IRRAS ANNUAL REPORT 2020

Improving patient outcomes

Clinical data shows length of hospitalization for chronic subdural hematoma patients decreased by over 50% compared to the US average, from six days with traditional drainage to just under three days with IRRA*flow*. In addition, no recurrent bleeding or complications were observed.

Reducing cost of care

This documented decrease in length of treatment, as well as a reduction in complications associated with legacy treatments, also leads to reduced economic burden on hospital systems and frees up valuable bed space in intensive care units, which is especially important during the COVID-19 pandemic.

1.2

billion USD

Addressable EU and US market for IRRAflow with an annual growth of 8 – 10%. *(se page 11)*

400

million USD

Addressable market for Hummingbird with an annual growth of 6%. *(se page 11)*

Sales presence covering 18 markets. Installed IRRA*flow* systems increased from 27 to 73 during 2020.

7.4

Net sales, SEK Million 2020

Bringing Needed Innovation to Neurocritical Care

Our vision is to make life better for millions of people around the world by improving the standard of care for intracranial bleeding and traumatic brain injury.

IRRAS AB is a global medical device company. By addressing complications associated with common treatment methods in neurocritical care, our solutions are designed to improve patient outcomes and decrease cost of care.

Content

IRRAS AB (publ) is listed on Nasdaq Stockholm (ticker: IRRAS).
For more information, please visit www.irras.com

2020 in brief

Q1

Stronger resources

After securing CE Mark recertification for IRRA*flow* in late December 2019, the EU launch of the product is resumed, and a collaboration with Helsinki University to further study IRRA*flow* is signed. The new COVID-19 pandemic forces us to quickly adjust strategy to better support physicians and patients remotely.

Q2

Successful treatments during escalating pandemic

IRRAS completes a rights issue of SEK 217 million and lists on Nasdaq Stockholm. The COVID-19 pandemic escalates with restrictions on travel and hospital access. Still, patient treatments are completed in the US, Finland, Israel, Kuwait and Portugal.

Q3

First Hummingbird Solo patient treated

CE Mark for IRRA*flow* is extended until 2024, and the first patient is treated with Hummingbird Solo. In both Europe and the US, activity increases as COVID pandemic slows. Patient treatments continue and new clinical evaluations begin. Clinical data shows IRRA*flow* reduces hospital stay by more than 50% compared to traditional methods of treatment.

Q4

Increase of installed units

Purchasing agreement for Hummingbird is signed with US hospital network Premier, and our distribution network further expands to Netherlands, Latin America, Greece, and Southeastern Europe. Year ends with a revenue growth of 40% and with an increase of installed IRRA*flow* systems from 27 to 73.

Key figures 2020

- **Net revenue** amounted to SEK 7.4 million (5.3).
- **Operating loss (EBIT)** amounted to SEK –134.3 million (–151.5).
- **Loss after tax** amounted to SEK –135.9 million (–151.1).
- **Earnings per share** before and after dilution amounted to SEK –2.46 (–5.61).
- **The Board of Directors** proposes that no dividend should be paid.

The Group's available liquidity amounted to SEK 135.6 million at year-end.

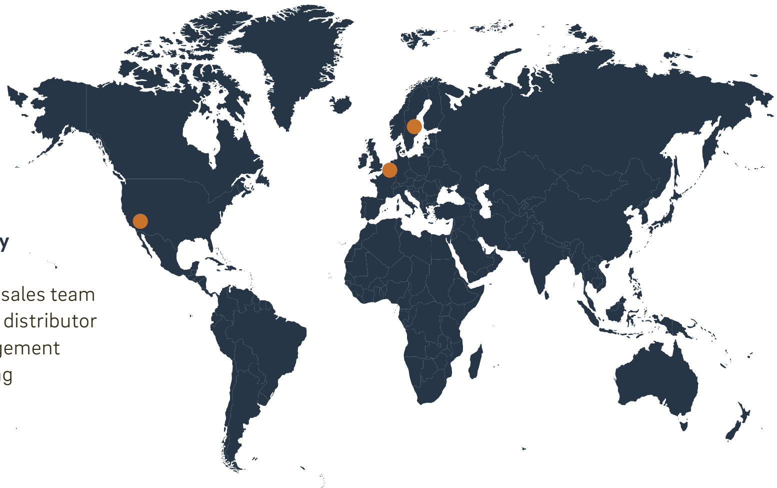
The average number of employees in the Group during the year was 43 (35).

Our locations

Sweden
Stockholm
- Legal headquarters
- Finance
- IT
- IR
- Listed on Nasdaq Stockholm

USA
San Diego, CA
- Sales & marketing
- R&D
- General operations

Germany
Munich
- Direct sales team
- Global distributor management
- Training



Global presence

US
- Company´s direct sales team

Europe
- Company's direct sales team in Germany, Switzerland and the Nordic countries
- International sales management and distribution hub
- Distributors in place for Poland, Spain, Portugal, the Netherlands, Greece, Austria, UK, Italy and South Eastern Europe

The rest of the world, *Asia*
- Registration ongoing in key markets

Latin America
- Key markets covered by existing distribution agreements
- Initial market approvals received in Costa Rica and Argentina and registration ongoing in additional key countries

Middle East, Africa
- Registration ongoing in key markets
- Distributors in place for Israel and Kuwait

Growth and milestones achieved despite COVID-19 resurgence

Despite the far-reaching impact of the global COVID-19 pandemic, 2020 was a year of significant achievements for IRRAS. Even with a reduction in the number of stroke patients, reduced access to hospitals, and prolonged travel restrictions worldwide, our company's development continued, and we achieved a number of important milestones. Our products positively impacted the lives of more patients than ever before. Clinical data was released that confirmed our products' significant advantages compared to currently used technologies. In addition, our European launch of IRRA*flow* began and started to positively impact our growth, and, in the United States, the Hummingbird Solo product was introduced. Moving forward, we expect these positive trends to deliver significant growth as our product launches continue and COVID-related impacts ease.

Significant need for our neurocritical care products confirmed

The aging population is one of the most significant trends worldwide that will ultimately impact our healthcare system. As the population ages, the incidence of stroke and intracranial bleeding conditions will also increase. Chronic subdural hematoma (cSDH) is expected to be one of the most common cranial neurosurgical conditions by 2030, growing by 8–10% annually. As a result of this growth, the treatment for cSDH is also assumed to become the most commonly performed neurosurgical procedure. Our company's vision is to deliver innovative products to improve the lives of this growing group of patients, and, with our IRRA*flow* and Hummingbird product lines, IRRAS is well positioned to improve patient outcomes and reduce the overall healthcare costs.

During the year, research from the University of California - Irvine Medical Center demonstrated that IRRA*flow* shortened the length of hospitalization for cSDH patients by over 50% compared to the US average, from six days with traditional drainage to just under three days with IRRA*flow*. In addition, no recurrent bleeding or complications, such as infection or catheter occlusions, were observed. Furthermore, even with COVID restrictions in place, patient treatment continued as numerous impactful IRRA*flow* evaluations were completed, including at two well-known comprehensive stroke centers, Buffalo General Medical Center and West Virginia University Hospital, in the US, and BGU Kliniken Halle Bergmannstrost in Germany. Feedback from these evaluations reinforced that IRRA*flow* treatment can improve outcomes and reduce complications compared to established treatment methods.

An increasing amount of supporting clinical evidence

A key step in accelerating adoption of any new medical device is the confirmation of its superiority compared to existing treatment methods through the generation of meaningful clinical data. The initial lack of evidence is an expected hurdle early in a product's life cycle, and, during 2020, our company took meaningful steps to expand the clinical evidence base. In addition to the evidence released from UCI that highlighted the clinical utility and reduced treatment time with IRRA*flow*, much work was also done elsewhere to add more clinical data. Following several completed evaluations of IRRA*flow* in 2020, an increasing amount of peer-reviewed manuscripts are planning to be published during 2021 that further document the system's value proposition. Other controlled clinical trials will also be initiated that compare treatment with IRRA*flow* to traditional passive drainage. An expanding pool of available clinical data will enhance our ability to drive widespread adoption of the product, as it will increase product awareness and strengthen our ability to navigate the product approval process at new hospitals.

Reducing the length of stay for patients with intracranial bleeding can also create significant cost savings for hospitals. Currently, 590,000 patients are treated for intracranial bleeding and traumatic brain injury in the US and EU every year. Given the superior performance of our products compared to current standard of care, early data show that we can have a positive impact on both the patients' lives but also on overall healthcare costs as a whole. In Europe and the US alone, we estimate that the total available market for our products exceeds $1.5B each year. Our products are currently the most innovative available treatment methods in neurocritical care, and, in coming years, IRRAS will only have to capture single digit market share of this existing market to exceed our corporate goals.

Driving commercial growth

During 2020, one of our key areas of focus, especially during COVID-19 lockdowns, has been to better prepare the organization for commercial growth. The sales organization has been prepared to generate and support increased demand in the near future. In Europe, new sales leaders have been hired to manage our direct commercial operations in Germany and the Nordic markets. In the US, our recent commercial growth has been focused on adding nurse education specialists to focus primarily on training new customers on using our products.

During the year, restricted travel and hospital access impacted our ability to provide in-person training to our customers, so our IRRAS team developed a comprehensive a set of world-class digital sales and training capabilities. The IRRAS Academy mobile application provides detailed training videos for every aspect of patient treatment and has been downloaded almost 1000 times.

While all of these efforts have been helpful in navigating 2020's challenges, our commercial momentum was still severely impacted by hospital around the world having to shift focus to treating COVID-19. With full-scale vaccination programs starting during the first half of 2021 in most of our markets, we expect things to return to normal by the second half of the year.

Another area in which we have focused our efforts to preparing for future growth is through the continued expansion of our network of distribution partners in markets where IRRAS does not employ a direct salesforce. In Europe, distribution agreements were signed in many key markets, including the United Kingdom, Spain, Italy, Holland, Poland, Serbia, Croatia, and several other markets. Our company has partnered with leading distributors of world-class neurosurgical medical devices in their respective regions, initial customer interest has been confirmed and patient treatment have started in many of these markets. During 2020, IRRAS also established a partnership with a distribution partner that provides access to Latin America for the first time. As of today, IRRA*flow* has received regulatory clearance in Costa Rica and Argentina, and regulatory clearance is also being pursued in multiple other countries in the region. With well-trained distribution partners, stocked with equipment, we are set for accelerated growth as COVID-related restrictions ease throughout 2021.

In August, our chairman Anders P. Wiklund passed away after a short period of illness. Anders was a wonderful person and an exceptional leader who provided so much to IRRAS. He is missed tremendously by me personally and by the entire IRRAS organization.

As we enter 2021, the future prospects of IRRAS look stronger than ever before. Our extensive patent portfolio provides strong protection of our innovative ideas, and the CE Marks for IRRA*flow* and Hummingbird (expected during the first half of the year) will expand the European opportunity for our products. Most importantly, though, the demand for a new standard of care within neurocritical care is higher than ever. We are well positioned to take advantage of this demand and will continue to better the lives of patients all over the world. In the process, as IRRAS contributes to society, we will continue to create shareholder value. We thank you for your continued support and look forward to keeping you updated with our progress.

Sincerely,

Kleanthis G. Xanthopoulos, Ph.D.
CEO

Vision and strategy

IRRAS' vision is to make life better for millions of people around the world by creating medical products that are established as the new standard of care for intracranial bleeding and traumatic brain injury.

In order to achieve this vision, IRRA*flow* and Hummingbird ICP must continue to revolutionize care through significantly improved care outcomes for patients with less time in intensive care and other care settings as well as economic benefits for hospitals and other caregivers.

The company is focused on providing innovative solutions, based on its IRRA*flow* and Hummingbird ICP technologies, for both traumatic brain injuries and hemorrhagic events. Both products were designed with the goal of dramatically improving patient outcomes, reducing patient-time in the intensive care unit, and providing health economic benefits to hospitals and healthcare providers. The following tactics are crucial to IRRAS' growth strategy:

- **Commercializing IRRA*flow* and Hummingbird ICP for neurocritical care** and becoming the market leader for treatment of intracranial bleeding and traumatic brain injury.
- **Strategically building up global sales** through marketing to selected key markets, such as the US and Germany, via the company's own sales organization and through selected distributors in other important markets.
- **Continuing to develop new products** and exploiting the full potential of the IRRAS proprietary platforms in other applications for intracranial treatment as well as other parts of the body.
- **Achieving additional advances in patient care** by developing and acquiring cutting-edge medical technology.

Our core values

IRRAS' fundamental values are characterized by the Greek word *FILOTIMIA* which means respect, honor, team before self, empathy and a sense of purpose.

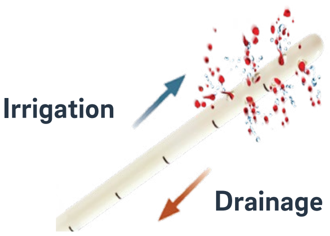
- We are **committed** to better patient outcomes in heart and mind
- We are **innovative** and **constantly improving**
- We remain committed to **win**, but in the **right** way
- We face challenges with **optimism**
- We have the **courage** to push limits

Our products

IRRAS is focused on delivering innovative medical solutions to improve the lives of critically ill patients. IRRAS designs, develops, and commercializes neurocritical care products that transform patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methodologies.

IRRA*flow*

The world's first irrigating intracranial drainage system



Intelligent Digital Pump enables Automated Irrigation

Integrated, Continuous ICP Monitoring

The company's flagship product, IRRA*flow*, is the world's first irrigating intracranial drainage system. Its unique mechanism of action addresses the complications associated with the current methods of managing intracranial fluid by using a dual lumen catheter that combines active irrigation with ongoing fluid drainage. Additionally, IRRA*flow* incorporates ICP monitoring and uses a proprietary software to regulate treatment based on desired pressure levels.

Hummingbird

The next generation of advanced neuromonitoring

Bolt-Based Parenchymal ICP Monitoring

Single Access Multimodal Monitoring with Drainage

Parenchymal ICP Control Module

Cranial Access Kit

The Hummingbird ICP Monitoring System includes proprietary single and multi-lumen cranial access bolts, parenchymal intracranial pressure (ICP) monitoring, and a cranial access kit, which is used for every cranial procedure. Hummingbird Neuromonitoring products help clinicians manage patients suffering from conditions that cause an elevated intracranial pressure, including traumatic brain injury, subarachnoid hemorrhage, and stroke. They are designed for accuracy, reliability, and ease of use, addressing the needs of both the hospital and the patient.

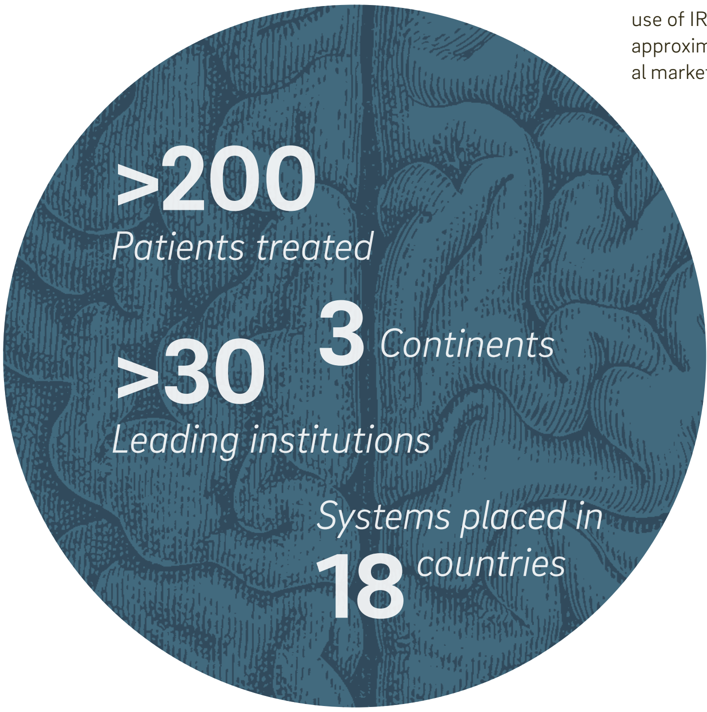
Four reasons to invest in IRRAS

1.

An innovative product portfolio that offers advanced technologies to diagnose and treat neurocritical care patients.

IRRAS' proprietary IRRA*flow* and Hummingbird ICP product families are groundbreaking innovations in neurocritical care.

IRRA*flow* is the world's first irrigating intracranial drain and is the only system that combines controlled drainage, automated irrigation, and integrated monitoring of the patient's intracranial pressure (ICP). Compared with traditional methods of managing excess intracranial fluid, more efficient treatment using IRRA*flow* may result in fewer complications, shorter time in hospital for patients, and overall lower costs for hospitals and caregivers.



2.

A high clinical need means major market potential

IRRA*flow*, the company's lead commercial product, is used to treat patients suffering from hemorrhagic strokes and chronic subdural hematomas, both life-threatening conditions involving intracranial bleeding. In addition to IRRA*flow*, the company's Hummingbird ICP product family also offers an important diagnostic tool to monitor patients' conditions after traumatic brain injury has occurred. This tool is important to determine when intervention with a tool such as IRRA*flow* will be required.

A total of approximately 590,000 patients (200,000 – hemorrhagic stroke, 155,000 – chronic subdural hematoma, 235,000 – traumatic brain injury) are surgically treated for these conditions per year in the US and EU countries alone. The US and EU markets thus amount to more than USD 1.2 billion for intracranial bleeding and another USD 400 million for traumatic brain injury. Additionally, the adjacent field of acute subdural hematomas caused by trauma is an additional market segment where there is potential for the use of IRRA*flow*. In the US and EU, the number of cases are approximately 130,000 per year, which indicates an additional market potential worth approximately USD 420 million.

3.

A scalable business model with favorable margins

IRRA*flow* consists of a control unit (the hardware) and consumables (catheters and tube sets) which generate continual revenue.

The margin on these products is excellent. Procurement of the system is financed through the public healthcare sector and insurance companies.

Additionally, Hummingbird utilizes a control unit (hardware) and consumables (various bolts and neuromonitoring catheters) to employ the same razor-razorblade model with attractive margins.

4.

Global coverage

The company's products are sold through its own direct sales and marketing organization in in key markets in Europe and the US. The company's own sales channels in key markets are complemented by a global network of distribution partners.

The need for a new standard of care

IRRAS initial clinical focus areas are neurosurgical treatments that require the drainage of excess cerebrospinal fluid (CSF) and monitoring and regulation of intracranial pressure (ICP). The treatments are often needed after patients experience hemorrhagic strokes (bleeding in the brain), chronic subdural hematoma (blood collection on the surface of the brain), or traumatic brain injuries (TBI) (violent blow or jolt to the head or body).

Early data indicates that the IRRA*flow* and Hummingbird ICP technologies offer significant treatment advantages over conventional ICP monitoring and drainage tools when treating these serious brain pathologies.

IRRA*flow*, the company's lead commercial product, is used to drain fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematomas. Both conditions have high rates of mortality. IRRA*flow* addresses complications that often arise from current treatment methods and can become the new standard of care. Simultaneously, the Hummingbird ICP Monitoring family of products offers an important diagnostic tool to monitor patients' conditions after traumatic brain injury. This tool determines when intervention with a therapeutic tool, such as IRRA*flow*, is required. It is also more accurate and easier to use than other ICP monitoring systems.

A high clinical need

When intracranial bleeding is seen, it is most often in the form of hemorrhagic stroke or chronic subdural hematoma. Approximately 355,000 patients per year are treated for these conditions in the US and EU countries alone. These markets thus amount to roughly USD 990 million per year.[1] There are also important markets outside the US and EU, such as Japan, China, Brazil, and Australia, with well-functioning health insurance systems that offer further opportunities.

The adjacent field of acute subdural hematomas caused by trauma is another potential market segment for IRRA*flow*. In the US and EU, the number of such acute cases is approximately 130,000 per year, which increases the market potential by roughly USD 420 million. This leads to a combined market opportunity for intracranial bleeding of USD 1.4 billion every year.[2]

In addition to these occurrences of intracranial bleeding each year, there is also a sizable market opportunity for patients that experience a brain injury but do not need to have collected blood drained. Of the 69 million people who experience a traumatic brain injury each year, 5.4 million occur in IRRAS' initial target markets of the US and EU. 1.3 million of these injuries require hospitalization, and 20% require ICP monitoring. 90% of this ICP monitoring is invasive. The potential treatment of these 235,000 patients equals an additional USD 400 million in market opportunity.

Life-saving treatments

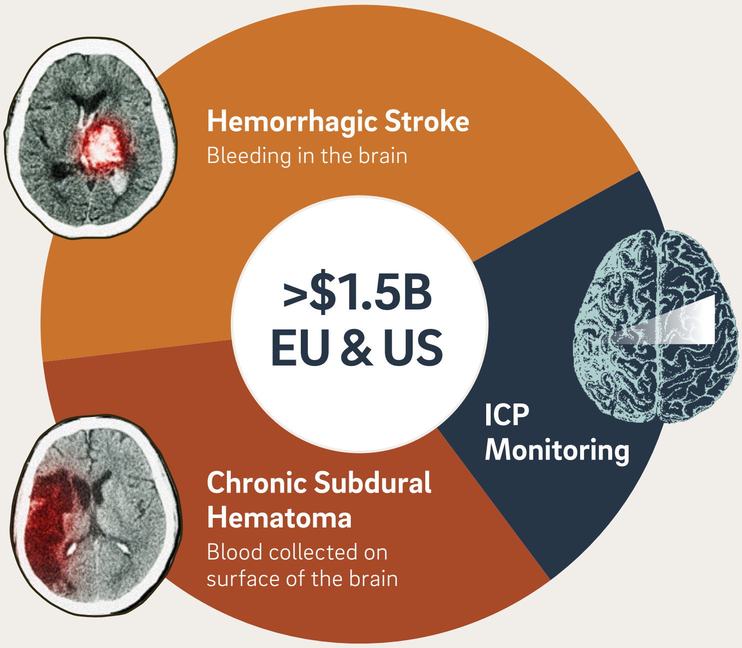
After a brain injury occurs or an intracranial blood vessel ruptures, an increase in ICP can cause harmful effects on the brain. Increased ICP is the most common cause of death in neurosurgical intracranial pathologies. Without treatment, the result may be moderate to severe brain damage or death. Thus, an immediate assessment of the patient's ICP is required. If an increase in intracranial pressure occurs, it must be reduced rapidly. The surgical intervention to reduce intracranial pressure by draining the collected fluid is usually performed on an emergency basis. The optimal treatment strategy can only be determined after the pressure has been reduced. Continual ICP monitoring is critical to understand how the patient is responding to treatment.

Traditional treatment options for intracranial bleeding and chronic subdural hematoma

Treatment for intracranial bleeding is generally performed with an external ventricular drain (EVD). This passive system relies on gravity alone to drain excess fluid in an attempt to reduce ICP. An EVD catheter is inserted through a small burr hole in the patient's cranium, which evacuates blood and collections of fluid to an external drainage bag. The drainage rate is controlled by changing the bag's height relative to the tip of the catheter inside the cranium.

Although an EVD is currently the most common treatment option for intracranial bleeding or elevated ICP, the technology is associated with several well-known complications such as catheter blockage, infections, excess drainage, and secondary bleeding, any or all of which can result in a negative impact on patient outcome. It is also known that EVDs can lead to incomplete drainage and extended treatment times.

Sizable Neurocritical Care Market Opportunity



Intracranial Bleeding >$1.25B

8–10% CAGR[1), 2), 3), 4)]

Hemorrhagic Stroke

9 – 27% of all strokes[6), 7)]

~200k Surgically operated, EU & US[2)]

40% of stroke deaths[8)]

Chronic Subdural Hematoma

30% of fatal head injuries

155k Surgically operated, EU & US[2)]

Traumatic Brain Injury $400M

6% CAGR[5)]

5.4M EU & US brain injuries each Year[10), 11)]

~1.3Mk Hospitalizations annually[10), 11)]

~20% require ICP monitoring[12)]

~90% of monitoring is invasive[12)]

1) http://www.strokecenter.org/patients/about-stroke/stroke-statistics/
2) Market data from L3 and internal analysis. Combination of incidence rates combined with market specific DRG data.
3) Neuroscience Intensive Care Unit, Department of Neurosurgery, Mount Sinai School of Medicine, New York, NY, USA Report: National trend in prevalence, cost, and discharge disposition after subdural hematoma from 1998–2007
4) Estimates are based on total amount of hemorrhagic stroke and chronic subdural hematoma cases in the EU and US. Number of cases multiplied by an average charge of EUR 2,600 for IRRAS per set of disposables (one set of disposables required per case). Market potential excludes control unit.
5) Dewan, Michael & Rattani, Abbas & Gupta, Saksham & Baticulon, Ronnie & Hung, Ya-Ching & Punchak, Maria & Agrawal, Amit & Adeleye, Amos Olufemi & Shrime, Mark & Rubiano Escobar, Andres & Rosenfeld, Jeffrey & Park, Kee. (2018). Estimating the global incidence of traumatic brain injury. Journal of Neurosurgery. 130. 1–18.
6) https://www.cdc.gov/stroke/types_of_stroke.htm
7) Steiner, T., Salman, R. A.-S., Beer, R., Christensen, H., Cordonnier, C., Csiba, L., … Wagner, M. (2014). European Stroke Organization (ESO)
8) https://www.stroke.org/understand-stroke/what-is-stroke/hemorrhagic-stroke/
9) http://neurosurgery.ucla.edu/acute-subdural-hematomas
10) Centers for Disease Control and Prevention (2019). Surveillance Report of Traumatic Brain Injury-related Emergency Department Visits, Hospitalizations, and Deaths—United States, 2014. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.
11) Center-TBI EU Traumatic Brain Injury Fact Sheet and Policy Brief
12) Market Study Report, Global Intracranial Pressure (ICP) Monitoring Devices Market Growth, 2019–2024.

Next-generation treatment with IRRAflow

IRRA*flow* significantly advances the treatment as it is the only system that integrates drainage, targeted fluid irrigation, and measurement of intracranial pressure into one product. The system uses automated irrigation to ensure continuous drainage and reduce the occurrence of catheter blockage, which can also lower the risk of infection during treatment.

The efficacy of IRRA*flow*'s active fluid exchange has been demonstrated so far in patients in Greece, India, Germany, Finland, Hong Kong, Kuwait, Israel, Portugal, and the US. In these cases, treatment times have been reduced compared to EVD treatment. No incidences of catheter occlusion have been seen when IRRA*flow*'s irrigation has been active.

Traumatic brain injury – head injury that impairs brain function

A traumatic brain injury (TBI) is a blow to the head or a penetrating head injury that disrupts normal brain function. TBI can result when the head suddenly and violently hits an object or when an object pierces the skull and enters brain tissue. Symptoms can be mild, moderate, or severe, depending on the extent of damage to the brain. Mild cases may result in a brief change in mental state or consciousness. Severe cases can result in extended periods of unconsciousness, coma, or even death.

IRRAS acquired the Hummingbird ICP family of neuromonitoring products in 2019 to offer its customers the opportunity to monitor ICP after a traumatic brain injury. After launching the product line in the US in 2020, the company now provides a more extensive product portfolio across the entire spectrum of neurocritical care.

Traditional diagnosis options for traumatic brain injury

In traumatic brain injury, the main goal after the primary impact damage has been inflicted is to prevent any secondary injury to the brain. This secondary injury is often caused by increased pressure that harms an otherwise sensitive and

vulnerable brain. The key to avoiding secondary injury is maintaining normal or slightly elevated blood and intracranial pressure levels. Various ICP monitoring devices can assist health care personnel in assessing a patient's condition and determining their need for care.

Placement of an ICP monitor into the brain can help detect excessive swelling of the brain and increased intracranial pressure.

When calculating ICP with competitive systems, the lack of continuous calibration can result in unprecise ICP values. The difference between the starting ICP value when the sensor is initially calibrated, and the ICP value that is measured when the sensor is removed is called "drift." A large difference between these two values means that the indicated ICP measure was not the "true" ICP at any time while the device was implanted in the patient. The cumulative pressure difference can have important implications for the treatment and prognosis of the patient.

Next-generation treatment with Hummingbird ICP Monitoring

The Hummingbird ICP Monitoring family of products offers both single and multi-lumen bolts that meet the need for brain monitoring to diagnose traumatic brain injury.
The Hummingbird products accomplish this by using an air bladder to measure ICP with a mechanism that effectively recalibrates the system on an hourly basis without requiring the use of a large piece of capital equipment. This allows the system to operate for extended periods with virtually no drift. The system is also relatively easy and intuitive to use and setup.

The accuracy and simplicity has led to a positive initial reaction in the US to the launch of the Hummingbird product line. The launch progress was slowed due to the COVID-19 pandemic, but, during the 4th quarter of 2020, a purchasing agreement was signed with the Premier network of approximately, 4,000 US hospitals, which will help to accelerate progress moving forward. Additionally, during Q3 2020, the Hummingbird Solo line extension was launched, which will compete directly with market-leading parenchymal ICP monitoring systems. Finally, the company expects that CE Mark certification of the Hummingbird product line will be finalized during 2021, which will expand the revenue-generating capabilities of the product line.

Well-established payment models

Medical devices used by caregivers are usually financed by insurance companies or public payment systems. In the US and many European markets, both IRRA*flow* and Hummingbird are paid via an established DRG system, a classification of the hospital's compensation for a procedure. The payment is based on resource usage, the length of the hospital stay, and the medical devices' costs.

Depending on the treatment, an average DRG payment in Germany, the largest EU market, can reach EUR 36,700. Approximately EUR 4,000 of this payment can be earmarked for IRRA*flow*'s single-use disposables or EUR 500 – EUR 2,000 for Hummingbird's single-use disposables. The hospital is typically responsible for the investments of small pieces of capital equipment for both systems.

In the US, caregivers are paid directly by patients and various public and private third-party payers, including federal Medicare, state-run Medicaid, and private health insurance policies. The average DRG payment can range from USD 35,000 to USD 50,000, depending upon procedure complexity.

Regulations and requirements

A high level of product safety driven by requirements for regulatory compliance and oversight by regulatory authorities and supervisory bodies is fundamental to medical devices.

National regulations in Europe are based on the joint safety and functionality requirements of the EU directives, regulations and ordinances regulating medical devices. Products must be CE certified to confirm that they comply with these regulatory requirements. A product that has been evaluated and given CE certification in one country has access to nearly all of the entire EEA market. IRRA*flow* received its latest CE Mark certification in December of 2019. The company has also submitted the needed paperwork to support CE Mark of the Hummingbird system under the new Medical Device Regulation (MDR). The company projects to have that in place this during 2021.

The FDA provides the corresponding approval for sales and marketing in the US. Both IRRA*flow* and Hummingbird have been cleared for use in FDA regulated markets, including the US. Many countries in Asia, Latin America, the Middle East, and Africa are not subject to CE marking or FDA approval. Instead, they have other registration processes that sometimes include direct registration.

Dr. Horace Mitchell, 76 – treated with IRRA*flow*

Dr. Horace Mitchell, 76, is a retired president of California State University Bakersfield. Normally, he is healthy and leads a very active life, but, last year, he fell in his home and hit the back of his head. Since it was a mild injury, Dr. Mitchell didn't think much of it, but, after several weeks, he started noticing that something was wrong.

"I have always been very outgoing, my wife noticed that I got somewhat withdrawn and I felt weak in my legs," says Dr. Mitchell.

Without him knowing it, the accident had resulted in a subdural hematoma, which occurs when a blood clot under the outermost layer of the brain grows and puts pressure on the brain. Typical symptoms are headaches, weakness, seizures and slurring of speech. Subdural hematoma is one of the most common medical issues for older people. As we age the brain shrinks which can cause the veins attached to the outer layer to bleed. Most often it is caused by trauma, and even a mild bump to the head is sometimes enough.

"It got to the point where I had to go to the emergency room," continues Dr. Mitchell.

Initially the cause of his symptoms wasn't diagnosed correctly, and he was given antibiotics. When the symptoms didn't disappear, he finally got the right diagnosis by Dr. Sumeet Vadera at the UCI Medical Center.

"I immediately saw that Dr. Mitchell was the ideal candidate for a treatment with IRRA*flow*," says Dr. Vadera. "We made an incision to drain as much blood as we could."

"In Dr. Mitchell's case we could shorten the hospital stay to only a day and a half instead of the usual six days with traditional hematoma removal. Through the treatment with IRRAflow the risk of a clot recurring was also significantly reduced"

While traditional treatment methods frequently run into problems such as catheter blockage, IRRA*flow*'s integrated system with automated irrigation lowers that risk which also reduces the risk of infection during the treatment.

"In Dr. Mitchell's case we could shorten the hospital stay to only a day and a half instead of the usual six days with traditional hematoma removal. Through the treatment using IRRA*flow* there is also a risk of a clot recurring is also significantly reduced," says Dr. Vadera.

Dr. Mitchell felt no pain after the surgery and returned home the day after. He says he is now back to normal and enjoying life.

"It felt very good to be able to pick up my tennis racket, go out and hit some balls and enjoy it. I have also been getting to see people that I haven't seen for a while. For me it feels like being back and being more myself than I have been for a while!"

Looking inside the black box

"Brain physiology can be very complex," he notes.

The University of New Mexico (UNM) Hospital has been a valued partner throughout the development process of the Hummingbird system to monitor patients' intracranial pressure (ICP). UNM is one of the world's leaders in multi-modal monitoring where a variety of intracranial parameters are measured simultaneously to more thoroughly assess a patient's condition after stroke or traumatic brain injury.

To date, UNM's experience with Hummingbird in its state of the art 24-bed Neuroscience Intensive Care Unit has produced the clinical data that has been published to date on the system, and their customer feedback has played a key role in the product's development.

UNM Assistant Professor of Neurosurgery Dr. Andrew Carlson is extremely experienced with the Hummingbird Quad system, which allows the measurement of ICP and three other functions through a single access site. He also recently became the first neurosurgeon in the world to use the latest addition to the product line, Hummingbird Solo, which is used to measure intracranial pressure for patients with risk of elevated pressure in the skull that can occur due to intracranial bleeding or traumatic brain injury.

While the IRRA*flow* system drains excess blood and fluid from the skull, Hummingbird is designed to assess and monitor the extent of brain injury.

"A slender sensor that is the width of a pencil tip is inserted through a single drilled hole in the skull to monitor intracranial pressure, spinal fluid, blood oxygen levels, and other factors. It's extremely easy to put in," said Dr.Carlson about the device.

Neurocritical care patients must be monitored closely for elevated intracranial pressure, a potentially lethal condition in which excess fluid and swelling inside the skull damages fragile brain tissue. Pressure monitoring takes on added importance when a patient is in a coma and unable to undergo conventional tests for neurological functioning. Such a situation creates a challenging environment where it can be difficult to ensure that all necessary data points are collected.

"Brain physiology can be very complex," he notes. "It can be hard to sort out if someone has too much blood flow or not enough blood flow, or if they have swelling. Treatments might be very different depending on all of those factors," and the Hummingbird system can ensure that these measurements are providing the needed information for treatment decisions.

"It's a way to look inside the black box," concludes Dr. Carlson.

Meaningful Progress during Unprecedented Times

During a year filled with unexpected challenges, there was progress on multiple fronts. Product awareness, clinical data, and treatment experience accelerated during the global launch of IRRA*flow* and the US launch of Hummingbird.

Throughout 2020, the impact of the COVID-19 pandemic challenged the IRRAS commercial activities. Regardless of these disruptions, meaningful progress was still accomplished. Successful evaluations were completed at important stroke centers in the US, the company's network of distribution partners expanded, and the global system installed base increased throughout the year, setting the stage for accelerated growth in future quarters.

Need for IRRA*flow* technology confirmed

Legacy technologies, known as external ventricular drains (EVD), are considered the gold standard for draining excess fluid and monitoring intracranial pressure (ICP) after a hemorrhagic stroke or traumatic brain injury. However, EVDs have not evolved much over time. In fact, the basic concept to use passive, gravity-driven drainage was first introduced in 1744 by Claude-Nicolas Le Cat. During the initial introduction of the IRRA*flow* system's in the US, the previously minimal innovation led to a favorable reception due to the system's unique mechanism that combines ICP monitoring, automated irrigation, and controlled fluid drainage.

Navigating Rapidly Evolving Conditions

After beginning the commercial release of IRRA*flow* in the United States in 2019, IRRAS' commercial organization expanded its efforts in early 2020 to include the US launch of Hummingbird and the introduction of IRRA*flow* into the EU. During Q1, it became apparent that 2020 would become a year unlike any other. As COVID-19 began to significantly impact both the US and EU, IRRAS had to adjust its commercial strategies accordingly.

During late Q1 and throughout Q2, pandemic regulations increased with lockdowns imposed by local government. As a result, travel was restricted, and normal sales activities were no longer possible as hospitals eliminated outside access.

During this time, IRRAS slowed the growth of its direct sales force. Instead, focus changed to adding neurocritical nurse education specialists to provide product training and nursing support during evaluations.

Additionally, the company ran a digital customer engagement campaign to continue to drive brand awareness. Finally, a key strategic decision was made to focus commercial efforts on expanding and training European distribution partners.

Even though direct connection with customers was disrupted, initial product shipments and virtual training with IRRAS' distributors in new European markets continued. Thus, the company is in a better position for post-pandemic growth.

As COVID-related restrictions were eased in Q3, normal commercial efforts began to resume. During this time, revenue growth correspondingly increased, and new customers in the US and Europe began product evaluations. Successful evaluations were completed at multiple influential stroke centers in the US. Patient treatments and revenues were initiated in Germany, Denmark, and Sweden. Additionally, a key hospital purchasing agreement was signed for the Hummingbird product line in the United States.

During the second half of the Q4, a new wave of COVID-19 variants impacted the US and EU again and caused another series of lockdowns. Commercial activity was again negatively affected, especially as travel was stopped within Europe. In spite of the impact from COVID-19, the annual revenue still grew by 40% from 2019 to 2020.

The company is watching this latest wave of restrictions closely. However, its confidence remains high that the work that was completed during 2020 has put IRRAS in a position to navigate this situation and expand its impact on patients around the world.

Commercial Strategy Moving Forward

Intracranial bleeding and traumatic brain injury are global problems that continue to grow as the population ages, and

cardiovascular disease progresses. Accordingly, IRRA*flow* can become a new standard of care for treatments worldwide, with a market opportunity of USD 1.5 billion.
To take advantage of the significant opportunity, IRRAS remains focused on building consistent usage and strong product support in its initial markets and key hospitals before more rapid expansion. This strategy of "going deep before going wide" ensures that the system has a strong foundation to build on moving forward.

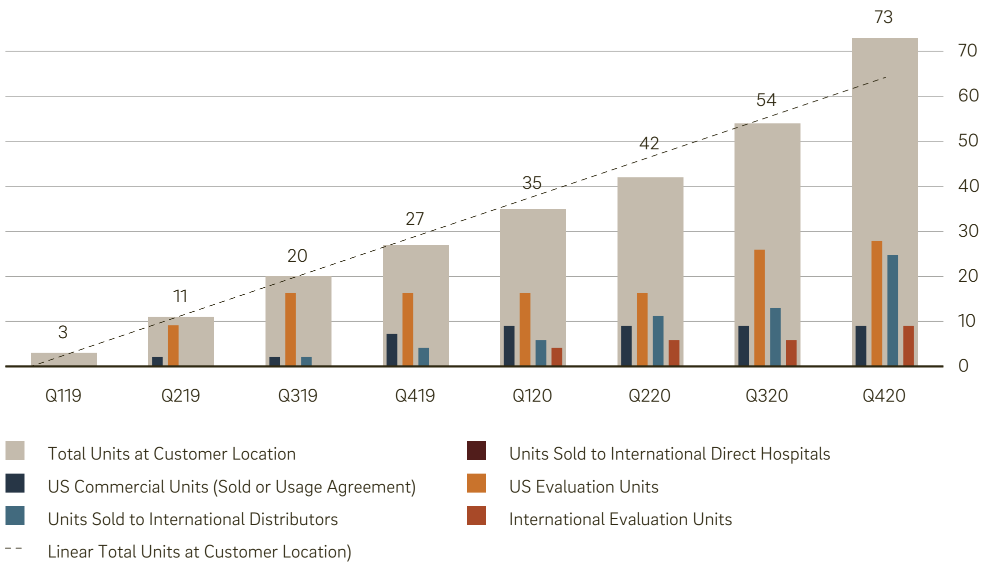
IRRAS continues to view the EU and US as its key markets. These markets have the most potential patients, combined with well-established health care systems and high demands for innovative medical device solutions. They also have attractive end-user price points and attractive reimbursement levels. The company's products are supported by favorable, established reimbursement levels for patients with traumatic brain injury or hemorrhagic stroke. Procurement of the systems is primarily financed through the public sector and insurance companies.

In the United States, the approval process at new hospitals can take more than six months. This extended timeline is especially applicable to new technology in the current situation where hospital treatment volumes are down, budgets are strictly scrutinized and hospitals are likely to favour different placement agreements for IRRAS control units over a capital purchase. Despite this process, the company continues to generate patient treatment experience and clinical data to build its key opinion-leading neurosurgeons network and the story about reducing length of stay in the ICU is more impactful than ever.

Although the COVID pandemic negatively impacted the number of new customers added by IRRAS, the company exited the year with six sales professionals and three nurse education specialists in the US. Also, the commercial efforts were strategically focused in areas where access and interaction remained possible.

While overall commercial growth during 2020 was slower than initially projected due to COVID-19, IRRAS is ready for meaningful growth in 2021. Recently completed hospital evaluations in the US will shortly convert to commercial customers, and additional evaluations will start or resume as restrictions are lifted.

IRRA*flow* Global Install Base



In Europe, similar progress has been seen. Five sales professionals and one training manager are currently responsible for driving business and supporting the distribution network in the direct markets of Germany and the Nordic countries. The product approval process is underway at approximately ten German hospitals. Key hospitals throughout other European markets, including Sweden, the United Kingdom, Holland, Portugal, and others, have completed IRRA*flow* training. These markets will initiate patient treatments as conditions return to normal in 2021. While travel has been difficult, our distribution partners' network has grown significantly, and training has continued.

At the end of 2020, active distribution relationships had been established with partners in the United Kingdom, Portugal, Spain, the Netherlands, Poland, Austria, Italy, Greece, and countries in Southeastern Europe, including Serbia and Croatia.

As more product advocates are identified, the number of IRRA*flow* and Hummingbird treatments performed are expected to continue to increase. IRRA*flow* received recertification of its CE Mark in December 2019. IRRAS has since completed the process to extend its certification for IRRA*flow* until May 2024. The extension ensures product availability to support growing adoption, even as the regulatory landscape changes in the EU. The company has also submitted the needed paperwork to receive the CE Mark certification for the Hummingbird product family. The company expects approval to market the product line in Europe during 2021.

Both the IRRA*flow* and Hummingbird product lines combine a small, intelligent piece of capital equipment with high-quality, innovative consumables. Its customers include a growing number of hospitals that offer neurocritical care. The procurement model is similar to a traditional razor/razorblade model. Capital equipment is acquired through upfront purchase or placement, while most of the revenue comes from continued disposable sales.

Due to the similarities and how the products complement each other, the IRRAS direct sales team can effectively sell both IRRA*flow* and Hummingbird in both the US and Europe.

To be prepared for the product's European commercial release, the company is also adding Hummingbird to selected distribution partners' product portfolios.

The Rest of the World

While most of IRRAS's efforts thus far have focused on the US and Europe, the company has also selectively started to establish business relationships in other important markets. During 2020, patient treatments continued in Israel and Kuwait. The first revenue-generating IRRA*flow* systems were also shipped to Latin America to support launches in Costa Rica and Argentina.

IRRAS will continue to target markets outside the EU and US through select distributors established in the neurosurgical segment. This approach ensures quick access to important markets in other parts of the world, with the same detailed focus on education, training, and patient outcomes seen in the company's direct sales markets.

In 2020, IRRAS initiated the Medical Device Single Audit Program (MDSAP) process. This process will confirm that the company's quality management system meets the strict thresholds needed to support regulatory approval in Brazil, Japan, Australia, and Canada. Distribution partners have already been finalized in Brazil and Australia. Together with its respective distributors, IRRAS drives the approval process in countries where regulatory approval has not yet been received.

Driving to Deliver Impactful Clinical Data

With disruptive products, such as IRRA*flow*, it is vital to continually expand the pool of evidence that differentiates the product from legacy treatments. During 2020, IRRAS established meaningful partnerships with leading neurosurgical hospitals, including Helsinki University Hospital and Karolinska Institute, to use IRRA*flow* and capture associated clinical data. With these partnerships moving forward, impactful clinical data to support IRRA*flow* will continue to be published in peer-reviewed scientific publications.

An example of such clinical data was presented this year by Dr. Jordan Davies, from the University of California Irvine (UCI) Medical Center, at the 18th Annual Meeting of the Neurocritical Care Society (NCS). He presented a poster that showed that the IRRA*flow* system safely treats chronic subdural hematomas while also decreasing complications, bleeding recurrence, and length of hospitalization. Dr. Davis' research stated that "Novel, continuous irrigation and drainage of the subdural space following chronic subdural hematoma evacuation is safe and shows decreased recurrence, complications, and length of stay." This research documented UCI's treatment of six chronic subdural hematoma patients using the IRRA*flow* system. The research shows that patients experienced no complications or bleeding recurrence. They were only hospitalized for an average of 2.83 days, which is less than half of the United States' national average of six days.

A Pipeline of Innovative Products

IRRAS performs its research and development in San Diego, California, a well-known center for developing innovative solutions in the life science industry. Development is mostly conducted with the company's own resources. It focuses on expanding the applications and areas of use for IRRA*flow* and Hummingbird in collaboration with clinicians.

During 2020, the company launched a laser pointer that facilitates the correct alignment of the IRRA*flow* control unit with the catheter position in each patient's skull. For the first time, patients were also treated with Hummingbird Solo, a single lumen ICP monitoring probe. It allows IRRAS to target the ICP monitoring market more broadly in the EU and US, worth approximately USD 400 million. Critical development was also completed on a more stable IRRA*flow* catheter, and the next IRRA*flow* control unit was completed.
This updated control unit will add the ability to communicate with the central nursing station. It will also add interactive training software and allows positioning of the system's drainage bag at a greater variety of heights based on the clinical setting.

IRRAS plans to add a larger IRRA*flow* catheter for draining large amounts of fluid from subdural hematomas, updated packaging, and line extensions to the Hummingbird product line in the near future. On a longer time horizon, the company plans to combine the functionality of both the IRRA*flow* and Hummingbird product lines.

Production of both product lines is driven and continuously monitored by the product development team. During the year, IRRAS began to consolidate its manufacturing partners. The company also took steps to bring the IRRA*flow* control unit's manufacturing and final distribution of its products in-house. These are essential steps to improve the company's margins while also improve controlling quality throughout the process.

Well-Protected by Robust IP Portfolio

IRRAS' broad patent portfolio protects the underlying technologies used in the IRRA*flow* and Hummingbird ICP Monitoring product families. For IRRA*flow*, the patent protection focuses on the system's combination of irrigation and drainage to keep the system free from catheter blockages. It also protects the potential future areas of use, such as infection, orthopedics, the abdomen, drug delivery, and cancer. With Hummingbird, the protection consists of multiple patent families covering the unique method for accessing and monitoring brain tissue with an air-based approach.
This protection protects the company's products through 2038. The IP-portfolio is continually reviewed as new patent opportunities arise through development projects in progress.

Robust Intellectual Property Portfolio until 2038

3 patent families protecting the IRRA*flow* franchise:

- Method of use and function for fluid exchange catheter
- Methods for unblocking fluid exchange catheter
- Alternative uses for dual-lumen catheter
- Updated enhancements for IRRA*flow* 2.0 system

Foundational patent protection includes the following status:

- Alternative uses for dual-lumen catheter
- Updated enhancements for IRRA*flow* 2.0 system
- Patents Issued:
  - 3 (US), 36 (EU), Additional patents in Japan, Australia, Russia, Canada, India
- Patents pending:
  - 3 (US), 2 (Outside US)

5 patent families protecting the Hummingbird franchise:

- System and methodology for intracranial access and to direct monitor probe into healthy brain tissue
- Manual and automatic air management for detecting ICP
- Air-based catheter approach

Patent protection for multiple applications includes the following status:

- Patents Issued: 5 (US), 2 (Outside US)
- Patents pending: 3 (US), 4 (Outside US)

The share

Since May 20, 2020, IRRAS' share has been listed on Small Cap, Nasdaq Stockholm after having been listed on First North Premier Growth Market since 2017. During the year, the share price fell, and the number of shares traded increased. At year-end, IRRAS had 3,201 shareholders.

Market capitalization and turnover

The final share price on December 31, 2020 was SEK 8.35, which gave the company a market capitalization of MSEK 553.

As of March 19, 2021, the last payment price was SEK 6.38, which gave a market value of MSEK 423. During the financial year 2020, an average of 261,409 shares were traded per day. A total of 65.9 million IRRAS shares were traded in 2020 at a value of MSEK 499. The price decline in 2020 amounted to 64 percent. During the year, the OMX SPI Index rose by 13 percent.

Share capital

As of December 31, 2020, the share capital of IRRAS amounted to SEK 1,988,440.20, distributed on 66,281,340 shares with a quota value of SEK 0.03 per share. This is an increase during the year of 37.5 M shares. IRRAS has only one class of shares and all shares have equal rights to shares, and all company's assets and profits.

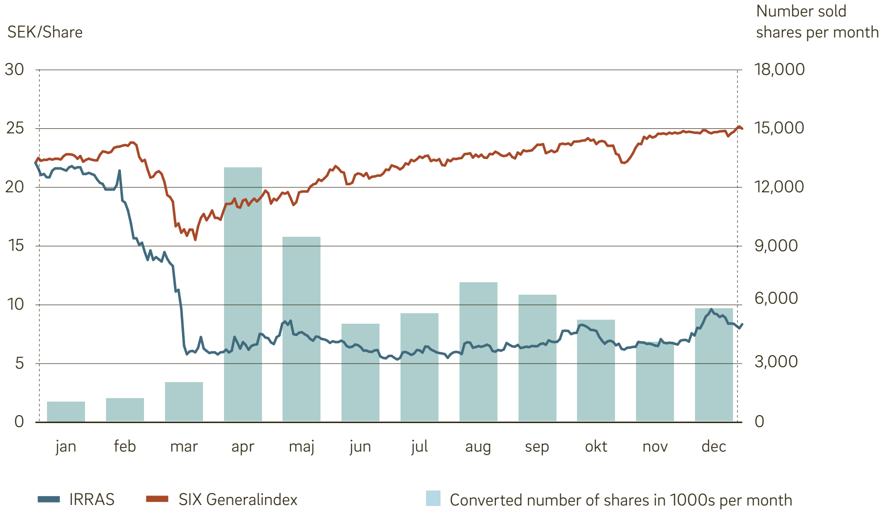
Shareholder agreement

The Board of Directors of IRRAS is not aware of any shareholder agreements or other agreements between the company's shareholders, which are intended to have joint influence over the company. The Board also does not know of any agreements or similar that may change the control over the company.

Dividend and dividend policy

The Board of Directors of IRRAS has proposed to the Annual General Meeting that no dividend be paid for the financial year 2020. Before a positive cash flow is achieved, the Board does not intend to propose to the AGM that a dividend be paid.

IRRAS SHARE PRICE 2020-01-01 – 2020-12-31



Source: Web Financial Group

SHAREHOLDERS AS OF DECEMBER 31, 2020 AND THEREAFTER KNOWN CHANGES

	No of shares/ votes	Percent
Bacara Holdings Limited	16,234,097	24.49%
Fourth National Pension Fund	6,139,362	9.26%
Lexington Holding Assets Ltd	3,155,727	4.76%
Carl-Olof and Jenz Hamrins Foundation	3,000,000	4.53%
Christos Panotopoulos	2,744,000	4.14%
March Asset Management	1,380,449	2.08%
Dr. Kleanthis G. Xanthopoulos	1,101,498	1.66%
Avanza Pension	938,014	1.42%
Lovisa Hamrin	849,024	1.28%
Deka Investments	551,592	0.83%
Other shareholders	30,187,577	45.54%
Total number of shares	**66,281,340**	**100.00%**

TABLE OF HOLDINGS

Holdings	Number of shareholders
1–500	1,857
501–5 000	726
5 001–100 000	582
100 001–500 000	26
500 001–	10
Totalt	**3,201**

DEVELOPMENT OF SHARE CAPITAL

As per November 21, 2011, the company's registered share capital totaled SEK 50,000, divided between 50 shares, each with a par value of SEK 100. Since then, the share capital has undergone the following changes:

Year	Transaction	Increase in share capital	Increase in number of shares	Share capital, total	Number of shares	Par value, SEK
2011	Foundation	50,000	10,000	50,000	10,000	5.00
2013	New share issue[1)]	9,180	1,836	59,180	11,836	5.00
2016	Share split	–	11,824,164	59,180	11,836,000	0.005
2016	New issue[2)]	18,250	3,650,000	77,430	15,486,000	0.005
2016	Change of convertibles[3)]	8,657	1,731,419	86,087	17,217,419	0.005
2017	Bonus share issue	430,435.48	–	516,522.57	17,217,419	0.03
2017	New issue[4)]	193,333	6,444,444	709,855.89	23,661,863	0.03
2018	New issue[5)]	10,683.33	356,111	720,539.22	24,017,974	0.03
2019	New issue[6)]	144,000.00	4,800,000	864,539.22	28,817,974	0.03
2020	New issue[7)]	1,123,900,98	37,463,366	1,988,440,20	66,281,340	0.03

1) The subscription price in the share issue was SEK 14,800 per share, corresponding to SEK 14.80 per share adjusted for the share split carried out during 2016.
2) The subscription price in the share issue was SEK 25 per share.
3) The conversion rate in connection with the exchange of the convertible debt was SEK 17.50.
4) The subscription price in the share issue was SEK 45 per share.
5) Share program to the CEO. Issue price SEK 0.00 per share.
6) New issue price SEK 22.00 per share.
7) The subscription price in the rights issue was SEK 5,80 per share.

Administration Report

The Board of Directors and CEO of IRRAS AB (publ), corporate registration number 556872-7134, with its registered office in Stockholm, Sweden, hereby submits the Annual Report and consolidated financial statements for the fiscal year from January 1 to December 31, 2020. Earnings from the year's operations, and the financial position of the Parent Company and the Group, are presented in the Administration Report and the subsequent statements of profit or loss, profit or loss and other comprehensive income, financial position, changes in equity, cash flows, income statement, balance sheet and notes with supplemental information.

The company's shares have been listed on Nasdaq Stockholm since May 2020.

Operations

IRRAS is a global medical technology company focused on delivering innovative medical solutions to improve the lives of critically ill patients. IRRAS designs, develops, and commercializes neurocritical care products that transform patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methodologies. IRRAS markets and sells its innovative IRRA*flow* and Hummingbird ICP Monitoring product lines to hospitals worldwide, through its direct sales organization in the United States and select European countries as well as an international network of distribution partners.

IRRA*flow* is an FDA-cleared and CE-marked, fully integrated, closed-circuit medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure. The Hummingbird line includes nine FDA-approved products that help clinicians diagnose and manage patients' intracranial pressure after a traumatic brain injury, subarachnoid hemorrhage, and/or stroke. The combination of IRRA*flow* and Hummingbird creates a unique product portfolio. Along with strong patent protection, this provides IRRAS with a solid foundation to establish a leading position in the neurocritical care market.

IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California in the US.

In December 2019, the company received renewed CE mark approval for the IRRA*flow* catheter throughout the EU and the relaunch of the product began in early 2020. Going forward, the focus will be on broadening the user base for both product lines and a launch of the Hummingbird line in the EU.

The IRRAS business model is built on selling digital control units and then leveraging recurring revenue streams by selling consumables (primarily catheters, digital pumps and cranial access bolts) which integrate with the control units.

Group structure

IRRAS AB, with its headquarters registered in Stockholm, is the Parent Company of the Group. The Parent Company has two wholly owned subsidiaries: IRRAS GmbH in Germany and IRRAS USA Inc in the US.

The Swedish Parent Company is responsible for such Group-wide functions as finance and investor relations. The US company is responsible for the manufacturing and development of new and existing products as well as sales in North America. The German subsidiary is primarily a sales company with a focus on European and distributor sales.

MULTI-YEAR OVERVIEW

	Group				Parent Company			
Amounts in TSEK	Jan 1, 2020–Dec 31, 2020	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017-Dec 31, 2017	Jan 1, 2020–Dec 31, 2020	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017-Dec 31, 2017
Earnings								
Net revenue	7,390	5,288	5,994	11,973	4,726	1,551	13,081	3,969
Gross margin, %	neg.	neg.	neg.	53%	neg.	neg.	39%	16%
Operating loss (EBIT)	–134,316	–151,486	–143,328	–61,464	–40,091	–47,384	–43,018	–45,309
Net loss for the period	–135,916	–151,144	–138,842	–60,901	–41,224	–46,434	–39,565	–45,169
Financial position								
Total assets	209,035	158,992	205,284	329,252	517,486	369,650	315,265	349,854
Equity	182,353	131,470	184,154	316,030	509,352	360,532	307,419	338,877
Equity ratio, %	87%	83%	90%	96%	98%	98%	98%	97%

Significant events during the fiscal year

Change of Chairman of the Board of Directors
Anders P. Wiklund, Chairman of the Board of Directors of IRRAS, passed away in August and was replaced by Marios Fotiadis, a current board member of IRRAS.

COVID-19 delayed short term sales development, while the commercial launch of IRRA*flow* and Hummingbird continued
During the second quarter, the company announced that its commercial launch and short term revenue had been affected by the COVID-19 pandemic, but that progress had still been made in the global commercial launch in spite of the challenges. The pandemic continued to limit the company's access to customers during the second half of the year and revenue in 2020 was in the end much lower than internal forecasts in the beginning of the years indicated.

IRRAS was listed on Nasdaq Stockholm
In May 2020 Nasdaq Stockholm's listing committee approved the Company for listing on Nasdaq Stockholm's main list. In connection with the list change from Nasdaq First North Premier Growth Market to Nasdaq Stockholm's main list, the Company prepared a prospectus that was approved and registered by the Swedish Financial Supervisory Authority.

Loan through US stimulus package
In May, a loan of USD 0.8 million, corresponding to SEK 6.8 million as of he balance sheet date, was received as a part of the US stimulus package Paycheck Protection Program which targeted smaller companies with the aim of stimulating the economy and helping companies to recover more quickly from the restrictions due to covid-19. The loan can be forgiven if the recipient meets certain requirements and as of the publishing date of the annual report, the company is waiting for response to its loan forgiveness application. Upon approval, the loan will be recognized as a grant.

Rights issue
A rights issue in IRRAS AB in April resulted in a contribution of SEK 217 million before fees. The number of shares increased by 37,463,366 to a total of 66,281,340.

Sales and market

IRRAS' initial clinical focus is neurosurgical treatments that require the drainage of excess cerebrospinal fluid (CSF) as well as monitoring and regulation of intracranial pressure (ICP). The treatments are often administered in conjunction with traumatic brain injuries (powerful blows or bumps to the head or body), hemorrhagic strokes (bleeding in the brain) or chronic subdural hematoma (blood collection on the surface of the brain). IRRA*flow*, the company's leading commercial product, is used to drain fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematoma, two serious conditions with high rates of mortality. IRRA*flow* addresses complications that commonly arise from current treatment methods, and has the potential to become the new standard of care. The company's Hummingbird products also offer an important diagnostic tool for monitoring the patient's condition after a traumatic brain injury. This is a critical tool for determining when the use of a therapeutic tool, such as IRRA*flow*, will be required.

Around half a million people in the US and Europe suffer from hemorrhagic strokes and chronic subdural hematoma annually. Approximately 355,000 of these people are treated surgically each year, and IRRAS estimates that the market value of IRRA*flow* in Europe and the US is currently just over USD 1.2 billion per year. At the same time, some 1.3 million people are admitted to hospital for traumatic brain injuries in Europe and the US each year, and approximately 235,000 of these people require invasive monitoring. Accordingly, the market value of the Hummingbird line in these regions is estimated at approximately USD 400 million per year.

The number of patients is expected to increase sharply in the coming years as a result of population growth, an aging population and an increased share of patients receiving treatment.

From its commercial launch until today, IRRA*flow* has been used in over 200 cases of hemorrhagic stroke and subdural hematoma in the US and Europe without any reported cases of catheter blockages or related infections, which are else commonly seen.

During 2020 IRRA*flow* was relaunched in the European market and the German sales team was slightly expanded. A new sales manager was also hired for the Nordic region. The responsibility of finding and training new distribution partners lies with the European sales team and 2020 saw a steady growth of new well established distributors in spite of the pandemic.

After receiving CE mark approval in December 2019, the company continued with the European launch of IRRA*flow* by resuming its customer engagement in Germany in early 2020. The company plans to employ an additional direct sales representative outside Germany to facilitate launch preparations in the Nordic markets in Sweden, Norway, Denmark and Finland. In other European markets, similar support is currently provided by distribution partners that are well established in neurosurgical circles.

Earnings and financial position in the Group

Net revenue for the 2020 fiscal year totaled SEK 7.4 million (5.3). Of this revenue, SEK 3.2 million (4.5) is attributable to sales in the US, SEK 3.8 million (0) to sales in Europe and SEK 0.4 million (0.7) to sales in the rest of the world. The renewed CE mark from late 2019 enabled the resumption of sales in Europe in 2020, but sales development was heavily affected by COVID-19 in both Europe and the US during the year.

The gross loss for 2020 totaled SEK –16.1 million (–33.2).

The cost of sales includes direct production costs for sold products, amortization of capitalized development expenses, overhead expenses for the production department and personnel expenses for employees in the department. The improved result compared to previous year is mainly due to increased revenue and lower costs for the production department. Amortization of capitalized development expenses amounted to SEK 10.7 million (9.8).

Operating expenses for 2020 totaled SEK 118.2 million (118.4).

Sales expenses has increased slightly in the US compared to previous year due to a growing sales force and regulatory costs, but costs for administration and development has decreased, in part thanks to a reduced need for external consultants. Of the total SEK 36.7 million (37.8) R&D costs for the year, SEK 7.8 million (8.0) was capitalized and SEK 28.9 million (29.8) was expensed. The expensed R&D costs mainly include personnel costs for employees and consultant fees in the R&D department. The department primarily focuses on making improvements to already registered products that are not expected to extend the lifetime of the products. Capitalized development expenses include expenses for development projects involving products for which sales have not yet been initiated.

The net of other operating income and operating expenses for 2020 amounted to SEK 0.7 million (0.0). Other operating income is primarily made up of exchange rate differences.

The operating loss for 2020 totaled SEK –134.3 million (–151.5) and net financial items totaled SEK –1.6 million (0.3).

The loss before tax for 2020 amounted to SEK –135.9 million (–151.1). The net loss for the year totaled SEK –135.9 million (–151.1).

Cash flow from operating activities for 2020, after changes in working capital, totaled SEK –132.7 million (–153.7). The positive change in cash flow is primarily attributable to the reduced loss. A rights issue was completed during the year, generating net proceeds of SEK 189.5 million for the company.

Total net investments for 2020 totaled SEK 8.7 million (15.4).

Of the total net investments, investments in intangible assets amounted to SEK 7.8 million (14.8). In 2019 capitalized patent expenses attributable to the acquisition of assets from Innerspace totaled SEK 6.7 million. Investments in tangible assets totaled SEK 0.9 million (0.6) and sales of financial investments amounted to SEK 55.5 million (55.2).

Capital requirements for the year were financed with funds from the share issues carried out in 2020 and 2019. Cash amounted to SEK 29.5 million (47.2) at the start of the period and SEK 135.6 million (29.5) at year-end.

Production

The US subsidiary, IRRAS USA Inc, is a registered manufacturer of the company's products. All production is outsourced to US manufacturers with the exception of IRRA*flow*'s control unit, which IRRAS is responsible for manufacturing.

Development

The development of existing and new products is a central and prioritized aspect of IRRAS' operations, and encompasses several ongoing development projects related to IRRA*flow* and the Hummingbird product lines.

Development expenses for the next few years are expected to increase slightly as work on the next generation of IRRA*flow* is planned to start.

IRRAS' overall production strategy is focused on developing innovative, user-friendly, reliable and high-quality proprietary systems. IRRAS continued to strengthen its internal competence for the development of control units and consumables. This in-house expertise is supplemented by external consultants. Product development is carried out by the US subsidiary.

Apart from new development, the development department also makes product improvements in order to improve and enhance the efficiency of the components included in the manufacturing process in cooperation with third-party suppliers.

R&D costs recognized as revenue account for 24% (25%) of total operating expenses.

Risks and uncertainties

Like all business operations, IRRAS' operations are exposed to risks and uncertainties. In the opinion of the Board of Directors, the most important risks at present are sales and market risks, risks related to COVID-19, development risks, currency risks, financing risks, legislative and regulatory risks, competition risks, product liability requirements, intellectual property risks, dependency on key individuals and supplier risks.

Sales and market risks
The company's future sales depend on its success with current and new customers. If the company fails to attract and retain new customers or experience a delayed market adoption, this could negatively affect the company's future development, growth and financial position.

Risks related to COVID-19
The covid-19 restrictions that have been introduced during 2020 has had a major effect on the company's ability to visit potential customers and train new customers. The pandemic has also caused a reduced usage of IRRAS' products due to limited capacity at the hospital's intensive care units. If the restrictions continue, they are expected to have a continued large effect on the company, even if some level of sales remains possible.

Development risks
There is always a risk that current and future R&D projects may be delayed, become more costly or prove to be unsuccessful. This could impact the company negatively.

Currency risks
The Group is exposed to currency risks in the form of transaction exposure and translation exposure. Transaction exposure is relatively low, since the revenue and expenses of the respective companies are presently in their local currencies. Revenue and expenses for the German subsidiary are primarily in EUR, whereas the US subsidiary's revenue and expenses are primarily in USD.

Translation exposure is relatively high. The consolidation of income statements and balance sheets in the Group entails an exposure to currency rate fluctuations in USD (for the operations of the US subsidiary) and in EUR (for the operations of the German subsidiary). At present, the Group does not use derivatives to hedge its exposure to currency risks. Currency rate fluctuations could negatively impact the company's continued development, growth and financial position.

Financing risk and going concern
The company´s available cash and cash equivalents is not sufficient to cover the planned operations in the next 12 months. In light of this, work is underway on possible financial solutions and the Board considers that the prospects are good to finance the company´s operations. However, if sufficient financing is not obtained, there is a risk that conditions for going concern are not fulfilled

Under the Board's policy, the Group is to maintain a strong financial position, which helps the company to retain the confidence of its investors, its creditors and the market. It also creates a foundation for further development of its operations, with continued long-term support for its goal of securing dividends for the company's owners.

Until the company has achieved long-term, sustainable profitability, its policy is to maintain a low level of debt and a high level of equity.

Legislative and regulatory risks
Clinical studies, manufacturing, marketing and distribution of medical devices and equipment takes place in a regulated market. If IRRAS does not obtain future clearance from government authorities or cannot maintain its existing clearances, this will negatively impact its operations.

Risk related to competitors
There is a risk that competitors could develop technology and products that prove to be superior to IRRAS' technology and products and that IRRAS' sales could therefore decline.

Risk related to product liability requirements
Since the company develops and sells medical devices, the company could be exposed to liability requirements. A risk of product liability requirements could arise in conjunction with manufacturing, clinical studies, inappropriate handling, and sales and marketing of products.

Risks related to protecting the company's intellectual property or infringements of third-party patents
The company's position with respect to patent law in the industry for medical devices is uncertain and involves complex medical, legal and technical assessments that can give rise to uncertainties regarding the validity, scope and priority of a certain patent. There is a risk that the company may be unable to develop products that are patentable or to obtain the necessary patent protection, that the patent may not have a sufficient scope to adequately protect against competitors with similar technologies or products, or that it may not be possible to maintain the patents granted. If IRRAS were to use intellectual property that belongs, or is claimed to belong, to another party, the holder of the patent could initiate an intellectual property infringement proceeding against the company.

Dependence on key individuals
IRRAS has a specific high-tech focus, and is therefore dependent on recruiting and retaining personnel. Should IRRAS lose key employees, or fail to recruit new qualified employees, this could negatively impact the company.

Supplier risks

IRRAS relies on third-party suppliers and manufacturers of the company's products. There is always a risk that such external players could fail to meet their commitments to the extent the company wishes and deems necessary. IRRAS is working to secure alternate third-party suppliers to facilitate deliveries even if a supplier encounters problems. IRRAS is also working to ensure it has sufficient inventory levels to avoid temporary disruptions to deliveries of supplementary products for IRRA*flow*.

Future development

In 2020, the company's commercial launch was understandably slowed by the global COVID-19 pandemic. In spite of these challenges, meaningful progress was seen, and, in 2021, increasing patient treatments and growing revenue will again be the company's main focus. This growth will be accomplished by adding reference accounts for IRRA*flow* throughout the United States and Europe, increasing the contribution of our distribution partners as they complete training and become more self-sufficient, and launching the Hummingbird product family in Europe after receiving its CE Mark certification.

Furthermore, we remain focused on ensuring that the needed elements are in place to support this growth. Impactful projects are underway to capture meaningful clinical data that supports the use of our products, and the company has begun to bring more of its manufacturing processes in-house to better control supply and quality, while also driving down costs.

IRRAS also has a number of product targets for the coming year. The company plans to introduce at least four more product improvements, including a new Hummingbird bolt, an improved drainage system and a new generation IRRA*flow* catheter.

Significant events after the end of the fiscal year

Early in 2021, IRRAS finalized a partnership with Aarhus University in Denmark to collaborate on clinical trial and research projects, including ACTIVE clinical study that compares IRRA*flow* to traditional drainage for IVH patients.

Key US customers, Buffalo General Medical Center and West Virginia University Hospital, transitioned to commercial customers after evaluations were completed in Q4 2020.

The company also successfully completed a Medical Device Single Audit Program (MDSAP) quality system audit, which confirms that IRRAS' internal processes exceed requirements required by key medical device markets of Japan, Brazil, Canada, and Australia.

The IRRAS share and ownership structure

In 2020, the number of shares increased by 37,463,366 ordinary shares and as of 31 December 2020 the total number of shares amounted to 66,281,340 ordinary shares. The company has not issued any Series C shares. IRRAS has four outstanding incentive programs for employees and key employees. The incentive programs may increase the number of shares by currently 4,332,000 ordinary shares. The Company has only issued ordinary shares and these shares rank pari passu in respect of each other and no transfer restrictions apply in accordance with Swedish law or the Articles of Association regarding the transferability of the shares, voting rights, rights to the assets of the Company or dividends. The shares have a quota value of SEK 0.03 each.

SHAREHOLDERS AS OF DECEMBER 31, 2020 AND KNOWN CHANGES THEREAFTER

	No. of shares	% of shares/votes
Bacara Holdings Limited	16,234,097	24.49%
The Fourth Swedish National Pension Fund	6,139,362	9.26%
Lexington Holding Assets Ltd (BVI)	3,155,727	4.76%
The Carl-Olof and Jenz Hamrins Foundation	3,000,000	4.53%
Christos Panotopoulos	2,744,000	4.14%
March Asset Management	1,380,449	2.08%
Dr. Kleanthis G. Xanthopoulos	1,101,498	1.66%
Avanza Pension	938,014	1.42%
Lovisa Hamrin	849,024	1.28%
Deka Investments	551,592	0.83%
Other shareholders	30,187,577	45.54%
Total number of shares	**66,281,340**	**100.00%**

Personnel

The average number of employees in the Group for 2020 was 43 (35), of whom 6 (4) are in the parent company. The breakdown of the average number of employees by country was 6 (4) in Sweden, 34 (28) in the US and 3 (3) in Germany. The average number of women in the Group was 16 (12) and the average number of men was 27 (23).

IRRAS depends on its ability to attract and retain employees with a high level of competency and experience. If IRRAS loses key individuals or has difficulty in attracting employees with key expertise, this could negatively impact IRRAS' operations and operating profit, and delay or complicate sales development and development initiatives at IRRAS. IRRAS therefore aims to be perceived as an attractive employer with committed employees and a proactive personnel policy. The company continuously addresses issues related to competency development, work environment and equality.

Quality assurance

IRRAS is certified under ISO 13485:2016 and FDA 21 CFR Part 820. In 2018, IRRAS received an updated ISO 13485:2016 certificate and new CE Mark approval for its IRRA*flow* CNS System control unit and tube set. In 2019, CE Mark approval was also received for the IRRA*flow* CNS System catheters. The control unit and tube set are medical device Class IIb products and the catheter belongs to Class III. FDA clearance was obtained for the IRRA*flow* CNS System in 2018, and clearance for an extended period of use was obtained in 2019. Regulatory approval has also been received in Israel, Kuwait, Costa Rica and Argentina. Work to secure registration clearance is also under way in a number of additional countries, including Australia and Brazil. During 2019, the company acquired the assets to Innerspace, which includes ten 510(k) FDA-cleared products under the trade name Hummingbird, and DermaPort, a 510(k) FDA cleared product.

Sustainability

IRRAS' environmental impact is deemed to be low. The choice of products, services and suppliers is taken into account in order to achieve an efficient use of resources in areas such as health and safety, energy consumption, carbon emissions, water consumption and air pollution. IRRAS' employees are to act in an ethical manner and in accordance with laws and other regulations. In 2018, the Group introduced a Code of Conduct, which all employees, suppliers and customers are to follow.

Guidelines for salary and other remuneration to senior executives in company management

The following guidelines for remuneration to senior executives were approved at the 2020 Annual General Meeting.

The guidelines apply to the CEO and other senior executives. Remuneration that is included in the guidelines shall include salary and other remuneration to senior executives. Remuneration is equated with transfers of securities and the concession of the right to acquire securities from the company in the future. The guidelines do not apply to the company's incentive programs where senior executives in company management retain the right to acquire shares in the company in the future. To give an understanding of the company's total remuneration package, the company's incentive program is described for your information in a separate section following the proposal for guidelines for salary and other remuneration to senior executives in company management.

The guidelines contribute to the company's business strategy, long-term interests and sustainability

The company's business strategy is to develop medical devices that create a new standard of care for hemorrhagic stroke and traumatic brain injuries. Management's task is to commercialize these new innovative devices that are based on a unique technology and make IRRAS a globally acknowledged company. The goal with the remuneration package is to enable the Group to attract and retain qualified senior executives at a reasonable cost to the company.

Different forms of remuneration

To retain and attract competent employees as senior executives in company management, the remuneration must be competitive and based on prevailing market conditions. Remuneration consists of a fixed salary, variable remuneration and pension and other benefits. Beyond this, the Annual General Meeting can decide on long-term incentive programs such as share-based or share price-based incentive programs. The incentive program will contribute to long-term value growth. In order to avoid encouraging the company's senior executives to take unnecessary risks, there must be a fundamental balance between fixed and variable remuneration. Each senior executive is to be offered a market-level fixed salary based on the degree of difficulty of the work as well as the individual's experience, responsibilities, qualifications and performance. In addition, each senior executive may, from time to time, be offered variable remuneration (bonuses) to be paid in cash. The variable remuneration is to be based on clear, predetermined and measurable criteria and financial performance, and on business objectives that are defined in advance. Variable remuneration should also be used to promote the company's long-term value creation. Variable remuneration may not exceed 12 months' fixed salary for the CEO and 6 months' fixed salary for other senior executives in company management.

The standard age of retirement is to be 65. Pension terms are to be in accordance with market practice and based on fee-based pension schemes. Other benefits that can be provided include a company car, health programs, healthcare insurance and health insurance, life insurance and memberships.

Termination of employment

The period of notice should normally be 6 months if the termination has been on the initiative of the company and 6 months if the termination has been on the initiative of the senior executive in company management. With reference to foreign senior executives, adjustments may be made to comply with local regulations and market conditions. Remuneration to the CEO after termination must not exceed the CEO's salary during the period of notice together with severance pay of 24 months, which also encompasses bonuses and other benefits. In accordance with the guidelines, fixed salary during the period of notice and severance pay for other senior executives are not to exceed 12 months' fixed salary.

Salary and terms of employment

In the preparation of these guidelines for remuneration to senior executives in company management, salary and terms of employment for the company's employees have been observed by including information about the employee's total remuneration. Additionally, the various components of the remuneration, the increase in remuneration and the rate of increase over time have been a part of the Remuneration Committee's and the Board's basis of decision when evaluating whether the guidelines for remuneration and the limitations set out herein are reasonable. In the remuneration report, which will be prepared and presented in conjunction with the 2021 Annual General Meeting, with respect to paid remuneration as well as remuneration in arrears covered by these guidelines, the development of the disparity between remuneration for senior executives in company management and remuneration for other employees will be reported.

The decision-making process to determine, review and implement the guidelines

The Board Of Directors has established a Remuneration Committee whose primary tasks are to make preparations for the Board Of Directors' decision to propose guidelines for remuneration for the CEO, evaluate variable remuneration for senior executives in company management and evaluate the application of guidelines for remuneration and provisions for key individuals, as resolved on by the Annual General Meeting. The Remuneration Committee shall also monitor and evaluate the application of the guidelines for the remuneration of senior executives in company management, which the Annual General Meeting must resolve on by law, as well as the current remuneration structures and remuneration levels in the company.

The Board of Directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the Annual General Meeting for decision. The CEO and other senior executives in company management do not participate in the Board of Directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

Derogation from the guidelines

The Board of Directors may temporarily resolve to derogate from the guidelines, in whole or in part, if in a specific case there is special cause for the derogation and the derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability.

This proposal is consistent in all material respects with the guidelines that were adopted by the 2019 Annual General Meeting.

Description of the company's incentive program

The company has four outstanding incentives programs of which the first was introduced in 2016. During the year, two incentive programs have expired and one program been added. The programs are resolved at the Annual General Meeting. Share options are awarded to senior executives in company management and other key individuals following approval by the Board of Directors. For more information on the company's incentive programs, refer to note 2 and 10.

Parent Company

The Parent Company IRRAS AB, with its registered office in Stockholm, is responsible for Group management, monitoring the Group and providing operational support for the operating subsidiaries.

Net revenue for the Parent Company in 2020 totaled SEK 4.7 million (1.6). This amount primarily pertains to invoicing of management fees and other remuneration from subsidiaries. The Parent Company reported an operating loss of SEK −40.1 million (−47.4). Revenue and expenses declined during the year since certain selling and development expenses are now reported by the US subsidiary. As of December 31, 2020, equity in the Parent Company totaled SEK 509.4 million (360.5). The company's registered share capital at December 31, 2020 totaled SEK 1,984,440, allocated among 66,281,440 shares. The Parent Company's receivables from Group companies consist of long-term loans and current receivables, which amounted to SEK 23.1 million (17.2) at year-end.

The Parent Company's risks and uncertainties are the same as those described for the Group in the section "Risks and uncertainties".

Corporate governance report

IRRAS AB applies the Swedish Corporate Governance Code. For a description of how the company manages corporate governance issues, refer to the corporate governance report on pages 64–69. The Group's system for internal control and risk management is described in the section "Internal control report" in the corporate governance report.

Proposed appropriation of the company's earnings

The Board proposes that the unappropriated earnings as of December 31, 2020 — SEK 476,774,027 — be carried forward.

For changes in equity during the fiscal year, refer to the Parent Company and consolidated statement of changes in equity.

For all other information, refer to the following financial statements and notes.

Consolidated statement of profit or loss

AMOUNTS IN TSEK	Note	Jan 1, 2020–Dec 31, 2020	Jan 1, 2019–Dec 31, 2019
Net revenue	5	7,390	5,288
Cost of sales		–23,487	–38,442
Gross loss		**–16,097**	**–33,154**
Other operating income	7	1,594	1,083
Marketing and selling expenses		–47,024	–43,057
Administrative expenses	9	–42,950	–45,485
R&D costs		–28,937	–29,823
Other operating expenses	7	–901	–1,051
Operating loss	6	**–134,316**	**–151,486**
Financial income		8	682
Financial expenses		–1,596	–332
Profit from financial items	8	**–1,588**	**350**
Loss before tax		**–135,903**	**–151,136**
Income tax	12	–12	–8
Net loss for the year		**–135,916**	**–151,144**
Earnings per share before and after dilution, SEK	25	–2,46	–5,61
Number of shares before dilution, average		55,152,011	26,937,426
Number of shares after dilution, average		55,152,011	26,937,426

Consolidated statement of profit or loss and other comprehensive income

AMOUNTS IN TSEK	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Net loss for the year	**–135 916**	**–151,144**
Other comprehensive income for the year:		
Items that may be subsequently reclassified to profit or loss		
Translation differences for the year on translation of foreign operations	–3 246	–1,087
Other comprehensive income for the year, net of tax	**–3 246**	**–1,087**
Total comprehensive income for the year	**–139 162**	**–152,231**

Consolidated statement of financial position

AMOUNTS IN TSEK	Note	Dec 31, 2020	Dec 31, 2019
ASSETS			
Non-current assets			
Capitalized development expenses	13	33,294	36,228
Patents	13	6,521	8,201
Tangible assets	14	1,310	947
Right-of-use assets	14	3,788	6,225
Financial investments	15	–	–
Total non-current assets		**44,914**	**51,601**
Current assets			
Inventory	16	18,074	14,440
Advance payments to suppliers		2,865	1,531
Accounts receivable		5,056	2,803
Other receivables	17	1,292	1,498
Prepaid expenses and accrued income	18	1,229	1,992
Current investments	15	–	55,613
Cash and cash equivalents		135,604	29,514
Total current assets		**164,121**	**107,391**
TOTAL ASSETS		**209,035**	**158,992**
EQUITY			
Share capital		1,988	865
Other paid-in capital		726,668	537,387
Reserves		–6,281	–3,035
Retained earnings, including net loss for the year		–540,023	–403,746
Total equity		**182,353**	**131,470**
LIABILITIES			
Non-current liabilities			
Lease liabilities	14	76	2,022
Other provisions		–	–
Total provisions		**76**	**2,022**
Current liabilities			
Lease liabilities	14	3,922	4,030
Accounts payable		3,450	7,481
Other liabilities		7,329	731
Accrued expenses and deferred income	20	11,906	13,258
Total current liabilities		**26,607**	**25,499**
TOTAL EQUITY AND LIABILITIES		**209,035**	**158,992**

Consolidated statement of changes in equity

	Note	Share capital	Other paid-in capital	Reserves	Retained earnings, including net loss for the year	Total equity
Opening equity January 1, 2019		**721**	**440,208**	**–1,948**	**–254,826**	**184,154**
Comprehensive income						
Net loss for the year					–151,144	**–151,144**
Other comprehensive income						
Translation differences for the year on translation of foreign operations				–1,087		**–1,087**
Total comprehensive income		**–**	**–**	**–1,087**	**–151,144**	**–152,231**
Transactions with shareholders						
Incentive programs	10				2,224	**2,224**
New share issue		144	105,456			**105,600**
Issue expenses			–8,277			**–8,277**
Total		144	97,179	–	2,224	**99,547**
Closing equity December 31, 2019	19	**865**	**537,387**	**–3,035**	**–403,746**	**131,470**

Consolidated statement of changes in equity *cont.*

	Note	Share capital	Other paid-in capital	Reserves	Retained earnings, including net loss for the year	Total equity
Opening equity January 1, 2020		**865**	**537,387**	**–3,035**	**–403,746**	**131,470**
Comprehensive income						
Net loss for the year					–135,916	**–135,916**
Other comprehensive income						
Translation differences for the year on translation of foreign operations				–3,246		**–3,246**
Total comprehensive income		**–**	**–**	**–3,246**	**–135,916**	**–139,162**
Transactions with shareholders						
Incentive programs	10				–361	**–361**
New share issue		1,124	216,164			**217,288**
Issue expenses			–26,882			**–26,882**
Total		1,124	189,281	–	–361	**190,044**
Closing equity December 31, 2020	19	**1,988**	**726,668**	**–6,281**	**–540,023**	**182,353**

Consolidated statement of cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Cash flow from operating activities			
Operating loss (EBIT)		–134,316	–151,486
Adjustments for non-cash items			
– Reversal of depreciation/amortization		16,326	12,576
– Other non-cash items		–	–
– Incentive programs	10	–361	2,224
Interest received		8	485
Interest paid		–378	–145
Tax paid		–12	–8
Cash flow from operating activities before changes in working capital		**–118,733**	**–136,353**
Changes in working capital			
Increase/decrease in inventory		–6,177	–11,146
Increase/decrease in operating receivables		–4,216	–4,205
Increase/decrease in operating payables		–3,567	–2,038
Cash flow from operating activities		**–132,693**	**–153,742**
Cash flow from investing activities			
Investments in intangible assets		–7,795	–14,824
Investments in tangible assets		–882	–589
Sale of tangible asset		–	2
Sales of financial investments		55,465	55,208
Cash flow from investing activities		**46,788**	**39,797**
Cash flow from financing activities			
New share issue		217,288	105,600
Issue expenses		–26,882	–8,277
Loans from credit institutions		6,813	–
Lease liability	14	–3,786	–1,538
Cash flow from financing activities		**193,433**	**95,785**
Cash flow for the period		**107,529**	**–18,160**
Cash and cash equivalents at the beginning of the period		29,514	47,244
Exchange rate differences in cash and cash equivalents		–1,439	430
Cash and cash equivalents at the end of the period		**135,604**	**29,514**

Parent Company statement of profit or loss

AMOUNTS IN TSEK	Note	2020-01-01 Dec 31, 2020	2019-01-01 Dec 31, 2019
Net revenue	5	4,726	1,551
Cost of sales		–10,728	–9,836
Gross loss		**–6,002**	**–8,284**
Other operating income	7	940	187
Marketing and selling expenses		–4,555	–1,074
Administrative expenses	9	–29,503	–35,823
R&D costs		–467	–1,540
Other operating expenses	7	–505	–850
Operating loss	6	**–40,091**	**–47,384**
Other interest income and similar profit/loss items		304	1,042
Interest expenses and similar profit/loss items		–1,436	–92
Profit from financial items	8	**–1,133**	**950**
Loss before tax		**–41,224**	**–46,434**
Tax on loss for the year	12	–	–
Net loss for the year		**–41,224**	**–46,434**

Parent Company statement of profit or loss and other comprehensive income

	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Net loss for the year	**–41,224**	**–46,434**
Other comprehensive income for the year, net of tax	**–**	**–**
Total comprehensive income for the year	**–41,224**	**–46,434**

Parent Company balance sheet

AMOUNTS IN TSEK	Note	Dec 31, 2020	Dec 31, 2019
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenses	13	33,294	36,228
Patents	13	1,582	1,898
Total intangible assets		**34,876**	**38,126**
Tangible assets			
Equipment, tools, fixtures and fittings	14	203	310
Total tangible assets		**203**	**310**
Financial assets			
Participations in Group companies	24	340,893	232,980
Receivables from Group companies	11	23,101	17,226
Other securities held as non-current assets	15	–	–
Total financial assets		**363,994**	**250,206**
Total non-current assets		**399,073**	**288,642**
Current assets			
Current receivables			
Trade receivables		9	–
Other receivables	17	756	859
Prepaid expenses and accrued income	18	734	1,865
Total current receivables		**1,499**	**2,724**
Current investments	15	**–**	**55,613**
Cash and bank balances		**116,914**	**22,670**
Total current assets		**118,413**	**81,008**
TOTAL ASSETS		**517,486**	**369,650**

Parent Company balance sheet *cont.*

AMOUNTS IN TSEK	Note	Dec 31, 2020	Dec 31, 2019
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19	1,988	865
Fund for development expenses		30,589	31,720
Total restricted equity		**32,578**	**32,584**
Non-restricted equity			
Share premium reserve		693,092	503,810
Retained earnings		–175,094	–129,429
Net loss for the year		–41,224	–46,434
Total non-restricted equity		**476,774**	**327,947**
Total equity		**509,352**	**360,532**
Current liabilities			
Accounts payable		1,464	2,814
Other liabilities		384	287
Accrued expenses and deferred income	20	6,286	6,018
Total current liabilities		**8,134**	**9,118**
TOTAL EQUITY AND LIABILITIES		**517,486**	**369,650**

Parent Company statement of changes in equity

	Restricted equity		Non-restricted equity			
AMOUNTS IN TSEK	Share capital	Fund for development expenses	Share premium reserve	Retained earnings	Net loss for the year	Total equity
Equity January 1, 2019	**721**	**31,779**	**406,631**	**–92,148**	**–39,565**	**307,419**
Comprehensive income						
Appropriation of earnings as decided at AGM				–39,565	39,565	**–**
Net loss for the year					–46,434	**–46,434**
Total comprehensive income	**–**	**–**	**–**	**–39,565**	**–6,869**	**–46,434**
Transactions with shareholders						
Incentive programs				2,224		**2,224**
New share issue	144		105,456			**105,600**
Issue expenses			–8,277			**–8,277**
Total transactions with shareholders	**144**	**–**	**97,179**	**2,224**	**–**	**99,547**
Dissolution, fund for development expenses		–59		59		**–**
Equity December 31, 2019	**865**	**31,720**	**503,810**	**–129,429**	**–46,434**	**360,532**

Parent Company statement of changes in equity *cont.*

	Restricted equity		Non-restricted equity			
AMOUNTS IN TSEK	**Share capital**	**Fund for development expenses**	**Share premium reserve**	**Retained earnings**	**Net loss for the year**	**Total equity**
Equity January 1, 2020	**865**	**31,720**	**503,810**	**–129,429**	**–46,434**	**360,532**
Comprehensive income						
Appropriation of earnings as decided at AGM				–46,434	46,434	**–**
Net loss for the year					–41,224	**–41,224**
Total comprehensive income	**–**	**–**	**–**	**–46,434**	**5,210**	**–41,224**
Transactions with shareholders						
Incentive programs				–361		**–361**
New share issue	1,124		216,164			**217,288**
Issue expenses			–26,882			**–26,882**
Total transactions with shareholders	**1,124**	**–**	**189,281**	**–361**	**–**	**190,044**
Dissolution, fund for development expenses		–1,131		1,131		**–**
Equity December 31, 2020	**1,988**	**30,589**	**693,092**	**–175,094**	**–41,224**	**509,352**

Parent Company statement of cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2020–Dec 31, 2020	Jan 1, 2019–Dec 31, 2019
Cash flow from operating activities			
Operating loss (EBIT)		–40,091	–47,384
Adjustments for non-cash items			
– Reversal of impairment		11,151	10,249
– Non-cash provisions		–	–
– Incentive programs	10	754	1,939
Interest received		8	845
Interest paid		–218	–34
Cash flow from operating activities before changes in working capital		**–28,396**	**–34,384**
Changes in working capital			
Increase/decrease in other current receivables		3,377	24,879
Increase/decrease in operating payables		7,366	1,213
Total changes in working capital		**10,744**	**26,093**
Cash flow from operating activities		**–17,652**	**–8,291**
Cash flow from investing activities			
Investments in participations in subsidiaries		–118,597	–163,950
Investments in intangible assets		–7,795	–7,963
Investments in tangible assets		–	–
Sales of financial investments		55,465	55,208
Repayment of loans to subsidiaries		–7,583	13,002
Cash flow from investing activities		**–78,510**	**–103,704**
Cash flow from financing activities			
New share issue		217,288	105,600
Issue expenses		–26,882	–8,277
Cash flow from financing activities		**190,405**	**97,323**
Cash flow for the period		**94,244**	**–14,672**
Cash and cash equivalents at the beginning of the period		22,670	37,342
Cash and cash equivalents at the end of the period		**116,914**	**22,670**

Notes

NOTE 1 GENERAL INFORMATION

IRRAS AB is registered in Sweden and has its registered office in Stockholm. The visiting address of the head office is Vasagatan 16, SE-111 20 Stockholm, Sweden.

All amounts are reported in thousands of Swedish krona (TSEK) unless otherwise stated. Figures in parentheses refer to the previous year.

The Annual Report has been prepared in accordance with Swedish accounting standards, and the consolidated financial statements have been prepared in accordance with the international accounting standards referred to in Regulation (EC) No. 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards. The Annual Report and consolidated financial statements provide a true and fair view of the financial position and financial performance of the Parent Company and of the Group. The respective Administration Reports for the Parent Company and the Group provide a true and fair overview of development of the operations, financial position and financial performance of the Parent Company and the Group, and describe the significant risks and uncertainties facing the Parent Company and the companies forming the Group.

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of preparation

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU as well as RFR 1 *Supplementary Accounting Rules for Groups*.

The Parent Company's financial statements have been prepared in accordance with RFR 2 *Accounting for Legal Entities* and the Swedish Annual Accounts Act. Where the Parent Company applies accounting policies that differ from the Group, this is indicated separately at the end of this section on accounting policies.

The significant accounting policies applied in these consolidated financial statements are presented below.

The preparation of financial statements in accordance with IFRS requires the use of critical accounting estimates. It also requires that management make certain judgments in the application of the Group's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are of significance to the consolidated financial statements, are stated in Note 4.

New and amended standards applied by the Group in the current period

The following standards have entered into force or changed in 2020.

IFRS 3 Business Combinations became effective on January 1, 2020 and introduces a simplified assessment of whether an acquisition comprises an asset acquisition. A concentration test is used to determine whether gross assets comprise a single identifiable asset or a group of similar assets. If the test determines that the acquisition is an asset acquisition, a detailed assessment must be performed in accordance with the requirements of IFRS 3.

Amendment to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors.

The IASB has published an amendment to IFRS 16 Leases related to COVID-19, which became effective on 1 January 2020. The change concerns the rental discounts that have arisen as a direct result of COVID-19 and makes it possible to exempt these from modification rules in IFRS 16.

None of the new and changed standards has had any material impact on the consolidated financial statements.

Standards, amendments and interpretations of existing standards that will become effective in 2021 or later and are expected to impact the financial statements

Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform—Phase 2, becomes effective on January 1, 2021. The amendments are related to ongoing reforms of reference rates such as IBOR and the application of alternative risk-free interest rates. Companies need to disclose risks related to the interest rate benchmark reform.

From 2022, amendments to IFRS 3, IAS 16 and IAS 37 will be introduced.

IFRS 17 becomes effective in 2023.

None of the upcoming standards are expected to have any material impact on the consolidated financial statements.

Consolidated financial statements

Subsidiaries

Subsidiaries are all companies over which the Group has control. The Group controls a company when it has exposure or rights to variable returns from its stake in the company and has the ability to affect the amount of the returns through its power over the entity. Subsidiaries are included in the consolidated financial statements as of the date on which the controlling influence is transferred to the Group. They are excluded from the consolidated financial statements as of the date on which the controlling influence ceases.

Segment reporting

Since IRRAS' equity instruments are traded in a market, IFRS 8 Operating Segments is applicable. An operating segment is a part of a company whose operating earnings is regularly reviewed by the chief operating decision-maker in the Group, which makes decisions about which resources are to be allocated to the segment and evaluates the segment's earnings.

IRRAS' operations are currently focused on development and sales in the IRRA*flow* product field, which is why management has decided to monitor the operations as a single reporting unit. Therefore, until further notice the company will have one operating segment that is wholly reflected in the Group's financial statements. The CEO and Group management are deemed to be the chief operating decision-makers.

Earnings per share

Earnings per share have been calculated as net income divided by the average number of shares outstanding. The split in share capital has been taken into account for all reported periods. In the event of a negative result being reported, earnings per share after dilution correspond to earnings per share before dilution. When positive earnings are reported in the future, the options may give rise to dilution.

Foreign currency translation

Functional currency and reporting currency

Items included in the financial statements for the Group are measured using the currency of the primary economic environment in which the entity operates (the functional currency). In the consolidated financial statements, the Swedish krona (SEK) is used as the reporting currency, which is also the Parent Company's functional currency and reporting currency.

Transactions and balance sheet items

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing on the transaction date. Exchange gains and losses arising from the payment of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at the closing day rate are recognized in profit or loss. Exchange differences on lending and borrowing are recognized in net financial items, while other exchange differences are included in operating profit.

Group companies

The earnings and financial position of all Group entities that have a functional currency other than the reporting currency are translated to the Group's reporting currency as follows:

(a) assets and liabilities for each balance sheet are translated at the closing day rate;
(b) income and expenses for each statement of profit or loss are translated at average exchange rates (provided this average rate constitutes a reasonable approximation of the accumulated effect of the rates applicable on the transaction date; otherwise, income and expenses are restated at the exchange rate prevailing on the transaction date); and
(c) all exchange differences arising from the above are recognized as a separate component of other comprehensive income.

Upon consolidation, exchange differences arising from the translation of net investments in foreign operations are recognized in equity. When a foreign operation is disposed of in whole or in part, the exchange rate differences recognized in equity are transferred to profit or loss and recognized as a part of the capital gain/loss.

Goodwill and fair value adjustments arising upon the acquisition of a foreign operation are treated as assets and liabilities of that operation and are restated at the rate at the closing day rate.

Intangible assets

Capitalized expenses for development and similar activities

Development expenses directly attributable to the development and testing of identifiable products that are adjusted on behalf of IRRAS are recognized as intangible assets if they have likely financial advantages.

Directly attributable expenses capitalized as part of the asset include the portion of costs for staff and materials that is attributable to development. When capitalizing expenses, the Group's ability to finance its remaining development is taken into account. Capitalized development expenses are recognized as intangible assets and are amortized starting from the date when the asset is ready for use.

Patents

Patents acquired separately are recognized at cost. Patents acquired through a business combination are recognized at fair value on the acquisition date. Patents have a finite useful life and are recognized at cost less accumulated amortization and any impairment. Patent expenses are recognized as an intangible asset at the time the patent is granted.

Amortization period for intangible assets

Patents	4–18 years
Capitalized expenses for development and similar activities	5 years

Tangible assets

All tangible assets are recognized at cost less depreciation. The cost includes expenditures directly attributable to the acquisition of the asset.

In the Group, tangible assets consist of equipment.

Subsequent expenditure is added to the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that the future economic benefits associated with the asset will accrue to the Group and the cost of the asset can be measured reliably. The carrying amount of the replaced part is derecognized from the balance sheet. All other forms of repair and maintenance are recognized as expenses in profit or loss during the period in which they arise.

Depreciation of tangible assets in order to distribute their cost down to the estimated residual value over the estimated useful life is calculated on a straight-line basis as follows:

Depreciation period for tangible assets

Equipment, tools, fixtures and fittings	3–5 years

Gains and losses on disposals are determined by comparing the sales proceeds and the carrying amount, and are recognized in other operating income and other operating expenses in profit or loss.

See also the following section regarding the description of impairment of non-financial assets.

Leases

When a contract is entered into, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for specific period of time in exchange for consideration. Contracts can contain both lease and non-lease components. The Group allocates the consideration in the contract to lease and non-lease components on the basis of their relative standalone prices. For leases of buildings in which it is a lessee, the Group has elected not to separate lease and non-lease components and instead recognizes these components as a single lease component. The leases do not impose any covenants or restrictions except that the lessor retains the right to pledge the leased assets. The leased assets may not be used as security for borrowing purposes.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the present value of the following lease payments:

1. fixed payments (including in-substance fixed payments), less any lease incentives
2. variable lease payment that depend on an index or a rate, initially measured using the index or rate as at the commencement date
3. amounts expected to be payable by the lessee under residual value guarantees
4. the exercise price of a purchase option if the Group is reasonably certain to exercise that option
5. payments of penalties for terminating the lease, if the lease term reflects the Group exercising an option to terminate the lease.

Lease payments to be made for reasonably certain extension options are also included in the measurement of the liability.

These lease payments are discounted by the rate implicit in the lease or the incremental borrowing rate, which is the rate that would be paid to borrow the necessary funds to obtain an asset of a similar value to the right-of-use asset in a similar economic environment with similar terms and security. If the lease changes, the lease liability is remeasured and adjusted in accordance with the right-of-use asset.

Right-of-use assets are measured at cost, comprising the following:

1. the amount of the initial measurement of lease liability
2. any lease payments made at or before the commencement date less any lease incentives received
3. any initial direct costs
4. restoration costs.

The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to utilize a call option, the right-of-use asset is depreciated over the useful life of the asset.

As in the past, payments associated with short-term leases for office premises and vehicles and all low-value leases are expensed on a straight-line basis in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise office equipment.

Impairment of non-financial assets

Tangible assets and intangible assets that are depreciated or amortized are assessed with respect to impairment whenever events or changes in circumstances indicate that the carrying amount might not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less selling expenses and its value in use. When assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash *flow*s (cash-generating units).

An impairment loss is reversed if there is any indication that the impairment no longer exists and there has been a change in the assumptions underlying the calculation of the recoverable amount. A reversal is only recognized to the extent that the carrying amount of the asset after the reversal does not exceed the carrying amount that would have been recognized, less any depreciation or amortization where applicable, if no impairment loss had been recognized.

Impairment of tangible assets

The assets' useful lives are reviewed at each balance sheet date and adjusted if necessary. An asset's carrying amount is immediately impaired to its recoverable amount if the asset's carrying amount exceeds its estimated recoverable amount.

Impairment of intangible assets

Intangible assets are tested for impairment on at least an annual basis.

Financial instruments

General principles

Purchases and sales of financial assets and liabilities are recognized on the transaction date — meaning the date on which the Group commits to purchase or sell the asset or liability. Financial assets and liabilities are initially recognized at fair value plus transaction costs if not measured at fair value through profit or loss. Financial assets and liabilities measured at fair value through profit or loss are initially recognized at fair value, while attributable transaction costs are recognized in profit or loss. Financial assets are derecognized from the balance sheet when the rights to receive cash *flow*s from the instrument have expired or have been transferred, and the Group has transferred virtually all risks and benefits associated with ownership. Financial liabilities are derecognized from the balance sheet when the contractual obligations have been fulfilled or otherwise extinguished.

Accounts receivable, accounts payable and other financial liabilities are recognized after the acquisition date at amortized cost using the effective interest method.

For purposes of disclosure, the fair value of borrowings is calculated by discounting the future contractual cash *flow*s at the current market interest rate available to the Group for similar financial liabilities.

Classification of financial assets and liabilities

The Group classifies financial assets and liabilities in accordance with IFRS 9. The classification determines how the financial assets and liabilities are measured and recognized. The Group's policies for classifying and measuring financial assets are based on an assessment of both (i) the company's business model for administering financial assets; and (ii) the properties of the contractual cash *flow*s from the financial assets.

Financial assets measured at amortized cost are debt instruments administered with the objective of realizing the instrument's cash *flow* by obtaining contractual cash *flow*s that consist only of the principal and interest on the outstanding principal. The following financial assets are measured at amortized cost on the basis that the assets are held as part of a business model whose objective is to hold financial assets for the purpose of collecting the contractual cash *flow*s and that the terms agreed on for the assets give rise at fixed points in time to cash *flow*s that comprise only payments of the principal and interest on the outstanding principal:

- Financial investments
- Other receivables
- Accrued income
- Current investments
- Cash and cash equivalents

The Group currently holds no financial assets measured at fair value through profit or loss or at fair value through other comprehensive income.

All of the Group's financial liabilities, which consist of borrowing and accounts payable, are classified as other financial liabilities and are measured at amortized cost.

Impairment of financial assets

A loss allowance for expected credit losses is to be calculated and recognized for financial assets measured at amortized cost and financial assets measured at fair value through other comprehensive income. The Group holds no financial assets measured at fair value through other comprehensive income. The loss allowance for credit losses is initially calculated and recognized based on 12 months' expected credit losses. If the credit risk has increased significantly since the financial asset was initially acquired, the loss allowance for credit losses is calculated and recognized based on expected credit losses for the full remaining term of the asset. For accounts receivable that do not contain a material financing component, a simplified method is applied and the loss allowance for credit losses is calculated and recognized based on expected credit losses for the entire remaining term regardless of whether or not the credit risk has significantly increased. The calculation of expected credit losses is based primarily on information regarding historical losses for similar receivables and counterparties. The historical information is continually evaluated and adjusted based on the current situation, and the Group's expectations regarding future events.

Accounts receivable

Accounts receivable are initially recognized at fair value and subsequently at amortized cost using the effective interest method, including any provision for impairment. The carrying amount of accounts receivable, after any impairment, is assumed to correspond to its fair value due to the short-term nature of this item.

Cash and cash equivalents

Cash and cash equivalents include cash, bank balances and other current investments with a maturity of three months or less from the acquisition date.

Share capital

Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares are recognized, net of tax, in other paid-in capital as a deduction from the proceeds.

Accounts payable

Accounts payable are initially recognized at fair value and subsequently at amortized cost using the effective interest method. The carrying amount of accounts payable is assumed to correspond to its fair value due to the short-term nature of this item.

Borrowings
Borrowings (including from credit institutions, related parties and other long-term borrowings) are initially recognized at fair value, net of transaction costs. Borrowings are subse- quently recognized at amortized cost, and any difference between the amount received (net of transaction costs) and the repayment amount is recognized in profit or loss over the term of the loan applying the effective interest method.

Borrowings are classified as current liabilities unless the Group has an unconditional right to defer payment of the liability for at least 12 months after the balance sheet date.

Borrowing costs (interest expenses and transaction costs) are recognized in profit or loss in the period in which they are incurred. Accrued interest not paid is recognized in borrowings in the balance sheet. As of the balance sheet date, neither the Group nor the Parent Company had any outstanding loans payable.

Inventory
Inventory is recognized according to the standard cost method. The value of the products in inventory comprises the direct costs of acquisition and indirect costs such as personnel costs, depreciation, maintenance, etc. The calculation of indirect production costs is based on a method of calculating standard costs. This method is reviewed on a regular basis to ensure a reasonable calculation of relevant invoices. Changes in the method for calculating indirect production costs could impact the gross margin and the overall valuation of the inventory. A required provision for obsolescence is made in accordance with individual assessments.

Current and deferred tax
The current tax expense is calculated on the basis of the tax rules enacted or substantively enacted on the balance sheet date in the countries in which the Parent Company's subsidiaries operate and generate taxable income. Management regularly evaluates the claims made in tax returns with respect to situations in which applicable tax rules are subject to interpretation and, when deemed appropriate, makes provisions for amounts that are likely to be paid to the tax authorities.

Deferred tax is recognized in its entirety, according to the balance sheet method, for all temporary differences arising between the tax base of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is determined using tax rates (and tax laws) that have been enacted or substantively enacted on the balance sheet date and are expected to apply when the deferred tax asset is realized or the deferred tax liability is settled.

Deferred tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. As of the balance sheet date, no loss carryforwards had been recognized as a deferred tax asset in the Group.

Employee benefits
Pension obligations

The Group has defined-contribution pension plans for employees residing in Sweden. For these defined-contribution pension plans, IRRAS pays fees to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no additional payment obligations once the fees have been paid.

The fees are recognized as personnel costs as they are earned through employees performing services for the company. Prepaid fees are recognized as an asset to the extent that a cash reimbursement or reduction of future payments will accrue to the Group. Costs for service in earlier periods are recognized directly in profit or loss. Remuneration upon termination is expensed directly in the period when the obligation to work has ended.

The Group neither pays pensions nor has pension obligations for employees residing in the US or Germany.

Share-based remuneration

The Group has share-based remuneration plans in which the company obtains services from employees as compensation for the Group's equity instruments. Information about these plans is presented in Note 10.

Incentive programs

IRRAS has four incentive programs outstanding for employees, key personnel and Board members. The value of the personnel option programs is recognized as a personnel cost, with an equivalent increase in equity. The total amount expensed is based on the calculated fair value of the allotted options at the start of the program, and is allocated on a straight-line basis over the vesting period.

Non-market-based conditions for vesting, including a condition concerning continued employment, are taken into account in the assumption regarding the number of options expected to be vested. The options allotted in incentive programs are vested over one, two or three years, respectively, and in one case over four years (graded vesting); see Note 10. The cost of the partial programs is allocated over the respective vesting periods, which results in the cost of the respective incentive programs being highest in the first year and subsequently declining each year. At the end of each reporting period, the company re-examines its assessments with respect to the number of shares it expects to be vested based on the non-market-based vesting terms. Any deviations from the original assessments that the re-examination gives rise to impact the total accrued cost to be recognized, and thereby the cost for the current period. The fair value of the options is not remeasured after the start of the program.

When the options are exercised, the company issues new shares. Payments received less any directly attributable transaction costs are credited to share capital (quota value) and other paid-in capital when the options are exercised.

Social security contributions on the benefit that are expected to arise in connection with an increase in value are recognized on a continual basis over the vesting period, taking into account the changes in value, if applicable, based on the country where the employee resides.

Provisions
Provisions are recognized when the Group has a legal or informal obligation as a result of a past event, it is probable that an out*flow* of resources will be required to settle the obligation, and the amount of the obligation can be estimated reliably. No provisions are recognized for future operating losses. As of the balance sheet date, there were no provisions regarding individually signed endowment insurances in the Group. The provisions are measured at the market value of the amount expected to be required to settle the obligation.

Revenue recognition
The Group applies IFRS 15 Revenue from Contracts with Customers, which entails that information about the type of revenue, the time of settlement, uncertainties related to revenue recognition and cash *flow* attributable to the company's customer contracts must be provided. In accordance with IFRS 15, revenue must be recognized when the customer receives control of the goods or services sold and has the possibility of using and gaining benefits from the goods or services. For revenue recognition, IRRAS AB recognizes primary geographic markets and time.

Sales of goods

The Group's revenue is generated in part from the sale of products developed and produced in the Group.

Revenue from the sale of goods is recognized when the control associated with ownership of the goods is transferred from the Group to the customer, when the Group no longer exerts any real control over the goods sold and control passes to the customer, when revenue and related expenses can be estimated reliably, and when it is probable that the economic benefits associated with the sale of goods will accrue to the Group.

Government grants and official remuneration

Government grants and official remuneration, including non-monetary grants recognized at fair value, are recognized as revenue in profit or loss. The Group does not recognize revenue until there is reasonable assurance that the conditions associated with the grants or remuneration have been met and it is decided that they will be received. The grants and remuneration are initially recognized as revenue on the date they are received. At present, there are no grants or remuneration.

Interest income

Interest income is recognized over the maturity period using the effective interest method.

Accounting policies in the Parent Company

The accounting policies in the Parent Company are consistent in all material respects with the consolidated financial statements. The Parent Company's financial statements are prepared in accordance with RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act. RFR 2 specifies exemptions from and amendments to the standards released by IASB as well as interpretations issued by IFRIC. These exceptions and amendments are to apply from the date on which the legal entity applies the specified standard or interpretation within its consolidated financial statements.

The Parent Company uses the formats set out in the Annual Accounts Act, which includes using a different presentation of equity.

The Parent Company does not apply IFRS 9 Financial Instruments. Financial instruments are measured at cost. The policies for impairment testing and loss risk allowance in IFRS 9 are applied for financial assets and for receivables from other Group companies.

The Parent Company applies the exemption rule in RFR 2 and does not apply IFRS 16 Leases. As a lessee, lease payments are expensed on a straight-line basis of the lease term.

Shares in subsidiaries are recognized at amortized cost less any impairment. When there is an indication that shares and participations in subsidiaries have decreased in value, an estimate is made of the recoverable amount. If the recoverable amount is lower than the carrying amount, an impairment loss is recognized. Impairment is recognized under "Profit from participation in Group companies". The cost of participations in subsidiaries includes transaction costs. Transaction fees are expensed in the consolidated financial statements in the period in which they arise.

For the Parent Company, the option programs entail (to the extent they give rise to option expenses in the subsidiaries) that the issue of equity instruments is deemed to be a shareholder contribution in the subsidiaries from the Parent Company, which is why it is recognized as an investment in subsidiaries and not as a personnel cost in profit or loss. Like other contributions, the investment is tested for impairment. If impairment is required for shares in subsidiaries, a financial expense is recognized in Parent Company profit or loss.

NOTE 3 FINANCIAL RISK MANAGEMENT

In the course of its operations, the Group is exposed to various types of financial risks including currency risk, interest rate risk, credit risk and liquidity/financing risk. The Group's overall risk management policy focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on earnings and liquidity due to financial risks. As of December 31, 2020, the Group's financial risks were continued limited, since the business is still in a relatively early stage.

The Group's CFO is responsible for risk management, in accordance with guidelines established by the Board. The risk function includes identifying and evaluating financial risks. The Group does not apply hedge accounting in accordance with the regulations of IAS 39.

Currency risk

The Group is exposed to currency risks in the form of transaction exposure and translation exposure. Transaction exposure means the exposure to currency risk that arises in conjunction with deposits and payments in foreign currencies. Translation exposure means the exposure to currency risk that arises upon the translation of the assets and liabilities of foreign subsidiaries and upon the translation of receivables and liabilities in foreign currency at the closing day rate. The primary exposure to currency risk derives from the translation of the subsidiary in the US (translation exposure). The Group's transaction exposure is relatively low, since the Group companies operate primarily in their local markets and their revenue and expenses are therefore in the same currency.

The Group's net profit for the year includes exchange differences in EBIT and net financial items; see Notes 7 and 8 for further information.

Transaction exposure

If the average exchange rate for the EUR against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's sales would have been positively/negatively impacted by approximately TSEK 363 (75). If the average exchange rate for the USD against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's sales would have been positively/negatively impacted by approximately TSEK 376 (454).

Translation exposure

The average exchange rate is used in the translation of the statements profit or loss of foreign subsidiaries, while net assets are measured at the closing day rate. The relevant currencies in this context are the EUR and the USD.

Of the Group's loss before tax during the fiscal year, approximately TSEK –1 (–341) was attributable to the German subsidiary, and net assets totaled TSEK –16,256 (–16,896) as of the balance sheet date. If the average exchange rate for the EUR against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's loss before tax for the fiscal year would have been impacted by approximately TSEK 0.1 (34) upon translation of the foreign subsidiary's statement of profit or loss. If the exchange rate for the EUR against the SEK had been 10% higher/lower compared to the closing exchange rate at the end of the fiscal year, with all other variables unchanged, the Group's net assets at the end of the fiscal year would have been impacted by approximately TSEK 1,626 (1,690) upon the translation of the foreign subsidiary.

Of the Group's loss before tax during the fiscal year, approximately TSEK –95,182 (–105,892) was attributable to the US subsidiary, and net assets totaled TSEK 30,855 (20,961) as of the balance sheet date. If the average exchange rate for the USD against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's loss before tax for the fiscal year would have been impacted by approximately TSEK 9,518 (10,590) upon translation of the foreign subsidiary's statement of profit or loss. If the exchange rate for the USD against the SEK had been 10% higher/lower compared to the closing exchange rate at the end of the fiscal year, with all other variables unchanged, the Group's net assets at the end of the fiscal year would have been impacted by approximately TSEK 3,086 (2,096) upon the translation of the foreign subsidiary.

The Group's cash and cash equivalents and accounts payable are largely denominated in the local currencies of the respective companies, which means that translation exposure for changed exchange rates has no material impact on the Group's earnings. This is due to the fact that translation effects on receivables and liabilities in the local currencies of the respective Group companies impact equity and not profit or loss.

Interest rate risk
Interest rate risk is the risk that net interest income will vary and/or develop negatively due to changes in the market since most of the Group's cash is in the Swedish Parent Company and the Group has limited interest-bearing liabilities. Where possible, the level of interest rate risk is to be kept low by fixing interest rates through the purchase of bonds.

Sensitivity analysis – interest rate risk.
If the interest rate level during the year had been 100 basis points higher, net interest income and equity would have been affected by TSEK 1,170 (547) before tax. The sensitivity analysis is based on an interest rate scenario that company management considers to be reasonably possible over the coming 12 months.

Credit risk
Credit risk, or counterparty risk, is the risk that the counterparty to a financial transaction may default on the maturity date. Credit risk is managed at the Group level through a careful evaluation of new counterparties, and subsequently, a continual evaluation of existing counterparties. Credit risks are primarily attributable to accounts receivable, investments in bonds and balances in banks and financial institutions. As of December 31, 2020, outstanding claims against third parties were minimal, apart from bank balances. All bonds had matured as of December 31, 2020.

The financial investments 2019 were primarily comprised of securities issued by major listed credit institutions

	Group		**Parent Company**	
Financial investments (amounts in TSEK)	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Bonds, rating				
A	–	5,064	–	5,064
A–	–	20,260	–	20,260
BBB	–	–	–	–
N/A	–	30,289	–	30,289
Total	**–**	**55,613**	**–**	**55,613**

Bank balances are invested in banks with a credit rating of A or higher, and are available on demand. Considering the short tenor and the counterparties' high level of creditworthiness, the credit risk associated with these balances is deemed to be low and the expected credit losses are deemed to be negligible.

	Group		**Parent Company**	
Cash and cash equivalents (amounts in TSEK)	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Rating				
AA–	117,819	22,670	116,914	22,670
A+	17,785	6,844	–	–
Total	**135,604**	**29,514**	**116,914**	**22,670**

Maturity analysis
Other financial liabilities in the Group comprise operating payables and lease liabilities. Operating payables fall due for payment within one year. The nominal undiscounted cash flow that is to be settled within one year corresponds to the carrying amount as of the balance sheet date. Lease liabilities are effectively secured as the rights to the leased assets recognized in the financial statements revert to the lessor in the event of default. Of the total lease liability, SEK 4 million falls due within 12 months and SEK 0.1 million within 24 months.

Financial instruments by category

Group	**Dec 31, 2020**	**Dec 31, 2019**
	Amortized cost	**Amortized cost**
Assets in the balance sheet		
Financial investments	–	–
Current tax receivables	–	–
Accounts receivable	5,056	2,803
Other receivables	1,292	1,498
Accrued income	–	67
Current investments	–	55,613
Cash and cash equivalents	135,604	29,514
Total	**141,952**	**89,496**

	Dec 31, 2020	**Dec 31, 2019**
Group	**Other financial liabilities**	**Other financial liabilities**
Liabilities in the balance sheet		
Non-current lease liabilities	76	2,022
Accounts payable	3,450	7,481
Lease liabilities	3,922	4,030
Other liabilities	7,329	731
Accrued expenses	11,906	13,258
Total	**26,683**	**27,522**

The carrying amount of financial investments, current receivables and current liabilities is a reasonable approximation of fair value.

Liquidity risk/financing risk and going concern
As of December 31, 2020, the Group had available liquidity of TSEK 135,604. Liquidity consists of bank balances. From a capital structure perspective, current investments and financial investments are also included in net debt even though they are not classified as cash and cash equivalents.

At year-end, there were only external borrowings of TSEK 6,813 in the Group, as a result of the relief loan in the US subsidiary. The objective regarding the capital structure is to safeguard the Group's ability to continue its operations in order to generate returns for shareholders and benefits for other stakeholders, and to maintain an optimal capital structure to minimize the cost of capital.

The Group´s liquidity is not sufficient to cover the planned operations in the next 12 months. In light of this, work is underway on possible financial solutions and the Board considers that the prospects are good to finance the company´s operations. However, if sufficient financing is not obtained, there is a risk that conditions for going concern are not fulfilled.

	Group		Parent Company	
Net debt (amounts in TSEK)	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Interest-bearing liabilities				
Interest-bearing liabilities				
Cash and cash equivalents	–135,604	–29,514	–116,914	–22,670
Current investments	–	–55,613	–	–55,613
Financial investments	–	–	–	–
Lease liabilities	3,998	6,052	–	–
Net debt	**–131,606**	**–79,075**	**–116,914**	**–78,283**

NOTE 4 CRITICAL ACCOUNTING ESTIMATES AND ASSUMPTIONS IN APPLYING THE GROUP'S ACCOUNTING POLICIES

Critical accounting estimates and assumptions
The Group makes estimates and assumptions concerning the future. The accounting estimates resulting from these will, by definition, seldom correspond to the actual outcome. The estimates and assumptions that could cause a risk of material adjustment to the carrying amounts of assets and liabilities within the next fiscal year are summarized below.

Incentive programs
In 2016, a personnel option program was introduced for a number of employees in IRRAS' foreign subsidiaries. In 2017 and 2018, an additional four incentive programs were introduced for employees in Sweden and abroad.

During 2020, a sixth program for employees in Sweden and abroad was introduced at the same time as two incentive programs expired. The vesting and exercise periods of the options span several fiscal years, and assumptions and estimates have therefore been made regarding the probable exercise date. Furthermore, additional assumptions and estimates were made concerning the inputs for the valuation of the options. Two of the incentive programs contains non-market-based performance conditions. This means that estimates need to be made concerning when it will be more likely than not that the conditions will be met; only at that point will an expense be recognized for the incentive program.

For additional information regarding assumptions in the measurement of the options and conditions, see *Summary of significant accounting principles* and *Note 10 Employee benefits*.

Capitalized development expenses
IRRAS regularly assesses the value of capitalized development expenses.

The most critical assumption, which has been the subject of evaluation by management, is whether capitalized expenses will generate future economic benefits that, at a minimum, correspond to the amounts capitalized. Project capitalization begins when a research project is transferred to development of a clearly defined sellable product or product enhancement. Capitalization ends and amortization begins when the product is ready for launch. As of the balance sheet date, management's assessment is that future cash *flows* will be sufficient to cover the investments and that no need for impairment therefore exists.

NOTE 5 NET REVENUE

Net revenue is divided into different groups of countries as follows:

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Germany	105	–	1,400	1,551
Europe, excluding Germany	3,679	–	–	–
USA	3,183	4,542	3,326	–
Other countries	423	746	–	–
Total net revenue by geographic market	**7,390**	**5,288**	**4,726**	**1,551**

Parent Company sales refer entirely to management fees and other remuneration from subsidiaries.

NOTE 6 BREAKDOWN OF EXPENSES BY TYPE OF COST

Operating profit/loss by type of cost

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Net revenue	7,390	5,288	4,726	1,551
Capitalized work for own account	7,795	7,963	7,795	7,963
Other operating income	1,594	1,083	940	187
Raw materials and consumables	–480	–3,278	–	–
Other external costs	–49,892	–70,162	–20,272	–26,774
Personnel costs	–83,495	–78,754	–21,624	–19,213
Depreciation, amortization and impairment	–16,326	–12,576	–11,151	–10,249
Other operating expenses	–901	–1,051	–505	–850
Operating loss (EBIT)	**–134,316**	**–151,486**	**–40,091**	**–47,384**

NOTE 7 OTHER OPERATING INCOME AND OTHER OPERATING EXPENSES

Other operating income

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Exchange differences	1,291	651	933	167
Gain on disposal of equipment	–	3	–	–
Gain on disposal of right-of-use assets	17	1	–	–
Other	286	429	7	20
Total other operating income	**1,594**	**1,083**	**940**	**187**

Other operating expenses

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Exchange differences	901	1,030	505	850
Loss on disposal of equipment	–	21	–	–
Total other operating expenses	**901**	**1,051**	**505**	**850**

NOTE 8 FINANCIAL ITEMS

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Financial income				
Exchange differences	–	–	–	–
Interest income	8	485	304	845
Other financial income	–	197	–	197
Total financial income	**8**	**682**	**304**	**1,042**
Financial expenses				
Exchange differences	1,218	187	1,218	59
Interest expenses	219	37	218	34
Upplåningskostnader				
Interest expenses on leases	159	107	–	–
Other financial expenses	–	–	–	–
Total financial expenses	**1,596**	**332**	**1,436**	**92**
Profit from financial items, net	**–1,588**	**350**	**–1,133**	**950**

NOTE 9 AUDIT FEES

Audit engagements include statutory audits of the annual accounts and consolidated financial statements and the administration by the Board and CEO as well as audits and other reviews performed under agreement or contract. Audit engagements also include other duties that are incumbent upon the company's auditors as well as advisory services or other assistance resulting from observations made during such a review or the completion of other such duties.

In 2020, KPMG conducted a review of the company's prospectus in in connection with the rights issue, which is listed below as the other audit assignments.

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
KPMG				
Audit engagement	574	1,011	574	1,011
Other audit engagements	583	24	583	24
Other advisory services	17	483	17	483
Total	**1,174**	**1,517**	**1,174**	**1,517**

NOTE 10 EMPLOYEES, PERSONNEL EXPENSES AND REMUNERATIONS FOR SENIOR EXECUTIVES

Costs for salaries, other remuneration and social security expenses

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Salaries and remuneration	68,026	62,197	16,917	14,054
of which variable salary	*6,099*	*7,847*	*3,225*	*2,425*
Social security expenses	6,092	5,308	2,332	2,149
Incentive programs	−361	2,224	754	1,939
Pension costs	903	558	903	558
Total	**74,660**	**70,287**	**20,907**	**18,700**

Average number of employees

	Jan 1, 2020– Dec 31, 2020		Jan 1, 2019– Dec 31, 2019	
	Average number of employees	Of whom men	Average number of employees	Of whom men
Parent Company				
Sweden	6	69%	4	48%
Total in the Parent Company	**6**	**69%**	**4**	**48%**
Subsidiaries				
Germany	3	60%	3	67%
USA	34	63%	28	69%
Total in subsidiaries	**37**	**62%**	**31**	**69%**
Group total	**43**	**63%**	**35**	**67%**

Salaries and other remuneration allocated among senior executives[1)]

	Jan 1, 2020– Dec 31, 2020				Jan 1, 2019– Dec 31, 2019			
	Base salary, board remuneration[2)]	Variable remuneration[3)]	Pension costs	Share-based remuneration[4)]	Base salary, board remuneration[2)]	Variable remuneration[3)]	Pension costs	Share-based remuneration[4)]
Group								
Board members, CEOs and other senior executives, of whom:	15,809	3,362	305	–	17,328	3,140	1,692	3,173
President and CEO Kleanthis G. Xanthopoulos	5,882	1,946	–	–	5,824	2,065	–	3,124
Deputy CEO and CFO Fredrik Alpsten[5)]	–	–	–	–	377	–	1,536	–
Deputy CEO and CFO Sabina Berlin[6)]	1,243	194	305	–	547	81	156	–
Chairman of the Board Anders P. Wiklund[7]	428	–	–	–	553	–	–	–
Chairman of the Board Marios Fotiadis[7)]	353	–	–	–	223	–	–	–
Board membert Saied Esmaeilzadeh	–	–	–	–	83	–	–	–
Board member Anita Tollstadius	340	–	–	–	282	–	–	–
Board member Eva Nilsagård	340	–	–	–	323	–	–	–
Board member Catherine Gilmore-Lawless	436	–	–	–	254	–	–	–
Other senior executives[8)]	6,787	1,222	–	–	8,861	994	–	49
Total	**15,809**	**3,362**	**305**	**–**	**17,328**	**3,140**	**1,692**	**3,173**
Parent Company								
Board members, CEOs and other senior executives, of whom:	9,022	2,140	305	–	8,466	2,146	1,692	3,124
President and CEO Kleanthis G. Xanthopoulos	5,882	1,946	–	–	5,824	2,065	–	3,124
Deputy CEO and CFO Fredrik Alpsten[5]	–	–	–	–	377	–	1,536	–
Deputy CEO and CFO Sabina Berlin[6)]	1,243	194	305	–	547	81	156	–
Chairman of the Board Anders P. Wiklund[7]	428	–	–	–	553	–	–	–
Chairman of the Board Marios Fotiadis[7]	353	–	–	–	223	–	–	–
Board member Saied Esmaeilzadeh	–	–	–	–	83	–	–	–
Board member Anita Tollstadius	340	–	–	–	282	–	–	–
Board member Eva Nilsagård	340	–	–	–	323	–	–	–
Board member Catherine Gilmore-Lawless	436	–	–		254	–	–	–
Total	**9,022**	**2,140**	**305**	**–**	**8,466**	**2,146**	**1,692**	**3,124**

1) With exception for share-based remuneration, the table shows remuneration earned during the year. Share-based remuneration is reported to the extent that it has been the subject to vesting during the year.
2) Includes holiday pay
3) Variable remuneration earned during the year and paid out the following year. Consists only of bonus.
4) Calculated as the number of shares in the company's incentive program vested during the year multiplied by the share price for IRRAS' share on the balance sheet date minus the exercise price for the options. As the share price was below the exercise price for certain vested options, those are reported to zero value in the table above.
5) Deputy CEO until June 2019. For 2019, the reported remuneration shows the period January-June.
6) Deputy CEO from July 2019. For 2019, the reported remuneration shows the period July-December.
7) After the Chairman of the Board, Anders P. Wiklund, passed away in August 2020, he was replaced by Marios Fotiadis as Chairman of the Board.
8) Other senior executives refers to the management group, except the CEO and deputy CEO. In 2020, this included Will Martin, Kellie Fontes and Adam Sampson. In 2019, the management group comprised Will Martin, Kellie Fontes, Adam Sampson, Vinny Podichetti (as of March 2019 until September 2019) and Lance Boling (until June 2019).

Gender distribution among Board members and other senior executives

	Jan 1, 2020– Dec 31, 2020		Jan 1, 2019– Dec 31, 2019	
	Number on balance sheet date	Of whom men	Number on balance sheet date	Of whom men
Group				
Board members	5	40%	6	50%
CEO and other senior executives	5	60%	5	60%
Group total	**10**	**50%**	**11**	**55%**
Parent Company				
Board members	5	40%	6	50%
CEO and other senior executives	2	50%	2	50%
Parent Company total	**7**	**43%**	**8**	**50%**

Share-based remuneration

IRRAS has introduced share-based remuneration for employees in the form of incentive programs and share rights for the purpose of motivating and rewarding employees through participation in order to benefit the company's long-term interests. The fair value of the options at the start of the program is recognized as a personnel cost with a corresponding increase directly in equity. The cost of the incentive programs awarded to employees in the subsidiaries is recognized in the Parent Company's accounts as a participation in Group companies. See Note 23.

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Cost of share-based remuneration				
Incentive program 1	–315	–69	587	1,426
Incentive program 2	–306	89	–	–
Incentive program 3	–	–	–	–
Incentive program 4	–	–	–	–
Incentive program 5	–92	2,204	–15	514
Incentive program 6	352	–	182	–
Total	**–361**	**2,224**	**754**	**1,939**

Options whose vesting depends on performance conditions that are not market conditions were measured using the Black & Scholes valuation model. The share price and the risk-free interest rate used are those in effect on the valuation date. The assessment of the volatility taken into account in the valuation is based on historical share volatility for equivalent companies.

Incentive program 1

In May 2016, employees were allotted 1,900,000 options at no cost, which based on the terms of employment are vested over periods of one to four years, respectively, with one quarter vested annually starting in May 2016. The deadline to exercise the vested options is September 30, 2025. As of December 31, 2020, there were 1,808,048 options outstanding, of which 1,401,476 were issued to company management.

Incentive program 2

In May 2017, employees were allotted 350,000 options — and 300,000 in 2018 — at no cost, which based on the terms of employment are vested over periods of one to three years, respectively, with one third vested annually starting in January 2017. The first third of the options are vested after one year; the remaining options are subsequently vested pro rata on a monthly basis. The deadline to exercise the vested options is September 30, 2025. As of December 31, 2020, there were 367,440 options outstanding, of which 265,000 were issued to company management.

Incentive program 3

The total program comprised 400,000 warrants. The deadline to exercise the vested warrants was October 31, 2020 and all warrants expired without having been exercised.

Incentive program 4

The total program comprised 100,000 warrants. The deadline to exercise the vested warrants was October 31, 2020 and all warrants expired without having been exercised.

Incentive program 5

The total program comprises 732,000 options, which based on the terms of employment are vested over periods of one to three years, respectively, with one third vested annually starting in June 2018. The deadline to exercise the vested options is March 3, 2023. As of December 31, 2020, there were 517,232 options outstanding, of which 105,541 were issued to company management.

When it comes to exercising the issued options, the Board has introduced performance requirements for the allotted options.

34% (11% for 2019, 11% for 2020 and 12% for 2021) of the options can only be exercised by the employee if the company meets the sales targets set by the Board for 2019, 2020 and 2021.

33% (11% for 2019, 11% for 2020 and 11% for 2021) of the options can only be exercised by the employee if the company obtains its planned registration clearance in Europe, the US and the rest of the world within the period of time prescribed.

33% (11% for 2019, 11% for 2020 and 11% for 2021) of the options can only be exercised by the employee if the company launches the six new products announced in 2019, 2020 and 2021.

Milestones for the registration clearance and launch of two new products was obtained in 2019, which means that 22% of the options are deemed to be vested. Registration of new products or in new markets and launch of new products proceeded according to plan in 2020, which means that 22% of the options are deemed to be vested.

Incentive program 6

A new incentive program was approved at the Annual General Meeting on April 28, 2020. The total program comprises 1,050,000 personnel options. The options are granted based on the achievement of corporate goals and are vested over three years with one third vested annually. Each option entitles the holder to subscribe for one new share at an exercise price calculated at the grant date and can be exercised between the third and the eight anniversaries of the commencement date, subject to the requirement that the options are vested. The program ends at the next Annual General Meeting in 2021.

As of December 31, 2020, there were 507,024 options outstanding, of which 304,024 were issued to company management.

	Incentive programs					
	Program 1	Program 2	Program 3	Program 4	Program 5	Program 6
Number of personnel options allotted As of Dec 31, 2018	**1,880,000**	**643,000**	**320,000**	**100,000**	**268,750**	**0**
Forfeited during the period	–187,142	–130,000	–	–	–187,000	–
Exercised during the period	–	–	–	–	–	–
Allotted during the period	15,476	6,912	–	–	553,487	–
As of Dec 31, 2019	**1,708,334**	**519,912**	**320,000**	**100,000**	**635,237**	**0**
Forfeited during the period	–154,786	–152,472	–320,000	–100,000	–150,505	–
Exercised during the period	–	–	–	–	–	–
Allotted during the period	254,500	–	–	–	32,500	507,024
As of Dec 31, 2020	**1,808,048**	**367,440**	**0**	**0**	**517,232**	**507,024**

	No. outstanding as of Dec 31, 2020	No. vested as of Dec 31, 2020	Exercise price	Share price on valuation date, range	Volatility, expected	Option value per share, range	Expected dividend per share	Maturity
Personnel options								
Incentive program 1	1,808,048	1,537,441	13.6	5.8–34.6	30%	0.0–21.5	–	Sep 30, 2025
Incentive program 2	367,440	342,878	35.0	25–34.6	30%	1.5–7.9	–	Sep 30, 2025
Incentive program 3	–	–	50.0	30.0	30%	–	–	Oct 31, 2020
Incentive program 4	–	–	50.0	30.0	30%	–	–	Oct 31, 2020
Incentive program 5	517,232	287,807	25.86	13.8–43.3	30%	0.0–19.2	–	Mar 3, 2023
Incentive program 6	507,024	–	*	5.7–7.5	50%	0.1–3.0	–	Nov 30, 2028
Total incentive programs	**3,199,744**	**2,168,126**						

* The redemption price depends on the allotment date.

Defined-contribution plans

There are defined-contribution pension plans that are safeguarded through insurance in SPP. The fees for the year for pension insurance signed with SPP totaled TSEK 903 (558).

NOTE 11 RELATED-PARTY TRANSACTIONS

Related parties are defined as the members of company management in the Parent Company, the Board of Directors of the Parent Company and subsidiaries. Shares in the subsidiaries and lending between Group companies are eliminated in the consolidated financial statements, which is why detailed accounts of these amounts are not presented. For the Parent Company, the subsidiaries constitute related parties.

Parent Company	Dec 31, 2020	Dec 31, 2019
Receivables from Group Companies, non-current	23,101	17,226
Receivables from Group Companies, current	–	–

During the fiscal year, Parent Company sales regarding management fees to subsidiaries totaled TSEK 1,400 (1,551) and allocation of earnings to subsidiaries totaled TSEK 3,326 (0), which corresponds to 100% of sales. Purchases from subsidiaries regarding allocation of earnings amounted to TSEK 0 (6,109). No portion of this amount was outstanding on the balance sheet date.

Apart from the information in Note 10, the following transactions took place with related parties during the fiscal year and comparison years:

The Group purchased office equipment from a party related to President and CEO Xanthopoulos. The cost for the year totaled TSEK 7 (231). The Group also purchased educational services from a party related to President and CEO . The cost for the year totaled TSEK 387 (0).

The Group leased offices from a party related to President and CEO Kleanthis G. Xanthopoulos until April 2019. The cost for the year totaled TSEK 0 tkr (38).

Transactions with related parties took place on market terms.

NOTE 12 INCOME TAX

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Current tax for the year	7	–	–	–
Current tax attributable to previous years	5	8	–	–
Total tax on net loss for the year	**12**	**8**	**–**	**–**

The differences between the recognized tax expense and the actual tax expense based on the prevailing tax rate is as follows:

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Loss before tax	–135,903	–151,136	–41,224	–46,434
Income tax calculated according to the Group's applicable tax rate	29,083	32,343	8,822	9,937
Non-taxable income	77	42	–161	42
Non-deductible expenses	–18	–903	–17	–837
Unrecognized deductible expenses	5,753	1,771	5,753	1,771
Loss carryforwards for which no deferred income tax asset was recognized	–42,938	–42,234	–14,396	–10,913
Tax effect of utilized, previously not measured, loss carryforwards	–	–	–	–
Effects of foreign tax rates	8,042	8,980	–	–
Adjustment of current tax for previous years	5	8	–	–
Income tax	**5**	**8**	**–**	**0**

The Group's effective tax rate was deemed to be 21.4% (21.4), which is the tax rate for the Swedish Parent Company. The effect of foreign tax rates is therefore attributable to the fact that the tax rate in the countries where the subsidiaries operate is different to that of the Group. The tax rate applied for Germany is 31% (31) and the tax rate applied for the US is 29.85% (29.85). In the period from 2019 until 2021, the Parent Company's tax rate will change. For 2019 to 2020, the tax rate will be 21.4 percent. For 2021, it will be lowered to 20.6%.

Temporary differences arise in the event that the recognized taxable value of assets and liabilities are different. Deferred tax liabilities pertaining to temporary differences attributable to investments in subsidiaries are not recognized since the Parent Company can govern the point in time for reversal of the temporary differences. Temporary differences also with respect to pension obligations and incentive programs, which the Group has chosen to recognize at SEK 0 for the year.

	Group		Parent Company	
	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019	Jan 1, 2020– Dec 31, 2020	Jan 1, 2019– Dec 31, 2019
Accumulated loss carryforwards	574,124	437,237	281,798	214,527

Of the accumulated loss carryforwards, TSEK 74,646 is blocked through 2021.

NOTE 13 INTANGIBLE ASSETS

A summary of the intangible assets (in TSEK) and changes in intangible assets during the reported periods is presented below:

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Capitalized development expenses				
Opening cost	57,092	49,129	57,092	49,129
Assets capitalized during the year	7,795	7,963	7,795	7,963
Closing accumulated cost	**64,887**	**57,092**	**64,887**	**57,092**
Opening amortization	–20,864	–11,038	–20,864	–11,038
Amortization for the year	–10,728	–9,826	–10,728	–9,826
Closing accumulated amortization	**–31,592**	**–20,864**	**–31,592**	**–20,864**
Closing carrying amount	**33,294**	**36,228**	**33,294**	**36,228**

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Patents				
Opening cost	11,188	4,429	4,429	4,429
Purchases	–	6,758	–	–
Exchange differences	–819	–	–	–
Closing accumulated cost	**10,369**	**11,188**	**4,429**	**4,429**
Opening amortization	–2,987	–2,215	–2,531	–2,215
Amortization for the year	–917	–772	–316	–316
Exchange differences	55	–	–	–
Closing accumulated amortization	**–3,848**	**–2,987**	**–2,847**	**–2,531**
Closing carrying amount	**6,521**	**8,201**	**1,582**	**1,898**

Amortization and impairment of capitalized development expenses are recognized in profit or loss under "Cost of sales", and amortization and impairment of patents are recognized under "R&D costs".

NOTE 14 TANGIBLE ASSETS

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Opening cost	1,339	784	532	532
Purchases	785	594	–	–
Sales and disposals	–	–47	–	–
Exchange differences	–90	8	–	–
Closing accumulated cost	**2,034**	**1,339**	**532**	**532**
Opening depreciation	–392	–161	–223	–116
Sales and disposals	–	26	–	–
Depreciation for the year	–348	–257	–106	–106
Exchange differences	17	–1	–	–
Closing accumulated depreciation	**–724**	**–392**	**–329**	**–223**
Closing carrying amount	**1,310**	**947**	**203**	**310**

Leases

Right-of-use assets	**Dec 31, 2020**	**Dec 31, 2019**
Properties	3,504	6,225
Vehicles	284	0

In 2019, a lease agreement was signed by IRRAS Inc, which lasted until July 31, 2021 and the Group signed and terminated a lease concerning a vehicle. In 2020 a lease agreement were signed for IRRAS Inc which extend until December 31, 2021 and the IRRAS Inc terminated a lease on November 30, 2020. IRRAS GmbH signed a lease concerning a vehicle during the year. Lease payments are discounted applying an incremental borrowing rate of 3.5%.

Group	**Dec 31, 2020**	**Dec 31, 2019**
Opening cost	6,225	–
Acquisitions for the year	2,370	8,074
Completed obligations	–864	–211
Accumulated depreciation	–3,189	–1,638
Exchange differences	–754	–
Closing carrying amount	**3,788**	**6,225**
Lease liabilities		
Current	3,922	4,030
Non-current	76	2,022
Closing carrying amount	**3,998**	**6,052**

Payments associated with short-term leases and leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a term of 12 months or less. Low-value assets comprise vehicles and office equipment.

The statement of profit or loss shows the following amounts relating to leases:

Group	2020	2019
Depreciation of right-of-use assets		
Properties	–3,739	–1,638
Vehicles	–26	–42
Disposal of right-of-use assets	576	42
Vehicles		
Total	**–3,189**	**–1,638**
Revenue attributable to the disposal of vehicles (included in other operating income)	–	1
Revenue attributable to the disposal of properties (included in other operating income)	17	–
Interest expenses (included in financial expenses)	–159	–107
Expenditure attributable to short-term leases (included in administrative and selling expenses)	–623	–2,736
Expenditure attributable to leases for which the underlying asset is of a low value that are not short-term leases (included in administrative expenses)	–82	–87
Expenditure attributable to lease payments not included in lease liabilities (included in administrative expenses)	–	–9

The total cash out*flow* for leases in 2020 was TSEK 3,786 (1,538).

NOTE 15 FINANCIAL INVESTMENTS

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
At the beginning of the year	55,613	110,821	55,613	110,821
Sales	–55,613	–55,208	–55,613	–55,208
Closing carrying amount	**–**	**55,613**	**–**	**55,613**

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Bonds, non-current	–	–	–	–
Bonds, current	–	55,613	–	55,613
Closing carrying amount	**–**	**55,613**	**–**	**55,613**

The bonds in the Parent Company are classified as *"Other securities held as non-current assets"* and *"Current investments"*, respectively, while those in the Group are classified as *"Financial investments"* and *"Current investments"*, respectively. These are measured at amortized cost using the effective interest method.

The fair value of the holdings essentially corresponds to the carrying amount; see Note 3.

NOTE 16 INVENTORY

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Finished goods and goods for resale	18,074	14,440	–	–
Closing carrying amount	**18,074**	**14,440**	**–**	**–**

NOTE 17 OTHER RECEIVABLESY

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Tax account	301	104	301	104
Cash deposits	596	833	104	104
VAT receivables	395	561	351	651
Other receivables	–	–	–	–
Total other receivables	**1,292**	**1,498**	**756**	**859**

NOTE 18 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Prepaid rent	48	50	48	48
Prepaid insurance costs	270	294	106	269
Accrued interest	–	67	–	67
Other items	912	1,579	581	1,481
Total prepaid expenses and accrued income	**1,229**	**1,992**	**734**	**1,865**

Other items primarily comprise prepaid expenses to Nasdaq and IT licenses.

NOTE 19 SHARE CAPITAL

Parent Company	**No. of shares**	**Share capital (SEK)**
Opening balance at January 1, 2019	**24,017,974**	**720,539**
New share issue	4,800,000	144,000
Closing balance at December 31, 2019	**28,817,974**	**864,539**
New share issue	37,463,366	1,123,901
Closing balance at December 31, 2020	**66,281,340**	**1,988,440**

The number of shares shown in the above table is the number that is recorded in the Parent Company share register. For more information, refer to the Parent Company statement of changes in equity. A specification of changes in equity is presented in the statement of changes in equity, which follows the company's balance sheet.

The shares have a quota value SEK 0.03 per share.

NOTE 20 ACCRUED EXPENSES AND DEFERRED INCOME

	Group		Parent Company	
	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Accrued salaries	7,451	6,797	4,104	3,490
Accrued vacation pay	1,407	2,094	252	136
Accrued social security contributions	739	649	739	649
Other personnel-related items	482	201	482	201
Consultancy fees	1,378	2,861	418	1,068
Audit	270	450	270	450
Other	178	207	21	24
Total accrued expenses and deferred income	**11,906**	**13,258**	**6,286**	**6,018**

NOTE 21 COMMITMENTS

Obligations in respect of operating leases

	Group		Parent Company	
Group	Dec 31, 2020	Dec 31, 2019	Dec 31, 2020	Dec 31, 2019
Within one year	143	150	143	143
Within one to five years	–	–	–	–
Later than five years	–	–	–	–
	143	**150**	**143**	**143**

NOTE 22 SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE

Early in 2021, IRRAS finalized a partnership with Aarhus University in Denmark to collaborate on clinical trial and research projects, including ACTIVE clinical study that compares IRRA*flow* to traditional drainage for IVH patients.

Key US customers, Buffalo General Medical Center and West Virginia University Hospital, transitioned to commercial customers after evaluations were completed in Q4 2020.

The company also successfully completed a Medical Device Single Audit Program (MDSAP) quality system audit, which confirms that IRRAS' internal processes exceed requirements required by key medical device markets of Japan, Brazil, Canada, and Australia.

NOTE 23 PARTICIPATIONS IN GROUP COMPANIES

Parent Company	**Dec 31, 2020**	**Dec 31, 2019**
Opening cost	232,980	68,745
Investment	109,028	163,950
Incentive programs	–1,115	284
Closing carrying amount	**340,893**	**232,980**

The Parent Company holds participations in the following subsidiaries, both of which were formed in 2016:

Name	**Corp. Reg. No.**	**Domicile**	**% of capital and votes**	**No. of shares**	**Carrying amount Dec 31, 2020**	**Carrying amount Dec 31, 2019**
IRRAS GmbH	DE308005079	Munich	100%	1	1,639	1,643
IRRAS USA Inc	611800152	La Jolla	100%	9,500,000	339,254	231,337
					340,893	**232,980**

For the Parent Company, the option programs entail (to the extent they give rise to option expenses in the subsidiaries) that the issue of equity instruments is deemed to be a shareholder contribution in the subsidiaries from the Parent Company, which is why it is recognized as an investment in subsidiaries and not as a personnel cost in profit or loss. Like other contributions, the investment is tested for impairment. If impairment is required for shares in subsidiaries, a financial expense is recognized in Parent Company profit or loss.

NOTE 24 PROPOSED APPROPRIATION OF EARNINGS

The Board proposes that the unappropriated earnings as of December 31, 2020 — SEK 476,774,029 — be carried forward.

For changes in equity during the fiscal year, refer to the Parent Company and consolidated statement of changes in equity.

NOTE 25 EARNINGS PER SHARE

	Before dilution		**After dilution**	
SEK	**2020**	**2019**	**2020**	**2019**
Earnings per share	–2.46	–5.61	–2.46	–5.61

The amount used in the numerator corresponds with the net loss for the year attributable to the Parent Company's shareholders, TSEK –135,916 (–151,144). The amount used in the denominator is recognized below.

The weighted average number of shares totaled 55,152,011 (26,937,426), which was impacted by new share issues during the fiscal year in question and the preceding fiscal year. The number of shares outstanding at the end of the year was 66,281,340 (28,817,974).

Instruments that could give rise to dilution effects and changes after the balance sheet date

The weighted average number of shares after dilution and earnings after dilution are the same as before dilution. Since the Group recognized a loss for the year and for the preceding fiscal year, potential ordinary shares would not give rise to dilution in terms of the average number of shares. There are incentive programs which, as of the date on which the Group recognizes a profit, will result in a dilution effect. For more information regarding the terms of the incentive programs and the number of options issued, refer to Notes 2 and 10. No changes in the number of shares before or after dilution have taken place after the balance sheet date.

The above Annual Report and consolidated financial statements have been approved for publication by the Board of Directors and the CEO.

Stockholm, 29 March, 2021

The consolidated statement of profit or loss and other comprehensive income, the statement of financial position and the Parent Company statement of profit or loss and balance sheet will be submitted for adoption at the Annual General Meeting on April 28, 2021.

Marios Fotiadis
Chairman of the Board

Kleanthis G. Xanthopoulos, PhD
CEO and Board member

Catherine Gilmore-Lawless
Board member

Eva Nilsagård
Board member

Anita Tollstadius
Board member

Our Auditor's Report was submitted on
30 March, 2021
KPMG AB

Duane Swanson
Authorized Public Accountant

Auditor's Report

To the general meeting of the shareholders of IRRAS AB, corp. id 556872-7134

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of IRRAS AB (publ) for the year 2020, except for the corporate governance statement on pages 64–69. The annual accounts and consolidated accounts of the company are included on pages 24–59 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2020 and its financial performance and cash *flow* for the year then ended in accordance with the 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 position of the group as of 31 December 2020 and their financial performance and cash *flow* for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 64–69. 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 adopts the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of 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.This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

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

Material uncertainty as to going concern

Without qualifying our opinion above, we bring to your attention the information on page 27 of the administration report and in note 3 on page 49 which states that the cash and cash equivalents are not sufficient to cover planned operations for the coming 12 months. In light of this, work is underway on possible financing solutions.These conditions indicate the existence of a material uncertainty as to the company's ability to continue as a going concern.

Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

Intangible assets and investment in subsidiaries

See disclosure 4,13, 23 and accounting principles on 45 and 48 in the annual account and consolidated accounts for detailed information and description of the matter.

Description of key audit matter

The consolidated carrying value at 31 December 2020 of intanbible assets totals 39.8 MSEK and is subject to impairment tests. The intangible assets are comprised of capitalized development costs of 33.3 MSEK and patents of 6.5 MSEK.

The impairment tests are dependent management's estimates and judgments in determining the future revenue, oprating results, working capital and investment levels. Another important assumption is which discount rate to be used in order to reflect the time value of money as well as the specific risks the operations face.

The parent company investment in subsidiaries as of 31 December 2020 totaled 341 MSEK. The same type of impairment test is used for the subsidiaries and is based on the same method and assumptions as used in the impairment test of goodwill.

Response in the audit

We have assessed whether the impairment tests for intangible assets and investments in subsidiaries have been prepared in accordance with the prescribed method and also assessed the reasonableness of the impairment tests of the carrying value for intangible assets in the consolidated accounts and investments in subsidiaries in the parent company..

Moreover, we have evaluated the assumptions used in the calculating future cash flows and discount rates by reviewing and assessing the written documentation and plans.

We have also examined the sensitivity analysis prepared by group management to evaluate how reasonable changes in the assumptions may impact the valuation.

We have also reviewed the disclosures related to impairment tests as stated in the annual accounts and consolidated accounts

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 1–23 and 64–73. The other information comprises also of the remuneration report which we obtained prior to the date of this auditor's report. The Board of Directors and the Managing Director are responsible for this other information.

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

In connection with our audit of the annual accounts 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 Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts 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 Managing Director 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. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

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 when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

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

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

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

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, measures that have been taken to eliminate the threats or related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

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 administration of the Board of Directors and the Managing Director of IRRAS AB (publ) for the year 2020 and the proposed appropriations of the company's profit or loss.

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

Basis for Opinions
We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of 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 that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director
The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's 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. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

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

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

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

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

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

The auditor's examination of the corporate governance statement
The Board of Directors is responsible for that the corporate governance statement on pages 64–69 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR´s auditing standard RevR 16 The auditor´s examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2–6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of IRRAS AB (publ) by the general meeting of the shareholders on the 28 04 2020. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2015.

Stockholm 30 March 2021

KPMG AB

Duane Swanson
Authorized Public Accountant

Corporate governance report

Corporate governance at IRRAS AB defines the decision-making systems, clarifies roles and the allocation of responsibilities among the Board, management and controlling bodies, and safeguards transparency in relation to the Group's stakeholders.

Corporate governance at IRRAS AB

Corporate governance is defined by Swedish law, particularly the Swedish Companies Act and the listing agreement with Nasdaq Stockholm. IRRAS AB follows the Swedish Code of Corporate Governance ("the Code").

General meetings

The general meeting is the company's highest decision-making body. The shares in the company are all of the same type; each share grants the right to one vote. The Annual General Meeting (AGM) elects the Board of Directors and auditors, and passes resolutions in accordance with the Companies Act and the Articles of Association. At the AGM, the Board presents the Annual Report and the consolidated financial statements.

The auditors present the Auditor's Report and the report on the consolidated financial statements. The notice to attend the AGM, which is published through a press release and on the company's website, provides information on the matters before the meeting. Resolutions passed at the AGM are made public through press releases and can be found on the website.

The 2021 AGM will be held on April 28. Due to the spread of COVID-19, the Board of Directors has resolved that the Annual General Meeting should be conducted without the psysical presence of shareholders, representatives or third parties and that the shareholders before the General Meeting should be able to exercise their voting right only by absentee ballot.

Nomination Committee

The AGM determines how the Nomination Committee is to be appointed. At the AGM on April 28, 2020, it was resolved that the Nomination Committee would consist of four members: representatives of the three largest shareholders at the end of September plus the Chairman of the Board.

Prior to the AGM, Christer Hellström, representing the company's largest shareholder, Bacara Holdings Limited, was appointed Chairman of the Nomination Committee. The Nomination Committee prepares documentation for resolution by the AGM regarding the election and remuneration of the Chairman of the AGM, the Board of Directors, the Chairman of the Board and the auditors.

The Nomination Committee reports on its activities at the AGM. No remuneration is paid for work on the Nomination Committee. The shareholders can turn to the Nomination Committee with proposals and viewpoints regarding the composition of the Board of Directors. The election of auditors took place at the AGM in 2020.

The composition of the Nomination Committee as of October 2020 is shown in the table below.

Name	Representing	Shareholding, %, December 31, 2020
Christer Hellström	Bacara Holdings Limited	24.49
Salameh Sweis	Lexington Holding Assets Ltd (BVI)	4.76
Carl-Mikael Lindholm	The Carl-Olof och Jenz Hamrins Foundation	4.53
Marios Fotiadis	Chairman of the Board	-

The Board of Directors

Under the Articles of Association, the Board of Directors is to consist of no less than three and no more than seven members, without deputies. Changes to the Articles of Association are resolved by the general meeting. The Board of Directors consists of five members. At the AGM on April 28 14, 2020, Anders P. Wiklund was elected Chairman of the Board and Eva Nilsagård, Catherine Gilmore-Lawless, Marios Fotiadis, Anita Tollstadius and Kleanthis G. Xanthopoulos were elected as Board members. After the passing of Anders P. Wiklund in August 2020, the Board of Directors elected Marios Fotiadis as Chairman of the Board.

The responsibilities of the Board are regulated in the Companies Act and the rules of procedure. The rules of procedure establish the allocation of Board duties between the Board and the Board committees as well as between the Board and the CEO. Under the rules of procedure, the Board is to: decide on strategy and budget; adopt the annual report and other external financial reporting, important policies and authorization instructions; elect the CEO and evaluate the CEO's activities; establish rules for internal control and monitor how internal control is functioning; decide on major investments and far-reaching agreements; decide on the direction of the Board's activities; appoint the Audit Committee and Remuneration Committee; and evaluate the Board's activities. Moreover, the Board is also to adopt the required guidelines for the company's conduct in society for the purpose of ensuring its long-term ability to create value. The Board must also monitor compliance with adopted guidelines on remuneration to senior executives, and propose guidelines for remuneration to the AGM.

MEMBERS OF THE BOARD AFTER THE ANNUAL GENERAL MEETING ON APRIL 28 2020

Name	Period	Function	Attendence	Independent of management	Independent of owners	Shareholding	Elected	Attendance Audit Committee	Attendance Remuneration Committee
Anders P. Wiklund	1/1–18/8	Chairman*	11/11	Yes	Yes	13,182	2016	-	2/2
Marios Fotiadis	1/1–31/12	Chairman*	13/15	Yes	No	19,389,824	2012	-	-
Catherine Gilmore-Lawless	14/5–31/12	Member	15/15	Yes	Yes	0	2019	-	4/4
Eva Nilsagård	1/1–31/12	Member	15/15	Yes	Yes	11,500	2018	6/6	-
Anita Tollstadius	1/1–31/12	Member	15/15	Yes	Yes	11,500	2017	6/6	4/4
Kleanthis G. Xanthopoulos	1/1–31/12	Member and CEO	15/15	No	No	1,101,487	2015	-	-

*Marios Fotiadis has held the position as Chairman of the Board for the period August 18, 2020 to December 31, 2020, after succeeding Anders P. Wiklund

The Chairman of the Board leads the Board's activities. The Chairman of the Board is to monitor the development of the company and ensure that the Board of Directors receives the information required for the Board to fulfill its commitments.

In accordance with the rules of procedure, the Chairman of the Board is to represent the company in ownership issues.

The Group has a simple legal and operational structure, and structured governance and internal control systems. In light of this, the Board has chosen not to have a separate internal audit function.

Remuneration to Board members

At the AGM in April 2020, it was resolved that a fee of SEK 540,000 would be paid to the Chairman of the Board, and a fee of SEK 336,000 to Catherine Gilmore-Lawless and SEK 240,000 to each of the other non-executive Board members. A fee of SEK 100,000 would be paid on an annual basis to the Chairman of each of the Audit Committee and Remuneration committee and 50,000 to each of the committee members.

Board activities

Board meetings are prepared by the Chairman of the Board together with the CEO and Deputy CEO of the company. The Board receives printed material prior to every meeting. Certain issues are addressed by the Audit Committee and the Remuneration Committee. Recurring matters addressed at Board meetings include a review of the business situation as well as financial reporting. The minutes are taken by the company's CFO.

Evaluating Board activities

The Board of Directors evaluates Board activities in accordance with the rules of procedure. This takes place both through discussions within the Board and through an annual external evaluation. No evaluation was held in 2021 since the Board was restructured in the fall of 2020, but the nomination committee has held evaluation meetings with all Board members.

Summary of Board meetings during the year

In 2020, the Board held 15 meetings. At each ordinary Board meeting, the business situation and financial reporting were discussed. The external auditors did not take part in any meetings during the year, but took part in four audit committee meetings during the year. Issues discussed in addition to recurring agenda items include continual reviews of long-term strategies, financing, reviews of new product opportunities, product quality, production strategy, revenue forecasts and the 2021 budget. The members of the Board are presented in the table at the top of the page.

Audit Committee

Since the inaugural Board meeting in April 2020, the Audit Committee has consisted of Board members Eva Nilsagård (Chairman) and Anita Tollstadius.

The primary task of the Committee is to ensure the quality of the financial reports, which includes internal control, review of material reporting and measurement issues, and review of the company's external reports. The Audit Committee evaluates the audit work and assists the Nomination Committee with proposals for the election of auditors and fees for the audit work. The Audit Committee establishes which services other than audit services the company can procure from its auditors. Certain meetings between the Audit Committee and the external auditors are to take place without the presence of employees. The Audit Committee reports to the Board of Directors. A total of six meetings were held in 2020.

Remuneration Committee

From the inaugural Board meeting in April 2020 to August 2020, the Remuneration Committee consisted of Catherine Gilmore-Lawless (Chairman), Anders Wiklund and Anita Tollstadius. From August 2020 the Remuneration Committee has consisted of Catherine Gilmore-Lawless (Chairman) and Anita Tollstadius.

The primary task of the Committee is to propose salaries, other remuneration and terms of employment for the CEO. The Committee develops proposals for remuneration policies and terms of employment for other senior executives in Group management as well as proposals for incentive programs. The Remuneration Committee is to ensure compliance with the established guidelines for remuneration to senior executives. The Committee held four meetings during the year.

Authorization for the Board

At an extraordinary general meeting on March 2, 2020, the Board was authorized to, with or without deviation from the shareholders' preemptive rights, on one or more occasions prior to the next AGM, to make decisions regarding an increase in the company's share capital through new issue of shares, convertibles and/or warrants, corresponding to an issue payment of maximum around MSEK 250. Later in April 2020 a rights issue was made, adding MSEK 217 to the company before fees.

Policies for remuneration and other terms of employment for Group management

The AGM establishes policies for remuneration to Group management. Proposals are prepared by the Remuneration Committee. The core principle is that IRRAS is to offer market-based terms that allow the company the recruit and retain skilled personnel. Remuneration to Group management is to consist of fixed salary, variable remuneration, a long-term incentive program, pension and other customary benefits. The remuneration is based on the individual's commitment and performance in relation to predetermined individual and company-wide goals. Individual performance is evaluated on a continual basis.

Audit

The company's auditors are elected at the AGM for a period of one year. At the scheduled AGM in 2020, KPMG was elected as the company's auditor, with Authorized Public Accountant Duane Swanson serving as auditor in charge for the audit in the Group. The company's auditor conducts a review of at least one interim report per year on the company's behalf. Other statutory audits of the Annual Report, the consolidated financial statements and accounting as well as the administration of the Board and the CEO are performed in accordance with the International Standards on Auditing and good auditing practice in Sweden. The auditors meet with the Board and the full Audit Committee on a yearly basis, both with and without company management present and summarizes audits and reviews and provides updates on coming changes in the regulations.

Financial reporting to the Board of Directors

The Board of Directors establishes which reports are to be prepared to enable the Board to monitor the company's development. The quality of the financial reporting to the Board is evaluated primarily by the Audit Committee.

External financial information

In accordance with the company's information policy, which is adopted annually by the Board, the company submits financial information in the form of interim report, year-end reports, annual reports and press releases in conjunction with significant events that could affect the share price. The disclosure of information follows the requirements indicated in the listing agreement with Nasdaq Stockholm. The Board of Directors discusses external financial reports before they are published. The information policy also establishes how communication is to take place, and who is to represent the company. The information distributed through press releases is also made available on the company's website, as is other information that is deemed valuable.

Internal control report

Under the Companies Act and the Code, the Board of Directors is responsible for internal control. The Board's internal control activities are based on the company's control environment, risk assessment, control activities, information and communication, and monitoring. Internal control is a process that is impacted by the Board, company management and other employees, and is designed to provide reasonable assurance that the company's goals with respect to suitable and efficient operations, reliable financial reporting and compliance with laws and regulations are achieved.

Control environment

The Board of Directors has overall responsibility for establishing and maintaining proper internal control by shaping the organization, decision-making channels, authorizations and responsibilities as expressed in policies and guidelines. Shared values create consensus and strengthen internal control. The struture created in 2017 and improved during the following years worked well in 2020 and only minor adjustments to specific controls were made. The Board establishes certain policies and instructions, including authorization instructions. The Board and company management consider quick, correct reporting to be important. The accounting function ensures that all operations are evaluated and their efficiency enhanced. The evaluation of internal control in the Group follows a plan approved annually by the Audit Committee. Responsibility for creating processes with suitable internal control lies with the respective heads of divisions.

Risk assessment

The company has established a process for risk assessment and risk management in order to ensure that the risks the company is exposed to are handled within the framework established by the Board. This is monitored by the Audit Committee through regular reporting from company management, which presents risk status updates and ongoing activities for managing the company's risks. Risk assessments with mitigation actions are regularly presented to the Board of Directors, which also resolves on the company's risk appetite.

Business processes are evaluated with regard to efficiency and risk. This includes identifying risks for inaccuracies in the financial reports. The company's support processes are also analyzed. An overall risk assessment is conducted yearly. The risks are graded and linked to processes. Processes deemed to be critical include development, manufacturing, sales and support processes such as accounting and IT. Processes for payments, salaries and pensions are also deemed to be critical and are included in evaluations. Any risks of material errors or shortcomings in the financial reports are to be reported to the Audit Committee.

Control activities

Identified risks regarding financial reporting are managed through control measures that limit the identified risks and ensure correct and reliable reporting. Control activities are developed by documenting important processes and defining central activities, after which the controls for them are determined and implemented.

All of the company's risk management activities and controls are managed in the Stratsys support system.

Information and communication

The Board and company management have established information and communication channels to ensure the company's financial reporting is complete and correct. Policy documents such as internal policies, guidelines and instructions are available through the company's quality system. Personnel from Group management regularly visit all the companies in the Group.

Monitoring

The Board of Directors has determined that internal control is to be monitored through self-assessment and testing of controls. Self-assessment means that the person responsible for each control evaluates the process and decides how well it has performed during the period. Regular testing of all of the company's controls is conducted by an internal, independent party, and is reported to the Audit Committee together with planned measures to improve any weaknesses in the controls.

The company's improvement efforts in 2020 included improved process documentation with focus on processes related to the company's ERP. The purpose of the review is to identify the overall control environment and material risks, and to introduce shared rules regarding overall control issues.

The Audit Committee monitors the company's internal control activities through continual feedback, and has regular contact with the external auditors, which also contributes to the Board's overall picture of internal control.

Planned activities for 2021

Focus in 2021 will be on the company's project processes and on an updated process mapping of all major financial processes in the company.

Board of Directors

Marios Fotiadis
Born in 1973. Board member since 2012 and Chairman of the Board since 2020.

Education: Marios Fotiadis holds a B.Sc. from the University of Denver and an MBA from Columbia University.

Other experience: Marios Fotiadis has more than 20 years of experience from positions within private equity and venture capital in the life science sector, including as a partner of Advent International and TVM Capital. Prior to that, he started his career in private equity and venture capital at SG Capital Partners

Other current assignments: Marios Fotiadis is Chairman and CEO of Cerus Advisors DMCC and a Board member of Bacara Holdings Ltd, Shoreline BioSciences, Levant Capital, KLARIS S.A., Sente Inc, Opocrin S.p.A. and Plastic Unbound Limited.

Previous assignments over the past five years: Board member of Mediolanum Farmaceutici Spa, Rossart Ltd, Lexington Holding Assets and Vandel Group JLT.

Shareholding in the company: 16,234,097 shares via Bacara Ltd and 3,155,727 shares via Lexington Holding Assets Ltd.

Independent in relation to the company and its management, but not in relation to its major shareholders.

Catherine Gilmore-Lawless
Born in 1960. Board member since 2019. Chairman of the Remuneration Committee.

Education: Catherine Gilmore-Lawless holds an MBA from McGill University and a BComm from Concordia University.

Other experience:
Catherine Gilmore-Lawless has more than 30 years of experience of neurosurgery. Her experience includes more than 15 years in various senior positions at Elekta Instrument AB, including CEO of Elekta's US subsidiary, where she played an instrumental role in the US launch of new neurotechnology. Her other positions at Elekta included Senior Vice President, Marketing and Vice President, Clinical Intelligence, Neuroscience.

Other current assignments: Vice President, Strategic Intelligence and Partnerships, Americas at Elekta. Consultant to the International Stereotactic Radiosurgery Society, board member of Clinical Laserthermia Systems and owner of Gage Hospitality Group.

Previous assignments over the past five years: Catherine Gilmore-Lawless previously served as Senior Vice President of Elekta AB.

Shareholding in the company: 0 shares.

Independent in relation to the company and its management and in relation to major shareholders.

Eva Nilsagård
Born in 1964. Board member since 2018. Chairman of the Audit Committee.

Education: Eva Nilsagård holds an B.Sc. in finance and an Executive MBA from the School of Business, Economics and Law at the University of Gothenburg.

Other experience: Eva has more than 30 years of experience from senior management positions within finance, strategy and business development from global listed and private companies, mainly in the life science and automotive sectors.

Other current assignments: Board member of SEK (Svensk Exportkredit AB), and Board member and Chairman of the Audit Committee of AddLife AB, Bufab AB, Hansa Biopharma AB, Xbrane Biopharma AB and chairman of Spermosens AB. She is the founder and CEO of Nilsagård Consulting AB.

Previous assignments over the past five years: Acting CFO of OptiGroup AB, Acting Nordic Finance Director for Staples, Acting Managing Director in Sweden for BEWiSynbra AB, CFO of Plastal Industri AB and SVP Strategy & Business Development at Volvo Group Trucks Sales & Marketing EMEA.

Shareholding in the company: 11,500 shares.

Independent in relation to the company and its management and in relation to major shareholders.

Anita Tollstadius
Born in 1955. Board member since 2017. Member of the Audit Committee and Remuneration Committee.

Education: Anita Tollstadius holds an M.Sc. in Pharmacy from Uppsala University and an MBA from the Stockholm School of Economics.

Other experience: Anita Tollstadius has more than 30 years of experience from global operations in the pharmaceutical industry and has held several senior positions within strategic marketing, communication and organizational development. She has also been CEO for 9 years at a listed company.

Other current assignments: Board member of MediCheck AB.

Previous assignments over the past five years: Board member of OssDsign AB and CEO of ContextVision AB.

Shareholding in the company: 11,500 shares.

Independent in relation to the company and its management and in relation to major shareholders.

Kleanthis G. Xanthopoulos Ph.D.
Born in 1958. Board member since 2015.

Education: Kleanthis G. Xanthopoulos holds a B.Sc. in biology from Aristotle University, an M.Sc. in microbiology and a Ph.D. in molecular biology from Stockholm University, and was an Associate Professor at Karolinska Institutet in Stockholm, Sweden.

Other experience: Kleanthis G. Xanthopoulos has more than 25 years' experience from operational positions in the life science sector. He also has extensive experience as an investor in life science companies in the US and Europe and founded four life science companies before joining IRRAS, of which two have been listed on Nasdaq (Anadys Pharmaceuticals, Inc. which was acquired by F. Hoffmann-La Roche Inc. in 2011, and Regulus Therapeutics Inc).

Other current assignments: Board member of Zosano Pharma Inc., Sente Inc., Connect Biopharma, Shoreline Biosciences and of Helios Inc.

Previous assignments over the past five years: Chairman of the Board of Apricus Biosciences and Bioniz, Board member of LDO spa, Managing General Partner at Cerus Advisors and President and CEO of Regulus Therapeutics.

Shareholding in the company: 1,101,487 shares and 1,275,000 personnel options via the 2016/2025 incentive program ,43,237 personnel options via the 2018/2022 inventive program and 125,000 personnel options via the 2020/2028 inventive program.

Not independent in relation to the company, its management or its major shareholders.

Senior executives

Kleanthis G. Xanthopoulos Ph.D.

Born in 1958. President and CEO since 2015.

For more information, refer to the above under the heading "Board Of Directors".

Will Martin

Born in 1975. President and Chief Commercial Officer since 2018.

Education: B.A. in finance and computer applications from the University of Notre Dame and an MBA from Johns Hopkins University.

Other experience: Will Martin most recently served as General Manager of Peripheral Vascular (PV) Devices for Philips Healthcare. In this role, he oversaw the growth and expansion of Philips Healthcare into the PV interventional space and was responsible for defining and owning the global PV business strategy. During his tenure, the PV segment was one of the fastest growing businesses in Philips. Prior to Philips, Will Martin was Vice President of Commercial Operations and Vice President of Marketing and Business Development at AtheroMed, Inc. He served as Vice President of Sales and Marketing at Hotspur Technologies, Inc. and Vice President of International Sales at AccessClosure, Inc., and held other key commercial roles at Boston Scientific Corporation, Aventis Pharmaceuticals and Corning, Inc.

Other current assignments: Board member of Morris Innovative.

Previous assignments over the past five years: General Manager of Philips Healthcare.

Shareholding in the company: 20,000 shares, 230,000 personnel options via the 2017/2021 incentive program, 98,500 personnel options via the 2016/2025 incentive program and 100,000 personnel options via the 2020/2028 incentive program.

Sabina Berlin

Born in 1983. Chief Financial Officer since 2019 and employed since 2017.

Education: Sabina Berlin has a master's degree in auditing and financial control from the School of Business, Economics and Law at the University of Gothenburg.

Other experience: Sabina Berlin has extensive experience in the areas of business control, accounting and business analysis.

Other current assignments: Chairman of the Board of Zymology Consulting AB.

Previous assignments over the past five years: From 2014 to 2017, Sabina Berlin served as CEO and a Board member of Juno Ekonomi AB.

Shareholding in the company: 7,736 shares, 17,500 personnel options via the 2018/2022 incentive program and 52,000 personnel options via the 2020/2028 incentive program.

Shareholding through related parties: 12,880 shares.

Adam Sampson

Born in 1968. Vice President of Product Excellence since 2018.

Education: Adam Sampson has a B.Sc. in Mechanical Engineering from San Diego State University and holds an extensive range of technical, business and management certifications.

Other experience: Adam Sampson is a global executive with strategic and tactical product leadership experience spanning the life sciences, high performance computing, construction and government contracting industries. He has made a career of developing profitable new products and strengthening core revenue streams with worldwide customers such as American Express, eBay, Kohler and Roca. He has been essential to the development, commercialization and sustaining of 14 new product platforms, all IP novel, of which nine were major profit-generating engines. Adam Sampson is a catalyst for continuous growth and improvement by integrating a customer focus with operational excellence and emerging technologies. He has optimized or created five entire product life cycle processes and is the inventor, or managed the inventors, behind over 30 issued patents plus numerous active patent applications.

Other current assignments: None.

Previous assignments over the past five years: Adam Sampson served as Global VP of Engineering & Product Development at Fluidmaster.

Shareholding in the company: 0 shares, 55,500 peronnel options via the 2018/2022 incentive program, 15,000 peronnel options via the 2016/2025 incentive program, 15,000 peronnel options via the 2020/2028 incentive program.

Kellie Fontes

Born in 1961. Senior Director, Human Capital since 2018.

Education: B.Sc. in Speech Communication from Montana State University and a certificate in Human Resource Management from the University of California.

Other experience: Kellie Fontes has vast experience in human resources within the pharmaceutical and high-tech industries and brings in-depth knowledge of HR compliance and risk management. She has also led extensive coaching of senior leaders focused on building personal capabilities and execution of business strategy.

Other current assignments: None.

Previous assignments over the past five years: Kellie Fontes most recently served as Director, Employee Relations at General Atomics. Prior to General Atomics, she held several leading positions for nearly ten years at GlaxoSmithKline, including US Director, Employee Relations.

Shareholding in the company: 0 shares, 35,000 personnel options via the 2017/2021 incentive program, 12,976 personnel options via the 2016/2025 incentive program and 12,024 personnel options via incentive program 2020/2028.

Annual General Meeting

The Annual General Meeting is to be held on Wednesday 28 April 2021. Due to the spread of COVID-19, the Board of Directors has resolved that the Annual General Meeting should be conducted without the psysical presence of shareholders, representatives or third parties and that the shareholders before the General Meeting should be able to exercise their voting right only by absentee ballot.

Notice of Attendance

A shareholder who would like to participate in the General Meeting shall:

- be entered in the register of shareholders maintained by Euroclear Sweden AB by the record date Tuesday 20 April 2021; and

- announce their intention to attend the General Meeting no later than Tuesday 27 April 2021, by having submitted an absentee ballot in accordance with the instructions under the heading "Absentee Ballot" below such that the company has received the advance vote no later than Tuesday 27 April 2021.

In order to be entitled to participate in the General Meeting, a shareholder who has registered their shares in the name of a nominee, in addition to announcing their intention to participate by submit its absentee ballot, must temporarily request that their shares be registered in their own name so the shareholder is entered into the register of shareholders by 20 April 2021.This registration may be temporary (so-called voting right registration) and is requested with the nominee in accordance with the nominee's procedures and in advace as determined by the nominee. Voting right registrations completed no later than the second banking day following 20 April 2021, are considered when preparing the shareholder register.

Absentee Ballot

Shareholders may exercise their voting right at the General Meeting only by voting in advance, a so-called absentee ballot pursuant to section 22 of the Temporary Exemptions to Facilitate the Execution of General Meeting in Companies and Associations Act (2020:198).

A special form must be used for the absentee ballot. This is available on the company's website www.irras.com. Terms and conditions for the absentee ballot are included in the form. The completed and signed form for the absentee ballot must be sent by mail to IRRAS AB (publ), Attn: Sabina Berlin, P.O Box 160, 101 23 Stockholm or by e-mail to AGM@irras.com no later than 27 April 2021. The Shareholder may not add special instructions or conditions to the absentee ballot. If this occurs the vote (i.e. the absentee ballot in its entirety) will be invalid. If the shareholder submits an absentee ballot via proxy, the power of attorney must be attached to the form. The proxy form is available on the company's website, www.irras.com. If the shareholder is a legal person, the certificate of registration or other authorization document must be attached to the form.

Financial calendar

April 28, 2021
2021 Annual General Meeting

May 4, 2021
Q1 2021 interim report

August 26, 2021
Q2 2021 interim report

November 9, 2021
Q3 2021 interim report

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