>	<b>643</b>	<b>2,003</b>	<b>0</b>	<b>706</b>	<b>3,352</b>
	Additions	63	55	0	633	751
	Disposals	-7	-15	0	0	-22
<b>Dec 31, 2012</b>	<b>Accumulated amortization</b>	<b>699</b>	<b>2,043</b>	<b>0</b>	<b>1,339</b>	<b>4,081</b>
Dec 31, 2011	<b>Carrying values</b>	<b>173</b>	<b>296</b>	<b>0</b>	<b>2,853</b>	<b>3,322</b>
<b>Dec 31, 2012</b>	<b>Carrying values</b>	<b>128</b>	<b>241</b>	<b>0</b>	<b>2,220</b>	<b>2,589</b>

## 12 TANGIBLE ASSETS

EUR thousand		Fixtures/ leasehold improvements	Technical equipment	Other fixed assets	Total tangible assets
Jan 1, 2011	<b>Acquisition costs</b>	<b>541</b>	<b>3,863</b>	<b>97</b>	<b>4,501</b>
	Additions	0	353	4	357
	Disposals	-12	-1,204	-3	-1,219
Dec 31, 2011	<b>Acquisition costs</b>	<b>529</b>	<b>3,012</b>	<b>98</b>	<b>3,639</b>
	Additions	0	58	0	58
	Disposals	-24	-1,026	-27	-1,077
<b>Dec 31, 2012</b>	<b>Acquisition costs</b>	<b>505</b>	<b>2,044</b>	<b>71</b>	<b>2,620</b>
Jan 1, 2011	<b>Accumulated amortization</b>	<b>532</b>	<b>3,367</b>	<b>58</b>	<b>3,957</b>
	Additions	1	342	6	349
	Disposals	-11	-1,159	-3	-1,173
Dec 31, 2011	<b>Accumulated amortization</b>	<b>522</b>	<b>2,550</b>	<b>61</b>	<b>3,133</b>
	Additions	1	162	9	172
	Disposals	-18	-1,000	-25	-1,043
<b>Dec 31, 2012</b>	<b>Accumulated amortization</b>	<b>505</b>	<b>1,712</b>	<b>45</b>	<b>2,262</b>
Dec 31, 2011	<b>Carrying values</b>	<b>7</b>	<b>462</b>	<b>37</b>	<b>506</b>
<b>Dec 31, 2012</b>	<b>Carrying values</b>	<b>0</b>	<b>332</b>	<b>26</b>	<b>358</b>

Total depreciation of tangible assets added up to EUR 172 thousand in 2012, including unscheduled depreciation of EUR 1 thousand.

## 13 ASSETS SCHEDULE

EUR thousand		Intangible assets	Tangible assets	Total assets
Jan 1, 2011	<b>Acquisition costs</b>	<b>8,921</b>	<b>4,501</b>	<b>13,422</b>
	Additions	2,807	357	3,164
	Disposals	-5,054	-1,219	-6,273
Dec 31, 2011	<b>Acquisition costs</b>	<b>6,674</b>	<b>3,639</b>	<b>10,313</b>
	Additions	18	58	76
	Disposals	-22	-1,077	-1,099
<b>Dec 31, 2012</b>	<b>Acquisition costs</b>	<b>6,670</b>	<b>2,620</b>	<b>9,290</b>
Jan 1, 2011	<b>Accumulated amortization</b>	<b>4,423</b>	<b>3,957</b>	<b>8,380</b>
	Additions	3,957	349	4,306
	Disposals	-5,028	-1,173	-6,201
Dec 31, 2011	<b>Accumulated amortization</b>	<b>3,352</b>	<b>3,133</b>	<b>6,485</b>
	Additions	751	172	923
	Disposals	-22	-1,043	-1,065
<b>Dec 31, 2012</b>	<b>Accumulated amortization</b>	<b>4,081</b>	<b>2,262</b>	<b>6,343</b>
Dec 31, 2011	<b>Carrying values</b>	<b>3,322</b>	<b>506</b>	<b>3,828</b>
<b>Dec 31, 2012</b>	<b>Carrying values</b>	<b>2,589</b>	<b>358</b>	<b>2,947</b>

## 14 DEFERRED TAXES

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

EUR thousand	Deferred tax assets		Deferred tax liabilities	
	Dec 31, 2011	Dec 31, 2012	Dec 31, 2011	Dec 31, 2012
Intangible and tangible assets	208	99	856	662
Current assets	0	33	0	20
Current liabilities	55	16	0	64
<b>Total</b>	<b>263</b>	<b>148</b>	<b>856</b>	<b>746</b>

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 598 thousand (net) was determined.

Since its inception through December 31, 2011, the Company's tax loss carryforwards in Germany amounted to approximately EUR 140 million for corporate taxation and to approximately EUR 138 million for trade taxation. In addition, the Company expects to increase its cumulated tax losses for both types of taxes of more than EUR 11 million with the filing of its tax returns for 2012. 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 598 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 9 "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 141 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 1.0 million and can be utilized for up to 20 years.

Changes in capitalized deferred tax assets in the reporting year:

EUR thousand	2011	2012
<b>January 1</b>	<b>421</b>	<b>214</b>
Deferred tax expenses	-211	-104
Foreign currency adjustment	4	-4
<b>December 31</b>	<b>214</b>	<b>106</b>

## CURRENT ASSETS

### 15 INVENTORIES

EUR thousand	Dec 31, 2011	Dec 31, 2012
Consumables, raw materials, supplies	64	8
Finished goods	219	23
<b>Total inventories</b>	<b>283</b>	<b>31</b>

## 16 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, 2011	Dec 31, 2012
Trade receivables, gross	211	314
Allowance for bad debt	0	0
<b>Trade receivables, net</b>	<b>211</b>	<b>314</b>

At the balance sheet date, trade receivables in the amount of EUR 160 thousand were not due (Dec 31, 2011: EUR 58 thousand). Further trade receivables in the amount of EUR 129 thousand were not yet invoiced at the balance sheet date (Dec 31, 2011: EUR 134 thousand).

Receivables past due at the balance sheet date:

EUR thousand	Dec 31, 2011	Dec 31, 2012
Trade receivables past due up to 90 days	0	0
Trade receivables past due more than 90 days	0	2
<b>Trade receivables past due, net</b>	<b>0</b>	<b>2</b>

## 17 MARKETABLE SECURITIES

The marketable securities in the amount of EUR 509 thousand as of December 31, 2012 (Dec 31, 2011: EUR 1,428 thousand) are so-called "trust-preferred Securities" issued by a wholly owned subsidiary of Deutsche Bank AG. They are recognized as financial instruments "available for sale" according to IAS 39.9 *Financial Instruments: Recognition and Measurement* and are redeemable at the option of the issuer in whole from June 2015 on.

The reported securities are denominated in euro and are subject to the usual market and interest risks. The interest rate risks are price risks and interest rate cash flow risks. The fair value of the marketable securities is identified by their stock exchange quotations at each relevant balance sheet date. The securities have been traded on active markets in the reporting year

Time to maturity of marketable securities	Dec 31, 2011		Dec 31, 2012	
	Fair value in EUR thousand	in %	Fair value in EUR thousand	in %
less than 12 months	986	69.0	0	0.0
13–24 months	0	0.0	0	0.0
25–60 months	442	31.0	509	100.0
<b>Total marketable securities</b>	<b>1,428</b>	<b>100.0</b>	<b>509</b>	<b>100.0</b>

## 18 CASH AND CASH EQUIVALENTS

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.

At the balance sheet date, an amount of EUR 85 thousand of bank deposits was restricted cash.

Cash and cash equivalents decreased to EUR 2,205 thousand at the balance sheet date (Dec 31, 2011: EUR 12,557 thousand). 82.2% 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, 2011	Dec 31, 2012
Time deposits	12,089	434
Bank accounts, petty cash, checks	468	1,771
<b>Total cash and cash equivalents</b>	<b>12,557</b>	<b>2,205</b>

## 19 OTHER CURRENT ASSETS

EUR thousand	Dec 31, 2011	Dec 31, 2012
Prepaid expenses	576	362
Receivables from tax authorities	205	260
Claims based on granted projects against public authorities	84	54
Deposits	0	33
Interest receivables	27	10
Advance payments	8	8
Other	42	39
– thereof: with a prospective maturity > 1 year	38	38
<b>Total other current assets</b>	<b>942</b>	<b>766</b>

## EQUITY

**20 SHARE CATEGORIES AND CAPITAL STRUCTURE**

As of December 31, 2012, the share capital of Epigenomics AG comprised exclusively common shares with equal rights and a par value of EUR 1.00 each.

Equity structure of the Company as of the balance sheet date:

EUR thousand	Dec 31, 2011	Dec 31, 2012
<b>Share capital</b>	<b>8,818,417</b>	<b>8,818,417</b>
<b>Conditional Capital</b>	<b>853,914</b>	<b>4,381,280</b>
<i>Conditional Capital IV</i>	123,485	123,485
<i>Conditional Capital V</i>	129,535	129,535
<i>Conditional Capital VII</i>	304,246	304,246
<i>Conditional Capital VIII</i>	296,648	296,648
<i>Conditional Capital IX</i>	0	3,527,366
<b>Authorized Capital</b>	<b>4,409,207</b>	<b>4,409,207</b>
<i>Authorized Capital 2011/I</i>	881,841	881,841
<i>Authorized Capital 2011/II</i>	3,527,366	3,527,366

Conditional Capital IV and V cannot be used anymore to grant stock options as the corresponding authorizations for a granting time frame has expired. Up to 113,595 new shares can still be created upon exercise of granted options from the underlying stock option programs 03–07 and 06–10.

Conditional Capital VII allows the creation of new shares upon the exercise of stock options granted under the stock option program 09–13 and Conditional Capital VIII allows the creation of new shares upon the exercise of stock options granted under the stock option program 11–15.

In the Annual General Shareholders' Meeting on May 2, 2012, the shareholders of the Company resolved upon creating Conditional Capital IX and the corresponding addition of Section 5 Paragraph 5 to the Company's Articles of Association. The conditional capital increase serves the purpose of granting shares to holders or creditors of bonds or participation rights issued by the Company or a subsidiary on the basis of the authorization resolution of May 2, 2012, until May 1, 2017, if option or conversion rights are exercised, option or conversion obligations are performed or the Company exercises an election right to entirely or partially grant non-par value shares of the Company instead of payment of the due cash amount. The issuance of the new shares occurs at the respective option or conversion price or the lower issue price, in each case as further to be determined and specified in accordance with the aforementioned authorization resolution.



A capital increase based on Conditional Capital IX is only to be implemented if bonds or participation rights are issued in accordance with the authorization resolution of the Annual General Shareholders' Meeting of May 2, 2012, and only to the extent that

- option or conversion rights are exercised or
- holders or creditors of bonds or participation rights who are under an obligation to exercise an option or to convert perform their obligation to exercise the option or to convert or
- the Company exercises an election right to grant non-par value shares of the Company instead of paying a due cash amount

and to the extent that no cash settlement is granted or treasury shares or shares of another listed company are delivered. The newly issued shares shall carry dividend rights from the commencement of the fiscal year in which the shares are issued, or, if no resolution on the application of the profit of the fiscal year immediately preceding the year of the issuance has been adopted when the new shares are issued, from the commencement of this fiscal year immediately preceding the year of the issuance. The Executive Board is authorized, subject to Supervisory Board approval, to determine the further details concerning the implementation of the conditional capital increase.

The Conditional Capital IX and the corresponding amendment of the Articles of Association were registered with the commercial register on May 24, 2012.

## 21 CAPITAL RESERVE

The capital reserve increased from EUR 22,212 thousand at December 31, 2011, to EUR 22,299 thousand at December 31, 2012, exclusively due to stock option expenses.

## 22 RETAINED EARNINGS

Retained earnings decreased from EUR 1,303 thousand at the end of the previous year to EUR -14,272 thousand at December 31, 2012, caused by an offsetting against the Company's net loss of 2011.

## 23 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	2011	2012
<b>January 1</b>	<b>905</b>	<b>572</b>
Adjustments from the disposal of available-for-sale securities	-461	-5
Revaluation of marketable securities	128	-76
<b>December 31</b>	<b>572</b>	<b>491</b>

## 24 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 current liabilities, cash and cash equivalents, the securities available for sale and equity attributable to equity holders, comprising subscribed capital, capital reserve (including offset retained earnings) and other comprehensive income are subject to the Group's capital management.

In 2012, the Group's equity ratio decreased from 83.2% as of December 31, 2011, to 60.5% as of December 31, 2012.

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

### CURRENT LIABILITIES

## 25 TRADE PAYABLES

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

## 26 DEFERRED INCOME

Payments received in advance for services to be rendered by Epigenomics AG in the future are recorded as deferred income. Payments received for commercial collaborations are recognized as revenue over the respective contractual terms. Payments received for granted projects are recognized as other income according to the percentage of completion method. As of the balance sheet date, there are no repayment obligations for the Company resulting from deferred income.

EUR thousand	Dec 31, 2011	Dec 31, 2012
Payments for commercial collaborations	0	0
Payments for granted projects	0	306
<b>Total deferred income</b>	<b>0</b>	<b>306</b>

## 27 OTHER LIABILITIES

EUR thousand	Dec 31, 2011	Dec 31, 2012
Payables due to staff	390	149
Payables due to tax authorities	218	98
Accrued audit fees	105	55
Liabilities from derivative instruments	2	25
Payables due to social security institutions	2	17
Down payments received	35	9
Accrued Supervisory Board fees	4	1
Payables for onerous rental agreements	251	0
Other	6	3
<b>Total other liabilities</b>	<b>1,013</b>	<b>357</b>

## 28 PROVISIONS

As of December 31, 2012, the provisions of the Company added up to EUR 376 thousand (Dec 31, 2011: EUR 1,036 thousand). Substantially, they were recognized for:

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

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

Statement of changes in current provisions:

EUR thousand	Contract-related provisions	Payroll provisions	Statutory provisions	Other provisions	Total
<b>January 1, 2011</b>	<b>188</b>	<b>4</b>	<b>60</b>	<b>18</b>	<b>270</b>
Utilization	0	0	-60	-9	-69
Reversal	0	0	0	-9	-9
Additions	704	93	40	7	844
<b>December 31, 2011</b>	<b>892</b>	<b>97</b>	<b>40</b>	<b>7</b>	<b>1,036</b>
Utilization	-587	-37	-40	-1	-665
Reversal	-117	-37	0	-5	-159
Additions	0	54	70	40	164
<b>December 31, 2012</b>	<b>188</b>	<b>77</b>	<b>70</b>	<b>41</b>	<b>376</b>

## 29 FINANCIAL INSTRUMENTS

Primary financial instruments		Dec 31, 2011		Dec 31, 2012	
		Carrying amount	Fair value	Carrying amount	Fair value
EUR thousand					
<b>Assets</b>					
Loans and receivables	AC	362	362	458	458
<i>Trade receivables</i>		211	211	314	314
<i>Other current assets</i>		151	151	144	144
Financial assets available for sale	FV Rec. Eq.	1,428	1,428	509	509
<i>Marketable securities</i>		1,428	1,428	509	509
Cash and cash equivalents	n/a	12,557	12,557	2,205	2,205
<b>Liabilities</b>					
Financial liabilities measured at amortized cost	AC	1,895	1,895	1,815	1,815
<i>Trade receivables</i>		1,228	1,228	1,681	1,681
<i>Other current assets</i>		667	667	134	134

Derivative financial instruments		Dec 31, 2011		Dec 31, 2012	
		Carrying amount	Fair value	Carrying amount	Fair value
EUR thousand					
<b>Liabilities</b>					
Financial liabilities held for trading	FV Rec. PL	2	2	25	25
<i>Currency forward contracts</i>		2	2	25	25

AC = Amortized Cost

FV Rec. Eq. = Fair Value Recognized in Equity

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

## NOTES TO THE GROUP CASH FLOW STATEMENT

### 30 OPERATING ACTIVITIES

Cash flow from operating activities is derived indirectly on the basis of the net loss for the year before taxes on income.

### 31 INVESTING ACTIVITIES

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

Proceeds from the repayment of available-for-sale securities in the amount of EUR 1,000 thousand in the reporting year (2011: EUR 0) were attributable to a repayment of such securities by the issuer at maturity.

### 32 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 422 thousand (2011: EUR 36 thousand) were fully related to the preparation of the Company's capital increase after the reporting period in January 2013.

### 33 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	2011	2012
Cash flow from operating activities	-9,111	-10,884
Cash flow from investing activities	-2,842	954
Net proceeds from transactions in securities	-288	-1,000
<b>Cash consumption</b>	<b>-12,241</b>	<b>-10,930</b>

## RISKS AND RISK MANAGEMENT

### 34 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 2012 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](http://www.epigenomics.com)).

### 35 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 – if required – undertakes 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.

### 36 FOREIGN CURRENCY EXCHANGE RISK

The Group constantly faces a foreign currency exchange risk mainly through the fluctuations between the euro and the U.S. dollar. 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 current liabilities.

At the balance sheet date, a so-called “Target Profit Forward” currency contract with the Group’s main bank has been in place to secure the Group’s requirements for U.S. dollars throughout the term of the contract (until May 31, 2013). According to this contract, the Group has the right to buy USD 300 thousand at a fixed exchange rate of EUR/USD 1.3050 at the end of each calendar month if the actual exchange rate of this currency relation at these points in time is equal or below EUR/USD 1.3050. The right to buy USD 300 thousand at the end of each calendar month at EUR/USD 1.3050 while the actual rate is equal or below EUR/USD 1.3050 is limited up to a cumulative difference of EUR/USD 0.57. Once this cumulative difference is exceeded, the contract will be terminated. Contrawise, the Group has the obligation to buy USD 450 thousand at a fixed exchange rate of EUR/USD 1.3050 at the aforementioned due dates if the actual exchange rate of this currency relation is above EUR/USD 1.3050.



The foreign currency exchange risk between the euro and the U.S. dollar after the expiration date of the aforementioned forward contract has not been addressed yet by the Company at the balance sheet date, as a consequence of its low liquidity then. As soon as new liquidity will be raised, the Company will address this risk for the time after May 31, 2013, with a strategy adequate to the Company's financial projections.

Due to the limited volume of positions denominated in foreign currencies at the balance sheet 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.

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## **37** 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.

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## **38** 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 and given the historically low interest rates on the international capital markets, 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

**39 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. Details of the stock option program 11–15 can be found in the invitation to the Company's 2011 Annual General Shareholders' Meeting (AGM). This document as well 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. Stock options can only be granted from the SOPs 09–13 and 11–15.

Beneficiaries of all SOPs are the employees of the Company and the members of its Executive Board. 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. The options can only be exercised during certain exercise periods, the so-called "trading windows".

In general, stock options from the SOP 03–07 vest in four tranches over a total period of four years beginning with the issuance date and stock options from the SOPs 06–10, 09–13 and 11–15 vest over a total period of three years beginning with the issuance date. With regard to stock options granted to members of the Executive Board, the Supervisory Board can decide on other vesting rules.

**40 INFORMATION ON STOCK OPTIONS IN THE REPORTING YEAR**

In the reporting year, 200,000 stock options were granted under the SOPs 09–13 and 11–15 to Executive Board members and employees of the Company. 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%.

Expiry date	Jan 1, 2019	Mar 1, 2019	Total 2019
Number of granted stock options	80,000	120,000	200,000
Applicable share price at grant date (in EUR)	2.28	2.75	
Exercise price (in EUR)	2.51	3.03	
Historical volatility at grant date (in %)	63.8	67.9	
Risk-free interest rate (in %)	0.36	0.39	
Aggregate proceeds if shares are issued (in EUR)	200,800	363,600	564,400

A total of 316,768 stock options can still be granted to the beneficiaries from the SOPs 09–13 (103,816) and 11–15 (212,952).

Option holder	Options issued as of	Issued	Forfeited	Cancelled	Exercised	Options issued as of	Options exercisable as of
	<b>Dec 31, 2011</b> (2010)	<b>in 2012</b> (2011)				<b>Dec 31, 2012</b> (2011)	
Dr. Thomas Taapken	20,000	60,000	0	0	0	80,000	0
Geert W. Nygaard	77,000	60,000	0	78,001	0	317,721	40,666
Other option holders	220,959	80,000	30,565	11,672	0		
<b>All option holders</b>	<b>317,959</b> (283,990)	<b>200,000</b> (101,800)	<b>30,565</b> (28,293)	<b>89,673</b> (39,538)	<b>0</b> (0)	<b>397,721</b> (317,959)	<b>40,666</b> (57,823)
Average exercise price (in EUR)	16.08 (19.19)	2.82 (8.55)	15.36 (22.05)	5.65 (15.09)	n/a	11.79 (16.08)	13.29 (14.35)

Terms of outstanding stock options:

Term	Weighted-average exercise price in EUR as of	Stock options issued and outstanding as of	Weighted-average exercise price in EUR as of	Stock options issued and outstanding as of
	<b>Dec 31, 2011</b>		<b>Dec 31, 2012</b>	
2012	40.65	68	n/a	0
2013	27.30	20,300	34.65	9,800
2014	22.50	83,595	22.50	83,595
2015	10.53	6,000	12.70	1,000
2016	13.41	56,331	13.30	39,666
2017	18.00	63,265	17.73	54,728
2018	8.25	88,400	8.34	68,932
2019	n/a	n/a	2.73	140,000
<b>Total</b>	<b>16.08</b>	<b>317,959</b>	<b>11.79</b>	<b>397,721</b>

The weighted-average term of the outstanding stock options at December 31, 2012, was 5.0 years (December 31, 2011: 5.0 years).

## OTHER INFORMATION

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

Since October 1, 2012, Dr. Thomas Taapken is the sole Executive Board member of the Company. Dr. Taapken served as the Company's Chief Financial Officer from April 1, 2011, until September 30, 2012, and additionally took over the responsibility of acting Chief Executive Officer then. Geert Walther Nygaard, who has been the Company's Chief Executive Officer before, left the Executive Board and the Company as of September 30, 2012.

In 2012, the total remuneration of the members of the Executive Board amounted to EUR 1,098 thousand (2011: EUR 663 thousand), comprising EUR 518 thousand in fixed compensation (2011: EUR 620 thousand), EUR 0 thousand in bonus payments (2011: EUR 28 thousand) and EUR 580 thousand in other compensation payments (2011: EUR 15 thousand). A total of 120,000 stock options with a fair value at grant date of EUR 109 thousand have been granted to the members of the Executive Board in 2012 (2011: 40,000 stock options with a fair value at grant date of EUR 87 thousand).

In case of a change of control, Dr. Taapken is entitled to terminate his service agreement and would in such case be entitled to receive payment of the fixed compensation amount for the time remaining until his service agreement would have anyhow terminated.

By shareholders' resolution at the AGM on May 2, 2012, the size of the Supervisory Board of the Company has been reduced from six to three members. Heino von Prondzynski, Einsiedeln (CH), was newly elected to the Supervisory Board at that AGM and assumed the role of its chairman. The Supervisory Board is completed since that day by Ann Clare Kessler, Ph.D., Rancho Santa Fe, CA (U.S.A.) and Prof. Dr. Günther Reiter, Pfullingen (GER). Ms. Kessler, Ph.D., and Prof. Dr. Reiter were already members of the Company's Supervisory Board before.

Other members of the Supervisory Board until May 2, 2012, were Prof. Dr. Dr. h.c. Rolf Krebs, Mainz (GER), (Chairman), Prof. Dr. Dr. Dr. h.c. Uwe Bicker, Bensheim-Auerbach (GER), (Deputy Chairman), Joseph Anderson, Ph.D., Oxted, Surrey (GB) and Günter Frankenne, Berg/Neumarkt (GER).

In 2012, total remuneration of the members of the Supervisory Board amounted to EUR 159 thousand (2011: EUR 153 thousand) plus out-of-pocket expenses amounting to EUR 42 thousand (2011: EUR 23 thousand).

Further details to the composition of the Executive Board and the Supervisory Board and the remuneration of their members in the reporting year can be found in the "Remuneration Report" section of the Group management report 2012.

## 42 OTHER FINANCIAL OBLIGATIONS

For the Epigenomics Group, other financial obligations arise from a lease at the Berlin location. For the office space 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 453 thousand (undiscounted) has to be paid.

In Seattle, WA, the Company has terminated its former lease contract at 901 Fifth Avenue in 2012, as a consequence of the restructuring of the Group in 2011 and the reduction of its employee number at that location. The U.S. affiliate has now moved to 800 Fifth Avenue in Seattle and has a rental agreement in place with a term expiring on October 31, 2013. Until this date, a total rent of approximately EUR 47 thousand has to be paid.

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 350 thousand in total for the years 2013 and 2014.

Due to contracts with third parties, at the balance sheet date, Epigenomics had payment obligations of more than EUR 212 thousand for goods and services to be received in 2013. However, as delivery dates and effective delivery quantities and qualities are to some extent uncertain, the future payments resulting from those contractual obligations could also be lower.

Resulting from the "Target Profit Forward" currency contract (as described under notes item 36 "Foreign currency exchange risk" and under the conditions valid at the balance sheet date), the Company faces the obligation to buy between USD 1.5 million and USD 2.25 million in total at a fixed exchange rate of EUR/USD 1.3050 between January and May 2013.

## 43 INFORMATION ON THE AUDITORS OF THE COMPANY

As in the previous years, UHY Deutschland AG has been chosen as the Company's auditing firm for the financial year 2012. During the reporting year, a total amount of EUR 116 thousand (2011: EUR 149 thousand) has been expensed for miscellaneous services of this auditing firm for Epigenomics AG. Details are shown in the following table:

EUR thousand	2011	2012
Costs for audit services	96	76
Costs for other confirmation services	51	40
Costs for other services	2	0
<b>Total</b>	<b>149</b>	<b>116</b>

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.

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## **44 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 October 2012, the Executive Board and the Supervisory Board of the Company issued an updated declaration of compliance 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/declaration-of-compliance.html](http://www.epigenomics.com/en/news-investors/investors/corporate-governance/declaration-of-compliance.html)).

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## **45 INFORMATION ON OTHER TRANSACTIONS WITH RELATED PARTIES**

At the reporting date, the Company's payables due to members of its Executive Board amounted to EUR 0 (Dec 31, 2011: EUR 2 thousand) and the liabilities due to members of its Supervisory Board amounted to EUR 131 thousand (Dec 31, 2011: EUR 89 thousand).

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## **46 CLEARED FOR PUBLICATION**

These consolidated financial statements have been approved and cleared for publication by the Executive Board of the Company on March 6, 2013.

Berlin, March 6, 2013

**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, March 6, 2013

**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 Profit or Loss and Other Comprehensive Income, 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, 2012. 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 budget and projected income, the available liquidity at balance sheet date is not sufficient to sustain the Group's operations over the following 24 month. Even in consideration of the fresh liquid resources created by means of a capital increase in January 2013 before preparation of the consolidated financial statements, fresh funds must be raised no later than in the first quarter 2014 to avoid illiquidity according to the Company's plans.

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 at the latest in the first quarter of 2014.

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 financial situation". In consideration of available liquidity of EUR 2.7 million at balance sheet date, in consideration of the gross proceeds of approximately EUR 5.0 million generated by the capital increase and an estimated cash consumption in 2013 of up to EUR 7.5 million, the liquid resources will be consumed by the first quarter 2014 at the latest.

Berlin, March 6, 2013

**UHY Deutschland AG**  
**Wirtschaftsprüfungsgesellschaft**

(ppa. Kulla)	(Dr. Peters)
Wirtschaftsprüferin	Wirtschaftsprüferin
(German Public Auditor)	(German Public Auditor)



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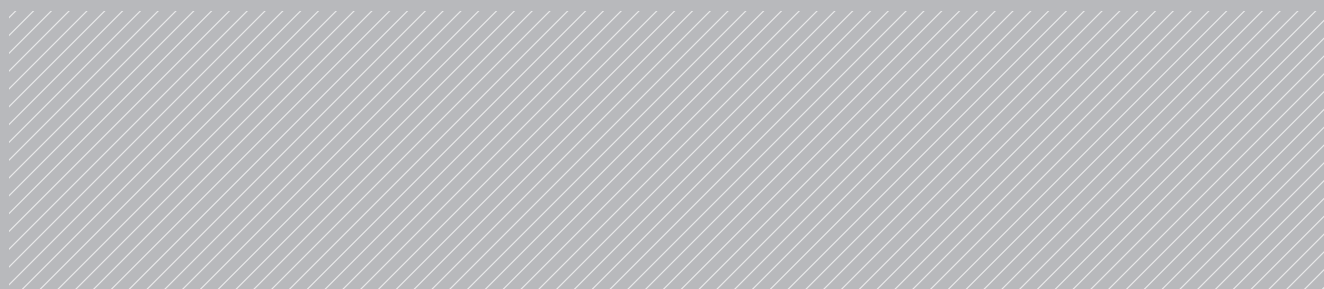
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## CORPORATE CALENDAR

Report on Business 2012 – Annual press conference and analyst meeting in Frankfurt am Main .....	Thursday, March 21, 2013
Annual General Shareholders' Meeting 2013 in Berlin .....	Monday, May 6, 2013
3-Month Report 2013 January 1–March 31, 2013 .....	Wednesday, May 8, 2013
6-Month Report 2013 January 1–June 30, 2013 .....	Wednesday, August 7, 2013
9-Month Report 2013 January 1–September 30, 2013 .....	Wednesday, November 6, 2013



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