

## Press release

### Epigenomics AG Releases Q1 Results

**Berlin, Germany, May 11, 2011** - Epigenomics AG (Frankfurt Prime Standard: ECX) today reports its Q1 financials for the period ended 31 March 2011.

### Key Financials

		Q1/11 (unaudited)	Q1/10 (unaudited)	% change
<b>Revenue</b>	<i>in mill. €</i>	0.62	0.62	-
<b>EBIT</b>	<i>in mill. €</i>	(2.74)	(2.61)	5%
<b>Net Loss</b>	<i>in mill. €</i>	(2.89)	(2.59)	12%
		<b>At Mar 31, 2011</b>	<b>At Dec 31, 2010</b>	
<b>Liquid Assets</b>	<i>in mill. €</i>	23.49	26.37	(11%)

### Financial Highlights

- Revenue for the period of EUR 0.6 million were equal to revenues in the comparative period (Q1 2010: EUR 0.6 million).
- Operational costs remained at similar levels at EUR 3.4 million (Q1 2010: EUR 3.4 million).
- Reflecting the increasing focus on commercial activities, R&D costs decreased significantly by 15% while SG&A costs increased by around 21% relative to the comparative period.
- EBIT (operating loss) increased by 5% to EUR 2.7 million (Q1 2010: EUR 2.6 million).
- Net loss for the period amounted to EUR 2.9 million (Q1 2010: EUR 2.6 million)
- Cash and cash equivalents amounted to EUR 21.5 million as at 31 March 2011 compared to EUR 24.6 at the year end 2010.
- 2011 guidance remains unchanged:
  - Revenues should be similar or marginally higher level in 2011, with key drivers coming from license payments, R&D funding, sales in Europe with growing royalty income coming from partner Septin9-based tests sales worldwide. Main cost drivers are sales and marketing activities and the development of Epi *proColon* 2.0.
  - Cash consumption is expected to remain around EUR 10 million - 12 million and should decrease gradually going forward as it is countered by positive cash flow from operations.

### Operational highlights

- Epigenomics' major focus for the period was furthering the pre-launch and operational efforts in advance of a potential FDA approval of Epi *proColon* 2.0 in the U.S.
- In Q1 2011, the Company completed the feasibility phase of its second-generation test, Epi *proColon*® 2.0 being developed simultaneously for the U.S. market and as a second-generation product for the European and ROW markets. Epigenomics has now entered into the development and verification phase. Clinical validation studies are planned for H2 2011.
- In February 2011, Epigenomics met the FDA to discuss the improved product concept, its intended use and clinical data required to support an application for its commercialisation. Epigenomics' application for Pre-market Approval is on track for submission by year-end.

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- Also in February 2011, Epigenomics has signed a collaboration agreement with QIAGEN for the development and commercialization of a colorectal cancer blood test. QIAGEN received a 2-year option on a worldwide non-exclusive commercial license and a research license for the <sup>m</sup>SEPT9 biomarker and certain DNA methylation technologies for the colorectal cancer detection in blood.
- In March 2011, Epigenomics' partner Quest Diagnostics Inc received approval for its Septin9 colorectal cancer blood test ColoVantage™ from the New York State's Department of Health. This increases the market availability of ColoVantage™ to the whole of the USA.

## Post reporting period events

- In April 2011, Dr. Thomas Taapken was appointed as Epigenomics' new CFO. Dr. Taapken joined from publicly listed Biotie Therapies, Turku, Finland. He has significant experience in transactions including acquisitions, mergers, divestitures and public offerings.
- Also in April 2011, Noel Doheny was appointed as Chief Executive Officer of Epigenomics' US subsidiary and will spearhead the activities around the Company's US commercial strategy. Mr. Doheny has 30+ years of experience in the field of diagnostics, with over 20 years in senior management of companies including Affymetrix and QIAGEN.
- In May 2011, Life Technologies agreed to supply Dynabeads® MyOne™ SILANE and associated reagents for Epigenomics' second generation colorectal cancer blood test Epi *pro*Colon® 2.0. These magnetic particles for DNA capture together with further modifications of the test, lead to a substantially improved clinical performance of the Epi *pro*Colon® 2.0 assay with 91% sensitivity at 87% specificity in a recent feasibility study.
- Also in May 2011, a health economic analysis performed by Dr. Uri Ladabaum of Stanford University and further scientists was presented at Digestive Disease Week 2011. In the study, the group comes to the conclusion that screening for colorectal cancer using Septin9 tests is a medically beneficial and health economically cost-effective strategy when it addresses the currently unscreened population in the U.S.. Patient behavior studies are underway at the University of Utah and the Huntsman Cancer Institutes in collaboration with ARUP Laboratories, Salt Lake City, UT, U.S.A., that investigate the impact of blood tests on patient acceptance of colorectal cancer screening and their potential to increase overall screening compliance. First results of the study indicated that the majority of the currently unscreened patients would take a Septin9 test for screening.
- In May 2011, Quest Diagnostics reported royalty-bearing sales of approximately 1,500 ColoVantage™ tests in Q1 2011. With approximately 4,000 tests performed in 2011 by the end of April, ColoVantage™ shows rapidly increasing adoption by physicians and robust performance in the clinical routine in the U.S.A.

Geert Nygaard, Chief Executive Officer of Epigenomics said: "As discussed at time of publication of our Full Year results, our primary focus in 2011 is to further establish the marketing and sales operations of the business and to emphasize the positioning of Epigenomics as a commercially-driven cancer molecular diagnostics company. We are also looking forward to the launch of our second generation Epi *pro*Colon® 2.0 test in Europe later this year and, as a key focus of our activities, to complete all necessary steps allowing us to submit the product for FDA review before the end of the year. Before a potential US approval in 2012, our 2011 revenues will be similar to last year's and we will continue to keep a strong control of costs, as we focus on our commercialization efforts."

The full 3-Months Financial Report 2011 is available for download at

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

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The Company's management will be available for investor meetings at the upcoming BioEquity 2011 meeting in Paris on 23-24 May 2011.

-Ends-

## **Notes to the Editor**

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## **Conference Details**

### **BioEquity Europe 2011**

May 23–24, 2011 • Paris, France

[www.ebdgroup.com/bee](http://www.ebdgroup.com/bee)

## **About Epigenomics**

Epigenomics ([www.epigenomics.com](http://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 including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

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