Epigenomics AG Highlights Operational Achievements and Reports Financial Results for First Six Months 2019

Berlin (Germany) and San Diego, CA (U.S.A.), August 7, 2019 - Epigenomics AG (FSE: ECX, OTCQX: EPGNY, the "Company") today announced the operational achievements plus financial results for the second quarter and the first half of 2019.

Operational highlights

- In January 2019, the Company announced positive results from a microsimulation model for the Epi proColon blood test. The results are awaiting publication.

- In March, the bipartisan "Donald Payne Sr. Colorectal Cancer Detection Act" (HR 1765) was reintroduced into the U.S. House of Representatives. In the meantime, the law has won numerous supporters in both parties and especially in the key committees of Congress. The latter is of great importance so that the law can be voted on - if not individually, then as part of a legislative package.

- On May 3, 2019, the Centers for Medicare & Medicaid Services (CMS) accepted the Company's application to review Epi proColon as part of a National Coverage Determination (NCD). Once the review process has been opened, there is a statutory timeframe of maximum nine months within which CMS must have reached a decision and Epigenomics therefore has clarity regarding the reimbursement of Epi proColon.

6M 2019 Financial results

- In the first half of 2019, product revenue increased by 84% year-on-year to EUR 660 thousand.

- License revenue decreased to EUR 19 thousand (6M 2018: EUR 413 thousand) due to the termination of the collaboration with the Chinese licensing partner.

- Total revenue in the first six months of 2019 decreased from EUR 771 thousand to EUR 679 thousand compared to the same period in the prior year due to lower license revenue, which were not fully offset by higher product revenue.

- Research and development costs increased from EUR 3,043 thousand in the previous year to EUR 3,867 thousand. This increase resulted from expenses related to the post-approval study for Epi proColon and the HCC (liver cancer test) study in the U.S.

- Selling and administrative expenses rose by from EUR 3,883 thousand to EUR 4,859 thousand in the reporting period, due to an increase in sales and marketing activities related increased product revenue and commercial preparation of reimbursement coverage.

- Overall, operating costs were lower than estimated for the first six months of 2019.
Operating expenses increased from EUR 7.1 million to EUR 9.4 million compared to prior year for the abovementioned reasons.

- Adjusted EBITDA (before share-based payment expenses) was EUR -7.2 million in the first six months of 2019 compared to EUR -5.4 million for the same period prior year.
- The net loss for the period was EUR -7.4 million vs. EUR -5.8 million for the prior year; the loss per share decreased to EUR 0.21 (6M 2018: EUR 0.24) due to the higher number of outstanding shares following the capital increase carried out in the second half of 2018.
- Cash consumption from operating activities increased by EUR 3.6 million to EUR 7.8 million in the first half of 2019 due to higher operating costs.
- As of June 30, 2019, liquidity amounted to EUR 9.1 million (including marketable securities) compared to EUR 17.1 million at year-end 2018.

Greg Hamilton, CEO of Epigenomics AG: "We continue to make progress on CMS reimbursement. CMS’s acceptance of our NCD is an important milestone. While the process of opening the NCD is taking longer than we would like we still remain optimistic and will continue to pursue all available paths to achieve coverage for Epi proColon. “

Outlook 2019: revenue forecast adjusted

Revenue

- Due to the delays in the reimbursement decision in the U.S. described above, the revenue forecast has been adjusted from between EUR 3.0 million and EUR 6.0 million to between EUR 2.0 million and EUR 4.0 million.

EBITDA / Cash consumption

- Epigenomics AG specifies its guidance for adjusted EBITDA (before share-based payment expenses). For the full year 2019, the Company expects an adjusted EBITDA within the range of EUR -12.5 million to EUR -14.0 million. Cash consumption is expected to be within a range of EUR -13.5 million to EUR -15.0 million, due to payments in the first quarter of 2019 for which the corresponding expenses had already been incurred in 2018.

Further information


Conference call for analysts and investors

Epigenomics AG will host a conference call for analysts and investors today at 4.00 pm (CET) / 10.00 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 30 232 531 411
Dial-in number UK: +44 1635 598 060
Dial-in number USA: +1 516-269-8983

Participants are kindly asked to dial in 10 minutes prior to the start of the call.
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, Europe, China and other selected countries. Epi proLung®, a blood test for the detection of lung cancer, and 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.

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