

Strong preclinical headline data

On December 14, Epigenomics released compelling pre-clinical headline data for its main value driver, the colorectal cancer diagnostic Epi proColon Next Generation. The test reported 84% sensitivity, implying a high likelihood that the recently launched clinical study will show sensitivity well above the US Medicare reimbursement threshold of 74%. We see a potential launch from late 2026 onwards but note that execution hinges on securing sufficient funds to complete the clinical trial and to cover costs through break-even. The company is seeking to raise at least EUR 150m over the coming years and is exploring all available financing options. We upgrade to Buy, PT EUR 0.70.

Strong pre-clinical headline data: 84% sensitivity at 90% specificity

The high sensitivity bodes well for a highly competitive product profile and for the technical success of the ongoing clinical trial, which is expected to read out from late 2025e, although we note that the timing is likely to depend on various factors affecting the speed of enrolment, notably the availability of funding. Epigenomics attributes the relatively high sensitivity to the addition of a second DNA methylation marker and three protein biomarkers (some licensed from MD Anderson) beyond Septin-9, thus producing a “multi-omics” solution.

Attractive commercial prospects, subject to sufficient funding

We anticipate a potential US launch of Epi proColon Next Generation from late 2026e and break-even in the late 2020's, subject to clinical and regulatory success. We see risk-adjusted peak sales potential of more than EUR 350m in the US alone. Epigenomics is seeking to raise EUR150m to EUR200m over the coming years to fund the clinical study as well as operations until break-even is achieved.

Investment thesis: Epi proColon Next Generation in the US as value driver

Our fair value estimate of EUR 0.70 per share is based mainly on the estimated project NPV for Epi proColon Next Generation in the US. It takes into account significant expected dilution from a potential future rights issue, which we regard as necessary to finance the clinical study needed to unlock the project value. Sources of upside notably include US peak penetration rates north of our estimate of 5% and regulatory and commercial success of Epi proColon Next Generation in ex-US markets. The possible failure to raise sufficient funds to conduct the planned clinical study represents the most immediate risk to our thesis. Other risks include clinical or regulatory failure of the project (we tag the likelihood of approval at 80%), lower than expected peak penetration rates and risks pertaining to inflation, which may be difficult to pass on, and the USD/EUR exchange rate.

With this note Marietta Miemietz assumes coverage of Epigenomics.

EURm	2020	2021	2022e	2023e	2024e
Revenues	1	6	1	1	1
EBITDA	(11)	(2)	(10)	(40)	(40)
EBIT	(12)	(2)	(11)	(41)	(41)
EPS	(2,02)	(0,22)	(0,69)	(2,52)	(2,49)
EPS adj	(2,02)	(0,22)	(0,69)	(2,52)	(2,49)
DPS	-	-	-	-	-
EV/EBITDA	-	-	-	-	-
EV/EBIT	-	-	-	-	-
P/E adj	-	-	-	-	-
P/B	4,99	0,32	0,82	-	-
ROE (%)	-	-	-	-	-
Div yield (%)	-	-	-	-	-
Net debt	(4)	(23)	(9)	43	83

Source: Pareto Securities

Target price (EUR)	0,70	▲	BUY
Share price (EUR)	0,37		
		—	HOLD
		▼	SELL

Forecast changes

%	2022e	2023e	2024e
Revenues	NM	NM	-
EBITDA	34	(91)	NM
EBIT adj	29	(95)	NM
EPS reported	13	NM	NM
EPS adj	13	NM	NM

Source: Pareto Securities

Ticker	ECXN.DE, ECX GR
Sector	Healthcare
Shares fully diluted (m)	16,4
Market cap (EURm)	6
Net debt (EURm)	-9
Minority interests (EURm)	0
Enterprise value 22e (EURm)	-3
Free float (%)	69

Performance



Source: FactSet

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Epi proColon Next Generation as value driver

*Multi-billion-dollar opportunity,
80%+ success probability*

Epi proColon Next Generation is intended to be the successor to Epigenomics' current blood-based colorectal cancer diagnostic kit Epi proColon. The inclusion of further biomarkers (based on both DNA methylation and protein) in addition to the methylation marker Septin9, which the current product is based on, is expected to enhance the test's sensitivity and specificity, thus reducing the rate of false positive as well as false negative test results. These enhanced performance characteristics would pave the way to automatic reimbursement by Medicare under the criteria laid out by CMS when it issued a negative reimbursement decision for the current product last year. Since then, Epi proColon Next Generation has matured and emerged as the company's main value driver. On 14 December, Epigenomics published headline results from the pre-clinical study, which showed 84% sensitivity at 90% specificity, well above the Medicare reimbursement threshold of 74%. We believe that this result bodes well for the potential success of the clinical study, which we estimate would unlock a multi-billion-dollar opportunity in the important US market alone, where break-even could be achieved from 2028e, we estimate. Strong adoption in Europe also looks possible; however, we would envisage a ca. ten-year time lag based on precedents. In this section, we profile Epi proColon Next Generation and present our US NPV model. Epigenomics' recent and upcoming newsflow is summarized below.

Recent and upcoming near-term newsflow

Date	Description	Relevance
September 2022	Epi proColon Next Generation - clinical study start	Epigenomics enrolled the first patient. The study aims to enrol ca. 20,000 patients with a view to safeguarding that roughly 16,000 would complete the study. The company expects the full clinical data to become available in late 2025 or early 2026. We believe that strong pre-clinical data bode well for the clinical data to exceed the CMS reimbursement threshold of 74% sensitivity at 90% specificity.
December 14, 2022	Epi proColon Next Generation - pre-clinical data headline release	The company announced headline results from the pre-clinical study, where the test achieved 84% sensitivity at 90% specificity. Management attributes this strong result to the inclusion of an additional undisclosed biomarker, some of which the company licensed from the renowned MD Anderson cancer centre, beyond Septin9.
2023e	Capital raise planned	The company is seeking to raise at least EUR 150m to fund the clinical study as well as operations until break-even is reached and is currently exploring all possible financing options including a full US listing.

Source: Pareto Securities Research, company data

Product characteristics, pre-clinical data and clinical development

Next Generation has been designed to exceed sensitivity & specificity-based reimbursement thresholds

Epi proColon Next Generation is a blood-based PCR test, or “liquid biopsy”. It is intended to be used in colorectal cancer screening. Like its predecessor product Epi proColon, which became the first FDA approved liquid biopsy kit in 2016, it detects the DNA methylation marker Septin 9. The assay further detects an additional DNA methylation marker plus three protein biomarkers that have been included to enhance the performance characteristics of the test with a view to achieving the threshold for automatic reimbursement published by CMS at the time of its negative reimbursement decision for the first-generation product. CMS requires a minimum sensitivity of 74% and specificity of at least 90% for reimbursement of Medicare patients; The original Epi proColon test narrowly missed the sensitivity threshold and demonstrated specificity in the low 80s percentage range in clinical studies. Management would also expect the Next Generation product to receive a recommendation as a universal front-line screening tool for colonoscopy refusers, while the first-generation product was relegated to the ca. 30m US patients who refuse both colonoscopy and stool tests.

It competes primarily with blood & stool tests and sequencing solutions

We expect Exact Science’s developmental blood-based test to be the closest competitor. The 24,000 BLUE-C registration study is currently underway and expected to read out next year. Additionally, results from the LUNAR-2 study of Guardant’s circulating tumour DNA (ctDNA)-based blood test have recently been released. We expect the blood tests to compete with various stool tests initially, ranging from the cheap FIT tests, which are at the low end of CMS’ sensitivity requirements, to high end tests such as ExactSciences’ Cologuard and its developmental follow-on product Cologuard 2.0, as well as Geneoscopy’s developmental RNA-FIT test, which is currently under evaluation in the 10,000 patient CRC-PREVENT trial. Next generation sequencing (NGS) tests represent a more sophisticated, but also a more complex solution that may be vying for share; we note that Freenome’s large PREEMPT CRC study is now fully enrolled, with data expected early next year. Colonoscopy, an expensive and somewhat invasive procedure, is expected to remain the colorectal cancer screening standard, as it allows for a high rate of detection and often immediate surgical removal of pre-cancerous lesions in addition to malignancies. It remains to be seen to what extent it may be supplemented by high-performance tests eventually; we also note that 30m eligible US patients do not follow colonoscopy-based screening recommendations.

We expect most of the above novel tests to show sensitivity north of 90% when measured over a three-year horizon, though we note that the aforementioned LUNAR-2 study reported a sensitivity of just 83%. Novel stool tests and NGS-based tests are expected to show 90%+ sensitivity, implying scope for relatively long test-free intervals, with test administration expected to be recommended every three years at the most. The blood-based non-NGS tests are expected to have somewhat lower sensitivity as a point estimate; consequently, we would expect them to be administered every year. Epigenomics estimates the cumulative sensitivity of its blood test to be on the order of 95% if measured over three consecutive years of test administration, implying that few cancers would be expected to be missed.

Strong pre-clinical headline data recently released: 84% sensitivity

On 14 December, Epigenomics released headline results from the pre-clinical study of Epi proColon Next Generation. The test showed 84% sensitivity at 90% specificity. This result not only comfortably exceeds the CMS reimbursement threshold of 74% sensitivity at 90% specificity but is also near the high end of the sensitivity that can be expected from a biomarker-based PCR-test designed to detect a heterogeneous cancer such as colorectal cancer, we reckon. Epigenomics attributes the high sensitivity, which could not have been achieved based on Septin9 alone, to the addition of DNA methylation and protein biomarkers, some of which are licensed from the MD Anderson Cancer Center. Additionally, the test detected 20% of advanced adenomas, a type of pre-cancerous lesion. The company notes that the 20% detection rate is equivalent to or better than Freenome’s pre-clinical rate of 41% when done annually compared to every three years for Freenome’s test.

... implying a highly competitive profile if replicated in the clinic

Overall, we take the view that the relatively high sensitivity of Epi proColon Next Generation renders the test candidate highly competitive, with overall cancer detection rates over a three-year horizon likely comparable to or higher than most other modalities and at the high end among blood tests based on specific biomarkers: Guardant’s test, which is expected to be administered at three-year intervals, showed overall sensitivity of 83% over that time horizon in the recently completed LUNAR-2 study, while Exact Sciences’ blood-based test designed for annual use is believed to have shown lower sensitivity pre-clinically. Freenome’s multiomics, machine-learning based test appears to be the only blood test that looks likely to demonstrate higher sensitivity than Epi proColon Next Generation in the clinic. Advanced adenoma detection rates look twice as high or higher for non-blood-based tests as well as Freenome’s blood test; however, this does not have a bearing on CMS reimbursement and we note that none of the tests can compete with the gold standard, colonoscopy, based on this metric.

The clinical study is expected to take several more years

... implying a launch from 2027e

The clinical study is expected to enroll 20,000 individuals aged 45+ who are undergoing routine colonoscopy in line with US cancer screening recommendations. The company estimates that the diagnosis of 65 cancers during the colonoscopy part of the study will be required for adequate powering, implying the need for ca. 16,000 and estimates the attrition rate (i.e. the proportion of patients who enroll in the trial and take the blood test, but do not proceed to colonoscopy) at 20% based on patient disposition in competitors' trials. Whilst the pre-clinical data may not necessarily be replicated exactly in the clinical study, the company would expect to achieve sensitivity of at least 79% to 84% based on the totality of the pre-clinical data. Participants' blood plasma will be frozen and stored, and any tumours detected during the colonoscopy procedure will be centrally adjudicated. Batch tests are expected to be run primarily at the end of the study to assess the concordance of the blood test results with findings from the colonoscopies. While the first patient was enrolled in September, recruitment timelines overall depend on various factors such as cost and financing, the presence or absence of Covid-related restrictions and competitor activity.

Epigenomics is currently seeking to ascertain the average cost per trial participant. While the company would not expect to pay for a material proportion of colonoscopies, it expects to incur significant expenses linked to investigator remuneration, phlebotomy (blood handling) and central adjudication of cancer cases. We therefore estimate that the average cost per patient is likely to be in the lower four figure range, implying that the full cost of the study could potentially approach \$80m. The company expects primary completion in late 2025 or early 2026, with the pace determined by funding and other factors. Assuming a regular ten-month FDA review period, this would imply the possibility of a launch from late 2026 onwards. We prudently assume a launch in 2027 in our forecast and valuation.

Commercial prospects of Epi proColon Next Generation

We explicitly forecast sales in the US, which represents a multi-billion-dollar opportunity based on the 30m individuals who currently refuse screening alone, with further upside to the extent that colonoscopy and stool test users might opt for an annual blood test. We also see significant potential in Europe but note typically significant lag time with respect to the adoption of diagnostic tests compared to the US.

Our US revenue model for Epi proColon Next Generation is shown below and rests on the following key assumptions:

- **Launch in 2027e.** This is our base case scenario, though we cannot rule out an earlier launch in the event of rapid recruitment into the clinical study, or conversely, slippage to 2028 or beyond in the event of slow recruitment or FDA delays.
- **Probability of technical & regulatory success (PTRS) of 80%.** Epigenomics had tagged the probability of market approval at 80% based on unpublished pre-clinical data. Following the strong pre-clinical data demonstrating 84% sensitivity, we consider the risk of disappointing clinical data with notably sensitivity below the CMS reimbursement threshold (which determines the commercial viability, in our view) to be low. However, some clinical and notably regulatory risk remains, and we cannot rule out the risk of non-approval, regulatory delays or a weaker than expected label.
- **Loss of exclusivity after 2040.** While the Septin9 patent expires in 2026, other biomarkers and the combination are patented beyond 2040. We assume a modest decline in revenues from the late 2030s onwards as technological obsolescence likely sets in. We would expect Epigenomics to develop successor products and/or tests for other cancers, implying that group revenues could well continue to grow through 2040 and beyond; however, our current valuation is based exclusively on Epi proColon Next Generation.
- **Eligible patient population of 95m** within three years of launch. We would expect all 100m Americans aged 45+ to be eligible to receive the test from a medical perspective (in contrast to the first-generation product, which is reserved for colonoscopy and stool test refusers owing to its performance characteristics). Provided that the test meets CMS' aforementioned performance criteria, Medicare reimbursement would be granted with immediate effect upon FDA approval, implying that all Americans aged 65+ would be covered immediately. We would expect Epigenomics to secure coverage by commercial plans over time to gain access to individuals aged 45 to 65; based on precedents, we would expect 95% of all lives to be covered within several years.
- **Price point of \$100.** This is the revenue expected to be booked by Epigenomics per test kit sold to laboratories. CMS has set the reimbursement rate for laboratories conducting blood tests with the required performance characteristics at \$192 per test. On this basis, we would expect Epigenomics to charge its laboratory customers approximately \$100 per test. We have not assumed any inflation adjustments, as the CMS reimbursement rate is not adjusted automatically. Still, we perceive scope for an increase in reimbursement rates and/or pricing flexibility on the part of Epigenomics should inflation accelerate significantly.

The US market alone represents a multi-billion-dollar opportunity

- **Testing frequency: annually.** The recommended intervals for performing colorectal cancer screening are a function of each test's performance characteristics: the more sensitive and specific a test is, the longer the recommended test-free intervals. We would expect a recommendation for annual testing for a PCR-based test such as Epi proColon Next Generation, as we would expect the risk of false positive or negative test results to be somewhat higher than for stool-based tests or next generation sequencing approaches. We acknowledge that some patients may skip testing in some years; this is reflected in our penetration assumptions.
- **Peak penetration rate in the mid-2030s in the mid-single digits.** This prudent estimate is based on the following considerations and assumptions:
 - **Patient preference for blood tests.** Epigenomics' market research has revealed a strong patient preference for blood tests over stool tests, and this remains unchanged even after the Covid pandemic. Individuals who require annual blood tests owing to other health conditions might opt to combine them with their colorectal cancer test for convenience. We would expect some of the ca. two thirds of screening-eligible individuals who currently undergo colonoscopy or stool testing as per the guidelines to add or switch to blood tests once their front-line use is permitted, while some of the remaining one third who currently refuse screening – Epigenomics' main target population – may reconsider their position as and when a reimbursed blood test is available. Exact Sciences' Colorectal Cancer Blood test looks set to be Epigenomics' main blood-based competitor. In the outer years, blood tests could lose share to next generation sequencing-based tests.
 - **Logistical simplicity.** Blood samples are easily processed through the phlebotomy network, and large laboratories are equipped to run large numbers of tests based on Epi proColon kits. We view this as an advantage over stool tests, which typically require clear laboratories and note complexity associated with sequencing.
 - **Positioning.** We regard the abovementioned convenience advantages as the principal differentiator. We would not expect the test to be able to compete with high end stool tests or Next Generation Sequencing (NGS) with respect to sensitivity, where some competing products have demonstrated over 90%. However, this disadvantage can be overcompensated with shorter testing intervals, i.e. annual testing, compared with three-year intervals for Cologuard and estimated three to five year intervals for NGS-based tests. We would not expect price to be a major factor in choosing between tests. While the reimbursement rate of \$192 per Epi proColon Next Generation test is lower than the ca. \$500 cost of high-end stool tests and the nearly \$900 expense likely associated with NGS tests, we note that the tests carry similar cost over time, with the higher-priced tests administered less frequently. We have factored a slight late-mover disadvantage into our forecasts, as Epi proColon Next Generation is expected to launch more than two years after competing tests.
 - **Competitors' marketing resources.** Some of Epigenomics' competitors have significant resources at their disposal to support marketing measures such as direct-to-consumer (DTC) campaigns. This potentially reduces Epigenomics' share of voice (though on a positive note, it also raises colon cancer awareness) and provides precedents that may be used as a benchmark to determine uptake over time as a function of marketing budgets. For example, Exact Sciences anticipates selling ca. 3m Cologuard stool tests this year, effectively implying coverage of ca. 9m patients, or nearly 10% share of the eligible population, after considering the recommended three-year testing intervals. This was achieved within six years of launch based on a ca. \$0.1bn annual marketing budget. We base our Epi proColon Next Generation forecast on significantly lower marketing spend, with expected lower penetration rates as a corollary, although we also expect clinics and laboratories, which stand to benefit financially from the use of blood tests, to add to Epigenomics' own share of voice. We note scope for upside if market dynamics as well as Epigenomics' funding levels in the outer years warrant higher investment.

Epi proColon Next generation US revenue forecast

	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e
Target population (m)	40	70	95	95	95	95	95	95	95	95	95	95	95	95	95
Price per test (\$)	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Penetration rate	0%	0%	1%	1%	2%	2%	3%	3%	4%	5%	5%	4%	4%	3%	3%
Epi proColon Next Generation sales - unadjusted (\$m)	0	28	100	125	156	195	243	304	380	475	428	385	346	312	280
Probability of FDA approval	10%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Risk-adjusted US sales recognized by Epigenomics (\$m)	0	22	80	100	125	156	195	243	304	380	342	308	277	249	224

Source: Pareto Securities Research, company data

We estimate the project value of Epi proColon Next Generation at ca. EUR295m in the US alone

Valuation: price target of EUR 0.70/share driven by US project NPV

Our valuation is based exclusively on our NPV model for Epi proColon Next Generation in the US. Whilst we would anticipate meaningful adoption in Europe eventually, we note a typical ten-year time lag relative to the adoption of diagnostic tests in the US. We are not aware of any plans on the part of Epigenomics to enter the fragmented Chinese market; any potential profits from Asian markets represent upside to our forecasts.

Our US project NPV model for Epi proColon Next Generation is shown below and rests on the following key assumptions, which appear consistent with Epigenomics' estimated financing requirement of EUR150m to EUR200m.

- **Risk-adjusted revenues** as detailed above.
- **COGS on the order of 15% to 20% of sales.** We assume production costs of \$20 per test initially, reducing to \$15 as volumes increase, and assume an ex-factory price per test of \$100 as detailed above. Note that we have included the cost for tests during the clinical trial in R&D expenses. We understand from management that the addition of biomarkers beyond Septin-9 has not materially affected production costs.
- **R&D expenses.** We expect the bulk of the expenses for the clinical trial to be incurred over the next several years and include the costs for potential post-approval commitments as well as costs for intellectual property and modest maintenance R&D spend thereafter.
- **Marketing expenses** have been risk-adjusted in line with the probability of FDA approval, which we tag at 80%. The bulk of our projected expenses relates to direct-to-consumer (DTC) advertising; they also include a small field force of about ten to 15 representatives as well as ancillary marketing expenses. The company does not envisage the necessity for annual marketing spend north of \$25m given the economic incentives of many hospitals and laboratories to promote its simple stool-based test. We note however that the commercial environment and the likely correlation between marketing spend and penetration rates in the late 2020's and beyond are difficult to predict with any accuracy at this stage; the company does not rule out significantly higher marketing spend in the event of a compelling business case at the time, subject to funding.
- **Break-even before the end of the decade.** Based on the above assumptions, we forecast operating profits from 2028 onwards, though we note that the break-even year depends heavily on Epigenomics' marketing budget at the time. As noted above, we believe that our marketing cost assumptions support our projected peak penetration rate in the mid-single-digit range, but flag potential scope to achieve higher peak sales as a function of marketing prowess. Epigenomics currently envisages material profits that would support dividend payments from 2030 onwards.
- **Tax rate of 20%** as it is difficult to predict the US corporate tax rate prevailing in each year. For simplicity, we have assumed positive taxes in the early years when the company is loss-making.
- **Discount rate of 12.5%**, reflecting the risks associated with the need to secure financing prior to unlocking the value of Epi proColon Next Generation.

Epi proColon Next Generation US NPV model

\$m unless noted otherwise	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e	2039e	2040e
Sales (risk-adjusted)				0	22	80	100	125	156	195	243	304	380	342	308	277	249	224
COGS (15-20% of sales)				0	-4	-14	-17	-20	-25	-31	-39	-49	-61	-55	-49	-44	-40	-36
R&D expenses	-30	-30	-30	-10	-5	-5	-4	-4	-3	-3	-3	-2	-2	-2	-2	-2	-2	-2
Marketing expenses (risk-adjusted)				-5	-15	-20	-20	-20	-20	-20	-20	-20	-20	-18	-16	-15	-13	-12
Other expenses (ca. 3% of sales)	-2	-2	-2	-2	-2	-2	-3	-4	-5	-6	-7	-9	-11	-10	-9	-8	-7	-7
EBIT	-32	-32	-32	-17	-4	38	56	77	103	135	174	224	285	257	231	207	186	168
Taxes at 20% tax rate	6	6	6	3	1	-8	-11	-15	-21	-27	-35	-45	-57	-51	-46	-41	-37	-34
Net profit	-26	-26	-26	-14	-3	31	45	62	82	108	139	179	228	205	185	166	149	134
NPV of profits	-23	-20	-18	-8	-2	15	20	24	28	33	38	44	49	39	32	25	20	16
Total Risk-adjusted Project NPV (\$m)	313																	
Total Risk-adjusted Project NPV (EURm)	295																	
Discount rate at 12.5%																		

Source: Pareto Securities Research, company data

Other DCF items include overheads, First Generation costs and tax-loss carry-forwards

Epigenomics' company value is projected to be somewhat lower at EUR280m, than the Epi proColon Next Generation project value owing to overhead costs and undisclosed Epi proColon First Generation post-approval commitments as summarized below. Note that we have assumed capital expenditure and working capital requirements to be negligible.

Epigenomics Company Fair Value estimate

	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e	2036e	2037e	2038e
EBIT Epi pro Colon Next Generation (EURm)(A)	-30	-30	-30	-16	-4	36	52	73	97	127	164	211	269	242	217	195
Overhead expenses and costs related to Epi proColon First Generation (EURm) (B)	-10	-10	-10	-5	-5	-3	-1	-1	0	0	0	0	0	0	0	0
Pretax income (EURm) (C=A+B)	-40	-40	-40	-21	-9	34	51	72	97	127	164	211	269	242	217	195
<i>Tax loss carry forward (TLCF) assumptions at 25% tax rate</i>																
TLCF from prior periods (EURm)	200	210	220	230	235	238	204	153	81							
TLCF generated in period (EURm)	10	10	10	5	2											
TLCF used in period (EURm) (D)						34	51	72	97	67						
TLCF at period end (EURm)	210	220	230	235	238	204	153	81								
Pretax income adjusted for TLCF (EURm) (E = C-D)	-40	-40	-40	-21	-9	0	0	0	0	60	164	211	269	242	217	195
Tax at 20% tax rate (EURm) (F)										-12	-33	-42	-54	-48	-43	-39
Net profit (EURm) (G=C+F)	-40	-40	-40	-21	-9	34	51	72	97	115	131	169	215	193	174	156
NPV of net profit at 12.5% discount rate (EURm) (G)	-36	-32	-28	-13	-5	17	22	28	33	35	36	41	47	37	30	24
Net cash (EURm) (H)	9															
Company fair value (EURm) (I=cumulative value of line G+H)	280															

Source: Pareto Securities Research, company data

Discount rate used: 12.5%. USD/EUR rate 1.06. Note that TLCFs are generated in Germany at an estimated tax rate of 25%, while Epi proColon Next Generation profits are expected to be taxed in the US. We have assumed that there is no expiry date for the TLCFs.

Our fair value estimate is highly sensitive to key assumptions such as

- **The peak penetration rate.** Doubling our above estimate from 5% to 10% would increase the estimated fair value of the company to more than EUR 700m.
- **Success probability.** Removing the adjustment for clinical and regulatory risk would increase our fair value estimate to more than EUR 380m.
- **Cost and operating margins.** An EUR 10m increase in the annual cost base without a commensurate increase in revenues, for example in the context of inflationary pressures that are not accompanied by a rise in the reimbursement rate, would reduce the company's estimated fair value to less than EUR 215m.
- **USD/EUR exchange rate.** Assuming parity would raise our fair value estimate to nearly EUR 300m.
- **Discount rate.** A one percentage point change in the discount rate used would change our fair value estimate by approximately EUR 40m.

Fair value per share depends to a significant extent on the expected dilution from future capital measures

The assumed fair value per Epigenomics share additionally depends to a significant extent on the expected dilution from upcoming financing measures. We would expect the company to raise the targeted amount of EUR 150m+ in several tranches. The market conditions prevailing at the time of any future rights issue as well as the relative maturity of the company and colorectal cancer test market are difficult to predict. Successful financing rounds, followed by a rapid pace of recruitment into the clinical study and the uptake of competing colorectal cancer diagnostics based on blood tests and other modalities could potentially provide an element of reassurance in this regard. We have prudently assumed that the full amount required to cover the company's projected losses until break-even is achieved will have to be raised under current conditions, implying that a high degree of dilution looks inevitable. We would revisit our assumptions following each capital raise.

Projected number of shares based on the expected dilution from financing measures

Number of shares (in millions)	
Shares outstanding (A)	16.4
<i>Capital measure assumptions</i>	
Total financing requirement based on anticipated losses (EURm)(X)	150
Current share price in EUR (Y)	0.39
Shares from capital measures (B = X/Y)	385.4
Total number of shares (A + B)	401.7

Source: Pareto Securities Research, Company data

We estimate the fair value per Epigenomics share at EUR 0.70

Based on the above, we set a price target of EUR 0.70 per share based on our estimates for the fair value of the company and the expected dilution from capital measures required to unlock this value.

Estimated fair value per Epigenomics share

Company fair value (EURm)	280
Number of shares (millions)	401.7
Fair value/share (EUR)	0.70

Source: Pareto Securities Research, Company data

Upside from ex-US markets; financing as the most immediate downside risk

In addition to the above sensitivities and the assumptions with respect to dilution, there are other upside and downside risks to our fair value estimates. We regard potential commercial success in Europe and/or any other ex-US markets as the principal source of upside. Potential failure to raise sufficient capital to complete the study in a timely manner or at all represents the most immediate downside risk to our forecasts, as the successful completion of the clinical study is a prerequisite for unlocking the value of Epi proColon Next Generation; severe delays could also adversely affect the asset's commercial prospects. Additionally, the clinical, regulatory and commercial risks typically associated with development-stage assets apply.

PROFIT & LOSS (fiscal year) (EURm)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Revenues	2	2	1	1	6	1	1	1
EBITDA	(10)	(13)	(14)	(11)	(2)	(10)	(40)	(40)
Depreciation & amortisation	(0)	(0)	(1)	(1)	(0)	(1)	(1)	(1)
EBIT	(10)	(13)	(15)	(12)	(2)	(11)	(41)	(41)
Net interest	(0)	(1)	0	(0)	(0)	(0)	(0)	-
Other financial items	-	-	-	-	-	-	-	-
Profit before taxes	(10)	(13)	(15)	(12)	(2)	(11)	(41)	(41)
Taxes	0	1	(2)	(0)	(0)	-	-	-
Minority interest	-	-	-	-	-	-	-	-
Net profit	(10)	(13)	(17)	(12)	(2)	(11)	(41)	(41)
EPS reported	(3,13)	(3,59)	(3,58)	(2,02)	(0,22)	(0,69)	(2,52)	(2,49)
EPS adjusted	(3,13)	(3,59)	(3,58)	(2,02)	(0,22)	(0,69)	(2,52)	(2,49)
DPS	-	-	-	-	-	-	-	-
BALANCE SHEET (EURm)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Tangible non current assets	1	1	2	1	1	2	2	2
Other non-current assets	2	3	0	0	0	-	-	-
Other current assets	4	2	2	2	1	1	1	1
Cash & equivalents	13	16	10	4	23	10	-	-
Total assets	20	22	14	7	25	13	3	3
Total equity	11	19	10	4	22	7	(44)	(84)
Interest-bearing non-current debt	-	-	-	-	-	1	1	1
Interest-bearing current debt	-	-	-	-	-	-	42	83
Other Debt	9	3	4	3	3	5	4	4
Total liabilities & equity	20	22	14	7	25	13	3	3
CASH FLOW (EURm)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Cash earnings	(9)	(11)	(13)	(10)	(3)	(12)	(41)	(41)
Change in working capital	(0)	1	(0)	1	(1)	2	(0)	(0)
Cash flow from investments	(1)	1	(0)	(0)	(0)	(1)	(0)	(0)
Cash flow from financing	11	13	7	3	22	-	42	41
Net cash flow	1	4	(6)	(7)	18	(11)	-	-
VALUATION (EURm)	2017	2018	2019	2020	2021	2022e	2023e	2024e
Share price (EUR end)	31,1	13,9	10,7	3,33	0,64	0,37	0,37	0,37
Number of shares end period	3	4	5	6	11	16	16	16
Net interest bearing debt	(13)	(16)	(10)	(4)	(23)	(9)	43	83
Enterprise value	89	35	41	16	(16)	(3)	49	90
EV/Sales	47,7	22,6	36,0	18,7	-	-	-	-
EV/EBITDA	-							
EV/EBIT	-	-	-	-	-	-	-	-
P/E reported	-	-	-	-	-	-	-	-
P/E adjusted	-							
P/B	9,6	2,8	5,3	5,0	0,3	0,8	-	-
FINANCIAL ANALYSIS	2017	2018	2019	2020	2021	2022e	2023e	2024e
ROE adjusted (%)	-	-	-	-	-	-	-	-
Dividend yield (%)	-	-	-	-	-	-	-	-
EBITDA margin (%)	-	-	-	-	-	-	-	-
EBIT margin (%)	-	-	-	-	-	-	-	-
NIBD/EBITDA	1,29	1,31	0,72	0,32	11,91	0,89	(1,07)	(2,10)
EBITDA/Net interest	-	-	-	-	-	-	-	-

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Appendix A

Disclosure requirements in accordance with Commission Delegated Regulation (EU) 2016/958 and the FINRA Rule 2241

The below list shows companies where Pareto Securities AS - together with affiliated companies and/or persons – owns a net long position of the shares exceeding 0,5 % of the total issued share capital in any company where a recommendation has been produced or distributed by Pareto Securities AS.

Companies	No. of shares	Holdings in %
Bonheur	239 535	0,56 %
Huddly	1 169 083	0,55 %
Pareto Bank	14 732 432	21,09 %
Selvaag Bolig	4 671 772	4,98 %
Sparebank 1 Nord-Norge	5 011 402	4,99 %
Sparebank 1 SMN	2 771 589	2,13 %
Sparebank 1 SR-Bank	2 405 875	0,94 %
SpareBank 1 Østfold Akershus	1 237 140	9,99 %
SpareBank 1 Østlandet	5 714 790	5,38 %
Sparebanken Møre	566 833	1,15 %
Sparebanken Sør	333 249	2,13 %
Sparebanken Vest	7 590 191	7,07 %
NEXT Biometrics	700 000	0,76 %
SpareBank 1 Sørst-Norge	2 608 539	4,13 %

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Please find below an overview of material interests in shares held by employees in Pareto Securities AS, in companies where a recommendation has been produced or distributed by Pareto Securities AS. "By material interest" means holdings exceeding a value of NOK 50 000.

Company	Analyst holdings*	Total holdings
AAC Clyde Space	0	72 700
Aker ASA	500	2 288
Aker BP	0	10 978
Aker Horizons	0	170 767
AMSC ASA	0	4 880
ArcticZymes Technologies	0	684
Atlantic Sapphire	0	7 500
AURELIUS Equity Opportunities	0	500
Austevoll Seafood	0	3 548
Awilco LNG	0	30 000
Beiships	0	40 000
Biolinvent	0	15 000
Bonheur	0	30 665
Borregaard ASA	0	515
Bouvet	0	980
BW Energy	0	81 374
BW Offshore	0	4 900
Cloudberry Clean Energy	0	100 000
Crayon	0	2 380
Desert Control	0	6 685
DNB	0	34 067
DNO	0	30 391
Edda Wind	0	5 000
Elkem	0	54 376
Elmera Group ASA	0	21 405
Embracer Group	0	8 600
Equinor	0	1 616
Europris	0	18 103
Flex LNG	0	1 135
Frontline	0	15 100

Company	Analyst holdings*	Total holdings
Gaming Innovation Group	0	15 000
Gjensidige Forsikring	519	1 160
Grieg Seafood	0	15 074
Hafnia Ltd.	0	96 000
Huddly	0	1 169 083
HydrogenPro	0	34 922
International Petroleum Corp	0	5 511
Kahoot	0	36 577
Kambi Group plc	0	430
Kitron	0	2 314
Komplett Bank	0	153 800
Kongsberg Gruppen	0	500
KWS	75	75
Lea bank	0	16 355
Lerøy Seafood Group	0	38 951
Media and Games Invest	0	10 000
Meltwater	0	24 000
Mowi	0	2 288
Multitude	0	2 443
NEXT Biometrics	0	700 000
NorAm Drilling	0	6 883
NORBIT ASA	0	3 706
Nordic Semiconductor	0	13 053
Norsk Hydro	0	83 711
Norske Skog	0	79 949
Northern Drilling Ltd.	0	195 000
Odffell Drilling	0	3 881
Orkla	0	12 416
Panoro Energy	0	12 733
Pareto Bank	0	762 086
PetroTal	0	74 000
Pexip Holding	0	511 795
Protector Forsikring	0	7 300
Pyrum Innovations	0	100
Quantafuel	0	17 665
REC Silicon	0	35 990
SallMar	0	3 500
Sandnes Sparebank	0	2 500
Sandvik	0	1 000
Scatec	0	30 129
Seadrill Ltd	0	7 950
SignUp Software	0	1 264
Sparebank 1 Nord-Norge	0	5 725
Sparebank 1 SMN	0	10 171
Sparebank 1 SR-Bank	0	8 045
SpareBank 1 Østlandet	0	1 100
Sparebanken Møre	0	1 080
Sparebanken Sør	0	15 940
Sparebanken Vest	0	3 294
Stolt-Nielsen	0	2 233
Storebrand	100	1 360
Storytel	0	5 390
Subsea 7	0	28 890
Telenor	0	3 004
TGS	0	600
TORM	0	2 500
Transocean	0	13 000
Valaris	0	2 000
Vestas Wind Systems	0	1 235
Vow	0	3 281
Vår Energi	0	91 273
Wilh. Wilhelmsen Holding	0	229
Yara	0	16 014
Zaptec	0	7 400

This overview is updated monthly (last updated 15.12.2022).

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Appendix B

Disclosure requirements in accordance with Article 6(1)(c)(iii) of Commission Delegated Regulation (EU) 2016/958

Overview over issuers of financial instruments where Pareto Securities AS have prepared or distributed investment recommendation, where Pareto Securities AS have been lead manager/co-lead manager or have rendered publicly known not immaterial investment banking services over the previous 12 months:

Add Energy	Vår Energi
Aker Clean Hydrogen	Waste Plastic Upcycling
Aker Offshore Wind	Wattif EV
Akershus Energi Varme AS	wheel.me
Alva Industries AS	Ymber AS
American Shipping Company	Øm Software
Aprila Bank ASA	
B2Holding AS	
Bekk og Strøm AS, SV Vattenkraft AB	
Biolinvent	
Bluewater Holding	
Boreal Holding AS	
Borr Drilling	
Broege Petroleum and Gas	
BW LPG	
Cabonline Group Holding AB	
Cadeler	
CERAFILTEC	
Cloudberry Clean Energy	
COOL Company	
DNO	
Dolphin Drilling	
Ensurge Micropower	
Esmailzadeh Holding	
First Camp Group	
Flex LNG	
Gram Car Carriers	
Green Transition Holding	
Hälsö Eco	
HMH Holding	
Hospitality Invest	
House of Control	
HydrogenPro	
Ice Group	
Idavang AS	
InoBat Auto	
International Petroleum Corporation	
Island Green Power Ltd	
KMC Properties	
Kraft Bank	
Kruse Smith	
Kvitebjørn Energi AS	
Magnora	
Memmo Family	
Milne Petroleum	
Multitude SE	
Navios Maritime Holdings	
NorAm Drilling	
Norse Atlantic	
Norske Skog	
Norwegian Block Exchange	
Odjfell Oceanwind	
Okea AS	
Otello Corporation	
Pandion Energy	
Pareto Bank	
PGS	
PHM Group	
Polight ASA	
Pronofa AS	
Protector Forsikring	
Proximar Seafood	
Pryme	
PuPac AB	
Qred Holding	
Quantfuel	
Salmon Evolution	
Sartorius-Herbst	
Schletter International B.V	
Shamaran Petroleum	
Slate European Holdings	
Standard Supply AS	
Swedencare	
Tierklinik Hofheim GbR	
Tise AS	
Trønderenergi AS	
Vestby Logistikk Holding	
Viking Venture 27 AS	

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Appendix C

Disclosure requirements pursuant to the Norwegian Securities Trading Regulation § 3-11 (4)

Distribution of recommendations	
Recommendation	% distribution
Buy	75 %
Hold	24 %
Sell	2 %

Distribution of recommendations (transactions*)	
Recommendation	% distribution
Buy	81 %
Hold	19 %
Sell	0 %

* Companies under coverage with which Pareto Securities Group has on-going or completed public investment banking services in the previous 12 months

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Azelo	Linkfire AS	Shamaran Petroleum Corp
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Boule Diagnostics AB	Media & Games Invest plc	Xbrane Biopharma AB
Cibus Nordic Real Estate AB	NGEx Minerals Ltd	VEF AB
Cinis Fertilizer AB	Oscar Properties AB	Vicare Pharma Holding AB
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Fleming Properties AB	Logistri Fastighets AB	

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Appendix E

Disclosure requirements in accordance with Article 6(1)(c)(i) of Commission Delegated Regulation (EU) 2016/958

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Pareto Securities acts as a designated sponsor for the following companies, including the provision of bid and ask offers. Therefore, we regularly possess shares of the company in our proprietary trading books. Pareto Securities receives a commission from the company for the provision of the designated sponsor services.

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GFT Technologies SE	OVB Holding AG	VERIANOS SE
Gigaset AG	ProCredit Holding AG	Viscom AG
Heidelberg Pharma AG	Progress-Werk Oberkirch AG	WPU - Waste Plastic Upcycling AS
INTERSHOP Communications AG		

Appendix F

Disclosure requirements in accordance with Article 6(1)(c)(iv) of Commission Delegated Regulation (EU) 2016/958

Sponsored Research

Pareto Securities has entered into an agreement with these companies about the preparation of research reports and – in return - receives compensation.

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Biotech AG Pkt.	Hypoport SE	Progress-Werk Oberkirch AG
Clig Digital AG	INTERSHOP Communications AG	PSI AG
Daldrup & Söhne AG	Kontron AG	Siegfried Holding AG
Dermapharm Holding SE	Leifheit AG	SMT Scharf AG
Enapter AG	Logwin AG	Surteco AG
epigenomics AG	MAX Automation SE	Szyzgy AG
ExpresZion Biotech Holding AB	Merkur Privatbank AG	Viscom AG
GERRY WEBER International AG	MLP SE	

This overview is updated monthly (last updated 15.12.2022).