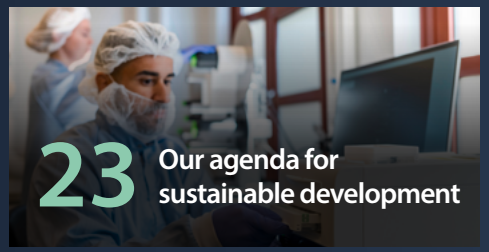
gradientech

Annual Report 2024

Precision medicine, for a sustainable world.

Contents



This is an interactive and clickable PDF
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Introduction

Gradientech is at the forefront of ultra-rapid antibiotic susceptibility testing (AST) and is helping improve the treatment of serious infectious disease. QuickMIC® is the fastest market-approved diagnostic system for determining phenotypic antibiotic susceptibility directly from blood cultures.

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Gradientech in brief

Gradientech brings next-generation diagnostics to the patient

Gradientech is a Swedish diagnostics company that develops, manufactures, and sells next-generation solutions in infectious medicine. Our market-approved QuickMIC® system has positioned us as a world leader in ultra-rapid antibiotic susceptibility testing (AST), helping sepsis patients with blood infections receive specific guidance on the right antibiotics at the right dose, quickly. This helps save lives, reduce healthcare costs, and lower the spread of antibiotic resistance in society – one of the greatest global health threats of our time. Our strategic focus is on the sale of instruments and associated tests to establish the QuickMIC system for routine diagnostics in clinical microbiology laboratories in hospitals across Europe. Following FDA clearance, we plan to launch QuickMIC for diagnostic use in the U.S. market together with our commercial partner, Hardy Diagnostics.

QuickMIC® in brief

The market's fastest AST system

QuickMIC® diagnoses which antibiotics a patient with bacteria in the blood should be treated with and identifies which antibiotics the bacteria are resistant to. By determining quantitative resistance values in just 2–4 hours, QuickMIC is currently the fastest AST system on the market for determining susceptibility directly from blood cultures. Its patented technology ensures unique precision, which, combined with the short test times, provides optimal conditions for precision diagnostics and rapid, individualised antibiotic treatment decisions for sepsis patients.

The design of the system with modular instruments makes it scalable and thus attractive to both small and large hospitals, with the possibility of sales without public tender processes. QuickMIC has received top industry design awards and has a prioritised review path with the US FDA through its breakthrough device classification.

Fastest

QuickMIC is the today fastest market-approved diagnostic system for antibiotic susceptibility testing with its 2-4 hours test time from positive blood cultures.

Modular

Up to 12 instruments can be stacked in a space-efficient way and controlled from a single computer – the hospital lab selects capacity and expands with the number of instruments based on test needs.

Precise

QuickMIC® is based on a technology platform that generates more precise and accurate results than other AST methods. By using real-time data without truncation, we are building the foundation for personalised antibiotic dosing in the future.

Milestones achieved in 2024

MARCH

First commercial evaluation in Sweden

In March, Gradientech's distributor for Sweden, Triolab AB, started its first commercial evaluation of the QuickMIC® system at Kalmar County Hospital. At the same time, Gradientech initiated a prospective observational study with QuickMIC® in urosepsis in collaboration with Örebro University Hospital.

APRIL

QuickMIC® results presented at ESCMID Global

Six abstracts with results from QuickMIC® studies were accepted to be presented at ESCMID Global 2024 in Barcelona, Spain, the world's largest congress for clinical microbiology and infectious diseases.

MAY

QuickMIC® is implemented in clinical practice in Eastern Europe

Gradientech's distributor Biomedica Medizinprodukte GmbH installed QuickMIC® for clinical use at a university hospital in Central Eastern Europe. The hospital thus became the first customer to use the system for ultra-rapid AST in its routine diagnostics.

JUNE

Successful preclinical evaluation in the US

Results from the preclinical evaluation of QuickMIC® at the Medical College of Wisconsin and the University of North Carolina were presented at the ASM Microbe 2024 conference in Atlanta, Georgia.

SEPTEMBER

Clinical studies for 510(k) clearance in the U.S.

In September, Gradientech initiated clinical 510(k) studies in the U.S. with the QuickMIC® system. The studies include antibiotic susceptibility testing of gram-negative bacteria from isolates and blood cultures and are being conducted at reputable hospitals.

OCTOBER

Scientific article on QuickMIC® published

A scientific article on the QuickMIC® system was published in October in the highly ranked Journal of Clinical Microbiology. The article describes the results from the regulatory clinical study that forms the basis for CE marking according to the new IVD Regulation.

OCTOBER

Hardy Diagnostics becomes commercial partner in North America

In October, Gradientech entered into an exclusive partnership with Hardy Diagnostics for the commercialisation of the QuickMIC® system in the U.S. and Canada. Hardy Diagnostics has also invested in Gradientech and is now one of the company's major shareholders.

NOVEMBER

QuickMIC® installed in Italy

In November, Gradientech's Italian distributor a.d.a. implemented the QuickMIC® system for routine clinical use at Molinette Hospital in Turin, one of Europe's largest university hospitals.

CEO statement

First routine customers in Europe and targeting the U.S. market

Accelerated efforts are needed to achieve our goals

"Accelerated efforts are needed to achieve our goals," states the ECDC, the European Centre for Disease Prevention and Control, in its report on the development of antibiotic resistance, published at the end of 2024.

Each EU country reports annually the number of hospitalised patients with blood infections caused by bacteria resistant to different antibiotic groups. The ECDC then compiles this data. The European Union's goal is to reduce antimicrobial-resistant infections by 20 percent by 2030, compared to 2019. Half the time has now passed, but we have not seen a reduction.

In its report, the ECDC concludes that we have very little chance of achieving the target by 2030 and emphasises the importance of implementing rapid diagnostics in hospitals to enable optimal use of antibiotics.

Unless stronger measures are taken, we will not see a decrease – rather, a continued increase in infections with resistant bacteria, an even greater burden on the healthcare system and an escalating number of deaths.

QuickMIC® in routine diagnostics in 2024

The resistance situation is currently at its worst in Southern and Southeastern Europe. It was therefore not surprising that a Romanian university hospital became the first to implement the QuickMIC system in its routine diagnostics. In 2024, more hospitals followed, and in addition to Romania, the QuickMIC system is now used in clinical practice in hospitals in Italy and Germany for ultra-rapid antibiotic susceptibility testing of patient samples in their daily routine diagnostics. In Italy, two additional hospitals, and in Bosnia and Herzegovina, the first, are now implementing our system in their routine diagnostics as of April.

So, which of Europe's approximately 3,000 hospitals are at the forefront and are implementing rapid AST diagnostics, and specifically the QuickMIC system – the fastest of the fast? They share a common trait: they are university hospitals, known for being leaders in adopting new technology. Most of these hospitals are located in countries with high levels of antimicrobial resistance, where rapid AST diagnostics can be truly lifesaving for the patients.

We already see among our first hospital customers the great advantage of our modular instrument design. QuickMIC offers an attractive solution for both smaller hospitals, testing around 200 samples per year, and larger hospitals with a sample flow of several thousand samples per year. Thanks to its setup with small, cost-effective instrument modules, hospitals have been able to implement the system through faster, direct tender processes.

Demo studies as part of the sales process

Another crucial advantage of smaller, cost-effective instrument modules is the flexibility they offer when introducing a new diagnostic solution. The sales process for diagnostic products differs markedly from that for pharmaceuticals. When a diagnostic product receives regulatory approval, the market is not immediately open – hospitals first want to evaluate the system in their own environment before making a purchase decision.

The less well-known the supplier and the newer the product on the market, the more extensive the evaluation studies become. We call them demo studies. Here, the advantage of the QuickMIC system's modular design becomes especially clear, as a demo study can be conducted with just a single instrument module, meaning less capital is tied up per study. Our goal in the sales process is to limit the length of demo studies and shorten the time from the first customer contact to the purchase decision. In the long term, the ambition is for QuickMIC to become so established that customers either pay in full for demo studies or make decisions without needing one.

Throughout the year, we have trained several of our distributors so that they can install and conduct demo studies themselves. We have also established a clear framework for the scope and duration of the studies. Our Distributor Certification Program is another step in this direction – becoming a certified QuickMIC installer and application specialist is an achievement to be proud of!

Hardy Diagnostics as commercial partner for the U.S. market

In the autumn of 2024, we signed a distribution agreement with Hardy Diagnostics for the U.S. market. This gives us a strong commercial partner capable of paving the way for QuickMIC in one of the world's largest diagnostic markets.

In connection with the agreement, Hardy Diagnostics invested in Gradientech and is now one of our major shareholders. Founded by Jay Hardy in the 1980s, Hardy Diagnostics is a well-established player in American clinical microbiology. The company operates two production facilities, primarily for manufacturing growth media and consumables for the microbiology market, as well as nine distribution facilities across the United States.

Gradientech and Hardy Diagnostics have established strong cooperation, and we are planning activities to prepare the market – including demo studies at reputable hospitals even before QuickMIC is FDA-cleared.

Clinical studies for market approval in the U.S.

Throughout the year, we completed the development and began production of the antibiotic panel adapted for the U.S. market. In the autumn of 2024, we started the clinical studies that will form the basis for the FDA applications. The studies include both bacterial isolates and blood cultures, with the aim of reaching a broad market. In early 2025, the third and final hospital joined the study, and our goal now is to complete all testing and submit the applications during 2025.

New Sales Manager based in Germany

In March 2025, we welcomed Mark Lischeid as Gradientech's new Sales Manager Central Europe, based in Germany. Mark has extensive experience in clinical microbiology and most recently worked at the Belgian diagnostics company Biocartis.

Germany is one of our priority markets for direct sales. Here, we have both hospitals that already use QuickMIC in their routine diagnostics, as well as others conducting demo studies. Mark will play a central role in our sales efforts in Central Europe, with a particular focus on Germany. I would like to extend a warm welcome to Mark.

I wish you all a nice spring and hope to see you at Gradientech's annual general meeting here in Uppsala on May 21.

Uppsala, April 2025

Sara Thorslund
CEO of Gradientech

Recommended further reading on the prevalence of antibiotic resistance

Visit the ECDC website and database
https://atlas.ecdc.europa.eu/

Market

Sepsis and antibiotic resistance are two global, time-critical challenges for both individuals and society, and they are high on the world's agenda. Innovation and the implementation of new diagnostic solutions that can quickly guide targeted treatment and reduce antibiotic misuse are important contributions. These advancements can save lives, improve patient outcomes, and reduce healthcare costs.

Sepsis >
Antibiotic resistance >
Drivers for implementing rapid AST >
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Sepsis

Sepsis affects nearly 50 million people throughout the world each year, and more than 11 million of these do not survive.[1] It is currently the most common cause of death among critically ill patients in hospitals, with mortality exceeding 45% for certain patient groups. Being able to quickly determine the optimal antibiotic for the individual patient can save lives and reduce the risk of permanent damage. Sepsis is also a diagnosis that generates high healthcare costs.[2] In the United States alone, the cost of care related to sepsis amounts to $62 billion annually.[3]

Sepsis can be described as a whole-body inflammation, and in the vast majority of cases, it is caused by bacteria. It usually starts with a local infection, such as pneumonia, urinary tract infection, or wound infection, or as an infection resulting from surgery. In many cases of sepsis, bacteria have entered the bloodstream and can be detected through blood tests and subsequent blood culture. Antibiotic susceptibility testing of the bacteria in the blood is crucial for determining which antibiotic treatment will be effective for the patient, which becomes especially important in large parts of the world where bacteria have developed resistance to several available antibiotics.

11
million die of sepsis every year

34,135
euros, the median cost of care for a sepsis patient in Europe

#1
most expensive diagnosis to treat, for example in the U.S.

1. K. E. Rudd et al., GK. E. Rudd et al., Global, regional, and national sepsis incidence and mortality, 1990-2017, The Lancet, Vol 395, Issue 10219 (2020)
2. Van den Berg M et al., Hospital-related costs of sepsis around the world: A systematic review exploring the economic burden of sepsis, Journal of Critical Care, Vol 71 (2022)
3. Buchman TG, Simpson SQ, Sciarretta KL, et al: Sepsis Among Medicare Beneficiaries: The Methods, Models, and Forecasts of Sepsis, 2012-2018. Crit Care Med 2020; 48:302-318

Antibiotic resistance

An increasing number of bacteria are becoming resistant to antibiotics. Antibiotic resistance is sometimes referred to as the silent pandemic – it spreads without being visible to the eye and significantly affects the healthcare system's ability to treat bacterial infections. This, in turn, leads to an increase in the number of hospital-related infections, blood infections[4] and sepsis cases, longer and more expensive hospital stays, and a greater risk of permanent disability in patients.[5] Antibiotic resistance also results in higher costs to society.

Being able to quickly determine which antibiotic is most effective for the individual patient and ensuring that the right treatment is crucial for antibiotics to remain effective in the future.[6] This is a major and important societal challenge that requires initiatives at both global and national levels.

1,000
billion USD in increased annual global health-care costs by 2050 compared to today, due to antibiotic resistance

2015
the WHO adopted a global action plan for combating antibiotic resistance

20-50%
of sepsis patients currently receive incorrect initial antibiotic treatment

4. Bakteriemi är ett sjukdomstillstånd där patienten har närvaro av levande bakterier i blodet
5. Antimicrobial resistance – The Silent Pandemic, Citi GPS: Global Perspectives & Solutions, Dec 2022
6. Kang, C.-I., et al. Antimicrobial Agents and Chemotherapy, Vol 49, 2005.

Drivers for implementing rapid AST

In 2017, the WHO made strategies against sepsis a key priority for the next decade, with a clear focus on minimising misdiagnoses and developing diagnostics.[7] By administering the right treatment in a timely manner, the chances of survival for sepsis patients increase.[8] The WHO also emphasises the need for diagnostic solutions that can quickly provide guidance and reduce unnecessary and incorrect use of antibiotics. The trend toward individualised treatment using precise and accurate diagnostic solutions, commonly referred to as precision medicine, also applies to infectious diseases. This is now evident in ongoing tenders at European hospitals for the implementation of rapid antibiotic susceptibility testing of sepsis samples. Additionally, an increasing amount of study data is showing quantifiable effects as a result of introducing rapid susceptibility testing in hospitals.[9]

Improved outcome of antibiotic exposure

The use of diagnostics for rapid susceptibility testing has been shown to result in reduced use of broad-spectrum antibiotics in favor of narrow-spectrum antibiotics, shorter treatment periods with fewer antibiotic, and more oral rather than intravenous antibiotic therapy.

Shorter hospital stays

Many studies have shown that rapid antibiotic susceptibility testing results in shorter hospital stays, and thus, lower healthcare costs per patient. These shorter hospital stays are the result of reduced illness duration due to the more timely administration of the right antibiotic treatment, and the ability for patients to switch to oral treatment more quickly.

Increased survival

Studies demonstrating an increased survival rate in sepsis patients as a result of the introduction of rapid susceptibility testing are still limited. These studies are complex, with many other factors influencing the outcome, such as the resistance situation in the area where the study is conducted or how well the hospital adapts its workflow to take advantage of faster diagnostic test results. However, an increased survival rate and reduced morbidity among patients are highly likely, though they remain to be proven in studies with large patient populations.

7. Resolution WHA70.7. In: Seventieth World Health Assembly, Geneva, 22-31 May 2017
8. Kumar A et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock, Crit Care Med 2006; 34:1589-96
9. MacVane S H et al., Evaluating the impact of rapid antimicrobial susceptibility testing for bloodstream infections: a review of actionability, antibiotic use and patient outcome metrics, Journal of Antimicrobial Chemotherapy, Vol 79 (2024)

The market for rapid AST

Global market

The global market for antibiotic susceptibility testing (AST) of blood samples is growing and is expected to reach a value of EUR 1.4 billion by 2028. Geographically, the U.S. market accounts for nearly half, valued at EUR 500 million today, and is expected to increase to over EUR 660 million by 2028. The European market, the second largest, represents just over a quarter of the global market and is expected to reach approximately EUR 370 million by 2028.

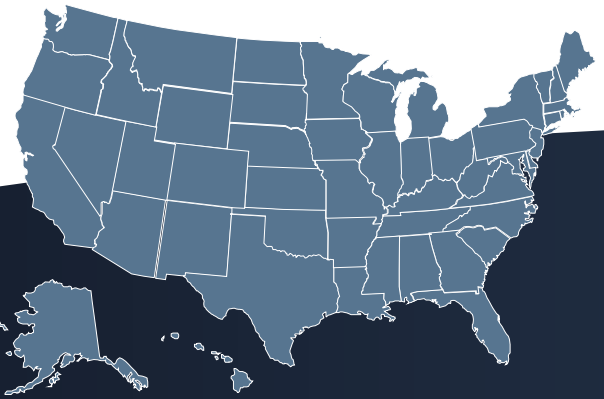
Our addressable market

Gradientech's products are approved for marketing in countries that accept CE-marked diagnostic products, as well as in the UK and Switzerland. Our addressable market is currently Europe, where Gradientech has distributors for Italy, the UK, Ireland, Portugal, the Nordic countries, the Baltics, Austria, Switzerland and several countries in Eastern Europe. Gradientech may also persue direct sales in countries that approve CE-marked diagnostic products where we do not have contracted distributors. With future FDA clearance, the U.S. market will be an important next target for Gradientech. In 2024, we entered into an agreement with Hardy Diagnostics for distribution in the United States and Canada. Hardy Diagnostics is an established and well-known player in the microbiology market since the 1980s with a large portfolio of self-manufactured products. Regulatory clinical studies toward FDA clearance began in the autumn of 2024.

Market players

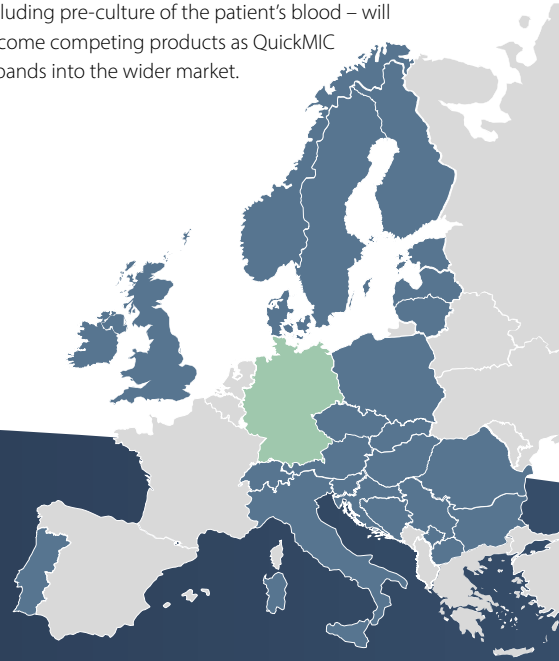
There are a few companies that, like Gradientech, have market-approved diagnostic systems for rapid antibiotic susceptibility testing of bacteria from blood cultures. The test times of these automated systems vary from about 6-7 hours, compared to 2-4 hours for the QuickMIC® system. Four of these systems are FDA-approved and can be sold in the U.S. market.[10]

During early market penetration of QuickMIC, competing products will primarily be other rapid AST systems. The more traditional systems – where the corresponding test times are around 40 hours, including pre-culture of the patient's blood – will become competing products as QuickMIC expands into the wider market.



6,500,000
annual AST tests of bacteria isolated from blood are performed in the United States

4,000
hospitals as the addressable market for QuickMIC® in the U.S. after FDA-clearance



10. S. H. MacVane et al. Evaluating the impact of rapid antimicrobial susceptibility testing for bloodstream infections: a review of actionability, antibiotic use and patient outcome metrics, J of Antimicrob Chemother, Vol 79, (2024)

A market in focus

Italy at the forefront of Europe

Italy is currently the strongest market in Europe for rapid diagnostics in antibiotic susceptibility testing. This is the result of several factors, including Italy's long tradition as a leading research nation in microbiology and infectious diseases, high levels of antibiotic resistance and healthcare-associated infections, policy initiatives, and the widespread implementation of rapid technological solutions that enable the full exploitation of time savings offered by new rapid diagnostics.

Gradientech works together with a.d.a. as our distributor in Italy. A.d.a. is a reputable player in the Italian clinical microbiology market, with a well-established network of contacts at leading Italian hospitals. In 2024, QuickMIC® was implemented in the routine diagnostic workflow at Molinette Hospital in Turin, one of the first hospitals in Europe to do so. Molinette is part of AOU Città della Salute e della Scienza, one of the largest university hospitals in Italy and in Europe, with the mission to provide first-class patient care and conduct top-level research.

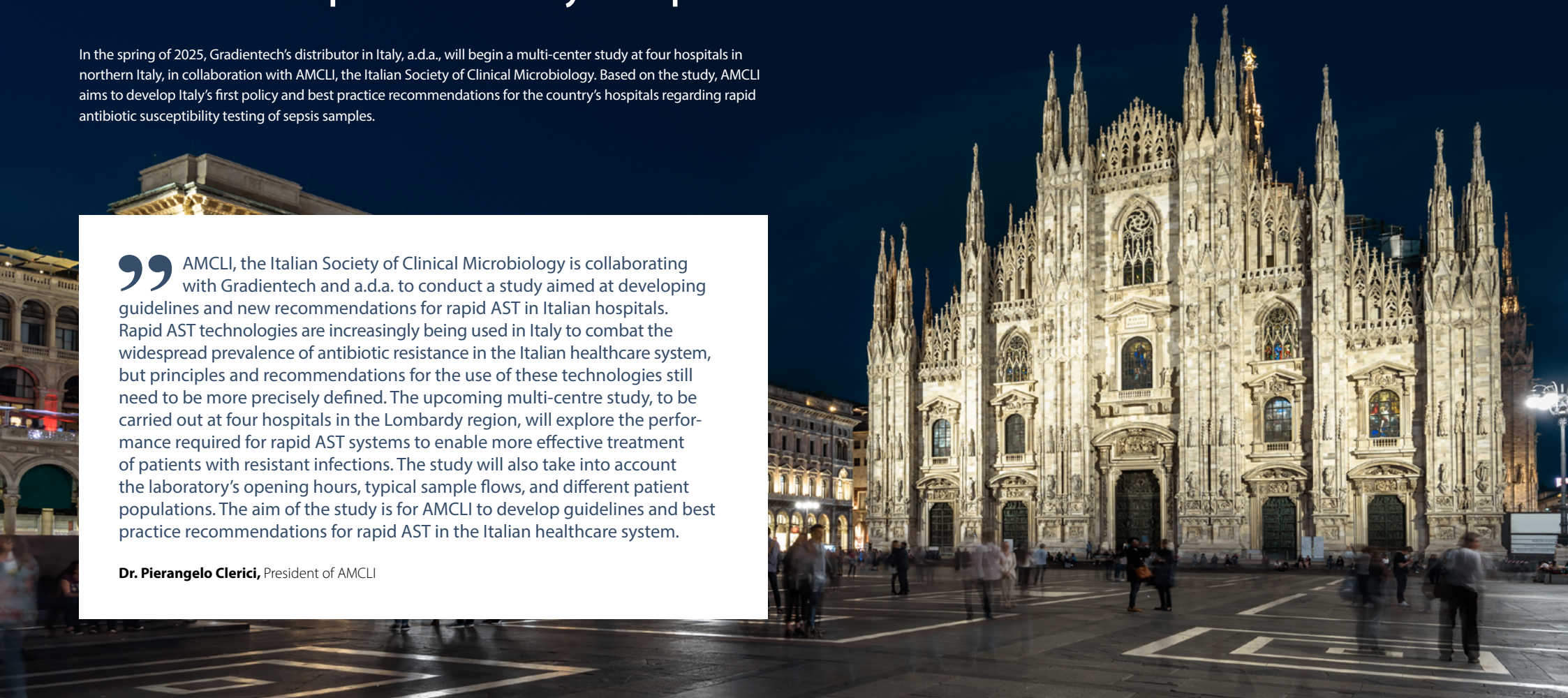
> After a successful evaluation of the QuickMIC system, we are now ready to implement the system in our clinical routine diagnostics. I'm very proud to offer our clinical staff the fastest AST system on the market. Fast and reliable AST results are essential for determining the right treatment for severe infections in critically ill patients.

Prof.ssa Cristina Costa, Head of the Clinical Microbiology Laboratory at the AOU Città della Salute e della Scienza Hospital.

Recommendations for rapid AST

Guidelines and policies for Italy's hospitals

In the spring of 2025, Gradientech's distributor in Italy, a.d.a., will begin a multi-center study at four hospitals in northern Italy, in collaboration with AMCLI, the Italian Society of Clinical Microbiology. Based on the study, AMCLI aims to develop Italy's first policy and best practice recommendations for the country's hospitals regarding rapid antibiotic susceptibility testing of sepsis samples.



> AMCLI, the Italian Society of Clinical Microbiology is collaborating with Gradientech and a.d.a. to conduct a study aimed at developing guidelines and new recommendations for rapid AST in Italian hospitals. Rapid AST technologies are increasingly being used in Italy to combat the widespread prevalence of antibiotic resistance in the Italian healthcare system, but principles and recommendations for the use of these technologies still need to be more precisely defined. The upcoming multi-centre study, to be carried out at four hospitals in the Lombardy region, will explore the performance required for rapid AST systems to enable more effective treatment of patients with resistant infections. The study will also take into account the laboratory's opening hours, typical sample flows, and different patient populations. The aim of the study is for AMCLI to develop guidelines and best practice recommendations for rapid AST in the Italian healthcare system.
>
> **Dr. Pierangelo Clerici,** President of AMCLI

Strategic direction

Gradientech's strategic focus is on the sale of instruments and associated tests to establish the QuickMIC® system for routine diagnostics in clinical microbiology laboratories in hospitals across Europe, with plans to expand into the U.S. market following FDA clearance.

Vision and values ›
Strategies ›

Vision

”Precision medicine – for a sustainable world.”

Our vision is that, with our products, healthcare will take the step toward precision medicine in infectious disease diagnostics, enabling both rapid and individualised treatment of sepsis patients – benefiting the individual patient, as well as promoting the rational use of antibiotics. Together, this contributes to a sustainable future where antibiotics remain an effective treatment option.

Business concept

Our business concept is to develop and offer the healthcare sector groundbreaking diagnostic products that increase patients' chances of survival and quality of life, while reducing healthcare costs.

Strategic focus areas

Our strategic focus is to drive sales of QuickMIC® through direct sales and distributors in the European market and continuously increase the number of instruments used in routine diagnostics in hospitals' clinical microbiology laboratories. In parallel, clinical studies are underway in the U.S. with the goal of a future FDA clearance of QuickMIC for commercialisation in the U.S. market.

- Implementation in routine diagnostics in Europe
- Market approval in the U.S.
- Global marketing strategy
- Quality and sustainability in everything we do

Read more on the following pages

Our values

At Gradientech, we share a common set of values that support our vision: our products should both be ground-breaking for our users and contribute to a more sustainable world. Our values shape our corporate culture and reflect what we stand for as a company.

Driven to impact

We don't just reach goals, we create lasting impact with every step. Together, we deliver.

Open and honest

We believe in clear, open communication and honesty in everything we do.

Pioneers in precision

We challenge the status quo and create solutions that push healthcare forward.

Powered by people

We collaborate and evolve with feedback from our customers, the environment and our team.

Read more in Products and expertise

Strategic focus area

Implementation in routine diagnostics in Europe

In the last two years since the CE marking of the QuickMIC® system, Gradientech, both independently and with distributors, has conducted numerous demo and research studies in hospitals across Europe. The goal of these studies is to allow leading hospital laboratories to evaluate the system's performance and management, with the aim of publishing study data at a minimum, and also to help with decision-making before a purchase or tender process. As is common when launching new diagnostic products, hospital customers typically want to see published data before implementing a new system in their own routine workflow. The decision to introduce new technology into routine diagnostics is also made easier when other hospitals are already using the product. Of the many studies conducted with QuickMIC in 2023, six were accepted and presented at ESCMID Global 2024, the leading congress for clinical microbiologists and infectious disease specialists.

In 2024, QuickMIC and its first gram-negative antibiotic panel were implemented in routine diagnostics at hospitals in several countries, primarily in Eastern and Southern Europe. Several direct tender processes are currently underway at hospitals where demo studies were conducted during the year.

Progress toward routine implementation of QuickMIC®

Market	Distributor agreement signed	QuickMIC® Regulatory Approved	Demo study in hospital	QuickMIC® in routine at the first hospital
United States	✓		✓	
Canada	✓			
Nordic countries	✓	✓	✓	
Baltics	✓	✓		
Germany		✓	✓	✓
Italy	✓	✓	✓	✓
Portugal	✓	✓	✓	
United Kingdom	✓	✓	✓	
Ireland	✓	✓		
Austria	✓	✓	✓	
Switzerland	✓	✓		
Poland	✓	✓		
Czech Republic	✓	✓	✓	
Slovakia	✓	✓		
Hungary	✓	✓	✓	
Romania	✓	✓	✓	✓
Bulgaria	✓	✓		
Slovenia	✓	✓	✓	
Croatia	✓	✓	✓	
Serbia	✓	✓		
Bosnia and Herzegovina	✓	✓	✓	✓
Macedonia	✓	✓	✓	

Strategic focus area

Market approval in the U.S.

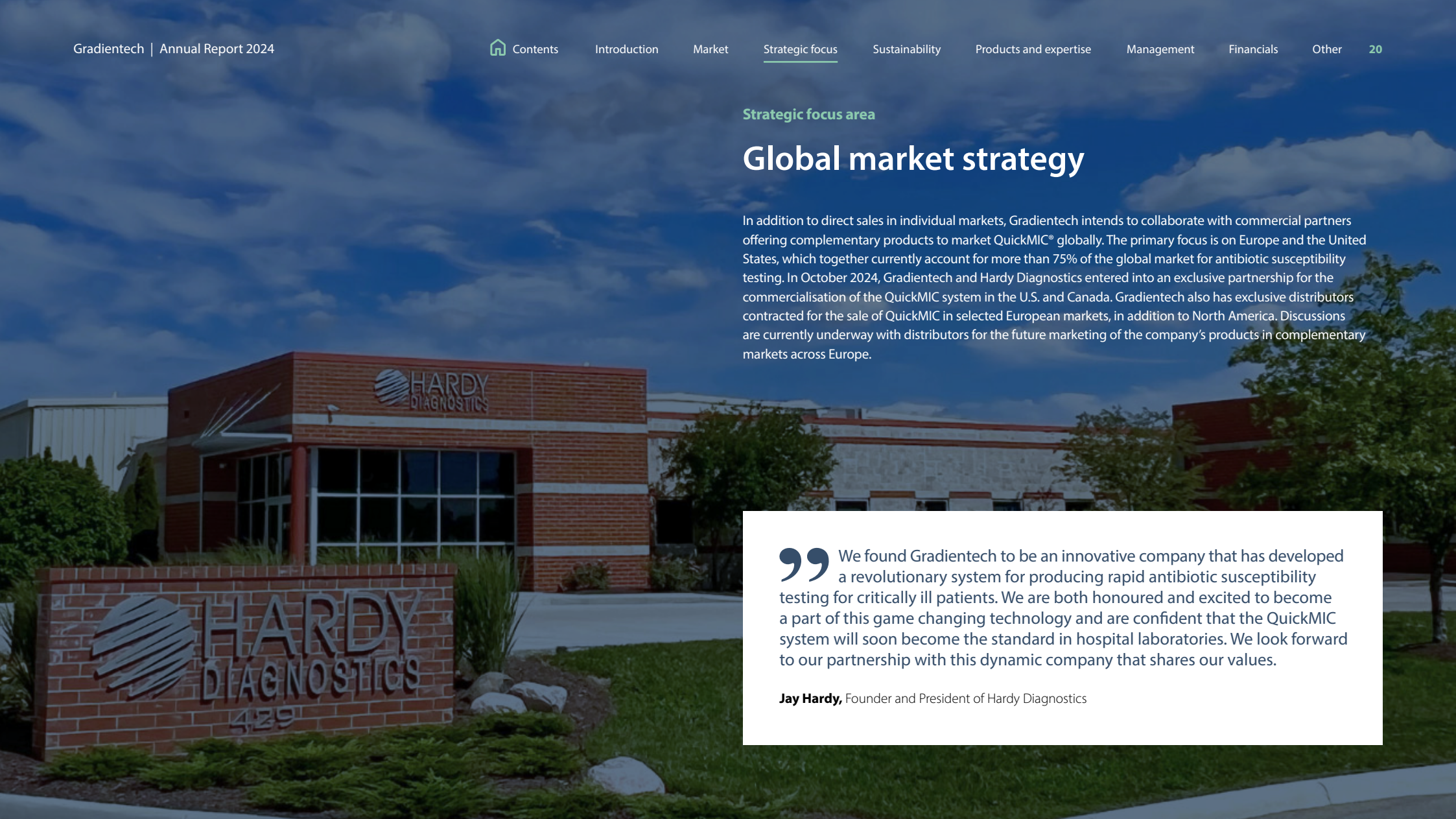
The U.S. Food and Drug Administration (FDA) approves diagnostic products for the U.S. market after reviewing the results of clinical studies, among other factors. Before approval, the FDA may classify a product as a Breakthrough Device if it believes the product is life-saving for patients and demonstrates performance that exceeds existing approved products in the U.S. market. This classification facilitates the path to market approval by allowing the FDA to review the design of the clinical study and by giving the product priority during the review process once the study is completed. QuickMIC® received Breakthrough Device designation in 2023, and the FDA has reviewed the setup of the ongoing clinical studies, which include both bacterial isolates and blood culture samples. Three hospitals in the U.S. are participating in the current clinical study, with the first two hospitals beginning testing in the autumn of 2024 and the third starting in early 2025. Gradientech plans to file both 510(k) applications with the FDA in 2025.

Hardy Diagnostics, as Gradientech's commercial partner, will sell QuickMIC in the U.S. market. Hardy Diagnostics is a well-established player in the microbiology market, with two of its own manufacturing facilities and nine distribution facilities located across the country.*

> Advancements in rapid antimicrobial susceptibility testing hold the potential to revolutionise the fight against infectious diseases, enabling clinicians to make faster, more accurate decisions that improve patient outcomes and help combat the rise of antibiotic resistance.

Prof. Nathan Ledeboer, Director of Clinical Pathology at the Department of Pathology and Laboratory Medicine at the Medical College of Wisconsin, USA. Member of Gradientech's Scientific Advisory Board since 2024.

*https://hardydiagnostics.com/



Strategic focus area

Global market strategy

In addition to direct sales in individual markets, Gradientech intends to collaborate with commercial partners offering complementary products to market QuickMIC® globally. The primary focus is on Europe and the United States, which together currently account for more than 75% of the global market for antibiotic susceptibility testing. In October 2024, Gradientech and Hardy Diagnostics entered into an exclusive partnership for the commercialisation of the QuickMIC system in the U.S. and Canada. Gradientech also has exclusive distributors contracted for the sale of QuickMIC in selected European markets, in addition to North America. Discussions are currently underway with distributors for the future marketing of the company's products in complementary markets across Europe.

> We found Gradientech to be an innovative company that has developed a revolutionary system for producing rapid antibiotic susceptibility testing for critically ill patients. We are both honoured and excited to become a part of this game changing technology and are confident that the QuickMIC system will soon become the standard in hospital laboratories. We look forward to our partnership with this dynamic company that shares our values.
>
> **Jay Hardy,** Founder and President of Hardy Diagnostics

Strategic focus area

Quality and sustainability in everything we do

As a medical device company, Gradientech and its operations are governed by regulatory standards and regulations designed to ensure that the products we develop and produce are safe to use and deliver accurate results. Gradientech operates within a quality management system that has been ISO 13485 certified since 2017, while also being guided daily by our vision of creating precision diagnostics for a sustainable world. We continue to develop our sustainability efforts, both through a deeper understanding of the challenges we face and through the active work of our sustainability team.

The team, consisting of the CEO, CFO, and representatives from production, development, and marketing, works on both short- and long-term sustainability strategies. The team focuses on three key areas: Healthcare, the Team, and Innovation and Knowledge.

Read more in Sustainability

Sustainability – Our three focus areas

Healthcare

The QuickMIC® system's ability to deliver fast and precise results when performing AST on sepsis samples can be crucial both for individual patients and for healthcare from a broader perspective.

The team

As Gradientech grows, it is important that we prioritise the work environment, invest in our employees, and offer opportunities for development. In this way, we can build a strong team that forms the foundation for Gradientech to support healthcare.

Innovation and knowledge

By being at the forefront of innovation and knowledge, we can engage and influence. Through our innovation and expertise, we can contribute both to limiting the spread of antibiotic resistance and to sustainable production.

Healthcare ›
The team ›
Innovation and knowledge ›

Our agenda for sustainable development

The UN's Sustainable Development Goals (SDGs) are a call to action for all parties, including businesses, to work together to improve the lives and conditions of both people and the planet. To achieve these goals, it is important that everyone contributes. At the same time, we live in a world where change is the natural thing, where changes come quickly and where there is a general belief that innovations are the solution to many of our major challenges we face.

Gradientech supports the UN's Sustainable Development Goals. We see our business as an integral part of the solution and work to contribute to these goals through both our long-term strategy and daily operations.

As a starting point in our sustainability efforts, we find Gradientech's key stakeholders – those who affect or are affected by us – such as our end users, employees, customers and distributors. We maintain regular dialogue with our stakeholders to understand their challenges, needs, and priorities. We believe this is one of the most important components in developing our business and advancing our strategic sustainability initiatives.

Our focus areas in sustainability

Based on stakeholder and materiality analyses, we have identified what is important to our stakeholders and where Gradientech has the greatest opportunity to be engaged and make an impact. From these analyses, we have defined three focus areas: **Healthcare**, **the Team** and **Innovation and Knowledge**. Each focus area has a long-term vision and value-generating activities. Starting from the 2023 financial year, we will track the identified KPIs linked to each focus area. These KPIs have annual targets for both the upcoming financial year and the longer term.

Our overall and fourth focus area is with us in everything we do – our "common and long-term vision". We define it as **Partnership**: industrial, financial and academic collaborations that create both innovation and profitability. Gradientech is a long-term partner in the fight against sepsis and antibiotic resistance, where our entire sustainability work is our toolbox in this important and challenging work.

Focus area

Healthcare

The world is currently facing a serious global health challenge, perhaps the most serious of our time – the spread of antibiotic resistance. The healthcare system is dependent on effective antibiotics both today and in the future, and healthcare providers, researchers, and other stakeholders are struggling to find solutions in this important field.

In 2024, we primarily focused on the first European hospitals implementing our QuickMIC® system in their routine diagnostics, and we initiated our clinical studies in the U.S. with the goal of future FDA clearance. We have successfully achieved both of these priorities and will continue to prioritise them in 2025.

In 2025, we will focus on supporting healthcare in both the European and U.S. markets by expanding our field organisation to support clinical studies and ensure successful testing at our customers' sites. We believe that to succeed globally, it is essential that our products are backed by an organisation capable of supporting healthcare around the clock. We will continue to prioritise the development of our support organisation in the coming year.

The KPIs we monitor include, for example, the number of QuickMIC systems implemented in routine diagnostics, the total number of patient samples in completed clinical studies, and the proportion of customer complaints relative to the number of support cases.

Vision

Gradientech's products are the first choice for rapid and precise antibiotic susceptibility testing for sepsis management.

Markets where QuickMIC® is implemented in routine clinical use

Target 2024	**Outcome** 2024 (Outcome 2023)
5#	4# (0#)

3 GOOD HEALTH AND WELL-BEING

Examples of activities carried out during the year

- Clinical studies at leading European university hospitals.
- First hospitals having implemented our system in their routine diagnostics workflow.
- Building of the service and support organisation.

Priorities 2025

- Increase the number of European hospitals in routine clinical use.
- Complete our clinical FDA studies and submit 510(k) applications.
- Conduct multi-center study in Italy.
- Introduce customer complaint measurement and trending.

Targets 2030

- → QuickMIC is used in clinical routine diagnostics in markets in Europe, North America, South America and Asia.
- → Clinical studies prove that our products save lives, lower healthcare costs and reduce incorrect antibiotic treatment.
- → All customers receive fast and adequate technical support – 24/7.

Focus area

The team

Gradientech's most important resource is our employees. As we grow, we must continuously develop our work environment and offer a workplace where all employees can thrive and reach their full potential.

Our overall priority in 2024 has continued to be focused on our long-term project to create Uppsala's most attractive workplace, ensuring that we retain our staff as we grow.

In 2024, we formed a working group – "the Team" within the focus area. Throughout the year, the group has focused on systematically analysing the results of our latest employee survey and implementing measures to further improve our work environment based on these insights.

The working group consists of representatives from various parts of the company and will, during the coming financial year, conduct a new employee survey, analyse and systematically work with the outcome.

The KPIs we monitor include, for example, employee turnover, diversity and the level at which our employees feel inspired at work, an effort we call "Keep People Inspired!"

Vision

Gradientech is Uppsala's most attractive workplace, where everyone feels welcome, and no one needs to look elsewhere to develop.

Employee turnover

Target 2024 **Outcome** 2024 (Outcome 2023)

<10% 12% (12%)

Examples of activities carried out during the year

- Formed "the Team" within the focus area.
- Systematic work with the results of the latest employee survey.

Priorities 2025

- Conduct a diversity and equality analysis.
- Systematic work with the results of our employee surveys with the aim of continuously improving our work environment.

Targets 2030

- Conduct employee surveys annually and work with the results to continuously improve the work environment.
- Maintain employee turnover of no more than 10 percent as the company grows.

Focus area

Innovation and knowledge

In the area of antibiotic resistance, there are high expectations that research and innovation will find solutions to reduce antibiotic resistance globally. The World Health Organization (WHO) and the national action plans of many countries emphasise the need to develop and implement new diagnostic solutions that can quickly guide optimised treatment, thereby reducing the misuse of antibiotics.

At Gradientech, we are at the forefront of innovation in the next generation of diagnostics for infectious diseases. Our QuickMIC® system not only has the shortest test time among rapid AST systems for sepsis samples, but also offers unique measurement precision.

In 2024, we have continued our efforts to actively reduce our environmental impact, focusing on increasing the proportion of bio-based or regenerated plastic in our QuickMIC tests. Another key focus area this year has been to expand our outreach and share knowledge through our various communication channels.

The KPIs we monitor include, for example, our visibility in external channels, and our progress toward becoming a category winnner in our product category "Ultra-rapid and precise AST".

Vision

Gradientech produces and transports products and knowledge worldwide with the lowest possible carbon footprint.

Posts on LinkedIn

Target 2024 >50#

Outcome 2024 (Outcome 2023) 68# (74#)

Examples of activities carried out during the year

- Implemented responsible management of antibiotic waste disposal.
- Implemented a foundation for a learning platform on our website.
- Increased internal knowledge in the area of "Producer Responsibility for Packaging".

Priorities 2025

- Continued work on social media content and further development of our learning platform on the website.
- Continued development work with our QuickMIC® tests to increase the proportion of bio-based or regenerated plastics.
- Reduce the proportion of waste in relation to production volume.

Targets 2030

- More than 400,000 visitors to our website per year.
- ISO 14001 certified.
- "Ultra-rapid and precise AST" is a recognised product category with reimbursement codes in Europe and the U.S.

Products and expertise

Gradientech brings together expertise and experience in areas ranging from development and microbiological testing to production and commercialisation. Our agile product development model includes close collaborations with internationally leading development and manufacturing partners, complementing our own expertise and operations.

Product portfolio >
QuickMIC® >
Patents and trademarks >
Expertise >

Product portfolio

The QuickMIC® system consists of modular instruments with dedicated analysis software and antibiotic-filled test cassettes, which serve as the system's consumables. Each instrument analysis one patient sample at a time against a panel of several antibiotics per test. Currently, the system includes a CE-marked test cassette for gram-negative bacteria, featuring a set of antibiotics that represent common treatment combinations for sepsis patients.

The susceptibility of gram-negative bacteria is almost exclusively diagnosed using growth-based AST methods, whereas gram-positive bacteria can also be tested using molecular diagnostic methods, to a slightly greater extent. However, molecular testing cannot provide information about which antibiotics the patient should be treated with. Therefore, the clinical need for rapid AST of gram-positive bacteria is currently of lower priority, and the market demand is highest for antibiotic panels intended for gram-negative bacteria.

Gradientech intends to complement its existing gram-negative antibiotic panel and build a product portfolio with different panels tailored to markets with varying antibiotic resistance situations. Currently, a second antibiotic panel for gram-negative bacteria is in development, featuring last-resort antibiotics, intended for markets in Southern and Eastern Europe with high levels of resistance in the community.

The antibiotic panel currently undergoing regulatory clinical studies in the U.S. contains a slightly different set of antibiotics compared to the CE-marked gram-negative panel. This difference is due to varying treatment practices in different markets regarding which antibiotics are used to treat patients.

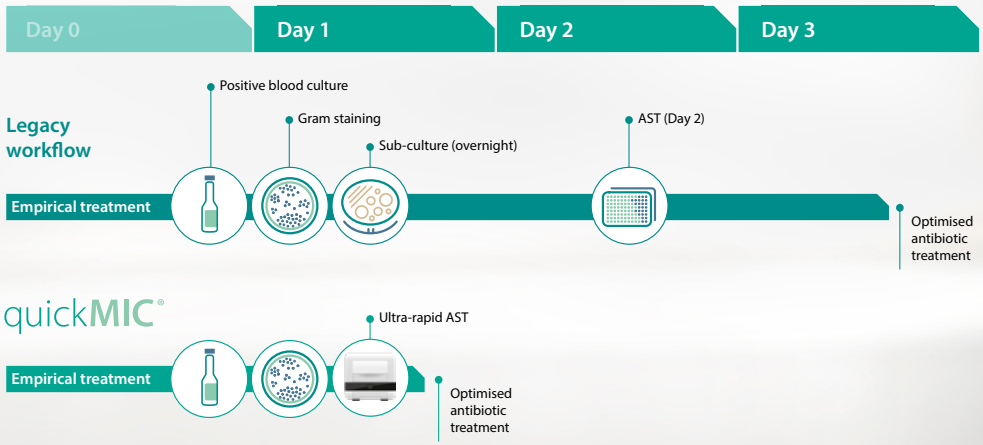
The modular design of the QuickMIC system allows instruments to be stacked for increased capacity, making the system scalable and attractive to both small and large hospital laboratories. The purchase of a few instrument modules can often be made without public tender processes, simplifying and shortening the sales process. In 2025, we plan to launch QuickMIC® CU, a control unit add-on module with an integrated screen and QR code reader, which is currently in development. This product will be optional for the user. The integrated screen solution minimises bench space by replacing the external computer otherwise needed for the instruments.

The QuickMIC system is CE-marked and may be marketed for diagnostic use in Europe, including countries that accept the CE marking, as well as in the UK and Switzerland. The system's antibiotic test cassette and analysis software need to be approved according to the new In Vitro Diagnostic Regulation (IVDR) by May 2027. In 2024, our notified body, BSI, conducted an audit of our quality management system in accordance with the IVDR and is currently reviewing the technical documentation for the products.

QuickMIC® – With the goal of setting a new standard

Gradientech's patented technology used in the QuickMIC® system combines microfluidics with real-time measurement of living cells – a method that allows for the measurement of the dynamic cell responses as bacteria react to stable concentration gradients of different antibiotics. These concentration gradients enable the QuickMIC system to output MIC (Minimum Inhibitory Concentration) values on a continuous measurement scale. This provides unparalleled precision compared to competing AST systems, which are limited to truncated measurements in two-fold dilution increments. In addition to significantly shorter response times compared to other AST systems, the enhanced precision of QuickMIC sets the stage for a new standard in susceptibility testing for better patient care – antibiotic dosing based on precise MIC values.[12]

Antibiotic Susceptibility Testing (AST) and Ultra-rapid AST



12. B. Berinson et al., A multicenter evaluation of a novel microfluidic rapid AST assay for Gram-negative bloodstream infections, Journal of Clinical Microbiology, Vol. 62, No. 10 (2024)

Patents and trademarks

Currently, Gradientech's products within the field of infection disease diagnostics include innovative microfluidics, image analysis and data analysis. Innovative technical solutions that arise in the course of our development work, manufacturing transfers or upscaling of production are continuously reviewed in consultation with our patent attorney to determine whether the innovations are patentable and of strategic importance for the company to seek patent protection. Our latest patent application focuses on predicting antibiotic resistance, or specific resistance mechanism, before the QuickMIC® system outputs the final resistance values for a bacterial sample. This prediction is based on data analysis utilising machine learning algorithms.

Gradientech's trademark portfolio is managed in collaboration with an external trademark agent.

Patents

Title	Country	Status	Description	Valid until
Resistance mechanism prediction	PCT	Pending	Prediction of antibiotic resistance prediction through machine learning	2043-08-29
Adhesive improving coating	PCT	Pending	Improved adhesion between hydrogels and a surface-modified plastic surface	2042-03-27
QuickMIC® cassette	UK/SE/DE/FR/CH/JP	Granted	Design and function of the QuickMIC cassette	2040-04-01
New use of fluidic device	USA (2 patents) /UK/ SE/DE/FR/CH/JP	Granted	Microfluidic system used for rapid AST	2034-07-10

Trademarks

Trademark	Country	Status	Class	Application year
GRADIENTECH	SE	Granted	1, 5, 9 och 42	2010
CELLDIRECTOR	SE/EU/USA	Granted	1, 5, 9, 10	2010
QUICKMIC	SE/EU/USA	Granted	5 och 10	2017

Broad expertise and specialist knowledge

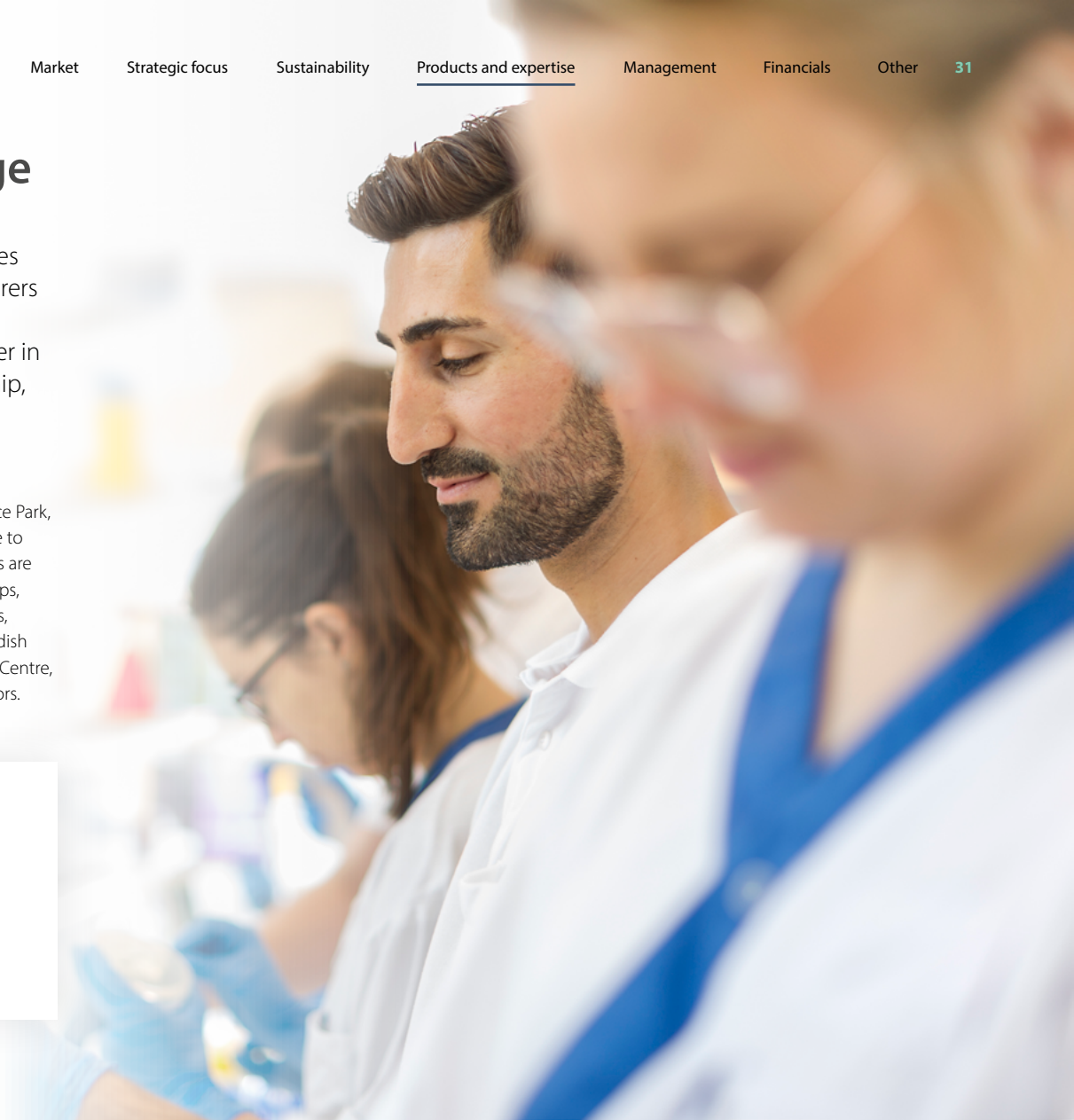
Gradientech is focused on maintaining agility and innovation as we grow in sales and manufacturing. We work closely with our international contract manufacturers on both production scale-up and the transfer of new products to production. Additionally, we collaborate closely with our distributors, often working together in the field during new hospital installations. We also manage studies in partnership, collecting and analysing data from users to build a solid foundation of sales materials that will help convince future customers.

In October 2024, a distribution agreement was signed with American Hardy Diagnostics for the sale of the QuickMIC® system in the U.S. and Canada. Since then, we have had time to build a close collaboration to create the best conditions for a successful market introduction in North America.

Gradientech is headquartered in Uppsala Science Park, one of Sweden's leading innovation hubs, home to several top life science companies. Our premises are adjacent to world-class academic research groups, Uppsala University Hospital's clinical laboratories, the Swedish Medical Products Agency, the Swedish National Food Agency, and Uppsala Innovation Centre, one of the world's top-ranked business incubators.

> At Gradientech, we combine our focus on innovation with an agile, science-driven commercial strategy. Through a customer-centric approach and close collaboration with our international partners, we ensure the delivery of solutions that make a meaningful impact in the market.

AnnaLotta Schiller, Chief Commercial Officer at Gradientech



Our expertise is based on knowledge in four main areas

Business acumen and commercialisation

Our business model focuses on offering unique products that meet a significant global need. We select commercial partners based on their experience, track record, and market knowledge.

System development in diagnostics

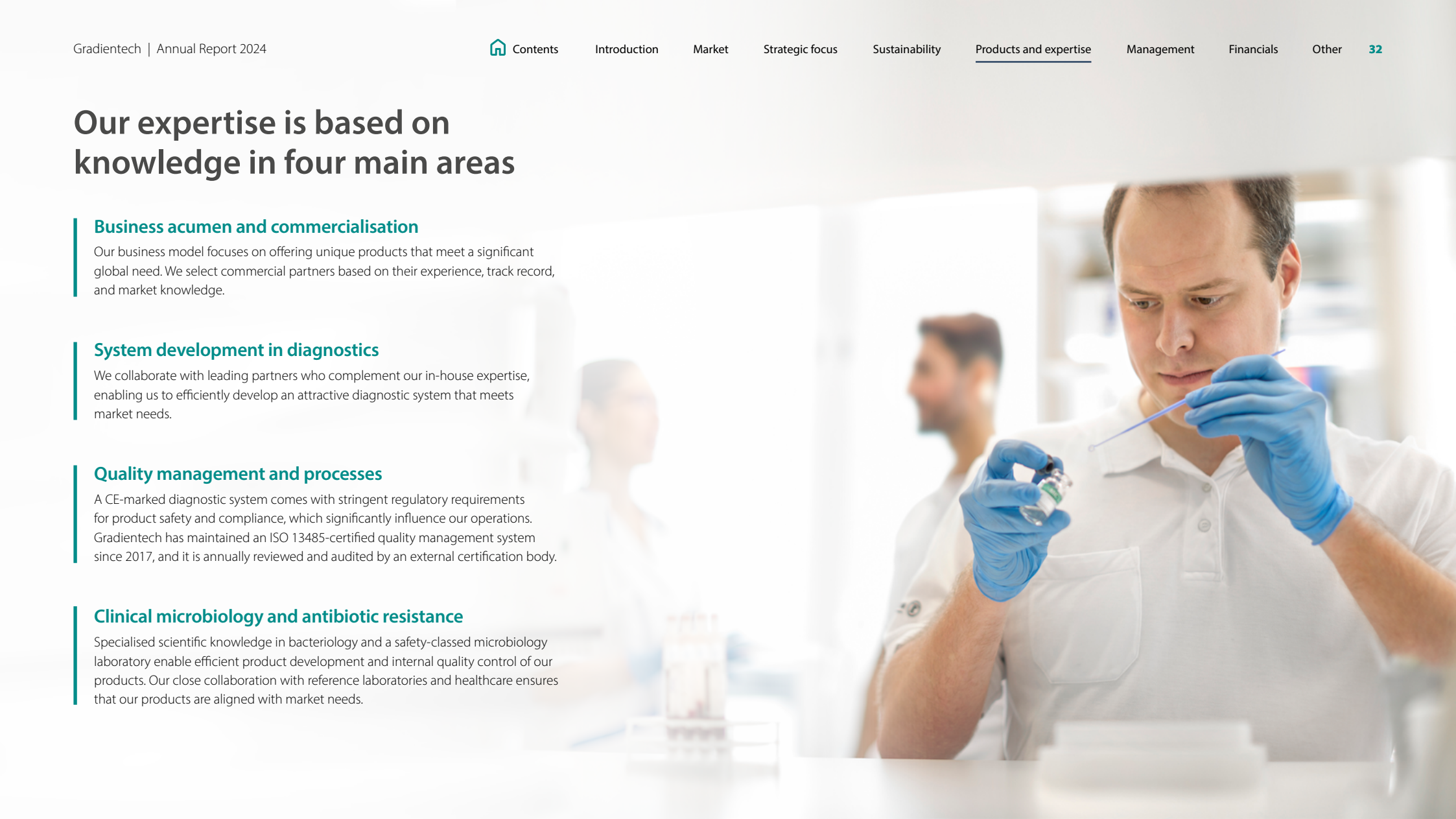
We collaborate with leading partners who complement our in-house expertise, enabling us to efficiently develop an attractive diagnostic system that meets market needs.

Quality management and processes

A CE-marked diagnostic system comes with stringent regulatory requirements for product safety and compliance, which significantly influence our operations. Gradientech has maintained an ISO 13485-certified quality management system since 2017, and it is annually reviewed and audited by an external certification body.

Clinical microbiology and antibiotic resistance

Specialised scientific knowledge in bacteriology and a safety-classed microbiology laboratory enable efficient product development and internal quality control of our products. Our close collaboration with reference laboratories and healthcare ensures that our products are aligned with market needs.



Management

Gradientech is a Swedish public limited company. Our corporate governance is based on the Swedish Companies Act, good stock market practices, the company's articles of association, internal policies and other relevant laws, rules and recommendations.

Corporate governance ›
Board of Directors ›
Senior executives ›
Scientific Advisory Board ›
The share and shareholders ›

Corporate governance

Corporate governance

Gradientech is a Swedish public limited liability company with 693 shareholders as per December 31, 2024. Gradientech's corporate governance is based on the Swedish Companies Act, good stock market practice, the company's Articles of Association, internal governing documents, and other applicable laws, rules and recommendations.

The company's internal governing documents mainly include the rules of procedure for the Board of Directors, the instructions for the CEO, financial reporting instructions, authorisation instructions and a financial policy. Gradientech also has a number of policy documents and instructions that contain principles and provide guidance for the company's operations and employees.

General meeting

The shareholders' influence in the company is exercised at the general meeting, which is the company's highest decision-making body. All shareholders who, on the record date for the general meeting, are registered in the share register maintained by Euroclear Sweden AB and listed in a CSD register or CSD account, are entitled to participate, either in person or by proxy.

The General meeting may decide on all matters relating to the company which do not, under the Swedish Companies Act or the Articles of Association, expressly fall within the exclusive expertise of another corporate body. For example, the general meeting may decide to increase or decrease the share capital, to amend the Articles of Association or that the company will go into liquidation. With regard to new issues of shares, convertibles or warrants, the general meeting, in addition to being able to decide such issues itself, may authorise the Board to decide on such issues

All shareholders, irrespective of the size of their shareholding, are entitled to have a specific matter addressed at the general meeting. Shareholders who wish to exercise this right must submit a written request to the company's Board of Directors. Such a request must normally be received by the Board in sufficient time to be included in the notice of the General meeting.

The Annual General Meeting (AGM) is held every year within six months of the end of the financial year. The Chairman of the meeting is to be elected by the Meeting.

The AGM is responsible for electing the company's Board of Directors and auditors, adopting the company's balance sheet and income statement, resolving on the appropriation of the company's profit or loss in accordance with the adopted balance sheet, and resolving on the discharge from liability of the company's Board members and CEO. The AGM also resolves on the fees to be paid to the Board members and the company's auditors

An Extraordinary General Meeting (EGM) may be convened by the Board of Directors when it deems it necessary to hold a meeting before the next AGM. The Board also convenes an EGM when an auditor or a shareholder holding more than 10% of the shares in the company requests in writing that a meeting be held to address a specific matter.

The notice convening a general meeting is to be published in Post- och Inrikes Tidningar and on the company's website. At the time of the notice, confirmation that the notice has been issued is be published in Svenska Dagbladet. Notices of the AGM and any EGMs at which amendments to the Articles of Association are to be considered are to be issued no earlier than six (6) weeks and no later than four (4) weeks prior to the meeting. Notices of other EGMs are to be issued no earlier than six (6) weeks and no later than two (2) weeks prior to the meeting

The 2024 AGM was held on 7 May 2024 at the company's premises at Dag Hammarskjölds väg 36 in Uppsala. At the Annual General Meeting, resolutions were passed on principles for the appointment of the Nomination Committee (see below). Furthermore, a resolution was passed to authorize the Board of Directors to carry out a new issue of shares, warrants and/or convertibles with preferential rights for existing shareholders and the same authorisation with or without preferential rights for existing shareholders corresponding to no more than 40% of the total number of shares in the company. The AGM also resolved to implement the employee stock option program 2024/2028 and to cancel the previous employee stock option program 2021/2024.

The 2025 AGM will be held on Wednesday, May 21, 2025 at 5:00 p.m. CET at Gradientech's premises at Uppsala Science Park.

Nominating committee

The 2024 AGM resolved that the Nomination Committee is to comprise representatives of the four largest shareholders as of August 31 of the year prior to the AGM.

If any shareholder declines to participate in the Nomination Committee, the right to appoint a representative passes to the next largest shareholder not represented in the Nomination Committee. The Nomination Committee may decide that the Chairman of the Board should be a member of the Nomination Committee, but not appointed as Chairman. Unless the Nomination Committee agrees otherwise, the member representing the largest shareholder in terms of votes is to be appointed Chairman of the Nomination Committee.

Information on the composition of the Nomination Committee is to be published at least six months prior to the AGM. No remuneration is to be paid to the members of the Nomination Committee.

Ahead of the AGM in May 2025, the Nomination Committee consists of the following members:

- Henrik Didner representing Monesi Förvaltnings AB
- Mikael Lönn
- Bengt Sjöholm representing a consortium of owners under management at Consensus Asset Management AB
- Fredrik Strömholm representing Svanboet Invest AB

The Nomination Committee is responsible for preparing proposals regarding the election of the AGM Chairman, Board members, Chairman of the Board, auditor, and remuneration to Board members and auditor.

Board of Directors

Duties of the Board

The Board of Directors is ultimately responsible for the organisation of the company and the management of the company's operations, which must be carried out in the interests of the company and all shareholders. The main tasks of the Board include handling strategic issues regarding operations, financing, earnings and financial position and continuously evaluating the company's financial situation. The Board is also responsible for ensuring that there are effective systems for monitoring and control of the company's operations and ensuring that the company's disclosure of information is transparent, accurate, relevant and reliable.

Composition and independence of the Board

According to Gradientech's Articles of Association, the Board is to comprise three to seven Board members with zero to two deputies. The Board is elected annually at the AGM for the period until the next AGM has been held.

At the time of publication of the Annual Report, the Board of Directors comprises six ordinary Board members: Gisela Sitbon (Chairman), Laura Chirica, Henrik Didner, Rolf Ehrnström, Nedal Safwat and Hilja Ibert. All Board members are elected for the period until the end of the next AGM, which will be held on Wednesday, May 21, 2025. However, each Board member is entitled to step down at any time. The company's Board members are presented in more detail in the "Board of Directors and auditors" section. A table showing when each member took up their position and the Board's assessment of the independence of each Board member is presented below

Chairman of the Board

The Chairman of the Board is responsible for leading the work of the Board and ensuring that the work of the Board is carried out effectively and that the Board fulfills its obligations. In addition, the Chairman, through contact with the CEO, is to continuously receive the information necessary to monitor the company's position, financial planning and performance.

The Chairman also consults with the CEO on strategic issues and checks that the Board's decisions are executed effectively. The Chairman of the Board is responsible for all contact with shareholders on ownership issues and for communicating the views of the owners to the Board.

The Board's working methods

The Board follows written rules of procedure that are reviewed annually and adopted at the statutory Board meeting held in conjunction with the AGM. The rules of procedure regulate, among other things, the Board's working methods and duties, decision-making procedures within the company, the Board's meeting procedures, the Chairman's duties and the division of duties between the Board and the CEO.

Instructions regarding financial reporting and instructions to the CEO are also adopted at the statutory Board meeting. The CEO serves as a rapporteur on strategic, economic and financial matters. In 2024, 21 protocolled meetings were held. Each member's attendance at Board meetings is shown in the table below.

Audit Committee and Remuneration Committee

The Board of Directors of Gradientech has decided not to establish a separate Audit Committee or Remuneration Committee. The Board as a whole is responsible for, among other things, quality assurance of the company's financial reporting, internal control and risk management as well as reviewing and evaluating the auditor's work and impartiality. The Board is also responsible for preparing matters relating to remuneration and other terms of employment for the CEO.

Remuneration to the Board members

The Chairman of the Board and members of the Board of Directors are paid in accordance with the resolution of the AGM. At the AGM in May 2024, it was resolved that the Chairman of the Board shall be remunerated with SEK 275,000 per year as salary and Boar members shall be remunerated with SEK 130,000 per year as salary.

The remuneration paid to the Board of Directors in 2024 is set out in Note 7.

Evaluation of the work of the Board of Directors

The Board's work is evaluated annually with the aim of enhancing its working methods and efficiency. The Chairman of the Board is responsible for the evaluation. The purpose of the evaluation is to understand the views of Board members on how the Board's work is conducted, what measures can be taken to make the Board's work more efficient, and whether the Board is well balanced in terms of expertise. The evaluation is an important basis for the work of the Nomination Committee.

Composition of the Board

			Independent in relation to:		
Name	Position	Board member since	the company and management	major shareholders	Attendance at Board meetings
Gisela Sitborn	Chairman	2020	Yes	Yes	21/21
Laura Chirica	Board member	2021	Yes	Yes	21/21
Henrik Didner	Board member	2018	Yes	No	20/21
Rolf Ehnström	Board member	2020	Yes	Yes	21/21
Nedal Safwat	Board member	2023	Yes	Yes	20/21
Hilja Ibert	Board member	2023	Yes	Yes	21/21

CEO and other senior executives

Duties of the CEO and other members of management

The CEO is appointed by the Board of Directors and manages the company's day-to-day affairs on an on-going basis in accordance with the Board's guidelines and instructions. The CEO presents matters to the Board so that the Board can make informed decisions. The CEO also keeps the Board regularly informed about the performance, financial position, liquidity and credit situation of the business and all important business events. The Management Team, led by the company's CEO, consists of people with responsibility for key areas within Gradientech.

Remuneration to the CEO and senior executives For all employees with a fixed monthly salary, defined contribution pension premiums are paid corresponding to the premiums of the collectively agreed ITP1 occupational pension scheme.

The company's CEO is entitled to a monthly fixed salary of SEK 95,800 in total with a mutual notice period of 6 months. The CEO is bound by a non-competition clause for 6 months from date of termination of the employment. Other senior executives are not bound by non-compete clauses.

The remuneration paid to the company's Board of Directors and CEO, as well as other employees during 2024, is set out in Note 7.

Audit and internal control

External auditor

The company's auditor is appointed by the general meeting. The auditor examines the company's Annual Report and accounts and the management of the Board of Directors and the CEO.

At the AGM in May 2024, the accounting firm Grant Thornton Sweden AB was elected as the company's auditors for the period until the end of the AGM to be held on May 21, 2025. Grant Thornton Sweden AB has been the company's auditor since 2017.

The auditor in charge is Authorised Public Accountant Stéphanie Ljungberg, who is a member of FAR. The Auditor's Report is signed by Stéphanie Ljungberg.

Remuneration to the auditor

Remuneration to the auditor is resolved on by the AGM. At the AGM in May 2024, it was resolved that fees to the auditor would be paid on a current account basis.

Internal audit and control

The Board of Directors' responsibility for internal control is governed by the Swedish Companies Act and the Swedish Annual Accounts Act, which require that information on the most important elements of Gradientech's internal control system and risk management in connection with the financial reporting each year be included in the Annual Report. Among other things, the Board is to ensure that Gradientech has a high level of internal control and formalized procedures that ensure compliance with established principles for financial reporting and internal control and that there are appropriate systems for monitoring and control of the company's operations and the risks with which the company and its operations are associated.

The overall purpose of internal control is to provide reasonable assurance that the company's operational strategies and objectives are followed and that the owners' investment is protected. Internal control should also ensure, with reasonable certainty, that the external financial reporting is reliable and prepared in accordance with generally accepted accounting policies, meets the requirements for information disclosure in accordance with internal policies and complies with applicable laws and regulations.

Control environment

Internal control is based on a control environment that includes the organisation, decision-making, authorities and responsibility. The Board has written rules of procedure that clarify the Board's responsibilities and regulate its division of tasks. The rules of procedure also specify the issues to be submitted to the Board for decision. The division of roles between the Board and the CEO is communicated in the Board's rules of procedure and in its instructions to the CEO.

The CEO also manages the operations based on the Swedish Companies Act and other laws and regulations. The Board monitors compliance with established financial reporting and internal control principles and maintains appropriate relations with the company's auditors. Management is responsible for the system of internal controls required to manage significant risks in the operating activities.

Risk assessment and control activities

A clear organisation and decision-making process aims to create a good awareness of risks among the employees and a balanced approach to risk-taking. Embedded control points also aim to minimize the risk of accounting misstatements

Board of Directors

Gisela Sitbon

Chairman since 2020

Born: 1958

Education: PhD in Medical Sciences, Karolinska Institutet.

Other current assignments: Gisela Sitbon is Chairman of the Board of Emplicure Consumer AB, Emplicure AB, Emplicure Pharma AB and Nanologica AB and Board member of UU Invest AB and Thioredoxin AB. In addition, she is the owner and Board member of Sitbon Bioscience Partner ZENZ AB.

Holdings: Gisela Sitbon holds 56,000 shares in the company. She holds no warrants in the company.

Gisela Sitbon is independent in relation to the company and management and in relation to the company's major shareholders.

Laura Chirica

Board member since 2021

Born: 1968

Education: PhD in Biochemistry, Umeå University.

Other current assignments: Laura Chirica is a Board member of Pre-Diagnostics AS. She is also CEO of Cellevate AB.

Holdings: Laura Chirica holds 7,035 shares in the company. She holds no warrants in the company.

Gisela Sitbon is independent in relation to the company and management and in relation to the company's major shareholders.

Henrik Didner

Board member since 2018

Born: 1958

Education: PhD, Uppsala University.

Other current assignments: Henrik Didner is owner and Chairman of the Board of Monesi Förvaltnings AB and Chairman of the Board of Uppsala University Invest AB. Henrik is also a Board member of G-Förvaltning AB, Oncodia AB, Axel Johansson Uppsala Nya Tidning Förvaltning AB and VBN Components AB.

Holdings: Henrik Didner holds 6,081,701 shares in the company through Monesi Förvaltnings AB. He holds no warrants in the company.

Henrik Didner is independent in relation to the company and management, but not in relation to the company's major shareholders.

Rolf Ehrnström

Board member since 2020

Born: 1953

Education: Master of Science in Biochemistry and Biotechnology, KTH Stockholm.

Other current assignments: Rolf Ehrnström is Chairman of the Board and CEO of Reomics AB. Rolf is also a Board member of Scandinavian Chemotech AB, Fluimedix A/S, ZipPrime Oy, Aplex Bio AB and Lynsight Oy. In addition, he serves as a consultant within life science and a member of various funding agencies (Vinnova, EITH, NOME and Uppsala Bio-X).

Holdings: Rolf Ehrnström holds 18,659 shares in the company through Reomics AB. He holds no warrants in the company.

Rolf Ehrnström is independent in relation to the company and management and in relation to the company's major shareholders.

Hilja Ibert

Board member since 2023

Born: 1960

Education: Hilja Ibert holds a PhD in Nutrition Science from the University of Bonn.

Other current assignments: Chairman of the Board of Gentian Diagnostics, a Norwegian listed company with products in the international immuno-diagnostic market. Hilja is also a Board member of VitaDx, a French company focusing on AI and image processing in the field of cancer cytology.

Holdings: Hilja Ibert holds no shares or warrants in the company.

Hilja Ibert is independent in relation to the company and management and in relation to the company's major shareholders.

Nedal Safwat

Board member since 2023

Born: 1975

Education: Bachelor of Science and PhD in Biochemistry from North Carolina State University, USA.

Other current assignments: Nedal Safwat is Vice President Portfolio and Product Management Office at Cepheid, US.

Holdings: Nedal Safwat holds no shares or warrants in the company.

Nedal Safwat is independent in relation to the company and management and in relation to the company's major shareholders.

Management

Sara Thorslund, PhD

Chief Executive Officer, CEO

Co-founder and CEO of Gradientech since its start in 2009. Sara Thorslund has received several awards for innovation and entrepreneurship during Gradientech's journey to an international diagnostics company. Presented as one of today's role models shaping our future in one of Mondial's book publications (2020). Author of more than ten peer-reviewed scientific publications and inventor of a handful of patents.

Born: 1977

Education: PhD in Material Science and Microstructure Technology, Uppsala University. Master of Science in Engineering Biology, Linköping University.

Tidigare erfarenhet: Co-founder of Gradientech AB 2009. Research in patient-centered microfluidic applications at Uppsala University.

Shareholding: 408,567

Warrant holding: 129,605 series 2024/2028 employee stock options.

Urban Adolfsson

Chief Financial Officer, CFO

Urban Adolfsson has a broad background in finance in various roles and organizations, including accounting, financial and business analysis, cash flow and investment planning as well as equity raising.

Born: 1971

Education: Master of Science in Business and Economics, Uppsala University.

Tidigare erfarenhet: Previous positions include audit assignments at Ernst & Young, senior positions in financial management at companies such as PA Resources, Envirotainer and most recently as CFO and interim CEO at Encare.

Shareholding: 2,552

Warrant holding: 64,849 series 2024/2028 employee stock options.

Marcus Berglund

Chief Technology Officer, CTO

Marcus Berglund joined Gradientech in 2017 as a technical project manager for instrument development. Since then, he has worked with on setting up antibiotic filling and been project manager for QuickMIC® from a system perspective.

Born: 1981

Education: Master of Science in Electronics Design, Linköping University.

Tidigare erfarenhet: Nearly 20 years of experience in industrial systems, electronics and software development in roles such as developer, project manager, team lead and consultant manager at life science, automotive and industrial companies such as Electroengine, Kontigo Care and BlueAir via Prevas AB.

Shareholding: 2,980

Warrant holding: 63,531 series 2024/2028 employee stock options.

AnnaLotta Schiller Vestergren
Chief Commercial Officer, CCO

AnnaLotta Schiller Vestergren started at Gradientech in the spring of 2024 with the responsibility for building and leading the commercial operations of the company.

Born: 1961

Education: PhD in molecular biology from the Swedish University of Agricultural Sciences. Miller Heiman-licensed strategic sales expert, marketing specialist and certified export salesperson from Jensen Education.

Previous experience: More than 30 years of experience in international sales and building commercial organisations within growing life science and biotech companies. Previous positions include commercial roles in companies such as Life Technologies, GE Healthcare, and Olink Proteomics.

Shareholding: -

Warrant holding: 53,124 series 2024/2028 employee stock options.

Ann-Sofie Andersson
Marketing and Communications Manager

Ann-Sofie Andersson joined Gradientech in 2013 as Sales and Marketing Manager. Long background from internationally leading diagnostics companies.

Born: 1964

Education: Marketing and university studies in cell biology and immunology, Uppsala University.

Previous experience: Over 30 years of experience within the life science sector such as Pharmacia Diagnostics (today Thermo Fisher), Anamar and Mercodia. Previous positions include roles such as Product Manager, International Marketing, Sales and Project Management. Broad experience in business development, quality assurance and distributor management.

Shareholding: –

Warrant holding: 72,354 series 2024/2028 employee stock options.

Christer Malmberg, PhD
Chief Scientist

Christer Malmberg has solid experience from research in clinical and diagnostic microbiology on methods for early detection of phenotypic effects of antibiotics as well as clinical studies of diagnostic methods. Joined Gradientech in 2014 as project manager for instrument development and Head of Research since 2020.

Born: 1984

Education: PhD in Medical Sciences and Master of Science in Molecular Biotechnology, Uppsala University.

Previous experience: Research background in clinical microbiology and antibiotic resistance. Project manager for instrument development and data analysis within Gradientech's product development operations.

Shareholding: 18,372

Warrant holding: 70,529 series 2024/2028 employee stock options.

Martin Karlsson, PhD

Production & Supply Manager

Martin Karlsson joined Gradientech in 2021 and has extensive industrial experience from the production of both pharmaceutical and medical devices. Martin devotes considerable focus to establishing processes for efficiency and quality to develop a successful manufacturing and purchasing organization at Gradientech.

Born: 1982

Education: PhD in Physical Chemistry, Uppsala University. Master of Science in Analytical Chemistry, Linköping University.

Previous experience: Ten years of experience from various position within the development and quality functions at Galderma (later Nestlé Skin Health), including Head of Quality Control.

Shareholding: –

Warrant holding: 64,849 series 2024/2028 employee stock options.

Cecilia Johansson, PhD

Head of Microbiology

Joined Gradientech in 2019, leading the company´s microbiology activities, and has extensive research experience working with clinically relevant bacteria and viruses. Cecilia Johansson is the author of more than 20 peer-reviewed scientific publications.

Born: 1975

Education: PhD in Medical Virology and Master of Science in Biology, Uppsala University.

Previous experience: More than 20 years of research experience and work with clinically relevant bacteria and viruses, and extensive experience in microbiological and molecular biological analysis methods.

Shareholding: –

Warrant holding: 64,850 series 2024/2028 employee stock options.

Anna-Lisa Tiensuu

Regulatory Affairs & Quality Assurance Manager

Anna-Lisa Tiensuu joined Gradientech in 2022. She has worked in the life science sector for more than 20 years, the last 15+ years focusing on global medical technology issues and quality management.

Born: 1964

Education: Master of Science in Engineering Physics and a Licentiate of Engineering Degree in Materials Science, Uppsala University.

Previous experience: Radi Medical Systems AB, St Jude Medical Systems AB and Thermo Fisher Scientific (Phadia AB).

Shareholding: 1,000

Warrant holding: 64,242 series 2024/2028 employee stock options.

Scientific Advisory Board

Gradientech has an international, advisory expert group, who are all leaders in the field of clinical microbiology. The members assist us with their solid experience and advice, and keep us constantly updated in clinical microbiology, a market that is developing rapidly.

Holger Rohde

MD Prof. Molecular Microbiology

Holger Rohde is Deputy Director of the Institute for Medical Microbiology, Virology and Hygiene at Universitätsklinikum Hamburg Eppendorf (UKE), Germany and Professor of Molecular Microbiology. Holger Rohde is a senior physician and specialist physician in microbiology, virology and infectious disease epidemiology. His research is focused on the role of biofilm formation in implant-associated staphylococcal infections. He is an advocate of rapid diagnostics and has long experience in the validation of innovative technologies. Holger Rohde is also head of the ESCMID AMR Action Subcommittee.

Jeffrey Bender

MD Prof. Clinical Pediatrics

Jeffrey Bender is an infectious disease specialist, medical microbiologist and Professor of Clinical Pediatrics at the City of Hope Comprehensive Cancer Center in Los Angeles, USA. His research is focused on understanding the function of the microbiome and its interactions with the host. Jeffrey Bender is also interested in vaccines, hospital epidemiology and the implementation of rapid diagnostics in the pediatric setting.

Elisabet Nielsen

Prof. Clinical Pharmacy

Elisabet Nielsen is a Professor in Clinical Pharmacy at the Department of Pharmacy, Uppsala University, Sweden. Elisabet conducts research in the area of translational and personalized medicine. She uses mathematical modelling to understand the dynamic interplay between bacteria, antibiotic and patient and its implication for optimized antibiotic use. She also has an interest in the implementation of model-based systems to support individualized antibiotic treatments.

Nathan Ledeboer

Prof. Pathology and Laboratory Medicine

Nathan Ledeboer is Professor and Chief of Clinical Pathology in the Department of Pathology and Laboratory Medicine at the Medical College of Wisconsin, USA. He served as the Medical Director of Microbiology and Molecular Diagnostics for Froedtert Hospital and Wisconsin Diagnostic Laboratories in Milwaukee, WI for 16 years before assuming the role of Associate Chief Medical Laboratory Officer for Froedtert Health. His research is focused on developing diagnostic tools for infectious diseases to improve patient care and hospital epidemiology and has led to numerous publications in peer-reviewed journals and more than 200 funded research projects.

The share and shareholders

Gradientech is a public company with thorough processes and procedures adapted to enable the company's share to be listed on a regulated marketplace.

Share capital

According to Gradientech's Articles of Association, the share capital is to amount to a minimum of SEK 1,000,000 and a maximum of SEK 4,000,000. The number of shares is to be a minimum of 10,000,000 and a maximum of 40,000,000. Each share entitles the holder to one vote at general meetings and each shareholder is entitled to a number of votes corresponding to the number of shares held in the company. All shares carry equal rights to Gradientech's assets and profit. The shares have been registered with Euroclear Sweden AB since January 2020.

As of December 31, 2024, the number of outstanding shares was 28,867,173 (23,960,753), each with a quota value of SEK 0.1, corresponding to a share capital of SEK 2,886,717.30 (2,396,075.30)

Owners

Given the prevailing market situation at the beginning of the year, the company's Board of Directors chose, in connection with the implementation of the rights issue whose subscription period ended in December 2023 and was registered with the Swedish Companies Registration Office during the first quarter of 2024, to finance the company on more than one occasion. In connection with the registration of the Rights Issue, the shares from conversion of the convertibles issued in 2023 were also registered - and a total of 6,165,503 shares were registered at the The Swedish Companies Registration Office.

At the end of the second quarter, the Board of Directors resolved, within the framework of the Annual General Meeting's authorization, to carry out a directed issue of shares to a limited number of existing shareholders. The number of shares in the company increased by 3,109,849 and the share capital increased

of SEK 310,984.90 and provided the company with approximately SEK 22.1 million before deduction of issue costs. During the fourth quarter, the company carried out a directed share issue of 1,796,571 shares to Hardy Diagnostics, which increased the share capital by SEK 179,657.10 and provided the company with approximately SEK 31.4 million before deduction of issue costs. After registration of all issues for the year, which provided Gradientech with a total of SEK 79.3 million before deduction of issue costs, the number of shares amounts to 28,867,173 shares and the share capital amounts to a total of SEK 2,886,717.30.

The table to the right shows the 12 largest shareholders as of December 31, 2024.

Outstanding incentive programs

Gradientech has an outstanding option program that is directed to the company's employees and other key employees.

At the Annual General Meeting on 7 May 2024, the shareholders decided to introduce an employee stock option program of 1,131,125 options entitle the holders to subscribe for 1,131,125 shares in Gradientech at a price of SEK 17.50 per share upon achievement of a number of milestones and a vesting period of approximately 3 years. The dilutive effect is estimated at approximately 4.5 percent upon full subscription. The shareholders also decided at the Annual General Meeting to cancel previous employee stock option programs issued in 2021. The employee stock options were granted free of charge.

Largest shareholders

Shareholder	Number of shares	Holdings and votes %
Monesi Förvaltnings AB	6,081,701	21.07%
A.D.A. SRL	2,298,309	7.96%
Hardy Diagnostics Inc	1,796,571	6.22%
Thomas Andersson Borstam	589,973	2.04%
Mikael Lönn	578,786	2.00%
Ingvar Andersson	557,074	1.93%
Svanboet Invest AB	531,239	1.84%
Almi Invest AB	485,180	1.68%
Nitator Förvaltnings AB	483,488	1.67%
Fredrik Skytt	469,123	1.63%
Ålandsbanken ABP	412,997	1.43%
Sara Thorslund	408,567	1.42%
Other	14,174,165	49.10%
Total	**28,867,173**	**100.00%**

Source: Euroclear as of 31 December 2024

Financials

Directors' report

The Board of Directors and the CEO of Gradientech AB submit the following Annual Report for the 2024 financial year.

The Annual Report has been prepared in Swedish kronor (SEK). Unless otherwise stated, all amounts are in thousands of SEK (SEK thousand). Figures in parentheses refer to the previous year.

Information regarding the operations

Gradientech is a Swedish in vitro diagnostic company that develops, manufactures and sells next-generation solutions for infectious diseases. Our market-approved QuickMIC® system positions us as a world leader in ultra-rapid antibiotic susceptibility testing (AST), enabling sepsis patients with bloodstream infections to receive personalised treatment with the right antibiotic at the right dose – in record time. This helps save lives, reduce healthcare costs, and combat the spread of antibiotic resistance, one of the greatest global health threats of our time.

Our strategic focus is on selling instruments and associated tests to establish the QuickMIC system as a routine diagnostic tool in clinical microbiology laboratories in hospitals across Europe. Following FDA approval, Gradientech plans to launch QuickMIC for diagnostic use in the US market, in collaboration with our commercial partner, Hardy Diagnostics.

The company's registered office is in Uppsala, Sweden.

Significant events during the financial year

During the year, the company announced the first hospitals to install the QuickMIC system in clinical routine use in Europe. Biomedica Medizinprodukte GmbH installed QuickMIC at a university hospital in central Eastern Europe and the company's Italian distributor a.d.a SRL installed QuickMIC at the Molinette Hospital in Turin, Italy.

The company commenced its clinical studies in the US during the third quarter for a 510(k) clearance of the QuickMIC system. The study, which is being conducted at well-renowned hospitals, includes antibiotic susceptibility testing of gram-negative bacteria, both directly from positive blood cultures as well as from bacterial isolated colonies. At the beginning of the year, the company completed its pre-clinical studies of the QuickMIC system in the US with successful results. Results from the pre-clinical evaluation at the Medical College of Wisconsin and the University of North Carolina in the US were presented at the ASM Microbe conference in Atlanta, Georgia, at the end of the second quarter.

The company announced at the beginning of the fourth quarter an exclusive partnership with Hardy Diagnostics for the commercialization of its QuickMIC system in the US and Canada. In addition to the commercial partnership, Hardy Diagnostics has invested in Gradientech, thereby becoming one of the company's major shareholders.

During the year, AnnaLotta Schiller was appointed as the company's Chief Commercial Officer and Dr. Nathan A. Ledeboer, a specialist within the Froedtert & Medical College of Wisconsin hospital network in the USA, was appointed as a new member of the company's prominent international Scientific Advisory Board.

During the year, the company announced the granting of patent rights in China for its cassette, the single-use test device in the QuickMIC diagnostic system. The company also received notice of the granting of patent rights in Japan for its QuickMIC cassette.

At the beginning of the first quarter, the shares from the Rights issue whose subscription period ended at the beginning of December 2023 were registered with the Swedish Companies Registration Office, together with the shares from the conversion of the convertible instruments issued during 2023. A total of 6,165,503 shares were registered with the Swedish Companies Registration Office and the Rights issue of shares raised approximately SEK 25.8 million for the company before deduction of issue costs. At the end of the second quarter, the Board of Directors decided, within the framework of the authorization of the Annual General Meeting, to carry out a Directed issue of shares to a limited number of existing shareholders. The number of shares in the company increased by 3,109,849 and raised approximately SEK 22.1 million for the company before deduction of issue costs. During the fourth quarter, the company carried out a Directed issue of 1,796,571 shares to Hardy Diagnostics and raised approximately SEK 31.4 million before deduction of issue costs.

Financing

After registration of all issues this year, which in total provided Gradientech with SEK 79.3 million before deduction of issue costs, the number of shares amounts to 28,867,173 shares and the share capital to a total of SEK 2,886,717.30.

In December, the Board of Directors decided to carry out a Rights issue of a maximum of 3,464,060 shares with a subscription period from 17 to 31 January 2025. The issue was fully subscribed and provided Gradientech with SEK 60.6 million before deduction of issue costs. Read more in Note 19, Significant events after the end of the financial year. The Board of Directors' assessment is that the issue proceeds together with existing cash will cover the company's liquidity needs until the end of 2025/2026. Due to uncertainty in the forecast, this means that financing at the time of submission of this

annual report is not secured for at least twelve months ahead. In the current market situation, the company's Board of Directors has chosen to finance the coming twelve-month period on more than one occasion. This means that additional issues need to be carried out during the next twelve-month period to ensure the company's continued financing.

At year-end, Gradientech had no long-term liabilities.

Anticipated future development and material risks and uncertainties

Below is a brief description of a number of risk factors that may affect Gradientech's future development. These are not ranked, nor do they claim to be exhaustive.

Risks related to the business and industry

The company launched the QuickMIC® system in 2022 and has since contracted a number of distributors for a selected number of European markets. The company has also contracted a distributor for the US market in 2024, where sales for diagnostic use will begin in connection with the company achieving approval from the United States Food and Drug Administration, FDA. Although sales take place to distributors, the commercialisation phase may be delayed by hospitals (the end customers) choosing to end the evaluation period without wanting to invest in the system. The company believes that if the risk is realised, it could result in reduced cash flow and an increased need for financing during the early commercialisation phase.

Regulatory risks

The development, marketing and sale of diagnostic medical devices are subject to extensive regulation and legislation. The company cannot predict with certainty whether, where, when and how these rules will change and whether such changes may adversely affect the company.

Competition

The company operates in an industry characterized by a number of very large global players and a number of smaller players developing the next generation of innovative products in the field. There can be no guarantee that the company's products will be preferred to the existing or future products of competing companies in the market. Nor can it be ruled out that competing companies may develop equivalent or better products.

Patents, trademarks and know-how

In the type of business that Gradientech conducts, there is always a risk that the company's patents or other intellectual property rights may not provide sufficient protection for the company, or that the company's rights cannot be maintained. Furthermore, patents may be infringed, leading to costly disputes. The outcome of such disputes cannot be guaranteed in advance. Negative outcomes of intellectual property disputes can result in the losing party losing protection, being banned from further use of the right in question or having to pay damages.

Financial risks

The financial risks related to interest rate risk are not significant as the company has no interest-bearing loans. However, through its activities, Gradientech is exposed to various financial risks such as fluctuations in the company's earnings and cash flow caused by changes in exchange rates. Currently, Gradientech's policy is not to hedge against financial risks related to currency transaction risks. This decision was made taking into account the current share of expenses, approximately 13% (8%), exposed to currency fluctuations in the company and the cost of hedging any risks. As the volume of currency-exposed transactions increases, the Board will evaluate a new currency policy.

Future financing and capital requirements

Historically, the company has generated negative results and the company's cash flow from operating activities has not been sufficient to meet the company's overall annual capital requirements. The cash flow generated is expected to remain negative until Gradientech enters into significant agreements for the sale of QuickMIC or other products that the company may commercialise. A continued lack of positive net revenue flows means that Gradientech will need to raise additional capital in the future. Access to, and conditions for, raising capital are affected by a number of factors, including the prevailing economic and investment climate, the current credit market, and the company's creditworthiness and market position. The raising of financing through a new issue of shares or share-related financial instruments may have a significant dilutive effect on the company's existing shareholders. In the event that Gradientech does not generate sufficient financing, the company may need to restrict or ultimately suspend planned commercial product development and investment activities until sufficient capital is secured.

Gradientech from a sustainability perspective

Sustainability is a central and natural part of Gradientech's business concept. We believe in sustainable and responsible business and take responsibility throughout the value chain as an employer, producer and market player. Based on what is important to our stakeholders, our long-term vision and our identified KPIs, we have identified three focus areas where we can make a difference, based on the UN Sustainable Development Goals (SDGs).

Read more in the "Sustainability" section

Ownership structure

As of December 31, 2024, the company had approximately 690 registered shareholders. The single largest shareholder is Monesi Förvaltnings AB with 21.07% of the number of registered shares as per December 31, 2024.

Read more in "The share and shareholders"

Statement of Changes in Equity

KSEK	Share capital	Unregistered share capital	Share premium reserve	Retained earnings	Total equity
Opening balance, Jan 1, 2023	**1,598**	**67**	**281,980**	**-237,067**	**46,578**
Profit/Loss					
Loss for the period				-63 678	-63,678
Total profit/loss	0	0	0	-63,678	-63,678
Transactions with shareholders					
New share issue, registered share capital	67	-67			0
New share issue	115		23,446		23,561
Ongoing new share issue		445	25,358		25,803
Ongoing conversion - Convertible loan		172	16,995		17,167
Issue costs			-981		-981
Total transactions with shareholders	182	550	64,818	0	65 550
Closing balance, Dec 31, 2023	**1,780**	**617**	**346,798**	**-300,744**	**48,451**
Opening balance, Jan 1, 2024	**1,780**	**617**	**346,798**	**-300,744**	**48,451**
Profit/Loss					
Loss for the period				-63,620	-63,620
Total profit/loss	0	0	0	-63,620	-63,620
Transactions with shareholders					
New share issue, registered share capital	617	-617			0
New share issue	491		53,014		53,504
Issue expenses			-2,911		-2,911
Total transactions with shareholders	1,107	-617	50,103	0	50,594
Closing balance, Dec 31, 2024	**2,887**	**0**	**396,901**	**-364,364**	**35,424**

Multi-year review

SEK thousand	2024	2023	2022	2021	2020
Balance sheet total	40,965	56,202	54,752	104,944	79,516
Net sales	4,457	1,950	988	141	61
Number of employees in average	33	34	23	16	11
Equity/assets ratio (%)	86,5	86,2	85,1	89,4	95,3

Net sales for 2024 amounted to SEK 4,457 thousand, compared with SEK 1,950 thousand in the preceding year. The increase is attributable to increased sales of the QuickMIC® system including associated consumables.

Proposed appropriation of profit or loss

The Board of Directors proposes that the amount available for distribution (SEK):

share premium reserve	396,901,289
retained earnings	-300,743,955
loss for the year	-63,619,849
	32,537,485
to be carried forward	32,537,485
	32,537,485

The company's earnings and financial position are presented in the following income statement, balance sheet and cash flow statement with accompanying notes.

Income statement

SEK thousand	Note	2024-01-01 –2024-12-31	2023-01-01 –2023-12-31
Operating income			
Net sales	4	4,457	1,950
Change in inventories of products in progress, finished goods and work in progress		-3,111	2,067
Other operating income		177	351
		1,523	**4,368**
Operating expenses			
Raw materials and consumables		-2,764	-1,762
Purchased services		-8,611	-12,251
Other external expenses	5, 6	-22,593	-22,020
Personnel costs	7	-29,551	-29,740
Depreciation of property, plant and equipment		-1,869	-1 827
Other operating expenses		-142	-261
		-65,530	**-67,861**
Operating loss	8	**-64,007**	**-63,493**
Profit from financial items			
Other interest income and similar profit/loss items	9	395	258
Interest expense and similar profit/loss items	10	-8	-443
		387	**-185**
Loss after financial items		**-63,620**	**-63,678**
Loss before tax		**-63,620**	**-63,678**
Loss for the year		**-63,620**	**-63,678**

Earnings per share

SEK thousand	2024-01-01 –2024-12-31	2023-01-01 –2023-12-31
Average number of shares, thousands, before dilution	25,444	17,507
Average number of shares, thousands, after dilution	26,575	24,287
Number of shares outstanding on the balance sheet date, thousands	28,867	17,795
Basic earnings per share, SEK	-2,50	-3,64
Diluted earnings per share, SEK	-2,50	-3,64

Balance sheet

SEK thousand	Note	2024-12-31	2023-12-31
ASSETS			
Subscribed but unpaid capital		0	25 803
Non-current assets			
Property, plant and equipment			
Equipment, tools, fixtures and fittings	11	3,645	5,514
Construction in progress and advance payments for tangible assets	12	198	0
		3,843	**5,514**
Total non-current assets		**3,843**	**5,514**
Current assets			
Inventories, etc.	13		
Raw materials and consumables		857	970
Goods in progress		656	267
Finished goods and goods for resale		972	4,359
		2,485	**5,596**
Current receivables			
Accounts receivables		1,163	371
Current tax assets		0	760
Other receivables		6,842	6,385
Prepaid expenses and accrued income	14	2,036	963
		10,041	**8,479**
Cash and bank balances		24,596	10,811
Total current assets		**37,122**	**24,886**
TOTAL ASSETS		**40,964**	**56,202**

SEK thousand	Note	2024-12-31	2023-12-31
EQUITY AND LIABILITIES			
Equity	15, 16		
Restricted equity			
Share capital		2,887	1,780
Unregistered share capital		0	617
		2,887	**2,396**
Non-restricted equity			
Non-restricted share premium reserve		396,901	346,798
Retained earnings		-300,744	-237,066
Loss for the year		-63,620	-63,678
		32,537	**46,054**
Total equity		**35,424**	**48,451**
Current liabilities			
Accounts payables		2,120	2,738
Other liabilities		1,109	2,242
Accrued expenses and deferred income	17	2,312	2,772
Total current liabilities		**5,540**	**7,752**
TOTAL EQUITY AND LIABILITIES		**40,964**	**56,202**

Cash flow statement

SEK thousand	Note	2024-01-01 –2024-12-31	2023-01-01 –2023-12-31
Operating activities			
Loss before financial items		-64,007	-63,493
Interest received		379	258
Interest paid		-8	0
Adjustments for non-cash items			
Depreciation/amortization		1,869	1,827
Profit from disposal of non-current assets		0	0
Cash flow from operating activities before change in working capital		**-61,767**	**-61,408**
Cash flow from change in working capital			
Increase(-)/decrease(+) in inventories		3,111	-2,067
Increase(-)/decrease(+) in operating receivables		-1,561	2,833
Increase(+)/decrease(-) in operating liabilities		-1,843	104
Cash flow from operating activities		**-62,060**	**-60,538**
Investing activities			
Investments in property, plant and equipment, net		-198	-2,376
Cash flow from investing activities		**-198**	**-2,376**
Net cash flow before financing activities		**-62,258**	**-62,914**
Financing activities			
New share issue and issue costs		76,028	52,548
Cash flow from financing activities		**76,028**	**52,548**
Cash flow for the year		**13,770**	**-10,366**
Cash and cash equivalents at beginning of year		**10,811**	**21,177**
Exchange rate differences, cash and cash equivalents		15	0
Cash and cash equivalents at end of year	18	**24,596**	**10,811**

Notes

Note 1

Accounting and valuation policies

General information

The annual report has been prepared in accordance with the Swedish Annual Accounts Act and General Recommendation BFNAR 2012:1 Annual Accounts and Consolidated Financial Statements (K3) of the Swedish Accounting Standards Board.

Receivables and liabilities in foreign currencies have been measured at the closing-day rate.

The accounting policies are unchanged from the previous year.

Revenue recognition

Revenue has been measured at the fair value of consideration received or receivable and recognised to the extent that it is probable that the economic benefits will accrue to the company and that the revenue can be reliably calculated.

The sale of goods is normally recognised as revenue when the significant risks and rewards associated with ownership of the goods have been transferred from the company to the buyer. Sales are recognised after deduction of value added tax and discounts. Transactions in foreign currencies are translated at the spot exchange rate on the transaction date.

Other revenue earned is recognised as follows:
Interest income: in line with effective returns.

Intangible assets

The company recognises internally generated intangible assets according to the capitalization method. This means that all expenditure relating to the development of an internally generated intangible asset is expensed immediately as it arises.

Property, plant and equipment

Property, plant and equipment are recognised at cost less accumulated depreciation accord-ing to plan and any impairment.

Depreciation of property, plant and equipment is applied to the asset's/component's depreciable amount over its useful life and begins when the asset/component is brought into use. Depreciation takes place on a straight-line basis over the estimated useful life of the asset taking the significant residual value into account.

The following periods of depreciation are applied:
Equipment and tools 10–20%

Additional expenses

Replacement of components and new components are included in the cost of the asset. Other additional expenses are added to the cost of the asset if it is likely that the future economic benefits associated with the asset will accrue to the company and the cost can be reliably calculated. If not, the expenses are expensed. Expenses for ongoing repairs and maintenance are expensed.

Derecognition from the balance sheet

Property, plant and equipment or components are derecognised from the balance sheet upon disposal or divestment or when no future economic benefits are expected from the use, disposal or divestment of the asset or component.

When property, plant and equipment are divested, the capital gain/loss is determined as the difference between the selling price and the asset's carrying amount and is recognised in the income statement in one of the items *Other operating income* or *Other operating expenses*.

Impairment testing of property, plant and equipment

On each balance sheet date, property, plant and equipment are tested for any indications of impairment. If the recoverable amount of the asset is less than the carrying amount, the asset is impaired to the recoverable amount.

The recoverable amount of an asset or cash-generating unit is the higher of its fair value less selling expenses and value in use.

Fair value less selling expenses comprises the price the company expects to be able to receive in a sale between knowledgeable parties that are independent of one another and have an interest in the transaction being carried out. Deductions are made for such costs that are directly attributable to the sale. The value in use comprises future cash flows that an asset or a cash-generating unit is expected to give rise to.

In testing for impairment, assets are grouped at the lowest levels at which there are separate identifiable cash flows (cash-generating units). For assets other than goodwill that have previously been impaired, a test is performed on each balance sheet date to determine whether the impairment should be reversed.

Accounts receivables/current receivables

Accounts receivables and current receivables are recognised as current assets at the amount expected to be paid after deduction of individually assessed doubtful receivables.

Note 1 cont.

Equity

Equity in the company consists of the following items:

Share capital which represents the nominal value of issued and registered shares.

Share premium reserve which includes any premium received from the issue of new share capital. Any transaction costs associated with the issue of new shares are deducted from the premium, taking into account any income tax effects.

Retained earnings and *profit/loss for the year*, meaning all retained earnings and share-based payments for the current and previous periods as well as the acquisition of own shares.

Leases

The company recognises all leases, both finance and operating, as operating leases. Operating leases are recognised as an expense on a straight-line basis over the lease term.

Inventories

Inventories are valued at the lower of cost and net realizable value on the balance sheet date. Cost is calculated according to the first in, first out (FIFO) method. Net realizable value is the estimated selling price less any applicable variable selling expenses. The cost of raw materials and consumables consists of the purchase price invoiced by the supplier and, where applicable, customs duties and freight. Work in progress consists of the costs of raw materials and con-sumables and mark-ups for manufacturing costs and quality control.

The selected valuation method means that inventory obsolescence has been taken into consideration.

Income tax

Reported income tax includes tax to be paid or received regarding the current year. Tax liabilities and assets are valued at the amount due to or from the Swedish Tax Agency, as estimated by the company. The assessment is based on tax rules and tax rates that have been enacted or have been announced and are highly likely to be adopted.

Employee benefits

Pensions

The company has only defined contribution pension plans. In a defined contribution plan, the company makes fixed contributions to a separate legal entity and has no obligation to make any further contributions.

Costs are charged to earnings as the benefits are earned.

Incentive program

At the AGM on May 7, 2024, the shareholders decided to introduce an employee stock option program of 1,131,125 options that entitle the holders to subscribe for 1,131,125 shares in Gradientech at a price of SEK 17.50 per share upon the achievement of milestones and a vesting period of three years. The dilutive effect is estimated at approximately 4.5 percent on full subscription. The shareholders also decided at the AGM to cancel the previous employee stock option program issued in 2021.

Government grants

Government grants are measured at fair value when it is reasonable and certain that the grant will be received and the company will meet the conditions associated with the grant. Government grants relating to expected costs are recognised as deferred income. Grants are recognised as revenue in the period in which the costs for which the government grant is intended to compensate are incurred.

Cash flow statement

The cash flow statement has been prepared using the indirect method. The recognised cash flow includes only transactions that have involved cash payments or disbursements.

In addition to cash funds, the company classifies the following as cash and cash equivalents: balances available in banks and other credit institutions.

Definitions of KPIs

Balance sheet total
The company's total assets.

Net sales
The business's main revenue, invoiced costs, incidental revenue and revenue corrections.

Number of employees
Average number of employees during the financial year.

Equity/assets ratio (%)
Adjusted equity (equity and untaxed reserves less deferred tax) as a percentage of the balance sheet total.

Note 2

Estimates and judgments

The preparation of financial statements and application of accounting policies are often based on management's judgments, estimates and assumptions that are deemed reasonable at the time they are made.

These estimates and judgments are based on historical experience and a number of other factors deemed reasonable under the prevailing circumstances. The results form the basis for judgments about carrying amounts of assets and liabilities that are not otherwise clear from other sources.

Note 2 cont.

Actual results may differ from these estimates and judgments. Estimates and assumptions are regularly reviewed.

The areas in which estimates and judgments can have a major impact for the company, and which can thereby affect the income statement and balance sheet in the future, are described below.

Recognition of deferred tax assets: The assessment of the extent to which deferred tax assets can be recognised is based on an assessment of the probability of the company's future taxable income against which deferred tax assets can be utilized. In addition, significant consideration is required when assessing certain legal and economic constraints or uncertainties in different jurisdictions.

Uncertainty in estimating the useful lives of depreciable assets: On each balance sheet date, a review is conducted of applicable assessments of the useful life of depreciable assets. The uncertainty of these judgments is due to technical obsolescence that could change the use of the asset.

Note 3

Tax loss carryforwards

The company has tax loss carryforwards that may be utilized against taxable profit in the future. The total unutilized loss carryforward amounts to SEK -382,206 thousand (-315,788).

The company's operations, namely the commercialisation of research results, are associated with a high level of risk. Accordingly, there is currently insufficient reason to capitalize the value of the tax loss carryforwards, and no deferred tax asset has therefore been recognised. When it is probable that taxable profit will be generated, the company will recognise a deferred tax asset. Capitalization of deferred tax would have given rise to a deferred tax asset of SEK 79 million as of December 31, 2024.

Note 4

Distribution of net sales

Net sales by geographic market, SEK thousand	2024	2023
Sweden	27	141
Europe (EU)	4,104	1,809
Norway	63	0
UK	263	0
	4,457	**1,950**

Note 5

Leases

Lease expenses for the year amounted to SEK 2,738 thousand (2,628).

Future lease payments, for non-cancellable leases, fall due for payment as follows:

SEK thousand	2024	2023
Within one year	2,294	2,265
Between one and five years	1,146	3,360
	3,440	**5,625**

This item mainly pertains to a lease for premises. The lease term extends until mid-August 2026.

Note 6

Auditors' fees

Audit engagement refers to the audit of the annual accounts and accounting records as well as the administration of the company by the Board of Directors and the CEO, other tasks incumbent on the company's auditor as well as advice or other assistance occasioned by observations made in the course of such audit or the performance of such other tasks.

SEK thousand	2024	2023
Grant Thornton Sweden AB		
Audit engagement	180	168
Audit services in addition to audit engagement	35	36
	215	**204**

Note 7

Employees and personnel costs

Average number of employees	2024	2023
Women	16	14
Men	17	20
	33	**34**

SEK thousand	2024	2023
Salaries and other remuneration		
Board and CEO	1,955	1,918
Other employees	18,901	18,876
	20,856	**20,794**
Social security expenses		
Pension costs for the Board and CEO	285	280
Pension costs for other employees	2,131	2,374
Statutory and contractual other social security contributions	4,925	4,607
	7,341	**7,261**
Total salaries, remuneration, social security expenses and pension costs	**28,197**	**28,055**

The group "Board and CEO" includes seven (seven) individuals.

Note 7 cont.

Gender distribution among senior executives	2024	2023
Percentage of women on the Board	50 %	50 %
Percentage of men on the Board	50 %	50 %
Percentage of women among other senior executives	100 %	100 %

Salary and Board fees 2024

In accordance with the AGM's resolution, the fees to be distributed to the Board for 2024 amounted to SEK 925 thousand (890). Board fees in 2024 were paid as follows: SEK 275 thousand (265) to the Chairman of the Board and SEK 130 thousand (125) to each of the Board members.

Salary and remuneration to the CEO in 2024 amounted to SEK 1,172 thousand (1,144).

No Board members have during 2024 conducted any services apart from the Board assignment (SEK 0).

CEO's terms of employment

CEO Sara Thorslund has the following terms of employment: A salary of SEK 95,800 per month is paid. Gradientech AB and Sara Thorslund have a mutual notice period of six months. The company pays a pension premium of SEK 5,000 per month in addition to the applicable ITP plan.

Note 8

Related party transactions

No transactions between Gradientech and its related parties were carried out during 2024 (2023: 0 SEK).

Note 9

Other interest income and similar profit/loss items

SEK thousand	2024	2023
Other interest income	379	258
Exchange differences	16	0
	395	**258**

Note 10

Interest expenses and similar profit/loss items

SEK thousand	2024	2023
Interest expense related to Convertible instruments	0	443
Other interest expenses	-8	0
	-8	**443**

Note 11

Equipment, tools, fixtures and fittings

SEK thousand	2024-12-31	2023-12-31
Opening cost	10,300	8,221
Purchases	0	3,231
Disposals	0	-1,152
Closing accumulated cost	**10,300**	**10,300**
Opening depreciation	-4,786	-3,257
Disposals	0	298
Depreciation for the year	-1,869	-1,827
Closing accumulated depreciation	**-6,655**	**-4,786**
Closing carrying amount	**3,645**	**5,514**

Not 12

Construction in progress and advance payments for tangible assets

KSEK	2024-12-31	2023-12-31
Opening cost	0	0
Purchases	198	0
Closing accumulated cost	**198**	**0**
Closing carrying amount	**198**	**0**

Note 13

Inventories

SEK thousand	2024-12-31	2023-12-31
Raw materials and consumables	857	970
Work in progress	656	267
Finished goods	972	4,359
	2,485	**5,596**

Note 14

Prepaid expenses and accrued income

SEK thousand	2024-12-31	2023-12-31
Prepaid rent	991	567
Exhibitions	543	204
IT-services	207	37
Other items	295	155
	2,036	**963**

Note 15

Number of shares and quota value

Name	Number of shares	Quota value
Number of Class A shares	28,867,173	0,1
	28,867,173	

Note 16

Appropriation of profit or loss

Proposed appropriation of profit or loss

The Board of Directors proposes the following appropriation of the available funds:

SEK thousand	2024-12-31
non-restricted share premium reserve	396,901
retained earnings	-300,744
loss for the year	-63,620
	32,537
to be carried forward	32,537
	32,537

Note 17

Accrued expenses and deferred income

SEK thousand	2024-12-31	2023-12-31
Accrued personnel costs	1,350	1,274
Accrued Board remuneration	76	192
Accrued accounting and auditing costs	248	262
Accrued issue expenses	7	70
Accrued IT related costs	0	270
Other items	631	704
	2,312	**2,772**

Note 18

Cash and cash equivalents

SEK thousand	2024-12-31	2023-12-31
Cash and cash equivalents		
Bank balances	24,596	10,811
	24,596	**10,811**

Note 19

Significant events after the end of the financial year

Gradientech announced in January to have started its third FDA 510(k) clinical study site in the US for the QuickMIC® system to ensure comprehensive clinical data collection for the regulatory FDA submission of the QuickMIC system and its gram-negative panel.

In the beginning of February Gradientech announced the outcome of the new issue of shares with preferential rights for existing shareholders, resolved by the Board of Directors on December 17, 2024. The Rights issue was fully subscribed, which means that Gradientech received approximately SEK 60.6 million before deduction of issue costs. Through the Rights issue, the company's share capital will increase by SEK 346,405.90 to SEK 3,233,123.20 and the number of shares will increase by 3,464,059 shares to 32,331,232 shares.

Note 20

Pledged assets and contingent liabilities

The company's pledged assets consist of pledged bank funds of SEK 50 thousand (50). The company has no contingent liabilities.

Date of signing

Uppsala, April 9, 2025

Gisela Sitbon
Chairman

Henrik Didner

Rolf Ehrnström

Laura Chirica

Hilja Ibert

Nedal Safwat

Sara Thorslund
CEO

Our Auditor's Report was submitted on April 9, 2025

Grant Thornton Sweden AB

Stéphanie Ljungberg
Authorised Public Accountant

Auditor's report

To the general meeting of the shareholders of Gradientech AB (publ)

Corporate identity number 556788 - 9505

Report on the annual accounts

Opinions

We have audited the annual accounts of Gradientech AB (publ) for the year 2024.

The annual accounts of the company are included on pages 45–56 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Gradientech AB (publ) as of 31 December 2024 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of share-holders adopts the income statement and balance sheet.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Gradientech AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Material Uncertainty Related to Going Concern

We would like to draw attention to the loss reported by the company of 63,620 kSEK for the year ended December 31, 2024. We would also like to refer to the Directors' Report in the Annual Report under the sections 'Financing' and 'Future financing and capital requirements,' where the company states that its future financing depends on the outcome of new capital from existing or new investors. The uncertainty regarding the future outcome of this means that there is a substantial uncertainty about the company's ability to continue as a going concern

Other Information than the annual accounts

This document also contains other information than the annual accounts and is found on pages 1–44 and 60–61. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error

and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Gradientech AB (publ) for the year 2024 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of Gradientech AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability.

As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Uppsala 9th April 2025

Grant Thornton Sweden AB

Stéphanie Ljungberg
Authorised Public Accountant

Dictionary

AST
Antibiotikaresistensbestämning, eng. Antibiotic Susceptibility Testing

Blood infection
Presence of bacteria in the blood

Breakthrough device
Classification by the US FDA of a medical device that is deemed to offer a more effective treatment or diagnosis of life-threatening diseases compared to what is available on the market, provides a prioritized regulatory review process

BSI
The company's certification body for ISO 13485 certification and notified bodies for audit according to IVDR

CE
Conformité Européenne, product labelling mainly in the EU and EEA

CE-IVD
Regulatory labelling of diagnostic products that have met a number of requirements for safety, quality, validity and traceability that are required for the product to be used for diagnostic use

ESCMID
The European Society of Clinical Microbiology and Infectious Diseases, the European organization in clinical microbiology and infectious diseases, organizes the annual world conference ESCMID Global

FDA
Food and Drug Administration, the U.S. Food and Drug Administration responsible for the market approval of diagnostic products in the U.S.

Gram-negative
The difference between gram-negative and gram-positive bacteria is how their cell walls are constructed

Isolates
A single species of a bacterium obtained in a pure culture

IVD
Refers to in vitro diagnostic medical devices

IVDR
Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices (5 April 2017)

MIC
Minimum Inhibitory Concentration, the antibiotic concentration that inhibits the growth of bacteria

Microfluidics
The study of how liquids that are physically delimited to the micrometer scale in at least one dimension, behave, measure and manipulate

QuickMIC®
Gradientech registered trademark, the company's diagnostic system for ultra-rapid antibiotic resistance determination

Sepsis
Conditions of life-threatening organ dysfunction caused by disrupted systemic response to infection

UN
United Nations

WHO
World Health Organisation

Shareholder information

Forthcoming reports

Interim Report Q1 2025	May 16, 2025
Interim Report Q2 2025	August 21, 2025
Interim Report Q3 2025	November 13, 2025
Year-end report 2025	February 20, 2026

AGM

The Annual General Meeting will be held on Tuesday, May 21, 2025 at 5:00 p.m. and will be held at Gradientech's premises at Uppsala Science Park.

May 21, 2025 at 5.00 p.m.

Gradientech's premises at Uppsala Science Park

gradientech

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