epigenomics

**Press release**

# Epigenomics AG Announces Q1 2013 Financial Results and Reports on Operational Highlights

***Berlin, Germany, and, U.S.A., May 8, 2013*** - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today announced its financial results for the first quarter ending March 31, 2013.

- U.S. Food and Drug Administration (FDA) accepted Premarket Approval (PMA) submission for Epi proColon® and granted priority review status
- Revenue Q1 2013 increased 46% compared to Q1 2012
- New distribution agreement for China signed
- R&D costs decreased 27% compared to Q1 2012
- EBIT in Q1 improved by 26% compared to Q1 2012
- Net cash flow in Q1 2013 positive due to successful capital increase in January

"During the first quarter of 2013, we continued to make progress on the regulatory path towards U.S. approval of Epi proColon®. After completion of our PMA submission late last year, the FDA notified us of having accepted the application for review and has granted priority review status to it. We are very positive about this decision and continue our constructive discussion with the agency. Several inspections have already been conducted and we are excited with the progress made so far", said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. "The successful capital raise earlier this year provides us with the funds to keep working on bringing the advantages of Epi proColon®, a convenient blood-based testing for early detection of colorectal cancer, to the screening eligible population."

**Q1 2013 Financial Results**

- Q1 2013 revenues increased by 46% to EUR 355 thousand (Q1 2012: EUR 243 thousand) due to an increase in product sales (+31%) and R&D service fees.
- R&D costs decreased by 27% to EUR 1.1 million (Q1 2012: EUR 1.4 million). This was primarily attributable to the comparison study, which was terminated at the end of 2012 and significantly had affected the 2012 numbers as well as to the now fully visible effects of the company restructuring in late 2011, resulting in a reduction in headcount from 46 employees at the end of Q1 2012 to 33 at the reporting date.
- As a result of the headcount reduction SG&A costs also declined significantly by 27% to EUR 1.0 million (Q1 2012: EUR 1.4 million).
- EBIT for Q1 2013 amounted to EUR -1.7 million (Q1 2012: EUR -2.3 million) and net loss to EUR 1.7 million (Q1 2012: EUR 2.3 million) – an improvement of about 26% each.
- Net cash flow in Q1 2013 was positive at EUR 2.8 million (Q1 2012: EUR -2.6 million). A major impact on liquidity resulted from the successful capital raise, through which Epigenomics recorded a net cash inflow of EUR 4.6 million. Cash outflow from operating activities was reduced to EUR 1.8 million (Q1 2012: EUR 2.5 million).

- Liquid assets at the end of the period amounted to EUR 5.5 million (December 31, 2012: EUR 2.7 million).

**Operational highlights**

- **FDA Approval Process Progresses as Planned:** During the first quarter of 2013, the U.S. Food and Drug Administration (FDA) notified the Company of having accepted the application for U.S. approval of Epi proColon® for review and has granted it priority review status. Several inspections have already been conducted so far and the progress made is encouraging. An advisory board panel review meeting is expected to be called by the FDA as part of the review process. The Company will continue to update the public on all major developments.
- In parallel, Epigenomics continues to make all necessary efforts in the U.S. to create awareness for the test and generate support in the medical and laboratory customer communities to achieve inclusion of the test in screening guidelines and assure the availability of reimbursement by insurance carriers once the product is approved.
- **Product Sales Increasing:** Sales of Epigenomics' products are increasing gradually. While this demonstrates the growing acceptance for the Company's products in the market, it also is a result of our maturing basis of customers and distributors.
- **Agreement with BioChain for China:** In March 2013, BioChain - a leading laboratory services provider in Asian markets - has licensed Epigenomics' methylated Septin9 marker to make a blood-based assay for the convenient detection of colorectal cancer (CRC) available in China, where prevalence of CRC is on the rise and growing awareness is creating a need for early detection.
- **Successful Capital Increase**: In January 2013, Epigenomics successfully completed a capital increase by way of a rights issue and a subsequent private placement, which extended the cash runway of the Company at least until the end of 2013. A total number of 3,149,430 new shares were issued at a price of EUR 1.58, resulting in gross proceeds of EUR 5.0 million.
- **Changes to the Executive Management:** Early April 2013, Epigenomics announced the appointment of Dr. Uwe Staub to the Executive Board of the Company as Chief Operating Officer (COO), a position he has held since September of 2012 in a non-executive function. He joined the Executive Board as a second member in addition to Dr. Thomas Taapken, acting CEO and CFO of Epigenomics AG.

**Outlook**

- The Company confirms its financial prognosis for the current business year as published in its Group management report for 2012. Prior to the approval of Epi proColon® as an IVD product in the U.S. market, Epigenomics remains cautious and does not expect revenue to increase significantly compared to 2012 levels. EBIT and net loss for 2013 are expected to be significantly lower than in 2012 as the effects of the 2011 restructuring measures now become fully visible as well as due to significantly reduced R&D expenses. Net loss and cash consumption for 2013 are both expected to be in the range of EUR 6.5 to 7.5 million.
- The most significant milestone for Epigenomics will be the expected U.S. approval for Epi proColon® by the FDA in the second half of 2013, in order to start the commercialization

of the product in the most relevant market of the world. This approval will heavily affect the future value of the Company and its financial situation.
- Current financial resources are expected to fund the Company's operations at least until the end of 2013. Since it is not anticipated that the Company will be able to generate sufficient cash flows from licensing income or from product sales in the short-term, Epigenomics will continue to evaluate all strategic options available, including the possibility of a further capital increase, in order to secure its business operations beyond this term.

**Further Information**

The full Q1 Financial Report 2013 can be obtained from Epigenomics' website at:
http://www.epigenomics.com/en/news-investors/investors/financial-reports/2013.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 *pro*Colon®, 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 and testing laboratories. Epigenomics is an international company with operations in Europe and the U.S.A.

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