Press release

Epigenomics AG Announces Q2 2015 and 6M 2015 Financial Results and Reports on Operational Highlights

- Q2 2015 revenue increased by 20%, mainly driven by an increase in product sales of 36%
- European Commission granted up to EUR 2.8 million to Epigenomics for development of blood-based Epi proLung® test
- Epigenomics significantly improved its financial situation by raising EUR 5.0 million in a capital increase
- Epigenomics reaches nearly 100% adherence for Epi proColon® in the ADMIT trial; results of the ADMIT trial have been submitted and discussed with the FDA; a decision on the approval is expected during the following few months
- Epigenomics' proprietary blood-based Septin9 test included in the Chinese Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer

Berlin (Germany), Germantown, MD (U.S.A.), **August 6, 2015 -** Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced its financial results for the second quarter and the first six months of 2015 ending June 30.

"The first six months of 2015 were characterized by the final steps towards FDA premarket approval (PMA) application for Epi proColon® and the preparation of the commercialization progress in the U.S.A. and China. In the U.S.A. we are convinced that the exciting results of the ADMIT trial, a nearly 100% adherence rate, will support the U.S. approval for our convenient blood-based colorectal cancer (CRC) test Epi proColon®. We have submitted the final data set to the FDA and are expecting their approval decision during the following few months. With regard to the commercialization in China, we are delighted that blood-based tests with our proprietary biomarker Septin9 have been included in the screening guidelines, which allows us to address CRC detection in this country with Epi proColon®," said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. "In addition we are also preparing for the future. Over recent years and together with our academic collaborators, we already have worked on a promising second product, Epi proLung®, based on a proprietary biomarker - SHOX2 for the detection of lung cancer in tissue. However, recent studies showed that SHOX2 can also easily be detected in blood. In a project, funded by the European Union, we are currently working on the analytical and clinical validation of a convenient blood-based test as a reflex test for lung cancer diagnosis, following positive radiological findings. The planned development approach for our innovative lung cancer test will also serve as a blueprint for the standardized validation of future blood-based epigenetic biomarker tests."

Q2/6M 2015 Financial Results

- Total Q2 2015 revenue was up 20% to EUR 487 thousand (Q2 2014: EUR 405 thousand); thereof, product revenue increased by 36% year-on-year (from EUR 212 thousand to EUR 289 thousand).

For the first six months 2015, revenue grew by 5% to EUR 854 thousand (6M 2014: EUR 812 thousand).

- Operating costs in Q2 2015 amounted to EUR 3.1 million from EUR 2.1 million in Q2 2014. This increase was completely in line with the Company's forecast and primarily attributable to significantly higher R&D costs of EUR 1.6 million (Q2 2014: EUR 0.9 million) covering expenses related to the protection of intellectual property and to an increase in provisions in conjunction with the phantom stock programs. SG&A costs increased to EUR 1.2 million (Q2 2014: EUR 1.0 million) mainly attributable to an increase in provisions relating to the phantom stock programs and to legal and consulting expenses. 6M 2015 operating costs increased to EUR 6.8 million (6M 2014: EUR 4.6 million).
- In line with the increase in operating costs, EBIT for Q2 2015 amounted to EUR -2.6 million (Q2 2014: EUR -1.6 million) and to EUR -5.7 million in 6M 2015 (6M 2014: EUR -3.6 million).
- Net loss of EUR 2.5 million was recognized in Q2 2015 (Q2 2014: EUR 1.8 million) which added up to EUR 5.6 million for 6M 2015 (6M 2014: EUR 4.1 million). Due to the increased number of shares outstanding at the end of Q2 2015, net loss per share increased only slightly to EUR 0.15 in Q2 2015 (Q2 2014: EUR 0.13) and to EUR 0.35 for the six month period 2015 (6M 2014: EUR 0.30).
- Cash outflow from operating activities was EUR 4.6 million in 6M 2015 – an increase of EUR 1.5 million compared to 6M 2014 (EUR 3.1 million) which was mainly attributable to the higher operating costs and to further building up our stock for expected product demand in months to come. Cash inflow from financing activities in 6M 2015 amounted to EUR 7.7 million (6M 2014: EUR 1.9 million) mainly attributable to the successful capital increase with pre-emptive rights in May 2015 (EUR 5.0 million in gross proceeds) and the conversion of five convertible notes issued in 2013 by their holders.
- Liquid assets amounted to EUR 10.6 million at the reporting date (Dec 31, 2014: EUR 7.5 million).

Summary of Operational Highlights

- **ADMIT trial completed with nearly 100% adherence to Epi proColon®:** At the beginning of May, the Company successfully completed the ADMIT trial, which was originally requested by the U.S. Food and Drug Administration (FDA) in the context of the approval process for the Company's blood-based test Epi proColon®. The results demonstrated a staggering 99.5% rate of adherence to CRC screening for the blood test; significantly greater than to FIT, with an observed difference of 11.4%. Seeing adherence to Epi proColon® approaching 100%, the ADMIT trial clearly confirms the Company's assumption that blood-based CRC screening has the potential to significantly lower the barrier for patients that have been historically non-compliant to participate in CRC screening programs. In May 2015, the Company has submitted the final data set to the FDA, which has meanwhile been presented and discussed with the FDA.
- **Design of post-marketing study finalized and submitted to the FDA:** The Company finalized the design of the proposed post-marketing study, aiming to show long-term benefit of blood-based CRC screening using Epi proColon® in a programmatic setting and submitted its study proposal to the FDA for approval.
- **Strengthening manufacturing capabilities:** To secure the commercialization progress of Epi proColon® following approval, Epigenomics significantly strengthened its manufacturing capabilities and mitigated potential supply chain risks by establishing a second source for product

manufacturing. Furthermore, the Company is evaluating further steps to shorten manufacturing lead times and reduce production costs while building product inventory in preparation of the launch of Epi proColon® in the U.S.A. and China.

- **Epigenomics' proprietary blood-based Septin9 test added to the Chinese Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer:** End of June, the Chinese Society of Digestive Endoscopy of the Chinese Medical Association and the Oncologic Endoscopic Committee of the Chinese Anti-Cancer Association published their Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer. In this guideline, Septin9-based tests, such as Epi proColon®, were clearly stated as the method for early CRC screening.

- **European Commission granted EUR 2.8 million to Epigenomics for development of blood-based Epi proLung® test:** Beyond Epi proColon®, the Company has accelerated its efforts towards the development of the next generation of product opportunities, building on the strong technological platform in DNA methylation and its leadership in the emerging field of liquid biopsies. A promising second product, Epi proLung®, has shown a proven ability to detect another proprietary biomarker, SHOX2, in blood samples of patients rather than in bronchial fluid, which is the substrate for the current version of Epi proLung®. Epigenomics received a grant in the amount of up to EUR 2.8 million from the European Commission within the framework of the Horizon 2020 program with the goal to develop the first ever convenient blood-based in-vitro diagnostic assay (IVD) for complementing systemic lung cancer diagnosis.

- **Cash runway extended into second half of 2016 by raising EUR 5.0 million in a capital increase:** 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. Based upon current projections, the gross proceeds in the total amount of EUR 5.0 million extend the cash runway of the Company at least into the second half of 2016, assuming complete conversion of all outstanding convertible bonds before the end of 2015.

Outlook

- Epigenomics confirms its prognosis for the fiscal year 2015 as outlined in the Group Management Report of its 2014 Annual Report. All business projections for 2015 are still based on the approval of Epi proColon® as an IVD product in the U.S. market in Q3 2015 and the generation of first product revenues following the commercialization start.
- The ADMIT trial has been completed within the expected time frame and the results of the study have been submitted and discussed with the FDA. The overall likelihood of a positive approval decision by the FDA and the expectations regarding the timing of this decision remain unchanged. Epigenomics expects revenue to increase in the second half of 2015 as soon as the approval is granted in the U.S.A. and important pricing and reimbursement decisions have been reached in China.
- The successful capital increase in the second quarter of 2015, together with the conversion of five convertible notes in 6M 2015, has improved the Company's financial situation. Under the assumption of a conversion of the remaining convertible notes by their holders before their maturity at the end of 2015, the Company's cash reach has been extended the second half of 2016.

Epigenomics is still convinced that a positive FDA decision will open up further financing options to the Company on the capital markets and management is determined to exercise such options in the Company's best interest.

Further Information

Conference call for press and analysts

The full 6-Month Financial Report 2015 can be obtained from Epigenomics' website at:
http://www.epigenomics.com/en/news-investors/investors/financial-reports/2015.html

Epigenomics' management will host a conference call with web presentation at 2:30 pm CET/ 8:30 am EDT today, Thursday, August 6, 2015. The conference call will be held in English.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 69 247 501 895
Dial-in number (within the UK): +44 203 367 9216
Dial-in number (within the U.S.): +1 408 916 9838
Participants are kindly requested to dial in 10 minutes prior to the start of the call.

The presentation accompanying the conference call and dial-in details for the web presentation will be available on Epigenomics' website: 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 on Epigenomics' website subsequently: 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 innovative 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, has received approval by the Chinese Food and Drug Administration for China and is under regulatory review by the U.S. Food and Drug Administration (FDA). Additionally, the Company markets its tissue assay for use in lung cancer diagnosis, Epi proLung®, in Europe. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies and testing laboratories. Epigenomics is an international company with operations in Europe and the U.S.A.

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