gradientech

Precision medicine, for a sustainable world.

2022 Annual Report

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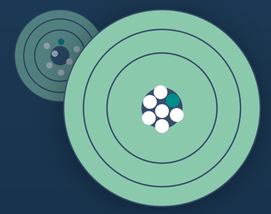
Precision medicine, for a sustainable world

Gradientech is a Swedish company that develops next-generation diagnostics in infectious disease medicine. Our products aim to be pioneering, create added value and improve the entire value chain for time-critical and severely ill patients, while reducing healthcare costs and lowering the spread of antibiotic resistance – one of the greatest global threats of our time.

Our first CE-marked diagnostic medical device, QuickMIC®, is based on the company's patented technology to create stable concentration gradients. The QuickMIC® system is now the fastest CE-IVD certified system for determining optimal antibiotic treatment for patients with sepsis. The company's current focus is to drive sales of QuickMIC® systems together with leading distributors in selected European countries, and to increase the number of installed systems on the market. A key strategy for achieving sales targets is to produce and publish data from successful studies together with leading clinical laboratories. Alongside of this, development and preparation for clinical studies in the US are ongoing with the aim of obtaining FDA clearance for QuickMIC®.

Modular

Up to 12 QuickMIC® instruments can be stacked space-efficiently and controlled from a single computer – a laboratory chooses capacity and increases the number of instruments based on testing needs.



Precise

QuickMIC® provides more accurate and precise results than conventional AST methods – we enable susceptibility testing that can provide the basis for personalized dosing.

Fastest

QuickMIC® is now the fastest CE-marked AST system on the market and delivers MIC values directly from a positive blood culture within 2 to 4 hours.

Milestones achieved in 2022

First distribution agreements in place

In July, Gradientech signed an exclusive distribution agreement with Biomedica for the commercialization of QuickMIC® in Austria, Switzerland and East-Central Europe. In September, we also signed an exclusive distribution agreement with Triolab Group for the commercialization of QuickMIC® in Sweden, Norway, Denmark, Finland and the Baltics.

QuickMIC® granted marketing authorization

In May, our first diagnostic medical device, QuickMIC®, and its Gram-negative antibiotic panel were CE-IVD certified. The certification was supported by the clinical study that demonstrated performance results exceeding the regulatory requirements for a new antibiotic susceptibility testing system. The clinical study also showed that our system has the shortest average time to results compared with competing systems on the market.

CE IVD

E-book launch

In 2022, we published our first e-book, *Next-generation antibiotic susceptibility testing – what's delaying the revolution?* Decision makers and other stakeholders have acquired access to a summary describing the importance of implementing rapid AST in general, and QuickMIC® in particular.

Important studies completed

In addition to regulatory studies at three external hospitals in Europe during the year, we also conducted post-market studies with East-Tallinn Central Hospital in Estonia and General University Hospital Dr. Balmis in Alicante, Spain. These studies are important for driving sales in a market where proof of performance and patient benefit from external users is a requirement for investing in new routine diagnostic tests.

Team reinforcement

During the year, we reinforced our Management Team with the addition of Peter Karlberg, VP Sales, with responsibility for sales and the commercial organization, Urban Adolfsson, CFO, and Anna-Lisa Tiensuu, Regulatory Affairs & Quality Assurance Manager. In addition, Marc van Nuenen was appointed VP Business Development US. Marc is stationed in the US and manages the company's business development activities in the US, including preparation for clinical studies with the purpose of obtaining FDA clearance.

We will be the first choice in AST

Marketing authorization in Europe with a view to the west

In spring 2022, we could finally place the CE mark on our QuickMIC® system and its first antibiotic panel – we had then compiled data from clinical studies to demonstrate that the regulatory requirements had been met. This means that we can now market our system for diagnostic testing of sepsis samples in Europe. We have now embarked on our commercialization journey, which we are driving direct to customers and together with our first distributors. At the same time, we are planning for pre-clinical and regulatory clinical studies in the US, with the aim of obtaining FDA clearance. A handful of leading hospitals in the US have already expressed an interest in serving as clinical partners when we can initiate the study.

Our focus now is to achieve our first recurring sales in Europe, and FDA clearance. At the same time, we are continuing to prepare for future sales of QuickMIC® in the US, in line with our commercialization strategy.

Economic, social and environmental sustainability

I would like to take this opportunity to tell you how we stepped up our sustainability efforts in 2022. By creating a Sustainability Team with people from various parts of our organization, we can embed sustainability across the entire company in a natural way. Sustainability involves so much more than reducing emissions. It's just as much about running a business that creates social and economic benefits.

During the year, we worked together to set short and long-term targets for our focus areas, based on our visions for each of the areas. Gradientech's products will be the first choice for fast and accurate susceptibility testing of sepsis samples, we will deliver products and knowledge worldwide with the lowest possible carbon footprint, and we will be the most attractive workplace in our home base of Uppsala in Sweden. We can achieve this by applying a structured approach in all three areas – economic, social and environmental sustainability. Read more about how we work and our targets in the section Sustainability.

Demonstrate the value of rapid AST

The value of rapid AST is a highly relevant issue. For a person with sepsis, it could be the difference between life and death, but also a considerably higher quality of life with fewer side effects and faster recovery. For hospitals it can make significant savings when a patient's stay in the expensive intensive care unit is shortened. Organizations such as the UN and the World Health Organization (WHO) are highly aware of the value of rapid AST in the fight to preserve the future of antibiotic effectiveness.

> Our focus now is to achieve our first recurring sales in Europe.

We know that rapid AST is being requested by more and more hospitals, where antibiotic resistance is a tangible fact. In 2023, we have therefore focused on securing the right distributors in southern Europe, and running studies together with leading university hospitals in southern Europe. The reason for our focus on studies to drive sales is that the market for routine clinical diagnostics requires data from leading laboratories and recognized experts in the field, preferably in their home market, in order to take the step to challenge their existing routines.

To educate our potential customers and market rapid AST in general, and QuickMIC® in particular, we released our first e-book *Next-generation antibiotic susceptibility testing – what's delaying the revolution?* at the end of the year. This is a way for us to help raise awareness and to drive the change towards a faster implementation of rapid AST.

During the first six months of 2023, Sweden is holding the Presidency of the Council of the European Union and, as the leading country within antibiotic stewardship that Sweden is – and has been for many years – the Swedish Presidency hosted a high-level meeting on antimicrobial resistance (AMR) on March 6–7 in Uppsala and Stockholm. The growing focus on AMR is a positive step towards constructive solutions and is raising public awareness of this ongoing silent pandemic. A recurring issue is who should pay – from the development of new antibiotics to a sustainable change in antibiotic prescribing – and the potential use of financial mechanisms to reduce sub-optimal antibiotic use.

Regardless, it is crucial for us as an industrial player to demonstrate the upside of health economics at the hospital level: that, in addition to patient benefit, considerable money can be saved by implementing the fastest susceptibility testing system for sepsis samples in the market. That is how we will build our product category with ultra-rapid and precise susceptibility testing and position ourselves as the first choice for clinical laboratories moving forward.

Uppsala in April 2023

Sara Thorslund
CEO of Gradientech

A prioritized solution for a growing threat to global health

Sepsis and antibiotic resistance are pressing global challenges for both individuals and communities, and are high on the agenda of leading organizations such as WHO.[1] They highlight the need to prioritize innovation and the implementation of new diagnostic solutions that can quickly guide to personalized treatment plans and reduce the misuse of antibiotics. The global market for antibiotic susceptibility testing of blood samples is growing and is expected to reach USD 1.38 billion by 2027.[2]

Sepsis – a global health crisis

Every three seconds, someone in the world dies of sepsis, and for every hour with incorrect or no treatment, the chance of survival decreases dramatically. The ability to make a rapid decision about the most effective antibiotic for an individual patient saves lives and reduces the risk of permanent damage.[3, 4]

Sepsis is often a life-threatening condition and is sometimes referred to as blood poisoning. Sepsis happens when bacteria enter the bloodstream and trigger a response from the immune system that can quickly cause a chain reaction throughout the body. The bacteria can also spread to other vital organs via the bloodstream, such as the heart, lungs and kidneys, and lead to damage or failure. In addition, the global increase in antibiotic resistance, where some bacteria have developed a resistance to antibiotics and the antibiotics are no longer effective, poses an additional threat in the case of sepsis. This means that the empiric antibiotic therapy works less often, making the choice of optimal treatment more difficult even after the diagnostic results have been received.[4]

Sepsis effects nearly 50 million people each year, and studies show that one in five deaths globally are associated with sepsis. Sepsis is the leading cause of death among patients in hospitals worldwide and nearly half of all hospital-related deaths are sepsis-related.[3] The number of cases is probably under-reported. A large proportion of the deaths never appear in the statistics since they are reported as infection-related in connection with, for example, malaria, diarrheal diseases and lower respiratory infections. Sepsis-related mortality is highest among newborns and the elderly, and the risk of dying from sepsis in hospital increases with age. Sepsis is the single diagnosis that is estimated to generate the highest healthcare costs.[5] In the US alone, the costs of sepsis care amount to USD 62 billion annually.[6]

In 2017, WHO recognized sepsis as a global health priority for the coming decade, with a focus on the elimination of incorrect diagnoses and the development of appropriate diagnostic tools.[1] With timely and appropriate interventions, the chances of survival increase dramatically. The need for fast and efficient treatment is therefore great, and a growing elderly population is expected to lead to higher costs for the treatment of sepsis.[2] The global market for antibiotic susceptibility testing of blood samples is expected to increase at a compound annual growth rate of 5.7% from 2021 and reach USD 1.38 billion by 2027.[2]

Sepsis worldwide[3,5,6]

1/5 of all global deaths are associated with sepsis

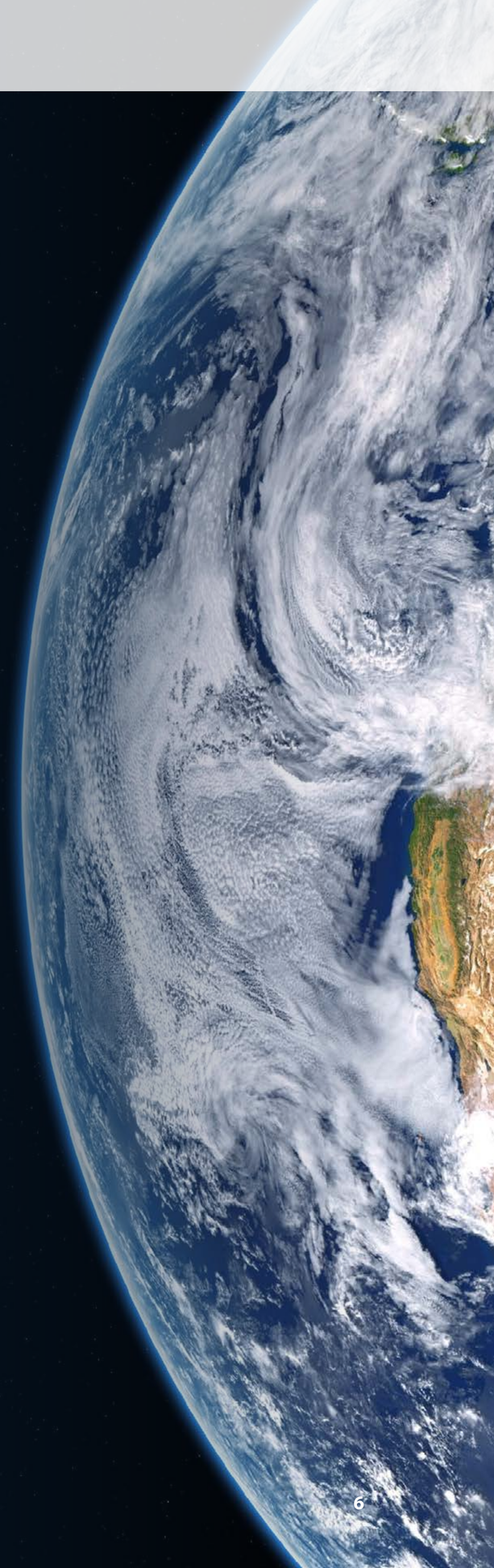
50 million sepsis cases each year

3 every 3 seconds, someone dies of sepsis

11 million deaths per year

#1 most expensive diagnosis to treat in the US

24 billion annually is spent on sepsis care in the US



Deaths caused by antibiotic resistance per year by 2050

In 2014, UK Prime Minister David Cameron commissioned a Review and asked economist Jim O'Neill to analyze the global problem of rising drug resistance and propose concrete actions to tackle it internationally. According to the Review's report, antibiotic resistance will cause about 10 million deaths per year by 2050, compared with the current figure of about 700,000 (2014) if we fail to act. This would mean that as many deaths would be caused by antibiotic resistance in 2050 as are now caused by sepsis – the most common cause of death from infection.[9]

Antibiotic resistance

Inappropriate, unnecessary or overuse of antibiotics are some of the reasons why antibiotic resistance is rising.[1, 7] Therefore, receiving fast information in order to treat the patient correctly is critical not only for the actual patient, but also for preserving the future of antibiotic effectiveness from a broader perspective.

Using antibiotics to treat most infections effectively has been possible for more than 60 years. Antibiotics have been a cornerstone of modern healthcare, and infection control is crucial to success in several fields of medicine, including surgery, maternity care, cancer therapy, and diabetes treatment and care. As a result, antibiotics have been routinely used, and the combination of overconsumption, incorrect diagnosis and irresponsible prescribing has led to increasing antibiotic resistance. This development has significantly affected the ability of healthcare providers to treat bacterial infections. In turn, this is leading to a growing number of hospital-related infections and sepsis cases, longer and more expensive hospital stays, and a higher risk of permanent damage in patients. It is also increasing social costs.[7] In Sweden, antibiotic resistance is predicted to generate additional social costs of approximately SEK 16 billion between 2018 and 2050, while annual cases of antibiotic resistance in Sweden are expected to reach 70,000 by 2050.[8] At global level, the UN predicts that antibiotic resistance could kill 10 million people per year by 2050 and lead to an economic catastrophe as bad as the 2008–2009 global financial crisis if no action is taken.[7, 9] In the past, identifying the exact cause of sepsis has not been as critical because broad-spectrum antibiotics have worked for a wide range of bacterial infections and conditions. As the name implies, broad-spectrum antibiotics can be used to treat a wide range of bacterial infections, which is useful if you do not know what type of bacteria is causing the infection.

In contrast to broad-spectrum antibiotics, narrow-spectrum antibiotics target a selected group of microorganisms. In this way, bacteria are treated more effectively while the risk of antibiotic resistance and unnecessary antibiotic treatment, which could have an adverse effect on the rest of the immune system, is reduced.[10]

WHO describes antibiotic resistance as one of the top health and development threats.[1] New resistance mechanisms are jeopardizing our ability to cure common infectious diseases such as pneumonia, tuberculosis and sepsis. As antibiotics become less effective, diseases are becoming more complex and sometimes impossible to treat. The ability to make a rapid decision about the most effective antibiotic for an individual sepsis patient, and using the right treatment, is highly significant for preserving the future of antibiotic effectiveness. This is a major and important social challenge that requires both global and local initiatives.

High risk of bloodstream infection

Authorities all over the world are focused on developing strategies and setting up initiatives to ensure responsible prescribing and use of antibiotics to slow down the spread of antibiotic resistance. These initiatives and policies are also intended to serve as support for decision-makers, regulatory bodies and end users, such as healthcare providers.

As an example of national initiatives, Swiss, US and Canadian authorities all launched projects in 2018 independently of each other to highlight and contribute to a framework for more responsible use of antibiotics.[7] Many countries have followed suit with national action plans, and it would be reasonable to assume that these initiatives will drive demand for rapid antibiotic susceptibility testing as authorities establish more comprehensive frameworks for antibiotic use and surveillance.[2]

In early 2020, the Swedish government updated the Swedish strategy to combat antibiotic resistance. The updated strategy refers to what needs to be done during 2020–2023 and emphasizes, for example, the importance of developing and optimizing existing diagnostics, and that the diagnostics should be kept up to date and used routinely in Swedish healthcare. Sweden has long been a pioneering nation and shown leadership in international efforts to inform about the emergence and spread of antibiotic resistance.[8] For example, during its Presidency of the Council of the European Union in the first six months of 2023, Sweden hosted a high-level meeting in Stockholm/Uppsala on March 6–7 with the aim of further strengthening the EU's efforts to combat antibiotic resistance and to show that Sweden is still highly committed to pursuing this issue.

The importance of rapid and accurate diagnosis

WHO also emphasizes the need to prioritize new diagnostic solutions that can provide fast guidance and reduce overuse and misuse of antibiotics.[1] A growing trend toward precision medicine – a tailored approach to the treatment of infectious diseases – is further increasing the need for sensitive and specific diagnostic tools. The cause of the infection and most effective treatment must be established rapidly. Having lab results available as early as possible in order to guide treatment plans will be highly significant for both patients and healthcare providers.[4]

The problem has been acknowledged and prioritized in healthcare, and important work is taking place in several areas to prevent and reduce the problems with bacterial resistance. One example is Antibiotic Stewardship programs, which are becoming increasingly common in hospitals, with the aim of providing patients with the most optimal treatment at the right time.[7]

Several US authorities are working actively with the problems associated with antibiotic resistance, which in various ways includes supporting and promoting the development of new diagnostic methods, such as ultra-rapid AST. We are seeing the effects of this through the strong interest we are receiving from US academic groups and clinical laboratories headed by well-known and highly reputable people in the AST field. This is motivating us at Gradientech in recognizing the US market product requirements and the generation of scientific data.

Marc van Nuenen
VP Business Development US

The antibiotic susceptibility testing market

Geographically, the US market for AST of blood samples was largest with a current value of nearly USD 500 million and is expected to reach over USD 660 million by 2027. This is followed by the European market, which is expected to reach about USD 370 million by 2027.[2]

Gradientech's diagnostic medical devices are authorized for marketing in the EU and those countries that accept CE-marked diagnostic medical devices. We now have distributors for the Nordic region, the Baltics, Austria, Switzerland and several countries in Eastern Europe. Gradientech is also authorized to conduct its own sales in EU countries where we have not yet contracted distributors.

Competition

There are a few companies like Gradientech with CE-marked diagnostic systems for rapid susceptibility testing of samples from sepsis patients. The testing times of the various systems vary from 5.5 to seven hours, compared with two to four hours for the QuickMIC® system.

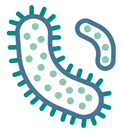
During the early market introduction of QuickMIC®, the other rapid AST systems are our main competitors, while the more traditional AST systems will be our competitors when we reach the broader market. Among the companies with CE-marked systems for rapid AST, in 2022, Swedish Astrego (urine AST) was acquired by Japanese Sysmex, and American Specific Diagnostics (blood AST) was acquired by bioMérieux – a world leader in the field of clinical microbiology. The most recent acquisition exceeded USD 400 million.

The main drivers of market growth[2]

More government initiatives to combat antibiotic resistance and its emergence

Technological progress and product development

The high global risk of infection, including sepsis



The increasing prevalence of antibiotic resistance

[1] World Health Organization, Fact Sheets – Antibiotic Resistance

[2] Meticulous Research, Global Antimicrobial Susceptibility Testing (Blood Samples) Market, 2021.

[3] K. E. Rudd et al., Global, regional, and national sepsis incidence and mortality, 1990–2017, The Lancet, Vol 395, Issue 10219 (2020)

[4] Malmberg C, et al., Front. Cell. Infect. Microbiol, 12:758262 (2022)

[5] Torio C (AHRQ), Moore B (Truven Health Analytics). National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2013. HCUP Statistical Brief #204. May 2016.

[6] 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

[7] Antimicrobial resistance – The Silent Pandemic, Citi GPS: Global Perspectives & Solutions, Dec 2022

[8] Swedish Government Offices, Swedish strategy for combating antibiotic resistance, 2020.

[9] Tackling drug-resistant infections globally: Final report and recommendations. Review on Antimicrobial resistance, May 2016

[10] Vital Signs: Preventing Antibiotic-Resistant Infections in Hospitals—United States, 2014.

[11] Watkins et al. Antibiotic stewardship in the era of precision medicine, JAC – Antimicrobial Resistance, Volume 4, Issue 3, June 2022

A sustainable future with access to antibiotics

Gradientech's business concept is to develop, manufacture and market pioneering products for users in healthcare or research environments, and ultimately to improve quality of life for patients and lower healthcare costs.

With the QuickMIC® diagnostic system, Gradientech is making it possible for attending doctors to receive rapid guidance on treating sepsis patients with the right antibiotics, and the right dose. In this way, more lives can be saved, healthcare costs lowered and the spread of antibiotic resistance limited, while optimizing the use of existing antibiotics. Our strategic focus now is to drive sales of QuickMIC® systems together with distributors in the European market by continuously increasing sales of instruments. Alongside of this, development and preparation for clinical studies in the US are ongoing with the aim of obtaining FDA clearance for QuickMIC®.

Vision and mission

Gradientech's vision is "Precision medicine, for a sustainable world." Every three seconds, someone in the world dies of sepsis. At least 11 million people die each year and many of them are children.[1] But sepsis can often be treated with the help of rapid diagnostics. However, the growing global prevalence of antibiotic resistance is making it even more difficult to identify the right treatment for sepsis patients. Due to this growing resistance, there is a risk that antibiotics will not be available in the future in the manner we are accustomed to.[2]

The vision for our products is to take the step towards precision medicine and achieve personalized treatment for sepsis patients[3], for the benefit of individual patients, and for the rational use of antibiotics. In combination, this is helping to achieve a sustainable future where antibiotics are still a treatment option.[2]

Operational targets

Using the company's QuickMIC® system for antibiotic susceptibility testing instead of the usual slower, manual or instrumental systems for the same purpose[4], hospital-based microbiology laboratories will be able to present fast and accurate results for the antibiotic susceptibility of bacteria to attending doctors. The antibiotic treatment can then be quickly adapted at a personal level to enable optimal treatment for the patient. The aim of our diagnostic solution is that sepsis patients have a greater chance of survival, experience fewer side effects from their antibiotic treatment, and require a shorter hospital stay. Rapid adjustment of inappropriate antibiotic prescribing and less overuse of broad-spectrum antibiotics is also helping to slow down the spread of antibiotic resistance, which is now a global health threat that could send us back to the pre-antibiotic era.[2]

> Gradientech's vision is "Precision medicine, for a sustainable world"

Completed in 2022

- CE-IVD certification of QuickMIC® and its Gram-negative antibiotic panel.
- First sales of the QuickMIC® instrument.
- Distribution agreements with Biomedica for the commercialization of QuickMIC® in Austria, Switzerland and East-Central Europe, and with Triolab Group for the commercialization of QuickMIC® in Sweden, Norway, Denmark, Finland and the Baltics.

Focus in 2023

- Conduct pre-clinical studies in the US.
- Promote the QuickMIC® system in Europe.
- Implement QuickMIC® in routine diagnostics for sepsis patients in Europe.
- Increase the number of installed instruments in clinical laboratories in Europe.

Strategies

Obtain IP protection

Gradientech develops, manufactures and sells microfluidic products for cell study applications, in infection diagnostics specifically. We regularly review our innovations to determine whether they are patentable and strategically significant for us to seek patent protection. We do this in consultation with our patent office and patent attorney, who have worked with our patent families for a long time. Our strategy is to protect technological solutions and applications in commercially viable markets, mainly in Europe and the US, but also in other selected markets in Asia, for example. Our trademark portfolio is managed in partnership with an external legal partner specialized in trademarks.

Read more in the "Patent portfolio" section.

Product development and manufacturing together with external partners

Gradientech's agile and flexible product development model includes close collaborations with international development partners and medical device contract manufacturers, which is a cost-efficient addition to the company's own expertise and activities.

Launch strategy

In 2022, the QuickMIC® system and its first antibiotic panel for Gram-negative bacteria associated with sepsis were launched in several European countries, where the device is now marketed via contracted distributors of medical diagnostic devices. We now have distributors for the Nordic region, the Baltics, Austria, Switzerland and several countries in Eastern Europe. The company's next focus will be to sign distributor agreements for selected markets in southern Europe. We can provide customers in other European countries with products via direct sales.

The QuickMIC® system requires FDA clearance before it can be marketed in the US. We are working with a US regulatory adviser on preparing our FDA studies. The first antibiotic panel for the US market is currently under development, and preparations for the clinical study in the US are ongoing.

Read more in the "Regulatory process" section.

Global market strategy

We are eventually planning to work with a commercial strategic partner, preferably with complementary products, to place the QuickMIC® system on the global market. At present, we are not planning to offer direct sales of QuickMIC® in the US following FDA clearance. Discussions are now being held with international players regarding future marketing in the US combined with other markets.

[1] K. E. Rudd et al., Global, regional, and national sepsis incidence and mortality, 1990–2017, The Lancet, Vol 395, Issue 10219 (2020)

[2] Antimicrobial resistance – The Silent Pandemic, Citi GPS: Global Perspectives & Solutions, Dec 2022

[3] Watkins et al. Antibiotic stewardship in the era of precision medicine, JAC – Antimicrobial Resistance, Volume 4, Issue 3, June 2022

[4] Malmberg C, et al., Front. Cell. Infect. Microbiol, 12:758262 (2022)

Sustainability

We are now living in a world where change is natural, where changes come in rapid succession, and where there is a general belief that innovation holds the key to many of the major challenges we are facing.

Gradientech and our activities are part of that change. During the year, we launched and commenced commercialization of the new QuickMIC® system – which is not only the fastest CE-marked system on the market for determining the best approach to antibiotic treatment of patients with sepsis, but is also based on a technology platform that can measure bacterial resistance with a precision that no other system can match. The benefits of this are translated into personalized treatment with the best approach for each patient. This is how we intend to build a new and leading product category in susceptibility testing that will outperform in terms of speed and precision. *"QuickMIC® – Speed. Precision. Accuracy."*

As a medical device company, Gradientech and our operations are governed by regulatory standards and regulations to ensure that the devices we develop and manufacture are safe to use and deliver the promised results. Our quality management system has been ISO 13485-certified since 2017, but we are also guided every day by our vision of "Precision medicine, for a sustainable world." During the year, Gradientech stepped up its sustainability efforts, and we participated in external training, while also building on our own knowledge internally. We created a Sustainability Team comprising the CEO, CFO and representatives from production, development and marketing. The team has drawn up a short-term and long-term sustainability strategy and in 2023, will roll out various projects, presented below, under priorities for coming years.

Our focus areas

In the sustainability process that we implemented and have described below, we identified three focus areas.

Healthcare

The Team

Innovation and Knowledge

What have you learned from our launch of a more strategic sustainability process at Gradientech?

It feels satisfying to be working with a company that takes a serious approach to sustainability. And it also inspires hope and motivation.

David Rönnholm
Product Development Manager
and member of the Sustainability Team

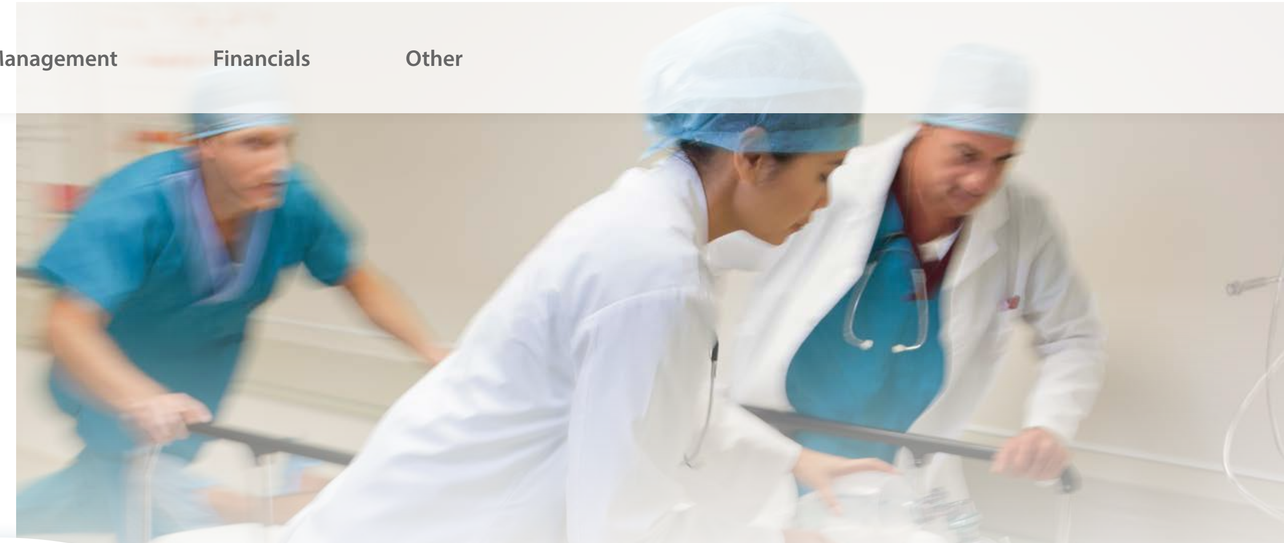
End users

Patients, doctors, laboratory employees.

Gradientech is dedicated to reducing inappropriate antibiotic prescribing, reducing patient deaths and shortening hospital stays for patients. Our solutions impose major demands on product safety and accurate clinical results, and our devices must be user friendly. All of this ensures that healthcare professionals can provide patients with safe and accurate treatment.

Stakeholder dialog

Gradientech identifies stakeholders as particularly important players who either affect, or are affected by, us. Our key stakeholders are end users, employees, customers and investors. We engage in a regular dialog with these stakeholders to gain insight into their needs, challenges and priorities. We believe that this is one of the most important elements for the development of our business and for helping to drive our sustainability strategy forward.



Customers

Distributors, partners, hospital managements, industrial partners, suppliers.

Gradientech currently collaborates with players including distributors, hospitals and sub-contractors, and considers them part of the team. We are all dedicated to fairness, equality and reducing our environmental impact. We strive to continuously develop, and spread innovation and knowledge, with the lowest possible carbon footprint.

Employees

Employees, prospective employees, consultants, students.

Gradientech aims to be an attractive employer in all respects. We want our employees and consultants to feel inspired, and we strive for low employee turnover by ensuring fair and equal treatment – a workplace where everyone feels welcome, and no one needs to seek another workplace in order to develop.

Investors

Our shareholders, new investors, contributors.

Gradientech creates long-term shareholder value by being at the leading edge of innovation, inspiring employees and partners and always maintaining a patient focus.

Our focus areas

We conducted a materiality assessment to identify the issues that are most important for our stakeholders and where Gradientech has the greatest ability to be involved and have an influence. Based on these results, we identified three focus areas. Each focus area contains a long-term vision and value-generating activities. As of 2023, we will be monitoring key performance indicators (KPIs) for each focus area – the KPIs have set targets for both 2023 and onwards. Our three focus areas are: Healthcare, the Team, and Innovation and Knowledge.

Our overall and fourth focus area permeates everything that we do – our "shared long-term vision." We believe in all forms of collaboration: industrial, financial and academic partnerships that lead to both innovation and profitability. Gradientech is a long-term partner in the fight against sepsis and antibiotic resistance, and sustainability is our toolbox in this important and challenging process.

17 PARTNERSHIPS FOR THE GOALS

Healthcare

The QuickMIC® system's ability to deliver rapid and precise results when AST testing sepsis patient samples could be crucial both for individual patients and for healthcare from a broader perspective.

Value generation

- Reduce inappropriate antibiotic prescribing
- Shorten hospital stays for individual patients
- Improve global health by providing better sepsis care

KPIs

- Secure the availability of systems used in routine
- Clinical studies
- Successful tests in relation to delivered tests

The Team

As Gradientech grows, it is important that we continuously review our occupational health and safety, invest in our employees and provide opportunities for development. This is how we create a team that enables Gradientech to support healthcare.

Value generation

- Maintain low employee turnover by promoting job satisfaction

KPIs

- Keep people inspired
- Diversity
- Employee turnover

Innovation and Knowledge

By being at the leading edge of innovation and knowledge, we can be involved and help shape the future. We can use our innovation and knowledge to help limit the spread of antibiotic resistance – one of the biggest threats to global health of our time – and to contribute to more sustainable production.

Value generation

- Raise public awareness of sepsis and antibiotic resistance
- Leading-edge innovation
- Reduce the environmental impact of our products

KPIs

- Visibility – in our own media channels, at meetings, talks and trade fairs as well as in journals and publications
- Optimized transportation
- Proportion of bio-based or regenerated plastic per cassette
- Optimized production
- Category winner – "Ultra-rapid and precise MIC"

Gradientech's Board takes sustainability seriously because it is our own personal belief that it generates both short and long-term value for the company. Sustainability is becoming increasingly important for companies because it not only helps to reduce operational risks, but also gives the company a good reputation, attracts and helps to retain talent, makes it easier to meet regulatory requirements, and increases opportunities for access to capital. By prioritizing sustainability, we, as a company, can generate long-term value for our stakeholders and help to create a more sustainable and fair future.

Simon Turner
Board member, Gradientech

Healthcare

Care, patients and global health are keywords for Gradientech's business. By never losing our focus on these keywords, we create reliable and high-quality products that are essential for healthcare.

Reduce inappropriate antibiotic prescribing

The world is currently facing a serious challenge to global health, possibly the most serious challenge of our time – the spread of antibiotic resistance. Healthcare is dependent on effective antibiotics both now and in the future, and healthcare providers, researchers and other players are fighting to find solutions in this important field. At Gradientech, we develop and commercialize our innovations in susceptibility testing and infectious diseases so that healthcare systems can provide the best possible care today, and still have access to effective antibiotics tomorrow.

Shorten hospital stays for individual patients

In 2022, our first diagnostic medical device, QuickMIC®, received CE-marking. This means that the system can be marketed and sold for diagnostic purpose. QuickMIC®, with its 2 to 4 hour delivery time, is the fastest system on the market for growth-based antibiotic susceptibility testing of sepsis samples. The system's ability to deliver rapid and accurate resistance results means that patients with sepsis can receive personalized treatment with the right antibiotics and the right dose much faster than with the usual methods of routine laboratory testing.

Improve global health by providing better sepsis care

Sepsis is a life-threatening condition that occurs when the immune system overreacts to an infection in the body. Sepsis affects about 50 million people every year, including 50,000 people in Sweden. Of these, about 11 million people die each year – or one person every three seconds. The problem is huge and growing. Rapid diagnostics can save lives, reduce healthcare costs and limit the overuse of broad-spectrum antibiotics, which is a plausible cause of the resistance crisis. Gradientech is proud to contribute with our QuickMIC® system, which is now the fastest CE-IVD certified system for antibiotic susceptibility testing of sepsis samples.

Priorities and targets

Gradientech is working actively to generate value for healthcare – both short and long-term. The KPIs for our "Healthcare" focus area are set out in the table below, including our long-term targets for 2030.

In 2023, our overriding priority to support healthcare is to continue expanding our field organization in order to support clinical studies, and to ensure successful results for our first customers. We eventually intend to have broadened our base to global markets such as North and South America, and Asia. To achieve global success, our systems must be supported by a customer service organization that can provide 24-hour support for healthcare customers.

3 GOOD HEALTH AND WELL-BEING

Long-term vision

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

KPIs		Targets 2030
Secure the availability of systems used in routine	→	QuickMIC® instruments are available in markets in Europe, North America, South America and Asia.
Clinical studies	→	Clinical studies show that our products save lives, lower healthcare costs and reduce inappropriate antibiotic prescribing.
Successful tests in relation to delivered tests	→	All customers receive fast and adequate technical support – 24/7.

The Team

Our co-workers are Gradientech's most valuable resource, and we are committed to health and safety, and to offering a workplace where employees can develop to their full potential.

Low employee turnover by promoting job satisfaction

Gradientech is a company that is growing in terms of employees, and we are convinced that job satisfaction is the key to employee retention and development.

As the company grows, we also need to continuously develop our health and safety management and offer a workplace where both new and existing employees can develop to their full potential. In 2023, we will commence an in-depth analysis of Gradientech, including a focus on what our employees are inspired by.

Gradientech only has employees in Sweden at present, but since we are expecting to grow and already sell our products in an international market, the analysis will also focus on diversity.

Priorities and targets

Gradientech works proactively to create employee value – both short and long-term. Our KPIs for "The Team" focus area, including our long-term targets for 2030, are presented in the table below.

In 2023, our overriding priority is to launch a long-term project to create Uppsala's most attractive workplace, and thereby ensure that we retain our employees as we grow. During the year, we will conduct an employee satisfaction survey to find out what individual employees are inspired by, and to analyze the company's workplace from a diversity and equality perspective.

Long-term vision

Gradientech is Uppsala's most attractive workplace, where everyone feels welcome, and no one needs to seek another workplace in order to develop.

KPIs		Targets 2030
Keep people inspired	→	We will define our long-term target on the basis of the employee satisfaction survey in 2023.
Diversity	→	We will define our long-term target on the basis of the diversity and equality analysis in 2023.
Employee turnover	→	Maintain a maximum employee turnover rate of 10% as the company grows.

Innovation and Knowledge

Gradientech is at the leading edge of innovation and develops next-generation diagnostics in infectious disease medicine. We want our products to be pioneering and enable the best, personalized treatment of patients that is currently available, while also helping to limit the spread of antibiotic resistance, which is one of the greatest threats to global health of our time.

Raise awareness of sepsis and antibiotic resistance

Awareness plays a crucial role in preventing the spread of sepsis and antibiotic resistance. Gradientech has stepped up to the challenge to help raise awareness and spread information about one of the biggest future challenges to global health of our time. We raise awareness by, for example, publishing articles and e-books, arranging seminars and talks, and spreading evidence-based knowledge via our social media channels.

Leading-edge innovation

In the field of antibiotic resistance, there are great expectations that research and innovation will find solutions and methods to reduce the global spread of antibiotic resistance. WHO and the national action plans of many countries highlight the need to develop and implement new diagnostic solutions that can provide rapid guidance on optimized treatment plans, and thereby reduce the misuse of antibiotics. Gradientech believes that broad partnerships are needed at all levels of society to improve the current standard of care for patients, and to limit the global spread of antibiotic resistance. We will contribute by doing what we are good at – leading-edge innovation. Our QuickMIC® system not only has the fastest delivery times of all rapid AST systems for sepsis samples, but also provides more precise MIC values, which enables personalized dosing of active antibiotics to further optimize antibiotic use.

Reduce the environmental impact of our products

Gradientech's quality management system was certified in 2017 and the company works closely with many of its sub-contractors and contract manufacturers, and has good knowledge of how they produce our components and sub-products. At the same time, we know it is highly likely that more things can be improved to make our production even more sustainable and will therefore, in 2023, focus on a number of surveys in relation to, for example, the proportion of bio-based or regenerated plastics in our products, transportation and production optimization. The goal of these activities and any subsequent changes is to achieve more sustainable production from an environmental perspective, but also to reduce costs.

Priorities and targets

Gradientech works proactively to spread innovations and knowledge – both short and long-term. The KPIs for our "Innovation and Knowledge" focus area, including our long-term targets for 2030, are presented in the table below.

In 2023, we have two overriding priorities in this focus area. The first is to be visible and share our knowledge by spreading information via diverse communication chanels. The second is to launch a long-term project to reduce our environmental impact. We will map our transport chain, analyze our proportion of production-related waste, and determine the proportion of re-generated or bio-based plastic in our test cassette to identify what is possible to improve moving forward. The mapping will form the basis for long-term decisions that, combined with a planned ISO 14001 certification, are important steps towards reducing our environmental impact.

3 GOOD HEALTH AND WELL-BEING

9 INDUSTRY, INNOVATION AND INFRASTRUCTURE

12 RESPONSIBLE CONSUMPTION AND PRODUCTION

Long-term vision

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

KPIs		Targets 2030
Visibility – via our own and external channels	→	At least 400,000 website visitors per year.
Optimized transportation	→	Gradientech is ISO 14001 certified.
Proportion of bio-based or regenerated plastic per cassette, including components	→	We will define our long-term target on the basis of the product analysis conducted in 2023.
Optimized production	→	We will define our long-term target based on the review of our transportation and production in 2023.
Category winner – "Ultra-rapid and precise MIC"	→	"Ultra-rapid and precise MIC" is a recognized product category associated with reimbursement codes in Europe and the US.

Continuous measurement scale and high resolution

Gradientech's patented technology combines microfluidics with real-time measurement of living cells – a method that makes it possible to measure the behavior of cells in response to stable gradients of biomolecules.

Concentration gradient combined with a superior visualization at the microscopic level allows for higher resolution and better reproducibility than traditional methods, properties that are important in fields such as precision diagnostics. The technology can be used in various biological and medical applications, including studies of cell migration and blood vessel formation, or the recently launched diagnostic application with ultra-rapid measurement of antibiotic resistance.

Technology applied in QuickMIC®

Our diagnostic medical device, QuickMIC®, delivers fast readings of minimum inhibitory concentration (MIC) values, which determine whether the bacteria are susceptible or resistant to the antibiotic tested. Hence the name QuickMIC®. These values are obtained by exposing the bacteria to a gradient of the selected antibiotic. During the process, the bacteria are imaged and the growth of the individual colonies is quantified using automated image and data analysis.

The technology in the QuickMIC® system is based on microfluidics, whose miniaturized fluid flows enable short turnaround times and require small sample sizes. Stable, linear concentration gradients of antibiotics are created within small sample volumes containing bacteria from the patient's blood. This ensures high resolution around the important clinical breakpoints, and makes it possible to deliver accurate answers to the effect that various antibiotics have on the bacteria in the patient's blood. Higher resolution, and the possibility of a continuous measurement scale, results in a faster diagnostic system with higher precision than systems based on the current reference method – the broth microdilution (BMD) method. The BMD method only measures the bacteria's response to the antibiotic at discrete measurement points, each of which represents a doubling of the concentration compared with the nearby measurement point. Our clinical study prior to CE-IVD certification for QuickMIC® and its Gram-negative panel showed a reproducibility of 99.1%, which is highly competitive.

Image *The graphical user interface presents the resistance levels (MIC values) for bacteria from a sepsis patient when the sample is tested against a panel of 12 antibiotics in a QuickMIC® cassette. When the system has measured a stable MIC value for an antibiotic, the color changes from blue to white in the graphical presentation and the resistance level is reported together with a final time stamp. Full bacterial growth in the positive control chamber, which is shown at the bottom, must be achieved before a stable MIC value can be reported for a tested antibiotic.*

Watch the video to see how our technology works

QuickMIC®

Clinically reliable MIC reading. Within 2 to 4 hours.

- **Ultra-rapid AST** Results within 2 to 4 hours.
- **Superior precision** Clinically actionable results.
- **Modular system** Start small, scale up.

First CE-marked diagnostic medical device

Gradientech develops and offers products and software for high-quality analysis of the behavior of cells in response to concentration gradients of biomolecules. Our first diagnostic medical device, QuickMIC®, is a CE-IVD marked system for determining optimal antibiotic treatment of sepsis patients – for faster and more personalized treatment of sepsis patients, lower healthcare costs, and to help combat the growing problem of antibiotic resistance by ensuring effective use of antibiotics.

DESIGN AWARD 2021

reddot winner 2021

The QuickMIC® system has received two international prizes for industrial design: The Red Dot Design Award[3] and iF Design Award.[4]

QuickMIC®

Ultra-rapid testing of antibiotic susceptibility

QuickMIC® determines the best approach to antibiotic treatment in patients with sepsis, and the antibiotics to which the patient's bacteria is resistant. The system uses a positive blood culture, and is intended primarily for use in clinical microbiology laboratories.. Quantitative resistance levels, or MIC values, are delivered within two to four hours. This makes QuickMIC® the fastest AST system for sepsis samples on the market, according to our own assessment, which is based on our knowledge of the market.[1] AST systems that deliver results within four hours are classified as ultra-rapid[2], and our assessment is that no other market approved, ultra-rapid AST system for sepsis samples that is currently available can compare with our device.

The QuickMIC® system comprises modular instruments with dedicated analysis software and antibiotic-filled cassettes, which are the system's consumables. One instrument analyzes one patient sample at a time against a panel of 12 antibiotics per run. The user selects an antibiotic cassette based on the Gram status of the bacteria. Hospital clinical laboratories perform a routine Gram stain if a blood culture has signaled positive and shown bacterial growth. Instruments can be stacked to increase capacity, making QuickMIC® attractive to both large and small laboratories.
The modular concept also has advantages such as built-in back-up – more modules are available if one module requires service – and the fact that decisions by end users to install the system entail a lower initial cost compared with large integrated systems.

The QuickMIC® system and its Gram-negative panel were designed for the European market and registered with the Swedish Medical Products Agency on May 23, 2022 in accordance with the In Vitro Diagnostic Medical Devices Directive (IVDD). On August 11, 2022, the low-risk products (instruments and sample preparation kit) were registered in accordance with the new In Vitro Diagnostic Medical Devices Regulation (IVDR). The QuickMIC® system is therefore authorized for marketing in the EU and those countries that accept CE-marked diagnostic medical devices up to at least May 2026, before the high-risk products (antibiotic-filled cassettes and analysis software) require approval by BSI, which is the company's Notified Body.

The QuickMIC® instrument has been certified by Intertek for electrical safety, electromagnetic compatibility and fire safety, and may also be placed on the market for research and development purposes for external users in the US.

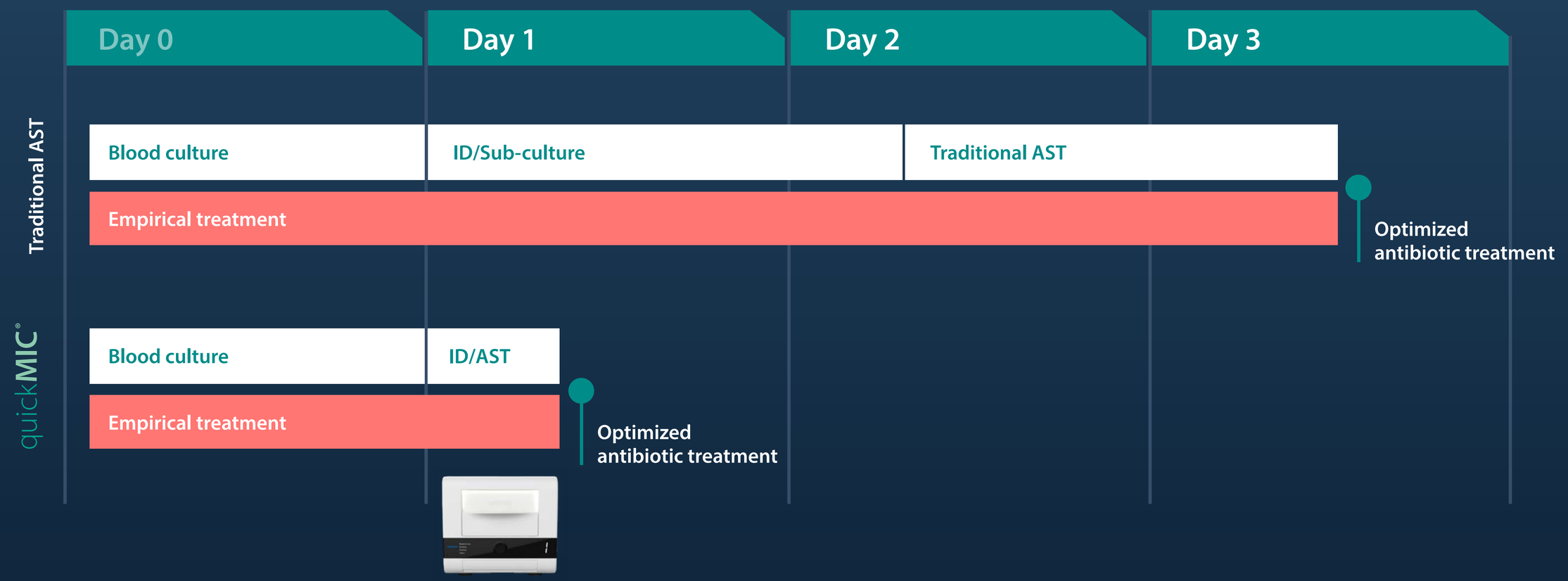
Clinical actionable AST
QuickMIC® has been designed to help clinicians make better founded decisions about antibiotic treatment and doses for improved treatment of sepsis patients.

Precise and reliable MIC values
QuickMIC® reports resistance levels with high accuracy and unparalleled precision. Combined with results within 2 to 4 hours, this means an ultra-rapid AST that you can trust.

Combat antibiotic resistance
Personalized treatment of sepsis patients reduces antibiotic use and helps to reduce the spread of antibiotic resistance.

QuickMIC® reduces the total turnaround time with days

The image below shows a schematic time comparison for the workflow in clinical laboratories with and without QuickMIC® for rapid AST directly from a sepsis patient's blood samples. Initial standardized blood culture to find samples of blood with bacteria is usually followed by rapid bacterial identification (hours). In laboratories that use traditional AST, this is followed by preparation of the blood culture to increase the amount of bacteria (24 hours) and then the actual AST (up to 24 hours). No preparation is required with QuickMIC® and the AST only takes a few hours, which means that results from the bacteria identification and AST are available simultaneously and can be used to optimize the patient's treatment at least 24 hours earlier than results from the laboratories that use traditional AST.



[1] Results from the company's clinical studies confirm compliance with all essential requirements for CE marking of QuickMIC® products
[2] Jasuja, J.K. et al. Eur J Clin Microbiol Infect Dis 39, 1305–1313 (2020)
[3] https://www.red-dot.org/project/quickmic-52010
[4] https://ifdesign.com/en/winner-ranking/project/quickmic/315704

Regulatory process

Companies that develop, produce and sell medical devices are subject to strict regulatory requirements and processes. The reason for this regulatory control is that end users and patients must be able to feel confident that the device is safe to use and that it will work as described by the manufacturer.

The former IVDD expired on May 26, 2022 and was replaced by a regulation entailing that most IVD devices now require an external review before the manufacturer can declare the device CE compliant. This also applies to AST systems.

The regulation also includes transitional provisions for devices that were CE-marked under the IVDD so they can remain on the EU market until their CE-marking expires. The expiry date for AST systems is May 26, 2026.

New IVD regulation since May 26, 2022

For the approval of an *in vitro* diagnostic medical device in the EU, the manufacturer must comply with the applicable provisions for quality management and product development and be able to demonstrate the performance of the device using analytical and performance studies. The results are compiled in technical documentation verifying conformity with the requirements for CE-marking of the device. Up until May 26, 2022, all diagnostic medical devices were required to comply with the IVDD for marketing authorization in the EU. On May 26, 2022, the new IVDR came into effect in the EU. Due to the shortage of notified body capacity, however, a transitional period was introduced to allow a gradual phase-in of the new rules for high-risk products under the IVDR, which is a maximum of five years depending on the class of the medical device.

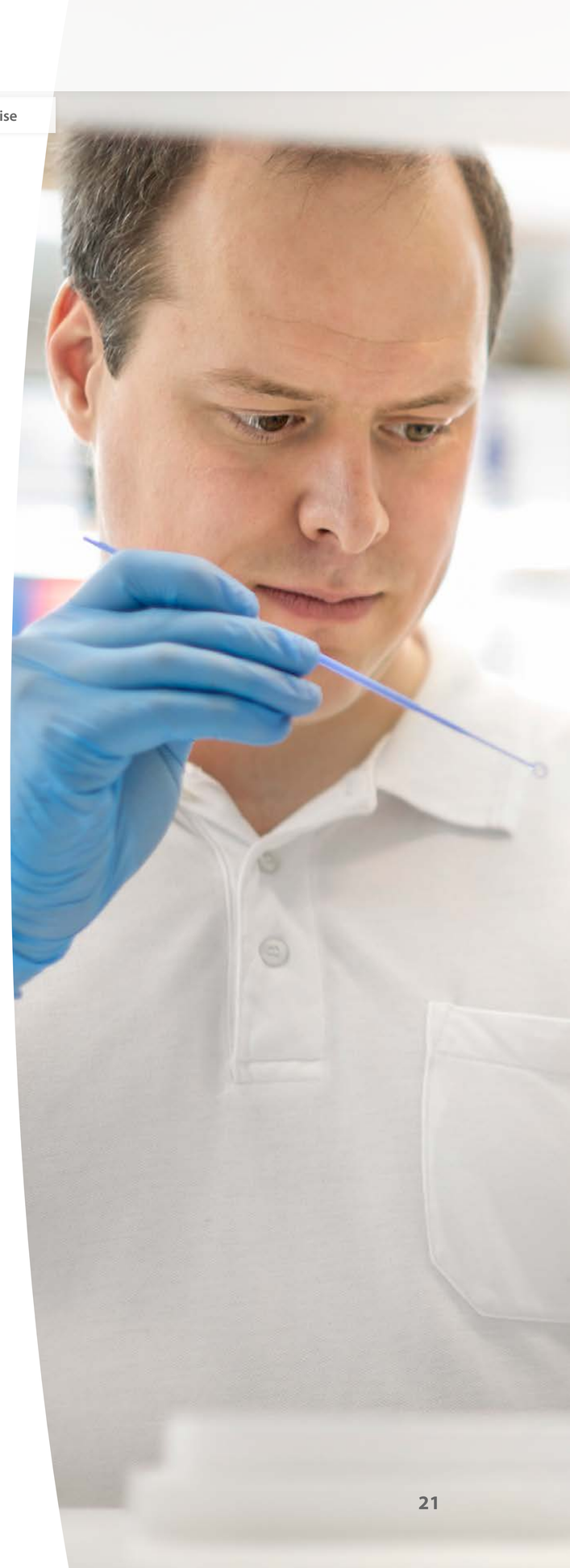
Under the IVDD, the QuickMIC® system was classified as a medical device only requiring a self assessment, with no involvement of a Notified Body, for certification. The system was registered with the Swedish Medical Products Agency on May 23, 2022 following the completion of clinical studies carried out with two external university hospitals to demonstrate compliance with the regulatory performance requirements. The QuickMIC® system's agreement with AST reference testing was 94.7%, compared with the minimum regulatory requirement of 90.0% (*EA, Essential agreement*). The reproducibility rate was 99.1%, which is highly competitive.

Under the IVDR, the QuickMIC® Instrument and QuickMIC® Prep Kit (for sample preparation) products are classified as low-risk products, while QuickMIC® Analyst (the analysis software) and QuickMIC® GN (the cassettes) require a review by the company's Notified Body (BSI). Since the low-risk products were registered with the Swedish Medical Products Agency on August 11, 2022, all of the current products in the QuickMIC® system can be placed on the market under the current provisions. The documentation for the review is currently being compiled, and the review is expected to take at least 12 months due to the long waiting times. The next antibiotic panel cannot be placed on the European market until the whole system has been CE-marked under the IVDR.

New provisions have applied in the UK since Brexit. However, Gradientech expects to be able to use the same clinical study data for the approval of QuickMIC® in the UK as for certification in the EU.

Regulatory process for the US

Before QuickMIC® can be placed on the US market for diagnostic testing, FDA clearance is required. Following discussions with our regulatory adviser in the US, we believe that QuickMIC® is eligible for 510(k) clearance. 510(k) clearance is possible if there is an equivalent FDA-cleared product that can be used for comparison with the QuickMIC® system. QuickMIC® is expected to be classified as a Class II Medical Device, which the FDA defines as devices with a moderate to high risk to the patient. In order to obtain FDA clearance for QuickMIC® and its first antibiotic panel, the panel needs to be updated to also include the current clinical breakpoints that are frequently used in the US for susceptibility testing. These breakpoints generally occur at higher antibiotic concentrations than the clinical breakpoints that apply in the EU and other parts of the world. The US panel for Gram-negative bacteria is under development.



Patents and trademarks

Gradientech develops and manufactures innovative microfluidic products, mainly for infection diagnostics applications. Innovations and improvements, such as technical solutions that arise during development or manufacturing transfers, are continuously reviewed in consultation with our patent attorney, to determine whether the innovations are patentable, and strategically significant for the company to seek patent protection. Our trademark portfolio is managed in collaboration with an external trademark agent.

Patent

Title	Country	Status	Description	Valid until
Adhesive improving coating	SE	Pending	Improved adhesion between hydrogels and a surface-modified plastic surface	Mar 27, 2042
QuickMIC® cassette	PCT	Pending	Design and function of the QuickMIC® cassette	Apr 1, 2040
New use of fluidic device	UK/SE/DE/FR/CH/JP/US (for the US: system and method patent)	Granted	Microfluidic system used for rapid AST	Jul 10, 2034
Capsule for fluidic systems	GB/SE/DE/FR/IR	Granted	Construction of a simple microfluidic encapsulation	Jun 30, 2031
Fluidic culture device	GB/SE/DE/FR	Granted	Microfluidic system for gradient formation in a 3D matrix	Nov 6, 2029

Trademarks

Trademark	Country	Status	Class	Year of application
GRADIENTECH	SE	Registered	1, 5, 9 and 42	2010
CELLDIRECTOR	SE/EU/US	Registered	SE: 1, 5, 9 and 10/EU: 1, 5 and 9/US: 1 and 9	2010
QUICKMIC	SE/US	Registered	5 and 10	2017

Broad competence combined with specialized knowledge

Our team has broad competence and specialized knowledge in all of our key areas – where development engineers and process competency meet microbiological expertise and commercial experience. Gradientech works with the world's leading experts in the field and engages with a dedicated international network, where we are all focused on new diagnostic solutions that can quickly guide to personalized treatment plans and reduce the misuse of antibiotics. Our shared vision for Gradientech's precision diagnostics offering is to contribute to a more sustainable world.

An innovative company in the early stages of commercialization

We believe that agility and a culture of responsibility attract people with a strong innovation mindset. We will continue our exciting journey, intertwining our project-oriented organization with a development focus with growing production and commercial teams. At the same time, we will remain agile and innovative.

One of the leading science parks in Sweden

Our headquarters are based in Uppsala Science Park, one of the leading innovation clusters in Sweden and home to several of the country's top life science companies. We share our location with world-leading academic research teams, Uppsala University Hospital's clinical laboratories, the Swedish Medical Products Agency, the Swedish National Food Agency, and Uppsala Innovation Center (UIC) – one of the highest ranked business incubators in the world.

Collaboration with world-leading experts

Gradientech's agile and flexible product development model includes close collaboration with leading international players in development and manufacturing, which complements our own expertise and operations.

This has enabled us to work more efficiently in terms of both costs and employees, throughout the entire development and manufacturing transfer of the QuickMIC® system.

Our expertise is based on knowledge in four main areas:

Diagnostic systems development

The unique features of microfluidics are used to generate stable linear concentration gradients which, together with real-time measurement of living cells, develop into unique and effective solutions for research and healthcare.

We collaborate with leading partners who complement our own expertise, enabling us to develop an efficient and attractive diagnostic system for antibiotic susceptibility testing that meets market needs.

Quality management and processes

Customer demands, combined with strict regulatory requirements on product safety and compliance, controls how we work and are crucial for the company. The processes that controls how we work are described, and included, in Gradientech's quality management system.

We have been ISO 13485-certified since 2017 and are subject to annual inspections and audits by external certification bodies.

Clinical microbiology and antibiotic resistance

Specialized scientific knowledge in bacteriology, and a safety-classed microbiology laboratory headed by an experienced microbiologist, enable efficient product development of our clinical application.

Our close collaboration with reference laboratories and healthcare also ensures a reliable and user-friendly product that is adapted to market needs.

Business acumen and commercialization

Our business model is based on offering unique products that address a major global unmet need. A modular and cost-efficient system lowers the investment required by customers. Commercial partners are selected on the basis of their experience, knowledge of the market and leading customers.

Our values

Gradientech has a shared set of values that support our vision of products that are both pioneering for our users and contribute to a more sustainable world. Our set of values shapes the company culture and reflect what we value as a company. Each keyword represents an important aspect of our identity and our ambitions.

Committed

We are goal-oriented and work as a team to reach our aims.

Innovative

We seek new ways to find solutions and opportunities.

Transparent

We are clear and honest in everything that we do.

Responsive

We act on feedback from our partners, customers, employees and our environment.

International Advisory Board

The company is supported by international group of expert advisers, who are all leaders in the field of clinical microbiology. The members assist us with their solid experience and advice, and keep us up to date with developments in the rapidly developing market of clinical microbiology.

Holger Rohde

MD Prof. Molecular Microbiology

Holger Rohde holds a professorship in Molecular Microbiology at the Institute for Medical Microbiology, Virology, and Hygiene at the Medical Center Hamburg-Eppendorf. Holger Rohde is a senior physician and medical specialist 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.

Jeffrey Bender

MD Assoc. Prof. Clinical Pediatrics

Jeffrey Bender is an infectious disease specialist, medical microbiologist and Associate Professor of Clinical Pediatrics at Children's Hospital Los Angeles. His research is focused on understanding the role of neonatal gut microbes and their host-microbial interactions. Jeffrey Bender is also interested in hospital epidemiology and the implementation of rapid diagnostics in the pediatric setting.

Elisabet Nielsen

Assoc. Prof. Clinical Pharmacy

Elisabet Nielsen is a Senior Lecturer and Associate Professor in Clinical Pharmacy at the Department of Pharmacy at Uppsala University in Sweden. Elisabet conducts research in the area of translational and precision medicine. She uses mathematical modeling to understand the dynamic interplay between bacteria, antibiotic and patient and its implication for optimized antibiotic use. Elisabet is also interested in the implementation of model-based systems to support personalized antibiotic therapy.

Corporate governance

Corporate governance

Gradientech is a Swedish public limited liability company with 674 shareholders following the share issue registered on February 2, 2023. 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, authorization 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 authorize 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 meeting Chairman is to be elected by the AGM.

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 2022 AGM was held on May 11, 2022 at the company's premises at Dag Hammarskjölds väg 36 in Uppsala. The AGM resolved on, among other things, principles for the appointment of the Nomination Committee (see below) and authorization of the Board of Directors to carry out a new share issue corresponding to a maximum of 20% of the total number of shares in the company.

The 2023 AGM will take place on Tuesday, May 9, 2023 at 5:00 p.m. at Gradientech's premises at Uppsala Science Park.

Nomination Committee

The 2022 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 2023, the Nomination Committee comprises the following members:

- Henrik Didner, representing Monesi Förvaltnings AB
- Allan Asp, representing Almi Fonder
- Andy Browning, appointed by Sara Thorslund and Johan Kreuger
- Mikael Lönn

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

Board of Directors

Duties of the Board

The Board of Directors is ultimately responsible for the organization 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, Ted Elvhage and Simon Turner. All Board members are elected for the period until the end of the next AGM, which will be held on Tuesday, May 9, 2023. 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 2022, ten minuted meetings were held. Each member's attendance at Board meetings is shown in the table on the right.

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 Board members

Fees are paid to the Chairman and members of the Board in accordance with the resolution adopted by the AGM. The AGM in May 2022 resolved that the remuneration to the Chairman of the Board is to amount 5 price base amounts per year in salary and that the remuneration to the Board members is to amount to 2 price base amounts per year as salary.

The remuneration paid to the Board in 2022 is presented in Note 7.

Evaluation of the Board's work

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.

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 day-to-day management of the Group 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 totaling SEK 90,000, with a mutual notice period of six months. The CEO is bound by a non-compete clause for six months from the date of termination of employment. Other senior executives are not bound by non-compete clauses.

The remuneration paid to the Board, the CEO and other employees in 2022 is presented 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 2022, 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 9, 2023. Grant Thornton Sweden AB has been the company's auditor since 2017.

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

Composition of the Board

			Independent in relation to:		
Name	**Position**	**Board member since**	**the company and management**	**major shareholders**	**Attendance at Board meetings**
Gisela Sitbon	Chairman	2020	Yes	Yes	10/10
Laura Chirica	Board member	2021	Yes	Yes	10/10
Henrik Didner	Board member	2018	Yes	No	10/10
Rolf Ehrnström	Board member	2020	Yes	Yes	10/10
Ted Elvhage	Board member	2014	Yes	Yes	10/10
Simon Turner	Board member	2020	Yes	Yes	9/10

Remuneration to the auditor

Remuneration to the auditor is resolved on by the general meeting. At the AGM in May 2022, 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 organization, 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 organization 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 Amplicon AB, Emplicure Holding AB, Emplipharm AB and Nanologica AB and a Board member of Annexin Pharmaceuticals AB, Encare AB and InSingulo AB. She is also owner and a Board member of Sitbon Bioscience Partner ZENZ AB.

Holding: Gisela Sitbon holds 6,000 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 SenzaGen AB. She is also CEO of Cellevate AB.

Holding: Laura Chirica holds 5,628 shares in the company. She holds no warrants in the company.

Laura Chirica is independent in relation to the company and management and in relation to the company's major shareholders.

Henrik Didner

Board member since 2018

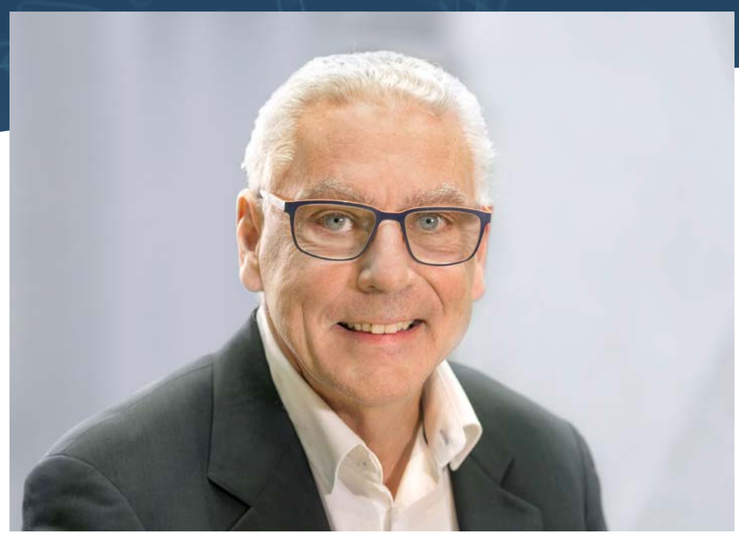
Born: 1958

Education: PhD, Uppsala University.

Other current assignments: Henrik Didner is co-owner and Chairman of the Board of Didner & Gerge Fonder AB, Monesi Förvaltnings AB and Uppsala universitet Invest AB. Henrik is also a Board member of G-Förvaltning AB, Oncodia AB, Axel Johansson Uppsala Nya Tidning Förvaltning AB, CLA Sweden AB, Baracken AB and VBN Components AB.

Holding: Henrik Didner holds 2,282,346 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 and SAGA Diagnostics AB. In addition, he serves as a consultant within life science and is a member of various funding agencies (Vinnova, EITH, NOME and Uppsala Bio-X).

Holding: Rolf Ehrnström holds 9,878 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.

Ted Elvhage

Board member since 2014

Born: 1968

Education: Bachelor of Science (chemistry major, biochemistry minor) from Millersville University, PA, USA.

Other current assignments: Ted Elvhage is CEO and Chairman of the Board of the owner-managed property company Rocad Holding AB and subsidiaries as well as a Board member of innovative growth companies both privately and through his wholly owned company XLNT Optimization, and runs the risk capital company Rymdkaptial AB, which invests in numerous spacetech companies such as Space Cowboys AB, The Exploration Company and Pythom Space. Ted is also a Board member of the listed company Fingerprint Cards AB.

Holding: Ted Elvhage holds 178,390 shares in the company. The shares are owned privately and through XLNT Optimization AB. He holds no warrants in the company.

Ted Elvhage is independent in relation to the company and management and in relation to the company's major shareholders.

Simon Turner

Board member since 2020

Born: 1988

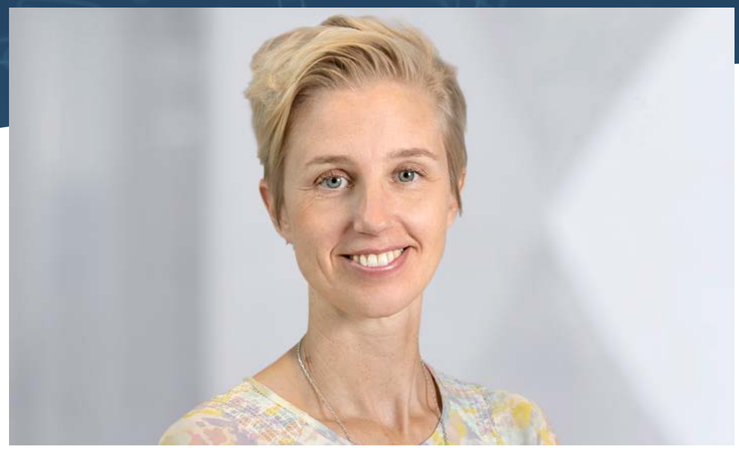
Education: BSc in Biomedical Sciences from King's College, UK, and Master of Science in International Business from SKEMA Business School, France.

Other current assignments: Simon Turner is a partner in Sofinnova Partners, which invests in the life science sector.

Holding: Simon Turner holds no shares or warrants in the company.

Simon Turner 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

Co-founder and CEO of Gradientech since its start in 2009. Sara Thorslund has received several innovation and entrepreneurship awards while growing Gradientech into an international diagnostics company. Presented as one of today's role models shaping our future in a book publication by Mondial (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.

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

Shareholding: 404,500

Warrant holding: 94,500 series 2021/2024 employee stock options.

Urban Adolfsson

Chief Financial Officer

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

Born: 1971

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

Previous experience: Previous positions includes audit assignments at Ernst & Young, senior positions in financial control at companies such as PA Resources and Envirotainer, and most recently as CFO and interim CEO at Encare.

Shareholding: 1,200

Warrant holding: 27,743 series 2021/2024 employee stock options.

Marcus Berglund

Chief Technology Officer

Marcus Berglund joined Gradientech in 2017 as a technical project manager for instrument development. Since then, he has worked with antibiotic filling and served as a project manager for QuickMIC®, contributing system expertise.

Born: 1981

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

Previous experience: Nearly 20 years of experience in industrial system, electronics and software development in various roles, including as a 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: 2,438

Warrant holding: 25,986 series 2021/2024 employee stock options.

Peter Karlberg

VP Sales

Peter Karlberg joined Gradientech in 2022 to build and lead the company's commercial operations.

Born: 1968

Education: BSc in Molecular Biology, Uppsala University. Diploma in Export Sales, Jensen Education.

Previous experience: More than 20 years of experience from international commercialization of expanding life science companies as well as launching new product lines for major companies. Peter Karlberg has served in leading commercial roles in companies such as Life Technologies and Thermo Fisher Scientific as well as smaller companies such as Fluidigm, Olink, Celsee, and Pyrosequencing. Was a Board member of Gradientech in 2010–2015.

Shareholding: 17,000

Warrant holding: 27,743 series 2021/2024 employee stock options.

Ann-Sofie Andersson

Marketing and Communication Manager

Ann-Sofie Andersson joined Gradientech in 2013 as Sales and Marketing Manager. Long history of experience from internationally leading diagnostic 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 from companies such as Pharmacia Diagnostics (today Thermo Fisher Scientific), Anamar and Mercodia. Previous positions include roles as Product Manager, International Marketing, Sales and Project Management. Broad experience in business development, quality assurance and distributor environment.

Shareholding: –

Warrant holding: 37,749 series 2021/2024 employee stock options.

Christer Malmberg, PhD

Chief Scientist

Christer Malmberg has solid experience from clinical and diagnostic microbiology research, investigating methods for early detection of phenotypic effects of antibiotics. Joined Gradientech in 2014 as a project manager for instrument development, and is currently head of research.

Born: 1984

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

Previous experience: Research background in clinical microbiology and antibiotic resistance. Since 2014, project manager for instrument development and data analysis within Gradientech's development project in AST diagnostics.

Shareholding: –

Warrant holding: 35,316 series 2021/2024 employee stock options.

Martin Karlsson, PhD

Production & Supply Manager

Martin Karlsson joined Gradientech in 2021 and has extensive industry experience from the production of pharmaceutical products and medical devices. Martin Karlsson devotes considerable focus to establishing processes for efficiency and quality in order to develop a successful production 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 positions within the development and quality functions at Galderma (later Nestlé Skin Health), including Head of Quality Control.

Shareholding: –

Warrant holding: 27,743 series 2021/2024 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: 27,743 series 2021/2024 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 issues concerning medical devices and quality management.

Born: 1964

Education: Master of Science in Engineering Physics and Licentiate of Engineering Degree in Material 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: 26,933 series 2021/2024 employee stock options.

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 500,000 and a maximum of SEK 2,000,000. The number of shares is to be a minimum of 5,000,000 and a maximum of 20,000,000. 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, 2022, the number of shares outstanding was 16,645,920 (12,205,823), each with a quotient value of SEK 0.1, corresponding to a share capital of SEK 1,664,592.00 (1,220,582.30).

Within the framework of the AGM's authorization, a rights issue of 1,271,057 shares was carried out in December 2022 to January 2023 at a price of SEK 20.50 per share, raising approximately SEK 26 million before issue expenses. After the issue, which was registered with the Swedish Companies Registration Office on February 2, 2023, the share capital amounts to SEK 1,724,525.00 and the number of shares to 17,245,250.

Owners

Within the framework of the AGM's authorization, the Board of Directors decided on December 16, 2022 to carry out a rights issue with a subscription period starting on December 27 and ending after the balance sheet date on January 18, 2023. Shares outstanding as of December 31, 2022 amounted to 16,645,920, of which the number of registered shares amounted to 15,974,193 distributed among 656 (680) shareholders. Based on the shares registered with Euroclear at year-end, the largest owners are shown in the table below. After the new share issue completed in January 2023 and registered with the Swedish Companies Registration Office on February 2, 2023, the number of shares amounts to 17,245,250 distributed among 674 shareholders.

Incentive programs outstanding

Gradientech has an option program outstanding aimed at the company's employees and other key employees.

At an EGM on January 22, 2021, the shareholders decided to introduce an employee stock option program of 525,000 options that entitle the holders to subscribe for 525,000 shares in Gradientech at a price of SEK 40.50 per share upon the achievement of four milestones and a vesting period of three years. The dilutive effect is estimated at approximately 4% on full subscription.

To ensure delivery of shares under the employee stock option program and to cover cash flow effects due to any social security contributions under the program, the meeting resolved to issue 615,000 warrants to the company itself. The employee stock options were granted free of charge.

Shareholder	Number of shares	Holding and votes, %
Monesi Förvaltnings AB	1,782,346	11.16
Almi Invest Östra Mellansveige	795,500	4.98
Nordnet Pensionsförsäkring AB	559,410	3.50
Almi Invest AB	485,180	3.04
Fredrik Skytt	469,123	2.94
Sara Thorslund	402,000	2.52
Johan Kreuger	400,000	2.50
Uppsala Universitet Invest AB	324,400	2.03
Mikael Lönn	282,364	1.77
Nitator Förvaltnings AB	259,658	1.63
Other	10,214,212	63.94
Total	**15,974,193**	**100.00**

Directors' Report

The Board of Directors and the CEO of Gradientech AB submit the following Annual Report for the 2022 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

The company conducts development, production and sales within diagnostics and offers products and software for high-quality analysis of how living cells react to various biomolecules. Its innovative products are based on microfluidic technology, which – combined with real-time measurement of living cells – enables unique and precise medical applications. The company's first diagnostic medical device, QuickMIC®, and its Gram-negative antibiotic panel received certification in May 2022. The product is used for ultra-rapid antibiotic susceptibility testing of positive blood cultures (meaning samples from sepsis patients) and is designed for testing in clinical microbiology laboratories. The company's registered office is in Uppsala, Sweden.

Significant events during the financial year

The company signed exclusive distribution agreements with Biomedica for the commercialization of QuickMIC® in Austria, Switzerland and East-Central Europe, and with Triolab Group for the commercialization of QuickMIC® in Sweden, Norway, Denmark, Finland and the Baltics.

QuickMIC® and its Gram-negative panel, CE-IVD, received certification during Q2. The certification was supported by the clinical study completed in the second quarter, which demonstrated performance results above the essential regulatory requirements for a new antibiotic susceptibility testing system and the shortest average time to resistance results compared with competing systems on the market. During the third quarter of the year, products in the QuickMIC® system with risk class A were registered in accordance with the new IVD Regulation (IVDR).

During the year, the company expanded its Management Team, adding Peter Karlberg, VP Sales, with responsibility for sales and the commercial organization, Urban Adolfsson, CFO, succeeding Hans Richter in his role as interim CFO, and Anna-Lisa Tiensuu, Regulatory Affairs & Quality Assurance Manager. During the Q2, the company's Scientific Advisory Board was expanded to include Elisabet Nielsen as a new adviser. Elisabet conducts world-leading research in the field of precision medicine and is a Senior Lecturer and Associate Professor in Clinical Pharmacy at Uppsala University.

In addition to the regulatory clinical studies that formed the basis for product approval of QuickMIC®, the company conducted reference studies together with university hospitals in Tallinn, Estonia and Alicante, Spain, during the second half of the year.

At the beginning of Q4, Marc van Nuenen took up the role of VP Business Development US, stationed in the US. Marc manages the company's business development activities in the US, including preparation for clinical studies with the purpose of obtaining FDA clearance of the QuickMIC® system.

In December, the Board of Directors decided on a share issue of approximately SEK 50 million, with preferential rights for existing shareholders.

Financing

In December 2021, the company carried out a combined rights issue and private placement. The issue comprised a total of 3,768,370 shares and raised SEK 77,251,585 before issue expenses. The issue proceeds were paid in January 2022 and registered with the Swedish Companies Registration Office on February 2, 2022.

Within the framework of the AGM's authorization, the Board of Directors decided on December 16, 2022 to carry out a rights issue comprising 2,457,568 shares at a price of SEK 20.50 per share. The subscription period started on December 27, 2022 and ended after the balance sheet date on January 18, 2023. As of the closing date on December 31, 2022, a total of 671,727 shares had been subscribed for, which increased the share capital by SEK 67,172.10 to a total of SEK 1,664,592.00. The final outcome after the balance sheet date included a total of 1,271,057 subscribed shares, which provided the company with SEK 26,056,668.50 before the deduction of issue expenses. As a result of the rights issue, the share capital increased by SEK 127,105.70 to a total of SEK 1,724,525.00 and the number of shares increased by 1,271,057 to a total of 17,245,250. The issue proceeds were paid in February 2023 and registered with the Swedish Companies Registration Office on February 2, 2023. At the time of publication of this Annual Report, financing for 2023 had not been secured for at least 12 months ahead. Given the current market situation, the company's Board of Directors chose, in connection with the rights issue, to finance 2023 on more than one occasion. This means that another issue will be carried out in 2023. Gradientech had no non-current liabilities at year-end.

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 recently launched the QuickMIC® system, which is the company's first diagnostic medical device, and contracted the first distributors for a number of selected European markets. The early commercialization phase may mean that revenue is delayed, even if the market shows a strong interest in the product. Hospitals may also terminate the evaluation period without subsequently choosing to invest in the system. The company believes that if the risk is realized, it could result in reduced cash flow and an increased need for financing during the early commercialization 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 6%, 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 commercialize. 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, 2022, the company had approximately 660 registered shareholders. The single largest shareholder is Monesi Förvaltnings AB with 11.16% of the number of shares.

Multi-year review

SEK thousand	2022	2021	2020	2019	2018
Balance sheet total	54,752	104,944	79,516	18,429	10,468
Net sales	988	141	61	129	91
Number of employees	23	16	11	7	6
Equity/assets ratio (%)	85.1	89.4	95.3	76.4	81.9

Net sales for 2022 amounted to SEK 988 thousand, compared with SEK 141 thousand in the preceding year. The increase is attributable to the commercialization of the QuickMIC® system, which took place in the fourth quarter of 2022.

Statement of changes in equity

SEK thousand	Share capital	Unregistered share capital	Share premium reserve	Retained earnings	Total equity
Opening balance, Jan 1, 2021	**1,221**	**0**	**197,327**	**-122,788**	**75,760**
Profit/loss					*0*
Loss for the period				-53,317	-53,317
Total profit/loss	0	0	0	-53,317	-53,317
Transactions with shareholders					*0*
Ongoing new share issue	0	377	76,875		77,252
Issue expenses			-5,925		-5,925
Total transactions with shareholders	0	377	70,950	0	71,327
Closing balance, Dec 31, 2021	**1,221**	**377**	**268,277**	**-176,105**	**93,770**
Opening balance, Jan 1, 2022	**1,221**	**377**	**268,277**	**-176,105**	**93,770**
Profit/loss					*0*
Loss for the period				-60,962	-60,962
Total profit/loss	0	0	0	-60,962	-60,962
Transactions with shareholders					
New share issue, registered share capital	377	-377			0
Ongoing new share issue	0	67	13,703		13,770
Issue expenses			0		0
Total transactions with shareholders	377	-310	13,703	0	13,770
Closing balance, Dec 31, 2022	**1,598**	**67**	**281,980**	**-237,067**	**46,578**

Proposed appropriation of profit or loss

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

share premium reserve	281,979,817
retained earnings	-176,104,682
loss for the year	-60,961,730
	44,913,405
to be carried forward	44,913,405
	44,913,405

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	Jan 1, 2022–Dec 31, 2022	Jan 1, 2021–Dec 31, 2021
Operating income			
Net sales	4	988	141
Change in inventories of products in progress, finished goods and work in progress		3,529	0
Other operating income		249	3,712
		4,766	**3,853**
Operating expenses			
Raw materials and consumables		-3,059	-3,668
Purchased services		-27,272	-32,214
Other external expenses	5, 6	-12,393	-7,675
Personnel costs	7	-21,684	-12,339
Depreciation of property, plant and equipment		-1,296	-1,019
Other operating expenses		-70	-260
		-65,774	**-57,175**
Operating loss	8	**-61,008**	**-53,322**
Profit from financial items			
Other interest income and similar profit/loss items	9	47	81
Interest expense and similar profit/loss items	10	-1	-76
		46	**5**
Loss after financial items		**-60,962**	**-53,317**
Loss before tax		**-60,962**	**-53,317**
Loss for the year		**-60,962**	**-53,317**

Earnings per share

	Jan 1, 2022–Dec 31, 2022	Jan 1, 2021–Dec 31, 2021
Average number of shares, thousands, before dilution	15,639	12,206
Average number of shares, thousands, after dilution	16,926	12,821
Number of shares outstanding on the balance sheet date, thousands	15,974	12,206
Basic earnings per share, SEK	-3.90	-4.37
Diluted earnings per share, SEK	-3.90	-4.37

Balance sheet

SEK thousand	Note	Dec 31, 2022	Dec 31, 2021
ASSETS			
Subscribed but unpaid capital		13,770	77,252
Non-current assets			
Property, plant and equipment			
Cost of improvements to leased property	11	0	0
Equipment, tools, fixtures and fittings	12	4,964	5,512
		4,964	**5,512**
Total non-current assets		**4,964**	**5,512**
Current assets			
Inventories, etc.	13		
Raw materials and consumables		485	0
Goods in progress		192	0
Finished goods and goods for resale		2,852	0
		3,529	**0**
Current receivables			
Accounts receivables		531	0
Current tax assets		471	313
Other receivables		9,306	5,945
Prepaid expenses and accrued income	14	1,004	1,198
		11,312	**7,456**
Cash and bank balances		21,177	14,724
Total current assets		**36,018**	**22,180**
TOTAL ASSETS		**54,752**	**104,944**
EQUITY AND LIABILITIES			
Equity	15, 16		
Restricted equity			
Share capital		1,598	1,221
Unregistered share capital		67	377
		1,665	**1,598**
Non-restricted equity			
Non-restricted share premium reserve		281,980	268,277
Retained earnings		-176,105	-122,788
Loss for the year		-60,962	-53,317
		44,913	**92,172**
Total equity		**46,578**	**93,770**
Current liabilities			
Accounts payables		4,049	2,962
Other liabilities		1,683	1,041
Accrued expenses and deferred income	17	2,443	7,171
Total current liabilities		**8,175**	**11,174**
TOTAL EQUITY AND LIABILITIES		**54,752**	**104,944**

Cash flow statement

SEK thousand	Note	Jan 1, 2022–Dec 31, 2022	Jan 1, 2021–Dec 31, 2021
Operating activities			
Loss before financial items		-61,008	-53,322
Interest received		47	81
Interest paid		-1	-76
Adjustments for non-cash items			
Depreciation/amortization		1,296	1,019
Profit from disposal of non-current assets		4	260
Cash flow from operating activities before change in working capital		**-59,662**	**-52,038**
Cash flow from change in working capital			
Increase(-)/decrease(+) in inventories		-3,529	0
Increase(-)/decrease(+) in operating receivables		-3,857	-3,967
Increase(+)/decrease(-) in operating liabilities		-98	3,518
Cash flow from operating activities		**-67,145**	**-52,487**
Investing activities			
Investments in property, plant and equipment, net		-752	-1,918
Cash flow from investing activities		**-752**	**-1,918**
Net cash flow before financing activities		**-67,897**	**-54,405**
Financing activities			
New share issue and issue costs		74,349	-2,025
Cash flow from financing activities		**74,349**	**-2,025**
Cash flow for the year		**6,453**	**-56,430**
Cash and cash equivalents at beginning of year		**14,724**	**71,154**
Cash and cash equivalents at end of year	**18**	**21,177**	**14,724**

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 recognized 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 recognized 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 recognized 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 recognized as follows:
Interest income: in line with effective returns.

Intangible assets

The company recognizes 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 recognized at cost less accumulated depreciation according 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 derecognized 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 recognized 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 recognized as current assets at the amount expected to be paid after deduction of individually assessed doubtful receivables.

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 recognizes all leases, both finance and operating, as operating leases. Operating leases are recognized 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 consumables 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 an EGM on January 22, 2021, the shareholders decided to introduce an employee stock option program of 525,000 options that entitle the holders to subscribe for 525,000 shares in Gradientech at a price of SEK 40.50 per share upon the achievement of four milestones and a vesting period of three years. The dilutive effect is estimated at approximately 4% on full subscription. To ensure delivery of shares under the employee stock option program and to cover cash flow effects due to any social security contributions under the program, the meeting resolved to issue 615,000 warrants to the company itself.

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 recognized as deferred income. Grants are recognized 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 recognized 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. 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 recognized 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 -251,116 thousand (-189,549). The company's operations, namely the commercialization 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 recognized. When it is probable that taxable profit will be generated, the company will recognize a deferred tax asset. Capitalization of deferred tax would have given rise to a deferred tax asset of SEK 52 million as of December 31, 2022.

Note 4 Distribution of net sales

Net sales by geographic market, SEK thousand	2022	2021
Sweden	0	135
Europe	984	6
Japan	4	0
	988	**141**

Note 5 Leases

Lease expenses for the year amounted to SEK 2,437 thousand (1,513). This item mainly pertains to a lease for premises. The lease term extends until mid-August 2026.

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

SEK thousand	2022	2021
Within one year	2,129	1,534
Between one and five years	4,460	5,479
	6,589	**7,013**

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.

Grant Thornton Sweden AB, SEK thousand	2022	2021
Audit engagement	153	124
Audit services in addition to audit engagement	7	12
	160	**136**

Note 7 Employees and personnel costs

SEK thousand	2022	2021
Average number of employees		
Women	12	9
Men	11	7
	23	**16**
Salaries and other remuneration		
Board and CEO	1,806	1,430
Other employees	12,760	7,291
	14,566	**8,721**
Social security expenses		
Pension costs for the Board and CEO	276	231
Pension costs for other employees	1,710	792
Statutory and contractual other social security contributions	3,176	1,706
	5,162	**2,729**
Total salaries, remuneration, social security expenses and pension costs	**19,728**	**11,450**

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

Gender distribution among senior executives, %	2022	2021
Percentage of women on the Board	33	33
Percentage of men on the Board	67	67
Percentage of women among other senior executives	100	100

Salary and Board fees 2022

In accordance with the AGM's resolution, the fees to be distributed to the Board for 2022 amounted to SEK 725 thousand (714). Board fees in 2022 were paid as follows: SEK 242 thousand (238) to the Chairman of the Board and SEK 97 thousand (95) to each of the Board members. Salary and remuneration to the CEO in 2022 amounted to SEK 1,082 thousand (938).

Board member Laura Chirica invoiced Gradientech AB for services rendered, through companies, during the financial year for a total of SEK 204 thousand (238).

CEO's terms of employment

CEO Sara Thorslund has the following terms of employment: A salary of SEK 90,000 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

SEK thousand	2022	2021
Purchases of services		
Consultancy services from Board members	204	308
	204	**308**

Note 9 Other interest income and similar profit/loss items

SEK thousand	2022	2021
Other interest income	47	0
Exchange rate differences	0	81
	47	**81**

Note 10 Interest expenses and similar profit/loss items

SEK thousand	2022	2021
Other interest expenses	-1	-2
Exchange rate differences	0	-73
	-1	**-75**

Note 11 Leasehold improvements

SEK thousand	Dec 31, 2022	Dec 31, 2021
Opening cost	0	400
Sales/disposals	0	-400
Closing accumulated cost	**0**	**0**
Opening amortization	0	-87
Sales/disposals	0	140
Amortization for the year	0	-53
Closing accumulated amortization	**0**	**0**
Closing carrying amount	**0**	**0**

Note 12 Equipment, tools, fixtures and fittings

SEK thousand	Dec 31, 2022	Dec 31, 2021
Opening cost	7,504	5,586
Purchases	752	1,918
Disposals	-35	0
Closing accumulated cost	**8,221**	**7,504**
Opening depreciation	-1,992	-1,027
Disposals	31	0
Depreciation for the year	-1,296	-1,093
Adjustment of opening depreciation due to change of depreciation period	0	128
Closing accumulated depreciation	**-3,257**	**-1,992**
Closing carrying amount	**4,964**	**5,512**

Note 13 Inventories

SEK thousand	Dec 31, 2022	Dec 31, 2021
Raw materials and consumables	485	0
Work in progress	192	0
Finished goods	2,852	0
	3,529	**0**

Note 14 Prepaid expenses and accrued income

SEK thousand	Dec 31, 2022	Dec 31, 2021
Prepaid rent	936	471
Grant from the Swedish Agency for Economic and Regional Growth (accrued income)	0	681
Other items	68	46
	1,004	**1,198**

Note 15 Number of shares and quotient value

Name	Number of shares	Quotient value
Number of Class A shares	15,974,193	0.1
	15,974,193	

Note 16 Appropriation of profit or loss

SEK thousand	Dec 31, 2022
Proposed appropriation of profit or loss	
The Board of Directors proposes the following appropriation of the available funds:	
non-restricted share premium reserve	281,980
retained earnings	-176,105
loss for the year	-60,962
	44,913
to be carried forward	44,913
	44,913

Note 17 Accrued expenses and deferred income

SEK thousand	Dec 31, 2022	Dec 31, 2021
Accrued personnel costs	1,229	715
Accrued accounting and auditing costs	236	213
Accrued issue expenses	253	3,901
Other items	725	2,342
	2,443	**7,171**

Note 18 Cash and cash equivalents

SEK thousand	Dec 31, 2022	Dec 31, 2021
Cash and cash equivalents		
Bank balances	21,177	14,724
	21,177	**14,724**

Note 19 Significant events after the end of the financial year

A reference study with the QuickMIC® system started with a university hospital in Florence, Italy.

Within the framework of the AGM's authorization, the Board of Directors decided on December 16, 2022 to carry out a rights issue comprising 2,457,568 shares at a price of SEK 20.50 per share. The subscription period ran from December 27, 2022 through January 18, 2023. The final outcome included a total of 1,271,057 subscribed shares, which provided Gradientech with SEK 26,056,668.50 before the deduction of issue expenses. As a result of the rights issue, the share capital increased by SEK 127,105.70 to a total of SEK 1,724,525.00 and the number of shares increased by 1,271,057 to a total of 17,245,250. The issue proceeds were paid in February 2023 and registered with the Swedish Companies Registration Office on February 2, 2023.

Within the framework of the AGM's authorization, the Board of Directors decided in April 2023 to carry out a directed issue comprising 550,000 shares at a price of SEK 20.50 per share. On full subscription, Gradientech will receive SEK 11,275,000.00 before deduction of issue expenses and the share capital will increase by SEK 55,000.00.

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 13, 2023

Gisela Sitbon
Chairman

Ted Elvhage

Henrik Didner

Rolf Ehrnström

Simon Turner

Laura Chirica

Sara Thorslund
CEO

Our Auditor's Report was submitted on April 13, 2023
Grant Thornton Sweden AB

Stéphanie Ljungberg
Authorized Public Accountant

Auditor's Report

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

Corporate Registration Number 556788-9505

Report on the annual accounts

Opinions

We have audited the annual accounts of Gradientech AB (publ) for 2022. The company's annual accounts are included on pages 35–43 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Swedish Annual Accounts Act and present fairly, in all material respects, the financial position of Gradientech AB (publ) as of December 31, 2022 and its financial performance and cash flow for the year then ended in accordance with the Swedish Annual Accounts Act. The Directors' Report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders 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 regarding the going concern basis of accounting

We would like to draw attention to the sections the sections "Financing" and "Future financing and capital requirements" in the Directors' Report, which state that the company is dependent on continued financing from its investors to continue as a going concern and that the company reported a loss for the financial year ending December 31, 2022. These circumstances indicate that there is substantial uncertainty that could lead to significant doubt concerning 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 1–34 and 46–47. The Board of Directors and the CEO 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 CEO

The Board of Directors and the CEO are responsible for the preparation of the annual accounts and for ensuring that they give a fair presentation in accordance with the Swedish Annual Accounts Act. The Board of Directors and the CEO are also responsible for such internal control as they deem necessary for the purpose of preparing annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, the Board and the CEO are responsible for assessing the company's ability to continue as a going concern. Where applicable, they disclose circumstances which could affect the company's ability to continue as a going concern and use the going concern assumption. The going concern assumption applies unless the Board of Directors and the CEO intend to liquidate the company or cease to operate, or have no realistic alternative to doing so.

Auditor's responsibilities

Our objectives are to obtain reasonable assurance that the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to submit an Auditor's Report containing our opinion. Reasonable assurance is a high degree of assurance, but does not constitute a guarantee that an audit conducted in accordance with ISA and generally accepted auditing standards in Sweden will always detect a material misstatement if it exists. Misstatements can arise from fraud or error and are considered material if they, individually or in the aggregate, can reasonably be expected to affect financial decisions made by users on the basis of the annual accounts.

As part of our audit in accordance with ISA, we exercise professional judgment and maintain professional skepticism throughout our 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 the accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the CEO.
- conclude on the appropriateness of the Board of Directors' and the CEO'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 draw the conclusion that there is a material uncertainty, we need to draw attention in our Auditor's Report to those disclosures which concern the material uncertainty in

the annual accounts or, if such disclosures are insufficient, modify our opinion on 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 a 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 gives a true and fair view.

We are required to inform the Board of Directors of, among other matters, the planned scope, focus and timing of the audit. We are also required to communicate significant audit findings, 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 CEO of Gradientech AB (publ) for 2022 and the proposed appropriation 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 Directors' Report and that the members of the Board of Directors and the CEO be discharged from liability for the financial year.

Basis for opinions

We have conducted our 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 CEO

The Board of Directors is responsible for the proposal for appropriation of the company's profit or loss. The preparation of a dividend proposal involves assessing whether the dividend is justifiable with regard to the equity, consolidation, liquidity and financial position requirements of the company arising from the nature, scope and risks of the company's operations.

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 CEO 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 responsibilities

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 CEO 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 Swedish Companies Act, the Swedish Annual Accounts Act or the Articles of Association.

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

Reasonable assurance is a high degree of assurance but does not guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or neglect that could give rise to a liability to indemnify the company, or that the proposed appropriation of the company's profit or loss is consistent with the Swedish 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 appropriation 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 a starting point in risk and materiality. This means that we focus our examination on such procedures, areas and circumstances that are material to the business and where deviations and violations would be particularly significant for the company's situation. We review and test the decisions that have been made, the bases for these decisions, the measures 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 appropriation of the company's profit or loss, we have examined whether the proposal is consistent with the Swedish Companies Act.

Uppsala, April 13, 2023

Grant Thornton Sweden AB

Stéphanie Ljungberg
Authorized Public Accountant

Definitions

APAC Asia-Pacific, includes the territory of East Asia, South Asia, South East Asia and Oceania.

AST Antibiotic susceptibility testing.

BMD Broth microdilution, reference method for antibiotic susceptibility testing.

BSI The company's certification body for ISO13485 certification. BSI is an EU-certified Notified Body for the IVDR.

CE-IVD Regulatory marking of diagnostic medical devices that have met a number of requirements, including safety, quality, validity and traceability, that are necessary for the product to be used for diagnostic testing.

CellDirector® Registered trademark of Gradientech, the company's research products.

CE marking Conformité Européenne, product marking mainly within the EU and the EEA.

Class A/B/C Classes of medical devices under the new IVDR based on the risk to patient and public health.

EUCAST The European Committee on Antimicrobial Susceptibility Testing, a European scientific committee that defines guidelines for interpreting antibiotic resistance.

FDA The US Food and Drug Administration, responsible for marketing authorization of in vitro diagnostic medical devices in the US.

GN Gram-negative bacteria. The opposite of Gram-positive bacteria. The difference between Gram-negative and Gram-positive bacteria is the structure of their cell walls. Gram-negative and Gram-positive bacteria are generally treated with different antibiotics.

GP Gram-positive bacteria. The opposite of Gram-negative bacteria. The difference between Gram-negative and Gram-positive bacteria is the structure of their cell walls. Gram-negative and Gram-positive bacteria are generally treated with different antibiotics.

IVD In vitro diagnostics, refers to medical devices for in vitro diagnostics.

IVDD Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

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

MIC Minimum inhibitory concentration for the antibiotic tested.

NAG medical devices The Swedish national working group for medical devices.

QA Quality assurance.

QuickMIC® Registered trademark of Gradientech, the company's diagnostic medical devices.

RAST The method for rapid AST developed by EUCAST whereby the customary disk diffusion plates for certain antibiotic-bacteria combinations, which are normally read after 18–24 hours, can instead be read after four, six or eight hours.

TLV The Swedish Dental and Pharmaceutical Benefits Agency.

WHO The World Health Organization.

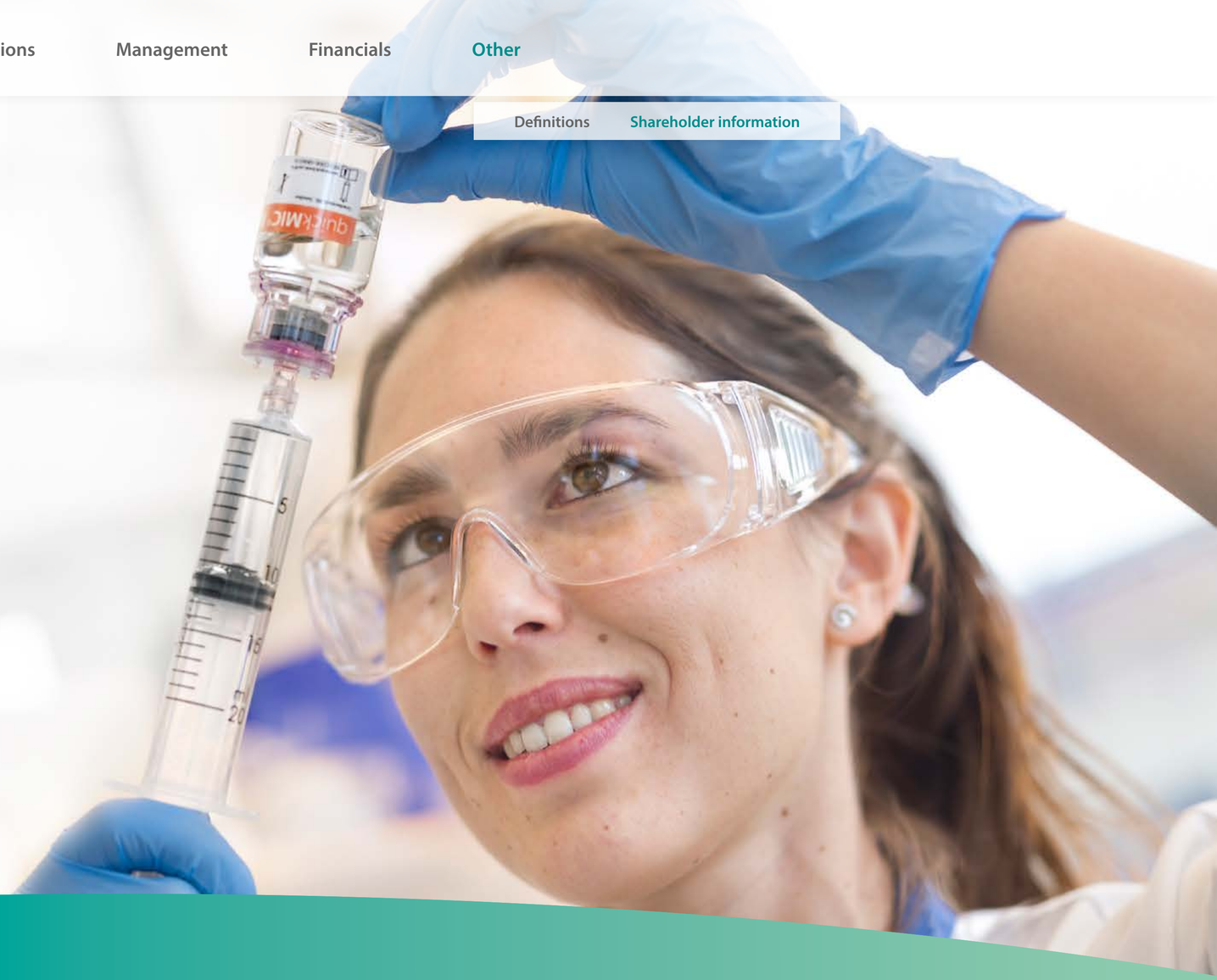
Shareholder information

Forthcoming reports

Interim report Q1 2023	May 17, 2023
Interim Report Q2 2023	August 24, 2023
Interim report Q3 2023	November 16, 2023
Year-end report 2023	February 22, 2024

AGM

The AGM will take place on Tuesday, May 9, 2023 at 5:00 p.m. and will be held at Gradientech's premises at Uppsala Science Park.



gradientech

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