

Press release

Epigenomics AG Reports Results for the Financial Year Ended December 31, 2014 and Provides Outlook for 2015

- *Epi proColon® approved for commercialization in China*
- *US Approval: ADMIT trial fully enrolled; expected to report data in Q2 2015*
- *Strong commitment from partners; EUR 4.2 million equity investment by BioChain*
- *Solid year-end financial position; liquidity at year end 2014 EUR 7.5 million*

Berlin (Germany) and Germantown, MD (U.S.A.), March 25, 2015 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced financial results for the fiscal year ending December 31, 2014 and provided an outlook for the year 2015.

Dr. Thomas Taapken, CEO/CFO of Epigenomics, commented "Despite the unexpected delay in the U.S. regulatory process for Epi proColon®, 2014 was a successful year for Epigenomics. We obtained market approval for our innovative and convenient blood-based colorectal cancer screening assay in China, which represents a major milestone in the history of our Company. Together with our partner BioChain, we are now seeking to address this tremendous market opportunity. Approval in the U.S.A., the largest global market for diagnostic products, is now reliant on our ADMIT trial which is nearing completion. Together with our partners in China and the U.S.A., we will work with healthcare organizations, key opinion leaders, payors and patients to increase awareness and compliance to CRC screening and thus pave the way for our commercial success."

2014 Financial Results

- In 2014, Epigenomics' total **revenue** amounted to EUR 1.5 million (2013: EUR 1.6 million). The slight decrease compared to the previous year was mainly due to the phase out of some existing licensing agreements ahead of the expected approval of the Epi proColon® test kit for commercialization in the U.S.A. Product sales fully met Epigenomics' expectations and increased to EUR 0.8 million in 2014 from EUR 0.6 million in 2013.
- **Total operating costs** increased to EUR 10.4 million (2013: EUR 9.5 million). This increase was in line with the 2014 guidance and partly driven by non-cash expenses for the Company's phantom stock programs. Driven both by the efforts towards the FDA approval and the set-up of the ADMIT trial, **research and development ("R&D") costs** increased by EUR 0.3 million to EUR 4.7 million (2013: EUR 4.4 million). **Selling, general and administrative ("SG&A") costs** were up EUR 0.4 million to EUR 4.9 million (2013: EUR 4.5 million).
- On this basis **operating loss (EBIT)** in 2014 widened to EUR 8.4 million (2013: EUR 7.3 million). Due to non-cash interest expenses in the amount of EUR 0.5 million for the convertible bond program, **net loss** increased to EUR 8.9 million (2013: EUR 7.4 million). This equals a **loss per share** of EUR 0.65 (2013: EUR 0.62).
- **Cash consumption** in 2014 amounted to EUR 8.1 million (2013: EUR 6.5 million), including capital expenditures of EUR 0.8 million relating to the establishment of new facilities in Berlin. Due to net cash inflows from financing activities of EUR 7.6 million in 2014 (2013: EUR 11.5 million), **net cash flow** amounted to EUR -0.5 million (2013: EUR 5.0 million).

- The Company's **liquidity** at year-end 2014 was EUR 7.5 million (Dec 31, 2013: EUR 8.0 million). The outstanding convertible notes have the potential to increase the liquidity by an additional amount of EUR 9.4 million on their conversion in 2015. However, in a repayment scenario, the Company would have to repay an amount of EUR 1.9 million to the bondholders before maturity of the notes at the end of 2015.

Outlook for 2015

- The FDA's approval decision for Epi proColon® in the U.S.A. remains a key target for the Company in 2015. Throughout this year and beyond, Epigenomics will actively support its partners BioChain and Polymedco in rolling out the test and making it an integral part of standardized CRC screening procedures in countries where it is approved. To this effect, securing reimbursement and heightening healthcare providers' awareness of the product will be a key activity for the Company in 2015, which will determine the commercial success.
- Epigenomics expects revenue in 2015 to be in the range of EUR 3.0 to 4.0 million with the bulk of this in the second half of the year. This assumes the approval of Epi proColon® in the U.S.A. around the middle of 2015. This growth in revenue is almost exclusively driven by the expected initial product sales in the U.S.A. and in China. EBIT for 2015 is expected to be at a lower level than in 2014 at EUR -10.0 to -11.0 million. Efforts to develop the U.S. market for the Company's lead product will initially hinder the operating result. In addition, expenditures in connection with the current ADMIT trial, as well as a post-approval study expected to be mandated as part of the FDA approval in the second half of 2015, will also be contributing factors.
- All business projections for 2015 are based on the approval of Epi proColon® as an IVD product in the U.S. market around mid-year and generation of first revenues during Q3 2015, which are initially expected to be at a moderate level. Nevertheless, since the overall likelihood and timing of such an approval decision is uncertain, efforts to provide the capital markets with a reliable prognosis on the Company's earnings situation are hampered. Any delay in the approval decision might result in a reduction of the revenue estimate on the one side, which would then be compensated by lower additional costs on the other.
- Based on the business plans for 2015, Epigenomics expects an increase in cash consumption compared to 2014 to a range between EUR 9.5 and 10.5 million. For 2016 and the years to come, cash utilization is expected to decrease in line with revenue growth.
- At this projected cash consumption for 2015 and considering possible additional cash inflows from conversion premiums of the outstanding convertible bonds, current financial resources are sufficient to support the Company's operations beyond 2015. Epigenomics is convinced that a positive FDA decision will open up further financing options on the capital markets and is determined to exercise such options in the Company's best interest. The Company will also continue to diligently explore all further strategic options.

Summary of Operational Highlights in 2014

- **Final steps towards Premarket Approval (PMA) for Epi proColon®:** In the June 2014 response letter from the FDA with respect to the PMA application for Epi proColon® it was determined that while the studies performed so far had established the clinical performance of the test, there was a need for additional data demonstrating that Epigenomics' convenient blood-based test will increase compliance to CRC screening in the intended use population, compared to those being offered a stool-based fecal immunochemical test (FIT). As a consequence, during the second half of 2014 Epigenomics worked closely with the agency to complete the design of the requested ADMIT trial (ADherence to Minimally Invasive Testing).
- **Enrollment into the ADMIT trial completed (after period-end); results expected Q2 2015:** In December 2014, the Company started the ADMIT trial which was conducted in patients that have been historically non-compliant to CRC screening according to current screening guidelines. Subjects were invited to a clinic visit and once enrolled into the trial, were randomized to either the FIT test to take home to complete and send back within six weeks, or to a blood draw for the Epi proColon® test, to be completed in the same time frame. The primary endpoint is a statistically significant increase in adherence to testing by subjects offered the Epi proColon® test compared to subjects given the FIT test. The study's secondary objectives include a measurement of compliance to colonoscopy in subjects with positive result for either test. Subject enrollment has now been completed and trial results will be submitted to the FDA following data analysis after completion of the six week response window. Results are expected to be announced during the second quarter 2015.
- **Polymedco reiterated commitment to support Epi proColon® in the U.S.:** Epigenomics' partner Polymedco, reiterated its commitment to support the launch and commercialization of the test in the United States. While the ADMIT trial was underway, Polymedco continued to diligently prepare for commercializing Epi proColon® once the product is approved and has therefore commenced training its sales staff as well as establishing customer and technical support functions. In addition, Polymedco strongly supported Epigenomics with continued logistics and personnel assistance in the ADMIT trial. This strong support was further underpinned by the commitment of Polymedco's President and CEO, Drew Cervasio, who, with a significant personal investment, has notably increased his ownership of Epigenomics to approximately 180,000 shares.
- **Epi proColon® approved in China:** In December 2014, together with its partner BioChain, Epigenomics received marketing approval for Epi proColon® from the China Food and Drug Administration (CFDA). The approval was based on a major clinical validation study completed by BioChain in April 2014, which demonstrated the potential for Epi proColon® to become an important tool for medical professionals in establishing and expanding CRC detection in China. BioChain is launching Epi proColon® into the Chinese market through its established distribution channels.
- **Share capital increase of EUR 4.2 million subscribed by BioChain:** In October 2014, BioChain invested EUR 4.2 million in a share capital increase by subscribing to a total of 1,351,089 Epigenomics shares issued under exclusion of the statutory subscription right of the shareholders. This new investment reinforces and deepens the joint commitment to the successful launch of Epi proColon® throughout the major markets of the U.S.A. and China, and is clear evidence of the shared commitment in the future success of the product and Epigenomics.
- **Relocation of Berlin headquarters:** In August 2014, Epigenomics successfully completed the relocation of its Berlin headquarters to a new facility within the city. The new headquarters are more adept to efficiently house the Company's operations and increase flexibility for the Company's long-term planning.

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Further information

Conference call for press and analysts

Epigenomics will host a German annual press conference in Frankfurt Main, Germany at 1:00 pm CET, today. The Company will also host an English conference call at 4.00 pm CET / 11 am EST, today. The presentation can be followed as a slide show on the website. Details of both events will be available on Epigenomics' website at <http://www.epigenomics.com/en/news-investors.html>.

The Annual Report 2014, which was released today, can be obtained from Epigenomics' website at: <http://www.epigenomics.com/en/news-investors/investors/financial-reports.html>.

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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, has received approval by the Chinese Food and Drug Administration for China and is under regulatory review by the U.S. Food and Drug Administration (FDA). Additionally, the Company markets its tissue assay for use in lung cancer diagnosis, Epi proLung®, in Europe. 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.

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