

# **Genetic Analysis**

Mangold Insight - Commissioned Research - 10 May 2022

### Better gastric health with new test

Mangold initiates coverage with a Buy recommendation in Genetic Analysis. The company sells a diagnostic system for microbiome analysis, called GA-Map, which makes it possible to diagnose and analyse the intestinal flora. There is a driving force to get microbiota tests from the research field to routine clinical use. Above all, there is significant market potential linked to diseases such as IBS and IBD.

### High growth expected

Genetic Analysis is on the verge of commercialising the GA-Map platform. The company is based on a platform strategy with recurring income from the sale of reagent kits to laboratories. Mangold estimates that the company can grow by 63 percent on average per year during the period 2021 to 2027. The company is estimated to be profitable from 2023, and be able to reach over 100 million in revenue from 2025. The market is growing and the company has no direct competitors.

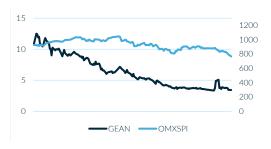
### Several triggers

Genetic Analysis falls into the category of undiscovered companies, where Mangold sees several triggers in the stock. The company's sales can pick up in the North American and European markets. There is great interest from the US, where both research and the number of clinical studies in microbiota have increased rapidly. In addition, a number of collaborations may turn out well. In a Basecase, we have chosen to set a price target of 7.00 kronor per share (NOK), which shows an upside of 100 percent in the stock.

### **Key Data**

Augusta Damle	/ /	25 / 9/			
Main Shareholders	Shares (M)	Capital			
Analyst	Ja	n Glevén			
Website	Genetic-Ana	lysis.com			
	13 n	nay 2022			
Ticker	GEAN				
Free float	66.3%				
No. of shares (million)		25			
Market cap (MNOK)		85			
Price (NOK)		3,43			
Risk		High			
Target Price (NOK)		7.00			

Main Shareholders	Shares (M)	Capital
Avanza Bank	6.4	25.6%
Bio-Rad Lab	5.3	21.3%
Nordnet Pension	2.7	10.8%
Biohit Oyi	1.4	5.7%
Molver AS	0.6	2.6%
LJM AS	0.6	2.2%
S. Munkhaugen AS	0.5	1.9%
Other	6.2	24.8%
Total	24.9	100.0%



Performance %	1m	3m	IPO
Genetic Analysis	-4,7	-33,0	-45,0
OMXSPI	-13,9	-16,7	-26,0

Key ratios	2 021	2022E	2023E	2024E	2025E
Sales (MNOK)	6,8	20,4	53,0	90,2	108,2
EBIT (MNOK)	-28,9	-24,0	-0,4	23,7	31,6
Profit before tax (MNOK)	-29,0	-24,1	-0,4	30,3	40,4
EPS, adjusted (NOK)	-1,16	-0,97	-0,02	1,22	1,62
EV/Sales	34,7	11,6	4,4	2,6	2,2
EV/EBITDA	neg	neg	neg	9,9	7,5
P/E	neg	neg	neg	2,8	2,1

## Genetic Analysis - Investment Case

### Better gastric health with new test

Mangold initiates coverage of Genetic Analysis with a Buy recommendation and a price target of 7.00 kronor (NOK) in Basecase. Mangold has chosen to value the company with a DCF-model and a required rate of return of 12 percent. A performed scenario analysis shows that the company's value can be significantly higher than that which we have set out. The analysis shows both a Bearcase and a Bullcase. Mangold has taken into account the full dilution of shares.

Buy the share - price target NOK 7.00

DCF shows an upside of 100 percent

#### To become standard

The company's product, GA-Map, is intended for in vitro diagnostics for the examination of samples from the human body in order to obtain information about treatment effects or disease states in the intestinal flora. There is significant market potential linked to IBS and IBD (see appendix). In the US and Europe, about 73 million people suffer from IBS, and about six million from chronic IBD. The company also sees opportunities in other disease indications with a significant need for cost-effective and reliable diagnostics. The market for microbiome tests is characterised by non-standardised research-based tests. There is a clear driving force to get microbiota tests from the research field to routine clinical use.

Diagnostic company with growth potential

Large market

Product in demand

### Plattform strategy

The company is based on a platform strategy with recurring income from the sale of reagent kits to laboratories. Mangold estimates that the company can grow by an average of 63 percent per year during the period 2021 to 2027. During the end of the period, the company is expected to be able to reach an industry EBIT margin of 30 percent. It should be possible for sales to reach 127 million in 2027, according to our Basecase.

Recurring revenue

### To grow in the US

Triggers consist of the company's sales gaining momentum in the North American and European markets. Sales will initially be made to larger labs. Genetic Analysis is in an early sales phase, and there is still great uncertainty about how its products will be received in the market. What speaks for the company's success is that there is great interest from the US, and that research and the number of clinical studies in microbiota have increased considerably.

Still an early phase for the company

### Asia in sight

At a later stage, Mangold sees that the company also can reach the Asian market, where there is significant interest in this type of product. The company has a partnership with American Bio-Rad, which may turn out well. If the company's products attain great demand and are successful in reaching the clinical market after positive statements from the FDA, we see the company as an acquisition target.

Success with the FDA can attract buyers

## Genetic Analysis - About the company

### The company in brief

Genetic Analysis is a diagnostics company active in medical technology with focus on the human microbiome (read more in the appendix). The company sells a diagnostic system for microbiomeanalysis, called GA-Map, which makes it possible to diagnose and analyse the intestinal flora. GA-Map is supported by approximately 20 scientific publications, and has been used in more than 50 clinical studies. Genetic Analysis was founded in 2008, based on research work in microbial diagnostics by Professor Knut Rudi, from the Norwegian University of Life Sciences (NMBU) in Ås. Ronny Hermansen is a CEO with more than 20 years of experience from the international diagnostic industry. The company is listed on Spotlight in Sweden.

Diagnostic company with a focus on microbiota

### The business

Genetic Analysis manufactures products and reagents in its own service laboratory in Oslo. In the event of increased volumes, operations can also be outsourced. The company has a product that is CE-marked, and ready to be commercialised in Europe, the US and Asia. Sales will take place via distributors, as well as direct sales in both Europe and the US. It will be possible to market GA-Map in Europe via an institute in Germany IMD (Institut für Medizinische Diagnostik), which is part of the Medicover Group. In China, the company collaborates with Thalys, which will use GA-Map in its lab in Shanghai (ICL - Independent Clinical Lab).

The product GA-Map will be sold in the US and Europe

The company is based on a platform strategy with recurring income from sale of reagent kits to laboratories. The company has a distribution and development agreement with the American life-science company Bio-Rad for the GA-Map Dysbios Test. There is also an agreement with Luminex to develop and commercialise tests for microbiota on the LX200 and Magpix platforms. Luminex develops instruments for laboratories, and has been part of the Collaborates with Thalys in China

Italian group DiaSorin since July 2021.

Recurring income

Bio-Rad is a shareholder in GA

GA-Map intends to analyse diseases of the intestinal flora. There is significant market potential linked to IBS and IBD. In the US and Europe, about 73 million people suffer from IBS, and about six million from chronic IBD. The company also sees opportunities in other disease indications with a significant need for cost-effective and reliable diagnostics, such as type 2 diabetes, liver disease (NAFLD/NASH), and colorectal cancer.

Aimed at diseases that are on the increase





Luminex LX200 and the associated GA-Map test can be seen in the image

### Genetic Analysis - Products

### Products and development work

Genetic Analysis medical devices for in vitro diagnostics are intended for use in examining samples from the human body in order to obtain information about treatment effects or disease states. The company has developed a platform, GA-Map, for use in laboratories. Through GA-Map it is possible to analyse and diagnose the intestinal flora. The company has developed two tests for this, one of which is aimed at IBS and IBD. Many patients with these diseases do not respond to treatment, and better diagnosis is needed. The second is for testing Covid-19.

GA-Map can analyse the intestinal flora

GA-Map has been developed to analyse a large number of bacteria in one reaction. Test results are generated using the clinically validated GA-Map algorithm, which enables the test results to be generated directly without the need for additional bioinformatics work. GA-Map automatically compares a predefined microbiota and a unique biobank of 7 000 samples from different disease states. Test results can then be published via software.

Test results can be published via software

### **GA-Map Dysbiosis Test Lx**

The test comprises a service product aimed at researchers for use in the clinical phase, PCR labs, dietitians, and those active in gastroenterology.

The test can identify and characterise dysbiosis. An imbalance can occur between good and bad bacteria in the intestinal flora in patients with diseases such as Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD). The test is used as a complement to patient treatment and clinical research. It identifies potential dysbiosis and creates a profile of the patient's microbiota.

The company's tests can identify IBS and IBD

Test data obtained is generated automatically and the result is illustrated in a report. This report contains 48 pre-selected bacterial markers. The tests will help healthcare professionals find the right treatment for dysbiosis. The test is performed with the analysis instrument Luminex 200 or Luminex Magpix, where several different tests can be performed simultaneously.

#### **COVID-19 Fecal Test**

This test is also a service product developed to be able to identify Covid-19 in microbiota. It is a faecal reagent kit for identifying SARS CoV-2 in stool samples. The market has so far been limited. The method has mainly been tested in China and Hong Kong with young children. In Europe, PCR tests in the nose and throat have been used, which explains a limited use. In Europe, the test has been used for special patient groups. In the future, the test may be used to monitor post-Covid dysbiosis.

Covid-19 tests can be used more widely

### For the laboratory

The company sells the GA-Map Dysbiosis Test Reagent Kit to molecular laboratories. The test is CE marked and an In Vitro-documented test. The product includes software that consists of a large reference database of normal and healthy microbiota. There are also faecal tests with supplementary software that can be used in the lab.

Molecular Labs are found in private routine labs, at major universities and pharmaceutical companies, such as Abbott

### Genetic Analysis - Development

### **Development work**

Genetic Analysis develops biomarkers for GA-Map. This will make it possible to use the platform to provide better treatment to patients with IBD or other diagnoses, such as Type 2 diabetes. Potential is also to be seen in the area of liver diseases (NAFLD/NASH) and colorectal cancer, which may become part of GA-Map. Clinical development for diagnostic products is less complicated than for medicines, and takes both less capital and time. The company collaborates with several organisations within research, including Akershus University Hospital in Oslo and Sahlgrenska University Hospital in Gothenburg.

Biomarkers will be developed

### Increased number of clinical studies

Maintaining and improving the intestinal bacterial ecosystem has had an increasing impact in clinical research. Approximately USD 6.5 billion has been invested in the development of intestinal flora-altering drugs, and roughly 1 100 clinical programmes at various stages with such drug candidates are ongoing, according to industry site Microbiome Times.

Increased number of clinical studies

Seres Therapeutics, which develops biological drugs, has entered phase 3 in the clinical drug development with its drug candidate SER-109. This has been described as a major advance and a paradigm shift for the entire microbioma market.

The success of Seres - a paradigm shift

Many years of research within the microbiota field have led to an increased understanding of the role and significance of microorganisms for the health of mankind. Around 500 000 microbiome tests are already carried out every year in laboratories in the US and the EU. The majority of the tests are performed with individiual lab-developed test methods and research techniques.

The number of microbiome tests is expected to increase

Using new technology, 16s rDNA sequencing, researchers have been able to analyse microbiota. With sequencing technology, researchers have gained a better picture of the microbiota in the intestine.

#### Starndardised tests are needed

The market for microbiome tests is characterised by non-standardised research-based tests. There is a clear driving force to get microbiota tests from the research field to routine clinical use. Pharmaceutical players are launching potential microbiome-altering drugs, which means an increased need for routine diagnostics.

Genetic Analysis will standardise microbiota tests

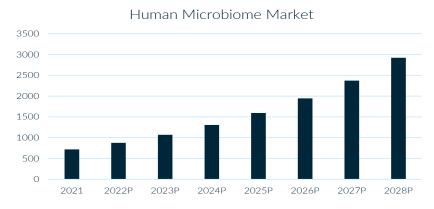
The company's patented and CE-marked GA-Map is the only microbiome platform for routine diagnostics, which compares the patient's results over time. With GA-Map, results for diagnosing patients' tests become cost-effective, standardised, and consistent.

### Genetic Analysis - Market

#### The Human Microbiome Market

The global market for "Human Microbiome" amounted to USD 719 million in 2021, and is expected to increase to USD 2.9 billion in 2028, according to study from the Insight Partners. Market growth is expected to average 22.2 percent per year during the period 2021 to 2028. Growth is driven by increased interest in intestinal flora and drug development. Especially early detection of disease and diagnosis. The market includes diagnostics and pharmaceuticals.

The Human Microbiome market will grow by more than 20 percent CAGR

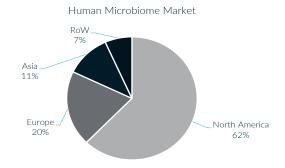


Source: The Insight Partners

North America is expected to drive growth in the coming years until 2028. A significant number of intestinal flora-changing drug candidates are under development, which contributes to growth. Research capital and various federal initiatives are also expected to contribute to the growth in the North American market. North America is expected to be the largest market, followed by Europe and Asia (APAC). In the long term, Genetic Analysis aims to grow in the American market. In order to succeed in this, a strong patent protection is required, which the company has, and that the product receives an FDA approval, something the company does not have. The company will initially seek FDA approval for IBD. Contact with the FDA is expected to begin during the second half of 2022. The company may initiate sales for research, a market that is more limited. A market for microbiota has been created China and is expected to drive growth in Asia. Chinese research has come a long way in microbiome research.

North America is expected to drive the entire microbiome market

Talks with the FDA will begin in the autumn



Source: Mordor Intelligence

### Genetic Analysis - R&D

### Several sub-segments in the market

The market can be divided into different segments. These generally consist of probiotics and foods of various kinds, which are expected to make up over 75 percent of the market by 2028. Diagnostic equipment, medicines, and other supplements are expected to make up the remaining share.

Diagnostics is a small part of a large market

The diagnostic segment can in turn be divided into different sub-segments. These are expected to change over time. There are players in the market of Medical and Research Diagnostics, processes that determine which disease or condition explains the patient's symptoms, commonly called diagnosis.

More precise treatment

This is expected to change to sub-segments within Companion Diagnostics and Consumer Diagnostics. Companion Diagnostics means that tests better match a patient to a specific drug or treatment.

Diagnostics @Home - a trend that increased during the pandemic

Consumer Diagnostics is a trend that accelerated during the pandemic. Tests for Covid-19 have resulted in patients getting used to digital channels. Test results are also expected to be more personalised in the future. Digital Health is an area that is also expected to increase considerably. Overall, tests performed by patients themselves are expected to increase (often referred to as Diagnostics @Home).

### Strategy

Sales have begun modestly, mostly in the North American market. The company is now expected to focus on sales in its main markets, the US and Europe.

The company will increase its sales in Europe and North America

### Step 1

In the first step, the company will sell GA-Map to laboratories that perform microbiota tests, or molecular laboratories in Europe and the US. This is intended to take place within 2-3 years.

#### Step 2

In step two, the company will expand its market for GA-Map within IBS and IBD. A GA-Map test shall become standard and should be performed before gastroscopy. An expanded collaboration with pharmaceutical companies is expected to be able to create combined products that provide better treatment. This goal is expected to be reached within 2-5 years.

GA-Map shall become standard

### Step 3

Potential is to be seen in performing tests for several types of diseases, such as type 2 diabetes, liver disease, and colorectal cancer. Here, the various-parties are an important part of the development. The goal can be reached between 3-6 years.

More diseases increase the potential

## Genetic Analysis - Estimates

#### **Estimates**

In 2021, the company achieved sales of 6.8 million (NOK). The goal in 2022 is to reach 25-35 million. In 2023, the company aims to break even with a turnover of 50-70 million. Mangold estimates that the company can reach 20 million in 2022 and over 100 million in 2025. The company has not released any price information for the product for competitive reasons. Mangold also believes that an analysis of market shares will be misleading as the company has no direct competitors.

Revenue of just over 50 million NOK in 2023

#### **GENETIC ANALYSIS - ESTIMATES**

	2021	2022E	2023E	2024E	2025E	2026E	2027E
Sales	7	20	53	90	108	121	127
Growth %		200%	160%	70%	20%	12%	5%

Source: Mangold Insight

To succeed with its strategy, Genetic Analysis needs to sign more distribution agreements in Europe, and get sales started in the North American market. Triggers for increased future sales consist of partners with pharmaceutical companies in microbiota biomarkers. Discussions with the FDA about IBD as a prognostic marker are an important milestone for the company to reach the US market with full potential. A similar scenario for China is also considered to have a significant effect on the price. This may lead to access to more markets in Asia, such as Japan, Korea and India, at a later stage.

American market in sight



Source: Mangold Insight

Costs in 2021 amounted to just over 42 million (NOK). During the fourth quarter, these stood at 14 million, which for a 12-month rolling average would mean 56 million. Mangold estimates that costs may fall a few more quarters, and expects total costs of 48 million in 2022, and somewhat higher in 2023 of 52 million. That in turn should be sufficient to take the company towards profitability, and break even in 2023.

Costs should decrease in relation to increased sales

## Genetic Analysis - Estimates

### **General Medtech margins**

Mangold has chosen to use industry-wide EBIT margins of around 30 percent for Genetic Analysis. It is reasonable to assume that the company will reach break even in 2023, with a revenue of just over 50 million. In the long run, the company can grow in both North America and Asia, which is likely to mean that our estimates are restrictive.

Average EBIT-margins for the industry have been used



Source: Mangold Insight

### **Financing**

The company was listed in October 2021, and in conjunction with this raised 60 million (NOK). At the end of 2021, the company's cash amounted to 46.8 million (NOK). The share issue is intended to finance the build up for increased sales, registration of products in new markets, and to scale up the company's manufacturing and logistics. The company has made the required investments and does not anticipate the need for any further in the coming years.

During 2021, the company had an average burn rate of around 10 million per quarter. In 2022, we expect that this will be lower, around 7 million, and that the company will then have sufficient capital until November 2022. At this point the company can be provided with an additional 43 million (NOK) in connection with the redemption of subscription warrants (TO1). Capital is intended to be used for product development and clinical documentation of IBD, as well as research linked to microbiome and other diseases. It is also possible for the company to raise capital in November 2023 against subscription warrants (TO2).

### Agreements in the sector

Enterome and Nestlé Health Science formed a joint venture with the intention of developing diagnostic-related products for the microbiome. Nestlé invested MEUR 20 in this project. (Read more about companies and investments in the appendix). Collaborations of this nature may become relevant even for Genetic Analysis.

The company was listed in October 2021

Raised 60 million

Cash and future TO should take the company to positive cash flow

Nestlé in a joint venture with Enterome

## Genetic Analysis - Valuation

### **Valuation**

Mangold has chosen to evaluate Genetic Analysis with a DCF model. A required rate of return (RRR) of 12 percent has been used, which is slightly above the recommendations according to the Risk Premium Study 2021 by PwC. Mangold has chosen a size-related risk premium supplement of 5 percent, and a market risk premium of 7 percent. Mangold has based this on the Norwegian tax rate, and expects full dilution of the number of shares. Based on these assumptions, we obtain a net present value (NPV) of 7.76 kronor.

Mangold obtains a fair value of 7.76 NOK

Price target is 7,00 NOK

### **GENETIC ANALYSIS - DCF**

(TNOK)	2022	2023	2024	2025	2026	2027	
EBIT	-24 044	-406	23 704	31 581	35 212	38 712	
Free cash flow	-33 898	-20 760	-435	21 690	28 599	37 111	
Terminal value							412 340

Assumptions	RRR	Growth	Тах
	12%	3%	28%
NPV			
Enterprise value	235 774		
Equity value	271 184		
Fair value per share (NOK)	7.76		
Price target (NOK)	7.00		

Source: Mangold Insight

### Scenario analysis

Mangold has chosen to carry out a scenario analysis where income increased by 10 percent in a Bullcase, and decreased by 10 percent in a Bearcase. These different scenarios have since been compared with different RRR, from 11 to 13 percent. With 10 percent higher growth and lower RRR, a fairvalue of the share can amount to more than 11 NOK.

Scenario analysis with different growth rates

#### **MANGOLD - SENSITIVITY ANALYSIS**

RRR %	Bear	Base	Bull
11%	6.94	9.00	11.07
12%	5.99	7.76	9.53
13%	5.24	6.78	8.32

Source: Mangold Insight

### **Key ratios**

Comparative valuation has not been taken into count. Companies within microbiota with market cap can be found in appendix. On the one hand, there is a clear lack of comparative companies and profitability some years away, which means uncertainty in key ratios. Relevant key figures on profitability will not arise until 2024 when EV/EBIT amounts to 10x.

### Management

Ronny Hermansen, CEO, has more than 25 years' experience from the international diagnostic industry. He has been involved in Genetic Analysis since the beginning of 2014, and has an MsBA (Cand. Merc) from the University of Aalborg, Denmark. Previous experience includes at Nycomed Amersham (later GE Healthcare) as Vice President of Finance in Operations. He was previously Group CFO of Axis-Shield from 2007 until it was acquired by American Alere in December 2011.

**Anita Patel Jusnes**, CCO, has more than 20 years' experience from the international pharmaceutical industry, including from the companies Glaxo Smithkline, Pronova Biopharma and Novartis. She has an MSc in Pharmacy from the University of Oslo. Extensive experience from product launches, development and implementation of growth strategies, and leading teams. She has been at Genetic Analysis since 2020.

**Christina Casén**, senior VP of clinical and medical affairs, has an MSc in molecular cell biology and more than 20 years' experience from the international diagnostics industry. She has previously worked for companies such as the Abbott Diagnostic Division, Axis Shield, and several start-ups in biotechnology. She has significant expertise in international network building, international project management in clinical research, and commercialisation of products. She has been at Genetic Analysis since 2009.

**Kari Furu**, CTO, has a doctorate in molecular biology from the University of Oslo. She has more than 10 years' experience from molecular biology research, product development and in vitro diagnostics. She has previously worked at the Cancer Registry of Norway and the University of Oslo. She has been at Genetic Analysis since 2016.

**Lars Tiller**, Head of Operations, will be responsible for manufacturing and logistics operations at Genetic Analysis. He has previously been at Alere Technologies (now Abbott Diagnostics).

**Eilert Aamodt**, CFO, has more than 20 years' experience from companies in media, industry and diagnostics, including Nycomed and GE Healthcare. He holds an MSc in Business Administration from the University of Erlangen-Nuremberg, Germany. He has been at Genetic Analysis since 2021.

#### **Board of Directors**

**Per Matsson,** chairman, has more than 35 years of international experience in the diagnostic industry. His recent positions have covered executive management positions as CTO in Phadia and as CTO in Thermo Fischer Scientific ImmunoDiagnostics division. He holds a PhD in cell biology, MBA studies in Management of Innovation, and is appointed professor at the Uppsala University and at the Veterinary Faculty, Swedish Agricultural University. Per is currently working as a senior advisor and board member for several companies and industry organizations and he is actively involved as a co-founder and Chair in several diagnostic companies. Per also serves as Scientific Advisor to the UK listed Intuitive Investments Group plc, a venture fund concentrating on investing in fast-growing life science companies.

**Andrew Stapletown**, board member, has a PhD from the University of Manchester in England and an MBA in Strategic Management from John F. Kennedy University, USA. He has over 30 years of international experience from leading positions within life science and the diagnostic industry. Andrew is also Vice President for the Corporate Business Development-team in Bio-Rad Laboratories Inc, with responsibility to handle M&A and the Corporate Venture-fund.

**Rune Sørum,** board member. has a master's degree in economics from the Copenhagen Business School. Rune is a Partner in Televenture Management. Prior to joining Televenture, Rune was a private investor and senior adviser to European companies operating in both Asia and the Middle East. Rune has held several board positions in Norwegian investment companies.

Camilla Huse Bondesson, board member, holds an Executive MBA from Stockholm University and is Chair of the Board of Immuneed and TdB Labs. Camilla has over 30 years of international operational and strategic experience from leading positions in companies in the biotechnology field, including as Head of Behring Diagnostica, International Product Manager for Biacore, Marketing Manager for Amersham Biosciences (now Cytiva), and VP Marketing for Gyros. Since 2004, Camilla has worked as a consultant and partner at Conlega, a consulting company within Life Science.

**Staffan Strömberg**, board member, has a PhD from the Royal Institute of Technology in Stockholm and over 23 years' experience in the pharmaceutical industry. He is the CEO of Infant Bacterial Therapeutics. In addition to his role as Head of Medical Technology Products at the Medical Products Agency, he has also been Vice President of Nicox France, and held senior positions at AstraZeneca. Staffan has specific experience of developing orphan drugs as he was R&D Manager for Swedish Orphan.

## Genetic Analysis - Background

#### Research into the microbiome

Knowledge of the human microbiome developed mainly during the early 2000s. A five-year research project was started in 2007 when the Human Microbiome Project (HMP) was launched. HMP was funded by the NIH (National Institutes of Health) to better understand how microorganisms affect health and disease. It has been described as a logical continuation of the Human Genome Project (HGP). The purpose of the HGP project was to determine the sequence of chemical base pairs that make up human DNA, and to map all the genes in the entire human genome.

The project was implemented in two phases. In the first phase, the genome was mapped and categorised. In the second, analyses of which parts of the genome are translated into proteins and the interaction with genes were performed. One of the objectives was to compare the microbiome of healthy individuals compared to that of the sick. Information about human microbiome can lead to new diagnostic techniques and treatments for a variety of diseases in humans.

The HMP project is a milestone for research into the microbiome

HMP funded by the NIH Common Fund between 2007 and 2016

Project in two phases

### Important projects

Three major projects have received research grants, which are intended to drive HMP forward. One consists of a research team between Stanford University and Washington University, who are examining microbes in the stomach, intestines, and nose. The purpose was to see changes in certain microorganisms in, for example, viral infections, something that can trigger diseases such as diabetes.

Further research has also been carried out by the Broad Institute, in collaboration with the Harvard School of Public Health. This research intends to provide a more detailed and functional directory of microbiota in the stomach and intestines of the healthy, as well as patients with IBD. This disease includes Crohn's disease and colitis, chronic colitis.

A third project has been carried out by Virginia Commonwealth University, which investigates how bacteria play a role in women's health, especially pregnant women and in cases of premature births.

According to current research, diseases such as type 2 diabetes, IBD, Alzheimer's disease, and various types of cancer, can be traced to changes in the microbiota in the human body's stomach and intestines.

Subsequent to the last three follow-up projects after HMP, research has gained momentum, and a large number of clinical studies have been started in order to develop new drugs.

Continued research at American universities

More projects drive knowledge forward

Research is gaining momentum

### Life Science companies within the microbiota field

#### **MANGOLD - MICROBIOTA COMPANIES**

Listed company	Country	Operations	Market value (SEK)
Seres Therapeutics	US	Drug development in the human microbiome	3 667
Evelo Biosciences	US	Drug development in the human microbiome	1 253
Finch Therapeutics	US	Drug development in the human microbiome	1 191
4D Pharma PLC	UK	Drug development in the human microbiome	1 143
Microba	AUS	Test-kit for microbiome	540
BiomX	ISR	Drug development in the human microbiome	439
Carbiotix	SWE	Foodtech to improve intestinal health	109
Snitt			1 192
Genetic Analysis	NOR	Diagnostic tests in human microbiome	78

Source: Mangold Insight Infront

**Seres Therapeutics** is a company from the US, listed on Nasdaq in 2019. The company has received funding from both the Mayo Clinic and Nestlé Health Science. The company develops drugs in areas such as infection and immune systems, with candidates for ulcerative colitis and other stomach diseases.

**Evelo Biosciences** is listed on Nasdaq and develops drugs in immunological diseases. The company develops drugs that can be taken orally and should be able to treat inflammatory diseases, such as eczema, IBD, RA and asthma.

**Finch Therapeutics** is listed on Nasdaq and has a number of projects relating to the stomach and intestines. The company has collaborated with Takeda in two projects aimed at ulcerative colitis and Crohn's disease. One project has reached phase 3 and is within C. difficile.

**4D Pharma** is a British company listed on AIM and Nasdaq as ADS. The company develops drugs in the field of Biotherapeutics, i.e. substances that are developed by living organisms to treat diseases. The company has six different clinical programmes ongoing. The company has a collaboration with Merck & Co (MSD).

**BiomX** is listed on Nasdaq and is a so-called Phage Therapy company (Bacteriophage). The company uses viruses to treat infections caused by bacteria. The company has four projects, of which three are in clinical phase, and one is within IBD.

**Carbiotix** is listed on Spotlight. It is a company founded in 2014 in Lund and has developed LinkGut, a test platform for gastrointestinal health. With the LinkGut service, users will be able to achieve better control of their intestinal health in combination with prebiotic fibre.

**Microba** was listed in April 2022 on ASX in Australia. The company has attracted capital from a number of investors, including American Ginkgo Bioworks in connection with the IPO. Microba has developed a test that is distributed by Synlab within the EU and Genova Diagnostics in the US.

### Unlisted companies in the microbiota field

**Microbiotica**: is an unlisted company from Cambridge in the UK. The company has ongoing projects within LBT (Live Bacterial Therapeutics). The projects are undergoing a preclinical phase, and are within the areas of immunooncology and ulcerative colitis. The company received financing from Flerie Invest, a Swedish investment company in life sciences, of MEUR 50 in March 2022, in a consortium that also included Chinese Tencent. The purpose of the investment was to finance clinical studies, phase 1b, for microbiota projects MB097 (cancer) and MB310 (UC).

**Enterome**: a French unlisted company focused on drug development in microorganisms and the immune system. The company has drug candidates mainly for cancer, but also for IBD, Crohn's disease, and food allergies. Enterome has a collaboration with Takeda. A joint venture has also been formed with Nestlé, Microbiome Diagnostics Partner (MDP). Nestlé invested MEUR 20 in this project, the aim of which was to develop diagnostic products for IBD and liver diseases (NAFLD and NASH). No news on possible successes of this joint venture has been announced. The company also has a collaboration with Bioaster, a research lab in Lyon France in microbiology which specialises in microbiota.

**Ferring Pharmaceuticals**: a private company with Swedish roots, but now located in Switzerland. The company has on several occasions acquired companies in microorganisms. Rebiotix, one of these, is an American company that was acquired in 2018 with projects in the clinical phase. A phase 3 study is underway with a candidate against C. difficile. It is a bacterium that can cause severe diarrhoea.

**Vedanta Biosciences:** is a private company from Boston in the US, that develops drugs for diseases of the stomach and intestines, as well as various solid tumours. The company raised MUSD 68 in 2021 to fund studies with an LBP to prevent C. dificile. The company's collaboration with Bristol Myers-Squibb in a project with Opdivo did not turn out well.

**Second Genome**: is an unlisted company from San Francisco in the US. The company researches microorganisms and has been around since 2010. Its programme consists of projects in IBD and solid cancer.

**Exeliom**: is a private French company with projects within IBD. One drug candidate for Crohn's disease has come the furthest and will undergo clinical studies.

**Goodgut**: is a Spanish company with diagnostic tests for diseases of the stomach and intestines.

**Ysopia**: a private French company that will conduct phase 2 studies with live bacteria, Christensenella minuta, in order to treat obesity.

**Eligo Bioscience**: a private French company that develops antibiotics to treat microbiome-related diseases and which are associated with bacteria.

### Intestinal flora (Gut microbiota)

The intestinal flora is an ecosystem of bacteria and microorganisms that forms an important part of our immune system and accounts for a large part of the body's metabolism. There are a large number of bacteria and other microorganisms (microbiota) in the human body. Most are essential, but there are also some that are harmful. Microorganisms can be viruses, bacteria, parasites, yeasts or moulds. Without these microorganisms, humans would quickly become ill. About 80 percent of the bacteria that live in the body are found in the intestinal system. Many of the most common intestinal diseases are due to a disturbed balance of microbiota.

### **Dysbios**

Dysbiosis means changes in the microbiome that can adversely affect health. In general, dysbiosis means an imbalance in the intestinal flora. Dysbiosis has been linked to several different diseases, such as IBS, allergies, and obesity. Human intestines contains billions of bacterial cells and more than a thousand different bacterial species. Normal intestinal microflora has several major bacterial divisions. The larger and dominant ones are Bacteriodetes and Firmicutes.

The intestines contains bacteria that are both protective and can be harmful. In healthy individuals, a homeostatic balance prevails. Homeostasis includes mechanisms needed for continuous monitoring and control of certain conditions, such as temperature and fluid balance. In dysbiosis, an imbalance occurs with either overrepresentation or a lack of bacteria.

### Inflammatory Bowel Disease (IBD)

These diseases include Ulcerative colitis, Crohn's disease, and unclassified colitis. IBD is characterised by chronic inflammation of the intestinal mucosa. The cause of the diseases has not yet been fully identified. It usually begins between the ages of 15-40, and goes into remission, with periods of long or no disease activity.

**Ulcerative colitis** (inflammation of the colon), is inflammation that attacks the rectum or colon. The most common symptoms are diarrhoea, with varying amounts of blood and mucus in the stool. The disease usually creeps in with relatively mild gastrointestinal problems for a period before it breaks out and becomes acute.

**Crohn's disease** is a chronic inflammatory bowel disease that occurs in the gastrointestinal tract. Diagnosis is usually made with rectoscopy, colonoscopy, X-ray, and blood and stool samples. In about 10 percent of cases, it is difficult to differentiate between ulcerative colitis and Crohn's disease, as many symptoms are the same. Treatment is by means of medication. The disease cannot be cured, however treatment aims to keep it under control. Surgery or stoma may be appropriate in some cases.

**C. difficile** (Clostridioides difficile) is a bacterium whose spores can survive for a long time, and are easily spread and difficult to eliminate. Problems with C. difficile usually occur after an antibiotic treatment upsets the normal intestinal flora. Problems with diarrhoea are common.

**Irritable Bowel Syndrome (IBS)**, affects patients who have suffered from a hypersensitive or easily irritated bowel for at least three months. IBS is a functional gastrointestinal disorder, which means that it cannot be indicated with samples or examinations. IBS is a common disease that is characterised by abdominal pain and stool disorders, but where knowledge of the causes is lacking. Diagnostic criteria for IBS consist of recurrent abdominal pain. There is no cure for IBS, however, symptoms can be relieved. Diet becomes important for these patients, who receive help from a dietitian.

**SIBO** (Small Intestinal Bacterial Overgrowth), overgrowth of bacteria in the small intestine. Bacteria that are supposed to stay in the large intestine have crept into the small intestine. The reasons for this can be the use of antibiotics, a diet rich in sugar, the use of drugs for acid reflux, and heartburn. Symptoms include abdominal pain and diarrhoea as well as decreased nutritional intake.

**NAFLD** (Non-alcoholic Fatty Liver Disease), fatty liver is the most common disease, with a global prevalence of 25 percent, and is an increased inflow of fatty acids to the liver. This can occur due to an increased intake of fat with the diet, however, insulin resistance is the main cause.

**NASH** (Non-alcoholic steatohepatitis), inflammation of the liver that can lead to cirrhosis and the development of liver cancer.

**Type 2-diabetes**, difficult to keep blood sugar levels in the blood low enough. The body's ability to produce insulin is insufficient. Studies have shown that there is a link between the intestinal flora and the development of type 2 diabetes. The type 2 diabetes market is expected to grow to USD 59 billion by 2025, according to Global Data.

#### Glossary:

Microbes: collective name for microorganisms such as bacteria, fungi, and viruses.

Microbiota: the microbes that are found in a certain place form a microbiota.

Microbiome: the genes of these organisms.

Prebiotics: dietary fiber that becomes a nutrient for bacteria in the intestines.

Probiotics: living microorganisms that can provide health benefits when ingested.

Fermented food: food that contains lactic acid bacteria, inhibits and kills unwanted bacteria. Increases the absorption of important vitamins and minerals.

Biomarkers: should be measurable and quantifiable biological parameters that indicate health-related assessments of, for example, disease risk.

# Genetic Analysis - SWOT

### **Strengths**

- Technological lead
- Few competitors
- Experienced management

### Weaknesses

- Company in an early phase
  - Low sales volumes
    - Loss generating

SWOT

### **Opportunities**

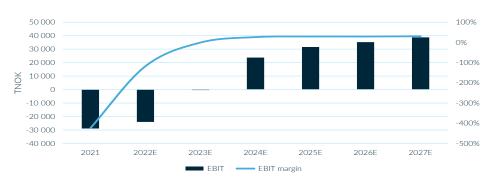
- First mover advantage, take market share
  - Attract knowledgeable personnel
    - Scalable business model

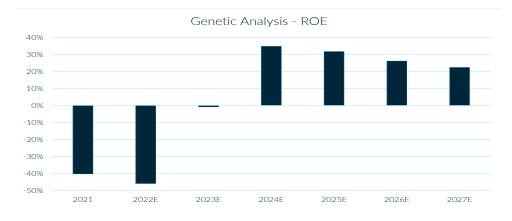
### **Threats**

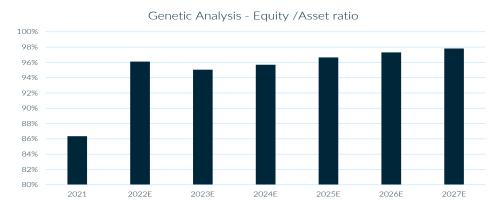
- Takeover
- Lack of capital
- Hesitant market



Genetic Analysis - Operating profit and margin







# Genetic Analysis - Income statement

Income statement (TNOK)	2020	2021	2022E	2023E	2024E	2025E	2026E
Revenues	7 754	13 379	21 400	54 040	91 168	109 202	122 186
Gross profit	6 727	12 098	15 280	40 250	68 626	82 151	91 889
Staff costs	-16 426	-22 835	-23 922	-23 922	-27 185	-32 621	-38 058
Other operating expenses	-6 052	-13 602	-10 810	-11 891	-13 080	-14 388	-15 826
Depreciation	-6 202	-4 531	-4 592	-4 842	-4 658	-3 561	-2 792
Operating result	-21 953	-28 870	-24 044	-406	23 704	31 581	35 212
Operating margin	-380%	-425%	-118%	-1%	26%	29%	29%
Net interest	183	135	44	44	44	44	44
Profit after net financial	-22 136	-29 005	-24 088	-449	23 660	31 538	35 168
items							
Taxes	0	0	0	0	O	-6 625	-8 831
Net profit	-22 136	-29 005	-24 088	-449	30 285	40 368	45 015

Source: Mangold Insight

Balance sheet	2020	2021	2022E	2023E	2024E	2025E	2026E
Assets							
Cash & bank balances	24 194	46 810	18 260	456	4 602	33 079	69 482
Accounts receivable	1 930	8 419	16 767	43 595	74 111	88 933	99 605
Inventory	763	1 885	2 367	168	378	618	741
Fixed assets	28 647	27 610	25 894	19 369	15 527	11 869	9 308
Total assets	45 590	55 619	83 490	54 564	59 955	91 199	132 061
Liabilities							
Accounts payable	7 591	9 968	671	1 511	2 470	2 964	3 320
Liabilities	1 405	1 432	1 459	1 459	1 459	1 459	1 459
Total liabilities	8 996	11 400	2 130	2 970	3 929	4 423	4 779
Equity							
Restricted equity	46 623	99 871	104 303	109 303	109 303	109 303	109 303
Unrestricted equity	0	-27 781	-51 869	-52 318	-22 034	18 335	63 350
Total equity	46 623	72 090	52 434	56 985	87 269	127 638	172 653
Total liabilities and equity	55 619	83 490	54 564	59 955	91 199	132 061	177 432

Source: Mangold Insight

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Mangold Insight grades its share recommendations over a 12-month period, according to the following structure:

Buy – An upside in the share of at least 20%

Increase - An upside in the share of 10-20%

Neutral - An upside and downside in the share of 0-10%

Decrease - A downside in the share of 10-20%

Sell - A downside in the share of at least 20%