Press release

Epigenomics AG Announces H1 2014 and Q2 2014 Financial Results and Reports on Operational Highlights

Berlin (Germany) and **Germantown, MD (*U.S.A.), August 12, 2014*** - 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 half of 2014 ending June 30.

- H1 2014 revenue increased by 16% to EUR 812 thousand compared to H1 2013, mainly driven by an increase in product sales of 31%
- Earnings prognosis for 2014 remains unaltered despite delay in the expected market approval for Epi proColon® in the U.S.A.
- U.S. Food and Drug Administration (FDA) issued response letter requesting further data
- Results from Epi proColon® clinical studies published in renowned U.S. scientific journals
- Chinese partner BioChain filed Epi proColon® for market approval in China with China Food and Drug Administration (CFDA).

“The first six months of 2014 were characterized by the pending decision of the FDA in relation to the premarket approval (PMA) application for Epi proColon®. Although, FDA's response to our PMA submission was unexpected, we are now more than ever convinced that finally the approval of our patient-friendly blood-based test for CRC screening is very likely, and that it is ultimately a matter of time to complete the additional data requested by the FDA. Our joint U.S. commercialization partner Polymedco remains fully committed to begin commercialization once our product is approved and we are well underway in gearing up manufacturing capabilities, in order to be able to supply the demand once the product will be on the market”, said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “With regard to the commercialization in China, we are delighted that our partner BioChain filed the test sooner than anticipated for regulatory approval with the CFDA. We are proud to contribute to the future of CRC screening with a convenient blood test that has the potential to significantly improve uptake and adherence and ultimately reduce CRC incidence and mortality as well as resulting healthcare cost.”

Q2/H1 2014 Financial Results

- Total Q2 2014 revenue was up 18% to EUR 405 thousand (Q2 2013: EUR 343 thousand) and H1 2014 revenue increased by 16% to EUR 812 thousand (H1 2013: EUR 698 thousand); thereof, product revenue increased year-on-year by 31% from EUR 327 thousand to EUR 427 thousand.
- Operating costs in Q2 2014 amounted to EUR 2.1 million and remained nearly unchanged to Q2 2013. H1 2014 operating costs increased to EUR 4.6 million (H1 2013: EUR 4.3 million) mainly due to an increased usage of materials and higher costs for patent protection.
- Corresponding with this increase in operating costs, Q2 2014 EBIT was EUR -1.6 million and nearly unchanged to Q2 2013; H1 2014 EBIT amounted to EUR -3.6 million (H1 2013: EUR -3.3 million). Net loss amounted to EUR 1.8 million in Q2 2014 (Q2 2013: EUR -1.6 million) and to EUR 4.1 million in H1 2014 (H1 2013: EUR 3.4 million), respectively.
- Net loss per share dropped slightly to EUR 0.13 from EUR 0.14 in Q2 2013 and increased only marginally to EUR 0.30 in H1 2014 from EUR 0.29 in H1 2013.
- Cash outflow from operating activities was EUR 3.1 million in H1 2014 – a decrease of EUR 0.7 million compared to H1 2013 (EUR 3.8 million) which was mainly attributable to the changes in current and non-current liabilities from operations. Cash inflow from financing activities amounted to EUR 1.9 million and was mainly due to the issuance of 428,000 new shares in context with the conversion of four convertible notes.
- Liquid assets amounted to EUR 6.8 million at the reporting date (Dec 31, 2013: EUR 8.0 million).

Operational highlights

- **Update on Regulatory Status with Epi proColon®:** Following the meeting of the Molecular and Clinical Genetics Panel of FDA's Medical Devices Advisory Committee ("Advisory Committee") end of March 2014, in which the members in their majority voted positively that the benefits of Epi proColon® outweigh the risks of the test for use in screening eligible patients, the Company continued to diligently collaborate with FDA. A follow-on meeting with FDA's PMA review team was held in April 2014 to define an approval path to launch Epi proColon® in the U.S.A. This meeting focused on detailed discussions regarding submitted data, product labeling and design of the proposed post-approval study as well as on topics raised at the recent Advisory Committee meeting.
- **Response Letter from FDA:** In June 2014, the Company received the awaited response letter from the FDA. In this letter, the agency determined that whilst the studies performed so far have established the clinical performance characteristics of the test, the PMA application does not yet contain sufficient evidence to warrant an approval for Epi proColon®. The main item stressed revolved around the need for additional data demonstrating that the blood-based Epi proColon® test will increase compliance to CRC screening in the intended use population, i.e. in those patients who today do not undergo CRC screening by guideline-recommended methods such as colonoscopy or stool-based fecal immunochemical tests (FIT). However, the FDA provided helpful guidance on how to amend the PMA to make it approvable.
- **Additional Study to Demonstrate Increased Compliance and Adherence Requested:** The trial is intended to be conducted in a population that is non-compliant to CRC screening according to current screening guidelines and may include patients actively managed by CRC screening programs within healthcare systems. The Company

already started discussions with several healthcare organizations to participate in such a study. The Company foresees that conducting the study can likely be done with a reasonable number of patients that could be enrolled within a few months. Considering the time needed to allocate for the study initiation and logistics, the Company is aiming to submit study data to complete the PMA application before the end of this year or shortly thereafter.

- **Results of two Major Studies with Epi proColon® Published in Renowned Scientific Journals**: The results from the U.S. clinical validation study for Epi proColon® as well as from its head-to-head comparative study with FIT have been published in two renowned scientific peer reviewed journals, Clinical Chemistry (www.clinchem.org) and PLOS ONE (www.plosone.org). This is of particular importance as payors, policymakers, medical societies and guideline bodies will rely on this information for their decision-making processes.
- **Chinese Partner BioChain Filed Epi proColon® for Approval in China Sooner than Anticipated:** BioChain, a leading clinical diagnostics company in cancer and genetic tests in China and the U.S.A., has completed a major clinical validation study with Epi proColon®. The results, confirming the excellent clinical performance of the test, and the filing for regulatory approval of Epi proColon® with the CFDA are significant milestones towards commercialization of this sophisticated CRC screening test also in the Chinese market.
- **Relocation of Epigenomics' Berlin headquarters to be Completed:** In August, Epigenomics will complete the relocation of its Berlin headquarters to a new facility within the city, which will be more adept to efficiently house operations and allows for higher flexibility for the Company's long-term planning.

Outlook

- The most significant milestone for Epigenomics is the timely roll-out of the additional study with Epi proColon® to address FDA's outstanding requests for the approval decision in the U.S.A.
- With regard to the earnings prognosis for the current business year, there are no significant changes compared to the Company's statements in the consolidated management report for 2013. Although, the expected market approval for Epi proColon® in the U.S.A. is affected by a delay, the earnings prognosis for 2014 remains unaltered, as the initial guidance did not include any significant product revenues from the U.S. market. According to the 2013 management report, Epigenomics expects revenue in 2014 to slightly increase from 2013's level. Net loss for 2014 is expected to be in the range of EUR 7.5 to 8.5 million. In line with the expected net loss range, cash consumption for the fiscal year 2014 is projected at a slightly increased level compared to 2013 in the range of EUR 7.0 to 8.0 million.
- The financial prognosis might be adjusted upon further conversions of issued convertible notes or if redemptions of these occur. Given the unexpected delay of the U.S. market approval, Epigenomics will carefully consider and potentially execute all strategic options available to the Company. These options explicitly include further capital market transactions that would provide sufficient funds to the Company until U.S. market approval for Epi proColon®.

Further Information

Conference call for press and analysts

The full 6-Month Financial Report 2014 can be obtained from Epigenomics' website at: http://www.epigenomics.com/en/news-investors/investors/financial-reports/2014.html

Epigenomics' management will host a conference call with web presentation at 3pm CET/ 9am EST today, Tuesday, August 12, 2014. The conference call will be held in English.

The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 69 247501895
Dial-in number (within the UK): +44 203 3679216
Dial-in number (within the U.S.): +1 408 9169838
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 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 under regulatory review by the FDA for the U.S.A. and the Chinese Food and Drug Administration for China. 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.

Epigenomics legal disclaimer

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