Epigenomics AG

Germany / Pharmaceutical/Biotechnology
Primary Exchange: Frankfurt
Bloomberg: ECX
ISIN: DE000A11QW50

Update

RATING	**BUY**
PRICE TARGET	**€ 7.30**
Return Potential	101.7%
Risk Rating	High

REIMBURSEMENT PRICE CONCERNS CREATE BUYING OPPORTUNITY

Epigenomics' share price has been under pressure in recent weeks due to worries as to whether Epi proColon will receive reimbursement coverage and at what price. No FDA-approved diagnostic product has ever failed to achieve reimbursement coverage and so we think fears in this regard are largely unwarranted. Concerns over price have been sparked by the retreat in November by Centers of Medicare & Medicaid Services (CMS) from their preliminary price determination for the product of USD125. CMS' final determination transferred part of the responsibility for price determination to regional administrative bodies thereby prolonging the process by a year. The rationale for this move was that Epi proColon has no direct comparator test. It is true that no diagnostic test is wholly comparable with Epi proColon. But the pricing of the components of Exact Sciences' competing colorectal cancer diagnostic product, Cologuard, may give some indication as to the eventual price of Epi proColon. Cologuard includes two quantitative molecular assays to detect aberrantly methylated DNA (NDRG4 and BMP3). Epi proColon also detects aberrantly methylated DNA using its SEPT-9 biomarker. Cologuard's NDRG4 and BMP3 biomarkers are together reimbursed at USD282 under code 81315. This suggests that Epi proColon's biomarker should be reimbursed at half this figure or USD141. This would be 13% above the figure the market expected before CMS' announcement of 17 November. The renewed and prolonged uncertainty as to the pricing of Epi proColon is exasperating given that clarity had already apparently been achieved. However, we think that investors can be sanguine about both reimbursement coverage and eventual pricing. We maintain our Buy recommendation and price target of €7.30.

Share price at lowest level since late 2015/early 2016 Epigenomics' (ECX) share price is now lower than at any time since a period of uncertainty during late 2015/16 as to whether Epi proColon would achieve FDA approval. In our view, the current weakness in the share price is mainly due to worries about the price at which Epi proColon will eventually be reimbursed. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017E	2018E	2019E
Revenue (€ m)	1.51	2.08	4.20	1.14	4.07	14.71
Y-o-y growth	-5.1%	38.2%	101.8%	-72.8%	255.7%	261.7%
EBIT (€ m)	-8.38	-9.26	-12.31	-11.03	-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	-10.96	-13.92	-18.05
EPS (diluted) (€)	-0.65	-0.52	-0.55	-0.48	-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	-9.11	-13.81	-15.93
Net gearing	-91.2%	-105.6%	-85.2%	-75.9%	-89.5%	-102.2%
Liquid assets (€ m)	7.50	8.56	12.28	15.02	14.48	13.55

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.

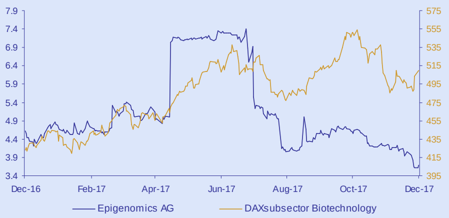
MARKET DATA

As of 18 Dec 2017

Closing Price	€ 3.62
Shares outstanding	24.01m
Market Capitalisation	€ 86.93m
52-week Range	€ 3.62 / 7.41
Avg. Volume (12 Months)	102,059

Multiples	**2016**	**2017E**	**2018E**
P/E	n.a.	n.a.	n.a.
EV/Sales	18.2	66.9	18.8
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2017

Liquid Assets	€ 16.88m
Current Assets	€ 18.55m
Intangible Assets	€ 0.85m
Total Assets	€ 22.38m
Current Liabilities	€ 9.28m
Shareholders' Equity	€ 13.01m

SHAREHOLDERS

Wilhelm K.T. Zours	8.4%
Globetrotter (BVI) Holdings	5.7%
Can Reach International Limited	5.5%
Summit Hero Holding	4.8%
Free float and other	75.6%

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ECX guidance for increased clarity on coverage by end 2017/early 2018 Reimbursement has two components – coverage and price. Of these, the most important is coverage as Epi proColon will not be able to gain traction in the US without reimbursement coverage by private and public payers. Price is important but secondary to coverage, as viable business with Epi proColon is possible at a wide range of prices. We continue to believe that the risk that Epi proColon will not achieve reimbursement coverage is small. No FDA-approved diagnostic product has ever failed to achieve reimbursement coverage. Reimbursement is thus apparently a question of when rather than if. There are two routes to coverage by payers in the U.S. – either through a national coverage determination (NCD) or legislation. We think Epi proColon is most likely to achieve coverage through NCD and that NCD is in turn most likely to be triggered by the inclusion of Epi proColon in the guidelines of one of the cancer screening guideline issuing societies. With regard to legislation, a bill to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests (the FDA approved Epi proColon in April 2016) was introduced in the House of Representatives in March 2017. It is currently in the first stage of the legislative process. Management has stated that its best estimate with regard to increased clarity on reimbursement coverage for Epi proColon is "by year-end or early 2018". However, management has also reminded investors that the reimbursement process is complicated and that this timing cannot be guaranteed.

Price determination by "gapfilling" There have been several twists and turns in the newsflow relating to price determination for Epi proColon. Centers of Medicare & Medicaid Services (CMS) made a preliminary price determination for the product of USD84 late in 2016 based on a crosswalk to test code 81287. ECX' management had hoped for a price determination nearer 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. This new rate had the status of a preliminary determination with the final determination due in November. On 17 November CMS announced that it had agreed that the original crosswalk determination was not appropriate and that reimbursement for Epi proColon should be determined by "gapfilling". Gapfilling is used when no comparator test is available and requires each of the regional Medicare Administrative Contractors (MACs) to determine and publish a preliminary rate. The MACs are expected to issue a preliminary price determination in April 2018. CMS will then issue a preliminary determination based on the median of the MACs' pricing in September 2018 and a final determination in November 2018 which will be valid from 1 January 2019.

Cologuard components may provide guidance for Epi proColon pricing The renewed and prolonged uncertainty as to the pricing of Epi proColon is exasperating given that clarity had already apparently been achieved. However, we think it unlikely that the eventual price determination for the product will be significantly below CMS' September verdict of USD125. Indeed we think it probable that the outcome will be above USD125. Management has stated that it believes the crosswalk to code 81287 "undervalues the test" and that it will "work with the MACs to set an appropriate price that reflects the novel nature of the first FDA-approved blood test for colorectal cancer screening". No diagnostic test is wholly comparable with Epi proColon. But the pricing of the components of Exact Sciences' competing colorectal cancer diagnostic product, Cologuard, may give some indication as to the eventual price of Epi proColon. Cologuard consists of quantitative molecular assays to detect aberrantly methylated DNA (NDRG4 and BMP3) and DNA mutations (KRAS) in stool plus a fecal hemoglobin immunoassay. Epi proColon is also based on detecting aberrantly methylated DNA (of the v2 region of the Septin9 gene n blood plasma). Cologuard's NDRG4 and BMP3 biomarkers are together reimbursed at USD282 under code 81315.

This suggests that Epi proColon's biomarker should be reimbursed at half this figure or USD141. This would be 13% above the figure the market expected before CMS' announcement of 17 November.

Epi proLung receives CE-IVD mark ECX this morning announced that its blood-based lung cancer test, Epi proLung, has received the CE-IVD mark. For the time being, however, our valuation of the product at €21m (see figure 3) remains low relative to Epi proColon. This is because there are currently no screening guidelines for lung cancer in Europe and so in the near to medium term it is unlikely that Epi proLung will displace standard lung cancer diagnostics procedures on this market. These include low-dose CT scan, bronchoscopy, bronchial lavage and lung puncture. From talking to management, we also gather that ECX is unlikely to start the development process in the US until an enhanced version of the product is available.

Figure 1: Q3/17 results vs. our forecasts

All figures in €m	Q3-17A	Q3-17E	Delta	Q3-16A	Delta	9M-17A	9M-16A	Delta
Sales	0.35	0.27	29.6%	0.86	-59.3%	0.87	2.42	-63.9%
EBIT	-1.20	-3.28	-	-2.62	-	-8.46	-10.72	-
margin	*neg.*	*neg.*	-	*neg.*	-	*neg.*	*neg.*	
Net income	-1.14	-3.20	-	-2.34	-	-7.61	-9.96	-
margin	*neg.*	*neg.*	-	*neg.*	-	*neg.*	*neg.*	
EPS (in €, diluted)	-0.05	-0.14	-	-0.11	-	-0.33	-0.50	-

Source: First Berlin Equity Research; Epigenomics AG

Q3/17 results were better than we expected ECX' Q3/17 results published on 15 November showed sales of €0.3m (Q3/16: €0.9m; FBe: €0.3m) and EBIT of €-1.2m (Q3/16: €-2.6m; FBe: €-3.20m). The numbers (see figure 1 above) were better than we expected for two reasons. Firstly, share based compensation swung from €-1.1m in Q2/17 to positive €0.9m in Q3/17 due to the decline in the share price following the failure of the Cathay Fortune takeover offer to achieve the required acceptance rate of 75%. Secondly, costs (e.g. marketing costs) anticipated at the time of the early July profit warning have not been incurred as rapidly as management expected. For this reason, ECX has increased its full year guidance for EBITDA (not including share-based expenses) to a range of €-10.5m to €-11.5m (previously: €-12.5m to €-14.0m). Revenue guidance remains unchanged in the range €1.0m to €1.5m. Cost containment in recent months has been influenced by the need to conserve cash pending clarity on reimbursement for Epi proColon in the U.S. Changes to our forecasts relate primarily to change in 2017 guidance discussed above.

Figure 2: Changes to our forecasts

	FY 2017E			FY 2018E			FY 2019E		
All figures in €m	New	Old	Delta	New	Old	Delta	New	Old	Delta
Sales	1.14	1.07	6.8%	4.07	4.07	-0.1%	14.71	14.71	0.0%
EBIT	-11.03	-13.81	n.a.	-14.00	-14.00	n.a.	-18.33	-18.33	n.a.
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*	*neg.*	-
Net income	-10.96	-13.66	n.a.	-13.92	-13.92	n.a.	-18.05	-18.11	n.a.
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-	*neg.*	*neg.*	-
EPS (in €, diluted)	-0.48	-0.59	n.a.	-0.58	-0.58	n.a.	-0.72	-0.73	n.a.

Source: First Berlin Equity Research estimates

New hires to help manage reimbursement process In preparation for sales growth following the start of reimbursement, ECX recently announced two new appointments to its management team. Dr Jorge Garces will join the company's management board on 1 December as President and Chief Scientific Officer. In this role he will oversee Operations, R&D, Clinical Affairs, Regulatory and Quality. Prior to joining ECX, Dr Garces was CEO at AltheaDx Inc. and before that was CEO at Enigma Diagnostics, Inc.

Meanwhile, Nicholas T. Potter, PhD accepted the role of Director of Reimbursement and Medical Affairs on 1 November 2017. His role at ECX will be to establish the strategic approach to payers for the blood-based menu of methylated cancer detection technologies. Dr Potter spent the past 14 years of his career at MPLN, Inc. where he was Laboratory's Director of Molecular Diagnostics, CSO, and then EVP of Clinical Affairs. ECX has also appointed Mr Alfred Weber to the Management Board as Executive Vice President Finance. Mr Weber has been with ECX for seventeen years - most recently as Senior Vice President Finance, Accounting and Controlling.

Recent capital raises extend cash reach to the end of Q4/18 At €-6.7m (9M/16: €-8.1m) cashflow from operating activities for the first nine months was close to the net result of €-7.6m (9M/16: €-10.0m). Cashflow from investing activities was small at €-0.7m (9M/16: €-0.7m). Cashflow from financing in 9M/17 amounted to €11.9m (9M/16: €7.6m). Nearly all of this figure was raised during the third quarter. Within the context of its takeover 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 to the end of 2018.

We maintain our Buy recommendation and price target of €7.30 We think that concerns about both reimbursement coverage and eventual pricing of Epi ProColon are overblown. We maintain our Buy recommendation and price target of €7.30.

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	€10M	176,000K	€100	€17,600M	0.02%	€10M	40%	15%	-
Epi proColon	CRC-US	€386M	80,000K	€113	€9,065M	1.00%	€549M	10%	15%	-
Septin9 IVD	CRC-CN	€44M	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	€12M	383,000K	€91	€34,818M	0.10%	€519M	3%	25%	2 Years
PACME PV		€461M			€131,310M		€1,829M			
Costs PV[3]		€270M								
NPV		€192M								
Net Cash (pro-forma)*		€48M								
Fair Value		€240M								
Share Count (pro-forma)*		32,832K								
Fair Value Per Share		€7.31								

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**	**1,143**	**4,066**	**14,708**
Cost of goods sold	**731**	**1,175**	**1,634**	**80**	**2,555**	**9,403**
Gross profit	**776**	**907**	**2,567**	**874**	**1,511**	**5,305**
Marketing costs	**0**	**0**	**0**	**0**	**2,627**	**7,497**
PACME	**776**	**907**	**2,567**	**874**	**-1,116**	**-2,192**
G&A	4,907	5,149	10,247	8,207	10,000	11,031
R&D	4,688	5,762	5,119	4,148	3,660	5,883
Other operating income (expense)	436	740	487	265	775	775
Operating income (EBIT)	**-8,383**	**-9,264**	**-12,312**	**-11,027**	**-14,000**	**-18,331**
Net financial result	-498	15	16	67	80	280
Pre-tax income (EBT)	**-8,881**	**-9,249**	**-12,296**	**-10,960**	**-13,920**	**-18,050**
Income taxes	27	264	1,135	0	0	0
Net income / loss	**-8,854**	**-8,985**	**-11,161**	**-10,960**	**-13,920**	**-18,050**
Diluted EPS	**-0.65**	**-0.52**	**-0.55**	**-0.48**	**-0.58**	**-0.72**
EBITDA	**-7,613**	**-8,596**	**-11,850**	**-10,323**	**-13,283**	**-18,110**
Ratios						
Gross margin	51.5%	43.6%	61.1%	76.5%	37.2%	36.1%
PACME margin	51.5%	43.6%	61.1%	76.5%	-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%	718.0%	245.9%	75.0%
R&D	311.1%	276.8%	121.9%	362.9%	90.0%	40.0%
Y-Y Growth						
Total revenues	-5.1%	38.2%	101.8%	-72.8%	255.7%	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**	**16,281**	**16,636**	**18,847**
Cash and liquid assets	7,495	8,563	12,284	15,024	14,481	13,552
Receivables	307	177	2,248	457	1,626	3,677
Inventories	753	1,077	257	343	244	882
Other current assets	413	959	414	457	285	735
Non-Current Assets, Total	**2,352**	**1,822**	**3,019**	**3,680**	**2,480**	**4,265**
Property, plant & equipment	1,013	684	713	709	447	735
Goodwill & other intangibles	1,291	792	755	686	407	588
Deferred taxes	48	346	1,551	2,286	1,626	2,942
Total Assets	**11,320**	**12,598**	**18,222**	**19,962**	**19,117**	**23,112**
Shareholders' Equity & Debt						
Current Liabilities, Total	**3,805**	**5,283**	**3,709**	**8,518**	**2,480**	**8,531**
Convertible bond	1,926	1,070	0	6,461	0	0
Accounts payable	897	1,923	1,089	1,143	1,830	6,619
Prepayments	55	635	302	57	122	294
Current provisions	416	894	1,852	171	122	441
Other current liabilities	511	761	466	686	407	1,177
Longterm Liabilities, Total	**1,407**	**217**	**89**	**160**	**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	160	447	1,324
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders equity	**6,108**	**7,098**	**14,424**	**11,284**	**16,189**	**13,258**
Total consolidated equity and debt	**11,320**	**12,598**	**18,222**	**19,962**	**19,117**	**23,112**
Ratios						
Current ratio (x)	2.36	2.04	4.10	1.91	6.71	2.21
Quick ratio (x)	2.16	1.84	4.03	1.87	6.61	2.11
Net gearing	-91.2%	-105.6%	-85.2%	-75.9%	-89.5%	-102.2%
Book value per share (€)	0.39	0.39	0.63	0.47	0.67	0.53
Net cash	5,569	7,493	12,284	8,563	14,481	13,552
Return on equity (ROE)	-140.9%	-136.1%	-103.7%	-85.3%	-101.3%	-122.6%

CASH FLOW STATEMENT

All figures in EUR '000	2014	2015	2016	2017E	2018E	2019E
EBIT	**-8,383**	**-9,264**	**-12,312**	**-11,027**	**-14,000**	**-18,331**
Depreciation and amortization	770	668	346	704	717	221
EBITDA	**-7,613**	**-8,596**	**-11,966**	**-10,323**	**-13,283**	**-18,110**
Changes in working capital	367	476	-1,491	1,691	-425	2,591
Other adjustments	4	-7	174	150	80	280
Operating cash flow	**-7,242**	**-8,127**	**-13,283**	**-8,482**	**-13,628**	**-15,239**
Investments in tangible assets	-868	-206	-1,061	-7	237	-362
Investments in intangibles	-6	-7	-207	-624	-414	-329
Proceeds from investment grants	0	357	871	0	0	0
Free cash flow	**-8,116**	**-7,983**	**-13,680**	**-9,113**	**-13,805**	**-15,929**
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**	**5,475**	**19,723**	**15,000**
Other changes in cash	**51**	**19**	**-21**	**-83**	**639**	**0**
Net cash flow	**-462**	**1,068**	**3,721**	**2,740**	**-543**	**-929**
Liquid assets, start of the year	7,957	7,495	8,563	12,284	15,024	14,481
Liquid assets, end of the year	**7,495**	**8,563**	**12,284**	**15,024**	**14,481**	**13,552**
EBITDA/share	**-0.56**	**-0.50**	**-0.58**	**-0.45**	**-0.55**	**-0.72**

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...26	↓	↓	↓	↓
27	18 November 2016	€4.93	Buy	€9.80
28	2 May 2017	€7.17	Add	€7.50
29	6 October 2017	€4.73	Buy	€7.30
30	Today	€3.62	Buy	€7.30

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

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