

## MANY HUMAN LIVES

COULD BE SAVED THROUGH EARLIER DETECTION OF CANCER.  
WE CAN HELP. EPIGENOMICS – FINDING CANCER EARLY



ANNUAL REPORT 2010



.....

**WE** together with our partners develop and commercialize molecular diagnostic products for cancer that have the potential to change the paradigm of early cancer detection. After only one year on the market our Epi *pro*Colon blood test helps to detect colorectal cancer in its earliest stages day by day – cancer that otherwise would have gone unnoticed as many men and women are reluctant to be tested by conventional screening methods. Potentially saving many lives through a more timely diagnosis of this common yet fatal disease is most rewarding for us at Epigenomics. It is this compassion and vision that has driven us to bring our unique technology and biomarkers to market.



## COMMERCIALIZATION

2010

### MOLECULAR DIAGNOSTICS FOR CANCER

We **directly commercialize** our Epi *proColon* and Epi *proLung* tests in Germany, Austria, Switzerland, and France and through a growing network of distributors in other countries. At the same time we **license** our biomarkers non-exclusively to some of the largest and most distinguished companies in the diagnostics industry.



## ADMINISTRATION

Our small but professional team provides the infrastructure for executing our strategy by flawlessly fulfilling all financial, legal and statutory requirements of a publicly listed company, secures equity financing as well as stringent control of our spendings and adequately communicates with all stakeholders.

EUR **33.1** million  
raised in financing

## RESEARCH

We have developed DNA methylation technologies for routine diagnostic use and continuously improve and apply them to novel diagnostic questions in our research group.

Program/Application	Product Name	Biomarker-ID	Clinical Proof-of-Concept	Clinical Evaluation
<b>Colorectal Cancer</b>				
Early Detection (blood plasma)	Epi proColon 1.0 (EU)	<sup>®</sup> SEPT9		
	Epi proColon 2.0 (EU)	<sup>®</sup> SEPT9		
	Epi proColon 2.0 (US)	<sup>®</sup> SEPT9		
Monitoring (blood plasma)	–	<sup>®</sup> SEPT9 + undisclosed biomarker		
<b>Lung Cancer</b>				
Aid in Diagnosis (bronchial lavage)	Epi proLung BL 1.0 (EU)	<sup>®</sup> SHOX2		
Aid in Diagnosis (blood plasma)	–	<sup>®</sup> SHOX2		
<b>Prostate Cancer</b>				
Prognosis** (tissue)	–	<sup>®</sup> PITX2		
Aid in Diagnosis (tissue/urine)	LDTs by Partners*	<sup>®</sup> GSTP1		

\* IVD development not planned by Epigenomics

\*\* Development on Affymetrix GeneChip platform discontinued; in development as real-time PCR assay

## PRODUCT PROGRAMS

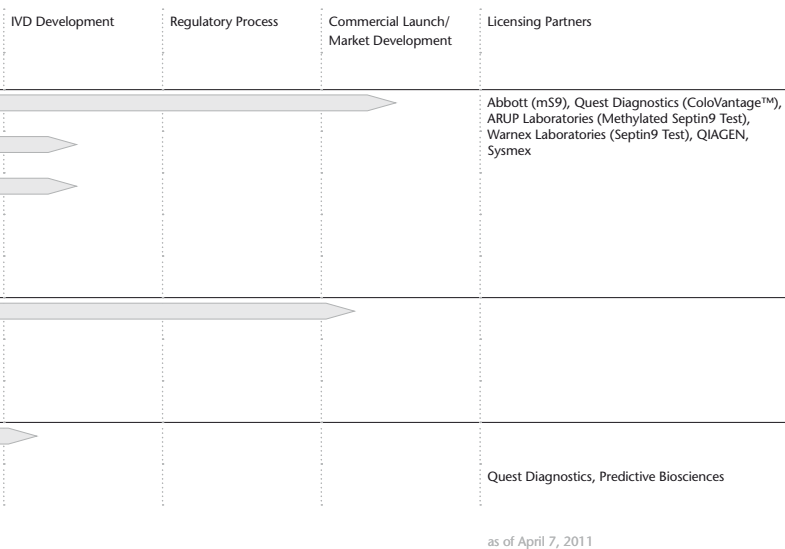
We focus our business around three programs: colorectal, lung and prostate cancer.



Foreword by the CEO .....	4
Report of the Supervisory Board .....	8
Questions to the new CFO .....	13
Strategy .....	15
Products & Markets .....	20
Our Stock .....	38
Outlook .....	112

## DEVELOPMENT

Our experienced team develops in vitro diagnostic test kits for use in molecular diagnostic laboratories to detect and measure the biomarkers delivered by our research group.



## MANUFACTURING & LOGISTICS

Starting in 2011, our Epi *pro*Colon test kits will be manufactured by Next-Pharma. For the supply logistics of our products we successfully work with Arvato since early 2010.

## EARLIER DETECTION ...

- 90%** 5-year-survival when detected early e.g. through screening
- 10%** 5-year-survival when detected in advanced metastatic stage
- 300+** million people should be screened in Europe, U.S., and Japan
- 50-70%** of people aged 50+ do not participate in any screening
- 60%** of cancers are diagnosed in advanced stages
- 600,000** people worldwide die of the disease every year

... of colorectal cancer could potentially save more lives than any new therapy!



# THE TEST PUT ME AT EASE

SEPTIN9: NEGATIVE – CHRISTINE BAUER IS A NURSE AND A PASSIONATE FIELD HOCKEY PLAYER. SHE TOOK THE SEPTIN9 TEST FOR GOOD REASON AND ALTHOUGH THE TEST WAS NEGATIVE WILL DO IT AGAIN...



**At the age of 49** Christine Bauer is not yet eligible for colorectal cancer screening under German guidelines. But when a relative was diagnosed with colorectal cancer the passionate field hockey player felt uneasy about waiting until 55, the age at which Germans should have their first screening colonoscopy. As a nurse working in the endoscopy department of a hospital she assists for many years day by day during colonoscopy. No wonder, she is more than familiar with the procedure and not scared in the least. However, her experience with the necessary bowel cleansing is a different story. "I once went through it several times for diets. It was terrible. I will surely do it again if I have to undergo colonoscopy for screening at 55, but for now, I opted for the Septin9 blood test. It doesn't take any time and as a nurse I know that it is at least as efficient as the stool tests." The Septin9 test returned negative. "I feel very good, now that I did the test. It put my mind at ease. But I also know I have to keep track of it as colorectal cancer can develop with age. I am sure I will get myself tested again before I will have my first screening colonoscopy."

# FOREWORD

BY THE

## CHIEF EXECUTIVE OFFICER

### DEAR SHAREHOLDERS,

The year 2010 has been a year of outstanding milestone achievements and excellent progress for Epigenomics on its path to become a world-leading cancer molecular diagnostics company.

→ **EARLY IN 2010**, we successfully completed our PRESEPT Study. This prospective clinical study enrolled with more than 7,900 subjects from a population of men and women 50 years of age and older scheduled to have screening colonoscopy at 22 clinical sites in the United States and 10 sites in Germany. Under the leadership of an independent clinical study steering committee and measured at three independent laboratories, the study successfully met its primary endpoints and demonstrated that our proprietary biomarker *m*SEPT9 is very effective in identifying individuals with cancer before symptoms occur. Data was presented at the year's Digestive Disease Week (DDW) in May of 2010. Septin9 testing in this setting identified 67% of individuals with colorectal cancer while only 12% of individuals not having cancer tested positive. The PRESEPT Study is the largest privately sponsored study in colorectal cancer screening conducted to date setting a new standard in the validation of biomarkers. The clinical study steering committee has submitted the full clinical results from PRESEPT to a medical journal for peer review and eventual publication. We also expect results from a cost effectiveness analysis of this approach to colorectal cancer early detection based on the PRESEPT results to be published in parallel with the clinical results. We anticipate that these publications will help us make a compelling case for a convenient, simple, and easy-to-use blood test for early detection of colorectal cancer furthering our goal to help saving lives by convincing more people to participate in screening.

### → FOLLOWING THE LAUNCHES OF THE SEPTIN9-BASED BLOOD TESTS OF OUR PARTNERS

Abbott Molecular and Quest Diagnostics in late 2009 and early 2010, additional commercial launches of Septin9 tests have made 2010 another year of meeting key commercial milestones. In summer of 2010, ARUP Laboratories, based in Salt Lake City, UT, U.S.A., launched its version of the Septin9 blood testing service for colorectal cancer. ARUP Laboratories also published data from their CLIA validation study demonstrating an outstanding 90% sensitivity for colorectal cancer at 89% specificity of our *m*SEPT9 biomarker when measured with ARUP's laboratory developed test. This underscores the enormous biological and clinical potential that *m*SEPT9 as a single DNA methylation biomarker holds. Later in the year, our partner Warnex Laboratories launched its Septin9 blood test for colorectal cancer testing services in Canada.





Geert W. Nygaard, Chief Executive Officer

Within no more than six months of having taken a non-exclusive license from us, Warnex Laboratories demonstrated its ability to efficiently validate and commercially launch a novel test on an aggressive timeline. In both cases, Epigenomics has received certain license fees and going forward, we are entitled to significant royalty payments based on our partners' sales.

➤ **THROUGHOUT 2010, WE HAVE CONTINUED TO IMPLEMENT OUR COMMERCIAL STRATEGY**

of direct product sales in Germany, Austria and Switzerland complemented by building a network of distributor relationships for markets such as Israel, Turkey and the Middle East. We expect to continue building our distribution network across major markets in Europe and to be opportunistic in other geographies. Our product sales in 2010 for Epi *proColon* have been slower than expected, leading to a situation where overall revenue declined to EUR 1.8 million for 2010 as product sales have not yet fully compensated for the non-recurring partnering milestone revenue from 2009. Yet, we are excited about having built a strong customer base across clinical laboratories in our home markets. To date, we have shipped over 5,000 Epi *proColon* tests to customers and have identified several colorectal cancer cases that otherwise would probably have remained undetected for quite some time. It is hugely gratifying to us as an organization but also to each and every one of us individually to see that our product has started to save lives in clinical practice.

→ **OUR PRODUCT PIPELINE HAS CONTINUED TO MATURE SUBSTANTIALLY** with the launch of our second CE-marked cancer molecular diagnostic test in July of 2010. We launched an assay for our biomarker *m*SHOX2, Epi *proLung*, for a confirmatory diagnostic application using bronchial lavage samples to help doctors make a better and more definitive diagnosis of lung cancer. The launch followed a successful clinical performance evaluation study demonstrating that 81% of individuals with lung cancer could be identified with the test and only 5% of individuals without cancer were positive in this lung cancer diagnostic setting. In R&D, we have continued to focus on making improvements to our Septin9 blood test before embarking on our pivotal trial for U.S. FDA approval in 2011. We have recently demonstrated in two independent studies that two optimized versions of our assay can detect 86% and 91% of all colorectal cancer cases at a specificity of 93% and 87% respectively using a simple blood draw. We have also completed the early concept phase of our colon cancer monitoring program as well as developed a brand-new generation of DNA methylation discovery technology with much improved genome coverage and outstanding sensitivity for even the most subtle of DNA methylation differences.

→ **OUR TRANSFORMATION FROM A RESEARCH ORGANIZATION TO A PRODUCT DRIVEN CANCER MOLECULAR DIAGNOSTICS COMPANY** continues to progress on many fronts. During 2010, we not only passed surveillance audits to maintain ISO 13485 certification for the design, development, manufacturing and distribution of IVD products at both our sites in Berlin, Germany, and Seattle, WA, U.S.A., but we have also obtained Canadian Medical Devices Conformity Assessment System (CMDCAS) certification for both facilities. This highlights our continued commitment to quality in all activities. We have implemented warehousing and product supply logistics for our Epi *proColon* and Epi *proLung* products in Europe by teaming up with Arvato, a logistics services provider specialized inter alia on the pharmaceutical and diagnostic industry. Furthermore, we negotiated and signed a long-term contract manufacturing agreement under full cGMP conditions for our Epi *proColon* IVD kits with NextPharma in San Diego, CA, U.S.A. Securing access to an instrument platform used for currently FDA-cleared tests and teaming up with the leading FDA consulting firm for diagnostics DOCRO, Inc. has put us in a position where in Q4 of 2010, we have submitted to the FDA our pre-IDE materials for an Epi *proColon* Septin9 blood-based test. We expect to complete our clinical evaluation studies in 2011 using already collected samples from the PRESEPT cohort and submit to the FDA for regulatory approval before year-end 2011.

➤ **2010 HAS ALSO BEEN A HIGHLY SUCCESSFUL YEAR FOR EPIGENOMICS** in terms of our ability to raise additional capital needed to execute on our corporate business plan. Abingworth led a fully marketed public rights offering which allowed us to raise EUR 33.1 million in gross proceeds in early April 2010. This has significantly de-risked our balance sheet and put us in a strong position to execute our business plan. The funds have been earmarked for driving commercialization in key European markets, completing our FDA approval process and subsequently building the commercial infrastructure needed to successfully bring Epi *pro*Colon to the U.S. market.

➤ **LOOKING AT 2010, I CAN ONLY CONCLUDE THAT WE HAVE HAD A TREMENDOUS YEAR** and many great successes. With two IVD products now on the market and customers, patients and doctors able to access Septin9 blood tests for colorectal cancer in the U.S.A., in Canada, Europe, and Asia/Pacific through us or our business partners, we feel extremely well positioned to drive our commercialization forward, grow our revenue stream, broaden our customer base, sign additional non-exclusive licensing deals for our cancer molecular diagnostics products and in the process improve our earnings situation to a point where within the next several years we can emerge as a growing and leading cancer molecular diagnostics company.

On behalf of the Executive Board, I would like to sincerely thank all of our employees, our partners, our customers, and in particular our shareholders for their continued strong commitment and trust in our organization. I am convinced that 2011 will turn out to be another very rewarding year for Epigenomics in which our cancer molecular diagnostic tests will continue to save many lives by finding cancer early.

Yours sincerely,

Geert Walther Nygaard  
Chief Executive Officer

# REPORT

OF THE

## SUPERVISORY BOARD

### DEAR SHAREHOLDERS,

As in previous years, so also during the fiscal year 2010, 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. Based on detailed written and oral reports of the Executive Board and intensive discussion of all relevant issues concerning financial and operational business aspects as well as the Company's business strategy during the Supervisory Board's meetings, our advice was given with a view to the best interests of all of Epigenomics' shareholders. The dialog between all members of the Supervisory Board and the Executive Board continued to be very close and multiple conference calls as well as individual discussions were held. Thus, the Supervisory Board was continuously kept informed about the Company's financing efforts during the rights offering in the first part of 2010 following the completion of the PRESEPT clinical study. In fact, the Supervisory Board received updates on PRESEPT data analysis in an almost real-time manner throughout the first quarter. The Supervisory Board was also appraised of all corporate planning including financial, capital expenditure and human resources planning, as well as the general performance of the business. To the extent that German corporate law or existing Executive Board Rules of Procedure required approval for certain decisions or actions to be taken by the Executive Board, such approvals were given by the Supervisory Board after detailed examination of the documentation provided and intensive discussions.

### WORK OF THE SUPERVISORY BOARD

During 2010, five ordinary plenary meetings of the Supervisory Board with the Company's Executive Board took place on March 17, June 8, September 22, and November 23 as well as 24. These meetings were held in Berlin or Frankfurt am Main to ensure cost efficiency. Also, multiple conference calls between the Supervisory Board and the Executive Board were held at regular intervals throughout 2010 to discuss all important aspects of the financing transaction and PRESEPT clinical study completion. In addition, the Chairman of the Supervisory Board and the members of the Executive Board were in regular contact between Supervisory Board meetings. Thus, the Supervisory Board was kept up to date on the Company's current business situation and key events, such as the rights offering in March 2010 as well as the closing of the non-exclusive deal with Warnex Laboratories. At all of its meetings, the Supervisory Board specifically discussed the Company's corporate and financial situation, the progress of its product development programs with a keen focus on the commercialization of the Epi *pro*Colon IVD kit as well as the PRESEPT Study, its business development, marketing and sales priorities and activities as well as the Company's business strategy.



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

Important topics of the Supervisory Board meetings in 2010 were the approval of the annual financial statements, updating the 5-year business plan, the execution of the non-exclusive licensing strategy, the rights offering from authorized capital, the Company's business development issues as far as approvals for terms and conditions of new collaboration contracts were required, the budget for 2011 and several strategic opportunities presented to the Company. At its meeting on November 24, 2010, the Supervisory Board considered in detail the operational budgets, financial planning and resource allocations scheduled for the year 2011.

Due to the Company's difficult financial situation going into 2010, key focus of the Supervisory Board's advisory and monitoring activities were the Company's capital needs and future financial stability. Whilst in early 2010, prime emphasis was put on monitoring the successful completion of the PRESEPT clinical study, later in Q1 of 2010, the Supervisory Board interacted very closely with the Executive Board and the Company's advisors regarding the implementation of the successful capital increase by means of a publicly marketed rights offering. Another key area was the changing statutory framework and corporate governance implications. For each Supervisory Board meeting, all members of the Supervisory Board received extensive written reports well in advance of the individual meetings, prepared by the Executive Board with the input of the respective senior managers of all functional areas. These documents were sufficiently detailed and comprehensive to analyze and discuss all relevant topics of the respective agenda of the Supervisory Board meetings and to pass all required resolutions.

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 with a clear focus on the Epi *pro*Colon product and the PRESEPT Study. Whenever necessary, resolutions were passed by written vote in compliance with the Company's Articles of Association.

## COMMITTEES

The work of the Supervisory Board was continuously supported by its two committees: the Audit and Corporate Governance Committee chaired by Günter Frankenne, who has returned the chair to Prof. Dr. Günther Reiter in early 2011, as well as the Personnel and Compensation Committee chaired by Prof. Dr. Dr. h.c. Rolf Krebs. Both committees held several meetings or telephone conferences in 2010. The Audit and Corporate Governance Committee convened four times in 2010 dealing mainly with accounting issues, the quarterly financial statements, the annual financial statements, and other topics within the scope of responsibility of the Committee. The auditor attended all of these meetings. The Audit and Corporate Governance Committee further advised and monitored the Executive Board in questions relating to the Company's risk management and ensured compliance with the German Corporate Governance Code in its revised form with the purpose to continuously build and reinforce trust of the shareholders in the management of the Company. Special emphasis was put on discussion of recent updates to the German Corporate Governance Code such as the 'diversity requirement'.

The Personnel and Compensation Committee held more meetings and conference calls in 2010 in order to discuss matters related to the compensation of the Executive Board as well as strategic personnel issues such as the planned and seamless transition to a new CFO following the announced departure of long-standing CFO and co-founder of Epigenomics AG Oliver Schacht, Ph.D., effective March 31, 2011. The committee managed the search process for suitable CFO candidates and presented its proposals and draft contracts to the entire Supervisory Board. The Personnel and Compensation Committee was also deeply involved in the selection of a headhunter to recruit a new head for the subsidiary Epigenomics, Inc. into a commercially focused marketing and sales role for the U.S. market. Based upon the proposals developed by the Personnel and Compensation Committee, the entire Supervisory Board approved the new contract for Dr. Thomas Taapken as new CFO of Epigenomics AG starting from April 1, 2011 and approved the mutual contract dissolution with Oliver Schacht, Ph.D.

The Supervisory Board is pleased to have attracted an outstanding CFO candidate and to further evolve and strengthen the Company's leadership to continue execution on its strategy and business plans going forward. Reports of the meetings of the committees were presented at the plenary sessions of the Supervisory Board.

## CORPORATE GOVERNANCE

The Supervisory Board, advised by its Audit and Corporate Governance Committee, also continuously reviewed all issues of legal compliance and adequate risk management given the continued challenging global economic environment, the tight financial resources of the Company, as well as compliance to corporate governance principles by Epigenomics.

Both the Executive Board and the Supervisory Board regard the commitment to good corporate governance an important measure for enhancing the confidence of current and future shareholders, corporate partners and employees. In December 2010, 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 the corporate governance report of this annual report and is also permanently made available to shareholders on Epigenomics' website. In its Declaration, the Company has committed itself to the German Corporate Governance Code, and only in some cases adopted Company-specific principles deviating from these recommendations. For more detailed information regarding corporate governance issues, please refer to the corporate governance and remuneration reports of this annual report.

## AUDIT OF THE ANNUAL FINANCIAL STATEMENTS

The independent auditing company UHY Deutschland AG Wirtschaftsprüfungsgesellschaft, Berlin, has audited the annual financial statements and the related management report of Epigenomics AG for fiscal 2010 in compliance with the principles of the German Commercial Code (HGB) as well as the consolidated financial statements and the consolidated management report for fiscal 2010 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.

The consolidated financial statements and the consolidated management report were prepared in accordance with Section 315a HGB using international accounting standards IFRSs. UHY's audit was conducted in accordance with German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer in Deutschland e. V. (IDW, Institute of Public Auditors in Germany).

The above-mentioned documents were submitted to the Supervisory Board by the Executive Board in a timely manner.

The Audit and Corporate Governance Committee discussed these documents in detail. The UHY audit reports were presented to all members of the Supervisory Board and were discussed in depth at the plenary meeting on March 30, 2011, 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 and consolidated financial statements as well as the Company's risk management system. UHY also provided a report on the scope and focal points of the audit. As a result of the findings and examination by the Audit and Corporate Governance Committee and the entire Supervisory Board, the Supervisory Board raised no objections, but accepted and confirmed the results of the audit. Following its own review, the Supervisory Board formally approved the annual financial statements and the consolidated financial statements as of December 31, 2010, without exception and modification in its meeting on March 30, 2011, in the presence of the external auditors. By the Supervisory Board's approval, the annual financial statements of Epigenomics AG are thus adopted as submitted in accordance with Section 172 AktG.

Regarding the existing internal control system and risk management system as the Company's early warning system, the auditor stated that in its opinion the system is suitable to meet all legal requirements. Both the Audit and Corporate Governance Committee and the entire Supervisory Board ensured that appropriate risk management and risk mitigation strategies were implemented during 2010.

The Supervisory Board would like to use the opportunity to thank Oliver Schacht, Ph.D., for his dedication, professionalism and commitment to Epigenomics. As the Company's CFO over the past 12 years, Oliver Schacht, Ph.D., has been a key member of the team and we wish him the best of luck in his new endeavors.

The Supervisory Board welcomes Dr. Thomas Taapken as new CFO and is looking forward to working with him.

Last but not least, the Supervisory Board would like to thank the Executive Board, the senior management as well as all employees for their commitment, dedication and efforts during the year 2010.

Berlin, March 2011

For the Supervisory Board

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



# QUESTIONS TO THE NEW CFO

DR. THOMAS TAAPKEN JOINED EPIGENOMICS ON APRIL 1, 2011 TO SUCCEED OLIVER SCHACHT, PH.D., AS CHIEF FINANCIAL OFFICER. HERE HE INTRODUCES HIMSELF BY ANSWERING FIVE QUESTIONS WE WERE ASKED BY MANY OF OUR SHAREHOLDERS WHEN THEY LEARNED ABOUT THOMAS TAAPKEN JOINING EPIGENOMICS.



Dr. Thomas Taapken, Chief Financial Officer

Thomas Taapken joined Epigenomics from Biotie Therapies Corp. (Finland), where he held the position of CFO and was a member of the Executive Management Team. He was appointed to this position in 2008, following a business combination between Biotie Therapies and elbion NV, where Thomas Taapken had been CFO since 2005. His extensive international experience in the life sciences industry includes previous positions as Investment Partner at DVC Deutsche Venture Capital from 2003 to 2005 and San Francisco-based US venture capital firm Burrill & Company from 1998 to 2002. He also worked several years at Sanofi-Aventis in the U.S.A. and Germany, managing corporate venture capital activities, as well as in the areas of corporate & business development and research. Throughout his career, he has been involved in numerous transactions spanning acquisitions, mergers, divestitures, as well as private and public offerings.

## **DID YOU KNOW EPIGENOMICS BEFORE YOU WERE APPROACHED FOR THE CFO POSITION?**

➤ **TAAPKEN:** Actually, I was quite familiar with Epigenomics before joining from my time at Deutsche Venture Capital. DVC was Epigenomics' largest Venture Capital Investor when Epigenomics successfully went public in 2004 amid a critical phase for most life science companies in Europe. I have avidly followed the company since then and have gotten to know many members of its management and supervisory board who I'm very eager to start working with.

#### WHAT MADE YOU JOIN EPIGENOMICS AT THIS STAGE?

→ **TAAPKEN:** I was impressed with the steps the Company has taken over the last few years of becoming a commercially focused entity, moving away from its early days as a science driven start-up. I feel the most exciting days for the Company lie ahead as it executes on its mission of building a world-leading cancer molecular diagnostics company. The combination of its dynamic entrepreneurial spirit, strong scientific foundation and determination to succeed, all embodied in an impressive and fully committed team makes this Company very special. I was honored to be asked to take the position upon Oliver Schacht's decision to leave the company.

#### WHAT DO YOU SEE AS THE MAJOR OPPORTUNITIES AND CHALLENGES FOR EPIGENOMICS GOING FORWARD?

→ **TAAPKEN:** There are very few companies in our space that have made it from a scientific concept to commercialization. Having launched the first generation of products into the diagnostics market clearly differentiates Epigenomics from some of its toughest competitors. The key challenge going forward will be to maintain its "first mover advantage" and turn it into tangible, commercial success. Key issues such as regulatory trials and subsequent approval as well as test reimbursement will be critical for the Company but are also part of its potential success.

#### WHAT FOCUS WILL YOU SET IN YOUR ROLE AS CFO?

→ **TAAPKEN:** Clearly, Epigenomics is now at a turning point in its corporate history and is positioned to become a leading molecular diagnostic company. The future success of the Company is linked to the expansion of its colorectal cancer screening test into further key diagnostic markets, particularly in the U.S.A., developing a focused, yet healthy pipeline of diagnostic markers, increased investor awareness and ultimately, stringent execution of its business strategy. My background and experience in similar roles should enable me to help the company deliver on these expectations set by the Supervisory Board, the executive team in addition to investors and further stakeholders.

#### WHAT CAN YOU TELL US ABOUT THE PERSON THOMAS TAAPKEN?

→ **TAAPKEN:** The ultimate driving force behind my dedication, commitment and passion for this industry is the vision of making a real difference for patients afflicted by devastating diseases. Nevertheless, many stakeholders are involved in this marathon of better diagnostic and treatment options for patients. Taking the role as CFO of Epigenomics for me also means responsibility towards shareholders, employees and business partners. My working style is characterized by building and fostering strong relationships with all of them, listening to their needs and optimally trying to balance their purviews. However, leadership also means making difficult decisions and taking decisive action when necessary which I am willing to do. Lastly, honesty and integrity are key values that I expect from others, as much as I strive to live them myself.

# STRATEGY

## SENIOR MANAGEMENT INTERVIEW

WHEN GEERT NYGAARD JOINED EPIGENOMICS AS CEO IN 2007, HE ESTABLISHED THE SENIOR MANAGEMENT FORUM. THIS DECISION BODY CONSISTS OF THE CEO AND THE CFO AS THE TWO EXECUTIVE BOARD MEMBERS AS WELL AS THE SENIOR VICE PRESIDENTS. IT IS IN THIS FORUM WHERE ALL MAJOR STRATEGIC AND MAJOR OPERATIONAL ASPECTS ARE DISCUSSED AND DECIDED. IN THIS Q&A, THE SENIOR MANAGEMENT FORUM GIVES INSIGHT INTO EPIGENOMICS' STRATEGY TO ESTABLISH ITSELF AS A MAJOR CANCER MOLECULAR DIAGNOSTICS COMPANY.

**MR. NYGAARD, CAN YOU LAY OUT THE CORNERSTONES OF EPIGENOMICS' STRATEGY GOING FORWARD?**

➔ **GEERT NYGAARD, CEO:** Our strategy has been very consistent since I joined in early 2007: We want to develop Epigenomics into a leading cancer molecular diagnostics company. To fulfill this mission, we have implemented a dual business strategy. This strategy consists of direct commercialization of in vitro diagnostic products such as our Epi *proColon* blood test for colorectal cancer and non-exclusive licensing of our biomarkers and technologies to diagnostic industry partners with broad customer access such as Abbott, QIAGEN, Sysmex, Quest Diagnostics, ARUP Laboratories, and Warnex Laboratories.

Dr. Achim Plum, Geert Nygaard



Dr. Uwe Staub



#### WHERE DO YOU SEE THE ADVANTAGES OF THIS STRATEGY, WHAT ARE THE CHALLENGES?

→ **NYGAARD:** We strongly believe that we ourselves are the best advocates of our products and we can only develop products that fit our customers' needs if we are out there selling them ourselves. On the other hand, we have not yet established a broad global presence and the customer access to fully leverage a product like Epi *proColon* that could potentially be used by more than 300 million men and women in the U.S.A., Europe, and Japan, a market that is theoretically worth several billion euros. Here our partners come into play. Through our non-exclusive licensing approach we maximize our global reach, access to the installed base of several molecular diagnostics platforms, and access to customers. Certainly it is a challenge to coordinate these many players to unify the marketing message and at the same time ensure that their respective Septin9 tests get the sufficient attention from their marketing and sales organizations. To the extent permitted, we try to address these challenges by close interactions with our partners and coordination on several hierarchical levels.

Dr. Jürgen Beck



Albert Weber

#### HOW WILL THE ORGANIZATION GROW GOING FORWARD?

→ **NYGAARD:** As we have a very effective R&D organization able to release one to two new products or product generations per year, our emphasis will primarily lie on evolving on developing our commercial capabilities and reach. This will mean adding functions and people, such as management and sales agents to the European marketing and sales organizations, but most importantly we will need to establish a commercial presence in the U.S.A., strategically the most important market going forward. As a starting point to this process, we are in the process of hiring a new head for our Seattle based subsidiary. We are looking at candidates with significant experience in the U.S. diagnostics market. The future head of our U.S. operations will work closely with our Corporate Development function to detail a commercial plan for the U.S. and take responsibility for implementing this plan.

**WHAT MAKES THE U.S. SUCH AN ATTRACTIVE MARKET FOR YOUR Epi proColon PRODUCT?**

→ **ACHIM PLUM, SEN. VP CORPORATE DEVELOPMENT:** The United States is the largest homogenous market for diagnostics. Further the U.S. is characterized by a relative openness to medical innovations, with relatively clear and evidence-based pathways to guideline inclusion and reimbursement. On the payor side, private insurance plans and health management organizations take a leading role, which are in general very open to preventive medicine and long-term cost effectiveness. Although the approval process by the FDA can be in-depth and rigorous, the process also provides a hurdle to competition. An IVD product approved by the FDA can be a very significant value-creating step for the Company.

**WHAT ARE YOUR PLANS FOR FURTHER PRODUCTS?**

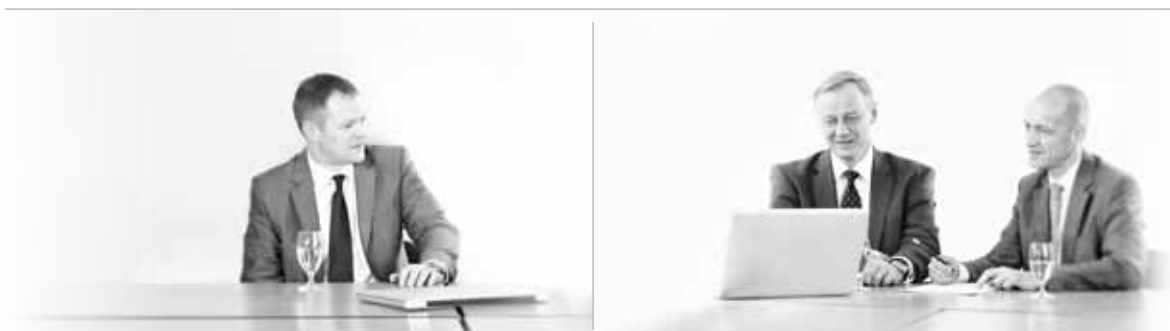
→ **UWE STAUB, SEN. VP PRODUCT DEVELOPMENT:** The immediate development priority is obviously our Epi proColon 2.0 product for the U.S. and European market. So far, we made very good progress in establishing an assay procedure that requires less time, is based on cGMP manufactured components and works on platform that was already cleared by the FDA for IVD use with other assays. The prototype of this product has recently shown excellent clinical performance in a feasibility study.

→ **JÜRGEN BECK, SEN. VP MEDICAL AFFAIRS:** Once you are in the market place with diagnostics products you immediately realize that a key factor to success is building the network and the credibility in the respective indication area. Thus, from a medical affairs perspective it makes a lot of sense to expand the portfolio further in a few disease indications rather than spreading the portfolio over many disease areas.

→ **ANDREW SLEDZIEWSKI, SEN. VP RESEARCH:** Limiting disease indications also makes sense from a biological point of view. Biology is complex and clinically validated, high-quality biomarkers like *m*SEPT9, *m*SHOX2 and *m*PITX2 are rare and extremely valuable assets. We have found and evaluated these biomarkers in a particular context and learned a lot about them in the process. From a risk/reward perspective it makes most sense to put highest priority on finding additional related applications for these biomarkers. We are particularly interested in testing whether our *m*SEPT biomarker could also be applied to monitoring patients for relapse or assessing their prognosis after first line therapy. For this purpose we have developed a quantitative assay for *m*SEPT9 and have started a proof-of-concept study at the University Hospital Halle lead by Prof. Schmoll, one of Germany's leading oncologists for colorectal cancer. Similarly, we are looking into further evaluating *m*SHOX2 in blood plasma thereby opening new ways for additional applications for *m*SHOX2 in lung cancer beyond the utility of the current bronchial lavage test for the diagnostic work up of patients with suspected lung cancer.

**PERSONALIZED MEDICINE IS GETTING A LOT OF ATTENTION THESE DAYS.  
WHAT ROLE DOES IT PLAY IN YOUR STRATEGY?**

→ **PLUM:** Personalized medicine has been on our agenda now for almost a decade and we have gathered a lot of experience in the field. We have an ongoing collaborative service business in which we discover and validate biomarkers for partners in the pharmaceutical industry and develop assays for them to be used for clinical trials and clinical routine. This business contributes to our top line and is margin positive. However, despite a lot of discussion, historically the commitment in the pharmaceutical industry to enter into long-term and value-based arrangements has been too low to build a sustainable growth-oriented business around companion diagnostics. Accordingly, we in the past put our strategic focus on stand-alone diagnostics such as Epi *pro*Colon. This paradigm is now changing fundamentally, partly due to regulatory pressure on the pharmaceutical industry and more success stories like KRAS testing. As a result, discussions today are much more mature and tangible compared to when we started. Going forward, we see this business gaining in strategic importance for us, both in partnerships as well as in our own pipeline.



**DR. TAAPKEN, YOU JUST JOINED EPIGENOMICS AS CFO AND BRING IN  
A BACKGROUND IN M&A. WILL M&A BE OF RELEVANCE GOING FORWARD?**

→ **THOMAS TAAPKEN, CFO:** For a company like Epigenomics with a proprietary product that has an enormous potential there is always the risk – or opportunity – of being acquired. But this is a decision our shareholders will have to take once an offer is on the table. We do not tailor our strategy to this scenario but rather believe that we should focus on building true value and grow the business ourselves. However, in doing so we will frequently be faced with “build or buy” decisions, e.g. with regard to setting up a commercial infrastructure in strategic markets like the U.S., broadening our product portfolio, or venture stronger into personalized medicine. It is our responsibility to continuously assess our options while executing our strategy and that includes looking at possible M&A opportunities that make sense from a corporate strategy perspective and an investor’s point of view.

**WHAT WILL BE IMPORTANT MILESTONES IN THE NEXT TWO YEARS?**

→ **NYGAARD:** The upcoming milestones are closely related to expanding our customer access and geographic reach and drive market penetration. After we have just given an option to one of the four worldwide licensing slot to QIAGEN we want to complete the Septin9 consortium by filling the last remaining slot with one global or several regional partners. With regard to our own Epi *pro*Colon and Epi *pro*Lung products we want to broaden our distributor network in Europe and beyond, start selling the products ourselves in additional key markets and most importantly finalize the development of Epi *pro*Colon 2.0 for launch in Europe and submission for FDA approval. The approval of this product by the agency and its



Dr. Thomas Taapken

launch into the U.S. market will certainly be major milestones going forward. Further, we expect the publication of the PRESEPT Study data and a health economic cost effectiveness analysis based on the study results in the course of 2011. The ongoing and planned studies on patient screening behavior by us and our partners that are expected to supply important additional arguments for reimbursement should deliver results throughout 2011 and 2012. Also we hope to embark on a patient focused behavioral study with one of the German health insurance companies. Beyond seeing Epi *pro*Colon through development and FDA submission, our R&D will focus on expanding the clinical utility of our biomarkers in closely related application areas and we expect to publish the results of some proof-of-concept studies and advance these respective products into development.





# I WAS RELIEVED

AS A SHAREHOLDER OF EPIGENOMICS,  
DR. ULRICH GRÖLLMANN WAS ALWAYS A  
CLOSE FOLLOWER OF THE COMPANY AND  
ONE OF THE FIRST TO TAKE THE SEPTIN9 TEST.  
SEPTIN9: POSITIVE – TWO POLYPS REMOVED  
IN COLONOSCOPY



**Dr. Ulrich Gröllmann, 61,** worked as a chemist in the Berlin-based European Research Institute of a large Japanese chemical company until his recent early retirement. For many years he did research into advanced and more environmentally friendly high tech polymers, pigments, inks and coatings. No wonder that high tech companies are also of interest to him as a private investor. In the internet he regularly visits stock market forums hunting for promising stories for his investments. Beginning of last year he found an announcement by Epigenomics that its Septin9 test for colorectal cancer was launched and now available throughout Germany. This message was highly interesting to him in two very specific ways: "The idea to detect colorectal cancer in its earliest stages with a simple blood test was so revolutionary to me that I immediately bought shares of the company. On the other hand I several times had done the known chemical fecal occult blood tests at my family doctor's office. But I was never a big fan of this simple yet relatively unreliable test. I knew that numerous circumstances could lead to a false-negative or a false-positive result. But for a long time I also had reservations against undergoing a colonoscopy: By chance I met a gentleman who regularly underwent colonoscopies. He told me that it would depend on the experience and skill of the doctor in how far this procedure would put a strain on the patient and that it also could result in complications." The news on the market introduction of the Septin9 test virtually "electrified" Dr. Gröllmann and he got himself tested immediately. "The test result returned positive and persuaded me to undergo colonoscopy after all. During this colonoscopy two polyps were found and removed. I was relieved when I learned that both polyps were indeed benign. In theory, I am now good for the next ten years until the next colonoscopy is due. But based on my experience, I will get myself tested a couple of times in between."



## PRODUCT

# Epi *pro*Colon<sup>®</sup> & CO.

OUR FLAGSHIP PRODUCT IS Epi *pro*Colon, A CONVENIENT BLOOD TEST THAT DETECTS THE BIOMARKER *m*SEPT9 AND CAN FACILITATE THE EARLY DETECTION OF COLORECTAL CANCER. Epi *pro*Colon AND THE SEPTIN9 TESTS OFFERED BY OUR LICENSING PARTNERS IN THE DIAGNOSTIC INDUSTRY MAY HELP TO OVERCOME THE SINGLE BIGGEST HURDLE IN EFFECTIVE COLORECTAL CANCER SCREENING – PATIENT COMPLIANCE.

## CATCHING CANCER EARLY

**COLORECTAL CANCER IS LARGELY CURABLE** – when detected early. The five-year survival rate for patients is about 90% if the cancer is diagnosed at an early stage while it is still localized, i.e. it has not spread outside of the wall of the colon. Accordingly, effective population-wide screening aimed at catching the cancer in early, still asymptomatic stages is considered key to lowering the mortality from this disease. Despite of numerous screening initiatives propagating stool tests and colonoscopy for regular screening starting from the age of 50 in many countries, colorectal cancer is still the second leading cause of cancer related death in developed countries. The widely accepted reason for the high mortality rate is the lack of patient adherence to current screening guideline recommended methodologies.

## GET MORE PEOPLE SCREENED

**ACCORDING TO A SURVEY IN THE U.S.A.**, only about 4 in 10 people undergo colonoscopy for screening and only 12% use stool tests in the recommended intervals. About 50% of U.S. citizens aged 50 years and older do not get screened at all<sup>1</sup>. In Germany, 62% of women and 72% of men were not screened at all for colorectal cancer between 2003 and 2008<sup>2</sup>. Similar numbers apply to France and many other countries with similar prevalence of the disease. And even in countries like the United Kingdom where publicly organized screening programs are in place that track citizens and invite them to stool testing on a regular basis by mail, a significant number of people cannot be motivated to comply.



e<sup>pi</sup>pro  
colon



When we set out to make use of our unique DNA Methylation technology for cancer diagnostics, we had the vision to develop a blood test as an alternative or additional option to conventional non-invasive or invasive methods of colorectal cancer early detection. A blood test that has the potential to get more people screened as it can easily be integrated into a regular health check-up, does not require any preparation or significant involvement of the patient and is entirely under control of healthcare professionals.

#### TEST AVAILABLE WORLD-WIDE

**TODAY**, our Epi proColon test and the Septin9 blood tests developed by our licensing partners Abbott, Quest Diagnostics, ARUP Laboratories, and Warnex Laboratories are offered in Europe, Middle East, Asia/Pacific and North America. More partners such as Sysmex and QIAGEN are working on their versions of the Septin9 test.

With more and more patients getting tested with Septin9 tests and an increasing number of colorectal cancers being detected at early stages, cases that otherwise may have progressed unnoticed, our vision has become a reality: Finding cancer early. In blood.

<sup>1</sup> National Health Interview Survey Public Use File, 2005, National cancer for Health Statistics, Centers for Disease Control and Prevention, 2006; American Cancer Society, Surveillance Research

<sup>2</sup> Altenhofen, L et al (2009): Projekt wissenschaftliche Begleitung von Früherkennungs-Koloskopien in Deutschland; Altenhofen, L et al (2009): Ergebnisse der Vorsorgedarmspiegelung 2003–2008 – eine Bilanz

R&amp;D

## *m*SEPT9 – CLINICAL EVIDENCE IS KEY

EVIDENCE IS KEY IN THE MEDICAL ADOPTION OF A SCREENING TEST. IN BUILDING A CONVINCING BODY OF EVIDENCE AROUND THE MEDICAL UTILITY OF OUR *m*SEPT9 BIOMARKER FOR COLORECTAL CANCER SCREENING, OUR CLINICAL RESEARCH FOCUSES ON THREE AREAS – PERFORMANCE, HEALTH ECONOMICS AND COMPLIANCE – WHILE OUR DEVELOPMENT ALREADY WORKS ON THE NEXT PRODUCT GENERATION...

### A RELIABLE INDICATOR

**AT THE CORE** of Epi *pro*Colon and the colorectal cancer blood tests offered by our partners is the *m*SEPT9 biomarker. In our research, we discovered that the gene SEPT9 is specifically methylated in the DNA of colorectal cancer cells. As tumors shed DNA fragments into the blood stream even in the earliest disease stages, cell free-methylated DNA of the gene SEPT9, detected in blood plasma is a reliable indicator, i.e. biomarker, for the presence of colorectal cancer. This has been shown by us and our partners in a dozen case control studies with blood samples from more than 4,000 subjects in total. But we took it a step further: In the prospective PRESEPT Study, sponsored by us and overseen by an independent Clinical Study Steering Committee of distinguished clinical researchers in the field, Septin9 testing was compared against colonoscopy as the accepted gold standard in colorectal cancer screening and with good success.

When study data were first presented at the Digestive Disease Week 2010 in Chicago, it became clear that this study with more than 7,900 subjects – the largest of its kind ever conducted – effectively had shown that Septin9 testing can indeed be applied to population wide early detection of colorectal cancer in a typical average risk screening population.

The results from the PRESEPT Study were the starting point for a health economic analysis of screening with Septin9 blood tests conducted independently by Prof. Uri Ladabaum at Stanford University. In the scenarios studied, Uri Ladabaum focused among other things on the effect of compliance on cost effectiveness of screening methods including Septin9 testing. He will present data from this study at this year's Digestive Disease Week.



## STUDYING PATIENT SCREENING BEHAVIOR

**WHILE WE EXPECT** the PRESEPT Study data and the health economic analysis to be published in a peer-reviewed medical journal in the course of 2011, current clinical research by our partners and us focuses on the real-life impact a blood test could have on compliance to colorectal cancer screening recommendations. To this end we have initiated a study in Germany that focuses on demographic characteristics of current test users. Further studies in planning focus on patient preferences in the choice of screening methods.

In the U.S.A., our partner ARUP Laboratories has taken the lead in initiating a three phase study with the Huntsman Cancer Institute also located in Salt Lake City, Utah, on factors that influence patient screening behavior and the impact of the availability of a blood test on this behavior. Data on clinical performance, health economic benefit and patient's acceptance of colorectal cancer early detection through Septin9 blood testing will be instrumental in our discussions with private and public healthcare and payor organizations on adoption and reimbursement of the Septin9 tests.

## Epi *proColon* 2.0

**WHILE THE FIRST GENERATION** Epi *proColon* test is currently marketed in Europe and the Middle East, our development team works on the second generation test for the U.S. market, and also as a next generation product for Europe and other markets. Improvements include the usage of cGMP grade raw materials, cGMP manufactured reagents, usability with a FDA-cleared real-time PCR device, fewer handling steps, shorter time to result, less kit components and smaller packaging. But most importantly, a prototype of Epi *proColon* 2.0 has shown an excellent improved clinical performance of 91% sensitivity at 87% specificity in a recent clinical feasibility study. This successful feasibility study paves the way to finalize the product design, enter into clinical validation and prepare a submission to the FDA and the launch as a second generation CE-marked IVD product in Europe.

MARKETING & SALES

# HOME MARKET CENTRAL EUROPE

Epi *proColon* IS MARKETING BY EPIGENOMICS' OWN MARKETING AND SALES ORGANIZATION IN GERMANY, AUSTRIA AND SWITZERLAND. A LOT HAS BEEN ACHIEVED SINCE THE LAUNCH OF THE PRODUCT IN OCTOBER 2009. AND A LOT OF WORK LIES STILL AHEAD.



## ESTABLISH DIRECT CUSTOMER ACCESS

**EPIGENOMICS IS TRANSITIONING** from a mainly R&D driven biotechnology company to a product driven commercial molecular diagnostics company with direct access to our customers. We started to serve the home market of Germany, Austria and Switzerland ourselves when we launched Epi *proColon* in Europe in October 2009. The very valuable experience we gathered in this market we share with our IVD partners and distributors and thereby support them in tailoring their strategy to their needs and markets.

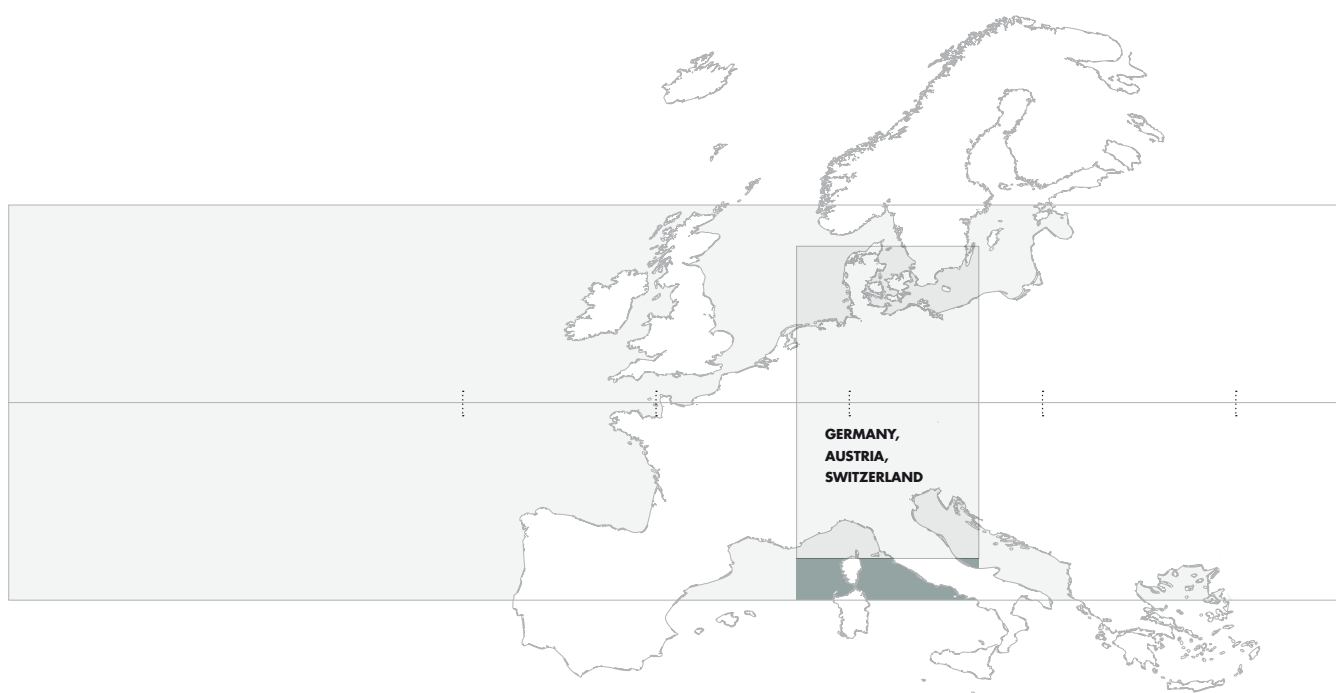
## FOUR STEPS TO SUCCESS

**BUILDING A NEW MARKET** in molecular diagnostic takes several years and is best pursued in a phased and hierarchical approach.

In the **LAUNCH PHASE**, the focus lies on making the test available and generating acceptance among the opinion leaders in the field. During 2010 we have made the Epi *proColon* test available in 17 laboratories throughout Germany including some of the large laboratory networks like synlab and Limbach.

In Switzerland, Septin9 testing is available through Viollier and Unilabs, the two largest providers of laboratory testing in the country. In Austria a first laboratory started offering Septin9 testing in collaboration with a German laboratory while we continue expanding our reach in this region. At the same time we have entered into an intensive and open dialogue with leading gastroenterologists and patient advocacy groups through participation in medical conferences and through hosting of a number of roundtable discussions.

With widespread support secured at this level, we have initiated the **INTRODUCTORY PHASE** in spring 2010 with a focus on generating awareness among the prescribing physicians – mainly primary care physicians, urologists and gynecologists. Together with the laboratories offering Septin9 testing and regional gastroenterologists CME seminars for physicians on colorectal cancer screening were organized. These were accompanied by numerous congress participations as well as campaigns directed at medical publications targeting the prescribing physicians. In total, Epigenomics attended more than 35 meetings and created a coverage of 101 publications in medical media and the general press with a total circulation of 16.4 million.



As an effect of this effort, a survey in mid 2010 indicated that one third of the interviewed German primary care physicians have heard about the Septin9 tests and the majority of these believed that it may be a useful tool to increase the compliance to colorectal cancer screening. In parallel we have seen an increasing number of early adopters among physicians and patients starting to use the Septin9 test. With the prescribing doctor identified as the key gatekeeper in the process we have initiated a number of programs to convince this important group of the benefits of Septin9 blood testing for colorectal cancer early detection. These activities include observational studies in Germany and Switzerland as well as a direct outreach via a small but specialized rental sales force in some pilot regions with a high proportion of self-payors and privately insured patients.

Through these and further activities centered around prescribing physicians, certain patient segments\* and increasingly private insurance companies we strive to move the market into the **ADOPTION PHASE** characterized by increased routine prescription of the tests by physicians for self-payors and privately insured patients.

However, to move into the **PENETRATION PHASE** with widespread use of the test, guideline inclusions and a general reimbursement decision under the public health care schemes of the market countries are required.

In Germany, this process can take several years. To this end we have initiated a dialogue with several public German health insurance providers on patient acceptance studies and pilot projects in which the test would be reimbursed and offered to insured patients in certain regions for a certain period of time. With these activities and data on clinical performance, health economic benefit and patient adherence gathered in the numerous studies and pilot projects described above, we strive to achieve generalized reimbursement in Germany and other market countries.

## MAXIMIZING SYNERGIES WITH PARTNERS

**WE COORDINATE** our educational activities as well as studies and health economic analyses for European markets with our partner Abbott who have launched their version of the Septin9 test under the brand name RealTime PCR *mS9* Colorectal Cancer Assay in December 2009 in Europe and Asia/Pacific. While the sales forces of both companies promote differentiated products under their respective brand names to the laboratories with some level of competition, we take great care to educate on the utility of all Septin9 blood tests when communicating with physicians, patient advocacy groups and patients to avoid confusion and maximize the synergies in our non-exclusive partnering approach to building this novel market.

\* within the framework of applicable laws and regulations

MARKETING & SALES

# EUROPE AND BEYOND

TO MAXIMIZE OUR REACH IN EUROPE AND BEYOND WE HAVE STARTED BUILDING A NETWORK OF DISTRIBUTORS. YET, SOME COUNTRIES MAY BE BEST SERVED BY OURSELVES...



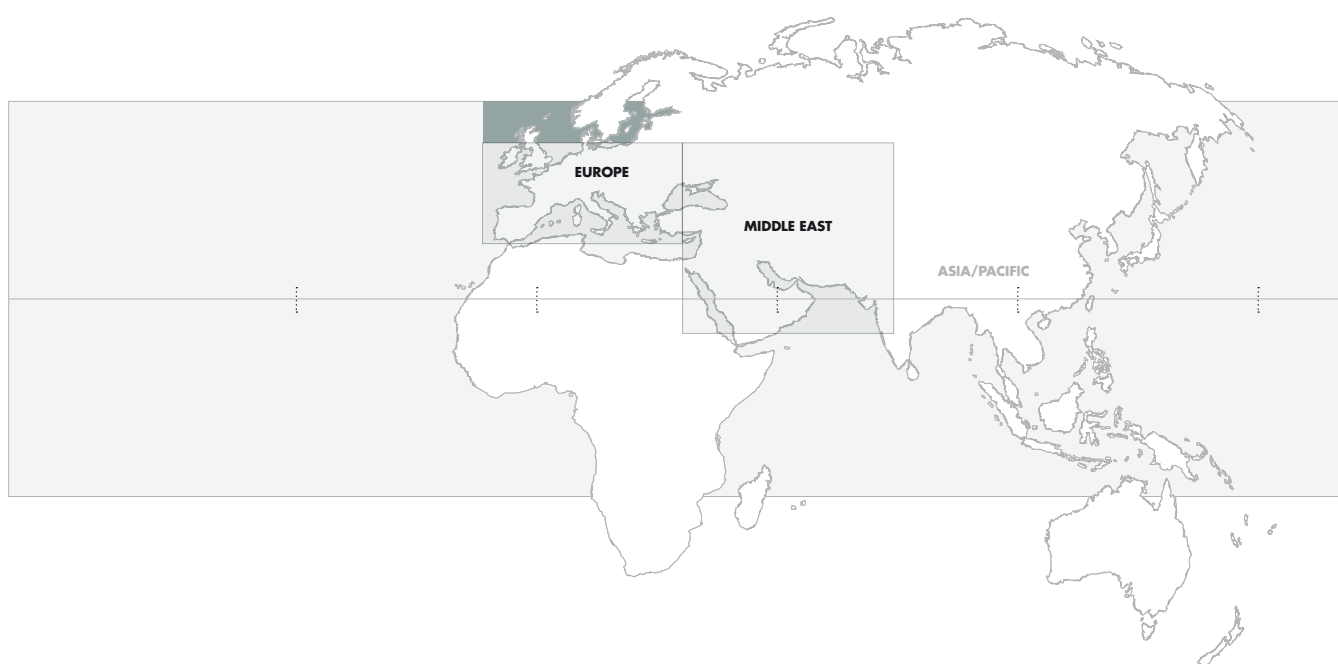
## OPPORTUNITY BEYOND THE HOME MARKET

**A CE-MARKED IVD PRODUCT** may be sold in all of Europe and through mutual recognition of the EU's conformity assessment with no or few additional regulatory hurdles in a number of other countries beyond. Despite the recent publication of European screening guidelines, the colorectal cancer screening landscape in Europe today is still very heterogeneous ranging from nationwide screening programs with simple stool tests in different stages of planning and implementation to screening on demand by stool tests or colonoscopy in Germany. Despite these numerous efforts, the majority of the European population is currently not screened at all.

## BUILDING A DISTRIBUTOR NETWORK

**THIS PROVIDES** an enormous opportunity for our Epi *proColon* test that we are not yet able to leverage all by ourselves. For this reason we have started building a network of distributors with an initial focus on countries that are best served by local organizations with a very good understanding of the particularities of their markets and the stakeholders involved. In the selection of distributors for Epi *proColon* we give preference to those who have a track record of success with building markets for comparable products and have a molecular and/or cancer diagnostic focus in their product portfolio. First distribution agreements were signed in 2010 with Pronto Diagnostics for Israel, DATEKS for Turkey, and DPC for Lebanon and the Middle East. More agreements are to be expected in 2011.





## THE “BIG FIVE” REQUIRE A CLOSER LOOK

**IN THE KEY STRATEGIC MARKETS** in Europe other than Germany, namely the UK, France, Italy, Spain, we take a case by case decision on whether these markets are best served through agreements with local distributors or directly by ourselves. This decision follows a thorough analysis of the laboratory market structure, the colorectal cancer screening market, screening guidelines and compliance, reimbursement system, size of private payor segment, our partner’s footprint in these markets and further important factors.

**WHEN THIS ANALYSIS WAS COMPLETED FOR FRANCE,** we came to the conclusion that this high potential market is best served through our own marketing and sales organization for a number of reasons, the most important one being the structure of the laboratory market. Although most laboratory testing in France is performed by a large number of small local laboratories, their test menu is restricted to the most conventional IVD tests. The more complex molecular diagnostic tests are performed for these laboratories by a handful of highly centralized

laboratories that can be served in a key account approach by Epigenomics’ own sales and technical support team. Furthermore, we have contracted an experienced French molecular diagnostics expert for liaising with key opinion leaders, supporting the laboratories in the educational process as well as developing and implementing a reimbursement strategy.

**IN MANY ASIAN SOCIETIES** colorectal cancer is an increasing problem due to continuing “westernization” of life style and diet. Yet, with the limited resources at our disposal, we have decided for now to address these markets as well as the Pacific region only opportunistically.

MARKETING & SALES

# GOING WEST – Epi *pro*Colon FOR THE U.S.A.

LAUNCHING Epi *pro*Colon IN THE U.S.A. COMES WITH SIGNIFICANT REGULATORY HURDLES. BUT WE BELIEVE TAKING THE EFFORT WILL PAY OFF.



## AIMING FOR FDA-APPROVAL

**Epi *pro*Colon** belongs to a class of in vitro diagnostic tests that requires a Premarket Approval (PMA) by the FDA prior to launch in the U.S.A. To successfully obtain approval by the agency, we have to work under a quality system that is compliant with FDA regulations, develop the test on a real-time PCR instrument that is ideally already cleared by the FDA for other applications, manufacture the test kit under cGMP and provide sufficient valid scientific evidence from appropriately designed clinical studies that assures that Epi *pro*Colon is “safe and effective for its intended use”. Once all parts are completed the Premarket Approval Application will be submitted to the FDA for consideration which may involve a review at a public meeting with an FDA advisory panel. The statutory review time for a PMA is 180 days but could take significantly longer, as the agency may come back with additional requests for information to clarify open issues, each time halting the statutory review time.

Despite the significant effort involved and the uncertainties in timeline and chances of success that come with this regulatory pathway, we believe that bringing Epi *pro*Colon to the U.S. as an FDA-approved IVD test is a key driver of our company value.

## 53 MILLION POTENTIAL CUSTOMERS

**THE UNITED STATES** is the largest homogeneous market for in vitro diagnostic products. For Epi *pro*Colon this means that about 53 million U.S. citizens aged 50 and older for which screening for colorectal cancer is recommended currently do not participate in any screening and are potential customers for us and our partners. Also, the market is dominated by private health insurances and health management organizations as integrated providers of health care for whom prevention is high on the agenda as it may be key to overall cost effectiveness and may help to maximize their long term profitability. In contrast to many countries in Europe, direct-to-patient advertising is allowed and it is a widely held view in the diagnostics industry that every marketing dollar spent in the U.S.A. has the potential for a multiple in return.



## GREAT DEVELOPMENT PROGRESS TOWARD U.S. PRODUCT

**OVER THE COURSE** of the second half of 2010 and in early 2011 we have made great progress towards our U.S. product. We upgraded our quality system to fully comply with U.S. regulations, contracted a cGMP manufacturer and developed a prototype assay that uses cGMP grade reagents and cGMP manufactured kit components and optimized this prototype on a FDA-cleared real-time PCR device. Similar to Europe, we will pursue an open platform concept, i.e. develop the test for a real-time instrument that is not restricted for use with our reagents. In a recent feasibility study a prototype developed for this instrument showed excellent clinical performance.

We originally discussed the design of our PRESEPT Study and our plans to reuse the cohort as a central part of our clinical validation with the FDA in 2007 and recently have re-initiated our dialogue with the agency in a pre-IDE meeting in February 2011. Since then we are in discussion with the agency on the intended use and the cornerstones of our clinical validation plan. Based on FDA feedback we are finalizing the product's intended use and the cornerstones of our clinical validation plan with the advice of DOCRO, one of the leading regulatory consulting firms in the diagnostics space.

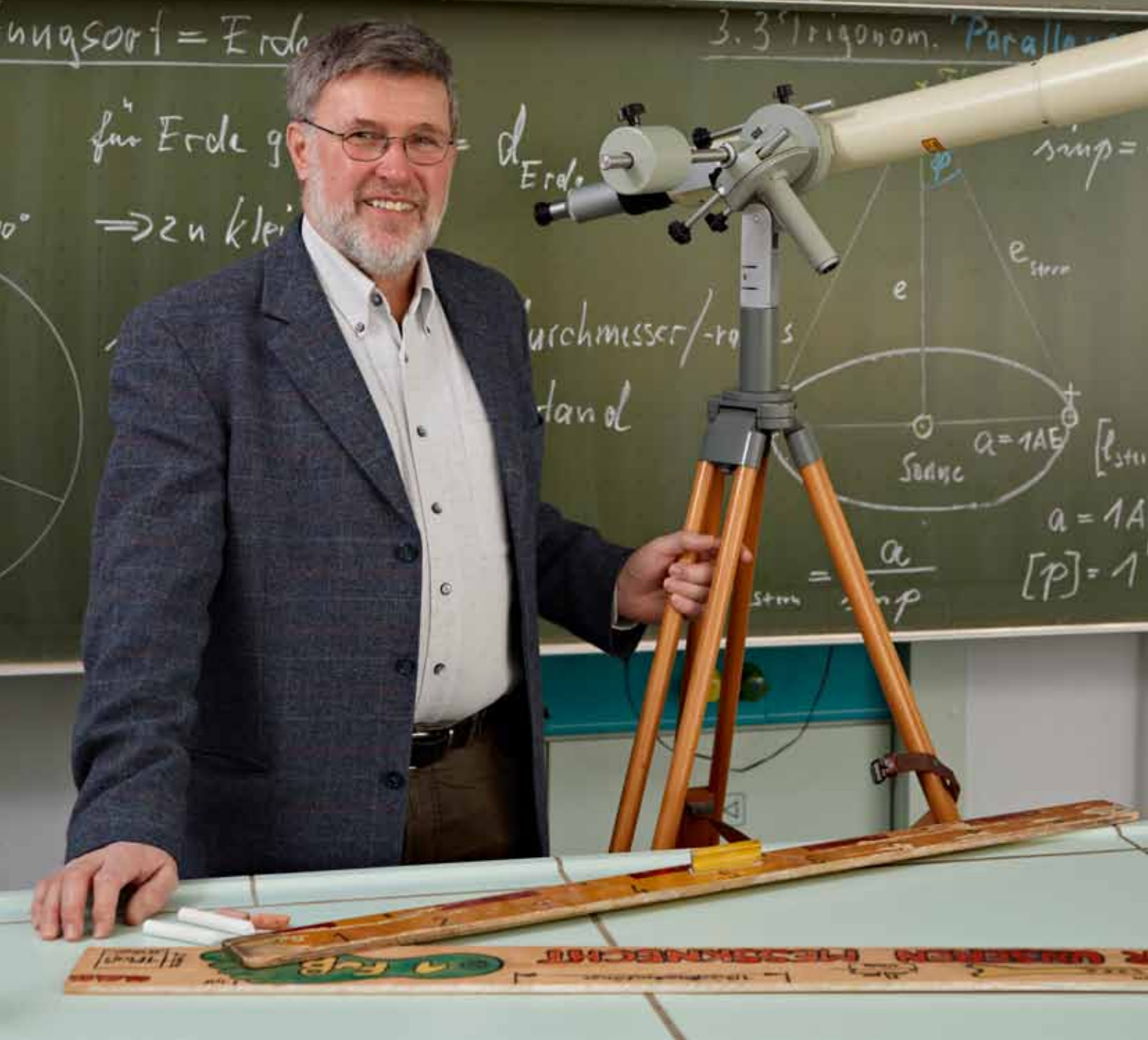
## GEARING UP FOR U.S. LAUNCH

**WHILE WE ARE DRIVING** our U.S. product development and the regulatory process with the FDA forward we have initiated a project and assigned a dedicated project team to detail our U.S. commercialization plan and implement all necessary steps to secure a successful launch following FDA approval. Immediate activities in progress include the development of a reimbursement and screening guideline roadmap in collaboration with Boston Healthcare Associates, the expansion of our network of key opinion leaders and the recruiting of an experienced U.S.-based marketing and sales executive to head our office in Seattle and convert this part of our organization into a commercial operation serving the U.S. market.

While we are working development and submission for approval of our Epi *pro*Colon IVD test kit and gearing up for its commercial launch, the availability of laboratory-developed Septin9 tests by our partners Quest Diagnostics (ColoVantage™) and ARUP Laboratories (Methylated Septin9 Test) provide a unique opportunity to increase awareness among key opinion leaders and patient advocacy groups and conduct studies in the U.S.A. that can support the medical adoption of our innovative approach to the early detection of colorectal cancer.

# JUST IN TIME

SEPTIN9: POSITIVE ADENOMA REMOVED. WHEN IT COMES TO HIS HOBBIES, MR. JÜRGEN MEYE IS THE QUINTESSENTIAL MAN. WHEN IT COMES TO SCREENING, HE IS TOO... WELL, USED TO BE.





**Mr. Jürgen Meyes, 68, hobbies**

could not be more masculine. From early childhood he has been fascinated with space. He is a qualified teacher of mathematics, physics, and astronomy. But when he got the opportunity to move to teach astronomy at a high-school with its own observatory in the former German Democratic Republic he did not hesitate a second. With the access to the observatory he now could share his passion for astronomy with his students under much better conditions. After reunification and the liberation of the tight radio traffic regulations that came along with it he fulfilled another dream and became a licensed amateur radio operator. Today he enjoys connecting with people around the globe as much as building his own radio equipment. But what makes Mr. Meyes also a typical representative of his gender is his reluctance to get screened for cancer. "My wife already had two colonoscopies. She and my son wanted me to also have one, but I always managed to get around it. Us men, we try to avoid the issue as best we can." As all "nagging" could not convince Mr. Meyes to have a colonoscopy, his son, Dr. Axel Meyes who works in the diagnostic laboratory Labor Ostsachsen, saw a new chance when he introduced the Septin9 test in his laboratory. He convinced both of his parents to get the blood test. While Mrs. Meyes was Septin9 negative, Mr. Meyes tested positive ... and finally agreed to a colonoscopy in which a large adenoma with first signs of progression to a tumor was removed. His gastroenterologists told him to come back in two years time for a follow-up. "This time, I will not need any nagging by my family to make me go."



MANUFACTURING & LOGISTICS

# FOCUSING ON CORE COMPETENCIES

OUTSOURCING HELPS US TO FOCUS OUR RESOURCES ON THOSE THINGS WE CAN DO BEST: DEVELOP PROPRIETARY IVD TESTS AND DRIVE THEIR MEDICAL ADOPTION IN THE MARKET. CGMP MANUFACTURING AND LOGISTICS WE OUTSOURCED TO THE EXPERTS IN THESE DISCIPLINES.

## OUTSOURCING GENERIC ASPECTS OF OUR BUSINESS

**WHILE THE DEVELOPMENT** of molecular diagnostic tests for cancer and their commercialization are tasks that are at the core of our business we decided to de-risk our approach by outsourcing some more generic aspects of our business to the respective experts in their fields. In a broader sense, this also includes an open platform concept in which we refer to available generic laboratory instrumentation rather than developing and commercializing our own equipment and instrument software. Also we obtain most reagents for our tests from third-party suppliers minimizing the complexity of the manufacturing process.

## CONTRACT MANUFACTURING IN A CGMP FACILITY

**WHILE WE MANUFACTURE** the first generation of our Epi *proColon* product and our Epi *proLung* product in our facility in Berlin, Germany, we have contracted NextPharma Technologies to manufacture the second generation Epi *proColon* 2.0 under cGMP in their facility in San Diego, CA, U.S.A. This decision was partially driven by the fact that establishing cGMP manufacturing would have required building or renting a new facility. While this may be an option in the future once Epi *proColon* is widely used and test volumes surge, it was not advisable from an economic and risk perspective to go down this path now. We will, however, retain the responsibility for all aspects of quality control including the release of manufactured lots.



## ARVATO MANAGES LOGISTICS

**FOR WAREHOUSING** and international distribution of our Epi *pro*Colon and Epi *pro*Lung test kits, we are working with Arvato Services Healthcare, a subsidiary of Arvato AG, a part of the Bertelsmann Group, since early 2010. After manufacturing, the kits are shipped to Arvato's facility where kits are stored under appropriate and controlled conditions. Orders received by Epigenomics are forwarded to Arvato who take over all tasks associated with commissioning and confectioning of the shipment, packaging, customs declarations and other necessary paper work as well as organizing the transportation via established carriers.



PRODUCT

# Epi *proLung*<sup>®</sup> – DIAGNOSING LUNG CANCER

WITH CERTAINTY. IN JULY 2010 AFTER LESS THAN THREE YEARS OF R&D WE LAUNCHED OUR SECOND IVD PRODUCT IN EUROPE: THE Epi *proLung* BL REFLEX ASSAY, AN AID IN DIAGNOSIS FOR PATIENTS SUSPECTED TO HAVE LUNG CANCER.

## A SENSITIVE INDICATOR FOR LUNG CANCER

**THE CONFIRMATION** of malignant disease in patients suspected to have lung cancer, e.g. based on symptoms and findings in a diagnostic imaging procedure like X-Ray or CT, is not as straight forward as it may seem. In many of these cases it is not possible for clinicians and pathologists to confirm the diagnosis based on the microscopic analysis of material taken at the time of first bronchoscopy. In these cases, additional invasive diagnostic procedures may be required to confirm the presence of lung cancer. This bears additional risks to the patient and can delay the definitive diagnosis and consequently the start of therapy.

We have developed the Epi *proLung* BL Reflex Assay to address this specific unmet need in the diagnosis of lung cancer: the difficulty of diagnosing a malignant lung disease in patients with inconclusive cytology results. The Epi *proLung* BL Reflex Assay measures methylated DNA of the SHOX2 gene in the patient's bronchial fluid obtained during routine bronchoscopy for cytology. This "SHOX2 biomarker is a very sensitive and reliable indicator for the presence of lung cancer when detected in bronchial lavage fluid. The Epi *proLung* BL Reflex Assay can thereby help provide clarity to doctors and patients faster and without further invasive interventions.

The performance of the Epi *proLung* BL Reflex Assay has been established in a performance evaluation study with samples from 75 lung cancer patients and 79 patients with other lung diseases (e.g. infections, sarcoidosis, scleroderma, COPD). The assay identified 81% of the cancer cases while only 5% of the control subjects had false-positive results.





© Keystone

epi<sup>pro</sup>lung

## ADDRESSING AN ATTRACTIVE NICHE MARKET

**COMPARED TO Epi proColon,** Epi proLung is a test that addresses a small but attractive niche market. We market this product predominantly to highly specialized medical professionals such as pathologists and pulmonologists. Accordingly, our marketing approach for this product is very science driven. Since the launch of Epi proLung we have initiated studies with key opinion leaders in Germany, Switzerland, Hungary, and the UK to create further and independent evidence around the clinical utility of this test and have submitted several scientific papers on our own clinical studies with the <sup>m</sup>SHOX2 biomarker to medical journals for peer-review and publication. Similarly to Epi proColon we market and sell Epi proLung directly in the home markets of Germany, Austria, and Switzerland and through a growing network for distributors elsewhere in

Europe and beyond. So far, the <sup>m</sup>SHOX2 biomarker has not been licensed to any of our partners in the diagnostic industry but this may become an option going forward as the value of this new approach to lung cancer diagnosis is reflected in adoption of Epi proLung in the medical community.

Early proof-of-concept data indicates that <sup>m</sup>SHOX2 may also be a biomarker for lung cancer when detected in blood plasma, offering further opportunities to expand the utility of <sup>m</sup>SHOX2 testing to applications in risk stratification or augmentation of performance of diagnostic imaging procedures.

# OUR STOCK

THE YEAR 2010 HAS SEEN A STRONG REBOUND OF MAJOR GLOBAL FINANCIAL MARKETS. THE FINANCING WINDOW FOR LIFE SCIENCES COMPANIES OPENED UP AGAIN IN THE UNITED STATES AND IN EUROPE.

## SUCCESSFUL CAPITAL INCREASE

Epigenomics experienced a 42% decrease in its stock price year on year comparing the Xetra closing prices of 2010 and 2009. In our successful financing transaction in March/April 2010, we issued 14,697,361 new shares at a price of EUR 2.25 each raising about EUR 33.1 million in gross proceeds. Our stock closed at EUR 2.05 (Xetra) at year-end 2010, down slightly since the capital increase in April 2010. With volatility being significant, trading volumes in Epigenomics stock (Ticker symbol: ECX) decreased from almost 270,000 shares on average per day on Xetra in the first quarter of 2010 to just around 58,000 shares per day on Xetra in the fourth quarter of 2010. As of December 31, 2010, a total number of 44,092,085 shares were issued. The following major shareholder groups (see on page 39) controlled more than 3% each of Epigenomics' total shares outstanding.

## ANALYSTS MAINTAINED "BUY" RECOMMENDATIONS

Three analysts covered Epigenomics' stock during 2010 providing updates on their views and recommendations. Fairesearch's Dr. Martin Schnee (via Close Brothers Seydler Research AG, until June 30, 2010), equinet's Edouard Aubery, and independent analyst Thomas Schiessle (via Midas Group) all maintained "buy" recommendations and price targets significantly above year-end trading prices.

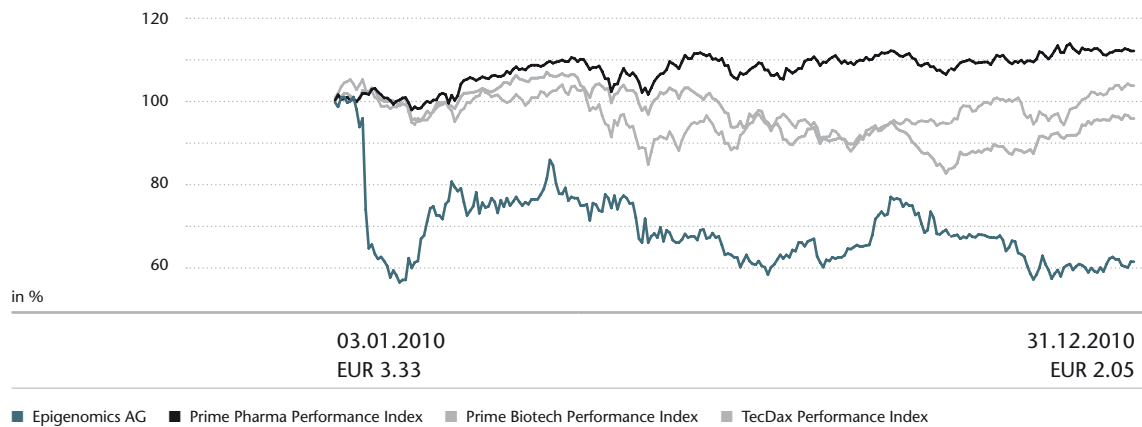
## GREAT INVESTOR INTEREST SINCE PRODUCT LAUNCHES

There has been great interest in Epigenomics from investors in Germany and abroad especially since the launch of our first two own products Epi *proColon* and Epi *proLung*. For this reason, we maintain an ongoing and active dialog with the investment community and are always available to answer questions about Epigenomics.

## TRANSPARENT DIALOG WITH SHAREHOLDERS

In 2010 as in the previous years, we continuously provided our shareholders with timely, accurate and comprehensive information giving them the best possible basis for making informed investment decisions in Epigenomics' stock. We invited to an annual press conference and an analyst meeting on April 19, 2010, in Frankfurt am Main, hosted our Annual General Shareholders' Meeting in Berlin on June 8, 2010, with a participation of approximately 53.5% of the share capital, and offered conference calls on important Company updates. Throughout the year, we also presented at several investor meetings and published updates on our clinical data at major scientific conferences in the United States and in Europe. Furthermore, we continued to provide opportunities for a close dialog with shareholders as well as interested investors at numerous road show meetings in Germany, Austria, the Benelux, in Switzerland as well as in the United Kingdom and the United States.

## EPIGENOMICS STOCK PERFORMANCE



Shareholder	Voting rights threshold
Abingworth LLP *	> 15%
Bellevue Funds (Lux) SICAV *	> 5%
Baker Brothers	
VCG Venture Capital Gesellschaft *	> 3%
Omega Fund II L.P. *	
Baden-Württembergische Versorgungsanstalt für Ärzte, Zahnärzte und Tierärzte *	
LBBW Asset Management Investmentgesellschaft *	

\* (total held, controlled or advised)

## Key data on Epigenomics' stock

ISIN	DE000A0BVT96
Security code number	A0BVT9
Stock exchange abbreviation	ECX
Reuters	ECXG.DE
Stock exchange	Frankfurt Stock Exchange Regulated Market (Prime Standard)
1 <sup>st</sup> day of trading	July 19, 2004
Designated Sponsor	ICF Kursmakler AG Wertpapierhandelsbank equinet AG (since July 1, 2010) Close Brothers Seydler AG Wertpapierhandelsbank (until June 30, 2010)
Number of shares (Dec 30, 2010)	44,092,085
Free float (Dec 30, 2010)	65.45%
Market capitalization (Dec 30, 2010)	EUR 90,388,774
Year-end closing price	EUR 2.05
Highest price	EUR 3.57
Lowest price	EUR 1.90

## CONTENTS CONSOLIDATED MANAGEMENT REPORT

Economic Environment .....	41
Business Activities, Strategy and Organization .....	42
Five-year Overview .....	48
Financials .....	49
Employees .....	51
Supplementary Report .....	51
Opportunities and Risks .....	52
Prognosis Report .....	56
Corporate Governance .....	58
Additional Mandatory Disclosures for Listed Companies Pursuant to Section 315 Paragraph 4 of the German Commercial Code (HGB) .....	67

# CONSOLIDATED MANAGEMENT REPORT

## ECONOMIC ENVIRONMENT

### GLOBAL ECONOMIC SITUATION

The year 2010 was characterized by a gradual recovery from the worst worldwide recession in many decades. Following the near-collapse of the housing markets, especially in the U.S.A., coupled with banking collapses in 2008/2009, the global economic environment started to recover in late 2009 and continued its growth in many regions in 2010. Global stock market indices showed strong recoveries in 2010, but labor markets, again especially in the U.S.A., have not yet benefited fully. The markets for debt, equities and currencies stabilized and improved throughout the year. Clearly, the decisive government actions taken by many countries around the world in 2009 showed positive effects in 2010.

These macroeconomic improvements were accompanied by another moderately volatile year with some higher fluctuations for the euro/U.S. dollar relation during Q2. The exchange rate between the euro and the U.S. dollar started at the beginning of 2010 with a rate of EUR/USD 1.41, hit a low of EUR/USD 1.19 in Q2, rose during Q3 and Q4 to EUR/USD 1.42, and finally closed below EUR/USD 1.34. Forecasts by leading analysts for 2011 show as usual significant spreads.

Economic outlooks of leading experts for 2011 trend towards cautious optimism of continued moderate growth rates for major economies. However, there are still warning signs out there and some experts do not rule out a second dip into recession either.

### IMPACT OF THE GLOBAL SITUATION ON THE LIFE SCIENCES INDUSTRY AND ON EPIGENOMICS IN YEAR 2010

Traditionally, the healthcare and life sciences industry has been viewed as a “defensive sector” with less dependency on strong ups and downs of the economic development and a demand for its goods and services little dependent of crises. Basically, this assumption should be valid for the future as well. However, some big players in the pharmaceutical industry have yet again announced cost saving programs and layoffs highlighting that nobody will be completely left untouched by this crisis. More importantly, there are going to be implications on healthcare in general and diagnostics in particular under the U.S. healthcare reform. Over time it is likely that the high profitability of healthcare businesses can not be maintained and pricing will come under increasing scrutiny and pressure in the globally largest single healthcare market. It is still unclear what structural implications this may have for the diagnostics industry. The latter should also be able to benefit from an increased focus on prevention and early detection of disease in several important markets. Colorectal cancer (CRC) screening continues to be high on many healthcare systems’ agendas as an area of attention and future growth.

As Epigenomics is not solely dependent on general consumer demand – apart from the willingness of self-payers to bear the cost of the CRC screening test until broad reimbursement kicks in – and our customers to date are primarily clinical laboratories as well as diagnostics and pharmaceutical corporations, we expect the danger of our own business getting hit hard by these macroeconomic and political developments to be small.

The molecular diagnostics segment of the life sciences industry continues to be one of the most attractive and sought-after investment opportunities. Growth rates in molecular diagnostics are substantially higher than in the diagnostics industry overall. The application area oncology 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 blood test, that market opportunity alone is in excess of USD 3.7 billion p.a. to the diagnostics industry. With about 320 thousand new cases of CRC p.a. in the EU and about 143 thousand new CRC cases in the U.S. every year and still more than 60% of all CRC being detected at symptomatic stages when survival rates are much lower than in early stages, the overall market potential for a test like *Epi proColon* is unchanged.

We are fully aware of the economic and political challenges we face and are preparing ourselves as far as possible for the years to come. In the chapters "Opportunities and Risks" and "Prognosis Report" of this management report, reference is made to the individual implications that the global situation could have on our business and our Group if applicable. Nonetheless, despite all the difficult times and crises, in April 2010, we have been able to find leading investors willing to further invest in our Company and its future development.

## 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 mission continues to be building a world-leading cancer molecular diagnostics company based on DNA methylation. All our research and development (R&D) activities as well as our commercialization efforts are geared towards fulfilling this mission. With our own products *Epi proColon* Early Detection Assay (*Epi proColon*) and *Epi proLung* BL Reflex Assay (*Epi proLung*) launched as well as with products now commercially available by our partners Abbott Molecular Diagnostics, Inc. ("Abbott"), Quest Diagnostics, Inc. ("Quest"), ARUP Laboratories, Inc. ("ARUP") and Warnex, Inc. ("Warnex"), we have taken major steps in fulfilling the mission during 2010.

Following a dual-business model, we develop and commercialize cancer diagnostic tests in colorectal cancer, in lung cancer and in the future in prostate cancer indications; both via direct marketing and sales efforts and through non-exclusive licensing partnerships. All our cancer molecular diagnostic tests target substantial market opportunities and address significant unmet medical needs with a view to providing patients and physicians with benefits from more convenient and superior diagnostic tests.

### CORPORATE GOALS, STRATEGY AND MANAGEMENT

We take a very focused and goal-oriented approach to managing and monitoring progress of strategy execution. Every year, the Supervisory Board and the Executive Board of the Company define milestones and deliverables in terms of revenue, operating results, partnering and deal-making targets as well as in product development and clinical studies. During 2010, we have updated our five-year corporate business plan and confirmed our dual-business strategy of non-exclusive partnering and licensing rights to our biomarkers for high-volume cancer screening tests as well as developing and commercializing in vitro diagnostic (IVD) kits for these biomarkers. We are addressing certain market segments through own product development as well as through direct marketing and sales efforts.

In the first quarter of 2010, there was an essential corporate goal of securing additional funding for our operations for the years to come. This was successfully achieved in early April with the completion of our capital increase raising gross proceeds of EUR 33.1 million.

For 2010, the most important corporate goals beyond financing were to progress development as well as commercialization of our key value driver and lead product, a blood-based test for colorectal cancer detection. There were several distinct goals and elements to that strategy in 2010 and we have successfully met most of them. Our U.S. licensing partner ARUP has released a blood-based colorectal cancer test based on our *m*SEPT9 biomarker and technology licenses. Furthermore, we have extended and expanded our collaboration with Japanese Sysmex Corporation ("Sysmex") and added Canadian Warnex, Inc. to the list of our commercial partners. We have evolved Epigenomics into an IVD company with an ISO-certified quality management system covering requirements for IVD development, manufacturing and commercialization for both our sites, including individual requirements for the Canadian market.

Our development team once again demonstrated its ability to develop, manufacture and launch CE-marked IVD kits with the launch of our lung cancer test based on the *m*SHOX2 biomarker. Under the brand name of Epi *pro*Lung BL Reflex Assay, this test is now available to clinicians in Europe.

Another strategic corporate goal was the successful completion of our prospective, multi-center PRESEPT clinical study in the U.S.A. and in Germany. We achieved this goal in Q1 of 2010 and presented the data from this clinical study at Digestive Disease Week (DDW) in May 2010. Recent clinical case control studies published at major conferences by ARUP and by ourselves demonstrated the performance improvements made to the Septin9 assay. Sensitivity/specificity combinations of 91%/87%, 90%/89% and 86%/93% respectively, highlight the unique clinical and biological potential of the *m*SEPT9 biomarker.

Finally we also provide high-value-added biomarker research services and solutions to customers in the pharmaceutical and life sciences industry.

We continued to follow our strategy while focusing on key value drivers, maintaining lean and efficient operations. We manage our resources such that cash reach target for the next several years can be ensured.

## OVERVIEW OF OUR BUSINESS

In 2010, we have continued to evolve Epigenomics as a commercially oriented and product-driven company. To achieve this objective, we continue to pursue a dual strategy. On the one hand, we are focusing on driving market acceptance and sales numbers of our blood-based Septin9 test Epi *pro*Colon for colorectal cancer early detection and of our second-launched CE-marked IVD product Epi *pro*Lung. On the other hand, we rely on our partners' efforts to successfully commercialize their colorectal cancer blood tests detecting the *m*SEPT9 biomarker.

Within only six months of its launch, our blood-based Septin9 test Epi *pro*Colon for the early detection of colorectal cancer was available nationwide in Germany and Switzerland. Furthermore, in the fourth quarter of 2010, we increased the availability of Epi *pro*Colon by expanding the commercial reach for this product beyond our home markets (Germany, Austria, Switzerland). We signed an exclusive distribution agreement with Pronto Diagnostics Ltd., Tel Aviv, Israel, for commercialization of our test in Israel, an exclusive distribution agreement with Dateks Company Ltd., Ankara, Turkey, for commercialization of our test in Turkey and an exclusive distributor agreement with DPC Lebanon S.A.R.L., Beirut, Lebanon, for the commercialization of our test in the Middle East (Lebanon, United Arab Emirates, Saudi Arabia, Qatar, Kuwait, Syria, Jordan, and Egypt).

As a result of our active approach to partnering, our Septin9 test is now commercially available in North America, in Europe, in the Middle East and in the Asia/Pacific region in different formats on multiple platform devices such as the Abbott *m*2000, the Roche LightCycler® 480 and AB 7500 Fast real-time PCR System platforms.



In January 2010, Quest introduced its blood-based laboratory-developed test (LDT) for aiding the detection of colorectal cancer in the U.S.A. The test was independently developed by Quest based on our proprietary DNA methylation biomarker *m*SEPT9.

In July 2010, our licensee ARUP Laboratories Inc., Salt Lake City, UT, U.S.A., launched an LDT for the blood-based detection of colorectal cancer. The test is also based on the *m*SEPT9 biomarker and on our DNA methylation technologies non-exclusively licensed to ARUP in August 2009. According to ARUP, their developed and validated Septin9 test identifies nine out of ten people with previously undetected colorectal cancer, including those with early-stage disease.

In May 2010, we licensed the rights to establish and commercialize an LDT for Septin9 in Canada to the Canadian life sciences company Warnex, Inc., Laval, QC. A molecular diagnostic Septin9 testing service based on this LDT was launched by Warnex on December 6, 2010. Prior to the launch, Warnex's Septin9 test was independently developed and successfully validated using blood samples from colorectal cancer patients and individuals with no apparent disease as verified by colonoscopy.

Earlier in the third quarter of 2010, we launched our second CE-marked IVD product *Epi proLung* in Europe. This novel molecular diagnostic test can help pathologists and clinicians to establish the presence of malignancy with more certainty in patients with suspected lung cancer when conventional diagnostic procedures fail or deliver inconclusive results. The clinical utility of this novel test was demonstrated in a performance evaluation study, the final step of an IVD product development. The clinical study confirmed previous research studies, showing that methylated SHOX2 DNA as measured with the *Epi proLung* test is a sensitive (81%) and highly specific (95%) biomarker for the detection of lung cancer in bronchial lavage specimen.

During 2010, we have further executed on our non-exclusive partnering and commercialization strategy by providing a commercial LDT license to Predictive Biosciences, Inc., Lexington, MA, U.S.A. ("Predictive") for the prostate cancer biomarker GSTP1. Under the terms of the original agreement, Predictive had obtained rights to develop a prostate cancer test incorporating this well-known DNA methylation biomarker and an option to license GSTP1 for commercialization of this test as a laboratory service in the United States. Based on strong continued progress in developing the test, Predictive exercised this option, triggering a one-time license fee to us. We will also be entitled to royalties on future sales generated with Predictive's prostate cancer test, which is still in development.

Throughout 2010, we have further advanced and optimized our IP portfolio. In March 2010, we announced that our Company received a "Notice of Allowance" notification by the Japanese Patent Office stating that they intend to grant a patent for our HeavyMethyl™ technology. This notification is equivalent to a "Rule 71(3) notification" by the European Patent Office. The patent is already granted in the U.S.A., in Europe, China, Russia, Australia, South Korea, and New Zealand.

In April, 2010, we announced that our Company received a "Notice of Allowance" notification stating that the U.S. Patent and Trademark Office intends to grant a patent for our *m*SEPT9 DNA methylation biomarker. Already in 2008, we had received the grant of the corresponding patent in Europe. The application for which we received the Notice of Allowance covers "a method for the detection or classification of colorectal cancer by means of the DNA methylation status of the SEPT9 gene".

In November 2010, we initiated an observational clinical study for the *Epi proColon* test to examine adoption patterns in the marketplace. The objective is to enroll up to 3,000 patients into this observational study with the help of nearly 300 primary care physicians.

Our R&D activities focused during the first quarter of 2010 on the completion and evaluation of the PRESEPT colorectal cancer screening study with the successful enrollment of a total of 7,941 screening-eligible average-risk subjects until the end of 2009, including 53 cases of previously undetected colorectal cancer. After the enrollment one of the several blood samples collected from each study subject was used in an academic medicine study to verify the performance of the *m*SEPT9 biomarker in the PRESEPT cohort when compared against the results of colonoscopy performed on all study subjects.

The independent Clinical Study Steering Committee, responsible for the supervision of the PRESEPT Study and the publication of the study results, presented the final data from the PRESEPT Study at Digestive Disease Week (DDW), the major clinical conference in the gastrointestinal field, in May of 2010. Results showed 66.7% sensitivity for CRC at 88.4% specificity when looking at the commercially relevant three replicate testing for Septin9. With this performance, the PRESEPT Study had met its objective of detecting the majority of prevalent and incident cancers in a screening cohort, a requirement for the non-invasive screening tests set forth in current joint guidelines by the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology<sup>1</sup>. With a specificity of 88.4%, the Septin9 testing result meets the targeted specificity range of 85% to 90%, which – based on an initial health economic analysis – should support public and private payer coverage and reimbursement. The final data of the PRESEPT Study should be published in a top-tier journal in second half-year of 2011.

As of December 31, 2010, our financial position including marketable securities showed a total liquidity amounting to EUR 26.4 million, an increase by EUR 20.2 million compared to the year-end 2009. This raise is largely a result of net cash inflows of EUR 30.3 million from the successful capital increase in April 2010.

Our revenue decreased by 58% from EUR 4.3 million for fiscal 2009 to EUR 1.8 million for 2010. This decrease is mainly accounted for by the inclusion in the previous year's comparables of a significant portion of revenue from a one-off milestone payment under the Abbott collaboration agreement. Simultaneously, our cash consumption (i.e. cash used in operating and investing activities excluding transactions in securities) has decreased significantly year on year as certain larger one-time cash inflows occurred in early 2010, which had already been recognized as revenue in 2009.

#### MARKETING, SALES AND BUSINESS DEVELOPMENT

During 2010, we further strengthened our marketing and sales team. At the end of 2010, this team in Europe comprised nine full time and one part-time staff plus one agent in France. The team has successfully trained more than 20 laboratories on the Epi *pro*Colon test in Germany, Switzerland, and Austria, with training initiated in some laboratories in France. Further, first distributors for other countries were trained in the second half of 2010.

In addition, our marketing team has supported our licensing partners Abbott, Quest, ARUP, and Warnex in their marketing activities to ensure a coherent positioning and branding of their respective blood-based colorectal cancer testing based on the *m*SEPT9 biomarker.

Our marketing campaigns have generated significant interest and media coverage with a clear focus on our home market Germany, Switzerland, and Austria but also in France, the U.K., in Benelux, and in the United States. In the course of the year 2010, we presented our Epi *pro*Colon product, clinical data on the *m*SEPT9 biomarker and product development progress as well as latest research at the following leading conferences:

<sup>1</sup> Levin B, et al., *Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: a joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. Gastroenterology* 2008; 134(5): 1570-95.

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12. Central-European Lung Cancer Conference December 2–4, 2010, in Budapest, Hungary

Days of Colo-Proctology, November 26–27, 2010, in Paris, France

Nord GASTRO, November 26–27, 2010, in Celle, Germany

AIO Herbsttagung, November 18–20, 2010, in Berlin, Germany

FEMMES & CANCERS 2010, November 17–19, 2010, in Biarritz, France

Gastro Update Hall 2010, November 12–13, 2010, in Hall (Tirol), Austria

Bayrischer Internistenkongress, November 6–7, 2010, in Munich, Germany

Bavaria GASTRO, October 28–30, 2010, in Würzburg, Germany

UEWG 2010 Congress, October 23–27, 2010, in Barcelona, Spain

DGGG Gyn Kongress, October 5–8, 2010, in Munich, Germany

DGKL, September 29–October 2, 2010, in Mannheim, Germany

DGVS Conference 2010, September 15–18, 2010, in Stuttgart, Germany

ISOBM 2010, September 3–8, 2010, in Munich, Germany

International Symposium on Molecular Diagnostics, June 3–5, 2010, in Graz, Austria

Society of Pathology Conference, May 27–30, 2010, in Berlin, Germany

94<sup>th</sup> Annual Conference of the German Pathology Society e.V., May 27–30, 2010, in Berlin, Germany

Digestive Disease Week, May 1–5, 2010, in New Orleans, LA, U.S.A.

German Society of Internal Medicine Congress (DGIM), April 9–14, 2010, in Wiesbaden, Germany

5<sup>th</sup> European Multidisciplinary Colorectal Cancer Congress, March 28–30, 2010, in Nice, France

DKG – 29. German Cancer Congress, February 24–27, 2010, in Berlin, Germany

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We have also intensified our dialog with leading patient advocacy groups such as the foundations Felix-Burda-Stiftung and LebensBlicke e. V. in Germany and the Colorectal Cancer Coalition (C3) in the United States.

Our business development efforts were primarily geared towards closing new licensing deals such as the Warnex deal in Canada, and to then managing the ongoing collaborations such as the Abbott, Quest, ARUP, Sysmex, Predictive, and QIAGEN partnerships. We continue to identify potential new partners in our non-exclusive partnering model for Septin9-based colorectal cancer test development and commercialization.

As of the end of 2010, we were engaged in several ongoing negotiations with regard to signing up licensees and partners for the development and commercialization of diagnostic products. It is our goal to commercialize Septin9 testing as Epigenomics directly as well as together with up to three non-exclusive IVD partners (including Abbott) in the medium term.

## RESEARCH AND DEVELOPMENT (R&D)

### *Colorectal Cancer (Septin9)*

During 2010, our R&D focus remained on the most advanced product development program: our Septin9 test. The following achievements in that program formed the cornerstones of our 2010 R&D efforts:

- Completed PRESEPT clinical study meeting its primary endpoints.
- Established contract manufacturing agreement with NextPharma Technologies, Inc., San Diego, CA, U.S.A., for the manufacturing of our Septin9 test kits.
- Secured platform access for a leading FDA-approved device for our own U.S. Epi *proColon* IVD test.
- Signed up DOCRO, Inc., Seymour, CT, U.S.A. on the regulatory side to support our FDA approval process for Epi *proColon*.
- Submitted briefing booklet to the FDA for Epi *proColon*.
- Improved clinical performance of Septin9 test.
- Trained multiple clinical labs in Germany, Austria, Switzerland and France on Septin9 testing.
- Developed several assays in research for possible development of next generations of CRC blood tests, e.g. in monitoring applications.
- Established third generation of our proprietary methylation biomarker discovery platform DMH.

### Lung Cancer

During 2010, we made excellent progress in the clinical development of our lung cancer program. We successfully validated and then launched a bronchial-lavage-based diagnostic test in Europe. We have also continued our research into possible blood-based applications and line extensions of the SHOX2 biomarker.

### Prostate Cancer

During 2010, our prostate cancer molecular diagnostic tests based on <sup>18</sup>F-PITX2 (a tissue-based prognostic test following radical prostatectomy) and <sup>18</sup>F-GSTP1 (a biopsy- or urine-based assay to help diagnosing prostate cancer) have taken a back seat in R&D to the colorectal and lung cancer programs.

We have successfully out-licensed our <sup>18</sup>F-GSTP1 biomarker and DNA methylation technologies non-exclusively for U.S. LDT rights to Quest and Predictive. We continue to look for commercial partners for our prostate cancer programs.

### 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 ISO 13485. ISO 13485 is an internationally recognized quality management standard developed for medical devices by the International Organization for Standardization (ISO), a world-wide federation of national standards bodies. ISO 13485 specifies 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 an ISO-13485-compliant quality management system demonstrates our commitment to develop safe and effective diagnostic products.

In 2010, we have successfully undergone surveillance audits for our ISO 13485 certification for our quality management system. We passed this audit at both our headquarters in Berlin and our subsidiary in Seattle for the design, development, manufacture, and distribution of IVD products. We have also successfully completed Canadian Medical Devices Conformity Assessment System (CMDCAS) certification audits in Berlin and Seattle fulfilling the quality systems requirements for Canada.

This demonstrates the continued commitment to and the use of a quality management system that conforms to the international quality management standards for medical devices including IVD products such as our tests for colorectal, lung, and prostate cancer. The certificate is granted for five years with annual surveillance audits by the certification body.

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

## FIVE-YEAR OVERVIEW

– according to the consolidated financial statements –

EUR thousand (unless stated otherwise)	2006	2007	2008	2009	2010
<b>Income statement</b>					
Revenue	3,504	2,567	2,586	4,260	1,787
Gross profit	-1,516	1,693	888	1,462	1,313
R&D costs	-8,702	-10,471	-10,028	-7,349	-7,222
EBIT <sup>2</sup>	-15,761	-13,504	-12,750	-10,218	-11,449
EBITDA <sup>3</sup>	-14,193	-12,259	-10,242	-9,442	-10,307
Net loss for the year	-15,402	-13,151	-12,271	-10,223	-11,476
Earnings per share basic and diluted (in EUR) <sup>4</sup>	-0.92	-0.74	-0.47	-0.35	-0.28
<b>Balance sheet</b>					
Non-current assets	10,559	9,070	5,857	5,716	5,463
Current assets	19,575	13,844	14,426	10,638	28,375
Total assets	30,134	22,914	20,283	16,354	33,838
Equity	26,198	17,821	16,568	12,084	31,295
Equity ratio (in %)	86.9	77.8	81.7	73.9	92.5
Non-current liabilities	0	0	38	9	0
Current liabilities	3,935	5,093	3,677	4,261	2,543
<b>Cash flow statement</b>					
Cash flow from operating activities	-14,378	-11,516	-9,800	-10,629	-9,479
Cash flow from investing activities	2,610	1,049	1,468	-195	-315
Cash flow from financing activities	807	4,547	11,500	4,964	30,394
Net cash flow (currency-adjusted)	-10,953	-5,920	3,168	-5,860	20,600
Cash and cash equivalents at year-end	12,566	6,646	9,814	3,954	24,554
<b>Other information</b>					
Investments in tangible and intangible assets	2,920	65	258	324	439
Number of employees at year-end	145	112	90	86	82
Share price at year-end (in EUR)	3.50	1.95	2.00	3.52	2.05

<sup>2</sup> EBIT = earnings before interest and taxes<sup>3</sup> EBITDA = earnings before interest, taxes, depreciation and amortization<sup>4</sup> 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).

## FINANCIALS

### RESULTS OF OPERATIONS

In 2010, we achieved total revenue of EUR 1.8 million, a decrease of 58% compared to EUR 4.3 million in 2009. Revenue was generated from product sales of our Epi *proColon* kits as well as from continued and newly signed collaborations and licensing agreements in the form of R&D payments, licensing fees and royalty income. The drop in revenue was mostly due to the revenue recognition of non-recurring milestones in 2009, recognition from non-recurring service projects completed in 2009, as well as one-time revenue from the execution of a licensing option in 2009 – all with no corresponding events in the reporting year. This shortfall has not been fully compensated by starting product sales yet. During 2010, our product sales and commercial R&D activities have contributed revenue of EUR 0.6 million, whereas revenue of EUR 1.2 million was generated from out-licensing activities.

Cost of sales decreased significantly from EUR 2.8 million to EUR 0.5 million due to the aforementioned decrease in revenue as well as due to the completion of sample collection within our collaboration with Abbott which had strongly affected this cost position in the previous year. Furthermore, the completion of work packages during the year within other partnerships has led to a drop of collaboration-driven expenses in 2010. Gross profit amounted to EUR 1.3 million, a decrease of 10% compared to EUR 1.5 million in 2009 but we could significantly improve our gross margin from around 34% in 2009 to almost 73% in 2010.

Other income increased to EUR 1.0 million in 2010 from EUR 0.5 million in 2009, as currency exchange rate gains and income from the reversal of provisions positively affected the total number. Furthermore, higher income related to third-party research grant – in particular one-time grant of EUR 188 thousand as a partial reimbursement and co-funding of the clinical trial PRESEPT under the Qualifying Therapeutic Discovery Projects (QTDP) program by the U.S. Internal Revenue Service – has led to higher other income in the year 2010.

In 2010, Research and Development costs ("R&D") decreased from EUR 7.3 million in 2009 to EUR 7.2 million in 2010. The vast majority of our R&D expenditures in 2010 were still focused on our CRC programs. The completion of the PRESEPT Study as well as the development of a U.S. product concept for our expected FDA approval trial, including manufacturing outsourcing, were significant parts of our R&D in 2010. Also the research on a CRC monitoring test and next-generation discovery capabilities contributed to 2010 R&D costs.

Selling, general and administrative costs increased significantly by 30% from EUR 4.5 million in 2009 to EUR 5.8 million in 2010 as a result of intensified marketing, sales and supporting activities for our Epi *proColon* test on the one hand as well as due to the test launch of our second IVD product Epi *proLung* and to some moderate pre-marketing activities in this connection on the other hand.

Other expenses increased from EUR 408 thousand in 2009 to EUR 773 thousand in 2010 mainly caused by lower currency exchange rate losses. Furthermore other expenses included unplanned amortization on intangible assets of EUR 537 thousand, which were necessary due to the determined impairment of in-licensed technologies.

In 2010, operating loss (EBIT) increased by 12% from EUR 10.2 million in 2009 to EUR 11.5 million as the reduction in partnering revenue could only partially be compensated by increasing product sales. Nevertheless, our overall operating costs decreased by 5% in 2010. This decrease was largely attributable to our further streamlined operations and commercially focused strategy execution. This optimization led to cost savings, e.g. in other services (-41%), IP legal costs (-28%), consumables (-20%), facilities (-18%), and licence fees (-10%). Additionally, costs for external R&D (-84%) and for samples (-82%) decreased due to the finalization of the PRESEPT Study and as a result of the completion of aforementioned non-recurring service projects within our biomarker solution activities. All of the cost reductions were partially countered by more than quadrupling of marketing costs (+460%) due to our above mentioned increasing of commercialization activities. Further increases could be observed in training and literature (+143%), other legal and consulting (+49%) as well as in support contracts and repairs costs (+19%).

In the reporting period, our net loss amounted to EUR 11.5 million at the end of 2010 and was therefore 12% higher than in the corresponding period 2009.

## FINANCIAL POSITION AND CASH FLOW

At the end of the reporting year, our cash and cash equivalents amounted to EUR 24.6 million. Total net cash flow in 2010 amounted to EUR 20.6 million compared to a negative net cash flow of EUR 5.9 million in 2009. It was strongly influenced by the successful capital increase completed in April 2010. However, the overall financial position was as well affected by the net cash consumption for operating activities.

Cash outflow from operating activities amounted to EUR 9.5 million and was lower than the cash outflow of 2009 (EUR 10.6 million), mainly due to the inflow of a milestone payment from Abbott in first quarter of 2010.

Our net cash flow from investing activities was negative at EUR 0.3 million in 2010 (2009: EUR -0.2 million). Cash outflow related to non-current assets was only partially compensated by a cash inflow from the redemption of a corporate bond previously held under marketable securities.

Net cash inflow from financing activities amounted to EUR 30.3 million attributable to the aforementioned capital increase in April 2010 and its gross proceeds of about EUR 33.1 million.

## NET ASSET POSITION

Our balance sheet total increased significantly from EUR 16.4 million at the end of 2009 to EUR 33.8 million at a year-end 2010 mainly due to the capital increase, which improved our balance sheet during the period and simultaneously overcompensated the ongoing net cash consumption by our operations.

Total non-current assets decreased slightly from EUR 5.7 million on December 31, 2009, to EUR 5.5 million at the end of the reporting year. As in previous periods, the capitalized goodwill of EUR 2.6 million was tested for impairment and could be successfully confirmed. The slight decrease of total non-current assets was mainly related to extraordinary amortization of two technology licenses which we terminated in 2010. This effect overcompensated the capitalization of development costs for our lung cancer test *Epi proLung*, which was launched in July 2010.

Current assets increased from EUR 10.6 million to EUR 28.4 million. This significant increase is largely a result of the aforementioned capital increase. Trade receivables decreased significantly from EUR 2.0 million as of December 31, 2009, to EUR 0.5 million at year-end 2010 among others due to a large milestone payment received in the first quarter of 2010. Other current assets fell from EUR 2.3 million to EUR 1.4 million mainly due to a shortfall of the accrued financing costs at year-end 2009 in connection with the capital increase in preparation at that time.

In 2010, our subscribed capital increased by 14,697,361 shares to a total of 44,092,085 shares at a nominal par value of EUR 1.00 each due to the aforementioned capital increase. Other comprehensive income improved over the reporting year to EUR -0.9 million as a result of a reduced portfolio of available-for-sale securities and simultaneously increased fair values of the remaining papers.

Current liabilities decreased to EUR 2.5 million at year-end 2010. Especially trade payables dropped by EUR 1.0 million compared to December 31, 2009, mainly as a result of the payments in connection with the aforementioned capital increase in the first quarter of 2010. Our deferred income decreased by EUR 0.5 million. Provisions decreased from EUR 0.6 million to EUR 0.3 million at the balance sheet date.



## EMPLOYEES

	Berlin	Seattle	Total
<b>Number of employees as at Dec 31, 2010</b>	69	13	82
Number of employees as at Dec 31, 2009	68	18	86
<b>Employees on average 2010</b>	67	16	83
Employees on average 2009	65	18	83

The Epigenomics Group employed a total staff of 82 as at December 31, 2010. From them, 51 were directly involved in R&D activities and 31 worked in commercial and general administration.

At the end of the reporting year, 42 out of 69 of our employees in Berlin worked in R&D and 27 in commercial and general administration. At our headquarters in Berlin, we have maintained a strong product development team focusing on our IVD kit development activities, a small manufacturing group as well as our corporate research, IP and quality functions. Also during 2010, we have added a Head of Medical Affairs, whose goal is to build a strong clinical team around him.

Furthermore, at the end of the reporting year, 9 out of 13 of our employees in our Epigenomics, Inc. subsidiary in Seattle worked in R&D and 4 in commercial and general administration. Following the successful completion of the PRESEPT Study, we have adjusted the size of our clinical study management team at Epigenomics, Inc. in Seattle and focused the organization on future tasks such as regulatory affairs in our progress towards obtaining future FDA approval, building U.S. commercial capabilities, maintaining a network of sites for clinical case control studies. To that end, we have continued our efforts in training and developing key personnel in-house and also selectively hiring additional expertise from outside into the organization.

The number of employees in Berlin also includes two apprentices.

Overall personnel costs totaled EUR 6.7 million in 2010, compared to the previous year's EUR 6.3 million, an increase of 6%.

## SUPPLEMENTARY REPORT

On January 11, 2011, we announced Dr. Thomas Taapken as our new Chief Financial Officer (CFO), succeeding our current CFO Oliver Schacht, Ph.D., effective April 1, 2011.

On January 13, 2011, we announced that we have concluded the feasibility phase in the development of an improved product concept for our DNA-methylation-based blood test Epi *proColon*. This improved product concept is being developed for the U.S. market and as a second-generation product for the European and other markets. Performance data showed a sensitivity of 91% at a specificity of 87% with excellent detection rates for early-stage cancers (78% stage I detection and 100% stage II detection). At the same time, we announced that the FDA has set a date in February 2011 for a pre-IDE meeting to discuss with Epigenomics the product concept, its intended use and the clinical data required to support an application for marketing of the product in the United States.

On February 28, 2011, we announced that we signed a collaboration agreement in Colorectal Cancer Blood Testing with QIAGEN N.V. ("QIAGEN"). Under the terms of the agreement, QIAGEN receives an option to a worldwide non-exclusive commercial license to our proprietary "SEPT9 biomarker and DNA methylation technologies for the detection of colorectal cancer in blood. The option can be exercised by QIAGEN within the next two years. Furthermore, we have granted QIAGEN a research license to the "SEPT9 biomarker and the technologies.

Under this license, QIAGEN is currently developing a novel sample preparation technology that meets the requirements for the future broad implementation of methylation-based molecular diagnostics, such as Septin9-targeted blood testing for the detection of colorectal cancer, on QIAGEN's modular molecular testing platform QIASymphony. We will support QIAGEN in the R&D phase through know-how transfer and the collection of clinical specimens as required.

Under the terms of the option agreement, we will receive an upfront payment from QIAGEN and will be reimbursed for any R&D support and clinical specimens provided during the R&D phase. Upon QIAGEN exercising the option we would receive a further license payment. Once QIAGEN commercializes a colorectal cancer blood test based on our biomarkers and technology, we would be entitled to royalties on QIAGEN's net sales as well as certain commercial milestones upon reaching specific revenue targets.

## 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 systems is to identify risks systematically at the earliest possible stage, estimate their likelihood of occurrence as well as potential qualitative and quantitative impact, and design and implement 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 auditors and the Audit and Corporate Governance Committee of the Supervisory Board throughout the year.

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

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

### BUSINESS-RELATED OPPORTUNITIES AND RISKS

After the launch of our first IVD product, the colorectal cancer screening test *Epi proColon* in October 2009, we launched our second IVD product *Epi proLung* in July 2010. Our ability to generate significant and growing revenue from our colorectal cancer screening test and our lung cancer diagnostic test will depend, among other things, on the successful marketing and commercialization of both tests. Such marketing and commercialization require predominantly the successful launch of the products in reference laboratories and their acceptance by the medical community and third-party payers in each country. Because of the critical importance of reimbursement of the tests by third parties and by gaining mass

acceptance, we have – together with our partners – to convince important private health organizations and guideline issuing bodies to include our tests in their cancer screening guidelines.

Furthermore, we will only be able to generate revenue in the United States if our colorectal cancer screening test is eventually approved by the U.S. Food and Drug Administration (“FDA”). In order to achieve that, we have initiated our own campaign for regulatory approval of the Epi *pro*Colon test in the U.S.A. To that end, we have retained the services of DOCRO, Inc., a leading regulatory affairs consulting group with a proven track record of successful client submissions for both 510k clearance and PMA approvals of molecular diagnostics and oncology products. In October 2010, in preparation of a possible pre-IDE meeting with the FDA on our Epi *pro*Colon product for the U.S. market, we have submitted a so-called Briefing Booklet to the FDA. In this booklet we have provided background information to the FDA by describing the product concept, its intended use and the clinical validation we are planning to do in order to support this intended use. We expect to use samples already collected during the PRESEPT Study for our pivotal trial in 2011.

As part of our dual-business model we are also dependent on our partners, in particular large diagnostic companies and reference laboratories, to develop, commercialize, sell and distribute our products and their own products based on our licensed markers/technologies, respectively.

Partnering and licensing is one way we already generate revenue in the form of royalty income. Upon the first launch of the Epi *pro*Colon in Europe and the Asia/Pacific region by our collaboration partner Abbott in 2009, product launches by our other partners followed during 2010. In January 2010, Quest introduced its LDT for aiding the detection of colorectal cancer in the United States. In July 2010, ARUP launched the second LDT for the blood-based detection of colorectal cancer in the U.S.A. Finally, in December 2010, Warnex launched in Canada a first molecular diagnostic blood testing service for colorectal cancer based on Septin9.

However, we also continue to be subject to certain partnering-related risks. Our partnerships are still in early commercial phases and need to develop their full commercial potential in the future. Also, we still intend to close additional non-exclusive licensing and partnering deals for Septin9 in order to fully leverage multiple platforms in all key markets around the world and address the broadest possible market potential. Although we are currently in discussion with additional potential partners, there can be no assurance that these negotiations will be successful and that we will obtain sufficiently favorable terms. If our existing partners do not market or do not market sufficiently our products or are not successful in marketing them, we may not find additional partners or the planned royalty income will not be achieved.

The colorectal cancer screening field has seen intensified competition over the past year. 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.

Building the extensive clinical network for our PRESEPT Study as well as a network of clinical sites for additional case-control studies has somewhat mitigated the risk of having timely and sufficient access to large numbers of high-quality patient samples. This clinical network in the U.S.A. and in Europe allows us to tap into vast resources and leverage the opportunities we have in our partnered programs with Abbott, Quest, ARUP, Warnex, Sysmex and potential future partners.

Failure to obtain regulatory approval, lack of market acceptance and penetration, insurance company resistance to reimburse our tests would all have material impact on our revenue, earnings and financial position as well as our ability to raise further capital and can lead to a total loss of value in our stock. Similar risks exist in all our partnered programs and might also make the entering into additional alliances harder.

## 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 2011 at the earliest.

Throughout 2010, Epigenomics continued to be party to an opposition proceeding concerning certain IP in the bisulfite area that Roche Diagnostics GmbH and F. Hoffmann-La Roche AG had filed. In 2010, Epigenomics and Roche have each filed an appeal against the ruling by the Opposition Division. Upon the request of the European Patent Office, we have commented on the new appeal reasons filed by Roche and Roche has commented the new appeal filed by us. Roche has made us an offer to assign all relevant IP rights to Epigenomics and the parties are in good faith discussions to resolve the matter amicably.

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.

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

## OPPORTUNITIES AND RISKS RELATED TO THE REGULATORY ENVIRONMENT

The regulatory environment in cancer molecular diagnostics has become more challenging especially with regard to LDTs/homebrew assays. This could impact the timing and cost as well as our ability to meet such regulatory standards. In parts, the regulatory frameworks are not fully established or clarified as evidenced by a number of warning letters sent by the FDA to a number of diagnostics companies and large reference laboratories. This in turn could negatively impact on revenue generation and put a burden on our cost base and earnings, financial position and ability to compete effectively. To mitigate this risk, we have established a corporate function dealing with quality systems as well as regulatory affairs. We seek advice from experienced advisors to prepare the organization for any potential issues. For example, for the preparation of FDA approval we have retained the services of DOCRO, Inc., one of the leading regulatory affairs consulting groups in the United States with a successful track record of guiding companies through the FDA approval process for cancer molecular diagnostic products. Strict management of our interactions with reference laboratories as well as seeking an early dialog with the FDA as evidenced by submitting a Briefing Booklet are an integral part of our risk management policies.

## FINANCIAL OPPORTUNITIES AND RISKS

As of December 31, 2010, our available liquidity (cash, cash equivalents, and marketable securities) amounted to EUR 26.4 million. To ensure availability of sufficient liquidity for our medium- and longer-term operations, it was necessary to significantly strengthen our financial position at the beginning of the reporting year. With the successful completion of the capital increase in April 2010, the short- to medium-term financial risks the Company is facing have been significantly reduced. However, our operating activities are still loss making and therefore consuming cash.

As we are located in Germany as well as in the United States and as we are operating on a global basis means 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 price 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 must be mentioned that foreign currency-related transactions always offer opportunities as well.

Our portfolio of securities faces price risks in the form of interest rate, issuer and market related impairment risks. All past investments in marketable securities still contained in our portfolio have been made under the Company's investment policy, which was and is approved by the Supervisory Board. This policy stipulates to open only positions with an "investment grade" rating. However, to minimize those risks we have not made any new investments in securities for more than five years. In close cooperation with our banks, advisors and the Supervisory Board, we continuously aim at finding an appropriate balance between exposure to these opportunities and risks. This has been a continuing area of focus in 2010 due to the aftermath of the global financial crisis. The financial crisis has made it harder to liquidate any security at short notice no matter how good the rating of the issuer is. Wherever possible, we have sold or redeemed these securities and as part of our risk mitigation strategy have exclusively been investing in money market instruments on euro or U.S. dollar basis to maximize availability of the liquidity by simultaneously accepting the rather poor returns that could be earned in global money markets at the still historically low interest rates.

In 2011 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. This has been further strengthened in 2010 by the addition of Abingworth LLP as the Company's single-largest institutional shareholder after the capital increase in the first quarter of 2010 and the position built by Baker Brothers Investments.

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

With the inflow of EUR 33.1 million from the capital increase in year 2010, the successful PRESEPT Study meeting its primary endpoints, two products commercially available as CE-marked IVD tests by Epigenomics in Europe, multiple Septin9 blood tests available globally via our partners Abbott, Quest, ARUP, and Warnex as well as with the signature of several distributor agreements, we have substantially de-risked the Epigenomics investment case during 2010. With a lot of the financing and clinical development risks significantly reduced, our focus going forward will be on managing our commercial execution risks such as guideline inclusion and reimbursement in major markets, future product development and regulatory approval risks.

## PROGNOSIS REPORT

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

Over the next two years, we plan to further establish Epigenomics as a marketing and sales operation as well as to increase the public perception of Epigenomics as a commercially-driven cancer molecular diagnostics company. The key strategic focus will be on further driving market acceptance and sales of our Epi *proColon* and Epi *proLung* tests as well as on all our partners' Septin9-based CRC tests. To that end, our operational execution in 2011 will focus heavily on finalizing the FDA approval trial for Epi *proColon* and delivering positive final clinical results from that trial. Also, we will be working with our partner Abbott to assist them in completing their clinical trial required to file with the FDA for approval of an IVD kit for the U.S. market. We will strive to broaden the number of laboratories in Europe and the United States as well as in other countries where Septin9 testing is offered. A major focus for commercial execution will be on driving sales of Epi *proColon* in Germany, Austria, and Switzerland while also expanding the geographic coverage via agents and distributors to simultaneously start selling in other major European and significant Near and Middle East markets.

One important cornerstone to the successful implementation of our corporate strategy for broad market penetration will be to close additional non-exclusive licensing deals for Septin9-based CRC screening in 2011 and beyond. This will be a cornerstone of our business development efforts going forward whilst, simultaneously, we will take great care to optimize the value of Septin9 through careful timing of such deals.

During the next 12 to 24 months, we expect to complete our own FDA approval trial for a blood-based CRC test and obtain regulatory approval by the FDA for the U.S. market. We also expect to further progress our product pipeline in CRC monitoring applications on the one hand and our lung cancer clinical studies on the other. The goal is to establish Epigenomics as a cancer molecular diagnostics player with proprietary products in the market via our own direct sales and marketing activities and through distributors.

According to our current plans, our R&D activities shall concentrate on the current product pipeline in colorectal, lung, and prostate 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 or even expand our clear leadership in DNA methylation technologies and provide selected partners access to our know-how, expertise and IP in this field via licenses and services.

### EXPECTED ECONOMIC CONDITIONS IN THE NEXT TWO YEARS

We expect overall economic conditions and the capital market environment to continue to be challenging albeit improving in 2011 and 2012. We foresee capital markets to be fundamentally intact and despite any possible set-backs, we believe that life sciences companies should be able to raise equity capital based on solid fundamental performance in 2011 and 2012. With unemployment rates at historically very high levels in the U.S.A. and also in Europe (excluding Germany), we believe that hiring for open positions and filling positions with top candidates will be feasible within our expected compensation ranges. However, as companies on the customer and partner side contract and cut budgets and R&D spending, it may become harder to close business deals that are front-loaded and provide us with cash inflows in advance needed according to our mid-term business plans.

With currency movements remaining volatile between the U.S. dollar and the euro in the past 12 months and prognoses over the next 12 months anywhere from EUR/USD 1.20 to EUR/USD 1.50, we have decided to lock-in our budget rate for 2011 at EUR/USD 1.3770.

### OUTLOOK ON EARNINGS SITUATION

If we can close additional Septin9 licensing agreements in 2011 and 2012, we are expecting revenue from our partnering activities in diagnostics at similar or marginally higher levels for the next two years compared to 2010. Key drivers of revenue growth should be our Epi *proColon* IVD kit sales in Europe as well as the growing royalty income from our current partners' sales of Septin9-based tests worldwide (Abbott, Quest, ARUP, Warnex) as well as potential future licensing partners. We expect EBIT and net loss for 2011 to be at similar levels to 2010, despite the expected increase in revenue since we will need to spend significant amounts for marketing and sales activities, for driving guideline inclusion into colorectal cancer screening guidelines of our tests and for reimbursement lobbying with health insurance and payor organizations to cover the costs of our tests. We will also need to sponsor the required clinical trials for our own planned FDA-approved version of Epi *proColon* and make investments in automation development for higher throughput in the application of our CRC test, as well as in R&D activities towards next-generation products. Cash consumption for the fiscal years 2011 and 2012 should be at a similar level compared to 2010, i.e. around EUR 10 to EUR 11 million p.a. and should start to decrease gradually in 2013 as revenue growth is expected to lead to a ramp-up in cash inflows. Based on our current five-year strategic business plan, we do not expect to reach breakeven before 2014.

### OUTLOOK ON FINANCIAL SITUATION

With EUR 26.4 million in liquid resources (cash, cash equivalents and marketable securities) at year-end 2010 and a projected cash consumption of around EUR 11 million each in 2011 and 2012, current financial resources will last for at least the next two years. We expect to aggressively evaluate all opportunities in our business development and deal-making efforts to sign cash flow generating deals. At the same time, we will also look to ensuring appropriate levels of authorized capital to be approved by upcoming shareholder meetings to ensure maximum flexibility on the financing side for our commercial execution strategy.

### OPPORTUNITIES OVER THE NEXT TWO YEARS

The next 24 months hold the opportunity to provide the commercial proof of concept for our DNA-methylation-based cancer diagnostics. The products developed by us and our partners for blood-based CRC testing have matured to a stage where they are ready for broad commercialization in the global markets. FDA approvals for both our own as well as Abbott's Septin9 tests offer the opportunity to address the largest and most attractive global IVD market: the United States.

Lung cancer raises many clinical questions implicating huge medical needs for better diagnostics based on molecular tests. Our <sup>18</sup>F-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 this dreadful disease.

There are clear opportunities in prostate cancer testing with PITX2 and GSTP1, which have potential in a prognostic setting in prostatectomy specimen as well as in biopsy samples – the latter by far the larger market opportunity – and over the long term potentially also in other cancers. These are further potential partnering and licensing opportunities.

For our shareholders there is the clear opportunity to see the increased enterprise value from catalytic events such as additional licensing partnerships, successful clinical trials for FDA approval of our Epi *proColon* and Abbott's Septin9 blood test but as well the publication of the PRESEPT Study results in a top-tier journal.



## OVERALL PROGNOSIS FOR THE EPIGENOMICS GROUP

On balance, there are many pivotal milestones (i.e. FDA approval, further partnering) to be reached over the next 24 months. The next two to three years should see the final stages of a transformation of Epigenomics into a commercially sound and sustainable molecular diagnostics company driven by growing top-line revenue and product sales for the medium and long term.

Taken together all of the measures noted above should put us in a financial position that allows the Company – based on an assumption of growing molecular diagnostic products business, increasing royalty streams and deal-making revenues, a lean organization and cost structure, and potentially some added financing measures – to reach breakeven in the medium term, however, not before 2014.

## CORPORATE GOVERNANCE

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

As in previous years, corporate governance was important for all of us at Epigenomics. We welcome the German Corporate Governance Code (the “Code”) and its most recent 2010 amendments. 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 new and amended version of the German Corporate Governance Code.

Epigenomics’ corporate governance principles in certain aspects go well beyond legal requirements and recommendations of the German Corporate Governance Code. For example, we have established binding internal guidelines on insider trading and made these part of all employment agreements. We have appointed our Manager Legal Affairs as Corporate Governance Compliance Officer to ensure adherence to the corporate governance principles. The Compliance Officer is required to submit regular compliance reports to the Executive Board, which are then passed on to the Supervisory Board.

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

### DECLARATION OF COMPLIANCE 2010 WITH THE GERMAN CORPORATE GOVERNANCE CODE PURSUANT TO SECTION 161 OF THE GERMAN STOCK CORPORATION ACT AKTG\*

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

Pursuant to Section 161 of the German Stock Corporation Act (Aktiengesetz – AktG), the Executive Board and the Supervisory Board of Epigenomics as a listed company have to explain each year, which recommendations of the German Corporate Governance Code were or were not complied with. This statement is made permanently accessible to the general public in German and English language on the Company’s website under [www.epigenomics.com/en/investor\\_relations/corporategovernance/](http://www.epigenomics.com/en/investor_relations/corporategovernance/).

\* not part of the audited consolidated management report

The Executive Board and the Supervisory Board of Epigenomics AG hereby declare that since the last declaration of compliance in December 2009, Epigenomics AG has complied with the recommendations of the German Government Commission on the German Corporate Governance Code in the version of June 18, 2009, and May 26, 2010, respectively, and will comply in the future with the recommendations of the German Government Commission on the German Corporate Governance Code in the version of May 26, 2010, in each case with the following exemptions, partly due to specific corporate particularities. The declaration for the period after the last declaration of compliance until July 1, 2010, is based on the German Corporate Governance Code (hereinafter also "DCGK") in the version of June 18, 2009 ("Code 2009"). For the Corporate Governance Code practice of Epigenomics AG since July 2, 2010, the declaration refers to the recommendations of the German Corporate Government Code in the version of May 26, 2010 ("Code 2010"), which was published in the electronic Federal Gazette ("Elektronischer Bundesanzeiger") on July 2, 2010.

### Section 2.3.2

The Company could not and cannot comply with the recommendation to send notification of the convening of the Annual General Shareholders' Meeting with the convention documents to all domestic and foreign financial services providers, shareholders, and associations of shareholders by electronic means if the approval requirements are fulfilled. Due to the existing free float of shares, a sufficiently secured identification and addressing of all shareholders cannot be assured. However, irrespective of the notification pursuant to Section 125 AktG, the Company transmits these documents upon request by electronic means for informational purposes.

### Section 3.8 Paragraph 2 and 3

The D&O (directors' & officers') liability insurance taken out by Epigenomics AG for its Executive Board and Supervisory Board members includes a deductible. However, we think a deductible is not a precondition for responsible management; responsible management rather is a self-evident duty of all Executive and Supervisory Board members.

- Therefore, an amount of a deductible of at least 10% of a damage at least up to the amount of one and a half times the fixed annual compensation of the Executive Board members pursuant to Section 3.8 Paragraph 2 of the Code 2009 was for us no matter of particular interest. Therefore, we did not comply with the recommenda-

tion in Section 3.8 Paragraph 2. Epigenomics AG does not intend to amend its current D&O insurance agreements for Executive Board members. An adjustment of the insurance agreements for Executive Board members will take place according to the current statutory regulation regarding the deductibles in consideration of the respective transitional provisions for the period after expiration of the particular existing service contract of the Executive Board members.

- For the same reason, we did not and do not comply with the recommendation in Section 3.8 Paragraph 3 regarding the agreement of a respective self-contribution amount in the D&O insurance policy for Supervisory Board members.

### Section 4.1.5

Regarding the occupation of the leadership positions in the Company, the Executive Board considers the company-specific situations as well as an appropriate diversity. We are convinced that flat requirements for the selection of suitable candidates constraints the Executive Board inadequately.

### Section 4.2.3 Paragraph 2 and 3

At the time of this declaration and also in the past, the service contracts of the Executive Board members of Epigenomics AG do not and did not stipulate a multi-year assessment basis for variable compensation components and take and took neither positive nor negative developments into account when determining variable compensation components. Therefore, the stock options granted to Executive Board members in the past were not related to demanding, relevant comparison parameters. With respect to the existing deviation from the Code for the reporting period, we considered and consider that referring to comparison parameters does not improve the responsibility and the motivation of the Executive Board members and that a possibility of limitation (cap) is not necessary due to the structure of the existing stock option programs. With regard to the period after the publication of the Code 2009 and of the Code 2010, the deviation is therein justified, that the existing service contracts of the Executive Board members have been already signed before the Code 2009 and before the Code 2010 respectively as well as the new statutory provisions came into effect and hence do not reflect the recommendations in Section 4.2.3 of the Code 2009 and of the Code 2010 and the new statutory provisions regarding the implementation of variable compensation components.

Therefore, Epigenomics AG has to implement the new statutory regulations for Executive Board members only in case of an amendment of the existing compensation components. In case of a future decision on the Executive Board compensation, the Supervisory Board will, as a matter of course, follow the new statutory regulations as well as the recommendations of the Code 2010 and will thereby decide upon a future compliance with the recommendations of the Code for variable compensation components.

#### *Section 4.2.3 Paragraph 4 and 5*

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

#### *Section 5.3.2 Sentence 2*

With respect to the composition of the Audit Committee, the Supervisory Board emphasizes an appropriate qualification of all members of the Audit Committee in order to implement and execute properly all duties and responsibilities, which were assigned to the Audit Committee by the Supervisory Board. Furthermore, the Supervisory Board emphasizes that at least one of the Committee members has specialist knowledge and experience in the application of accounting principles and internal control processes. In order to provide equal treatment for all members of the Committee, especially with regard to the number of additional tasks of the chairman of the Committee, the Supervisory Board introduced a rotation system regarding the chairmanship. Until December 31, 2008, the chairman of the Committee met the special requirements for a professional qualification. Due to the rotation system, the chairmanship changed on January 1, 2009. Since then, the chairman of the Committee was not and is not the person, who meets the special requirements for a professional qualification. Accordingly, the Supervisory Board did not and does not comply with the recommendation in Section 5.3.2 Sentence 2, that the chairman of the Audit Committee must have specialist knowledge and

experience in the application of accounting principles and internal control processes. This will be warranted by the rotation system starting as of January 1, 2011. At this time, there are no plans to an extraordinary recomposition of the Audit Committee.

#### *Section 5.3.3*

The Supervisory Board took and takes the view that the requirement to form a nomination committee composed exclusively of shareholder representatives which proposes suitable candidates to the Supervisory Board for recommendation to the Annual General Shareholders' Meeting is not necessary with regard to the size of the Company. This task has been addressed amongst others to the Company's Personnel and Compensation Committee.

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

In the past, the Supervisory Board and Executive Board has respected for the filing of its members the company-specific situation, potential conflicts of its interests as well as the international activities of the Company through an appropriate diversity.

Deviating from the revised recommendations in Section 5.1.2 Paragraph 2 as well as the rewritten recommendations in Section 5.4.1 Paragraph 2, we consider the commitment to institute special age limits for members of the Executive Board and Supervisory Board as an inadequate limitation of the voting rights of our shareholders.

In addition, we are convinced that flat requirements for the composition of the Executive Board as requested in Section 5.1.2 Paragraph 1 constrain the Supervisory Board inadequately for its selection of suitable members of the Executive Board. Same shall apply for the flat requirements of the composition of the Supervisory Board as requested in Section 5.4.1 Paragraph 2 and Paragraph 3. We are basically convinced that these requirements are an inadequate limitation of the single selection of suitable candidates for the Supervisory Board. Notwithstanding, such target influences the voting right from our shareholders inadequately.

Accordingly, we did not and will not comply with these recommendations of the DCGK.

**Section 5.4.3 Sentence 3**

We do not comply with the recommendation to communicate the nominee proposals for the Supervisory Board chairmanship to the shareholders. As pursuant to Section 10 Paragraph 4 of the Company's Articles of Association, the Supervisory Board itself elects among its members a chairperson. According to Section 2 Paragraph 1 Sentence 2 of the Rules of Procedure of the Supervisory Board, the election of the chairperson shall take place subsequent to the Annual General Shareholders' Meeting in which at least one new member of the Supervisory Board has been elected, in a meeting to be held without specific convocation. As a consequence, a previous announcement of the nominee proposals cannot be realized. Accordingly, Epigenomics AG did not and will not comply with the recommendation in Section 5.4.3 Sentence 3.

**Section 5.4.5 Sentence 2**

The Supervisory Board cannot comply with the recommendation in Section 5.4.5 Sentence 2 of the Code 2009, that one Supervisory Board member which is an executive board member of a publicly quoted company, should not hold more than three supervisory board mandates in publicly quoted non-group companies or in supervisory bodies of companies with similar requirements. The Supervisory Board considers an adequate 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 of the Code 2009 and of the Code 2010, as long as it is ensured, that all Supervisory Board members have sufficient time to pursue the duties of their mandates.

**Section 5.4.6 Paragraph 1 Sentence 3**

The Company adheres to the recommendation concerning compensation for Supervisory Board activities and committee activities for the Supervisory Board with the exception that there will be a separate compensation for the committee chairmanship only but not just for the mere membership in a committee. Since the committee activities are evenly distributed among the members of the Supervisory Board, a separate compensation appears not necessary regarding the bare membership in committees. Accordingly, we did not and will not comply with the recommendation in Section 5.4.6 Paragraph 1 Sentence 3.

**Section 5.4.6 Paragraph 2**

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

*Berlin, December 2010*

On behalf of the Supervisory Board:

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

On behalf of the Executive Board:

Geert Walther Nygaard  
(CEO)

Oliver Schacht, Ph.D.  
(CFO)

**DECLARATION OF GOVERNANCE**

According to Section 289a of the German Commercial Code (HGB), the Declaration of Governance was made permanently accessible to the general public in German and English language on Epigenomics AG's website under [www.epigenomics.com/en/investor\\_relations/corporategovernance/](http://www.epigenomics.com/en/investor_relations/corporategovernance/).

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

The internal control and risk management system (ICR) of Epigenomics has been set up by the Company's top management who also takes responsibility for it. The ICR is not defined as a comprehensive standardized system across the entire enterprise but rather scope of control and intensity are adjusted according to the respective risk. In addition, control options are used at all Company levels and supervision by the management is established. Epigenomics has developed an individual top-down approach for Company-wide controls and supervision including a proof of effectiveness. A flexible setup of the reporting system – supported by established tools and adjusted to the Company's needs – ensures transparency and targeted supervision by the internal control system. Financial and non-financial indicators are taken into account.

The supervision of the ICR takes place continuously by the Supervisory Board and the Executive Board. Apart from truth and fairness of the financial reporting it also includes the securing of efficiency and cost-effectiveness of the daily business as well as compliance with relevant regulations and internal guidelines. The supervision of the accounting procedures goes hand in hand with the supervision of the ICR.

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

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

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

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

The Company's controlling system is primarily based on miscellaneous planning, monitoring and reporting tools. Qualitative information derives from a self-developed project documentation database, and quantitative information is processed in both Group entities by Navision™, a widely used enterprise resource planning software. Our accounting and controlling departments provide all relevant controlling information to the Executive Board on a monthly basis. An ongoing education of the team members is ensured.

For internal control purposes, we set up an annual budget based on the current five-year strategic business plan of the Company and a corresponding set of goals. The budget is developed bottom-up from all cost centers and R&D projects. All budgets are extensively reviewed internally by the senior management team and the Executive Board, and a final approval of the annual budget by our Supervisory Board is mandatory.

Primary focus of our regular internal management reporting lies in comparing actual versus budgeted values for a comprehensive set of metrics. From these, we compile the external quarterly reports. Each quarterly report is accompanied by an internal forecast, which provides us with an updated estimate of expected full-year results and performance vis-à-vis target numbers and public guidance. Actual versus budget comparisons of financial performance indicators are also drawn on a regular basis within the framework of the internal reporting system and are reported monthly to the top management of the Company. The focus is on cost and liquidity control. Deviations versus budget or historical values are analyzed on a short-term basis and supplemented by a presentation of alternative options. The reporting is supplemented as needed with additional data requested by the Supervisory Board or the Executive Board as well as the controlling team.

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



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

According to Section 15a of the German Securities Trading Act (Wertpapierhandelsgesetz) and Section 6.6 Paragraph 1 of the German Corporate Governance Code, persons discharging managerial responsibilities within an issuer of financial instruments are required to disclose their personal transactions in shares of the issuer and financial instruments based on them, especially derivatives, to the issuer and to the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht – BaFin). The duty to

disclose applies to the members of the Executive Board and the Supervisory Board. Moreover, the duty of disclosure also applies to persons who have regular access to insider information about the Company and are empowered to make significant managerial decisions. The duty to disclosure also applies to persons and certain legal entities closely associated with a person discharging managerial duties at the Company. The duty to disclose does not apply if the purchase or sale transactions do not exceed EUR 5 thousand in a calendar year.

The following declared securities transactions took place during 2010.

Members of the Executive Board	Date	Type	Number of shares	Transaction value in EUR
Geert Walther Nygaard, CEO	Jan 21, 2010	Purchase	20,000	44,200
Geert Walther Nygaard, CEO	March 29, 2010	Purchase	10,002	22,505
Oliver Schacht, Ph.D., CFO	March 29, 2010	Purchase	10,000	22,500

## COMPENSATION REPORT OF THE EXECUTIVE BOARD AND THE SUPERVISORY BOARD

The Executive Board of Epigenomics AG consisted in the reporting period of the two members Geert Walther Nygaard (CEO) and Oliver Schacht, Ph.D. (CFO).

The Executive Board 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.

### Compensation of the Executive Board

The compensation of the members of the Company's Executive Board is composed of a fixed and a variable component. The variable amount is determined on the basis of a variety of criteria, including the achievement of individual performance goals and performance goals for the Company, which are set by the Supervisory Board on a yearly basis. Total compensation – which is reviewed by the Supervisory Board annually – is compared to national and international benchmarks. Compensation takes into account the economic and

financial situation of the Company as well as size and complexity of international operations and responsibilities. Apart from the fixed and the variable components, there is a third compensation component: a long-term performance-based compensation in the form of stock option grants.

In 2010, the aggregate compensation of the members of the Executive Board amounted to EUR 0.9 million. It consisted of EUR 0.6 million in fixed salary and the remainder of EUR 0.3 million in variable and other salary components.

In June 2009, the Supervisory Board had signed new contracts with CEO Geert Walther Nygaard (effective February 1, 2010) and with CFO Oliver Schacht, Ph.D. (effective January 1, 2010). The service agreement with Mr. Nygaard is for a term of five years (2010–2015) and the service agreement with Mr. Schacht for a term of three years (2010–2012). In December 2010, Mr. Schacht announced his resignation from the Executive Board effective at March 31, 2011. The planned departure of Mr. Schacht did not lead to any additional expenses or payments in 2010. For Mr. Schacht, the Company paid rent in monthly installments for his apartment in Berlin and reimbursed incidental apartment expenses – due to his simultaneous activity as CEO for Epigenomics, Inc. in Seattle.

\* not part of the audited consolidated management report

The service agreement with Mr. Nygaard contains post-contractual non-compete provisions for a period of two years after the respective service agreement has ended. During such period, Mr. Nygaard is entitled to 100% of his last basic salary as a non-competition payment.

Furthermore, in case of a change of control, Mr. Nygaard is entitled to terminate his respective new 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 expired.

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

in EUR

**2010 (2009)**

Members of the Executive Board in 2010	Fixed compensation	Variable compensation	Other compensation	Total compensation
<b>Geert Walther Nygaard</b>				
Chief Executive Officer	390,000	160,470 <sup>5</sup>	0	550,470
	(380,000)	(96,795)	(0)	(476,795)
<b>Oliver Schacht, Ph.D.</b>				
Chief Financial Officer	230,430	139,580 <sup>5</sup>	10,093	380,103
	(199,677)	(107,550)	(10,146)	(317,373)
<b>Total compensation</b>	<b>620,430</b>	<b>300,050</b>	<b>10,093</b>	<b>930,573</b>
	(579,677)	(204,345)	(10,146)	(794,168)

<sup>5</sup> The variable compensation numbers for the year 2010 comprise also a part of a bonus for the year 2009 and an additional payment, which was assigned in 2010 respectively.

In accordance with Section 6.6 Paragraph 2 of the German Corporate Governance Code, the ownership of shares in the Company or related financial instruments by the Executive Board and the Supervisory Board will be reported if these directly or indirectly exceed 1% of the shares issued by the Company.

As of December 31, 2010, Mr. Nygaard owned 50,000 shares of the Company (Dec 31, 2009: 19,998) and Mr. Schacht owned 127,050 shares of the Company (Dec 31, 2009: 117,050).



At the balance sheet date, the members of the Executive Board held 530,000 stock options of the Company.

In 2010, a total of 140,000 stock options were granted to and no stock options were exercised by the members of the Executive Board.

	as of Dec 31, 2010 (Dec 31, 2009)			in 2010 (2009)	
	Stock options held	Weighted average exercise price in EUR	Vested options	Weighted average exercise price in EUR	Exercised options
Members of the Executive Board					
<b>Geert Walther Nygaard</b>	285,000	3.87	191,666	4.36	0
	(215,000)	(4.13)	(120,000)	(4.50)	(0)
<b>Oliver Schacht, Ph.D.</b>	245,000	4.00	151,666	4.33	0
	(181,613)	(4.07)	(116,613)	(4.51)	(0)

### Compensation of the Supervisory Board

Epigenomics AG's Supervisory Board consists of six members with broad experience in the pharmaceutical, diagnostics or financial industries. Effective March 31, 2010, Mr. Heino von Prondzynski resigned from his Supervisory Board position at Epigenomics AG, due to taking over an additional mandate as chairman of the Supervisory Board of another company at the beginning of 2010. After his resignation, shareholders of Epigenomics AG elected Mr. Joseph Anderson, Ph.D., Partner at Abingworth LLP – a main investor in our Company – to become a member of the Supervisory Board of Epigenomics AG at our Annual General Shareholders' Meeting held on June 8, 2010.

Members of the Supervisory Board in 2010<sup>6</sup> were:

#### Prof. Dr. Dr. h.c. Rolf Krebs – Mainz (D) – Chairman

- Retired speaker of the Executive Board of Boehringer Ingelheim Pharma GmbH & Co. KG
- Other supervisory and advisory board mandates as of Dec 31, 2010: Air Liquide S.A., Ganymed Pharmaceuticals AG (Chairman), Merck KGaA (Chairman), Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, E. Merck oHG, Barmenia Versicherungen
- Mandates terminated in 2010: none

#### Prof. Dr. Dr. Uwe Bicker – Bensheim-Auerbach (D)

– Deputy Chairman

- Honorary professor at the University of Heidelberg
- Other supervisory and advisory board mandates as of Dec 31, 2010: Siemens Healthcare Diagnostics Holding GmbH (Chairman), Definiens AG, Future Capital AG, Sanofi Aventis S.A.
- Mandates terminated in 2010: none

#### Günter Frankenne – Berg/Neumarkt (D)

- Managing partner of STRATCON Strategy Consulting
- Other supervisory and advisory board mandates as of Dec 31, 2010: 4SC AG, Concentro AG (Chairman), KeyNeurotek AG (Chairman), November AG (Chairman), Verbena AG, Curadis GmbH, ViroLogik GmbH (Chairman), iMTM GmbH
- Mandates terminated in 2010: none

<sup>6</sup> The "other supervisory board mandates" indicate memberships in other supervisory boards or domestic and international control boards according to Section 125 Paragraph 1 Sentence 5 of the German Stock Corporation Act.

**Ann Clare Kessler, Ph.D. – Rancho Santa Fe, CA (U.S.A.)**

- Independent consultant
- Other supervisory and advisory board mandates as of Dec 31, 2010: MedGenesis Therapeutix, Inc., AltheaDx, Inc., Gen-Probe Inc., GenScript Inc.
- Mandates terminated in 2010: none

**Joseph Anderson, Ph.D. – Oxted, Surrey (U.K.)***(since June 8, 2010)*

- Partner of Abingworth LLP, London, U.K., fund investment manager and head of public equities at Abingworth
- Other supervisory and advisory board mandates as of Dec 31, 2010: Algeta ASA, Amarin Corporation plc, Abingworth BioEquities
- Mandates terminated in 2010: none

**Heino von Prondzynski – Einsiedeln (CH)***(until March 31, 2010)*

- Independent consultant
- Other supervisory and advisory board mandates as of Mar 31, 2010: Koninklijke Philips Electronics N.V. (Royal Philips Electronics), QIAGEN N.V., Hospira, Inc., Caridian BCT, HTL Strefa S.A., Nobel Biocare Holding AG
- Mandates terminated in 2010: none

**Prof. Dr. Günther Reiter – Pfullingen (D)**

- Professor at the ESB Business School, Reutlingen
- Other supervisory and advisory board mandates as of Dec 31, 2010: Deltoton GmbH
- Mandates terminated in 2010: none

The Supervisory Board of Epigenomics AG has established two committees: an Audit and Corporate Governance Committee as well as a Personnel and Compensation Committee (for further details please refer to our Declaration of Governance permanently accessible on Epigenomics' website under [www.epigenomics.com/en/investor\\_relations/corporategovernance/](http://www.epigenomics.com/en/investor_relations/corporategovernance/)).

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**Compensation of the members of the Supervisory Board in 2010:**

in EUR	Annual retainer compensation	Meeting fees	Compensation as committee chairman	Total compensation
Prof. Dr. Dr. h.c. Rolf Krebs	30,000	5,000	5,000	40,000
Prof. Dr. Dr. Uwe Bicker	20,000	10,000	0	30,000
Joseph Anderson, Ph.D. <i>(since June 8, 2010)</i>	5,833	8,000	0	13,833
Günter Frankenne	10,000	10,000	5,000	25,000
Ann Clare Kessler, Ph.D.	10,000	10,000	0	20,000
Heino von Prondzynski <i>(until March 31, 2010)</i>	2,500	2,000	0	4,500
Prof. Dr. Günther Reiter	10,000	10,000	0	20,000
<b>Total compensation 2010</b>	<b>88,333</b>	<b>55,000</b>	<b>10,000</b>	<b>153,333</b>
Total compensation 2009	90,000	62,000	10,000	162,000

In addition, the members of the Supervisory Board were reimbursed for expenses totaling EUR 27 thousand in 2010 (2009: EUR 21 thousand).

The compensation structure previously approved by the Annual General Shareholders' Meeting in 2005 has been left unchanged in 2010 and is based on an annual cash retainer, meeting-related fees plus additional payments for committee chairing work. The compensation did not comprise any performance-related elements or long-term incentive components.

During the reporting year, the members of the Supervisory Board held no stock options nor any other convertible instrument nor any other equity-linked compensation entitlement of the Company. As of December 31, 2010, the only Supervisory Board member that held any shares in Epigenomics AG is Mrs. Kessler, Ph.D., who owned 14,000 shares together with her husband.

#### 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 (HGB), the Company is required to report on certain structures governed by company law and other legal relationships, in order to provide a better overview of the Company and disclose any impediments to a takeover.

#### SHAREHOLDERS WITH DIRECT OR INDIRECT SHARE- HOLDINGS OF MORE THAN 10% OF THE VOTING RIGHTS

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

#### COMPOSITION OF SHARE CAPITAL

As of December 31, 2010, the share capital of Epigenomics AG comprises exclusively common shares with equal rights and a par value of EUR 1.00 each. During the reporting year, the number of shares increased from 29,394,724 to 44,092,085 shares. Under certain conditions, shareholders may not be entitled to vote according to Section 136 of the German Stock Corporation Act (Aktiengesetz – AktG). We are not aware of any contractual restrictions related to voting rights or the transfer of shares.

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

The appointment and withdrawal of members of the Executive Board is subject to the provisions of Sections 84 and 85 of the German Stock Corporation Act (AktG).

The Supervisory Board shall appoint members of the Executive Board for a maximum period of five years. It is permissible to appoint members to the Executive Board on more than one occasion or to extend their period of office, on each occasion for a maximum of five years.

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

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

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

The share capital is increased conditionally by up to EUR 139,625.00 divided into 139,625 of bearer shares of common share with a calculatory par value of EUR 1.00 each (Conditional Capital III). The conditional capital increase can only be carried out to the extent that option rights were issued on the basis of the share option program 01–05 of the Company, amended according to the resolution of the Annual General Shareholders' Meeting dated August 1, 2003, resolved at the Annual General Shareholders' Meeting on April 27, 2001, and the holders of these share options exercise their right to subscribe to shares of the Company and the Company does not transfer its own shares in fulfillment of these option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. The Supervisory Board is authorized to lay down the further details regarding the implementation of the conditional capital increase as far as the granting of options to members of the Executive Board is concerned. In other cases, the Executive Board is authorized to lay down the further details. The Supervisory Board is authorized to amend the wording of Section 5 Paragraphs 1, 2 and 5 of the Articles of Association in accordance with the volume of the capital increase from conditional capital.

The share capital is increased conditionally by up to EUR 617,426.00 divided into 617,426 of bearer shares of common share with a calculatory par value of EUR 1.00 each (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 share option program 03–07 of the Company, amended according to the resolution of the Annual General Shareholders' Meeting dated August 1, 2003, and the holders of these share options exercise their right to subscribe to shares of the Company and the Company does not transfer its own shares in fulfillment of these option rights. The new shares will participate in the profit from the beginning of the financial year in which they are issued. The Supervisory Board is authorized to lay down the further details regarding the implementation of the conditional capital increase as far as the granting of options to members of the Executive Board is concerned. In other cases, the Executive Board is authorized to lay down the further details. The Supervisory Board is authorized to amend the wording of Section 5 Paragraphs 1, 2 and 6 of the Articles of Association in accordance with the volume of the capital increase from conditional capital.

The share capital is conditionally increased by up to EUR 647,679.00, divided into up to 647,679 registered common shares with a par value of EUR 1.00 each (Conditional Capital V). The conditional capital increase can only be carried out to the extent that option rights are issued to the shareholders on the basis of the Company's share option program 06–10, which was resolved by the Annual General Shareholders' Meeting on July 10, 2006, and the holders of these share options avail themselves of their right to acquire shares in the Company and the Company does not grant any shares of its own to fulfil these option rights. The new shares will participate in the profit as of the beginning of the financial year in which they were issued. The Supervisory Board is empowered to establish the further details of the execution of the conditional capital increase as far as the granting of subscription rights to Executive Board members is concerned. In all other respects, the Executive Board is empowered to establish such details. The Supervisory Board is empowered to amend the version of Section 5 Paragraphs 1 and 8 of the Articles of Association to reflect the conditional capital increase.

The share capital is conditionally increased by up to EUR 1,521,234.00 divided into 1,521,234 bearer shares of common stock with a face value of EUR 1.00 per share (Conditional Capital VII). This conditional capital increase is only implemented to the extent that the option rights from the Company's share option program 09–13 that was resolved by the Annual General Shareholders' Meeting of May 11, 2009, are issued and the holders of these share options avail themselves of their right to subscribe to shares in the Company and the Company does not grant any shares of its own to fulfil these option rights. The new shares will participate in the profit from the beginning of the financial year in which they were issued. The Supervisory Board is authorized to determine the further details of the conditional capital increase where the granting of subscription rights to members of the Executive Board is concerned. In all other respects, the Executive Board is authorized to determine these details. The Supervisory Board is authorized to amend the wording of Section 5 Paragraphs 1 and 4 of the Articles of Association in accordance with the volume of the capital increase from conditional capital.

# CONSOLIDATED FINANCIAL STATEMENTS AND NOTES

– according to International Financial Reporting Standards (IFRSs) –

## CONTENTS

Group Income Statement .....	70
Group Balance Sheet .....	71
Group Cash Flow Statement .....	72
Statement of Changes in Group Equity .....	73
Notes to the Consolidated Financial Statements .....	74
<i>Basic Information, Principles and Methods</i> .....	74
<i>Notes to the Group Income Statement</i> .....	83
<i>Notes to the Group Balance Sheet</i> .....	89
<i>Notes to the Group Cash Flow Statement</i> .....	101
<i>Risks and Risk Management</i> .....	101
<i>Information on Stock Option Programs</i> .....	103
<i>Other Information</i> .....	106

## GROUP INCOME STATEMENT

FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31, 2010

EUR thousand	Notes	2009	2010
Revenue	1	4,260	1,787
Cost of sales		-2,798	-474
<b>Gross profit</b>	2	<b>1,462</b>	<b>1,313</b>
Other income	3	535	1,012
Research and development costs	4	-7,349	-7,222
Selling, general and administrative costs	4	-4,458	-5,779
Other expenses	6	-408	-773
<b>Earnings before interest and taxes (EBIT)</b>	7	<b>-10,218</b>	<b>-11,449</b>
Interest income	8	191	165
Interest expenses	8	-8	0
Other financial result	8	14	-152
<b>Net loss for the year before taxes on income</b>		<b>-10,021</b>	<b>-11,436</b>
Taxes on income	9	-202	-40
<b>Net loss for the year</b>		<b>-10,223</b>	<b>-11,476</b>
<b>Earnings per share (basic and diluted) in EUR</b>	10	<b>-0.35</b>	<b>-0.28</b>

## STATEMENT OF INCOME AND EXPENSES RECOGNIZED IN GROUP EQUITY

EUR thousand	Notes	2009	2010
<b>Net loss for the year</b>		<b>-10,223</b>	<b>-11,476</b>
Fair value adjustments of securities	22	408	139
<b>Total income and expenses recognized in Group equity</b>	22	<b>408</b>	<b>139</b>
<b>Total comprehensive income</b>		<b>-9,815</b>	<b>-11,337</b>

## GROUP BALANCE SHEET AS OF DECEMBER 31, 2010

<b>ASSETS</b> EUR thousand	Notes	<b>Dec 31, 2009</b>	<b>Dec 31, 2010</b>
<i>Non-current assets</i>			
Intangible assets	11, 13	4,753	4,498
<i>thereof: goodwill</i>	11, 13	2,625	2,625
Tangible assets	12, 13	572	544
Deferred taxes	14	391	421
<b>Total non-current assets</b>		<b>5,716</b>	<b>5,463</b>
<i>Current assets</i>			
Inventories	15	160	162
Trade receivables	16	1,993	476
Marketable securities	17	2,182	1,815
Cash and cash equivalents	18	3,954	24,554
Other current assets	19	2,349	1,368
<b>Total current assets</b>		<b>10,638</b>	<b>28,375</b>
<b>Total assets</b>		<b>16,354</b>	<b>33,838</b>

<b>EQUITY AND LIABILITIES</b> EUR thousand	Notes	<b>Dec 31, 2009</b>	<b>Dec 31, 2010</b>
<i>Equity</i>			
Subscribed capital	20	29,395	44,092
Capital reserve	21	6,227	22,078
Retained earnings		-12,271	-22,494
Net loss for the year		-10,223	-11,476
Other comprehensive income	22	-1,044	-905
<b>Total equity</b>		<b>12,084</b>	<b>31,295</b>
<i>Non-current liabilities</i>			
Liabilities from leasing contracts		9	0
<b>Total non-current liabilities</b>		<b>9</b>	<b>0</b>
<i>Current liabilities</i>			
Trade payables	24	2,091	1,134
Liabilities from leasing contracts		28	9
Deferred income	25	720	240
Other liabilities	26	851	890
Provisions	27	571	270
<b>Total current liabilities</b>		<b>4,261</b>	<b>2,543</b>
<b>Total equity and liabilities</b>		<b>16,354</b>	<b>33,838</b>



# GROUP CASH FLOW STATEMENT

FOR THE PERIOD FROM JANUARY 1 TO DECEMBER 31, 2010

EUR thousand	Notes	2009	2010
<b>Cash and cash equivalents at the beginning of the year</b>		<b>9,814</b>	<b>3,954</b>
<i>Operating activities</i>	29		
<b>Net loss for the year before taxes on income</b>		<b>-10,021</b>	<b>-11,436</b>
Corrections for:			
Depreciation on tangible assets		330	265
Amortization of intangible assets		446	877
Losses from the disposal of assets		0	6
Stock option expenses	5	175	290
Foreign currency exchange losses		12	-31
Interest income	8	-191	-165
Interest expenses	8	8	0
Taxes		-79	-81
Non-cash income		-106	0
<b>Operating result before changes in net current assets</b>		<b>-9,426</b>	<b>-10,275</b>
Changes in trade receivables and other current assets		-2,107	2,313
Changes in inventories		-35	-2
Changes in current liabilities		736	-1,701
<b>Liquidity earned from operating activities</b>		<b>-10,832</b>	<b>-9,665</b>
Interest received		211	186
Interest paid		-8	0
<b>Cash flow from operating activities</b>		<b>-10,629</b>	<b>-9,479</b>
<i>Investing activities</i>	30		
Payments for investments in tangible assets		-209	-205
Payments for investments in intangible assets		-115	-234
Additions to capitalized development costs	11	-371	-376
Proceeds from the sale of marketable securities		500	500
<b>Cash flow from investing activities</b>		<b>-195</b>	<b>-315</b>
<i>Financing activities</i>	31		
Payments for the creation of new shares		-189	-2,648
Proceeds from the issue of new shares	20	5,182	33,069
Payments for lease financing		-29	-27
<b>Cash flow from financing activities</b>		<b>4,964</b>	<b>30,394</b>
<b>Cash flow</b>		<b>-5,860</b>	<b>20,600</b>
<b>Cash and cash equivalents at the end of the year</b>		<b>3,954</b>	<b>24,554</b>

STATEMENT OF CHANGES IN GROUP EQUITY  
AS OF DECEMBER 31, 2010

EUR thousand	Notes	Subscribed capital	Capital reserve	Retained earnings	Net loss for the year	Other compreh. income	Group equity
<b>Dec 31, 2008</b>		<b>26,724</b>	<b>3,567</b>	<b>-12,271</b>	<b>0</b>	<b>-1,452</b>	<b>16,568</b>
<b>Total comprehensive income</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>-10,223</b>	<b>408</b>	<b>-9,815</b>
Capital increase from the issue of shares		2,671	0	0	0	0	2,671
Premium from the issue of shares		0	2,511	0	0	0	2,511
Financing costs		0	-26	0	0	0	-26
Stock-based compensation		0	175	0	0	0	175
Transfer of net loss for the year 2009 to retained earnings		0	0	-10,223	10,223	0	0
<b>Dec 31, 2009</b>		<b>29,395</b>	<b>6,227</b>	<b>-22,494</b>	<b>0</b>	<b>-1,044</b>	<b>12,084</b>
<b>Total comprehensive income</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>-11,476</b>	<b>139</b>	<b>-11,337</b>
Capital increase from the issue of shares	20	14,697	0	0	0	0	14,697
Premium from the issue of shares	21	0	18,372	0	0	0	18,372
Financing costs		0	-2,811	0	0	0	-2,811
Stock-based compensation	5	0	290	0	0	0	290
<b>Dec 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>

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## BASIC INFORMATION, PRINCIPLES AND METHODS

### DESCRIPTION OF BUSINESS ACTIVITY

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

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

### GENERAL PRINCIPLES

The consolidated financial statements of Epigenomics AG have been prepared according to Section 315a of the German Commercial Code ("HGB") under regulations according to the German Accounting Law Modernisation Act ("Bilanzrechtsmodernisierungsgesetz – BilMoG") and the International Financial Reporting Standards (IFRSs) of the International Accounting Standards Board (IASB), London, in effect at the closing date December 31, 2010, as mandatory and applicable in the European Union. Further, these statements are in accordance with the German Accounting Standards (GASs).

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

The reporting period as defined in these consolidated financial statements is the period from January 1, 2010, to December 31, 2010. The reporting currency is the euro.

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

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

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

- *Amendments (2009) to IAS 1: Presentation of Financial Statements*
- *Amendments (2009) to IAS 7: Statement of Cash Flow*
- *Amendments (2009) to IAS 17: Leases*
- *Amendments (2009) to IAS 36: Impairment of Assets*
- *Amendments (2009) to IAS 38: Intangible Assets*
- *Amendments (2009) to IAS 39: Financial Instruments: Recognition and Measurement*
- *Amendments (2009) to IFRS 1: First-time Adoption of International Financial Reporting Standards*
- *Amendments (2009) to IFRS 2: Share-based Payment*

Further, the IASB has issued the following standards and interpretations in 2010 which will be mandatory effective for the financial year beginning at or after February 1, 2010, July 1, 2010, January 1, 2011, or July 1, 2011:

- *Amendments to IAS 1: Presentation of Financial Statements*
- *Amendments to IAS 24: Related Party Disclosures*
- *Amendments to IAS 32: Financial Instruments: Presentation*
- *Amendments to IFRS 1: First-time Adoption of International Financial Reporting Standards*
- *Amendments to IFRS 3: Business Combinations*
- *Amendments to IFRS 5: Non-current Assets Held for Sale and Discontinued Operations*
- *Amendments to IFRS 7: Financial Instruments: Disclosures*
- *Amendments to IFRS 8: Operating Segments*
- *IFRIC 13: Customer Loyalty Programmes*
- *IFRIC 14: IAS 19 – The Limit on a Defined Benefit Asset, Minimum Funding Requirements and their Interaction*
- *IFRIC 19: Extinguishing Financial Liabilities with Equity Instruments*

The Company anticipates that most of these amendments will be adopted in the Group's financial statements for the period beginning January 1, 2011. The Company does not expect a potential material impact of the adoption of these amendments.

## MANAGEMENT'S JUDGMENT AND EXPECTATIONS

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

Management's expectations on the future are usually based on the current economic outlook according to the consensus prognoses by leading economic and financial research institutions and independent analysts. After the turbulences on the financial and capital markets over the past years, there is disagreement within these groups whether the global situation will improve in 2011 or another year of unsteadiness must be expected.<sup>1</sup> The plans of the Group's management do not expect Epigenomics to be very dependent on the overall economic situation in the short term. The Group's operating activities are not very dependent on the availability or the price development for commodities or industrial supplies but rather on the relevant labor markets. For the coming months, management does not expect significant changes in labor markets, which could affect the Group's operating activities.

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 1.35–1.40 throughout 2011. 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 health care system planned by the Obama administration may influence activities of all life sciences companies. However, at the present time, 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.

<sup>1</sup> For more detailed considerations reference is made to the "Prognosis Report" of the Group Management Report.

## CONSOLIDATION GROUP

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

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

## PRINCIPLES OF CONSOLIDATION

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

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

## ACCOUNTING AND VALUATION PRINCIPLES

### *Goodwill*

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

Management's expectations regarding the future cash flows of the cancer screening business were based on the most recent business plans and are, however, subject to risks and uncertainty. The underlying expectations are based on the Company's collaboration with its development partner Abbott Molecular, Inc., which has licensed the Company's key value driver – the Septin9-based colorectal cancer IVD test – for further development and worldwide commercialization. Based on this collaboration, the product development plans of the Company's cancer screening business have been extrapolated accordingly and present the basis of the capitalized goodwill (for the generally underlying assumptions to the aforementioned business plan see also "Management's judgment and expectations").

All of those assumptions are key sources of estimation uncertainty and bear a significant risk of causing a material adjustment in the future to the carrying amount of the capitalized goodwill. However, no impairment of the capitalized goodwill has been determined in 2010.

### *Intangible assets*

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

### *Capitalized development costs*

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

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

The amount initially recognized for the capitalization of development costs is the sum of expenditure incurred from the date when the intangible assets first met the aforementioned recognition criteria. Where no internally generated intangible asset can be recognized, development expenditure is charged to profit or loss in the period in which it is incurred. Subsequent to initial recognition, capitalized development costs are reported at cost less accumulated amortization and impairment losses, on the same basis as intangible assets acquired separately.

### *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 costs 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" (item 13), fully depreciated tangible assets are shown under acquisition/production cost and accumulated depreciation until the assets in question are decommissioned. In the case of disposal, assets and related depreciation are eliminated from the accounts. Income or expense resulting from the disposal of assets (proceeds less residual carrying value) is shown in the income statement under other income/other expenses.

If the carrying value of the tangible assets calculated according to the above principles exceeds the recoverable amount of these assets at the closing date, it will be taken into account by means of an unplanned depreciation. The amount to be adjusted is determined by sale proceeds or – if higher – the net present value of future cash flows estimated from value in use of the asset. An impairment test will be done annually for assets or groups of assets for which an unplanned decrease in value is assumed. If there is no longer any reason for unplanned 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 and the corresponding tax balance sheets of the companies involved. Further, deferred tax assets are recognized from tax loss carryforwards to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and that they are expected to reverse in the foreseeable future. If such a realization is not probable, a valuation allowance is recognized against the tax loss carryforwards.

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

#### *Inventories*

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

#### *Financial instruments*

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



### **Primary financial instruments**

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

### **Marketable securities**

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

### **Derivative financial instruments**

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

### **Impairment of financial assets**

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

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

### **Cash equivalents**

A cash equivalent is defined as a financial instrument being readily convertible on a short-term basis to a known amount of cash and carrying an insignificant risk of changes in value (IAS 7.6 *Statements of Cash Flow*). Financial instruments generally qualify as cash equivalents when they are more closely related to the money markets than to the bond markets and are issued by a debtor rated "investment grade". All such cash equivalents must be convertible into primary cash at any time.

### **Prepaid expenses**

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

### ***Current liabilities***

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

### ***Trade payables***

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

### ***Deferred income***

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

### ***Provisions***

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

### ***Revenue recognition***

Revenue from the sale of products and the rendering of other services is recognized when delivery has taken place, transfer of risk has been completed, the amount of future returns can be reasonably estimated and collection of the receivable is probable.

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

Milestone payments are recognized as revenue according to the milestone payment method. Revenue under the milestone payment method is recorded and recognized when acknowledgement of having achieved applicable performance requirements is received from the partner.

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

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

### *Cost of sales*

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

### *Government grants*

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

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

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

### *Research and development costs*

Research and development costs (R&D costs) include the personnel expenses for the R&D staff, material expenses, depreciation and amortization, service fees, licensing fees and other direct expenses in connection with the Company's research and/or development activities (including but not limited to 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*

The former income statement positions "marketing and business development costs" and "general and administrative costs" have been merged first for the reporting year into a new position called "selling, general and administrative costs" (SG&A). This disclosure is compatible with industry standards. The reasons for this aggregation are among others to achieve a better comparability with the financial statements of other international life sciences companies and competitors as well as to demonstrate the development of Epigenomics from a research-focused to a product-driven company. Furthermore, the aggregation solves the problem of a cost allocation free of arbitrariness either to marketing and business development costs on the one hand or to general and administrative costs on the other hand which has not always been possible in the past. Thus, SG&A costs include:

- all direct personnel and material expenses of the corresponding departments;
- 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.

The comparable numbers of the previous year have been adjusted accordingly.

### *Stock option expenses*

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

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

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

In particular, assumptions and estimates are required for:

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

### CURRENCY TRANSLATION

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

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.

The exchange rate of the U.S. dollar and the British pound, the two major foreign currencies in the consolidated financial statements, changed during the reporting year as follows:

Reporting date rates	Dec 31, 2009	Dec 31, 2010
EUR/USD	1.4406	1.3362
EUR/GBP	0.88810	0.86075

Average rates	2009	2010
EUR/USD	1.3963	1.3207
EUR/GBP	0.88998	0.85601

## NOTES TO THE GROUP INCOME STATEMENT

### 1 REVENUE

Total revenue was comprised of the following revenue types:

	2009		2010	
	EUR thousand	% of total	EUR thousand	% of total
Licensing and royalty income	1,709	40.1	1,202	67.3
Product sales and other	230	5.4	454	25.4
R&D payments	2,321	54.5	131	7.3
<b>Total</b>	<b>4,260</b>	<b>100.0</b>	<b>1,787</b>	<b>100.0</b>

Of total revenue, 56% (2009: 56%) was generated from European customers and 44% (2009: 44%) from customers in North America and in the Rest of the World. Of total revenue, 63% was generated by the three largest customers.

### 2 COST OF SALES/GROSS PROFIT/GROSS MARGIN

EUR thousand	2009	2010
Revenue	4,260	1,787
Cost of sales	2,798	474
<b>Gross profit</b>	<b>1,462</b>	<b>1,313</b>
Gross margin in %	34.3	73.5

### 3 OTHER INCOME

EUR thousand	2009	2010
Third-party research grants	99	320
– thereof: from public authorities	75	287
Exchange gains from currency conversion	241	300
Income from the reversal of provisions	9	235
Income from option exercises	0	67
Corrections of invoices of the previous year	108	60
Income from the sale of assets	34	18
Insurance recoveries	7	4
Various refunds	11	3
Income from subleasing	23	0
Other	3	5
<b>Total</b>	<b>535</b>	<b>1,012</b>

### 4 COST ANALYSIS

2009 EUR thousand	Cost of sales	R&D costs	SG&A costs	Total
Materials and consumables	747	1,376	39	2,162
Depreciation and amortization	114	598	64	776
Personnel costs	204	3,798	2,306	6,308
Other costs	1,733	1,948	2,049	5,730
Capitalized development costs	0	-371	0	-371
<b>Total</b>	<b>2,798</b>	<b>7,349</b>	<b>4,458</b>	<b>14,605</b>

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

## 5 PERSONNEL COSTS

EUR thousand	2009	2010
Personnel remuneration	5,373	5,607
Stock option expenses	175	290
Social security expenses	760	814
– thereof:		
Employer's contribution to the national pension fund (Germany)	252	274
Employer's contribution to a 401(k) savings plan (U.S.A.)	55	58
<b>Total personnel costs</b>	<b>6,308</b>	<b>6,711</b>
Average number of employees	83	83
– thereof: employees in sales, marketing and administration	23	28
Personnel costs/employee	76	81

## 6 OTHER EXPENSES

EUR thousand	2009	2010
Extraordinary amortization on intangible assets	0	537
Exchange rate losses from currency conversion	401	229
– thereof: due to the translation of deferred tax assets	70	-31
Losses from the disposal of assets	7	6
Other	0	1
<b>Total</b>	<b>408</b>	<b>773</b>

## 7 OPERATING RESULT (EBIT)

In the reporting year, the recorded operating result before interest and taxes (EBIT) and the operating result before interest, taxes, depreciation and amortization (EBITDA) developed as follows:

EUR thousand	2009	2010
<b>EBIT</b>	<b>-10,218</b>	<b>-11,449</b>
Depreciation	329	265
Amortization	447	877
<b>EBITDA</b>	<b>-9,442</b>	<b>-10,307</b>



## 8 FINANCIAL RESULT

EUR thousand	2009	2010
<b>Interest and related income</b>	<b>191</b>	<b>165</b>
Interest from cash and cash equivalents	79	101
Interest from available-for-sale financial assets	104	64
Interest from derivative instruments	8	0
<b>Other financial income</b>	<b>28</b>	<b>0</b>
Fair value adjustment for derivative instruments	28	0
<b>Total financial income</b>	<b>219</b>	<b>165</b>
<b>Interest expenses</b>	<b>-8</b>	<b>0</b>
Interest expenses for derivative instruments	-8	0
<b>Other financial expenses</b>	<b>-14</b>	<b>-152</b>
Fair value adjustment for derivative instruments	0	-144
Adjustment from disposal of available-for-sale financial assets	-12	-6
Other finance costs	-2	-2
<b>Total financial expenses</b>	<b>-22</b>	<b>-152</b>
<b>Financial result</b>	<b>197</b>	<b>13</b>

In the reporting year, a net loss of EUR 144 thousand for derivative instruments has been recognized (2009: net gain of EUR 28 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 income taxes in the amount of EUR 40 thousand (2009: EUR 202 thousand) comprise exclusively taxes recorded by the Company's U.S. subsidiary in Seattle.

EUR thousand	2009	2010
Current tax expenses	34	40
Deferred tax expenses due to loss carryforwards	80	0
Deferred tax expenses due to temporary differences between IFRSs and U.S. tax law	88	0
<i>Tangible assets</i>	78	0
<i>Current liabilities</i>	10	0
<b>Total taxes on income</b>	<b>202</b>	<b>40</b>

For the calculation of deferred taxes of the U.S. subsidiary, a local tax rate of 34% was applied.

Calculation of applicable tax charge:

	2009	2010
Corporate tax rate	15.0%	15.0%
Solidarity charge	5.5%	5.5%
Trade tax rate	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	2009	2010
<b>Net loss for the year before taxes on income</b>	<b>-10,021</b>	<b>-11,436</b>
<i>Weighted-average tax rate for the Group</i>	<i>29.5%</i>	<i>29.7%</i>
<b>Expected tax expense</b>	<b>-2,957</b>	<b>-3,401</b>
loss carryforwards not capitalizable	3,396	3,895
effect from foreign tax rates	3	-13
tax effect from non-deductible operating expenses	25	26
capital-increase-related expenses	-259	-586
stock option expenses	52	86
other temporary effects	-6	33
<b>Effective tax expense</b>	<b>202</b>	<b>40</b>
<b>Effective tax rate</b>	<b>-2.0%</b>	<b>-0.3%</b>

The expected tax expense for the reporting year has been calculated by applying the expected Group's weighted-average tax rate to the net loss of the Group before taxes on income. It amounted to 29.7% in the reporting year (2009: 29.5%).

## 10 EARNINGS PER SHARE

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

	2009	2010
Net loss for the year in EUR thousand	-10,223	-11,476
Weighted-average number of shares issued	29,172,133	40,417,745
Earnings per share (basic and diluted) in EUR	-0.35	-0.28

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 44,092,085.

## NOTES TO THE GROUP BALANCE SHEET

## NON-CURRENT ASSETS

**11 INTANGIBLE ASSETS**

EUR thousand		Software	Licenses/ patents	Goodwill	Devel- opment costs	Total intangible assets
Jan 1, 2009	<b>Acquisition costs</b>	<b>617</b>	<b>4,661</b>	<b>3,351</b>	<b>88</b>	<b>8,717</b>
	Additions	82	210	0	371	663
	Disposals	-13	0	0	0	-13
Dec 31, 2009	<b>Acquisition costs</b>	<b>686</b>	<b>4,871</b>	<b>3,351</b>	<b>459</b>	<b>9,367</b>
	Additions	158	139	0	325	622
	Disposals	0	-1,068	0	0	-1,068
<b>Dec 31, 2010</b>	<b>Acquisition costs</b>	<b>844</b>	<b>3,942</b>	<b>3,351</b>	<b>784</b>	<b>8,921</b>
Jan 1, 2009	<b>Accumulated amortization</b>	<b>590</b>	<b>2,843</b>	<b>726</b>	<b>22</b>	<b>4,181</b>
	Additions	30	360	0	56	446
	Disposals	-13	0	0	0	-13
Dec 31, 2009	<b>Accumulated amortization</b>	<b>607</b>	<b>3,203</b>	<b>726</b>	<b>78</b>	<b>4,614</b>
	Additions	34	709	0	134	877
	Disposals	0	-1,068	0	0	-1,068
<b>Dec 31, 2010</b>	<b>Accumulated amortization</b>	<b>641</b>	<b>2,844</b>	<b>726</b>	<b>212</b>	<b>4,423</b>
Dec 31, 2009	<b>Carrying values</b>	<b>79</b>	<b>1,668</b>	<b>2,625</b>	<b>381</b>	<b>4,753</b>
<b>Dec 31, 2010</b>	<b>Carrying values</b>	<b>203</b>	<b>1,098</b>	<b>2,625</b>	<b>572</b>	<b>4,498</b>

The licenses and patents listed represent mainly the acquisition costs for acquired patents and exclusive rights of use to property rights of third parties. Those acquisition costs are usually caused by upfront payments. The majority of the licenses require the Company to pay additional annual minimum fees that are expensed. The license contracts may usually be cancelled at short notice. However, some of those licenses are vital for the Company's business model.

In December 2010, the capitalized goodwill was tested for impairment in order to comply with IFRS 3 *Business Combinations* and IAS 36 *Impairment of Assets*. It had originated in the acquisition of Orca Biosciences (now: Epigenomics, Inc.) in 2001 and is assigned in content to the Company's cancer screening business as the relevant cash-generating unit. The Company's current business plan projections for the screening business were used for the test. According to this plan, future cash inflows will be generated in a partnering model from direct product sales as well as from milestone payments, R&D payments, and royalty income by third parties. The plans are based on the existing and future collaboration contracts with the Company's partners.

Growth rates were anticipated in line with industry comparables. Due to the business model, the expected product life cycle and the underlying terms of the patents, cash flows were planned for a period of ten years. All future cash flows are measured by the net present value method. The appropriate discount rate, which has been applied in the reporting year, was 25%. No impairment had to be recognized.

In 2010, the Company capitalized the expenditures amounting to EUR 325 thousand which had incurred in connection with the development of its Epi *proLung* product as the recognition criteria according to IAS 38.57 were met. The useful life of these capitalized development costs was defined as three years with regard to the expected product life cycles.

In 2010, the acquisition costs for intangible assets in the amount of EUR 622 thousand (2009: EUR 663 thousand) did not include any non-cash items (2009: EUR 176 thousand).

## 12 TANGIBLE ASSETS

EUR thousand		Fixtures/ leasehold improve- ments	Technical equipment	Other fixed assets	Total tangible assets
Jan 1, 2009	<b>Acquisition costs</b>	<b>814</b>	<b>4,838</b>	<b>72</b>	<b>5,724</b>
	Additions	10	175	27	212
	Disposals	-283	-931	-7	-1,221
Dec 31, 2009	<b>Acquisition costs</b>	<b>541</b>	<b>4,082</b>	<b>92</b>	<b>4,715</b>
	Additions	0	233	11	244
	Disposals	0	-452	-6	-458
<b>Dec 31, 2010</b>	<b>Acquisition costs</b>	<b>541</b>	<b>3,863</b>	<b>97</b>	<b>4,501</b>
Jan 1, 2009	<b>Accumulated depreciation</b>	<b>763</b>	<b>4,209</b>	<b>60</b>	<b>5,032</b>
	Additions	44	281	5	330
	Disposals	-283	-929	-7	-1,219
Dec 31, 2009	<b>Accumulated depreciation</b>	<b>524</b>	<b>3,561</b>	<b>58</b>	<b>4,143</b>
	Additions	8	251	6	265
	Disposals	0	-445	-6	-451
<b>Dec 31, 2010</b>	<b>Accumulated depreciation</b>	<b>532</b>	<b>3,367</b>	<b>58</b>	<b>3,957</b>
Dec 31, 2009	<b>Carrying values</b>	<b>17</b>	<b>521</b>	<b>34</b>	<b>572</b>
<b>Dec 31, 2010</b>	<b>Carrying values</b>	<b>9</b>	<b>496</b>	<b>39</b>	<b>544</b>

## 13 ASSETS SCHEDULE

EUR thousand		Intangible assets	Tangible assets	Total assets
Jan 1, 2009	<b>Acquisition costs</b>	<b>8,717</b>	<b>5,724</b>	<b>14,441</b>
	Additions	663	212	875
	Disposals	-13	-1,221	-1,234
Dec 31, 2009	<b>Acquisition costs</b>	<b>9,367</b>	<b>4,715</b>	<b>14,082</b>
	Additions	622	244	866
	Disposals	-1,068	-458	-1,526
<b>Dec 31, 2010</b>	<b>Acquisition costs</b>	<b>8,921</b>	<b>4,501</b>	<b>13,422</b>
Jan 1, 2009	<b>Accumulated depreciation/amortization</b>	<b>4,181</b>	<b>5,032</b>	<b>9,213</b>
	Additions	446	330	776
	Disposals	-13	-1,219	-1,232
Dec 31, 2009	<b>Accumulated depreciation/amortization</b>	<b>4,614</b>	<b>4,143</b>	<b>8,757</b>
	Additions	877	265	1,142
	Disposals	-1,068	-451	-1,519
<b>Dec 31, 2010</b>	<b>Accumulated depreciation/amortization</b>	<b>4,423</b>	<b>3,957</b>	<b>8,380</b>
Dec 31, 2009	<b>Carrying values</b>	<b>4,753</b>	<b>572</b>	<b>5,325</b>
<b>Dec 31, 2010</b>	<b>Carrying values</b>	<b>4,498</b>	<b>544</b>	<b>5,042</b>

As in the previous year, 98% of the non-current assets stated at the balance sheet date are located at the Group's headquarter in Germany and the remaining 2% in the U.S.A.

## 14 DEFERRED TAX ASSETS

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

EUR thousand	Deferred tax assets		Deferred tax liabilities	
	Dec 31, 2009	Dec 31, 2010	Dec 31, 2009	Dec 31, 2010
Intangible and tangible assets	229	217	121	177
Current assets	0	2	253	2
Current liabilities	0	40	26	0
<b>Total</b>	<b>229</b>	<b>259</b>	<b>400</b>	<b>179</b>

Since all the aforementioned matters must be settled with the same fiscal authority in accordance with IAS 12.71 *Income Taxes* et seqq., a balancing of the respective tax income and expenses has been performed. As the current forecasts of the Company with regard to achieving the break even point are still subject to significant uncertainty, valuation allowances have been recognized for all of the resulting net deferred tax assets.

Since its inception through December 31, 2009, the Company's tax loss carryforwards in Germany amounted to approximately EUR 110 million (for corporate taxation) and to approximately EUR 109 million (for trade taxation). In addition, the Company expects to increase its cumulated tax losses for both types of taxes by around EUR 13 million with the filing of its tax returns for 2010. 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. In the Company's view, the aforementioned tax loss carryforwards must be recognized up to their full amounts as uncertain regarding a future utilization.

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 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 421 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 2.3 million and can be utilized for up to 20 years.

Changes in capitalized deferred tax assets in the reporting year:

EUR thousand	2009	2010
<b>Jan 1</b>	<b>629</b>	<b>391</b>
Deferred tax expenses	-168	0
Foreign currency adjustment	-70	30
<b>Dec 31</b>	<b>391</b>	<b>421</b>



## CURRENT ASSETS

**15 INVENTORIES**

EUR thousand	Dec 31, 2009	Dec 31, 2010
Consumables, raw materials, supplies	123	111
Finished goods	37	51
<b>Total inventories</b>	<b>160</b>	<b>162</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, 2009	Dec 31, 2010
Trade receivables, gross	1,993	482
Allowance for bad debt	0	6
<b>Trade receivables, net</b>	<b>1,993</b>	<b>476</b>

At the balance sheet date, trade receivables in the amount of EUR 274 thousand were not due (Dec 31, 2009: EUR 1,603 thousand). Further trade receivables in the amount of EUR 157 thousand were not yet invoiced at the balance sheet date (Dec 31, 2009: EUR 352 thousand). Receivables in the amount of EUR 45 thousand (Dec 31, 2009: EUR 38 thousand) were past due but not impaired as there were no indications that they were uncollectible.

EUR thousand	Dec 31, 2009	Dec 31, 2010
Trade receivables past due up to 30 days	38	13
Trade receivables past due 61-90 days	0	23
Trade receivables past due more than 90 days	0	9
<b>Total</b>	<b>38</b>	<b>45</b>

## 17 MARKETABLE SECURITIES

All marketable securities in the amount of EUR 1,815 thousand as of December 31, 2010 (Dec 31, 2009: EUR 2,182 thousand) are recognized as financial instruments "available for sale" according to IAS 39.9 *Financial Instruments: Recognition and Measurement*.

Under the investment policy of the Company, each investment in securities is subject to certain strict criteria. These include among others the limitation to securities nominated in euro currency only and an official capital market rating of the issuer or the securities not below "investment grade". However, the Company has not invested in any marketable securities during the last five reporting years.

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

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

EUR thousand	Dec 31, 2009	Dec 31, 2010
Corporate bonds	1,966	1,534
Debt certificates	216	281
<b>Total</b>	<b>2,182</b>	<b>1,815</b>

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

Time to maturity of marketable securities	Dec 31, 2009		Dec 31, 2010	
	Fair value EUR thousand	in %	Fair value EUR thousand	in %
1–2 years	896	41.1	972	53.5
> 5 years	1,070	49.0	562	31.0
Unlimited	216	9.9	281	15.5
<b>Total</b>	<b>2,182</b>	<b>100.0</b>	<b>1,815</b>	<b>100.0</b>

## 18 CASH AND CASH EQUIVALENTS

Cash and cash equivalents increased to EUR 24,554 thousand at the balance sheet date (Dec 31, 2009: EUR 3,954 thousand). Approximately 98% of those funds were denominated in euro currency at the balance sheet date. The remainder is predominantly denominated in U.S. dollar currency. The total amount is allocated to three different banks.

EUR thousand	Dec 31, 2009	Dec 31, 2010
Time deposits	1,230	23,936
Bank accounts, petty cash, cheques	2,724	618
<b>Total</b>	<b>3,954</b>	<b>24,554</b>

## 19 OTHER CURRENT ASSETS

EUR thousand	Dec 31, 2009	Dec 31, 2010
Prepaid expenses	923	901
Receivables from tax authorities	389	233
Claims based on granted projects	59	89
– thereof: claims against public authorities	59	89
Interest receivables	59	38
Excess payments	18	13
Advance payments	13	9
Deferred financing costs	843	0
Other	45	85
– thereof: with a prospective maturity > 1 year	38	38
<b>Total</b>	<b>2,349</b>	<b>1,368</b>

### EQUITY

## 20 NOTES TO SHARE CATEGORIES AND CAPITAL STRUCTURE

As of December 31, 2010, the share capital of Epigenomics AG comprised exclusively common shares with equal rights and a par value of EUR 1.00 each. During the reporting year, the number of shares issued increased from 29,394,724 to 44,092,085 shares. A total of 14,697,361 new no-par value bearer shares were created by a capital increase entirely using Authorized Capital 2009 I and Authorized Capital 2009 II within a financing transaction in March 2010 at a price of EUR 2.25 each. This capital increase was registered with the commercial register Charlottenburg on March 31, 2010. In the reporting year, no new shares have been created by the exercise of stock options.

Equity structure of Epigenomics AG as of December 31:

EUR	Dec 31, 2009	Dec 31, 2010	Variance
<b>Share Capital</b>	<b>29,394,724</b>	<b>44,092,085</b>	<b>14,697,361</b>
<b>Conditional Capital</b>	<b>2,925,964</b>	<b>2,925,964</b>	<b>0</b>
<i>Conditional Capital III</i>	139,625	139,625	0
<i>Conditional Capital IV</i>	617,426	617,426	0
<i>Conditional Capital V</i>	647,679	647,679	0
<i>Conditional Capital VII</i>	1,521,234	1,521,234	0
<b>Authorized Capital</b>	<b>14,697,361</b>	<b>0</b>	<b>-14,697,361</b>
<i>Authorized Capital 2009/I</i>	2,939,472	0	-2,939,472
<i>Authorized Capital 2009/II</i>	11,757,889	0	-11,757,889

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

After December 31, 2010, Conditional Capital V cannot be used anymore to grant stock options as the underlying authorization for a granting time frame has expired on December 31, 2010. However, new shares can still be created upon exercise of options from this older program (06–10). In 2010, a total number of 33,000 stock options have been granted to Company's employees out of this stock option program.

Conditional Capital VII allows the creation of new shares upon the exercise of stock options granted under the stock option program 09–13. During the reporting year, a total number of 395,000 stock options have been granted to members of the Company's Executive Board and to its employees from this stock option program.

In March 2010, Authorized Capital 2009/I and Authorized Capital 2009/II were entirely used by the Executive Board to increase, with the consent of the Supervisory Board, the Company's share capital as part of the aforementioned financing transaction.

## 21 CAPITAL RESERVE

In the reporting year, the capital reserve increased by EUR 15,851 thousand to EUR 22,078 thousand (2009: EUR 6,227 thousand). The main reasons for this were the net effect of EUR 15,561 thousand from the capital increase executed in March 2010 as well as expenses of EUR 290 thousand from issued stock options.

## 22 OTHER COMPREHENSIVE INCOME

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

EUR thousand	2009	2010
<b>Balance as of January 1</b>	<b>1,452</b>	<b>1,044</b>
Adjustments from the sale of financial instruments available for sale	-27	-20
Revaluation of financial instruments available for sale	-381	-119
<b>Balance as of December 31</b>	<b>1,044</b>	<b>905</b>

## 23 CAPITAL MANAGEMENT

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

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

In 2010, the Group's equity ratio increased from 73.9% as of December 31, 2009, to 92.5% as of December 31, 2010. This growth is mainly attributable to the increased equity due to the capital increase in April 2010 with a simultaneous decrease in liabilities.

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

### CURRENT LIABILITIES

## 24 TRADE PAYABLES

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

## 25 DEFERRED INCOME

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

EUR thousand	Dec 31, 2009	Dec 31, 2010
Payments for commercial collaborations	660	214
Payments for granted projects	60	26
<b>Total</b>	<b>720</b>	<b>240</b>

As of December 31, 2010, the complete deferred income which will be released in the form of revenue recognition has a duration of less than 12 months (Dec 31, 2009: EUR 667 thousand).

## 26 OTHER LIABILITIES

EUR thousand	Dec 31, 2009	Dec 31, 2010
Payables due to staff	416	384
Payables due to tax authorities	234	196
Liabilities from derivative instruments	0	144
Accrued audit fees	119	107
Payables due to social security institutions	21	26
Accrued Supervisory Board fees	0	17
Down payments received	45	3
Other	16	13
<b>Total</b>	<b>851</b>	<b>890</b>

## 27 PROVISIONS

As of December 31, 2010, the provisions of the Company added up to EUR 270 thousand. Substantially, they were recognized for:

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

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

## Statement of changes in current provisions:

EUR thousand	Contract- related provisions	Payroll provisions	Other provisions	Total
<b>January 1, 2009</b>	<b>188</b>	<b>228</b>	<b>65</b>	<b>481</b>
Utilization	0	0	-50	-50
Reversal	0	0	-9	-9
Additions	0	83	66	149
<b>December 31, 2009</b>	<b>188</b>	<b>311</b>	<b>72</b>	<b>571</b>
Utilization	0	-80	-56	-136
Reversal	0	-227	-6	-233
Additions	0	0	68	68
<b>December 31, 2010</b>	<b>188</b>	<b>4</b>	<b>78</b>	<b>270</b>



## 28 NOTES TO FINANCIAL INSTRUMENTS

AC = Amortized Cost

FV Rec. Eq. = Fair Value Recognized in Equity

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

Primary financial instruments		Dec 31, 2009		Dec 31, 2010	
EUR thousand	Valuation principle	Carrying amount	Fair value	Carrying amount	Fair value
<b>Assets</b>					
Loans and receivables	AC	2,170	2,170	693	693
<i>Trade receivables</i>		1,993	1,993	476	476
<i>Other current assets</i>		177	177	217	217
Financial assets available for sale	FV Rec. Eq.	2,182	2,182	1,815	1,815
<i>Marketable securities</i>		2,182	2,182	1,815	1,815
Cash and cash equivalents	n/a	3,954	3,954	24,554	24,554
<b>Liabilities</b>					
Financial liabilities measured at amortized cost	AC	2,551	2,551	1,531	1,531
<i>Trade liabilities</i>		2,091	2,091	1,134	1,134
<i>Liabilities from leasing contracts</i>		37	37	9	9
<i>Other current liabilities</i>		423	423	388	388

Derivative financial instruments		Dec 31, 2009		Dec 31, 2010	
EUR thousand	Valuation principle	Carrying amount	Fair value	Carrying amount	Fair value
<b>Assets</b>					
Financial assets held for trading	FV Rec. PL	4	4	0	0
<i>Currency forward contracts</i>		4	4	0	0
<b>Liabilities</b>					
Financial liabilities held for trading	FV Rec. PL	0	0	144	144
<i>Currency forward contracts</i>		0	0	144	144

## NOTES TO THE GROUP CASH FLOW STATEMENT

### 29 OPERATING ACTIVITIES

Cash flow from operations is derived indirectly on the basis of the net loss for the year before taxes on income. Liquid assets comprise cash (bank deposit and cash in hand) and cash equivalents (being convertible on a short-term basis to a known amount of cash, highly liquid financial instrument, which carry a very low risk of changes in value).

### 30 INVESTING ACTIVITIES

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

### 31 FINANCING ACTIVITIES

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

Payments for the creation of new shares in the reporting year of EUR 2,648 thousand were related fully to the Company's capital increase in March 2010. From those payments amounting to EUR 189 thousand showed in the previous year, a part of EUR 163 thousand is also to be allocated to the capital increase in the reporting year.

### 32 CASH CONSUMPTION

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

EUR thousand	Dec 31, 2009	Dec 31, 2010
Cash flow from operating activities	-10,629	-9,479
Cash flow from investing activities	-195	-315
Net proceeds from the sale of marketable securities	-500	-500
<b>Cash consumption</b>	<b>-11,324</b>	<b>-10,294</b>

## RISKS AND RISK MANAGEMENT

### 33 GENERAL

For a comprehensive overview of the risks the Company is facing reference is made to the "Opportunities and Risks" section of the Group management report 2010 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)).

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## 34 LIQUIDITY RISK

The liquidity risk of Epigenomics results from the Group's potential inability to meet its financial liabilities, i.e. not paying its suppliers, creditors or lenders.

To secure the Company's liquidity, Epigenomics constantly monitors the capital markets and undertakes if required all necessary efforts to raise fresh capital to avoid illiquidity. Short-term liquidity is ensured by maintaining internal cash forecasts and a corresponding strategy of managing time deposits with the Company's house banks.

Epigenomics has a strict cost management in place to avoid unnecessary spending. On the procurement side it always tries to reduce purchase prices by closing favorable contracts and negotiating all relevant conditions.

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## 35 FOREIGN CURRENCY EXCHANGE RISK

The Group constantly faces a foreign currency exchange risk through the fluctuations between the euro and the U.S. dollar as well as to a limited extent the British Pound Sterling. The risk mainly originates from the need to purchase goods and services partially in U.S. dollar. Also, certain services of the Group are sold in U.S. dollar. The Group constantly tries to mitigate or to eliminate this risk as far as possible. Wherever possible, the Group exerts its influence in negotiations to avoid this risk and mainly uses derivative financial instruments in the shape of forward contracts to minimize this risk. These instruments are recognized at fair value on the Group balance sheet as current assets or short-term liabilities. Changes in fair value are charged to profit or loss as the Company currently does not meet the requirements of IAS 39 *Financial Instruments: Recognition and Measurement* regarding hedge accounting.

Due to the limited volume of positions denominated in foreign currencies at the reporting date, an increase or a decrease of the euro to 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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## 36 CREDIT RISK

The Company's overall credit risk is low. Securities have only been acquired under careful observation of the Company's investment policy, i.e. a strict selection by the credit ratings of the issuers has been conducted. However, the worldwide financial market crisis of 2008/2009 has shown that even top-rated issuers can suddenly face a threatening situation or even collapse. Additionally, since 2008, it has become clear that there is a pending risk of illiquid markets.

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

## 37 INTEREST RATE RISK

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

As the Group's time deposits have usually maturities of up to a maximum of 180 days, the interest rate risk of these financial instruments can be considered negligible.

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

## 38 EXPIRED STOCK OPTION PROGRAMS

As of the balance sheet date, the Epigenomics Group (via Epigenomics AG) had four fixed stock option programs in place. Details of the three programs 01–05, 03–07 and 06–10 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. These three programs have expired as of the balance sheet date, i.e. no stock options can be granted from those programs in the future. In general, the rights under all three 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 stock price at grant date and the statutory waiting period of two years as well as vesting must have been completed. If employees leave the Company before the options are vested these forfeit without compensation.

## 39 CURRENT STOCK OPTION PROGRAMS

Stock options can be only granted from the latest, the fourth stock option program (09–13). This stock option program was introduced in 2009 and approved by the Annual General Shareholders' Meeting on May 11, 2009. The Company's share capital was therefore conditionally increased by up to 5.69% of the share capital registered before the capital increase, i.e. by up to EUR 1,521,234.00 by issuance of up to 1,521,234 bearer shares of common stock with an accounting par value of EUR 1.00 each (Conditional Capital VII). The Executive Board of the Company is authorized until the expiration (December 31, 2013) to issue subscription rights with respect to shares out of the stock option program 09–13 in one or more annual tranches in favor of beneficiaries according to the conditions of this program, once the Conditional Capital VII becomes effective by registration in the commercial register. In case of Executive Board members being beneficiaries, only the Supervisory Board can grant such options. Each individual subscription right entitles the beneficiary to subscribe to one bearer share of common stock of the Company with a par value of EUR 1.00 each against payment of the exercise price. Beneficiaries of the program are the Company's Executive Board members ("group 1"; a maximum of 30 % of the total volume, i.e. altogether a maximum of 456,370 of the subscription rights) and the employees of the Company and of subordinated affiliated companies within the meaning of Sections 15 et seq. AktG, but excluding the members of the Management Board of subordinated affiliated companies ("group 2"; a maximum of 70% of the total volume, i.e. altogether a maximum of 1,064,864 of the subscription rights).

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

The subscription rights of every tranche shall vest completely or partially for group-1-beneficiaries, if and to the extent that the Supervisory Board of the Company declares such vesting of subscription rights vis-à-vis a group-1-beneficiary in compliance with the rules set out hereafter. The declaration of vesting of subscription rights vis-à-vis a group-1-beneficiary by the Company's Supervisory Board requires a corresponding prior resolution by the Supervisory Board. The Supervisory Board adopts its decision regarding the "if" and the extent of the vesting of subscription rights of a group-1-beneficiary at its free discretion taking into account the individual services of the individual beneficiary and the development of the Company. The Supervisory Board can declare the complete or partial vesting of subscription rights issued in one tranche in favor of group-1-beneficiaries at any time after the issuance of these subscription rights. In case the Supervisory Board does not decide on the vesting vis-à-vis one or more of the group-1-beneficiaries, the subscription rights of every tranche shall vest for group-1-beneficiaries in the same way as for group-2-beneficiaries (see above).

Subscription rights of each tranche can be exercised for the first time after their vesting as described before and after expiration of the statutory waiting period. The statutory waiting period starts with the issuance of the subscription rights of a tranche and ends two years after the issuance of the subscription rights of such tranche. The restriction of the exercise of the subscription rights to certain exercise periods and the subscription rights being subject to the compliance with all exercise conditions remain unaffected by the expiration of the waiting period.

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

The subscription rights can only be exercised against payment of the exercise price to the Company. The exercise price corresponds to the average stock exchange closing price, increased by 10%, of the 20 stock exchange trading days preceding the issuance of the subscription rights in the Exchange Electronic Trading (XETRA) system, in no case, however, less than the final stock exchange price of the share on the day the subscription rights were issued ("market value" or "fair market value"). Furthermore, the subscription rights regarding a tranche can only be exercised in case the price of the Company's share has reached or surpassed the payable exercise price at least once within the period between the issuance of the subscription rights of this tranche and the exercise of these subscription rights (performance target).

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

The subscription rights granted to the beneficiaries under the stock option program 09-13 are non-transferable. In case subscription rights are not or cannot be exercised until the end of their term, they expire without compensation. The same applies for vested subscription rights.

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

## 40 DEVELOPMENT OF STOCK OPTIONS IN THE REPORTING YEAR

In 2010, a total number of 33,000 stock options were granted under the Company's stock option program 06-10 to employees of the Company. Under the Company's stock option program 09-13, a total number of 140,000 stock options were granted to the Company's Executive Board and a total number of 255,000 were granted to 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 for each of the new rights was fixed at the average closing price of the 20 trading days before the grant date. The aggregate proceeds to the Company if these options were exercised and shares were issued would amount to EUR 1,546,520.

Details of stock options granted in 2010:

Expiry date	Jan 1, 2017	Feb 1, 2017	July 1, 2017	Oct 1, 2017	Total 2017
Number	315,000	70,000	10,000	33,000	428,000
Share price at grant date (in EUR)	3.52	2.78	2.23	2.44	3.28
Exercise price (in EUR)	3.87	3.06	2.45	2.69	3.61
Historical volatility at grant date	58.45%	59.93%	59.27%	58.20%	58.69%
Risk-free interest rate	1.78%	1.61%	0.83%	1.00%	1.67%
<b>Aggregate proceeds if shares are issued (in EUR)</b>	<b>1,219,050</b>	<b>214,200</b>	<b>24,500</b>	<b>88,770</b>	<b>1,546,520</b>

A total number of 912,234 stock options can still be granted to the Company's employees and Executive Board members from the stock option program 09-13.

	Options issued as of Dec 31, 2009	Options issued in 2010	Options forfeited	Options cancelled	Options exercised	Options issued as of Dec 31, 2010
<b>Option holder</b>						
Geert Walther Nygaard	215,000	70,000	0	0	0	285,000
Oliver Schacht, Ph.D.	181,613	70,000	6,613	0	0	245,000
<b>Total Executive Board</b>	<b>396,613</b>	<b>140,000</b>	<b>6,613</b>	<b>0</b>	<b>0</b>	<b>530,000</b>
Other option holders	715,845	288,000	51,620	62,250	0	889,975
<b>Total options</b>	<b>1,112,458</b>	<b>428,000</b>	<b>58,233</b>	<b>62,250</b>	<b>0</b>	<b>1,419,975</b>
<b>Average exercise price (in EUR)</b>	<b>3.99</b>	<b>3.61</b>	<b>5.56</b>	<b>3.33</b>	<b>n/a</b>	<b>3.84</b>

The number of options issued as of December 31, 2010, includes 665,973 exercisable rights (December 31, 2009: 568,299).

Terms of outstanding options:

Term	Weighted-average exercise price in EUR as of	Options issued as of	Weighted-average exercise price in EUR as of	Options issued as of
	Dec 31, 2009		Dec 31, 2010	
2010	4.53	8,763	n/a	0
2011	4.53	124,700	4.53	121,700
2012	7.30	25,340	8.13	340
2013	5.48	110,660	5.46	107,940
2014	4.47	442,995	4.50	417,995
2015	2.11	30,000	2.11	30,000
2016	2.70	370,000	2.68	335,000
2017	n/a	0	3.60	407,000
<b>Total</b>		<b>1,112,458</b>		<b>1,419,975</b>

## OTHER INFORMATION

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

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

- Geert Walther Nygaard, Berlin (D), Chief Executive Officer
- Oliver Schacht, Ph.D., Seattle, WA (U.S.A.), Chief Financial Officer;  
Chief Executive Officer of Epigenomics, Inc.

In 2010, the total remuneration of the members of the Executive Board amounted to EUR 931 thousand (2009: EUR 794 thousand), comprising EUR 621 thousand in fixed compensation (2009: EUR 580 thousand), EUR 300 thousand in bonus payments<sup>2</sup> (2009: EUR 204 thousand) and EUR 10 thousand in other compensation payments (2009: EUR 10 thousand). A total of 140,000 stock options with a fair value at grant date of EUR 130 thousand have been granted to the members of the Executive Board in 2010 and in 2009 a total of 70,000 stock options with a fair value at grant date of EUR 41 thousand had been granted to the Company's Executive Board members.

In case of a change of control, Mr. Nygaard 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. In December 2010, Mr. Schacht has announced his resignation from the Company's Executive Board as of March 31, 2011.

<sup>2</sup> The variable compensation numbers for fiscal year 2010 comprise also a part of a bonus for the year 2009 and an additional payment, which was assigned in 2010 respectively.



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

- Prof. Dr. Dr. h.c. Rolf Krebs, Mainz (D), Chairman
- Prof. Dr. Dr. Uwe Bicker, Bensheim-Auerbach (D), Deputy Chairman
- Joseph Anderson, Ph.D., Oxted, Surrey (U.K.) (since June 8, 2010)
- Günter Frankenke, Berg/Neumarkt (D)
- Ann Clare Kessler, Ph.D., Rancho Santa Fe, CA (U.S.A.)
- Heino von Prondzynski, Einsiedeln (CH) (until March 31, 2010)
- Prof. Dr. Günther Reiter, Pfullingen (D)

In 2010, total remuneration of the members of the Supervisory Board amounted to EUR 153 thousand (2009: EUR 162 thousand) plus out-of-pocket expenses amounting to EUR 27 thousand (2009: EUR 21 thousand).

Further details to the composition of the Executive Board and the Supervisory Board and the compensation of their members in the reporting year can be found in the "Compensation Report" section of the Group management report 2010.

## 42 OTHER FINANCIAL OBLIGATIONS

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

- a) For the Berlin location at Kleine Präsidentenstrasse 1, there is a fixed-term lease with a term expiring on August 31, 2014. Until this date, a total rent of approximately EUR 1.32 million (undiscounted) has to be paid.
- b) For the Seattle location, there is a fixed-term lease with a term expiring on June 30, 2017. Until this date, a total rent of approximately USD 1.98 million (undiscounted) has to be paid. This contract includes an option for early termination as of November 30, 2012. In connection with such an early termination, Epigenomics would have to pay a total rent of USD 374 thousand for the period from January 1, 2011, to November 30, 2012, and early termination fees currently estimated at USD 673 thousand to the landlord.

In the previous years, Epigenomics acquired numerous exclusive licenses to third-party intellectual property. This means that there are some obligations to pay minimum license fees in years to come. Additionally, Epigenomics has the obligation to reimburse most of those third parties for costs incurred in connection with the maintenance and the prosecution of the licensed rights. Those costs are mainly charges for patent attorneys or office actions and are difficult to forecast regarding their amounts and timing. The expected amount due to various licensors stands at approximately EUR 446 thousand for the years 2011 and 2012. However, most of these agreements could be terminated by Epigenomics at short notice. There is only one case in which Epigenomics is under a long-term binding obligation. However, this payment obligation will not exceed EUR 20 thousand per year.

Due to contracts with third parties, at the balance sheet date, Epigenomics had payment obligations of EUR 568 thousand for services and goods to be received in 2011. However, as delivery dates and effective delivery quantities are to some extent uncertain, the future payments resulting from those contracts could also be lower.

## 43 INFORMATION ON THE AUDITORS OF THE COMPANY

As in the previous years, UHY Deutschland AG had been chosen as the Company's auditing firm for the financial year 2010. During the reporting year, a total amount of EUR 199 thousand (2009: EUR 273 thousand) has been expensed for miscellaneous services of this auditing firm for Epigenomics AG. Details are shown in the following table:

EUR thousand	2009	2010
Costs for audit services	95	104
Costs for other confirmation services	178	95
<b>Total</b>	<b>273</b>	<b>199</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 mainly for services in connection with the preparation of the capital increase as well as for critical reviews of quarterly reports. The costs for audit services comprise EUR 8 thousand higher expenditures compared with the previous year.

## 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 December 2010, the Executive Board and the Supervisory Board of the Company issued the declaration of conformity in accordance with Section 161 of the German Stock Corporation Act (Aktiengesetz). The declaration has been published on the Company's website ([www.epigenomics.com/en/investor\\_relations/corporategovernance/](http://www.epigenomics.com/en/investor_relations/corporategovernance/)).

## 45 INFORMATION ON OTHER TRANSACTIONS WITH RELATED PARTIES

At the reporting date, the Company's bonus payables due to members of its Executive Board amounted to EUR 189 thousand (Dec 31, 2009: EUR 205 thousand) and the liabilities due to members of its Supervisory Board amounted to EUR 38 thousand (Dec 31, 2009: EUR 66 thousand).

## 46 INFORMATION ON MATERIAL EVENTS AFTER THE END OF THE REPORTING PERIOD

For material non-adjusting events after the balance sheet date reference is made to the "Supplementary Report" section of the Group management report 2010.

## 47 CLEARED FOR PUBLICATION

These consolidated financial statements have been approved and cleared for publication by the Executive Board of the Company on February 28, 2011.

Berlin, February 28, 2011

The Executive Board

## RESPONSIBILITY STATEMENT

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

Berlin, February 28, 2011

The Executive Board

## AUDITOR'S REPORT

"We have audited the consolidated financial statements prepared by Epigenomics AG, Berlin, comprising the Group balance sheet, the Group statement of comprehensive income (Group income statement and statement of income and expenses recognized in Group equity), statement of changes in Group equity, Group cash flow statement and the notes to the consolidated financial statements, together with the Group management report for the business year from January 1 to December 31, 2010. 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."

Berlin, March 1, 2011

UHY Deutschland AG  
Wirtschaftsprüfungsgesellschaft

(Lauer)  
Wirtschaftsprüfer  
[German Public  
Auditor]

(ppa. Kulla)  
Wirtschaftsprüferin  
[German Public  
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## OUTLOOK: COMMERCIAL OPERATIONS 2011/2012

### U.S. ACTIVITIES

- Build a core commercial team in the U.S. prior to Epi *proColon*® 2.0 launch in 2011/12 with plans to significantly expand the organization post product launch
- Develop and implement strategy for U.S.-guideline inclusion and reimbursement

### EUROPEAN ACTIVITIES

- Accelerate direct product sales of Epi *proColon*® in Europe to double the number of tests sold by year-end
- Continue to build a commercial presence in key European markets and selected markets ex-Europe
- Work towards guideline inclusion and reimbursement of Septin9 tests in key markets
- Drive medical adoption of Epi *proLung*® in key markets

### SIGN-UP FURTHER LICENSING PARTNERS FOR BIOMARKERS AND TECHNOLOGIES

## OUTLOOK: PRODUCTS & PIPELINE 2011/2012

### U.S.-FOCUSED ACTIVITIES

- Finalize development of Epi *proColon* 2.0 with enhanced performance, improved handling, and shorter time to result
- Run U.S. pivotal clinical trial for Epi *proColon* 2.0 in H2/11
- Submit for FDA premarket approval (PMA) of Epi *proColon* 2.0 in the U.S. within 2011
- See PRESEPT Study and Septin9 Cost Effectiveness Analysis for the U.S. published in a peer-reviewed medical journal during H2/2011

### EUROPE-FOCUSED AND GENERAL ACTIVITIES

- Launch Epi *proColon* 2.0 in Europe within 2011
- R&D into automation and further clinical applications of our validated biomarkers (e.g. CRC Monitoring)

## DISCLAIMER

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

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## GROUP KEY FIGURES

EUR thousand (unless stated otherwise)	2009	2010
Revenue	4,260	1,787
Research and development costs	-7,349	-7,222
Earnings before interest and taxes (EBIT)	-10,218	-11,449
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-9,442	-10,307
Net loss for the year	-10,223	-11,476
Weighted-average number of shares issued (notional par value: EUR 1.00 each)	29,172,133	40,417,745
Earnings per share (basic and diluted) in EUR	-0.35	-0.28
Cash flow from operating activities	-10,629	-9,479
Cash flow from investing activities	-195	-315
Cash flow from financing activities	4,964	30,394
Cash flow total	-5,860	20,600

EUR thousand (unless stated otherwise)	Dec. 31, 2009	Dec. 31, 2010
Liquid assets at balance sheet date (incl. marketable securities)	6,136	26,369
Total equity at balance sheet date	12,084	31,295
Equity ratio in %	73.9	92.5
Total assets at balance sheet date	16,354	33,838
Share price at balance sheet date in EUR (Xetra)	3.52	2.05
Number of employees at balance sheet date	86	82

## IMPRINT

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# HIGHLIGHTS 2010

## JANUARY 2010

Quest releases ColoVantage™ Septin9 laboratory-developed test for use by doctors and patients in the U.S.A.

## FEBRUARY 2010

Colorectal cancer test Epi *proColon* is available nationwide in Germany and Switzerland

We introduce the new Epi *proLung* test at German Cancer Congress and present clinical study data

## MARCH 2010

PRESEPT prospective colorectal cancer screening study meets its primary objective

Successful capital increase – We placed all 14,697,361 new shares offered resulting in gross proceeds of about EUR 33.1 million

Japanese Patent Office grants patent for our detection technology HeavyMethyl™

## APRIL 2010

Laboratory network synlab with 55 German sites offers the Epi *proColon* test

United States Patent and Trademark Office grants mSEPT9 biomarker patent for colorectal cancer early detection

## MAY 2010

Canadian Warnex Medical Laboratories acquires LDT license to biomarker mSEPT9

The Principle Investigator of the PRESEPT Study presents study results at Digestive Disease Week in Chicago

## JUNE 2010

We successfully complete a performance evaluation study for the Epi *proLung* BL Reflex Assay

## JULY 2010

We launch Epi *proLung* BL Reflex Assay as an IVD product in Europe

ARUP Laboratories launches Septin9 laboratory-developed blood test for colorectal cancer in the U.S.A.

We retain DOCRO, Inc., for the preparation and support of the approval process for Epi *proColon* 2.0 in the U.S.A.

## AUGUST 2010

Dr. Jürgen Beck becomes our Senior Vice President Medical Affairs

## SEPTEMBER 2010

NextPharma Technologies becomes world-wide contract manufacturer for Epi *proColon*

## OCTOBER 2010

Pronto Diagnostics Ltd. becomes exclusive distributor for Epi *proColon* in Israel

DATEKS Company Ltd. becomes exclusive distributor for Epi *proColon* in Turkey

ARUP Laboratories presents data of their Septin9 laboratory-developed test at a U.S. conference: 90% sensitivity at 89% specificity

We present data for Septin9 obtained in a new independent study at two conferences in Europe and U.S.A.: 87% sensitivity at 93% specificity

We submit pre-IDE information on Epi *proColon* 2.0 to the FDA to initiate dialog on regulatory pathway and requirements with the agency

## NOVEMBER 2010

DPC LEBANON becomes exclusive distributor for Epi *proColon* and Epi *proLung* in Middle East

We initiate clinical observational study for Epi *proColon* in Germany and Switzerland

Predictive Biosciences extends its licensing agreement for our prostate cancer biomarker mGSTP1, originally signed in April 2009

## DECEMBER 2010

Warnex Medical Laboratories launches Septin9 laboratory-developed blood test in Canada

Dr. Thomas Taapken is appointed as our new CFO effective April 1<sup>st</sup>, 2011 and takes over from Oliver Schacht, Ph.D., who will leave the Company effective March 31<sup>st</sup>, 2011

# GLOSSARY

**ASSAY.** Chemical reactions that allow the detection or quantification of substances or biomarkers in samples.

**BIOCHIP.** Microarray. Technology for the simultaneous measurement of multiple biomarkers.

**BIOMARKER.** A characteristic that is objectively measured and evaluated as an indicator of normal biologic or pathogenic processes or pharmacological responses to a therapeutic intervention.

**BIOPSY.** Sample of tissue from a living body extracted for diagnostic purposes.

**BRONCHIAL LAVAGE.** Flushing of parts so of the lung with a saline solution in order to wash out cells for inspection by a pathologist.

**BRONCHOSCOPY.** Visual inspection of the airways with an endoscope.

**CE MARKING.** The CE marking is a mandatory safety mark on many products placed on the market in the European Economic Area (EEA). By affixing the CE marking, the manufacturer assures that the item meets the essential requirements of all applicable EU directives.

**CLINICAL PROOF OF CONCEPT.** Demonstration that a diagnostic or therapeutic procedure (concept) can in principle be applied with success.

**CME.** Continued Medical Education. Physicians in many countries have to continuously undertake further training within certified events.

**COLONOSCOPY.** Invasive endoscopic examination of the large colon and the end section of the small bowel with a CCD camera or a fiber optic camera on a flexible tube passed through the anus. Frequently used to diagnose colorectal cancer and other colon diseases.

**CROSS-LICENSING AGREEMENT.** Contract between two parties, that gives each party access to the patents of the other party.

**CT. COMPUTER TOMOGRAPHY.** Diagnostic imaging procedure that allows three-dimensional reconstruction of the body structure by use of serial x-ray images.

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

**DNA METHYLATION.** Natural biological process by which a chemical methyl group is added stably to cytosine, one of the four bases of the DNA. DNA methylation serves the regulation of genes and the stability of the genetic information.

**ENDOSCOPE.** Optical device for the inspection of body cavities and minimally invasive surgery. See also colonoscopy.

**ENDOSCOPY.** Visual inspection of body cavities by use of an endoscope. See also colonoscopy.

**FALSE-POSITIVE RATE.** Percentage of healthy individuals, falsely identified as sick due to the imprecision of a diagnostic procedure.

**FDA.** Food and Drug Administration. U.S. Government agency responsible for the approval of drugs and medical devices (e.g. IVD tests).

**FOBT.** Fecal Occult Blood Test. Test that detects not readily visible blood in stool, a possible indicator of colorectal cancer.

**IMMUNOLOGICAL FOBTs. FIT.** Tests, that detect human blood in a stool sample by the use of antibodies.

**INCIDENCE.** Number of new cases per year in a specific disease indication.

**IN VITRO.** In a test tube.

**IVD.** In vitro diagnostic. Diagnostic procedure that is performed on a sample retrieved from the body, e.g. in a laboratory.

**IVD PLATFORM.** One or more instruments or devices by means of which an in vitro diagnostic test can be performed and the results analyzed.

**LDT.** Laboratory-developed test. Assay for a biomarker developed within a diagnostic laboratory following certain quality standards (CLIA) that can be offered – with certain restrictions – by that laboratory in the U.S. without prior regulatory clearance by the FDA. Also known as “home-brew” test.

**METHYLATED SEPT9 DNA.** DNA of the SEPT9 gene that at specific cytosine positions shows the pattern of methyl-groups typical for colorectal cancer.

**~GSTP1.** DNA methylation biomarker GSTP1, i. e. the use of methylated DNA of the GSTP1 gene as a biomarker.

**MILESTONE PAYMENT.** One-time payment between contractual parties upon reaching important goals within a collaboration.

**MOLECULAR DIAGNOSTICS.** Diagnostics based on genetic and epigenetic information.

**MONITORING.** The tracing of potential recurrence or assessment of progression of a disease.

**~PITX2.** DNA methylation biomarker PITX2, i. e. the use of methylated DNA of the PITX2 gene as a biomarker.

**~SEPT9.** DNA methylation biomarker SEPT9, i. e. the use of methylated DNA of the SEPT9 gene as a biomarker.

**NON-EXCLUSIVE LICENSING MODEL.** Strategy for the commercialization of patents by which several licensees in a geographic region obtain the rights to use one or more patents for the same application.

**ONCOLOGY.** The branch of medicine that studies tumors (cancer) and seeks to understand their development, diagnosis, treatment, and prevention.

**PCR.** Polymerase chain reaction. Method to multiply a section of the DNA in a test tube.

**PET.** Positron Emission Tomography. Diagnostic imaging procedure, by which the distribution of a slightly radioactive substance in an organism is visualized to map biochemical and physiological processes.

**PROGNOSIS.** Prediction of how a patient’s disease will progress, and the chance of recovery.

**REAGENTS.** Chemical substances needed for the performance of an assay.

**REFERENCE LABORATORY.** Centralized diagnostic laboratory that provides testing services for routine and specialty applications.

**RNA.** Ribonucleic acid. Molecule built of similar components as DNA that mainly as an information carrier is involved in the use of genetic information to direct the synthesis of proteins. Compared to DNA, RNA is chemically and biologically considerably less stable.

**RT PCR.** Real-time PCR. PCR in which the amplification of a DNA segment is continuously measured.

**SCREENING.** The systematic and preventive mass screening of an asymptomatic population for early detection of disease.

**SENSITIVITY.** The measure of a test’s ability to accurately detect the presence of a disease. For example, a sensitivity of 90% means that out of 100 patients who actually have the disease, 90 are correctly diagnosed.

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

**TEST KIT. TEST REAGENT KIT.** A set of reagents, consumables and processing instructions necessary to perform a diagnostic laboratory test.

**TEST PANEL.** Combination of different biomarkers in a diagnostic test.

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

**VALIDATION.** Establishing documented evidence that a process or system, when operated within established parameters, can perform effectively and reproducibly and meet its predetermined specifications and quality attributes.

## CORPORATE CALENDAR

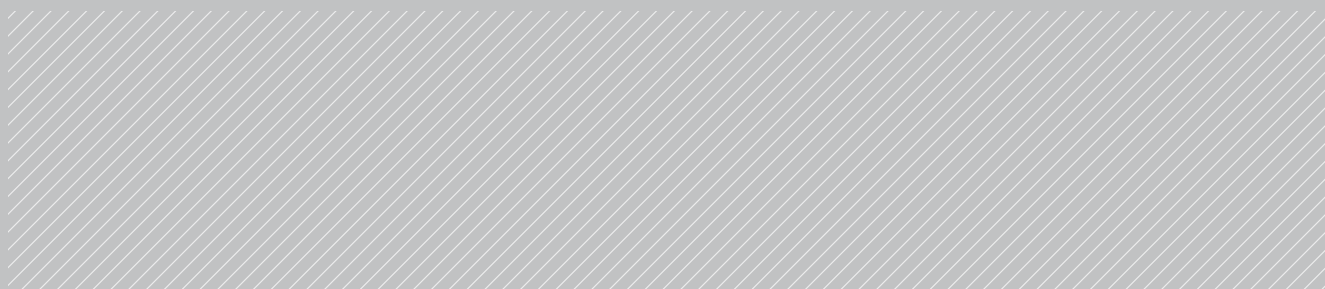
Report on Business 2010 – Annual press conference  
and Analyst meeting in Frankfurt am Main ..... Thursday, April 7, 2011

3-Month Report 2011  
January 01–March 31, 2011 ..... Wednesday, May 11, 2011

Annual General Shareholders' Meeting 2011 in Berlin ..... Tuesday, June 28, 2011

6-Month Report 2011  
January 01–June 30, 2011 ..... Wednesday, August 10, 2011

9-Month Report 2011  
January 01–September 30, 2011 ..... Wednesday, November 09, 2011



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