



IRRAS

IRRAS ANNUAL REPORT 2021

## Improving patient outcomes

Published clinical data shows that treatment with IRRAflow can reduce the length of hospitalization for chronic subdural hematoma patients over 50%. Treatment with IRRAflow lasted under 3 days compared to the US average of 6 days with traditional drainage, and also resulted in zero complications or bleeding recurrence.

## Reducing cost of care

IRRAflow's documented shortening of treatment duration and the associated reduction in complications that are associated with legacy treatments also reduces the overall cost of care, decreasing the overall economic burden on healthcare systems, and maximizing valuable bed space in intensive care units.

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**1.8**  
**billion USD**

*IRRAflow 's addressable market for intracranial bleeding in Europe and US with an annual growth rate of 8 – 10%.*

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**600**  
**million USD**

*Hummingbird addressable market for intracranial pressure monitoring in Europe and US.*

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**Sales presence covering more than 25 markets across 4 continents. Installed IRRAflow systems increased from 73 to 131 during 2021.**

**22**

*Net sales, SEK Million 2021*

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# Bringing Needed Innovation to Neurocritical Care

IRRAS AB is a global medical device company that is focused on bringing needed innovation to neurocritical care. Patients suffering from traumatic brain injury and intracranial bleeding deal with significant rates of morbidity and mortality, yet are generally treated with technologies that were introduced more than 30 years ago. Our products have been designed to address complications associated with these traditional treatment methods, thereby improving patient outcomes, reducing treatment time, and decreasing the overall cost of care.

IRRAS AB (publ) is listed on Nasdaq Stockholm (ticker: IRRAS).

For more information, please visit [www.iras.com](http://www.iras.com)

## Content

This is a translation of the Swedish original. In case of any inconsistency between the Swedish and English version, the Swedish version shall prevail.

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# 2021

in brief

## Q1

### Investing in our future growth

IRRAS secures the Medical Device Single Audit Program (MDSAP) certification, enabling the company to pursue key regulatory clearances.

Began production of IRRAlow control unit at IRRAS' first in-house production facility.

## Q2

### Increased share of recurring revenue

Increasing treatments at key institutions result in increased revenue contribution from customer reorders.

IRRAS completed a direct share issue of SEK 66 million to extend our financial runway.

## Q3

### New CEO

Will Martin assumes role of President and Chief Executive Officer of IRRAS.

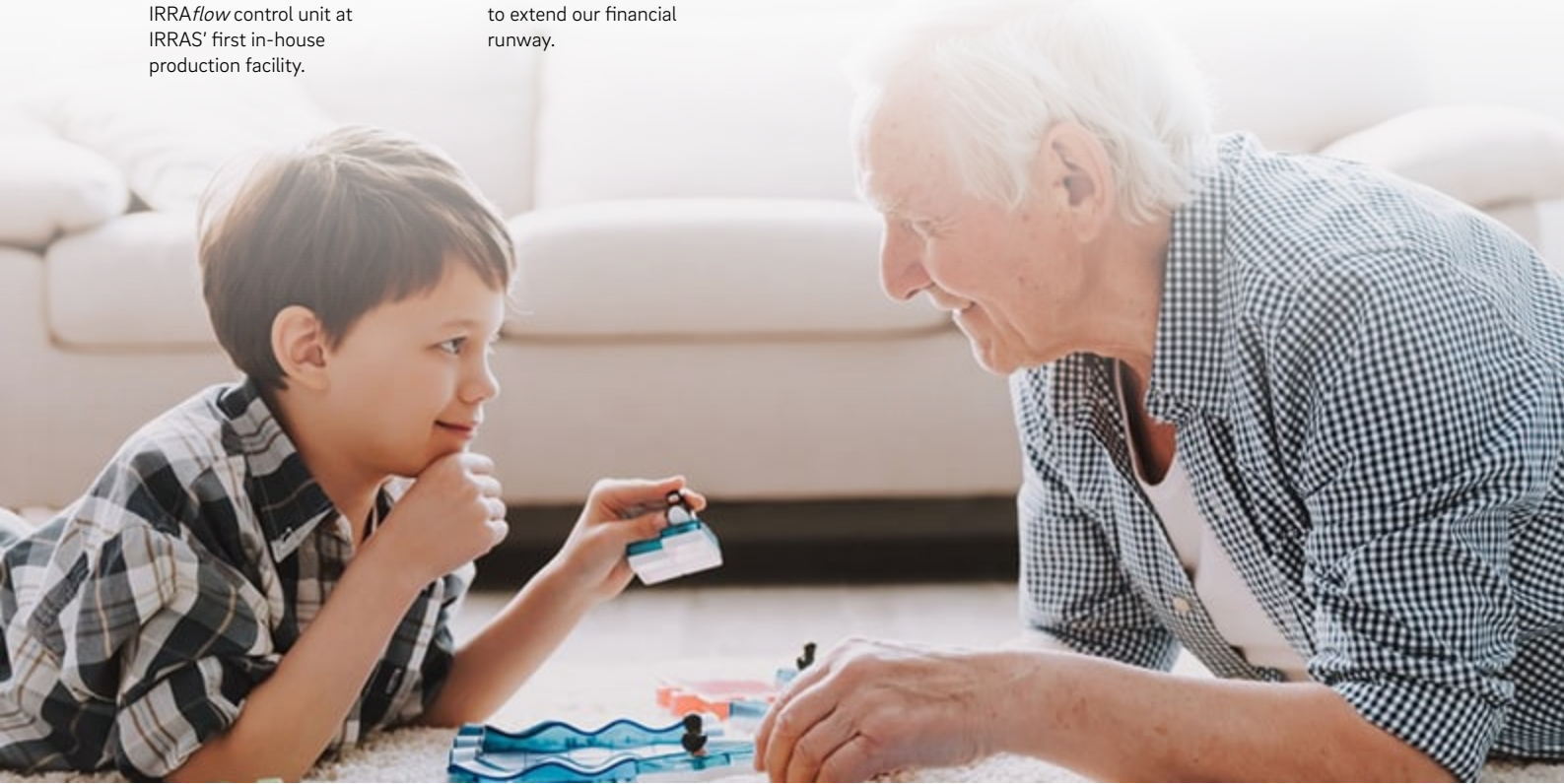
IRRAS secures non-dilutive loan financing up to 10M EUR from European Investment Back to fund efforts in European Union..

## Q4

### Increase of installed IRRAlow Systems

Year ends with annual revenue of 22.4M SEK, up from 7.4M SEK in 2020.

The number of IRRAlow Systems installed globally also increased throughout the year from 73 to 131.



## Key figures 2021

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- Net revenue amounted to SEK 22.4 million (7.4).
- Operating loss (EBIT) amounted to SEK –136.5 million (–134.3).
- Loss after tax amounted to SEK –136.3 million (–135.9).
- Earnings per share before and after dilution amounted to SEK –1.89 (–2.46).
- The Board of Directors proposes that no dividend should be paid.
- The Group's available liquidity amounted to SEK 55.9 million at year-end.
- The average number of employees in the Group during the year was 53 (43).

## Our locations

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### Sweden - Stockholm

- Legal headquarters
- Finance
- Direct sales team
- IR
- Listed on Nasdaq Stockholm

### USA - San Diego

- Sales & marketing
- R&D
- Manufacturing
- Regulatory & Quality

### Germany - Munich

- Direct sales team
- Global distributor management
- Training

### Netherlands - Amsterdam

- Direct sales team
- Global logistics management

## Increasing global commercial presence

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### US

- Company's direct sales and education team

### Europe

- Company's direct sales team in Germany, Switzerland and the Nordic countries
- International sales management and distribution warehouse located in the Netherlands
- Distributors in place for Poland, Spain, Portugal, the Netherlands, Switzerland, Greece, Austria, UK, Italy, Bulgaria, Czech Republic, the Baltic nations, Serbia, Croatia, Romania, and Northern Macedonia.

### Asia - Pacific

- Registration ongoing in Australia
- Distributor selection ongoing in other key markets

### Latin America

- Key markets covered by existing distribution agreement
- Initial market approvals received in Costa Rica, Mexico, Panama, Ecuador, and Argentina with registration ongoing in additional key countries

### Middle East, Africa

- Distributors in place for Israel, Kuwait, Jordan, and the United Arab Emirates
- Registration ongoing in other key markets

# Meaningful progress seen despite continued COVID-19 impact

2021 was a year of transformational growth, despite the COVID-19 pandemic with restricted travel and reduced capacity in the neurosurgical intensive care units. In spite of these challenges, our growth accelerated, resulting in numerous important milestones. Our products positively impacted the lives of more patients than ever before. Clinical data confirmed our products' significant advantages compared to currently used technologies. We expect these trends to deliver significant growth as our product launches continue.

## Increasing adoption for our neurocritical care products confirmed

As the global population ages, the incidence of stroke and intracranial bleeding will increase, and the associated impact of required care will further burden the global healthcare system. For instance, the treatment of chronic subdural hematomas (cSDH) is projected to become the most commonly performed neurosurgical procedure by 2030. Our company's unified focus is improving the historic subpar outcomes for this growing group of patients, and 2021 confirmed that IRRAS is making needed progress toward accomplishing that goal.

Our revenue and number of patient treatments increased quarterly throughout the year, confirming that commercial adoption of our cutting-edge products continues to grow. In the United States, the number of IRRAS *flow* systems installed at customer locations grew by 79% during 2021 as new hospitals initiated IRRAS *flow* evaluations, and, more importantly, as successful evaluations are finished and customers continue commercial patient treatments.

Our commercial strategy follows the razor/razor blade model where much of our long-term revenue is expected to be generated by recurring disposable reorders. 2021 showed this strategy was beginning to take shape. There is no more important metric for an early-stage commercial company than reorder rate, and recent quarters have shown an increasing percentage of US revenue resulting from increased usage by commercial customers. After growing revenue during each quarter of 2021, 79% of our US revenue during the 4th quarter was driven by disposable reorders, which is a critical indicator of product adoption.

This growing product adoption was made possible in the United States by the relationships that our team has built with thought-leading neurosurgeons at key comprehensive stroke centers, and these customers form a strong foundation for our growing commercial business.

Our field sales and education team is now using the best practices developed with these accounts to successfully navigate our new hospital evaluations, both in the US and other countries around the world.

While COVID restrictions continued to impact our team's ability to travel during 2021, we also began to see increased contribution from our direct customers in Europe and growing network of distribution partners. Long-term, it is critical that we drive meaningful revenue growth from both of these groups, and it was important to see this contribution during the past year.

In our direct markets, our partnership with Aarhus University in Denmark resulted in commercial product adoption as well as the initiation of both collaborative clinical trial and product development projects. In Germany, the largest market opportunity in Europe, we

now have ongoing evaluations at a number of customers with significant interest from others as COVID allows training to begin.

Over the past several years, we've discussed our team's significant focus on expanding our network of distribution partners in markets where IRRAS does not employ a direct salesforce, and during 2021, these efforts began to make an impact on our performance. Much of continental Europe and Latin America are now governed by distribution agreements, and patient treatments and corresponding revenue from these markets shall continue to increase as the commercial activity increases for these partners.

## Increased investment in differentiated clinical evidence

The key next step in increasing IRRAS *flow* adoption and moving the product toward the standard of care is confirming its superiority over traditional passive drainage by generating meaningful clinical data. During 2021, physicians published more than 5 additional manuscripts to document their clinical results with IRRAS *flow*, and these publications documented several critical items for the first time in peer-reviewed journals. Thought-leading surgeons from Buffalo General Medical Center documented the use of IRRAS *flow* to treat an intraventricular hemorrhage after traditional drainage had failed, and their case report concluded, "Our case demonstrates clear radiographic and clinical superiority of the IRRAS *flow* system compared to standard EVD."

In addition, the University of California – Irvine published the long-term follow-up of their early clinical experience with IRRAS *flow* in the treatment of chronic subdural hematomas that was previously presented at the 2021 American Academy of Neurosurgeons conference. This publication confirmed continued patient improvement up to 30 days after hospital release, zero bleeding recurrence, and the reduction of required treatment time by more than 50%.

Finally, multiple publications during the year documented the ability of IRRAS *flow* to deliver therapeutic medication in a controlled manner directly into the brain tissue. By the end of 2021, neurosurgeons had published successful clinical use of IRRAS *flow* to deliver thrombolytic medication, antibiotics, and anti-spasm medication. This clinical documentation opens up an exciting new market opportunity for IRRAS, and we are expanding our focus to take advantage through additional clinical data generation and potential label expansion.

Our increased patient treatment experience and these new clinical publications have prepared IRRAS to begin a critical next phase of our clinical data generation. To date, much of our clinical work has been documenting clinical experience with the IRRAS *flow* system through case reports, but, moving forward, we are now investing in comparative clinical studies that are designed to confirm IRRAS *flow*'s superiority and ability to reduce required treatment time and overall cost.

We are working with leading institutions in both the US and Europe to generate this data, and we are excited to collect results that we believe will be transformational for IRRAS and our products. Such an expanding pool of available clinical data will enhance our ability to drive widespread adoption of IRRAS*flow* as it will increase product awareness and strengthen our ability to navigate the product approval process at new hospitals.

### **Progress across all functional areas**

During 2021, while our key area of focus was driving increased product usage in spite of COVID-19 lockdowns, the entire IRRAS organization also demonstrated important progress to help support future commercial growth.

IRRAS opened its first in-house manufacturing facility during the year to produce IRRAS*flow* control unit, and after being certified by all required regulatory agencies, the facility has increased our production capabilities while significantly reducing the associated cost. Additionally, the IRRAS quality management system was validated under the stringent MDSAP audit program, which confirms the maturity of our systems and will allow us to seek product approval in important markets such as Australia and Brazil during 2022.

Significant progress was also made during the year toward securing CE Mark certification for the Hummingbird system under Europe's new Medical Device Regulations. Technical files for each Hummingbird product were submitted with feedback received from our notified body, DEKRA. Our team is working with DEKRA now to address their remaining questions, which will help us also make this important product line available to European patients.

### **Well-positioned for future growth**

2021 was another challenging year for all of us, but we are proud of our company's ability to navigate difficult times and add shareholder value. We have now posted 6 consecutive quarters of revenue growth through continued COVID uncertainty without significantly increasing our sales and marketing spend, and the entire IRRAS organization is well prepared to support future growth.

As we enter 2022, the future prospects of IRRAS look stronger than ever before. Our patent portfolio has been expanded to cover targeted drug delivery and provides strong protection of our innovative ideas. The demand for new solutions within neurocritical care remains high, and IRRAS is well positioned to take advantage of this opportunity. Each day, our team is improving the lives of more patients around the world, and, as we continue to grow, we remain focused on building a company that drives shareholder value.

We thank you for your continued support and look forward to keeping you updated on our progress.

Sincerely,

### **Will Martin**

President and 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.

By revolutionize care through significantly improved care outcomes for patients reducing time in intensive care and other care settings as well as economic benefits for hospitals and other caregivers, we can achieve our vision.

The company is focused on providing innovative solutions for both traumatic brain injuries and hemorrhagic events. Both the *IRRAflow* and Hummingbird product lines 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 *IRRAflow* 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.
- **Optimizing the current *IRRAflow* system to exceed customer needs**, and, as patient treatment experience expands, develop a network of leading neurosurgeons to help document the positive impact of our products.
- **Transition the company's clinical affairs** focus from documenting treatment experience through case series to **enrolling controlled, comparative clinical trials that document the superiority of *IRRAflow***.
- Take the necessary regulatory and clinical steps to **capitalize upon the drug delivery market opportunity** that has been confirmed through early clinical publications.

## 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



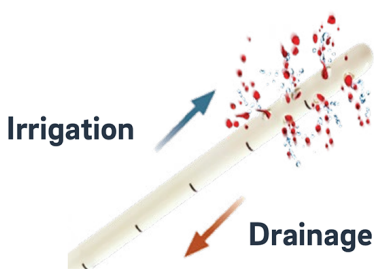


# Our products

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, eliminate complications associated with current treatments, reduce needed treatment time, and decrease the overall cost of care.

## IRRAflow

*The world's first irrigating intracranial drainage system*



The company's flagship product, IRRAflow, 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



**Intelligent Digital Pump  
enables Automated  
Irrigation**



**Integrated, Continuous  
ICP Monitoring**

combines active irrigation with ongoing fluid drainage. Additionally, IRRAflow 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 *IRRAflow* and Hummingbird ICP product families are groundbreaking innovations in neurocritical care. *IRRAflow* 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 *IRRAflow* 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**

*IRRAflow*, 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 *IRRAflow*, the company's Hummingbird ICP product family offers an important diagnostic tool to monitor the patients' conditions after traumatic brain injury has occurred. This tool is important to determine when intervention with a tool such as *IRRAflow* 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 amount to more than USD 1.8 billion for intracranial bleeding and another USD 600 million for traumatic brain injury. Additionally, the ability of *IRRAflow* to deliver therapeutic medications directly into the brain has been confirmed, which allows IRRAS to target a portion of the \$4.6 billion intracranial drug delivery market opportunity.

**>300 Patients treated**

**>30 Leading institutions**

**Systems placed in 18 countries**

### 3.

#### **A razor / razor blade model that is being confirmed with increased product adoption**

Both IRRAflow and Hummingbird consist of a small piece of capital equipment that is reused and single use disposables, which are expected to generate a majority of the Company's revenue.

As the products' commercial launch progresses, this model is being confirmed at key direct hospital customers in the United States. During 2021, the percentage of the company's US revenue driven by disposable reorders from existing commercial customers increased, starting at 16% in Q1 and ending at 79% in Q4 of total revenue. At the beginning of the year, more US revenue was generated from orders to support evaluations and commercial stocking orders, and, during the course of the year, more revenue was generated through repeat product utilization.

### 4.

#### **An increasing pool of supporting clinical evidence**

The clinical effectiveness of both IRRAflow and Hummingbird has been documented through the publication of numerous manuscripts in peer-reviewed scientific journals, and this clinical evidence will help the Company acquire new customers and treat more patients.

During 2021 alone, the clinical superiority of IRRAflow was shown in a side-by-side case report from Buffalo General Medical Center, and the ability of IRRAflow to safely and effectively deliver therapeutic medications directly into the brain was confirmed in multiple publications and scientific presentations. This drug delivery capability opens up an exciting market opportunity for IRRAS that the Company is now working to incorporate into its future growth plans.



# 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 commercial experience and clinical data indicates that the *IRRAflow* and Hummingbird ICP Monitoring technologies offer significant treatment advantages over conventional ICP monitoring and drainage tools when treating these serious brain pathologies.

*IRRAflow*, 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. *IRRAflow* 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 *IRRAflow*, is required.

## 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 during neurocritical care treatment. Without controlling elevated ICP, moderate to severe brain damage or death may occur. Thus, immediate and ongoing assessment of the patient's ICP is required so that an increase in intracranial pressure can be reduced rapidly. The surgical intervention to reduce ICP consists of draining excess fluid (such as collected blood) and is usually performed on an emergency basis. The optimal long-term treatment strategy can only be determined after the pressure has been reduced, and continuous ICP monitoring is critical to understand how the patient is responding to treatment.

## A high clinical need

When intracranial bleeding is seen, it is most often in the form of hemorrhagic stroke due to a ruptured aneurysm or chronic subdural hematoma after a fall. Approximately 355,000 patients per year are treated for these conditions in the US and EU countries alone. These markets amount to more than USD 1.8 billion per year.<sup>1</sup> There are also important markets outside the US and EU, such as Japan, China, Brazil, and Australia, with modern, well-functioning health insurance systems that offer further potential.

The adjacent field of acute subdural hematomas caused by trauma is another potential market segment for *IRRAflow*. 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 more than USD 2.2 billion every year.<sup>2</sup>

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 600 million in market opportunity. Between intracranial bleeding and ICP monitoring after TBI, IRRAS can target a total market opportunity that can grow to approximately USD 2.8 billion each year in the US and Europe alone.

## 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 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 complications that are well documented in scientific publications, including 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.

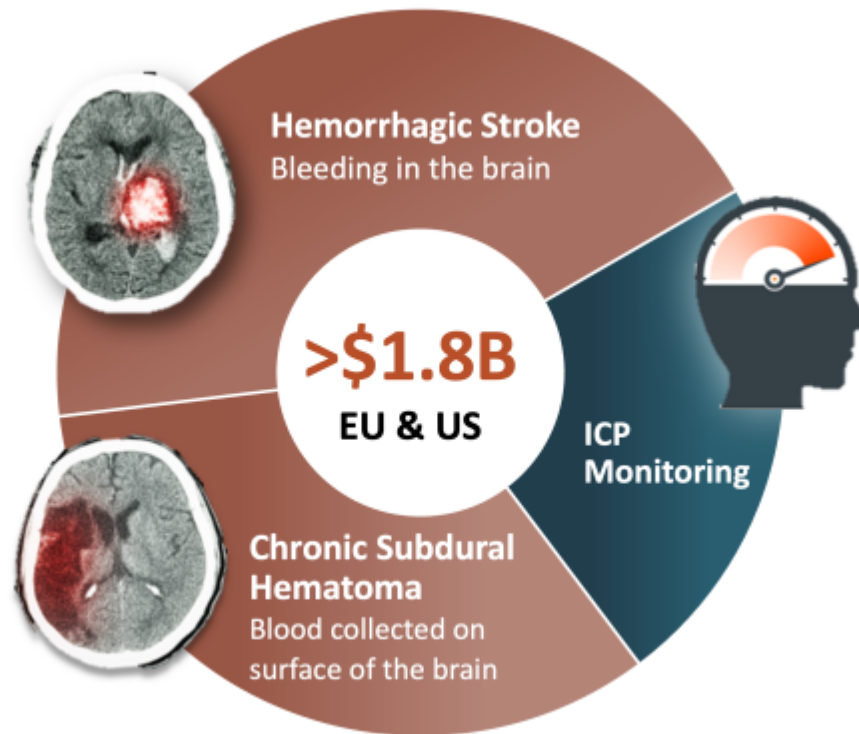
## Next-generation treatment with *IRRAflow*

Patients that suffer from hemorrhagic stroke or traumatic brain injuries are some of the sickest patients in the neurosurgical ICU, and there has been limited advancements since competitive EVDs were introduced many decades ago.

*IRRAflow* has been designed to significantly advance treatment of these critically ill patients as it is the only system that integrates needed fluid drainage, targeted fluid irrigation, and measurement of intracranial pressure into one product. The system uses automated irrigation to ensure continuous drainage, reduce the occurrence of catheter blockage and associated infection, and dilute toxic blood byproducts, making them easier to remove.

The efficacy of *IRRAflow*'s active fluid exchange has been demonstrated so far in patients in countries around the world, including Mexico, Panama, Italy, Denmark, Germany, Finland, Greece, India, Hong Kong, Kuwait, Israel, Portugal, Lithuania, Italy, the US, and others. In these cases, the system's irrigating mechanism of action has been proven effective with reduced treatment times compared to EVD treatment and zero incidences of catheter occlusion when *IRRAflow*'s irrigation has been actively employed.

**Sizable Neurocritical Care Market Opportunity**



# Intracranial Bleeding >\$1.8B

# Traumatic Brain Injury \$600M

**Hemorrhagic Stroke**  
 9–27% of all strokes<sup>6), 7)</sup>  
 ~200k Surgically operated, EU & US<sup>2)</sup>  
 40% of stroke deaths<sup>8)</sup>  
**Chronic Subdural Hematoma**  
 30% of fatal head injuries  
 155k Surgically operated, EU & US<sup>2)</sup>

**5.4M EU & US brain injuries each Year<sup>10), 11)</sup>**  
 ~1.3Mk Hospitalizations annually<sup>10), 11)</sup>  
 ~20% require ICP monitoring <sup>12)</sup>  
 ~90% of monitoring is invasive <sup>12)</sup>

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 & Shrim, 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](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 Hummingbird ICP Monitoring

The Hummingbird ICP Monitoring family of products complements IRRARflow by offering both single and multi-lumen bolts that meet the need for brain monitoring to diagnose traumatic brain injury and assess the need for interventional treatment.

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 inaccuracy building up in its ICP measurement. The system is also relatively easy and intuitive to use and setup.

This accuracy and simplicity have led to a positive initial reaction in the US to the launch of the Hummingbird product line with the product being adopted as front-line therapy at a number of US hospitals. The launch progress has been slowed due to the COVID-19 pandemic and hospitals delaying needed upgrades to current systems, but, IRRAS has signed a purchasing agreement with the Premier network of approximately 4,000 US hospitals, which will help to accelerate progress moving forward.

The company is also working to finalize CE Mark certification of the Hummingbird product line under the new European Medical Device Regulation (MDR), 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, the use of both IRRARflow and Hummingbird is reimbursed 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 device's costs.

Depending on the treatment, an average DRG payment in Germany, the largest EU market, can reach up to EUR 36,700. Approximately EUR 3,000 of this payment can be earmarked for IRRARflow's single-use disposables or EUR 500 – 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, hospitals 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 60,000, depending upon procedure complexity. In the US, pricing for IRRARflow's single-use disposables generally averages USD 4,000, and USD 600 – 2,500 for Hummingbird's single-use disposables.

### Regulations and requirements

Before any medical device can be commercially marketed, it must demonstrate compliance to the regulatory requirements outlined by global regulatory authorities.

Approval in Europe is based on the joint European Union directives and regulations regulating medical devices. Products that prove that they conform to these regulatory requirements are considered CE Mark certified, which allows that the product can be sold in all EU countries. IRRARflow received its latest CE Mark certification in December of 2019, which is valid until April 2024. The company has also submitted the needed paperwork to obtain CE Mark of the Hummingbird system under the EU's new Medical Device Regulations (MDR), and the Company anticipates the receipt of this certification in 2022.

The United States Food and Drug Administration, FDA provides the corresponding approval for sales and marketing in the US. Both IRRARflow and Hummingbird have been cleared for use in FDA-regulated markets, including the US. Many countries in Asia, Latin America, the Middle East, Australia, Canada, and Africa are not subject to the CE Mark or FDA approval process. Instead, they generally have direct registration processes that build upon the documentation required in Europe or the US. During 2021, IRRAS' quality management system received certification under the Medical Device Single Audit Program (MDSAP).

MDSAP is a stringent audit process that was established to enable medical device manufacturers to undergo one single regulatory audit that covers the requirements of participating regulatory jurisdictions in Australia (TGA), Brazil (ANVISA), Canada (Health Canada), Japan (MHLW) and the United States (FDA). By successfully completing the MDSAP audit, IRRAS has demonstrated that it satisfies strict requirements related to the design, development, manufacturing, and sale of its products. During 2022, IRRAS plans to use this MDSAP certification as the starting point to secure product regulatory clearance in these markets, starting with Brazil and Australia.

# CASE STUDY

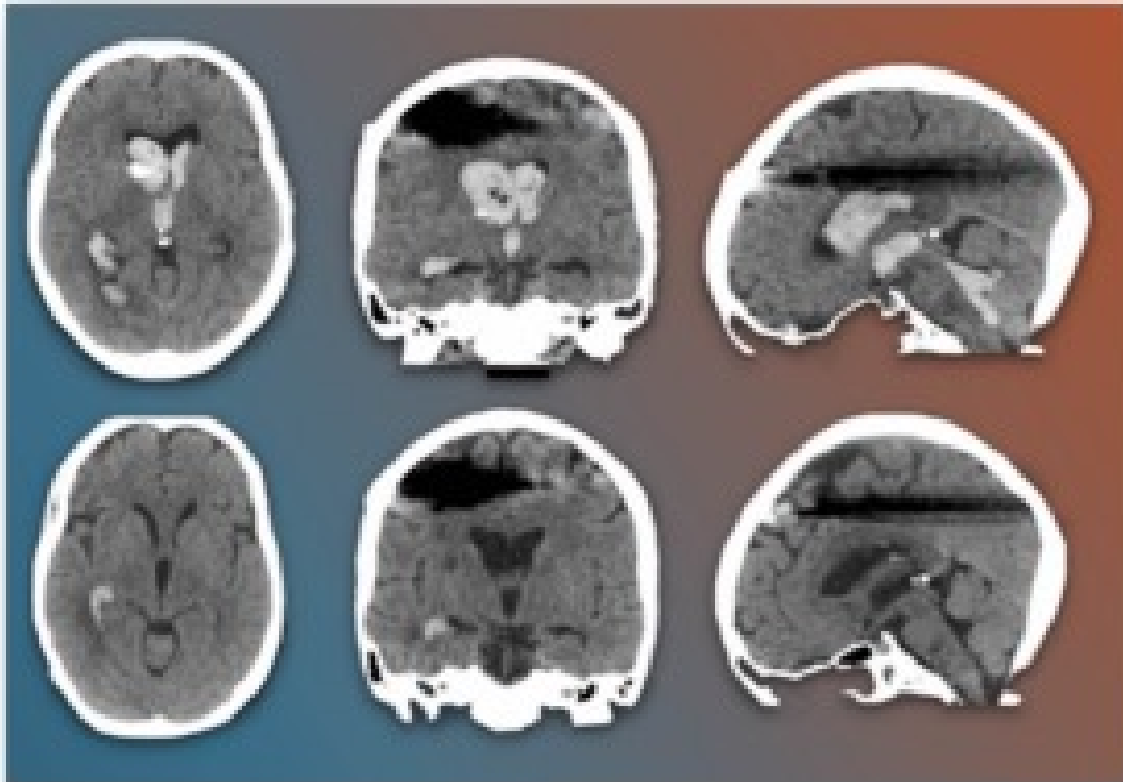
## *Helsinki University Hospital*

**Presented at  
CNS Annual  
Meeting 2021**

- IRRAflow with infused tPA significantly increases rate of blood removal, reduces treatment time.
- 90% removal of blood in 72 hours
- All cases were completed in ~5 days\*

\*Compared to 14 days of ICU time in the CLEAR III Trial<sup>1</sup>

<sup>1</sup>Hanley, D.F., et.al. Thrombolytic Removal of Thrombolytic removal of intraventricular haemorrhage in treatment of severe stroke: results of the randomised, multicentre, multiregion, placebo-controlled CLEAR III trial. *Lancet*. 2017 Feb 11;389(10069):603-611. doi: 10.1016/S0140-6736(16)32410-2. Epub 2017 Jan 10. PMID: 28081952; PMCID: PMC6108339.

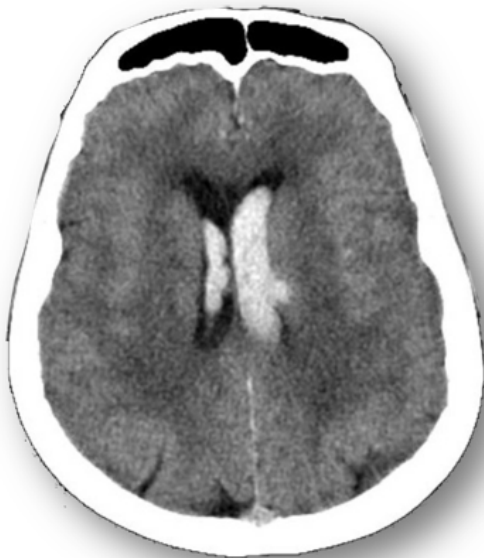


# CASE STUDY

## Cottage Health

### Treatment Results

- Head CT done prior to discharged showed continued improvement
- IRRAf<sup>low</sup> catheter irrigation was stopped after 36-hours and catheter clamped
- ICPs remained low at 1-5 mm Hg
- Patient exam improved with GCS of 14
- Catheter removed on day 3 post placement
- She was discharge to acute rehab on hospital day 8



Pre-IRR<sup>A</sup>flow  
Treatment



Post-IRR<sup>A</sup>flow  
Treatment



# Progress Accelerates as COVID Headwinds Continue

Despite another year filled with challenges, IRRAS showed meaningful progress on all fronts. Product awareness, clinical data generation, and patient treatment experience accelerated as the launch of *IRRAflow* and Hummingbird continues. Throughout 2021, the impact of the COVID-19 pandemic presented continued challenges to IRRAS commercial activities. Even though these disruptions persisted longer than initially anticipated, the IRRAS team generated noticeable advancement throughout the year.

## Need for *IRRAflow* technology confirmed

Legacy technologies, known as external ventricular drains (EVD), are considered the gold standard for draining blood and 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 *IRRAflow* system in the US, this lack of innovation resulted in a favorable reception, thanks to the system's unique mechanism that combines ICP monitoring, automated irrigation, and controlled fluid.

## Navigating Persistent Uncertainty Conditions

After beginning the commercial release of *IRRAflow* 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 *IRRAflow* into Europe. Unfortunately, during the first half of 2020, the impact of the COVID-19 pandemic forced the company to adjust its commercial ways of working. IRRAS invested in the development of mobile training resources to overcome COVID travel restrictions, next generation software was developed that guided nurses through the patient treatment, and commercial investment was shifted toward education resources.

IRRAS returned to revenue growth during the 3rd quarter of 2020, but the impact of COVID continued to linger throughout all of 2021. At certain points in the year, as vaccination rates increased globally, normal customer interaction was again possible, but, as the Delta and Omicron variants spread, lockdowns and restrictions returned.

The most significant impact to IRRAS' growth continues to be reduced access to hospital intensive care units as excess capacity is used to treat patients with COVID-19 and staff interaction for training is not permitted. In these situations, hospitals are more hesitant to allocate funding to new products. Therefore, progress has been repeatedly delayed at many direct hospitals which have expressed interest in evaluating IRRAS products.

The impact of COVID restrictions has been more widely felt in our European markets as regional differences and travel restrictions throughout the continent have impacted our team's capabilities.

Even though direct connection with customers was disrupted at times, our team remained opportunistic and focused its efforts on customers where normal interaction and support was possible. Key customer relationships in regions of the United States flourished, and patient treatments accelerated. Additionally, the IRRAS network of distribution partners continued to grow, and virtual training programs prepared these partners for commercial launch as conditions allowed. These virtual activities enabled initial patient treatments being

completed during the year in Italy, Greece, Portugal, Serbia, Lithuania, and Northern Macedonia.

Despite the impact from COVID-19 during the year, IRRAS' annual revenue still grew by 303% from MSEK 7.4 in 2020 to MSEK 22.4 in 2021.

The building blocks are in place for continued growth, and IRRAS' confidence remains high that the work that was completed during 2021 has positioned the company to continue to successfully 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, *IRRAflow* can become a new standard of care for treatments worldwide with a market opportunity of more than USD 2.2 billion globally.

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. This strategy of "going deep before going wide" ensures that the system has a strong foundation of support from leading physicians and a solid base of recurring revenue to build upon moving forward.

IRRAS continues to view Europe and the US as its key markets. These markets have the largest pool of potential patients, combined with well-established health care systems and high demands for innovative medical device solutions. These markets also have attractive end-user price points and attractive reimbursement levels.

Both the *IRRAflow* and Hummingbird systems incorporate a small piece of capital equipment (control unit) that is reused and single use disposables. IRRAS expects this razor / razor blade model to result in more than 80% of its long-term revenue to be driven by disposable reorders as more patients are treated.

In order to fully take advantage of this strategy, it is important to maximize the number of systems that are in place globally to support patient treatments, and, during 2021, IRRAS made significant progress in growing this install base of control units.

In total, 131 *IRRAflow* systems has been delivered globally by the end of 2021, up from 73 at the beginning of 2021. During the year, much of this growth is attributed to the growth of commercial customers that have stocked *IRRAflow* for continued use after a successful product evaluation. Commercial *IRRAflow* systems in the US grew by 333% during 2021 from 9 systems to 30. During Q1 of 2021, 17% of US revenue was driven by disposable reorders, and that percentage grew to 54%, 64%, and 79% throughout the remainder of the year. At the beginning of the year, more US revenue was generated

from orders to support evaluations and commercial stocking orders, and, during the course of the year, more revenue was generated through repeat product utilization, confirming that the razor / razor blade model was making a difference.

Similar growth is expected to continue in 2022 in the US, and a comparable evolution should be seen with international direct markets and the company's distribution partners.

During the year, the number of systems at direct customer facilities in Europe grew from 2 to 16, and the number of systems deployed to distribution partners globally grew from 22 to 52. As more patients are treated with these systems, additional disposable revenue will be generated from product reorders, much like was observed in the US during 2021.

In the United States, the approval process at new hospitals can take six to nine months. This extended timeline is especially applicable to new technology in the current situation where COVID has caused hospital budgets to be closely scrutinized. Currently, most hospitals are favoring disposable usage agreements instead of a capital purchase for IRRAS control units. Despite this extended process, the company continues to successfully navigate product evaluations to expand its base of commercial customers.

2021 also resulted in a record number of patient treatments, which is building momentum and expanding available clinical evidence. Of note, COVID's impact of hospital ICU bed space has allowed *IRRAflow*'s reduced treatment time to be well received by new customers.

Although COVID-related restrictions slowed the number of new customers added by IRRAS, the company generated a double digit revenue growth percentage throughout the year. This growth was attained by strategically focusing our team's efforts in areas where access and interactions remained possible. Furthermore, IRRAS was able to support this commercial growth by ending the year with spending on sales and marketing at a comparable level as the beginning of 2020. By investing in more training and education resources, IRRAS now has more resources available to support customers globally without added costs.

In Europe, similar progress has been seen. Five sales professionals and two training managers are currently responsible for driving growth and fostering adoption in our key direct markets of Germany and the Nordic countries and working with our distribution partners in other geographies. In our direct markets, the product approval and training process is underway at more than ten German hospitals, and evaluation patient treatments will begin in the new year as COVID restrictions permit.

Other key hospitals throughout European markets, including Sweden, the United Kingdom, Portugal, Italy, Greece, the Baltic countries, and the Balkan region have completed *IRRAflow* training. While travel has been difficult, our network distribution partners has continued to grow, our training has continued virtually, and patient treatments have begun. As more procedures are performed, product advocates will be identified and the number of *IRRAflow* treatments will continue to increase.

IRRAS has completed the process to extend its CE Mark certification for *IRRAflow* until April 2024 under the existing European Medical Device Directives (MDD). The extension ensures product availability to support growing adoption, even as the regulatory landscape changes in the EU. During 2022, IRRAS will take the necessary steps to upgrade its *IRRAflow* CE Mark to the new Medical Device Regulations (MDR). The company has also submitted the needed paperwork to receive the CE Mark certification under MDR for the Hummingbird product family. The company expects approval to market the product line in Europe during 2022.

Due to the similarities and how the products complement each other, the IRRAS direct sales team can effectively sell both *IRRAflow* and Hummingbird in both the US and Europe. Additionally, IRRAS will utilize and expand upon its existing distributor base to assist in launching the Hummingbird product line.

### The Rest of the World

While most of IRRAS' efforts thus far have focused on the US and Europe, the company has selectively started to establish business relationships in other important markets. IRRAS currently has distribution partners in place in Kuwait, Israel, the United Arab Emirates, and Jordan, and, during 2021, patient treatments occurred in Israel and Kuwait. Additionally, the *IRRAflow* product registration was extended for another two years in Israel.

At the same time, IRRAS' Latin American distribution partner has secured product registration for *IRRAflow* in Costa Rica, Argentina, Ecuador, Panama, and Mexico. Patients have been treated with *IRRAflow* in each of these markets, and work is being done to finalize registration in Uruguay and Colombia.

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 2021, IRRAS was also certified through the Medical Device Single Audit Program (MDSAP). This process confirmed 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, Canada, and Australia, and the regulatory process to gain approval has been started. Together with its respective distributors, IRRAS drives the approval process for Hummingbird and *IRRAflow* in countries where regulatory approval has not yet been received.

### Driving to Deliver Impactful Clinical Data

With disruptive products, such as *IRRAflow*, it is vital to continually expand the pool of evidence that differentiates the product from legacy treatments. During 2021, IRRAS and its partnerships with leading neurosurgical hospitals, including Helsinki University Hospital, Aarhus University, Buffalo General Medical Center, and West Virginia University Hospital resulted in the publication of numerous manuscripts that described the use of *IRRAflow* in a variety of clinical settings.

These publications in peer-reviewed scientific publications are critical elements of IRRAS' long-term growth plans. As IRRAS and its physician partners capture the early experience with *IRRAflow* and share the best practices and outcomes with the neurosurgery community, it will result in broader awareness and greater adoption.

An example of such clinical data was presented by Dr. Behnam Rezaei Jahromi from Helsinki University at the 2021 Congress of Neurological Surgeons (CNS) Annual Meeting. Dr. Rezaei presented a case series of 5 patients in which *IRRAflow* in combination with infusion of thrombolytic medication resulted in:

- In all 5 cases, CT scans confirmed that 90% of collected blood was removed in 72 hours or less.
- In all cases, complete treatment with the device, from catheter insertion to removal, was completed in an average of 5 days.

Furthermore, during 2021, 5 additional peer-reviewed manuscripts were also published to document the impact of *IRRAflow* in treating critically ill patients. Highlights from these publications include:

- A side-by-side case report from Buffalo General Medical Center that described the clinical superiority of *IRRAflow* after traditional drainage had failed during the treatment of an intraventricular hemorrhage. This case report concluded, "Our case demonstrates clear radiographic and clinical superiority of the *IRRAflow* system compared to standard EVD."
- Surgeons from the University of California – Irvine published their long-term follow-up of their early clinical experience using *IRRAflow* to treat chronic subdural hematomas that was previously presented at the 2021 American Academy of Neurosurgeons (AANS) conference. This publication confirmed continued patient improvement up to 30 days after hospital release, zero bleeding recurrence, and the reduction of required treatment time from 6 days to 2.83 days.
- The ability of *IRRAflow* to safely and effectively deliver therapeutic medications directly into the brain was confirmed in multiple publications and scientific presentations. This drug delivery capability opens up an exciting market opportunity for IRRAS that the company is now working to incorporate into its future growth plans.

Further expanding upon these results is a critical next step as it provides clinicians an established protocol to effectively deliver drugs into the brain to improve clinical outcomes. To this end, IRRAS and the surgeons from the University of Helsinki have started the Active Removal of Cerebral Hemorrhage (ARCH) study to prospectively study the impact of *IRRAflow*'s continuous irrigation of thrombolytic medication in a multi-center prospective randomized trial. Trial enrollment has begun in Helsinki with additional site identification also underway. The primary investigators expect the trial to be completed in early 2023 with results published in late 2023 to early 2024.

### 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 optimizing the *IRRAflow* and Hummingbird product lines and exploring ways to expand their applications and areas of use.

During 2021, the company launched a next-generation version of the *IRRAflow* catheter that provides enhanced drainage rates and improved kink resistance. This catheter provides improved ability to remove large amounts of collected blood, and it also provides better pushability to aid in catheter tip placement. Critical development was also completed on the next *IRRAflow* control unit, which will be introduced in phases during 2022. This updated control unit will introduce interactive training software and allow positioning of the system's drainage bag at a greater variety of heights based on the clinical setting. After appropriate regulatory clearance, the next generation *IRRAflow* control unit will also add the ability to communicate with the central nursing station.

In the future, IRRAS plans to add a larger *IRRAflow* catheter for draining large amounts of fluid from subdural hematomas, updated packaging, extended product shelf lives, and line extensions to the Hummingbird product line. On a longer time horizon, the company plans to combine the functionality of both the *IRRAflow* and Hummingbird product lines and expand the ability of the *IRRAflow* system to quantify and characterize fluid that is drained from the intracranial space. It is expected that the 10M EUR in funding from the EIB financing agreement will help fund many of these projects as increased investment is expected to occur within the EU.

# Robust Intellectual Property Portfolio Provides Critical Protection until 2038

## Well-Protected by Robust IP Portfolio

IRRAS' broad patent portfolio protects the underlying technologies used in the *IRRAflow* and Hummingbird ICP Monitoring product families. For *IRRAflow*, the patent protection focuses on the system's combination of irrigation and drain- age to keep the system free from catheter blockages.

During 2021, the most recent patent was issued in the US that provides protection regarding potential future areas of use, such as drug delivery, infection, orthopedics, and treatment in other areas of the body. With Hummingbird, the protection consists of multiple patent families covering the proprietary air connection, a unique method for probe access to the brain tissue, and monitoring ICP with an air-based pressure monitoring method.

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.

## Enabling New *IRRAflow* patent issued

- This latest IRRAS patent, 11123483 B2, provides intellectual property protection for administering at least one drug to a patient using a fluid exchange catheter system (namely *IRRAflow*)

## Foundational patent protection encompasses multiple uses for a dual-lumen fluid exchange catheter

- Seven key issued patents
- Protection across the top 17 markets
- Three additional related technologies with patents pending

## 4 core technologies with IP protect 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
- Catheter coupling method

## Patent protection for multiple applications includes the following status:

- 10 Patents issued with coverage across the top 10 markets



# 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 decreased. At year-end, IRRAS had 2,803 shareholders.

## Market capitalization and turnover

The closing price on December 31, 2021, was SEK 3.90, which corresponds to a market capitalization of MSEK 310. On March 21, 2022, the closing price was SEK 1.90, corresponding to a market capitalization of SEK 151 million. An average of 100,983 shares were traded per day and a total of 25.5 million in 2021. The SEK/share price decline by 53 percent while the OMX SPI Index rose by 35 percent.

## Share capital

As of December 31, 2021, the share capital of IRRAS amounted to SEK 2,384,440.20, distributed on 79,481,340 shares with a quota value of SEK 0.03 per share. In 2021 the share capital have increased 13.2 M shares. IRRAS has only one class of shares. Each share have an equal part to the company's assets and profit and equal voting right.

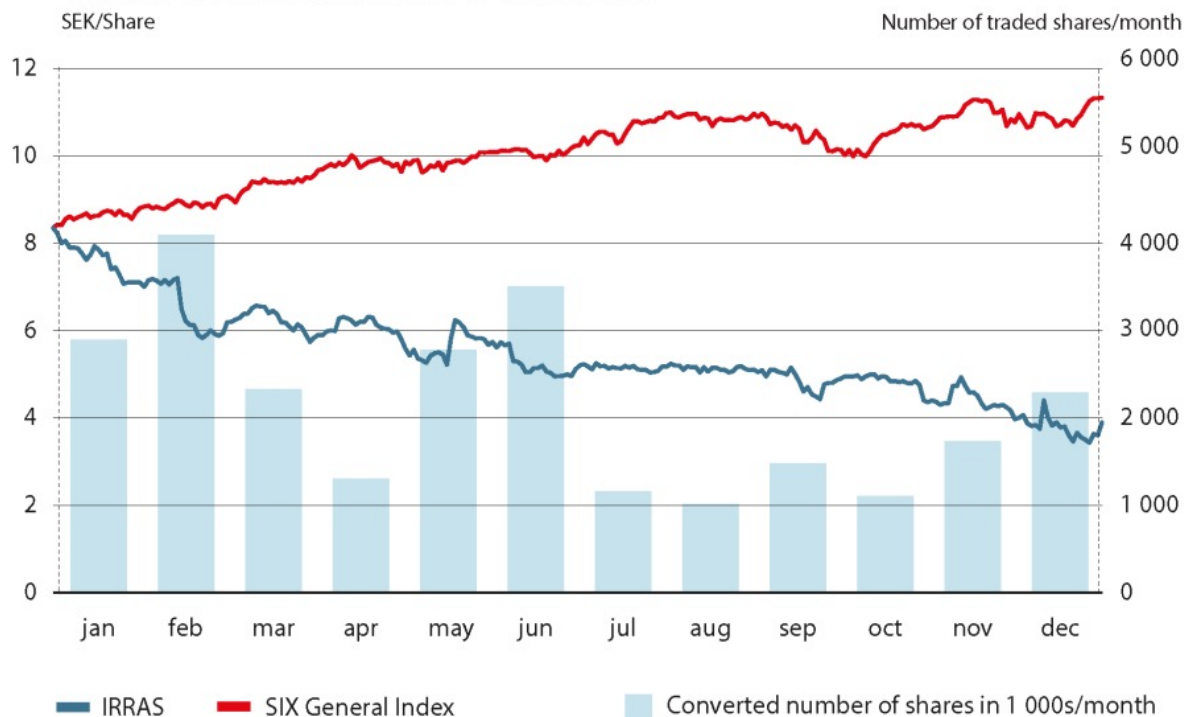
## Shareholder agreement

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. Nor are they aware of any significant agreements to which the company is a party and which take effect or change or cease to apply if control of the company changes as a result of a public takeover bid.

## Dividend and dividend policy

The Board of Directors of IRRAS has proposed to the Annual General Meeting that no dividend will be paid for the financial year 2021. The Board do not intend to propose a dividend to the AGM prior to a positive cash flow is achieved by IRRAS.

## SHARE PRICE DEVELOPMENT DURING 2021



**SHAREHOLDERS AS OF DECEMBER 31, 2021 AND THEREAFTER KNOWN CHANGES**

	No of shares/votes	Percent
Bacara Holdings Ltd	18,683,339	23.51%
Fourth Swedish National Pension Fund	7,359,362	9.26%
Carl-Olof och Jenz Hamrins Stiftelse	3,800,000	4.78%
Lexington Holding Assets Ltd	3,155,727	3.97%
Staffan Persson	2,950,005	3.71%
Christos Panotopoulos	2,403,000	3.02%
Second Swedish National Pension Fund	2,000,000	2.52%
March Asset Management	1,888,783	2.38%
Avanza Pension	1,557,631	1.96%
Kleanthis G. Xanthopoulos	1,301,498	1.64%
Other shareholders	34,381,995	43.26%
<b>Total number of shares</b>	<b>79,481,340</b>	<b>100.00%</b>

**OWNERSHIP STRUCTURE DECEMBER 31, 2021**

Size class	Number of known owners
1-500	1,499
501-5 000	781
5 001-100 000	481
100 001-500 000	28
500 001-	14
<b>Total</b>	<b>2,803</b>

**DEVELOPMENT OF THE SHARE CAPITAL**

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 share 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 share issue (4)	193,333	6,444,444	709,855.89	23,661,863	0.03
2018	New share issue (5)	10,683.33	356,111	720,539.22	24,017,974	0.03
2019	New share issue (6)	144,000	4,800,000	864,539.22	28,817,974	0.03
2020	New share issue (7)	1,123,900.98	37,463,366	1,988,440.20	66,281,340	0.03
2021	New share issue (8)	396,000	13,200,000	2,384,440.20	79,481,340	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.

8) The subscription price in the rights issue was SEK 5,00 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, 2021. 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 IRRASflow 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.

IRRASflow is an FDA-cleared, CE-marked, fully-integrated medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure.

The Hummingbird product 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 IRRASflow 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.

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, has three wholly owned subsidiaries: IRRAS GmbH in Germany, IRRAS BV in the Netherlands, and IRRAS 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 focused on developing a direct sales channel with German hospitals, and the Dutch entity houses both direct sales resources and the IRRAS international distribution location.

## MULTI-YEAR OVERVIEW

Amounts in TSEK	Group					Parent Company				
	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2019	Jan-Dec 2018	Jan-Dec 2017	Jan-Dec 2021	Jan-Dec 2020	Jan-Dec 2019	Jan-Dec 2018	Jan-Dec 2017
<b>Earnings</b>										
Net Revenue	22,386	7,390	5,288	5,994	11,973	742	4,726	1,551	13,081	3,969
Gross margin, %	neg.	neg.	neg.	neg.	53%	neg.	neg.	neg.	39%	16%
Operating Loss (EBIT)	-136,522	-134,316	-151,486	-143,328	-61,464	-38,076	-40,091	-47,384	-43,018	-45,309
Net loss fore the period	-136,335	-135,916	-151,144	-138,842	-60,901	-258,252	-41,224	-46,434	-39,565	-45,169
<b>Financial position</b>										
Total assets	132,594	209,035	158,992	205,284	329,252	319,256	517,486	369,650	315,265	349,854
Equity	111,634	182,353	131,470	184,154	316,030	313,864	509,352	360,532	307,419	338,877
Equity ratio, %	84%	87%	83%	90%	96%	98%	98%	98%	98%	97%

## Significant events during the fiscal year

### Change of Chief Executive Officer

On July 1, 2021, Will Martin, previously IRRAS' Chief Commercial Officer, assumed the role Chief Executive Officer. Kleanthis G. Xanthopoulos, Ph.D., the company's previous CEO, remains on IRRAS' Board of Directors.

### IRRAS extended its financial runway

A directed share issue took place in June 2021 which generated proceeds of SEK 66 million before fees.

IRRAS signed a 10M EUR loan agreement with the European Investment Bank (EIB) that provides non-dilutive financing to accelerate product development and clinical data generation in the EU. The loan has not been used at December 31, 2021.

### CE-Mark and certified quality system received

IRRAS decided during the year to change its notified body partner for global regulatory and quality system to DEKRA for its CE-Mark of the IRRAS*flow* system and ISO 13485:2016 certification of its quality system. After the recently conducted review by DEKRA the CE-Mark for the IRRAS*flow* up until May 2024.

### Meaningful clinical data published and comparative clinical trials initiated

Helsinki University Hospital published a case series that confirmed the ability of IRRAS*flow* to treat aggressive brain infections by delivering antibiotics directly into the intracranial space.

Buffalo General Medical Center published a comparative case report that highlighted the superiority of IRRAS*flow* over traditional drainage and documented delivery of thrombolytic medication for the first time in published literature. The ARCH and ACTIVE clinical studies that will compare IRRAS*flow* to traditional drainage were initiated.

## 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).

IRRAS*flow*, is used to drain collected blood and other fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematoma, two serious conditions with high rates of mortality. IRRAS*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 IRRAS8, 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 IRRAS*flow* in Europe and the US is currently just over USD 1.8 billion per year. The intracranial drug delivery capability of IRRAS*flow* may significantly increase this addressable market opportunity.

At the same time, 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 600 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, IRRAS*flow* has been used in over 350 patient treatments in the US and Europe without any reported cases of catheter blockages, which are reported in up to 47% of cases where traditional drainage is used.

During 2021, the launch of IRRAS*flow* continued in the US and Europe. While COVID-19 slowed commercial activities, the US sales team developed key customers at important comprehensive stroke centers, including Buffalo General Medical Center and West Virginia University. The company's international sales team added direct customers in Germany, Sweden, and Denmark and expanded the network of distribution partners across Europe and the Middle East.

During the year, additional training and education resources were added in both the US and Sweden.

## Earnings and financial position in the Group

### Net revenue

Net revenue for the 2021 fiscal year totaled SEK 22.4 million (7.4). Of this revenue, SEK 13.4 million (3.2) is attributable to sales in the US, SEK 7.0 million (3.8) to sales in Europe and SEK 2.0 million (0.4) to sales in the rest of the world. Sales development was still heavily affected by COVID-19 in both Europe and the US during the year.

### Gross profit/loss

The gross loss for 2021 totaled SEK -28.0 million (-16.1). 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. Amortization of capitalized development expenses amounted to SEK 11.4 million (10.7), for the period januari to december 2021.

### Operating expenses

Operating expenses for 2021 totaled SEK 116.3 million (118.2). Sales expenses has increased slightly in the US compared to previous year due to a growing sales force and regulatory costs. Of the total SEK 30.4 million (36.7) R&D costs for the year, SEK 6.7 million (7.8) was capitalized and SEK 23.7 million (28.9) was expensed. The expensed R&D costs mainly include personnel costs for employees and consultant fees. 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 2021 amounted to SEK 7.7 million (0.7). Other operating income is primarily made up of exchange rate differences. The SEK 6.9 million loan from the Paycheck Protection Program was waived during the year.

#### Operating income/loss (EBIT)

The operating loss for 2021 totaled SEK -136.5 million (-134.3), for the period januari to december 2021.

#### Net financial income

Net financial items totaled SEK 0.2 million (-1.6), for the period januari to december 2021.

#### Earnings

The loss before tax for 2021 amounted to SEK -136.3 million (-135.9). The net loss for the year totaled SEK -136.3 million (-135.9), for the period januari to december 2021.

#### Cashflow, investment and liquidity

Cash flow from operating activities for 2021, after changes in working capital, totaled SEK -130.5 million (-132.7).

Total net investments for 2021 totaled SEK 7.2 million (8.7). Of the total net investments, investments in intangible assets amounted to SEK 6.7 million (7.8). Investments in tangible assets totaled SEK 0.6 million (0.9) and sales of financial investments amounted to SEK 0 million (55.5).

Cash amounted to SEK 55.9 million (135.6) at year-end.

#### Parent Company

Net revenue for the Parent Company in 2021 totaled SEK 0.7 million (4.7). This amount primarily pertains to invoicing of management fees and other remuneration from subsidiaries.

The operating income/loss amounted to MSEK -38,1 (-40,1) for the period January – December 2021. The net loss for the period amounted to MSEK -258,3 (-41,2) and includes write-down of shares in subsidiaries by MSEK -220,5 (0).

As of December 31, 2021, equity in the Parent Company totaled SEK 313.8 million (509.4).

The Parent Company's receivables from Group companies consist of long-term loans and current receivables, which amounted to SEK 13.7 million (23.1) at year-end.

#### Personnel

The average number of employees in the Group for 2021 was 53 (43), of whom 7 (6) are in the parent company. The breakdown of the average number of employees by country was 7 (6) in Sweden, 42 (34) in the US and 4 (3) in Germany. The increase of employees in the US was with the departments of sales, production and development and is in line with the company's strategy.

The average number of women in the Group was 26 (16) and the average number of men was 27 (27). 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.

#### Production

The US subsidiary, IRRAS Inc, is a registered manufacturer of the company's products. IRRAS in-house manufactures the *IRRAflow* capital equipment and partners with select contract manufacturers for the manufacturing of sterilized consumable products. IRRAS directly distributes all of its products.

#### Development

The optimization of existing products and the continued development of additional innovative solutions is a critical element of IRRAS' long-term strategy. The IRRAS product development team has developed a product development roadmap that projects related to both the *IRRAflow* and the Hummingbird product lines.

Total development expenses in 2022 are expected to be less than 2021 as work continues to further improve the product lines. IRRAS' overall engineering strategy is focused on developing innovative, user-friendly, reliable, and high-quality proprietary fluid exchange systems. IRRAS continued to strengthen its internal competence with the in-house development of a next generation *IRRAflow* control unit and enhanced consumables. Internal expertise is supplemented by external consultants that provide specific competencies. Product development is carried out by the US subsidiary.

In addition to these research and development efforts, IRRAS' manufacturing engineering department is focused on continuous improvements in its sourcing and production processes in order to enhance its manufacturing efficiency. R&D costs recognized as revenue account for 20% (24) of total operating expenses.

#### Quality assurance

IRRAS is certified under ISO 13485:2016 and FDA 21 CFR Part 820. In 2021, IRRAS received an updated ISO 13485:2016 certificate that was certified under Europe's new Medical Device Regulations, and its manufacturing facility was inspected and certified by the state of California, the US FDA, and its notified body, DEKRA, on behalf of Europe for product shipping.

Also, during 2021, IRRAS' quality system was certified under the Medical Device Single Audit program (MDSAP), which allows the company to seek product regulatory approval in key markets, including Brazil, Australia, Canada, and Japan.

Initial FDA clearance in the US was obtained for the *IRRAflow* CNS System in 2018. Clearance for an extended period of use was obtained in 2019, and an additional 510(k) filing will be submitted during 2022 in the US to seek clearance for the *IRRAflow* bedside monitor communication capability. CE Mark approval for its *IRRAflow* CNS System control unit and tube set was received in the spring of 2018, and, in December 2019, CE Mark approval was also received for the *IRRAflow* CNS System catheters. The control unit and tube set are medical device Class IIb products and the catheter belongs to Class III.

In addition to the US and EU, regulatory approval for *IRRAflow* has also been received in Israel, Kuwait, Mexico, Ecuador, 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 nine 510(k) FDA-cleared Hummingbird products, and DermaPort, a 510(k) FDA cleared product for vascular access.

#### 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, and external stakeholders.

### The IRRAS share and ownership structure

In 2021, the number of shares increased by 13,200,000 ordinary shares and as of 31 December 2021 the total number of shares amounted to 79,481,340 ordinary shares. The shares have a quota value of SEK 0.03 each. The company has not issued any Series C shares.

For the issued common shares, no differences or restrictions apply in accordance with law or the Articles Of Association regarding the transferability of the shares, voting rights, rights to the company's assets or dividends.

At the turn of the year, the numbers of shareholders in IRRAS was 2 803 (3 201) with Bacar Holdings Ltd as the majority shareholder with 24 (24) percentage of the capital and the votes. No other shareholder owns more than 10 percent of the votes. The ten largest shareholders together accounts for 57 (54) percent of the capital and the votes. For more information about the IRRAS share, see page 19-20.

IRRAS has five outstanding incentive programs for employees and key employees. The incentive programs may increase the number of shares by currently 5,332,000 ordinary shares.

### 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 and is still in effect. 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 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 2022 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.

### Description of the company's incentive program

The company has five outstanding incentives programs of which the first was introduced in 2016. During the year, no incentive programs have expired and one program been added. 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.

### 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, risk related to the competitors, risk related to the product liability requirements, risks related to the protecting the company's intellectual property or infringements of third-party patents.

#### 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 were introduced globally during 2020 continued during outbreaks throughout 2021. These restrictions have a major effect on the company's ability to visit and train distributors and direct customers. The pandemic has also caused reduced usage of IRRAS' products due to reduced capacity for neurosurgical patients in hospital's intensive care units. As restrictions continue to ease, the company's commercial progress should increase.

#### 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.

#### 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 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 contract manufacturers and an extensive raw material supply chain. The COVID-19 pandemic has stressed the global supply chain as shipping lead times and raw material availability have been negatively impacted. IRRAS has mitigated supply disruptions to date and continues to take proactive steps with vendors to ensure required production demand can be met. While IRRAS remains focused on meeting all required inventory needs, continued supply chain disruptions could result in unexpected product availability impact.

### Corporate governance report

IRRAS AB (publ) applies the Swedish Corporate Governance Code. The Corporate governance report is an integrated part of the Administration Report and is to be found on pages 60-67. The Group's system for internal control and risk management is described in the section "Internal control report" in the corporate governance report.

## Significant events after the end of the 2021 fiscal year

### **IRRAS Expands Intellectual Property Portfolio with Issuance of Additional Patent for IRRAS*flow* System.**

A third patent was issued to expand the company's protection of the IRRAS*flow* system by providing coverage of the system's ability to administer therapeutic drugs using its catheter's dual-lumen design and controlled irrigation capabilities.

### **Presentation of Largest Dataset to Date**

In February IRRAS presented the largest compilation of clinical data on IRRAS*flow*. The result presented confirms the improved outcomes of the IRRAS*flow* system resulted in a 0% catheter occlusion rate throughout the treatment period.

### **IRRAS Launches Next-Generation of the IRRAS*flow* System in the United States.**

The company has started the commercial launch of the next generation IRRAS*flow* control unit, the company's latest innovation to improve the treatments of patients with intracranial haemorrhage.

### **Current conflict in Ukraine**

IRRAS is following the current conflict in Ukraine. Currently we do not expect any meaningful impact on our business.

## Future development

In 2020 and 2021, the company's commercial launch was understandably slowed by the global COVID-19 pandemic. Despite these challenges, meaningful progress has been made across all corporate functions, and, in 2021, increasing patient treatments resulted in growing revenue throughout the year.

In 2022, increasing commercial adoption and continuing revenue growth will remain the company's primary focus. This growth will be accomplished by investing in impactful comparative clinical data and using this evidence to add reference accounts for IRRAS*flow* throughout the United States and Europe, increasing the contribution of our distribution partners as eps with vendors to ensure required production demand can be met. While IRRAS remains focused on meeting all required inventory needs, continued supply chain disruptions could result in unexpected product availability impact they complete training and become more self-sufficient, and launching the Hummingbird product family in Europe after receiving its CE Mark certification.

Additionally, during 2022, IRRAS plans to introduce its next-generation IRRAS*flow* capital equipment and extended shelf-life for each of its disposable products. The company will proceed in expanding its manufacturing in order to control the offering, quality and reduce the costs.

## Proposed appropriation of the company's earnings

The Board proposes that the unappropriated earnings as of December 31, 2021 – SEK 283,501,165 – to be carried forward.

# Consolidated statement of profit or loss

AMOUNTS IN TSEK	Note	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Net revenue	5	22,386	7,390
Cost of goods sold		-50,365	-23,487
<b>Gross loss</b>		<b>-27,979</b>	<b>-16,097</b>
Other operating income	7	8,097	1,594
Marketing and sales costs		-53,065	-47,024
Administrative costs	9	-39,505	-42,950
Research and development costs		-23,679	-28,937
Other operating expenses	7	-391	-901
<b>Operating loss (EBIT)</b>	<b>6</b>	<b>-136,522</b>	<b>-134,316</b>
Financial income		299	8
Financial expenses		-112	-1,596
<b>Loss from financial items</b>	<b>8</b>	<b>187</b>	<b>-1,588</b>
<b>Loss before tax</b>		<b>-136,335</b>	<b>-135,903</b>
Income tax	12	-	-12
<b>Net loss for the year</b>		<b>-136,335</b>	<b>-135,916</b>
Earnings per share before and after dilution, SEK	26	-1.89	-2.46
Average number of shares before dilution		72,316,866	55,152,011
Average number of shares after dilution		72,316,866	55,152,011

# Consolidated statement of profit or loss and other comprehensive income

AMOUNTS IN TSEK	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Net loss for the year</b>	<b>-136,335</b>	<b>-135,916</b>
<b>Other comprehensive income for the year:</b>		
<i>Items that may be recognized to profit and loss</i>		
Exchange differences on the translation of foreign operations	2,851	-3,246
<b>Other comprehensive income for the year, net after tax</b>	<b>2,851</b>	<b>-3,246</b>
<b>Total comprehensive income for the year</b>	<b>-133,484</b>	<b>-139,162</b>

# Consolidated statement of financial position

AMOUNTS IN TSEK	Note	2021-12-31	2020-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
Capitalized development expenses	13	28,592	33,294
Patents	13	6,057	6,521
Tangible assets	14	1,103	1,310
Right-of-use assets	14	4,038	3,788
Financial investments	15	–	–
<b>Total non-current assets</b>		<b>39,790</b>	<b>44,914</b>
<b>Current assets</b>			
Inventories	16	12,368	18,074
Advance payments to suppliers		1,007	2,865
Trade receivables		16,262	5,056
Other receivables	17	1,631	1,292
Prepaid expenses and accrued income	18	5,680	1,229
Current financial investments	15	–	–
Cash and cash equivalents		55,855	135,604
<b>Total current assets</b>		<b>92,804</b>	<b>164,121</b>
<b>TOTAL ASSETS</b>		<b>132,594</b>	<b>209,035</b>
<b>EQUITY</b>			
Share capital		2,384	1,988
Other paid-in capital		787,811	726,668
Reserves		-3,430	-6,281
Retained earnings, including profit/loss for the year		-675,132	-540,023
<b>Total equity</b>		<b>111,633</b>	<b>182,353</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Lease liabilities		161	76
<b>Total non-current liabilities</b>		<b>161</b>	<b>76</b>
<b>Current liabilities</b>			
Lease liabilities		3,515	3,922
Trade payables		5,459	3,450
Other liabilities		2,423	7,329
Accrued expenses and deferred income	20	9,403	11,906
<b>Total current liabilities</b>		<b>20,800</b>	<b>26,607</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>132,594</b>	<b>209,035</b>

# Consolidated statement of changes in equity

AMOUNTS IN TSEK	Note	Share capital	Other paid-in capital	Reserves	Retained earnings, including net loss for the year	Total equity
<b>Opening balance as of 2020-01-01</b>		<b>865</b>	<b>537,387</b>	<b>-3,035</b>	<b>-403,746</b>	<b>131,470</b>
<b>Comprehensive income</b>						
Net loss for the year					-135,916	-135,916
Other comprehensive income						
Exchange differences on the translation of foreign operations				-3,246		-3,246
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-3,246</b>	<b>-135,916</b>	<b>-139,162</b>
<b>Transactions with shareholders</b>						
Incentive programs	10				-361	-361
New share issues		1,124	216,164			217,288
Issue expenses			-26,882			-26,882
<b>Total</b>		<b>1,124</b>	<b>189,281</b>	<b>-</b>	<b>-361</b>	<b>190,044</b>
<b>Closing balance as of 2020-12-31</b>	19	<b>1,988</b>	<b>726,668</b>	<b>-6,281</b>	<b>-540,023</b>	<b>182,353</b>



# Consolidated statement of changes in equity *(cont.)*

AMOUNTS IN TSEK	Note	Share capital	Other paid-in capital	Reserves	Retained earnings, including net loss for the year	Total equity
<b>Opening balance as of 2021-01-01</b>		1,988	726,668	-6,281	-540,023	<b>182,353</b>
<b>Comprehensive income</b>						
Net loss for the year					-136,335	<b>-136,335</b>
Other comprehensive income						
Exchange differences on the translation of foreign operations				2,851		<b>2,851</b>
<b>Total comprehensive income</b>		<b>-</b>	<b>-</b>	<b>2,851</b>	<b>-136,335</b>	<b>-133,484</b>
<b>Transactions with shareholders</b>						
Incentive programs	10				1,195	<b>1,195</b>
New share issues		396	65,604			<b>66,000</b>
Issue expenses			-4,461		31	<b>-4,430</b>
<b>Total</b>		<b>396</b>	<b>61,143</b>	<b>-</b>	<b>1,226</b>	<b>62,765</b>
<b>Closing balance as of 12/31/2021</b>	19	<b>2,384</b>	<b>787,811</b>	<b>-3,430</b>	<b>-675,132</b>	<b>111,633</b>

# Consolidated statement of cash flows

AMOUNTS IN TSEK	Note	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Cash flow from operating activities</b>			
Operating loss (EBIT)		-136,522	-134,316
Adjustments for non-cash items			
- Reversals of depreciation and amortization		16,819	16,326
- Other non-cash items		-1,923	-
- Incentive programs	10	1,195	-361
Interest received		1	8
Interest paid		-151	-378
Tax paid		-	-12
<b>Cash flow from operating activities before changes in working capital</b>		<b>-120,581</b>	<b>-118,733</b>
<i>Changes in working capital</i>			
Increase/decrease in inventory		1,970	-6,177
Increase/decrease in operating receivables		-12,900	-4,216
Increase/decrease in operating liabilities		971	-3,567
<b>Cash flow from operating activities</b>		<b>-130,540</b>	<b>-132,693</b>
<b>Cash flow from investing activities</b>			
Investments in intangible assets		-6,707	-7,795
Investments in tangible assets		-565	-882
Sales of financial investments		-	55,465
<b>Cash flow from investing activities</b>		<b>-7,272</b>	<b>46,788</b>
<b>Cash flow from financing activities</b>			
New share issues		66,000	217,288
Issue expenses		-4,461	-26,882
Loans from credit institutions		-	6,813
Amortization of lease liabilities		-4,320	-3,786
<b>Cash flow from financing activities</b>		<b>57,219</b>	<b>193,433</b>
<b>Cash flow for the period</b>		<b>-80,593</b>	<b>107,529</b>
Cash and cash equivalents at the beginning of the period		135,604	29,514
Effects of exchange rate changes on cash and cash equivalents		844	-1,439
<b>Cash and cash equivalents at the end of the period</b>		<b>55,855</b>	<b>135,604</b>

# Parent Company income statement

AMOUNTS IN TSEK	Note	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Net revenue	5	742	4,726
Cost of goods sold		-11,953	-10,728
<b>Gross loss</b>		<b>-11,211</b>	<b>-6,002</b>
Other operating income	7	282	940
Marketing and sales costs		-6,742	-4,555
Administrative costs	9	-20,289	-29,503
Research and development costs		35	-467
Other operating expenses	7	-150	-505
<b>Operating loss (EBIT)</b>	6	<b>-38,076</b>	<b>-40,091</b>
Interest income and similar items		350	304
Interest expenses and similar items		-220,527	-1,436
<b>Loss from financial items</b>	8	<b>-220,176</b>	<b>-1,133</b>
<b>Loss before tax</b>		<b>-258,252</b>	<b>-41,224</b>
Income tax for the year	12	-	-
<b>Net loss for the year</b>		<b>-258,252</b>	<b>-41,224</b>

# Parent Company statement of profit or loss and other comprehensive income

AMOUNTS IN TSEK	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Net loss for the year</b>	<b>-258,252</b>	<b>-41,224</b>
<b>Other comprehensive income for the year, net after tax</b>	<b>-</b>	<b>-</b>
<b>Total comprehensive income for the year</b>	<b>-258,252</b>	<b>-41,224</b>

# Parent Company balance sheet

AMOUNTS IN TSEK	Note	2021-12-31	2020-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Capitalized development expenses	13	28,592	33,294
Patents	13	1,266	1,582
<b>Total intangible assets</b>		<b>29,858</b>	<b>34,876</b>
<b>Tangible assets</b>			
Equipment, tools and plant	14	97	203
<b>Total tangible assets</b>		<b>97</b>	<b>203</b>
<b>Financial assets</b>			
Participations in Group companies	23	227,816	340,893
Receivables, Group companies	11	13,685	23,101
Long-term financial investments	15	–	–
<b>Total financial assets</b>		<b>241,501</b>	<b>363,994</b>
<b>Total non-current assets</b>		<b>271,456</b>	<b>399,073</b>
<b>Current assets</b>			
<b>Current receivables</b>			
Trade receivables		–	9
Receivables, Group companies	11	173	–
Other receivables	17	808	756
Prepaid expenses and accrued income	18	983	734
<b>Total current receivables</b>		<b>1,964</b>	<b>1,499</b>
<b>Current financial investments</b>	15	–	–
<b>Cash at bank</b>		<b>45,836</b>	<b>116,914</b>
<b>Total current assets</b>		<b>47,800</b>	<b>118,413</b>
<b>TOTAL ASSETS</b>		<b>319,256</b>	<b>517,486</b>

# Parent Company balance sheet

## *(cont.)*

AMOUNTS IN TSEK	Note	2021-12-31	2020-12-31
<b>TOTAL EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Restricted equity</b>			
Share capital	19	2,384	1,988
Reserve for development expenses		27,979	30,589
<b>Total restricted equity</b>		<b>30,363</b>	<b>32,578</b>
<b>Unrestricted equity</b>			
Share premium reserve		754,266	693,092
Retained earnings		-212,512	-175,094
Net loss for the year		-258,252	-41,224
<b>Total unrestricted equity</b>		<b>283,501</b>	<b>476,774</b>
<b>Total equity</b>		<b>313,864</b>	<b>509,352</b>
<b>Current liabilities</b>			
Trade payables		925	1,464
Payables, Group companies	11	104	-
Other liabilities		402	384
Accrued expenses and deferred income	20	3,960	6,286
<b>Total current liabilities</b>		<b>5,391</b>	<b>8,134</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>319,256</b>	<b>517,486</b>

# Parent Company statement of changes in equity

AMOUNTS IN TSEK	Restricted equity		Unrestricted equity Share premium reserve	Retained earnings	Net loss for the year	Total equity
	Share capital	Reserve for development expenses				
<b>Opening balance as of 2020-01-01</b>	<b>865</b>	<b>31,720</b>	<b>503,810</b>	<b>-129,429</b>	<b>-46,434</b>	<b>360,532</b>
<b>Comprehensive income</b>						
Appropriation of earnings as decided at AGM				-46,434	46,434	-
Net loss for the year					-41,224	-41,224
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-46,434</b>	<b>5,210</b>	<b>-41,224</b>
<b>Transactions with shareholders</b>						
Incentive programs				-361		-361
New share issues	1,124		216,164			217,288
Issue expenses			-26,882			-26,882
<b>Total transactions with shareholders</b>	<b>1,124</b>	<b>-</b>	<b>189,281</b>	<b>-361</b>	<b>-</b>	<b>190,044</b>
Dissolution, reserve for development expenses		-1,131		1,131		-
<b>Closing balance as of 2020-12-31</b>	<b>1,988</b>	<b>30,589</b>	<b>693,092</b>	<b>-175,094</b>	<b>-41,224</b>	<b>509,352</b>

# Parent Company statement of changes in equity (cont.)

AMOUNTS IN TSEK	Restricted equity		Unrestricted equity		Retained earnings	Net loss for the year	Total equity
	Share capital	Reserve for development expenses	Share premium reserve				
<b>Opening balance as of 2021-01-01</b>	<b>1,988</b>	<b>30,589</b>	<b>693,092</b>		<b>-175,094</b>	<b>-41,224</b>	<b>509,352</b>
Comprehensive income							
Appropriation of earnings as decided at AGM					-41,224	41,224	-
Net loss for the year						-258,252	-258,252
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>		<b>-41,224</b>	<b>-217,029</b>	<b>-258,252</b>
<b>Transactions with shareholders</b>							
Incentive programs					1,195		1,195
New share issues	396		65,604				66,000
Issue expenses			-4,430				-4,430
<b>Total transactions with shareholders</b>	<b>396</b>	<b>-</b>	<b>61,174</b>		<b>1,195</b>	<b>-</b>	<b>62,765</b>
Dissolution, reserve for development expenses		-2,611			2,611		-
<b>Closing balance as of 2021-12-31</b>	<b>2,384</b>	<b>27,979</b>	<b>754,266</b>		<b>-212,512</b>	<b>-258,252</b>	<b>313,864</b>

# Parent Company statement of cash flows

AMOUNTS IN TSEK	Note	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Cash flow from operating activities</b>			
Operating loss (EBIT)		-38,076	-40,091
Adjustments for non-cash items			
- Reversals of depreciation and amortization		11,832	11,151
- Incentive programs	10	365	754
Interest received		-11	8
Interest paid		-	-218
<b>Cash flow from operating activities before changes in working capital</b>		<b>-25,890</b>	<b>-28,396</b>
<i>Changes in working capital</i>			
Increase/decrease in other current receivables		-116	3,377
Increase/decrease in other current liabilities		2,485	7,366
<b>Total changes in working capital</b>		<b>2,369</b>	<b>10,744</b>
<b>Cash flow from operating activities</b>		<b>-23,522</b>	<b>-17,652</b>
<b>Cash flow from investing activities</b>			
Participations in subsidiaries		-102,389	-118,597
Investments in intangible assets		-6,707	-7,795
Sales of financial investments		-	55,465
Repayments of loans to subsidiaries		-	-7,583
<b>Cash flow from investing activities</b>		<b>-109,096</b>	<b>-78,510</b>
<b>Cash flow from financing activities</b>			
New share issues		66,000	217,288
Issue expenses		-4,461	-26,882
<b>Cash flow from financing activities</b>		<b>61,539</b>	<b>190,405</b>
<b>Cash flow for the period</b>		<b>-71,078</b>	<b>94,244</b>
Cash and cash equivalents at the beginning of the period		116,914	22,670
<b>Cash and cash equivalents at the end of the period</b>		<b>45,836</b>	<b>116,914</b>



# Notes

## NOTE 1 GENERAL INFORMATION

IRRAS AB (publ) is registered in Sweden and has its registered office in Stockholm. The address of its head office is Vasagatan 16, Stockholm, Sweden.

All amounts are presented in thousands of SEK (TSEK) unless otherwise stated. Figures in brackets refer to the previous year. Rounding differences may occur.

## NOTE 2 SUMMARY OF PRINCIPAL ACCOUNTING POLICIES

### Basis for the preparation of the financial statements

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the EU and 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 different accounting policies than the Group, this is stated separately at the end of this accounting policy section.

The principal accounting policies applied when preparing these consolidated financial statements are set out below.

The preparation of financial statements in accordance with the IFRS requires the use of significant estimates for accounting purposes. Management is also required to make certain judgements when applying the Group's accounting policies. The areas involving a high degree of judgement or complexity, or where the assumptions and estimates are material to the consolidated financial statements, are stated in Note 4.

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

A few amendments to existing standards and interpretations became effective for the financial period from January 1, 2021.

No new or amended standards have had a material impact on the Group's financial statements.

### *Standards, amendments and interpretations of existing standards effective from 2022 or later that are expected to have or are already having an impact on the financial statements*

Amendments to IFRS 3, IAS 16 and IAS 37 will be introduced as of 2022. Amendments to IFRS 17 will become effective in 2023.

No future or amended standards are expected to have a material impact on the Group's financial statements.

## Consolidated financial statements

### *Subsidiaries*

Subsidiaries are all the companies where the Group has a controlling influence. The Group controls an entity if it is exposed to, or has the right to receive, variable returns from its investment in the entity, and is able to affect those returns through its influence over the entity. Subsidiaries are included in the consolidated financial statements from the date on which control was transferred to the Group. Subsidiaries are removed from the consolidated financial statements from the date on which control ceases.

### *Segment reporting*

As IRRAS' equity instruments is traded in a public market, IFRS 8 *Operating Segments* is applied. An operating segment is a part of a company whose operating performance is regularly reviewed by the Group's "Chief Operating Decision Maker", who decides on the resources to be allocated to the segment and evaluates the segment's performance.

IRRAS' activities are currently focused on development and sales in the IRRASflow product area. Management has therefore decided to monitor the business as a single reporting entity. The company therefore has only one segment for the time being, which is fully reflected in the Group's financial statements. The chief operating decision makers are considered to be the Chief Executive Officer and Senior Executive Team .

### *Earnings per share*

Earnings per share have been calculated as the net profit/loss divided by the average number of shares. Where a loss is reported, the diluted earnings per share are equal to the basic earnings per share. When a profit is made in the future, the options may have a dilutive effect.

### *Foreign currency translation Functional and reporting currency*

The items included in the financial statements for the Group's various entities are measured in the currency of the economic environment in which each entity principally operates (the functional currency). The reporting currency used in the consolidated financial statements is the Swedish krona (SEK), which is also the Parent Company's functional and reporting currency.

### Transactions and balance sheet items

Foreign currency transactions are translated into the functional currency at the exchange rates prevailing on the transaction date. Foreign exchange gains/losses arising from the settlement of such transactions, and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies, are recognized in the income statement. Exchange differences on loans and borrowings are recorded in net financial income, while other exchange differences are included in operating profit/loss.

### Group companies

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

- (a) the assets and liabilities in each balance sheet are translated at the exchange rate on the balance sheet date;
- (b) the income and expenses in each income statement are translated at the average exchange rate (if this average rate is a reasonable approximation of the cumulative effect of the exchange rates prevailing on the transaction date, otherwise the income and expenses are translated at the exchange rate on the transaction date); and
- (c) any exchange differences arising are recognized as a separate component of other comprehensive income.

On consolidation, exchange differences arising from the translation of net investments in foreign operations are taken to equity. On the disposal of a foreign operation, in whole or in part, the exchange differences recognized in equity are recorded in the income statement in capital gains/losses.

### Intangible assets

#### Capitalized expenditure on development and similar projects

Development costs that are directly attributable to the development and testing of identifiable products adapted for IRRAS are recognized as intangible assets if they have probable economic benefits.

Directly attributable expenditure capitalized in assets includes the share of expenditure on employees and materials attributable to development. On capitalization, the Group's ability to finance ongoing development is taken into account. Capitalized development costs are recognized in intangible assets and amortized from the date when assets are ready for use.

#### Patents

Patents acquired separately are stated at cost. Patents acquired through business combinations are stated at fair value on the acquisition date. Patents have a finite useful life and are recognized at cost less accumulated amortization and any impairment losses. Patent costs incurred are recognized as intangible assets only when patents are granted.

#### Amortization period for intangible assets

Patents	4 to 18 years
Capitalized expenditure on development and similar projects	5 years

### Tangible assets

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

The Group's tangible assets consist of equipment. Additional expenditure is added to the carrying amount of an asset, or recognized as a separate asset, as appropriate, only when it is probable that the

future economic benefits associated with the asset will flow to the Group and the cost of the asset can be reliably measured. The carrying amount of replaced parts is removed from the balance sheet. All other repairs and maintenance are expensed in the income statement in the period in which they occurred.

Tangible assets are depreciated on a straight-line basis, in order to spread their acquisition cost down to their estimated residual value over their estimated useful lives, as follows:

#### Depreciation period for tangible assets

Equipment, tools and plant	3 to 5 years
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Gain and losses on disposals for disposals are determined by comparing the sales proceeds and the carrying amount, and are recognized in other operating income and operating expenses in profit and loss.

### Leases

When an arrangement is entered into, the Group assesses whether the arrangement is, or contains, a lease and should be accounted for in accordance with IFRS 16 *Leases*. An arrangement is, or contains, a lease if it assigns the right to control an identified asset's use for a specified period in return for consideration. An arrangement may contain both lease and non-lease components. The Group allocates the contractual consideration to lease and non-lease components based on their relative stand-alone prices. For lease payments relating to real estate of which the Group is the lessee, it has been decided not to separate the lease and non-lease components and instead to account for them as a single lease component. The leases do not contain any specific conditions or restrictions, except that the lessor retains the rights in respect of the pledged leased assets. The leased assets may not be used as collateral for loans.

Assets and liabilities arising from leases are initially recognized at their present value. The lease liabilities include the present value of the following lease payments:

1. fixed payments after the deduction of any lease incentives received
2. variable lease payments linked to an index or a price, initially measured using the index or price on the commencement date
3. the amounts expected to be paid by the lessee under residual value guarantees
4. the exercise price of any option to buy if the Group is reasonably certain to exercise such an option
5. the penalties payable on the termination of the lease, if the lease term reflects that the Group will exercise an option to terminate the lease.

The lease payments that will be made for reasonably certain renewal options are also included in the valuation of the liability.

Lease payments are discounted at the implied interest rate for the lease, or at the marginal lending rate, which is the interest rate that would be payable in order to borrow the funds necessary to purchase an asset of a similar value to the right-of-use asset in a similar economic environment with similar terms and collateral. If changes are made to the lease, the lease liability is revalued and adjusted against the right-of-use asset.

Right-of-use assets are valued at cost and include the following:

1. the amount of the lease liability originally measured as
2. the lease payments made on or before the commencement date, net of any lease incentives received
3. the initial direct costs
4. the cost of restoring the asset to the condition specified under the terms of the lease.

Right-of-use assets are amortized on a straight-line basis over the shorter of the useful life and the lease term. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is amortized over the useful life of the underlying asset.

Payments for short-term arrangements relating to office premises and vehicles, and all low-value leases, are charged to the income statement on a straight-line basis as with previous operating leases. Short-term arrangements are leases with a term of 12 months or less. Low-value leases include office equipment.

#### **Impairment of non-financial assets**

Tangible assets and amortizable intangible assets are assessed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized in the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and its value in use. When assets are assessed for impairment, the assets are grouped together at the lowest levels for which there are separate identifiable cash flows (cash-generating units).

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

#### **Impairment of tangible assets**

The useful lives of assets are reviewed on each balance sheet date and adjusted if necessary. The carrying amount of an asset is immediately written down 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 at least once every financial year.

#### **Financial instruments**

##### **General principles**

Purchases and sales of financial assets and liabilities are recognized on the issue date. Other Financial assets and liabilities are recognized when the Group is included in the terms of an agreement. Financial assets and liabilities that are not recognized at fair value through profit or loss are initially recognized at fair value plus transaction costs. Financial assets and liabilities at fair value through profit or loss are initially recognized at fair value, while the related transaction costs are recognized in the income statement. Financial assets are derecognized when the right to receive cash flows from instruments has lapsed or been transferred and the Group has transferred substantially all the risks and rewards of ownership. Financial liabilities are derecognized when the obligations under contracts have been discharged or otherwise extinguished.

Trade receivables, trade payables and other financial liabilities are stated after the acquisition date at amortized cost using the effective interest method. The fair value of borrowings is calculated, for disclosure purposes, by discounting the future contracted cash flows at the current market rate of interest 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 *Financial Instruments*. The classification of financial assets and liabilities determines how they are measured and recognized. The Group's policies for the classification and measurement of financial assets are based on an assessment of both (i) the company's business model for the management of financial assets, and (ii) the characteristics of the contractual cash flows from the financial assets.

Financial assets measured at amortized cost are debt instruments that are managed with the aim of realizing the instruments' cash flows by receiving contractual cash flows consisting solely of principal and interest on the principal amounts outstanding. The following financial assets are measured at amortized cost as the assets are held as part of a business model whose aim is to hold financial assets for the purpose of collecting contractual cash flows, and the assets' contractual terms give rise to cash flows at specified times that consist solely of payments of principal and interest on the principal amounts outstanding;

- Financial investments
- Other receivables
- Accrued income
- Short-term investments
- Cash and cash equivalents

The Group does not currently hold any financial assets that are measured at fair value through profit or loss or at fair value through other comprehensive income.

All of the Group's financial liabilities, consisting of borrowings and trade payables, are classified as other financial liabilities and are measured at amortized cost.

#### **Impairment of financial assets**

The provision for expected credit losses is calculated and recognized for financial assets measured at amortized cost, and for financial assets measured at fair value through other comprehensive income. The Group has no financial assets measured at fair value through other comprehensive income. The provision for credit losses is initially calculated and recognized based on twelve months' expected credit losses. If the credit risk has significantly increased since a financial asset was first recognized, a provision for credit losses is calculated and recognized based on the expected credit losses for the entire remaining life of the asset. For trade receivables, which do not contain a significant financing component, a simplified approach is taken and the provision for credit losses is calculated and recognized based on the expected credit losses for the entire remaining term, whether or not the credit risk has significantly increased. Expected credit losses are calculated based mainly on historical loss data for similar receivables and counterparties. The historical information is continually evaluated and adjusted based on the current situation and the Group's expectations of future events.

#### **Trade receivables**

Trade receivables 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 trade receivables, net of any impairment, is assumed to be equal to their fair value, as this item is short-term in nature.

**Cash and cash equivalents**

Cash and cash equivalents include cash in hand, bank deposits and other short-term investments maturing three months or less after their acquisition date.

**Share capital**

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

**Trade payables**

Trade payables are initially recognized at fair value and subsequently at amortized cost using the effective interest method. The carrying amount of trade payables is assumed to be equal to their fair value, as this item is short-term in nature.

**Borrowings**

Borrowings (borrowings from credit institutions, borrowings from related parties and other long-term borrowings) are initially recognized at fair value, net of transaction costs. Borrowings are subsequently stated at amortized cost, and any difference between the amount received (net of transaction costs) and the amount to be repaid is recognized in the income statement over the term of the loan, using the effective interest rate method.

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

Borrowing costs (interest and transaction costs) are recognized in the income statement in the period to which they relate. Accrued interest is recorded in borrowings in the balance sheet. As of the balance sheet date, neither the Group nor the Parent Company had any loans.

**Inventories**

Inventories are stated at standard cost. The value of the products in inventory consists of direct purchase costs, and indirect costs, such as personnel costs, depreciation and maintenance. Indirect production costs are calculated using a standard costing method. This method is regularly revised to ensure the reasonable calculation of the relevant factors. Changes to the method for calculating indirect production costs may have an impact on the gross margin and the overall valuation of inventory. The provision for obsolescence required is made following individual assessments.

**Current and deferred tax**

The current tax expense is calculated based on the tax rules enacted, or substantively enacted, at the balance sheet date, in the countries where the Parent Company's subsidiaries operate and generate taxable income. Management regularly evaluates claims made in tax returns relating to situations where the applicable tax rules are subject to interpretation and, where deemed appropriate, recognizes provisions for the amounts likely to be due to the tax authorities.

Deferred tax is recognized in full, using the balance sheet approach, on all temporary differences arising between the value of assets and liabilities for tax purposes and their carrying amounts in the consolidated financial statements. Deferred tax is calculated based on the tax rates (and laws) that have been enacted, or substantively enacted, at the balance sheet date, and are expected to apply when the relevant deferred tax assets are realized or deferred tax liabilities are settled.

Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilized. As of the balance sheet date, the Group has not recognized any tax losses as deferred tax assets.

**Employee benefits****Pension obligations**

The Group has defined contribution pension plans for Swedish residents. For its defined contribution pension plans, IRRAS pays contributions to publicly- or privately-administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations once the contributions have been paid.

The contributions are recognized as personnel costs as employees earn them by rendering services to the company. Prepaid contributions are recognized in assets to the extent that cash repayments or reductions in future payments may flow to the Group. Costs relating to services rendered in previous periods are recognized directly in the income statement. Compensation for dismissal is directly expensed in the period in which employment ceased.

The Group does not pay pensions to, or have pension obligations towards, employees living in the US and Germany. One employee in the Netherlands is reimbursed for the cost of private pension insurance, but the Group has no pension obligations in the country.

**Share-based payments**

The Group has share-based payment plans whereby employees render services to the company as consideration for Group equity instruments. Information about these plans is provided in Note 10.

**Incentive programs**

IRRAS has five outstanding incentive programs for employees, key personnel and Board members. The value of the employee stock option plans is recognized in personnel costs with a corresponding increase in equity. The total amount expensed is based on the estimated fair value of the options granted on the introduction of the plans and is amortized on a straight-line basis over the vesting period.

Non-market vesting conditions, such as continued employment conditions, are taken into account in the assumption regarding the number of options that are expected to vest. The options granted under some incentive programs vest over 1, 2 and 3 years respectively, and in one case 4 years (so called 'graded vesting'). See Note 10. The cost of each sub-program is spread over the respective vesting period, meaning that the cost of each incentive program is greatest in the first year and decreases each year thereafter. At the end of each reporting period, the entity reassesses its estimates of the number of shares that are expected to vest based on the non-market vesting conditions. Any difference from the original estimates arising from the reassessment has an impact on the cumulatively recognized expense and the expense for the current period.

The fair value of the options is not revalued after the programs' inception. When the options are exercised, the company issues new shares. The payments received, net of any directly attributable transaction costs, are credited to the share capital (quota value) and other paid-in capital when the options are exercised.

Social security contributions on the benefits expected from any appreciation in value are recognized over the vesting period, taking any changes in value into account, where applicable depending on the employee's country of residence.

### Provisions

Provisions are recognized when the Group has a legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and the amount has been reliably estimated. No provisions are made for future operating losses. As of the balance sheet date, the Group has not recognized any provisions for individual endowment policies. Provisions are measured at the market value of the amount expected to be required to settle the obligation.

### Revenue recognition

The Group's revenues are generated from the sale of products developed and produced within the Group.

The Group recognizes revenue from the sale of goods when control associated with ownership of the goods is transferred from the Group, when the Group no longer exercises effective control over the goods sold and control is transferred to the customer, the revenue and related expenses can be reliably measured, and it is probable that the economic benefits associated with the sale of the goods will flow to the Group.

### Interest income

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

### Accounting policies of the Parent Company

The accounting policies of the Parent Company are substantially consistent with the Group's. The Parent Company's financial statements have been prepared in accordance with RFR 2 *Accounting for Legal Entities* and the *Swedish Annual Accounts Act*. RFR 2 sets out exemptions from and amendments to the standards issued by the IASB and the statements issued by the IFRIC. The exemptions and amendments will be applied from the date on which the legal entity applies the specified standard or statement to its consolidated financial statements.

The Parent Company uses the presentation formats set out in the Swedish Annual Accounts Act, which has implications that include a different presentation of equity.

The Parent Company does not apply IFRS 9 *Financial Instruments*. Financial instruments are measured at cost. The impairment testing and loss allowance policies under IFRS 9 are applied to financial assets, including amounts owed by other Group companies.

The Parent Company applies the exemption rule in RFR 2 and does not apply IFRS 16 *Leases*. Lease payments made as a lessee are expensed on a straight-line basis over the term of leases.

Shares in subsidiaries are carried at cost less any impairment losses. When there is an indication that shares and investments in subsidiaries have decreased in value, their recoverable amount is calculated. If this is less than their carrying amount, an impairment loss is recognized. Impairment losses are recognized in the item *Profit/loss from investments in Group companies*. The cost of investments in subsidiaries includes transaction costs. In the consolidated financial statements, transaction costs are expensed in the period in which they are incurred.

For the Parent Company, issues of equity instruments in connection with option plans are considered to be shareholder contributions to subsidiaries from the Parent Company, insofar as they relate to the cost of options for the subsidiaries' employees, and are therefore recognized as investments in subsidiaries rather than as personnel costs in the income statement. The investments are then assessed for impairment, like other contributions. If investments in subsidiaries need to be impaired, this results in the recognition of a financial expense in the Parent Company's income statement.

### NOTE 3 MANAGEMENT OF FINANCIAL RISKS

The Group's activities expose it to various financial risks, including currency risk, interest rate risk, credit risk and liquidity/financing risk. The Group's overall risk management policy is focused on the unpredictability of the financial markets and seeks to minimize the potential adverse effects of financial risks on earnings and cash flow.

Risk management is ensured by the CFO, in accordance with guidelines set by the Board of Directors. The risk function covers the identifying and evaluating of financial risks. The Group does not apply hedge accounting under the rules set out in IFRS 9.

#### Currency risk

The Group is exposed to currency risk in the form of transaction exposure and translation exposure. Transaction exposure refers to the exposure to currency risk arising from receipts and payments in foreign currencies. Translation exposure refers to the exposure to currency risk arising from the translation of the assets and liabilities of foreign subsidiaries, and the translation of foreign currency assets and liabilities, at the rate on the balance sheet date. The main currency risk exposure arises from the translation of the US subsidiary's assets and liabilities (translation exposure). The Group's transaction exposure is relatively limited, as Group companies mainly operate in their local markets and therefore generate income and incur expenses in the same currency.

The Group's profit or loss for the year includes exchange differences in operating profit/loss and in net financial income. See Notes 7 and 8 for more information.

#### Transaction exposure

If the average EUR/SEK exchange rate had been 10% higher/lower than the average exchange rate during the financial year, with all other variables held constant, the Group's sales would have been positively/negatively impacted by approximately SEK 851 thousand (363). If the average USD/SEK exchange rate had been 10% higher/lower than the average exchange rate during the financial year, with all other variables held constant, the Group's sales would have been positively/negatively impacted by approximately SEK 1,338 thousand (376).

### Translation exposure

The income statements of foreign subsidiaries are translated at the average exchange rate for the year, while net assets are valued at the exchange rate prevailing on the balance sheet date. The currencies involved are the EUR and USD.

Approximately SEK -297 thousand (-1) of the Group's profit/loss before tax for the financial year were attributable to the German subsidiary, whose net assets amounted to SEK -16,862 thousand (-16,256) at the balance sheet date. If the average EUR/SEK exchange rate had been 10% higher/lower than the average exchange rate during the financial year, with all other variables held constant, the Group's profit/loss before tax for the financial year would have been impacted by approximately SEK -0.3 thousand (0.0) by the translation of the foreign company's income statement. If the EUR/SEK exchange rate had been 10% higher/lower than the exchange rate on the balance sheet date at year-end, with all other variables held constant, the Group's net assets would have been impacted by approximately SEK -1,686 thousand (-1,625) at year-end by the translation of the foreign company's assets and liabilities.

Approximately SEK -98,543 thousand (-95,182) of the Group's profit/loss before tax for the financial year were attributable to the US subsidiary, whose net assets amounted to SEK 28,331 thousand (30,855) at the balance sheet date. If the average USD/SEK exchange rate had been 10% higher/lower than the average exchange rate during the financial year, with all other variables held constant, the Group's profit/loss before tax for the financial year would have been impacted by approximately SEK -9,854 thousand (-9,518) by the translation of the foreign company's income statement. If the USD/SEK exchange rate had been 10% higher/lower than the exchange rate on the balance sheet date at year-end, with all other variables held constant, the Group's net assets would have been impacted by approximately SEK 28,331 thousand (30,855) at year-end by the translation of the foreign company's assets and liabilities.

The Group's cash and cash equivalents and trade receivables are largely denominated in the local currency of the respective companies, which means that the translation exposure to exchange rate fluctuations does not have a significant impact on the Group's earnings. This is because the translation effects on the respective Group companies' receivables and payables in local currency affect equity rather than the income statement.

### Interest rate risk

Interest rate risk is the risk that net interest income will fluctuate and/or develop negatively due to changes in market interest rates. The Group's net interest income is largely dependent on developments in the Swedish market, as the majority of the Group's cash is held by the Swedish Parent Company and the Group had no interest-bearing liabilities as of December 31, 2021. Interest rate risk will be kept low by fixing the Group's interest rates, where possible, by buying bonds.

### Sensitivity analysis – interest rate risk

If interest rates during the year had been 100 basis points higher, all other things being equal, there would have been a SEK 1,020 thousand (1,170) impact on net interest income and equity before tax. The sensitivity analysis is based on an interest rate scenario that management believes is reasonably plausible over the next 12 months.

### Credit risk

Credit risk or counterparty risk is the risk of a counterparty to a financial transaction not meeting their obligations when they fall due. Credit risk is managed at Group level by thoroughly evaluating new counterparties, and then continuously evaluating existing counterparties. Credit risks mainly relate to trade receivables and deposits with banks and financial institutions. Bad debt provision for assumed losses is recorded based on the previous payment and loss record of the client. Historical losses are considered and adjusted for current and forward looking information which may impact the client solvency. As of December 31, 2021, the bad debt provision amounts to SEK 932 tsek (321).

Bank deposits are made with banks that have a credit rating of A or higher and are available on demand. The credit risk exposure for these deposits is considered to be low and the expected credit losses are deemed to be negligible, given the short maturities and the high creditworthiness of the counterparties involved.

Cash and cash equivalents (amounts in TSEK)	Group		Parent Company	
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
Rating				
AA-	53,603	117,819	45,836	116,914
A+	2,252	17,785	–	–
<b>Total</b>	<b>55,855</b>	<b>135,604</b>	<b>45,836</b>	<b>116,914</b>

### Maturity analysis

The Group's other financial liabilities consist of operating and lease liabilities. Its operating liabilities are due within one year. The amounts recognized at the balance sheet date represent the nominal undiscounted cash flows to be settled within one year. Lease liabilities comprise the rights in respect of leased assets that revert to lessors if payments are not made. Of the total lease liabilities, SEK 4 million fall due within 12 months and SEK 0.1 million fall due in 2023.

### Financial instruments by category

Group	2021-12-31 Amortized cost	2020-12-31 Amortized cost
<b>Balance sheet assets</b>		
Trade receivables	16,262	5,056
Other receivables	1,631	1,292
Cash and cash equivalents	55,855	135,604
<b>Total</b>	<b>73,748</b>	<b>141,952</b>

Group	2021-12-31 Other financial liabilities	2020-12-31 Other financial liabilities
<b>Balance sheet liabilities</b>		
Non-current lease liabilities	161	76
Trade payables	5,459	3,450
Lease liabilities	3,515	3,922
Other liabilities	2,423	7,329
Accrued expenses	1,658	1,826
<b>Total</b>	<b>13,216</b>	<b>16,603</b>

The carrying amounts of financial investments, current receivables and current liabilities are a reasonable approximation of their fair value.

#### Liquidity risk/Financing risk and Going concern

As of December 31, 2021, the Group had liquid assets of SEK 55,855 thousand (135,604). The Group's liquid assets consist of bank deposits. 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.

As of December 31, 2021, the Group had no external borrowings. The SEK 6,813 thousand US support loan was forgiven during the year.

The capital structure is intended to safeguard the Group's ability to continue operating as a going concern, so that it can generate returns for shareholders and benefits for other stakeholders, and to maintain an optimal capital structure in order to keep the cost of capital low.

The Company's available cash and cash equivalents are not sufficient to cover the operations planned for the next 12 months. Possible financing options are therefore being explored. Given the Company's recent performance, the Board believes, however, that its prospects for finding financing for the Company's operations are good. If sufficient financing cannot be found, there is a risk that the conditions for continued operation as a going concern may not be met.

Net debt (amounts in TSEK)	Group		Parent Company	
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
<b>Interest-bearing liabilities</b>				
Cash and cash equivalents	-55,855	-135,604	-45,836	-116,914
Lease liabilities	3,676	3,998	-	-
<b>Net assets/debt</b>	<b>-52,179</b>	<b>-131,606</b>	<b>-45,836</b>	<b>-116,914</b>

#### NOTE 4 CRITICAL ESTIMATES AND JUDGEMENTS MADE IN THE APPLICATION OF THE GROUP'S ACCOUNTING POLICIES

##### Critical accounting estimates and assumptions

The Group makes estimates and assumptions about the future. The resulting accounting estimates will, by definition, rarely reflect actual outcomes. The estimates and assumptions that may result in material adjustments being made to the carrying amounts of assets and liabilities within the next financial year are summarized below.

##### Incentive programs

The option vesting and exercise period covers several financial years, which means that assumptions and estimates had to be made regarding probable exercise dates. Additional assumptions and estimates were also required regarding the inputs to option valuations. Two of the incentive programs include non-market-related performance conditions. This means that estimates need to be made as to when it is more likely than not that the conditions will be met. Only then does an expense begin to be recognized for the incentive programs.

For further information about the assumptions used in the valuation of options and conditions, see *Summary of principal accounting policies*, and *Note 10 Salaries, other remuneration and social security contributions*.

##### Capitalized development costs

IRRAS continuously assesses the value of capitalized costs relating to development projects.

The most critical assumption, assessed by management, is whether capitalized expenditure will generate future economic benefits that are at least equal to the capitalization amount. A project starts to be capitalized when it goes from being a research project to a development project for a clearly defined marketable product or product improvement. Capitalization ends and amortization begins when the product is ready for launching. As of the balance sheet date, management believes that future cash flows will marginally cover the investments made, which means that there is no need for impairment.

#### NOTE 5 SEGMENT INFORMATION

Net revenue breaks down as follows:

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
	Germany	1,999	105	742
Europe, excluding Germany	4,997	3,679	-	-
US	13,391	3,183	-	3,326
Other countries	1,999	423	-	-
<b>Total net revenue by geographic market</b>	<b>22,386</b>	<b>7,390</b>	<b>742</b>	<b>4,726</b>

The Group or the Parent company do not generate net sales in Sweden. The Parent company's sales consists entirely of management fees and other remuneration from subsidiaries.

The Group's geographical distribution of its total intangible assets is: Sweden 29,858 tsek (34,876) and US 4,791 tsek (4,939).

The Group's geographical distribution of its total tangible assets is: Sweden 97 tsek (203), Germany 691 tsek (309) and US 4 353 tsek (4 587).

**NOTE 6 COSTS BY COST CATEGORY**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Net revenue	22,386	7,390	742	4,726
Capitalized work for own account	6,707	7,795	6,707	7,795
Other operating income	8,097	1,594	282	940
Change in inventory	-8,926	3,873	-	-
Raw materials and consumables	-11,286	-4,354	-	-
Other external expenses	-52,489	-49,892	-17,947	-20,272
Personnel costs	-83,801	-83,495	-15,877	-21,624
Depreciation, amortization and impairment	-16,819	-16,326	-11,832	-11,151
Other operating expenses	-391	-901	-150	-505
<b>Operating loss (EBIT)</b>	<b>-136,522</b>	<b>-134,316</b>	<b>-38,076</b>	<b>-40,091</b>

**NOTE 7 OTHER OPERATING INCOME & OTHER OPERATING EXPENSES****Other operating income**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Exchange differences	355	1,291	282	933
Gains on the disposal of right-of-use assets	-	17	-	-
Other	7,742	286	-	7
<b>Total other operating income</b>	<b>8,097</b>	<b>1,594</b>	<b>282</b>	<b>940</b>

**Other operating expenses**

The item Other includes waiver of the SEK 6,813 tsek loan from the Paycheck Protection Program which was granted in 2020.

**Other operating expenses**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Exchange differences	-391	-901	-150	-505
<b>Total other operating expenses</b>	<b>-391</b>	<b>-901</b>	<b>-150</b>	<b>-505</b>

**NOTE 8 FINANCIAL ITEMS**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Financial income</b>				
Exchange differences	298	-	298	-
Interest income	1	8	350	304
<b>Total financial income</b>	<b>299</b>	<b>8</b>	<b>648</b>	<b>304</b>
<b>Financial expenses</b>				
Exchange differences	-29	-1,218	-28	-1,218
Impairment of participations in Group companies	-	-	-220,784	-
Interest expenses	-12	-219	-12	-218
<b>Borrowing costs</b>				
- leases, reversal of discounting	-71	-159	-	-
<b>Total financial expenses</b>	<b>-112</b>	<b>-1,596</b>	<b>-220,825</b>	<b>-1,436</b>
<b>Net profit/loss from financial items</b>	<b>187</b>	<b>-1,588</b>	<b>-220,176</b>	<b>-1,132</b>

During 2021, the Parent company recognized an impairment of shares in subsidiaries by SEK 221 million, taking into consideration the present value of cash flows and weighted cost of capital.

**NOTE 9 AUDIT FEES**

Audit engagement means the statutory audit of the annual report, consolidated financial statements and accounts, and of the Company's management by the Board of Directors and the Chief Executive Officer, and any other audits or reviews carried out in accordance with an agreement or contract. It also includes any other tasks that it is the responsibility of the company's auditor to perform, and any advice or other assistance resulting from observations made during such an audit or the performance of such other tasks.

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
KPMG				
Audit engagement	916	574	916	574
Other audit assignments	144	583	144	583
Other advisory services	-	17	-	17
<b>Total</b>	<b>1,059</b>	<b>1,174</b>	<b>1,059</b>	<b>1,174</b>



**NOTE 10 EMPLOYEES, PERSONNEL COSTS AND REMUNERATION OF SENIOR EXECUTIVES****Costs of salaries, other remuneration and social security contributions**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Salaries and other remuneration,	66,413	68,026	11,516	16,917
of which variable, etc.	8,948	6,099	-1,546	3,225
Social security expenses	6,231	6,092	2,183	2,332
Incentive programs	365	-361	365	754
Pension costs	870	903	870	903
<b>Total</b>	<b>73,880</b>	<b>74,660</b>	<b>14,935</b>	<b>20,906</b>

**Average number of employees**

	2021-01-01 2021-12-31		2020-01-01 2020-01-01	
	Average number of employees	Of which men	Average number of employees	Of which men
<b>Parent Company</b>				
Sweden	7	80%	6	69%
<b>Parent Company total</b>	<b>7</b>	<b>80%</b>	<b>6</b>	<b>69%</b>
<b>Subsidiaries</b>				
Germany	4	24%	3	60%
US	42	49%	34	63%
<b>Subsidiary total</b>	<b>46</b>	<b>47%</b>	<b>37</b>	<b>62%</b>
<b>Group total</b>	<b>53</b>	<b>51%</b>	<b>43</b>	<b>63%</b>

**Salaries and other remuneration granted to senior executives (1)**

Group	2021-01-01 2021-12-31				2020-01-01 2020-12-31			
	Basic salary and Board remuneration (2)	Variable remuneration (3)	Pension costs	Share-based payments (4)	Basic salary and Board remuneration (2)	Variable remuneration (3)	Pension costs	Share-based payments (4)
Chairman of the Board Marios Fotiadis	540	-	-	-	353	-	-	-
Chairman of the Board Anders P. Wiklund	-	-	-	-	428	-	-	-
Board member Catherine Gilmore-Lawless	471	-	-	-	436	-	-	-
Board member Eva Nilsagård	395	-	-	-	340	-	-	-
Board member Anita Tollstadius	380	-	-	-	340	-	-	-
<b>Board of Directors total</b>	<b>1,786</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,897</b>	<b>-</b>	<b>-</b>	<b>-</b>
CEO Kleanthis G. Xanthopoulos (5)	2,668	-	-	-	5,882	1,946	-	-
Executive Vice President and CFO Sabina Berlin (6)	791	-	201	-	1,243	194	305	-
<b>Parent Company total</b>	<b>5,245</b>	<b>-</b>	<b>201</b>	<b>-</b>	<b>9,022</b>	<b>2,140</b>	<b>305</b>	<b>-</b>
President and CEO Will Martin (5)	2,200	1,004	-	-	-	-	-	-
Other senior executives (7)	5,245	716	-	-	6,787	1,222	-	-
<b>Total</b>	<b>12,690</b>	<b>1,720</b>	<b>201</b>	<b>-</b>	<b>15,809</b>	<b>3,362</b>	<b>305</b>	<b>-</b>

1) The table shows the remuneration earned during the financial year, with the exception of share-based payments, which are recognized to the extent that they vested during the financial year.

2) Includes holiday pay.

3) Variable remuneration earned during the financial year and paid in the following year. Refers to bonuses only.

4) Calculated as the number of shares in the company's incentive program vested during the year, multiplied by the price of the IRRAS share on the balance sheet date, less the exercise price of the options. Where the share price was lower than the exercise price, the value is shown to be zero in the table above.

5) Kleanthis G. Xanthopoulos Ph.D. stepped down as CEO, but remains on the company's Board of Directors. Will Martin was appointed as the new CEO as of July 1, 2021.

6) Executive Vice President and CFO until June 2021.

7) Other senior executives refers to the members of the management team other than the CEO and Executive Vice President. This includes the VP, Product Excellence and the Senior Director, Human Capital. VP, Commercial officer Will Martin is included until June 30, 2021 and CFO Griffen Strapp from July 1, 2021.

**Gender distribution of Board members and other senior executives**

Group	2021-01-01	Of which men	2020-01-01	Of which men
	Number at balance sheet date		Number at balance sheet date	
Board members	5	40%	5	40%
CEO and other senior executives	4	75%	5	60%
<b>Group total</b>	<b>9</b>	<b>56%</b>	<b>10</b>	<b>50%</b>
<b>Parent Company</b>				
Board members	5	40%	5	40%
CEO and other senior executives	–	50%	2	50%
<b>Parent Company total</b>	<b>5</b>	<b>40%</b>	<b>7</b>	<b>43%</b>

The company has introduced share-based payments for employees in the form of incentive programs, with the aim of motivating and rewarding them through share ownership, in the Company's long-term interests. The fair value of a program's options on inception is recognized in personnel costs with a corresponding direct increase in equity. The costs of the incentive programs granted to subsidiaries' employees are recognized as investments in Group companies in the Parent Company's accounts.

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
<b>Share-based payment expenses</b>				
Incentive program 1	157	-315	–	587
Incentive program 2	6	-306	–	–
Incentive program 5	89	-92	47	-15
Incentive program 6	794	352	299	182
Incentive program 7	150	–	19	–
<b>Total</b>	<b>1,195</b>	<b>-361</b>	<b>365</b>	<b>754</b>

Options whose vesting depends on non-market performance conditions have been valued using the Black & Scholes valuation model. The share price and the risk-free interest rate used are those prevailing at the valuation date. The volatility taken into account in the valuation model is assessed based on the historical share volatility for equivalent companies.

**Incentive program 1**

In May 2016, 1,900,000 options were granted to employees free of charge, vesting over periods of 1 year, 2 years, 3 years and 4 years, respectively, with one quarter vesting annually starting in May 2016, based on employment conditions. The last date for exercising vested options is September 30, 2025. As of 12/31/2021, 1,685,280 options were outstanding, of which 126,476 were issued to management.

**Incentive program 2**

In 2017, 350,000 options were granted to employees free of charge, and 300,000 options in 2018, vesting over periods of 1 year, 2 years and 3 years, respectively, with one third vesting annually starting in January 2017, based on employment conditions. The first third of the options vested after 1 year. The options then vested monthly. As of 12/31/2021 278,000 were outstanding, of which 265,00 were issued to management.

**Incentive program 5**

The total program comprises 732,000 options, vesting over periods of 1 year, 2 years and 3 years, respectively, with one third vesting annually starting in June 2018, based on employment conditions. Each option entitles its holder to subscribe for one new share until June 15, 2022, subject to the vesting of the options. The last day for exercising the options is June 15, 2022. As of 12/31/2021, 278,000 options were outstanding, of which 49,990 were issued to management.

**Incentive program 6**

At the Annual General Meeting on April 28, 2020, a new incentive program was decided on. The total program comprises 1,050,000 employee stock options. The options are granted based on the achievement of company objectives, and vest over 3 years, at a rate of one third a year. Each option entitles its holder to subscribe for one new share at a subscription price calculated on the grant date, and may be exercised between the third anniversary and the eighth anniversary of the grant date, subject to the vesting of the options. The program will run until the 2028 AGM.

As of 12/31/2021, 803,673 options were outstanding, of which 188,920 were issued to management.

**Incentive program 7**

At the Annual General Meeting on April 28, 2021, a new incentive program was decided on. The total program comprises 1,000,000 employee stock options. The options are granted based on the achievement of company objectives, and vest over 3 years, at a rate of one third a year. Each option entitles its holder to subscribe for one new share at a subscription price calculated on the grant date, and may be exercised between the third anniversary and the eighth anniversary of the grant date, subject to the vesting of the options.

As of 12/31/2021, 450,500 options were outstanding, of which 236,000 were issued to management.

	Incentive programs Program 1	Program 2	Program 3	Program 4	Program 5	Program 6	Program 7
<b>Number of employee stock options granted</b>							
<b>As of 2018-12-31</b>	<b>1,880,000</b>	<b>643,000</b>	<b>320,000</b>	<b>100,000</b>	<b>268,750</b>	<b>0</b>	<b>0</b>
Forfeited during the period	-187,142	-130,000			-187,000	-	-
Exercised during the period	-	-			-	-	-
Granted during the period	15,476	6,912			553,487	-	-
<b>As of 2019-12-31</b>	<b>1,708,334</b>	<b>519,912</b>	<b>320,000</b>	<b>100,000</b>	<b>635,237</b>	<b>0</b>	<b>0</b>
Forfeited during the period	-154,786	-152,472	-320,000	-100,000	-150,505	-	-
Exercised during the period	-	-			-	-	-
Granted during the period	254,500	-			32,500	507,024	-
<b>As of 2020-12-31</b>	<b>1,808,048</b>	<b>367,440</b>	<b>0</b>	<b>0</b>	<b>517,232</b>	<b>507,024</b>	<b>0</b>
Forfeited during the period	-122,768	-89,440			-172,488	-49,938	
Exercised during the period							
Granted during the period						346,587	450,500
<b>As of 2021-12-31</b>	<b>1,685,280</b>	<b>278,000</b>	<b>0</b>	<b>0</b>	<b>344,744</b>	<b>803,673</b>	<b>450,500</b>

	Number outstanding as of 2021- 12-31	Number vested as of 2021-12-31	Exercise price	Share price on the valuation day, range	Expected volatility	Value of options per share, range	Expected dividend per share	Maturity
<b>Employee stock options program</b>								
Incentive program 1	1,685,280	1,685,280	13.6	5,8 - 34,6	30%	0,0 - 21,5	-	September 30, 2025
Incentive program 2	278,000	278,000	35.0	25 - 34,6	30%	1,5 - 7,9	-	October 31, 2021
Incentive program 3	-	-	50.0	30.0	30%	-	-	October 31, 2020
Incentive program 4	-	-	50.0	30.0	30%	-	-	October 31, 2020
Incentive program 5	344,744	344,744	25.86	13,8 - 43,3	30%	0,0 - 19,2	-	June 15, 2022
Incentive program 6	803,673	803,673	*	5,7 - 7,5	50%	0,1 - 3,0	-	April 28, 2028
Incentive program 7	450,500	450,500	*	2,5 - 7,5	37%	0,1 - 6,0	-	April 28, 2029
<b>Incentive program total</b>	<b>3,562,197</b>	<b>3,562,197</b>						

\* The exercise price depends on the grant date

#### **Defined contribution plans**

The Group has defined contribution pension plans, which are covered by insurance from SPP. The contributions for the year for pension insurance taken out with SPP amounted to SEK 903 thousand (558).

**NOTE 11 RELATED-PARTY TRANSACTIONS**

Related parties are defined as the Parent Company's management, the Parent Company's Board of Directors and subsidiaries. Shares in subsidiaries and intercompany loans are eliminated in the consolidated financial statements, which means that more detailed information is not provided about these amounts. For the Parent Company, subsidiaries are related parties.

Parent Company	2021-12-31	2020-12-31
Long-term receivables, Group companies	13,685	23,101
Short-term receivables, Group companies	173	-
Short-term liabilities, Group companies	104	

During the financial year, management fee-related sales by the Parent Company to subsidiaries amounted to SEK 0 thousand (1,400), and profit-sharing with subsidiaries to SEK 742 thousand (3,326), accounting for 100% of the revenue. Profit-sharing-related purchases from subsidiaries amounted to SEK 1,443 thousand (0). No part of this amount was outstanding at the balance sheet date.

The following related-party transactions took place during the financial year and comparative years in addition to those disclosed in Note 10: the Group purchased training services from a person related to Board member Kleanthis G. Xanthopoulos. The cost for the period from January to December 2021 amounted to SEK 356 thousand (387).

The Group also purchased software from a person related to Sabina Berlin, IRRAS' former CFO. The cost for the period from January to December amounted to SEK 12 thousand (0).

The Group purchased consulting services from Board member Kleanthis G. Xanthopoulos to assist with the transition between CEOs. The cost for the period from January to December amounted to SEK 240 thousand (0).

**NOTE 12 INCOME TAX**

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Current tax for the year	-	7	-	-
Current tax attributable to previous years	-	5	-	-
<b>Total tax on net loss for the year</b>	<b>-</b>	<b>12</b>	<b>-</b>	<b>-</b>

The differences between the reported tax expense and an estimated tax expense based on the applicable tax rate are as follows:

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Loss before tax	-136,335	-135,903	-258,252	-41,224
Income tax calculated at the Group's applicable tax rate	28,085	29,083	53,200	8,822
Non-taxable income	77	77	77	-161
Non-deductible expenses	-342	-18	-45,653	-18
Unrecognized deductible expenses	919	5,753	919	5,753
Tax losses for which no deferred tax assets have been recognized	-37,885	-42,938	-8,544	-14,396
Effect of foreign tax rates	9,146	8,042	-	-
Current tax adjustments attributable to previous years	-	5	-	-
<b>Income tax</b>	<b>-</b>	<b>5</b>	<b>-0</b>	<b>-0</b>

The Group's applicable tax rate is considered to be 20.6% (21.4%), which is the tax rate of the Parent Company. The effect of foreign tax rates therefore depends on the difference between the tax rates in the countries where the subsidiaries operate and the Group's tax rate. The applicable tax rate for Germany is 31% (31%) and the applicable tax rate for the USA is 29.85% (29.85%).

**Temporary differences**

Temporary differences exist where the carrying amounts of assets and liabilities differ from their value for tax purposes. Deferred tax liabilities are not recognized in respect of temporary differences relating to investments in subsidiaries, as the Parent Company has control over the timing of the temporary differences' reversal. Temporary differences also exist in respect of incentive programs, for which the Group has chosen to recognize an amount of SEK 0 for the year.

	Group		Parent Company	
	2021-01-01 2021-12-31	2020-01-01 2020-12-31	2021-01-01 2021-12-31	2020-01-01 2020-12-31
Accumulated losses amount to	743,556	574,124	323,272	281,798



The following lease-related amounts are recognized in the income statement:

Group	2021	2020
Amortization of rights of use		
Properties	-3,673	-3,739
Vehicles	-335	-26
Disposal of rights of use	-	576
Vehicles		
<b>Total</b>	<b>-4,007</b>	<b>-3,189</b>
Income from the disposal of vehicles (included in other operating income)		
Income from the disposal of properties (included in other operating income)	-	17
Interest expenses (included in financial expenses)	-71	-159
Expenditure related to short-term leases (included in administrative and sales costs)	-904	-623
Expenditure related to non-short-term low-value asset leases (included in administrative costs)	-47	-82

The total lease-related cash flow came to SEK 4,320 (3,786) in 2021.

The lease is for two offices with an option to extend to one additional office. The lease does not contain any specific conditions, except that the lessor retains the rights in respect of the pledged leased assets. The lease ran until 07/31/2021.

Assets and liabilities arising from leases are initially recognized at their present value. Lease liabilities include the present value of fixed payments after the deduction of any lease incentives.

The lease payments are discounted at the lease's marginal lending rate of 3.5%. Lease payments are split between debt repayment and interest. Interest is recognized in the income statement over the lease term in such a way as to ensure a fixed rate of interest for the lease liability recognized in the respective period.

Right-of-use assets are valued at cost and include the amount that the lease liability was originally valued at, the lease payments made on or before the commencement date less lease incentives, the initial direct costs, and the cost of restoring the asset to the condition specified under the terms of the lease. Right-of-use assets are amortized over the lease term.

Payments for short-term arrangements and low-value leases are charged to the income statement on a straight-line basis. Short-term arrangements are leases with a term of 12 months or less. Low-value leases include vehicles and office equipment.

## NOTE 15 FINANCIAL INVESTMENTS

	Group 2021-12-31	2020-12-31	Parent Company 2021-12-31	2020-12-31
At the beginning of the year	-	55,613	-	55,613
Purchases	-	-	-	-
Sales	-	-55,613	-	-55,613
<b>Closing carrying amount</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>

## NOTE 16 INVENTORIES

	Group 2021-12-31	2020-12-31	Parent Company 2021-12-31	2020-12-31
Finished goods and goods for resale	12,368	18,074	-	-
<b>Closing carrying amount</b>	<b>12,368</b>	<b>18,074</b>	<b>-</b>	<b>-</b>

## NOTE 17 OTHER RECEIVABLES

	Group 2021-12-31	2020-12-31	Parent Company 2021-12-31	2020-12-31
Tax account	68	301	68	301
Cash deposits	865	596	104	104
Recoverable VAT	490	395	428	351
Other receivables	208	-	208	-
<b>Total other receivables</b>	<b>1,631</b>	<b>1,292</b>	<b>808</b>	<b>756</b>

## NOTE 18 PREPAID EXPENSES AND ACCRUED INCOME

	Group 2021-12-31	2020-12-31	Parent Company 2021-12-31	2020-12-31
Prepaid rent	48	48	48	48
Prepaid insurance costs	284	270	82	106
Other items	5,349	912	853	581
<b>Total prepaid expenses and accrued income</b>	<b>5,680</b>	<b>1,229</b>	<b>983</b>	<b>734</b>

Other items consist primarily of prepaid clinical trial costs.

**NOTE 19 SHARE CAPITAL**

Parent Company	Number of shares	Share capital (SEK)
Opening balance as of January 1, 2020	28,817,974	864,539
New share issues	37,463,366	1,123,901
<b>Closing balance as of December 31, 2020</b>	<b>66,281,340</b>	<b>1,988,440</b>
New share issues	13,200,000	396,000
<b>Closing balance as of December 31, 2021</b>	<b>79,481,340</b>	<b>2,384,440</b>

The Company's share capital is divided into 79,481,340 shares with a quota value of SEK 0.30 per share. All shares has equal voting right.

**NOTE 20 ACCRUED EXPENSES AND DEFERRED INCOME**

	Group		Parent Company	
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
Accrued salaries	5,439	7,451	1,629	4,104
Accrued holiday pay	1,452	1,407	217	252
Accrued social security contributions	466	739	466	739
Other personnel-related items	388	482	388	482
Consultancy fees	898	1,378	539	418
Auditing	660	270	660	270
Other	100	178	62	21
<b>Total accrued expenses and deferred income</b>	<b>9,403</b>	<b>11,906</b>	<b>3,960</b>	<b>6,286</b>

**NOTE 21 COMMITMENTS****Short-term operating lease commitments**

	Group		Parent Company	
	2021-12-31	2020-12-31	2021-12-31	2020-12-31
Due in less than one year	904	143	570	143
Due in between one and five years	-	-	-	-
Due in more than five years	-	-	-	-
<b>Total</b>	<b>904</b>	<b>143</b>	<b>570</b>	<b>143</b>

Also see Note 14 regarding right-of-use assets in addition to the commitments disclosed in this note.

**NOTE 22 EVENTS AFTER THE BALANCE SHEET DATE****Additional treatments and evaluation agreements**

The company has been granted another US patent "Fluid Exchange Catheter System" in the United States. It is the third US patent to protect the intellectual property rights of the company's leading product, IRRAf<sup>low</sup>.

**Presentation of the largest amount of data to date**

In February, the company presented the largest collection of clinical data to date on IRRAf<sup>low</sup>. The results presented confirmed the effectiveness of IRRRA automatic flushing of the flow system by showing an occlusion rate of 0% throughout the treatment period.

**IRRAS launches the next generation IRRAf<sup>low</sup> system in the USA**

The company has begun the commercial launch of the next generation of IRRAf<sup>low</sup>'s control unit, the company's latest innovation to improve the treatment of patients with intracranial haemorrhage.

**Current conflict in Ukraine**

IRRAS is following the development of the current conflict in Ukraine. We do not expect any meaningful impact on our business.

**NOTE 23 INVESTMENTS IN GROUP COMPANIES**

Parent Company	2021-12-31	2020-12-31
Opening cost	340,893	232,980
Investments	102,389	109,028
Incentive programs	830	-1,115
Impairment of participations	-216,295	-
<b>Closing carrying amount</b>	<b>227,816</b>	<b>340,893</b>

For information on impairment of participations in Group companies, see Note 8.

**The Parent Company's investments in Group companies**

Name	Comp. reg. number	Registered office	Percentage of shares and votes	Number of shares	Carrying amount as of 2021-12-31	Carrying amount as of 2020-12-31
IRRAS GmbH	DE308005079	Munich	100%	1	696	1,639
IRRAS USA Inc	611800152	La Jolla	100%	9,500,000	227,120	339,254
IRRAS B.V.	83420622	Assendelft	100%	1	-	-
					<b>227,816</b>	<b>340,893</b>

The cost of options for the subsidiaries' employees, are recognized as investments in subsidiaries rather than as personnel costs in the income statement and are assessed for impairment and may be impaired and recognized as financial expense in the Parent Company's income statement.

**NOTE 24 PROPOSED APPROPRIATION OF EARNINGS**

The Board of Directors proposes that the available earnings as of December 31, 2021, of SEK 283,501,165 to be carried forward.

**NOTE 25 EARNINGS PER SHARE**

	Before dilution		After dilution	
	2021	2020	2021	2020
SEK				
Earnings per share	-1.89	-2.46	-1.89	-2.46

Earnings per share are calculated as the profit/loss for the year attributable to equity holders of the parent divided by the weighted average number of shares outstanding during the year.

**Instruments that may have a dilutive effect in the future and changes after the balance sheet date**

As the Group is reporting a loss for the period and the previous financial year, any future ordinary shares will not be dilutive in terms of the average number of shares. Current incentive programs that will have a dilutive effect on the date when the Group reports a profit. The weighted average number of shares and earnings are the same after dilution as before dilution.

For more information about the terms of the incentive programs and the number of options granted, see Note 2 and Note 10. There have been no changes to the number of shares before or after dilution since the balance sheet date.



The annual report has been prepared in accordance with the accounting principles generally accepted in Sweden, 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 July 19, 2002 on the application of international accounting standards. The annual report and the consolidated financial statements give a true and fair view of the position and performance of the Parent Company and the Group. The administration report for the Parent Company and the Group gives a true and fair view of the development of the Parent Company's and the Group's operations, position and performance, and describes the principal risks and uncertainties faced by the Parent Company and the companies within the Group.

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 May 24, 2022.

Stockholm, 28 April, 2022

Marios Fotiadis  
*Chairman of the Board*

Catherine Gilmore-Lawless  
*Board member*

Eva Nilsaård  
*Board member*

Anita Tollstadius  
*Board member*

Kleanthis G. Xanthopoulos, PhD  
*Board member*

Will Martin  
*President and CEO*

Our Auditor's Report was submitted on  
29 April, 2022  
KPMG AB

Duane Swanson  
*Authorized Public Accountant*

# Auditor's Report

To the general meeting of the shareholders of IRRAS AB (publ), 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 2021, except for the corporate governance statement on pages 60-67. The annual accounts and consolidated accounts of the company are included on pages 21-55 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 2021 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 2021 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 60-67.

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 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

We bring to your attention the information in the administration report (page 25) and in note 3 (page 45) which states that the cash and cash equivalents are not sufficient to cover planned operations for the coming 12 months. It also states in the administration report that the outlook to obtain financing through various sources is considered to be good based on the recent development of the company but also there is a risk that the basis of going concern cannot be used if sufficient financing is not arranged. These circumstances indicate that there are material uncertainties that may cast significant doubt on the Group's ability to continue as a going concern. We have not modified our opinions in regards to this.

### 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 note 4, 13, 23 and accounting principles on page 40 and 43 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 2021 of capitalized development costs amounted to 26 MSEK. These intangible assets equal approximately 22 % of the consolidated total assets and are subject to an impairment testing.

The impairment testing of these assets are dependent on management's estimates and judgments of future revenues, operating results, as well as required levels of working capital and investments. Another important assumption is the discount rate to be used in order to reflect the time value of money as well as the specific risks associated with the operations.

The parent company investment in subsidiaries as of 31 December 2021 totaled 228 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 related to intangible fixed assets have been prepared in accordance with the prescribed method as well as assessed the reasonableness in the group's test of the carrying value of the intangible assets in the consolidated accounts and investments in subsidiaries in the parent company.

Additionally, we have considered the reasonableness of the predicted future cash flows as well as the discount rates used through evaluation of the group's written documentation and forecasts. 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 compliance with the accounting principles and disclosures related to capitalized development costs 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 1-20 and pages 68-70. 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

### ***Auditor's audit of the administration and the proposed appropriations of profit or loss***

#### **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 2021 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 Esef report**

##### **Opinion**

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for IRRAS AB (publ) for year 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report #237Gi0MWvOCXBUE= has been prepared in a format that, in all material respects, enables uniform electronic reporting.

##### **Basis for opinion**

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of IRRAS AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

#### **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 Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

**Auditor's responsibility**

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 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 aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error.

In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of the assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

**The auditor's examination of the corporate governance statement**

The Board of Directors is responsible for that the corporate governance statement on pages 60-67 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.

**Other matters**

The company has on several occasions failed to pay taxes on a timely basis.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of IRRAS AB (publ) by the general meeting of the shareholders on the 28 April 2021. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2015.

Stockholm 29 April 2022

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").

## Annual General Meetings

The Annual General Meeting (AGM) 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 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 for resolution.

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 to be dealt with at the meeting. Resolutions passed at the AGM are made public through a press release and can be found on the company's website.

The 2022 AGM will be held on May 24. Due to the spread of COVID-19, the Board of Directors has resolved that the Annual General Meeting should be conducted without the physical 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 Nomination Committee represents IRRAS shareholders. The Nomination Committee evaluates the composition of the Board and nominate candidates to the AGM for election as; chairman of the AGM, Chairman of the Board and Board members, and auditors. Furthermore, the Nomination Committee propose remuneration for the Board members and auditors. Shareholders can make proposals to the AGM through the Nomination Committee. No remuneration is paid for the work performed in the Nomination Committee.

At the Extraordinary General Meeting on September 1, 2017 it was decided on the principles to appoint the Nomination Committee, which applies until further notice. This imply that the AGM do not vote each year for the principles on, how to nominate the Nomination Committee and its mission, unless the principles or the mission needs adaption. The Nomination Committee should consist of, the Chairman of the Board of Directors and three members, who been nominated by the three largest shareholders per the voting right at the end of the third quarter each year. By the three largest shareholders per the voting rights, it references, the larges registered shareholders, or shareholders known by other means, at the end of the third quarter each year. The Nomination Committee should between themselves nominate their Chairman. The Chairman of the Board or any other Board member can not be the Chairman of the Nomination Committee. The composition of the Nomination Committee needs to be published on the Company's website.

On these conditions, the Nomination Committee in front of the AGM 2022 consists of:

Name	Nominated by	Ownership share % September 30, 2021
Christer Hellström	Bacara Holdings Ltd.	24,83
Arne Lööv	Fjärde AP-fonden	9,26
Carl-Mikael Lindholm	Carl-Olof och Jens Hamrins Stiftelse	4,78
Marios Fotiadis	Styrelseordförande, IRRAS AB	–

Christer Hellström, who represents the Company's largest shareholder, Bacara Holdings Ltd., was elected Chairman of the Nomination Committee.

## The Board of Directors

Under the Articles of Association, the Board of Directors must consist of no less than three and no more than seven members, without deputies. Changes to the Articles of Association are resolved by a General Meeting. The Board of Directors consists of five members. At the AGM on April 28, 2021, Marios Fotiadis was re-elected Chairman of the Board and Eva Nilsagård, Catherine Gilmore-Lawless, Anita Tollstadius and Kleanthis G. Xanthopoulos were re-elected as Board members.

The responsibilities of the Board are regulated in the Companies Act and the rules of procedure. The rules of procedure establish the allocation of the Board's duties between the Board and the Board committees, as well as, inbetween 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.

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 them to fulfill their 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.

**MEMBERS OF THE BOARD AFTER THE ANNUAL GENERAL MEETING ON 28 April 2021**

Boardmembers	Elected	Independent in relation to the company and senior executive team	Independent in relation to major shareholders	Shareholding	Attendance Board meeting (15)	Attendance Audit Committee (5)	Attendance Remuneration Committee (4)
Marios Fotiadis, chairman	2012	Yes	No	21,839,066	13/15		
Catherine Gilmore-Lawless	2019	Yes	Yes	-	14/15		4/4
Eva Nilsagård	2018	Yes	Yes	11.500	15/15	5/5	
Anita Tollstadius	2017	Yes	Yes	11.500	15/15	5/5	4/4
Ph.D. Kleantith G. Xanthopoulos	2015	No	No	2,403,000	15/15		

**Remuneration to Board members**

At the AGM in April 2021, it was resolved that a fee of SEK 540,000 would be paid to the Chairman of the Board, and a fee of SEK 265,000 to each and every one of the Board members who are not employed by the company. To Board members who are not employed by the company but living in the US an additional fee is to be paid corresponding to SEK 106,000. For work performed in the audit committee a fee of SEK 130,000 is to be paid to the Chairman of the Audit Committee, and SEK 65,000 for other members. For work performed in the remuneration committee a fee of SEK 100,000 is to be paid to the Chairman of the Remuneration Committee, and SEK 50,000 to other 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 the 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 2021, the Board held 15 meetings. At each ordinary Board meeting, the business situation and financial reporting were discussed. The external auditors took part in one meeting during the year, and took part in two 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 2022 budget.

**Audit Committee**

Since the inaugural Board meeting in April 2021, 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 five meetings were held in 2021.

**Remuneration Committee**

From the inaugural Board meeting in April 2021, the Remuneration Committee has consisted of Board member 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, 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 July 15, 2021, 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.

### **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 to 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 AGM in 2021, 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 Audit Committee on a yearly basis, both with and without company management present and summarize 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, decisionmaking channels, authorizations and responsibilities as expressed in policies and guidelines. Shared values create consensus and strengthen internal control. The structure created in 2017 and improved during the following years worked well in 2021 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 department manager.

### **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 2021 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 2022**

In 2022 the company will maintain the focus on the 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:** 18,683,339 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 independent 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 neuro technology. 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:** - 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 a 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.

# Board of Directors continued



**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 OssDesign 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-LaRoche 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:** 1,301,498 shares and 1,443,237 personnel options.

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

# Senior executives



## Will Martin

Born in 1975. CEO and President since 2021.

**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, Peripheral Vascular devices, Philips Healthcare.

**Shareholding in the company:** 20,000 shares, 435,116 personnel options.



## Griffen Stapp

Born in 1986. Interim Chief Financial Officer since 2021.

**Education:** Griffen Stapp has a master's degree in Business Administration with an emphasis in Accounting from Cal State University of San Marcos.

**Other experience:** Griffen Stapp is a former CPA who has extensive experience in the areas of internal controls, auditing, and business analytics. Other current assignments: Board Member of California Communication Access Foundation and Wesley House. Advisory Board Member of Clear Blue Sea

**Previous assignments over the past five years:** From 2019 to 2021 Griffen Stapp was the Head of Finance for New Leaf Biofuel. From 2015 to 2019 Griffen Stapp was the CFO for Gaia Medical Biosciences.

**Shareholding in the company:** 25,000 shares, 25,000 personnel options.



## 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:** - shares, 100,500 personnel options.

# Senior executives continued

**Kellie Fontes**

Born in 1961. Vice President Human Capital since 2022, employed in 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:** - shares, 76,120 personnel options.

# Use of performance measures not defined by IFRS

IRRAS financial statements are prepared in accordance with IFRS. The company applies the guidelines of the European Securities and Market Authority (ESMA) for alternative performance measures. To follow the financial performance of the Company, IRRAS is using certain performance measure not defined in IFRS. It is the Company's opinion that this information facilitates an analysis of the Group's development. The table below shows the Company's performance indicators and their definition. The indicators are calculated based on the financial numbers reported including IFRS 16.

	Jan-Dec 2021	Jan-Dec 2020
<b>Gross margin (Gross profit or loss/Net revenue)</b>		
Gross profit/loss, SEK million	-28.0	-16.1
Netrevenue, SEK million	22.4	7.4
Gross margin, %	Neg.	Neg.
<b>EBITmargin (Operating loss (EBIT)/Net revenue)</b>		
Operating loss (EBIT), SEK million	-136.5	-134.3
Netrevenue, SEK million	22.4	7.4
EBITmargin, %	Neg.	Neg.
<b>EBITDA (Earnings before interest, taxes, depreciation and amortization)</b>		
Operating loss (EBIT), SEK million	-136.5	-134.3
Total depreciation and amortization	16.8	16.3
EBITDA	-119.7	-118.0
<b>EBITDA margin (EBITDA/Net revenue)</b>		
EBITDA	-119.7	-118
Netrevenue, SEK million	22.4	7.4
EBITDA margin, %	Neg.	Neg.
<b>Return on equity (Net profit or loss for the period/Average equity)</b>		
Net loss for the period, SEK million	-136.3	-135.9
Average equity SEK million	147.5	156.9
Return on equity, %	Neg.	Neg.
<b>Equity ratio</b>		
Equity	111.6	182.4
Total assets	132.6	209
Equity ratio, %	84%	87%

## Definitions:

*Gross profit/loss:* Net revenue less cost of sales

*Gross margin:* Gross profit/loss divided by net revenue

*EBITDA:* Earnings before net financial income/expenses, tax and depreciations and amortizations

*EBITDA margin:* EBITDA divided by net revenue

*Operating loss (EBIT):* Gross profit or loss deducted for total operating expenses

*EBIT margin:* Operating profit or loss divided by net revenue

*Return on equity:* Net profit or loss for the period divided by average equity

*Equity ratio:* Total equity divided by Total Assets

# Annual General Meeting

The Annual General Meeting is to be held on Tuesday 24 May 2022. Due to the spread of COVID-19, the Board of Directors has, in accordance with the Swedish Act on temporary exceptions to facilitate the execution of general meetings in companies and other associations (Sw. lagen (2022:121) om tillfälliga undantag för att underlätta genomförandet av bolags- och föreningsstämmor), resolved that the Annual General Meeting should be conducted without the physical presence of shareholders, representatives or third parties and that the shareholders before the Annual 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 Monday 16 May 2022; and
- announce their intention to attend the General Meeting no later than Monday 23 May 2022, 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 Monday 23 May 2022

In order to be entitled to participate in the Annual 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 16 May 2022. 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 advance as determined by the nominee. Voting right registrations made no later than the 18 May 2022, will be considered when preparing the shareholder register.

## Absentee Ballot

Shareholders may exercise their voting right at the Annual 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 Annual General Meeting in Companies and Associations Act (2022:121).

A special form must be used for the absentee ballot. This is available on the Company's website [www.iras.com](http://www.iras.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: Sten Gustafsson, P.O Box 160, 101 23 Stockholm or by e-mail to [AGM@iras.com](mailto:AGM@iras.com) no later than 23 May 2022.

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.iras.com](http://www.iras.com). If the shareholder is a legal person, the certificate of registration or other authorization document must be attached to the form.

## Financial Calendar

In 2022, the quarterly interim reports are planned to be published on the following dates:

April 27, 2022	Q1 2022 interim report
July 22, 2022	Q2 2022 interim report
November 10, 2022	Q3 2022 interim report

## IR contacts

Will Martin  
President and CEO

Sten Gustafsson  
Director, Investor Relations  
+46 (0)10 211 51 72

e-mail: [IR@IRRAS.com](mailto:IR@IRRAS.com)

# Addresses

**Head office:****IRRAS AB (publ)**

Vasagatan 16  
SE-111 20 Stockholm  
Sweden  
Tel: +46 (0) 10 211 51 70

**IRRAS GmbH**

Prielmayerstr. 3  
80335 Munich  
Germany

**IRRAS B.V.**

Industrieweg 6 D  
1566JP Assendelft  
The Netherlands

**IRRAS USA Inc**

11975 El Camino Real, Suite 304  
San Diego, CA 92130  
USA

E-mail:  
info@irras.com



