epigenomics

Press release

Epigenomics AG Announces Q1 2014 Financial Results and Reports on Operational Highlights

Berlin (Germany) and Germantown, MD (*U.S.A.), May 13, 2014* - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced its financial results for the first quarter ending March 31, 2014.

- Q1 2014 revenue increased by 14% compared to Q1 2013 to EUR 407 thousand driven by increased product sales
- Liquid assets at period-end increased to EUR 8.4 million due to proceeds from conversion of convertible notes
- FDA Advisory Committee provides recommendations for Epi proColon® in the U.S.
- Chinese partner BioChain completed major clinical validation study and submitted an application to the CFDA for the approval of Epi proColon® in China

"Over the last weeks, additional progress was made in the regulatory process for our blood-based screening assay for the early detection of colorectal cancer (CRC) Epi proColon®, since the FDA Medical Devices Advisory Committee voted positively that the test's benefits outweigh its risks for use in patients who meet the criteria. Subsequently, we met again with the agency to discuss topics raised in the Advisory Committee meeting, including the design of the proposed post-approval study", said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. "Another important step towards commercialization of our key value driver was taken by our Chinese partner BioChain with the earlier than expected completion of a major clinical validation study with Epi proColon® and the official start of the market approval process with the Chinese Food and Drug Administration (CFDA) in China. We are expecting the test could enter the Chinese market in 2015. Overall, we are very pleased with the excellent progress we made with our test in many regions of the world and strongly believe that the launches of Epi proColon® will help to increase the number of people being tested early for CRC."

Q1 2014 Financial Results

- Q1 2014 revenue increased by 14% to EUR 407 thousand (Q1 2013: EUR 355 thousand); thereof, product revenue in Q1 2014 increased by more than 30% year-on-year (from EUR 163 thousand to EUR 215 thousand).
- Q1 2014 operating costs increased to EUR 2.5 million, up 14% from EUR 2.2 million in Q1 2013. This increase was primarily attributable to higher R&D cost of EUR 1.3 million (Q1 2013: EUR 1.1 million) due to higher costs for international patent protection. SG&A costs of EUR 1.0 million remained almost at last year's level.

- EBIT for Q1 2014 amounted to EUR -2.0 million (Q1 2013: EUR -1.7 million) and net loss to EUR 2.2 million (Q1 2013: EUR 1.7 million), including interest expenses in the amount of EUR 0.2 million (Q1 2013: EUR 0) incurred in connection with the issued convertible notes. Due to the increased number of shares outstanding at the end of Q1 2014, net loss per share increased only slightly from EUR 0.16 to EUR 0.17 compared to Q1 2013.
- Net cash flow in Q1 2014 was EUR 0.4 million. Cash inflow from financing activities amounted to EUR 1.9 million and was mainly attributable to the issuance of 428,000 new shares in context with the conversion of convertible notes. Cash outflow from operating activities was EUR 1.5 million – a decrease of EUR 0.3 million compared to Q1 2013 (EUR 1.8 million) - mainly attributable to changes in current and non-current liabilities from operations.
- Liquid assets at the end of the period amounted to EUR 8.4 million (December 31, 2013: EUR 8.0 million). Four of the 25 convertible bonds issued in December 2013 have been converted and EUR 2.1 million was raised this way during Q1 2014. These conversions have not only given more financial leeway but as well reduced the redemption amount in a non-conversion scenario.

Operational highlights

- **Final Phase of U.S. Market Approval Process, Expert Panel Recommends Epi proColon®:** On March 26, the meeting of the Molecular and Clinical Genetics Panel of FDA's Medical Devices Advisory Committee ("Advisory Committee") was held in conjunction with the premarket approval (PMA) for Epigenomics' blood-based CRC screening test Epi proColon® in the U.S.A. The Advisory Committee reviewed the Company's clinical data and the performance of Epi proColon®, discussed data and questions presented by the FDA as well as testimonies shared during the open public hearing. After deliberations, the Advisory Committee members in their majority voted positively that the benefits of Epi proColon® outweigh the risks for use in patients who meet the criteria. Epigenomics is diligently preparing itself, together with its U.S. commercial partner Polymedco, for the planned U.S. commercialization in order to ensure the optimum market introduction and roll-out of Epi proColon® in North America.
- **Major Progress with Epi proColon® in China (after the End of the Reporting Period), Commercialization Expected for 2015:** In April, Epigenomics announced that its Chinese partner BioChain has completed a major clinical study to validate Epi proColon® for the early detection of CRC with the goal to gain market approval for the test in China. In addition, BioChain has officially submitted an application to the CFDA in April for such approval. The commercialization of Epi proColon® in China is expected to start in 2015.
- **Argentina Becomes First Country outside of Europe to Launch Epi proColon®:** In March, Epigenomics' local partner in Buenos Aires, VSA Alta Complejidad S.A. ("VSA"), received approval to market the Epi proColon® kit for the blood-based detection of CRC in Argentina, a country where CRC mortality rates are still among

the highest for males and females. The test was made available by VSA in the same month on the occasion of the international "Colon Cancer Awareness Month" campaign.

- **Clinical Study with Epi proColon® Completed with Excellent Results in the Czech Republic:** A study conducted by MU Dr. Zdenek Beneš , CSc., Head, Medical Department of Thomayer Hospital, Prague, confirmed that blood-based Septin9 testing could be an attractive screening alternative to established methods for a population that would otherwise be non-compliant to CRC screening. In this case control study comprising 57 patients, Epi proColon® 2.0 CE showed a sensitivity of 92% and a specificity of 97%.
- **Intellectual Property Coverage for Epi proColon® Strengthened in the U.S. and in China:** The Company was granted patent protection for the method used in Epi proColon® to analyze Septin9 DNA methylation by the United States Patent and Trademark Office (USPTO). In addition, Epigenomics received a "Notice of Allowance" from the Chinese Patent and Trademark Office for a patent covering Epigenomics' Septin9 DNA methylation biomarker (mSEPT9) for use in the diagnosis of CRC.

Outlook

- The most significant milestone for Epigenomics over the next weeks remains the approval decision for Epi proColon® by the FDA.
- With regard to the earnings prognosis for the current business year, there are no significant changes compared to our statements in the consolidated management report for 2013. However, Epigenomics might adjust its product revenue prognosis upwards for 2014, if market approval for Epi proColon® in the U.S.A. would be granted in due course. According to the 2013 management report, Epigenomics expects revenue in 2014 to slightly increase from 2013 levels. 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 fiscal 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. However, the Company will continue to diligently explore and potentially execute all strategic options available to further strengthen its liquidity position. These options explicitly include further capital market transactions.

Further Information

Conference call for press and analysts

The full Q1 2014 Financial Report can be obtained from Epigenomics' website at:
http://www.epigenomics.com/en/news-investors/investors/financial-reports/2014.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.

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