



Epigenomics AG Reports Q3 and Nine Months 2009 Results

Date: Tuesday, 10.11.2009

Key Figures 9M 2009

Revenue, EBIT and net loss significantly improved

- **Revenue: EUR 3.2 million in 9M 2009, up by 77% (9M 2008: EUR 1.8 million)**
- **EBIT: EUR – 7.1 million in 9M 2009, improved by 17% (9M 2008: EUR –8.5 million)**
- **Net loss: EUR – 7.1 million in 9M 2009, decreased by 13% (9M 2008: EUR –8.1 million)**
- **Liquid assets: EUR 9.5 million at end of September 2009 (31/12/2008: EUR 12.1 million)**

Operational Highlights Fiscal Year (FY) 2009 to Date

- **Launched Epi proColon, the first CE-marked IVD kit for colorectal cancer blood testing**
- **Colorectal cancer blood test available to patients through Swiss diagnostic laboratory Viollier AG and four German laboratories**
- **Progressed PRESEPT colorectal cancer clinical study**
- **Development of Abbott Septin9 product on track for European launch in Q4/ 2009**
- **Signed licensing deal with ARUP Laboratories for non-exclusive U.S. rights to ^mSEPT9 for laboratory-developed test (LDT) use**
- **Finalized clinical evaluation of ^mSHOX2 lung cancer biomarker and initiated product development**
- **Strengthened intellectual property position by cross license with DxS Ltd., since then acquired by Qiagen**

Epigenomics to present today at investor conference at the German Equity Forum of the Deutsche Börse Group in Frankfurt/ Main, Germany

Press release, Berlin, Germany, and Seattle, WA, U.S.A., November 10, 2009

The molecular diagnostics company Epigenomics AG (Frankfurt Prime Standard: ECX) today reported financial results for the third quarter and for the first nine months of 2009, which ended September 30, 2009, and provided a corporate update.

Commenting on the operational progress in the year 2009 to date, Geert Nygaard, the company's Chief Executive Officer said: "With the launch of our CE-marked Epi proColon test, we have reached one of the most significant milestones in Epigenomics' history so far. Septin9 colorectal cancer blood testing is now available to doctors and patients at several laboratories in Europe. With our partner Abbott expected to launch their Septin9-based product for the European market before the end of the year and Quest Diagnostics expected to launch their Septin9 testing service in the U.S.A. in Q4 2009, we will further expand the availability of the test to the benefit of the cancer screening population."

"The significant progress in our licensing partnerships, our IVD product development, and the excellent progress in our clinical PRESEPT Study are all reflected in our 9-months financials. As of the end of Q3 we have already met our goals of growing our revenue for fiscal 2009 to more than 3 million Euros and to significantly improve our earnings", added Oliver Schacht, the company's Chief Financial Officer.

First 9 Months of 2009 – Financial Review

Epigenomics' revenue in 9M 2009 amounted to EUR 3.2 million, an increase of more than 77% compared to EUR 1.8 million during the same period in 2008. The revenue during the first nine months was generated from continued and newly signed collaborations and licensing agreements in the form of R&D payments, licensing fees, reimbursements as well as sales of Research-Use-Only products.

EBIT for 9M 2009 of EUR – 7.1 million showed a 17% improvement over EBIT for the corresponding period in 2008 of EUR – 8.5 million.

R&D costs dropped from EUR 6.8 million in 9M 2008 to EUR 5.1 million in the reporting period primarily resulting from increased resource allocation to commercial collaboration projects and a corresponding shift to cost of sales. Costs of sales increased to EUR 2.1 million compared to EUR 0.7 million in 9M 2008, mainly as a result of increased product development expenses associated with collaboration agreements with Abbott and Philips and costs for the acquisition of clinical samples under the agreement with Abbott. Net loss for the reporting period amounted to EUR – 7.1 million, a substantial reduction compared to EUR – 8.1 million in 9M 2008. Basic loss per share improved from EUR – 0.32 in 9M 2008 to EUR – 0.24 in 9M 2009.

In 9M 2009, Epigenomics' cash flow and its financial position were mainly affected by the continued net cash consumption from operating activities and the successful PIPE financing transaction in February 2009. Overall, the financial position in 9M 2009 has developed according to plan with short-term liquidity as of September 30, 2009, of EUR 9.5 million – a decrease of EUR 2.6 million from EUR 12.1 million at year-end 2008 - mainly due to net cash consumption for operating activities as well as for investments in tangible and intangible assets.

Cash outflow from operating activities in 9M 2009 totaled EUR 8.0 million (9M 2008: EUR 6.9 million). Cash inflow from investing activities amounted to EUR 0.3 million (9M 2008: EUR 1.0 million), primarily due to a redemption of marketable securities. Cash flow from financing activities was positive at EUR 5.1 million (9M 2008: EUR 11.5 million), due to the capital increase in February 2009.

Operational Review and Highlights of FY 2009 to date

In 2009 to date, Epigenomics focused its development and commercialization on its Septin9 blood test for colorectal cancer. The test is the first IVD blood test ever offered for colorectal cancer early detection in Europe. As the first laboratory network, Swiss Viollier AG, started offering the test to patients, general practitioners and gastroenterologists in Switzerland in July. Several German laboratories, including Labor Dr. Limbach & Kollegen (Heidelberg), Labor Krone (Bad Salzuflen), MVZ Dr. Stein & Kollegen (Moenchengladbach) and MVZ Dr. Eberhard & Partner (Dortmund) started offering Septin9 testing as of October 1, 2009.

Epigenomics also successfully completed the development of its Septin9 in vitro diagnostic (IVD) test kit. The CE-marked IVD product was launched in Europe under the brand name Epi *pro*Colon on October 6, 2009. The test can now be sold to any suitably equipped molecular diagnostics laboratory in Europe as an aid in the detection of colorectal cancer.

Throughout the reporting period, Epigenomics also progressed the PRESEPT colorectal cancer screening study. Enrollment in this prospective study for the Septin9 biomarker reached 6,376 subjects at the end of Q3 with more than three quarters of the expected 50 colorectal cancer cases already identified by colonoscopy. By 31st October enrollment into the PRESEPT Study had reached over 7,000 subjects with almost 90% of CRC cases identified by colonoscopy. Testing of PRESEPT samples using the Epi *pro*Colon test has been initiated by Epigenomics in three independent clinical laboratories, namely Quest Diagnostics, ARUP Laboratories, and Charité – Universitätsmedizin Berlin in October 2009. Testing of the samples will be completed in late 2009 or early 2010, depending on when the last of the targeted 50 cancer cases is enrolled into the study. The laboratories as well as Epigenomics will be completely blinded to any testing results until the last sample has been tested.

Quest Diagnostics, Inc., made solid progress in the development of its Septin9 test and announced that it would start offering Septin9 testing to doctors and patients in the U.S. still within 2009. Moreover, Epigenomics expects its collaboration partner Abbott Molecular, Inc. to launch their CE-marked Septin9 blood test optimized for the Abbott m2000 platform as planned towards the end of 2009 in Europe.

During the third quarter Epigenomics has continued to implement its non-exclusive commercialization strategy by signing a license agreement for the mSEPT9 biomarker with ARUP Laboratories, Inc., Salt Lake City, UT, U.S.A. ARUP is the second non-exclusive reference laboratory licensee for the U.S. market and is expected to launch its Septin9

testing service in the U.S. in 2010.

In a lung cancer study conducted in cooperation with the Charité - Universitätsmedizin Berlin, Germany, Epigenomics has demonstrated that the ^mSHOX2 biomarker that is at the core of the Company's bronchial lavage test for lung cancer is also a promising biomarker for lung cancer blood testing. The study with about 340 patients demonstrated that in a population of patients undergoing diagnostic work-up for suspected lung cancer, of which typically about 40% actually have the cancer, an ^mSHOX2 test can potentially predict the presence of the disease with 92% probability (positive predictive value).

Epigenomics also further strengthened its technology position by cross-licensing certain technologies with its partner DxS Ltd. enabling both partners to use DxS' Scorpions® technology for DNA methylation research and IVD products. DxS has recently been acquired by Qiagen, also a long-term partner of Epigenomics.

Outlook

In Q4 2009, Epigenomics' focus will remain on driving commercialization of the colorectal cancer blood test based on the ^mSEPT9 biomarker by direct marketing and sales of the Epi *proColon* IVD test kit, as well as by supporting the non-exclusive licensees in their endeavors to develop and launch ^mSEPT9-based blood tests for colorectal cancer. Therefore, significant parts of the operational activities in the last quarter of 2009 will continue to be directed towards executing the PRESEPT Study and delivering first clinical results from that trial either in late 2009 or in early 2010.

Cooperation with Abbott to support them in completing the final phases of their product development will be continued, with the strategic goal of having Abbott launch a CE-marked IVD blood test for colorectal cancer detection based on ^mSEPT9 in Europe by the end of 2009.

The key strategic focus in marketing and business development activities in late 2009 and 2010 will be on closing additional non-exclusive licensing deals for colorectal cancer screening and ^mSEPT9. The timing of any future ^mSEPT9 deals with expected results from the PRESEPT Study as well as the expected Abbott product launch in Europe will be carefully coordinated. The goal is to maximize value to Epigenomics in any future licensing deals for ^mSEPT9.

All R&D activities will be focused on progressing programs in the current product pipeline in colorectal, lung and prostate cancer.

Full-year revenue for 2009 is expected to be higher than 2008 revenue, as it exceeded the 2008 revenue already as of September 30, 2009. This increase in revenue resulted from existing collaborations, from the additional partnerships and license agreements that have been entered into as well as from initial direct product sales.

In Q4 revenue is expected to come from partnering activities in diagnostics as milestones are expected to be reached (e.g. CE-marked Septin 9 kit launch by Abbott in Europe and Quest Diagnostics' launch of a Septin9 testing service in the U.S.). Further, initial sales of the Epi *proColon* IVD test kit and a number of biomarker R&D collaborations with pharmaceutical companies and academic institutions are expected to also contribute to revenue growth. Due to continued strict cost discipline EBIT and net loss for the full year 2009 are expected to show an improvement over the previous year. Net cash consumption for 2009 is anticipated to be at a very similar level compared to 2008, i.e. at around EUR 10 million.

Epigenomics' investor conference at the German Equity Forum of the Deutsche Börse Group today

The German Equity Forum of the Deutschen Börse Group takes place from November 9th to November 11th, 2009 at the Congress Center Messe Frankfurt, Ludwig-Erhard-Anlage 1, 60327 Frankfurt/ Main, Germany.

The investor conference for the presentation of Epigenomics' current financial results takes place today, Tuesday, November 10th, 2009 from 4:30pm to 5:15pm, room Zurich.

About Epigenomics

Epigenomics is a molecular diagnostics company with a focus on the development of novel products for cancer. Using DNA methylation biomarkers Epigenomics' tests on the market and in development aim at diagnosing cancer at an early stage before symptoms occur and thereby may reduce mortality from this dreaded disease.

Epigenomics' product portfolio contains Epi *pro*Colon, a CE-marked IVD blood test for the early detection of colorectal cancer based on the validated biomarker *m*SEPT9, and further proprietary DNA methylation biomarkers at various stages of development for colorectal, lung and prostate cancer detection in blood, bronchial lavage, and urine specimens. Epigenomics' biomarker *m*SEPT9 for the early detection of colorectal cancer in a simple blood sample has demonstrated continuously highest performance in eight clinical case-control studies with in total more than 3,300 individuals tested. A large prospective clinical study – PRESEPT – to evaluate the performance characteristics and the health economic benefit of colorectal cancer screening with the *m*SEPT9 biomarker in a representative screening population is currently under way (www.presept.net). Once completed, the PRESEPT Study will be one of the largest commercially sponsored colorectal cancer screening clinical studies ever conducted. The clinical performance and health economic analysis results are expected to support future coverage of *m*SEPT9 testing by public and private health insurers worldwide. Epigenomics' partners developing IVD test kits for the *m*SEPT9 biomarker can co-fund and access the PRESEPT sample collection to conduct clinical trials for regulatory filings in the U.S.

For development and global commercialization of IVD test products, Epigenomics pursues a dual business strategy in which direct commercialization of proprietary diagnostic test products is combined with non-exclusive licensing to diagnostic industry players with broad customer access. Strategic diagnostics industry partners include Abbott Molecular, Philips, Sysmex Corporation, Quest Diagnostics Incorporated, and ARUP Laboratories, Inc. for diagnostic test products and services, and QIAGEN N.V. for sample preparation solutions and research products.

Partners in the health care industry and the biomedical research community can access Epigenomics' portfolio of proprietary DNA methylation technologies and biomarkers through research products, Biomarker Services, IVD Development Collaborations, and Licensing. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary in Seattle, WA, U.S.A. For more information, please visit Epigenomics' website at www.epigenomics.com.

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[back](#)