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EANS-News: Epigenomics AG Reports First Half 2010 Results

10.08.2010 - 08:01 Uhr, Epigenomics AG

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6-month report/Molecular diagnostics

Subtitle: Key Figures

* Revenue: EUR 1.0 million in H1 2010 (H1 2009: EUR 2.1 million) * EBIT: EUR -5.4 million in H1 2010 (H1 2009: EUR -4.8 million) * Net loss: EUR 5.4 million in H1 2010 (H1 2009: EUR 4.8 million) * Liquid assets: EUR 32.3 million as of 30/06/2010 (31/12/2009: EUR 6.1 million)

Highlights of the First Half 2010 and year to date

- * Financial position improved significantly
- * Broadened availability of Epi proColon product in Europe
- * ARUP launches Septin9 testing for colorectal cancer in the U.S.A.
- * Septin9 colorectal cancer biomarker patent granted in the U.S.A.
- * Licensed Septin9 non-exclusively to Canadian Warnex Medical Laboratories
- * Presented final prospective PRESEPT colorectal cancer clinical study data at leading conference
- * Demonstrated 81% sensitivity at 95% specificity for SHOX2 lung cancer biomarker in EU pivotal clinical study
- * Launched Epi proLung BL Reflex Assay in Europe

Press release, Berlin, Germany, and Seattle, WA, U.S.A., August 10, 2010 (euro adhoc) - Epigenomics AG (Frankfurt Prime Standard: ECX), a cancer molecular diagnostics company, today reported financial results for the second quarter and first half of 2010, which ended June 30, 2010.

Commenting on the first six months of 2010, Geert Nygaard, the company's Chief Executive Officer said: "We have made substantial progress in establishing our Septin9 blood test as an innovative tool for the early detection of colorectal cancer in our home market, and it is very encouraging to see the support we receive from key opinion leaders in educating primary care physicians. By June more than one third of German family doctors have been made aware of the Septin9 test and more importantly we see increasing numbers of cancer cases being successfully identified by our Septin9 test. Each case represents an individual that would otherwise probably not have been screened, with potentially fatal consequences".

Financial Review

Revenue in H1 2010 decreased by 53% to EUR 1.0 million, from 2.1 million in the corresponding period of 2009. The main reason for this decrease was revenue recognition from non-recurring service projects that had been initiated in 2008 as well as revenue from sample collection under the Abbott collaboration agreement, which were both included in revenue in the first half of 2009. H1 2010 revenue was generated from product sales of the Epi proColon kits as well as from continued collaboration and licensing agreements in the form of R&D payments and licensing income.

R&D costs increased from EUR 3.4 million in the first half of 2009 to EUR 3.6 million in the current reporting period. Cost of sales fell significantly to EUR 0.3 million compared to EUR 1.5 million in H1 2009, mainly due to the completion of the clinical sample collection within the collaboration with Abbott, which strongly affected cost of sales in 2009. Furthermore, the completion of some work packages within partnerships led to a drop of collaboration-driven product development expenses at the end of H1 2010. This resulted in an improved gross margin for H1 2010 compared to H1 2009.

Selling, general and administrative costs increased from EUR 2.1 million in H1 2009 to EUR 2.8 million in H1 2010 due to intensified marketing, sales and technical sales support activities for the Epi proColon colorectal cancer screening test as well as preparation activities for the launch of the second IVD product, the Epi proLung BL Reflex Assay.

EBIT for H1 2010 decreased to EUR -5.4 million, compared to EUR -4.8 million for the corresponding period in 2009.

Net loss for the current reporting period amounted to EUR 5.4 million, compared to EUR 4.8 million in H1 2009. Basic loss per share improved from EUR 0.17 in H1 2009 to EUR 0.15 in H1 2010.

In the first half of 2010, Epigenomics' financial position has improved significantly, mainly driven by the successful capital increase. Liquid assets amounted to EUR 32.3 million as of June 30, 2010, compared to EUR 6.1 million as of December 31, 2010. Therefore, the overall result was a net cash inflow in H1 2010 of EUR 26.5 million.

Operational Highlights

During the first half of 2010, Epigenomics focused on transforming the organization into a product-driven company and on further pursuing its dual business model of both direct commercialization and partnering. The main goal was driving market acceptance and thereby sales for the company's Septin9 blood test Epi proColon for colorectal cancer screening and in supporting the partners' commercial activities.

In the second quarter of 2010, Epigenomics has further strengthened its market presence in Germany through the 55 German sites of the European laboratory network synlab starting to offer the Epi proColon test. This additional laboratory network offering Septin9 testing makes this innovative product even more broadly available to doctors and patients in Europe.

In further execution of its dual business model, in May 2010 Epigenomics non-exclusively licensed its biomarker Septin9 to Canadian life sciences company Warnex Medical Laboratories. Under the terms of the licensing agreement, Warnex has obtained the rights to establish a laboratory-developed test for Septin9 and to offer colorectal cancer blood testing services in Canada. Epigenomics expects Warnex' Septin9 blood test to be launched within the next few months. During the first half of 2010, Epigenomics also signed a warehousing, logistics and distribution agreement with Arvato AG, a Bertelsmann subsidiary specializing in services for the diagnostics and healthcare industry.

Epigenomics intellectual property position has been strengthened by the United States Patent and Trademark Office granting a patent for the Septin9 DNA methylation biomarker in U.S.A. on July 6, 2010.

After the successful completion and evaluation of data from the PRESEPT Study in the first quarter of 2010, the principle investigator of the PRESEPT Study, Prof. Timothy R. Church, PhD, School of Public Health, University of Minnesota, MN, U.S.A. presented data during this year's Digestive Disease Week in New Orleans in May demonstrating that the Septin9 biomarker can detect up to 66.7% of the cancer cases at a specificity of 88.4% in a representative screening cohort of about 8,000 study subjects. This makes Septin9 the only DNA methylation biomarker for colorectal cancer that has been fully validated in a true prospective screening cohort under conditions as applied in the clinical routine.

In July, Epigenomics has launched its second CE-marked in vitro diagnostic product Epi proLung BL Reflex Assay in Europe. The launch followed the successful completion of a pivotal performance evaluation study for the product. The diagnostic test is being developed as an aid in the diagnosis of lung cancer and may help pathologists confirm the diagnosis of malignant lung disease when current diagnostic procedures fail to establish the presence of malignancy in patients with suspected lung cancer. With a demonstrated sensitivity of 81% at a specificity of 95%, the study confirmed previous research studies showing that methylated SHOX2 DNA is a sensitive and highly specific biomarker for the detection of lung cancer in bronchial lavage specimens.

Outlook H2 2010

In the second half of 2010, Epigenomics intends to continue its transformation from an R&D-driven organization into a market-driven diagnostics industry player. The Company anticipates all commercially available Septin9-based tests to increase sales gradually during 2010 and to accelerate in 2011 and beyond. Furthermore, Epigenomics expects to maintain a solid base of collaboration, licensing and partnering-based revenue generation which assumes the closing of additional IVD partnerships. Royalty income from sales of Abbott's RealTime mS9 Colorectal Cancer product and Quest's ColoVantage testing service should also gradually start to contribute in H2 2010 with accelerated growth expected in 2011 and beyond. The launch of ARUP's laboratory developed test in July 2010 and the expected launch of Warnex' Septin9 testing service later in 2010 should also add to royalty income going forward.

Epigenomics markets and sells its Epi proLung test directly in its home markets (Germany,

Austria, and Switzerland) and intends to work with distributors in other countries. The Company also plans to initiate its own campaign for regulatory approval of the Epi proColon test in the USA, using additional patient samples collected as part of PRESEPT in H2 2010. To that end, Epigenomics has retained the services of DOCRO, Inc., a leading regulatory affairs group and contract research organization with a proven track record of successful client submissions for both 510k clearance and PMA approvals of molecular diagnostics and oncology products. The management also expects Abbott to progress their clinical trial for regulatory approval of their RealTime mS9 colorectal cancer test and to file for regulatory approval for the United States by 2011.

In-house R&D efforts in the area of colorectal cancer biomarkers will focus on enhanced clinical characteristics for colorectal cancer early detection as well as on expansion of the clinical utility into disease monitoring and adenoma detection. Also, Epigenomics will continue to develop a next generation biomarker discovery tool based on its proprietary DMH (differential methylation hybridization) array. This new generation technology will provide significant improvements in terms of number of features analyzed as well as sensitivity for subtle methylation differences, paving the way to address unmet clinical questions.

Financials for H2 2010 are expected to be characterized by continued fiscal discipline and ongoing focus on commercialization. Epigenomics now anticipates 2010 revenue to be below 2009 revenue, and as a consequence, EBIT is expected to be lower than 2009 at around EUR -12 million. Cash consumption is expected to be around EUR 11 to 12 million for the full year 2010.

Further Information

The full 6-Months Report 2010 can be obtained from Epigenomics' website at:
www.epigenomics.com/en/investor_relations/Financial_Information/

Epigenomics' management will host a conference call on the second quarter and half year 2010 results at 3pm CET today, Tuesday 10th August 2010. The dial-in numbers for the conference call are:

Dial-in number (within Germany): +49 (0)69 247 501 899 Dial-in number (within the US): +1 212 444 0297

Participants are kindly requested to dial in 10 minutes prior to the start of the call.

The presentation accompanying the conference call will be available for download on the Epigenomics website:

http://www.epigenomics.com/en/download/corporate_material/

A recording of the conference call will be provided on Epigenomics' website subsequently:

http://www.epigenomics.com/en/download/corporate_material/

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 the CE-marked IVD test Epi proColon, the world's first regulatory cleared molecular diagnostic test for the detection of colorectal cancer in blood that is based on the biomarker Septin9, and further proprietary DNA methylation biomarkers and IVD products at various stages of development for colorectal, lung and prostate cancer. 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, Sysmex Corporation, Quest Diagnostics Incorporated, and ARUP Laboratories, Inc. for diagnostics test products and services, and QIAGEN N.V. for sample preparation solutions and research products. The company is headquartered in Berlin, Germany, and has a wholly owned subsidiary, Epigenomics Inc., in Seattle, WA, USA. For more information, please visit Epigenomics' website at www.epigenomics.com

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inquiry note:

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Branche: Biotechnology
ISIN: DE000A0BVT96
WKN: A0BVT9
Index: Prime All Share, Technology All Share
Börsen: Frankfurt / regulated dealing/prime standard
Berlin / free trade
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Stuttgart / free trade
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Originaltext:

Epigenomics AG

ISIN:

DE000A1K0516

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