epigenomics

9-MONTH REPORT

JANUARY 1 - SEPTEMBER 30

# QUARTERLY DEVELOPMENT OF KEY FIGURES (UNAUDITED)

in EUR thousand (except where indicated)	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015
Statement of Profit or Loss					
Revenue	284	411	367	487	471
Gross profit	185	144	238	240	163
EBIT	-1,773	-2,994	-3,164	-2,568	-2,530
EBITDA	-1,588	-2,787	-2,956	-2,370	-2,394
Net loss for the period	-1,842	-2,949	-3,164	-2,459	-2,411
Balance Sheet (at the respective reporting dates)					
Non-current assets	2,463	2,352	2,196	1,971	1,842
Current assets	5,333	8,968	8,354	13,093	12,414
Non-current liabilities	816	1,407	1,895	2,118	1,372
Current liabilities	3,955	3,805	4,284	4,290	5,488
Equity	3,025	6,108	4,371	8,656	7,396
Equity ratio (in %)	38.8	54.0	41.4	57.5	51.9
Total assets	7,796	11,320	10,550	15,064	14,256
Statement of Cash Flows					
Cash flow from operating activities	-2,158	-1,966	-2,243	-2,364	-2,970
Cash flow from investing activities	-649	-182	-45	-29	-25
Cash flow from financing activities	17	5,724	1,042	6,697	2,184
Net cash flow	-2,790	3,576	-1,246	4,304	-811
Cash consumption	-2,807	-2,148	-2,288	-2,393	-2,995
Cash and cash equivalents at the end of the period	3,137	6,715	5,469	9,773	8,962
Stock					
Weighted-average number of shares issued	13,513,114	14,239,821	15,616,372	16,947,163	17,816,484
Earnings per share (basic and diluted, in EUR)	-0.14	-0.21	-0.20	-0.15	-0.14
Share price at the end of the period (in EUR)	3.73	5.10	5.93	5.40	4.85
Number of employees at the end of the period	38	37	37	38	40

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# EPIGENOMICS AG – REPORT ON THE FIRST NINE MONTHS OF 2015

#### DEAR SHAREHOLDERS,

As announced on November 4, 2015, Epigenomics received a response letter from the U.S. Food and Drug Administration (FDA) in relation to the premarket approval (PMA) application for our blood-based colorectal cancer (CRC) screening test Epi proColon<sup>®</sup>.

In its letter, the FDA requested additional data demonstrating that the blood-based Epi proColon<sup>®</sup> test will increase compliance to CRC screening in the intended use population, i.e. in those patients with a history of non-compliance to recommended CRC screening programs. In the previous ADMIT (Adherence to Minimally Invasive Testing) study, Epigenomics demonstrated that Epi proColon<sup>®</sup> increases CRC participation in patients being offered this convenient blood-based test. While the adherence to Epi proColon<sup>®</sup> was nearly 100%, the participation rate to the FIT (fecal immunochemical testing, FIT)-test of 88% by far exceeded the levels seen in many studies for stool tests. The FDA's request for additional data suggests that the chosen population in the ADMIT trial was not fully suitable to support the targeted study result.

While disappointed by the FDA's notice, we will make every effort to address the outstanding questions as soon as possible. This includes a meeting with the FDA in the near-term in order to discuss how to best address the outstanding questions. It is expected that an additional study to demonstrate increased compliance and adherence of patients to blood-based CRC testing will be needed. Details of the study will be determined in dialogue with the FDA.

Together with our strategic commercialization partner Polymedco, we will continue to diligently prepare for commercializing Epi proColon<sup>®</sup> in the United States.

As a result of the FDA notice we adjusted our financial outlook for fiscal year 2015. As communicated in the past, such decision has a relevant impact on the achievement of important projected financial parameters for 2015.

Revenue is now projected to exceed last year's figure of EUR 1.5 million, but significantly below our previous outlook of EUR 3 to 4 million, which was based on the assumption of a market entry in the U.S. already in 2015. EBIT is now projected at the lower end, or may slightly fall short, of the previous outlook range of EUR -10.0 to -11.0 million. Cash consumption is expected at the upper end of, or may slightly exceed, the previous outlook range of EUR 9.5 to 10.5 million.

The third quarter was characterized by numerous activities to promote Epi proColon<sup>®</sup> in those markets, where the product is already available. Together with our Chinese partner BioChain, we are further driving marketing of Epi proColon<sup>®</sup> in China. We experienced a promising third quarter with increasing sales, driven mainly by the publication of the "Guideline on Screening, Endoscopic Diagnosis and Treatment of Early Colorectal Cancer" by the Chinese Society of Digestive Endoscopy (CSDE) and The Society of Oncological Endoscopy of the Chinese Anti-Cancer Association (CACA) in June. In these guidelines Septin9-based tests, such as Epi proColon<sup>®</sup>, were stated as a method of choice for early CRC screening. We will continue to actively support BioChain in their ongoing efforts with the different provincial governments to secure adequate pricing and reimbursement decisions, to increase market adoption and fuel the commercial success of this innovative blood-based test for early detection of CRC in China. We also presented our product at one of the most important conferences for diagnostic laboratories in Asia, LabAsia, the "Malaysia 5th International Scientific Instrument and Laboratory Equipment Exhibition and Conference" in October in Kuala Lumpur.

In September 2015, we presented and promoted our proprietary DNA methylation biomarker technology at the renowned conference "Circulating Nucleic Acids in Plasma and Serum (CNAPS) IX Meeting" in Berlin. In October, we hosted an Epigenomics awareness day for CRC screening together with a local laboratory (Institut für Molekulare Diagnostik, IMD) as part of the Berlin "Health Week". During this day, interested parties were informed about the risks of CRC and were invited to undergo CRC screening using our Epi proColon<sup>®</sup> test. A high level of interest among the pre-invited participants again proved the ability of this test to serve as a convenient alternative to standard screening methods such as FIT in CRC screening. Most recently, we were present at the United European Gastroenterology Week (UEGW) in Barcelona, where we had the opportunity to showcase our products and services to over 12,000 experts in the field.

In the third quarter we also made good progress towards the development of a next generation innovative in vitro diagnostic (IVD) assay for a systemic, bloodbased diagnosis of lung cancer. Our new assay will be based on a combination of proprietary Epigenomics DNA methylation biomarkers, including the already known SHOX2 as well as the new PTGER4 biomarkers.

Starting from our existing product Epi proLung<sup>®</sup>, which detects the lung cancer biomarker SHOX2 in bronchial fluid, we aim to leverage our strong platform in DNA methylation and our expertise in the emerging field of liquid biopsy to develop a more convenient and blood-based alternative to existing testing methods. In November 2015, after the reporting period, we announced and presented preliminary performance data on the new test at the annual meeting of the Association of Molecular Pathologists (AMP) in Austin, Texas. We have completed a first clinical evaluation study of this test, in which we analyzed its performance in two independent case-control sets of lung cancer blood samples. The training set (30 plasma samples) and the larger testing study (151 plasma samples) included all major histological types and covered a broad range of lung cancer stages (IA to IV). The DNA methylation panel displayed high sensitivity in detecting lung cancer and superior performance compared to protein biomarkers. The findings observed in the training study were confirmed in the testing study. Test sensitivity was reported at 95% with a specificity of 64%, thus allowing to use it as a confirmatory test for positively tested patients in a low dose spiral computed tomography (LDCT) screening. Additional studies will be necessary to complete its development, but we are on a very promising path, given the data obtained so far, which we are expecting to publish in peer-reviewed literature in the near future. The development of the test is co-financed by a grant of up to EUR 2.8 million from the European Commission within the framework of the Horizon 2020 program, which was awarded to us earlier this year.

Going forward, we will devote the highest priority to addressing the FDA's request for additional data demonstrating increased compliance and adherence of patients to blood-based CRC testing with Epi proColon<sup>®</sup>. As in the past, Epigenomics is committed to provide information about the regulatory way forward to its shareholders and to the public in a timely and comprehensive manner.

We want to take this opportunity to thank our employees for their ongoing dedication and you, our shareholders, for your continuing support and trust.

Yours sincerely,

Dr. Thomas Taapken (CEO/CFO) Dr. Uwe Staub (COO)

# OUR STOCK

Epigenomics AG – Common Shares	Frankfurt Stock Exchange, Regulated Market (Prime Standard)		
ISIN	DE000A11QW50		
Security code number	A11QW5		
Ticker symbol	ECX		
Reuters	ECXG.DE		
Bloomberg	ECX:GR		
Designated sponsor	equinet Bank AG		
Analyst coverage	Edison Investment Research Limited (Hans Bostroem) equinet Bank AG (Marietta Miemietz) First Berlin Equity Research GmbH (Simon Scholes) Kempen & Co. N.V. (Mark Pospisilik)		
	Maxim Group LLC (Jason McCarthy)		

Market Data (Xetra/Frankfurt)	Sept 30, 2014	Dec 31, 2014	Mar 31, 2015	June 30, 2015	Sept 30, 2015
Number of shares outstanding	13,517,558	15,480,422	15,888,272	17,476,609	17,884,459
Closing price (in EUR)	3.73	5.10	5.93	5.40	4.85
Market capitalization (in EUR)	50,379,939	78,950,152	94,217,453	94,321,259	86,757,511

	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015
Average daily trading volume (units)	24.864	58,005	81,160	48.914	46,675
Highest closing price (in EUR)	3.89	5.57	6.63	5.78	6.20
Lowest closing price (in EUR)	3.06	3.08	4.93	5.20	3.98

Epigenomics AG – American Depositary Receipts (ADRs)	OTCQX Trading
Structure	Sponsored Level 1 ADR
Ratio	1 ADR = 5 shares
Ticker symbol	EPGNY
CUSIP	29428N102
ISIN	US29428N1028
Depositary Bank/PAL	BNY Mellon

# FINANCIALS

#### FINANCIAL POSITION AND CASH FLOW

Cash outflow from operating activities was EUR 7.6 million in 9M 2015 – an increase of EUR 2.3 million compared to 9M 2014 (EUR 5.3 million) which was mainly attributable to the higher operating losses and to further building up our stock for expected product demand in the months to come. Cash inflow from financing activities in 9M 2015 amounted to EUR 9.9 million, mainly attributable to our capital increase conducted by way of a pre-emptive rights issue (EUR 5.0 million in gross proceeds) and the conversion of seven convertible notes issued in 2013. Our net cash flow in the first nine months of 2015 was EUR 2.2 million (9M 2014: EUR -4.1 million). Cash consumption increased to EUR 7.7 million in 9M 2015, up from EUR 5.9 million in the comparable period of 2014. Cash and cash equivalents amounted to EUR 9.0 million at the reporting date (Dec 31, 2014: EUR 6.7 million).

#### **RESULTS OF OPERATIONS**

In Q3 2015 we recognized revenue in the amount of EUR 471 thousand – a 66% increase compared to Q3 2014 (EUR 284 thousand). Hence, for the 9M period revenue increased by 21% compared to the previous year from EUR 1,095 thousand to EUR 1,324 thousand. This increase was attributable to product revenue (up 63% from EUR 551 thousand in 9M 2014 to EUR 898 thousand in 9M 2015), while licensing income dropped due to expired licensing agreements by 41% year on year (from EUR 110 thousand in 9M 2014 to EUR 65 thousand in 9M 2015) and R&D income decreased from EUR 434 thousand in 9M 2014 to EUR 361 thousand in 9M 2015 due to a lower order volume.

Cost of sales amounted to EUR 308 thousand in Q3 2015 (Q3 2014: EUR 99 thousand) and to EUR 683 thousand in 9M 2015 (9M 2014: EUR 464 thousand). As a consequence of the higher share of product revenue in total revenue, the gross margin dropped from 65% in Q3 2014 to 35% in Q3 2015 and from 58% to 48% in the 9M comparison.

Other income of EUR 222 thousand in Q3 2015 (Q3 2014: EUR 259 thousand) was mainly attributable to income from third-party research grants in the amount of EUR 186 thousand (Q3 2014: EUR 56 thousand). Over the 9M period, other income in 2015 remained nearly flat compared to 2014 at EUR 430 thousand.

Our R&D costs increased significantly from EUR 1,054 thousand in Q3 2014 to EUR 1,442 thousand in Q3 2015. This increase was mainly attributable to higher costs for the protection of our intellectual property, and to valuation allowances on the inventory, resulting from the delayed FDA decision on the approval of Epi proColon<sup>®</sup>. For the 9M period, R&D costs now add up to EUR 5,287 thousand – up from EUR 3,215 thousand in 2014.

Selling, general and administrative (SG&A) costs in Q3 2015 increased significantly to EUR 1,450 thousand compared to EUR 1,149 thousand in the same period of 2014. The increase was mainly attributable to strategic consulting services. Over the 9M period they increased from EUR 3,170 thousand in 2014 to EUR 3,962 thousand in 2015, mainly attributable to higher non-cash staff compensation in the form of phantom stock rights.

Other expenses of EUR 23 thousand in the reporting quarter (Q3 2014: EUR 14 thousand) and of EUR 83 thousand in 9M 2015 (9M 2014: EUR 63 thousand) were mainly attributable to foreign exchange rate losses.

Altogether, our operating costs amounted to EUR 3.2 million and EUR 10.0 million in Q3 2015 and 9M 2015, respectively, up from EUR 2.3 million and EUR 6.9 million in the comparable periods of 2014. The main drivers for this development were our ADMIT study in the first half of 2015 (without comparable event in 2014) and a significant increase in expenses for stock-based compensation, not least because of the well-grounded share price in 2015.

As a result of this increase in operating costs, EBIT for Q3 2015 and 9M 2015 amounted to EUR -2.5 million and EUR -8.3 million, respectively (Q3 2014: EUR -1.8 million and 9M 2014: EUR -5.4 million).

We closed Q3 2015 with a net loss of EUR 2.4 million (Q3 2014: EUR 1.8 million) which added up to EUR 8.0 million for 9M 2015 (9M 2014: EUR 5.9 million). Due to the increased number of shares outstanding during the third quarter of 2015, the net loss per share for this remained flat compared to Q3 2014 at EUR 0.14. In the nine month's view, our net loss per share increased from EUR 0.44 in 2014 to EUR 0.48 in 2015.

#### **NET ASSET POSITION**

Total non-current assets decreased from EUR 2.4 million at December 31, 2014, to EUR 1.8 million at the reporting date mainly as a result of the recognition of an investment grant, which has been recorded as a retroactive reduction of the acquisition costs of the subsidized fixed assets. Current assets increased from EUR 9.0 million at the end of 2014 to EUR 12.4 million at the reporting date mainly due to the capital increase in Q2 2015 in the amount of EUR 5.0 million and cash inflows from the conversion of convertible notes in the amount of EUR 3.6 million. This was partly offset by the utilization of liquidity for operating and investing activities. The increase in our inventories from EUR 0.8 million to EUR 1.4 million over the first nine months of 2015 was mainly attributable to preparatory measures for our aspired market entry in the U.S.A. and related activities in case of a positive approval decision for Epi proColon<sup>®</sup> by the FDA.

The increase in subscribed capital (up by EUR 2.4 million) and the capital reserve (up by EUR 6.9 million) in 9M 2015 was attributable to our capital increase with pre-emptive rights in May 2015 and the conversion of seven convertible notes. Offset against the net loss of EUR 8.0 million in 9M 2015, this led to an increase in total equity of EUR 1.3 million to EUR 7.4 million at the reporting date (Dec 31, 2014: EUR 6.1 million). The equity ratio decreased slightly to 51.9% at the reporting date (Dec 31, 2014: 54.0%).

Compared to the closing balance of 2014, non-current liabilities remained flat at EUR 1.4 million as of September 30, 2015, and mainly comprised of provisions for outstanding phantom stock rights.

Current liabilities increased from EUR 3.8 million at December 31, 2014, to EUR 5.5 million at September 30, 2015, mainly due to an increase in trade payables from EUR 0.9 million (December 31, 2014) to EUR 1.5 million (September 30, 2015) and to an increase in provisions from EUR 0.4 million (December 31, 2014) to EUR 1.4 million (September 30, 2015); the latter resulting from a larger number and a higher valuation of outstanding phantom stock rights. An opposite effect came from a decrease of liabilities from convertible notes due to a reduction of their remaining number in 9M 2015.

# **EMPLOYEES**

The total headcount of the Company as of September 30, 2015, was 40 (Dec 31, 2014: 37) and comprised 22 employees in R&D and 18 employees in SG&A functions.

# REPORT ON EVENTS AFTER THE REPORTING DATE

After the end of the reporting period, on October 15, 2015, 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.

After the end of the reporting period, on November 4, 2015, we announced that we had received a response letter from the U.S. Food and Drug Administration (FDA) in relation to our premarket approval (PMA) application for the Company's blood-based colorectal cancer (CRC) screening test Epi proColon<sup>®</sup>.

In its letter, the FDA provided guidance and recommendations on how to amend the PMA to make the test approvable. The agency requested additional data demonstrating that the blood-based Epi proColon® test will increase compliance to CRC screening in the intended use population, i.e. in those patients with a history of noncompliance to recommended CRC screening programs. The management of Epigenomics is taking immediate steps to address the FDA's requests. This includes a meeting with the FDA in the near-term in order to discuss how to best address the outstanding questions. It is expected that an additional study to demonstrate increased compliance and adherence of patients to blood-based CRC testing will be needed. Details of the study will be determined in dialogue with the FDA. As in the past, Epigenomics is committed to provide information about the regulatory way forward to its shareholders and to the public in a timely and comprehensive manner. Together with our strategic commercialization partner Polymedco, we will continue to diligently prepare for commercializing Epi proColon® in the United States. In the previous ADMIT (Adherence to Minimally Invasive Testing) study, we aimed to demonstrate that Epi proColon®

will increase CRC participation in patients being offered this convenient blood-based test as compared to those being offered a fecal immunochemical test (FIT). While the adherence to Epi proColon® was nearly 100%, the participation rate to the FIT-test of 88% by far exceeded the levels seen in many studies. The FDA's request for additional data suggests that the studied population in the ADMIT trial was not fully suitable for Epi proColon®.

As a result of this FDA letter, we simultaneously announced on November 4, 2015, that we had to adjust our financial outlook for fiscal year 2015 following the FDA response letter. The new projections for 2015 are described in the following Outlook section of this report.

# 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 2014 consolidated financial statements which are available on the Company's website (*www.epigenomics.com*). There were no significant changes in these opportunities and risks in the current reporting period.

# OUTLOOK

Following the receipt of the response letter from the FDA, which we reported after the end of the reporting period on November 4, 2015, our prognosis for the fiscal year 2015 had to be adjusted. Due to the further delay in the awaited market entry for Epi proColon<sup>®</sup> in the United States, we will not be able to recognize product revenue in the U.S. in the final quarter of 2015. Total revenue for 2015 is now expected to moderately exceed the previous year's figure of EUR 1.5 million. Thanks to strict cost control, this reduced revenue expectation will not fully affect EBIT and net loss. EBIT is now projected at the lower end, or may slightly fall short, of the previous outlook range of EUR -10.0 to -11.0 million.

While our current financial situation has not changed in light of the FDA letter, the outlook needs to be adjusted. Cash consumption for 2015 is now projected at the upper end of, or may slightly exceed, the previous outlook range of EUR 9.5 to 10.5 million. A conversion of the outstanding convertible notes before their maturity will now depend on the development of our share price in the remainder of 2015. Our cash reach is still expected to last into the second half of 2016. Nevertheless, we will have to bridge the extra time which will likely be needed to obtain final FDA approval decision, meaning that additional financing for the Company is required. We will increase our efforts to evaluate all financing options on the capital markets and are resolved to exercise such options in the Company's best interest.

# INTERIM CONSOLIDATED FINANCIAL STATEMENTS

as of September 30, 2015

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

EUR thousand	Q3 2014	Q3 2015	9M 2014	9M 2015
Revenue	284	471	1,095	1,324
Cost of sales	-99	-308	-464	-683
Gross profit	185	163	631	641
Gross margin (in %)	65	35	58	48
Other income	259	222	427	430
Research and development costs	-1,054	-1,442	-3,215	-5,287
Selling, general and administrative costs	-1,149	-1,450	-3,170	-3,962
Other expenses	-14	-23	-63	-83
Operating result/Earnings before interest and taxes (EBIT)	-1,773	-2,530	-5,390	-8,261
Interest income	4	4	15	13
Interest expenses	-71	0	-516	0
Other financial result	0	0	-1	-1
Net loss for the period before taxes on income	-1,840	-2,526	-5,892	-8,249
Taxes on income	-2	115	-14	216
Net loss for the period	-1,842	-2,411	-5,906	-8,033
Items that may be reclassified subsequently to profit or loss:				
Fair value adjustment of available-for-sale securities	-75	-105	0	-21
Other comprehensive income for the period	-75	-105	0	-21
Total comprehensive income for the period	-1,917	-2,516	-5,906	-8,054
Earnings per share (basic and diluted, in EUR)	-0.14	-0.14	-0.44	-0.48

# CONSOLIDATED BALANCE SHEET AS OF SEPTEMBER 30 (UNAUDITED)

ASSETS (EUR thousand)	Dec 31, 2014	Sept 30, 2015
Non-current assets		
Intangible assets	1,291	884
Tangible assets	1,013	664
Deferred tax assets	48	294
Total non-current assets	2,352	1,842
Current assets		
Inventories	753	1,408
Trade receivables	307	452
Marketable securities	780	759
Cash and cash equivalents	6,715	8,962
Other current assets	413	833
Total current assets	8,968	12,414
Total assets	11,320	14,256

EQUITY AND LIABILITIES (EUR thousand)	Dec 31, 2014	Sept 30, 2015
Equity		
Subscribed capital	15,480	17,884
Capital reserve	33,582	40,520
Retained earnings	-33,880	-42,734
Net loss for the period	-8,854	-8,033
Other comprehensive income	-220	-241
Total equity	6,108	7,396
Non-current liabilities		
Provisions	1,407	1,372
Total non-current liabilities	1,407	1,372
Current liabilities		
Trade payables	897	1,490
Deferred income	55	814
Convertible notes issued	1,926	1,177
Other liabilities	511	637
Provisions	416	1,370
Total current liabilities	3,805	5,488
Total equity and liabilities	11,320	14,256

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE PERIOD FROM JANUARY 1 TO SEPTEMBER 30 (UNAUDITED)

EUR thousand	9M 2014	9M 2015
Cash and cash equivalents at the beginning of the period	7,207	6,715
Operating activities		
Net loss for the period	-5,906	-8,033
Corrections for:		
Depreciation of tangible assets	85	132
Amortization of intangible assets	479	410
Losses from the disposal of non-current assets	1	6
Changes in provisions for phantom stock rights	126	767
Changes in other provisions	-72	152
Foreign currency exchange results	0	-5
Interest income	-15	-13
Interest expenses	516	0
Taxes	14	-217
Operating result before changes in net current assets	-4,772	-6,801
Changes in trade receivables and other current assets not attributable to investing or financing activities	-45	-570
Changes in inventories	-499	-655
Changes in current liabilities not attributable to investing or financing activities	75	476
Tax paid	-14	-26
Cash flow from operating activities	-5,255	-7,576
Investing activities		
Payments to acquire tangible fixed assets	-693	-109
Payments to acquire intangible fixed assets	0	-8
Interest received	0	18
Cash flow from investing activities	-693	-99

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE PERIOD FROM JANUARY 1 TO SEPTEMBER 30 (UNAUDITED)

EUR thousand	9M 2014	9M 2015
Financing activities		
Proceeds from the issue of new shares	17	0
Proceeds from capital increase with pre-emptive rights	0	5,000
Payments for the issue of new shares	0	-86
Proceeds from the issue of convertible notes	200	0
Proceeds from conversion of convertible notes	2,085	3,647
Payments for the issue of convertible notes	-424	0
Proceeds from grants/subsidies received	0	1,361
Cash flow from financing activities	1,878	9,922
Total net cash flow	-4,070	2,247
Cash and cash equivalents at the end of the period	3,137	8,962

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

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

September 30, 2015	17,884	40,520	-42,734	-8,033	-241	7,396
Costs for the capital increase with pre-emptive rights	0	-54	0	0	0	-54
Capital increase with pre-emptive rights	977	4,023	0	0	0	5,000
Transfer of net loss for the year 2014 to retained earnings	0	0	-8,854	8,854	0	0
Option premium on convertible notes	0	2,969	0	0	0	2,969
Conversion of convertible notes	1,427	0	0	0	0	1,427
Total comprehensive income	0	0	0	-8,033	-21	-8,054
December 31, 2014	15,480	33,582	-33,880	-8,854	-220	6,108
September 30, 2014	13,518	29,543	-33,880	-5,906	-250	3,025
Transfer of net loss for the year 2013 to retained earnings	0	0	-7,411	7,411	0	0
Option premium on convertible notes	0	2,027	0	0	0	2,027
Conversion of convertible notes	428	0	0	0	0	428
Premium from the issue of shares	0	10	0	0	0	10
Capital increase from the issue of shares	7	0	0	0	0	7
Total comprehensive income	0	0	0	-5,906	0	-5,906
December 31, 2013	13,083	27,506	-26,469	-7,411	-250	6,459
EUR thousand	Subscribed capital	Capital reserve	Retained earnings	for the period	comprehen- sive income	Consolidated equity
				Net loss	Other	

# NOTES to the Interim Consolidated Financial Statements

# BASIC INFORMATION, PRINCIPLES AND METHODS

#### **CORPORATE INFORMATION AND DESCRIPTION OF BUSINESS ACTIVITY**

Epigenomics ("Epigenomics" or the "Company") was founded as a limited liability company (GmbH) in 1998 and has its headquarters in Berlin, Germany. In 2000, the Company was converted into a stock corporation (AG) and entered into the commercial register ("Handelsregister") Charlottenburg under HRB 75861. Since July 19, 2004, it is listed in the Prime Standard segment of the Frankfurt Stock Exchange (ticker symbol: ECX).

In accordance with its Articles of Association, the object of the Company is the development and marketing of procedures and devices for the production in quantity of particular epigenetic parameters such as DNA methylation patterns as well as the information technology bases necessary for their procurement and evaluation. Epigenomics AG is a molecular diagnostics company developing and commercializing a pipeline of proprietary products for screening, early detection and diagnosis of cancer. The Company's products enable doctors to diagnose cancer earlier and more accurately, leading to improved outcomes for patients.

#### **GENERAL PRINCIPLES**

The present unaudited interim report for the Epigenomics Group comprises Condensed Interim Consolidated Financial Statements and an Interim Group Management Report in accordance with Section 37x (3) of the German Securities Trading Act (*Wertpapierhandelsgesetz – WpHG*). The Condensed Interim Financial Statements have been prepared according to the International Financial Reporting Standards (IFRSs) issued by the International Accounting Standards Board (IASB), London, and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC) under consideration of IAS 34 *Interim Financial Reporting* as adopted by the European Union (EU), applicable and effective at the closing date September 30, 2015. Further, these Interim Financial Statements are in accordance with German Accounting Standards (GASs) under consideration of GAS 16 *Interim Financial Reporting*, applicable and effective at the closing date September 30, 2015.

The reporting period as defined in these Condensed Interim Consolidated Financial Statements is the period from January 1, 2015, to September 30, 2015. The reporting currency is the euro (EUR).

This interim report should be read in conjunction with the Annual Report for fiscal 2014, which presents a more detailed analysis of the Group's business and a comprehensive disclosure of the Group's accounting principles and methods, which have been applied accordingly in the reporting period.

A critical review of this interim report was performed by the Company's auditor.

#### NOTES 16

#### **APPLICATION OF NEW STANDARDS IN THE REPORTING PERIOD**

The Group has mandatorily applied the following new or amended IFRS standards during the reporting period:

Amendments to IAS 19	Defined Benefit Plans: Employee Contributions
Annual Improvements to IFRSs	2010–2012 Cycle (Amendments to IFRS 2, IFRS 3, IFRS 8, IFRS 13, IAS 16, IAS 24 and IAS 38)
Annual Improvements to IFRSs	2011–2013 Cycle (Amendments to IFRS 3, IFRS 13 and IAS 40)

The adoption of these new or amended standards did not have a material impact on the Group's accounting.

#### **SCOPE OF CONSOLIDATION**

The scope of consolidation remained unchanged compared to December 31, 2014, and comprises the two companies Epigenomics AG, Berlin, Germany, and Epigenomics, Inc., Seattle, WA, U.S.A..

#### FAIR VALUE MEASUREMENT

For determining and disclosing the fair value of financial instruments, the Company uses the following hierarchy in accordance with IFRS 13 *Fair Value Measurement:* 

- Level 1: Quoted (unadjusted) prices in active markets for identical assets or liabilities
- Level 2: Inputs other than quoted prices included within level 1 that are observable for assets or liabilities, either directly (as prices) or indirectly (derived from prices)

Level 3: Inputs for assets or liabilities that are not based on observable market data (unobservable inputs)

The carrying amounts of financial assets and liabilities such as cash and cash equivalents, marketable securities, trade receivables, trade payables, convertible notes and other current liabilities approximate their fair values due to their short-term maturities. The fair value of marketable securities is based on quoted market prices (level 1). There were no transfers between level 1 and level 2 fair value measurements during the period, and no transfers into or out of level 3 fair value measurements during the reporting period.

# CURRENCY TRANSLATION

Foreign currency exchange rates applied in the reporting period are as follows:

Reporting date rates	Dec 31, 2014	Sept 30, 2015
EUR/USD	1.2141	1.1203

Average rates	9M 2014	9M 2015
EUR/USD	1.3487	1.1118

# NOTES TO THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

# REVENUE

Revenue by type:

	Q3 2014		Q3 2015	
	EUR thousand	in %	EUR thousand	in %
Product sales (own and third-party)	123	43.5	440	93.5
Licensing income	13	4.4	12	2.6
R&D income	148	52.1	19	3.9
Total revenue	284	100.0	471	100.0

	9M 201	9M 2014		15
	EUR thousand	in %	EUR thousand	in %
Product sales (own and third-party)	551	50.3	898	67.8
Licensing income	110	10.1	65	4.9
R&D income	434	39.6	361	27.3
Total revenue	1,095	100.0	1,324	100.0

Revenue by geographical market:

	Q3 201	Q3 2014		5
	EUR thousand	in %	EUR thousand	in %
Europe	250	88.2	99	21.1
America	34	11.8	28	5.9
Rest of the world	0	0.0	344	73.0
Total revenue	284	100.0	471	100.0

	9M 201	9M 2014		5
	EUR thousand	in %	EUR thousand	in %
Europe	830	75.8	730	55.1
America	90	8.2	81	6.2
Rest of the world	175	16.0	513	38.7
Total revenue	1,095	100.0	1,324	100.0

#### **OTHER INCOME**

EUR thousand	Q3 2014	Q3 2015	9M 2014	9M 2015
Third-party research grants	56	186	180	304
Foreign exchange rate gains	14	14	20	74
Recoveries and refunds	1	2	10	19
Income from the reversal of provisions	188	15	212	16
Correction of deferred liabilities	0	2	4	12
Other	0	3	1	5
Total other income	259	222	427	430

# **COST ALLOCATION BY FUNCTION**

Q3 2014					
EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	49	44	9	0	102
Depreciation and amortization	1	167	17	0	185
Personnel costs	47	414	500	0	961
Other costs	2	429	623	14	1,068
Total	99	1,054	1,149	14	2,316

Q3 2015 EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	226	299	8	0	533
Depreciation and amortization	1	114	21	0	136
Personnel costs	9	504	463	0	976
Other costs	72	525	958	23	1,578
Total	308	1,442	1,450	23	3,223

9M	2014	

EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	231	208	12	0	451
Depreciation and amortization	3	509	52	0	564
Personnel costs	175	1,006	1,193	0	2,374
Other costs	55	1,492	1,913	63	3,523
Total	464	3,215	3,170	63	6,912

<b>9M 2015</b> EUR thousand	Cost of sales	R&D costs	SG&A costs	Other expenses	Total
Materials and consumables	394	574	26	0	994
Depreciation and amortization	3	466	73	0	542
Personnel costs	168	1,718	1,706	0	3,592
Other costs	118	2,529	2,157	83	4,887
Total	683	5,287	3,962	83	10,015

Personnel costs include share-based payment expenses in Q3 2015 of EUR -8 thousand (Q3 2014: EUR 236 thousand) and in 9M 2015 of EUR 771 thousand (9M 2014: EUR 151 thousand).

# **OPERATING RESULT (EBIT) AND EBITDA**

EUR thousand	Q3 2014	Q3 2015	9M 2014	9M 2015
Operating result/Earnings before interest and taxes (EBIT)	-1,773	-2,530	-5,390	-8,261
Depreciation of tangible assets	29	37	85	132
Amortization of intangible assets	156	99	479	410
EBIT before depreciation and amortization (EBITDA)	-1,588	-2,394	-4,826	-7,719

#### **EARNINGS PER SHARE**

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).

	Q3 2014	Q3 2015	9M 2014	9M 2015
Net loss for the period (in EUR thousand)	-1,842	-2,411	-5,906	-8,033
Weighted-average number of shares issued	13,513,114	17,816,484	13,428,410	16,793,340
Earnings per share (basic and diluted, in EUR)	-0.14	-0.14	-0.44	-0.48

# NOTES TO THE CONSOLIDATED BALANCE SHEET

#### **NON-CURRENT ASSETS**

EUR thousand	Dec 31, 2014	Sept 30, 2015
Software	29	8
Licenses, patents	152	127
Development costs	1,110	749
Total intangible assets	1,291	884
Fixtures/leasehold improvements	754	491
Technical equipment	236	145
Other fixed assets	22	28
Prepayments and assets under construction	1	0
Total tangible assets	1,013	664
Deferred tax assets	48	294
Total non-current assets	2,352	1,842

Due to subsidies received in 9M 2015, acquisition costs for non-current assets which were capitalized in 2015 and in the previous year have been reduced retroactively by EUR 311 thousand. The subsidies are Public Financial Aid to the Commercial Economy (*Öffentliche Finanzierungshilfen an die gewerbliche Wirtschaft im Rahmen der Gemeinschaftsaufgabe "Verbesserung der regionalen Wirtschaftsstruktur"*) granted from German state and federal funds. In case of non-compliance with certain granting conditions, the subsidies might be reclaimed partially or in whole by the funding sponsors in the following years. Essentially, these granting conditions include the preservation of the current permanent jobs at the Company's Berlin site and the obligation to keep the subsidized assets for a period of at least five years after the end of the granted project (December 31, 2016) in the subsidized place of business. The Company expects that all conditions will be fulfilled.

#### **CURRENT ASSETS**

EUR thousand	Dec 31, 2014	Sept 30, 2015
Inventories	753	1,408
Trade receivables	307	452
Marketable securities	780	759
Cash and cash equivalents	6,715	8,962
Receivables from tax authorities	156	369
Prepaid expenses	150	295
Deposits	18	19
Claims based on projects granted by public authorities	0	14
Creditors with debit accounts	40	8
Interest receivables	9	5
Other	40	123
– thereof with a maturity of > 1 year	38	38
Total other current assets	413	833
Total current assets	8,968	12,414

## EQUITY

As of September 30, 2015, the share capital of Epigenomics AG exclusively comprised 17,884,459 registered common shares with equal rights and a par value of EUR 1.00 each. In 2015, total equity increased by EUR 1.3 million to EUR 7.4 million at the reporting day (Dec 31, 2014: EUR 6.1 million) as the capital increase in May 2015 and the conversion of convertible notes offset the net loss of 9M 2015.

#### **NON-CURRENT LIABILITIES**

#### Provisions

In Q3 2015 and former periods, the Company has issued phantom stock rights to its Executive Board members and to its staff which can be exercised by the beneficiaries under certain conditions from 2016 on.<sup>1</sup> If these conditions are met and the beneficiaries exercise their rights, the Company has the obligation to settle the debt from these rights in cash. The non-current provision for this potential obligation has been calculated in the amount of EUR 1,334 thousand as of September 30, 2015 (Dec 31, 2014: EUR 1,368 thousand), using the binomial model of Cox, Ross and Rubinstein.

## **CURRENT LIABILITIES**

#### Convertible notes issued

In December 2013, the Company had issued 25 convertible notes each denominated at EUR 107 thousand with an issue price of EUR 100 thousand each and an aggregate principal amount of EUR 2,675 thousand. In the course of Q3 2015, two further notes of the total issuance were converted by their holders into 407,850 new shares of the Company. The eleven convertible notes remaining are recognized at fair value (level 2) in the nominal amount of EUR 1,177 thousand as liabilities as of September 30, 2015 (Dec 31, 2014: EUR 1,926 thousand). The nominal amount is the reasonable estimate of the fair value due to the maturity of these instruments.

### **Other liabilities**

EUR thousand	Dec 31, 2014	Sept 30, 2015
Payables due to staff	199	337
Accrued audit fees	145	143
Payables due to financial/tax authorities	159	84
Accrued Supervisory Board remuneration	0	57
Payables to social security institutions	1	10
Other	7	6
Total other liabilities	511	637

#### Provisions

EUR thousand	Dec 31, 2014	Sept 30, 2015
Provisions for claims from phantom stock rights	199	1,000
Payroll provisions	128	283
Statutory provisions	50	23
Other provisions	39	64
Total provisions	416	1,370

# NOTES TO THE CONSOLIDATED STATEMENT OF CASH FLOWS

Cash comprises bank deposits and cash in hand. Cash equivalents are defined as instruments convertible to a known amount of cash on a short-term basis and carrying a very low risk of changes in value.

Cash flow from operating activities is derived indirectly from the net result for the period.

Cash flow from investing activities is based on actual payments.

Cash flow from financing activities is based on actual payments.

Due to common reporting practice the Group has changed the presentation of the consolidated statement of cash flows. The reporting line "interest received" is now attributed to the "cash flow from investing activities". In former periods, the Group had chosen to attribute "interest received" to the "cash flow from operating activities" in accordance with the option provided by IFRS. The change has no significant impact on the presentation of the consolidated statement of cash flows for the reporting period and the comparable period.

## CASH CONSUMPTION

The total of cash flow from operating activities and cash flow from investing activities less transactions in securities is monitored by the Company as "cash consumption". It amounted to EUR 7.7 million in the first nine months of 2015 (9M 2014: EUR 5.9 million).

# OTHER INFORMATION

#### **INFORMATION ON STOCK OPTIONS**

No new stock options were granted during the reporting period. Furthermore, no options were exercised, cancelled or forfeited. The total number of stock options still outstanding as of September 30, 2015, amounted to 21,065 with an average strike price of EUR 15.65.

#### **INFORMATION ON PHANTOM STOCK PROGRAMS**

In Q3 2015, the Company established a new phantom stock program ("PSP") for 2015. This program is called PSP 2015 and a total number of up to 200,000 phantom stock rights ("PSR") can be issued under this plan until December 31, 2015.

Beneficiaries of this program are the members of the Executive Board and the employees of the Company and its subsidiary. The Executive Board of the Company decides on the issuance of PSR from this program to employees of the Company and to executives and employees of its subsidiary. The Supervisory Board decides on the issuance of PSR from this program to the Executive Board members of the Company. A certain amount of PSR granted to a beneficiary at a certain point in time is defined as a tranche.

The term of the PSR begins with their issuance and ends five years after the beginning of their vesting period. The PSR of each tranche which are issued to beneficiaries, vest from the beginning of the first full calendar quarter over the three years following their issuance in five equal parts. PSR of each tranche can be exercised for the first time after their vesting, but not earlier than three years after the start of the vesting period. For PSR tranches issued to members of the Executive Board, the Supervisory Board of the Company has the option to determine individually the vesting conditions in each case. Basically, PSR can be exercised anytime in the two years between the end of their waiting period and the end of their term ("exercise period").

The holder of a PSR is entitled to exercise his right during the exercise period when the strike price at the exercise day is higher than the base value. By exercising the PSR, the holder earns an entitlement to obtain the "PSR premium" from the Company in cash. Thereby, the PSR premium equals the absolute difference between the strike price (arithmetic average of the Xetra closing rates of the five consecutive trading days prior to the exercise day) and the base value (average of the Xetra closing rates of the last five trading days before issuing) of the right up to a maximum of EUR 15.00.

Any PSR held by an employee or an Executive Board member of the Company or its subsidiary that have not yet vested expire without compensation in any case upon termination of the service or employment agreement by the beneficiary himself or if the service or employment agreement has been terminated by the Company for cause.

In Q3 2015, 59,000 new PSR from PSP 2015 were granted to the Company's CEO/CFO Dr. Taapken, 24,000 new PSR were granted to the Company's COO Dr. Staub, and 25,000 new PSR were granted to other employees of the Company, each with a base value of EUR 5.05. Until December 31, 2015, a remaining number of 92,000 PSR can still be issued from PSP 2015.

The number of outstanding phantom stock rights from the Company's three other PSP's remained unchanged in the reporting period compared to December 31, 2014, and amounted to 344,833 from PSP 2014, 740,000 from PSP 2013 and to 194,879 from PSP 03–15.

## **INFORMATION ON "DIRECTORS' DEALINGS"**

No "Directors' Dealings" announcements were published by the Company in the reporting quarter.

## HOLDINGS OF EPIGENOMICS AG'S EQUITY INSTRUMENTS AND PHANTOM STOCK RIGHTS BY THE COMPANY'S BOARD MEMBERS

(in units as of September 30, 2015)	Shares	Phantom stock rights
Dr. Thomas Taapken (CEO/CFO)	57,652	282,333
Dr. Uwe Staub (COO)	5,000	237,800
Executive Board total	62,652	520,133
Heino von Prondzynski (Chairman)	104,000	0
Ann Clare Kessler, Ph.D. (Vice Chairwoman)	7,800	0
Supervisory Board total	111,800	0

#### **INFORMATION ON EVENTS AFTER THE REPORTING DATE**

For an overview on events after the reporting date reference is made to the corresponding section in the group management report of this 9-month report.

This interim report was approved and cleared for publication by the Executive Board of the Company on November 10, 2015.

Berlin, November 10, 2015

The Executive Board

# DISCLAIMER

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

# FINANCIAL CALENDAR 2016

Annual Report 2015 January 1 – December 31, 2015 Annual press conference

Tuesday, March 26, 2016

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