

Press release

## Epigenomics AG Presents Mid-Year Results and Announces Restructuring Plan Heightening Focus on the Key U.S. Market

Focus to be on near term product opportunities and key markets; streamlining of operations

**Berlin, Germany, and Seattle, WA, U.S.A., August 10, 2011** - Epigenomics AG (Frankfurt Prime Standard: ECX), the cancer molecular diagnostic company, today announced financial results for the second quarter and first half of 2011 ending June 30, 2011. The Company also released plans to restructure its organization, with the goal of maximizing shareholder value through an increased focus on the key U.S. market.

Epigenomics' second generation blood test for colorectal cancer ("CRC") detection, Epi *proColon*® 2.0, remains on track to be submitted to the U.S. Food and Drug Administration ("FDA") for Premarket Approval ("PMA") in Q4 2011. Epi *proColon*® 2.0 is specifically designed to meet FDA requirements and show improved clinical performance, simplified handling and better automation capabilities compared to the currently marketed version of the product. Crucially, Epi *proColon*® 2.0 prototypes demonstrated higher test sensitivity at comparable specificity compared to earlier versions, which is a key differentiator and should underpin a successful launch in the U.S.

Following a strategic review of the opportunity presented by Epi *proColon*® 2.0, plans for developing a commercial operation in the U.S. are being accelerated. The Company will relocate its U.S. headquarters from Seattle, WA, to the East Coast in 2012 and step up efforts to prepare for a commercial launch. Early stage product and technology research will be discontinued and clinical research scaled down. Going forward, European commercialization will be mainly focused on key accounts. Epigenomics will reduce its total workforce by approximately 39 employees targeting a company size of 45 employees by year-end 2011.

Geert Nygaard, Chief Executive Officer of Epigenomics said: "Given the significant opportunity with the improved test, our efforts are now focused squarely on the approval and launch of our second generation Epi *proColon*® product, particularly in the U.S. As a result, we have brought forward the necessary operational changes to prepare for our U.S. product launch and focus the resources of the company on this key goal."

### Key Financials H1 2011

		<i>H1 2011 (unaudited)</i>	<i>H1 2010 (unaudited)</i>	<i>% change</i>
<b>Revenue</b>	in mill. €	0.99	0.97	1%
<b>EBIT</b>	in mill. €	(5.7)	(5.4)	-5%
<b>Net Loss</b>	in mill. €	(5.9)	(5.4)	-10%

		<i>At Jun 30, 2011</i> <i>(unaudited)</i>	<i>At Dec 31, 2010</i> <i>(audited)</i>
<b>Liquid Assets</b>	in mill. €	20.7	26.4
<b>Employees</b>		84	82

- Revenue for the half year of EUR 0.99 million (2010: EUR 0.97 million) generated from out-licensing and partnering activities and increasingly, from product sales
- Costs of sales amounted to EUR 0.25 million (H1 2010: EUR 0.31 million); gross margin improved to 75% from 68% in H1 2010
- Operating cost of EUR 6.6 million comparable to H1 2010 (EUR 6.6 million)
- R&D costs significantly decreased from EUR 3.6 million in H1 2010 to EUR 3.0 million in the reporting period
- Operating (EBIT) loss increased marginally by 5% to EUR 5.7 million (H1 2010: loss of EUR 5.4 million)
- Net loss for H1 2011 amounted to EUR 5.9 million (H1 2010: EUR 5.4 million)
- Cash consumption increased from EUR 4.4 million in H1 2010 to EUR 5.7 million in the reporting period due to a significant non-recurrent cash inflow from a collaboration partner in H1 2010 with no comparable inflow in H1 2011
- Cash and cash equivalents at June 30, 2011 were EUR 20.7 million (December 31, 2010: EUR 26.4 million)

## Update on Products

Patient preference for a blood-based test for CRC is confirmed by the continued fast adoption of ColoVantage™, a laboratory-developed Septin9 blood test aiding the detection of CRC, which is offered in the U.S. by Epigenomics' partner, Quest Diagnostics. ColoVantage™ testing volume continued to show strong growth during Q2 2011. With this positive backdrop, Epigenomics is increasingly excited by the potential for an FDA-approved IVD version of the test with broader claims for more widespread adoption.

The development of the Company's second generation blood test for CRC, Epi *proColon*® 2.0 for the U.S. and European markets remains on track. The Company has planned two key studies: a case control study with about 200 patient samples for CE-marking of the product in Europe followed by the pivotal clinical trial for FDA approval with prospectively collected blood samples of a screening cohort of about 8,000 subjects. The studies are expected to be finalized in Q4 2011. The launch of the CE-marked version of the product in Europe and a submission to the FDA for PMA review are planned before year-end 2011. In parallel, Epigenomics' licensee Abbott is working towards U.S. regulatory approval of their Septin9-based blood test for CRC screening.

For the European market, Epigenomics' second generation test is being validated for use with the Roche "LightCycler® 480" and Life Technologies' "AB 7500 Fast" real-time PCR systems. For the U.S. market, Epi *proColon* 2.0 is designed for use with Life Technologies' "AB7500 Fast Dx" real-time PCR instrument. An agreement with Life Technologies granting Epigenomics access to this FDA-cleared, real-time PCR instrument for the U.S. market was signed in July 2011.

With the U.S. being Epigenomics' key strategic market for CRC screening based on Septin9 blood tests going forward, the Company and its partners have intensified the dialogue with health care providers,

payers and further stakeholders. Guided by this dialogue, Epigenomics and its partners have embarked on numerous activities targeting the timely provision of evidence demonstrating the test's accurate clinical performance, cost-effectiveness, and ability to increase screening compliance.

Based on already generated data with prototype tests, the planned clinical validation studies with Epi *proColon*® 2.0 are expected to provide improved performance data. Already, cost-effectiveness has been clearly demonstrated in a recent study presented at this year's "Digestive Disease Week" conference in Chicago. The study concluded that screening for CRC using Septin9 tests was a medically beneficial and cost-effective strategy from the health economical perspective when addressing the currently unscreened population in the U.S.

Results from several surveys on patient behavior in the U.S. and Europe have demonstrated that blood tests for CRC screening have the potential to encourage more people to participate in screening. Sponsored by Epigenomics or its U.S. partners ARUP Laboratories and Quest Diagnostics, the studies were conducted by the University of Utah and the Huntsman Cancer Institute, The Colorectal Cancer Alliance, and europacoln. In these surveys, more than two out of three participating screening-eligible patients indicated that they would prefer a blood test and would be more likely to adhere to screening guidelines if such a test was offered as a screening method.

To further strengthen its position in the U.S. market, Epigenomics has started building a dedicated commercial team. This effort is being headed up by Noel Doheny, who recently joined Epigenomics as CEO of the Company's U.S. subsidiary Epigenomics Inc.

European market penetration of Epi *proColon*®, which currently addresses the self-payer segment in selected EU countries, continues to make progress, albeit at a moderate pace. Revenue derived from the first generation Epi *proColon*® test in the German and Swiss self-payer market remained on a low level and developed slower than expected. The slow market adoption emphasizes the importance of obtaining reimbursement of the test in key markets going forward, which is also a focus of the Company's accelerated U.S. market development plans.

Epigenomics continues working towards establishing its second product, Epi *proLung*®, as an aid in the diagnosis of lung cancer. To this end, Epigenomics is sponsoring investigator-driven studies directed at demonstrating the benefits of Epi *proLung*® in clinical practice. These studies are progressing as planned and are a key prerequisite for generating meaningful revenues from this product in the years to come.

## **Organizational Development & Restructuring**

With the U.S. product development of Epi *proColon*® 2.0 fully on track, the Company will increase its focus on this key market. As European sales in the self-payer segment are ramping up slower than expected, the Company will adapt its marketing and sales strategy to a key account approach. The Company – directly and increasingly through distributors – will mainly target payers and large institutional customers with deep reach into the healthcare system in select markets in Europe and beyond. At the same time, R&D efforts will be concentrated on existing and near term product opportunities. The planned restructuring measures are expected to further sharpen the focus of the organization. Specifically, the Company will implement the following key changes to the organization:

- From 2012 onwards, the U.S. headquarters will be relocated to a new business site, strategically located on the East Coast, as the nucleus for building and growing the U.S. commercial operations while retaining key Seattle staff in a satellite office.
- Direct commercialization in the European self-payer segment will be de-emphasized and a key account approach for Epi *proColon*® and Epi *proLung*® directed towards institutions such as healthcare providers, health insurers and further large institutional customers will be implemented to generate sustainable revenues in the mid to long term. The European sales and marketing team will be adjusted accordingly.
- Early stage product and technology research will be discontinued and clinical research scaled down and remaining R&D resources will be concentrated on second generation product development and support of existing products.
- Biomarker discovery and development capabilities will be maintained for collaborations with pharmaceutical companies in the area of personalized medicine.
- Further cost savings will be realized through scaling down administration and management in proportion to new company structure.

These measures are expected to be fully implemented by the end of 2011 and to be mainly reflected in the annual accounts of 2011. The Company intends to reduce its total workforce from 84 employees at the end of H1 2011 to approximately 45 employees by year-end 2011. Starting in 2012, the company expects to further grow its U.S. commercial operations to prepare for an Epi *proColon*® 2.0 product launch after the potential Premarket Approval by the FDA. Going forward, Epigenomics expects to realize annual savings on a comparable operational cost basis of approximately EUR 3.5-4.0 million. One-time restructuring costs are expected to be in the range of EUR 3 million, of which approximately EUR 0.7 million will not affect liquidity. The measures in connection with the restructuring plan will accelerate cash outflows in 2011 and the Company expects to end the year with around EUR 13 million in liquid assets. However, net cash outflows in 2012 will decrease accordingly. The management estimates that the existing liquid assets will fund the Company's operations well into 2013.

An updated financial guidance reflecting the full effects of the restructuring and cost saving measures will be provided at the time of the 9-Months Financial Report.

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## Conference call for press and analysts

The full 6-Months Financial Report 2011 can be obtained from Epigenomics' website at:  
<http://www.epigenomics.com/en/news-investors/investors/financial-reports.html>

Epigenomics' management will host a conference call and an audio webcast at 3pm CET/9am ET today, Wednesday 10th August 2011. The dial-in numbers for the conference call are:

Dial-in number (within Germany):	+49 30 86871428
Dial-in number (within the UK):	+44 203 3679216
Dial-in number (within the U.S.):	+1 408 9169838

Participants are kindly requested to dial in 10 minutes prior to the start of the call.

The presentation accompanying the conference call and dial-in details for the audio webcast will be available on Epigenomics' website: <http://www.epigenomics.com/en/news-investors.html>

A webcast of the conference call will be provided on Epigenomics' website subsequently:  
<http://www.epigenomics.com/en/news-investors.html>

## 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 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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