

epigenomics

INTERIM STATEMENT

JANUARY 1 – MARCH 31

Q1 2016

QUARTERLY DEVELOPMENT OF KEY FIGURES (UNAUDITED)

in EUR thousand (except where indicated)	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016
Statement of Profit or Loss					
Revenue	367	487	471	757	295
Gross profit	238	240	163	266	263
EBIT	-3,164	-2,568	-2,530	-1,002	-4,625
EBITDA	-2,956	-2,370	-2,394	-876	-4,501
Net loss for the period	-3,164	-2,459	-2,411	-951	-4,325
Balance Sheet (at the respective reporting dates)					
Non-current assets	2,196	1,971	1,842	1,822	2,054
Current assets	8,354	13,093	12,414	10,776	10,802
Non-current liabilities	1,895	2,118	1,372	217	665
Current liabilities	4,284	4,290	5,488	5,283	7,020
Equity	4,371	8,656	7,396	7,098	5,171
Equity ratio (in %)	41.4	57.5	51.9	56.3	40.2
Total assets	10,550	15,064	14,256	12,598	12,856
Statement of Cash Flows					
Cash flow from operating activities	-2,243	-2,364	-2,970	-550	-2,342
Cash flow from investing activities	-45	-29	-25	258	-52
Cash flow from financing activities	1,042	6,697	2,184	-891	1,993
Net cash flow	-1,246	4,304	-811	-1,183	-401
Cash consumption	-2,288	-2,393	-2,995	-292	-2,397
Cash and cash equivalents at the end of the period	5,469	9,773	8,962	7,779	7,388
Stock					
Weighted-average number of shares issued	15,616,372	16,947,163	17,816,484	18,088,384	18,700,159
Earnings per share (basic and diluted, in EUR)	-0.20	-0.15	-0.14	-0.05	-0.23
Share price at the end of the period (in EUR)	5.93	5.40	4.85	2.22	5.34
Number of employees at the end of the period					
	37	38	40	39	36

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EPIGENOMICS AG – INTERIM STATEMENT ON OPERATIONAL HIGHLIGHTS 2016

DEAR SHAREHOLDERS,

A few weeks ago, we were delighted to inform you that the U.S. Food and Drug Administration (FDA) had approved our lead product Epi proColon[®], the first and only blood-based colorectal cancer (CRC) screening test, for commercialization in the United States. This is a great achievement and a truly transformational event for Epigenomics, and it paves the way for us to offer an innovative, convenient and effective CRC screening option to millions of eligible Americans. The addressable market for Epi proColon[®] in the United States is huge: Although screening and early detection of CRC can save lives, about 35% of eligible U.S. population is not screened regularly.

For patients, Epigenomics' CRC test only requires a simple blood sample to be drawn as part of routine healthcare provider visits. There are no dietary restrictions or alterations in medication required. Given its significant benefits for patients, healthcare professionals and payors, Epi proColon[®] could help to meet the objective of 80% screening compliance of the eligible U.S. population as pursued by U.S. guideline bodies.

Epi proColon[®] was made commercially available in the U.S. under a joint agreement with our strategic partner Polymedco, a leader in non-invasive CRC screening technologies. Our highest priority is now the successful roll-out of Epi proColon[®] in the U.S. market and we were very pleased to announce recently that Laboratory Corporation of America Holdings (LabCorp), one of the world's leading healthcare diagnostics companies, is now the first laboratory in the U.S. to offer our test.

Securing laboratory reimbursement for Epi proColon[®] will be one of the key tasks going forward in our efforts to support our customers. In this respect, the recent designation of a tier-1 current procedural terminology (CPT) code specific to Epi proColon[®] was a major milestone towards broad reimbursement coverage. The code will come into effect with the updated coding handbook in January 2017. In the meantime, Epi proColon[®] can be reimbursed through an existing tier-2 CPT code.

To further strengthen the positioning of our test in the U.S. market and to address typical FDA requirements following the approval of new screening tests, we will initiate a post-approval study to demonstrate the long-term benefit of blood-based CRC screening using Epi proColon[®] in a programmatic setting. The study will likely be started by the end of 2016 and is expected to take several years.

In April, we also received very good news from China. The China Food and Drug Administration (CFDA) named the blood-based Septin9 CRC test – which was successfully developed and introduced into the Chinese markets by our strategic partner BioChain – an “innovative medical product”. According to the recently published “2015 Medical Device Registration Annual Report” only nine out of 7,530 approved medical devices in China received this label from the local regulators. The CFDA recognizes the domestic initiative and significant clinical value of blood-based Septin9 tests. This official recommendation will significantly support leveraging CRC screening programs in a country where CRC is a rapidly growing medical problem and where about 290 million people would be currently eligible for screening.

This distinction by the CFDA and even more so the U.S. FDA’s decision to approve Epi proColon® are tremendous achievements which signify more for us than just the authorization to market and successfully sell the test in the respective regions – it is also a strong validation of our proprietary technology of cancer detection via biomarkers in blood, so-called liquid biopsy, which we are utilizing to develop other tests for various cancer types.

Our second product, Epi proLung® is a next-generation molecular in-vitro diagnostic (IVD) assay for blood-based lung cancer detection. The diagnosis of lung cancer remains challenging and a highly-unmet medical need. Currently common radiological screening methods suffer from a high false positivity rate and therefore complementary confirmatory diagnostic methods are urgently needed for broad adoption of lung cancer screening.

In March, we entered into another strategic license agreement with BioChain on the development and commercialization of Epi proLung® in China. In the course of 2016, our partner is expected to initiate a clinical trial to validate our lung cancer detection test with the objective of gaining market approval by the CFDA for this test, too. In view of the high, rapidly growing prevalence of lung cancer among the Chinese population, the commercialization of a novel, blood-based test represents a major business opportunity for both companies. Epigenomics will receive upfront, milestone, and minimum annual payments as well as royalties on future revenues from BioChain and is entitled to commercialize this product exclusively in other markets outside China.

In April 2016, we presented data from our clinical research with our proprietary panel of blood-based DNA methylation biomarkers for the detection of lung cancer at the Annual Meeting 2016 of the American Association for Cancer Research (AACR) in New Orleans, LA, U.S.A. The data demonstrates the potential of our assay for the detection of lung cancer and encourages us to conduct additional, potentially larger studies to complete the development of the test.

Our financial situation in 2016 remains stable, also due to additional funds that were raised through the conversion of further convertible bonds. During the first quarter, our net cash flow was EUR -0.4 million. At the end of the quarter, a total of six bonds were still outstanding, potentially providing us with additional liquidity of up to EUR 3.1 million. In the future, we will continue to evaluate all financing options on the capital markets and are resolved to exercise such options in the Company's best interest.

The FDA approval of our lead product Epi proColon® is a vital milestone and a pay-off for our work over the past years and we are grateful for the passion, the outstanding effort and commitment of all our employees who have contributed significantly towards our success. In addition, we also would like to take the opportunity to thank our shareholders for the continuing support and trust. We look forward to keeping you informed about the market introduction of Epi proColon® in the U.S., the main market for CRC screening worldwide.

Yours sincerely,

Dr. Thomas Taapken
(CEO/CFO)

Dr. Uwe Staub
(COO)

FINANCIAL RESULTS Q1 2016

FINANCIAL POSITION AND CASH FLOW

Cash outflow from operating activities was EUR 2,345 thousand in Q1 2016 – a slight increase compared to Q1 2015 (EUR 2,243 thousand). Cash outflow from investing activities in Q1 2016 of EUR 52 thousand was nearly unchanged against the comparable period of 2015 (EUR 45 thousand). Cash inflow from financing activities in Q1 2016 amounted to EUR 1,993 thousand, mainly attributable to the conversion of four convertible notes issued in 2013. Our net cash flow in the first three months of 2016 was EUR -404 thousand (Q1 2015: EUR -1,246 thousand). Cash consumption increased to EUR 2,397 thousand in Q1 2016, up from EUR 2,288 thousand in the comparable period of 2015. Cash and cash equivalents amounted to EUR 7,388 thousand at the reporting date (Dec 31, 2015: EUR 7,779 thousand).

RESULTS OF OPERATIONS

In Q1 2016, we recognized revenue in the amount of EUR 295 thousand – a 20% decrease compared to Q1 2015 (EUR 367 thousand). Product revenue increased by 10% from EUR 169 thousand in Q1 2015 to EUR 186 thousand in Q1 2016, and licensing income increased due to initial payments from new out-licensing agreements by 156% year on year (from EUR 41 thousand in Q1 2015 to EUR 103 thousand in Q1 2016). Nevertheless, a sharp drop in R&D income in Q1 2016 (EUR 6 thousand) compared to Q1 2015 (EUR 157 thousand) led to an overall decrease in revenue due to a lower contract volume for our R&D services. As R&D income in Q1 2015 was generated exclusively in Europe, its decrease was the reason for the shift in the geographical split of total revenue from a 92.7% share in Europe in the three months of 2015 versus a 58.1% share in the three months of 2016.

Revenue by type:

	Q1 2015		Q1 2016	
	EUR thousand	in %	EUR thousand	in %
Product sales (own and third-party)	169	46.1	186	63.0
Licensing income	41	11.0	103	35.1
R&D income	157	42.9	6	1.9
Total revenue	367	100.0	295	100.0

Revenue by geographical market:

	Q1 2015		Q1 2016	
	EUR thousand	in %	EUR thousand	in %
Europe	340	92.7	172	58.1
North America	27	7.3	75	25.5
Rest of the world	0	0.0	48	16.4
Total revenue	367	100.0	295	100.0

Cost of sales amounted to EUR 32 thousand in Q1 2016 (Q1 2015: EUR 129 thousand). As a consequence of the higher share of licensing income and third-party product sales in total revenue, the gross margin increased from 65% in Q1 2015 to 89% in Q1 2016.

Other income of EUR 418 thousand in Q1 2016 (Q1 2015: EUR 122 thousand) was mainly attributable to income from third-party research grants in the amount of EUR 280 thousand (Q1 2015: EUR 86 thousand) and a correction of deferred liabilities of EUR 94 thousand (Q1 2015: EUR 5 thousand).

Our R&D costs decreased slightly from EUR 2,214 thousand in Q1 2015 to EUR 2,134 thousand in Q1 2016. The absence of study-related costs compared to Q1 2015, when our earnings situation was burdened with the ADMIT study, was compensated by a sharp increase in costs for phantom stock rights (PSR) issued to our staff in former reporting periods. The same effect was a main reason for the increase in selling, general and administrative (SG&A) costs in Q1 2016 to EUR 3,144 thousand compared to EUR 1,282 thousand in the same period of 2015. The valuation of these PSR had been significantly reduced by approximately EUR 1.6 million in the fourth quarter of 2015 as a consequence of the sharp price decrease of our share when we announced that the FDA had set our PMA process on "hold". This effect has now in Q1 2016 been more than reversed, when the share price came back again to previous levels after our appeal against the FDA's request for more data turned out to be successful. In addition, SG&A costs in Q1 2016 increased as well due to legal and consulting expenses for the pursuit of strategic objectives with regard to the future financing of the Company.

Other expenses of EUR 28 thousand in the reporting quarter (Q1 2015: EUR 28 thousand) were nearly exclusively attributable to foreign exchange rate losses.

Altogether, our operating costs amounted to EUR 5.3 million in Q1 2016, up from EUR 3.7 million in the comparable period of 2015. The main driver for this development was the aforementioned significant increase in non-cash expenses for share-based compensation. While personnel costs increased by EUR 1.8 million in Q1 2016 to EUR 3.3 million (from EUR 1.5 million in Q1 2015), expenses for services and consulting had a compensating effect as they decreased by EUR 0.6 million in the same period.

As a result of this increase in operating costs, EBIT for Q1 2016 amounted to EUR -4.6 million (Q1 2015: EUR -3.2 million).

We closed Q1 2016 with a net loss of EUR 4.3 million (Q1 2015: EUR 3.2 million), translating into a net loss per share for this period of EUR 0.23 (Q1 2015: net loss per share of EUR 0.20). It must be emphasized that the significant increase in net loss compared to last year's first quarter is mainly due to the aforementioned fact that the non-cash expenses for share-based payment (i.e. PSR costs) alone rose sharply by EUR 1.6 million as a consequence of the high volatility of our share between November 2015 and January 2016. Apart from this extraordinary one-off effect, our operating costs in Q1 2016 were at the same level as in Q1 2015.

NET ASSET POSITION

At the reporting date, total non-current assets increased from EUR 1.8 million as of December 31, 2015, to EUR 2.1 million due to a higher valuation of deferred tax assets. Current assets remained stable over the reporting period, amounting to EUR 10.8 million at March 31, 2016.

The increase in subscribed capital (up by EUR 0.8 million) and the capital reserve (up by EUR 1.7 million) in Q1 2016 was attributable to the conversion of four convertible notes. Offset against the net loss of EUR 4.3 million in Q1 2016, this led to a decrease in total equity of EUR 1.9 million to EUR 5.2 million at the reporting date (Dec 31, 2015: EUR 7.1 million). The equity ratio decreased to 40.2% at the reporting date (Dec 31, 2015: 56.3%).

Compared to the closing balance of 2015, non-current liabilities increased by EUR 0.5 million to EUR 0.7 million as of March 31, 2016 (Dec 31, 2015: EUR 0.2 million) and mainly consisted of provisions for outstanding phantom stock rights.

Current liabilities increased from EUR 5.3 million at December 31, 2015, to EUR 7.0 million at March 31, 2016, mainly due to a strong increase in provisions from EUR 0.9 million as of December 31, 2015, to EUR 2.8 million at the reporting date, resulting from the share price movement in Q4 2015 and Q1 2016 as mentioned above. An opposite effect came from a decrease of liabilities from convertible notes due to further conversions in Q1 2016. At the reporting date, there were six remaining convertible notes outstanding.

CURRENCY TRANSLATION

The Group's financial transactions are predominantly settled in euro (EUR) or U.S. dollar (USD). The EUR/USD exchange rates applied in the reporting period are as follows:

Average exchange rate	Q1 2015	Q1 2016
EUR/USD	1.1101	1.1064

Reporting date exchange rate	Dec 31, 2015	Mar 31, 2016
EUR/USD	1.0887	1.1385

REPORT ON POST-REPORTING DATE EVENTS

After the reporting date, we announced on April 13, 2016, that the U.S. Food and Drug Administration (FDA) has approved the Company's lead product, Epi proColon[®], the first and only FDA-approved blood-based colorectal cancer screening test. Epi proColon[®] will be made available in the United States under a joint commercialization agreement with the Company's strategic partner Polymedco, a leader in non-invasive colorectal cancer screening technology.

After the reporting date, we announced on May 9, 2016, that Laboratory Corporation of America Holdings (LabCorp) is the first laboratory network in the U.S.A. to offer Epi proColon[®] on the U.S. market. LabCorp, an S&P 500 company, is the world's leading healthcare diagnostics company.

After the end of the reporting period, on April 18, 2016, a further convertible note issued in December 2013 was converted by its holder. As a consequence, the Company's share capital was increased by 203,925 shares and subsequently, the Company received a cash inflow from financing in the amount of EUR 0.5 million.

OPPORTUNITIES AND RISKS

Opportunities and risks in relation to the Company's business operations are described in detail in the management report published with our 2015 consolidated financial statements which are available on the Company's website (www.epigenomics.com). There were no significant changes in the overall opportunities and risks situation in the reporting period.

OUTLOOK

Our earnings outlook for 2016 as published in our 2015 consolidated financial statements in March was based on the assumption of a positive FDA approval decision for Epi proColon[®] in Q2 2016. Given that this assumption was proven accurate on April 13, 2016, we can confirm our outlook for the current financial year, forecasting a revenue in the range of EUR 3 to 7 million with the bulk of this in the second half of the year. As we can now proceed in our strategy as planned, we can also confirm our expectations for EBIT and EBITDA for 2016 to be lower than the results of 2015. Ranges of EUR -9.0 to -11.0 million (EBIT) and EUR -8.5 to -10.5 million (EBITDA) are assumed for 2016. Our expectation for cash consumption in 2016 remains unchanged within a range between EUR 8.5 and 9.5 million. Our financial situation has benefited in the meantime from five conversions of convertible notes between January and April 2016. The positive impact on our share price by the FDA's approval decision has further increased the likelihood that the five convertible notes still outstanding will be converted by their holders before maturity at year-end 2016, so that we now expect that our current liquidity will take us well into 2017.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME
FOR THE PERIOD FROM JANUARY 1 TO MARCH 31 (UNAUDITED)

EUR thousand	Q1 2015	Q1 2016
Revenue	367	295
Cost of sales	-129	-32
Gross profit	238	263
<i>Gross margin (in %)</i>	65	89
Other income	122	418
Research and development costs	-2,214	-2,134
Selling, general and administrative costs	-1,282	-3,144
Other expenses	-28	-28
Operating result/Earnings before interest and taxes (EBIT)	-3,164	-4,625
Interest income	4	4
Net loss for the period before taxes on income	-3,160	-4,621
Taxes on income	-4	296
Net loss for the period	-3,164	-4,325
Items that may be reclassified subsequently to profit or loss:		
Fair value adjustment of available-for-sale securities	171	-109
Foreign currency effect from consolidation	0	-5
Other comprehensive income for the period	171	-114
Total comprehensive income for the period	-2,993	-4,439
Earnings per share (basic and diluted, in EUR)	-0.20	-0.23

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 Q1 2016, the weighted-average number of shares issued was 18,700,159 (Q1 2015: 15,616,372).

CONSOLIDATED BALANCE SHEET
AS OF MARCH 31 (UNAUDITED)

ASSETS (EUR thousand)	Dec 31, 2015	Mar 31, 2016
<i>Non-current assets</i>		
Intangible assets	792	755
Tangible assets	684	669
Deferred tax assets	346	630
Total non-current assets	1,822	2,054
<i>Current assets</i>		
Inventories	1,077	1,119
Trade receivables	177	355
Marketable securities	784	675
Cash and cash equivalents	7,779	7,388
Other current assets	959	1,265
Total current assets	10,776	10,802
Total assets	12,598	12,856

EQUITY AND LIABILITIES (EUR thousand)	Dec 31, 2015	Mar 31, 2016
<i>Equity</i>		
Subscribed capital	18,088	18,904
Capital reserve	40,945	42,641
Retained earnings	-42,734	-51,719
Net loss for the period	-8,985	-4,325
Other comprehensive income	-216	-330
Total equity	7,098	5,171
<i>Non-current liabilities</i>		
Provisions	217	665
Total non-current liabilities	217	665
<i>Current liabilities</i>		
Trade payables	1,923	2,189
Deferred income	635	404
Convertible notes issued	1,070	642
Other liabilities	761	953
Provisions	894	2,832
Total current liabilities	5,283	7,020
Total equity and liabilities	12,598	12,856

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE PERIOD FROM JANUARY 1 TO MARCH 31 (UNAUDITED)

EUR thousand	Q1 2015	Q1 2016
Cash and cash equivalents at the beginning of the period	6,715	7,779
<i>Operating activities</i>		
Net loss for the period	-3,164	-4,325
Adjustments for:		
Depreciation of tangible assets	52	31
Amortization of intangible assets	156	93
Foreign currency exchange results	-6	0
Financial income	-4	-4
Taxes	4	-296
Operating result before changes in operating assets and liabilities	-2,962	-4,501
Inventories	-517	-42
Trade receivables	198	-178
Other current assets	-138	-306
Non-current and current provisions	749	2,387
Trade payables and other liabilities	480	532
Deferred income	-48	-231
Tax paid	-4	-3
Cash flow from operating activities	-2,243	-2,342
<i>Investing activities</i>		
Payments to acquire intangible fixed assets	-5	-39
Payments to acquire tangible fixed assets	-40	-13
Cash flow from investing activities	-45	-52
<i>Financing activities</i>		
Payments for the issue of new shares	0	-91
Proceeds from the conversion of convertible notes	1,042	2,084
Cash flow from financing activities	1,042	1,993
Total net cash flow	-1,246	-401
Currency translation effects	0	10
Cash and cash equivalents at the end of the period	5,469	7,388

At the reporting date, EUR 24 thousand of cash and cash equivalents included restricted cash.

DISCLAIMER

This interim statement expressly or implicitly contains certain forward-looking statements concerning Epigenomics AG and its business. Such statements are not historical facts and sometimes are expressed by the words “will”, “believe”, “expect”, “predict”, “plan”, “want”, “assume” or similar expressions. Forward-looking statements are based on the current plans, estimates, forecasts and expectations of the Company and on certain assumptions, and they involve certain known and unknown risks, uncertainties and other factors which could cause the actual results, financial position, 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.

Readers of this interim statement are explicitly warned not to place undue reliance on these forward-looking statements, which are only valid as of the date of this interim statement. Epigenomics AG does not intend to and will not undertake to update any forward-looking statements contained in this interim statement as a result of new information, future events or otherwise.

CORPORATE CALENDAR 2016

Annual General Shareholders' Meeting 2016 in Berlin Wednesday, May 25, 2016

Half-yearly Report 2016 – January 1–June 30, 2016 Wednesday, August 10, 2016

Interim Statement 2016 – January 1–September 30, 2016 Wednesday, November 9, 2016



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This interim statement is also available
on the Company's website
(www.epigenomics.com) in both a
German and an English version.