

Epigenomics AG

Germany / Pharmaceutical/Biotechnology

Primary Exchange: Frankfurt

Bloomberg: ECX

ISIN: DE000A1K0516

Q3/2016 results

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€9.80**

98.9%

High

FOUR OF THE TOP SIX U.S. LABS NOW OFFERING EPI PROCOLON

Epigenomics has continued to energetically pursue the U.S. commercialisation of lead product, Epi proColon. The U.S. laboratory network, Sonic Labs, began offering Epi proColon to its patients this autumn. This means that four of the top six laboratories in the U.S. are now offering the product. Meanwhile reimbursement discussions with U.S. healthcare institutions are ongoing. Three Chinese investors, including Epigenomics' Chinese partner, Biochain, injected €7.1m into the company earlier this month. In our view this is a vote of confidence in long term prospects in both China and the U.S. We maintain our Buy recommendation but lower the price target from €10.30 to €9.80 to reflect cash burn since our last study in August and dilution caused by recent share issuance.

Q3/16 sales mix shifted towards the U.S. market Epigenomics' (ECX) Q3/16 report showed sales of €0.9m (FBe: €1.2m; Q3/15: €0.5m) and EBIT of €-2.6m (FBe: €-3.0m; Q3/15: €-2.5m). Sales were below our forecast because the €0.5m in revenues booked in the Rest of the World segment (mainly China) in Q2/16 was not repeated in Q3/16. Instead, ROW revenues were under €100k in Q3/16. Group EBIT was above our forecasts because the sales mix shifted towards the more profitable U.S. market.

€7.1m raised in China in November ECX announced on 7 November it had raised €5m in gross proceeds from the issue of 1.035m shares at a price of €4.83. UChip Technology Limited, a subsidiary of SummitView Capital, which is based in Shanghai, subscribed to the "majority" of the capital raise while Epigenomics' Chinese partner, BioChain, subscribed the remainder. The proceeds will be used to finance current operations and to expand the scope of U.S. commercialisation activities. On 16 November the company announced the issue of a further 474,800 shares at a price of €4.52 to raise gross proceeds of €2.1m. All of this capital raise was subscribed by the Chinese Institutional Investor, Cathay Fortune International. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2013	2014	2015	2016E	2017E	2018E
Revenue (€m)	1.59	1.51	2.08	5.06	21.37	49.03
Y-o-y growth	52.8%	-5.1%	38.2%	142.8%	322.6%	129.5%
EBIT (€m)	-7.29	-8.38	-9.26	-10.40	2.29	22.08
EBIT margin	-458.9%	-556.3%	-445.0%	-205.8%	10.7%	45.0%
Net income (€m)	-7.41	-8.85	-8.99	-10.18	2.44	22.16
EPS (diluted) (€)	-0.62	-0.65	-0.52	-0.50	0.10	0.94
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-6.52	-8.12	-7.98	-9.91	0.65	17.06
Net gearing	-93.3%	-91.2%	-105.6%	-109.6%	-105.4%	-96.7%
Liquid assets (€m)	7.96	7.50	8.56	18.86	19.51	36.57

RISKS

Risks to our price target include but are not limited to: development risk, financial risk, marketing risk and regulatory risk.

COMPANY PROFILE

Berlin-based Epigenomics AG is a molecular diagnostics company developing and commercialising a pipeline of proprietary products for the diagnosis of cancer. Lead product, Epi proColon®, is a blood-based screening test for the detection of colorectal cancer. Epi proColon® is currently marketed in the US, Europe and China.

MARKET DATA

As of 17 Nov 2016

Closing Price	€ 4.93
Shares outstanding	20.54m
Market Capitalisation	€ 101.22m
52-week Range	€ 1.81 / 6.55
Avg. Volume (12 Months)	129,648

Multiples	2015	2016E	2017E
P/E	n.a.	n.a.	46.8
EV/Sales	48.1	19.8	4.7
EV/EBIT	n.a.	n.a.	43.8
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2016

Liquid Assets	€ 7.27m
Current Assets	€ 9.78m
Intangible Assets	€ 0.76m
Total Assets	€ 12.40m
Current Liabilities	€ 4.86m
Shareholders' Equity	€ 6.85m

SHAREHOLDERS

BioChain	9.1%
Free Float	90.9%



We view the investment by these three Chinese companies as a validation of ECX' prospects in the country. Elsewhere in Asia, Epigenomics has signed an exclusive distribution agreement for Thailand, Vietnam, Malaysia and Singapore with the Singapore-based distributor, SPD Scientific PTE Ltd.

Figure 1: Q3/16 results vs. our forecasts

All figures in €m	Q3-16A	Q3-16E	Delta	Q3-15A	Delta	9M-16A	9M-15A	Delta
Sales	0.86	1.20	-28.0%	0.47	83.4%	2.42	1.32	83.3%
EBIT	-2.62	-3.00	-	-2.53	-	-10.72	-8.26	-
margin	neg.	neg.	-	neg.	-	neg.	neg.	-
Net income	-2.34	-2.60	-	-2.41	-	-9.96	-8.03	-
margin	neg.	neg.	-	neg.	-	neg.	neg.	-
EPS (in €, diluted)	-0.11	-0.12	-	-0.14	-	-0.50	-0.48	-

Source: First Berlin Equity Research; Epigenomics AG

Bipartisan support in the U.S. for Medicare coverage of FDA-approved colorectal cancer screening methods

On 29 September the U.S. Democratic Party Congressman Donald M. Payne, Jr. introduced a legislative initiative - the "Donald Payne Sr. Colorectal Cancer Detection Act of 2016" at a panel discussion held in Washington D.C. The initiative, which is bipartisan and is led on the Republican side by Congressman Charles Dent, aims to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer (CRC) screening blood-based tests. In our view, this initiative is another example of the strength of institutional will in the United States to raise colorectal cancer screening rates.

Epi proColon likely to be prime beneficiary of U.S. drive to raise CRC screening rates

The rate of screening for colorectal cancer among the screening-eligible population in the U.S. has been stagnant at around 65% over the past 10 years. The American Cancer Society targets an increase in the screening rate from the current 65 % to 80% by 2018. Closing the "screening gap" is estimated to be a USD2bn market opportunity. The label granted to Epi proColon by the FDA directly emphasises the potential to raise the colorectal cancer screening rate and so Epi proColon is likely to be a prime beneficiary of the US drive to raise CRC screening rates.

Election of Donald Trump unlikely to affect reimbursement of Epi proColon

US President-elect, Donald Trump, has signalled his attention to repeal at least part of the Affordable Care Act enacted by President Barack Obama. However, this is very unlikely to have any impact on the reimbursement of Epi proColon. Epi proColon is an FDA-approved screening assay. There has never been an FDA-approved screening assay which did not gain reimbursement coverage. ECX continues to make progress in targeting those laboratories, academic medical centres and integrated networks best placed to use and advocate for Epi proColon. The US laboratory network, Sonic Labs, began offering Epi proColon to its patients this autumn. This means that four of the top six laboratories in the U.S. are now offering the product. The other three are Quest (the U.S. market leader), LabCorp (no. 2 on the market) and ARUP.

ECX is funded well into 2017

ECX saw a free cash outflow of €8.8m during the first nine months of 2016 (9M/15: a free cash outflow of €6.3m). The company raised a net €5.0m from the issue of new shares in June and a further €2.6m from the conversion of five convertible notes. Total cash outflow during the first nine months of this year was €1.2m and cash and cash equivalents accordingly fell from €7.8m at end 2015 to €6.6m at the end of September. Including marketable securities, total liquid assets amounted to €7.3m at the end of the first nine months. As mentioned above, ECX has raised gross proceeds of €7.1m so far this month through the issue of new shares to BioChain, Cathay Fortune International and UChip Technology.



ECX still has five convertible notes outstanding. The notes mature before year end and generate a substantial return on conversion. It is therefore likely that they will be converted before year end generating further proceeds of €2.6m. According to management the current cash and liquid assets position is sufficient to fund the company “well in to 2017.” We continue to model a further small capital raise of €2.2m during the remainder of this year taking total net proceeds from equity issuance in 2016 to €15m.

We maintain our Buy recommendation but lower the price target from €10.30 to €9.80

In the light of the Q3 numbers, management has altered its FY2016 sales guidance range from €3.0m to €7.0m to €3.5m to €5.0m. EBITDA guidance is now €-9.5m to €-10.5m (previously: €-9.5m to €-11.5m). Our sales and EBITDA forecasts of €5.1m and €-9.8m respectively are broadly within this range and we leave them unchanged. The changes to our EPS forecasts shown in figure 2 below take account of the rise in the number of shares following the capital raises described above. We move our price target down from €10.30 to €9.80 to reflect dilution caused by recent share issuance and cash burn since our last study in August.

Figure 2: Changes to our forecasts

All figures in €m	FY 2016E			FY 2017E			FY 2018E		
	Old	New	Delta	Old	New	Delta	Old	New	Delta
Sales *	5.06	5.06	-0.1%	21.37	21.37	0.0%	49.03	49.03	0.0%
EBIT	-10.40	-10.40	-	2.29	2.29	0.0%	22.08	22.08	0.0%
margin	neg.	neg.	-	neg.	neg.	-	neg.	45.0%	-
Net income	-10.18	-10.18	-	2.44	2.44	0.0%	22.16	22.16	0.0%
margin	neg.	neg.	-	neg.	neg.	-	neg.	neg.	-
EPS (in €, diluted)	-0.49	-0.50	-	0.11	0.10	-5.7%	0.96	0.94	-1.9%

* including upfront and milestone payments

Source: First Berlin Equity Research

Figure 3: Pipeline valuation model

Compound	Project ¹⁾	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin ²⁾	Discount Factor	Time to Market
Epi proColon®	CRC-EU	€130M	48,010K	€117	€5,617M	10%	€721M	25%	25%	-
Epi proColon®	CRC-US	€229M	30,000K	€117	€3,518M	12%	€553M	25%	25%	-
Septin9 IVD	CRC-CN	€73M	290,000K	€59	€17,005M	5%	€1,451M	6%	32%	-
PACME PV		€432M			€26,140M		€2,656M			
Costs PV ³⁾		€220M								
NPV		€212M								
Milestones PV		€0M								
Net Cash (pro-forma)*		€18M								
Fair Value		€230M								
Share Count (pro-forma)*		23,497K								
Fair Value Per Share		€9.80								

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

CRC-EU - colorectal cancer in Europe

CRC-US - colorectal cancer in the US

CRC-CN - colorectal cancer in China

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.

This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

* Includes PV of cash and shares associated with recently announced and expected future capital injections

Source: First Berlin Equity Research

**Figure 4: Changes to our pipeline valuation model**

	Old	New	Delta
PACME PV	€432.4M	€432.4M	0.0%
Costs PV (4)	€220.5M	€220.5M	0.0%
NPV	€211.9M	€211.9M	0.0%
Milestones PV	€0.0M	€0.0M	n.m.
Net Cash	€24.0M	€18.4M	-23.1%
Fair Value	€235.9M	€230.3M	-2.4%
Share Count	22,960K	23,497K	2.3%
Price Target	€10.27	€9.80	-4.6%

Source: First Berlin Equity Research



INCOME STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Total revenue	1,588	1,507	2,082	5,056	21,366	49,028
Cost of goods sold	487	731	1,175	3,185	7,051	13,728
Gross profit	1,101	776	907	1,871	14,315	35,300
G&A	4,508	4,907	5,149	6,250	5,900	6,800
R&D	4,375	4,688	5,762	6,500	6,800	7,200
Other operating income (expense)	494	436	740	475	675	775
Operating income (EBIT)	-7,288	-8,383	-9,264	-10,404	2,290	22,075
Net financial result	11	-498	15	222	150	80
Pre-tax income (EBT)	-7,277	-8,881	-9,249	-10,182	2,440	22,155
Income taxes	-134	27	264	0	0	0
Net income / loss	-7,411	-8,854	-8,985	-10,182	2,440	22,155
Diluted EPS	-0.62	-0.65	-0.52	-0.50	0.10	0.94
EBITDA	-6,489	-7,613	-8,596	-9,848	3,197	23,063
Ratios						
Gross margin	69.3%	51.5%	43.6%	37.0%	67.0%	72.0%
EBIT margin	-458.9%	-556.3%	-445.0%	-205.8%	10.7%	45.0%
EBITDA margin	-408.6%	-505.2%	-412.9%	-194.8%	15.0%	47.0%
Net margin	-466.7%	-587.5%	-431.6%	-201.4%	11.4%	45.2%
Expenses as % of revenues						
G&A	283.9%	325.6%	247.3%	123.6%	27.6%	13.9%
R&D	275.5%	311.1%	276.8%	128.6%	31.8%	14.7%
Y-Y Growth						
Total revenues	52.8%	-5.1%	38.2%	142.8%	322.6%	129.5%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	863.8%
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	807.8%



BALANCE SHEET

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
Assets						
Current Assets, Total	8,914	8,968	10,776	21,186	25,920	52,257
Cash and liquid assets	7,957	7,495	8,563	18,861	19,510	36,568
Receivables	258	307	177	657	3,419	8,825
Inventories	275	753	1,077	1,365	2,137	4,903
Other current assets	424	413	959	303	855	1,961
Non-Current Assets, Total	2,167	2,352	1,822	2,629	3,110	5,519
Property, plant & equipment	247	1,013	684	1,011	2,137	4,903
Goodwill & other intangibles	1,920	1,291	792	1,517	824	126
Deferred taxes	0	48	346	101	150	490
Total Assets	11,081	11,320	12,598	23,816	29,030	57,776
Shareholders' Equity & Debt						
Current Liabilities, Total	4,080	3,805	5,283	5,460	8,547	15,689
Convertible bond	1,932	1,926	1,070	0	0	0
Accounts payable	1,030	897	1,923	2,831	4,273	6,864
Prepayments	67	55	635	708	1,068	2,451
Current provisions	635	416	894	708	1,068	1,961
Other current liabilities	416	511	761	1,213	2,137	4,413
Longterm Liabilities, Total	542	1,407	217	2,124	2,991	5,393
Convertible bond	0	0	0	0	0	0
Long term debt	0	0	0	0	0	0
Provisions	542	1,407	217	2,124	2,991	5,393
Minority interests	0	0	0	0	0	0
Shareholders equity	6,459	6,108	7,098	16,231	17,492	36,694
Total consolidated equity and debt	11,081	11,320	12,598	23,816	29,030	57,776
Ratios						
Current ratio (x)	2.18	2.36	2.04	3.88	3.03	3.33
Quick ratio (x)	2.12	2.16	1.84	3.63	2.78	3.02
Net gearing	-93.3%	-91.2%	-105.6%	-109.6%	-105.4%	-96.7%
Book value per share (€)	0.49	0.39	0.39	0.69	0.74	1.56
Net cash	6,025	5,569	7,493	17,791	18,440	35,498
Return on equity (ROE)	-139.6%	-140.9%	-136.1%	-87.3%	14.5%	81.8%



CASH FLOW STATEMENT

All figures in EUR '000	2013	2014	2015	2016E	2017E	2018E
EBIT	-7,288	-8,383	-9,264	-10,404	2,290	22,075
Depreciation and amortization	799	770	668	556	907	987
EBITDA	-6,489	-7,613	-8,596	-9,848	3,197	23,063
Changes in working capital	-31	367	476	1,321	-1,359	-3,029
Other adjustments	21	4	-7	222	150	80
Operating cash flow	-6,499	-7,242	-8,127	-8,305	1,989	20,113
Investments in tangible assets	-16	-868	-206	-479	-1,339	-3,060
Investments in intangibles	-4	-6	-7	-1,129	0	5
Proceeds from investment grants	0	0	357	0	0	0
Free cash flow	-6,519	-8,116	-7,983	-9,913	649	17,058
Convertible financing, net	2,867	-223	0	0	0	0
Net proceeds from conversion	0	3,648	4,169	5,211	0	0
Equity financing, net	8,660	4,178	4,863	15,000	0	0
Other changes in cash	235	51	19	0	0	0
Net cash flow	5,243	-462	1,068	10,298	649	17,058
Liquid assets, start of the year	2,714	7,957	7,495	8,563	18,861	19,510
Liquid assets, end of the year	7,957	7,495	8,563	18,861	19,510	36,568
EBITDA/share	-0.54	-0.56	-0.50	-0.49	0.14	0.98
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Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	911.4%
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	2526.4%
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	621.4%

FIRST BERLIN RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	11 June 2013	€1.69	Buy	€4.30
2...23	↓	↓	↓	↓
24	26 May 2016	€5.07	Buy	€10.30
25	20 June 2016	€4.57	Buy	€10.30
26	12 August 2016	€4.50	Buy	€10.30
27	Today	€4.93	Buy	€9.80

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BUY: An expected favourable price trend of more than 25% percent.

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REDUCE: An expected negative price trend of between 0% and -15%.

SELL: An expected negative price trend of more than -15%.

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- sensitivity of valuation parameters

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