epigenomics

Press release

Epigenomics AG Announces 2016 Second Quarter and Six Months Financial Results and Reports on Operational Highlights

- *Revenue increased by 159% in Q2 2016 over same period the prior year*
- *Epi proColon® successfully introduced into U.S. market – Leading U.S. laboratory network LabCorp® offers test nationwide*
- *Growing momentum in Epi proColon® roll-out as number of ordering U.S. laboratories increases*
- *Financial position improved by raising EUR 6.8 million in a private placement in May 2016*

Berlin (Germany) and Germantown, MD (U.S.A.), August 10, 2016 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY) today announced its financial results for the second quarter and the six months 2016 ending June 30.

"In the second quarter, we received FDA approval of the first ever blood based colorectal cancer screening test Epi proColon and have achieved all of our launch goals to date", said Greg Hamilton, CEO of Epigenomics AG. "Laboratory adoption and reimbursement coverage by private and public payers are in the center of our key initiatives, and I am very pleased with the progress we are making. We are convinced that a convenient, blood-based test like Epi proColon significantly lowers the hurdles for participation in colorectal cancer screening. As emphasized by the recent USPSTF recommendation, not enough people in the United States are using existing screening options."

Q2/6M 2016 Financial Results

- Total Q2 2016 revenue increased by 159% to EUR 1.3 million (Q2 2015: EUR 0.5 million) and 6M 2016 revenue was up 82% to EUR 1.6 million (6M 2015: EUR 0.9 million), mainly driven by an increase in Q2 product revenue, which was up by 319% year-on-year from EUR 0.3 million to EUR 1.2 million.
- Adjusted for non-cash expenses related to phantom stock programs, EBITDA in Q2 2016 was at EUR -3.5 million (Q2 2015: EUR -2.2 million); adjusted EBITDA for 6M 2016 amounted to EUR -5.7 million (6M 2015: EUR -4.5 million). Net loss amounted to EUR 3.3 million in Q2 2016 compared to EUR 2.5 million in Q2 2015, and EUR 7.6 million for 6M 2016 (6M 2015: EUR 5.6 million).
- Due to an increased number of shares outstanding as of June 30, 2016, net loss per share for Q2 2016 rose only slightly to EUR 0.16 (Q2 2015: EUR 0.15) and for 6M 2016 to EUR 0.39 (6M 2015: EUR 0.35).
- Cash consumption (cash outflow from operating and investing activities) was EUR 4.3 million in 6M 2016 compared to EUR 4.5 million in 6M 2015.
- Liquid assets (including marketable securities) amounted to EUR 13.2 million at the reporting date (December 31, 2015: EUR 8.6 million).

Operational Highlights

- **FDA approval for Epi proColon:** On 13 April 2016, the U.S. Food and Drug Administration (FDA) approved the Company's lead product, Epi proColon, the first and only FDA-approved blood-

based cancer screening test. Later in the quarter, our test was made commercially available in the U.S. under a joint commercialization agreement with Polymedco, Inc.

- **LabCorp is first laboratory to offer Epi proColon:** Laboratory Corporation of America Holdings (LabCorp), one of the world's leading healthcare diagnostics companies, was the first U.S. laboratory network to offer our test to its customers nationwide.
- **Reimbursement process for Epi proColon underway:** Epigenomics has taken further steps in order to secure future reimbursement coverage from private and public payors in the United States. This includes receiving a Tier 1 CPT Code in the CMS 2017 Laboratory Fee schedule of the Centers of Medicare & Medicaid (CMS). The company expects the preliminary price determination during the third quarter 2016. In addition, Epigenomics has initiated the application process for a National Coverage Determination (NCD) by CMS.
- **United States Preventive Task Force (USPSTF) included Epi proColon** in its new recommendation statement for CRC screening, published in the Journal of the American Medical Association (JAMA). In the recommendation, the USPSTF names Epi proColon ("SEPT9 DNA test") as one of several screening tests for the detection of early-stage CRC. The use of screening tests such as Epi proColon is recommended in the population of adults in the age group between 50 and 75. USPSTF is the first U.S. guideline body to recognize our novel CRC screening test after its recent FDA approval.
- **In April 2016, the Chinese Food and Drug Administration (CFDA)** named the blood-based Septin-9 CRC test, as successfully developed and introduced into the Chinese markets by our strategic partner BioChain, an "innovative medical product". According to the recently published "2015 Medical Device Registration Annual Report", only nine out of 7,530 approved medical devices received this label from the Chinese regulators.
- **Epigenomics continues to explore strategic options**. As previously announced, Epigenomics confidentially submitted a draft registration statement on Form F-1 to the United States Securities and Exchange Commission (SEC) for a potential U.S. public offering of American Depositary Shares (ADSs). The registration statement is not effective and the ADSs may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. The Company has not yet made a decision with regard to the timing or execution of a potential U.S. public offering.

Outlook for 2016

- We confirm our revenue outlook for the current financial year, forecasting full-year revenue in the range of EUR 3.0 to 7.0 million with the bulk generated in the second half of the year.
- Adjusted for expenses related to phantom stock programs, we expect our EBITDA to be in the range of EUR -9.5 to -11.5 million. The slight increase (previously: EUR -8.5 to -10.5 million) is mainly due to our investments in commercial efforts and legal and other related expenses in relation to the exploration of available strategic options, in particular a potential listing at NASDAQ.
- Going forward, Epigenomics will continue to provide forecasts based on revenue and EBITDA (adjusted for non-cash expenses related to phantom stock programs; those expenses depend on Epigenomics' share price development and, hence, are not subject of the Company's operational performance and planning).

- Epigenomics expects its liquid assets (incl. marketable securities) of EUR 13.2 million at the reporting date to be sufficient to fund operations well into 2017.

Further Information

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

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

Conference call/webcast 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.): + 1 408 9169838

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

Details and access to the webcast will be available on Epigenomics' website at http://www.epigenomics.com/en/news-investors.html

Both an audio replay of the conference call and a transcript of the conference call will be provided subsequently on Epigenomics' website 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 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. Epigenomics' second product, Epi proLung®, is in development as a blood-based test for lung cancer detection.

For more information, visit www.epigenomics.com.

Epigenomics legal disclaimer

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