

Epigenomics AG

Germany / Pharmaceutical/Biotechnology

Primary Exchange: Frankfurt

Bloomberg: ECX

ISIN: DE000A11QW50

Update

RATING**PRICE TARGET**

Return Potential

Risk Rating

BUY**€ 7.30**

54.4%

High

CMS RAISES PRICE POINT FOR EPI PROCOLON FROM USD84 TO USD125!

Late in 2016 the Centers of Medicare & Medicaid Services (CMS) made a preliminary price determination for Epi proColon of USD84 based on a crosswalk to test code 81287. ECX' management had hoped for a price determination nearer to USD160 and presented its reasoning for a crosswalk to a more highly remunerated test code to CMS in July 2017. On 22 September CMS published newly determined payment rates according to the Protecting Access to Medicare Act. CMS decided to maintain the crosswalk for Epi proColon to test code 81287 but increased the payment for this test code from USD84 to USD125 with effect from 1 January 2018. The new rate also has the status of a preliminary determination - the final determination will be published in November. However, we do not expect any change in the determination for test code 81287. The CMS announcement is very good news for ECX. The company's management has repeatedly pointed out that substantial capital will be required – even following clarification of reimbursement (which we expect by the end of this year) – to finance the marketing expenditure necessary to ensure that Epi proColon gains traction. A price level of USD125 will not only ensure that ECX earns higher margins on Epi proColon than would have been the case at USD84, but will also reduce the company's capital requirement and ensuing shareholder dilution. We lower the price target from €7.50 to €7.30. Our previous price target of €7.50 (dated 2 May) was based on the takeover offer from Cathay Fortune which in July failed to achieve the required acceptance rate of 75%. The recommendation moves from Add to Buy.

US reimbursement and guideline inclusion are top operational priorities

Operational priorities for the remainder of 2017 continue to be 1. reimbursement; 2. the inclusion of Epi proColon in the guidelines of the professional societies in the U.S. which offer advice on colon cancer screening; 3. the launch of Epi proLung. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017E	2018E	2019E
Revenue (€m)	1.51	2.08	4.20	1.07	4.07	14.71
Y-o-y growth	-5.1%	38.2%	101.8%	-74.6%	281.1%	261.7%
EBIT (€m)	-8.38	-9.26	-12.31	-13.81	-14.00	-18.33
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (€m)	-8.85	-8.99	-11.16	-13.66	-13.92	-18.11
EPS (diluted) (€)	-0.65	-0.52	-0.55	-0.59	-0.58	-0.72
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-8.12	-7.98	-13.68	-11.84	-13.86	-15.99
Net gearing	-91.2%	-105.6%	-85.2%	-68.6%	-87.0%	-102.9%
Liquid assets (€m)	7.50	8.56	12.28	12.02	11.42	10.43

RISKS

The main risk to our share price target is the failure of Epi proColon® to gain traction on the US market.

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 05 Oct 2017

Closing Price	€ 4.73
Shares outstanding	22.74m
Market Capitalisation	€ 107.49m
52-week Range	€ 4.05 / 7.41
Avg. Volume (12 Months)	109,065

ultiples	2016	2017E	2018E
P/E	n.a.	n.a.	n.a.
EV/Sales	23.4	92.2	24.2
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2017

Liquid Assets	€ 7.68m
Current Assets	€ 9.25m
Intangible Assets	€ 0.74m
Total Assets	€ 12.85m
Current Liabilities	€ 4.22m
Shareholders' Equity	€ 8.47m

SHAREHOLDERS

Globetrotter (BVI) Holdings	5.7%
Can Reach International	5.5%
Cathay Fortune International	5.1%
U Chip Technology	4.0%
Free float and other	79.7%



No FDA-approved diagnostic test has ever failed to achieve reimbursement

Management has stated that its best estimate with regard to increased clarity on reimbursement is “prior to year-end”. However, management has also reminded investors that the reimbursement process is complicated and that this timing cannot be guaranteed. The uncertainty over timing notwithstanding, investors should bear in mind that no FDA-approved diagnostic product has ever failed to achieve reimbursement in the U.S. Epi proColon was approved by the FDA in April 2016. Reimbursement is thus apparently a question of when rather than if.

Epi proLung to achieve CE status in Europe, pivotal Chinese trial ongoing

Management expects the lung cancer diagnostic product, Epi proLung, to achieve CE certification in Europe by the end of this year. ECX’ Chinese licensing partner, Biochain, is currently performing a clinical trial with Epi proLung. The goal of the trial is approval of the product by the China Food and Drug Administration (CFDA).

Q2/17 results impacted by absence of post-FDA approval inventory building

ECX’ Q2/17 results showed sales of €0.3m (Q2/16: €1.3m) and EBITDA adjusted for non-cash expenses related to phantom stock programmes of €-3.4m (Q2/16: €-3.5m). Q2/16 sales benefited from inventory building by ECX’ US commercialisation partner, Polymedco, following the FDA approval of Epi proColon in April 2016. A shift in the product mix towards higher margin license income meant that EBITDA before phantom stock programme expenses rose slightly despite the decline in revenues.

Profit warning in early July

Lack of clarity on the timing of reimbursement of Epi proColon in the US meant that 2017 revenue guidance given in the 2016 annual report was based on last year’s revenue figure of €4.2m less the €1.4m booked in connection with the exceptional sale of non-capitalised property rights. 2017 guidance included the proviso that inventory building seen last year following the FDA approval would not be repeated. However, management anticipated that an increase in underlying volume would compensate for most of this effect. At the end of the first half this expectation looked overoptimistic, especially given the likelihood of no reimbursement in the U.S. for Epi proColon before end 2017. On 6 July ECX reduced 2017 sales guidance to the range €1.0m to €1.5m (previously: about €2.5m). Meanwhile, 2017 guidance for adjusted EBITDA is now in the range of € -12.5m to €-14.0m (previously: € -12.0m to -13.5m).

Cathay Fortune convertible/private placement to extend cash reach to Q4/18

Cash outflow before changes in working capital was €6.9m in H1/17 (H1/16: an outflow of €7.9m). Management has pointed out that there is little scope to reduce cash consumption over the next few quarters as the company is constrained by the need to invest in educating the guideline-issuing professional societies in the U.S. and also by the obligation to carry out the post-approval trial of Epi proColon included in the PMA (premarket approval application) for the product. Cash and marketable securities were €7.7m at end H1/17 (H1/16: €13.9m) – down from €12.3m at end 2016. This suggested cash reach into Q1/18. In April 2017 Cathay Fortune International Company Limited (Cathay Fortune) made a takeover offer of €7.52 per share for ECX. This offer failed to achieve the required acceptance rate of 75%. However, within the context of its offer, Cathay Fortune made an irrevocable undertaking to invest €6.5m in a convertible bond to be issued by ECX. ECX issued the convertible to Cathay Fortune in early September. Later the same month ECX raised gross proceeds of €5.5m through the issue of 1.279m shares at €4.28 per share in the course of a private placement. These two capital raises should extend the company’s cash reach into Q4/18.

We lower price target from €7.50 to €7.30, raise recommendation from Add to Buy

Our pipeline valuation of ECX is shown below. The number of shares outstanding and net cash at end June 2017 were 22.735m and €7.7m respectively.



On the assumption that reimbursement for Epi proColon is set at USD125 we estimate that ECX will require a further €55m in addition to the proceeds of the Cathay Fortune convertible and the recent private placement in order to reach cashflow breakeven. We have assumed that this sum is financed through the issue of 11m new shares at €5.0. Our proforma net cash and share count figures discount both the number of new shares issued and proceeds at an annual rate of 15%. Our previous Add recommendation and price target of €7.50 (dated 2 May) were based on the failed takeover offer from Cathay Fortune which in July failed to achieve the required acceptance rate of 75%. Based on a reimbursement price of USD125, our model yields a valuation of €7.30 per share. We lower our price target from €7.50 to €7.30 and move the recommendation from Add to Buy.

Figure 1: 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	€10M	176,000K	€100	€17,600M	0.02%	€10M	40%	15%	-
Epi proColon	CRC-US	€377M	80,000K	€113	€9,065M	1.00%	€549M	10%	15%	-
Septin9 IVD	CRC-CN	€43M	383,000K	€136	€52,227M	0.30%	€741M	3%	20%	-
Epi proLung	LC-EU	€9M	176,000K	€100	€17,600M	0.02%	€10M	40%	15%	1 Years
Epi proLung	LC-CN	€11M	383,000K	€91	€34,818M	0.10%	€519M	3%	25%	2 Years
PACME PV		€450M			€131,310M		€1,829M			
Costs PV³⁾		€262M								
NPV		€188M								
Net Cash (pro-forma)*		€49M								
Fair Value		€237M								
Share Count (pro-forma)*		32,544K								
Fair Value Per Share		€7.28								

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 estimates



INCOME STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
Total revenue	1,507	2,082	4,201	1,067	4,066	14,708
Cost of goods sold	731	1,175	1,634	306	2,555	9,403
Gross profit	776	907	2,567	761	1,511	5,305
Marketing costs	0	0	0	0	2,627	7,497
PACME	776	907	2,567	761	-1,116	-2,192
G&A	4,907	5,149	10,247	9,365	10,000	11,031
R&D	4,688	5,762	5,119	5,513	3,660	5,883
Other operating income (expense)	436	740	487	310	775	775
Operating income (EBIT)	-8,383	-9,264	-12,312	-13,807	-14,000	-18,331
Net financial result	-498	15	16	150	80	219
Pre-tax income (EBT)	-8,881	-9,249	-12,296	-13,657	-13,920	-18,112
Income taxes	27	264	1,135	0	0	0
Net income / loss	-8,854	-8,985	-11,161	-13,657	-13,920	-18,112
Diluted EPS	-0.65	-0.52	-0.55	-0.59	-0.58	-0.72
EBITDA	-7,613	-8,596	-11,850	-13,103	-13,283	-18,110
Ratios						
Gross margin	51.5%	43.6%	61.1%	71.3%	37.2%	36.1%
PACME margin	51.5%	43.6%	61.1%	71.3%	-27.4%	-14.9%
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of revenues						
G&A	325.6%	247.3%	243.9%	877.7%	245.9%	75.0%
R&D	311.1%	276.8%	121.9%	516.7%	90.0%	40.0%
Y-Y Growth						
Total revenues	-5.1%	38.2%	101.8%	-74.6%	281.1%	261.7%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



BALANCE SHEET

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
Assets						
Current Assets, Total	8,968	10,776	15,203	13,192	13,579	15,728
Cash and liquid assets	7,495	8,563	12,284	12,018	11,424	10,433
Receivables	307	177	2,248	427	1,626	3,677
Inventories	753	1,077	257	320	244	882
Other current assets	413	959	414	427	285	735
Non-Current Assets, Total	2,352	1,822	3,019	3,436	2,480	4,265
Property, plant & equipment	1,013	684	713	662	447	735
Goodwill & other intangibles	1,291	792	755	640	407	588
Deferred taxes	48	346	1,551	2,134	1,626	2,942
Total Assets	11,320	12,598	18,222	16,628	16,060	19,993
Shareholders' Equity & Debt						
Current Liabilities, Total	3,805	5,283	3,709	8,382	2,480	8,531
Convertible bond	1,926	1,070	0	6,461	0	0
Accounts payable	897	1,923	1,089	1,067	1,830	6,619
Prepayments	55	635	302	53	122	294
Current provisions	416	894	1,852	160	122	441
Other current liabilities	511	761	466	640	407	1,177
Longterm Liabilities, Total	1,407	217	89	149	447	1,324
Convertible bond	0	0	0	0	0	0
Long term debt	0	0	0	0	0	0
Provisions	1,407	217	89	149	447	1,324
Minority interests	0	0	0	0	0	0
Shareholders equity	6,108	7,098	14,424	8,097	13,132	10,139
Total consolidated equity and debt	11,320	12,598	18,222	16,628	16,060	19,993
Ratios						
Current ratio (x)	2.36	2.04	4.10	1.57	5.47	1.84
Quick ratio (x)	2.16	1.84	4.03	1.54	5.38	1.74
Net gearing	-91.2%	-105.6%	-85.2%	-68.6%	-87.0%	-102.9%
Book value per share (€)	0.39	0.39	0.63	0.34	0.55	0.42
Net cash	5,569	7,493	12,284	5,557	11,424	10,433
Return on equity (ROE)	-140.9%	-136.1%	-103.7%	-121.3%	-131.1%	-155.7%



CASH FLOW STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
EBIT	-8,383	-9,264	-12,312	-13,807	-14,000	-18,331
Depreciation and amortization	770	668	346	704	717	221
EBITDA	-7,613	-8,596	-11,966	-13,103	-13,283	-18,110
Changes in working capital	367	476	-1,491	1,649	-384	2,591
Other adjustments	4	-7	174	150	80	219
Operating cash flow	-7,242	-8,127	-13,283	-11,304	-13,586	-15,300
Investments in tangible assets	-868	-206	-1,061	41	190	-362
Investments in intangibles	-6	-7	-207	-578	-459	-329
Proceeds from investment grants	0	357	871	0	0	0
Free cash flow	-8,116	-7,983	-13,680	-11,842	-13,856	-15,991
Convertible financing, net	-223	0	0	6,461	-7,100	0
Net proceeds from conversion	3,648	4,169	4,169	0	0	0
Equity financing, net	4,178	4,863	13,253	5,115	19,723	15,000
Other changes in cash	51	19	-21	0	639	0
Net cash flow	-462	1,068	3,721	-266	-594	-991
Liquid assets, start of the year	7,957	7,495	8,563	12,284	12,018	11,424
Liquid assets, end of the year	7,495	8,563	12,284	12,018	11,424	10,433
EBITDA/share	-0.56	-0.50	-0.58	-0.57	-0.55	-0.75
Y-Y Growth						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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...25	↓	↓	↓	↓
26	12 August 2016	€4.50	Buy	€10.30
27	18 November 2016	€4.93	Buy	€9.80
28	2 May 2017	€7.17	Add	€7.50
29	Today	€4.73	Buy	€7.30

Authored by: Simon Scholes, Analyst

Company responsible for preparation:

First Berlin Equity Research GmbH

Mohrenstraße 34
10117 Berlin

Tel. +49 (0)30 - 80 93 96 94 Fax +49 (0)30 - 80 93 96 87

info@firstberlin.com

www.firstberlin.com

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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- key sources of information in the preparation of this research report
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- sensitivity of valuation parameters

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