

Press release

Epigenomics AG Announces Nine Months 2012 Financial Results

Berlin, Germany, and Seattle, WA, U.S.A., November 7, 2012 - Epigenomics AG (Frankfurt Prime Standard: ECX), the German-American cancer molecular diagnostics company, today announced its financial results for the first nine months and third quarter ending September 30, 2012.

“During the third quarter of 2012, we made decisive steps forward towards the completion of our ongoing head-to-head comparison study between Epi proColon[®] and fecal immunochemical testing (FIT). The results of this study should become available soon and thus allow us to complete the Premarket Approval (PMA) application of our blood-based colorectal cancer (CRC) screening test“, said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG. “At this point, already ahead of potential regulatory approval of our product, around 1,000 laboratory developed Septin9 tests are being performed by our laboratory partners every week in the United States. We expect these partners to become future customers of Epi proColon[®], once we potentially receive regulatory approval for our test. At that time we also expect to be able to expand the market significantly. Furthermore, we are making all efforts necessary to create the awareness for the test and generate the support in the medical and laboratory customer communities in order to achieve the inclusion of the test in screening guidelines and assure the availability of reimbursement by insurance carriers.”

9M/Q3 2012 Financial Results

- Revenue in Q3 2012 of EUR 272 thousand was slightly higher than the comparable number for the previous year (Q3 2011: EUR 257 thousand) due to an increase of R&D service fees which offsets a decrease in licensing income. In the nine-month period, the decrease in revenue compared to the same period in 2011 amounts to EUR 570 thousand and is mainly attributable to a reduction in licensing income.
- Like in previous quarters of 2012 and in line with guidance, R&D costs increased notably in Q3 2012 to EUR 2.3 million from EUR 1.1 million in Q3 2011. This is mainly due to the ongoing FIT comparison study and activities in connection with the FDA approval process. Moreover, no capitalization of R&D expenses was recorded in 2012, compared to EUR 0.8 million of capitalized development costs in Q3 2012.
- SG&A costs in Q3 2012 amounted to EUR 1.8 million. This significant increase compared to EUR 1.4 million in Q3 2011 was mainly attributable to the termination of the contract of Epigenomics' former CEO Geert Walther Nygaard as of September 30, 2012. On a nine month basis, SG&A costs were still slightly lower than in the comparable period of 2011 (EUR 4.7 million vs. EUR 4.8 million).
- EBIT for Q3 2012 amounted to EUR -3.7 million – an improvement of 26.7% compared to Q3 2011 (EUR -5.0 million). EBIT for the first nine months of 2012 was EUR -9.4 million (2011: EUR -10.7 million).
- Net loss for Q3 2012 amounted to EUR 3.7 million (Q3 2011: EUR 4.8 million) and for 9M 2012 to EUR 9.4 million (9M 2011: EUR 10.7 million).
- Cash consumption in 9M 2012 was EUR 7.6 million (9M 2011: EUR 8.8 million).
- Liquidity at the end of the period amounted to EUR 6.2 million (December 31, 2011: EUR 14.0 million).

Operational highlights

- **FIT Comparison Study:** The ongoing head-to-head comparison study between Epi proColon[®] and FIT is on track since patient enrollment is almost completed. Headline data from the study is expected to be announced within weeks, allowing the company to complete the PMA submission to the FDA before the end of the year.
- **Changes to the Executive Management:** On September 25, 2012, Epigenomics announced the appointment of Dr. Thomas Taapken as sole member of the Executive Board of the company, effective October 1, 2012. Geert Walther Nygaard, previously CEO of Epigenomics, left the company, effective September 30, 2012.
- The responsibilities of Dr. Uwe Staub, former Senior Vice President Research & Development, were expanded by promoting him to Chief Operating Officer (COO) and granting him “Prokura” (power of attorney). Among other duties, Dr. Staub is responsible and oversees all activities in connection with the development and the approval process for Epi proColon[®].

Outlook

- Epigenomics actively continues to seek licensing and distribution partners as well as key account customers for its products. Since European marketing and sales efforts have been scaled down significantly, an increase in product-derived revenues is not expected prior to FDA approval of Epi proColon[®] (FDA decision on the PMA application expected in the second half of 2013) and the ability to sell Epi proColon[®] directly into the U.S. market.
- The necessity to invest into further clinical trials ahead of completion of the PMA submission to the FDA, which arose earlier in 2012 as well as additional one-time costs in connection with restructuring measures will lead to higher full year costs in comparison to originally announced plans for 2012. Nevertheless, operational costs are still expected to be significantly below 2011 numbers. The company still anticipates an improved EBIT and a narrowed net loss for 2012 compared to last year.
- Going forward, Epigenomics strives to significantly reduce the cash needs for 2013. Detailed financial guidance for 2013 will be provided latest with the announcement of full year 2012 results.
- Epigenomics’ current financial resources are not sufficient to support the company’s operations beyond the first quarter of 2013 and will force management to secure additional funds in the near future to remain operational in 2013 and beyond. Since it is not anticipated that the company will be able to generate sufficient cash flows from licensing income or from product sales in the short term, Epigenomics is evaluating its options to raise capital in the markets before the end of 2012 using all means it has at its disposition, including issuance of shares and convertible bonds.

Further Information

The full Nine Months Financial Report 2012 can be obtained from Epigenomics’ website at:
<http://www.epigenomics.com/en/news-investors/investors/financial-reports.html>

- Ends -

Contact Epigenomics AG

Antje Zeise
Manager IR | PR
Epigenomics AG
Tel +49 (0) 30 24345 368
ir@epigenomics.com
www.epigenomics.com

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 in development for the U.S.A. The Company's technology and products have been validated through multiple partnerships with leading global diagnostic companies including Abbott, QIAGEN, Sysmex, and Quest Diagnostics. Epigenomics is an international company with operations in Europe and the U.S.A.

Epigenomics legal disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Epigenomics AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Epigenomics AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

The information contained in this communication does not constitute nor imply an offer to sell or transfer any product, and no product based on this technology is currently available for sale by Epigenomics in the United States or Canada. The analytical and clinical performance characteristics of any Epigenomics product based on this technology which may be sold at some future time in the U.S. have not been established.