

Press release

## **Epigenomics AG Announces H1 2013 and Q2 2013 Financial Results and Reports on Operational Highlights**

*Berlin, Germany, and U.S.A., August 7, 2013* - Epigenomics AG (Frankfurt Prime Standard: ECX, OTC: EPGNY), the German-American cancer molecular diagnostics company, today announced its financial results for the first half and second quarter of 2013 ending June 30.

- Revenue in Q2 2013 increased by 120% to EUR 343 thousand compared to Q2 2012
- Operating costs decreased by 44% to EUR 2,098 thousand over Q2 2012
- EBIT in Q2 improved by 53% to EUR -1,607 thousand compared to Q2 2012
- Net cash flow in H1 2013 positive due to successful capital increase in January
- Level 1 ADR program established

“In the first half of 2013, we were pleased to see growing sales of our blood-based colorectal cancer (CRC) test, Epi proColon® in the European and Asian markets, demonstrating growing acceptance of this product. At the same time, we have continued to focus on the approval process at the U.S. Food and Drug Administration (FDA). A series of facility inspections by the FDA have been conducted and we are currently in a constructive dialogue with the agency, awaiting additional feedback on the review process and news regarding the expected advisory board panel meeting date in the near future. We remain confident and anticipate the approval decision regarding our lead product within the second half of this year”, said Dr. Thomas Taapken, CEO/CFO of Epigenomics AG.

### **H1 2013 Financial Results**

- Revenue in H1 2013 significantly increased by 75% to EUR 698 thousand (H1 2012: EUR 399 thousand) driven by strong product sales of EUR 327 thousand and R&D service fees of EUR 246 thousand (Q2 2013: EUR 343 thousand; Q2 2012: EUR 156 thousand; +120%)
- Operating costs decreased by 37% in H1 2013 compared to H1 2012 to EUR 4.3 million (H1 2012: EUR 6.8 million; Q2 2013: EUR 2.1 million; Q2 2012: EUR 3.8 million; -45%) This was primarily attributable to the completed clinical trial (i.e. FIT study) in 2012, which had significantly impacted the 2012 numbers. In addition, it mirrors the Company’s reduction in headcount from 44 employees at the end of H1 2012 to 32 at the reporting date.
- As a consequence of cost reductions, EBIT for H1 2013 improved by 42% to EUR -3.3 million (H1 2012: EUR -5.7 million) and net loss by 42% to EUR 3.3 million (H1 2012: EUR 5.7 million).
- Loss per share in H1 2013 amounted to EUR 0.29 compared to EUR 0.65 in H1 2012 (Q2 2013: EUR 0.14; Q2 2012: EUR 0.38).
- Net cash flow in H1 2013 was positive at EUR 0.8 million (H1 2012: EUR -5.0 million). A major impact on liquidity resulted from the successful capital raise in Q1 2013, through which Epigenomics recorded a net cash inflow of EUR 4.6 million.
- Cash outflow from operating activities was reduced to EUR 3.8 million (H1 2012: EUR 4.8 million). This outflow included payments in connection with the FIT comparison study completed in 2012 and payments for consulting and regulatory services during the ongoing FDA approval process.

- Liquid assets at the end of the period amounted to EUR 3.6 million (December 31, 2012: EUR 2.7 million).

## Operational highlights

- **FDA Approval Process Progresses as Planned:** In the second quarter of 2013, Epigenomics continued to focus on the U.S. approval of its blood-based CRC test, Epi proColon<sup>®</sup>, and proceeded on the regulatory path according to plan. A series of facility inspections by the FDA have been conducted and open topics have been addressed. The Company now awaits feedback from the agency on the review process and an advisory board panel review meeting is expected to be called in by the FDA. Epigenomics remains confident and anticipates the approval decision within the second half of this year. The Company will continue to update the public on all major developments.
- **Data of FIT Comparison Study Presented at DDW Conference:** In May 2013, results of the head-to-head comparative study between Epi proColon<sup>®</sup> and fecal immunochemical testing (FIT) were presented at a workshop of the World Endoscopy Organization (WEO) during the Digestive Disease Week (DDW) Conference in Orlando, Florida, U.S.A.
- **Product Sales Increasing:** Sales of Epigenomics' products have further gained ground, demonstrating the growing acceptance of the Company's products in the market. Sales through some of the Epigenomics' largest established laboratory customers have strengthened and especially the recent collaboration with the Chinese partner BioChain got off to a good start.
- **Level 1 ADR Program Established:** In July 2013, after the reporting period, Epigenomics announced the establishment of a Level 1 American Depositary Receipt (ADR) program. Epigenomics' ADRs can now be traded on the OTC (over-the-counter) market under the ticker symbol EPGNY.
- **Analysts Coverage Broadened:** Research analysts from Kempen & Co., Nomura Code Securities and First Berlin Equity Research have initiated coverage of Epigenomics with "buy" recommendations and valuations ranging between EUR 2.80 and EUR 4.30 per share.
- **Changes to the Executive Board:** In April 2013, Epigenomics announced the appointment of Dr. Uwe Staub to the Executive Board of the Company as Chief Operating Officer (COO), a position he has held already since September 2012 in a non-executive function.

## Outlook

- Based on the half-year results, Epigenomics is now confident to see an increase of revenue for 2013 compared to the previous year. The successful reduction of costs will enable the Company to reach its forecasted financial targets for 2013. In line with previous guidance, EBIT and net loss are expected to be in a range between EUR -6.5 million and EUR -7.5 million respectively for the full year. The expected net loss per share for 2013 will likely be in the range of EUR -0.54 to EUR -0.64, a significant reduction compared to 2012 (EUR -1.38). Cash consumption for 2013 is expected to be approximately EUR 7 million (2012: EUR 10.9 million).
- The most significant milestone for Epigenomics remains the expected U.S. approval for Epi proColon<sup>®</sup> by the FDA in the second half of 2013. This approval will heavily affect the future value of the Company and its ability to improve its financial situation going forward.
- Current financial resources are expected to fund the Company's operations into early 2014. Since it is not anticipated that the Company will be able to generate sufficient cash flows from licensing income or product sales in the short-term, Epigenomics is intensively evaluating all financing options available, including the possibility of a further capital increase, in order to secure its business operations beyond this term.

## **Further Information**

### **Conference call for press and analysts**

The full 6-Months Financial Report 2013 can be obtained from Epigenomics' website at:  
<http://www.epigenomics.com/en/news-investors/investors/financial-reports/2013.html>

Epigenomics' management will host a conference call with web presentation at 3pm CET/9am ET today, Wednesday, August 7<sup>th</sup>, 2013. 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.

The presentation accompanying the conference call and dial-in details for the web presentation will be available on Epigenomics' website: <http://www.epigenomics.com/en/news-investors.html>

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>

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### **About Epigenomics**

Epigenomics ([www.epigenomics.com](http://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

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diagnose cancer earlier and more accurately, leading to improved outcomes for patients. Epigenomics' lead product, Epi proColon<sup>®</sup>, 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 and testing laboratories. Epigenomics is an international company with operations in Europe and the U.S.A.

## **Epigenomics legal disclaimer**

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