Press release

Epigenomics AG Announces First Half 2012 Financial Results and Reports Operational Highlights

Berlin, Germany, and Seattle, WA, U.S.A., August 8, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today announced its financial results for the first half and second quarter ending June 30, 2012.

"During the second quarter of 2012 we maintained our focus on taking the remaining steps necessary to gain U.S. regulatory approval for Epi proColon®. The head-to-head comparative study against fecal immunochemical testing is progressing according to plan and is expected to be completed in the fourth quarter, thereby enabling us to finalize our FDA Premarket Approval (PMA) application.", said Geert Nygaard, Chief Executive Officer of Epigenomics AG. He continued: "We are also seeing progress in terms of commercialization. In June, we signed an additional LDT licensing agreement with U.S. based Companion Dx Reference Lab. The availability of a specific CPT-code for Septin9 testing is a further essential prerequisite for obtaining reimbursement once the coding reform for laboratory diagnostics in the U.S. will enter into force at the beginning of 2013. In addition, the decision of Swiss Life in France to reimburse up to 50% of the cost of the Septin9 blood based test for early detection of colorectal cancer as part of a preventive health program further validates our recently implemented commercialization approach in Europe by which we collaborate closely with key players in the healthcare system."

Q2 / H1 2012 Financial Results

- Revenue in Q2 2012 of EUR 156 thousand was significantly lower than the comparable number for the previous year (Q2 2011: EUR 364 thousand), as no R&D income was recognized, as well as product sales and licensing income lagged behind their comparables for the previous year.
- As expected, R&D costs increased notably in Q2 2012 from EUR 1.4 million in Q2 2011 to EUR 2.1 million. This is mainly due to the start of the FIT comparison study and increased activities towards the FDA approval process. In addition, capitalization of R&D expenses as development costs of EUR 302 thousand in Q2 2011 have to be considered in the comparison to last year's numbers since R&D expense did not impact the profit and loss statement at that time.
- SG&A costs decreased year-over-year from EUR 1.8 million in Q2 2011 to EUR 1.5 million in Q2 2012, primarily due to restructuring measures implemented in 2011 in the marketing and sales departments.
- EBIT for Q2 2012 amounted to EUR -3.4 million - a decrease of 15.7% compared to Q2 2011 (EUR -3.0 million). EBIT for the first six months of 2012 was on last year's level at EUR -5.7 million (H1 2011: EUR -5.7 million).
- Net loss for Q2 2012 amounted to EUR 3.4 million (Q2 2011: EUR 3.0 million) and for H1 2012 to EUR 5.7 million (H1 2011: EUR 5.9 million).
- Cash consumption in H1 2012 was EUR 5.0 million (H1 2011: EUR 5.8 million), which included increasing payments in connection with the activities towards the FDA approval process of Epi proColon®.

- Liquidity at the end of the period amounted to EUR 9.1 million (December 31, 2011: EUR 14.0 million).

Operational highlights

- **FIT comparison study:** In the second quarter of 2012, Epigenomics started a head-to-head comparative study of Epi proColon® to fecal immunochemical testing (FIT). This study will be an integral part of the fourth and last module of the PMA submission to be filed with the U.S. FDA. The goal of this study is to demonstrate non-inferiority of Epi proColon® to FIT. In April 2012, the Company announced the inclusion of the first study subject and the trail progressed significantly since then. It is anticipated that this study will be completed in the fourth quarter of 2012.
- **U.S. regulatory process for Epi proColon®:** In June 2012 the third module of the PMA application, relating to analytical validation of the test, was submitted to the FDA. The final module, containing all clinical data, is scheduled for submission before the end of the current year, which will then formally complete Epigenomics regulatory submission documentation.
- **Licensing agreement for Septin9 with Companion Dx:** In June 2012, Epigenomics announced the signature of an additional licensing agreement for its proprietary DNA methylation biomarker Septin9 with Companion Dx Reference Lab, Houston, TX, U.S.A. Under the terms of the agreement, Companion Dx obtained rights to establish and commercialize a blood-based LDT for the detection of colorectal cancer using methylated Septin9 as a biomarker. Epigenomics is entitled to double-digit royalties on test sales. With this licensing agreement, Epigenomics continues to execute on its U.S. commercialization strategy of creating market acceptance for Septin9 testing well ahead of the launch of a proprietary diagnostic product approved by the FDA. The growing uptake of the Septin9 assay through LDT licensees is encouraging. The agreement with Companion Dx complements the already existing LDT agreements with Quest Diagnostics, ARUP Laboratories and Gamma-Dynacare Medical Laboratories (formerly: Warnex Medical Laboratories) in North America. The availability of a specific CPT-code for Septin9 testing is a further essential prerequisite for obtaining reimbursement once the coding reform for laboratory diagnostics in the U.S. will enter into force at the beginning of 2013.
- **Reimbursement of the Septin9 blood based colorectal cancer test by Swiss Life in France** (after the end of the reporting period): In July 2012, Epigenomics announced that Swiss Life, France's third largest private health insurance company, will recommend the Septin9 blood based test for the early detection of CRC to their policyholders as part of their optional preventive health program. As the first French insurance company, Swiss Life is now offering up to 50% reimbursement of the Septin9 test at a cost of EUR 95. French Social Security does not currently cover the Septin9 test. Epi proColon® 2.0 CE has recently become commercially available in France so Epigenomics is now able to expand into the French market.

Outlook for 2012

- Throughout 2012, Epigenomics will continue to entertain an active dialog with screening guideline inclusion groups, reimbursement authorities, and has begun the process of speaking with patient advocacy constituents, predominantly in the US. Simultaneously,

the Company is extending its network in the medical expert community in order to gain support for its product by key opinion leaders in the field. Epigenomics has also started preparations for an FDA advisory panel meeting, which the Company expects to become part of the review process by the FDA.

- In line with the previous guidance, own product sales from IVD diagnostic products remained at a modest level during H1 2012. Epigenomics continues to seek potential licensing partners in the United States and distribution partners as well as key account customers in the rest of world. However, own product-derived revenues are expected to remain at modest levels prior to the U.S. approval of Epi proColon® by the FDA.
- EBIT and net loss are expected to narrow in 2012 in comparison to 2011 due to the effect from the restructuring plan implemented in 2011. However, a critically important strategic goal for 2012 remains to secure the future of the business. The necessity to invest into the regulatory related activities ahead of completion of the FDA submission will force the Company to secure additional resources to execute Epigenomics' plans. The Company is currently evaluating all strategic options available, including the possibility a capital markets transaction.
- Overall, the Company remains committed to completing the FDA submission later this year and on its ultimate goal of introducing Epi proColon® as the first approved blood-based test for the early detection of colorectal cancer into the U.S. market.

Further Information

Conference call for press and analysts

The full 6-Months Financial Report 2012 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 8th August 2012. The dial-in numbers for the conference call are:

Dial-in number (within Germany):	+ 49 69 247 501 899
Dial-in number (within the UK):	+44 203 147 4862
Dial-in number (within the U.S.):	+1 212 444 0296

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

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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 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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