**Press release**

# Epigenomics AG Announces Q3 Financial Results and Operational Highlights

*Main focus for Q4: to successfully file PMA with the FDA in the US and simultaneous re-launch in Europe with dramatically improved Epi proColon® 2.0 CE test*

***Berlin, Germany, and Seattle, WA, U.S.A., November 9, 2011*** - Epigenomics AG (Frankfurt Prime Standard: ECX), the cancer molecular diagnostic company, today announced financial results for the third quarter and nine months ending September 30, 2011.

After the announcement of a strategic restructuring in the second quarter of the year, Epigenomics has been working to complete the clinical development of Epi proColon® 2.0 and has been preparing for the planned submission of its PreMarket Approval (PMA) regulatory filing with the U.S. Food and Drug Administration (FDA).

Geert Nygaard, Chief Executive Officer of Epigenomics said: "Our third quarter performance has been set against a backdrop of turbulent financial markets and operational challenges with respect to the restructuring and reverse stock split. However, within the Company, we have made significant progress with the launch of our second generation product Epi proColon® CE in Europe and we are very pleased with the positive clinical results we have generated from our validation studies for this new product. We look forward to sharing the top-line results from our U.S. pivotal study later this year followed by our subsequent PMA filing with the FDA. Ultimately, we hope to be in a position to have the first FDA approved blood screen for colorectal cancer on the U.S. market."

**Key Financials Q3 2011 and 9M 2011**

| | | *Q3 2010 (unaudited)* | *Q3 2011 (unaudited)* | *9M 2010 (unaudited)* | *9M 2011 (unaudited)* |
|---|---|---|---|---|---|
| **Revenue** | EUR 000 | 363 | 257 | 1,336 | 1,242 |
| **EBIT** | EUR 000 | -3,010 | -5,032 | -8,443 | -10,748 |
| **Net Loss** | EUR 000 | -2,974 | -4,816 | -8,358 | -10,717 |
| | | | | | |
| | | | *Sept 30, 2011 (unaudited)* | | *Dec 31, 2010 (audited)* |
| **Liquid Assets** | EUR 000 | | 17,386 | | 26,369 |
| **Employees** | | | 77 | | 82 |

**Financial Highlights**

- Revenue for the nine months decreased to EUR 1.2 million (9M 2010: EUR 1.3 million) and was generated from product sales as well as from collaborations and licensing agreements
- Operating costs of EUR 12.2 million (9M 2010: EUR 10.2 million) were impacted by the one-time restructuring costs of EUR 2.8 million
- R&D costs significantly decreased by approx. 21% to EUR 4.1 million (9M 2010: EUR 5.2 million)
- SG&A costs increased significantly by nearly 16% to EUR 4.7 million (9M 2010 EUR 4.1 million) due to the increased market preparatory expenditure for the US market launch
- Operating loss (EBIT) increased to EUR10.7 million (9M 2010 loss EUR 8.3 million) driven mostly by the one-off restructuring costs
- Net loss for the period was EUR 10.7 million (9M 2010: EUR 8.4 million)
- A 5:1 reverse split of the share capital was implemented during Q3 which was approved at the Annual General Shareholders´ Meeting in June 2011. With the reverse split, the company now has 8,818,417 shares outstanding (H1 2010: 44,092,085 shares)
- Short-term liquidity as at September 30, 2011 was EUR 17.4 million, a decrease of EUR 9.0 million from EUR 26.4 million reported at the year-end 2010.

**Q3 2011 Overview**

Despite the challenging market environment and impact of the Company's restructuring, the Company has made significant progress with respect to the launch of its improved second generation Epi proColon® test into specific European countries based on very positive data generated in a case-controlled clinical validation study in September. The new test accurately identified 95% of the cancer cases (i.e. 95% sensitivity) at a specificity with respect to colorectal cancer of 85%. Most importantly, for stages I and II cancers, for which therapeutic interventions have the greatest likelihood of treatment success, the combined sensitivity was 91%. These results demonstrate a very significant improvement over the performance of the Company's first generation product. The successfully completed validation study performed in Europe enabled the start of the second validation study in the U.S. in September 2011 which is required for PMA submission to the FDA. This pivotal U.S study is being conducted at three external laboratories which will test blood samples from a study cohort of approximately 8,000 subjects and is expected to be completed before the year-end.

The Company recently presented the results of the first clinical validation study at the United European Gastroenterology Week meeting in Stockholm in October 2011 and announced the upcoming launch of its second generation product in Europe. To meet European market requirements, the alternative interpretative algorithm will be used with Epi proColon® 2.0 CE in Europe. This algorithm is optimized for specificity for cancer and has resulted in the test identifying more than 80% of the colorectal cancer cases while minimizing the number of false positive test results to 1%.

Earlier in the period, Epigenomics announced the results of surveys in the U.S. and Europe showing that the vast majority of patients would prefer blood tests over conventional methods for colorectal cancer screening.

During the third quarter, Epigenomics also readjusted its commercial strategy in the European markets, targeting payers and large institutional customers deeply entrenched in the healthcare system, including distributors of selected European countries. The launch of Epi proColon® 2.0 as a CE-marked product in

Europe is a means to re-enter the market with a significantly stronger value proposition to clinicians and patients.

The strategy review preceding the implemented restructuring also highlighted the increased importance of the U.S. market in the Company's plans. Licensee, Quest Diagnostics, Inc., has been the first to demonstrate the commercial opportunity of colorectal cancer blood tests in the U.S. and has demonstrated very encouraging volume growth since it started promoting its laboratory-developed Septin9 test, under the brand name ColoVantage in Q1 2011.

R&D efforts are being focused on existing and near-term product opportunities, with longer term projects being put on hold for the time being.

The restructuring measures that are being implemented up to the year end and into 2012 include:

- reduction of the employee number from 84 at the end of H1 2011 to a target size of 45 by the end of Q1 2012;
- implementation of a new commercialization approach in Europe, mainly targeting key accounts for Epi proColon® 2.0 CE and Epi proLung® aimed at institutions such as healthcare providers, health insurers and other large institutional customers;
- scale down direct marketing and sales efforts in the European self-payer segment;
- discontinuation of all early-stage and technology research activities;
- relocation of the US headquarters to the U.S. East Coast (2012 onwards).

The corporate restructuring mostly impacted the Q3 financial results but it will also impact Q4 results, albeit to a lesser extent. Going forward, Epigenomics expects to benefit from annual savings on a comparable operational cost structure of approximately EUR 3.5-4.0 million.

The main focus of the organization has remained on the development of the second generation blood-based Epi proColon® test with the goal to file a PMA with the FDA by the end of the year and the recent launch in Europe as a CE-marked IVD product. Epigenomics continues to work alongside its partners including Abbott Molecular, Qiagen and Sysmex to assist them in the commercialization of their own Septin9-based colorectal cancer tests.

**Outlook**

The most important milestone remains the filing of the PMA for the Epi proColon® 2.0 test with the FDA in the United States. In order to be successful, the Company needs first to complete the ongoing prospective clinical validation study and compile all necessary supplemental material.

The demonstrated success that Epigenomics' partner Quest Diagnostics has experienced in just over six months with its own version of the Septin9 test, ColoVantage™, underlines the management's view that the U.S. market should be the primary focus.

In Europe, where sales initially have been slower, the management believes that the re-entry into the market with a new strategy and a significantly improved second generation product will lead to a more sustainable revenue stream going forward.

Finally, on the financial side, the management expects revenues for the full year 2011 to be in the same range as in 2010. The combination of Epi proColon® 2.0 CE IVD kit sales in Europe, growing royalty income from partners' worldwide sales of Septin9-based tests, and income from prospective additional licensing fees from partners are expected to be the key drivers of revenue growth going forward. With respect to costs, it is expected that the restructuring will continue to have a residual impact in the fourth quarter and in 2012 until the restructuring and relocation of the US operations to the East Coast are completed.

**-Ends-**

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**Further Information**

The full 9-Months Financial Report 2011 can be obtained from Epigenomics' website at:
http://www.epigenomics.com/en/news-investors/investors/financial-reports.html

**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®, 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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