Press release

Epigenomics AG Announces 2018 Third Quarter and Nine Months Financial Results

Berlin (Germany) and San Diego, CA (U.S.A.), November 7, 2018 - Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY) today announced its financial results for the third quarter and the nine months 2018 ending September 30.

Recent operational highlights

• In September 2018, U.S. Congress urged the Centers of Medicare & Medicaid Services (CMS) to consider coverage of blood tests for colorectal cancer screening as part of the approved 2019 Health and Human Services (HHS) Appropriations Bill – a positive step towards legislative approval of CMS coverage for Epigenomics’ blood test for colorectal cancer screening Epi proColon®.

• In October 2018, CMS published the final reimbursement rate of $192 for Epi proColon. The $192 per test rate will be included in the 2019 Clinical Laboratory Fee Schedule that is expected to be published in November 2018.

• In October 2018, Epigenomics successfully completed a capital increase with subscription rights for existing shareholders generating gross proceeds of EUR 22.3 million. New shares that were not subscribed for during the subscription period were subsequently offered to selected qualified investors as part of an international private placement. The private placement was significantly oversubscribed. All shares of the private placement were allocated to multiple new institutional investors in the U.S.A, including healthcare funds.

• In October 2018, Epigenomics has received CE Mark for its blood test to aid in detecting liver cancer among patients with cirrhosis two months ahead of schedule. The test will be commercialized under the brand name “HCCBloodTest”. In 2019, the company plans to initiate a prospective clinical trial in the U.S. for submission to the FDA. Simultaneously, Epigenomics is evaluating options to expedite CFDA approval in China.

• In October 2018, the Veterans Administration – New York Harbor Healthcare System has commenced a study to assess the adherence impact of offering a blood-based colorectal cancer screening test and colonoscopy completion in patients who have refused colonoscopy and fecal immunochemical test (FIT). The goal of the study is to assess the potential of a blood-based test as an acceptable alternative for these screen-resistant individuals.

“We have made significant progress against our strategic goals over the last couple of weeks and months”, said Greg Hamilton, CEO of Epigenomics AG. “The successful completion of our capital increase gives us the opportunity to further pursue our mission of developing and commercializing liquid biopsy tests for some of the deadliest cancer diseases worldwide. I would like to thank our existing and new shareholders for the trust in our company as demonstrated by the strong participation in the recent capital increase.”
Q3/9M 2018 Financial Results

- Total Q3 2018 revenue increased to EUR 0.5 million (Q3 2017: EUR 0.3 million) and 9M 2018 revenue to EUR 1.3 million (9M 2017: EUR 0.9 million). In Q3 2018, product revenue increased by 73% to EUR 0.3 million.

- Adjusted for non-cash expenses related to share-based payment, EBITDA in Q3 2018 was at EUR -2.6 million (Q3 2017: EUR -2.0 million); adjusted EBITDA for 9M 2018 amounted to EUR -8.0 million (9M 2017: EUR -7.8 million). Net loss amounted to EUR -3.0 million in Q3 2018 compared to EUR -1.1 million in Q3 2017, and EUR -8.7 million for 9M 2018 (9M 2017: EUR -7.6 million). The increase in net loss was mainly due to higher R&D expenses, partially offset by growth in gross profit.

- Net loss per share for Q3 2018 increased to EUR -0.12 (Q3 2017: EUR -0.05) and for 9M 2018 to EUR -0.36 (9M 2017: EUR -0.33).

- Cash consumption (cash outflow from operating and investing activities) was EUR 6.9 million in 9M 2018 compared to EUR 7.3 million in 9M 2017.

- Liquid assets (including marketable securities) amounted to EUR 6.6 million at September 30, 2017 (December 31, 2017: EUR 13.7 million).

Outlook for 2018

- As recently announced in the prospectus for the capital increase, due to the delay of reimbursement decisions in the U.S.A, Epigenomics narrowed its revenue forecast for the full year 2018 to a range of EUR 1.5 million and EUR 2.5 million (previously: EUR 2.0 - 4.0 million).

- Adjusted EBITDA (excluding share-based payment expenses) is now expected to improve within the range EUR -11.0 million and EUR -13.0 million (previously: EUR -11.5 to -14.0 million).

Organizational matters

- The Supervisory Board resolved to extend the service agreement with the Company’s Chief Executive Officer Greg Hamilton until December 31, 2021.

Further Information


Conference call for analysts and investors

The Company will host a conference call and webcast at 4.00 pm CET / 10.00 am EST, today. The presentation can be downloaded from the Company’s website.

The dial-in numbers for the conference call are:

Germany: +49 69 2475 01899
UK: +44 20 3872 0885
USA: +1 516-269-8983
The webcast will be made available on:
https://webcast.meetyoo.de/index.html?e=LYcnz0C1xwt8

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

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics’ lead product, Epi proColon®, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epi proLung®, a test for lung cancer detection, and HCCBloodTest, a test for liver cancer, have received CE mark in Europe.

For more information, visit www.epigenomics.com.

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Forward-Looking Statements

This communication expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial condition, performance or achievements of Epigenomics AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Epigenomics AG is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.