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Press release

Epigenomics AG: Full Year Results for the Year Ended 31 December 2011

- Development of second generation product completed, PMA filing process initiated in the US
- Over 26,000 Septin9 laboratory-developed tests sold by North American partners in 2011
- Tight fiscal control after implemented restructuring in 2011

Berlin, Germany, and Seattle, WA, U.S.A., March 23, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today announced its full year results for the year ended 31 December 2011 and provided an outlook for 2012.

Geert Nygaard, Chief Executive Officer of Epigenomics commented: "2011 has been a challenging year for Epigenomics, but also a year where we have made significant progress in becoming a commercially-oriented, product-driven growth company. We are pleased to report the start of the regulatory process for our key product, Epi proColon® in the US, with two of the four PMA modules submitted to the FDA. The protocol for our Septin9 comparison study against FIT is in place and we are eager to get it underway so that we can file our final PMA module before year end. It remains the company's ultimate goal to introduce our test to the largest commercial market for molecular diagnostic products. We are encouraged to see that there is a growing market for our test in the U.S. with more than 26,000 Septin9 tests being performed in 2011 by our license partners."

2011 Financial Results

- Revenue of EUR 1.4 million (2010: EUR 1.8 million) generated from product sales of Epi proColon® kits, royalty payments, licensing income and partnering activities; decrease in revenues compared to 2010 is mainly due to lower collaborative income;
- Epi proColon® European product sales were up by 38% compared to 2010;
- Net loss widened by 36% to EUR -15.6 million (2010: EUR -11.5 million), mainly driven by one-time charges in connection with implemented restructuring measures and goodwill amortization;
- EUR -5.5 million of the net loss was attributable to the restructuring measures and to the amortization of the goodwill, EUR -4.6 million were non-cash effective costs;
- Cash consumption increased to EUR -12.2 million compared to EUR -10.3 million in 2010, mostly by one-time effects attributable to the restructuring;
- Cash and cash equivalents at year end 2011 were EUR 14.0 million (2010: EUR 24.6 million);

Outlook for 2012

- 2012 financial guidance: EBIT and net loss for 2012 to be at significantly lower levels than in 2011, in the range of EUR -9.5 and -11.0 million;
- Cash consumption in 2012 expected to be in the range of EUR -9.5 to -11.0 million;
- Epigenomics will diligently explore all viable strategic options, including the option of securing additional financial resources on the capital markets

Operational Highlights in 2011 and 2012 YTD

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Development completion and roll out of Epi proColon® 2.0 test: Epigenomics completed the development of its second generation blood-based Epi proColon 2.0® test, the first world-wide patient-friendly blood test for the early detection of colorectal cancer.

The Company performed a clinical validation study of Epi *pro*Colon® 2.0 CE in Europe and presented positive results at the *United European Gastroenterology Week Meeting* in Stockholm in October 2011. The test accurately identified 81% of the cancer cases at 99% specificity. Based on the very positive clinical results, Epigenomics subsequently launched the product in Europe. Results from a separate study in 184 study participants, which was conducted in collaboration with Semmelweis University in Budapest, Hungary, highlighted that the Septin9 biomarker detects colon cancer equally in both sides of the colon, which is a competitive advantage to presently used screening tests.

Epi proColon® pivotal clinical validation study: Epigenomics conducted a prospectively designed clinical validation study in the U.S. The results announced in December confirmed the results in a previously conducted academic study in a true screening population by showing 68% sensitivity at 80% specificity. Following discussions with the FDA, it has been confirmed that data from the U.S. clinical validation study could be assessed as part of a Modular Premarket Approval (PMA) review process. The first two PMA modules have already been submitted to the FDA, with the third and fourth modules to be submitted in the second quarter and second half of 2012 respectively. The FDA has furthermore requested Epigenomics to perform a head-to-head comparative study for colorectal cancer detection through comparison with fecal immunochemical testing (FIT) for the purpose of demonstrating non-inferiority of Epi proColon® to FIT. This study will become an integral part of the PMA submission. After consultation with the FDA, we have meanwhile agreed on the protocol for the study. Site identification and recruitment is currently ongoing with the aim of evaluating 100 cancer cases (post colonoscopy) and 200 asymptomatic average risk individuals (pre-colonoscopy). We will work diligently to complete this study and file the clinical, and last, module of our PMA filing still in 2012.

Pre-marketing activities in the U.S.: Although reimbursement levels are still to be determined, Septin9 was included in the new AMA coding document (CPT code 81401), which will be introduced in 2013. Epigenomics is also undertaking steps to increase awareness of the test among KOLs and the patient population. During the period Epigenomics and its partners announced the results of several 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.

Partnering activities: Overall in 2011, Epigenomics' LDT partners sold over 26,000 tests in North America. Quest, ARUP laboratories and Warnex in Canada (now part of Labcorp), continue to make their laboratory-developed Septin9 tests (LDT) available in North America. In 2011, Quest received approval of their test version, ColoVantage™, by the New York State's Department of Health and demonstrated encouraging sales volume growth since it started actively promoting the test across the U.S. ARUP presented the results of their clinical validation study at the *Association of Molecular Pathology Meeting* in November 2011. ARUP's Septin9 LDT assay detected 90% of the colorectal cancer cases at 88% specificity. In February 2011, QIAGEN signed a two-year option agreement to develop and commercialize a colorectal cancer blood test based on the Septin9 biomarker and certain DNA methylation analysis technologies. Abbott is also continuing their development efforts towards US regulatory submission of its own IVD Septin9 product based on a license from Epigenomics.

European marketing activities: The company's revised European marketing activities of targeting key European accounts is on-going. The test is now available through selected laboratories in Germany at a price of EUR 99 to the customer.

Epi proLung® developments: The company's second test, Epi proLung®, has recently shown very encouraging results in a clinical study in patients suspected of having lung carcinoma. Based on these

results, Charité University Hospital in Berlin, Germany, has announced that the assay will be introduced into its clinical practice as a routine aid in the diagnosis of lung cancer.

Corporate restructuring: In the summer of 2011, Epigenomics implemented restructuring measures to effectively control expenses in 2012 and beyond. The number of employees has decreased from 85 in mid-2011 to currently 45. 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.

Management changes: In 2011 Epigenomics added two experienced industry players to its management team. Dr. Thomas Taapken was appointed as Epigenomics' new CFO. He joined from publicly listed Biotie Therapies, Turku, Finland. Mr. Noel Doheny was appointed as Chief Executive Officer of Epigenomics' U.S. subsidiary. He has 30+ years of experience in the field of diagnostics, with over 20 years in senior management of companies including Affymetrix and QIAGEN.

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Conference calls for press and analysts

The Annual Report 2011, which was released today, can be obtained from Epigenomics' website at: http://www.epigenomics.com/en/news-investors/investors/financial-reports.html.

Epigenomics will host an annual press conference in Frankfurt Main, Germany in German language at 11 am CET today. The company will also be hosting a conference call and audio webcast on the same day for analysts at 3pm CET today. Details of both events will be available on Epigenomics' website at 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 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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