

Press release

Epigenomics AG Announces 2015 Third Quarter and Nine Month Financial Results and Reports on Operational Highlights

Berlin (Germany) and Germantown, MD (U.S.A.), November 18, 2015 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced its financial results for the third quarter and the nine months 2015 ending September 30.

- Q3 2015 revenue increased by 66% compared to Q3 2014 due to an increase in product sales
- 9M 2015 revenue increased by 21% year-on-year to EUR 1.3 million, mainly driven by an increase in product sales of 63%
- Cash and cash equivalents increased to EUR 9.0 million compared to year-end 2014 (EUR 6.7 million)

“We are encouraged by the positive sales development of our blood-based cancer screening test Epi proColon[®], especially in China”, said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “Going forward, steady improvements in the pricing and reimbursement environment in China will further support our partner BioChain’s commercial efforts in this important market. The recent inclusion of blood-based Septin9 testing in the Chinese screening guidelines for colorectal cancer was a major milestone to address the significant medical need arising from an increasing colorectal cancer incidence and mortality in China.”

Dr. Taapken commented further on the recent FDA response letter: “In the upcoming meeting scheduled with the FDA, we will seek to determine how to best address the outstanding questions. We remain highly committed to resolve those questions as soon as possible and will present respective proposals.”

Q3/9M 2015 Financial Results

- Total Q3 2015 revenue increased by 66% to EUR 471 thousand (Q3 2014: EUR 284 thousand) and 9M 2015 revenue was up 21% to EUR 1,324 thousand (9M 2014: EUR 1,095 thousand), mainly driven by an increase in product revenue, which was up by 63% year-on-year from EUR 551 thousand to EUR 898 thousand.
- Operating costs in Q3 2015 increased to EUR 3.2 million (Q3 2014: 2.3 million); 9M 2015 operating costs increased to EUR 10.0 million (9M 2014: EUR 6.9 million).
- In line with this development, Q3 2015 EBIT amounted to EUR -2.5 million (Q3 2014: EUR -1.8 million); 9M 2015 EBIT amounted to EUR -8.3 million (9M 2014: EUR -5.4 million). Net loss amounted to EUR 2.4 million in Q3 2015 compared to EUR 1.8 million in Q3 2014, and EUR 8.0 million for 9M 2015 (9M 2014: EUR 5.9 million).
- Due to an increased number of shares outstanding as of September 30, 2015, net loss per share for Q3 2015 remained flat compared to Q3 2014 at EUR 0.14 and rose slightly to EUR 0.48 in 9M 2015 from EUR 0.44 in 9M 2014.
- Cash consumption (cash outflow from operating and investing activities) was EUR 7.7 million in 9M 2015 compared to EUR 5.9 million in 9M 2014.
- Liquid assets (including marketable securities) amounted to EUR 9.7 million at the reporting date (December 31, 2014: EUR 7.5 million).

Operational Highlights

- **Inclusion in screening guidelines for colorectal cancer in China:** In July, our colorectal cancer (CRC) testing method targeted on our proprietary Septin9 biomarker was included in the Chinese Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer. In these guidelines, Septin9-targeted tests, such as Epi proColon[®], were stated as a method of choice for early CRC screening. The guideline is defined by 50 renowned Chinese specialists and further emphasizes the importance of improving early cancer screening, diagnosis and intervention.
- **Progress with in-vitro lung-cancer biomarker:** Starting from our existing product Epi proLung[®] we aim to leverage our strong platform in DNA methylation and our expertise in the emerging field of liquid biopsies to develop a more convenient and blood-based alternative to already available testing methods. In November 2015, after the reporting period, we announced and presented preliminary performance data on the new test at the annual meeting of the Association of Molecular Pathologists (AMP) in Austin, Texas.
- **Marketing efforts to promote Epi proColon[®]:** We presented our product at one of the most important conferences for diagnostic laboratories in Asia: LabAsia, the Malaysia 5th International Scientific Instrument and Laboratory Equipment Exhibition and Conference in October in Kuala Lumpur. In September 2015, we presented and promoted our proprietary DNA methylation biomarker technology at the renowned conference “Circulating Nucleic Acids in Plasma and Serum (CNAPS) IX Meeting” in Berlin. In October, we hosted an Epigenomics awareness day for CRC screening together with a local laboratory (Institut für Molekulare Diagnostik, IMD) as part of the Berlin “Health Week”.

Outlook

- As announced on November 4, 2015, we received a response letter from the U.S. Food and Drug Administration (FDA) in relation to the premarket approval (PMA) application for our blood-based CRC screening test Epi proColon[®]. We will make every effort to address the outstanding questions as soon as possible. This includes a meeting with the FDA in the near-term in order to discuss how to best resolve the outstanding issues.
- On November 4, 2015, we adjusted our financial prognosis for 2015 as a result of the FDA response letter. Revenue for FY 2015 is now projected to exceed last year’s figure of EUR 1.5 million, but will be significantly below our previous outlook of EUR 3-4 million, which was based on the assumption of a market entry in the U.S. already in 2015. EBIT is now projected at the lower end, or may slightly fall short, of the previous outlook range of EUR -10.0 to -11.0 million. Cash consumption is expected at the upper end of, or may slightly exceed, the previous outlook range of EUR 9.5 to 10.5 million.
- Our cash reach is still expected to last into the second half of 2016. Nevertheless, we will have to bridge the extra time which will likely be needed to obtain final FDA approval decision, meaning that additional financing for the Company is required. We will increase our efforts to evaluate all financing options on the capital markets and are resolved to exercise such options in the Company’s best interest. As of October 30, 15 (out of 25) convertible notes that we had issued in 2013 have been converted by their holders.

Further Information

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

Conference call for press and analysts

Epigenomics' management will host a conference call at 2:30 pm CET/ 8:30 am EDT today, Wednesday, November 18, 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.

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>

- Ends -

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 early detection of colorectal cancer. Epi proColon[®] is currently marketed in Europe and China. For more information, visit www.epigenomics.com.

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