Epigenomics AG

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

Comprehensive Update

RATING	**BUY**
PRICE TARGET	**€ 4.80**
Return Potential	61.6%
Risk Rating	High

STUDY RESULTS MAKE EPI PROCOLON A SHOO-IN FOR REIMBURSEMENT

Epi proColon was approved by the FDA in April 2016 but has still to secure the reimbursement coverage which is crucial for the generation of significant revenues. For diagnostic tests, a decision by Centers of Medicare and Medicaid Services (CMS) in favour of national coverage determination (NCD) is often triggered by the inclusion of the test in the guidelines of one of the CRC screening guideline issuing societies. The preeminent guideline issuing society is the American Cancer Society (ACS). However, the ACS did not include Epi proColon in its most recent guidelines in 2018. Reasons given by the ACS for non-inclusion of Epi proColon included the lack of a microsimulation model of the test to estimate its benefit-harm ratio. Earlier this month the National Cancer Institute-sponsored cancer intervention and surveillance modelling network (CISNET) published results of a microsimulation model comparing the incremental cost-effectiveness of screening alternatives to colonoscopy and FIT (fecal immunochemical test) in the Journal of the National Cancer Institute. The study stated that among the alternative screening methods studied which included computed tomographic colonography (CTC), PillCam, Cologuard and Epi proColon, "annual screening with Epi proColon is the test of choice." In 2019 CMS accepted ECX's application for an NCD review of Epi proColon. Results of this review are due by 28 August. As ACS bases its guideline decisions on CISNET microsimulation models, we expect a positive outcome. Our recommendation is Buy with a price target of €4.80 (previously: €7.10). The reduction in our price target largely reflects the 96% increase in shares outstanding since our last note of April 2018.

ECX's HCCBloodTest accounts for 19% of our valuation Sensitivity of ECX's liver cancer test, HCCBloodTest, at 91% is clearly better than the 65% figure for the current standard test, ultrasound with the biomarker alpha fetoprotein. We expect FDA approval of HCCBloodTest by the middle of this decade.

FINANCIAL HISTORY & PROJECTIONS

	2018	2019	2020E	2021E	2022E	2023E
Revenue (€ m)	1.53	1.13	0.84	8.45	19.94	48.94
Y-o-y growth	-17.8%	-26.6%	-25.2%	904.0%	135.9%	145.5%
EBIT (€ m)	-12.90	-14.67	-12.71	-13.39	-11.59	4.64
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	9.5%
Net income (€ m)	-12.69	-17.02	-12.77	-13.39	-11.59	4.64
EPS (diluted) (€)	-0.47	-0.46	-0.27	-0.25	-0.19	0.07
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€ m)	-9.64	-13.46	-14.29	-14.57	-13.46	-1.39
Net gearing	-92.1%	-105.1%	-79.9%	-88.4%	-101.0%	-106.5%
Liquid assets (€ m)	17.14	11.04	6.67	7.18	8.81	17.49

RISKS

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

COMPANY PROFILE

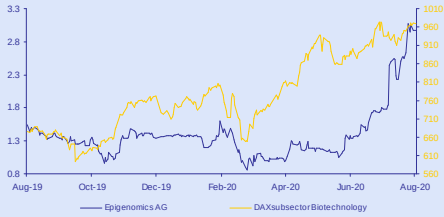
Berlin-based Epigenomics AG is a molecular diagnostics company developing and commercialising a pipeline of proprietary products for the diagnosis of cancer. Lead product, Epi proColon®, is a blood-based screening test for the detection of colorectal cancer. Epi proColon® is currently marketed in the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

MARKET DATA

As of 8/24/2020	
Closing Price	€ 2.97
Shares outstanding	47.13m
Market Capitalisation	€ 139.98m
52-week Range	€ 0.87 / 3.07
Avg. Volume (12 Months)	99,839

Multiples	2019	2020E	2021E
P/E	n.a.	n.a.	n.a.
EV/Sales	120.0	160.3	16.0
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2020	
Liquid Assets	€ 8.66m
Current Assets	€ 9.44m
Intangible Assets	€ 0.33m
Total Assets	€ 11.04m
Current Liabilities	€ 3.10m
Shareholders' Equity	€ 7.32m

SHAREHOLDERS

Deutsche Balaton Group	16.2%
Bridger Healthcare Ltd.	9.6%
Altium Growth Fund, LP	5.2%
683 Capital	5.2%
Free float and others	63.8%

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CONTENTS **PAGE**

INVESTMENT CASE

Epi proColon first and only FDA-approved blood-based test for colorectal cancer Epi proColon is the first and only FDA-approved blood-based test for the detection of colorectal cancer (CRC). The test is based on detecting aberrant DNA methylation of a specific region of the Septin 9 gene. Cytosine residues in the v2 region become methylated in colorectal cancer tissue but not in normal colon mucosa. This aberrant methylation can be detected by specific amplification of methylated DNA shed into the bloodstream by tumour cells.

CRC is the second most deadly cancer in the United States CRC is the second most deadly cancer in the United States behind lung cancer. The ACS estimates that there will be 53,000 deaths from CRC in the U.S. in 2020. Against this background, the ACS recommends that adults aged 45 years and older with an average risk of CRC undergo regular screening with either a high-sensitivity stool-based test or a structural (visual) examination such as colonoscopy. Options for CRC screening currently recommended by the ACS are: FIT annually; high-sensitivity, guaiac-based fecal occult blood test annually; multitarget stool DNA test (Cologuard) every 3 years; colonoscopy every 10 years; CTC every 5 years; and flexible sigmoidoscopy every 5 years. Recommended frequency of the last three of the six recommended screening methods is lower because these methods identify precancerous adenomas whereas the other tests don't. Up until May 2018 the ACS recommended screening for adults of 50 years and older. In May 2018 the organisation lowered the recommended age at which screening should begin to 45 years. This step was taken on the basis of a recent increase in CRC incidence in 45-50 year-olds. Epi proColon was approved in April 2016 and is indicated for screening of adults of 50 or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening.

Nearly 40% of U.S. adults over 50 currently unscreened for CRC The rationale for regular screening is that survival is greatly prolonged by early diagnosis. Five year survival rates for CRC diagnosed at the local, regional and distant stages are 90%, 71% and 14% respectively. Unfortunately, only 39% of patients are diagnosed with localised disease. Although screening is demonstrably effective, almost 40% of U.S. adults of 50 or over (over 30 million individuals) have not received guideline-compliant CRC screening. This figure has been stable for several years.

The need to raise the screening rate was a prime driver of the NCI's sponsorship of the CRC microsimulation model The most widely used CRC screening methods in the US are colonoscopy and FIT. But fear and disgust respectively are significant disincentives to use of these methods. The need to raise the screening rate was a prime driver of the NCI's sponsorship of CISNET to build a microsimulation model to assess the cost effectiveness of alternatives to colonoscopy and FIT such as CTC, PillCam, Cologuard and Epi proColon.

During 2016, 2017 and 2018 several guideline issuing societies including the ACS, the United States Preventive Services Tasks Force (USPSTF), the U.S. Multi-Society Task Force of Colorectal Cancer (MSTF) and the National Comprehensive Cancer Network (NCCN) did not include Epi proColon in updated screening guidelines. The societies cited several reasons for non-inclusion of the test in guidelines including:

1. low sensitivity and specificity relative to other FDA-approved screening methods
2. absence of a microsimulation model showing the test's benefit harms ratio
3. uncertainty as to the appropriate ratio for repeat testing.

Over the past twelve months, two microsimulation models comparing Epi proColon with competing CRC screening methods have been published. The first, developed at Harvard Medical School, and published in the periodical Cancer Medicine in late 2019, concluded that higher adherence to and frequency of screening using Epi proColon mitigate the test's disadvantages with respect to one-time sensitivity and specificity (see figure 1 below). In April NCCN incorporated Epi proColon into its guidelines even though these did not take into account the Harvard Medical School microsimulation model.

Figure 1: Sensitivity and specificity of CRC screening tests

Screening test	Sensitivity	Specificity	Source
Colonoscopy	95%	100%	van Rijn et al. 2006
CTC	84%	88%	Johnson et al. 2008
PillCam	92%	83%	Rex et al. 2015
FIT	74%	96%	Imperiale et al. 2014
Cologuard	92%	90%	Imperiale et al. 2014
Epi proColon	68%	79%	Potter et al. 2014

CISNET model evaluated alternatives to colonoscopy and FIT using incremental cost-effectiveness analysis But the most conclusive evidence in favour of epi proColon, in our view, was provided by the NCI-sponsored CISNET microsimulation model published earlier this month. Against the background of CRC screening in the U.S. stagnant at just over 60%, the model's authors noted, "it is important to evaluate which…alternative tests should be offered to individuals who are not willing to participate in FIT or colonoscopy screening." The CRC screening methods modelled included colonoscopy and FIT and the alternatives CTC, PillCam, Cologuard and Epi proColon. Screening strategies were compared using an incremental cost-effectiveness analysis, ranking each method based on costs. Strategies that were more costly and less effective than other methods were considered dominated. Remaining strategies were identified as providing good value for money i.e. were considered efficient. For the efficient strategies, the incremental cost-effectiveness ratios were calculated by dividing the additional costs by the additional quality-adjusted life years gained (QALYG) compared with the next less costly alternative strategy. A willingness-to-pay threshold of USD100,000 per QALYG was assumed. Costs of screening included screening-related complications, payments, coinsurance, cathartic bowel preparation agents, patient- and escort time costs. Disutilities included those associated with the test itself, and those related to fear or anxiety while waiting for the test result or a follow-up colonoscopy after a positive result.

Figure 2: Outcome per 1,000 50-year-olds for different screening strategies

Screening test	Interval (years)	No. of screening tests	No. of colonoscopies	LYG	QALYG	Total costs (USD m)*	ICER (USD per QALYG)*	ICER (USD per QALYG) without FIT and colonoscopy*
No screening	-	0	108	0	0	7286	-	-
FIT	1	15,044	2,349	162	189	6,793	Cost Saving	-
CTC	5	4,292	1,824	151	177	7,479	D	1,902
Colonoscopy	10	1,995	4,735	174	209	7,751	48,155	-
epi proColon	2	5,802	3,201	151	175	8,298	D	D
epi proColon	1	7,159	3,827	165	194	8,574	D	62,253
Cologuard	3	5,583	2,279	151	175	8,887	D	-
PillCam	10	2,383	2,173	141	165	8,951	D	-
PillCam	5	3,710	2,736	166	196	9,940	D	-
Cologuard	1	10,185	3,334	173	295	10,798	D	214,974

*3% discounted; LYG = life-years gained, QALYG = quality adjusted life-years gained, ICER = incremental cost-effectiveness ratio, D = dominated

Source: Department of Public Health Erasmus University Medical Centre, Netherlands. Sponsored by NCI as part of CISNET

CISNET authors identify Epi proColon as the test of choice among alternatives to FIT and colonoscopy As figure 2 shows, FIT and colonoscopy dominate all other screening strategies, but if these strategies are excluded, only two strategies are deemed to be cost-effective *and* below the willingness-to-pay threshold of USD100,000 per QALYG. These are CTC and annual screening with Epi proColon. The authors of the model go on to conclude that "for people who are unwilling to be screened with FIT or colonoscopy, annual screening with Epi ProColon is the test of choice given its cost-effectiveness profile compared to CTC, PillCam and Cologuard."

Our recommendation is Buy with price target of €4.80 (previously: €7.10) In 2019 CMS accepted ECX's application for an NCD review of Epi proColon. Results of this review are due by 28 August. Given that the ACS bases its guideline decisions on CISNET microsimulation models, we expect a positive outcome. ECX has developed a blood test, HCCBloodTest, for the diagnosis of liver cancer. Sensitivity of HCCBloodTest, at 91% is clearly better than the 65% figure for the current standard test, ultrasound with the biomarker alpha fetoprotein. We expect FDA approval of HCCBloodTest by the middle of this decade. We recommend investors to Buy the Epigenomics share with a price target of €4.80 (previously: €7.10). Epi proColon accounts for 81% of our valuation of the company and HCCBloodTest the balance. The reduction in our price target largely reflects the 96% increase in shares outstanding since our last note of April 2018.

VALUATION

Figure 3: Forecast for Epi proColon on the U.S. market

	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total US population (000s)	336,990	339,480	341,970	344,460	346,950	349,440	351,930	354,420
A. 50-85 year-olds at average risk of CRC (000s)	88,828	89,794	90,760	91,727	92,693	93,394	94,095	94,796
Percentage of A. currently unscreened	38%	38%	38%	38%	38%	38%	38%	38%
Unscreened A. (000s)	33,755	34,122	34,489	34,856	35,223	35,490	35,756	36,022
ECX share of unscreened A.	0.3%	0.7%	1.7%	4.0%	7.0%	10.0%	10.0%	10.0%
Epi proColon tests sold in U.S. (000s)	101	239	586	1,394	2,466	3,549	3,576	3,602
Reimbursement price (USD)	192	192	192	192	192	192	192	192
Sales price to laboratories (USD)	96	96	96	96	96	96	96	96
Sales (€000s)	8,453	19,939	48,944	116,389	205,827	296,262	298,486	300,710
Cost per test sold (USD)	15	12	10	10	10	10	10	10
Gross profit (€000s)	7,132	17,447	43,846	104,265	184,386	265,401	267,393	269,386
Gross margin (%)	84.4%	87.5%	89.6%	89.6%	89.6%	89.6%	89.6%	89.6%
Marketing (€000s)	1,522	3,589	8,810	20,950	37,049	53,327	53,727	54,128
Profit after costs and marketing expenses (€000s)	5,611	13,858	35,036	83,315	147,337	212,074	213,666	215,258
PACME margin (%)	66.4%	69.5%	71.6%	71.6%	71.6%	71.6%	71.6%	71.6%

Source: First Berlin Equity research forecasts

Epi proColon could be reimbursed by the end of November ECX has stated its commercial strategy is initially focused on the U.S. because this is where it sees the greatest opportunities for its products. For the time being we also restrict the scope of our valuation of both Epi proColon and HCC BloodTest to the U.S. Figure 3 above shows our forecasts for Epi proColon on the U.S. market. For all ECX products, our model runs to 2040, but for reasons of space we only show numbers to 2028. CMS is due to issue a preliminary National Coverage Determination by 28 August. This will be followed by a 30 day public comment period and within 60 days of the closing of the comment period CMS is required to issue its final determination. This suggests that Epi proColon could be reimbursed by the end of November and this is our central assumption.

Target population for Epi proColon in the U.S. is over 30 million As its label states, Epi proColon is indicated for adults, 50 years or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening. Adults at higher than average risk of CRC include those with a family history of CRC and/or with a personal or family history of conditions including inflammatory bowel disease, chronic ulcerative colitis or Crohn's disease. There are currently more than 85 million people between the ages of 50 and 85 in the U.S. who are at average-risk for CRC. 38% or ca. 32 million of this population have not been screened for CRC according to current guidelines. This is the target population for Epi proColon.

We assume Epi proColon's market share rises to 10% of the unscreened population by 2026 In December 2018 CMS announced a price point of USD192 for Epi proColon. This is 130% above the rate of USD83.67 originally published by CMS in 2017 and is expected to provide correspondingly higher motivation for laboratories to market the test. We assume that half of the USD192 will be allocated to the laboratories and that USD96 per test will be booked as revenue in ECX' P&L. ECX' marketing partner in the U.S. is Polymedco. The standard marketing fee in the U.S. is 15-18% of the sales price to the laboratory. Meanwhile, we estimate the manufacturing cost per test at USD15 initially and USD10 at volume. This implies a PACME margin (profit margin after cost of goods sold and marketing costs) to ECX of 72% from the third year following reimbursement. We assume ECX sells 100,000 tests in the US in 2021 equivalent to a market share of 0.3% of the currently unscreened population on the basis of one test per year. We assume Epi proColon's market share rises to 10% of the currently unscreened population by 2026 and stabilises at this level until the end of the forecast period in 2040.

Figure 4: Forecast for HCCBloodtest on the U.S. market

	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total US population (000s)	336,990	339,480	341,970	344,460	346,950	349,440	351,930	354,420
NASH-related cirrhosis patients (000s)	1,911	2,039	2,175	2,321	2,477	2,643	2,820	3,009
Other cirrhosis patients (000s)	508	512	516	521	525	529	533	537
High-risk hepatitis B patients (000s)	959	967	975	983	991	999	1,007	1,014
Total surveillance-eligible population (000s)	3,377	3,518	3,667	3,825	3,993	4,171	4,360	4,561
Surveillance rate (%)	24%	24%	25%	26%	27%	28%	29%	30%
Eligible population undergoing surveillance (000s)	811	844	917	995	1,078	1,168	1,264	1,368
A. No. tests carried out (two per patient)	1,621	1,688	1,833	1,989	2,156	2,336	2,529	2,736
ECX share of A.	-	-	-	2.0%	6.0%	14.0%	20.0%	20.0%
ECX HCCBloodTests sold in U.S. (000s)	-	-	-	40	129	327	506	547
Reimbursement price (USD)	-	-	-	345	345	345	345	345
Sales price to laboratories (USD)	-	-	-	173	173	173	173	173
Sales €000s	-	-	-	5,967	19,407	49,051	75,862	82,091
Cost per test sold (USD)	-	-	-	22.5	18	15	15	15
Gross profit €000s	-	-	-	5,189	17,382	44,786	69,265	74,953
Gross margin (%)	-	-	-	87.0%	89.6%	91.3%	91.3%	91.3%
Marketing (€000s)	-	-	-	1,074	3,493	8,829	13,655	14,776
Profit after costs and marketing expenses (€000s)	-	-	-	4,115	13,889	35,957	55,610	60,177
PACME margin (%)	-	-	-	69.0%	71.6%	73.3%	73.3%	73.3%

Source: First Berlin Equity research forecasts

HCCBloodTest superior to Ultrasound/alpha fetoprotein combination ECX's HCCBloodTest boasts persuasive performance data (sensitivity and specificity of 90.6% nd 87.2% respectively) and advantages in terms of convenience over the US/AFP combination. Against this background we expect the test's path to approval and reimbursement to be much more straightforward than that of Epi proColon and assume first revenues in the U.S. in 2024. Data on the prevalence of cirrhosis in the U.S. have evolved rapidly in recent years, due mainly in our view to increased focus on NAFLD (non-alcoholic fatty liver disease) and NASH (non-alcoholic steatohepatitis) as contributors to rapidly increasing patient numbers and growing awareness of liver cancer's rising importance relative to other cancer types.

3 million patients eligible for surveillance in U.S. We gather that the figure of 3m patients eligible for HCC surveillance used by ECX's competitor, Exact Sciences, is widely accepted. Articles we have read suggest that the HCC surveillance rate among eligible patients is 20-30%, but the usefulness of these numbers is questionable because the assumed number of eligible patients is not given.

But screening rate is lower than for CRC Nevertheless, we feel confident in our assumption of a screening rate of 28% by 2026 given the likelihood of increased institutional backing for HCC screening as prevalence of the disease rises and also because of the superior efficacy and convenience of a bloodtest. ECX has indicated a price of €300 for the HCC bloodtest. This compares with the reimbursement price of USD192 for Epi proColon set by CMS last November. One of the determinants of the level of CMS reimbursement for diagnostic tests is the number of biomarkers contained. Epi proColon contains the Septin9 biomarker. A price of €300 suggests that the HCCbloodtest will incorporate one or more biomarkers in addition to Septin9. We expect that marketing of the HCCbloodtest in the U.S. will be structured similarly to Epi proColon i.e. that 50% of the reimbursement price will be allocated to the laboratories and that 15-18% of the balance will be paid to the marketing partner. We estimate the manufacturing cost per test at USD22.50 initially and USD15 at volume. This implies a PACME margin (profit margin after cost of goods sold and marketing costs) to ECX of 72% from the third year of sales. We assume that the HCC surveillance rate in the U.S. will rise from an estimated 23% currently to 45% by 2040 as the incidence of liver cancer rises and institutional backing for surveillance of eligible cirrhosis/HBV patients strengthens. We further model that the ECX's share of the screened population reaches 20% by 2027.

Our valuation of the ECX share is €4.80 (previously: €7.10). The reduction in our price target largely reflects the 96% increase in shares outstanding since our last note of April 2018. Management has often pointed out that ECX will need to raise further funds following clarification of reimbursement for Epi proColon to ensure that the product gains traction on the U.S. market. We have assumed capital raises totalling €46m between the end of 2020 and the end of 2023. For this reason the proforma share count in our valuation is 30% above the current figure of 47.1m shares outstanding.

Figure 5: Overall valuation model

Compound	Project[1)]	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME[2)] Margin	Discount Factor	Patent Life	Time to Market
Epi proColon	CRC-US	€714M	32,907K	€167	€5,494M	10.0%	€324M	72%	15%	13	-
HCCBloodTest	HCC-US	€165M	3,245K	€300	€973M	20.0%	€216M	73%	15%	20	4 Years
PACME PV		€879M			€6,467M		€540M				
Costs PV[3)]		€631M									
NPV		€248M									
Net Cash (pro-forma)*		€45M									
Fair Value		€293M									
Share Count (pro-forma)*		61,014K									
Fair Value Per Share		€4.80									

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

CRC-US - colorectal cancer in the US
HCC-US - liver cancer in the US

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

EPI PROCOLON

Target market for Epi proColon is worth over USD3bn The number of people in the US at average risk for CRC between the ages of 50 and 85 is around 85 million. Around 38% of ths population is currently unscreened for CRC, implying at target market for Epi proColon of 32 million people. Centers of Medicare and Medicaid Services (CMS) have set a price of USD192 for Epi proColon. This is the amount the laboratory will be paid by Medicare once Medicare covers the test. We expect the price received by Epigenomics to be around half this figure. This implies a target market of over USD3bn.

Epi proColon revenues still small because product is not yet reimbursed Although the FDA approved Epi proColon in April 2016, the product has still to achieve the reimbursement coverage which is crucial for the generation of significant revenues. Lack of reimbursement coverage for Epi proColon is the reason why ECX generated revenue of only €1.1m in 2019. As we describe below, there are two routes to coverage by payers in the U.S. - national coverage determination (NCD) or legislation. For diagnostic tests, a decision by CMS in favour of an NCD is often triggered by the inclusion of the test in the guidelines of one of the CRC screening guideline issuing societies.

The major guideline issuing societies include the ACS, the United States Preventive Services Tasks Force (USPSTF), the U.S. Multi-Society Task Force of Colorectal Cancer (MSTF) and the National Comprehensive Cancer Network (NCCN). The first and so far only only one of these societies to include Epi proColon in its guidelines was the NCCN in April 2020.

In 2018 we expected the American Cancer Society (ACS) to include Epi proColon in its updated guidelines issued in May of that year. The ACS is the preeminent CRC screening guideline issuing society and inclusion of Epi proColon would have almost certainly triggered an NCD. In our view, the negative decision by the ACS was the main reason for the decline in ECX's share price from over €3.50 at the end of May 2018 to under €2.00 by the end of that year.

The ACS gave several reasons for the non-inclusion of the test in its guidelines. These included:

1. poor specificity compared with recommended screening options

2. limited base of evidence in asymptomatic screening populations

3. no microsimulation modelling of the newer version of the test to estimate its benefit, a benefit-harm ratio or a screening ratio for regular testing

4. not cleared by the FDA for unrestricted use in general routine screening (but only for average risk individuals who have repeatedly refused other forms of colorectal cancer screening)

National Coverage Determination review of Epi proColon In May 2019 ECX announced that CMS had accepted its application for an NCD review of Epi proColon. CMS' acceptance of the NCD application from ECX surprised us given that ACS did not include Epi proColon in its guidelines. However, ECX later stated that "CMS has determined that there is a rationale to accept the NCD review at this time." CEO Greg Hamilton further stated that "guidelines are important (to CMS), but they are not an absolute requirement… there are other clinical factors that are important for them as to whether this product is a benefit to their patients. And specifically, it's an FDA-approved product." We note that no FDA-approved diagnostic test has so far failed to achieve reimbursement. CEO Hamilton further stated: "One of the key things that (CMS') Coverage and Analysis Group looks for is the clinical utility of the product. And they define that as the benefits and harms of the product.

And in this space, the benefits are defined by number of life years gained…" Harms include the total number of colonoscopies in a patient population. These are two of the key outputs of the NCI-sponsored microsimulation model which we expect will help secure a positive outcome to CMS' NCD review by the end of this week.

Epi proColon reimbursement rate set at USD192 Reimbursement has two components – coverage and price. ECX has secured the second of these but not the first. The final reimbursement rate of USD192 for Epi proColon published by CMS on 14 December 2018 is higher than reimbursement rates for other large screening markets such as HPV human papillomavirus infection), HIV (human immunodeficiency virus) and HCV (hepatitis C virus). The CMS reimbursement rate also serves as a benchmark for the roughly one half of the U.S. healthcare market which is financed by private payers. If Epi proColon does achieve reimbursement coverage, the U.S. hospital system would be incentivised to offer the test as they would be able to participate in the resulting revenue stream. In addition the CRC screening population is larger than any other screening population.

Bipartisan support for reimbursement of Epi proColon in both House and Senate With regard to legislation, bills 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) have been introduced in both the House of Representatives and the Senate. The bipartisan appeal of these initiatives stems from the fact that large groups among both Democratic Party voters (African Americans) and Republican Party voters (inhabitants of rural areas) are overrepresented among the population which is unscreened for CRC. Given that Epi proColon is the only FDA-approved CRC screening blood-based test and now has bipartisan support in both House of Representatives and the Senate, legislation is a viable route to reimbursement. However, as with all legislation, the timing of a move to a vote is uncertain. For the time being CMS' NCD review looks much more likely to bear fruit in the near term.

HCCBLOODTEST

ECX HCC test has sensitivity of 90.6% vs. 60-65% for US/AFP combination ECX has developed a blood test, HCCBloodTest, for the diagnosis of liver cancer. Like Epi proColon, HCCBloodTest is based on a specific methylation of the Septin9 gene. In the general population aged 50-75 the DNA methylation status of this gene is a strong indicator of the presence of CRC and in cirrhosis patients of hepatocellular carcinoma (HCC), which is the most common form of liver cancer. Two independent clinical studies including 289 cirrhosis patients with or without liver cancer were carried out in France (initial study - 186 patients) and Germany (replication study -103 patients). Three blood samples were taken from each patient. Results published in March 2018 showed sensitivity and specificity of 90.6% and 87.2% using the "2 out of 3" triplicate algorithm. The sensitivity value is thus clearly better than the figure of 60-65% for the standard diagnostic combination of ultrasound (US) and alpha fetoprotein (AFP). ECX plans to begin a prospective clinical trial in the U.S. for submission to the FDA.

Liver cancer expected to be third most deadly cancer in U.S. by 2030 HCC is the most common form of liver cancer. In the U.S. it accounts for around 75% of liver cancer cases. Worldwide, HCC is the fifth most common cancer in men and the seventh in women. In 2012 521,000 men and 224,500 women died of HCC worldwide, making it the second most deadly type of cancer behind lung cancer. HCC mortality in the U.S. has been rising rapidly since the early 1970's. This trend is expected to continue over the next decade. 20,304 people died of liver cancer in the U.S. in 2010. Rahib et al. expect this figure to reach 33,000 in 2020 and 51,000 in 2030 and also that liver cancer will overtake breast, prostate, and colorectal cancers to become the third leading cause of cancer-related death by 2030. HCC mortality is rising in the U.S. because the population is increasing, the average age is rising and because of shifts in risk factors. The U.S. Census Bureau expects the population to grow by 7.4% from 333.9 million to 358.5 million between 2020 and 2030. However the population of 65 years and over, in which the incidence of HCC is highest, is forecast to jump 30% from 56 million to 72.8 million.

Liver cirrhosis is key risk factor for the development of HCC The prevalence of cirrhosis among HCC patients has been estimated at 85%-95%, and HCC incidence rate among cirrhosis patients at 2%-3% per year. Cirrhosis is a late stage scarring of the liver which occurs in response to alcoholism as well as the liver diseases and metabolic disorders.

Risk factors for HCC include are obesity, diabetes, hep. C, alcohol, smoking, hep. B Makarova-Rusher et al. calculated population attributable fractions (PAFs) for various HCC risk factors in the U.S. for the period 2000-2011 using data from the Surveillance, Epidemiology, and End Results (SEER)-Medicare linkage. The PAF was greatest for metabolic disorders (which include diabetes, obesity, impaired glucose tolerance, metabolic syndrome, and non-alcoholic fatty liver disease) at 32.0%, followed by hepatitis C (20.5%), alcohol (13.4%), smoking (9.0%), hepatitis B (4.3%) and genetic disorders (1.5%). The PAF for all these factors combined was 59.5%.

We expect obesity/diabetes/hep. C to drive increased HCC incidence to 2030 The attributable fraction associated with metabolic disorders increased from 26% to 36% during the period of the study while hepatitis C was stable at approximately 20%. These findings challenge the widespread assumption that hepatitis C is mainly responsible for the rising incidence of HCC in the U.S. However, we expect both these PAFs to drive increased HCC incidence to 2030.

In 2012 35% of U.S. adults were categorized as obese Although the increase in the incidence of obesity is levelling off, the obesity epidemic is predicted to continue with incidence in 2030 forecast to be 39.5%-50.7%. This trend will be reinforced by increasing proportion of Hispanics in the U.S. population, among whom the incidence of obesity is higher than average.

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV) that primarily affects the liver. It is spread primarily by blood-to-blood contact associated with intravenous drug use, poorly sterilised medical equipment, needlestick injuries in healthcare, and transfusions. There is no vaccine against the disease but chronic infection can be cured in about 95% of cases with antiviral medication such as sofosbuvir and simeprevir. According to the Global Burden of Disease Study, 143 million people were infected with hepatitis C as of 2015. Prevalence is highest in Africa and Central and East Asia. According to the Centers for Disease Control (CDC), an estimated 2.7 million people in the United States have chronic Hepatitis C infection. About 80% of people exposed to the virus develop chronic HCV. Symptoms of chronic HCV can be minimal to non-existent for several decades but may eventually lead to cirrhosis and liver cancer. About 75% of people infected with chronic HCV are unaware that they have the disease.

U.S. 1945-65 age cohort most severely affected by hep. C and will drive rise in HCC The existence of hepatitis C was first suggested in the 1970's and proven in 1989. Screening of blood products began in the U.S. in 1992. This made a substantial contribution to the decline in hepatitis C in post-1965 age cohorts. However, the prevalence of hepatitis C among the population born between 1945 and 1965 is ca. 2.5% (2.06 million people) - five times the rate seen among adults born in other years. This age cohort was not included in the Makarova-Rusher et al study because although some members would have become eligible for Medicare in 2010, they would not have reached the minimum age (68 years) for study inclusion.

5-10% of East Asia and sub-Saharan Africa adults affected by chronic hep. B Hepatitis B is an infectious disease caused by the hepatitis B virus (HCV) that primarily affects the liver. It is spread by exposure to infectious blood and body fluids and causes both acute and chronic infections. Between 5 and 10% of adults in East Asia and sub-Saharan Africa are affected by chronic hepatitis B. In Europe and North America prevalence is less than 1%. In regions in which the disease is common, the infection is most frequently acquired around the time of birth. 90% of those affected around the time of birth develop chronic hepatitis B. For those infected after the age of five this figure is less than 10%. Vaccines for the prevention of hepatitis B are available as are medications for the treatment of the chronic infection. None of the available medications can clear the infection but they do stop the virus from replicating thereby minimising liver damage. Chronic hepatitis B infection may be asymptomatic or may be associated with chronic inflammation of the liver (chronic hepatitis), leading to cirrhosis and then liver cancer after several years. About 65% of people infected with chronic hepatitis B are unaware that they have the disease.

Surveillance of cirrhotic adults with ultrasound/alpha fetoprotein recommended In its 2018 guidance document, the American Association for the Study of Liver Diseases (AASLD) recommends surveillance of adults with cirrhosis because it improves overall survival (OS). The recommended surveillance method is US with or without the biomarker AFP every six months. The recommended screening frequency for HCC is higher than for CRC because HCC tumours on average grow faster than CRC tumours. A 2003 study published by Kubota et al. found that HCC tumours on average doubled in volume every 94 days, whereas a 2013 study by Cho et al. found the equivalent figure for CRC tumours to be 1.2 years.

The AASLD states in its technical remarks that, "It is not possible to determine which type of surveillance test, US alone or the combination of US plus AFP, leads to a greater improvement in survival." However, the Association also states that "most"…."studies showed a benefit of the combination of US and AFP in improving OS."

The AASLD has two reservations with respect to US. First, the AASLD observes that surveillance using this method results in harms to patients relating to false positives and indeterminate results. Liver lesions found in the course of ultrasound surveillance are followed up with computed tomography (CT) and/or magnetic resonance imaging (MRI), which are associated with radiation exposure, contrast injury and expense.

Second, the AASLD points out that 20% of US surveillance procedures are classified as inadequate and that alternative surveillance modalities may be needed for obesity-, alcohol-, and non-alcoholic fatty liver disease (NAFLD)-related cirrhosis. The AASLD also notes “the imperfect sensitivity (~60%–65%) and specificity (~70%–95%)” of the two surveillance tests in combination.

In general the AASLD considers surveillance effective if it provides an increase in longevity of around 100 days. Surveillance that can be achieved at a cost of less than approximately USD50,000/year of life gained is considered cost-effective. Based on these criteria the AASLD recommends that surveillance be offered to patients with cirrhosis of varying etiologies when the risk of HCC is 1.5%/year or greater. For certain hepatitis B carriers without cirrhosis however, the AASLD recommends surveillance once the incidence of HCC exceeds 0.2% per annum. Asian HBV carriers are included while white HBV carriers are excluded. The former group is predominantly infected by HBV genotype C HBV which is associated with a higher risk of HCC than genotype A HBV which most white HBV patients have. Meanwhile non-cirrhotic HBV patients show significantly higher rates of disease-free survival on developing HCC than HCC patients with a cirrhotic background. HCC can develop in non-cirrhotic HCV patients but its incidence is much lower than in non-cirrhotic HBV patients. This is because HBV integrates into the host genome and has a direct oncogenic effect on the liver and can thus induce HCC in the absence of cirrhosis. HCV, by contrast, has a far lower direct oncogenic potential than HBV, and so most HCV-related HCC occurs against the background of advanced liver fibrosis or cirrhosis.

According to the Hepatitis B foundation over 2 million people in the U.S. are affected by chronic HBV of which over half are of Asian or Pacific Islander descent. The prevalence of HBV among these two population groups is put at 12.5%. After deducting cirrhosis sufferers with an HBV-etiology, we arrive at 408,000 people in the age groups specified by the AASLD. We further estimate that 13% of the ca. 1 million non-Asian Pacific islander population affected by HBV are black. Excluding cirrhosis sufferers from this population, we arrive at 110,000 people. The last component of the US population for which the AASLD recommends surveillance is non-cirrhotic hepatitis B carriers with a family history of HCC, which we estimate at 10,000 people.

We forecast an HCC screening rate of 28% by 2026 due to increasing institutional backing and the greater convenience of a blood test We estimate the U.S. total population eligible for HCC surveillance according to AASLD guidance at 3m people. Assuming surveillance of this population in accordance with AASLD guidance (i.e. twice a year) and pricing of ECX’s HCC blood test at €300, the target market for the product in the U.S. alone would be over USD1bn. However, the number of HCC surveillance procedures currently carried out each year in the U.S. is far below the 6m entailed by the above scenario. The literature suggests a screening rate of 20-30%. However, given the likelihood of increased institutional backing for HCC screening as prevalence of the disease rises and also because of the superior efficacy and convenience of a bloodtest, we forecast a screening rate of 28% by 2026.

H1/20 RESULTS

Figure 6: H1/20 results

	H1 20A	H1 19A	Δ %
Revenue	322	679	-52.6%
Cost of sales	-71	-165	57.0%
Gross profit	251	514	-51.2%
margin (%)	78%	76%	-
Research & development costs	-2,754	-3,867	28.8%
S,G&A costs	-3,901	-4,859	19.7%
Other income	764	768	-0.5%
Other expenses	-681	-536	-27.1%
Net other income	83	232	-64.2%
EBITDA before share-based payments	-5,659	-7,246	21.9%
Share-based payments	-389	-494	21.3%
EBITDA	-6,048	-7,740	21.9%
margin (%)	-1878%	-1140%	-
Depreciation and amortisation	-273	-240	-13.8%
EBIT	-6,321	-7,980	20.8%
margin (%)	-1963%	-1175%	-
Net interest	-18	83	n.a.
Other financial result	-1	-1	0.0%
Pretax result	-6,340	-7,897	19.7%
margin (%)	-1969%	-1163%	-
Tax	-14	482	n.a.
Net result	-6,354	-7,416	14.3%
margin (%)	-1973%	-1092%	-
EPS (€)	-0.14	-0.21	33.3%

Source: ECX

H1/20 revenues fell 53% to €0.3m (H1/19: €0.7m). Revenue fell in Q1/20 because some U.S. customers, who had stocked up on Epi proColon test kits in 2019 reduced inventories due to the delay in the reimbursement decision. Q2/20 revenue was hit by a sharp drop in U.S. business as a result of the pandemic. R&D costs fell 29% due to an almost complete halt in clinical trials in the U.S. - including the post approval study of Epi proColon. S,G&A expenses were 20% lower because of a pandemic-related decline in marketing activities. The EBITDA-loss before share-based payments narrowed to €-5.7m (H1/19: €-7.2m). The 2019 annual report included 2020 guidance for revenue and EBITDA before share-based payments of €1.0m to €2.0m and €-10.5m to €-12.5m respectively. In the H1/20 report management withdrew the revenue guidance without giving any new numbers citing uncertainty as to the effects of SARS-CoV-2. However, the previous guidance for EBITDA before share-based payments remains in place.

Cashflow from operating activities came in at €-5.5m during H1/20 (H1/19: €-7.8m). However net proceeds of €3.3m from the March capital raise reduced the net cash outflow to €2.4m (H1/19: a net cash outflow of €8.1m). In consequence cash and marketable securities fell from €11.0m at the end of 2019 to €8.7m at the end of June 2020. The current cash runway extends into Q1/21. It is likely that a capital raise will follow a positive NCD decision by CMS.

SHAREHOLDERS & STOCK INFORMATION

Stock Information	
ISIN	DE000A11QW50
WKN	A11QW5
Bloomberg ticker	ECX GR
No. of issued shares	47,130,000
Transparency Standard	Prime Standard
Country	Germany
Sector	Pharma & Healthcare
Subsector	Biotechnology

Source: Börse Frankfurt, First Berlin Equity Research

Shareholder Structure	
Deutsche Balaton Group	16.2%
Bridger Healthcare Ltd.	9.6%
Altium Growth Fund, LP	5.2%
683 Capital	5.2%

Source: Epigenomics AG

INCOME STATEMENT

All figures in EUR '000	2018	2019	2020E	2021E	2022E	2023E
Total revenue	**1,533**	**1,125**	**842**	**8,453**	**19,939**	**48,944**
Cost of goods sold	**440**	**253**	**175**	**1,321**	**2,492**	**5,098**
Gross profit	**1,093**	**872**	**667**	**7,132**	**17,447**	**43,846**
S,G&A	8,703	8,935	7,851	13,522	20,589	28,810
R&D	6,418	7,340	5,254	7,500	9,000	11,000
Other operating income (expense)	1,133	730	-267	500	550	600
Operating income (EBIT)	**-12,895**	**-14,673**	**-12,705**	**-13,389**	**-11,592**	**4,636**
Net financial result	-535	107	-39	0	0	0
Pre-tax income (EBT)	**-13,430**	**-14,566**	**-12,744**	**-13,389**	**-11,592**	**4,636**
Income taxes	738	-2,454	-30	0	0	0
Net income / loss	**-12,692**	**-17,020**	**-12,774**	**-13,389**	**-11,592**	**4,636**
Diluted EPS	**-0.47**	**-0.46**	**-0.27**	**-0.25**	**-0.19**	**0.07**
EBITDA before share-based payments	**-11,436**	**-14,161**	**-12,160**	**-12,834**	**-11,032**	**5,206**
Ratios						
Gross margin	71.3%	77.5%	79.2%	84.4%	87.5%	89.6%
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	9.5%
Net margin	n.a.	n.a.	n.a.	n.a.	n.a.	10.6%
Expenses as % of revenues						
S,G&A	567.7%	794.2%	932.4%	160.0%	103.3%	58.9%
R&D	418.7%	652.4%	624.0%	88.7%	45.1%	22.5%
Y-Y Growth						
Total revenues	-17.8%	-26.6%	-25.2%	904.0%	135.9%	145.5%
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	2018	2019	2020E	2021E	2022E	2023E
Assets						
Current Assets, Total	**18,274**	**12,123**	**7,027**	**10,564**	**16,583**	**36,581**
Cash and liquid assets	17,140	11,035	6,674	7,182	8,807	17,493
Receivables	164	89	211	2,113	4,985	12,236
Inventories	364	313	84	845	1,994	4,894
Other current assets	606	686	59	423	798	1,958
Non-Current Assets, Total	**3,553**	**1,866**	**1,497**	**1,157**	**922**	**952**
Property, plant & equipment	701	1,533	1,300	1,095	910	940
Goodwill & other intangibles	474	333	197	62	12	12
Deferred taxes	2,378	0	0	0	0	0
Total Assets	**21,827**	**13,989**	**8,524**	**11,721**	**17,505**	**37,533**
Shareholders' Equity & Debt						
Current Liabilities, Total	**3,167**	**3,619**	**476**	**2,468**	**5,484**	**12,566**
Convertible bond	0	0	0	0	0	0
Accounts payable	1,411	1,430	126	1,268	2,991	7,342
Prepayments	23	5	17	85	199	489
Lease liabilities	0	216	240	270	300	330
Current provisions	962	600	51	507	1,196	2,937
Other current liabilities	771	1,368	42	338	798	1,468
Longterm Liabilities, Total	**47**	**741**	**752**	**2,172**	**4,289**	**9,560**
Lease liabilities	0	697	600	650	700	750
Provisions	47	44	152	1,522	3,589	8,810
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders equity	**18,613**	**9,629**	**7,297**	**7,081**	**7,732**	**15,407**
Total consolidated equity and debt	**21,827**	**13,989**	**8,524**	**11,721**	**17,505**	**37,533**
Ratios						
Current ratio (x)	5.77	3.35	14.77	4.28	3.02	2.91
Quick ratio (x)	5.66	3.26	14.59	3.94	2.66	2.52
Net gearing	-92.1%	-105.1%	-79.9%	-88.4%	-101.0%	-106.5%
Book value per share (€)	0.52	0.22	0.14	0.13	0.15	0.29
Net cash	17,140	10,122	5,834	6,262	7,807	16,413
Return on equity (ROE)	-87.0%	-120.5%	-150.9%	-186.2%	-156.5%	40.1%

CASH FLOW STATEMENT

All figures in EUR '000	2018	2019	2020E	2021E	2022E	2023E
EBIT	**-12,895**	**-14,673**	**-12,705**	**-13,389**	**-11,592**	**4,636**
Depreciation and amortization	308	513	545	555	560	570
EBITDA	**-12,587**	**-14,160**	**-12,160**	**-12,834**	**-11,032**	**5,206**
Changes in working capital	1,090	-245	-1,883	-1,522	-2,098	-6,000
Stock option expenses	1,151					
Other adjustments	-5	899	-69	0	0	0
Operating cash flow	**-10,351**	**-13,506**	**-14,112**	**-14,356**	**-13,130**	**-795**
Investments in tangible assets	-91	-75	-112	-150	-175	-400
Investments in intangibles	-15	-47	-64	-65	-150	-200
Proceeds from investment grants	813	0	0	0	0	0
Interest received	17	169	0	0	0	0
Cashflow from investing activities	**724**	**47**	**-176**	**-215**	**-325**	**-600**
Free cash flow	**-9,644**	**-13,459**	**-14,288**	**-14,571**	**-13,455**	**-1,395**
Convertible financing, net	**-6,021**	**0**	**0**	**0**	**0**	**0**
Net proceeds from conversion	**0**	**0**	**0**	**0**	**0**	**0**
Equity financing, net	**19,295**	**7,349**	**10,000**	**15,000**	**15,000**	**10,000**
Other changes in cash	**17**	**5**	**-73**	**80**	**80**	**80**
Cashflow from financing activities	**13,274**	**7,120**	**9,927**	**15,080**	**15,080**	**10,080**
Net cash flow	**3,647**	**-6,105**	**-4,361**	**509**	**1,625**	**8,685**
Currency translation effects						
Liquid assets, start of the year	13,731	17,140	11,035	6,674	7,182	8,807
Liquid assets, end of the year	**17,140**	**11,035**	**6,674**	**7,182**	**8,807**	**17,493**
EBITDA/share	**-0.47**	**-0.38**	**-0.26**	**-0.24**	**-0.18**	**0.08**
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...34	↓	↓	↓	↓
35	6 October 2017	€ 4.73	Buy	€ 7.30
36	19 December 2017	€ 3.62	Buy	€ 7.30
37	16 April 2018	€ 3.61	Buy	€ 7.10
38	Today	€ 2.97	Buy	€ 4.80

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INFORMATION PURSUANT TO SECTION 34B OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO THE GERMAN ORDINANCE ON THE ANALYSIS OF FINANCIAL INSTRUMENTS [FINANV]

First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular the German Securities Trading Act [WpHG], Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and the German Ordinance on the Analysis of Financial Instruments [FinAnV] into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

CONFLICTS OF INTEREST

In accordance with Section 34b Paragraph 1 of the German Securities Trading Act [WpHG] and Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) financial analyses may only be passed on or publicly distributed if circumstances or relations which may cause conflicts of interest among the authors, the legal entities responsible for such preparation or companies associated with them are disclosed along with the financial analysis.

First Berlin offers a range of services that go beyond the preparation of financial analyses. Although First Berlin strives to avoid conflicts of interest wherever possible, First Berlin may maintain the following relations with the analysed company, which in particular may constitute a potential conflict of interest (further information and data may be provided on request):

- The author, First Berlin, or a company associated with First Berlin holds an interest of more than five percent in the share capital of the analysed company;
- The author, First Berlin, or a company associated with First Berlin provided investment banking or consulting services for the analysed company within the past twelve months for which remuneration was or was to be paid;
- The author, First Berlin, or a company associated with First Berlin reached an agreement with the analysed company for preparation of a financial analysis for which remuneration is owed;
- The author, First Berlin, or a company associated with First Berlin has other significant financial interests in the analysed company;

In order to avoid and, if necessary, manage possible conflicts of interest both the author of the financial analysis and First Berlin shall be obliged to neither hold nor in any way trade the securities of the company analyzed. The remuneration of the author of the financial analysis stands in no direct or indirect connection with the recommendations or opinions represented in the financial analysis. Furthermore, the remuneration of the author of the financial analysis is neither coupled directly to financial transactions nor to stock exchange trading volume or asset management fees.

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INFORMATION PURSUANT TO SECTION 64 OF THE GERMAN SECURITIES TRADING ACT [WPHG] (2ND FIMANOG) OF 23 JUNE 2017, DIRECTIVE 2014/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 15 MAY 2014 ON MARKETS IN FINANCIAL INSTRUMENTS AND AMENDING DIRECTIVE 2002/92/EC AND DIRECTIVE 2011/61/EU, ACCOMPANIED BY THE MARKETS IN FINANCIAL INSTRUMENTS REGULATION (MIFIR, REG. EU NO. 600/2014)

First Berlin notes that is has concluded a contract with the issuer to prepare financial analyses and is paid for that by the issuer. First Berlin makes the financial analysis simultaneously available for all interested security financial services companies. First Berlin thus believes that it fulfils the requirements of section 64 WpHG for minor non-monetary benefits.

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

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

ASSET VALUATION SYSTEM

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

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

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.

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

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