

Press release

## **Epigenomics AG Reports Financial Results for Fiscal Year 2020**

**Berlin (Germany) and San Diego, CA (U.S.A.), March 25, 2021** - Epigenomics AG (FSE: ECX, OTCQX: EPGNY, the "Company") today reported financial results (according to IFRS) for fiscal year 2020.

### **OPERATIONAL DEVELOPMENTS**

- Despite the solid foundation of scientific evidence in support of reimbursement for Epi proColon, the Centers for Medicare and Medicaid Services (CMS) issued a negative National Coverage Determination (NCD) on January 19, 2021. The Company as well as many of the experts as well as a majority of stakeholders disagree with CMS's decision as evidenced by the public NCD comments.
- The Company is currently reviewing all available options to revise the NCD decision. There are two main alternatives: First, there is the legislative pathway to coverage, which remains a viable alternative and is therefore being actively pursued. Second, there is the option of appealing against the decision and/or taking legal action. To optimize the chances of success, the Company must first wait for the new leadership within the U.S. Department of Health and Human Services and CMS to be inaugurated into their offices.
- In addition, Epigenomics AG has developed and validated a new colorectal cancer screening assay with clinical performance characteristics that meet the coverage criteria outlined by CMS in the final NCD. As a new test, a large prospective trial is required for FDA approval. Such a trial and subsequent FDA approval will take at least two to three years and require additional funding.
- The prospective study on Epigenomics' second promising blood test, the HCCBlood test for the detection of liver cancer in patients with cirrhosis, which was completed at the end of 2019, has been submitted for publication and accepted in a renowned scientific journal. The Company expects the journal to publish the article shortly.
- In addition, Epigenomics AG successfully placed a convertible bond in the amount of EUR 5.5 million in January 2021. Including the proceeds from the issue, the Company's liquidity reaches well into 2022.

### **STRATEGIC DEVELOPMENTS**

- Due to the negative NCD and capital constraints the Company is evaluating various strategic options. In particular, the Company is evaluating the market for a potential sale of the Company by way of a share deal (public takeover) or asset deal to one or more investors as part of an M&A transaction. For this purpose, a corresponding sales process has been set up and the Company is in discussions with several potential parties.

- The Company has mandated a leading international investment bank as advisor in connection with the sales process.

Greg Hamilton, CEO of Epigenomics AG: "Even though the NCD decision has set us back significantly at the start of the current fiscal year 2021, we believe that Epigenomics is a valuable liquid biopsy technology platform. We are investigating multiple options to maximize this value for shareholders."

## Financial results 2020

- Total revenue decreased to EUR 840 thousand (2019: EUR 1.1 million), mainly due to the impact of the COVID 19 pandemic. In particular, the number of tests in the U.S.A. declined, as some of the patients eligible for screening skipped or postponed their screenings due to the suspected risk of infection. Both product revenue (from EUR 988 thousand in the previous year to EUR 584 thousand) and license revenue (from EUR 137 thousand in the previous year to EUR 33 thousand in the reporting year) declined.
- Selling, general and administrative costs decreased from EUR 8.9 million (2019) to EUR 7.3 million, mainly due to reduced sales and marketing costs in the U.S. Similarly, research and development costs declined from EUR 7.3 million (2019) to EUR 3.7 million, again because of the COVID-19 pandemic, which severely hampered clinical trials in the U.S.
- EBITDA (before share-based payment expenses) improved to EUR -10.5 million (2019: EUR -13.3 million) due to reduced total operating costs and was thus at the lower end of the guidance from the beginning of 2020 (EUR -10.5 million to EUR -12.5 million).
- The net loss for the year fell to approximately EUR -11.7 million (2019: EUR -17.0 million); the loss per share also decreased to EUR -2.02 (2019: EUR -3.65).
- Cash consumption decreased to EUR -9.6 million in fiscal year 2020 (2019: EUR 13.5 million) due to lower operating costs.

## Outlook 2021

### Revenue

- The Company expects revenue for the fiscal year 2021 to be within the range of EUR 0.4 million to EUR 1.0 million. If the NCD decision made by CMS is successfully appealed or reversed in 2021, a change in the revenue guidance would be made.

### EBITDA / Cash consumption

- For EBITDA (before share-based payment expenses), Epigenomics forecasts a range of EUR -7.0 million to EUR -9.0 million. Based on the Company's 2021 business plan, cash consumption is expected to be in line with the EBITDA forecast (before share-based payment expenses).

## **Further information**

The Annual Report 2020 is available on the Epigenomics website at: <https://www.epigenomics.com/news-investors/financial-reports/>.

## **Conference call for analysts and investors**

Epigenomics AG will host a conference call for analysts and investors today at 4.00 pm (CET) / 11.00 am (EDT). The webcast can be accessed on the Company's website: <https://www.epigenomics.com/news-investors/financial-reports/>.

The dial-in numbers for the conference call are:

Dial-in number Germany: +49 69 6677 38007

Dial-in number UK: +44 20 3872 0888

Dial-in number U.S.A.: +1 862-701-3057

Participants are asked to dial in 10 minutes prior to the start of the conference call and to register using the link above.

An audio replay of the conference call will be provided on the Epigenomics' website subsequently.

## **About Epigenomics**

Epigenomics AG is a molecular diagnostics company focused on blood testing for the early detection of cancer. Based on its proprietary biomarker technology for the detection of methylated DNA, Epigenomics develops and markets blood tests for various cancer indications with high unmet medical need. Epigenomics' lead product is the blood test Epi proColon® for the early detection of colorectal cancer. Epi proColon is approved by the U.S. Food and Drug Administration (FDA) and is marketed in the United States and Europe as well as other selected countries. HCCBloodTest, a blood test for the detection of liver cancer, have received the CE Mark for marketing in Europe.

For further information please visit [www.epigenomics.com](http://www.epigenomics.com).

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## ***Note on forward-looking statements***

*This publication expressly or implicitly contains forward-looking statements concerning Epigenomics AG and its business. These statements involve certain known and unknown risks,*

*uncertainties and other factors that may cause Epigenomics AG's actual results, financial condition and performance to be materially different from any future results, performance or achievements expressed or implied by such statements. Epigenomics makes this announcement as of the date of this release and does not intend to update any forward-looking statements contained herein as a result of new information or future events or otherwise.*