IRRAS ANNUAL REPORT 2019

This is IRRAS

IRRAS AB is a global medical device company. Based on an innovative proprietary technology with strong IP protection, IRRAS intends to set new standards for neurocritical care. IRRAS designs, develops and commercializes products that improve patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methods in neurocritical care. IRRAS markets and sells its products to hospitals worldwide through its direct sales organizations in the U.S. and select European countries and a network of distribution partners in other markets.

IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. IRRAS AB (publ) is listed on Nasdaq First North Premier Growth Market (ticker: IRRAS).

For more information, please visit www.irras.com

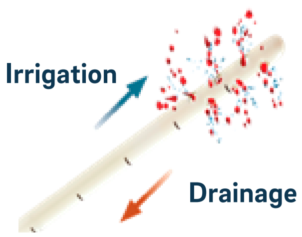
Content

Our products

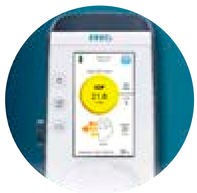
IRRAS focuses on designing, developing, and commercializing innovative solutions which offers more effective fluid management during and after surgical procedures. Our initial clinical focus is to support neurosurgical procedures, where excess cerebrospinal fluid (CSF) often needs to be drained and intracranial pressure (ICP) needs to be closely regulated.

IRRA*flow*

The world's first irrigating intracranial drainage system



Intelligent Digital Pump enables Automated Irrigation



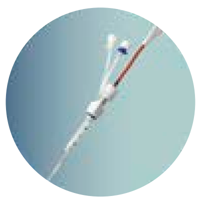
Integrated, Continuous ICP Monitoring

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

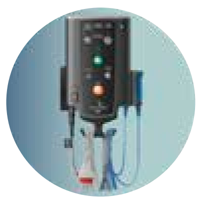
Hummingbird

Introducing 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.

2019 in brief

Q1

Initiation of US Patient Treatments

The company continued the US launch of IRRA*flow* and successfully treated the first US patients during the quarter.

Q2

First US sales and acquired assets

The company logged its first US sales early in the quarter and, in May, acquired assets, including the Hummingbird line. IRRAS also raised MSEK 106 in new capital.

Q3

New patent approved

A new patent was issued for IRRA*flow* and IRRAS announced new key hires to the company. Initial physician experience with IRRA*flow* was published.

Q4

CE mark received

In December, the company completed its CE Mark recertification for IRRA*flow*, which positioned the product to be reintroduced in Europe. The Hummingbird line was launched in the US.

Key figures 2019

- **Net revenue** totaled SEK 5.3 million (6.0).
- **Operating loss (EBIT)** amounted to SEK –151.5 million (–143.3).
- **Loss after tax** totaled SEK –151.1 million (–138.8).
- **Earnings per share** before and after dilution amounted to SEK –5.61 (–5.83).
- **The Board of Directors** proposes that no dividend should be paid.

The Group's available liquidity amounted to SEK 85.1 million at year-end.

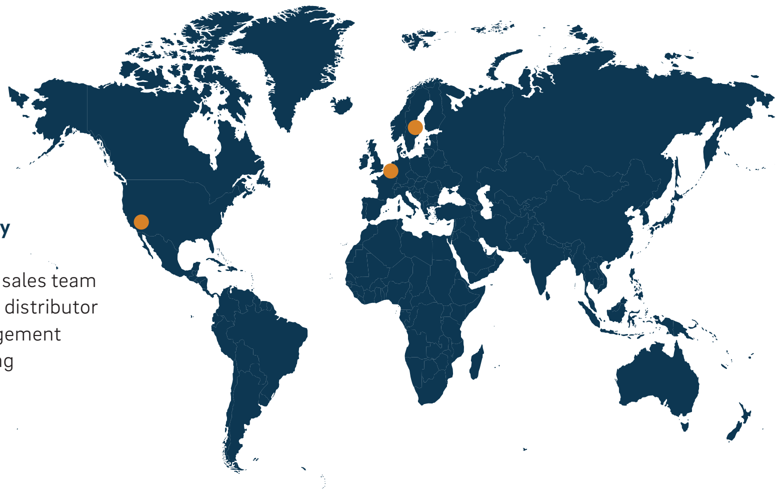
The average number of employees in the Group during the year was 35 (21).

Our locations

Sweden
Stockholm
- Legal headquarters
- Finance
- IT
- IR
- Listed on Nasdaq First North Premier Growth Market

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

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



Global presence

US
- Company´s direct sales team

Europe
- Company's direct sales team in Germany and Switzerland
- Launch in Scandinavia ready to start
- Distributors being trained in Spain and Portugal

The rest of the world, *Asia*
- Registration in key markets
- Initial patients treated in Hong Kong

Latin America
- Key markets covered by existing distribution agreements
- Initial market approvals received in Costa Rica and Argentina in 2019

Middle East, Africa
- Registration in key markets
- Launch in Israel and Kuwait during 2019

Comments from the President and CEO

2019 was the most transformational year for IRRAS since the company's inception in 2012. We accomplished our largest, most complex goals, recorded our first commercial revenues in the US, and overcame many operational and regulatory challenges, which made us stronger and better prepared for 2020 and beyond. We've executed a straightforward, purposeful strategy to advance our commercial product lines and build a globally-recognized neurocritical care company.

As I reflect on the past year, we made many advancements across several aspects of our business but also faced unexpected regulatory delays. During 2019, we assembled a strong, dedicated team committed to execute our goals ahead. Everyone at IRRAS has been working very hard in overcoming many challenges to deliver our life-saving products to patients. Approximately 580,000 patients per year are treated for hemorrhagic strokes, chronic subdural hematomas and traumatic brain injuries in the US and EU. The conventional treatments available to neurosurgeons and patients are limited and lack innovation. In 2019, we accomplished three key milestones to changing this treatment paradigm by obtaining the renewed CE Mark for the IRRA*flow* catheter in the European Union (EU), receiving 510(k) clearance for extended time use for IRRA*flow*, and launching our Hummingbird product line in the United States (US). The delays in the certification process were both unexpected and painful and were due to shortage of resources to review class III products at GMED, our notifying body. In addition, new requirements to redo some tests from the product's initial CE approval that were now over five years old further delayed the recertification. However, on the positive side, this process has left us with an even stronger product and well prepared for the coming new CE regulations known as MDD.

With the eight product codes that make up our IRRA*flow* and Hummingbird ICP monitoring product lines, IRRAS now has one of the most complete product portfolios in all of neurocritical care. IRRA*flow* is currently available in five markets (US, Germany, Finland, Israel, and Kuwait), while Hummingbird's products are currently cleared in the US. To expand our territories in 2020, our team is focused on securing product regulatory approval for the portfolio in additional markets. IRRA*flow* is being registered in non-CE Mark countries such as Taiwan, Mexico and others, while the CE Mark process is being prioritized for Hummingbird.

While we have a global focus at IRRAS, we know that a central component to our commercial success will be to amass resources, both internally and externally, to help us broaden the use of our IRRA*flow* and Hummingbird products in the US and the EU. The US and EU are the initial key markets of focus for IRRAS and are valued at more than 1,5 billion EUR. During 2019, while awaiting the recertification of our CE Mark in Europe, our team created product awareness and generated initial physician support at major stroke centers across the US. To date, we have introduced the IRRA*flow* technology to over 150 stroke centers in the US, and physician interest has been generated at approximately half of these facilities. IRRA*flow* pricing has been submitted at ~45 hospitals to initiate the new technology approval process which can typically take 6 months or longer. As of the beginning of March 2020, 29 IRRA*flow* systems are currently installed at US hospitals for potential patient treatment, either as commercial units or to support ongoing system evaluations. During the year, in the other international markets where IRRA*flow* has gained regulatory approval, patient treatments occurred in 3 of Israel's 7 neurocritical care centers, the first patient was treated with IRRA*flow* in Kuwait, and training and market development activities continued in Latin America to prepare for market introductions in Costa Rica and Argentina during 2020.

To complement the progress with IRRA*flow*, the Hummingbird intracranial pressure (ICP) Monitoring products were launched in the US, enabling us to record additional initial revenues from this product line. These products include proprietary single and multi-lumen cranial access bolts, parenchymal ICP monitoring, and a cranial access kit, which is required for every surgical cranial procedure. The Hummingbird family of products helps clinicians diagnose and manage patients' intracranial pressure after traumatic brain injury, a subarachnoid hemorrhage, and/or a stroke. The purchase of the Hummingbird line was a complementary addition to our portfolio and gave us access to global rights for already established products.

2020 is a pivotal year for IRRAS

Maintaining the right talent and culture at IRRAS is paramount to our success. We are proud to practice FILOTIMIA, which describes a complex set of virtues centered on the concept of "doing good" and one's actions being exemplary. At IRRAS, our mission is clear: to change the lives of millions by creating medical products that transform neurocritical care. We want our products to become the new standard of care in the field and bring much needed innovation to the way we treat patients suffering from hemorrhagic strokes, chronic subdural hematomas and traumatic brain injuries.

Work has started on insourcing some of the production of our IRRA*flow* control unit to prepare for commercial expansion. Our goal is to introduce at least three additional line extensions to the IRRA*flow* family of products, which include usability improvements to the tube set and performance enhancements to the catheters. We also plan to expand our commercial efforts across all product lines by introducing IRRA*flow* in at least four additional key global markets and expanding our customer base to more than 20 customers for our Hummingbird products.

COVID-19´s impact on IRRAS is still difficult to assess and we are continually evaluating are made of how the company will be affected. Although sales may be affected by other priorities in healthcare over a period of time, the underlying need remains in IRRA*flow*'s and Hummingbird's target patient group as these are critically ill patients and not subject to elective treatments. IRRAS keeps a close dialogue with suppliers and customers to follow all developments to minimize the negative impact of COVID-19. We are simultaneously also changing the sales methods to be able to run efficient meetings virtually and trainings through video conference.

In the coming year, our team is motivated and committed to delivering value to you, our shareholders, as we embark on a pivotal year in our company's maturation. We thank you for your continued support, and we look forward to keeping you updated on our progress in 2020.

Sincerely,

Kleanthis G. Xanthopoulos, Ph.D.
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.

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

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

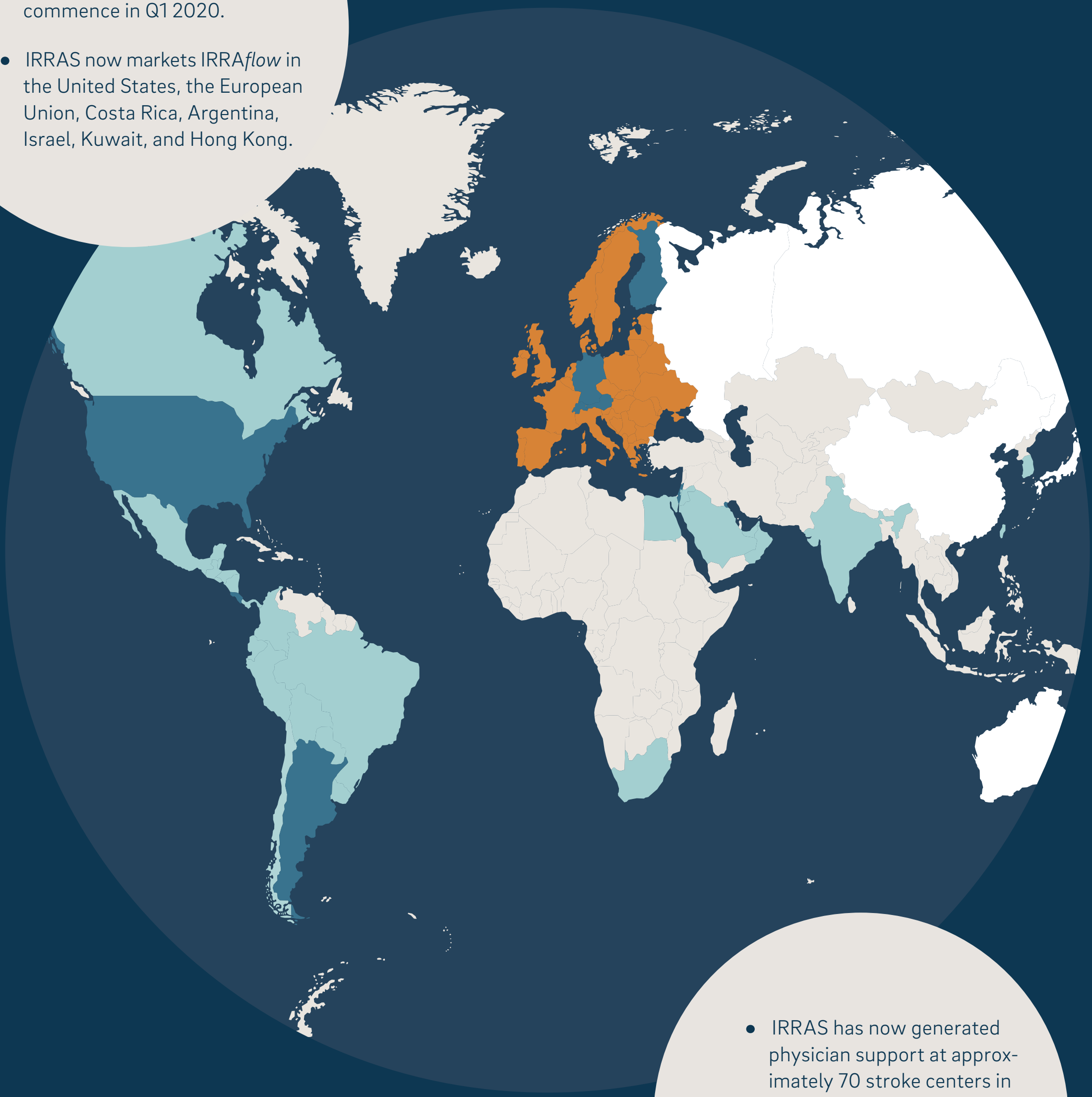
- **Commercializing IRRA*flow* and Hummingbird ICP for neurocritical care** and becoming the market leader for treatment of intracranial bleeding and traumatic brain injury.
- **Strategically building up global sales** through marketing to selected key markets, such as the US and Germany, by the company's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

Our core values

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

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

- IRRAS received CE Mark approval for its IRRA*flow* catheter in December 2019, allowing product relaunch in the EU to commence in Q1 2020.
- IRRAS now markets IRRA*flow* in the United States, the European Union, Costa Rica, Argentina, Israel, Kuwait, and Hong Kong.



- IRRAS has now generated physician support at approximately 70 stroke centers in the US.
- Of these 70 stroke centers, more than 20 have so far purchased IRRA*flow* components or are actively evaluating the system.

Current and anticipated markets

- Q1 2020 – Current Launch Markets (US, Costa Rica, Argentina, Hong Kong, Kuwait, Israel, Germany, Austria, Switzerland, Finland)
- Q2 2020 – Q4 2020 – Markets registered and ready for launch based on priority (CE-mark)
- Q2 2020 – Q4 2020 – Registration underway (Rest of Latin America (except for Venezuela, Suriname, Guyana, etc) Canada, Rest of Middle East, India, South Korea, Taiwan, South Africa)
- 2021, 2022 (Japan, China, Australia, Russia)

Four reasons to invest in IRRAS

1.

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

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

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

2.

A high clinical need means major market potential

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

Approximately 580,000 patients are treated for these conditions per year in the US and EU countries alone. The US and EU markets thus amount to approximately EUR 1.2 billion. Additionally, the adjacent field of acute subdural hematomas caused by trauma is an additional market segment where there is potential for the use of IRRA*flow*. In the US and EU, the number of cases are approximately 130,000 per year, which indicates an additional market potential worth approximately EUR 350 million.

3.

A scalable business model with favorable margins

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

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

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

4.

Global coverage

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

The need for a new standard of care

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

IRRAS believes that the IRRA*flow* and Hummingbird ICP technologies offer significant treatment advantages over conventional ICP monitoring and drainage tools in the treatment of these serious brain pathologies.

IRRA*flow*, the company's lead commercial product, is used to drain fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematomas. Both are serious conditions with high rates of mortality. IRRA*flow* addresses complications that commonly arise from current treatment methods and has the potential to become the new standard of care. At the same time, the company's Hummingbird ICP Monitoring family of products also offers an important diagnostic tool to monitor patients' conditions after traumatic brain injury has occurred. This tool is utilized to determine when intervention with a therapeutic tool, such as IRRA*flow*, will be required and has been shown to be more accurate and easier to use than other ICP monitoring systems.

A high clinical need

When intracranial bleeding is seen, it is most often in the form of hemorrhagic stroke or chronic subdural hematoma. Approximately 345,000 patients are treated for these conditions per year in the US and EU countries alone. The US and EU markets thus amount to approximately EUR 900 million.[1] There are also important markets outside the US and EU in countries such as Japan, China, Brazil, and Australia with well-functioning health insurance systems that offer further upside to this opportunity.

The adjacent field of acute subdural hematomas caused by trauma is an additional market segment where there is potential for the use of IRRA*flow*. In the US and EU, the number of cases is approximately 130,000 per year, which indicates an additional market potential worth approximately EUR 350 million for a total market opportunity for intracranial bleeding of EUR 1.2 billion each year.[2]

Hemorrhagic stroke and intracranial bleeding

Stroke is a global health problem that affects approximately 15 million people in the world every year. In developed countries, stroke is the most common cause of disability, the second most common cause of dementia, and the third most common cause of death. Approximately 15% – 20% of these cases are hemorrhagic strokes, the most serious type of stroke. This type of stroke is caused when a blood vessel suddenly bursts or a severe traumatic brain injury occurs, leading to bleeding in or around the brain.

About 460,000 people suffer from hemorrhagic stroke every year in the EU and US alone, and approximately 40% of these cases are treated through surgery. The condition is most common in people over the age of 65, and the number of cases is expected to increase, primarily due to smoking and an aging population.

Without a defined gold standard treatment, hemorrhagic stroke has a associated high rate of mortality. About 40% of patients die within 30 days, while about one-third of patients experience brain damage and permanent disability.

Due to improved outcomes and reduced treatment times compared to existing technology, use of IRRA*flow* can potentially contribute to reduced human suffering, higher quality of life for patients, and lower costs for healthcare providers.

1) These estimates are based on the total number of cases of hemorrhagic strokes and chronic subdural hematoma in the EU and US, as shown in the below images. The number of cases is multiplied by an average selling price of EUR 2,600 for IRRAS' disposable kits (one kit is typically required per case). Sales of the control unit are not included.
2) Based on about 130,000 additional cases and the same assumptions outlined in the reference above.

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 that experience a traumatic brain injury each year, 5.4 million of them are in IRRAS' key target markets of the European Union and the United States. 1.3 million of these injuries require hospitalization, and 20% require ICP monitoring. 90% of this ICP monitoring is invasive in nature. The potential treatment of these 235,000 patients equals an additional EUR 250M in market opportunity.

Life-saving treatments

After a brain injury occurs or an intracranial blood vessel ruptures, increase in ICP can cause deleterious effects on the brain, and increased ICP is the most common cause of death in neurosurgical intracranial pathologies. Without treatment, moderate to serious brain damage or death may result. Given this fact, immediate assessment of the patient's ICP must occur, and when increased intracranial pressure occurs, it must be reduced rapidly. The surgical intervention to reduce intracranial pressure by draining the collected fluid is usually performed on an emergency basis. Only after the pressure has been reduced can the optimal treatment strategy be determined for the patient. Throughout treatment, continual ICP monitoring is critical to understand how the patient is responding to treatment.

Traditional treatment options for intracranial bleeding and chronic subdural hematoma

A conventional external ventricular drainage system (EVD) is passive and relies on gravity alone to drain excess fluid in an attempt to reduce ICP. An EVD catheter is inserted through a small burr hole in the patient's cranium, and after placement, it evacuates blood and collections of fluid to a drainage bag attached to a bedside pole. The drainage rate is controlled by changing the height of the bag relative to the tip of the catheter inside the patient's skull.

Although an EVD is currently the most common treatment option for intracranial bleeding or elevated ICP, the technology is associated with several well-known complications such as catheter blockage, infections, excess drainage, and secondary bleeding, all of which can result in a negative impact on patient outcome. It is also documented that shorter time in the hospital and more thorough clot evacuation for hemorrhagic stroke patients leads to better patient outcomes.

Next-generation treatment with IRRAflow

IRRA*flow* is the only system on the market that integrates drainage, targeted fluid irrigation, and measurement of intracranial pressure into the same product. The system is designed to significantly improve patient outcomes by using its automated irrigation to reduce the occurrence of catheter blockage, which can also lower the risk of infection during treatment.

The efficacy of IRRA*flow*'s active fluid exchange has been demonstrated so far in patients in Greece, India, Germany, Finland, Hong Kong, Kuwait, Israel, and the US. In these cases, treatment times have been shown to be reduced compared with EVD treatment, and no incidences of catheter occlusion by clot has been seen. In follow-up care, no catheter-related infection has been documented in any of these cases.

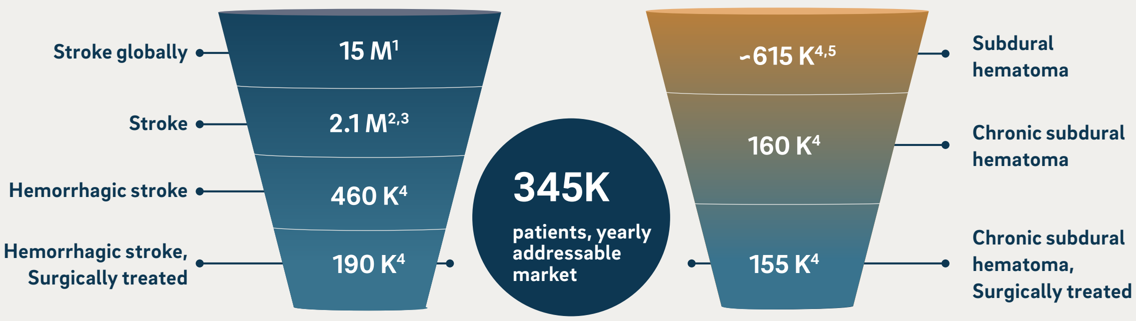
Traumatic brain injury – head injury that impairs brain function

A traumatic brain injury (TBI) is defined as a blow to the head or a penetrating head injury that disrupts the normal

I.2 billion EUR IRRA*flow* market potential, EU & USA CAGR, 8–10%

Hemorrhagic stroke - *Bleeding in the brain*

Subdural hematoma - *Blood collection in the brain*



1) World Stroke Organization. https://www.world-stroke.org/component/content/article/16-forpatients/84-facts-and-figures-about-stroke
2) Béjot Y, Bailly H, Durier J, Giroud M. Epidemiology of stroke in Europe and trends for the 21st century. Presse Med. 2016 Dec;45(12 Pt 2):e391-e398. doi: 10.1016/j.lpm.2016.10.003. Epub 2016 Nov 2.
3) http://www.strokecenter.org/patients/about-stroke/stroke-statistics/
4) Market data from L3 and internal analysis. Combination of incidence rates combined with market specific data.
5) 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

function of the brain. TBI can result when the head suddenly and violently hits an object or when an object pierces the skull and enters brain tissue. Symptoms of a TBI can be mild, moderate or severe, depending on the extent of damage to the brain. Mild cases may result in a brief change in mental state or consciousness, while severe cases may result in extended periods of unconsciousness, coma or even death. TBI globally affects 69 million people each year[1] most of whom have mild symptoms. In the US and EU annually, approximately 5.4 million people are affected by TBI.[2,3] Of those 5.4 million, 1.3 million have severe enough symptoms to be hospitalized, and 20% require monitoring of their intracranial pressure (ICP).[4] 90 % of this monitoring is invasive.[5] This leads to approximately 235,000 people requiring invasive monitoring in the US and EU due to TBI.

IRRAS acquired the Hummingbird ICP family of neuromonitoring products in 2019 to be able to offer its customers the opportunity to monitor ICP after a traumatic brain injury, meaning that the company can now provide a more complete product portfolio of tools across the entire spectrum of neurocritical care.

Traditional diagnosis options for traumatic brain injury

In traumatic brain injury, after the primary impact damage has been inflicted, the primary goal is to prevent any secondary injury to the brain. This secondary injury is often caused by increased pressure that harms an otherwise sensitive and vulnerable brain. The key way to avoid secondary injury is to try to maintain normal or slightly elevated blood and intracranial pressure levels. Various ICP monitoring devices may assist health care personnel in assessing a patient's condition and determining their needed care. Placement of an ICP monitor into the brain itself can help detect excessive swelling of the brain and increased intracranial pressure.

When calculating ICP with competitive systems, the lack of continuous calibration can cause the reporting of imprecise ICP values. The difference between the starting ICP value when the sensor is initially calibrated and the ICP value that is measured when the sensor is removed is termed "drift". A large difference between these two ICP measurements indicates that the ICP measured while the device was implanted in the patient was not the "true" ICP at any given moment. Therefore, the cumulative pressure difference can have important implications for the treatment and prognosis of the patient.

Next-generation treatment with Hummingbird ICP Monitoring

The Hummingbird ICP Monitoring family of products offers both single and multi-lumen bolts that address brain

Chronic subdural hematoma – blood collection in the brain

One-third of all serious head injuries result in the formation of a subdural hematoma. This occurs when a vein or other blood vessel bursts between the skull and the outermost membrane covering the brain, which causes blood collection (a hematoma) on the surface of the brain. This hematoma then exerts pressure on the surrounding brain tissue. Of the three types of subdural hematoma, IRRA*flow* is most often used for treatment of chronic subdural hematomas, which typically form and become symptomatic two to three weeks after the head injury. About 160,000 cases of chronic subdural hematoma occur in the US and EU per year. Surgery is performed in over 95% of cases, which results in approximately 155,000 cases of chronic subdural hematoma in the EU and US that are suitable for treatment with IRRA*flow*.

Approximately one-third of all chronic subdural hematoma patients die and another one-third become disabled to some degree. The total healthcare cost in the US alone is estimated at USD 1.6 billion. Chronic subdural hematoma is projected to become one of the most common cranial neurosurgical conditions by the year 2030, which, in turn, translates into the assumption that chronic subdural hematoma treatment may also become the most commonly performed neurosurgical procedure.

1) Dewan, Michael & Rattani, Abbas & Gupta, Saksham & Baticulon, Ronnie & Hung, Ya-Ching & Punchak, Maria & Agrawal, Amit & Adeleye, Amos Olufemi & Shrime, Mark & Rubiano Escobar, Andres & Rosenfeld, Jeffrey & Park, Kee. (2018). Estimating the global incidence of traumatic brain injury. Journal of Neurosurgery. 130. 1–18.
2) 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.
3) Center-TBI EU Traumatic Brain Injury Fact Sheet and Policy Brief.
4) Company estimate is based on approximate number of hemorrhagic stroke cases (250,000 in the major EU countries and 210,000 in the United States), multiplied by 30 percent , which is the projected increase due to the aging of the population from the "SAFE Report: The Burden of Stroke in Europe" and the "American Heart Association Report: Heart Disease and Stroke Statistics – 2017 Update". Company estimate based on approximate number of surgically operated hemorrhagic stroke cases (190,000) and chronic subdural hematoma cases (155,000) in the EU and the United States, multiplied by the average selling price of the single-use consumable compo nents (IRRA*flow* cassette and catheter) of the IRRA*flow* system.
5) Market Study Report, Global Intracranial Pressure (ICP) Monitoring Devices Market Growth, 2019–2024.

monitoring needs for the diagnosis of traumatic brain. The Hummingbird products meet these needs by using an air bladder to measure ICP with a mechanism of action that effectively recalibrates the system following every small change in the patient's ICP without requiring the use of a large piece of capital equipment. This automatic recalibration allows the system to operate for extended periods with virtually no drift. The system is also quite user friendly with straightforward and intuitive setup and operation.

Well-established payment models

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

Depending on the treatment, an average DRG payment in the Germany, the largest EU market, can reach EUR 36,700, of which approximately EUR 4,000 can be earmarked for IRRA*flow*'s single-use disposables or EUR 500 – EUR 2,000 for Hummingbird's single-use disposables. The small pieces of capital equipment for both systems are investments for which the hospital is typically responsible. In the US, the average DRG payment can range from USD 35,000 to USD 50,000, depending upon procedure complexity. In the US, caregivers are paid directly by patients and various public and private third-party payers, including federal Medicare, state-run Medicaid and private health insurance policies.

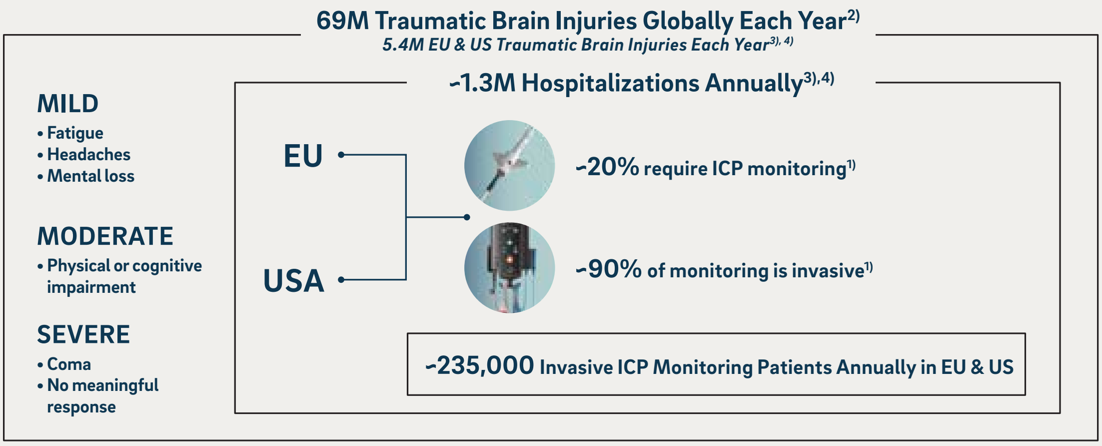
Regulations and requirements

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

National regulations in Europe are based on the joint safety and functionality requirements according to the EU directives and ordinances that regulate medical devices. Products must be CE certified to confirm that they comply with these regulatory requirements. A product that has been evaluated and given CE certification in one country has access to virtually all of the entire EEA market. IRRA*flow* received its latest CE Mark certification in December of 2019. The Hummingbird ICP monitoring system has not yet received CE Mark certification, but the Company expects to have that in place by the end of the year. The corresponding approval for sales and marketing in the US is provided by the FDA. Both IRRA*flow* and Hummingbird systems are FDA cleared for use in the US.

A large number of countries in Asia, Latin America, the Middle East and Africa are not encompassed by CE marking or FDA approval. Instead, they have their own registration processes that sometimes include direct registration.

Traumatic Brain Injury Market Opportunity for Hummingbird 250M EUR (EU & US) with 6% CAGR[1]



1) Market Study Report, Global Intracranial Pressure (ICP) Monitoring Devices Market Growth, 2019–2024.
2) Dewan, Michael & Rattani, Abbas & Gupta, Saksham & Baticulon, Ronnie & Hung, Ya-Ching & Punchak, Maria & Agrawal, Amit & Adeleye, Amos Olufemi & Shrime, Mark & Rubiano Escobar, Andres & Rosenfeld, Jeffrey & Park, Kee. (2018). Estimating the global incidence of traumatic brain injury. Journal of Neurosurgery. 130. 1–18.
3). 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.
4) Center-TBI EU Traumatic Brain Injury Fact Sheet and Policy Brief

Market penetration and portfolio expansion

During the year, progress was seen on multiple fronts. Product awareness was built in the neurocritical care community, and initial progress was seen during the US launch of IRRA*flow*. The first patient treatments were completed in the US, and revenue growth was seen throughout the year. In May, the Hummingbird ICP monitoring product family was acquired, and the IRRA*flow* CE Mark recertification process was finalized just before the end of the year.

Need for IRRAflow technology confirmed

Legacy technologies, known as external ventricular drains (EVD), are considered the gold standard for draining excess fluid and monitoring intracranial pressure (ICP) after hemorrhagic stroke or traumatic brain injury, but EVDs have not evolved much over the past several decades. In fact, the basic concept of an EVD to use passive, gravity-driven drainage is the same one that was first introduced in 1744 by Claude-Nicolas Le Cat. Because of this limited innovation, during the early phases of the IRRA*flow* system's introduction in the United States (US), there has been a favorable response to the system's unique mechanism of action that combines ICP monitoring, automated irrigation, and controlled fluid drainage.

Establishment of a sales organisation

After receiving clearance to market IRRA*flow* from the US Food and Drug Administration (FDA) in July 2018, IRRAS began to build a direct sales force to market the system to leading stroke centers throughout the country. This direct sales force, now consisting of seven sales professionals, is one of the company's strongest assets as they are exclusively focused on driving interest in the company's products. Many other companies at a similar stage choose to build a distribution network in larger markets, such as the US, but IRRAS has chosen to invest appropriately to ensure that it has complete control over the launch of its products in the world's largest neurosurgical market. A direct sales force also creates close relationships with the company's customers, which enables valuable input for product enhancements and line extensions.

At the end of the year, IRRAS also received recertification of its CE Mark for IRRA*flow*, which allows the company to again market the system in the European Union. Within Europe, the company will use a hybrid sales model by hiring direct sales professionals in certain key markets and signing distribution agreements for other countries. Currently, IRRAS has 4 direct sales professionals in Europe focused on direct sales in Germany and management of distribution partners in other markets. The company is also finalizing plans to add another sales professional to initiate direct sales in the Nordic region.

Expansion of product portfolio with complementary Hummingbird brand

In May 2019, IRRAS acquired the Hummingbird ICP Monitoring product family which comprises ten FDA-cleared products that include proprietary single and multi-lumen cranial access bolts, tools that monitor the patient's ICP within brain tissue, and a cranial access kit. The Hummingbird family of products helps clinicians diagnose and manage patients' ICP after traumatic brain injury or a stroke. The Hummingbird ICP Monitoring product line is designed for maximum accuracy, reliability, and ease of use to address the needs of both the hospital and the patient.

In December 2019, the company announced the launch of the first four Hummingbird products in the US, and the company expects to be able to engage more than 20 customers throughout the course of 2020.

The Hummingbird product family is not yet CE Marked, and the company is currently working to submit the needed paperwork to finalize that process. In both the US and Europe, the IRRAS direct sales team will be able to effectively sell both IRRA*flow* and Hummingbird due to the complementary nature of the products.

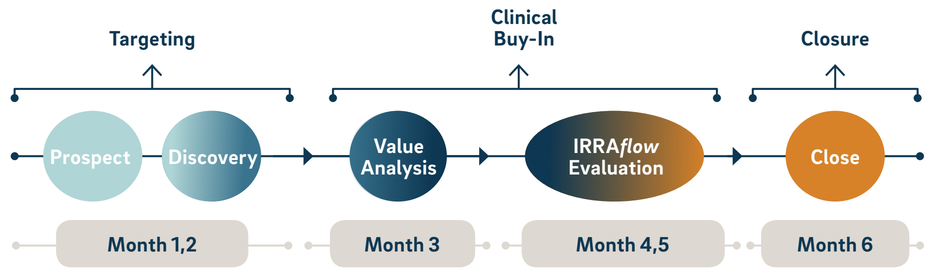
Sales/marketing strategy

Intracranial bleeding and traumatic brain injury are global problems that continue to grow as the population ages and cardiovascular disease progresses. As such, IRRA*flow* has the potential to become the new standard of care for treatments worldwide in these markets that approach a EUR 1.5 billion opportunity.

To take advantage of the significant market opportunity, the company remains focused on building strong product support in select, key markets and hospitals before it begins more rapid expansion. This strategy of "going deep before going wide" ensures that a strong foundation for the system is created initially that can be built upon moving forward. The company takes a thorough approach in order to ensure a successful launch, and it places significant emphasis on training and education for both its own direct sales force and via distributors.

IRRAS continues to view the EU and US as its key markets as they offer the largest potential patient populations, combined with well-established health care systems, a strong demand for innovative medical device solutions, attractive end-user price points, and attractive reimbursement levels. The company's products are supported by favorable, established reimbursement levels for patients with traumatic brain injury or hemorrhagic stroke. Procurement of the systems are primarily financed through the public sector and insurance companies.

In the United States, the process to navigate the approval process at new hospitals can take more than 6 months in many situations as shown in the chart below. This extended timeline is especially applicable to a new technology that is building its market awareness and clinical data evidence.



In spite of this process that must be navigated, the company continues to methodically build its network of advocates of its new technology, known as FlowPros, by targeting innovative neurosurgeons that embrace new technology. Throughout the year, the company made needed progress with both product adoption and accompanying revenue. With IRRA*flow*, IRRAS has now generated physician support at more than 70 stroke centers in the US, including 25 of the top 100 neurosurgical centers in the US. Of these centers, more than 20 have so far purchased IRRA*flow* components or are actively evaluating the system, including locations in the high-volume neurocritical care markets of Illinois, New York, and California. Similar adoption is expected with Hummingbird ICP Monitoring.

As more product advocates are identified, the number of IRRA*flow* treatments performed is increasing, and the company is heavily focused on building a pool of convincing clinical data. During the coming year, the company plans to expand its commercial footprint in the US to better take advantage of this increased awareness. With knowledge of the new treatment method and demand increasing, additional sales territories will be added with the objective of progressing IRRA*flow* toward becoming a new standard of care for the treatment of intracranial bleeding.

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

Product reintroduction underway in Europe

IRRA*flow* was initially launched in Germany and Austria in May 2017 and got off to a promising start, with revenue being generated in the third quarter. Unfortunately, the system could not be sold in Europe during the year due to a delay in the recertification of IRRA*flow*.

The recertification requirement initially arose because IRRAS' previous notification body decided it would no longer certify certain products under the CE Mark system. The control unit and tube set received new EU clearance in May 2018, but the remaining third component of the system, the innovative dual-lumen catheter, was considered a Class III product, which required a longer approval process.

IRRAS worked closely with GMED, its new notified body, to complete the needed testing and provide all of the documentation required throughout the year, which resulted in an updated CE Mark certification in December 2019.

In September, IRRA*flow* attracted considerable interest at the annual European Congress of Neurosurgery (EANS) in Dublin, with attendees from around the world. Dr. Behnam Rezai Jahromi from Helsinki University Hospital in Finland spoke about his early experience with IRRA*flow*, and IRRAS also hosted an Early Adopter Summit with engaged physicians to remain prepared for the eventual release of IRRA*flow*.

Activities in the European market during the year were focused on maintaining contact with the initial customers and translating the initial EU experience into support for the US launch. With the CE Mark now back in place, the company has recommenced its commercial activities in both its direct markets and with potential distribution partners.

The rest of the world

The company addresses markets outside the EU and US through selected distributors that are well established in the neurosurgical segment. This approach ensures accelerated access to important markets in other parts of the world with the same detailed focus on education, training, and patient outcomes that is seen in its direct sales markets.

During the year, IRRAS received regulatory approval in Israel, Costa Rica, Argentina, and Kuwait with initial patient treatments completed in Israel and Kuwait. In countries where regulatory approval has not yet been received, the approval process is being driven by IRRAS in close cooperation with its respective distributors.

A Pipeline of Innovative Products

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

During the year, the company released a software update for the IRRA*flow* control unit that enhanced product performance and facilitated staff training. An improved drainage bag that collects fluid removed from the patient was also introduced as was a series of improvements to the system's Tube Set. These improvements included more resilient tubing that was pre-connected to simplify IRRA*flow* system setup.

The launch of a more stable IRRA*flow* catheter, a larger IRRA*flow* catheter for draining large amounts of fluid from subdural hematomas, and a laser pointer that facilitates the correct alignment of the catheter in each patient are planned for the near future. On a longer time horizon, the company hopes to combine the functionality of both the IRRA*flow* and Hummingbird product lines.

After the acquisition of the Hummingbird ICP product line, the company focused on validating established manufacturing partners and ramping up production to support a full-scale launch of the Hummingbird product line that was announced during December.

Production of both product lines is driven and continuously monitored by the product development team. During the year, the company reviewed and expanded its supplier base in order to improve its delivery reliability.

Well-Protected by Robust IP Portfolio

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

Robust Intellectual Property Portfolio until 2038

3 patent families protecting the IRRA*flow* franchise:

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

Foundational patent protection includes the following status:

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

5 patent families protecting the Hummingbird franchise:

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

Patent protection for multiple applications includes the following status:

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

The share

Since November 22, 2017, IRRAS' share has been listed on First North Premier Growth Market, Nasdaq Stockholm. During the year, the share price fell, and the number of shares traded increased. At year-end, IRRAS had 2,107 shareholders.

Market capitalization and turnover

The final share price at December 31, 2019 was SEK 23.40, which gave the company a market capitalization of MSEK 674.

As of March 17, 2020, the last payment price was SEK 6.9, which gave a market value of MSEK 199. During the financial year 2019, an average of 46,294 shares were traded per day. A total of 11.5 million IRRAS shares were traded in 2019 at a value of MSEK 301. The price decline in 2019 amounted to 32 percent. During the year, the OMX SPI Index fell by 9 percent.

Share capital

As of December 31, 2019, the share capital of IRRAS amounted to SEK 864,539.22, distributed on 28,817,974 shares with a quota value of SEK 0.03 per share. This is an increase during the year of 4.8 M shares. IRRAS has only one class of shares and all shares have equal rights to shares, and all company's assets and profits.

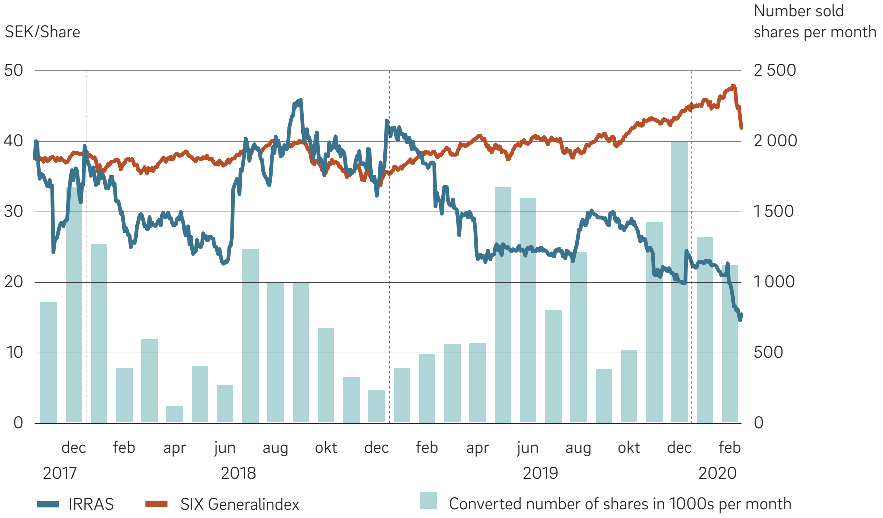
Shareholder agreement

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

Dividend and dividend policy

The Board of Directors of IRRAS has proposed to the Annual General Meeting that no dividend be paid for the financial year 2019. Before a positive cash flow can be achieved, the Board does not intend to propose to the AGM that a dividend be paid.

IRRAS SHARE PRICE 2017-11-22 – 2020-02-29



Source: Web Financial Group

SHAREHOLDERS AS OF DECEMBER 31, 2019 AND KNOWN CHANGES THEREAFTER

	No. of shares	% of shares/votes
Lexington Holding Assets Ltd (BVI)	3,155,727	10.95%
F.EX Endotherapy Limited	2,855,790	9.91%
Bacara Holdings Limited	1,430,725	4.96%
Consensus Asset Management AB	1,420,577	4.93%
Fjärde AP-Fonden (Fourth National Pension Fund)	1,245,000	4.32%
Dr. Kleanthis G. Xanthopoulos	842,878	2.92%
Dr Saeid AB	833,725	2.89%
Danica Pension	704,587	2.44%
March Asset Management	588,769	2.04%
Carl-Olof och Jenz Hamrins Stiftelse	550,000	1.91%
Other shareholders	15,190,196	52.71%
Total number of shares	**28,817,974**	**100.00%**

TABLE OF HOLDINGS

Holdings	Number of shareholders
1–500	1,145
501–5 000	544
5 001–100 000	382
100 001–500 000	26
500 001–	10
Totalt	**2,107**

DEVELOPMENT OF SHARE CAPITAL

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

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

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.

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, 2019. 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 income statements and balance sheets, statement of cash flows, statement of comprehensive income, statement of changes in equity and notes with supplemental information.

The company's shares have been listed on Nasdaq First North Premier since November 2017.

Operations

IRRAS AB is a medical technology company focused on the delivery of innovative solutions for brain injuries and intracranial bleeding. IRRAS designs, develops and commercializes products that improve patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methods in neurocritical care. IRRAS markets and sells its products to hospitals worldwide through its direct sales organizations in the US and select European countries and a network of distribution partners in other markets. In its efforts to meet these goals, IRRAS aims to become a predominant player in neurosurgery.

The company's product portfolio includes its original product IRRA*flow* as well as the Hummingbird ICP Monitoring product line, which was acquired in the second quarter of 2019. IRRA*flow* is an FDA-cleared and CE-marked, fully integrated, closed-circuit medical device system that enables intelligent intracranial fluid management as well as accurate, real-time monitoring of intracranial pressure. The Hummingbird line includes nine FDA-approved products that help clinicians diagnose and manage patients' intracranial pressure after a traumatic brain injury, subarachnoid hemorrhage, and/or stroke. The combination of IRRA*flow* and Hummingbird creates a unique product portfolio. Along with strong patent protection, this provides IRRAS with a solid foundation to establish a leading position in the neurocritical care market.

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

On December 19, 2019, the company received renewed CE mark approval for the IRRA*flow* catheter throughout the EU. In the fourth quarter of 2019, the Hummingbird product line was also launched in the US. Going forward, the focus will be on broadening the use of the products.

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

Group structure

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

MULTI-YEAR OVERVIEW

	Group				Parent Company			
Amounts in TSEK	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017 Dec 31, 2017	Jan 1, 2016–Dec 31, 2016	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017 Dec 31, 2017	Jan 1, 2016–Dec 31, 2016
Earnings								
Net revenue	5,288	5,994	11,973	–	1,551	13,081	3,969	–
Gross margin, %	neg.	neg.	53%	–	neg.	39%	16%	–
Operating loss (EBIT)	–151,486	–143,328	–61,464	–30,828	–47,384	–43,018	–45,309	–24,808
Net loss for the period	–151,144	–138,842	–60,901	–31,898	–46,434	–39,565	–45,169	–25,591
Financial position								
Total assets	158,992	205,284	329,252	98,260	369,650	315,265	349,854	103,693
Equity	131,470	184,154	316,030	95,115	360,532	307,419	338,877	101,030
Equity ratio, %	83%	90%	96%	97%	98%	98%	97%	97%

The Swedish Parent Company is responsible for such Group-wide functions as finance, investor relations and IT. The US company is responsible for the manufacture and development of new and existing products as well as sales in North America. The German subsidiary is primarily a sales company.

Significant events during the fiscal year

Renewed CE mark approval for the catheter and extended FDA 510(k) clearance.

Towards the end of the year, IRRAS received CE mark approval for sales of the IRRA*flow* catheter and extended FDA clearance for the use of IRRA*flow*. The CE mark approval supplemented the two CE marks previously obtained for the IRRA*flow* system's tube set with digital pump and control unit, allowing IRRAS to once again commercially market the IRRA*flow* system in the EU.

Acquisition of patent-protected assets that supplement IRRA*flow*

In the second quarter, IRRAS acquired patents from InnerSpace Neuro Solutions and the Alfred E. Mann Institute. The patents include Hummingbird ICP Monitoring, which is used for the diagnosis, monitoring and treatment of intracranial pressure in patients with traumatic brain injuries. The Hummingbird product line includes single and multi-lumen cranial access bolts, intracranial pressure monitoring and a cranial access kit. Hummingbird ICP Monitoring was launched in the US in December. IRRAS now has more than 45 global patents and patent applications for various types of innovative products for neurocritical care.

Launch in the US

In early January, the first patients in the US were treated with IRRA*flow*. The successful treatments were administered at the University of California, Irvine (UCI) Medical Center. Since then, more than 20 hospitals in the US have either purchased IRRA*flow* or are conducting an ongoing evaluation of the system.

Raising capital through directed share issue

In May, a directed share issue was completed, generating net proceeds of SEK 97.3 million for the company. The subscribers in the issue included a number of Swedish and international institutional investors.

Changes to the Board Of Directors and management group

The Annual General Meeting in May elected Catherine Gilmore-Lawless as a new Board member of IRRAS. Gilmore-Lawless is an American citizen and has 30 years of experience in the neuroscience sector.

In June, Fredrik Alpsten stepped down as CFO and Sabina Berlin was appointed as the company's new CFO. The company also announced that Lance Boling, VP Product Development, would revert to a consultant position for the company.

Awards and publications

Towards the end of the year, IRRA*flow* won CONNECT's "2019's Most Innovative New Product" Award in the medical device category. CONNECT is a nonprofit organization that helps innovative entrepreneurial companies in the technology and life sciences sectors.

In the third quarter, an article was published in the World Neurosurgery Journal concerning the initial clinical experience of IRRA*flow* in the US. The article, written by Dr. Sumeet Vadera and his team from the University of California, Irvine, examined the use of IRRA*flow* for chronic subdural hematoma, highlighting the system's safety, treatment results and cost efficiency.

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) and chronic subdural hematoma (blood collection on the surface of the brain). IRRA*flow*, the company's leading commercial product, is used to drain fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematoma, two serious conditions with high rates of mortality. IRRA*flow* addresses complications that commonly arise from current treatment methods, and has the potential to become the new standard of care. The company's Hummingbird products also offer an important diagnostic tool for monitoring the patient's condition after a traumatic brain injury. This is a critical tool for determining when the use of a therapeutic tool, such as IRRA*flow*, will be required.

Around half a million people in the US and Europe suffer from hemorrhagic strokes and chronic subdural hematoma annually. Approximately 345,000 of these people are treated surgically each year, and IRRAS estimates that the market value of IRRA*flow* in Europe and the US is currently just over EUR 1.2 billion per year. At the same time, some 1.3 million people are admitted to hospital for traumatic brain injuries in Europe and the US each year, and approximately 235,000 of these people require invasive monitoring. Accordingly, the market value of the Hummingbird line in these regions is estimated at approximately EUR 250 million per year.

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

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

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

Earnings and financial position in the Group

The figures for 2018 have been restated since certain costs in one of the subsidiaries have been reclassified in order to adjust the subsidiary's financial reporting to the Group's, thereby providing a more true and fair view of the Group's performance. This reclassification impacted the 2018 figures pertaining to the Group's cost of sales, gross profit/loss, selling expenses, administrative expenses and R&D costs. However, operating profit/loss has remained unchanged. The consolidated statement of financial position and the consolidated statement of cash flows have not changed.

	2018 annual report	**Reclassification**	**2019 annual report**
	2018-01-01 2018-12-31		2018-01-01 2018-12-31
Net revenue	5 994		5 994
Cost of sales	–19 959	–2 461	–22 420
Gross loss	**–13 965**	**–2 461**	**–16 426**
Other operating income	1 702		1 702
Marketing and selling expenses	–62 342	3 739	–58 603
Administrative expenses	–44 547	153	–44 394
Research and development expenses	–22 931	–1 431	–24 362
Other operating expenses	–1 245		–1 245
Operating loss (EBIT)	**–143 328**	**0**	**–143 328**

Net revenue for the 2019 fiscal year totaled SEK 5.3 million (6.0). Of this revenue, SEK 4.5 million (0) is attributable to sales in the US and SEK 0.7 million (0) to the rest of the world. Since the company was awaiting for the CE mark (European registration clearance) for the catheter during most of the period, sales in Europe amounted to SEK 0.0 million (6.0).

The gross loss for 2019 totaled SEK –33.2 million (–16.4). The cost of sales includes direct production costs for sold products, amortization of capitalized development expenses, overheads for the production division and personnel costs for employees in the division. The production division was expanded during the year in preparation for the launch in the US. Amortization of capitalized development expenses amounted to SEK 9.8 million (7.7).

Operating expenses for 2019 totaled SEK 118.4 million (127.4). Operating expenses primarily comprise selling expenses in the US, administrative expenses and R&D costs. Of the total SEK 37.8 million (38.6) R&D costs for the year, SEK 8.0 million (14.3) was capitalized and SEK 29.8 million (24.4) was expensed. The expensed R&D costs mainly include personnel costs for employees and consultant fees in the R&D division. The division 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 2019 amounted to SEK 0.0 million (0.5). Other operating income is primarily made up of exchange rate differences.

The operating loss for 2019 totaled SEK –151.5 million (–143.3) and net financial items totaled SEK 0.3 million (4.5).

The loss before tax for 2019 amounted to SEK –151.1 million (–138.8). The net loss for the year totaled SEK –151.1 million (–138.8).

Cash flow from operating activities for 2019, after changes in working capital, totaled SEK –153.7 million (–97.4). The negative change in cash flow is primarily attributable to the negative change in earnings. A directed share issue was completed during the year, generating net proceeds of SEK 97.3 million for the company.

Total net investments for 2019 totaled SEK 15.4 million (14.8). Of the total net investments, investments in intangible assets amounted to SEK 14.8 million (14.3). These intangible assets comprised capitalized development expenses and capitalized patent expenses attributable to the acquisition of assets from InnerSpace. Investments in tangible assets totaled SEK 0.6 million (0.5) and sales of financial assets amounted to SEK 55.2 million (35.1).

Capital requirements for the year were financed with funds from the share issues carried out in 2019 and 2017. Cash and cash equivalents amounted to SEK 47.2 million (98.3) at the start of the period and SEK 29.5 million (47.2) at year-end. At the end of the year, there was a total of SEK 55.6 million (110.8) in financial investments.

Production

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

Development

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

Development expenses for the next few years are expected to be on a par with those in 2019.

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

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

R&D costs recognized as revenue account for 25% (19) of total operating expenses.

Risks and uncertainties

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

Sales and market risks

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

Risks related to COVID-19

There is a risk that IRRAS is affected by COVID-19 if the company's ability to sell to and train new customers is limited by disease control measures and an increased strain on the healthcare system, or that the company's employees, consultants or suppliers cannot deliver according to expectation due to sickness or quarantine.

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 Group's available cash and cash equivalents do not cover the liquidity needed to pursue planned operations over the next 12 months. In light of this, the Board has resolved, supported by the authorization granted by the extraordinary general meeting held on March 2, 2020, to carry out a share issue of approximately SEK 217 million with preferential rights to the company´s existing shareholders. The rights issue is fully underwritten and the Board deems the company's prospects for financing its operations to be favorable. At the date of publication of the annual report the rights issue is not yet completed. If sufficient financing cannot be obtained, there is a risk that the company may not have the necessary prerequisites to continue as a going concern.

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

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

Legislative and regulatory risks

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

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

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

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

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

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

Future development

In 2019, both IRRA*flow* and Hummingbird met with an excellent reception in the market. In 2020, the main focus will be on increasing sales and the number of treatments administered in the USA as well as on relaunching IRRA*flow* in the European market.

On the regulatory front, the company will focus on applying for CE mark approval for the Hummingbird product line and facilitating the introduction of IRRA*flow* in additional global markets.

Work on production improvements and cost savings will continue in close cooperation with our suppliers.

IRRAS also has a number of product targets for the coming year. The company plans to introduce at least three more product improvements in the IRRA*flow* family, including improvements to the usability of the tube set and better capacity for the catheters.

Significant events after the end of the fiscal year

On March 15, the Board resolved, supported by the authorization granted by the extraordinary general meeting held on March 2, 2020, to carry out a share issue of approximately SEK 217 million with preferential rights to the company´s existing shareholders. At the date of publication of the annual report the rights issue is not yet completed. The record date for participation in the rights issue is March 24, 2020. The subscription period in the rights issue is expected to commence on March 26, 2020 and close April 9, 2020.

COVID-19´s impact on IRRAS is still difficult to assess and continuous evaluations are made of how the company will be affected. Although sales may be affected by other priorities in healthcare over a period of time, the basic need remains in IRRA*flow*´s and Hummingbird´s target patient groups. IRRAS keeps a close dialogue with suppliers and customers to follow the development. The sales methods have changed to be able to run efficient meetings virtually and provide training through video conference.

The IRRAS share and ownership structure

The number of shares increased by 4,800,000 during the year, totaling 28,817,974 at December 31, 2019. In addition, IRRAS has five incentive programs outstanding for employees and key personnel. Currently, the programs could increase the number of shares by 3,782,000. There is only one type of share, and there is no difference or limitation under the law or the Articles of Association regarding the transferability of the shares, voting rights, rights to company assets or dividends. The shares have a quota value of SEK 0.03 per share.

SHAREHOLDERS AS OF DECEMBER 31, 2019 AND KNOWN CHANGES THEREAFTER

	No. of shares	% of shares/votes
Lexington Holding Assets Ltd (BVI)	3,155,727	10.95%
F.EX Endotherapy Limited	2,855,790	9.91%
Bacara Holdings Limited	1,430,725	4.96%
Consensus Asset Management AB	1,420,577	4.93%
The Fourth Swedish National Pension Fund	1,245,000	4.32%
Dr. Kleanthis G. Xanthopoulos	842,878	2.92%
Dr Saeid AB	833,725	2.89%
Danica Pension	704,587	2.44%
March Asset Management	588,769	2.04%
The Carl-Olof and Jenz Hamrins Foundation	550,000	1.91%
Total ten largest shareholders	*13,627,778*	*47.29%*
Other shareholders	15,190,196	52.71%
Total number of shares	**28,817,974**	**100.00%**

Personnel

The average number of employees in the Group for 2019 was 35 (21), of whom 4 (3) are in the parent company. The breakdown of the average number of employees by country was 4 (3) in Sweden, 28 (13) in the US and 3 (5) in Germany. The average number of women in the Group was 12 (8) and the average number of men was 23 (13).

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

Quality assurance

IRRAS is certified under ISO 13485:2016. In 2018, IRRAS received an updated ISO 13485:2016 certificate and new CE approval for its control unit and tube set. In 2019, CE approval was also received for the catheter. The control unit and tube set are Class IIb products and the catheter belongs to Class III. FDA clearance was obtained for the IRRA*flow* system in 2018, and clearance for an extended period of use was obtained in 2019. Regulatory approval has also been received in Israel, Kuwait, Costa Rica and Argentina. Work to secure registration clearance is also under way in a number of countries. During the year, the company acquired Hummingbird, which includes ten FDA-cleared products.

Sustainability

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

Guidelines for remuneration to senior executives

The company's starting point is that salary and other terms and conditions of employment are designed to enable the Group to attract and retain qualified senior executives at a reasonable cost to the company. Remuneration to senior executives is to be determined in accordance with IRRAS' remuneration policy. Remuneration to senior executives consists of fixed salary, variable remuneration, pension and other benefits. In order to avoid encouraging senior executives to take unnecessary risks, there must be a fundamental balance between fixed and variable remuneration. Furthermore, IRRAS' Annual General Meeting may, if it so decides, offer long-term incentive programs such as share-based or share price-based incentive programs.

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 both on clear, predetermined and measurable criteria and financial performance, and on individual and business objectives that are defined in advance. Variable remuneration should also be used to encourage IRRAS' long-term value creation. Variable remuneration may not exceed 12 months' fixed salary.

Senior executives are to be offered pension terms that are in accordance with market practice in the respective countries where the individual members are domiciled. Non-monetary benefits are to facilitate the work of senior executives and are to correspond to what is considered reasonable in relation to market practice.

In accordance with the guidelines, fixed salary during the period of notice and severance pay for senior executives are not to exceed 24 months' fixed salary. To the extent the Board members elected by the Annual General Meeting perform work that goes above and beyond the activities of the Board, a fee is to be paid for such work. The remuneration is to be determined in accordance with market practice and be approved by the Board of Directors.

The Board of Directors is authorized to deviate from the guidelines if there are particular reasons to do so in individual cases. Before every Annual General Meeting, the Board of Directors is to consider whether or not to propose additional share-based or share price-based incentive programs to the Annual General Meeting. It is the general meeting of shareholders that resolves on such incentive programs. Incentive programs are intended to promote long-term value growth. New share issues and transfers of securities resolved on by the general meeting of shareholders under the regulations of Chapter 16 of the Companies Act are not covered by these guidelines insofar as the general meeting of shareholders has approved, or intends to approve such resolutions.

Proposed guidelines for salary and other remuneration to senior executives in company management

At the 2020 Annual General Meeting, the Board of Directors will propose the following guidelines for remuneration to senior executives.

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 program where senior executives in company management retain the right to acquire shares in the company in the future. To give an understanding of the company's total remuneration package, the company's incentive program is described for your information in a separate section following the proposal for guidelines for salary and other remuneration to senior executives in company management.

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

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

Different forms of remuneration

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

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

Termination of employment

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

Salary and terms of employment

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

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

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

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

Derogation from the guidelines

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

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

Description of the company's incentive program

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

Parent Company

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

Net revenue for the Parent Company in 2019 totaled SEK 1.6 million (13.1). This amount primarily pertains to invoicing of management fees and other remuneration from subsidiaries. The Parent Company reported an operating loss of SEK –47.4 million (–43.0). Revenue and expenses declined during the year since certain selling and development expenses are now reported by the US subsidiary. As of December 31, 2019, equity in the Parent Company totaled SEK 360.5 million (307.4). The company's registered share capital at December 31, 2019 totaled SEK 864,539, allocated among 28,817,974 shares. The Parent Company's receivables from Group companies consist of long-term loans and current receivables, which amounted to SEK 17.2 million (55.9) at year-end.

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

Corporate governance report

IRRAS AB applies the Swedish Corporate Governance Code. For a description of how the company manages corporate governance issues, refer to the corporate governance report on pages 59–62. The Group's system for internal control and risk management is described in the section "Internal control report" in the corporate governance report.

Proposed appropriation of the company's earnings

The Board proposes that the unappropriated earnings as of December 31, 2019 — SEK 327,947,075 — be carried forward.

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

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

Consolidated statement of profit or loss

AMOUNTS IN TSEK	Note	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Net revenue	5	5,288	5,994
Cost of sales		–38,442	–22,420
Gross loss		**–33,154**	**–16,425**
Other operating income	7	1,083	1,702
Marketing and selling expenses		–43,057	–58,603
Administrative expenses	9	–45,485	–44,394
R&D costs		–29,823	–24,363
Other operating expenses	7	–1,051	–1,245
Operating loss	6	**–151,486**	**–143,328**
Financial income		682	4,819
Financial expenses		–332	–333
Profit from financial items	8	**350**	**4,486**
Loss before tax		**–151,136**	**–138,842**
Income tax	12	–8	–
Net loss for the year		**–151,144**	**–138,842**
Earnings per share before and after dilution, SEK	26	–5.61	–5.83
Number of shares before dilution, average		26,937,426	23,815,328
Number of shares after dilution, average		26,937,426	23,815,328

Consolidated statement of profit or loss and other comprehensive income

AMOUNTS IN TSEK	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Net loss for the year	**–151,144**	**–138,842**
Other comprehensive income for the year:		
Items that may be subsequently reclassified to profit or loss		
Translation differences for the year on translation of foreign operations	–1,087	–1,140
Other comprehensive income for the year, net of tax	**–1,087**	**–1,140**
Total comprehensive income for the year	**–152,231**	**–139,981**

Consolidated statement of financial position

AMOUNTS IN TSEK	Note	Dec 31, 2019	Dec 31, 2018
ASSETS			
Non-current assets			
Capitalized development expenses	13	36,228	38,090
Patents	13	8,201	2,215
Tangible assets	14	947	624
Right-of-use assets	14	6,225	–
Financial investments	15	–	80,757
Total non-current assets		**51,601**	**121,685**
Current assets			
Inventory	16	14,440	3,352
Advance payments to suppliers		1,531	45
Accounts receivable		2,803	–
Other receivables	17	1,498	1,933
Prepaid expenses and accrued income	18	1,992	960
Current investments	15	55,613	30,065
Cash and cash equivalents		29,514	47,244
Total current assets		**107,391**	**83,599**
TOTAL ASSETS		**158,992**	**205,284**
EQUITY			
Share capital		865	721
Other paid-in capital		537,387	440,208
Reserves		–3,035	–1,948
Retained earnings, including net loss for the year		–403,746	–254,826
Total equity		**131,470**	**184,154**
LIABILITIES			
Non-current liabilities			
Lease liabilities	14	2,022	–
Other provisions		–	370
Total provisions		**2,022**	**370**
Current liabilities			
Lease liabilities	14	4,030	–
Accounts payable		7,481	8,626
Other liabilities		731	2,526
Accrued expenses and deferred income	20	13,258	9,608
Total current liabilities		**25,499**	**20,760**
TOTAL EQUITY AND LIABILITIES		**158,992**	**205,284**

Consolidated statement of changes in equity

	Note	Share capital	Other paid-in capital	Reserves	Retained earnings, including net loss for the year	Total equity
Opening equity January 1, 2018		**710**	**439,611**	**–808**	**–123,482**	**316,030**
Comprehensive income						
Net loss for the year					–138,842	**–138,842**
Other comprehensive income						
Translation differences for the year on translation of foreign operations				–1,140		**–1,140**
Total comprehensive income		**–**	**–**	**–1,140**	**–138,842**	**–139,981**
Transactions with shareholders						
Incentive programs	10				7,498	**7,498**
New share issue		11				**11**
Issue expenses*			597			**597**
Total		11	597	–	7,498	**8,106**
Closing equity December 31, 2018	19	**721**	**440,208**	**–1,948**	**–254,826**	**184,154**

*Reversal of previously reserved issue expenses

Consolidated statement of changes in equity *cont.*

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

Consolidated statement of cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018
Cash flow from operating activities			
Operating loss (EBIT)		–151,486	–143,328
Adjustments for non-cash items			
– Reversal of depreciation/amortization		12,576	8,141
– Other non-cash items		–	370
– Incentive programs	10	2,224	7,442
Interest received		485	569
Interest paid		–145	–160
Tax paid		–8	929
Cash flow from operating activities before changes in working capital		**–136,353**	**–126,036**
Changes in working capital			
Increase/decrease in inventory		–11,146	9,570
Increase/decrease in operating receivables		–4,205	8,939
Increase/decrease in operating payables		–2,038	10,092
Cash flow from operating activities		**–153,742**	**–97,435**
Cash flow from investing activities			
Investments in intangible assets		–14,824	–14,278
Investments in tangible assets		–589	–532
Sale of tangible asset		2	–
Sales of financial investments		55,208	35,096
Cash flow from investing activities		**39,797**	**20,286**
Cash flow from financing activities			
New share issue		105,600	30 744*
Issue expenses		–8,277	–5 568*
Lease liability	14	–1,538	–
Cash flow from financing activities		**95,785**	**25,176**
Cash flow for the period		**–18,160**	**–51,972**
Cash and cash equivalents at the beginning of the period		47,244	98,286
Exchange rate differences in cash and cash equivalents		430	931
Cash and cash equivalents at the end of the period		**29,514**	**47,244**

* Issue proceeds and expenses that were not paid as of December 31, 2017 but were paid during 2018.

Parent Company statement of profit or loss

AMOUNTS IN TSEK	Note	2019-01-01 Dec 31, 2019	2018-01-01 Dec 31, 2018
Net revenue	5	1,551	13,081
Cost of sales		–9,836	–7,965
Gross loss		**–8,284**	**5,116**
Other operating income	7	187	868
Marketing and selling expenses		–1,074	–4,084
Administrative expenses	9	–35,823	–35,654
R&D costs		–1,540	–8,254
Other operating expenses	7	–850	–1,010
Operating loss	6	**–47,384**	**–43,018**
Other interest income and similar profit/loss items		1,042	3,784
Interest expenses and similar profit/loss items		–92	–330
Profit from financial items	8	**950**	**3,454**
Loss before tax		**–46,434**	**–39,565**
Tax on loss for the year	12	–	–
Net loss for the year		**–46,434**	**–39,565**

Parent Company statement of profit or loss and other comprehensive income

	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Net loss for the year	**–46,434**	**–39,565**
Other comprehensive income for the year, net of tax	**–**	**–**
Total comprehensive income for the year	**–46,434**	**–39,565**

Parent Company balance sheet

AMOUNTS IN TSEK	Note	Dec 31, 2019	Dec 31, 2018
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenses	13	36,228	38,090
Patents	13	1,898	2,215
Total intangible assets		**38,126**	**40,305**
Tangible assets			
Equipment, tools, fixtures and fittings	14	310	416
Total tangible assets		**310**	**416**
Financial assets			
Participations in Group companies	24	232,980	68,745
Receivables from Group companies	11	17,226	29,595
Other securities held as non-current assets	15	–	80,757
Total financial assets		**250,206**	**179,097**
Total non-current assets		**288,642**	**219,818**
Current assets			
Current receivables			
Receivables from Group companies	11	–	26,330
Other receivables	17	859	1,206
Prepaid expenses and accrued income	18	1,865	504
Total current receivables		**2,724**	**28,040**
Current investments	15	**55,613**	**30,065**
Cash and bank balances		**22,670**	**37,342**
Total current assets		**81,008**	**95,446**
TOTAL ASSETS		**369,650**	**315,265**

Parent Company balance sheet *cont.*

AMOUNTS IN TSEK	Note	Dec 31, 2019	Dec 31, 2018
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19	865	721
Fund for development expenses		31,720	31,779
Total restricted equity		**32,584**	**32,500**
Non-restricted equity			
Share premium reserve		503,810	406,631
Retained earnings		–129,429	–92,148
Net loss for the year		–46,434	–39,565
Total non-restricted equity		**327,947**	**274,919**
Total equity		**360,532**	**307,419**
Provisions			
Other provisions	21	–	370
Total provisions		**–**	**370**
Current liabilities			
Accounts payable		2,814	1,705
Other liabilities		287	115
Accrued expenses and deferred income	20	6,018	5,655
Total current liabilities		**9,118**	**7,476**
TOTAL EQUITY AND LIABILITIES		**369,650**	**315,265**

Parent Company statement of changes in equity

	Restricted equity		Non-restricted equity			
AMOUNTS IN TSEK	Share capital	Fund for development expenses	Share premium reserve	Retained earnings	Net loss for the year	Total equity
Equity January 1, 2018	**710**	**23,401**	**406,034**	**–46,099**	**–45,169**	**338,877**
Comprehensive income						
Appropriation of earnings as decided at AGM				–45,169	45,169	**–**
Net loss for the year					–39,565	**–39,565**
Total comprehensive income	**–**	**–**	**–**	**–45,169**	**5,604**	**–39,565**
Transactions with shareholders						
Incentive programs				7,498		**7,498**
New share issue	11					**11**
Issue expenses			597*			**597**
Total transactions with shareholders	**11**	**–**	**597**	**7,498**	**–**	**8,106**
Provision, fund for development expenses		8,378		–8,378		**–**
Equity December 31, 2018	**721**	**31,779**	**406,631**	**–92,148**	**–39,565**	**307,419**

* Reversal of previously reserved issue expenses

Parent Company statement of changes in equity *cont.*

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

Parent Company statement of cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Cash flow from operating activities			
Operating loss (EBIT)		–47,384	–43,018
Adjustments for non-cash items			
– Reversal of impairment		10,249	8,108
– Non-cash provisions		–	370
– Incentive programs	10	1,939	4,313
Interest received		845	492
Interest paid		–34	–330
Cash flow from operating activities before changes in working capital		**–34,384**	**–30,065**
Changes in working capital			
Increase/decrease in other current receivables		24,879	–10,804
Increase/decrease in operating payables		1,213	2,732
Total changes in working capital		**26,093**	**–8,073**
Cash flow from operating activities		**–8,291**	**–38,137**
Cash flow from investing activities			
Investments in participations in subsidiaries		–163,950	–40,979
Investments in intangible assets		–7,963	–14,278
Investments in tangible assets		–	–343
Sales of financial investments		55,208	35,096
Repayment of loans to subsidiaries		13,002	–15,008
Cash flow from investing activities		**–103,704**	**–35,511**
Cash flow from financing activities			
New share issue		105,600	30 744*
Issue expenses		–8,277	–5 568*
Cash flow from financing activities		**97,323**	**25,176**
Cash flow for the period		**–14,672**	**–48,472**
Cash and cash equivalents at the beginning of the period		37,342	85,814
Cash and cash equivalents at the end of the period		**22,670**	**37,342**

*Issue proceeds and expenses that were not paid as of December 31, 2017 but were paid during 2018.

Notes

NOTE 1 GENERAL INFORMATION

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

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

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

NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of preparation

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

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

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

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

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

All applicable standards which became effective in 2019 up until the signing of this report have been applied to the consolidated financial statements.

IFRS 16 Leases

IFRS 16 Leases requires that lessees recognize assets and liabilities attributable to all leases, with the exception of leases that are shorter than 12 months and/or relate to a low value. The standard replaces IAS 17 Leases and associated interpretations. In IFRS 16, the distinction between an operating lease and a finance lease is eliminated and replaced with an approach based on the right of use and obligation to make ongoing payments as a lessee.

The Group has chosen the modified retrospective approach for the transition to IFRS 16, which entails that the comparative figures have not been restated to reflect the new requirements.

The Group has chosen to apply the exemption rules regarding short-term leases for the transition to IFRS 16, and the transition has not had any impact on the consolidated income statement and balance sheet since the leases were limited and consisted primarily of rent for premises with a lease term of less than 12 months.

Reconciliation of operating lease obligations	
Obligation for operating leases December 31, 2018	3,379
Less short-term leases	–3,379
Recognized lease liability January 1, 2019	**0**

Standards, amendments and interpretations of existing standards that will become effective in 2020 or later and are expected to impact the financial statements

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

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

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

Consolidated financial statements

Subsidiaries

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

Segment reporting

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

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

Earnings per share

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

Foreign currency translation

Functional currency and reporting currency

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

Transactions and balance sheet items

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

Group companies

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

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

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

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

Intangible assets

Capitalized expenses for development and similar activities

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

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

Patents

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

Amortization period for intangible assets

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

Tangible assets

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

In the Group, tangible assets consist of equipment.

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

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

Depreciation period for tangible assets

Equipment, tools, fixtures and fittings	3–5 years

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

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

Leases

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

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

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

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

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

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

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

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

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

Impairment of non-financial assets

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

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

Impairment of tangible assets

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

Impairment of intangible assets

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

Financial instruments

General principles

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

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

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

Classification of financial assets and liabilities

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

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

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

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

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

Impairment of financial assets

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

Accounts receivable

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

Cash and cash equivalents

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

Share capital

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

Accounts payable

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

Borrowings

The Group currently has no borrowings. Borrowings (including from credit institutions, related parties and other long-term borrowings) are initially recognized at fair value, net of transaction costs. Borrowings are subsequently recognized at amortized cost, and any difference between the amount received (net of transaction costs) and the repayment amount is recognized in profit or loss over the term of the loan applying the effective interest method.

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

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

Inventory

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

Current and deferred tax

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

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

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

Employee benefits

Pension obligations

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

The company has provided pension commitments whose value is linked to separate company-owned endowment insurances. The value of the endowment insurances covers the commitment to pay pensions at any given time. The company's obligation is limited to the amount for which the endowment insurance was acquired. The risk in the development of the endowment insurance, and thereby the pension that later results from the endowment insurance, is borne by the employee. Since the pension commitment and the value of the endowment insurances always correspond with each other, the carrying amount is zero. The Group transferred the endowment insurances in 2019 and no longer has any commitments. The gross amount is indicated in Note.

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

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

Share-based remuneration

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

Incentive programs

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

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

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

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

Share rights

There was an agreement between IRRAS and the CEO of IRRAS that entitled the CEO to 236,618 shares upon the company's listing and raising of capital in 2017, and 475,603 shares when 510(k) clearance was obtained. In the third quarter of 2017, an agreement was signed that the three largest owners of the company on a pro rata basis would provide the CEO with half of the shares in the shareholder program. Half of the shares the CEO received thus gave rise to no dilution. From an IFRS perspective, however, 100% of the shares were expensed from the signing of the agreement to the exercise date. The listing and raising of capital in November 2017 entitled the CEO to 236,618 shares, which were distributed in early 2018, and the US registration clearance entitled him to 475,603 shares, which were also distributed in 2018.

The value of the performance-based share rights, which were allotted free of charge, was expensed over the vesting period, which corresponded to the period when the remuneration was vested and the services were performed. The value was calculated as of the allotment date and recognized in equity. The assessment of the number of shares expected to be vested is based on non-market-based vesting conditions. The estimates were re-examined at the end of every reporting period; any deviations were recognized in profit or loss and equivalent adjustments were made to equity.

Provisions

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

Revenue recognition

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

Sales of goods

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

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

Government grants and official remuneration

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

Interest income

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

Accounting policies in the Parent Company

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

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

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

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

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

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

NOTE 3 FINANCIAL RISK MANAGEMENT

In the course of its operations, the Group is exposed to various types of financial risks including currency risk, interest rate risk, credit risk and liquidity/financing risk. The Group's overall risk management policy focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on earnings and liquidity due to financial risks. As of December 31, 2019, the Group's financial risks were limited since the business is still in a relatively early stage.

The CEO and Board of Directors of each company are responsible for risk management, in accordance with guidelines established by the Board. The risk function includes identifying and evaluating financial risks. The Group does not apply hedge accounting in accordance with the regulations of IAS 39.

Currency risk

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

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

Transaction exposure

If the average exchange rate for the EUR against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's sales would have been positively/negatively impacted by approximately TSEK 75 (606). If the average exchange rate for the USD against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's sales would have been positively/negatively impacted by approximately TSEK 454 (0).

Translation exposure

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

Of the Group's loss before tax during the fiscal year, approximately TSEK –341 (–5,700) was attributable to the German subsidiary, and net assets totaled TSEK –16,896 (–16,316) as of the balance sheet date. If the average exchange rate for the EUR against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's loss before tax for the fiscal year would have been impacted by approximately TSEK 34 (570) upon translation of the foreign subsidiary's statement of profit or loss. If the exchange rate for the EUR against the SEK had been 10% higher/lower compared to the closing exchange rate at the end of the fiscal year, with all other variables unchanged, the Group's net assets at the end of the fiscal year would have been impacted by approximately TSEK 1,690 (1,632) upon the translation of the foreign subsidiary.

Of the Group's loss before tax during the fiscal year, approximately TSEK –105,892 (–96,562) was attributable to the US subsidiary, and net assets totaled TSEK –20,961 (–36,292) as of the balance sheet date. If the average exchange rate for the USD against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's loss before tax for the fiscal year would have been impacted by approximately TSEK 10,590 (9,656) upon translation of the foreign subsidiary's statement of profit or loss. If the exchange rate for the USD against the SEK had been 10% higher/lower compared to the closing exchange rate at the end of the fiscal year, with all other variables unchanged, the Group's net assets at the end of the fiscal year would have been impacted by approximately TSEK 2,096 (3,629) upon the translation of the foreign subsidiary.

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

Interest rate risk

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

Sensitivity analysis – interest rate risk.

If the interest rate level during the year had been 100 basis points higher, net interest income and equity would have been affected by TSEK 547 (768) before tax. The sensitivity analysis is based on an interest rate scenario that company management considers to be reasonably possible over the coming 12 months.

Credit risk

Credit risk, or counterparty risk, is the risk that the counterparty to a financial transaction may default on the maturity date. Credit risk is managed at the Group level through a careful evaluation of new counterparties, and subsequently, a continual evaluation of existing counterparties. Credit risks are primarily attributable to accounts receivable, investments in bonds and balances in banks and financial institutions. As of December 31, 2019, outstanding claims against third parties were minimal, apart from investments in bonds and bank balances.

Financial investments primarily comprise securities issued by major listed credit institutions, 46% (41) of which have a credit rating of A or higher. 54% (50) of the holdings could not be given a credit rating, but are deemed to correspond to a rating of BB from Standard & Poor's. Considering the issuers' high level of creditworthiness, the credit risk associated with these investments is deemed to be low and the expected credit losses are deemed to be negligible.

	Group		Parent Company	
Financial investments (amounts in TSEK)	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Bonds, rating				
A	5,064	15,113	5,064	15,113
A–	20,260	30,321	20,260	30,321
BBB	–	10,069	–	10,069
N/A	30,289	55,317	30,289	55,317
Total	**55,613**	**110,821**	**55,613**	**110,821**

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

	Group		Parent Company	
Cash and cash equivalents (amounts in TSEK)	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Rating				
AA–	22,670	37,342	22,670	37,342
A+	6,844	9,902	–	–
Total	**29,514**	**47,244**	**22,670**	**37,342**

Maturity analysis

Other financial liabilities in the Group comprise operating payables and lease liabilities. Operating payables fall due for payment within one year. The nominal undiscounted cash flow that is to be settled within one year corresponds to the carrying amount as of the balance sheet date. Lease liabilities are effectively secured as the rights to the leased assets recognized in the financial statements revert to the lessor in the event of default. Of the total lease liability, SEK 4 million falls due within 12 months and SEK 2 million within 24 months.

Financial instruments by category

Group	Dec 31, 2019 Amortized cost	Dec 31, 2018 Amortized cost
Assets in the balance sheet		
Financial investments	–	80,757
Current tax receivables	–	–
Accounts receivable	2,803	–
Other receivables	1,498	1,933
Accrued income	67	87
Current investments	55,613	30,065
Cash and cash equivalents	29,514	47,244
Total	**89,496**	**160,085**

Group	Dec 31, 2019 Other financial liabilities	Dec 31, 2018 Other financial liabilities
Liabilities in the balance sheet		
Non-current lease liabilities	2,022	–
Accounts payable	7,481	8,626
Lease liabilities	4,030	–
Other liabilities	731	2,526
Accrued expenses	13,258	9,608
Total	**27,522**	**20,760**

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

Liquidity risk/financing risk and going concern

As of December 31, 2019, the Group had available liquidity of TSEK 29,514. Liquidity consists of bank balances. From a capital structure perspective, current investments and financial investments are also included in net debt even though they are not classified as cash and cash equivalents.

At year-end, there were no external borrowings in the Group. The objective regarding the capital structure is to safeguard the Group's ability to continue its operations in order to generate returns for shareholders and benefits for other stakeholders, and to maintain an optimal capital structure to minimize the cost of capital.

The Group's available cash and cash equivalents do not cover the liquidity needed to pursue planned operations over the next 12 months. In light of this, the Board has resolved, supported by the authorization granted by the extraordinary general meeting held on March 2, 2020, to carry out a share issue of approximately SEK 217 million with preferential rights to the company´s existing shareholders. The rights issue is fully underwritten and the Board deems the company's prospects for financing its operations to be favorable. At the date of publication of the annual report the rights issue is not yet completed. If sufficient financing cannot be obtained, there is a risk that the company may not have the necessary prerequisites to continue as a going concern.

	Group		Parent Company	
Net debt (amounts in TSEK)	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Interest-bearing liabilities				
Interest-bearing liabilities				
Cash and cash equivalents	–29,514	–47,244	–22,670	–37,342
Current investments	–55,613	–30,065	–55,613	–30,065
Financial investments	–	–80,757	–	–80,757
Lease liabilities	6,052	–	–	–
Net debt	**–79,075**	**–158,066**	**–78,283**	**–148,163**

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

Critical accounting estimates and assumptions

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

Incentive programs

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

The vesting and exercise periods of the options span several fiscal years, and assumptions and estimates have therefore been made regarding the probable exercise date. Furthermore, additional assumptions and estimates were made concerning the inputs for the valuation of the options. One of the incentive programs contains non-market-based performance conditions. This means that estimates need to be made concerning when it will be more likely than not that the conditions will be met; only at that point will an expense be recognized for the incentive program.

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

Capitalized development expenses

IRRAS regularly assesses the value of capitalized development expenses.

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

NOTE 5 NET REVENUE

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

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Germany	–	3,298	1,551	4,967
Europe, excluding Germany	–	2,696	–	–
USA	4,542	–	–	8,115
Other countries	746	–	–	–
Total net revenue by geographic market	**5,288**	**5,994**	**1,551**	**13,081**

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

NOTE 6 BREAKDOWN OF EXPENSES BY TYPE OF COST

Operating profit/loss by type of cost

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Net revenue	5,288	5,994	1,551	13,081
Capitalized work for own account	7,963	14,278	7,963	14,278
Other operating income	1,083	1,702	187	868
Raw materials and consumables	–3,278	–6,701	–	–
Other external costs	–70,162	–91,933	–26,774	–42,852
Personnel costs	–78,754	–57,281	–19,213	–19,275
Depreciation, amortization and impairment	–12,576	–8,141	–10,249	–8,108
Other operating expenses	–1,051	–1,245	–850	–1,010
Operating loss (EBIT)	**–151,486**	**–143,328**	**–47,384**	**–43,018**

NOTE 7 OTHER OPERATING INCOME AND OTHER OPERATING EXPENSES

Other operating income

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Exchange differences	651	1,525	167	868
Gain on disposal of equipment	3	–	–	–
Gain on disposal of right-of-use assets	1	–	–	–
Other	429	177	20	–
Total other operating income	**1,083**	**1,702**	**187**	**868**

Other operating expenses

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Exchange differences	1,030	1,245	850	1,010
Loss on disposal of equipment	21	–	–	–
Total other operating expenses	**1,051**	**1,245**	**850**	**1,010**

NOTE 8 FINANCIAL ITEMS

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Financial income				
Exchange differences	–	4,250	–	2,894
Interest income	485	569	845	889
Other financial income	197	–	197	–
Total financial income	**682**	**4,819**	**1,042**	**3,784**
Financial expenses				
Exchange differences	187	–	59	–
Interest expenses	37	160	34	156
Interest expenses on leases	107	–	–	–
Other financial expenses	–	173	–	173
Total financial expenses	**332**	**333**	**92**	**330**
Profit from financial items, net	**350**	**4,486**	**950**	**3,454**

NOTE 9 AUDIT FEES

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

During 2018 and 2019, KPMG invoiced for consulting services in connection with the company's preparations for a change of listing, but the majority of this work was carried out in 2018.

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
KPMG				
Audit engagement	1,011	770	1,011	770
Other audit engagements	24	–	24	–
Other advisory services	483	2,280	483	2,280
Total	**1,517**	**3,050**	**1,517**	**3,050**

NOTE 10 SALARIES, OTHER REMUNERATION AND SOCIAL SECURITY EXPENSES

Costs for salaries, other remuneration and social security expenses

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Salaries and remuneration	62,197	41,505	14,054	12,675
Social security expenses	5,308	3,272	2,149	1,464
Incentive programs	2,224	7,442	1,939	4,313
Pension costs	558	673	558	673
Total	**70,287**	**52,891**	**18,700**	**19,124**

Average number of employees

	Jan 1, 2019– Dec 31, 2019		Jan 1, 2018– Dec 31, 2018	
	Average number of employees	Of whom men	Average number of employees	Of whom men
Parent Company				
Sweden	4	48%	3	64%
Total in the Parent Company	**4**	**48%**	**3**	**64%**
Subsidiaries				
Germany	3	67%	5	67%
USA	28	69%	13	57%
Total in subsidiaries	**31**	**69%**	**18**	**60%**
Group total	**35**	**67%**	**21**	**60%**

Salaries and other remuneration allocated among senior executives

	Jan 1, 2019– Dec 31, 2019			Jan 1, 2018– Dec 31, 2018			
	Salaries and other remuneration	Pension costs	Incentive programs	Salaries and other remuneration	Pension costs	Incentive programs	Fees invoiced
Group							
Board members, CEOs and other senior executives, of whom:	25,010	645	2,569	16,583	492	5,315	783
President and CEO Kleanthis G. Xanthopoulos	9,922	–	1,726	7,117	–	4,313	–
Chairman of the Board Anders P. Wiklund	553	–	–	500	–	–	–
Board member Saied Esmaeilzadeh	83	–	–	200	–	–	–
Board member Anita Tollstadius	282	–	–	200	–	–	–
Board member Marios Fotiadis	223	–	–	200	–	–	–
Board member Eva Nilsagård	323	–	–	75	–	–	–
Board member Catherine Gilmore-Lawless	254	–	–	–	–	–	–
Other senior executives*	13,370	645	843	8,291	492	1,002	783
Total	**25,010**	**645**	**2,569**	**16,583**	**492**	**5,315**	**783**
Parent Company							
Board members, CEOs and other senior executives, of whom:	14,097	645	1,746	10,138	492	4,313	–
President and CEO Kleanthis G. Xanthopoulos	9,922	–	1,726	7,117	–	4,313	–
Chairman of the Board Anders P. Wiklund	553	–	–	500	–	–	–
Board member Saied Esmaeilzadeh	83	–	–	200	–	–	–
Board member Anita Tollstadius	282	–	–	200	–	–	–
Board member Marios Fotiadis	223	–	–	200	–	–	–
Board member Eva Nilsagård	323	–	–	75	–	–	–
Board member Catherine Gilmore-Lawless	254	–	–	–	–	–	–
Other senior executives*	2,457	645	20	1,846	492	–	–
Total	**14,097**	**645**	**1,746**	**10,138**	**492**	**4,313**	**–**

* Other senior executives refers to members of the management group, except the CEO. In 2019, this included Will Martin, Kellie Fontes, Adam Sampson, Sabina Berlin (as of June 2019), Vinny Podichetti (as of March 2019 until September 2019), Fredrik Alpsten (until June 2019), and Lance Boling (until June 2019).
In 2018, the management group comprised Fredrik Alpsten, Lance Boling, Will Martin (as of March 2018), Kellie Fontes (as of February 2018) and Christos Panatopoulos (until May 2018).

Gender distribution among Board members and other senior executives

	Jan 1, 2019–Dec 31, 2019		Jan 1, 2018–Dec 31, 2018	
	Number on balance sheet date	Of whom men	Number on balance sheet date	Of whom men
Group				
Board members	6	50%	6	67%
CEO and other senior executives	5	60%	5	80%
Group total	**11**	**55%**	**11**	**73%**
Parent Company				
Board members	6	50%	6	67%
CEO and other senior executives	2	50%	2	100%
Parent Company total	**8**	**50%**	**8**	**75%**

Share-based remuneration

IRRAS has introduced share-based remuneration for employees in the form of incentive programs and share rights for the purpose of motivating and rewarding employees through participation in order to benefit the company's long-term interests. The fair value of the options at the start of the program is recognized as a personnel cost with a corresponding increase directly in equity. The cost of the incentive programs awarded to employees in the subsidiaries is recognized in the Parent Company's accounts as a participation in Group companies. See Note 24.

	Group		Parent Company	
	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018	Jan 1, 2019–Dec 31, 2019	Jan 1, 2018–Dec 31, 2018
Cost of share-based remuneration				
Incentive program 1	–69	4,340	1,426	2,913
Incentive program 2	89	1,061	–	–
Incentive program 3	–	–	–	–
Incentive program 4	–	–	–	–
Incentive program 5	2,204	641	514	–
Share rights program	–	1,400	–	1,400
Total	**2,224**	**7,442**	**1,939**	**4,313**

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

Incentive program 1

In May 2016, employees were allotted 1,900,000 options at no cost, which based on the terms of employment are vested over periods of one to four years, respectively, with one quarter vested annually starting in May 2016. The deadline to exercise the vested options is September 30, 2025. As of December 31, 2019, there were 1,708,334 options outstanding, of which 1,310,476 were issued to company management.

Incentive program 2

In May 2017, employees were allotted 350,000 options — and 300,000 in 2018 — at no cost, which based on the terms of employment are vested over periods of one to three years, respectively, with one third vested annually starting in January 2017. The first third of the options are vested after one year; the remaining options are subsequently vested pro rata on a monthly basis. The deadline to exercise the vested options is October 31, 2021. As of December 31, 2019, there were 519,912 options outstanding, of which 265,000 were issued to company management.

Incentive program 3

The total program comprises 400,000 warrants. The warrants have no vesting conditions. The deadline to exercise the vested warrants is October 31, 2020. 260,000 warrants were issued in 2017 and 60,000 warrants were issued in 2018, all of which were acquired at market value. In total, 320,000 warrants had been issued as of December 31, 2019, of which 100,000 were issued to company management.

Incentive program 4

The total program comprises 100,000 warrants. The warrants have no vesting conditions. The deadline to exercise the vested warrants is October 31, 2020. 100,000 warrants were issued to the Chairman of the Board in September 2017, all of which were acquired at market value.

Incentive program 5

The total program comprises 732,000 options, which based on the terms of employment are vested over periods of one to three years, respectively, with one third vested annually starting in June 2018. The deadline to exercise the vested options is June 15, 2022. As of December 31, 2019, there were 635,237 options outstanding free of charge, of which 60,737 were issued to company management.

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

34% (11% for 2019, 11% for 2020 and 12% for 2021) of the options can only be exercised by the employee if the company meets the sales targets set by the Board for 2019, 2020 and 2021. The sales targets for 2020 and 2021 are currently being revised and will be linked to the company's externally communicated financial objectives.

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

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

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

Share rights program

There was an agreement between IRRAS and the CEO of IRRAS that entitled the CEO to 236,618 shares upon the company's listing and raising of capital in 2017, and 475,603 shares when 510(k) clearance was obtained. In the third quarter of 2017, an agreement was signed that the three largest owners of the company on a pro rata basis would provide the CEO with half of the shares in the shareholder program. While half of the shares the CEO receives give rise to no dilution, the cost of 100% of the shares was expensed during the period from the signing of the agreement to the exercise date. Both conditions have been met, and the CEO received his vested shares in 2018.

	Incentive programs					
	Program 1	Program 2	Program 3	Program 4	Program 5	Share rights
Number of personnel options/share rights allotted						
As of Dec 31, 2017	**1,860,000**	**350,000**	**260,000**	**100,000**	**–**	**712,221**
Forfeited during the period	–	–	–	–	**–**	**–**
Exercised during the period						–712,221
Allotted during the period	20,000	293,000	60,000	–	268,750	–
As of Dec 31, 2018	**1,880,000**	**643,000**	**320,000**	**100,000**	**268,750**	**0**
Forfeited during the period	–187,142	–130,000	–	–	–187,000	–
Exercised during the period	–	–	–	–	–	–
Allotted during the period	15,476	6,912	–	–	553,487	–
As of Dec 31, 2019	**1,708,334**	**519,912**	**320,000**	**100,000**	**635,237**	**–**

	No. outstanding as of Dec 31, 2019	No. vested as of Dec 31, 2019	Exercise price	Share price on valuation date, range	Volatility, expected	Option value per share, range	Expected dividend per share	Maturity
Personnel options/share rights per year								
Incentive program 1	1,708,334	1,676,429	13.6	25.0	30%	11.5–12.2	0	Sep 30, 2025
Incentive program 2	519,912	382,944	35.0	30.0	30%	1.9–4.8	0	Oct 31, 2021
Incentive program 3	320,000	–	50.0	30.0	30%	1.7	0	Oct 31, 2020
Incentive program 4	100,000	–	50.0	30.0	30%	1.7	0	Oct 31, 2020
Incentive program 5	635,237	37,088	25.86	24.4–36.9	30%	2.6–12.9	0	Jun 15, 2022
Share rights program	–	–	0.0	13.5–28.0	30%	N/A	0	–
Total incentive programs/share rights	**3,283,483**							

Defined-contribution plans

There are defined-contribution pension plans that are safeguarded through insurance in SPP. The fees for the year for pension insurance signed with SPP totaled TSEK 558 (268).

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Summary of pension benefits				
Pension cost safeguarded through endowment insurance	1,561	1,525	1,561	1,525
Total	**1,561**	**1,525**	**1,561**	**1,525**

There were other pension plans whose outcomes are linked to the trends for individually signed endowment insurances. The value of the endowment insurance covers the commitment to pay pensions at any given time, but not the obligation to pay special employer's contributions in conjunction with the pension being paid. The risk in the development of the endowment insurance, and thereby the pension that later results from the endowment insurance, is borne by the employee. The endowment insurance has been pledged as a security to the person entitled to the pension. No portion of the provision for the year is covered by the Pension Obligation Guarantee Act. The endowment insurance is recognized in profit or loss including changes in value. The pension commitment and the value of the endowment insurances correspond with each other, which means that the carrying amount is zero. The endowment insurances were transferred during the year. Gross amounts are presented in the table.

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Pension obligation				
Opening capital value	1,525	–	1,525	–
Cost for the year	1,364	1,699	1,364	1,699
Change in capital value	197	–173	197	–173
Transferred pension obligation	–3,086	–	–3,086	–
Closing capital value	**–**	**1,525**	**–**	**1,525**

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Separable asset				
Opening fair value	1,525	–	1,525	–
Signed endowment insurances for the year	1,364	1,699	1,364	1,699
Return for the year	197	–173	197	–173
Transferred assets	–3,086	–	–3,086	–
Closing fair value	**–**	**1,525**	**–**	**1,525**
Carrying amount	**–**	**0**	**–**	**0**

NOTE 11 RELATED-PARTY TRANSACTIONS

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

Parent Company	**Dec 31, 2019**	**Dec 31, 2018**
Receivables from Group Companies, non-current	17,226	29,595
Receivables from Group Companies, current	–	26,330

During the fiscal year, Parent Company sales regarding management fees to subsidiaries totaled TSEK 1,551 (4,967) and allocation of earnings to subsidiaries totaled TSEK 0 (8,115), which corresponds to 100% of sales. Purchases from subsidiaries regarding allocation of earnings amounted to TSEK 6,109 (0). No portion of this amount was outstanding on the balance sheet date.

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

	Group/Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Consultancy fees invoiced		
Chairman of the Board Anders P. Wiklund	–	145
CEO Dr. Kleanthis G. Xanthopoulos	–	1,730
Shareholder Dr. Christos Panotopoulos	–	250
Total	**–**	**2,125**

The Group leased offices from a party related to President and CEO Kleanthis G. Xanthopoulos until April 2019. The cost for the year totaled TSEK 38 (104). The Group also purchased office equipment from a party related to President and CEO Kleanthis G. Xanthopoulos. The cost for the year totaled TSEK 231 (179).

President and CEO Kleanthis G. Xanthopoulos had a consulting agreement with IRRAS via his company Helios Capital starting in 2015, in accordance with which he has invoiced for services rendered to the company (such as being its CEO) and for the costs he has incurred (such as travel expenses). The consulting agreement expired on November 22, 2017 and Kleanthis G. Xanthopoulos is now employed by IRRAS AB. Payments in 2018 relate to remuneration for 2017. For further information, refer to Note 10.

D. Christos Panotopoulos, the company's second-largest owner and Chief Scientific Officer until May 31, 2018, offered IRRAS consulting services with respect to his medical expertise via his company F.EX.Endotherapy Ltd. This agreement also entitled Christos Panotopoulos to invoice IRRAS for other costs such as travel expenses. The agreement expired on October 31, 2018. Christos Panotopoulos was previously a member of the management group and an ordinary Board member until September 1, 2017. See Note 10 Other employees.

Chairman Anders P. Wiklund had a consulting agreement with IRRAS until August 22, 2017 which entitled him to remuneration for the work he performed for the company. He was also entitled to invoice IRRAS for other costs such as travel expenses. In 2018, he invoiced for costs that are not included in the Board fee.

Transactions with related parties took place on market terms.

NOTE 12 INCOME TAX

	Group		**Parent Company**	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Current tax for the year	–	–	**–**	**–**
Current tax attributable to previous years	8	–	–	–
Total tax on net loss for the year	**8**	**–**	**–**	**–**

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

	Group		**Parent Company**	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Loss before tax	–151,136	–138,842	–46,434	–39,565
Income tax calculated according to the Group's applicable tax rate	32,343	30,545	9,937	8,704
Non-taxable income	42	–	42	–
Non-deductible expenses	–903	–2,191	–837	–1,425
Unrecognized deductible expenses	1,771	–131	1,771	–131
Loss carryforwards for which no deferred income tax asset was recognized	–42,234	–35,131	–10,913	–7,148
Tax effect of utilized, previously not measured, loss carryforwards	–	95	–	–
Effects of foreign tax rates	8,980	6,813	–	–
Adjustment of current tax for previous years	8	–	–	–
Income tax	**8**	**0**	**0**	**0**

The Group's effective tax rate was deemed to be 21.4% (22.0), which is the tax rate for the Swedish Parent Company. The effect of foreign tax rates is therefore attributable to the fact that the tax rate in the countries where the subsidiaries operate is different to that of the Group. The tax rate applied for Germany is 31% (31) and the tax rate applied for the US is 29.85% (29.85). In the period from 2019 until 2022, the Parent Company's tax rate will change. For 2019 to 2020, the tax rate will be 21.4 percent. For 2021, it will be lowered to 20.6%.

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

	Group		Parent Company	
	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018	Jan 1, 2019– Dec 31, 2019	Jan 1, 2018– Dec 31, 2018
Accumulated loss carryforwards	437,237	276,068	214,527	163,533

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

NOTE 13 INTANGIBLE ASSETS

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

	Group		Parent Company	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Capitalized development expenses				
Opening cost	49,129	34,851	49,129	34,851
Assets capitalized during the year	7,963	14,278	7,963	14,278
Closing accumulated cost	**57,092**	**49,129**	**57,092**	**49,129**
Opening amortization	–11,038	–3,336	–11,038	–3,336
Amortization for the year	–9,826	–7,703	–9,826	–7,703
Closing accumulated amortization	**–20,864**	**–11,038**	**–20,864**	**–11,038**
Closing carrying amount	**36,228**	**38,090**	**36,228**	**38,090**

	Group		Parent Company	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Patents				
Opening cost	4,429	4,429	4,429	4,429
Purchases	6,758	–	–	–
Closing accumulated cost	**11,188**	**4,429**	**4,429**	**4,429**
Opening amortization	–2,215	–1,898	–2,215	–1,898
Amortization for the year	–772	–316	–316	–316
Closing accumulated amortization	**–2,987**	**–2,215**	**–2,531**	**–2,215**
Closing carrying amount	**8,201**	**2,215**	**1,898**	**2,215**

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

NOTE 14 TANGIBLE ASSETS

	Group		Parent Company	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Opening cost	784	247	532	189
Purchases	594	534	–	343
Sales and disposals	–47	–	–	–
Exchange differences	8	2	–	–
Closing accumulated cost	**1,339**	**784**	**532**	**532**
Opening depreciation	–161	–40	–116	–27
Sales and disposals	26	–	–	–
Depreciation for the year	–257	–120	–106	–89
Exchange differences	–1	–1	–	–
Closing accumulated depreciation	**–392**	**–161**	**–223**	**–116**
Closing carrying amount	**947**	**624**	**310**	**416**

Leases

Right-of-use assets	**Dec 31, 2019**	**Dec 31, 2018**
Properties	6,225	–
Vehicles	0	–

In 2018, the Group's leases comprised only short-term leases and were recognized as operating leases. See Note 22. In 2019, leases were signed for IRRAS Inc which extend until July 31, 2021, and the Group signed and terminated a lease concerning a vehicle. Lease payments are discounted applying an incremental borrowing rate of 3.5%.

Group	**Dec 31, 2019**	**Dec 31, 2018**
Opening cost	–	–
Acquisitions for the year	8,074	–
Completed obligations	–211	–
Accumulated depreciation	–1,638	–
Closing carrying amount	**6,225**	**–**
Lease liabilities		
Current	4,030	–
Non-current	2,022	–
Closing carrying amount	**6,052**	**–**

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

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

Equipment, tools, fixtures and fittings **Group**	**2019**	**2018**
Depreciation of right-of-use assets		
Properties	–1,638	–
Vehicles	–42	–
Disposal of right-of-use assets	42	–
Vehicles		
Total	**–1,638**	**–**

Revenue attributable to the disposal of vehicles (included in other operating income)	1	
Interest expenses (included in financial expenses)	–107	–
Expenditure attributable to short-term leases (included in administrative and selling expenses)	–2,736	–
Expenditure attributable to leases for which the underlying asset is of a low value that are not short-term leases (included in administrative expenses)	–87	–
Expenditure attributable to lease payments not included in lease liabilities (included in administrative expenses)	–9	–

The total cash out*flow* for leases in 2019 was TSEK 1,538.

NOTE 15 FINANCIAL INVESTMENTS

	Group		**Parent Company**	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
At the beginning of the year	110,821	145,917	110,821	145,917
Sales	–55,208	–35,096	–55,208	–35,096
Closing carrying amount	**55,613**	**110,821**	**55,613**	**110,821**

	Group		**Parent Company**	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Bonds, non-current	–	80,757	–	80,757
Bonds, current	55,613	30,065	55,613	30,065
Closing carrying amount	**55,613**	**110,821**	**55,613**	**110,821**

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

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

NOTE 16 INVENTORY

	Group		**Parent Company**	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Finished goods and goods for resale	14,440	3,352	–	–
Closing carrying amount	**14,440**	**3,352**	**–**	**–**

NOTE 17 OTHER RECEIVABLES

	Group		**Parent Company**	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Tax account	104	38	104	38
Cash deposits	833	438	104	104
VAT receivables	561	565	651	565
Other receivables	–	891	–	498
Total other receivables	**1,498**	**1,933**	**859**	**1,206**

NOTE 18 PREPAID EXPENSES AND ACCRUED INCOME

	Group		**Parent Company**	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Prepaid rent	50	77	48	41
Prepaid insurance costs	294	622	269	202
Accrued interest	67	87	67	87
Other items	1,579	174	1,481	173
Total prepaid expenses and accrued income	**1,992**	**960**	**1,865**	**504**

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

NOTE 19 SHARE CAPITAL

Parent Company	**No. of shares**	**Share capital (SEK)**
Opening balance at January 1, 2018	**23,661,863**	**709,856**
New share issue	356,111	10,683
Closing balance at December 31, 2018	**24,017,974**	**720,539**
New share issue	4,800,000	144,000
Closing balance at December 31, 2019	**28,817,974**	**864,539**

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

The shares have a quota value SEK 0.03 per share.

NOTE 20 ACCRUED EXPENSES AND DEFERRED INCOME

	Group		Parent Company	
	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Accrued salaries	6,797	3,845	3,490	2,736
Accrued vacation pay	2,094	1,828	136	207
Accrued social security contributions	649	548	649	548
Other personnel-related items	201	103	201	103
Consultancy fees	2,861	2,703	1,068	1,700
Audit	450	350	450	350
Other	207	231	24	12
Total accrued expenses and deferred income	**13,258**	**9,608**	**6,018**	**5,655**

NOTE 21 PLEDGED ASSETS AND CONTINGENT LIABILITIES

The Parent Company held endowment insurances that were pledged as security for its pension commitments; refer to Note 10. The endowment insurances were transferred during the year. The fair value of the endowment insurance, including special employer's contributions, totaled TSEK 0 (1,895) as of December 31, 2019.

NOTE 22 COMMITMENTS

Obligations in respect of operating leases

	Group		Parent Company	
Group	Dec 31, 2019	Dec 31, 2018	Dec 31, 2019	Dec 31, 2018
Within one year	150	3,120	143	124
Within one to five years	–	259	–	–
Later than five years	–	–	–	–
	150	**3,379**	**143**	**124**

NOTE 23 SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE

On March 15, the Board resolved, supported by the authorization granted by the extraordinary general meeting held on March 2, 2020, to carry out a share issue of approximately SEK 217 million with preferential rights to the company´s existing shareholders. At the date of publication of the annual report the rights issue is not yet completed. The record date for participation in the rights issue is March 24, 2020. The subscription period in the rights issue is expected to commence on March 26, 2020 and close April 9, 2020.

COVID-19´s impact on IRRAS is still difficult to assess and continuous evaluations are made of how the company will be affected. Although sales may be affected by other priorities in healthcare over a period of time, the basic need remains in IRRA*flow*´s and Hummingbird´s target patient groups. IRRAS keeps a close dialogue with suppliers and customers to follow the development. The sales methods have simultaneously changed to be able to run efficient meetings virtually and training through video conference.

NOTE 24 PARTICIPATIONS IN GROUP COMPANIES

Parent Company	**Dec 31, 2019**	**Dec 31, 2018**
Opening cost	68,745	24,638
Investment	163,950	40,979
Incentive programs	284	3,129
Closing carrying amount	**232,980**	**68,745**

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

Name	**Corp. Reg. No.**	**Domicile**	**% of capital and votes**	**No. of shares**	**Carrying amount Dec 31, 2019**	**Carrying amount Dec 31, 2018**
IRRAS GmbH	DE308005079	Munich	100%	1	1,643	3,571
IRRAS USA Inc	611800152	La Jolla	100%	9,500,000	231,337	65,174
					232,980	**68,745**

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

NOTE 25 PROPOSED APPROPRIATION OF EARNINGS

The Board proposes that the unappropriated earnings as of December 31, 2019 — SEK 327,947,075 — be carried forward.

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

NOTE 26 EARNINGS PER SHARE

	Before dilution		After dilution	
SEK	**2019**	**2018**	**2019**	**2018**
Earnings per share	–5.61	–5.83	–5.61	–5.83

The amount used in the numerator corresponds with the net loss for the year attributable to the Parent Company's shareholders, TSEK –151,144 (–138,842). The amount used in the denominator is recognized below.

The weighted average number of shares totaled 26,937,426 (23,815,328), which was impacted by new share issues during the fiscal year in question and the preceding fiscal year. The number of shares outstanding at the end of the year was 28,817,974 (24,017,974).

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

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

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

Stockholm, 20 March, 2020

The consolidated statement of profit or loss and other comprehensive income, the statement of financial position and the Parent Company statement of profit or loss and balance sheet will be submitted for adoption at the Annual General Meeting on April 28, 2020.

Anders P. Wiklund
Chairman of the Board

Kleanthis G. Xanthopoulos, Ph.D.
CEO and Board member

Catherine Gilmore-Lawless
Board member

Marios Fotiadis
Board member

Eva Nilsagård
Board member

Anita Tollstadius
Board member

Our Auditor's Report was submitted on
20 March, 2020
KPMG AB

Duane Swanson
Authorized Public Accountant

Auditor's Report

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

Report on the annual accounts and consolidated accounts

Opinions

We have audited the annual accounts and consolidated accounts of IRRAS AB for the year 2019. The annual accounts and consolidated accounts of the company are included on pages 20–56 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2019 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 2019 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. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

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.

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

Material uncertainty related to going concern

Without qualifying our opinion above, we bring to your attention the information on (page 23) of the administration report and Note 3, (page 46) which discloses that the Group's available cash is insufficient to cover the operations as currently planned for the coming 12 months and the Board has resolved to carry out a preferential rights share issue. This share issue has not been completed as of the date for the issuance of these annual accounts. Accordingly there is a risk for the company to continue operations if sufficient financing is not arranged. This condition indicates the existence of a material uncertainty as to the company's ability to continue as a going concern.

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.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of IRRAS AB for the year 2019 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.

Stockholm 20 March 2020

KPMG AB

Duane Swanson
Authorized Public Accountant

Corporate governance report

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

Corporate governance at IRRAS AB

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

General meetings

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

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

The 2020 AGM will be held on April 28 at 11:00 a.m. at the IVA Conference Center, Grev Turegatan 16, Stockholm, Sweden.

Nomination Committee

The AGM determines how the Nomination Committee is to be appointed. At the AGM on May 14, 2019, it was resolved that the Nomination Committee would consist of four members: representatives of the three largest shareholders at the end of September plus the Chairman of the Board.

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

The Nomination Committee reports on its activities at the AGM. No remuneration is paid for work on the Nomination Committee. The shareholders can turn to the Nomination Committee with proposals and viewpoints regarding the composition of the Board of Directors. The election of auditors took place at the AGM in 2019.

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

Name	Representing	Shareholding, %, December 31, 2019
Christer Hellström	Bacara Holdings Limited	4.96
Marios Fotiadis	Lexington Holding Assets Ltd (BVI)	10.95
Christos Panotopoulos	F.EX Endotherapy Limited	9.91
Anders P. Wiklund	Chairman of the Board	0.05

The Board of Directors

Under the Articles of Association, the Board of Directors is to consist of no less than three and no more than seven members, without deputies. Changes to the Articles of Association are resolved by the general meeting. The Board of Directors consists of six members. At the AGM on May 14, 2019, Anders P. Wiklund was elected Chairman of the Board and Eva Nilsagård, Catherine Gilmore-Lawless, Marios Fotiadis, Anita Tollstadius and Kleanthis G. Xanthopoulos were elected as Board members.

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

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

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

MEMBERS OF THE BOARD AFTER THE EXTRAORDINARY GENERAL MEETING ON MAY 14 2019

Name	Period	Function	Attendence	Independent of management	Independent of owners	Shareholding	Elected	Member Audit Committee	Member Remuneration Committee
Anders P. Wiklund	1/1–31/12	Chairman	13/13	Yes	Yes	13,182	2016	No	Yes
Catherine Gilmore-Lawless	14/5–31/12	Member	7/7	Yes	Yes	0	2019	No	Yes
Marios Fotiadis	1/1–31/12	Member	12/13	Yes	No	4,586,452	2012	No	No
Eva Nilsagård	1/1–31/12	Member	12/13	Yes	Yes	5,000	2018	Yes	No
Anita Tollstadius	1/1–31/12	Member	13/13	Yes	Yes	2 000	2017	Yes	Yes
Kleanthis G. Xanthopoulos	1/1–31/12	Member and CEO	13/13	No	No	842,878	2015	No	No

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

Remuneration to Board members

At the AGM in May 2019, it was resolved that a fee of SEK 540,000 would be paid to the Chairman of the Board, and a fee of SEK 336,000 to Catherine Gilmore-Lawless and SEK 240,000 to each of the other non-executive Board members. A fee of SEK 100,000 would be paid on an annual basis to the Chairman of each of the Audit Committee and Remuneration committee and 50,000 to each of the committee members.

Board activities

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

Evaluating Board activities

The Board of Directors evaluates Board activities in accordance with the rules of procedure. This takes place both through discussions within the Board and through an annual external evaluation.

Summary of Board meetings during the year

In 2019, the Board held 13 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. 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 2020 budget. The members of the Board are presented in the table at the top of the page.

Audit Committee

Since the inaugural Board meeting in May 2019, 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 2019.

Remuneration Committee

Since the inaugural Board meeting in May 2019, the Remuneration Committee has consisted of Catherine Gilmore-Lawless (Chairman), Anders Wiklund and Anita Tollstadius.

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

Authorization for the Board

At the AGM on May 14, 2019, the Board was authorized under the prevailing Articles of Association, 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, warrants and/or convertible instruments in the company. The issues are to take place at market-based subscription prices, subject to market-based issue rebates where appropriate, and payment may, apart from cash payment, be made with non-cash consideration, through offset or on similar terms. The authorization is capped at 4,800,000 new shares, corresponding to 20% of the number of shares outstanding at the time. Later in May 2019 a new share issue was made, adding net MSEK 97,3 to the company.

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

Policies for remuneration and other terms of employment for Group management

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

Audit

The company's auditors are elected at the AGM for a period of one year. At the scheduled AGM in 2019, KPMG was elected as the company's auditor, with Authorized Public Accountant Duane Swanson serving as auditor in charge for the audit in the Group. The company's auditor conducts a review of at least one interim report per year on the company's behalf. Other statutory audits of the Annual Report, the consolidated financial statements and accounting as well as the administration of the Board and the CEO are performed in accordance with the International Standards on Auditing and good auditing practice in Sweden. The auditors meet with the Board and the full Audit Committee on a yearly basis, both with and without company management present and summarizes audits and reviews and provides updates on coming changes in the regulations.

Financial reporting to the Board of Directors

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

External financial information

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

Internal control report

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

Control environment

The Board of Directors has overall responsibility for establishing and maintaining proper internal control by shaping the organization, decision-making channels, authorizations and responsibilities as expressed in policies and guidelines. Shared values create consensus and strengthen internal control. In 2019, a great deal of work was put into additional improvements of the struture created in 2017 and 2018. The company has also worked to improve the documentation and policies for GDPR to create a systematic approach.

The Board establishes certain policies and instructions, including authorization instructions. The Board and company management consider quick, correct reporting to be important. The accounting function ensures that all operations are evaluated and their efficiency enhanced. The evaluation of internal control in the Group follows a plan approved annually by the Audit Committee. Responsibility for creating processes with suitable internal control lies with the respective heads of divisions.

Risk assessment

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

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

Control activities

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

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

Information and communication

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

Monitoring

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

The company's improvement efforts in 2019 included continued evaluation processes, process descriptions and compliance in the different legal entities. 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 2020

In 2020, the work on documenting the business and control processes and routines will continue and the control processes will be clarified and continue to be evaluated, primarily through self-assessment.

In addition, the company still aims to change to Nasdaq Stockholm's principal market.

Board of Directors

Anders P. Wiklund

Born in 1940. Board member since 2016 and Chairman of the Board since 2017. Member of the Remuneration Committee.

Education: Pharmacist (M.Sc. Pharm) from Farmaceutiska Institutet. He has also studied Business at Stockholm University.

Other experience: Anders P. Wiklund has more than 40 years of global experience in leading positions in pharmaceutical and biotechnology companies, including as co-founder of Esperion and former President and CEO of KabiVitrum Inc and KabiPharmacia Inc.

Other current assignments: Board member and partner of EffRX Pharmaceuticals SA, Board member of Life Medical Sweden AB and Chairman of the Board and owner of Wiklund International AB.

Previous assignments over the past five years: Board member of Peptonic Medical AB and investor in SinSa Labs AB. Anders P. Wiklund previously served as a consultant to IRRAS.

Shareholding in the company: 13,182 shares and 100,000 warrants via the 2017/2020 incentive program.

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

Marios Fotiadis

Born in 1973. Board member since 2012. Member of the Remuneration Committee.

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 Lexington Holding Assets, Klaris SA, Bacara SA, Plastics Unbound GmbH, Rossart Ltd, Sente Inc., Plastic Unbound Limited and Plastics Unbound Ltd (RAK).

Previous assignments over the past five years: Board member of Mediolanum Farmaceutici Spa and Vandel Group JLT.

Shareholding in the company: 1,430,725shares via Bacara Ltd and 3,155,727 shares via Lexington Holding Assets Ltd.

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

Catherine Gilmore-Lawless

Born in 1960. Board member since 2019. Chairman of the Remuneration Committee.

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

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

Other current assignments: Consultant to the International Stereotactic Radiosurgery Society and owner of Gage Hospitality Group.

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

Shareholding in the company: 0 shares.

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

Eva Nilsagård

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

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

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

Other current assignments: Board member of SEK (Svensk Exportkredit AB), and Board member and Chairman of the Audit Committee of AddLife AB, Bufab AB, Hansa Biopharma AB and Xbrane Biopharma 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: 5,000 shares.

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

Anita Tollstadius

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

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

Other experience: Anita Tollstadius has more than 30 years of experience from global operations and has held several senior positions within the life science sector.

Other current assignments: None.

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

Shareholding in the company: 5,000 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 three life science companies before joining IRRAS, two of which have been listed on Nasdaq (Anadys Pharmaceuticals, Inc. which was acquired by F. Hoffmann-La Roche Inc. in 2011, and Regulus Therapeutics Inc). Kleanthis G. Xanthopoulos has also financed and brokered numerous creative strategic alliances and partnership deals with large pharmaceutical partners.

Other current assignments: Board member and founder of Senté, Board member of Zosano Pharma Corporation and CEO of Helios Capital.

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: 842,878 shares and 1,275,000 personnel options via the 2016/2025 incentive program and 168 237 personnel options via the 2018/2022 inventive program.

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

Senior executives

Kleanthis G. Xanthopoulos Ph.D.

Born in 1958. President and CEO since 2015.

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

Will Martin

Born in 1975. Chief Commercial Officer since 2018.

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

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

Other current assignments: Board member of Morris Innovative.

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

Shareholding in the company: 0 shares, 230,000 personnel options via the 2017/2021 incentive program, 32,500 personnel options via the 2016/2025 incentive program and 66,500 personnel options via the 2018/2022 incentive program.

Sabina Berlin

Born in 1975. Chief Commercial Officer since 2018.

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

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

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

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

Shareholding in the company: 3,958 shares, 100,000 warrants via the 2017/2020 incentive program and 39,500 personnel options via the 2018/2022 incentive program.

Shareholding through related parties: 12,989 shares.

Adam Sampson

Born in 1968. Vice President of Product Excellence since 2018 and employed since 2010.

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

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

Other current assignments: None.

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

Shareholding in the company: 0 shares, 70,500 peronnel options via the 2018/2022 incentive program.

Kellie Fontes

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

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

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

Other current assignments: None.

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

Shareholding in the company: 0 shares, 35,000 personnel options via the 2017/2021 incentive program, 2,976 personnel options via the 2016/2025 incentive program and 10,000 personnel options via incentive program 2018/2022.

Annual General Meeting

The 2020 AGM will be held on Tuesday, April 28 at 11:00 a.m. at the IVA Conference Center, Grev Turegatan 16, Stockholm, Sweden.

Registration for attendance

Shareholders wishing to attend the AGM must:

- be registered in the share book kept by Euroclear Sweden AB as of Wednesday, April 22, 2020; and

- register with the company via e-mail to AGM@irras.com by Thursday, April 23, 2020 at the latest. Registrations may also be submitted to the company in writing well in advance of the meeting at: IRRAS AB (publ), Attn: Sabina Berlin, Box 160, 101 23 Stockholm, Sweden.
  When registering, please provide the shareholder's name, personal ID number (corporate registration number), address, telephone number, number of shares and any assistants (maximum two). Information submitted during registration will be processed and used for the 2020 AGM.

In order to exercise their voting rights at the AGM, shareholders whose shares are held by a nominee must temporarily register their shares in their own name.

Such re-registration must be completed by April 22, 2020 at the latest.

If participating through a proxy, original copies of the proxy form and any additional authorization documents must be submitted to the company well in advance of the AGM. Representatives of legal entities must additionally submit a certified copy of the proof of registration or similar authorization documents showing that they may represent the legal entity of their own accord. The company will provide shareholders with a proxy form, which can be obtained at the company's headquarters or from the company's website.

Financial calendar

April 28, 2020
2020 Annual General Meeting

May 14, 2020
Q1 2020 interim report

August 27, 2020
Q2 2020 interim report

November 10, 2020
Q3 2020 interim report

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