

Press release

## **Epigenomics AG Announces 2016 First Quarter Financial Results and Reports on Operational Highlights**

**Berlin (Germany) and Germantown, MD (U.S.A.), May 23, 2016** - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced its financial results for the first quarter 2016 ending March 31.

“During the first quarter 2016, our main efforts were focused on the final steps towards FDA approval for our blood-based colorectal cancer screening test Epi proColon®. After a promising product launch in the U.S. in the current second quarter and initial sales being recorded, we are fully confirming our outlook for 2016”, said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “Together with our partner Polymedco, we are focusing our efforts on driving adoption by clinical laboratories. In this respect, the recent launch of Epi proColon® by LabCorp® as the first U.S. laboratory network was a significant milestone.”

### **Q1/2016 Financial Results**

- Product revenue increased by 10% to EUR 186 thousand (Q1 2015: EUR 169 thousand)
- Total revenue decreased to EUR 295 thousand (Q1 2015: EUR 367 thousand) mainly due to a shortfall in R&D service income from EUR 157 thousand to EUR 6 thousand. Licensing income increased from EUR 41 thousand to EUR 103 thousand.
- Operating costs in Q1 2016 amounted to EUR 5.3 million, up from EUR 3.7 million in Q1 2015. The main driver for this development was a significant increase by EUR 1.6 million in non-cash expenses for share-based compensation, due to the high volatility of our share price between November 2015 and January 2016. Apart from this extraordinary one-off effect, our operating costs in Q1 2016 were at the same level as in Q1 2015.
- Net loss for Q1 2016 amounted to EUR 4.3 million (Q1 2015: EUR 3.2 million) translating into a net loss per share for this period of EUR 0.23 (Q1 2015: net loss per share of EUR 0.20).
- Cash consumption (cash outflow from operating and investing activities) was EUR 2.4 million in Q1 2016 compared to EUR 2.3 million in Q1 2015.
- Liquid assets (including marketable securities) amounted to EUR 8.1 million at the reporting date (Dec 31, 2015: EUR 8.6 million). During the first quarter 2016, four convertible notes were converted by their holders, providing the Company with additional liquidity of EUR 2.1 million.

### **Operational highlights**

- **FDA approval for Epi proColon®:** On April 12, the U.S. Food and Drug Administration (FDA) approved our lead product Epi proColon®, the first and only blood-based colorectal cancer (CRC) screening test, for commercialization in the United States. This is a great achievement and a truly transformational event for Epigenomics, and it paves the way for us

to offer an innovative, convenient and effective CRC screening option to millions of eligible Americans.

- **Chinese FDA names Septin9 CRC test “innovative medical product”:** According to the recently published “2015 Medical Device Registration Annual Report” only nine out of 7,530 approved medical devices in China received this label from the local regulators. The CFDA recognizes the domestic initiative and significant clinical value of blood-based Septin9 tests. This official recommendation will significantly support leveraging CRC screening programs in a country where CRC is a rapidly growing medical problem and where about 290 million people would be currently eligible for screening.
- **License agreement with BioChain:** In March 2016, we entered into another strategic license agreement with BioChain on the development and commercialization of Epi proLung® in China. In the course of 2016, our partner is expected to initiate a clinical trial to validate our lung cancer detection test with the objective of gaining market approval by the CFDA for this test, too. In view of the high, rapidly growing prevalence of lung cancer among the Chinese population, the commercialization of a novel, blood-based test represents a major business opportunity for both companies. Epigenomics will receive upfront, milestone, and minimum annual payments as well as royalties on future revenues from BioChain and is entitled to commercialize this product exclusively in other markets outside China.
- **Progress with in-vitro lung-cancer biomarker:** In April 2016, we presented data from our clinical research with our proprietary panel of blood-based DNA methylation biomarkers for the detection of lung cancer at the Annual Meeting 2016 of the American Association for Cancer Research (AACR) in New Orleans, LA, U.S.A. The data demonstrates the potential of our assay for the detection of lung cancer and encourages us to conduct additional, potentially larger studies to complete the development of the test.

## **Outlook 2016 fully confirmed**

- We are forecasting revenue for 2016 to be in the range of EUR 3 to 7 million with the bulk of this in the second half of the year.
- We also confirm our expectations for EBIT and EBITDA for 2016 within ranges of EUR -9.0 to -11.0 million (EBIT) and EUR -8.5 to -10.5 million (EBITDA).
- Our expectation for cash consumption in 2016 remains unchanged within a range between EUR 8.5 and 9.5 million. Our financial situation has benefited in the meantime from five conversions of convertible notes between January and April 2016.
- The positive impact on our share price by the FDA’s approval decision has further increased the likelihood that the five convertible notes still outstanding will be converted by their holders before maturity at year-end 2016, so that we now expect that our current liquidity will take us well into 2017.

## **Further Information**

The full interim statement on the operational highlights and financial results for Q1 2016 can be obtained from Epigenomics' website at:

<http://www.epigenomics.com/en/news-investors/investors/financial-reports/2016.html>

## **Conference call for analysts and investors**

The Company will also host an investor conference call at 2.30 pm CET / 8.30 am EDT, 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.): + 1 646 7129911

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>

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## **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 detection of colorectal cancer. Epi proColon® has recently received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, China and selected other countries. The company is based in Germany and the United States. For more information, visit [www.epigenomics.com](http://www.epigenomics.com).

## **Epigenomics legal disclaimer**

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