# Annual Report 2021

Clinical Laserthermia Systems AB (publ)

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# Contents

*"CLS's vision is to establish laser ablation as a standard therapy as an alternative to traditional surgery and in the longer term as a complementary systemic therapy of metastasized cancer for patient populations in which mortality unfortunately is too high at present."*

# CLS in brief

CLS develops and sells laser-based treatment systems for the removal of pathological tissue inside the body. Using scanning, the treatment is carried out and monitored with high precision, without the use of traditional open-surgery procedures and with minimal impact on surrounding tissue.

CLS's treatment systems are developed for use in urology, neurosurgery and oncology, for example in the removal of solid soft-tissue tumors in the prostate and areas of the brain that give rise to epileptic seizures.

The evident clinical benefit is a well-defined and safe treatment with few side effects that leads to more rapid recovery for the patient than in the use of open surgery.

CLS today is currently active in three market

**Urology** – localized prostate cancer
**Neurology** – glioblastoma and drug-resistant epilepsy
**Oncology** – metastasized cancer

This focus is also reflected in CLS's strong clinical program in all these market segments.

The company has broad market approval for its products, which are marketed under the TRANBERG® trademark in Europe and the United States.

CLS's new-generation TRANBERG® Thermal Therapy System has been developed for integration with ultrasound (US) and computed tomography (CT) scanning systems, while the latest TRANBERG® Thermal Therapy System with Thermoguide™ Workstation has been developed for use with magnetic resonance imaging (MRI). All these scanning systems are currently used in healthcare across the world, creating good prospects for rapid uptake among healthcare professionals in different parts of healthcare.

Both CLS systems contain capital goods parts with associated sterile disposable products and have various kinds of intellectual property rights protection, such as patent, copy and trademark protection.

CLS today sells products in the market segment of urology directly and through its distributor Clearpoint Neuro Inc. in the United States and through its own sales organization in Europe. CLS is headquartered in Lund, Sweden, and has marketing companies in Germany, the United States and Singapore.

CLS is listed on the Nasdaq First North Growth Market under the ticker CLS B.

# Significant events

**Approval for investigator-initiated clinical study of localized prostate cancer**
In June 2021, CLS and Otto von Guericke University Hospital in Magdeburg, Germany received approval to start an investigator-initiated clinical study of treatment of localized prostate cancer with the TRANBERG® Thermal Therapy System. Ten patients will be included in the study, which is estimated to continue for 18 months and be completed in 2023.

**Oversubscribed rights issue**
In May 2021, CLS made a rights issue and private placement, both of which had to be expanded. The company raised a total of just over SEK 71 million, of which SEK 51.4 million through the expanded rights issue and SEK 20 million through the expanded private placement. The capital is being used for the ongoing commercialization of the TRANBERG® Thermal Therapy System and to support clinical cooperation. The successful raising of capital is clear evidence of the potential in CLS's product offering.

**Deepened cooperation supports commercialization**
During 2021, CLS developed its cooperation with partners and hospitals around the world, in oncology, urology and neurosurgery, to obtain the clinical evidence needed to take CLS products to market in these segments. Examples of important ongoing cooperations and cooperations entered into during the year are those with Clearpoint Neuro Inc. in the United States, in neurology, and Otto von Guericke University Hospital in Germany, in urology. The talks held with Radboud University Medical Center in the Netherlands, Urological Research Network LLC in the United States and Skåne University Hospital in Sweden on planned clinical trials have also advanced CLS's position in the market establishment process in Europe and the United States.

**Regulatory milestones**
In 2021, CLS continued to apply for and receive approvals from regulatory authorities for the next generation of TRANBERG® Thermal Therapy Systems. In December 2021, CLS submitted a 510(k) clearance application, prepared in cooperation with Clearpoint Neuro Inc., to the US Food and Drug Administration for the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation for use in pathogenic brain tissue laser ablation. In March, CLS received US FDA 510(k) clearance for the next-generation TRANBERG® Laser Applicator non-cooled and the TRANBERG® Introducer for use with or without scanning systems based on magnetic resonance imaging (MRI).

**Strengthened management team**
CLS continued to strengthen its organization and management team. Liselotte Nilsson joined CLS as Vice President Marketing & Scientific Marketing. She has extensive experience of marketing, commercial and scientific market communication, as well as product management. Anders Qvarlander was recruited to fulfill the role of Vice President Regulatory Affairs & Quality Assurance. He brings with him capability in managing medical device registrations, assisting in market launches and quality assurance of commercial medical device activity. Both Nilsson and Qvarlander form part of the management team.

**Scientific article published in Frontiers in Oncology**
In July 2021, a scientific article written by CLS co-founder and senior scientific adviser Professor Karl-Göran Tranberg was published under the title 'Local Destruction of Tumors and Systemic Immune Effects' in the journal Frontiers in Oncology. The article was concerned with the potential offered by laser ablation in generating an immune response to fight cancer

# CEO's comments

CLS's vision is to establish laser ablation as a standard treatment as an alternative to traditional surgery and in the longer term as a complementary systemic treatment of metastasized cancer for patient populations in which mortality unfortunately is too high at present.

CLS took many important steps in this direction in 2021. We are approaching full-scale commercialization in focal therapy after having developed the second generation of the TRANBERG® Thermal Therapy System, which makes our treatment system integratable with the systems for scanning and instrument positioning used in healthcare today.

Laser ablation therapy performed with the CLS product offering in urology, neurosurgery and oncology means that more patients have access to effective treatment with fewer side effects. At the same time, our products and systems are driving a switch from costly, open surgery to more effective, minimally invasive image-guided treatments in expensive specialist medical care.

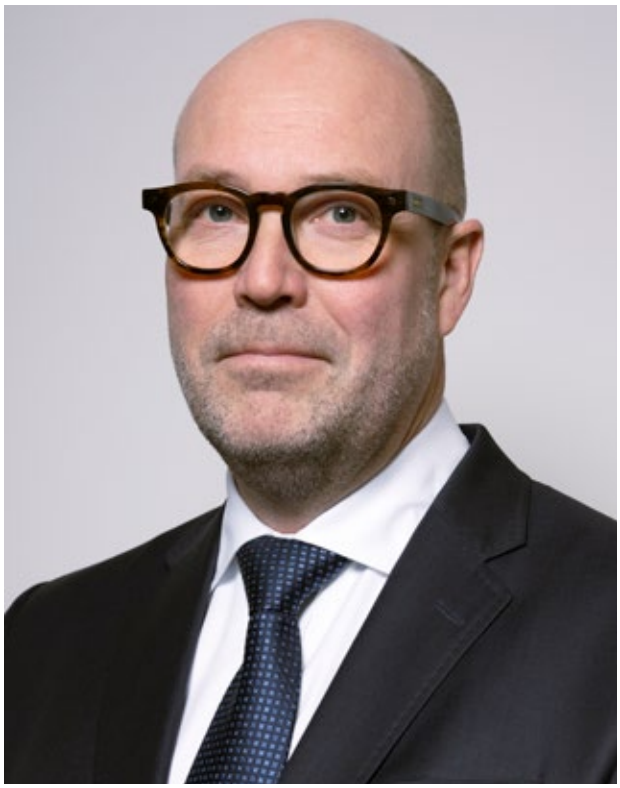
An important element in CLS's success in 2021 was that our strategic focus pointed to continued positive development towards:

1) creating the right product offering and customer experience through partnership
2) generating demanded evidence through clinical cooperation
3) increasing the pace of commercialization through focused market cultivation and communication

CLS products are in commercial use today, and our strategic focus has borne fruit in the form of our initial sales and in the growing interest in our new generation of TRANBERG® products, which we are seeing in all the market segments, indications and geographical areas we address.

**Continued success with the clinical program**
CLS is continuing to develop and establish new partnerships and cooperations to secure our position in the market. One of the most exciting developments during the year was the go-ahead for the investigator-initiated study in which our new-generation TRANBERG® Thermal Therapy System is used in laser ablation, guided and monitored by what is known as MRI-US fusion-guided therapy, for focal treatment of localized prostate cancer conducted at Otto von Guericke Hospital in Magdeburg, Germany. In Toronto, Canada, the investigator-initiated study for focal MRI-guided laser ablation of localized prostate cancer was resumed after a brief pause.

We look forward to starting a clinical study together with Skåne University Hospital in 2022 to evaluate the safety of MRI-guided laser ablation of brain tumors (glioblastoma) with use of the TRANBERG® Thermal Therapy System



*Dan J. Mogren*

with Thermoguide ™ Workstation together with Clearpoint Neuro's CE-marked neuronavigation platform. At the same time, studies are being performed in Switzerland by Immunophotonics and in Portugal by CLS to evaluate our imILT® protocol in combination with drug therapy. The results are expected to provide important clinical evidence on the way to commercialization in the market segment of oncology and in the indication area of metastasized cancer.

**Deepened partnerships**
CLS has a number of cooperations to advance our clinical development program. One of these that has been most successful, particularly in 2021, is the cooperation with Clearpoint Neuro Inc. in neurosurgery and treatment of pathogenic brain tissue. Following extensive initiatives by both parties, CLS was able to submit a 510(k) clearance application to the US Food and Drug Administration (FDA) for the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation. When this is granted, it will mean a decisive step towards market establishment in neurology in the United States through our partner Clearpoint Neuro Inc.

**Success in raising capital**
In May 2021, CLS completed an oversubscribed rights issue and private placement that raised a total of just over SEK 71 million for the company before issue expenses, of which just over SEK 51 million came through the rights issue and SEK 20 million through the private placement.

The fact that both the rights issue and the private placement were oversubscribed is acknowledgment of the high level of interest in the company among both existing and new shareholders. It is also evidence that many investors see the potential offered by the second generation of the TRANBERG® Thermal Therapy System and the work being done to establish CLS in the market in Europe, the United States and the Asia-Pacific region.

As part of the private placement, CLS was able to welcome several new shareholders, including Khattar Holdings in Singapore, which has an active holding in Advanced Medical Systems, our joint venture partner in the Asia-Pacific region.

*"With our new organizational structure in place we are well positioned to drive CLS forward in our market egments of urology, neurosurgery and oncology"*

**New supplier of sterilization services for disposable articles In**
2021, CLS was able to secure three new suppliers of sterilization services for the disposable articles associated with our TRANBERG® Thermal Therapy System. This redundancy creates greater certainty for CLS and the partners we cooperate with in the future. The new supplier agreements came about after our previous supplier's CE mark was withdrawn. As soon as this came to CLS's attention, all disposable articles were recalled and continued deliveries were suspended, leading to a brief pause in our clinical studies during the time when we were looking for new suppliers and received the necessary authority approvals

**Strengthening of CLS's management and organization**
A number of important recruitments were made to the CLS management and organization during the year to strengthen our commercialization efforts and provide much-needed support and utilize feedback from our partners on the TRANBERG® product portfolio.

One such key recruitment is Liselotte Nilsson, who in her role as Vice President Marketing & Scientific Marketing supports our work on disseminating information about our products to the market and investors. Another key recruitment is Anders Qvarlander in the role of Vice President Regulatory Affairs & Quality Assurance. In acknowledgment of the significance of the European market to CLS, Perjan Pleunis was also appointed as dedicated Vice President, Sales Europe.

Another important development in the organization was the creation of the role of Clinical Application Specialist for the market segments of urology and oncology. These employees represent the link between CLS and the users of our TRANBERG® products. The role provides support to the users, both out in the field and in-house, irrespective of whether routine use, clinical studies or product evaluation ahead of a forthcoming procurement is concerned. The role also provides important feedback from the market for our future continued development.

**Well positioned to put our strategy into practice**
2022 will be another exciting year for us in which the pace of commercialization and market establishment will increase. With our new organizational structure in place we are well positioned to drive CLS forward in our market segments of urology, neurosurgery and oncology. In the indication of prostate cancer in the market segment of urology, we are expanding with new clinical studies, product evaluations and partnerships to further increase the pace in Europe and the United States. We have also launched a new graphic identity and website. Both are important tools in our work to reach out with messages and information and are used to optimize the work of establishing and commercializing our product portfolio in the geographical markets where we are active.

We look forward to having you on board for our continued journey to supply specialist physicians in urology, oncology and neurosurgery across the world with better tools for safer, more cost-effective care that improves quality of life!

# Description of operations

# Three segments with great potential

CLS focuses on the demand for laser ablation that exists in the segments of urology, neurosurgery and oncology. Clinical evidence is obtained through cooperation with leading physicians and hospitals that lays the foundation for CLS products being in demand and used in these segments. At the same time, the company exploits the development opportunities that exist to continue to offer solutions that work well and are competitive.

The second generation of the TRANBERG® Thermal Therapy System is compatible with existing scanning systems, such as magnetic resonance imaging (MRI) and ultrasound (US). This enables the user to monitor and check the treatment in real time and at a level of detail that is not possible with most other present-day competing treatment systems. The evident clinical benefit is safe, well-defined treatment, few side effects and rapid recovery from the procedure as it is performed entirely without the use of open surgery.

**Urology for treatment of localized prostate cancer**
Laser ablation offers a focal treatment method in localized prostate cancer and fills a gap between active monitoring (without treatment) and radical treatment (surgery). Many prostate cancer patients under active monitoring and treating specialists are looking for treatment options instead of adopting a 'wait and see' attitude. Laser ablation means that, with a small procedure, the tumor can be treated very precisely to remove or control its growth without damaging surrounding tissue, which radically reduces the otherwise high risk of side effects.

The market for minimally invasive treatment of prostate cancer is large. WHO estimates that around 1.2 million people around the world are diagnosed annually with localized prostate cancer[1]. The markets in Europe and the United States for minimally invasive treatment of prostate cancer were valued in 2019 at around USD 35 billion, and this value is expected to grow by nearly 12 percent annually by 2027[2].

CLS's establishment of the TRANBERG® product portfolio has progressed furthest in the indication area of prostate cancer. More than 250 treatments have been carried out with the first generation of TRANBERG® products, and most products have been sold in the United States. Investigator-initiated studies are now being conducted in Germany, the Netherlands and the United States with respect to the second generation, further driving market establishment and commercialization in all the geographical regions in which CLS is active.

**Neurosurgery – for treatment of glioblastoma and drug-resistant epilepsy**
Neurosurgery requires precision as it may mean that nerve centers that control important bodily functions need to be bypassed and protected during surgical procedures. Laser ablation – which in neurosurgery is called laser interstitial thermal therapy (LITT) – performed using stereotaxis or neuronavigation, as it is also called, offers many benefits. In particular, areas of the brain that are not normally accessible to surgery, are treated with LITT as the procedure is performed in a minimally invasive manner through holes drilled into the cranium. In addition, LITT is used only on the lesion or the tumor, and surrounding healthy tissue is not affected.

The cooperation between CLS and Clearpoint Neuro in neurosurgery is aimed at developing and commercializing a fully integrated system for MRI-guided stereotactic laser ablation with very high precision. By integrating the technologies of the two companies in one product solution, the user is able, in an MRI-guided process with high very precision, to, identify target tissue, navigate and position the applicator for laser ablation in the target tissue. The ablation can be followed in real time by MRI-based temperature and ablation monitoring, and the treatment can be optimized with respect to desired treatment effect and risk of complications.

Clearpoint Neuro's commercial launch in the United States is expected to take place as soon as the 510(k) clearance application submitted by CLS to the US FDA in December 2021, for use of the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation for MRI-guided LITT treatment of pathological brain tissue, has been approved.

One of the indication areas in neurology that CLS focuses on is glioblastoma. There will also be commercial focus on LITT treatment of areas of the brain that give rise to epileptic seizures in patients with drug-resistant epilepsy.

Glioblastoma is a highly aggressive and normally untreatable cancer. Glioblastoma is the most common type of brain tumor and affects up to 5 in 100,000 people[3]. The pharmaceutical market for glioblastoma is expected to grow to a value of nearly USD 1.8 billion by 2027, with annual rate of growth of 13 percent[4].

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[1] WHO Global Cancer Observatory (iarc.fr)

[2] https://www.medgadget.com/2021/01/north-america-and-europe-minimally-invasive-prostate-cancer-surgery-market-is-accounted-for-us-86187-4-million-in-2019-with-11-9-cagr-by-2027-coherent-market-insights.html

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7302718/

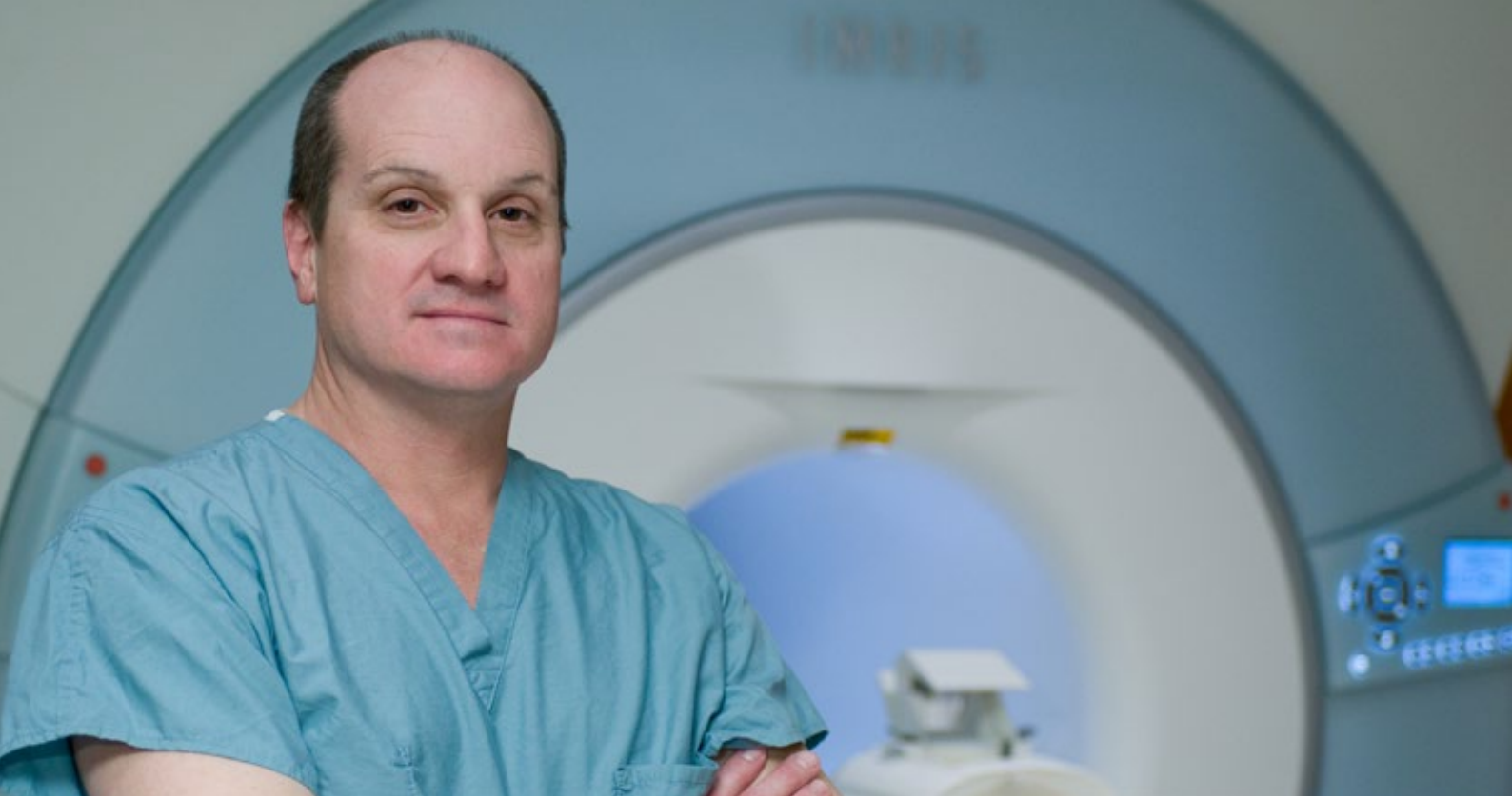
[4] https://www.ihealthcareanalyst.com/global-glioblastoma-multiforme-drugs-market/


**Oncology – for treatment of metastasized cancer**
CLS's business originates in the extensive research and development by the co-founder Karl-Göran Tranberg of an ablation method that entails cautiously heating cancerous tumor cells for a long time, which does not just kill the treated tumor locally but also activates the immune system to systemically attack cancer cells throughout the body, what is known as an abscopal effect.

To take this method further, CLS developed its own immunostimulating ablation protocol – known as imILT® – for treatment of advanced cancer such as metastasized cancer

More than 30 million people are expected to be affected by cancer in 2040 and more than 16 million to die from it. Advanced treatments – such as imILT® – will offer a growing number of patients in late stages of their cancer disease more effective and more tolerable treatment than is available today.

CLS's new generation of TRANBERG® products is integrated with scanning systems of the US and MRI types for image guidance. The new generation has also been enhanced to provide the level of precision and accuracy needed for control and monitoring of our immunostimulating ablation protocol imILT®. With imILT®, treatment of metastatic cancer can take place as monotherapy or in combination with drug-based immunotherapy such as checkpoint inhibitors.



# Interview with Dr Eric Walser, University of Texas Medical Branch

*Dr Eric Walser is an internationally recognized interventional radiologist with extensive clinical experience of using non-surgical ablation for the treatment of small tumors as an alternative to traditional surgery. Dr Eric Walser uses the TRANBERG® Thermal Therapy System to treat localized prostate cancer.*

**How do you use MRI-guided laser ablation today to treat prostate cancer?**
I use it in intermediate-grade prostate cancer when the disease has not spread outside the prostate.

**How do you view the potential for this type of treatment of prostate cancer?**
As laser ablation is associated with low risk and high precision, I see significant potential for this method of treatment in prostate cancer. Focal therapy and treatment systems such as the TRANBERG® Thermal Therapy System mean that it is possible to measure the temperature around the tumor that is visible by MRI. This is not possible with other treatments.

**What benefits does laser ablation have for the patients?**
An important benefit for patients is that they can obtain laser ablation treatment without needing to be hospitalized. This obviously means that the disruption to the patient's day-to-day life is reduced. Other benefits are that few patients experience pain after the procedure, and the incidence of erectile dysfunction is lower for patients who have undergone laser ablation.

**What benefits does laser ablation have over other methods of treatment?**
Focal therapy such as laser ablation has few side effects, and the patients experience less pain and blood in the urine, which can be side effects of other treatments. There are other methods, such as high-intensity focused ultrasound, which to a greater degree leads to erectile dysfunction and requires general anesthetic. In addition, these methods take longer to perform than laser ablation.

# Strategic focus

**Creating the right offering and customer experience through partnerships**
To enable it to provide the right customer offering in the market segment and indication area concerned, CLS enters into partnerships with suppliers of complementary systems and solutions.

Examples of this are CLS's partnerships and cooperation with global suppliers of scanning systems for image guidance, such as Siemens Healthineers, GE Healthcare and Philips Healthcare, whose systems are used by health services in all of CLS's market segments around the world. Another example is the company's successful partnership with Clearpoint Neuro, which is focused on the market segment of neurosurgery.

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**Generating supporting clinical evidence through cooperations**
By cooperating with hospitals, clinics and partners, CLS creates the clinical evidence needed to provide support for the company's market approvals, establishment and commercialization of the TRANBERG® portfolio in the company's market segments and indication areas.

This takes place in the clinical programs CLS runs in each market segment. The program consists of both sponsored and investigator-initiated studies.

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**Commercialization – through increased market cultivation and communication**
CLS's commercialization strategy specifies successive establishment of the company's TRANBERG® portfolio, starting in urology, followed by neurosurgery and oncology. Establishment takes place geographically, based on market approvals, available reimbursement models for the customer and supported by generated and published clinical evidence in each indication area.

The conditions necessary for increased market cultivation are created through partnership with suppliers of complementary products and integration solutions with jointly set commercial targets and broad market communication, starting in Europe and the United States. Examples of this are the partnerships and cooperations CLS has for example with Siemens Healthineers AG and Clearpoint Neuro Inc.

CLS's market cultivation and sales take place regionally and locally through its own marketing companies in the United States, Germany and Singapore.

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# Creating the right offering and customer experience through partnerships

Minimally invasive treatment of tumor disease performed with ablation makes strict demands on precision in monitoring and control of the procedure. This is not possible to achieve without integration between the constituent parts, which together make up a complete system for image guidance.

To enable it to provide the right level for the company's product offering in the market segment and indication area concerned, CLS enters into partnerships with suppliers of complementary systems and integration solutions. Examples of this are CLS's partnerships and cooperation with global suppliers of scanning systems for image guidance, such as Siemens Healthineers, GE Healthcare and Philips Healthcare, whose scanning systems based on magnetic resonance imaging (MRI) are used by health services in all our market segments around the world.

Other examples are partnerships and cooperation with the American companies Clearpoint Neuro Inc. and Focalyx Inc., which provide integratable software-supported solutions for procedure planning, navigation and positioning of CLS's sterile instruments in the treatment of structures in the brain and prostate. CLS's partnership with the French company Image Guided Therapy bolsters the company's unique solution for MRI-based software-supported monitoring and control of the whole ablation process, a solution that today is integrated into CLS's most advanced systems for MRI-guided ablation and imILT® treatments.

**TRANBERG® Thermal Therapy System – the second generation**
CLS's new-generation TRANBERG® Thermal Therapy System has been developed to be integrated with scanning systems of the ultrasound (US) and computed tomography (CT) types, while the latest TRANBERG® Thermal Therapy System with Thermoguide™ Workstation has been developed for use with magnetic resonance imaging (MRI).

CLS's new generation of TRANBERG® products have been developed to also be integrated with software-supported solutions for procedure planning, navigation and positioning of CLS's sterile instruments in the treatment of structures in the brain and prostate.

The company's systems contain capital goods with associated sterile disposable products and have various kinds of intellectual property rights protection, such as patent, copy and trademark protection.

The TRANBERG® Thermal Therapy System and the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation have been developed to generate, monitor and control the energy required to heat and destroy pathological tissue inside the body by laser. During the ablation, it is possible, with varying degree of precision, depending on which of the company's systems are used, to monitor and control heating and cell destruction to ensure treatment results and make sure that surrounding healthy tissue is not damaged.

The TRANBERG® portfolio today consists of the following products/product groups:

*TRANBERG® Mobile Laser Unit –*
This unit contains a laser source and control panel with several options for controlling treatment effect and time. To facilitate operation, there are two touchscreens for a complete overview and precise monitoring.
The TRANBERG® Mobile laser unit is CE-marked and has 510(k) clearance from the US FDA.

*TRANBERG® Laser Applicators and Introducers –*
These sterile disposable instruments have been developed for image-guided minimally invasive access to and ablation of the target tissue with high precision. The TRANBERG® portfolio includes several non-cooled laser applicators for different ablation sizes and shapes. CLS's unique applicator design optimizes the distribution of heat in the tissue and eliminates the external liquid and gas cooling used by our competitors, which greatly simplifies and improves the whole work flow. The applicators are available in two lengths adapted for use with MRI fusion ultrasound or direct MRI image guidance.

These products are CE-marked and have 510(k) clearance from the US FDA.

*TRANBERG® Thermoguide™ Workstation –*
This is the latest addition to CLS's product range for precise temperature and ablation monitoring in real time, based on information obtained from the MRI scanner on which the TRANBERG® Thermoguide™ is based. This product is connected to the TRANBERG® Mobile Laser Unit, together making up the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation.

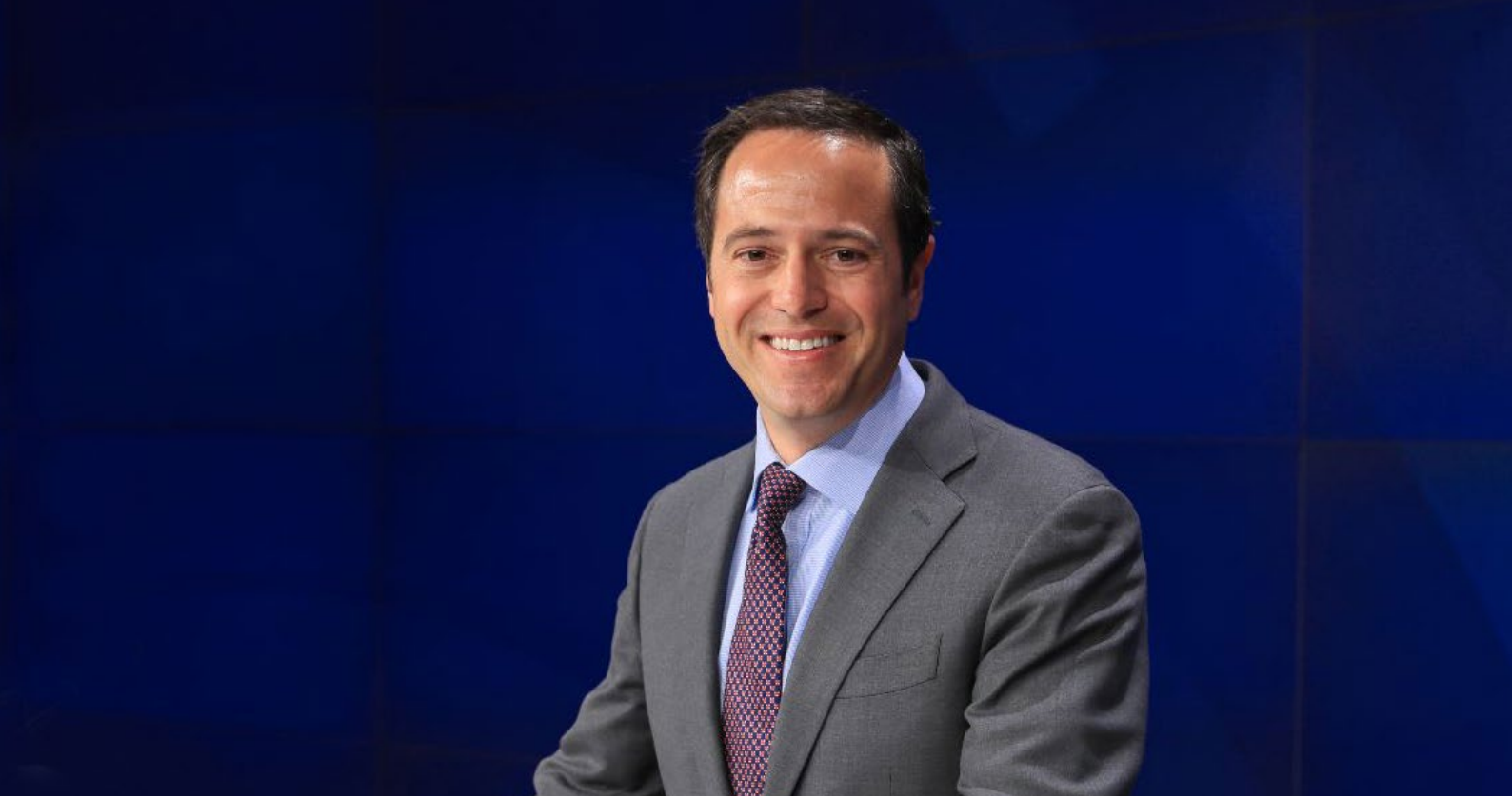
This product is CE-marked.

*TRANBERG® Thermal Therapy System with Thermoguide™ Workstation –*
The system has been developed for high-precision MRI image-guided treatments, where the Thermoguide™ Workstation continuously provides a two-dimensional graphic presentation of tissue temperature and calculated cell destruction in real time on high-resolution anatomical images obtained from the MRI scanner. Information that enables the user to follow and adjust the treatment continuously in a very precise way.

All the products included in the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation are CE-marked, and the system is awaiting 510(k) clearance from the US FDA.

*TRANBERG® Temperature Probes –*
The temperature probes are used with scanning systems of the ultrasound (US) and computed tomography (CT) types. These thin temperature probes measure the temperature in the tissue in real time and are available with either one or four sensors, which means up to a total of ten measuring points during treatment.

These products are CE-marked and have 510(k) clearance from the US FDA.



# Interview with Joseph M. Burnett, CEO of ClearPoint Neuro Inc.

*CLS's partner ClearPoint Neuro has extensive experience of selling its products, including the ClearPoint® Neuro Navigation System, to hospitals and physicians. Joseph M. Burnett has been the company's CEO since 2017.*

**Can you please tell us about ClearPoint Neuro?**
We are a public company listed on Nasdaq with a market value of around 250 million dollars. Our primary platform is ClearPoint Neuro Navigation, which enables surgeons to perform minimally invasive surgical procedures in the brain while the patient is lying in an MRI scanner. All the material used in the platform is made of plastic, porcelain and other materials that are compatible with an MRI scanner. The advantage is that the surgeon is able to monitor how the operation is progressing inside the body in real time, and from CLS's point of view it is important that the patient is in an MRI scanner before the laser ablation can begin.

**Describe your cooperation with CLS!**
Every time you look for a cooperation or a partnership, you want to be sure that a problem is being solved.The problem that we are trying to solve together with CLS is that the market for laser ablation for neurology has advanced very slowly over the last ten years. Progress has been made in epilepsy and brain tumors, but there is no company that is able to carry out the whole procedure from start to finish. Somewhere along the way, responsibility is handed over from the navigation team to the laser ablation therapy team. With our partnership, we are able to build both product lines so that they become completely mutually compatible, ensuring a smooth, fast and simple procedure. That is precisely what is required for the laser ablation market to take off.

**With FDA approval, your partnership will be able to enter a commercial phase, what potential is there in CLS's products?**
The potential is firstly in how large the market is on the neurosurgery side, and secondly how competitive CLS's products are and how well they can solve the hospitals' problems. If we can jointly streamline the navigation in the brain and the laser ablation therapy so that the procedure becomes more efficient and stays within a time of three to four hours, hospitals will be able to do two or three more procedures per day in the same MRI scanner, to which it is often difficult to obtain access. We already have our sales channels in place as we have a presence in the hospitals with our equipment and know the surgeons, so when we add CLS laser ablation and gain approval it can proceed quickly.

**What else are you looking forward to in the partnership?**
I look forward to working closely with CLS, continuing to merge our differing expertise and steadily develop new products to remain an innovative partnership, which neurosurgeons today are not accustomed to.

# Generating supporting clinical evidence – through cooperations

*CLS today has cooperations around Europe and North America that generate quantitative and qualitative clinical evidence in each indication area with the new generation of TRANBERG® products. If high-end results are obtained, it means a well-supported and effective process for market approval, establishment and commercialization of CLS's product offering in cultivated market segments and geographical areas.*

## Treatment and indication areas in urology

MRI or MRI/US fusion image-guided laser ablation (FLA) for focal tumor therapy in localized prostate cancer with transperineal or transrectal minimally invasive tumor access.

The purpose of the ongoing clinical program in urology is to generate quantitative and qualitative clinical evidence for the new generation of TRANBERG® products. Clinical data is to provide support for an effective process for establishment and commercialization of the product offering in the indication area of localized prostate cancer in Europe, the United States and, in the next stage, the Asia-Pacific area.

**Ongoing studies**

*Toronto General Hospital, Toronto, Canada*
Investigator-initiated study of focused laser ablation (FLA) of localized prostate cancer.

The study will include a total of 55 patients with early-stage prostate cancer.
***Status:*** The study was briefly paused in 2021 due to CLS's replacement of its supplier of sterile disposable products. Patient recruitment and treatment began in 2017.

*Radboud University Medical Center, Nijmegen, Netherlands*
Investigator-initiated study of MRI-guided focal laser ablation (FLA) of localized prostate cancer.

The study will include a total of 10 patients with low- to intermediate-grade prostate cancer.
***Status:*** Ethical approval was obtained in February 2022, and the first patient was treated in April 2022.

*Otto von Guericke University, Magdeburg, Germany*
Investigator-initiated trial of treatment with MRI-ultrasound fusion-guided focal laser ablation (FLA) of localized prostate cancer.

The study will include a total of 10 patients.
***Status:*** Ethical approval has been obtained and patient recruitment and treatment began in December 2021

*Urological Research Network, Miami, USA*
Clinical phase 1 study in which Focalyx Technologies, which is developing image-guided fusion technology, is using the TRANBERG® Thermal Therapy System for MRI-US function image-guided laser ablation (FLA) of low- to intermediate-grade localized prostate cancer.

The study is being performed by Urological Research Network. The study will include 5+ 15 patients.
***Status:*** The first patient was treated in April 2022.

## Treatment and indication areas in neurosurgery

MRI-guided stereotactic laser ablation (LITT) for focal tumor therapy in the brain in glioblastoma and as treatment of drug-resistant epilepsy with transcranial minimally invasive access.

The purpose of the ongoing clinical program is to open up indication areas in neurosurgery in Europe for the new generation of TRANBERG® Thermal Therapy System with Thermoguide™ Workstation; this is done by producing the safety and user data required for marketing authorization through CE marking under the new Medical Device Regulation (MDR). In Europe, a sponsored clinical study is starting in 2022 that lays the foundation for continued work on establishing an integrated system in Europe.

**Ongoing studies**

*Skåne University Hospital, Lund, Sweden*
CLS-sponsored evaluation of the safety and feasibility of image-guided laser ablation treatment of glioblastoma performed with the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation together with Clearpoint Neuro's CE-marked neuronavigation platform.

The study will include a total of 5 patients.

## Treatment and indication areas in oncology

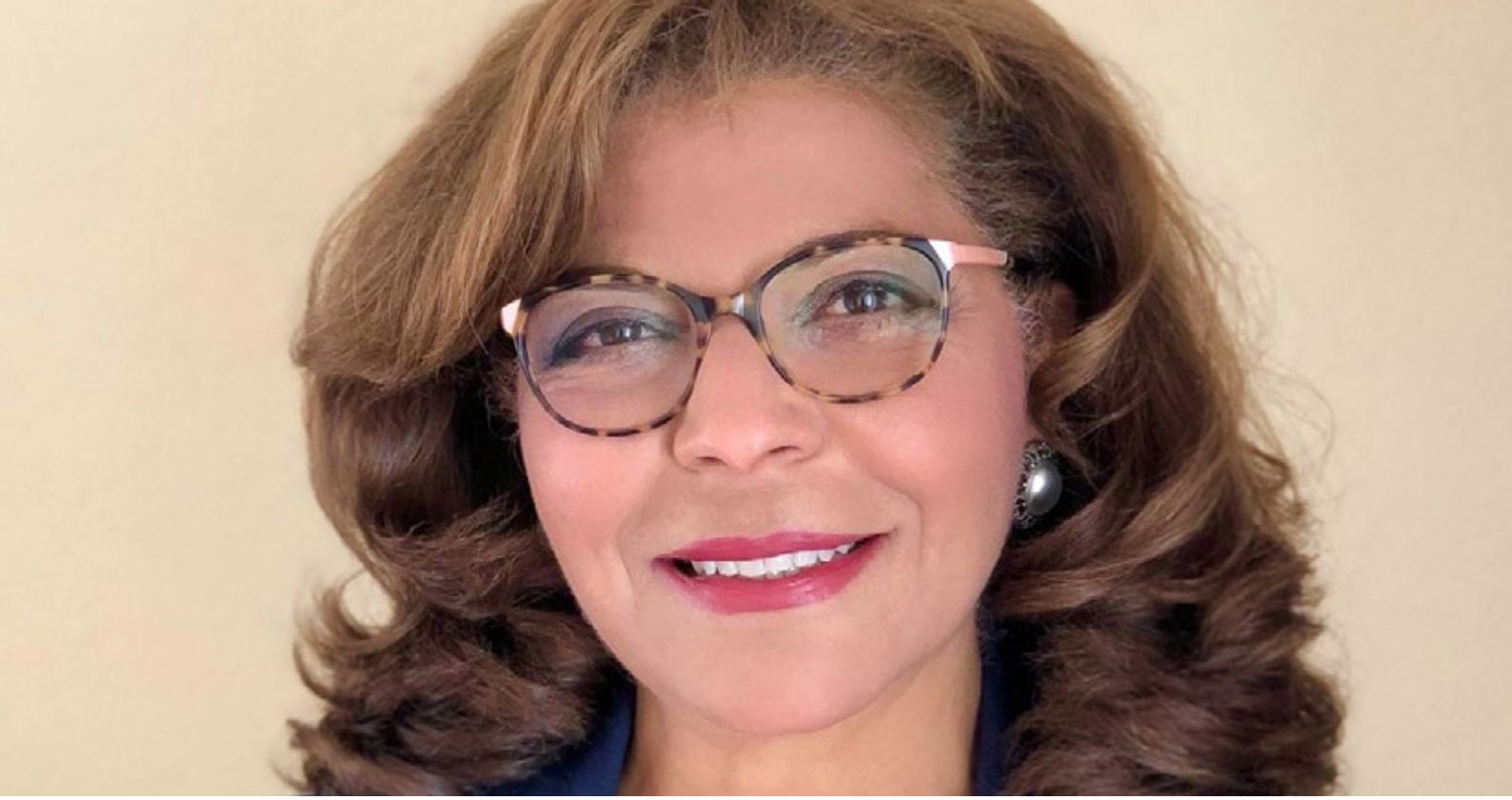
MRI- or ultrasound-guided immunostimulating laser ablation (imILT®) for abscopal tumor therapy in advanced (metastatic) cancer with minimally invasive tumor access.

CLS's studies in immunostimulating laser ablation (imILT®) are in an early phase and have shown with grants from EU Horizon 2020 that CLS has a safe (imILT®) treatment protocol. Treatment efficacy is also being evaluated in ongoing clinical studies in which (imILT®) treatment is performed.

**Ongoing studies**

*Immunophotonics, Switzerland*
Development cooperation in which the TRANBERG® Thermal Therapy System and the imILT® method are used in combination with Immunophotonics' drug candidate IP-001 in a clinical phase 1b/2a study concerning treatment of cancer patients with solid tumors in metastatic cancer. The study is entirely funded by Immunophotonics. CLS invoices for disposable instruments and leases the laser units used in the study.

The study will include a total of 33 patients with solid tumors, soft-tissue sarcoma and skin cancer.
***Status:*** Phase 2a started.



# Interview with Hoda Tawfik, VP Clinical Affairs

**You started working as VP Medical Affairs at CLS in 2021. What was it that attracted you to the company?**
What attracted me was the innovative design of CLS technology and the opportunity for development in many different clinical areas with a large unmet medical need.

**What is your view of the potential of laser ablation and the TRANBERG® Thermal Therapy System in this area?**
Focal ablation technology has European CE marking for certain indications, for example prostate cancer which represents a huge market. There is also an opportunity to develop LITT treatment in pathological brain lesions, which opens up opportunities to treat diseases with a large unmet medical need, such as glioblastoma, but also epilepsy.

**How does the clinical program assist CLS in establishing its products in the market?**
The clinical program at CLS rests on two pillars. The first is to promote the implementation of investigator-initiated studies, that is to say clinical trials, as well as registration of data for the indications where we already have CE marking, such as prostate cancer. As a result, we can introduce TRANBERG® Thermal Therapy Systems for focal ablation in the medical networks, gain the confidence of treating physicians and establish the technology in the market. The second pillar is to explore the feasibility and effectiveness of TRANBERG® Thermal Therapy Systems in new indications for which CE marking has not yet been obtained, such as brain tumors and epilepsy. It opens the way to new markets and establishes treatment options for TRANBERG® Thermal Therapy Systems.

**What progress was made in the clinical program in 2021?**
In 2021 we supported the commencement of several investigator-initiated studies for prostate cancer at renowned clinical centers such as the university hospital in Magdeburg and the university hospital in Nijmegen. We also planned for other investigator-initiated studies with prostate cancer patients in and outside Europe. In addition, we initiated our first clinical trial on patients with brain tumors at Skåne University Hospital in Lund. The study will provide our first data concerning the feasibility of LITT in glioblastoma using the TRANBERG® Thermal Therapy System. We also started the planning of further studies to establish LITT in the brain and support the application for CE marking in this indication. As well as this, we continued our studies in the United States and Switzerland.

**What are the objectives for the clinical program in 2022?**
The clinical objectives for 2022 are to obtain first results from the investigator-initiated studies in prostate cancer to establish the TRANBERG® Thermal Therapy System in the urology market and start marketing and commercializing our products. The second objective is to obtain results from the first study on brain tumors and, based on that, to continue to develop LITT in the brain and move on with our strategy to have this product certified.

# Commercialization – through increased market cultivation and communication

*Minimally invasive laser ablation will soon benefit more patients through the launch of the new generation of TRANBERG® Thermal Therapy System in the United States and Europe, followed by the Asia-Pacific region. CLS's marketing organization today is working actively on market cultivation and selling-in.*

The CLS business model includes licensing as well as commercialization in-house and through distributors. Which route is taken depends among other things on the market, CLS's level of expertise and ambition, what partners the company has and the company's financial position.

The company has a well-established pricing and payment model for end-customers, the benefits and risks of which are well known. CLS offers time-limited agreements for evaluation of the product offering, after which commercial negotiations are initiated.

CLS's commercialization strategy specifies successive establishment of the company's TRANBERG® portfolio in selected market segments, starting in urology, followed by neurosurgery and oncology. Establishment takes place geographically, based on market approvals, available reimbursement models for the customer and supported by generated and published clinical evidence in each range of indications.

The conditions necessary for increased market cultivation are created through partnership with suppliers of complementary products and integration solutions with jointly set commercial targets and broad market communication, starting in Europe and the United States. Examples of this are the partnerships and cooperations CLS has, for example, with Siemens Healthineers AG, Clearpoint Neuro Inc. and Focalyx Inc.

The path to market for CLS's new technology platform and product generation is divided into three stages, where status and choice of path differ somewhat depending market segment and range of indications.

**Urology**
CLS is currently at the first stage, which is the prelaunch phase, with a transition during the year to the next stage, which entails limited launch of the TRANBERG® portfolio in Europe and the United States for image-guided laser ablation as focal therapy in tumor therapy in patients with localized prostate cancer.

During the ongoing prelaunch phase, the TRANBERG® portfolio has been optimized for integration with scanning systems for image guidance and systems for navigation and positioning of associated sterile disposable instruments.

CLS products are currently in clinical trials, known as investigator-initiated studies, where clinical evidence is obtained to support the company's continued launch and commercialization in urology. CLS is present at the studies to provide support to the investigators and respond to any needs for adjustment and continued development.

At the same time, the Company is cultivating hospitals and prostate centers with larger or prominent programs for diagnosis and treatment of prostate cancer in Europe and the United States. CLS offers these stakeholders product evaluation agreements running for three to six months, depending on market and legal structure. These agreements move on to negotiations on subsequent procurement on usual commercial terms.

**Neurosurgery**
CLS's agreement with Clearpoint Neuro Inc. means that a licensing right to CLS technology has been granted to Clearpoint Neuro. This enables them to commercialize the system for LITT therapy in neurosurgery, which is based on integration of the CLS and Clearpoint Neuro technology platforms.

The process is currently at the first stage, which is the prelaunch phase, with an expected transition during the year to the next stage, which means a limited launch of the integrated system in the United States on a smaller selection of the approximately 100 clinics currently using Clearpoint Neuro's existing product platform. If a good response is received, CLS anticipates a scale-up in the United States and a limited launch in Europe based on the forthcoming CE marking.

**Oncology**
CLS is at the first stage, which is the prelaunch phase, including in this market segment.

During the ongoing prelaunch phase, the TRANBERG® portfolio has been optimized for integration with scanning systems for image guidance and systems for navigation and positioning of associated sterile disposable instruments. Based on the clinical evidence obtained in the part of the phase 1a/2a study conducted by Immunophotonics, where CLS is present to provide support to the investigators and respond to any needs for adjustment and continued development and discuss how a joint commercial initiative in immunostimulating systemic treatment of advanced cancer might be designed.

In line with its strategy for market establishment in Europe, CLS has also had an agreement since 2019 with the private Hospital da Luz in Aveiro, Portugal, on imILT® treatment of advanced cancer with the TRANBERG® Thermal Therapy System, which is incorporated into a CLS registry study.

**Subsequent steps in CLS's launch activity**
Full market launch in each segment is intended to take place as and when supporting clinical evidence from the limited launch phase becomes available for publication and presentation at selected international and regional medical conferences. This step means further strengthening of CLS's internal commercial organization and sales channels to lend support to the increased effort.

**CLS has a global presence**
To cope with the development and commercialization of the company's TRANBERG® products, CLS has built up an organization focused on the head office in Lund and separate marketing companies around the world.

The company's head office in Lund contains CLS's management, development department, central quality and regulatory departments, and the financial and economic department. Clinical studies, marketing and sales activities and strategic partnerships and cooperations are also coordinated from the head office.

**Europe**
CLS regional marketing companies in Germany address the European urology market, focusing on Germany, the Netherlands, Spain, Portugal and France. The company's European organization also includes a person responsible for CLS sales in Europe, the company's product manager and the newly recruited application specialist in urology.

**United States**
CLS's American subsidiary in California has an organization adapted to the US prostate cancer market, which is notable for highly advanced commercial minimally invasive focal therapy of localized prostate cancer and other soft-tissue diseases with image-guided laser ablation. The company's organization in the United States contains a CEO, also responsible for CLS sales in the United States, a quality manager and an application specialist in urology.

CLS's products are used commercially at several hospitals in the United States. Sales at present principally consist of disposable instruments and take place through the American subsidiary and the company's US distributor Clearpoint Neuro.

CLS is currently collecting clinical data for the second generation of the TRANBERG® Thermal Therapy System with fusion-guided laser ablation of prostate cancer. Read more about this study on page 17.

There is growing interest in the company's TRANBERG® products in the market segment of urology. This is due to minimally invasive focal therapy with laser ablation already being an established treatment at smaller, private clinics where revenue today is generated both through existing reimbursement systems and directly from patients who pay for their own treatment.

**Asia-Pacific Region**
In Singapore there is a part-owned subsidiary tasked with establishing CLS and the company's TRANBERG® products in the Asia-Pacific region. The subsidiary is a joint venture owned in equal parts by CLS and Advanced Medical Systems Pte Ltd, which is a supplier of medical products and services with a broad network in the Asia-Pacific region.

Market approval for the second generation of the TRANBERG® portfolio is expected to be received in the first half of 2022 for image-guided laser ablation as minimally invasive local tumor therapy in patients with localized prostate cancer. With a launch model equivalent to that in Europe and the United States, the company's operations in 2022 are therefore focused on establishing CLS and the TRANBERG® portfolio in the market segment of urology followed by neurosurgery and oncology.

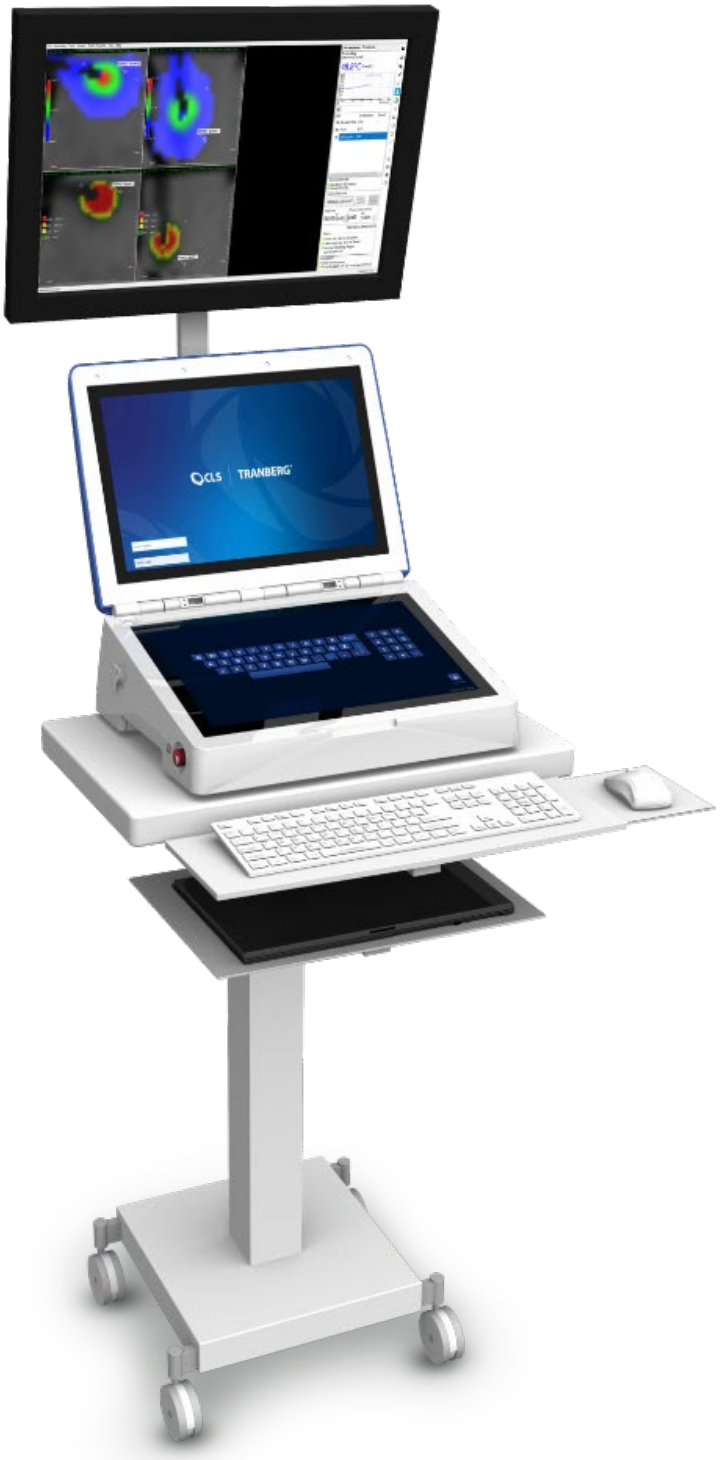
**Activities in 2022**
CLS will expand its organization in 2022 with the addition of further clinical specialists who have an important role to play in training and supporting users of TRANBERG® products at the start-up stage. CLS is also committed to further strengthening its market communication through the launch at the beginning of 2022 of a new brand platform, new website and new social media initiatives. These initiatives will form the basis for a more full-scale commercial launch in urology in Europe and the United States during the latter half of 2022.

# Patents and trademarks

CLS has patented a large number of advances based on its imILT® protocol, which will safeguard the company's unique position in the market in image-guided laser ablation therapy for many years to come.

CLS's patent strategy is aimed at protecting its technology and its various functions, for example with regard to positioning CLS's laser fiber during laser ablation and monitoring the effect on treated tissue. CLS has a strong patent portfolio consisting of granted patents, divided patents and patent applications distributed across the company's unique innovations. CLS's ambition is to ensure patent protection across all its strategic markets, including the United States, Europe and the Asia-Pacific Region.

An example of a patent granted in 2021 concerns CLS's proprietary disposable introducer, which measures tissue temperature in laser ablation. It reduces the need for the separate temperature probes that at present are introduced into the treatment area in order to monitor and guide the treatment. Tissue Temp Introducer, as the product is called, facilitates the treatment situations in which the physician finds it difficult to place more than one instrument in the treatment area.



| Patent number | Description | Approved areas | Application | Priority year | Expiry year |
|---|---|---|---|---|---|
| **Apparatus and methods for determining a property of a tissue** | | **CN, EP, ES, FR, GB, IE, IT, PL, SE, TR, US, HK, DE** | **US** | | |
| SE532142C | Apparatus for determining thermal properties in a tissue | SE | | 2007 | 2027 |
| EP 2532319 B1 | Divided application for EP2532319A1 | DE, EP, ES, FR, GB, IE, IT, PL, TR | | 2008 | 2028 |
| US 8,753,381 B2 | Apparatus and methods for determining a property of a tissue | US | | 2007 | 2031 |
| US 9,884,201 | Divisional application to: US 8,753,381 B2 | US | | 2007 | 2031 |
| EP2192868 A4 | Apparatus and methods for determining a property of a tissue | EP, ES, FR, GB, IT, DE | | 2007 | 2028 |
| 201510108207.5 | Apparatus and methods for determining a property of a tissue | CN, HK | | 2007 | 2028 |
| **Apparatus and method for controlling immunostimulating laser thermotherapy** | | **AU, CN, EP, DE, JP** | **EP, BR, CN, HK,JP, KR, US** | | |
| EP2991730B1 | Apparatus and methods for controlling immunostimulating laser thermotherapy | EP, ES, IT, NL, DE, FR, GB,SE | IT, ES, NL | 2013 | 2034 |
| 2014261409 | Apparatus and methods for controlling immunostimulating laser thermotherapy | AU | | 2013 | 2034 |
| 2019032801320740 | Apparatus and methods for controlling immunostimulating laser thermotherapy | CN | | 2013 | 2034 |
| CN 109498152 A | Apparatus and methods for controlling immunostimulating laser thermotherapy | CN | | 2013 | 2034 |
| 6709153 | Apparatus and methods for controlling immunostimulating laser thermotherapy | JP | | 2013 | 2034 |
| US 10,960,223 B2 | Apparatus and methods for controlling immunostimulating laser thermotherapy | US | | 2013 | 2034 |
| **Apparatus and method for controlling laser thermotherapy** | | **EP** | **EP, AU, BR, CA, CN, HK, IN, JP, KR, US** | | |
| EP 3335660 B1 | Apparatus and method for controlling laser thermotherapy | EP, DE, ES, FR, GR, DE, IT, SE | | 2016 | 2036 |
| **Probe positioning device** | | **SE** | | | |
| | Probe positioning device | SE | | 2017 | 2037 |
| **Laterally emitting optical waveguide and method for introducing micromodifications into an optical waveguide** | | **US** | **EP, AU, BR, CA, CN, HK, IN, JP, KR, US** | 2015 | |
| US 10,641,950 | Laterally emitting optical waveguide and method for introducing micromodifications into an optical waveguide | US | | 2015 | 2036 |
| US 11,333,824 | | US | | 2015 | 2036 |
| US 11,215,750 | | US | | 2015 | 2036 |
| 2016278511 | | AU | | 2015 | 2036 |
| Lateral abstrahlende lichtwellenleiter<br>Ansökan: DE 20 2015 009 023.0<br><br>Patent nr 202015009023.0 | | DE | | 2016 | 2025 |

AU: Australia, BR: Brazil, CA: Canada, CN: China, DE: Germany, EP: European patent, ES: Spain, FR: France, GB Great Britain; HK: Hong Kong, IE: Ireland, IN: India, IT: Italy, JP: Japan, KR: South Korea, PL: Poland, PCT: Patent Cooperation Treaty, SE: Sweden, TR: Turkey, US: United States

PCT: An international patent application, what is known as a PCT application, enables you with one application, in one language, to have novelty searching and preliminary patentability assessment carried out by one authority for around 150 countries.

# Sustainability statement

*To ensure continued positive development, sustainability needs to be set high on the CLS agenda. The company works hard to quality-assure its products and processes. An environment-improving approach and ability to attract and retain the right skills are also priority sustainability issues.*

As more and more people around the world are affected by cancer and other diseases that are difficult to treat, new treatment options are required that are less expensive and can lead to more people having access to care. CLS has an important role to fulfill here. CLS contributes through its products to more patients being able to access safer and more precise treatment, which can be of importance to their life and quality of life. Laser ablation is also a method that can be used under local anesthetic, making it broadly available, while saving resources for society and healthcare.

**Quality systems and certifications**
CLS has a quality management system and is certified according to standard ISO 13485, which is a requirement to be able to market the company's products in most major markets. CLS shows through the certification that the company meets exacting requirements among other things with regard to formal documentation and product safety.

CLS also has what is known as a notified body, which ensures and verifies that CLS products comply with the EU medical device regulations (Medical Device Regulation, MDR). The notified body carries out certification (CE marking), inspection and testing to monitor that CLS's work and products meet the requirements set out in the Regulation.

The ISO 13485 standard greatly assists CLS in fulfilling MDR, which replaced the former MDD (Medical Device Directive) on May 26, 2021. CLS continued its work on implementing the new rules during the year. At the end of the year, CLS, together with the company's partner ClearPoint Neuro Inc., applied for expanded market approval in the United States for the second generation of the TRANBERG® Thermal Therapy System for ablation of brain lesions.

**Clinical trials and studies**
In its work on clinical trials, CLS follows the guidelines for Good Clinical Practice (GCP), which are described in the international standard ISO 14155. ISO 14155 covers the whole process from start to finish, including design, execution, registration and reporting.

CLS's clinical trials also need to be approved by the Swedish Medical Products Agency. In January 2022, the clinical evaluation of the TRANBERG® Thermal Therapy System at Skåne University Hospital was approved by the Medical Products Agency. A total of five patients with glioblastoma are being treated with the TRANBERG® Thermal Therapy System with Thermoguide™ Workstation.

In cases where it is necessary to perform tests on animals, CLS follows the Swedish legislation adapted to EU Directive 2010/63/EU on the protection of animals used for scientific purposes. The EU Directive strengthens work on the 3R principle in research with animal studies. It is CLS's firm objective to follow this principle and reduce the number of animals used (Reduce), refine the methods (Refine) or replace animal studies with alternative methods (Replace).

**Environment**
CLS's operations do not require any permits under Swedish environmental legislation. The company does not generate any environmentally hazardous waste or waste that in some other way requires special handling. However, CLS consider itself to have a duty always to be guided by an environment-improving approach. Being economical with materials, water and energy must therefore be self-evident for all employees.

CLS's operations at the head office in Lund are not energy-demanding and do not lead to any extensive impact on the environment. The head office is located in Medicon Village, a research hub that endeavors to work sustainably and where the buildings share surplus heat and cooling through the new technological solution Ectogrid. As a result, carbon dioxide emissions are estimated to be 60 percent lower than with a conventional district heating solution. CLS also has access through Medicon Village to energy-efficient technical equipment, online meetings and waste separation at source.

**Supplier control**
CLS fulfills applicable requirements in ISO 13485 regarding quality control, which includes suppliers being classified based on whether they supply products or services that affect or may affect a final product or final user directly. Agreements are used to ensure quality of supplies, both for the business portion and for quality. In addition, account is taken of the fulfillment of associated work environment legislation. CLS also conducts an annual review of the company's suppliers as part of a Management Review. All certificates from suppliers are requested and updated in accordance with prevailing rules.

# CLS's Employees

*CLS is a knowledge-intensive company whose HR work aims to ensure the correct skills, an open atmosphere at work and good wording conditions for all employees. All in order to create a more long-term sustainable organization.*

**Training and skills**
CLS attaches great importance to recruiting and retaining employees with the right skills. Development of skills is encouraged, and employees are expected to take the initiative to attend courses and conferences in relevant areas. The company also holds joint training programs for the company's employees, for example regarding the new rules that apply to CLS and its operations in the sector. In addition to the right skills, the company values having curious and committed employees with experience that means that they can think big and in new ways.

**Open atmosphere at work**
CLS aims for an open and transparent corporate culture. To achieve this there is a need for clear communication that means that enable everyone to feel involved and understand their rule in the development of the company. It is also important that employees can give and take feedback, openness that can contribute to development but also reduce the risk of conflicts in the group.

The company puts great trust in the ability of the individual and strives for a culture that makes it possible to maintain a good balance between work and leisure, which is particularly important when there are exacting requirements for performance. Overall, an open atmosphere at work contributes to creating a more effective and more sustainable organization.

**Good working conditions**
All employees at CLS must be treated equally in terms of working conditions and terms of employment. CLS has a number of staff who are attached to the company as consultants, on employment-like terms, and the company's ambition is for consultancy contracts and contracts of employment not to differ in any material respects. Staff are expected to treat one another with respect and comply with Swedish legislation in the way they act toward everyone in and outside the organization.

**Wellness grants and sickness insurance benefits**
Within the Medicon Village research park there is a gym and opportunities for group exercise sessions at lunch time for anyone wishing to join in. Staff are also encouraged to make use of the wellness grant the company offers. CLS also have sickness insurance that provides extended protection in the event of sickness.

# Corporate governance

# Corporate governance report

**Introduction**
The CLS Group comprises Clinical Laserthermia Systems AB (CLS) and the wholly owned subsidiaries, CLS Americas Inc. and CLS GmbH. The number of employees is twelve, of whom eight are in Sweden, two in Germany and two in the United States. In addition to these, four consultants are attached to the company.

**External and internal regulatory frameworks**
CLS is a Swedish public limited liability company whose governance, management and control is distributed between its shareholders, Board of Directors, chief executive officer and company management. Governance of the company is based on Clinical Laserthermia System's Articles of Association, the Swedish Companies Act, rules and recommendations pertaining to the company's listing on Nasdaq First North Growth Market, Stockholm, and other applicable laws and rules. CLS is not one of the group of companies obliged to comply with the Swedish corporate governance code with effect from July 1, 2008. It is, however, the Board of Directors' intention to gradually adapt the company to this code.

**Nomination Committee**
The Nomination Committee assesses the Board of Directors and its work. As a basis for its proposals ahead of the 2022 AGM, the Nomination Committee has assessed whether the current Board of Directors' composition is appropriate and fulfills the requirements imposed on the Board of Directors as a consequence of the company's current position and future positioning in the market.

The Nomination Committee for the 2022 AGM includes the following representatives of the largest shareholders:

- Lars-Erik Eriksson
- Hans von Celsing
- Karl-Göran Tranberg

Lars-Erik Eriksson was appointed Chair of the Nomination Committee until the 2022 AGM.

**Board of Directors**
The Board of Directors held its statutory meeting on June 28, 2021, and held 13 minuted online meetings in 2021. There were six Board members during the year. Other salaried employees attend Board meetings in a reporting role or in administrative positions. The company's auditor reports to the Board of Directors every year through its review of the financial statements and presents its assessment of the internal controls. In addition to the monitoring and reporting of continuous business operations and profitability trends, Board work has comprised, for example, issues pertaining to strategic development and focus, regulatory issues, investments in product development and new product concepts, issues of a financial nature and the company's intellectual property rights.

**Audit Committee**
The CLS Audit Committee comprises Hans Von Celsing, Lars-Erik Eriksson and Paolo Raffaelli.

**Remuneration Committee**
The CLS Remuneration Committee comprises Hans Von Celsing, Lars-Erik Eriksson and Sandy Brandmeier.

**Clinical Advisory Board**
This advisory body comprises Marika Crohns, Rolf Kiessling and Karl-Göran Tranberg.

**Shareholders**
The number of owners of CLS Class B shares at December 31, 2021 was just over 4,000.

**2021 Annual General Meeting**
4.52% of the shares were represented, and 11.84% of the voting power was represented at the AGM held on June 28, 2021.

The following resolutions were passed at the AGM:

- In accordance with Board of Directors' proposal, it was resolved that no dividend would be issued.
- The Board members and CEO were discharged from liability for the 2020 financial year.
- The Board is required to consist of six full members. In accordance with the proposal of the Nomination Committee, Hans von Celsing, Lars-Erik Eriksson, Marika Crohns and Gunilla Savring were re-elected, and Paolo Raffaelli and Sandy Brandmeier were elected as new members. The AGM re-elected Hans von Celsing as Chairman of the Board. Dillon AB was re-elected as auditor.
- It was further resolved that a fee be paid to the Board of Directors of a total of SEK 750,000, of which SEK 250,000 to the Chairman and SEK 125,000 each to the other Board members (Lars-Erik Eriksson does not receive a Board fee).
- The Annual General Meeting resolved that the company's Nomination Committee be appointed ahead of the 2022 Annual General Meeting in accordance with the Nomination Committee's proposal.
- The Annual General Meeting resolved to authorize the Board, on one or more occasions, during the period up to the next Annual General Meeting and with or without pre-emptive rights for the shareholders, to decide upon issuance of new shares/convertible instruments/warrants, however that such issue must not lead to the company's share capital exceeding the company's maximum permitted share capital according to the articles of association.

It must be possible for such an issuance decision to be made with a provision on report, offset or other condition. The purpose of the authorization is to give the Board flexibility in its work of ensuring that the company can be supplied with capital in an appropriate manner for financing of operations and, in the case of a new share issue with deviation from the shareholders' pre-emptive rights, to supply the company with new strategic shareholders. Issuance of shares pursuant to the authorization must take place on market terms.

**Financial reporting**
The Board of Directors monitors the quality of financial statements through instructions to the CEO and by imposing requirements on the content of financial reports that are delivered to the Board on a continuous basis. The Board stays abreast of and ensures the issuing of financial reports, such as quarterly and annual reports, and has delegated company management to ensure the issuing of requisite press releases with financial content, as well as presentation material in connection with meetings with the media, shareholders and financial institutions.

**External auditors**
The auditor in charge at Dillon AB is Authorized Public Accountant Oskar Kantoft. Kantoft does not have any shareholdings in the company. Dillon AB has not received remuneration for any services other than audit services.

Remuneration of auditors for the last two years is presented in its entirety in Note 3 of the consolidated financial statements.

**Operating activities**
The CEO has overarching responsibility for the Group and issues of strategic operations. The Board is responsible for ensuring that there is an efficient system in place for internal control and risk management. The CEO has been delegated responsibility for working on these issues. The organization's powers and responsibilities are defined in policies, guidelines and descriptions of responsibilities.

**Remuneration of senior executives**
Guidelines on the remuneration of senior executives established by the 2018 AGM essentially entail as follows.

The fixed remuneration of members of Group management and the CEO is to be competitive and based on the individual's areas of responsibility and performance. Variable remuneration is to be limited and linked to predetermined and measurable criteria aimed at promoting the company's long-term value creation. Variable remuneration may constitute a maximum of 25 percent of fixed salary and must be set for each financial year. The Board must annually consider whether or not to propose a share-based or share-price-based incentive scheme to the AGM.

Members of Group management and the CEO are entitled to defined-contribution pension plans.

The CEO's notice of termination by the company is 12 months, while notice from the individual concerned is six months. For members of Group management, the notice of termination is three months from either party.

Senior executives comprise the Chief Executive Officer and the company's management team, which in 2021 consisted of seven persons. Remuneration for senior executives during the year amounted to SEK 5,157,279.

**Auditors' fees**
Dillon AB is tasked with the audit engagement. Audit engagements refer to the audit of the annual accounts, the accounting records and the administration of the Board of Directors and the CEO, other duties that are incumbent on the company's auditor and advice or other assistance occasioned by findings during such audits or the conduct of other such duties. In 2021, fees for the audit engagement totaled SEK 155,720 (131,000).

**Related-party transactions**
Transactions with related parties and personnel are indicated in Note 4 and Note 6 of the annual accounts.

**Internal control and risk management in financial reporting**
*Internal control*
The CLS Group's internal control of financial reporting is an integral component of its corporate governance. It includes procedures for safeguarding the Group's assets and ensuring accuracy in financial reporting, thereby protecting shareholders' investments in the company.

The Group's organization is designed for rapid response to market changes. Operational decisions are thus made at the company level, while decisions about strategy, focus, acquisitions and overall financial issues are made the CLS's Board of Directors. The CEO reports regularly to the Board to increase knowledge, oversight and control of the company's accounts, financial reporting and risk management.

**Risk assessment**
Risk assessment is based on the Group's financial objectives. The overall financial risks are defined and essentially industry-specific. By performing risk analyses based on the Group's balance sheet and income statement, CLS identifies the risks that potentially threaten the attainment of the company's business and financial objectives.

# Board of Directors

**Board of Directors**
The company's Board during the financial year consisted of five full members, including the Chairman of the Board, without deputy members.

| Name | Position | Year born | Independence in relation to | |
|---|---|---|---|---|
| | | | The company management | The Company's executive major shareholders |
| Hans von Celsing | Chairman | 1950 | Yes | Yes |
| Marika Crohns | Board Member | 1967 | Yes | Yes |
| Lars-Erik Eriksson | Board Member, CFO | 1949 | No | No |
| Paolo Raffaelli | Board Member | 1965 | Yes | Yes |
| Sandy Brandmeier | Board Member | 1961 | Yes | Yes |

*Hans von Celsing, Chairman of the Board, Chairman of the Board since 2013.*

*Shares in the Company: 100,000 Class A shares and 60,000 Class B shares.*

| Other current assignments | Position |
|---|---|
| Advanced Oncotherapy Plc. | Board Member |
| Peptonic Medical AB | Chairman |
| Partner Fondkommission AB | Chairman |
| ADAM SA | Chairman |

Hans von Celsing holds a Master of Science in Business Economics from the Stockholm School of Economics and an MBA from Harvard Business School. Von Celsing has extensive experience from the medical device industry, focusing on strategic marketing, international start-ups and management issues. He was Vice President of Elekta (1986-98), where he was responsible for much of the company's international marketing efforts, particularly in the United States and Asia. During the late 1990s, von Celsing started Neuroventures Capital, a US-based venture capital company and several companies in medicine and biotechnology, including Plasma Surgical Ltd, where he was CEO until 2007. Von Celsing has a worldwide network, which includes clinics, researchers and industry contacts.

*Marika Crohns, Board member*
*Board member since 2020.*

Shares in the Company: None.

| Other current assignments | Position |
|---|---|
| PRiMe International Oy | Owner, Chief Executive Officer |

Marika Crohns is a doctor of medicine and specialist in oncology and radiology. Crohns is the head of Medical Affairs at the pharmaceutical company Sanofi in oncology, hematology and transplantation. Crohns has 18 years of professional experience from Sanofi at the local, regional and global levels.

# Board of Directors

*Lars-Erik Eriksson, Board member and CFO*

*Board member since 2006 and CFO.*

Shares in the Company:

300,000Class A shares and 666,579 Class B shares [13]

| Other current assignments | Position |
|---|---|
| Elano AB | Board member |
| Salitre AB | Board member |
| SBF6 Lda | Board member |
| CLAR WINE AB | Chairman |
| Shape i Lund AB | Deputy Board member |
| ED-Consult Handelsbolag | Partner |
| SagnEri II Handelsbolag | Partner |

Lars-Erik Eriksson holds an MSc in economics and started his career at Kooperativa Förbundet in the 1970s. In the 1980s, he worked for the Sparbanken banking group where he served as CEO of various companies and as chief auditor for Sparbankerna in Sweden. Thereafter, Eriksson was appointed CEO of a subsidiary of the listed Independent Group. He was active within Föreningsbanken's Swedish and foreign companies in the 1990s. Since the 1990s, Eriksson has been self-employed and worked as an entrepreneur, both in Sweden and abroad, with assignments including as subsidiary CEO for Ikano and director on various boards in the Ikano Group. He has extensive experience in project management with a large network, in the banking world in particular. Eriksson was Chief Executive Officer of CLS between 2006 and 2020.

*Paolo Raffaelli*

Shares in the Company: None

| Other current assignments | Position |
|---|---|
| None | |

Paolo Raffaelli has over 20 years of executive experience in Life Science and the medical devices industry, with extensive experience of sales and marketing, across European and international markets. Raffaelli has been based in Stockholm, Brussels and the United States. He holds a BSc in computer science from La Sapienza University in Rome, and an MBA from IMD Business School in Lausanne, Switzerland.

*Sandy Brandmeier*

Shares in the Company: None

| Other current assign-ments | Position |
|---|---|
| The Hearing Industries Association | |

Sandy Brandmeier has spent most of her career working in the healthcare sector and has deep commercial experience. Brandmeier has fulfilled roles as General Manager at GE Healthcare and as CEO of Danaher Life Sciences. She is currently President of a company with sales of USD 1 billion in the United States, at Sonova, a global leader in hearing care. Brandmeier also has experience from other industries, having held a CEO role in the education sector for six years and a position as Deputy Chairman, business development at a start-up company. Brandmeier holds an MBA from the University of Wisconsin in Madison and lives in the United States.

[13] Through related companies

# Management team

*Dan J. Mogren, CEO*

Shares in the Company: 126,384
Class B shares[14]

| Other current assignments | Position |
|---|---|
| Medinovus AB | Chairman of the Board, CEO |
| OLDTIMERS & SPORTSCARS HANDELSBOLAG | Partner |

Dan Mogren is a trained naval officer has studied on the General Management program at the IMD Business School. Mogren has held most senior positions in international food industry and medical device companies from the 1990s to the present day. Mogren was a management consultant in the medical device sector from 2009 to 2020 and Chief Commercial Officer at CLS 2011-2020. He was appointed acting Chief Executive Officer in November 2020. Mogren is the founder of Medinovus AB, a Swedish management consultancy.

*Stephan Dymling, Chief Technology*

*Shares in the Company: 81,080*
*Class B shares* [15]

| Other current assignments | Position |
|---|---|
| GPX Medical AB | Board member |
| BibbInstruments AB | Board member |
| Allinug AB | Board member |

Stephan Dymling holds a PhD in ultrasound diagnostics from Lund University and has 30 years of experience in the medical device sector. He has held senior positions in research and development in several start-up companies and was previously head of the medical device department at Lund University Hospital. Dymling has extensive experience of medical devices in Sweden and internationally.

*Lars-Erik Eriksson, Board member and CFO*

See information under “Board of Directors” above.

*Lotta Nilsson, VP Marketing*

Shares in the Company: None

| Other current assignments | Position |
|---|---|
| None | |

Liselotte Nilsson holds a masters in molecular biology and has many years of experience of marketing of medical devices. She has been responsible for international product launches and has held positions as product and marketing manager in ProstaLund, Phase Holographic Imaging and Svar Life Science.

[14] Through related companies
[15] Own holding and through related companies

# Management team

*Cristina Pantaleone, Manager Technical Product Development*

Shares in the Company: 20,799

| Other current assignments | Position |
|---|---|
| None | |

Cristina Pantaleone gained a Master of Science in Physics Engineering, specializing in nanooptics and photonics, from the Politecnico di Milano and a Master of Science in Physics Engineering, specializing in medical technology, from Lund Institute of Technology (LTH), as part of the Top Industrial program. Managers for Europe. Pantaleone has experience in the development of medical devices, expertise in light-tissue interaction and a deep understanding of CLS's technology and product range.

*Hoda Tawfik, VP Clinical Affairs*

Shares in the Company: None

| Other current assignments | Position |
|---|---|
| None | |

Hoda Tawfik holds a PhD from Düsseldorf University and is a Prof. Dr. in pharmacology. Tawik has previously held senior positions at Magforce AG and as Director Global Clinical Operations at MediGene AB.

*Anders Qvarlander, VP Quality Assurance & Regulatory Affairs*

Shares in the Company: None

| Other current assignments | Position |
|---|---|
| None | |

Anders Qvarlander holds a chemistry degree from Lund University and has 20 years' experience in the area of medical devices. He has represented Operations, R&D, Marketing and QA in senior positions in several different companies, both large and small. Qvarlander's experience covers a wide range of products, sectors and geographical markets, creating the basis for a holistic approach.

# Financial information

# Administration Report

2021 Administration Report for Clinical Laserthermia Systems AB.

**General information about the business**
Clinical Laserthermia Systems (CLS) is a medical device company that develops and sells the TRANBERG® Thermal Therapy System. The system comprises a laser unit and various instruments and disposable products for the treatment of patients. The products are optimized to leverage considerable precision and control when performing soft-tissue laser ablation supported by MRI, ultrasound or, if required, open surgery. In addition, a platform has been developed that makes it possible to measure and control temperature using MRI.

**Research and development**
CLS continued work during the year on developing together with its partner Clearpoint Neuro a system aimed at making it possible in future also to use the TRANBERG® Thermal Therapy System for treatment of tumors in the brain and spine. The company is now working on gaining approval in the United States for neurosurgery and prostate cancer treatment with MRI guidance. CLS has launched a study in neurology at Skåne University Hospital

**Financial development**
Net sales for the Group totaled SEK 2,245 million (1,332). Most of the company's sales are made outside Sweden. The company's revenues from sales for the full year of 2021 were adversely impacted by the ongoing pandemic, due to resetting of priorities in healthcare.

Costs for the period are impacted primarily by expenses linked to the ongoing 510(k) application to the US FDA for the updated system. The company has started writing off capitalized costs in Research and Development. Corrections have also been made to advance payments. On the assets side, bonds and securities pertain to the company's investment of cash and cash equivalents.

The remaining portion of SEK 5,000 thousand of the loan facility pledged by Modelio Equity, Munkekullens förvaltnings AB and Formue Nord was exercised in February 2021. In April 2021, the company raised a total of around SEK 71.5 million through new share issues.

**Reimbursement systems**
The pricing of CLS's products is impacted by national reimbursement systems and, particularly in the United States, by national insurance schemes approving CLS's treatment methods. The company's success consequently depends in part on the extent to which the Company's products manage to gain approvals from insurance companies. If reimbursement from the insurance schemes is not sufficient or is restricted in certain markets, this will have an adverse impact on the prospects of the company or its partners selling the company's products with sufficient profitability, which may impact the Company's earning capacity and future sales growth.

**Patents**
CLS is dependent on know-how and corporate secrets to be able to carry on its business and strives to protect such information at all times, including by means of non-disclosure agreements with employees, consultants and partners. However, it is impossible for CLS to fully protect the company against the unauthorized disclosure of information, which poses a risk of the Company's competitors learning of and benefiting from the know-how developed by CLS.

**Product development**
CLS will continue to develop its products. There is always a risk that this may take longer than planned and consequently delay market launch.

**Product liability**
The Board judges the company's current insurance cover to be satisfactory, in terms of the nature and scope of operations.

**Legislative and regulatory framework**
CLS operates in areas that are highly regulated by legislation and various regulatory frameworks. The transition from MDD to MDR rules will put a strain on CLS in both financial and personnel terms.

## Future outlook

CLS intends to focus on the indication areas of brain tumor and drug-resistant epilepsy and prostate cancer through LITT and FLA therapy, respectively. In colon cancer and pancreatic cancer it takes place through imILT® treatment of metastases in the liver. In Neurosurgery, we will collaborate with our partner Clearpoint Neuro.

In geographical terms, we will operate in the United States, the EU and the Asia-Pacific region, In the United States with partners, in the EU with our own organization and in the Asia-Pacific region through a joint venture with Advanced Medical Systems Pte Ldt.

A number of studies will be carried out in the immediate future before moving on to a full-scale launch on the market. These studies are focused on neurosurgery, urology and imILT® treatment of liver metastases.

## Proposed appropriation of profits

The Board of Directors and CEO propose that the following available profits (SEK):

| | |
|---|---|
| Accumulated loss | -240 793 748 |
| Share premium reserve | 339 829 332 |
| Loss for the year | -54 786 831 |
| **Total** | **44 248 753** |
| Allocated so that transferred to new account | 44 248 753 |
| **Total** | **44 248 753** |

The Board of Directors proposes that no dividend be paid for the 2021 financial year. The Group's and Parent Company's earnings and financial position are presented in the following income statement, balance sheet and cash flow statements with supplementary disclosures and will be presented to the AGM on June 28, 2022.

# Trend in share capital

| Year | Event | Quotient value | Increase in number of shares | Increase in share capital (SEK) | Total number of shares | Total share capital (SEK) |
|---|---|---|---|---|---|---|
| 2006 | New share issue (formation) | 100 | 1 020 | 102 000,00 | 1 020 | 102 000,00 |
| 2007 | New share issue | 100 | 180 | 18 000,00 | 1 200 | 120 000,00 |
| 2007 | New share issue | 100 | 75 | 7 500,00 | 1 275 | 127 500,00 |
| 2008 | New share issue | 100 | 100 | 10 000,00 | 1 375 | 137 500,00 |
| 2008 | New share issue | 100 | 14 | 1 400 | 1 389 | 138 900,00 |
| 2008 | Bonus issue | 370 | N/A | 375 030 | 1 389 | 513 930,00 |
| 2008 | Share split | 0,0925 | 5 554 611 | N/A | 5 556 000 | 513 930,00 |
| 2008 | New share issue | 0,0925 | 251 000 | 23 217,50 | 5 807 000 | 537 147,50 |
| 2008 | New share issue | 0,0925 | 369 000 | 34 132,50 | 6 176 000 | 571 280,00 |
| 2009 | New share issue | 0,0925 | 770 000 | 71 225 | 6 946 000 | 642 505,00 |
| 2010 | New share issue | 0,0925 | 2 754 398 | 254 781,815 | 9 700 398 | 897 286,82 |
| 2010 | Exercise of subscription warrants | 0,0925 | 1 300 | 120,25 | 9 701 698 | 897 407,07 |
| 2010 | Exercise of subscription warrants | 0,0925 | 68 592 | 6 344,76 | 9 770 290 | 903 751,83 |
| 2011 | Exercise of subscription warrants | 0,0925 | 1 244 621 | 115 127,44 | 11 014 911 | 1 018 879,27 |
| 2012 | New share issue | 0,0925 | 416 666 | 38 541,61 | 11 431 577 | 1 057 420,00 |
| 2012 | New share issue | 0,0925 | 1 694 600 | 156 750,50 | 13 126 177 | 1 214 171,38 |
| 2012 | Exercise of subscription warrants | 0,0925 | 22 681 | 2 097,99 | 13 148 858 | 1 216 269,37 |
| 2012 | New share issue | 0,0925 | 596 667 | 55 191,70 | 13 745 525 | 1 271 461,07 |
| 2012 | Exercise of subscription warrants | 0,0925 | 20 262 | 1 874,23 | 13 765 787 | 1 273 335,30 |
| 2012 | Exercise of subscription warrants | 0,0925 | 797 924 | 73 807,97 | 14 563 711 | 1 347 143,27 |
| 2013 | New share issue | 0,0925 | 2 427 285 | 224 523,86 | 16 990 996 | 1 571 667,13 |
| 2013 | Exercise of subscription warrants | 0,0925 | 57 000 | 5 272,50 | 17 047 996 | 1 576 939,63 |
| 2014 | New share issue | 0,0925 | 2 595 427 | 240 077,00 | 19 643 423 | 1 817 016,63 |
| 2015 | New share issue | 0,0925 | 642 850 | 59 463,62 | 20 286 273 | 1 876 480,25 |
| 2016 | New share issue | 0,0925 | 3 120 965 | 288 689,26 | 23 407 238 | 2 165 169,51 |
| 2016 | Offset share issue | 0,0925 | 285 714 | 26 428,54 | 23 692 952 | 2 191 598,06 |
| 2016 | New share issue | 0,0925 | 89 978 | 8 322,97 | 23 782 930 | 2 199 921,03 |
| 2017 | New share issue | 0,0925 | 3 397 561 | 314 274,39 | 27 180 491 | 2 514 195,42 |
| 2017 | Private placement | 0,0925 | 1 470 588 | 136 029,39 | 28 651 079 | 2 650 224,82 |
| 2017 | Private placement | 0,0925 | 44 664 | 4 131,42 | 28 695 743 | 2 654 356,24 |
| 2018 | New share issue | 0,0925 | 5 721 207 | 529 211,648 | 34 416 941 | 3 183 567,84 |
| 2018 | Private placement | 0,0925 | 186 871 | 17 285,5675 | 34 603 821 | 3 200 853,46 |
| 2019 | Private placement | 0,0925 | 90 732 | 8 392,71 | 34 694 553 | 3 209 246,16 |
| 2020 | Private placement | 0,0925 | 862 068 | 79 741,30 | 35 556 601 | 3 288 987,46 |
| 2020 | Private placement | 0,0925 | 1 277 241 | 113 519,79 | 36 783 842 | 3 402 507,25 |
| 2020 | Rights issue | 0,0925 | 8 673 638 | 802 311,52 | 45 457 480 | 4 204 818,77 |
| 2021 | New share issue | 0,0925 | 16 377 250 | 1 514 895,63 | 61 834 750 | 5 719 714,40 |
| 2021 | New share issue | 0,0925 | 3 173 274 | 293 527,85 | 65 008 024 | 6 013 242,24 |
| 2021 | New share issue | 0,0925 | 100 000 | 9 250 | 65 108 024 | 6 022 492,25 |
| 2021 | New share issue | 0,0925 | 714 286 | 66 071,46 | 65 822 310 | 6 088 563,71 |

# The company's ten largest shareholders at December 31, 2021

| Shareholders | Class A shares 10 votes/share | Class B shares 1 vote/share | Holdings, % | Votes, % |
|---|---|---|---|---|
| Avanza pension | 0 | 5 273 295 | 8,01 | 7,40 |
| Nordnet Pensionsförsäkring AB | 0 | 3 233 644 | 4,91 | 4,54 |
| Handelsbanken Liv Försäkringsaktiebolag | 0 | 3 057 189 | 4,64 | 4,29 |
| Ålandsbanken, W8IMY | 0 | 2 154 011 | 3,27 | 3,02 |
| Deutsche Bank AG, W8IMY | 0 | 1 497 783 | 2,28 | 2,10 |
| KG Tranberg Medical AB | 200 000 | 1 271 499 | 2,24 | 4,59 |
| Arne Håkanson | 0 | 1 060 000 | 1,61 | 1,49 |
| Elano Aktiebolag | 300 000 | 698 317 | 1,52 | 5,19 |
| SIX SIS AG, W8IMY | 0 | 952 905 | 1,45 | 1,34 |
| Hans Von Celsing | 100 000 | 108 000 | 0,32 | 1,56 |
| | | | | |
| Total 10 largest shareholders – votes | 600 000 | 19 306 643 | 30,24 | 35,53 |
| Total other shareholders | 0 | 45 915667 | 69,76 | 64,47 |
| **Total** | **600 000** | **65 222 310** | **100,00** | **100,00** |

Source: Euroclear

# Significant events during the year

**1st quarter**

- On January 11, CLS received an order for disposable instruments from Immunophotonics, Inc., which is conducting a study of cancer patients with solid tumors in which CLS TRANBERG® products are being used.
- On February 9, CLS received an order for disposable instruments from two of CLS's existing customers, the greater part from the University of Texas Medical Branch (UTMB). The total value of the order was around SEK 750,000.
- On February 15, the CLS Board decided to exercise a loan facility totaling SEK 15 million. In addition, CLS entered into agreements with Modelio Equity AB, Lubrica Equity AB and Formue Nord Focus A/S concerning a new loan of SEK 20 million and a loan facility of SEK 20 million.
- On March 25, CLS announced that the company's supplier of sterilization services for the disposable instruments used in ablation therapy with the TRANBERG® Thermal Therapy System had discovered serious deficiencies in its sterilization processes.
- On March 30, CLS received 510(k) clearance from the US FDA for the TRANBERG® Laser Applicator, which is included in the company's second generation of products for image-guided ablation therapy.
- On March 31, CLS held an extraordinary general meeting which resolved to approve the Board's decision on a rights issue and a private placement to Modelio Equity AB, Lubrica Equity AB and Formue Nord Markedsneutral A/S.

**2nd quarter**

- On April 5, CLS announced that CLS's supplier of sterilization services could no longer guarantee that CLS products were not affected by the deficiencies in the sterilization processes. CLS recalled all sterile disposable instruments and halted new deliveries.
- On May 3, CLS announced that new share issues had contributed around SEK 71.5 million to the company. The rights issue, which was oversubscribed, contributed around SEK 47.7 million before deduction of issue expenses. The private placement of around SEK 10 million was fully subscribed, and the Board decided to expand it by a further approximately SEK 10 million. Khattar Holdings, a family-owned investment company in Singapore, took part in the private placement in an amount of around SEK 5 million.
- On May 12, CLS announced that the 510(k) clearance application to the US FDA for CLS's second generation of the TRANBERG system had been deferred to the second half of 2021 due to a change in the workforce at the company's local partner in the United States.
- On June 4, the CLS Board decided to exercise SEK 15 million of the loan facility totaling SEK 20 million, which was obtained in February 2021, from Modelio Equity AB, Lubrica Equity AB and Formue Nord Fokus A/S.
- On June 24, CLS announced that Otto von Guericke University Magdeburg has gained approval from the ethics committee and from the competent authority in Germany (BfArM) for an investigator-initiated study of treatment of localized prostate cancer using focal laser ablation with the CLS TRANBERG® Thermal Therapy System.
- On June 28, CLS held its annual general meeting. The founder of CLS, Karl-Göran Tranberg, was thanked on stepping down from the Board. Along with the former Board member Rolf Kiessling, Tranberg will continue as adviser to the company on the CLS Medical Advisory Board.

**3rd quarter**

- On July 12, CLS announced that the company had received approval from Health Canada for its updated sterilization documentation and for a new supplier of sterilization services, ROSE GmbH. CLS and University Health Network, which includes Toronto General Hospital in Toronto, was consequently able to resume its clinical study concerning treatment with MRI-focal laser ablation of early-phase prostate cancer.
- On August 26, CLS announced that the company is in the final phase of work on adapting the Thermoguide™ Workstation, which is used for temperature monitoring and control of MRI-guided ablation for GE Healthcare's MRI scanners.
- On September 15-18, CLS attended the Congress of the German Society of Urology in Stuttgart, where it demonstrated use of the TRANBERG® Thermal Therapy System in image-guided ablation.

**4th quarter**

- On October 12, CLS reported that a new clinical study of ablation treatment of vascular malformations, using the TRANBERG® Thermal Therapy System, indicated that the method is safe and effective. The study is described in detail in a scientific article published in the Journal of Vascular and Interventional Radiology.

- On October 15, CLS announced a strengthening of the company's organization and management team, with Liselotte Nilsson taking up a new position as VP Marketing & Scientific Marketing and Anders Qvarlander succeeding Lotta Ljungberg as VP Regulatory Affairs & Quality Assurance. At the same time, Gunilla Savring left her role as Chief Investor Relations Officer, and the position will be filled until further notice by the acting CEO Dan J. Mogren and the CFO Lars-Erik Eriksson.

- On November 17, CLS released the whole of its range of TRANBERG® sterile disposable products back onto the US market. This took place with CLS's new supplier of sterilization services, Rose GmbH.

- On November 29, CLS was able to release the whole of its range of TRANBERG® sterile disposable products back onto the European market, and contracts were signed with another two suppliers of sterilization services, Steril Verona S.r.l. and Sterigenics International Inc.

- On December 31, CLS submitted a 510(k) clearance application to the FDA for the second-generation TRANBERG® Thermal Therapy System with Thermoguide™ Workstation for brain lesion ablation.

# Significant events after the end of the financial year

- On February 9, CLS announced that the company had signed a contract with Skåne University Hospital to sponsor a clinical evaluation of safety and feasibility regarding image-guided laser ablation therapy of glioblastoma with the CLS TRANBERG® Thermal Therapy System med Thermoguide™ Workstation.

- On February 10, the acting CEO Dan J. Mogren started a planned period of sick leave which continued until March 31. The Company's Board of Directors appointed Lars-Erik Eriksson, the Company's CFO and former CEO, as Deputy CEO during this period.

- On February 18, CLS announced that Radboud University Medical Center in Nijmegen, the Netherlands, had received ethical approval for an investigator-initiated study to evaluate safety and feasibility regarding MRI-guided focused laser ablation therapy of localized prostate cancer in low- and intermediate-risk patients with the TRANBERG® Thermal Therapy System with the Thermoguide™ Workstation.

- On March 8, CLS launched a new website to further strengthen communication with the company's customers. The website was based on a new brand platform with clear messaging concerning the benefits the company's products offer for effective and minimally invasive laser ablation therapy, primarily for patients with tumor diseases.

- On March 23, CLS announced that the company had had a new patent registered in China. The patent is entitled "Temp feedback controlled cooled probe", and is equivalent to the European patent "Apparatus and Method for Controlling Immunostimulating Laser Thermotherapy" that was approved in 2019.

- On March 29, CLS announced that the CLS TRANBERG® Thermal Therapy System will be used by Focalyx Technologies, who are developing image-guided fusion technology to conduct a study with 20 patients. The title of the clinical phase 1 study is "Targeted MRI/US Fusion Transperineal Laser Ablation of Low-to-Intermediate Risk Prostate Cancer".Den 13 april lanserade CLS en CE-märkt version av Thermoguide™ Workstation för användning också med MR-scanners från GE Healthcare.

- On April 13, CLS launched a CE-marked version of the Thermoguide™ Workstation for use also with MRI scanners from GE Healthcare.

- On April 21, CLS announced that the company had signed a contract with Quadia Diagnostic Imaging Center in Piaseczno, Poland, for commercial evaluation of CLS's second generation of the TRANBERG® Thermal Therapy System with the Thermoguide™ Workstation for MRI-guided stereotactic focal laser ablation of localized prostate cancer.

- On April 28, CLS accounted that approximately SEK 12.2 million had been contributed to the company through exercise of TO3 series subscription warrants, equivalent to an exercise rate of approximately 34 percent. One subscription warrant gave entitlement to subscribe for one new Class B share in CLS at a subscription price of SEK 3.50 per share.

- On May 18, the company announced that the Board of Directors had appointed Dan J. Mogren as permanent CEO of CLS. Dan J. Mogren has been acting CEO since December 1, 2020.

## *Multi-year overview (SEK thousands)*

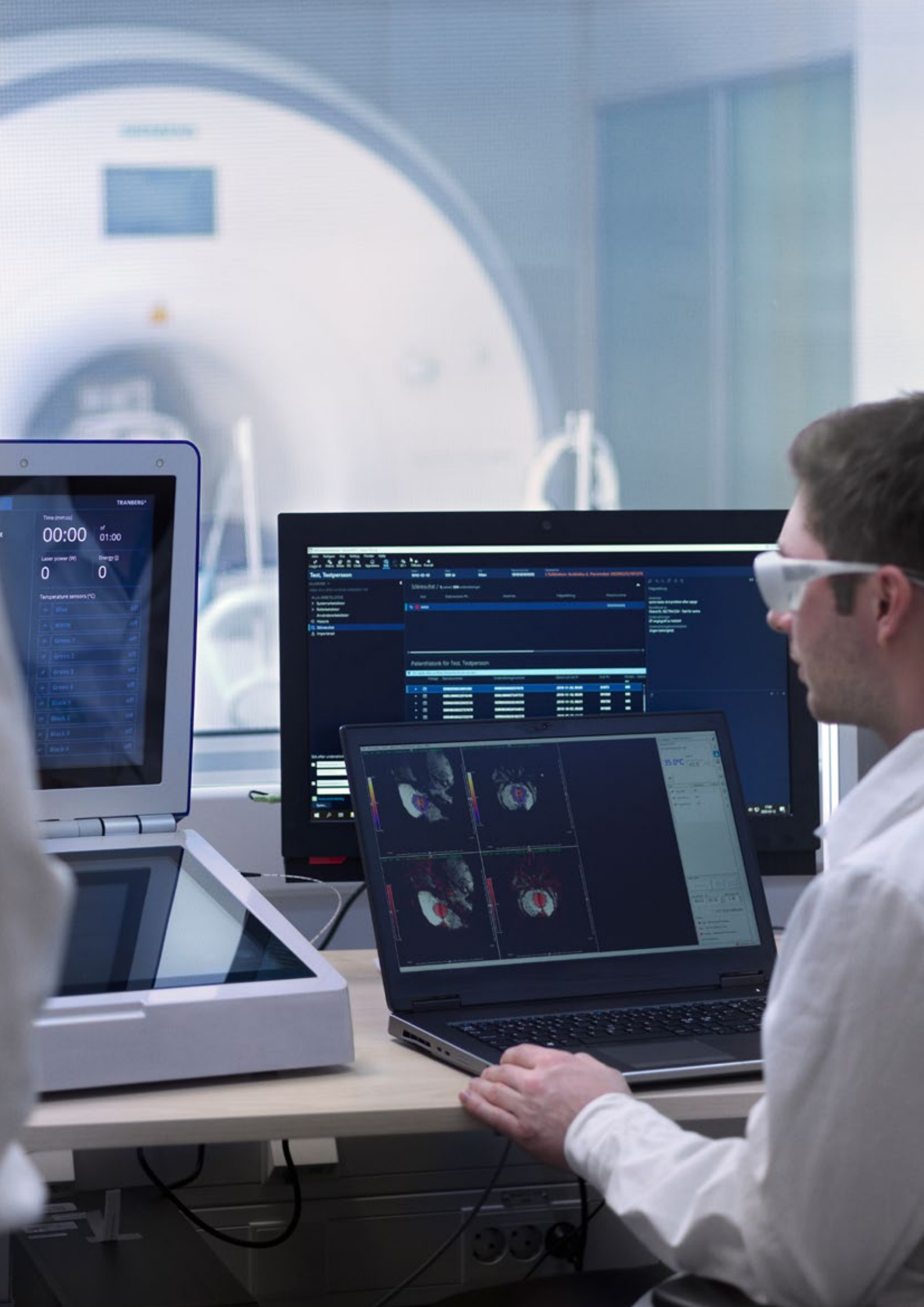
| Group | 2021 | 2020 | 2019 | 2018 | 2017 |
|---|---|---|---|---|---|
| Equity/assets ratio (%) | 32 | 31 | 18 | 86 | 73 |
| Quick ratio (%) | 83 | 51 | 28 | 364 | 163 |
| Change in equity (%) | 52 | 184 | -86 | 51 | 93 |
| Profit/loss after financial items | -64 141 | -57 939 | -43 375 | -32 859 | -21 264 |
| Capital raised from new share issues | 71 277 | 62 426 | 725 | 50 269 | 36 761 |
| R&D investments | 0 | 0 | 0 | 2 015 | 1 718 |

| Parent Company | 2021 | 2020 | 2019 | 2018 | 2017 |
|---|---|---|---|---|---|
| Equity/assets ratio (%) | 55 | 68 | 45 | 89 | 77 |
| Quick ratio (%) | 84 | 53 | 29 | 389 | 160 |
| Change in equity (%) | 44 | 45 | -58 | 57 | 99 |
| Profit/loss after financial items | -54 787 | -50 630 | -37 033 | -27 667 | -17 088 |
| Capital raised from new share issues | 71 277 | 62 426 | 725 | 50 269 | 36 761 |
| R&D investments | 0 | 0 | 0 | 2 015 | 1 718 |

## *Change in equity (SEK thousands)*

| Group | Share capital | Other paid-in capital | Reserves | Other equity | Profit/loss for the year | Total |
|---|---|---|---|---|---|---|
| **Opening balance at Jan 1, 2020** | **3 209** | **213 753** | **286** | **-166 876** | **-43 375** | **6 997** |
| New share issue | 996 | 61 430 | | | | 62 426 |
| Appropriation as adopted by AGM: | | | | -43 375 | 43 375 | |
| Reversal as a result of amortization of development expenses for the year | | -528 | | 528 | | |
| Translation differences | | | 2 073 | 371 | | 2 444 |
| Profit/loss for the year | | | | | -57 939 | -57 939 |
| **Closing balance at Dec 31, 2020** | **4 205** | **274 655** | **2 359** | **-209 352** | **-57 939** | **13 928** |
| **Opening balance at Jan 1, 2021** | **4 205** | **274 655** | **2 359** | **-209 352** | **-57 939** | **13 928** |
| New share issue | 1 884 | 69 393 | | | | 71 277 |
| Appropriation as adopted by AGM: | | | | - 57 939 | 57 939 | |
| Reversal as a result of amortization of development expenses for the year | | -527 | | 527 | | |
| Translation differences | | | -2 656 | 2 861 | | 205 |
| Profit/loss for the year | | | | | -63 615 | -63 615 |
| Minority share | | | | | -610 | -610 |
| **Closing balance at Dec 31, 2021** | **6 089** | **343 521** | **-297** | **-263 903** | **-64 225** | **21 185** |

| Parent Company | Share capital | Development expenditure fund expenditure | Share premium reserve | Retained earnings | Net profit/ loss for the year | Total |
|---|---|---|---|---|---|---|
| **Opening balance at Jan 1, 2020** | **3 209** | **4 747** | **209 007** | **-154 186** | **-37 033** | **25 744** |
| New share issue | 996 | | 61 429 | | | 64 425 |
| Appropriation as adopted by AGM: | | | | -37 033 | 37 033 | |
| Reversal as a result of amortization of development expenses for the year | | -528 | | 528 | | |
| Profit/loss for the year | | | | | -50 630 | -50 630 |
| **Closing balance at Dec 31, 2020** | **4 205** | **4 219** | **270 436** | **-190 691** | **-50 630** | **37 539** |
| **Opening balance at Jan 1, 2021** | **4 205** | **4 219** | **270 436** | **-190 691** | **-50 630** | **37 539** |
| New share issue | 1 884 | | 69 393 | | | 71 277 |
| Appropriation as adopted by AGM: | | | | -50 630 | 50 630 | |
| Reversal as a result of amortization of development expenses for the year | | -527 | | 527 | | |
| Profit/loss for the year | | | | | -54 787 | -54 787 |
| **Closing balance at Dec 31, 2021** | **6 089** | **3 692** | **339 829** | **-240 794** | **-54 787** | **54 028** |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# Consolidated income statement and other comprehensive income for the period (SEK thousand)

| Statement of comprehensive income | Note | Jan 1, 2021 -Dec 31, 2021 | Jan 1, 2020 -Dec 31, 2020 |
|---|---|---|---|
| Net sales | 1 | 2 245 | 1 332 |
| Change in finished goods inventory | | 1 401 | 941 |
| Other operating income | 2 | 161 | 281 |
| | | **3 807** | **2 554** |
| | | | |
| Operating expenses | | | |
| Merchandise | | -7 276 | -1 397 |
| Other external expenses | 3, 4, 5 | -42 639 | -40 140 |
| Personnel expenses | 6 | -11 560 | -9 630 |
| Depreciation of property, plant and equipment | | -2 788 | -3 056 |
| Other operating expenses | 7 | -226 | -427 |
| | | **-64 489** | **-54 650** |
| **Operating profit/loss** | | **-60 682** | **-52 096** |
| | | | |
| Profit/loss from financial items | | | |
| Profit/loss from other securities and receivables held as non-current assets | 9 | 2 913 | -2 610 |
| Other interest and similar income | 10 | 34 | 39 |
| Interest and similar expenses | 11 | -6 406 | -3 272 |
| | | -3 459 | -5 843 |
| **Profit/loss after financial items** | | **-64 141** | **-57 939** |
| | | | |
| **Profit/loss before tax** | | **-64 141** | **-57 939** |
| **Minority share of profit/loss for the period** | | **526** | **0** |
| | | | |
| **PROFIT/LOSS FOR THE YEAR** | | **-63 615** | **-57 939** |
| Basic and diluted earnings per share, SEK | 29 | -1,12 | -1,31 |
| | | | |
| Other comprehensive income | | | |
| Items that may be reclassified to profit or loss | | | |
| Translation of foreign subsidiaries | | -2 656 | 2 073 |
| **TOTAL COMPREHENSIVE INCOME FOR THE YEAR** | | **-66 271** | **-55 866** |
| Profit/loss for the year attributable to Parent Company shareholders | | -66 271 | -55 866 |

# Consolidated statement of financial position at end of period (SEK 000)

| Assets | Note | December 31, 2021 | December 31, 2020 |
|---|---|---|---|
| Non-current assets | | | |
| **Intangible assets** | | | |
| Capitalized expenditure for research and development, and similar work | 12 | 17 313 | 19 011 |
| Concessions, patents, licenses, trademarks and similar rights | 13 | 2 279 | 2 237 |
| | | **19 592** | **21 248** |
| | | | |
| **Property, plant and equipment** | | | |
| Equipment, tools, fixtures and fittings | 14 | 1 477 | 2 054 |
| | | | |
| **Financial assets** | | | |
| Non-current lease receivables | | 84 | 198 |
| Other non-current receivables | | 121 | 0 |
| Deferred tax asset | 16 | 3 039 | 0 |
| **Total non-current assets** | | **24 313** | **23 500** |
| | | | |
| Current assets | | | |
| **Inventories etc.** | 18 | | |
| Finished goods and goods for resale | | 4 155 | 2 754 |
| Advance payments to suppliers | | 453 | 2 859 |
| | | **4 608** | **5 613** |
| | | | |
| **Current receivables** | | | |
| Accounts receivable | | 531 | 345 |
| Current tax assets | | 0 | 39 |
| Other receivables | 19 | 4 849 | 2 526 |
| Current component of non-current leasing receivables | 19 | 113 | 113 |
| Prepayments and accrued income | 20 | 1 159 | 392 |
| | | **6 652** | **3 415** |
| | | | |
| **Current investments** | | | |
| Bonds, securities | 21 | 29 459 | 11 276 |
| | | | |
| Cash and bank balances | 21 | 1 706 | 595 |
| **Total current assets** | | **42 425** | **20 899** |
| | | | |
| **TOTAL ASSETS** | | **66 738** | **44 399** |

# Consolidated statement of financial position at end of period (SEK thousands)

| Equity and liabilities | Note | December 31, 2021 | December 31, 2020 |
|---|---|---|---|
| **Equity** | 22 | | |
| Equity attributable to Parent Company shareholders | | | |
| Share capital | | 6 089 | 4 205 |
| Development expenditure fund | | 3 692 | 4 219 |
| Other paid-in capital | | 339 828 | 270 436 |
| Reserves | | -297 | 2 359 |
| Retained earnings including loss for the year | | -327 518 | -267 291 |
| Minority share | | -610 | 0 |
| **Equity attributable to Parent Company shareholders** | | **21 184** | **13 928** |
| | | | |
| **Total equity** | | **21 184** | **13 928** |
| | | | |
| **Non-current liabilities** | | | |
| Liabilities to credit institutions | 23 | 100 | 200 |
| Other liabilities | | 0 | 240 |
| | | | |
| **Current liabilities** | | | |
| Current component of non-current liabilities to credit institutions | 23 | 100 | 400 |
| Accounts payable | | 4 314 | 4 460 |
| Current tax liabilities | | 306 | 0 |
| Other liabilities | 24 | 35 950 | 20 301 |
| Accruals and deferred income | 25 | 4 784 | 4 870 |
| | | **45 454** | **30 031** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | | **66 738** | **44 399** |

# Consolidated cash flow statement for the period (SEK thousands)

| Cash flow statement | Note | Jan 1, 2021 -Dec 31, 2021 | Jan 1, 2020 -Dec 31, 2020 |
|---|---|---|---|
| **Operating activities** | | | |
| Receipts from customers | | 2 354 | 1 698 |
| Cash paid to suppliers and employees | | -62 123 | -53 833 |
| Tax paid | | 0 | 0 |
| **Cash flow from operating activities before changes in working capital** | | **-59 769** | **-52 135** |
| | | | |
| Interest paid | | -6 406 | -3 272 |
| **Cash flow from operating activities** | | **-66 175** | **-55 407** |
| | | | |
| **Investing activities** | | | |
| Acquisition of property, plant and equipment | 27 | -146 | -348 |
| Acquisition of intangible assets | 26 | -409 | 0 |
| Acquisition of financial assets | | 113 | -198 |
| Sale of short-term investments | | 34 | 38 |
| **Cash flow from investing activities** | | **-408** | **-508** |
| | | | |
| **Financing activities** | | | |
| New share issue | | 71 277 | 62 425 |
| Proceeds from borrowings | | 15 000 | 15 000 |
| Repayment of borrowings | | -400 | -15 400 |
| **Cash flow from financing activities** | | **85 877** | **62 025** |
| | | | |
| **CASH FLOW FOR THE PERIOD** | | **19 294** | **6 110** |
| | | | |
| **Cash and cash equivalents at beginning of period** | | 11 871 | 5 761 |
| Exchange differences | | 0 | 0 |
| **Cash and cash equivalents at end of period** | 21 | **31 165** | **11 871** |

# Parent Company statement of comprehensive income and other comprehensive income for the period (SEK thousands)

| Income statement | Note | Jan 1, 2021 -Dec 31, 2021 | Jan 1, 2020 -Dec 31, 2020 |
|---|---|---|---|
| Net sales | 1 | 1 717 | 1 738 |
| Change in finished goods inventory | | 1 401 | 941 |
| Other operating income | 2 | 156 | 134 |
| | | **3 274** | **2 813** |
| | | | |
| **Operating expenses** | | | |
| Purchase of goods | | -7 276 | -1 341 |
| Other external expenses | 3 ,4, 5 | -36 654 | -36 591 |
| Personnel expenses | 6 | -8 719 | -7 080 |
| Depreciation of property, plant and equipment | | -2 595 | -2 856 |
| Other operating expenses | 7 | -221 | -419 |
| | | **-55 465** | **-48 287** |
| **Operating profit/loss** | 8 | **-52 191** | **-45 474** |
| | | | |
| **Profit/loss from financial items** | | | |
| Profit/loss from other securities and receivables held as non-current assets | 9 | 2 913 | -2 610 |
| Other interest and similar income | 10 | 896 | 715 |
| Interest and similar expenses | 11 | -6 405 | -3 261 |
| | | -2 596 | -5 156 |
| **Profit/loss after financial items** | | **-54 787** | **-50 630** |
| | | | |
| **Profit/loss before tax** | | **-54 787** | **-50 630** |
| | | | |
| **PROFIT/LOSS FOR THE YEAR** | | **-54 787** | **-50 630** |

# Parent Company statement of financial position at end of period (SEK thousands)

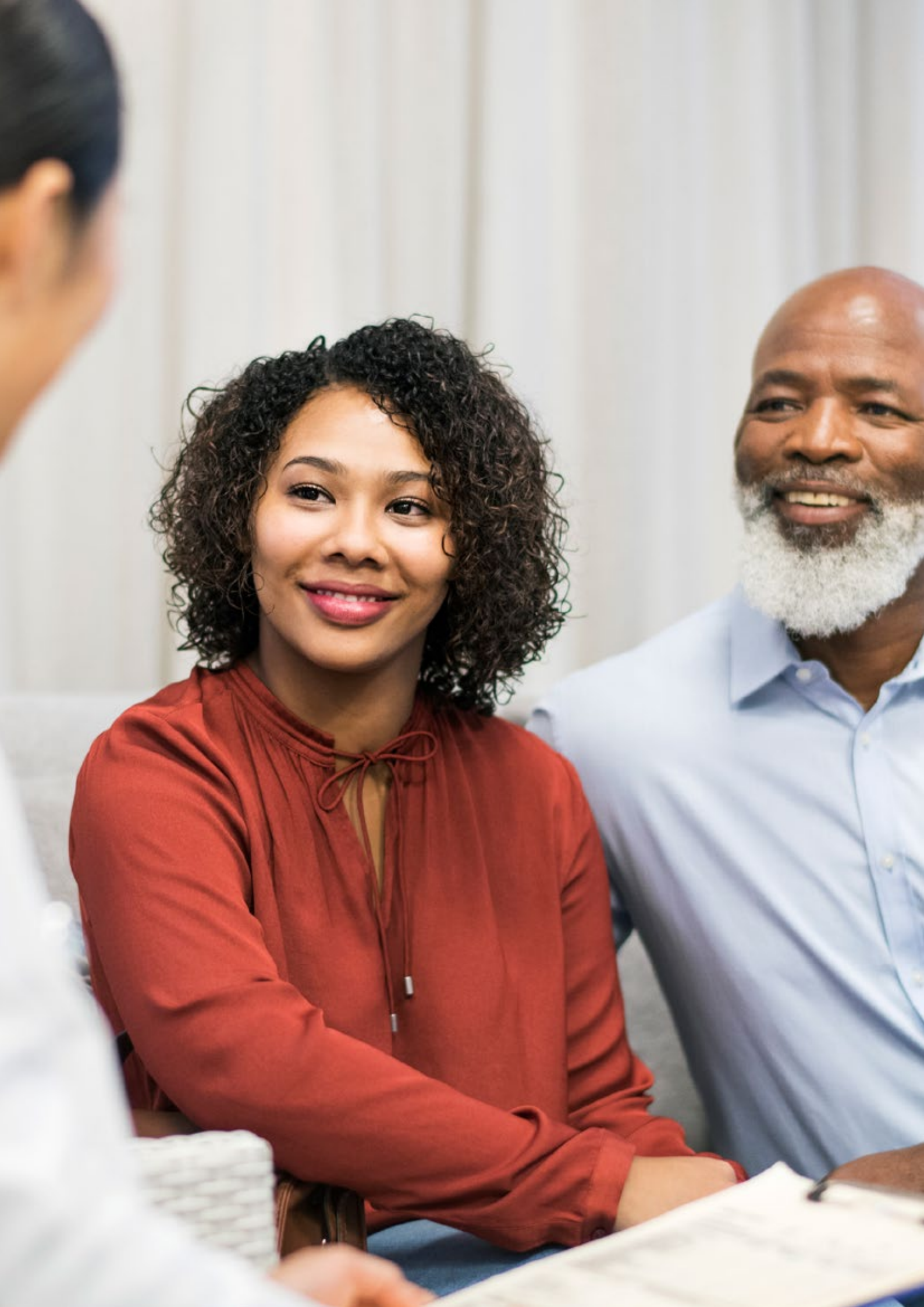
| Assets | Note | December 31, 2021 | December 31, 2020 |
|---|---|---|---|
| Non-current assets | | | |
| **Intangible assets** | | | |
| Capitalized expenditure for development and similar | 12 | 17 314 | 19 011 |
| | | | |
| **Property, plant and equipment** | | | |
| Equipment, tools, fixtures and fittings | 14 | 1 425 | 1 815 |
| | | | |
| **Financial assets** | | | |
| Shares in Group companies | 15 | 242 | 242 |
| Non-current receivables from Group companies | 17 | 37 560 | 24 901 |
| Non-current lease receivables | | 85 | 198 |
| | | **37 887** | **25 341** |
| | | | |
| **Total non-current assets** | | **56 626** | **46 167** |
| | | | |
| Current assets | | | |
| **Inventories etc.** | 18 | | |
| Finished goods inventory | | 4 155 | 2 754 |
| Advances to suppliers | | 453 | 2 859 |
| | | **4 608** | **5 613** |
| | | | |
| **Current receivables** | | | |
| Accounts receivable | | 503 | 345 |
| Receivables from subsidiaries | | 1 464 | 1 042 |
| Current tax assets | | 0 | 40 |
| Other receivables | 19 | 4 445 | 2 312 |
| Current portion of non-current lease receivables | 19 | 113 | 113 |
| Prepayments and accrued income | 20 | 521 | 392 |
| | | **7 046** | **4 244** |
| | | | |
| **Current investments** | | | |
| Other short-term investments | 21 | 29 459 | 11 276 |
| | | | |
| **Cash and bank balances** | 21 | 1 190 | 362 |
| **Total current assets** | | **42 303** | **21 495** |
| | | | |
| **TOTAL ASSETS** | | **98 929** | **67 662** |

# Parent Company statement of financial position at end of period (SEK thousands)

| Equity and liabilities | Note | December 31, 2021 | December 31, 2020 |
|---|---|---|---|
| **Equity** | 22 | | |
| **Restricted equity** | | | |
| Share capital | | 6 089 | 4 205 |
| Development expenditure fund | | 3 692 | 4 219 |
| | | **9 781** | **8 424** |
| | | | |
| **Unrestricted equity** | | | |
| Share premium reserve | | 339 828 | 270 436 |
| Retained earnings | | -240 794 | -190 691 |
| Profit/loss for the year | | -54 787 | -50 630 |
| | | **44 247** | **29 115** |
| | | | |
| **Total equity** | | **54 028** | **37 539** |
| | | | |
| **Non-current liabilities** | | | |
| Liabilities to credit institutions | 23 | 100 | 200 |
| | | | |
| **Current liabilities** | | | |
| Liabilities to credit institutions | 23 | 100 | 400 |
| Accounts payable | | 4 193 | 4 403 |
| Tax liabilities | | 306 | 0 |
| Other liabilities | 24 | 35 450 | 20 281 |
| Accruals and deferred income | 25 | 4 752 | 4 839 |
| **Total current liabilities** | | **44 801** | **29 923** |
| | | | |
| **TOTAL EQUITY AND LIABILITIES** | | **98 929** | **67 662** |

# Parent Company cash flow statement for the end of the period (SEK thousands)

| Cash flow statement | Not | Jan 1, 2021 -Dec 31, 2021 | Jan 1, 2020 -Dec 31, 2020 |
|---|---|---|---|
| Operating activities | | | |
| Receipts from customers | | 1 438 | 1 420 |
| Cash paid to suppliers and employees | | -52 655 | -47 248 |
| Tax paid | | 0 | 0 |
| **Cash flow from operating activities before changes in working capital** | | **-51 217** | **-45 828** |
| | | | |
| Interest paid | | -6 405 | -3 261 |
| **Cash flow from operating activities** | | **-57 622** | **-49 089** |
| | | | |
| Investing activities | | | |
| Acquisition of property, plant and equipment | 27 | -99 | -348 |
| Acquisition of financial assets | | -8 772 | -6 414 |
| Acquisition of intangible assets | 26 | -409 | 0 |
| Sale of short-term investments | | 34 | 38 |
| **Cash flow from investing activities** | | **-9 246** | **-6 724** |
| | | | |
| Financing activities | | | |
| New share issue | | 71 277 | 62 425 |
| Proceeds from borrowings | | 15 000 | 15 000 |
| Repayment of borrowings | | -400 | -15 400 |
| **Cash flow from financing activities** | | **85 877** | **62 025** |
| | | | |
| **CASH FLOW FOR THE PERIOD** | | **19 009** | **6 212** |
| | | | |
| Cash and cash equivalents at beginning of period | | 11 638 | 5 426 |
| | | | |
| Exchange differences | | 0 | 0 |
| **Cash and cash equivalents at end of year** | 21 | **30 647** | **11 638** |



# Notes

## GENERAL INFORMATION

The consolidated financial statements of Clinical Laserthermia Systems AB (publ) (CLS) have been prepared in accordance with the Swedish Annual Accounts Act (ÅRL), International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and the interpretations issued by the International Financial Reporting Interpretations Committee (IFRIC) as adopted by the European Commission for application within the EU. In addition, the Swedish Financial Reporting Board's recommendation RFR 1 "Supplementary Accounting Rules for Groups" has been applied.

The Parent Company's annual accounts were prepared in accordance with the Swedish Annual Accounts Act and Recommendation RFR 2 "Accounting for Legal Entities" of the Swedish Financial Reporting Board. The consolidated financial statements and annual reports are presented in Swedish kronor (SEK) and refer to the period January 1 – December 31 for income statement items, and December 31 for balance sheet items. Assets and liabilities are recognized in accordance with the cost method. Investments in Group companies are recognized at cost. If the carrying amount of an investment exceeds the recoverable amount, an impairment loss is recognized (see "Impairment" section below).

## STANDARDS AND INTERPRETATIONS

### *IFRS 15 – Revenue recognition*

IFRS 15 regulates revenue recognition. The principles on which IFRS 15 is based are intended to provide users of financial statements additional valuable information about the company's revenue. Under the expanded disclosure requirements, information on the type of revenue, date of settlement, uncertainties associated with the recognition of revenue and cash flows attributable to the company's customer contracts must be disclosed. Revenue has to be recognized under IFRS 15 when the customer obtains control of the sold good or service and is able to use and benefit from the good or service. IFRS 15 replaces IAS 18 Revenue and IAS 11 Construction Contracts and the related SIC and IFRIC interpretations. IFRS 15 came into effect on January 1, 2018. The introduction of IFRS 15 has not materially impacted how the Group recognizes revenue and consequently, no transition method has been considered relevant.

### *IFRS 9 - Financial Instruments*

IFRS 9 replaces IAS 39 Financial Instruments: Recognition and measurement. The new standard significantly differs from the current standard, IAS 39. The standard comprises new principles for the classification and measurement of financial assets. The method of measurement is chosen based on the company's purpose for holding an asset ("business model") and the financial instrument's contractual cash flows. The Group has assessed the effects of the introduction of IFRS 9, and does not consider that there are any material differences between the new standard and the Group's previous principles for the classification and measurement of financial instruments, or impairment losses for doubtful receivables. The Group applies the standard with effect from January 1, 2018. At every closing date, the company assesses the credit risk for trade receivables and calculates a loss allowance.

### *IFRS 16 – Leases*

CLS has chosen to apply IFRS 16 as of January 1, 2019. IFRS 16 replaces the IFRS standards that currently regulate the recognition of leases – more precisely, IAS 17, IFRIC 4, SIC-15 and SIC-27. Many of the assessments required for financial leases under IFRS 16 are already currently required under IAS 17. The challenge with IFRS 16 is that there is now a considerably greater volume of agreements encompassed by these estimations and assessments, including rental agreements that are capitalized as assets and liabilities in the balance sheet, with the resulting effect that the cost in the income statement is distributed between depreciation in operating profit/loss and interest expenses in net financial items The Company applies a simplified transition approach.

The standard requires assets and liabilities attributable to all leases, with some exceptions, to be recognized in the statement of financial position. This accounting treatment is based on the view that the lessee has a right to use an asset during a specific period of time as well as an obligation to pay for this right. Depreciation in the income statement is to be reported separately from interest expenses attributable to the lease liability. As an effect of the transition to IFRS 16, the company's other external expenses are reduced, while finance costs and total assets increase. The Group applies IFRS 16 retrospectively, as well as the practical expedient for short-term leases.

None of the other IFRSs or IFRIC interpretations not yet in effect are expected to have any material impact on the Group.

## SIGNIFICANT ESTIMATES AND ASSESSMENTS

The preparation of financial statements in accordance with IFRS requires that company management make assessments and estimates as well as assumptions that impact the profit or loss statement and balance sheet, as well as other disclosures. Estimates, assessments and assumptions are reviewed regularly. The actual outcome may differ from the assessments, estimates and assumptions made. The Board of Directors and CEO perform continuous assessments of deferred tax and intangible assets. The Parent Company has deferred tax assets that totaled SEK 59,290 thousand at the end of the period, corresponding to a loss carryforward of SEK 287,815 thousand [1]).

[1]) Av försiktighetsskäl har uppskjuten skattefordran inte redovisats.

The measurement of loss carryforwards and the company's capacity to use unutilized loss carryforwards are based on the assumption that the company will generate taxable profits within the foreseeable future. Intangible assets are measured at least annually or more frequently if there are indications of impairment.

The Group's cash and cash equivalents at the end of the year amounted to SEK 31,165 thousand (11,871 thousand). In view of the share issue made in 2020, which contributed a total of approximately SEK 71,277 thousand to the company before issue expenses and expected revenue, and the share issues carried out in the first quarter of 2021, the Board considers the existing working capital to be sufficient to run the company for the next twelve-month period and beyond. Should these conditions change, additional raising of capital may be considered. CLS may, subject to shareholder approval, issue new shares, repurchase shares or increase/reduce borrowings. The capital structure is reviewed regularly. On December 2021, Group equity amounted to SEK 21 184 thousand (13,928), and equity In CLS AB amounted to SEK 54,028 thousand (37,539).

## CONSOLIDATED FINANCIAL STATEMENTS

CLS's consolidated financial statements comprise those of the Parent Company, CLS AB, and the subsidiaries, CLS America Inc. and CLS Berlin GmbH. Subsidiaries are included in the consolidated financial statements from the time when controlling influence is transferred to the Group and are not included in the consolidated financial statements from the time when the controlling influence ceases. Internal profits and intra-Group transactions are eliminated in the consolidated financial statements.

Subsidiaries are recognized in accordance with the purchase method of accounting. The acquisition is treated as a transaction through which the Group indirectly acquires the subsidiary's assets and assumes its liabilities and contingent liabilities. The consolidated acquisition cost is determined by means of an acquisition analysis in connection with the acquisition. In the plan, the cost is determined for the shares or operations, and for the fair value of the acquired identifiable assets, assumed liabilities and contingent liabilities on the acquisition date. The acquisition cost of the subsidiaries' shares or business consists of their fair values on the transfer date for the assets acquired and liabilities arising or assumed and for equity instruments issued as payment and in exchange for the acquired net assets, as well as transaction costs directly attributable to the acquisition. For business combinations where the acquisition cost exceeds the net value of acquired assets and assumed liabilities and contingent liabilities, the difference is recognized as goodwill. Where the difference is negative, this difference is recognized directly in the income statement.

The financial statements of subsidiaries are included in the consolidated financial statements as of the acquisition date until the date when the controlling influence ceases. Accounting policies for subsidiaries have been changed where appropriate to guarantee consistent application of the Group's policies.

## FOREIGN CURRENCIES

### Functional currency

The functional currency is the currency of the primary economic environments in which the companies conduct their business operations. The Parent Company's functional currency is the Swedish krona (SEK), which is also the presentation currency of the Parent Company and Group.

### Currency translation

Transactions in foreign currency
Transactions in foreign currency are translated to the functional currency at the exchange rate prevailing on the transaction date. Monetary assets and liabilities in foreign currency are recalculated to the functional currency at the exchange rate prevailing on the balance-sheet date. Exchange-rate differences arising on translation are recognized in net profit for the year. Exchange-rate gains and losses for operating receivables and payables are recognized in profit or loss, while exchange-rate gains and losses for financial assets and liabilities are reported under financial items.

### Translation of foreign operations

Assets and liabilities in foreign operations are translated from the foreign operation's functional currency to the Group's presentation currency, SEK, at the prevailing exchange rate on the balance sheet date. Revenue and expenses in foreign operations are translated to SEK using the average exchange rate prevailing on the transaction date. Translation differences arising from the translation of foreign operations are recognized under other comprehensive income.

## INVENTORIES

Inventories, through application of the FIFO (first in, first out) method, have been measured at the lower of cost and net realizable value.

## CASH FLOW STATEMENT

The cash flow statement is prepared in accordance with IAS 7, Statement of Cash Flows, using the indirect method. The reported cash flow only includes transactions involving incoming or outgoing payments. Cash and cash equivalents includes cash, bank balances and current investments.

## NOTE 1 Net sales

Sales are based on a measure known as net sales, which excludes any revenue that is not attributable to the sales of products and services. Senior management assesses operations from a product perspective, where the operations exclusively comprise an operating segment* that is used for making strategic decisions. The segment consists of the Company's mobile laser unit and related disposable products. Reference is made to the income statement and balance sheet with respect to the primary segment reporting. Revenue is recognized in profit or loss when material risks and benefits that are associated with the ownership of the goods are transferred to the customer. Revenue for service assignments are recognized in profit or loss upon the assignment's completion, since the services undertaken by CLS are rendered over a very short time.

| Revenue | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Sweden | 0 | 0 | 0 | 0 |
| Other countries | 2 245 291 | 1 332 177 | 1 717 385 | 1 738 744 |
| **Total** | **2 245 291** | **1 332 177** | **1 717 385** | **1 738 477** |

*A segment is an identifiable reporting component of the Group that supplies products or services within a specific economic environment, and which is exposed to risks and opportunities that differ from other segments. Operating segments are reported in a way that corresponds to the internal reporting that is submitted to the chief operating decision-maker. At CLS, this function is identified as the Group CEO.

## NOTE 2 Other revenue

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Exchange gains | 153 086 | 134 005 | 153 086 | 134 005 |
| Other | 8 201 | 146 814 | 2 783 | 0 |
| **Total** | **161 287** | **280 819** | **155 869** | **134 005** |

## NOTE 3 Auditors' fees

Audit engagement refers to the examination of the annual accounts and the administration of the Board of Directors and the Chief Executive Officer, other duties it is incumbent on the company's auditor to carry out and advice or other assistance that is necessitated by findings in such an examination or the fulfillment of such other duties.

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| **Dillon AB** | | | | |
| Audit assignment | 155 720 | 131 000 | 155 720 | 131 000 |
| Audi activities in addition to the audit engagement | 0 | 0 | 0 | 0 |
| Tax advisory services | 0 | 0 | 0 | 0 |
| Other services | 0 | 0 | 0 | 0 |
| **Total** | **155 720** | **131 000** | **155 720** | **131 000** |

## NOTE 4 Related-party transactions

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Gunilla Savring via Savring Consulting AB | 897 180 | 958 300 | 897 180 | 958 300 |
| Rolf Kiessling via Immocon AB | 35 000 | 92 000 | 35 000 | 92 000 |
| Dan Mogren via Medinovus AB | 210 213 | 1 115 871 | 210 213 | 1 115 871 |
| Arne Ferstad via Ankor Consultant Ltd | 0 | 12 620 | 0 | 12 620 |
| L-E Eriksson via Elano AB | 768 000 | 64 000 | 768 000 | 64 000 |
| Hans von Celsing via Berkshire Investment Management Ltd | 928 000 | 917 000 | 928 000 | 917 000 |
| K-G Tranberg via KG Tranberg Medical | 0 | 211 000 | 0 | 211 000 |
| **Total** | **2 838 393** | **3 370 791** | **2 838 393** | **3 370 792** |

## NOTE 5 Leases

Property, plant and equipment leases are classified as finance leases, if the Group, as lessee, assumes substantially the economic risks and rewards incidental to ownership . At commencement of the lease term, finance leases are recognized in the balance sheet at the lower of the fair value of the leased asset and the present value of the minimum lease payments. The corresponding payment obligations, after deduction of financial expenses, are included in the balance sheet items Long-term borrowing and Short-term borrowing. Each lease payment is apportioned between the finance charge and the reduction of the liability. Interest recognized in the income statement is allocated over the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability during each period.

Rent of premises pertains to the premises of the Parent Company and the subsidiaries, CLS America Inc. and CLS Berlin GmbH. The Group's companies have a current 12-month notice of termination. CLS America Inc. has a lease that runs until April 30, 2023. CLS Berlin GmbH has a lease that runs until May 31, 2023.

| Expenses for the year | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2021 |
|---|---|---|---|---|
| Rent of premises | 812 432 | 805 164 | 505 968 | 492 463 |
| **Total** | **812 432** | **805 164** | **505 968** | **492 463** |

| Future payment obligations, nominal value | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Rent of premises | | | | |
| Less than 1 year | 828 374 | 750 156 | 520 200 | 505 968 |
| Between 1 and 5 years | 458 995 | 374 969 | 346 800 | 337 312 |
| **Totalt** | **1 287 369** | **1 125 125** | **867 000** | **843 280** |

## NOTE 6 Personnel

All employees of the Parent Company are covered by a pension plan. Depending on the starting date of employment, the retirement plan is managed by SPP or other personal choice of plan manager, and classified as a defined-contribution pension plan. In a defined-contribution scheme, fixed payments are made to a separate unit and there are no subsequent legal or formal obligations to pay any additional fees. Fees for pension insurance are recognized as an expense in profit or loss as they arise.

| Average number of employees | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Total | 11 | 7 | 7 | 5 |
| Of whom women | 6 | 4 | 5 | 3 |

| **Salaries and benefits were paid as follows:** | | | | |
|---|---|---|---|---|
| Board and CEO | 2 733 090 | 1 812 096 | 2 733 090 | 1 812 096 |
| Other employees | 5 562 758 | 6 271 348 | 3 004 258 | 3 990 701 |
| **Total salaries** | **8 295 848** | **8 083 443** | **5 737 348** | **5 802 797** |
| Social security expenses | 1 260 462 | 1 289 566 | 1 144 561 | 1 035 714 |
| Pension expenses of CEO | 411 882 | 0 | 411 882 | 0 |
| Pension expenses of other employees | 1 575 104 | 181 619 | 1 575 104 | 181 619 |
| **Total social security and pensionexpenses** | **3 247 448** | **1 471 185** | **3 131 547** | **1 217 333** |

## Remuneration and other benefits to the Board of Directors, CEO and senior executives

| | Basic salary/ Board fees | Pension expenses | Total |
|---|---|---|---|
| Dan Mogren, CEO | 1 140 000 | 411 882 | 1 551 882 |
| Hans von Celsing, Chairman of the Board | 285 000 | 0 | 285 000 |
| Lars-Erik Eriksson, Member | 720 591 | 929 246 | |
| Paolo Raffaelli | 62 500 | 0 | 62 500 |
| Rolf Kiessling, Member | 80 000 | 0 | 80 000 |
| Gunilla Savring, Member | 142 500 | 0 | 142 500 |
| Karl-Göran Tranberg, Member | 80 000 | 0 | 80 000 |
| Catherine Gilmore-Lawless | 80 000 | 0 | 80 000 |
| Marika Crohns, Member | 142 500 | 0 | 142 500 |
| **Total** | **2 733 091** | **1 341 128** | **2 424 382** |

The Board in 2021 comprised three men and three women. In 2020, the Board comprised three women and four men. The senior management team comprises the Chief Executive Officer and the management group, four men and three women.

## NOTE 7 Other operating expenses

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Exchange losses | 220 842 | 419 065 | 220 842 | 419 065 |
| Other interest expenses | 5 652 | 7 628 | 0 | 0 |
| **Total** | **226 494** | **426 693** | **220 842** | **419 065** |

## NOTE 8 Intra-Group purchases and sales

| | Parent Company 2021 | Parent Company 2020 |
|---|---|---|
| Percentage of total purchasing for the year from other Group companies | 0,0% | 0,0% |
| Percentage of total sales for the year made to other companies in the Group | 89,2% | 57,4% |

## NOTE 9 Profit/loss from other securities and receivables held as non-current assets

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Exchange-rate differences | 2 913 149 | -2 610 303 | 2 913 149 | -2 610 303 |
| **Total** | **2 913 149** | **-2 610 303** | **2 913 149** | **-2 610 303** |

## NOTE 10 Other interest and similar income

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Other interest income | 128 | 0 | 861 437 | 676 958 |
| Exchange rate differences | | 132 | | 132 |
| Profit/loss on sales | 34 354 | 38 456 | 34 354 | 38 456 |
| **Total** | **34 482** | **38 588** | **895 791** | **715 546** |

## NOTE 11 Interest expense and similar profit and loss items

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Other interest expenses | 6 405 200 | 3 271 129 | 6 405 200 | 3 261 505 |
| Exchange rate differences | | 163 | | 163 |
| **Total** | **6 405 200** | **3 271 292** | **6 405 200** | **3 261 668** |

## NOTE 12 Capitalized expenditure for research and development work

The Group's expenditure is capitalized when it meets the conditions for recognition as an intangible asset in accordance with IAS 38. The amortization period commences once the asset has been commercialized. Capitalized expenditure has an amortization period of 10 years.

Assets are assessed for decrease in value whenever events or changes in circumstances indicate that the carrying amount is not recoverable. An impairment loss is determined in the amount by which the asset's carrying amount exceeds its recoverable amount, which is the higher of net realizable value and value in use. In calculating value in use, future cash flows are discounted at an interest rate that takes account of the market's assessment of risk-free interest rate and risk associated with the specific asset. For intangible assets with indefinite useful lives and intangible assets that are not yet ready for use, the recoverable amount is calculated annually.

| Capitalized expenditure | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Opening cost | 23 763 914 | 23 763 914 | 23 763 914 | 23 763 914 |
| Purchases for the year | 408 836 | | 408 836 | |
| **Closing cost** | **24 172 750** | **23 763 914** | **24 172 750** | **23 763 914** |
| Opening accumulated depreciation | -4 752 782- | -2 376 391 | -4 752 782 | -2 376 391 |
| Amortization for the year | -2 106 368 | -2 376 391 | -2 106 368 | -2 376 391 |
| **Closing accumulated depreciation** | **-6 859 150** | **-4 752 782** | **-6 859 150** | **-4 752 782** |
| **Carrying amount** | **17 313 600** | **19 011 132** | **17 313 600** | **19 011 132** |

## NOTE 13 Concessions, patents, licenses, trademarks, etc.

**Patents**

The Group's patent expenses are capitalized when they meet the conditions for recognition as intangible assets under IAS 38. Patents have a limited useful life and are therefore stated at cost, less accumulated amortization. The amortization period commences once the patent has been commercialized, i.e. launched as a new product or application. An amortization period of 10 years for patents is justifiable by the fact that most of these have at least this period of validity, with the possibility of extension beyond that period.

Assets are reviewed for decrease in value whenever events or changes in circumstances indicate that the carrying amount is not recoverable.

| Patents and licenses | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Opening cost | 2 289 553 | 2 289 553 | 0 | 0 |
| **Closing cost** | **2 286 553** | **2 286 553** | **0** | **0** |
| Opening accumulated amortization | 0 | 0 | 0 | 0 |
| Amortization for the year | 0 | 0 | 0 | 0 |
| **Opening carrying amount** | **2 236 566** | **2 324 826** | 0 | 0 |
| **Exchange rate difference Closing accumulated amortization** | **42 202** | **-88 260** | **0** | **0** |
| **Carrying amount** | **2 278 768** | **2 236 566** | **0** | **0** |

## NOTE 14 Property, plant and equipment

Property, plant and equipment, consisting of laboratory equipment, other equipment and computer equipment, is recognized at cost, less accumulated depreciation. Depreciation is based on the assets' costs, useful lives and potential residual value. The residual values and useful lives of the assets are tested, and adjusted if necessary, at each balance sheet date. Gains and losses on divestments are determined by comparing the sale proceeds with the carrying amount and are recognized in profit and loss.

Items of property, plant and equipment are subject to straight-line depreciation over the estimated useful life of the asset, based on the asset's cost, as follows:

Laboratory equipment 5 years
Other equipment 5 years

| Equipment, tools, fixtures and fittings | Group 2021 | Group 2020 | Parent Comapany 2021 | Parent Comapany 2020 |
|---|---|---|---|---|
| Opening cost | 4 062 758 | 3 714 959 | 3 098 297 | 2 750 498 |
| New acquisitions | 146 050 | 347 799 | 99 050 | 347 799 |
| Reclassification | 0 | 0 | 0 | 0 |
| Disposals | 0 | 0 | 0 | 0 |
| **Closing cost** | **4 208 808** | **4 062 758** | **3 197 347** | **3 098 297** |
| Opening accumulated depreciation | -2 008 778 | -1 307 780 | -1 283 447 | -803 899 |
| Depreciation on disposal | 0 | 0 | 0 | 0 |
| Amortization for the year | -683 503 | -689 178 | -488 762 | -479 548 |
| Exchange rate difference | -39 264 | -11 820 | 0 | 0 |
| **Closing accumulated depreciation** | **-2 731 545** | **-2 008 778** | **- 1 772 209** | **-1 283 447** |
| **Carrying amount** | **1 477 263** | **2 053 980** | **1 425 138** | **1 814 850** |

## NOTE 15 Investments in Group companies

| | Parent Comapany 2021 | Parent Comapany 2020 |
|---|---|---|
| Opening cost | 242 122 | 242 122 |
| Acquisitions for the year | 0 | 0 |
| **Closing accumulated cost** | **242 122** | **242 122** |
| **Carrying amount** | **242 122** | **242 122** |

| Name | Registered office | Corp. reg. no. | Share-holding | Number of shares | Carrying amount |
|---|---|---|---|---|---|
| Clinical Asia Pacific Pte. Ltd | Singapore | 202004466N | 50% | 32 500 | 0 |
| CLS America Inc. | San Diego, USA | 47-1229568 | 100% | 1000 | 672 |
| CLS Berlin GmbH | Berlin, Tyskland | DE312254134 | 100% | 25 000 | 241 450 |

| Name | Registered office | Corp. reg. no. | Share-holding | Number of shares |
|---|---|---|---|---|
| Clinical Asia Pacific Pte. Ltd | Singapore | 202004466N | | -1 052 406 |
| CLS America Inc. | San Diego, USA | 47-1229568 | -21 190 546 | -5 018 949 |
| CLS Berlin GmbH | Berlin, Tyskland | DE312254134 | -10 192 906 | -3 279 862 |

## NOTE 16 Deferred tax asset

Group deferred tax asset at the end of the period totaled SEK 3,038,683. The deferred tax asset is attributable to unutilized deductions for loss in the subsidiary CLS America Inc. In addition to this deduction for loss, there is a deferred tax asset of SEK 59,290 thousand attributable to an unutilized deduction for loss of SEK 287,815 thousand in the parent company Clinical Laserthermia Systems AB. For precautionary reasons, the company has decided not to record this tax asset.

| | Group 2021 | Group 2020 | Parent Comapany 2021 | Parent Comapany 2020 |
|---|---|---|---|---|
| **Deferred tax assets** | | | | |
| Carryforward of unused tax losses | 3 038 683 | 0 | 0 | 0 |
| **Total deferred tax asset** | **3 038 683** | **0** | **0** | **0** |

## NOTE 17 Receivables from Group companies

| Amount at Dec 31 | Parent Comapany 2021 | Parent Comapany 2020 |
|---|---|---|
| Opening cost | 24 901 127 | 20 618 424 |
| Additional receivables | 9 746 578 | 6 893 006 |
| Currency adjustment | 2 912 765 | -2 610 303 |
| **Closing cost** | **37 560 470** | **24 901 127** |
| **Closing accumulated impairment** | | **0** |
| **Closing carrying amount** | **37 560 470** | **24 901 127** |

## NOTE 18 Inventories

| Amount at Dec 31, 2021 | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Finished products and goods for resale | 4 155 189 | 2 754 267 | 4 155 189 | 2 754 267 |
| Advance payments suppliers | 452 817 | 2 859 031 | 452 817 | 2 859 031 |
| **Carrying amount** | **4 608 006** | **5 613 298** | **4 608 006** | **5 613 298** |

## NOTE 19 Other receivables

| Amount at Dec 31, 2021 | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| VAT receivables | 1 336 208 | 1 437 123 | 1 295 751 | 1 264 812 |
| Current portion of non-current lease receivables | 113 188 | 113 188 | 113 118 | 113 188 |
| Other | 3 512 515 | 1 088 712 | 3 149 224 | 1 047 185 |
| **Total** | **4 961 911** | **2 639 023** | **4 558 163** | **2 425 185** |

The Group does not currently hold any derivatives. The Group's financial instruments mainly comprise trade receivables, cash and cash equivalents, liabilities to credit institutions and trade payables, and are recognized in accordance with the trade date principle. Trade receivables consist of amounts to be paid by customers for products sold or services rendered within operating activities. They are included in current assets with the exception of items with a due date more than 12 months after the balance-sheet date, which are classified as non-current assets. Trade receivables are initially recognized at fair value and in subsequent periods at amortized cost. Due to their short-term nature, these receivables are recognized at nominal amounts, with no discounting. Any impairment of trade receivables is recognized under operating expenses. The fair value of trade receivables corresponds with their carrying amount. The credit quality of receivables for which no loss allowance has been recognized is considered to be good.

Operating liabilities are recognized at cost. Trade payables are recognized at the value that the company intends to pay the supplier in order to discharge the contractual obligation. Trade payables are initially recognized at fair value and subsequently at amortized cost by applying the effective interest method.

| | Group Carrying amount | Group Fair value | Parent Company Carrying amount | Parent Company Fair value |
|---|---|---|---|---|
| Financial assets | | | | |
| Accounts receivable | 531 105 | 531 105 | 1 966 639 | 1 966 639 |
| Other receivables | 4 961 911 | 4 961 911 | 4 558 163 | 4 558 163 |
| Cash and cash equivalents | 31 165 064 | 31 165 064 | 30 648 947 | 30 648 947 |
| **Financial liabilities** | | 0 | | 0 |
| Non-current liabilities to credit institutions | 100 000 | 100 000 | 100 000 | 100 000 |
| Accounts payable | 4 314 629 | 4 314 629 | 4 192 655 | 4 192 655 |
| Other liabilities | 35 949 878 | 35 949 878 | 35 449 813 | 35 449 813 |

Trade receivables are stated at the amount expected to be received following individual testing. At December 31, 2021, the Group had SEK 508,270 in past-due trade receivables.

## NOTE 20 Accruals and deferred income

| Amount at December 31 | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Prepaid insurance premiums | 199 787 | 57 904 | 199 787 | 57 904 |
| Other items | 958 567 | 334 001 | 321 133 | 334 001 |
| **Total** | **1 158 354** | **391 905** | **520 920** | **391 905** |

## NOTE 21 Cash and cash equivalents

Cash and cash equivalents in the balance sheet and cash flow statement consist of cash deposits in banks and short-term investments.

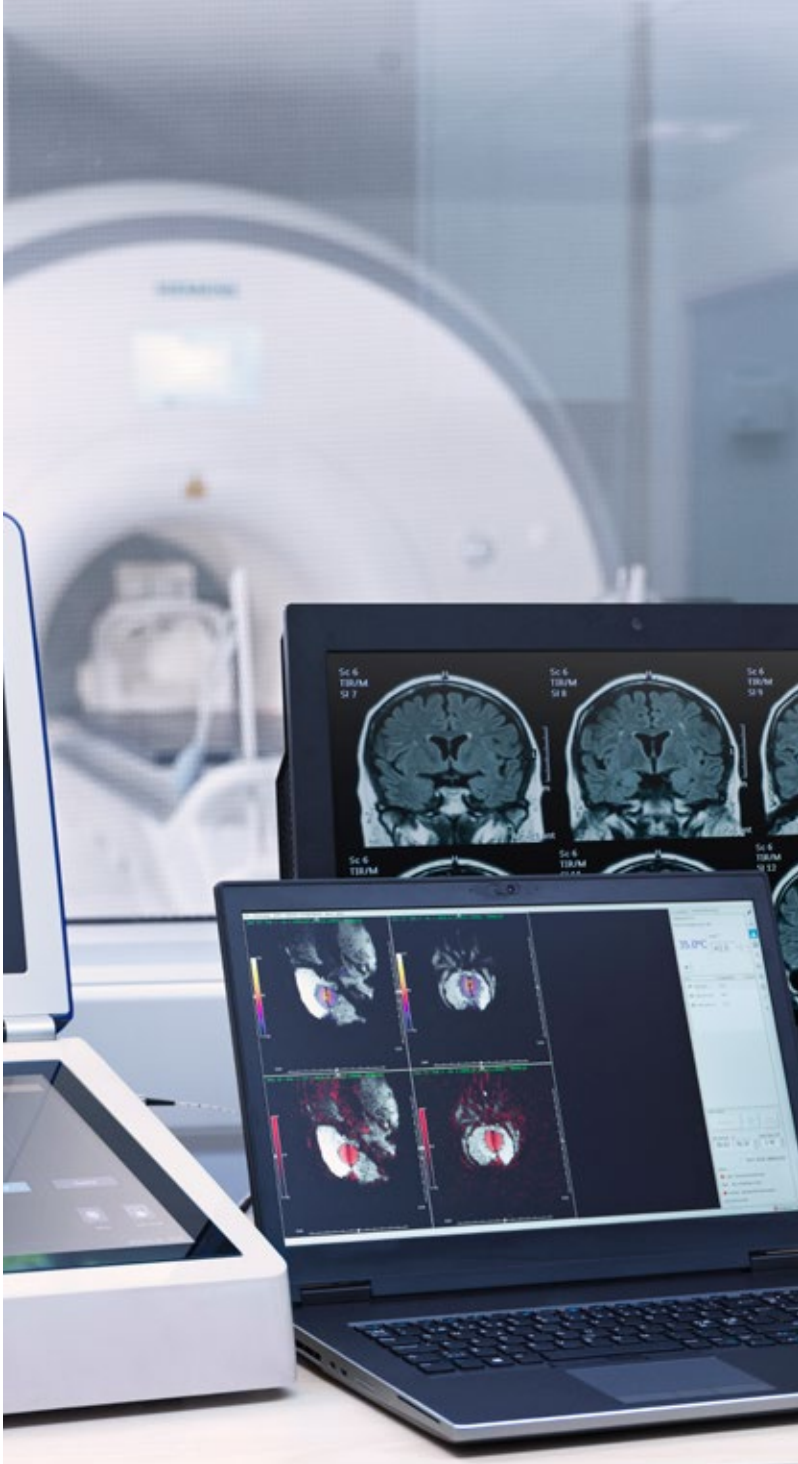
| Amount at Dec 31 | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Bonds, securities etc. | 29 458 917 | 11 275 840 | 29 458 917 | 11 275 840 |
| Bank balances | 1 706 147 | 594 670 | 1 190 030 | 362 168 |
| **Total** | **31 165 064** | **11 870 510** | **30 648 947** | **11 638 008** |

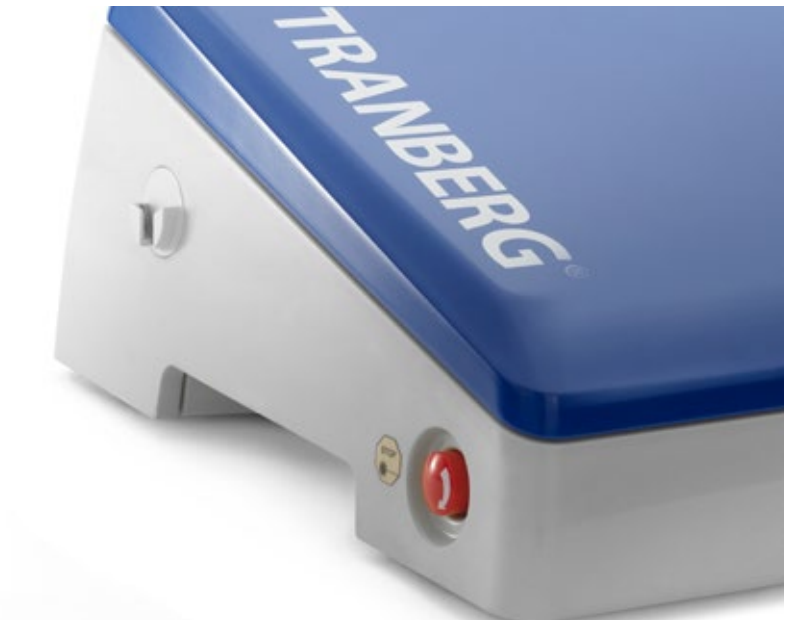
At December 31, 2021, the fair value of bonds and securities was SEK 29,458,916.

## NOTE 22 Shares

All of the shares are issued and fully paid.

| Number of shares | Quotient value | Shares |
|---|---|---|
| At December 31, 2020 | 0,09 | 45 457 500 |
| New share issued registered May 24, 2021 | 0,09 | 16 377 250 |
| New share issued registered May 24, 2021 | 0,09 | 3 173 274 |
| New share issued registered July 13, 2021 | 0,09 | 100 000 |
| New share issued registered July 13, 2021 | 0,09 | 714 286 |
| **At December 31, 2021** | **0,09** | **65 822 310** |

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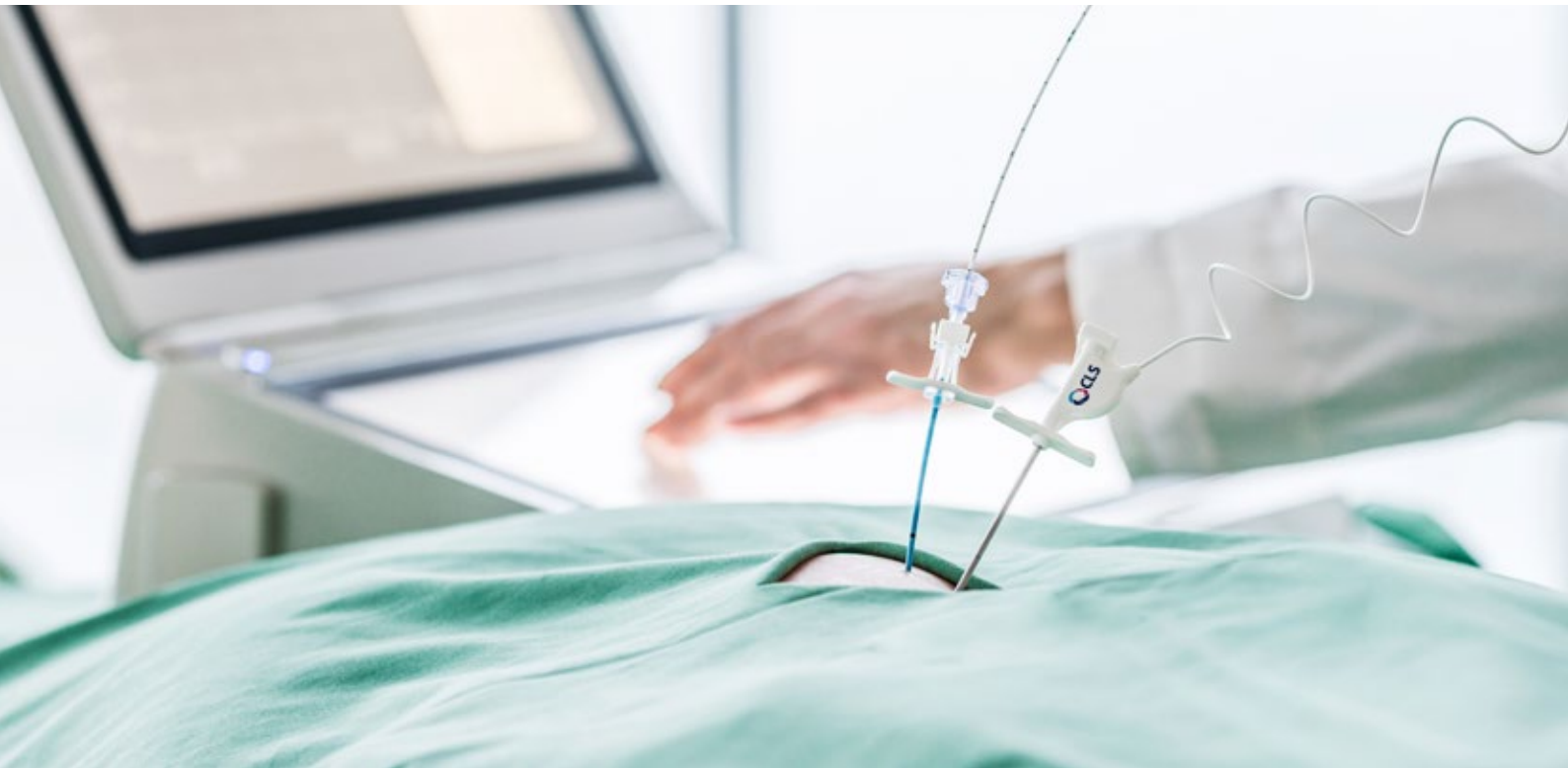


## NOTE 23 Liabilities to credit institutions

Liabilities to credit institutions pertain in their entirety to bank promissory notes.

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| **Non-current interest-bearing liabilities** | | | | |
| Falling due after 1 and 5 years | 100 000 | 200 000 | 100 000 | 200 000 |
| **Total** | **100 000** | **200 000** | **100 000** | **200 000** |
| **Current interest-bearing liabilities** | | | | |
| Falling due within 1 year | 100 000 | 400 000 | 100 000 | 400 000 |
| **Total** | **100 000** | **400 000** | **100 000** | **400 000** |

## NOTE 24 Other liabilities

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Bond loans | 73 500 | 73 500 | 73 500 | 73 500 |
| Loans | 35 000 000 | 20 000 000 | 35 000 000 | 20 000 000 |
| Other items | 35 876 378 | 20 227 909 | 35 376 313 | 20 207 727 |
| **Total** | **35 949 878** | **20 301 409** | **35 449 813** | **20 281 227** |

| **Lending institution** | **mount** | **Loan agree-ment** | **Monthly interest rate** | **Term** |
|---|---|---|---|---|
| Modelio Equity | 5 000 000 | June 1, 2021 | 1,25% | 12 months |
| Lubrica Equity | 5 000 000 | June 1, 2021 | 1,25% | 12 months |
| Formue Nord Fokus | 5 000 000 | | 1,25% | 12 months |
| Modelio Equity | 6 666 667 | February 11, 2021 | 1,25% | 12 months |
| Lubrica Equity | 6 666 667 | February 11, 2021 | 1,25% | 12 months |
| Formue Nord Fokus | 6 666 666 | February 11, 2021 | 1,25% | 12 months |
| **Total** | **35 000 000** | | | |

## NOTE 25 Accruals and deferred income

| Average number of employees | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Accrued salary-related expenses | 1 424 326 | 2 532 764 | 1 424 326 | 2 532 764 |
| Interest rate | 320 992 | 1 606 250 | 289 584 | 1 606 250 |
| Other items | 3 037 807 | 731 507 | 3 037 807 | 700 150 |
| **Total** | **4 783 125** | **4 870 521** | **4 751 717** | **4 839 164** |

## NOTE 26 Investments in intangible assets

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Change in balance-sheet item | -1 655 330 | 2 464 651 | -1 697 532 | 2 376 391 |
| Depreciation according to plan for the year | 2 106 368 | -2 376 391 | 2 106 368 | 2 379 391 |
| Exchange differences | -42 202 | -88 260 | | 0 |
| **Total** | **408 836** | **0** | **408 836** | **0** |

## NOTE 27 Investments in property, plant and equipment

| | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| Change in balance-sheet item | -576 717 | -353 199 | -389 712 | -131 749 |
| Depreciation according to plan for the year | 683 503 | -689 178 | 488 762 | -479 548 |
| Exchange rate differences | 39 264 | -11 820 | | |
| **Total** | **146 050** | **347 799** | **99 050** | **347 799** |

## Note 28 Pledged assets and contingent liabilities

| Amount at Dec 31 | Group 2021 | Group 2020 | Parent Company 2021 | Parent Company 2020 |
|---|---|---|---|---|
| for promissory note | 2 000 000 | 2 000 000 | 2 000 000 | 2 000 000 |
| **Total** | **2 000 000** | **2 000 000** | **2 000 000** | **2 000 000** |

## Note 29 Earnings per share

Basic earnings per share is calculated by dividing comprehensive income for the year attributable to Parent Company shareholders by the weighted-average number of shares outstanding during the period.

Diluted earnings per share is calculated by dividing comprehensive income for the year attributable to Parent Company shareholders by the number of shares at year-end.

| | Group 2021 | Group 2020 |
|---|---|---|
| Net profit for the year, SEK | -64 141 678 | -57 938 881 |
| Weighted average number of outstanding shares | 57 517 970 | 44 163 594 |
| Number of shares at end of year | 65 822 310 | 45 457 500 |
| **Basic and diluted earnings per share, SEK** | **-1,12** | **-1,31** |

## Note 30 Risks and uncertainties

**Financing need and capital**
CLS may need further capital to implement its expansion plans and establishments in new markets. There is also uncertainty as to whether CLS will succeed in obtaining necessary capital.

**Key individuals and employees**
CLS's key individuals have great experience and many years of experience in the company's area of business. Loss of one or more key individuals may have adverse consequences for the company's operations and earnings.

**Competition**
Significant resources are currently being invested in the whole area of Cancer, both in the pharmaceutical industry and in the area of medical devices. There is a risk of competitors, with access to greater resources and investment capital than CLS, carrying out extensive investments and product development of new treatment methods that compete with those of the Company. Such investments may lead to competitors more quickly or more effectively being able to develop methods that are more effective, easier to administer or more affordable than the Company's method for cancer therapy and to competitors being more successful in obtaining patent protection and commercializing their products than CLS.

**Economic development and foreign-exchange risks**
External factors such as influence, changes in exchange rates and interest rates, access and demand and economic downturns and upturns may have an impact on operating expenses, selling prices and share valuation. CLS's future revenue and share valuation may be adversely affected by these factors, which are beyond the company's control. Part of the revenue from sales may be received international currencies. Exchange rates may change substantially.

**Market growth**
The measures and restrictions introduced in various countries as a result of COVID-19 have affected the Company's opportunities to travel and reach out to hospitals in its principal markets to meet potential customers. Such worsened opportunities to address markets have in turn limited the Company's prospects of receiving revenue from sales.

It appears at present that opportunities to visit clinics have increased, which is favorable to CLS.

**Financial risks**
*Forecast reliability*
CLS operates in a relatively new market. This limits the predictability of the company's future performance with respect to its operations. Deviations from projected customer orders and cash-flow forecasts could adversely impact the Group's earnings, liquidity and continuing operations.

*Currency risk*
A large part of the Group's overheads are in SEK. On the other hand, the Group's revenues are heavily dependent on other currencies – primarily USD and EUR. The estimates below are based on an assumption of the impact that an exchange-rate fluctuation of 5 percent would have on budget sales in 2021.

| Estimated exchange rate, 2021 | Net volume 2021, SEK thousands 2021, tkr | Impact on earnings/equity in SEK thousands in the event of a 5% fluctuation |
|---|---|---|
| USD: 9,80 | 5 393 | +/- 270 |
| EUR: 10,50 | 3 015 | +/- 150 |

*Credit risk*
Credit risk is an exposure to losses in the event that a counterparty of a financial instrument cannot meet its obligations. The company does not deem that there are any significant credit risks in relation to any particular customer or counterparty.

## Note 31 Proposed appropriation of profits

The Board of Directors and CEO propose that the following available profits (SEK):

| | |
|---|---|
| Accumulated loss | -240 793 748 |
| Share premium reserve | 339 829 332 |
| Loss for the year | -54 786 831 |
| **Total** | **44 248 753** |
| Allocated so that transferred to new account | 44 248 753 |
| **Total** | **44 248 753** |

The Board of Directors and CEO affirm that the consolidated financial statements have been prepared in accordance with international financial reporting standards, IFRS, as adopted by the EU, and provide a fair and accurate account of the Group's financial position and earnings. The Parent Company's accounts were prepared in accordance with generally accepted accounting policies in Sweden and provide a fair and accurate account of the Parent Company's financial position and earnings.

The administration report for the Group and Parent Company provides a fair and accurate overview of the performance of the Parent Company and the Group's operations, financial position and earnings, and describes the material risks and uncertainties faced by the Parent Company and Group companies.

The annual report and the consolidated financial statements were approved for publication by the Board of Directors on June 7, 2022. The consolidated income statement and consolidated balance sheet, and the Parent Company's income statement and balance sheet will be submitted for adoption at the Annual General Meeting on June 28, 2022.

**Lund, June 7, 2022**

Hans von Celsing
Chairman

Marika Crohns

Lars-Erik Eriksson

Paolo Raffaelli

Sandy Brandmeier

Dan J. Mogren
Chief Executive Officer

**Our audit report was submitted on June 7, 2022**
**Dillon AB**

Oskar Kantoft
Authorized Public Accountant

# Auditor's report

**To the general meeting of shareholders of Clinical Laserthermia Systems AB (publ)**
Corp. reg. no. 556705-8903

## Report on the annual accounts and consolidated accounts

***Opinions***
We have audited the annual accounts and consolidated accounts of Clinical Laserthermia Systems AB (publ) for the 2020 financial year.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the parent company and the Group as of December 31, 2020 and of its financial performance and cash flows for the year according to the Swedish Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial financial performance and cash flows of the Group for the year according to International Financial Reporting Standards (IFRS) as adopted by the EU, and the Swedish Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopt the income statement and balance sheet for the Parent Company and Group.

***Basis of 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 *Auditors' responsibility* section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe the audit evidence we have obtained to be sufficient and appropriate to providing a basis for our opinions.

***Other information than the annual accounts and consolidated accounts***
This document also contains other information than the annual accounts and consolidated accounts and is found on pages 4–8. The Board of Directors and the CEO are responsible for this other information.

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

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated 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 consolidated accounts and that they give a fair presentation in accordance with the Swedish Annual Accounts Act and, concerning the consolidated accounts, in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU, and according to the Swedish Annual Accounts Act. The Board of Directors and the CEO are also responsible for such internal control as they deem necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

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

***Auditor's responsibility***
Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement if such exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts is available at the Swedish Inspectorate of Auditors' website: www.revisorsinspektionen.se/rn/showdocument/documents/rev_dok/revisors_ansvar.pdf.
This description is part of the auditor's report.

## Report on other legal and regulatory requirements

***Opinions***
In addition to our audit of the annual accounts and consolidated accounts, we have also audited the Board of Directors' and the CEO's administration of Clinical Laserthermia Systems AB (publ) for the 2020 financial year, and the proposed appropriations of the company's profit or loss.

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

***Basis of opinions***
We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditors' responsibility* section. We are independent of the Parent Company and the Group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe the audit evidence we have obtained to be sufficient and appropriate to providing a basis for our opinions.

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

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. Among other matters, this includes the continuous assessment of the company's and Group's financial standing and ensuring that the company's organization is conducive to accounting and asset management, and that the company's financial affairs are otherwise satisfactorily controlled. The CEO must manage the ongoing administration according to the Board of Directors' guidelines and instructions and, among other things, take those measures necessary to fulfill the company's accounting in accordance with the legal requirements in place, as well as managing the assets of the company in a satisfactory manner.

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

- has undertaken any action or has been guilty of any omission that could result in liability to the company, or

- in any other manner has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

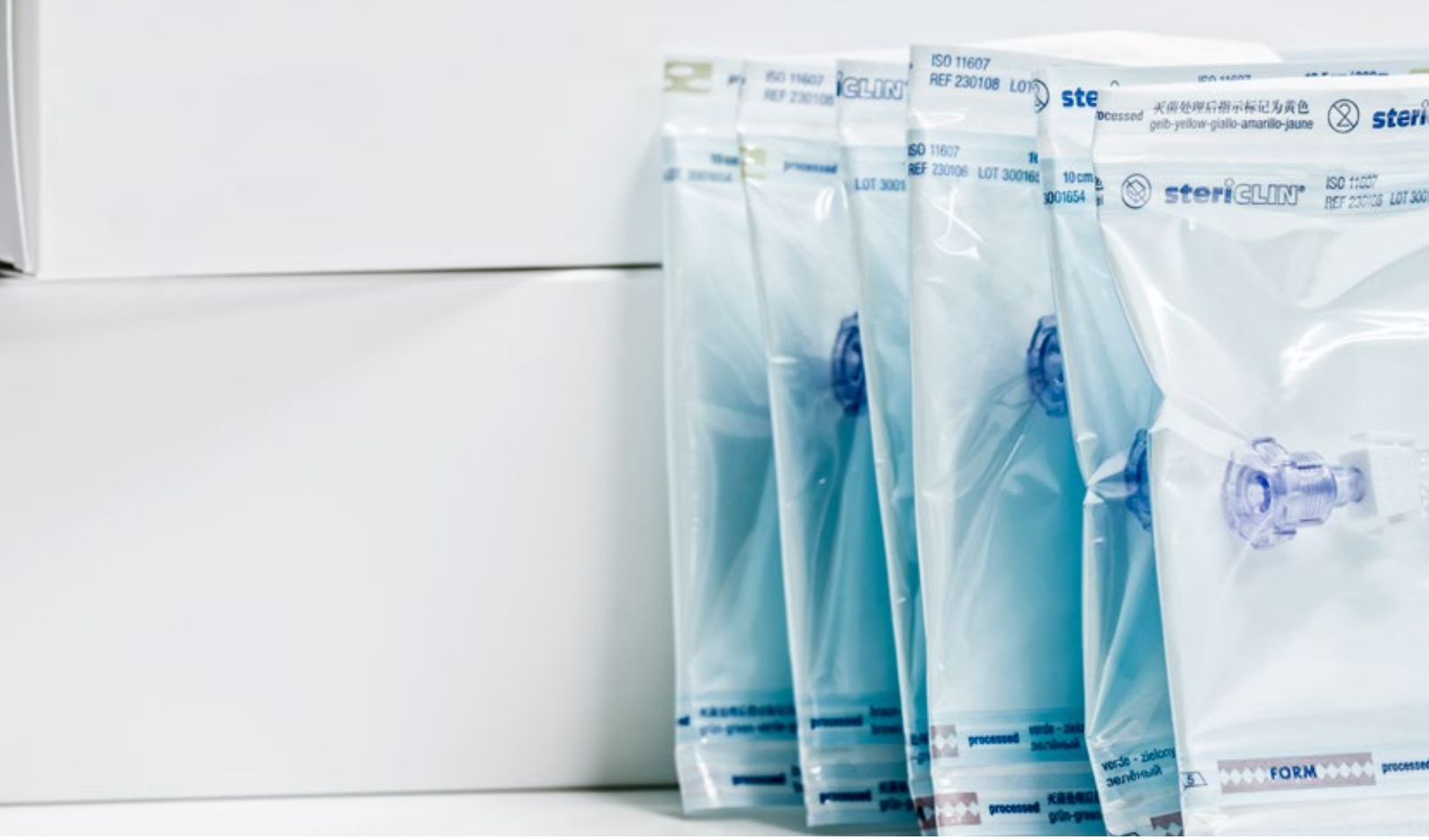
Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's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

A further description of our responsibility for the audit of the administration is available at the Swedish Inspectorate of Auditors' website: http://www.revisorsinspektionen.se/rn/showdocument/documents/rev_dok/revisors_ansvar.pdf.
This description is part of the auditor's report.

Malmö, July 7, 2021

Dillon AB

Oskar Kantoft
Authorized public accountant




# Financial calendar

| | |
|---|---|
| Annual General Meeting | June 28, 2022 |
| Interim report 2/22 January–June | August 25, 2022 |
| Interim report 3/22 January–September | November 17, 2022 |
| Year-end report for 2022 | February 23, 2023 |

CLS's financial reports are available on the company's website. Our financial calendar can also be found there. www.clinicallser.see under IR

# Glossary

| Word/phrase | Definition |
|---|---|
| Systemic therapy | Treatment of specific tumor disease throughout the body. |
| Minimally invasive | Operative method in which open invasive surgery is not used. It signifies use of specially developed instruments with observation of the operative area by scanning technology or similar arrangement. Reduced extent of injury with minimally invasive surgery means that long periods of hospitalization can be avoided. |
| Immunotherapy | Treatment that uses cells or antibodies to strengthen the body's immune system. |
| Metastasized cancer | Cancer that has spread. |
| CE Marking | Market approval in Europe. |
| FDA approval | Market approval in the United States. |
| Chemotherapy | Used to prevent tumor cells from dividing. |
| Laser ablation | Removal of body tissue by killing cells with the heat that arises when high energy from laser light is deposited in the cells. |
| FLA | Focused laser ablation. |
| LITT | Laser interstitial thermal therapy. |
| imILT | Immunostimulating interstitial laser thermotherapy. |
| MRI | Magnetic resonance imaging (MRI scanner). Scanning technique used to detect and classify certain diseases and to guide instruments that are introduced into the body with the aim of taking tissue samples or treating inside the body. |
| Stereotaxis | Use of a computer and imaging technology to create 3D images with high precision. |
| US | Ultrasound scanner. Scanning technique used to detect and classify certain diseases and to guide instruments that are introduced into the body with the aim of taking tissue samples or treating inside the body. |
| MRI fusion ultrasound | The real-time ultrasound image used to guide the user in identifying target tissue and navigating the introduction of a biopsy needle or laser applicator and that has been strengthened with a fusion-guided, graphically enhanced MRI image from a patient's diagnostic session. |
| Image-guided | A procedure performed, usually in a minimally invasive manner, using scanning equipment and specially developed instruments.<br>Images of the inside of the body and the instruments used in the procedure are displayed on the scanning equipment screens. As a result, an image-guided procedure can be monitored and controlled with high precision, without the need for surgery. |
| Focal therapy/treatment | Image-guided ablation for example with laser which is performed to remove a tumor for example in the prostate where as little of the surrounding healthy tissue as possible is removed. To minimize the risk of the cancer returning, a margin of 5-10 mm is often used, depending on organ and type of cancer. |

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