

Press release

## Epigenomics AG Announces Q1 2012 Financial Results and Operational Highlights

*Berlin, Germany, and Seattle, WA, U.S.A., May 9, 2012* - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, announced today its financial results for the first quarter ending March 31, 2012.

Geert Nygaard, Chief Executive Officer of Epigenomics said: "During the first quarter of 2012, we continued with U.S. registration process for our colorectal cancer (CRC) screening assay, Epi proColon<sup>®</sup> and so far submitted two of the four premarket approval (PMA) modules to the U.S. Food and Drug Administration (FDA). We've also embarked on an additional clinical study, a comparison of Epi proColon<sup>®</sup> against fecal immunochemical testing (FIT), which is necessary for our regulatory submission and are actively gearing up our pre-commercialization activities. We are very pleased that Septin9 testing was recognized and included in the Current Procedural Terminology (CPT<sup>®</sup>) coding document issued by the American Medical Association in 2012. Epigenomics remains focused on completing the FDA submission later this year and on its ultimate goal of introducing Epi proColon<sup>®</sup> as the first approved blood-based test for the early detection of colorectal cancer in the U.S. market."

### Q1 2012 Financial Results

- Revenue of EUR 0.2 million was lower than in Q1 of previous year (EUR 0.6 million) when a one-off payment was recognized for granting an option to Qiagen for a non-exclusive commercial license to Epigenomics' proprietary methylated Septin9 biomarker.
- R&D costs decreased to EUR 1.4 million (Q1 2011: EUR 1.6 million) as a consequence of the termination of early-stage research activities.
- SG&A costs dropped from EUR 1.6 million in Q1 2011 to EUR 1.4 million in Q1 this year mainly due to the restructuring measures in the marketing and sales departments.
- EBIT amounted to EUR -2.3 million, a 16.0% improvement compared with Q1 2011 (EUR -2.7 million).
- Net loss decreased by EUR 0.5 million compared to Q1 2011 to now EUR 2.3 million.
- Cash consumption was EUR 2.5 million (Q1 2011: EUR 2.8 million), which included EUR 0.3 million related to the restructuring in 2011 as well as increasing payments in connection with the activities for the FDA approval process of Epi proColon<sup>®</sup> in the U.S.
- Liquidity at the end of the period amounted to EUR 11.5 million (December 31, 2011: EUR 14.0 million).

### Operational highlights

- In January 2012, Epigenomics announced the publication of a study by Prof. Dr. Matthias Ebert (*Medical Faculty Mannheim of the University of Heidelberg*) entitled "TFAP2E-DKK4 and Chemoresistance in Colorectal Cancer" in *The New England Journal of Medicine*. In this study, involving more than 200 patients in four cohorts, Prof. Dr. Ebert and his team demonstrated that hypermethylation of the TFAP2E gene was correlated with non-responsiveness to the commonly used chemotherapeutic agent 5-

fluorouracil (5-FU). This is one of the first studies to identify a methylation-based biomarker for resistance to chemotherapy.

- In February 2012, Epigenomics announced the results from a study conducted in collaboration with Prof. Dr. Béla Molnár and his team (*Semmelweis University in Budapest, Hungary*). In the study, the blood-based detection of methylated Septin9 in CRC cases was assessed in the left and right side of the colon in 184 patients and showed 96% sensitivity and 85% specificity. Sensitivity for detection of left- and right-sided cases was 96% and 94% respectively, thus showing no significant difference between cancer detection in either side of the colon.
- Also, in February 2012, the Company announced the results from a clinical study with the Epi proLung<sup>®</sup> BL assay conducted by Prof. Dr. Manfred Dietel and his team (*Charité Universitätsmedizin Berlin, Germany*). Based on the study results, Charité announced that the assay would be introduced into its clinical practice as a routine aid in the diagnosis of lung cancer in patients with negative or suspicious cytological results. The results of this study will be presented by Prof. Dr. Dietel at the Annual Meeting of the German Association of Pathologists in Berlin in May 2012.
- In March 2012, the Company announced the results of a survey on CRC screening preferences conducted by Jennifer Taber et al. (*Department of Psychology, University of Utah, Huntsman Cancer Institute, ARUP Laboratories*). Given the performance of the ARUP Septin9 test (90% sensitive, 89% specific; Warren et al. 2011) at a price of USD 180 for this test, the survey indicated that two thirds of previously unscreened individuals would prefer a Septin9 blood test to other screening methods.
- In March 2012, Epigenomics delivered the second module of its PMA submission to the FDA, including the sections in relation to the hardware and software validation of the instrumentation needed to run the test. The Company has meanwhile responded to additional questions and remarks brought forward by the FDA. The third module, relating to analytical validation, is scheduled to be submitted still in Q2 2012 and the final module, including all clinical data, is planned to be submitted in H2 2012. A head-to-head comparative study with the goal of demonstrating non-inferiority of Epi proColon<sup>®</sup> to FIT will be an integral part of the clinical module. The design of the clinical study has been discussed with the FDA and the study has been initiated. The first study subject was enrolled into the study in April 2012.
- This year's Annual General Shareholders' Meeting (AGM) of Epigenomics AG, which took place in Berlin on May 2, 2012, voted with vast majority in favor of the proposed Supervisory Board changes regarding size (reduction from six to three members) and composition. The Supervisory Board members Ann Clare Kessler, Ph.D., and Prof. Dr. Günther Reiter were confirmed by the AGM for a further term. . Mr. Heino von Prondzynski was elected by a large majority as new member to the Supervisory Board. In its constitutive session, the newly elected Supervisory Board appointed Mr. von Prondzynski as its Chairman.

## Outlook for 2012

- At the upcoming Digestive Disease Week (DDW) in San Diego, CA from May 19-22, 2012, Epigenomics will be hosting a corporate booth. Furthermore, the results from the studies on Septin9 conducted by Prof. Dr. Béla Molnár and collaborators from the *Semmelweis University in Budapest, Hungary* will be presented in poster sessions at DDW.

- Throughout 2012, Epigenomics is and will continue to entertain active dialogs with screening guideline inclusion groups, reimbursement authorities, and has begun the process of speaking with patient advocacy constituents.
- In line with the previous guidance, product sales from IVD diagnostic products remained at a modest level during Q1 2012. Epigenomics continues to seek potential licensing and distribution partners as well as key account customers for its products. Product-derived revenue is expected to be at modest levels prior to the U.S. approval of Epi proColon®.
- A critically important strategic goal for 2012 remains securing the future of the business, since the scarcity of funds might pose a potential threat to the execution of Epigenomics' plans. The Company is currently evaluating all options available, including the possibility to secure additional financing through a capital markets transaction.

## **2012 Digestive Disease Week Poster Details and other Activities**

Epigenomics AG will be hosting a corporate booth No. 1355, Halls A-C, San Diego Convention Center, San Diego, CA, U.S.A.

### **Poster presentations:**

Session: Biomarkers of GI Cancers (P8225)

Details: Sunday, May 20, 2012, 8:00 a.m. - 5:00 p.m. PT

Location: San Diego Convention Center, Halls C-G

#### **Title: Plasma Methylated Sept9 Is a Screening Marker in Both Left- and Right-Sided Colon Cancer. Comparison to FOBT and CEA Results**

Lead Author: Professor Dr. Kinga Toth from the 2nd Department of Internal Medicine of Semmelweis University in Budapest, Hungary

Abstract No. Su1895

#### **Title: Sept9 DNA Methylation in Healthy, Adenoma and Colorectal Cancer Patients: a Comparison Between Tissue and Plasma Specimens**

Lead Author: Professor Dr. Kinga Toth from the 2nd Department of Internal Medicine of Semmelweis University in Budapest, Hungary

Abstract No. Su1892

### **Further Information**

The full 3-Months Financial Report 2012 can be obtained from our website under:

<http://www.epigenomics.com/en/news-investors/investors/financial-reports.html>

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## **About Epigenomics**

Epigenomics (www.epigenomics.com) is a molecular diagnostics company developing and commercializing a pipeline of proprietary products for cancer. The Company's products enable doctors to diagnose cancer earlier and more accurately, leading to improved outcomes for patients. Epigenomics' lead product, Epi proColon<sup>®</sup>, is a blood-based test for the early detection of colorectal cancer, which is currently marketed in Europe and is in development for the U.S.A. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

## **Epigenomics legal disclaimer**

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