



epigenomics

9-Month Report → 2009

JANUARY 1 – SEPTEMBER 30

# 9-Month Report 2009 —

## January 1 – September 30

### Group Key Figures

EUR thousand (unless stated otherwise)	Q3 2008 (unaudited)	Q3 2009 (unaudited)	9M 2008 (unaudited)	9M 2009 (unaudited)
Revenue	320	1,172	1,831	3,248
Research and development costs	-2,114	-1,711	-6,849	-5,102
Earnings before interest and taxes (EBIT)	-2,648	-2,286	-8,536	-7,053
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-2,319	-1,982	-7,751	-6,449
Net loss for the period	-2,515	-2,257	-8,147	-7,070
Weighted-average number of shares issued (notional par value: EUR 1 each)	26,710,886	29,394,724	25,771,101	29,097,936
Earnings per share (basic and diluted) in EUR	-0.09	-0.08	-0.32	-0.24
Cash flow from operating activities			-6,916	-8,005
Cash flow from investing activities			993	282
Cash flow from financing activities			11,484	5,085
Cash flow total			5,561	-2,638
EUR thousand (unless stated otherwise)			Dec 31, 2008 (audited)	Sept 30, 2009 (unaudited)
Liquid assets at balance sheet date (incl. marketable securities)			12,100	9,544
Total equity at balance sheet date			16,568	15,257
Equity ratio in %			81.7	80.9
Total assets at balance sheet date			20,283	18,858
Share price at balance sheet date in EUR (Xetra)			2.00	2.95
Number of employees at balance sheet date			90	83

# Management Discussion & Analysis as of September 30, 2009

## The Third Quarter of 2009 – 9M Overview

During the first nine months of 2009, Epigenomics has made great strides towards commercializing its *m*SEPT9 blood-based test for colorectal cancer. The test is the first blood test ever for colorectal cancer detection offered in Europe. As the first laboratory network, Swiss Viollier AG started offering the test to patients, general practitioners and gastroenterologists in Switzerland in July. Several German laboratories, including Labor Dr. Limbach & Kollegen (Heidelberg), Labor Krone (Bad Salzflen), Labor Dr. Stein & Kollegen (Moenchengladbach) and Laboratoriumsmedizin Dortmund Dr. Eberhard & Partner, will start offering *m*SEPT9 testing on October 1, 2009. We also expect Quest Diagnostics, Inc. (“Quest”), who has made solid progress in test development during the first nine months of 2009, to launch a laboratory-developed test (“LDT”) version of *m*SEPT9 in the U.S.A. in due course. Moreover, we expect our collaboration partner Abbott Molecular, Inc. (“Abbott”) to launch a colorectal cancer screening test based on our *m*SEPT9 biomarker as a CE-marked in-vitro diagnostics (“IVD”) test kit in Europe by the end of 2009. Finally, given the excellent progress during the first nine months of 2009, we expect to obtain initial results from our PRESEPT clinical study in late 2009 or early 2010. Enrollment as of September 30, 2009, was 6,376 subjects with more than three quarters of the expected 50 colorectal cancer cases already identified by colonoscopy.

During Q3, we have made significant progress in our non-exclusive commercialization strategy by signing a license agreement for our *m*SEPT9 biomarker with ARUP Laboratories, Inc. (“ARUP”), Salt Lake City, UT, U.S.A. This is our second non-exclusive reference laboratory licensee for the U.S. market. We expect ARUP to begin implementing an LDT of the blood-based colorectal cancer test and to launch it in the U.S.A. as a testing service in 2010.

We further strengthened our intellectual property (“IP”) portfolio by cross-licensing certain IVD DNA methylation detection technologies with our partner DxS Ltd. for the use of their Scorpions<sup>®</sup> technology in exchange for the non-exclusive license to certain of Epigenomics’ IP covering the use of Scorpions<sup>®</sup> technology for DNA methylation. In September 2009, DxS Ltd. has been acquired by Qiagen N.V., another of our long-term licensing partners.

During Q3 2009, we have also demonstrated in a clinical study that our *m*SHOX2 biomarker for lung cancer detection not only works in bronchial lavage samples but also in blood plasma.

Q3 2009 was also very much focused on presenting some of our clinical studies at leading conferences. Epigenomics was present or presented at the following meetings:

- ECCO 15 – 34th ESMO Multidisciplinary Congress – Berlin, Germany
- Swiss Society of Gastroenterology (SSG) – Zurich, Switzerland
- European Respiratory Society (ERS) 2009 Annual Congress – Vienna, Austria
- World Lung Cancer Conference 2009 – San Francisco, CA, U.S.A.
- AACC Annual Meeting 2009 – Chicago, IL, U.S.A.

#### *Highlights of the first nine months of 2009*

##### *Colorectal Cancer*

- Progressed PRESEPT colorectal cancer clinical study to enroll 6,376 subjects with more than 75% of the expected 50 colorectal cancer cases already identified by September 30, 2009.
- Signed ARUP licensing deal for non-exclusive U.S. LDT rights.
- Announced the launch of <sup>m</sup>SEPT9 blood testing service for colorectal cancer early detection by the Swiss diagnostic laboratory Viollier AG and four German laboratories.
- Delivered prototype <sup>m</sup>SEPT9 colorectal cancer blood test to Abbott, so that they can continue on track towards product launch in Europe by the end of 2009.
- Received new third-party research grant by the German Federal Ministry of Education and Research for colorectal cancer and polyp detection research.

##### *Lung & Prostate Cancer*

- Finalized clinical evaluation of <sup>m</sup>SHOX2 lung cancer biomarker and initiated product development.
- Demonstrated solid performance of <sup>m</sup>SHOX2 lung cancer biomarker in blood plasma in a clinical study.
- Made <sup>m</sup>PITX2 biomarker testing available under an Early Access Program in Germany.
- Entered into a licensing agreement with Quest Diagnostics regarding our proprietary <sup>m</sup>GSTP1 biomarker for prostate cancer.
- Entered into a non-exclusive licensing agreement for <sup>m</sup>GSTP1 with U.S.-based Predictive Biosciences, Inc.

##### *Corporate*

- Received ISO 13485:2003 certification for the design, development, manufacturing, and distribution of IVD products.
- Placed new shares in a PIPE (private investment in public equity) transaction at a premium.

### *Research and Development*

During the first nine months of 2009, our R&D activities constantly focused on executing the PRESEPT colorectal cancer screening study. The PRESEPT Study is a multi-center study to evaluate the clinical performance of <sup>m</sup>SEPT9 and its health economic benefit in a U.S. colorectal cancer screening-guideline-eligible population. It enrolls individuals who have an average or increased disease risk according to U.S. guidelines and who undergo a routine screening colonoscopy. The approximately 7,500 individuals we intend to enroll are expected to yield about 50 colorectal cancer cases.

Within the study in the U.S.A. and in Germany, the 32 initiated clinical sites have enrolled a total of 6,376 subjects in the study by the end of September 2009. At the end of Q3 2009, we have already identified more than 75% of the 50 expected colorectal cancer cases by colonoscopy, which were previously undetected. The PRESEPT Study is a great step forward in the realization of our goal of detecting cancers based on <sup>m</sup>SEPT9 with a standard blood test. We expect to obtain initial results by the end of the year 2009 or early in 2010.

During the first nine months of 2009, we also successfully completed the development of our own **Epi proColon** IVD kit. The blood test for colorectal cancer was developed by Epigenomics for use on the Roche LightCycler<sup>®</sup> 480 platform, CE marked and launched as an IVD test kit on October 6, 2009, for use by any molecular diagnostics laboratory in Europe.

In the second quarter of 2009, we have successfully obtained an ISO 13485:2003 certification for the design, development, manufacturing, and distribution of IVD products. This certification was granted for the quality system established for our headquarters in Berlin, Germany, and our wholly owned subsidiary Epigenomics, Inc. in Seattle, WA, U.S.A. This corporate milestone demonstrates our commitment to implementing and applying a quality management system conforming to the international quality management standard for medical devices that also includes IVD products such as Epigenomics' tests for colorectal, lung, and prostate cancer indications.

In the third quarter of 2009, we successfully completed a clinical study using our <sup>m</sup>SHOX2 biomarker in blood plasma samples from 188 patients with confirmed lung cancer of all stages and 155 control patients consisting of individuals with benign lung disease, healthy subjects and smokers. The study, which has been conducted in cooperation with the Charité – Universitätsmedizin Berlin, Germany ("Charité"), has confirmed <sup>m</sup>SHOX2 as a promising lung cancer biomarker. The study demonstrated that in a population of patients undergoing diagnostic work-up for suspected lung cancer, of which typically about 40% actually have the cancer, a <sup>m</sup>SHOX2 test can potentially predict the presence of the disease with 92% probability (positive predictive value).

### Product development pipeline

In all of our product development programs and commercial partnerships, we have made progress according to our plans. On October 6, 2009, we have launched our CE-marked IVD test kit for colorectal cancer detection under the **Epi proColon** brand (see “Supplementary Report”).

After the launch of *m*SEPT9 testing by Swiss laboratory Viollier AG in July 2009 and four leading German laboratories from October 1, 2009, onwards, we expect further European laboratories to start offering *m*SEPT9 testing in late 2009 or in 2010 using our **Epi proColon** test kit as well as Quest and ARUP to start offering *m*SEPT9 LDTs in the U.S.A. at the end of 2009 and no earlier than 2010, respectively. Furthermore, it is expected that our partner Abbott will launch its *m*SEPT9 IVD test kit for broad commercialization in Europe by the end of 2009.

We intend to launch our lung cancer diagnostic test in Europe in the first half of 2010 and to commercialize it ourselves. Furthermore, our *m*PITX2 prostate cancer prognostic assay is now available under an Early Access Program in Europe.

Indications & applications	Marker Identification	Clinical proof of concept	Clinical evaluation	Research assay & EAP**	LDT*** development & launch	IVD development & launch	Marketing & Sales by
<b>Colorectal cancer</b>							
Screening (blood)	<i>m</i> SEPT9			Q2 / 09	Q4 / 09	Q4 / 09	Epigenomics. Quest Diagnostics. Abbott. Sysmex
	OTHER BIOMARKERS						
<b>Lung cancer</b>							
Screening (blood / sputum)	1-3 BIOMARKERS						
Diagnosis (BL* / brushings)	<i>m</i> SHOX2 + OTHERS			Q4 / 09		H1 / 10	Epigenomics
<b>Prostate cancer</b>							
Screening (urine)	1-3 BIOMARKERS						
Diagnosis (biopsies)	<i>m</i> GSTP1			Q1 / 08			Epigenomics. Quest Diagnostics
Prognosis (surgical tissue)	<i>m</i> PITX2			Q2 / 09			Epigenomics & Partner

\* Bronchial lavage \*\* Early Access Program \*\*\* Laboratory-developed test

### Financial highlights

Revenue for the first nine months of 2009 increased by 77% to EUR 3.2 million, from EUR 1.8 million in the same period of 2008. 9M revenue was generated from continued and newly signed collaborations and licensing agreements. EBIT for 9M 2009 of EUR -7.1 million showed a 17% improvement over EBIT for the corresponding period in 2008 of EUR -8.5 million. Overall, operating costs during the first nine months of 2009 decreased by 5% to EUR 10.7 million, compared to the same period in 2008 (EUR 11.3 million).

### Our Stock

Trading volume in Epigenomics' stock increased significantly during Q3 2009 from an average of approximately 12,000 shares a day in Q2 2009 to over 20,000 shares per day, an increase of more than 65%. The share price closed at EUR 2.95 at the end of Q3 2009 on Xetra after a volatile third quarter with a peak of EUR 3.39 per share, an increase of 52% compared to the share price from our most recent capital increase in Q1 2009 (EUR 1.94).

During 9M 2009, a total of 2,671,088 new shares were issued from Authorized Capital 2008/I as part of the capital increase in February 2009.

Key data on Epigenomics' stock (as of September 30, 2009)

Ticker:	ECX
Exchange:	Frankfurter Wertpapierbörse, Amtlicher Markt (Prime Standard)
Security code number:	A0BVT9
ISIN:	DE000A0BVT96
Shares outstanding:	29,394,724
Price range in 9M 2009:	EUR 1.57 – 3.39 (Xetra closing prices)
Analyst coverage:	Midas Research: Thomas Schießle fairesearch: Dr. Martin Schnee*

\* Under the label of Close Brothers Seydler Research AG

## Financials

### *Financial position and cash flow*

In the first nine months of 2009, Epigenomics' cash flow and its financial position were mainly affected by the continued net cash consumption from operating activities as well as by the successful PIPE financing transaction. Overall, the financial position in 9M 2009 has developed according to plan with short-term liquidity as of September 30, 2009, of EUR 9.5 million – a decrease of EUR 2.6 million from the EUR 12.1 million at year-end 2008, mainly due to net cash consumption for operating activities as well as for investments in tangible and intangible assets.

Cash outflow from operating activities in 9M 2009 totalled EUR 8.0 million (9M 2008: EUR 6.9 million). Cash inflow from investing activities amounted to EUR 0.3 million (9M 2008: EUR 1.0 million), primarily due to a redemption of marketable securities. Cash flow from financing activities was positive at EUR 5.1 million (9M 2008: EUR 11.5 million), due to the capital increase in February 2009.

### *Results of operations*

In Q3 2009, revenue increased markedly to EUR 1,172 thousand from EUR 320 thousand in the comparable period of 2008. This significant improvement of over 260% is mainly attributable to the progress made in our collaboration with Abbott, as well as to revenue recognition from the cross-license agreement with DxS and under our collaboration agreement with Philips Electronics Netherland B.V. Our commercial R&D activities contributed revenue of EUR 482 thousand, whereas revenue of EUR 690 thousand was generated from out-licensing activities during Q3 2009.

Cost of sales of EUR 586 thousand decreased as a percentage of revenue from 66% in Q3 2008 (EUR 212 thousand) to 50% in Q3 2009, mainly as a result of a higher share of licensing income in total revenue. Therefore, we have generated a gross profit of EUR 586 thousand in the reporting quarter – a significant increase compared to EUR 108 thousand in Q3 2008.

Other income decreased to EUR 37 thousand in Q3 2009 from EUR 438 thousand in Q3 2008, whereas this number in Q3 2008 had been strongly affected by unscheduled income from the reversal of provisions and from currency conversion.

Expenses for our R&D projects, which are not partnered with external business partners, are being treated as R&D costs. The latter have dropped by 19% from EUR 2,114 thousand in the third quarter of 2008 to EUR 1,711 thousand in Q3 2009, primarily resulting from increased resource allocation to our commercial collaboration projects and a corresponding shift to cost of sales.

Marketing and business development costs increased by 72% from EUR 195 thousand in Q3 2008 to EUR 335 thousand in Q3 2009 due to our increased pre-marketing, sales and business development activities for the preparation of the test launch of our **Epi proColon** colorectal cancer blood test.

General and administrative costs decreased by 12% from EUR 873 thousand in Q3 2008 to EUR 771 thousand in Q3 2009 mainly resulting from reduced staff costs.

In the reporting period, other expenses increased considerably to EUR 92 thousand compared to previous year (Q3 2008: EUR 12 thousand), due to currency exchange rate losses.

EBIT amounted to EUR -2,286 thousand in Q3 2009. Thus, our operating result has improved by 14% compared to an EBIT of EUR -2,648 thousand in Q3 2008, as a result of the aforementioned effects of increased revenue at lower costs.

The sharp decrease in our interest income during the reporting quarter compared to Q3 of the previous year can be explained by a lower level of cash and cash equivalents on the one hand and by historically low interest rates for euro deposits on the capital markets on the other.

Finally, our net loss for the period improved by more than 10% from EUR 2,515 thousand in Q3 2008 to EUR 2,257 thousand in Q3 2009.

#### *Net assets position*

Epigenomics' balance sheet total decreased from EUR 20.3 million as of December 31, 2008, to a total of EUR 18.9 million as of September 30, 2009. Key driver was the net consumption of liquidity by operations partly compensated by a cash inflow from our capital increase in the meantime.

Total non-current assets of EUR 5.8 million as of September 30, 2009, decreased slightly compared to year-end 2008 mainly due to a capitalization of development costs and acquired license rights.

During 9M 2009, total current assets decreased from EUR 14.4 million as of December 31, 2008, to EUR 13.0 million as of September 30, 2009.

Our subscribed capital increased from EUR 26.7 million as of December 31, 2008, to EUR 29.4 million as of September 30, 2009, and simultaneously the capital reserve from EUR 3.6 million to EUR 6.1 million, mostly attributable to the capital surplus from the PIPE financing transaction in February 2009.

The equity ratio decreased slightly from 81.7% at the end of 2008 to 80.9% as of September 30, 2009.

## Employees

	Berlin	Seattle	Total
Number of employees as of September 30, 2009	65	18	83
Number of employees as of December 31, 2008	70	20	90
Number of employees as of September 30, 2008	69	23	92

The reason for the significant decrease in the total number of employees over the last 12 months was the development from a research-driven organization to a company with a stronger focus on late-stage product development and commercialization resulting in more streamlined operations in Berlin and Seattle.

## Supplementary Report

The following events occurred after the end of the reporting period:

On October 5, 2009, one of our shareholders withdrew his complaint from July 2008 relating to TOP 4 (authorization to issue convertible bonds) of the Agenda of the Annual General Shareholders' Meeting (AGM) on June 3, 2008. As a consequence, there are no further complaints outstanding against the resolutions of any of our AGMs.

On October 6, 2009, we announced the launch of our own CE-marked IVD blood test for colorectal cancer in Europe under the **Epi proColon** brand. **Epi proColon** is the first CE-marked in vitro diagnostics product that is directly marketed by Epigenomics to molecular diagnostic laboratories in Europe. **Epi proColon** is an innovative molecular diagnostic test that can detect tumor-derived methylated DNA of the Septin9 gene (<sup>m</sup>SEPT9) in blood plasma as a reliable indicator, or biomarker, of colorectal cancer. In a performance evaluation study, the final step of Epigenomics' IVD product development, with routine blood draws from about 260 colorectal cancer patients and from subjects without any evidence of colorectal cancer as controls, the **Epi proColon** test detected two thirds of the cancer cases in early, still localized disease stages.

On October 8, 2009, we announced that we have initiated the testing of the biomarker <sup>m</sup>SEPT9 in blood plasma samples collected in the PRESEPT Study in three independent clinical laboratories. We expect to reach the study's original enrollment target of around 7,500 subjects during Q4 of 2009 but will continue enrolling until the study population comprises 50 colorectal cancer cases, a target expected to be reached either in late 2009 or early 2010. <sup>m</sup>SEPT9 testing will be performed by three independent high-profile laboratories, namely Quest Diagnostics Incorporated headquartered in Madison, NJ, U.S.A., ARUP Laboratories, Salt Lake City, UT, U.S.A., and the Institute of Laboratory Medicine and Pathobiochemistry of the Charité – Universitätsmedizin Berlin, Germany. The laboratories will use our recently launched CE-marked **Epi proColon** test kit to detect the <sup>m</sup>SEPT9 biomarker in the PRESEPT blood samples for this research study. Following a predefined statistical analysis plan, a subset of about 1,500 of the about 7,500 PRESEPT blood plasma samples that includes all 50 CRC cases, several hundred cases with polyps and a random selection of about 900 to 1,000 colonoscopy-verified subjects with no evidence of disease as controls will be tested for <sup>m</sup>SEPT9.

Following the processing of all samples, the results of <sup>m</sup>SEPT9 testing will be compared to the findings by colonoscopy plus the histopathology of the polyps and cancer cases by an independent biostatistical group at the University of Minnesota.

The blood plasma samples will be processed in several batches, the first of which will be tested in the first half of October 2009 with further batches scheduled for later in October, November, and December of 2009. Testing of the last batch will commence once the 50<sup>th</sup> cancer subject has been identified. We expect that preliminary results will be available either in late 2009 or early 2010.

### Opportunities and Risks

Our opportunities and risks result, as outlined in the management report published with the consolidated financial statements 2008, from the following categories:

- business-related opportunities and risks,
- IP-related opportunities and risks,
- regulatory opportunities and risks,
- financial opportunities and risks,
- other opportunities and risks.

The successful capital increase in February 2009 as well as the deals signed with Sysmex and Quest can be seen as risk-mitigating factors with regard to our business-related and financial risks. Moreover, through the creation of Authorized Capital 2009/I and Authorized Capital 2009/II approved by the vast majority of our shareholders at our Annual General Shareholders' Meeting held on May 11, 2009, we have significantly expanded our strategic and tactical options to finance the product development and commercialization of our colorectal cancer screening test as well as the clinical R&D in our lung and prostate cancer programs.

### Prognosis Report for Q4 2009

In Q4 2009, our focus will remain on driving commercialization of our colorectal cancer blood test based on <sup>m</sup>SEPT9 by direct marketing and sales of our **Epi proColon** IVD test kit as well as by supporting our non-exclusive licensees in their endeavours to develop and launch <sup>m</sup>SEPT9-based blood tests for colorectal cancer. Therefore, significant parts of our operational activities in the last quarter of 2009 will continue to be directed towards executing the PRESEPT Study and delivering clinical results from that trial. To that end, we have qualified and trained three independent clinical laboratories, namely Quest, ARUP, and the Charité, which have already started the actual testing of PRESEPT blood plasma samples in October 2009. The measurements will be executed in four batches and we expect to complete testing of the final batch as soon as 50 colorectal cancer cases have been identified and all relevant clinical information from these cases becomes available either in late 2009 or early 2010. Until then the laboratories as well as Epigenomics will be completely blinded to any testing results.

We will continue working with Abbott to support them in completing the final phases of their product development with the strategic goal of having Abbott launch a CE-marked IVD test kit for colorectal cancer screening based on <sup>m</sup>SEPT9 in Europe by the end of 2009.

The key strategic focus in our marketing and business development activities in late 2009 and 2010 will be on closing additional non-exclusive licensing deals for colorectal cancer screening and <sup>m</sup>SEPT9 – along the lines of the deal already concluded with Sysmex in Q1 2009 and with ARUP in Q3 2009. We will carefully coordinate the timing of any future <sup>m</sup>SEPT9 deals with expected results from the PRESEPT Study as well as the expected Abbott product launch in Europe. Our goal is to maximize value to Epigenomics in any future licensing deals for <sup>m</sup>SEPT9.

Our R&D activities will be focused on progressing programs in our current product pipeline in colorectal, lung and prostate cancer.

Currently we expect full-year revenue for 2009 to be higher than 2008 revenue, as we exceeded the 2008 revenue already as of September 30, 2009. This increase in revenue results from our existing collaborations, from the additional partnerships and license agreements we have entered into as well as from initial direct product sales. In Q4, we expect our revenue to come from our partnering activities in diagnostics as milestones are expected to be reached (e.g. CE-marked Septin 9 kit launch by Abbott; Quest LDT launch) and from initial sales of our **Epi proColon** IVD test kit. In Q4, we expect a number of biomarker R&D collaborations (e.g. two additional follow-on collaborative projects with Janssen Pharmaceutica N.V. – (a Johnson & Johnson company) to also contribute to revenue growth. Due to continued strict cost discipline we expect EBIT and our net loss for the full year 2009 to show an improvement over the previous year. We expect net cash consumption for 2009 to be at a very similar level compared to 2008, i.e. at around EUR 10 million.

Overall, we are very excited about the progress made in terms of product development, commercialization and our commercial partnerships. We remain committed to delivering on our goals and milestones, and, in the process, to build value.

# Interim Consolidated Financial Statements as of September 30, 2009

## Group Income Statement – unaudited for the period from January 1 to September 30, 2009

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
<b>Revenue</b>	<b>320</b>	<b>1,172</b>	<b>1,831</b>	<b>3,248</b>
Cost of sales	-212	-586	-678	-2,063
<b>Gross profit</b>	<b>108</b>	<b>586</b>	<b>1,153</b>	<b>1,185</b>
Other income	438	37	901	429
Research and development costs	-2,114	-1,711	-6,849	-5,102
Marketing and business development costs	-195	-335	-662	-814
General and administrative costs	-873	-771	-2,667	-2,407
Other expenses	-12	-92	-412	-344
<b>Operating result (EBIT)</b>	<b>-2,648</b>	<b>-2,286</b>	<b>-8,536</b>	<b>-7,053</b>
Interest income	180	37	556	169
Interest expenses	-7	0	-23	-8
Other financial result	8	-1	21	13
<b>Net loss for the period before taxes on income</b>	<b>-2,467</b>	<b>-2,250</b>	<b>-7,982</b>	<b>-6,879</b>
Taxes on income	-48	-7	-165	-191
<b>Net loss for the period</b>	<b>-2,515</b>	<b>-2,257</b>	<b>-8,147</b>	<b>-7,070</b>
<b>Earnings per share (basic and diluted) in EUR</b>	<b>-0.09</b>	<b>-0.08</b>	<b>-0.32</b>	<b>-0.24</b>

## Statement of income and expenses recognized in Group equity – unaudited

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
<b>Net loss for the period</b>	<b>-2,515</b>	<b>-2,257</b>	<b>-8,147</b>	<b>-7,070</b>
Fair value adjustments of securities	-228	341	-415	594
<b>Total income and expenses recognized in Group equity</b>	<b>-228</b>	<b>341</b>	<b>-415</b>	<b>594</b>
<b>Total comprehensive income</b>	<b>-2,743</b>	<b>-1,916</b>	<b>-8,562</b>	<b>-6,476</b>

## Group Balance Sheet – unaudited

as of September 30, 2009

<b>ASSETS</b> EUR thousand	Dec 31, 2008	Sept 30, 2009
<b>Non-current assets</b>		
Intangible assets	4,536	4,785
<i>thereof goodwill</i>	2,625	2,625
Tangible assets	692	580
Deferred taxes	629	461
<b>Total non-current assets</b>	<b>5,857</b>	<b>5,826</b>
<b>Current assets</b>		
Inventories	125	148
Trade receivables	727	1,511
Marketable securities	2,286	2,368
Cash and cash equivalents	9,814	7,176
Other current assets	1,474	1,829
<b>Total current assets</b>	<b>14,426</b>	<b>13,032</b>
<b>Total assets</b>	<b>20,283</b>	<b>18,858</b>
<b>EQUITY AND LIABILITIES</b> EUR thousand		
<b>Equity</b>		
Subscribed capital	26,724	29,395
Capital reserve	3,567	6,061
Retained earnings	0	-12,271
Net loss for the period	-12,271	-7,070
Other comprehensive income	-1,452	-858
<b>Total equity</b>	<b>16,568</b>	<b>15,257</b>
<b>Non-current liabilities</b>		
Liabilities from leasing contracts	38	16
<b>Total non-current liabilities</b>	<b>38</b>	<b>16</b>
<b>Current liabilities</b>		
Trade payables	1,027	979
Liabilities from leasing contracts	28	28
Deferred income	1,254	987
Other liabilities	887	746
Provisions	481	845
<b>Total current liabilities</b>	<b>3,677</b>	<b>3,585</b>
<b>Total equity and liabilities</b>	<b>20,283</b>	<b>18,858</b>

## Group Cash Flow Statement – unaudited

for the period from January 1 to September 30, 2009

EUR thousand	9M 2008	9M 2009
<b>Cash and cash equivalents at the beginning of the period</b>	<b>6,646</b>	<b>9,814</b>
<b>Operating activities</b>		
<b>Net loss for the period before taxes on income</b>	<b>-7,982</b>	<b>-6,879</b>
Corrections for:		
Depreciation on tangible assets	359	256
Amortization of intangible assets	426	348
Losses from the disposal of assets	1	1
Stock option expenses	117	120
Foreign currency exchange losses	-5	0
Interest income	-556	-169
Interest expenses	23	8
Taxes	-229	-62
<b>Operating result before changes in net current assets</b>	<b>-7,846</b>	<b>-6,377</b>
Increase in trade receivables and other current assets (9M 2008: decrease)	1,667	-1,116
Increase in inventories (9M 2008: decrease)	133	-23
Decrease in current liabilities	-1,395	-680
<b>Liquidity earned from operating activities</b>	<b>-7,441</b>	<b>-8,196</b>
Interest received	525	191
<b>Cash flow from operating activities</b>	<b>-6,916</b>	<b>-8,005</b>
<b>Investing activities</b>		
Payments for investments in tangible assets	-40	-146
Proceeds from investment grants	100	0
Payments for investments in intangible assets	-67	-72
Proceeds from the sale of marketable securities	0	500
Proceeds from the divestment of financial assets	1,000	0
<b>Cash flow from investing activities</b>	<b>993</b>	<b>282</b>
<b>Financing activities</b>		
Payments for the creation of new shares	-2,037	-76
Proceeds from the issue of new shares	13,533	5,182
Payments for lease financing	-12	-21
<b>Cash flow from financing activities</b>	<b>11,484</b>	<b>5,085</b>
<b>Cash flow total</b>	<b>5,561</b>	<b>-2,638</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>12,207</b>	<b>7,176</b>

## Statement of Changes in Group Equity – unaudited

as of September 30, 2009

EUR thousand	Subscribed capital	Capital reserve	Retained earnings	Net loss for the period	Other compreh. income	Group equity
<b>Dec 31, 2007</b>	<b>18,253</b>	<b>13,712</b>	<b>-13,151</b>	<b>0</b>	<b>-993</b>	<b>17,821</b>
<b>Total comprehensive income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-8,147</b>	<b>-415</b>	<b>-8,562</b>
Stock-based compensation	0	117	0	0	0	117
Capital increase from issue of shares	8,458	0	0	0	0	8,458
Premium from issue of shares	0	5,075	0	0	0	5,075
Financing costs	0	-2,192	0	0	0	-2,192
<b>Sept 30, 2008</b>	<b>26,711</b>	<b>16,712</b>	<b>-13,151</b>	<b>-8,147</b>	<b>-1,408</b>	<b>20,717</b>

EUR thousand	Subscribed capital	Capital reserve	Retained earnings	Net loss for the period	Other compreh. income	Group equity
<b>Dec 31, 2008</b>	<b>26,724</b>	<b>3,567</b>	<b>-12,271</b>	<b>0</b>	<b>-1,452</b>	<b>16,568</b>
<b>Total comprehensive income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-7,070</b>	<b>594</b>	<b>-6,476</b>
Stock-based compensation	0	120	0	0	0	120
Capital increase from issue of shares	2,671	0	0	0	0	2,671
Premium from issue of shares	0	2,511	0	0	0	2,511
Financing costs	0	-137	0	0	0	-137
<b>Sept 30, 2009</b>	<b>29,395</b>	<b>6,061</b>	<b>-12,271</b>	<b>-7,070</b>	<b>-858</b>	<b>15,257</b>

# Notes to the Q3/9M 2009 Consolidated Financial Statements

## Basic Information, Principles and Methods

### *General principles*

The presented unaudited interim consolidated financial statements of Epigenomics AG are prepared according to the International Financial Reporting Standards (IFRSs) of 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 in effect at the closing date September 30, 2009, as mandatory applicable in the European Union. Further, these statements are in accordance with German Accounting Standards (GASs) under consideration of GAS 16 Interim Financial Reporting. New standards adopted by the IASB and/or the German Accounting Standards Committee (GASC) apply from the date on which they came into effect. A critical review of this interim report was performed by the Company's auditors.

The reporting period as defined in these interim consolidated financial statements is the period from January 1, 2009, to September 30, 2009. The reporting currency is the euro.

In the reporting period, the Group has applied the revised standard IAS 1 – Presentation of financial statements, as issued by the IASB in September 2007, for the first time. Furthermore, in the reporting period, IFRS 8 – Operating Segments, has become effective on January 1, 2009. This standard has no impact on the Group's accounting.

The income statement has been prepared using the cost of sales method.

### *Consolidation group*

The consolidation group remained unchanged compared to the one as of December 31, 2008, and comprises the two companies Epigenomics AG, Berlin, Germany, and Epigenomics, Inc., Seattle, WA, U.S.A.

### *Consolidation, accounting and valuation principles*

The presented unaudited interim consolidated financial statements should be read in connection with the audited consolidated financial statements of Epigenomics AG for the year ended December 31, 2008. The consolidation, accounting and valuation principles presented in those statements were still valid during the reporting period unless explicitly mentioned otherwise below.

All intercompany transaction results, revenue, expenses, profits, receivables, and payables between the Group companies are eliminated in full on consolidation.

### Currency translation

The exchange rate of the U.S. dollar and the British pound, the two major foreign currencies in the interim consolidated financial statements, changed during the reporting period as follows:

Reporting date rates	Dec 31, 2008	Sept 30, 2009
EUR/USD	1.3917	1.4643
EUR/GBP	0.95250	0.90930
Average rates	9M 2008	9M 2009
EUR/USD	1.5257	1.37031
EUR/GBP	0.78459	0.88737

### Notes to the Group Income Statement

#### Revenue

Revenue in Q3 2009 of EUR 1,172 thousand (Q3 2008: EUR 320 thousand) stems from the following sources:

EUR thousand	Q3 2008	in % of total	Q3 2009	in % of total	9M 2008	in % of total	9M 2009	in % of total
R&D payments	91	28.4	429	36.5	601	32.8	1,728	53.2
Licensing and royalty income	229	71.6	690	58.9	831	45.4	1,347	41.4
Reimbursements	0	0.0	52	4.5	399	21.8	155	4.8
Other	0	0.0	1	0.1	0	0.0	18	0.6
<b>Total</b>	<b>320</b>	<b>100.0</b>	<b>1,172</b>	<b>100.0</b>	<b>1,831</b>	<b>100.0</b>	<b>3,248</b>	<b>100.0</b>

#### Gross profit/Gross margin

The gross profit in Q3 2009 of EUR 586 thousand (Q3 2008: EUR 108 thousand) equals a gross margin of 50% (Q3 2008: 34%).

*Other income*

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
Exchange gains from currency conversion	337	13	388	236
Corrections of invoices of the previous year	0	0	0	79
Third-party research grants	2	21	81	42
Income from the sale of assets	0	0	19	31
Income from subleasing	14	0	43	22
Recoveries and refunds	13	2	48	17
Income from reversal of provisions	69	0	316	0
Other	3	1	6	2
<b>Total</b>	<b>438</b>	<b>37</b>	<b>901</b>	<b>429</b>

*Cost analysis**Q3 2008*

EUR thousand	Materials / consumables	Depreciation and amorti- zation	Personnel costs	Other costs	Capitalized development costs	Total
Cost of sales	8	25	4	175	0	212
R&D costs	257	287	988	582	0	2,114
M&BD costs	0	3	82	110	0	195
G&A costs	1	13	445	414	0	873
<b>Total</b>	<b>266</b>	<b>328</b>	<b>1,519</b>	<b>1,281</b>	<b>0</b>	<b>3,394</b>

*Q3 2009*

EUR thousand	Materials / consumables	Depreciation and amorti- zation	Personnel costs	Other costs	Capitalized development costs	Total
Cost of sales	200	20	38	328	0	586
R&D costs	458	269	909	389	-314	1,711
M&BD costs	7	3	144	181	0	335
G&A costs	1	12	374	384	0	771
<b>Total</b>	<b>666</b>	<b>304</b>	<b>1,465</b>	<b>1,282</b>	<b>-314</b>	<b>3,403</b>

*9M 2008*

EUR thousand	Materials/ consumables	Depreciation and amorti- zation	Personnel costs	Other costs	Capitalized development costs	Total
Cost of sales	53	52	214	359	0	678
R&D costs	995	687	3,483	1,767	-83	6,849
M&BD costs	0	8	374	280	0	662
G&A costs	2	39	1,395	1,231	0	2,667
<b>Total</b>	<b>1,050</b>	<b>786</b>	<b>5,466</b>	<b>3,637</b>	<b>-83</b>	<b>10,856</b>

*9M 2009*

EUR thousand	Materials/ consumables	Depreciation and amorti- zation	Personnel costs	Other costs	Capitalized development costs	Total
Cost of sales	563	70	189	1,241	0	2,063
R&D costs	812	485	2,795	1,324	-314	5,102
M&BD costs	25	10	441	338	0	814
G&A costs	6	38	1,216	1,147	0	2,407
<b>Total</b>	<b>1,406</b>	<b>603</b>	<b>4,641</b>	<b>4,050</b>	<b>-314</b>	<b>10,386</b>

*Personnel costs*

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
Personnel remuneration	1,322	1,231	4,678	3,950
Social security expenses	203	177	671	571
Stock option expenses	-6	57	117	120
<b>Total personnel costs</b>	<b>1,519</b>	<b>1,465</b>	<b>5,466</b>	<b>4,641</b>

The number of employees as of September 30, 2009, amounted to 83 (December 31, 2008: 90; September 30, 2008: 92).

*Other expenses*

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
Exchange losses from currency conversion	12	91	302	342
Write-down of doubtful receivables	0	0	45	0
Other	0	1	65	2
<b>Total</b>	<b>12</b>	<b>92</b>	<b>412</b>	<b>344</b>

### Operating result (EBIT) and EBITDA

In the reporting period, the recorded operating result before interest and taxes (EBIT) and the operating result before interest, taxes, depreciation and amortization (EBITDA) improved as follows:

EUR thousand	Q3 2008	Q3 2009	variance in %	9M 2008	9M 2009	variance in %
<b>EBIT</b>	<b>-2,648</b>	<b>-2,286</b>	<b>13.7</b>	<b>-8,536</b>	<b>-7,053</b>	<b>17.4</b>
Depreciation	126	75	40.5	359	256	28.7
Amortization	203	229	-12.8	426	348	18.3
<b>EBITDA</b>	<b>-2,319</b>	<b>-1,982</b>	<b>14.5</b>	<b>-7,751</b>	<b>-6,449</b>	<b>16.8</b>

### Financial result

EUR thousand	Q3 2008	Q3 2009	9M 2008	9M 2009
Interest and related income	180	37	556	169
Other financial income	9	0	24	28
<b>Total financial income</b>	<b>189</b>	<b>37</b>	<b>580</b>	<b>197</b>
Interest expenses	-7	0	-23	-8
Other financial expenses	-1	-1	-3	-15
<b>Total financial expenses</b>	<b>-8</b>	<b>-1</b>	<b>-26</b>	<b>-23</b>
<b>Total financial result</b>	<b>181</b>	<b>36</b>	<b>554</b>	<b>174</b>

### Taxes on income

Income taxes of EUR 7 thousand had to be recorded exclusively for the U.S. subsidiary Epigenomics, Inc. in Q3 2009 (Q3 2008: EUR 48 thousand). The amount comprised merely state and local taxes of Epigenomics, Inc.

### 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 in the respective period.

	Q3 2008	Q3 2009	9M 2008	9M 2009
Net loss for the period in EUR thousand	-2,515	-2,257	-8,147	-7,070
Weighted-average number of shares issued	26,710,886	29,394,724	25,771,101	29,097,936
<b>Earnings per share (basic and diluted) in EUR</b>	<b>-0.09</b>	<b>-0.08</b>	<b>-0.32</b>	<b>-0.24</b>

The outstanding stock options granted by the Company are antidilutive according to IAS 33.41 and 33.43. Therefore, the earnings per share (diluted) equal the earnings per share (basic). The number of shares issued as of the balance sheet date amounted to 29,394,724.

## Notes to the Group Balance Sheet

### Non-current assets

During 9M 2009, non-current assets decreased slightly by EUR 31 thousand, mainly due to the amortization of intangible assets and depreciation of fixed assets, which overcompensated the capitalization of newly acquired license rights.

Deferred tax assets decreased to EUR 461 thousand during 9M 2009 (Dec 31, 2008: EUR 629 thousand). This effect is attributable to reduced tax loss carryforwards of the U.S.-based subsidiary Epigenomics, Inc.

### Current assets

Current assets decreased during the first nine months of 2009 by EUR 1,394 thousand. This decrease reflects mainly the Group's consumption of liquid assets for operating activities in 9M 2009, which amounted to EUR 8,005 thousand. The cash inflows from financing and investing activities partly compensated this effect.

Trade receivables amounted to EUR 1,511 thousand (Dec 31, 2008: EUR 727 thousand). The increase of EUR 784 thousand is mainly due to increased trade receivables based on the collaborations with the Company's partners.

### *Equity*

The increases in share capital from EUR 26,724 thousand as of December 31, 2008, to EUR 29,395 thousand as of September 30, 2009, and in the capital reserve from EUR 3,567 thousand as of December 31, 2008, to EUR 6,061 thousand as of September 30, 2009, were almost exclusively a result of the capital increase in February 2009, when 2,671,088 new shares were issued at a price of EUR 1.94 each.

### *Current liabilities*

Current liabilities decreased from EUR 3,677 thousand as of December 31, 2008, by EUR 92 thousand to EUR 3,585 thousand as of September 30, 2009.

Deferred income decreased to EUR 987 thousand as of September 30, 2009 (Dec 31, 2008: EUR 1,254 thousand). It includes income from commercial R&D collaborations, which amounted to EUR 900 thousand, whereas deferred income from granted projects amounted to EUR 87 thousand. Deferred income in the amount of EUR 189 thousand as of September 30, 2009 (Dec 31, 2008: EUR 597 thousand), which will be recognized as revenue, has a duration exceeding twelve months. This corresponds to our usual licensing business cycle.

## Notes to the Group Cash Flow Statement

### *Operating activities*

Cash flow from operating activities is derived indirectly on the basis of the net loss for the period before taxes on income. Cash comprises bank deposits and cash in hand. Cash equivalents are defined as instruments being convertible on a short-term basis to a known amount of cash and carrying a very low risk of changes in value.

### *Investing activities*

Cash flow from investing activities is ascertained in respect of payment.

### *Financing activities*

Cash flow from financing activities is ascertained in respect of payment.

## Other Information

### *Information on other transactions with related parties*

Epigenomics has a consulting agreement in place with its former CSO, Dr. Kurt Berlin, to advise and support the Company on strategic, scientific, technological, licensing and IP-related matters. Under the agreement, Dr. Berlin has received a net amount of EUR 70 thousand in the first nine months of 2009. Thereof, EUR 40 thousand are related to a one-time bonus for 2008 and EUR 8 thousand to an invoice for his services from December 2008. In the nine months of 2009, an amount of EUR 29 thousand was charged through profit or loss.

### *Changes in stock options*

In the third quarter of 2009, a total of 270,000 stock options were granted. No options were exercised in Q3 2009. In the first nine months of 2009, a total of 70,000 stock options were granted to the members of the Company's Executive Board and 300,000 stock options were granted to employees of the Company, thereof 100,000 stock options under the stock option program 06–10 and 270,000 stock options under the new stock option program 09–13. The total number of stock options held by the members of the Executive Board as of September 30, 2009, aggregated to 396,613 and the total number of stock options held by other beneficiaries aggregated to 715,845.

### *Directors' dealings*

In the first nine months of 2009, no directors' dealings took place.

As of September 30, 2009, CEO Geert Walther Nygaard owned 20,000 shares of the Company and CFO Oliver Schacht, Ph.D., owned 117,050 shares of the Company. The Supervisory Board member Ann Clare Kessler, Ph.D., owned 14,000 shares of the Company.

This 9-month report has been approved and cleared for publication by the Executive Board of Epigenomics AG on October 19, 2009.

Berlin, October 19, 2009  
The Executive Board

## Corporate Calendar 2009

### Annual Report 2009

Reporting period: January 1 – December 31, 2009  
Wednesday, March 31, 2010

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

### *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 current plans, estimates, prognoses 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 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.

Readers of this interim report are explicitly warned not to inadequately trust 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.