

epigenomics



INTERIM STATEMENT 9M
JANUARY 1 - SEPTEMBER 30, 2020

**SAVING LIVES
THROUGH BLOOD-BASED
CANCER DETECTION**

QUARTERLY DEVELOPMENT OF KEY FIGURES (UNAUDITED)

– according to the financial reporting –

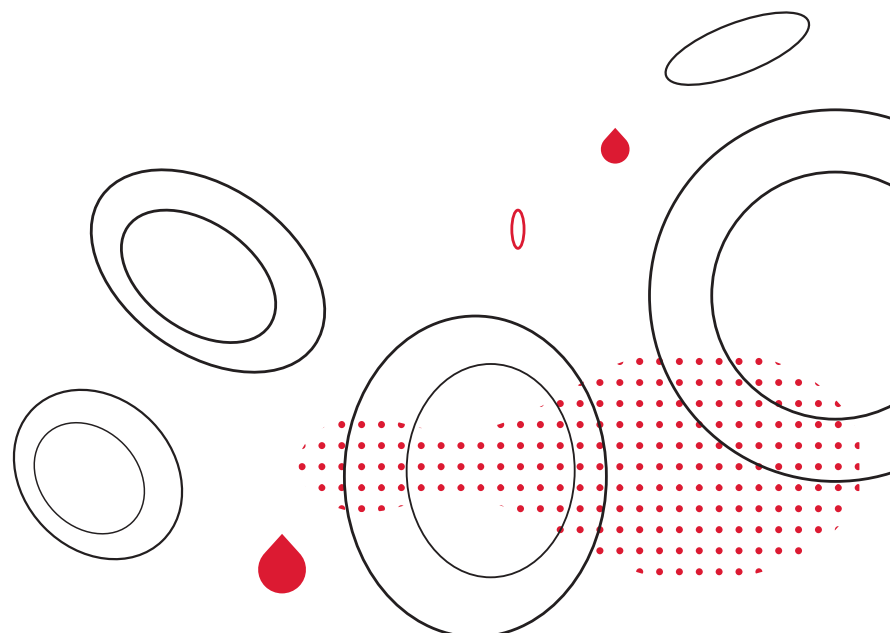
in EUR thousand except where indicated

	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
Revenue					
Gross profit	168	278	239	83	219
EBIT	129	229	182	68	176
EBITDA	-2,844	-3,850	-2,966	-3,356	-2,741
EBITDA before share-based payment costs	-2,706	-3,716	-2,828	-3,220	-2,611
Net loss for the period	-2,487	-3,555	-2,641	-3,018	-2,430
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Balance Sheet (at the respective reporting dates)					
Non-current assets	5,247	1,866	1,748	1,606	1,466
Current assets	7,716	12,123	11,803	9,435	7,364
Non-current liabilities	806	741	687	625	563
Current liabilities	3,232	3,619	6,592	3,099	2,723
Equity	8,925	9,629	6,272	7,317	5,544
Equity ratio (in %)	68,8	68,8	46,3	66,3	62,8
Total assets	12,963	13,989	13,551	11,041	8,830
Statement of Cash Flows					
Cash flow from operating activities	-3,067	-2,665	-3,272	-2,244	-1,983
Cash flow from investing activities	26	65	-12	18	2
Cash flow from financing activities	-73	7,460	3,363	-213	-96
Net cash flow	-3,114	4,860	79	-2,439	-2,077
Cash consumption	-3,041	-2,601	-3,284	-2,226	-1,981
Cash and cash equivalents at the end of the period	5,501	10,155	10,252	7,809	5,735
Stock					
Weighted-average number of shares issued	36,021,540	41,025,641	43,527,692	47,129,846	47,129,846
Earnings per share (basic and diluted, in EUR)	-0.07	-0.19	-0.07	-0.07	-0.06
Share price at the end of the period (in EUR)	1.35	1.37	1.14	1.41	2.45
Number of employees at the end of the period					
	42	41	40	39	38

INTERIM STATEMENT ON FINANCIAL RESULTS FOR 9M 2020

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CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE PERIOD FROM JANUARY 1 TO SEPTEMBER 30 (UNAUDITED)

EUR thousand	Q3 2019	Q3 2020	9M 2019	9M 2020
Revenue	168	219	847	541
Cost of sales	-39	-43	-204	-114
Gross profit	129	176	643	427
Gross margin (in %)	76,8	80,4	75,9	78,9
Other income	993	508	1,761	1,272
Research and development costs	-1,787	-658	-5,654	-3,412
Selling, general and administrative costs	-2,012	-1,540	-6,871	-5,442
Other expenses	-167	-1,227	-703	-1,908
Operating result/Earnings before interest and taxes (EBIT)	-2,844	-2,741	-10,824	-9,063
Interest income	43	4	155	16
Interest expenses	-17	-13	-46	-43
Other financial result	0	0	-1	0
Net loss for the period before taxes on income	-2,818	-2,750	-10,716	-9,090
Taxes on income	224	-4	706	-19
Net loss for the period	-2,594	-2,754	-10,010	-9,109
Items that may be reclassified subsequently to profit or loss:				
Exchange rate differences from the conversion of foreign entities	-479	748	-517	726
Fair value adjustment of financial instruments measured at fair value through other comprehensive income	76	52	123	25
Other comprehensive income for the period	-403	800	-394	751
Total comprehensive income for the period	-2,997	-1,954	-10,404	-8,358
Earnings per share (basic and diluted, in EUR)	-0.07	-0.06	-0.28	-0.20

The earnings per share (basic and diluted) are calculated by dividing the Group's net loss for the period by the weighted-average number of shares issued and admitted to trading in the respective period. The outstanding stock options and convertible notes issued by the Company are anti-dilutive according to IAS 33.41 and 33.43. Therefore, the earnings per share (diluted) equal the earnings per share (basic). In Q3 2020, the weighted-average number of shares issued was 47,129,846 (Q3 2019: 36,021,540). In the first nine months of 2020, the weighted average number of shares issued was 45,929,128 (9M 2019: 36,021,540).

OPERATING RESULT (EBIT) AND EBITDA

EUR thousand	Q3 2019	Q3 2020	9M 2019	9M 2020
Operating result/Earnings before interest and taxes (EBIT)	-2,844	-2,741	-10,824	-9,063
Amortization and depreciation	138	130	378	403
EBIT before amortization and depreciation (EBITDA)	-2,706	-2,611	-10,446	-8,660
Share-based payment costs	219	181	713	570
EBITDA before share-based payment costs	-2,487	-2,430	-9,733	-8,090

CONSOLIDATED BALANCE SHEET
AS OF SEPTEMBER 30 (UNAUDITED)

ASSETS EUR thousand	Dec 31, 2019	Sept 30, 2020
Non-current assets		
Intangible assets	333	191
Property, plant and equipment	1,533	1,275
Total non-current assets	1,866	1,466
Current assets		
Inventories	313	197
Trade receivables	89	91
Marketable securities	880	905
Cash and cash equivalents	10,155	5,735
Other current assets	686	436
Total current assets	12,123	7,364
Total assets	13,989	8,830

EQUITY AND LIABILITIES EUR thousand	Dec 31, 2019	Sept 30, 2020
Equity		
Subscribed capital	43,528	47,130
Capital reserve	69,251	69,922
Retained earnings	-85,807	-102,827
Net loss for the period	-17,020	-9,109
Other comprehensive income	-323	-428
Total equity	9,629	5,544
Non-current liabilities		
Lease liabilities	697	519
Provisions	44	44
Total non-current liabilities	741	563
Current liabilities		
Trade payables	1,430	557
Lease liability	216	225
Deferred income	5	85
Other liabilities	1,368	905
Provisions	600	951
Total current liabilities	3,619	2,723
Total liabilities	13,989	8,830

CONSOLIDATED CASH FLOW STATEMENT

FOR THE PERIOD FROM JANUARY 1 TO SEPTEMBER 30 (UNAUDITED)

EUR thousand	9M 2019	9M 2020
Cash and cash equivalents at the beginning of the period	16,487	10,155
Operating activities		
Net loss for the period	-10,010	-9,109
Adjustments for:		
Share-based payment expenses	726	570
Amortization of intangible assets	146	146
Depreciation of property, plant and equipment	232	257
Losses from the disposal of non-current assets	1	0
Foreign currency exchange results	-176	0
Financial income	-155	-16
Financial expenses	48	44
Taxes	-706	19
Operating result before changes in operating assets and liabilities	-9,894	-8,089
Changes in operating assets and liabilities:		
Inventories	61	115
Trade receivables	-106	2
Other assets	-242	246
Non-current and current provisions	-258	357
Trade payables and other liabilities	-367	-192
Deferred income	-7	80
Tax paid	-27	-18
Cash flow from operating activities	-10,840	-7,499

EUR thousand	9M 2019	9M 2020
Investing activities		
Payments to acquire intangible assets	-41	-11
Payments to acquire property, plant and equipment	-71	-6
Interest received	94	24
Cash flow from investing activities	-18	7
Financing activities		
Proceeds from the issue of new shares	0	3,998
Payments for the issue of new shares	-179	-754
Payments for leases	-162	-190
Cash flow from financing activities	-341	3,054
Net cash flow	-11,199	-4,438
Currency translation effects	213	18
Cash and cash equivalents at the end of the period	5,501	5,735

At the reporting date, EUR 84 thousand of cash and cash equivalents included restricted cash.

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY AS OF SEPTEMBER 30 (UNAUDITED)

EUR thousand	Subscribed capital	Capital reserve	Retained earnings	Net loss for the period	Other comprehensive income	Group equity
Dec 31, 2018	36,022	68,802	-73,115	-12,692	-404	18,613
Total comprehensive income	0	0	0	-10,010	-394	-10,404
Transfer of net loss for the year 2018 to retained earnings	0	0	-12,692	12,692	0	0
Costs for the creation of new shares	0	-10	0	0	0	-10
Share-based payment expenses	0	726	0	0	0	726
Sept 30, 2019	36,022	69,518	-85,807	-10,010	-798	8,925
Dec 31, 2019	43,528	69,251	-85,807	-17,020	-323	9,629
Total comprehensive income	0	0	0	-9,109	751	-8,358
Transfer of net loss for the year 2019 to retained earnings	0	0	-17,020	17,020	0	0
Costs for the creation of new shares	0	-295	0	0	0	-295
Capital increase without subscription rights	3,602	0	0	0	0	3,602
Premium from capital increase without subscription rights	0	396	0	0	0	396
Share-based payment expenses	0	570	0	0	0	570
Sept 30, 2020	47,130	69,922	-102,827	-9,109	428	5,544

FINANCIALS Q3 AND 9M 2020

FINANCIAL POSITION AND CASH FLOW

In the first nine months of 2020, cash outflow from operating activities decreased from EUR 10,840 thousand by EUR 3,341 thousand to EUR 7,499 thousand due to the operating result (EBIT) for the first nine months of 2020, which improved by EUR 1,761 thousand year-over-year.

Cash outflow from investing activities decreased by EUR 25 thousand to EUR 7 thousand in the first nine months of 2020 (9M 2019: EUR 18 thousand).

Cash inflow from financing activities amounted to EUR 3,054 thousand in the first nine months of 2020 (9M 2019: cash outflow of EUR 341 thousand). Payments from lease agreements are included in financing cash flow in the amount of EUR 190 thousand (9M 2019: EUR 162 thousand).

Our net cash flow for the first nine months of 2020 was EUR -4,438 thousand (9M 2019: EUR -11,199 thousand). Cash consumption for the first nine months of 2020 decreased to EUR 7,492 thousand compared to EUR 10,858 thousand in the corresponding period of the prior year.

Cash and cash equivalents amounted to EUR 5,735 thousand at the reporting date (December 31, 2019: EUR 10,155 thousand).

RESULT OF OPERATIONS

In Q3 2020 we recorded revenue of EUR 219 thousand, an increase compared to Q3 2019 (EUR 168 thousand). However, total revenue for the first nine months of 2020 decreased from EUR 847 thousand for the first nine months of 2019 to EUR 541 thousand due to lower product sales in the U.S.A., as many eligible persons postponed their medical checkups in the current pandemic situation.

Cost of sales amounted to EUR 43 thousand in Q3 2020 (Q3 2019: EUR 39 thousand) and to EUR 114 thousand in the first nine months of 2020 (9M 2019: EUR 204 thousand). Our gross margin increased in Q3 from 77% in 2019 to 80% in 2020 and in the first nine months from 76% to 79%.

Other income of EUR 508 thousand in Q3 2020 (Q3 2019: EUR 993 thousand) was mainly due to foreign exchange gains.

R&D costs decreased from EUR 1,787 thousand in Q3 2019 to EUR 658 thousand in Q3 2020, mainly due to the fact that almost all clinical studies in the U.S. came Covid-19-related to a standstill. Among others, our post-approval study for Epi proColon was affected by this. Between April and September 2020, R&D-related expenses for internal projects were also reduced noticeably due to short-time work at the Berlin site. In the nine-month period, R&D costs decreased by EUR 2,242 thousand from EUR 5,654 thousand in the prior year to EUR 3,412 thousand in the reporting period.

Our selling, general and administrative (SG&A) costs decreased to EUR 1,540 thousand in Q3 2020 from EUR 2,012 thousand in the corresponding period of 2019. In the first nine months, selling, general and administrative expenses decreased significantly by EUR 1,429 thousand from EUR 6,871 thousand in the prior year to EUR 5,442 thousand in the reporting period. This was mainly due to the reduction of sales and marketing activities in the U.S.A., as almost all relevant events (such as conferences and trade shows) were cancelled due to the pandemic and thus travel activities came to a standstill.

Other expenses of EUR 1,227 thousand in Q3 2020 (Q3 2019: EUR 167 thousand) were exclusively due to exchange rate losses from currency translation.

Overall, our operating costs decreased to EUR 3.5 million in Q3 2020 for the reasons mentioned above, compared to EUR 4.0 million in the same period of the previous year. On a nine-month comparison, total operating costs decreased from EUR 13.4 million to EUR 10.9 million in the same period of the reporting year. Excluding the high foreign exchange losses, operating costs for the 9-month period 2020 are even EUR 3.7 million lower than in the prior year.



A net loss of EUR 2.8 million was recognized in Q3 2020 (Q3 2019: EUR 2.6 million); excluding the foreign exchange result, the quarterly loss is reduced from EUR 3.4 million in Q3 2019 to EUR 2.0 million in Q3 2020. For the first nine months of 2020, the net loss was EUR 9.1 million (9M 2019: EUR 10.0 million). The net loss per share for the quarter decreased from EUR 0.07 to EUR 0.06 and for the first nine months of 2020 to EUR 0.20 (9M 2019: EUR 0.28) when compared to the same period of the prior year.

NET ASSET POSITION

As of the reporting date, non-current assets decreased from EUR 1.9 million as of December 31, 2019, to EUR 1.5 million. Current assets decreased from EUR 12.1 million at the beginning of the reporting period to EUR 7.4 million as of September 30, 2020, mainly due to the cash consumption during this period.

Due to the net loss for the period, total equity decreased by EUR 4.1 million to EUR 5.5 million as of the reporting date (December 31, 2019: EUR 9.6 million). The equity ratio decreased to 62.8% as of the reporting date (December 31, 2019: 68.8%).

Compared to the closing balance sheet of 2019, non-current liabilities decreased to EUR 563 thousand as of September 30, 2020 (December 31, 2019: EUR 741 thousand). This includes liabilities from lease agreements in the amount of EUR 519 thousand.

Current liabilities decreased from EUR 3.6 million as at December 31, 2019, to EUR 2.7 million as at September 30, 2020, mainly due to the balance sheet date related amount of trade payables.

REPORT ON POST-BALANCE SHEET DATE EVENTS

On October 16, 2020 - and thus after the end of the reporting period - we announced that the U.S. Centers for Medicare & Medicaid Services (CMS), the national health insurance provider in the U.S., issued a negative reimbursement proposal in connection with the National Coverage Determination (NCD) of Epi proColon, Epigenomics' blood test for colorectal cancer screening.

The proposed NCD is preliminary. According to the statutes, a 30-day public comment period will now begin, which will be used to further convince CMS of the benefits of Epi proColon in the fight against colorectal cancer. The public response during the initial public comment period at the beginning of the NCD was overwhelmingly favorable for Epigenomics. Following the comment period, CMS will publish their final decision within 60 days. If the final decision is also negative, the Company intends to take the opportunity to appeal the decision.

Furthermore, we announced on October 26, 2020, that - in accordance with German commercial law - a loss of more than half of Epigenomics AG's nominal share capital has been incurred. Budgeted operating losses were mainly responsible for this anticipated development. A loss in the amount of half of the nominal share capital triggers a legal obligation according to Section 92 para. 1 German Stock Corporation Act (Aktiengesetz) to convene without undue delay a general shareholders' meeting, to which the Executive Board notifies of the loss. The invitation to such an extraordinary general shareholders' meeting, which will take place on November 27, 2020, was published by the Company in due time on November 5, 2020.

On November 3, 2020, we eventually announced that we are planning to propose to the extraordinary General Shareholders' Meeting, which is to be convened on November 27, 2020 and conducted as a virtual general meeting, in addition to the notification of loss pursuant to Section 92 par. 1 AktG, the reduction of the share capital to EUR 5,891,230.00 and a further authorization to issue convertible bonds in a nominal amount of up to EUR 5.5 million.

The capital reduction is to take place in two steps. First, the share capital shall be reduced by EUR 6.00 from EUR 47,129,846.00 to EUR 47,129,840.00 by withdrawing six treasury shares acquired free of charge. Secondly, the share capital of the Company shall be reduced by means of an ordinary capital reduction in accordance with Section 222 et seq. AktG by EUR 41,238,610.00 from EUR 47,129,840.00 to EUR 5,891,230.00. The ordinary capital reduction shall be carried out by combining the shares of the Company in the ratio 8:1. The ordinary capital reduction serves partly to cover losses and partly to allocate to the Company's capital reserves.

The new authorization to issue convertible bonds with a nominal value of up to EUR 5.5 million, which is also to be proposed to the extraordinary General Shareholders' Meeting, shall be limited until March 31, 2021. It stipulates a term of the convertible bonds of about three years. If the bonds have not been previously converted, there is a conversion obligation at the end of the term.

In case that the authorization is exercised, the Company has today concluded a so-called backstop agreement with several shareholders, namely Deutsche Balaton Aktiengesellschaft and its affiliated companies. Under this agreement, Deutsche Balaton Aktiengesellschaft has undertaken, under certain conditions, to subscribe for or acquire new convertible bonds with a total nominal value of up to EUR 4 million if the authorization is exercised.

OPPORTUNITIES AND RISKS

The opportunities and risks to which our Company's business activities are exposed are described in detail in the Group management report, which we published together with the consolidated financial statements for 2019, which are available on the Company's website (www.epigenomics.com).

As can be seen in the above mentioned report on post-balance sheet date events, our application for reimbursement of Epi proColon by the U.S. health insurance provider CMS was provisionally denied on October 16, 2020. As a consequence, this negative decision led to a massive drop in the price of our share to below the EUR 1.00 mark. With our current forecast for the consumption of financial resources, our liquid funds will last until the end of the first quarter of 2021. In order to avoid insolvency, we are dependent on the inflow of fresh capital until then.

On the one hand, there is now an existence-threatening risk for us in that the price of our shares will remain below the value of EUR 1.00 and we will not be able to issue new shares below their nominal value of EUR 1.00. In order not to have to rely on a recovery of the share price on the stock market, we are planning to have our shareholders decide on a capital reduction by combining shares (reverse stock split) at an Extraordinary General Meeting (convened for November 27) before the end of the current fiscal year. This could cause the share price to rise above the nominal value again and make us financially viable again. However, there is a risk that our shareholders will not pass this resolution, even if it can be considered minor.

A further risk threatening the existence of the Company is that in its final decision – which is expected in mid-January 2021 – CMS will maintain its view that Epi proColon is not reimbursable. In this case, our short to medium-term business and planning basis would cease to exist. Further financing would then be unlikely, as the share price would come under further pressure and existing shareholders and other investors would hardly be willing to subscribe to new shares even if the share price was high enough for a new issue. In order to be able to use the opportunity of an appeal against a possibly negative final decision of CMS, the Company would also need sufficient financial resources to be able to pursue such a presumably lengthy and cost-intensive path. There is a further risk in the event that the announcement of the final decision is delayed by several weeks or even months compared to the announced date and we have not succeeded in raising new capital before then.

However, we are in close contact with CMS and also see the possibility to appeal against a negative reimbursement decision.



OUTLOOK

Due to the ongoing uncertainty regarding the impact of Covid-19, we have already explained in the 6-Month Report 2020, like many other listed companies, we have withdrawn our revenue forecast for 2020. As our cost reduction programs initiated in spring, including short-time work at the Berlin site, are now showing clear success, we can revise our forecasts for adjusted EBITDA and cash consumption slightly upwards and make them more precise:

- EBITDA before stock-based compensation in full year 2020: EUR -10.0 million to -11.0 million (previously: -10.5 million to -12.5 million)
- Cash consumption in full year 2020: EUR 10.0 million to 11.0 million (previously: EUR 10.5 million to EUR 12.5 million)

This interim statement was approved and cleared for publication by the Executive Board of the Company on November 3, 2020.

Berlin, November 3, 2020

The Executive Board



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