Epigenomics AG

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

Update

RATING	**BUY**
PRICE TARGET	**€ 7.10**
Return Potential	96.9%
Risk Rating	High

BUYING OPPORTUNITY AHEAD OF CLARIFICATION OF REIMBURSEMENT

The Epigenomics share price is currently experiencing a renewed bout of weakness caused in part by overall market jitters but also by uncertainty surrounding reimbursement of Epi proColon. Management stated in late 2017 that its best estimate with regard to increased clarity on reimbursement coverage for Epi proColon was "by year-end or early 2018". We believe that this statement was based on the expectation of near-term inclusion of Epi proColon in the guidelines of one of the cancer screening guideline issuing societies. We gather that there is currently a lively debate within the guideline issuing societies as to whether the recommended age from which regular colorectal cancer screening takes place should be lowered from 50 years to 45 years. This may account for the delay. We believe that clarity on reimbursement of Epi proColon will be forthcoming by the end of June. We maintain our Buy recommendation but lower the price target to €7.10 (previously: €7.30) to reflect a move in the EURUSD exchange rate underlying our model from 1.10 to 1.20.

2017 revenue fall due largely to absence of reimbursement 2017 results showed a 55.6% decline in revenue to €1.9m (FBe: €1.1m; 2016: €4.2m) while EBITDA before share-based payments came in at €-9.4m (FBe: €-10.3m; 2016: €-9.7m). In 2016 Epigenomics' U.S. distribution partner, Polymedco, purchased products for €1.4m post FDA approval. Epi proColon has still to achieve reimbursement and so Epigenomics (ECX) was unable to complete a similar transaction in 2017. Meanwhile, one-off items from rights transfers (licensing income, including for previous years) were also €0.6 million lower in 2017 than in the prior year. EBITDA before share-based payments improved by €0.3m because of the shift in the revenue mix to high-margin licensing income. This amounted to €1.3m in 2017 (2016: €0.6m) of which two thirds was booked in the final quarter. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2014	2015	2016	2017	2018E	2019E
Revenue (€ m)	1.51	2.08	4.20	1.86	3.73	13.48
Y-o-y growth	-5.1%	38.2%	101.8%	-55.6%	100.0%	261.7%
EBIT (€ m)	-8.38	-9.26	-12.31	-10.29	-13.60	-16.74
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (€ m)	-8.85	-8.99	-11.16	-10.23	-13.52	-16.51
EPS (diluted) (€)	-0.65	-0.52	-0.55	-0.44	-0.56	-0.60
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-8.12	-7.98	-13.68	-10.14	-11.12	-14.57
Net gearing	-91.2%	-105.6%	-85.2%	-68.0%	-87.6%	-102.4%
Liquid assets (€ m)	7.50	8.56	12.28	13.73	11.08	11.51

RISKS

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

COMPANY PROFILE

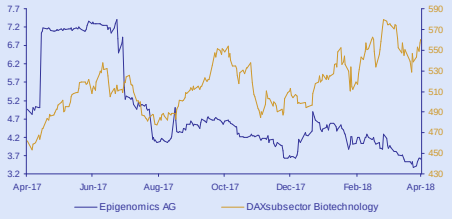
Berlin-based Epigenomics AG is a molecular diagnostics company developing and commercialising a pipeline of proprietary products for the diagnosis of cancer. Lead product, Epi proColon®, is a blood-based screening test for the detection of colorectal cancer. Epi proColon® is currently marketed in the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

MARKET DATA

As of 13 Apr 2018	
Closing Price	€ 3.61
Shares outstanding	24.01m
Market Capitalisation	€ 86.57m
52-week Range	€ 3.39 / 7.41
Avg. Volume (12 Months)	94,973

Multiples	**2017**	**2018E**	**2019E**
P/E	n.a.	n.a.	n.a.
EV/Sales	42.6	21.3	5.9
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2017	
Liquid Assets	€ 13.73m
Current Assets	€ 16.86m
Intangible Assets	€ 0.67m
Total Assets	€ 19.77m
Current Liabilities	€ 9.15m
Shareholders' Equity	€ 10.58m

SHAREHOLDERS

Wilhelm K.T. Zours	8.4%
Can Reach International Limited	5.5%
Summit Hero Holding	4.8%
Biochain Institute Inc.	4.7%
Free float and other	76.6%

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The surprisingly large Q4/17 licensing income figure explains why sales and EBITDA before share-based payments were above both our forecasts (see figure 1) and management guidance which was for €1.0 - €1.5m and €-10.5m - €-11.5m respectively. Profitability is also benefiting from cost containment which is influenced by the need to conserve cash pending clarity on reimbursement.

Figure 1: 2017 results vs. our forecasts

All figures in €m	FY-17A	FY-17E	Delta	FY-16A	Delta
Sales	1.86	1.14	63.5%	4.20	-55.6%
EBITDA ex-share based payment expenses	-9.37	-10.32		-9.67	
margin	*neg.*	*neg.*	-	*neg.*	
EBIT	-10.29	-11.03	-	-12.31	-
margin	*neg.*	*neg.*	-	*neg.*	-
Net income	-10.24	-10.96	-	-11.16	-
margin	*neg.*	*neg.*	-	*neg.*	-
EPS (in €, diluted)	-0.44	-0.48	-	-0.55	-

Source: Epigenomics, First Berlin Equity Research estimates

Share price under pressure due to reimbursement worries ECX' share price has again been under pressure in recent weeks due to worries about whether Epi proColon will receive reimbursement on the critical U.S. market. 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.

Two routes to reimbursement There are two routes to coverage by Medicare in the U.S. – either through a national coverage determination (NCD) or legislation. We still think that 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.

Reimbursement for Epi proColon now supported by House *and* Senate With regard to legislation, a bipartisan 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. In March 2018 Senators Shelley Moore Capito (Republican) and Martin Heinrich (Democrat) introduced the "Colorectal Cancer Detection Act of 2018" to the United States Senate. Both initiatives aim to provide payment and coverage under the Medicare program for FDA-approved qualifying colorectal cancer (CRC) screening blood-based tests. Given that Epi proColon is the only FDA-approved CRC screening blood-based test and now has bipartisan support in both the Senate and the House of Representatives, legislation is looking like an increasingly viable route to reimbursement

Debate over screening age may account for guideline delay ECX' management stated in late 2017 that its best estimate with regard to increased clarity on reimbursement coverage for Epi proColon was "by year-end or early 2018". We believe that this statement was based on the expectation of near-term inclusion of Epi proColon in the guidelines of one of the cancer screening guideline issuing societies. From talking to ECX' management, we gather that there is currently a lively debate within the guideline issuing societies as to whether the recommended age at which regular CRC screening takes place should be lowered from 50 years to 45 years. This may account for the delay.

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 by the end of May 2018 and a final determination in November 2018 which will be valid from 1 January 2019. As we explained in detail in our note of 19 December 2017, we think it unlikely that the eventual price determination for Epi proColon will be significantly below CMS' September verdict of USD125. Indeed we think it probable that the outcome will be above USD125.

Buy recommendation maintained; price target lowered to €7.10 (previously: €7.30) ECX had cash and marketable securities of €13.7m at the end of 2017. Management expects 2018 cash consumption to be in line with guidance on EBITDA before share-based payment expenses - i.e. €-11.5 - €-14.0m. This implies cash reach into the second half of 2018. Management has repeatedly pointed out that substantial capital will be required - even following clarification of reimbursement - to finance the marketing expenditure necessary to ensure that Epi proColon gains traction. We believe that clarity on reimbursement of Epi proColon will be forthcoming by the end of June and expect management to make use of the presumably higher share price to raise new capital. On the assumption that reimbursement for Epi proColon is set at USD125 we estimate that ECX will require a further €55m in order to reach cashflow breakeven. We continue to assume that €15.0m of this sum will be raised later this year. Management guidance for 2018 is for sales of €2.0m - €4.0m and EBITDA before share-based payment expenses of €-11.5m - €-14.0m. These numbers are close to our forecasts which we have changed to reflect a move in the EURUSD exchange rate underlying our model from 1.10 to 1.20 (see figure 2 below). We maintain our Buy recommendation but lower the price target to €7.10 (previously: €7.30) to reflect the changed exchange rate assumption.

Figure 2: Changes to our forecasts

	FY 2018E			FY 2019E		
All figures in €m	**New**	**Old**	**Delta**	**New**	**Old**	**Delta**
Sales	3.73	4.07	-8.4%	13.48	14.71	-8.3%
EBITDA ex-share based payment expenses	-12.89	-13.28		-14.94	-16.54	
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-
EBIT	-13.60	-14.00	n.a.	-16.74	-18.33	n.a.
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-
Net income	-13.52	-13.92	n.a.	-16.51	-18.11	n.a.
margin	*neg.*	*neg.*	-	*neg.*	*neg.*	-
EPS (in €, diluted)	-0.56	-0.58	n.a.	-0.60	-0.72	n.a.

Source: First Berlin Equity Research estimates

VALUATION MODEL

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	€9M	176,000K	€92	€16,133M	0.02%	€9M	40%	15%	-
Epi proColon	CRC-US	€370M	80,000K	€104	€8,309M	1.00%	€503M	10%	15%	-
Septin9 IVD	CRC-CN	€43M	383,000K	€125	€47,875M	0.30%	€679M	3%	20%	-
Epi proLung	LC-EU	€9M	176,000K	€92	€16,133M	0.02%	€9M	40%	15%	1 Years
Epi proLung	LC-CN	€12M	383,000K	€83	€31,917M	0.10%	€475M	3%	25%	2 Years
PACME PV		€443M			€120,368M		€1,676M			
Costs PV[3)]		€256M								
NPV		€187M								
Net Cash (pro-forma)*		€49M								
Fair Value		€236M								
Share Count (pro-forma)*		33,264K								
Fair Value Per Share		€7.09								

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

Figure 4: Changes to our pipeline valuation model

	Old	New	Delta
PACME PV	**€461.4M**	**€443.4M**	**-3.9%**
Costs PV	€269.6M	€256.4M	-4.9%
NPV	**€191.8M**	**€187.1M**	**-2.5%**
Net Cash (pro forma)	€48.2M	€48.8M	1.3%
Fair Value	€240.0M	€235.9M	-1.7%
Share Count (pro forma)	32,832K	33,264K	1.3%
Price Target	**€7.31**	**€7.09**	**-3.0%**

Source: First Berlin Equity Research estimates

INCOME STATEMENT

All figures in EUR '000	2014	2015	2016	2017	2018E	2019E
Total revenue	**1,507**	**2,082**	**4,201**	**1,864**	**3,727**	**13,482**
Cost of goods sold	**731**	**1,175**	**1,634**	**246**	**2,342**	**8,619**
Gross profit	**776**	**907**	**2,567**	**1,618**	**1,385**	**4,863**
Marketing costs	**0**	**0**	**0**	**0**	**2,408**	**6,872**
PACME	**776**	**907**	**2,567**	**1,618**	**-1,023**	**-2,009**
G&A	4,907	5,149	10,247	8,035	10,000	10,112
R&D	4,688	5,762	5,119	4,329	3,355	5,393
Other operating income (expense)	436	740	487	457	775	775
Operating income (EBIT)	**-8,383**	**-9,264**	**-12,312**	**-10,289**	**-13,602**	**-16,739**
Net financial result	-498	15	16	-160	80	226
Pre-tax income (EBT)	**-8,881**	**-9,249**	**-12,296**	**-10,449**	**-13,522**	**-16,513**
Income taxes	27	264	1,135	214	0	0
Net income / loss	**-8,854**	**-8,985**	**-11,161**	**-10,235**	**-13,522**	**-16,513**
Diluted EPS	**-0.65**	**-0.52**	**-0.55**	**-0.44**	**-0.56**	**-0.60**
EBITDA	**-7,613**	**-8,596**	**-11,850**	**-9,577**	**-12,887**	**-16,536**
Ratios						
Gross margin	51.5%	43.6%	61.1%	86.8%	37.2%	36.1%
PACME margin	51.5%	43.6%	61.1%	86.8%	-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%	431.1%	268.3%	75.0%
R&D	311.1%	276.8%	121.9%	232.2%	90.0%	40.0%
Y-Y Growth						
Total revenues	-5.1%	38.2%	101.8%	-55.6%	100.0%	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	2017	2018E	2019E
Assets						
Current Assets, Total	**8,968**	**10,776**	**15,203**	**16,859**	**13,054**	**16,364**
Cash and liquid assets	7,495	8,563	12,284	13,731	11,078	11,510
Receivables	307	177	2,248	937	1,491	3,371
Inventories	753	1,077	257	293	224	809
Other current assets	413	959	414	1,898	261	674
Non-Current Assets, Total	**2,352**	**1,822**	**3,019**	**2,914**	**2,274**	**3,910**
Property, plant & equipment	1,013	684	713	720	410	674
Goodwill & other intangibles	1,291	792	755	668	373	539
Deferred taxes	48	346	1,551	1,526	1,491	2,696
Total Assets	**11,320**	**12,598**	**18,222**	**19,773**	**15,327**	**20,274**
Shareholders' Equity & Debt						
Current Liabilities, Total	**3,805**	**5,283**	**3,709**	**9,153**	**2,274**	**7,820**
Convertible bond	1,926	1,070	0	6,536	0	0
Accounts payable	897	1,923	1,089	952	1,677	6,067
Prepayments	55	635	302	0	112	270
Current provisions	416	894	1,852	1,103	112	404
Other current liabilities	511	761	466	562	373	1,079
Longterm Liabilities, Total	**1,407**	**217**	**89**	**43**	**410**	**1,213**
Convertible bond	0	0	0	0	0	0
Long term debt	0	0	0	0	0	0
Provisions	1,407	217	89	43	410	1,213
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders equity	**6,108**	**7,098**	**14,424**	**10,577**	**12,644**	**11,241**
Total consolidated equity and debt	**11,320**	**12,598**	**18,222**	**19,773**	**15,327**	**20,274**
Ratios						
Current ratio (x)	2.36	2.04	4.10	1.84	5.74	2.09
Quick ratio (x)	2.16	1.84	4.03	1.81	5.64	1.99
Net gearing	-91.2%	-105.6%	-85.2%	-68.0%	-87.6%	-102.4%
Book value per share (€)	0.39	0.39	0.63	0.44	0.46	0.37
Net cash	5,569	7,493	12,284	7,195	11,078	11,510
Return on equity (ROE)	-140.9%	-136.1%	-103.7%	-81.9%	-116.5%	-138.3%

CASH FLOW STATEMENT

All figures in EUR '000	2014	2015	2016	2017	2018E	2019E
EBIT	**-8,383**	**-9,264**	**-12,312**	**-10,289**	**-13,602**	**-16,739**
Depreciation and amortization	770	668	346	343	715	202
EBITDA	**-7,613**	**-8,596**	**-11,966**	**-9,946**	**-12,887**	**-16,536**
Changes in working capital	367	476	-1,491	-86	1,800	2,375
Other adjustments	4	-7	174	456	80	226
Operating cash flow	**-7,242**	**-8,127**	**-13,283**	**-9,576**	**-11,007**	**-13,935**
Investments in tangible assets	-868	-206	-207	-400	288	-332
Investments in intangibles	-6	-7	-1,061	-183	-398	-301
Proceeds from investment grants	0	357	871	17	0	0
Free cash flow	**-8,116**	**-7,983**	**-13,680**	**-10,142**	**-11,117**	**-14,568**
Convertible financing, net	**-223**	**0**	**0**	**0**	**-7,100**	**0**
Net proceeds from conversion	**3,648**	**4,169**	**4,169**	**6,398**	**0**	**0**
Equity financing, net	**4,178**	**4,863**	**13,253**	**5,101**	**15,000**	**15,000**
Other changes in cash	**51**	**19**	**-21**	**90**	**564**	**0**
Net cash flow	**-462**	**1,068**	**3,721**	**1,447**	**-2,653**	**432**
Liquid assets, start of the year	7,957	7,495	8,563	12,284	13,731	11,078
Liquid assets, end of the year	**7,495**	**8,563**	**12,284**	**13,731**	**11,078**	**11,510**
EBITDA/share	**-0.56**	**-0.50**	**-0.58**	**-0.41**	**-0.54**	**-0.60**
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...27	↓	↓	↓	↓
28	2 May 2017	€7.17	Add	€7.50
29	6 October 2017	€4.73	Buy	€7.30
30	19 December 2017	€3.62	Buy	€7.30
31	Today	€3.61	Buy	€7.10

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

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First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

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STRONG BUY: An expected favourable price trend of more than 50% combined with sizeable confidence in the quality and forecast security of management.

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

ADD: An expected favourable price trend of between 0% and 25%.

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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The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

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- **valuation methods and principles**
- **sensitivity of valuation parameters**

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