Press release

Epigenomics AG Reports Results for the Financial Year Ended December 31, 2015 and Provides Outlook for 2016

- *Product revenue growth of 88% year-on-year driven by successful start of commercialization of Epi proColon® in China*
- *FDA review for approval of Epi proColon® expected to be completed soon*
- *Outlook 2016: Strong revenue growth upon launch in the U.S.A.*

Berlin (Germany) and Germantown, MD (U.S.A.), March 18, 2016 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced financial results for the fiscal year ending December 31, 2015 and provided an outlook for the year 2016.

Dr. Thomas Taapken, CEO/CFO of Epigenomics, commented: "The most important achievement of our work in 2015 is the progress we made with the Pre-Market Approval (PMA) application for our lead product Epi proColon®. We are now in advanced talks with the FDA on the outstanding topics, with the main topics being resolved. We are very confident that the approval process of Epi proColon® can be completed in the near future."

"In 2015 we also saw remarkable progress with our Epi proColon® test in China. The inclusion of Septin9-based tests as the method of choice in the Chinese Guideline on Screening, Endoscopic Diagnostics and Treatment of Early CRC was a major milestone for us. Together with our partner BioChain we further strengthened our marketing activities around Epi proColon® and were able to accelerate commercial success. Product revenues increased significantly, though, still on a moderate level, and we are optimistic that Septin9 testing will make the difference in colorectal cancer screening in the important Chinese market."

2015 Financial Results

- In 2015, Epigenomics' total **revenue** increased by 38% to EUR 2.1 million (2014: EUR 1.5 million), exceeding the previous year's figure and thereby meeting the Company's revised guidance. For the first time, the biggest share of revenue (EUR 1.6 million; 2014: EUR 0.8 million) derived from product sales, which grew 88% year-over-year, following the approval of Epi proColon® in China. Consequently, revenue in Asia amounted to EUR 1.0 million. In Europe, revenue amounted to EUR 0.9 million as product sales and R&D income were in line with the Company's expectations.

- **Total operating costs** increased to EUR 12.2 million (2014: EUR 10.5 million). **Research and development costs** increased by EUR 1.1 million to EUR 5.8 million (2014: EUR 4.7 million) driven by both the ongoing FDA approval process and in particular the conduct of the ADMIT trial and the development activities for a blood-based lung cancer assay. **Selling, general and administrative costs** were up EUR 0.2 million to EUR 5.1 million (2014: EUR 4.9 million) attributable primarily to increased expenses for legal advice and auditing.

- **Operating loss (EBIT)** in 2015 increased to EUR -9.3 million (2014: EUR -8.4 million), but compares favorably with the Company's financial prognosis of EUR -10.0 and EUR -11.0 million. **Net loss** of EUR -9.0 million (2014: EUR -8.9 million) also remained below our 2015 guidance range (EUR -10.0 million to EUR -11.0 million). Due to an increase in the average number of shares outstanding as compared to 2014, the loss per share in 2015 fell to EUR -0.52 (2014: EUR -0.65).

- **Cash consumption** in 2015 amounted to EUR 8.0 million (2014: EUR 8.1 million) and was significantly below of the prognosis range of EUR 9.5 to 10.5 million as we recorded EUR 1.4 million in proceeds from grants and subsidies which were not predictable at the beginning of the year. Due to net cash inflows from financing activities in the amount of EUR 9.0 million in 2015 (2014: EUR 7.6 million), **net cash flow** amounted to EUR 1.1 million (2014: EUR -0.5 million).

- The Company's **liquidity** at year-end 2015 was EUR 8.6 million (Dec 31, 2014: EUR 7.5 million). After year-end, three further convertible notes were converted by their holders and the Company received a further cash inflow from financing amounting to EUR 1.6 million. The seven outstanding convertible notes have the potential to increase the liquidity by an additional amount of EUR 3.6 million upon their conversion in 2016.

Summary of Operational Highlights in 2015

- **Epi proColon® with successful results in ADMIT trial in the U.S.A.:** In May 2015, the Company successfully completed the ADMIT trial (ADherence to Minimally Invasive Testing), which was requested by the FDA as part of the approval process for Epi proColon®. In this trial, adherence to the blood-based test approached nearly 100%, outperforming Fecal Immunochemical Testing (FIT) by 11.4%, which clearly confirms the Company's assumption

that blood-based CRC screening has the potential to significantly lower the barriers for patients who have been historically noncompliant to participate in CRC screening programs.

- **Approaching FDA approval decision:** In November 2015, Epigenomics received a formal response letter, in which the agency requested additional data demonstrating that the blood-based Epi proColon® test will increase compliance to CRC screening in the intended use population. Following discussions with the agency, Epigenomics appealed the FDA's decision on additional data requirements as the Company strongly believed that an approval for the intended use of Epi proColon® is warranted based on the data already submitted. The agency notified in January 2016 that the already submitted and available data for Epi proColon® would allow the agency to come to a final determination on its safety and effectiveness. Epigenomics expects the final stages of the review process will be completed in the near future. Upon approval, Epi proColon® will be the first and only FDA-approved blood-based test for the early detection of colorectal cancer.

- **Preparing for product launch:** Together with its strategic commercialization partner Polymedco, Epigenomics is taking preparatory measures for launching Epi proColon® in the U.S. market. This includes, for example, the necessary technical validation of selected major laboratories. To secure the commercialization progress, the Company also significantly strengthened its manufacturing capabilities and is evaluating further steps to shorten manufacturing lead times and reduce production costs while building product inventory in preparation of the product launch.

- **Further progress with commercialization of blood-based Septin9 testing in China:** In July 2015, new "Guidelines on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer" were published in China stating that Septin9-based tests, such as Epi proColon®, one of the methods of choice for early CRC screening. Epigenomics believes this to be an important step that will help BioChain in their ongoing efforts to establish Septin9-based tests in routine healthcare screening programs and increase market adoption while at the same time securing adequate pricing and reimbursement decisions for the commercial success of this innovative blood-based test in China.

- **Epi proLung®: Next generation blood-based lung cancer test with impressive performance data in first clinical evaluation study:** During 2015, Epigenomics further developed its next generation innovative in vitro molecular diagnostic (IVD) assay for blood-based lung cancer diagnosis. Starting from its existing product Epi proLung® which detects the lung cancer biomarker SHOX2 in bronchial fluid, the Company aims to develop an easy-to-use blood-based alternative to existing testing methods leveraging its huge expertise in the emerging field of liquid biopsies and its strong platform in DNA methylation. The development is partly financed by a grant of up to EUR 2.8 million from the European Commission within the framework of the Horizon 2020 program awarded to Epigenomics in April 2015.

- In November 2015, Epigenomics announced preliminary performance data of a first clinical evaluation study of this **new blood-based Epi proLung® test**. Data displayed high sensitivity in detecting lung cancer and superior performance compared to protein biomarkers allowing to use it as a confirmatory test for positively tested patients in a low dose spiral computed tomography (LDCT) screening and alternatively as an early detection test to guide patients into additional imaging-based diagnostic procedures, such as LDCT or others.

- **Solid financial position:** In May 2015, the Company successfully completed a capital increase by way of a pre-emptive rights issue, which was significantly over-subscribed. All of the 976,562 new registered shares offered were taken up by existing shareholders of the Company. The proceeds were used to strengthen the Company's liquidity, to finance certain market introductory measures for Epi proColon® in the U.S.A., to strengthen its manufacturing capabilities as well as to build product inventory.

Outlook for 2016

- The Companys's business projections for 2016 are based on the successful introduction of Epi proColon® in the U.S. market. However, it is difficult at this pre-FDA approval stage to provide the capital markets with a reliable prognosis on our earnings situation. In our planning, we assumed that Epi proColon® will generate initial revenue in the U.S. market during Q2 2016, even if initially only on a moderate level. Given the increased initial resources necessary to facilitate a successful market introduction, the earnings situation may not benefit in the short-term, but should improve over time.

- Based on the aforementioned assumptions and associated uncertainties, our revenue estimate for 2016 is expected in the range of EUR 3 to 7 million with the bulk of this in the second half of the year. This growth in revenue versus the 2015 number will almost entirely be driven by the expected product sales in the U.S.A. For China, we expect BioChain to be selling more units of the domestically manufactured Septin9 product, shifting our revenue from kit sales to a royalty stream in 2016. As they still depend on the development of the ongoing reimbursement discussions with the Chinese authorities, this is another difficult-to-predict effect.

- Efforts to develop the U.S. market for the lead product will initially weigh down operating results. Reflecting these product launch costs, we expect EBIT for 2016 to be lower than in 2015, in the range of EUR -9.0 to -11.0 million. Any delay in the approval decision might result in a reduction of our revenue estimate on the one side, which would then be compensated in its impact on the expected loss by lower additional costs on the other.

- Based on our business plans for 2016, we expect an increase in cash consumption compared to 2015 to a range between EUR 8.5 and 9.5 million. For 2017 and the years to come, cash utilization for operating and investing activities is expected to decrease along with the revenues ramping up.

- Starting from EUR 8.6 million in liquid assets at the beginning of 2016 plus a remaining inflow potential from convertible notes of EUR 5.2 million, current financial resources are sufficient at the projected cash consumption to support the Company's operations beyond 2016. Epigenomics is convinced that a positive FDA decision will open up further financing options on the capital markets and is determined to exercise such options in the Company's best interests. The Company will also continue to diligently explore all further available strategic options.

Further Information

The Full Year Report 2015 can be obtained from Epigenomics' website at:
www.epigenomics.com/en/news-investors/investors/financial-reports/2015.html

Annual press conference / Conference call for analysts and investors

Epigenomics will host its Annual Press Conference in Frankfurt Main, Germany at 11:00 am CET, today.

The Company will also host an investor conference call at 3.00 pm CET / 10 am EST, today. The presentation can be followed as a slide show on the website.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 30 232531366

Dial-in number (within the UK): +44 203 3679216

Dial-in number (within the U.S.A.): +1 408 9169838

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

Both an audio replay of the conference call and a transcript of the conference call will be provided on Epigenomics' website subsequently: http://www.epigenomics.com.

Details of both events will be available on Epigenomics' website at
http://www.epigenomics.com/en/news-investors.html

- Ends –

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The Company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon®, is a blood-based screening test for the early detection of colorectal cancer. Epi proColon® is currently marketed in Europe and China. For more information, visit www.epigenomics.com.

Contact Epigenomics AG

Peter Vogt, Investor & Public Relations
Epigenomics AG
Geneststraße 5
10829 Berlin
Phone +49 (0) 30 24345 386
ir@epigenomics.com
www.epigenomics.com

For U.S. press inquiries:

Epigenomics, Inc.
20271 Goldenrod Lane, Suite 2027
Germantown, Maryland 20876
pr@epigenomics.com

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