



Epigenomics AG reports third quarter 2005 financial results

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Press release, Berlin, Germany and Seattle, WA, USA

Epigenomics AG (Frankfurt, Prime Standard: ECX), a molecular diagnostics company developing tests based on DNA methylation, today reported financial results for the third quarter ending September 30, 2005.

Third Quarter 2005:

For the third quarter 2005, costs continued to be tightly controlled. Research & development expenditure decreased in Q3 2005 to EUR 2.0 million from EUR 2.09 million in the same period 2004. Revenue decreased by nearly 28% to EUR 2.11 million compared with the same period in 2004 due to one-off milestone revenue recognition in Q3 2004. Primarily, revenue was generated through our ongoing partnerships with Roche Diagnostics as well as Qiagen, Philip Morris, Pfizer and Biogen Idec.

Earnings before interest and taxes (EBIT) was in line with our expectations and guidance given for the full year at EUR 3.03 million. Net loss for Q3 2005 amounted to EUR 2.77 million (Q3 2004: EUR 2.61 million). Net loss per share was EUR 0.17 compared to EUR 0.16 in Q3 2004. The figures were calculated on 16.39 and 16.09 million shares, respectively. Marketing & business development expenses increased to EUR 0.51 million (Q3 2004: EUR 0.44 million) and general & administrative costs decreased from EUR 1.14 million in Q3 2004 to EUR 0.88 million.

Highlights of the Third Quarter 2005 included:

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- Successful extension of the Roche Diagnostics R&D collaboration by a minimum of 6 months and with an option to further extend and possibly expand for another 18 months in Q1-2006
- Progressed our own product development pipeline in both tissue tests as well as blood-based tests
- Retirement of Gary Schweikhardt and resignation of Aron Braun, due to personal reasons
- Hiring of Dr Michael Wandell as Group Vice President Clinical, Regulatory and Quality Affairs
- New SBU management and Executive Board responsibilities were defined with Christina Dahlstroem to head the SBU Pharma Technology and Christian Piepenbrock to become COO and head of SBU Diagnostics

First Nine Months 2005:

In the first nine months ending September 30, 2005, revenue remained relatively stable at EUR 5.74 million (9M 2004: EUR 5.68 million). Total operating expenses for the first nine months amounted to EUR 15.87 million compared to EUR 14.49 million in 2004. Research and development expenditure increased by 6% from EUR 5.80 million in 2004 to EUR 6.16 million for the first nine months of the year, cost of sales, i.e. costs for partnered program execution, increased 19% to EUR 5.36 million compared to EUR 4.53 million for the same period 2004. General and administrative expenses were EUR 2.95 million compared to EUR 2.75 million in the same period of 2004. Earnings before interest and taxes (EBIT) in the first nine months was EUR -8.92 million compared to EUR -7.94 million for 2004. Net loss for the nine months decreased by almost 8% to EUR 8.19 million from EUR 8.86 million. Basic loss per share was EUR 0.50 in the first nine months of 2005 from EUR 0.68 in the same

period 2004.

In line with previous guidance, Epigenomics expects to generate full-year 2005 revenues to reach between EUR 8.5 and EUR 10 million in FY 2005. Also in line with expectations and previous guidance, EBIT for FY 2005 is expected to be significantly below FY 2004. Current guidance for EBIT is between EUR -10.5 and -12 million for FY 2005.

As of September 30, 2005, cash, cash equivalents, short-term investments and marketable securities totaled EUR 34.22 million compared with EUR 41.04 million at the end of December 2004. The net cash burn for operating activities of EUR 7.09 million for the first nine months of 2005 was reduced by 6% compared to EUR 7.55 million for the same period in 2004.

As announced earlier this week, initial analysis of a blinded test study for our Tamoxifen treatment response test showed that the candidate markers could not be independently validated. The data strongly points towards issues with the technical protocols followed rather than problems with the markers themselves. In addition, the collected data shows irregularities with sample quality and input DNA concentrations which led to an unusually high rate of sample exclusions. The markers were also observed when samples with low concentrations of input DNA were excluded. The PITX2 marker used in the test has previously been identified and validated in a number of independent studies, totalling approximately 1200 patients.

Epigenomics and partner Roche Diagnostics are jointly conducting data analysis and additional experiments. Epigenomics expects to need no more than a few months to investigate the technical issues and then successfully run a further study within another 6 to 9 months to resolve the situation. Roche Diagnostics has an option to license the Tamoxifen treatment response test as part of its multi diagnostic product development collaboration with Epigenomics.

During the third quarter, we successfully extended our product development collaboration with Roche, which was an endorsement to our collaboration to date. Despite the recent set-back of the inconclusive Tamoxifen treatment response test study, Epigenomics is working diligently with Roche to determine the optimal future development path of the partnered DNA methylation tests, including the Tamoxifen breast cancer response test as well as our colon cancer screening test. Currently we believe that the specific technical issues faced in the Tamoxifen study would have no bearing on our colon screening validation study, which is on track and on schedule for completion by year-end. Decisions on both the Tamoxifen and colon cancer screening tests are anticipated by the end of November and year-end, respectively, noted Oliver Schacht, CFO of Epigenomics. Independent of any licensing decision by Roche we have every reason to believe in the product potential of our Tamoxifen breast cancer treatment response test and are committed to taking that product further in development.

About Epigenomics

Epigenomics is a molecular diagnostics company with a focus on the development of novel products for cancer. By detecting and interpreting

DNA methylation patterns, Epigenomics tests can potentially diagnose disease at an early stage and help guide physicians to select an appropriate therapy. Epigenomics collaborates with Roche Diagnostics on the development of several diagnostic products in cancer. The company has its headquarters in Berlin, Germany, and a wholly owned subsidiary in Seattle, USA. For more information, please visit our website at www.epigenomics.com.

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