IRRAS ANNUAL REPORT 2018

This is IRRAS

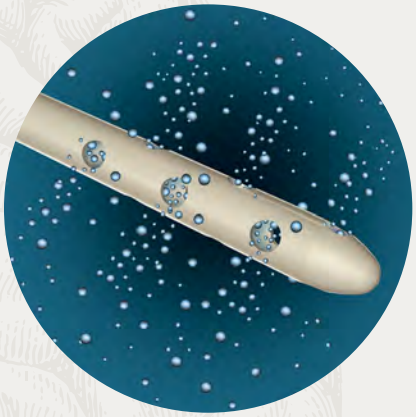
IRRAS AB is a publicly traded, commercial-stage medical technology company focused on developing and commercializing innovative solutions for brain surgery. The company's initial product, IRRA*flow*®, addresses the complications associated with the current treatment methods of intracranial bleeding with a dual lumen catheter that combines active irrigation with ongoing fluid drainage. Regularly during treatment, the catheter is automatically flushed to prevent common catheter occlusions from forming. Because IRRA*flow* is a completely closed system, it is designed to reduce the documented infection risk of these procedures.

With its unique product portfolio protected by patents and patent applications, IRRAS is well positioned to establish itself as a leader in the medical device market. IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. The IRRAS share is listed on the Nasdaq First North Premier exchange.

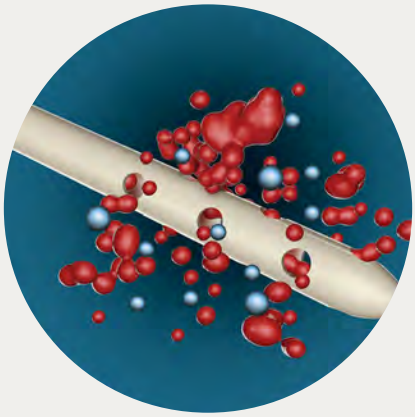
For more information, please visit www.irras.com

Content

IRR*igation*



AS*piration*



IRRA*flow*

The only system for active treatment of intracranial bleeding through controlled active drainage and irrigation combined with accurate ICP monitoring.

IRRA*flow* features:

Active Fluid Exchange

Active fluid exchange entails:

- **Automated irrigation** to counteract traditional shortcomings such as blockages and EVD-related infections
- **Drainage** of collected blood to alleviate the effects of primary bleeding

Continual monitoring

Integrated ICP monitoring entails:

- **Continual** pressure monitoring with no risk of leakage
- **Combination** of drainage, fluid supply and ICP monitoring in the same system

User friendly

An easy-to-read touchscreen with:

- **Automated** software
- **Customized** alarms
- **Drainage control**

2018 in brief

Q1

Strengthening the executive management team

IRRAS strengthened its executive management team during the quarter. Will Martin joined the company as Chief Commercial Officer and Kellie Fontes came on board as Senior Director, Human Capital.

Q2

Updated ISO and CE certification

The control unit and the tube set were recertified during the spring. The high workload at the notified body delayed the recertification of the catheter, which is a Class III product requiring more time for review.

Q3

FDA clearance

In July, IRRA*flow* received 510(k) clearance for US registration from the US Food and Drug Administration (FDA).

Q4

US launch initiated

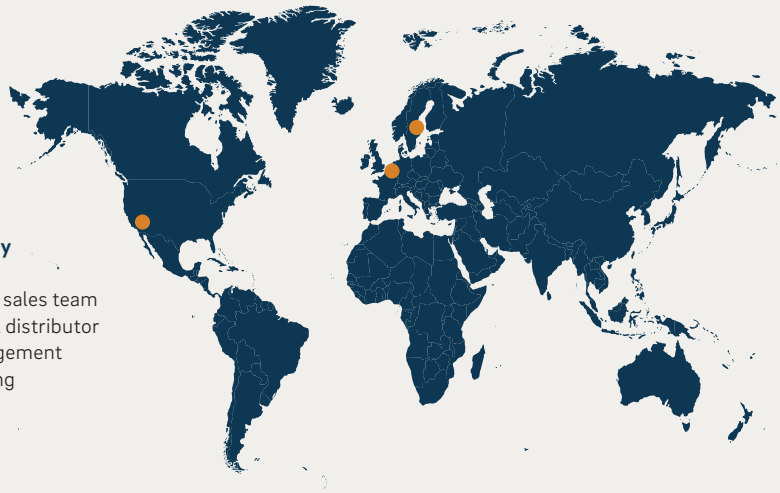
In the fourth quarter, the company initiated its US launch with the hiring of its initial direct sales professionals. It initiated contact with several hospitals and trained future users of the system.

OUR LOCATIONS

USA
San Diego, CA
- Executive team
- Sales & marketing
- R&D
- Operations

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

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



Key figures 2018

- **Net revenue** totaled SEK 6.0 million (12.0).
- **Operating loss (EBIT)** amounted to SEK -143.3 million (-61.5).
- **Loss after tax** totaled SEK -138.8 million (-60.9).
- **Earnings per share** before and after dilution amounted to SEK -5.83 (-3.40).
- **The Board of Directors** proposes that no dividend be paid.

The Group's available liquidity amounted to SEK 158 million at year-end.

The average number of employees in the Group during the year was 21 (8). In April 2019, the number of employees was 34.

Important events after the end of the year

First patients in US successfully treated with IRRA*flow*®
The first patients in the US were successfully treated with IRRA*flow*® in January at the University of California - Irvine Medical Center.

Financial objectives
In March, new financial objectives were announced for IRRAS. *See page 11 for more information.*

Global partnership with Healthlink
IRRAS has entered into a partnership with Healthlink Europe & International to ensure that IRRAS' global customer base is given rapid and convenient access to the company's product range.

IRRAS is evaluating a possible listing of the company's share on Nasdaq Stockholm's principal market in 2019
A listing on Nasdaq's principal market in Sweden is part of the company's strategy to become a leading medical device company and an industry leader in the area of intracranial bleeding.

Letter from the President and CEO

I am very proud of the strong foundation the IRRAS team built in 2018 and we are optimistic in our ability to continue to develop innovative products that will change the lives of millions. We took several major steps forward in the U.S., our most important market that has great potential for IRRAS and its innovative solutions for brain surgery.

In the summer we received 510(k) clearance from the U.S. Food and Drug Administration (FDA) allowing us to initiate the launch of IRRA*flow* in the U.S. We also worked to ensure IRRAS had the right people and partnerships needed to get IRRA*flow* in the hands of medical professionals.

IRRAS expanded its management team to ensure it has the top talent to execute on its ambitious growth plans. Will Martin was hired as Chief Commercial Officer, Kellie Fontes as Senior Director Human Capital, and Eva Nilsagård joined the IRRAS' board. We also added top talents to our product development and manufacturing teams in the U.S. with Adam Sampson now Vice President of Product Excellence and Dino De Cicco as Senior Director of Product Development. We continued to strengthen our team in the past few months with the appointment of Vinny Podichetty, MD, MS. as Vice President of Global Clinical Affairs.

To ensure a successful US launch, we enhanced our sales and marketing teams with talented individuals who have a demonstrated track record of success in introducing disruptive medical devices to the market. Multiple hospitals in the U.S. are already being trained, and patients have been treated successfully.

In bringing IRRA*flow* to the U.S. market, our sales team is executing on our strategy of "going deep before we go wide". We partner with appropriate physicians and facilities to maximize our chances for strong clinical results during this critical stage of launch. This methodical approach helps to build the needed foundation for our long-term business by targeting interested physicians and educating health care providers on the advantages of our product compared with competitive alternatives.

2019 will be a pivotal year for IRRAS and we are off to a promising start. In January 2019, we successfully treated our first patient with IRRA*flow* in the U.S. Thanks to our innovative product, we currently see expressed interest from physicians at more than 30 hospitals around the U.S., and we are now navigating their respective approval and evaluation processes. It is common that this process can be four to six months long before revenue is generated. With an enthusiastic initial response from physicians, due to our unique "active fluid exchange" mechanism of action, we have seen a strong commitment to reduce the hospitals' required approval time.

While much of our focus was on building our business in the U.S. during the past year, we also continued our efforts in other global markets including Europe. The European CE Mark recertification of our catheter has not yet been received. We have a good, ongoing dialogue with the notified body, LNE/G-MED. We expect the launch of IRRA*flow* in the EU will resume shortly after the approval.

At IRRAS, our mission is clear: to change the lives of millions by creating medical products that transform the current treatment of intracranial bleedings. We believe that IRRA*flow* will ultimately become the new standard of care in this field, and, during 2018, we made significant progress toward accomplishing this mission.

With the US launch, the anticipated recertification of the CE mark in the EU, our registration of our product in additional countries, and our portfolio of differentiated technology and unique products, we are confident that we are setting the foundation to become domain dominant in the neurocritical care market. The future of IRRAS is bright.

Finally, I want to say a big thank you to all employees for a strong effort during the year. Thanks also to our customers, partners and investors for their confidence, we look forward to a successful cooperation.

Kleanthis G. Xanthopoulos, Ph.D.
President and CEO

Needed innovation in neurocritical care

IRRA*flow* is a technical innovation and with the potential to revolutionize treatment of intracranial bleeding with significantly improved treatment outcomes and economic benefits for the health sector.

IRRA*flow* is an integrated, closed-circuit medical device system that enables controlled management of cerebrospinal fluid (CSF) while providing reliable, continual monitoring of intracranial pressure (ICP).

When the brain is injured or becomes infected, the normal flow of fluid in the brain is disturbed, which may lead to a build-up of fluid and swelling. The increased build-up of fluid must be drained to avoid increased intracranial pressure, which can be life-threatening. Increased intracranial pressure and complications of treatment lead to high rates of disability and death.

IRRA*flow* integrates drainage, targeted fluid injection and measurement of intracranial pressure into the same product. A dual-lumen catheter is used to combine active irrigation of fluids with ongoing fluid drainage. Regularly during treatment, the IRRA*flow* catheter is automatically flushed to prevent common occlusions from forming. At the same time, the system measures intracranial pressure and issues an alert when the pressure increases or decreases in an undesirable way.

IRRA*flow* is designed to reduce the occurrence of catheter blockage, a relatively common complication of the current treatment method that only uses passive, gravity-assisted drainage. Because IRRA*flow* is a completely closed system, it minimizes the risk of bacterial introduction, which can also reduce the infection risk from treatment.

Designed to improve patient safety and economic benefits for the health sector — Benefits for both caregivers and patients

- **Automation.** Reliance on manual supervision in the ICU is reduced with continuous digital monitoring and automated alerts, and drainage is ensured with automatic catheter flushing.
- **Active drainage.** Fluid is managed in a closed system. Pressure is continually monitored and adjusted through synchronized flushing and drainage. This means that the rate of drainage can be actively controlled and optimized for each patient.
- **Time in hospital.** During early European experience with IRRA*flow*, both treatment and hospitalization time were significantly reduced compared with the current standard treatment. The cost savings has been estimated at approximately EUR 13,000 per patient.
- **Functioning procedure.** IRRA*flow* fits into current clinical practice, which ensures a smooth transition for neurosurgeons, ICU teams and caregivers.
- **Upgrades.** The control unit is prepared for development, and new functions are installed via software updates.
- **Reduced risk.** Since sales began in May 2017, patients have been treated using IRRA*flow* in the US, Greece, India, Germany, Finland and Hong Kong. No cases of catheter blockage or system-related infections have been documented.

The IRRA*flow* system consists of a control unit with consumables (catheters and tube sets). It is the only system on the market that offers drainage, automated irrigation and ICP monitoring, which enables a transition from passive to active drainage. The system has four fully integrated and synchronized functions:

1.

A **catheter drainage system** with a flushing pump and drainage mechanism that interact with a dual lumen (channel) catheter to both flush and evacuate fluid to and from the body. The system is synchronized in order to monitor local pressure within a pre-programmed range.

2.

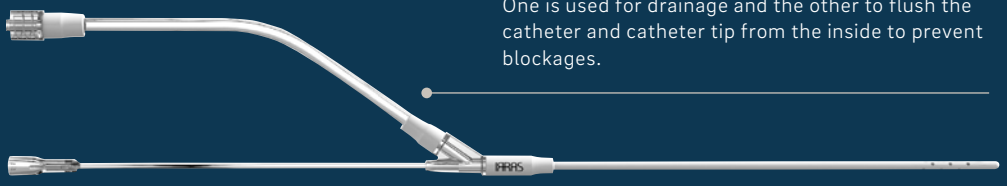
An ICP **monitoring and measurement system** using a method that employs a liquid column for accuracy and reliability.

3.

Safety alarms that can be customized to each patient are activated when the pressure is higher or lower than a pre-programmed range.

4.

Irrigation flushes can be programmed in terms of frequency and quantity, preventing blockages of the catheter and possibly reducing complications.



The patented catheter has two lumens (channels). One is used for drainage and the other to flush the catheter and catheter tip from the inside to prevent blockages.

LANCE BOLING,
VICE PRESIDENT, PRODUCT DEVELOPMENT

INTERVIEW

We are currently focusing exclusively on intracranial bleeding. In the longer term, we see a multitude of opportunities, and it is important to choose the right strategic direction.

What have your priorities been during the past year?

We are always working on refining functions and product development. We have expanded our supplier base to ensure access to products, and streamlined our manufacturing, resulting in lower production costs. We are also involved in internal education and training, including training of our new regional managers in the US, as well as registration processes for technology issues.

Who is on the current product development team?

We added several key personnel to this function during the year, and we now have a dedicated and highly experienced team of five people in total.

Can you list some examples of improvements you made during the year?

We have complemented our two previous catheters with a model with a flow speed between those two, which allows for a broader range of potential uses. Its design is slightly more stable and it is therefore somewhat easier to use. We are currently developing a catheter for the treatment of premature infants.

We are also working on integrating the system with hospitals' existing monitoring systems, so that the values can be seen on the screens in ward control rooms. Another example is that we have moved the pressure sensor closer to the tip of the catheter, producing a stronger signal. We are also continually working on software updates.

How do you ensure that your products are user friendly?

Users are an extremely important part of the development process. We have carried out numerous interviews with European physicians and neurosurgeons who have clinical experience with the system. One common request has been to reduce the system's complexity, which is one reason why we developed the new medium-sized catheter.

What are your plans for the longer term? Are there other types of treatments where IRRAflow could be used?

We are currently focusing exclusively on intracranial bleeding. In the longer term, we see a multitude of opportunities, and it is important to choose the right strategic direction.

The system is a technology platform that can be combined with numerous functions. One example could be an innovative method for the targeted delivery of drugs to the brain and central nervous system. The pressure that occurs during drug delivery needs to be monitored, and any excess fluid may need to be evacuated. We also see opportunities in the treatment of other parts of the body, such as abdominal infections that need to be drained. We have the platform, ideas and patents to ensure that IRRA*flow* remains the leading technology, far ahead of our competitors.

Four reasons to invest in IRRAS

1.

A unique product designed to improve patient safety and reduce the cost of care for neurosurgical procedures.

IRRAS' proprietary IRRA*flow* technology platform is a groundbreaking innovation in neurosurgery and the only system for therapeutic treatment of intracranial bleeding through controlled active drainage and flushing combined with simultaneous pressure monitoring.

Compared with conventional methods, treatment using IRRA*flow* may result in fewer complications, shorter time in hospital for patients and lower costs for hospitals and caregivers.

2.

A high clinical need means major market potential

IRRA*flow* is initially being used to treat patients suffering from hemorrhagic strokes and chronic subdural hematoma, both life-threatening conditions involving intracranial bleeding. An estimated 350,000 patients undergo surgery for these conditions every year in the EU and US alone.

IRRAS estimates the market potential for surgical treatment of hemorrhagic strokes and chronic subdural hematoma in the EU and US to be EUR 900 million per year. There is additional potential in the adjacent field of acute subdural hematoma caused by trauma, where IRRAS estimates the market in the EU and US to be 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.

4.

Good market penetration

The company's products are sold through its own direct sales and marketing organization 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.

Financial objectives

IRRAS' Board of Directors has adopted the following financial objectives.

The objectives for the 2021 fiscal year are:

- **Income** to exceed SEK 275 million
- **Gross margin** higher than 72%
- **In the fourth quarter 2021,** the company is to have positive cash *flow*

The Board does not intend to propose a dividend to shareholders before the company is able to generate long-term sustainable profitability. It aims to continue focusing on further developing and expanding its operations and sales.

Therefore, available financial resources and profit must be reinvested in the operations to finance IRRAS' long-term strategy.

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.

In order to achieve this vision, IRRA*flow* 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's initial focus is to commercialize IRRA*flow* for treatment of intracranial bleedings, while developing other applications at the same time. The following are crucial to IRRAS' growth strategy:

- **Commercializing IRRA*flow* for neurocritical care** (central nervous system) and becoming the market leader for the treatment of intracranial bleedings.
- **Gradually 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 *Philotimia* which means respect, honor, team before self, empathy and a sense of purpose.

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

Our organization

US
- Company´s direct sales team

Europe
- Company's direct sales team in Germany and Austria
- 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 expected in 2019

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

VISION

To change the lives of millions across the world by creating medical products that become standard of care.

MISSION

We exist to create transformative solutions that positively impact the equality of patient's lives and overall cost of care.

Planned sales channels

- Q3 2018 – Current launch markets
- Q4 2018, Q2 2019 – Markets registered and scheduled for launch
- 2019 – Registration under way
- 2020 – Longer registration markets

The need for a new standard of care

IRRA*flow* is used to drain fluids and monitor intracranial pressure in patients with hemorrhagic strokes and chronic subdural hematoma. 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.

A high clinical need

IRRAS' initial clinical focus is neurosurgical treatments that require the drainage of excess CSF as well as monitoring and regulation of ICP.

The treatments are often for hemorrhagic strokes (bleeding in the brain) and chronic subdural hematoma (blood collection on the surface of the brain). 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 with well-functioning health insurance systems.

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 cases is approximately 130,000 per year, which indicates an additional market potential worth approximately EUR 350 million. [2]

Life-saving treatment

When a patient suffers from increased intracranial pressure, it must be reduced rapidly. The treatment is performed on an emergency basis and is critical to address before the underlying brain pathology leading to increased intracranial pressure can be treated. An increase in ICP can cause deleterious effects on the brain and is the most common cause of death in neurosurgical intracranial pathologies. Without treatment, moderate to serious brain damage or death may be the result.

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. Continual monitoring is critical for patients with elevated ICP. Equally important as the role of ICP monitoring is the availability of treatment options to reduce and regulate ICP.

Hemorrhagic stroke — bleeding in the brain

Stroke is a global health problem that affects approximately 15 million people in the world every year. 15% of these cases are hemorrhagic strokes, the most serious type of stroke. Stroke is caused when a blood vessel suddenly bursts, leading to bleeding in or around the brain.

About 460,000 people suffer from strokes every year in the EU and US alone, and more than 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 an aging population.

Hemorrhagic stroke has a high rate of mortality. About 40% of patients die within 30 days, while about one third experience brain damage and permanent disability.

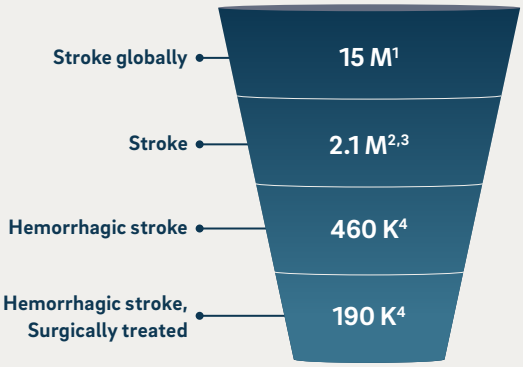
IRRAS estimates that direct and indirect healthcare costs and lost productivity amounted to EUR 45 billion in the EU in 2015, and USD 33 billion in the US in 2013.

Use of IRRA*flow* can potentially contribute to reduced human suffering, higher quality of life for patients and lower costs for healthcare providers.

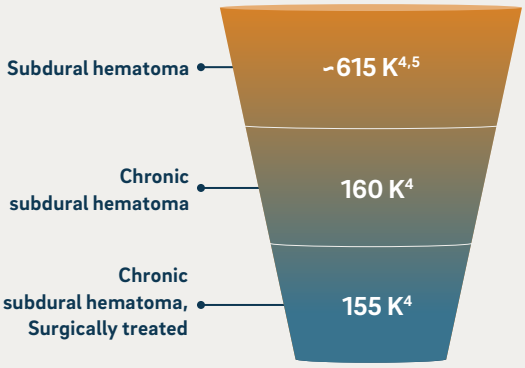
1) These estimates are based on the total number of cases of hemorrhagic strokes and chronic subdural hematoma in the EU and US, as shown in the previous images. The number of cases is multiplied by an average fee of EUR 2,600 for IRRAS per single-use installation (one installation is required per case). The market potential encompasses ongoing sales of consumables. Sales of the control unit are not included.
2) Based on about 130,000 additional cases and the same assumptions as in the observation above.

Market potential, EU & USA
CAGR, 8-10%

Hemorrhagic stroke
Bleeding in the brain



Subdural hematoma
Blood collection in the brain



345,000
patients, annual potential market (50% EU & 50% USA)

Estimated Market potential of EUR ***1,2 billion*** per year

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

Conventional treatment options

A conventional external ventricular drainage system (EVD) is passive and relies on gravity alone. An EVD catheter is inserted through a small burr hole in the patient's cranium. It evacuates blood and collections of fluid to an aspiration bag attached to a bedside pole. The aspiration rate is controlled by changing the height of the aspiration 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, which all can result in a negative impact on patient outcome. It is also documented that shorter time in hospital for hemorrhagic stroke patients leads to better patient outcomes.

Treatment with IRRA*flow*

IRRA*flow* is the only system on the market that integrates drainage, targeted fluid injection and measurement of intracranial pressure in the same product. The system is designed to significantly improves care outcomes by reducing the occurrence of catheter blockage and lowering the risk of infection during treatment.

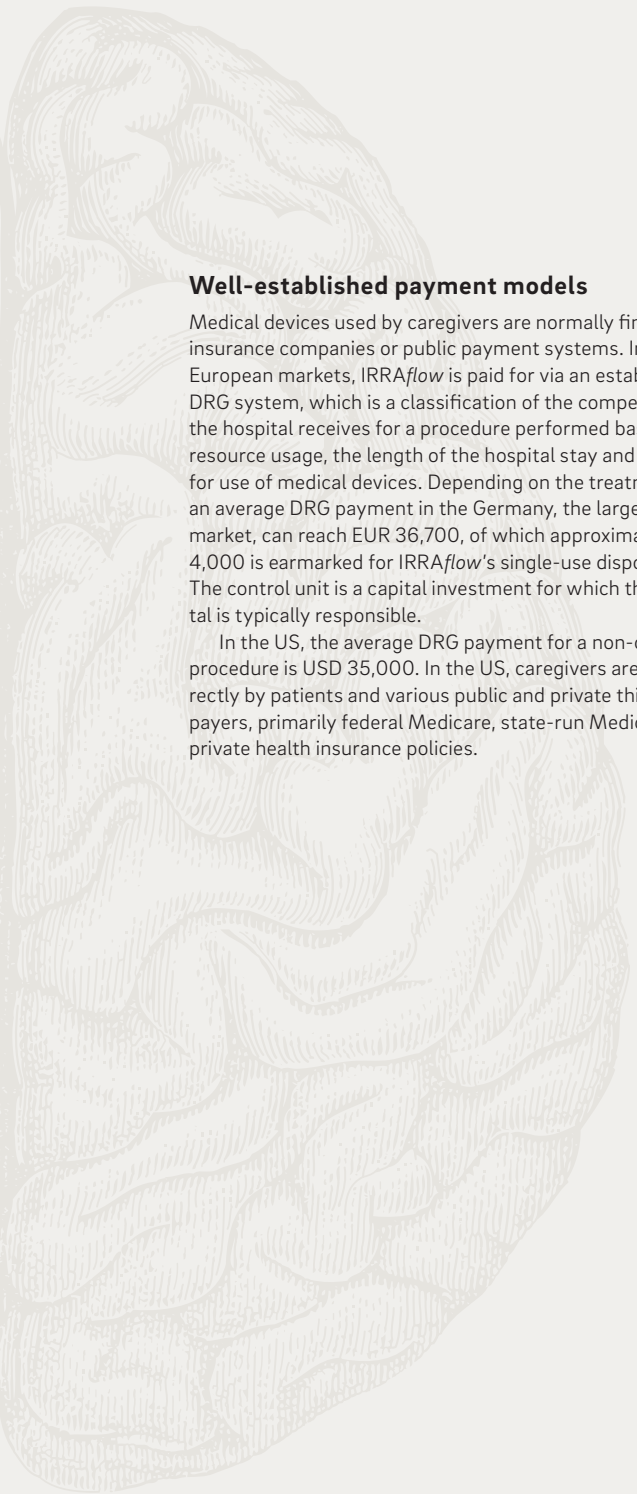
The efficacy of fluid management with IRRA*flow* has been demonstrated so far in patients in Greece, India, Germany, Finland, Hong Kong and the US. In these cases, treatment times were significantly shorter compared with EVD treatment, and in follow-up care. No infection was documented in any of these cases.

Chronic subdural hematoma — blood collection in the brain

One third of all serious head injuries result in 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 and thus pressure on the brain tissue. There are three types of subdural hematoma. IRRA*flow* is currently marketed for treatment of the chronic type. 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 indicates that approximately 155,000 cases of chronic subdural hematoma in the EU and US are suitable for treatment with IRRA*flow*.

Approximately one third of all chronic subdural hematoma patients die and another one third become permanently disabled.

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 could mean that chronic subdural hematoma fluid drainage may become the most commonly performed neurosurgical procedure.



Well-established payment models

Medical devices used by caregivers are normally financed by insurance companies or public payment systems. In many European markets, IRRA*flow* is 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 is earmarked for IRRA*flow*'s single-use disposables. The control unit is a capital investment for which the hospital is typically responsible.

In the US, the average DRG payment for a non-complex procedure is USD 35,000. In the US, caregivers are paid directly by patients and various public and private third-party payers, primarily federal Medicare, state-run Medicaid and private health insurance policies.

Regulations and requirements

A high level of product safety with 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 regulatory requirements. A product that has been evaluated and given CE certification in one country has access to the entire EEA market. The corresponding approval for sales and marketing in the US is provided by the FDA.

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.

IRRA*flow* launched in the US

Several milestones were reached during the year. IRRA*flow* received FDA clearance and was launched in the US in the fourth quarter. The first American patient was treated at the beginning of 2019. In Europe, a recertification was delayed, which prevented continued sales during the year.

A scalable business model

IRRAS sells the IRRA*flow* control unit with high-quality, innovative consumables in the form of catheters and cassettes. Its customers include a growing number of hospitals that offer neurocritical care. After an investment in the control unit, sales of the associated consumables are continual.

Product sales are supported by service agreements and favorable reimbursement levels. Procurement of the system is primarily financed through the public sector and insurance companies.

IRRAS views the EU and US as it key markets since there is a strong demand for medical device solutions and these markets show favorable growth, high profitability and attractive reimbursement levels. The company markets to the US and Germany through its own sales organizations, while it markets to the rest of the EU and global markets through selected distributors.

Sales/marketing strategy

Intracranial bleeding is a global problem, and IRRA*flow* has the potential to become the new standard of care for treatments worldwide. Initially, the company's strategy is to keep a narrow geographical focus and "go deep before going wide" in order to create recognition and a foothold for IRRA*flow*. The company takes a thorough, long-term approach in order to ensure a successful launch, and it places significant emphasis on training and education. The same thoroughness applies to sales through its own organization and via distributors.

The company is methodically building a network of advocates of its new technology by identifying and contacting neurosurgeons considered to be innovators and early adopters of new technology. As more product advocates are identified, the number of IRRA*flow* treatments performed is gradually increasing, and, over time, the company is focused on building a pool of convincing clinical data. As knowledge of the new treatment method and demand increase, geographical market coverage will expand with the objective of establishing IRRA*flow* as a new standard of care for the treatment of intracranial bleeding.

FDA clearance in the US market

An eagerly awaited milestone was reached in July 2018, when IRRAS received 510(k) clearance — or registration clearance — from the FDA, giving the company the right to market and sell IRRA*flow* in the US.

Once the clearance was received, the carefully planned build-up of the sales organization truly gained momentum. Six regional sales managers with previous experience in launching innovative medical devices in the US market were recruited and trained.

IRRA*flow* was launched in October 2018, when it was presented at the annual Congress of Neurological Surgeons (CNS) in Houston in the US. The conference is an important forum for the latest research and technology in neurosurgery, and attracts participants from around the world.

At the end of 2018, relationships had been established with over 20 selected neurological clinics and hospitals around the US, which initiated evaluations, tests and internal approval processes. The first American patient was treated successfully with IRRA*flow* at the beginning of 2019 at the University of California - Irvine Medical Center.

Progress 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 for most of 2018 due to a delay in the recertification of IRRA*flow*.

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

Facilitating the recertification process and maintaining a good ongoing dialogue with the certification body is a high priority for IRRAS.

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

WILL MARTIN,
CHIEF COMMERCIAL OFFICER

INTERVIEW

A positive reception in the US market. First patients treated

IRRAS is building up its own sales organization in the US. How are you doing this?

When we received FDA clearance in July, we immediately recruited four regional sales managers who began addressing their respective markets in October. Two more people have been added to the team since the beginning of the year, and we have expanded to six regions. All of them are extremely competent, with significant experience in successfully introducing innovative medical devices.

We have also recruited people to our marketing organization. We were able to present IRRA*flow* at CNS in Houston in October, an important forum for the latest research and technology in neurosurgery.

How do you approach potential customers and users with an unfamiliar, completely new, high-tech product?

We are taking a methodical, long-term approach to building up a network of product advocates for IRRA*flow*, and we are keenly focused on ensuring positive clinical outcomes. Our strategy is to "go deep before going wide", which means that we are targeting a select number of neurocritical care centers in each region where there is a high level of interest in the product. We are currently marketing to more than 30 institutions that are a combination of local community hospitals and larger academic centers. We work closely with the caregivers to ensure a high level of accessibility, provide them with all of the necessary training and tools, and offer continuous support during their initial product experience.

What is the actual sales process?

Initial contact is made with the chief neurosurgeons, including pioneers who are focused on providing cutting-edge therapy for their patients. Others quickly realize the advantages since the mechanism of action is so innovative and the treatment time can be so much shorter. At the same time, we immediately engage every component of the decision-making process. We interact early in the process with the purchasing departments, ICU nurses, neurologists, residents, etc.

How has the launch of the product been received by hospitals?

We have experienced an extremely positive response and have already made incredible progress. In the US, it's common for it to take between four and six months from the first contact with the physician until the first evaluation treatment, after which revenue may be generated. In light of this timeline, we are quite pleased that the first treatment took place quite early, at the beginning of January.

Recertification in Europe has taken longer than expected. How has the German sales organization handled this?

Our sales team in Germany has stayed in touch with our customers and kept them updated. We have not been able to actively market the system during this period, but we have also continued identifying and training potential distribution partners so that we can quickly accelerate sales when the CE marking is regained. Our company culture is focused on cooperation, so our early commercial experiences in Europe have been extremely valuable in preparing for the US launch. The team has also closely supported other functions by translating customer input into needed guidance for product development and manufacturing projects.

Have you faced similar challenges before?

Yes, this is my fourth start-up, and we've delivered successful exits to investors of my previous endeavors. I've devoted a large part of my career to giving patients access to innovative medical technology. Over the last 20 years, I've worked exclusively to lead the commercialization, marketing and business development of growing medical device firms. We have an amazing opportunity to revolutionize the treatment of hemorrhagic stroke, and I look forward to helping make IRRA*flow* the new standard of care.

US launch. The company has prepared to recommence sales in Germany and Austria as soon clearance is received as well as for launch in the Nordic region and the Iberian countries. The European sales organization has also helped to educate and train their colleagues in the US and new distribution partners.

In October, IRRA*flow* attracted considerable interest at the annual European Congress of Neurosurgery (EANS) in Brussels, with attendees from around the world.

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 rapid access to important markets in other parts of the world.

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 new products

IRRAS performs its research and development in San Diego, California, a well-known center for the development and manufacturing of equipment 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* through small modifications.

The launch of a smaller version of the IRRA*flow* catheter for premature infants, a more stable medium-sized catheter and a laser pointer that adapts and facilitates the correct placement of the catheter in each patient are planned for the near future.

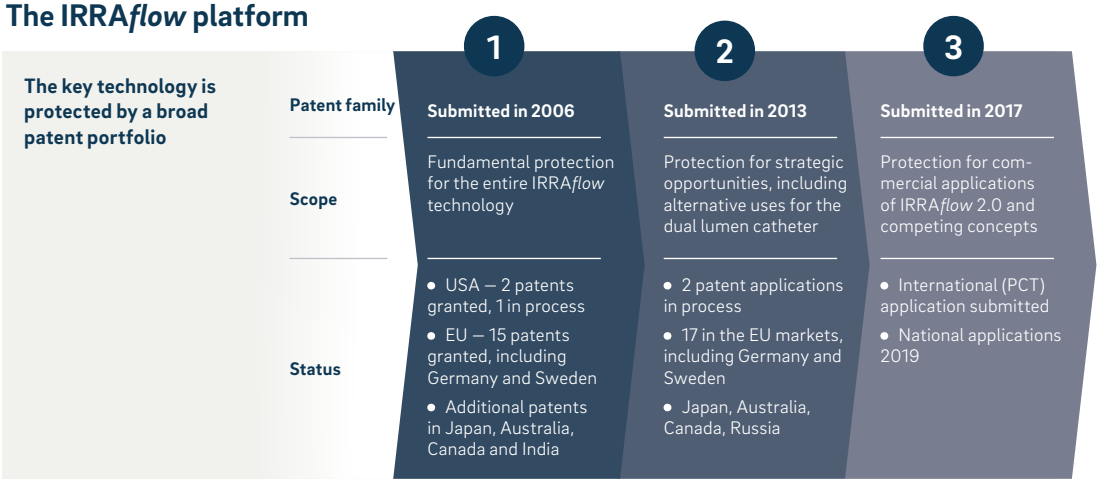
The software was continually updated during the year, and the pressure sensor was moved closer to the tip of the catheter, which strengthens the signal. The company also continually works on software updates.

Production is also driven and 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 patents

The technology platform and consumables used by IRRA*flow* are protected by a broad patent portfolio. The patent protection focuses on the market for intracranial bleeding and also includes potential future areas of use, such as infection, orthopedics, the abdomen, drug delivery and cancer. This protection is continually reviewed as new patent opportunities arise through development projects in progress.

The IRRA*flow* platform



KELLIE FONTES,
SENIOR DIRECTOR, HUMAN CAPITAL

INTERVIEW

It's incredibly exciting to be growing our talent pool while building a culture of respect, empathy, team before self and doing things the right way

You've grown from 7 to 34 employees since you've joined IRRAS in February 2018 – or nearly 500%. How do you ensure that you find the right people when the company is growing so fast?

Finding the right people starts with defining who you are and what you stand for as an organization. The talent we attract must not only have the skills and expertise to raise the bar, but must be a fit with our culture. Our core values are the foundation of what we do and how we do it. It's incredibly exciting to be growing our talent pool while building a culture of respect, empathy, team before self and doing things the right way. Each and every hire is critical to the success of IRRAS in supporting our vision and mission and further embedding our values as we grow the business.

IRRAS is still in the build-up phase and needs experienced key personnel. What do you offer to attract them?

We've had great success in bringing in highly talented people. What we do well is give people the unique opportunity to do meaningful work that has a direct impact in helping save the lives of patients. Several of those who have joined IRRAS have left large organizations to come to a place where they know they can make a difference. As a small company in a competitive market, equity plays a huge role in attracting key talent as well. Our employees join IRRAS as shareholders, with a vested interest in the long term success of the company. We've seen first hand how ownership ignites passion, commitment and dedication.

What key roles have you recruited for?

Our key recruitment focus has been in our US Commercial Operations organization. We've hired 6 Territory Sales Managers and 2 Product Managers, all bringing excellent knowledge and experience to the table. In the Manufacturing and Product Development functions, we appointed a VP, Product Excellence, Senior Director, Product Development and 3 Engineers to increase operational excellence and support our ongoing efforts in enhancing our product and building our pipeline.

How do you ensure that the people you recruit will remain in the long term and not just while the company is being built?

As IRRAS grows, so will the opportunities for employees to develop and grow with the company. Career development is an important retention tool. We want our people to know they will have every opportunity to build on the talent they bring to the company, and that the sky is the limit at IRRAS as far as growth potential. Incentive plans that include stock option grants are also key in gaining long term commitment from new and existing employees.

Will you continue this fast paced recruitment in 2019?

We expect to double in size by the end of 2019, expanding our US Sales force and our EU team upon receipt of the CE mark for our catheter. We'll continue on this growth trajectory in the coming year, with focus on building our commercial sales, product excellence and new product development teams. It's an exciting time for IRRAS now and will continue to be as we grow our IRRAS family and in doing so, positively impact the lives of so many people in the work we do.

The share

The IRRAS share has been listed on Nasdaq Stockholm First North Premier since November 22, 2017. During the year, both the share price and the number of shares traded increased. IRRAS had 1,221 shareholders at year-end.

Market capitalization and turnover

The last price paid as of December 31, 2018 was SEK 33.90, giving IRRAS a market capitalization of SEK 814 million. The last price paid as of March 31, 2019 was SEK 30.30, giving a market capitalization of SEK 727 million. An average of 29 553 shares were traded per day during the 2018 fiscal year. In total, 7,4 million IRRAS shares were traded in 2018 for a value of SEK 245 million. The rise in share price in 2018 amounted to 12%. The OMX SPI Index declined by 9% during the year.

Share capital

On December 31, 2018, the share capital in IRRAS amounted to SEK 720,539.22, distributed among 24,017,974 shares with a quota value of SEK 0.03 per share. This corresponds to an increase of 356,111 shares during the year. IRRAS has only one class of shares, and all shares entitle the holder to the same participation rights in the company's assets and profits.

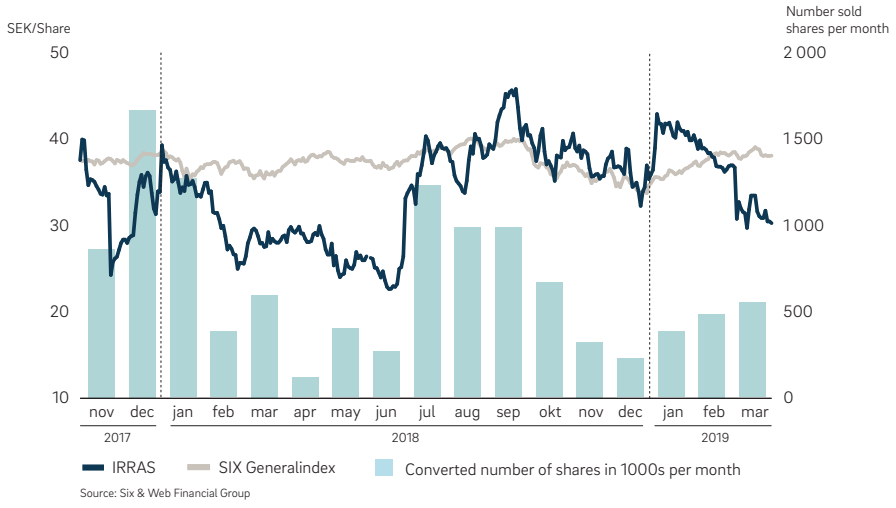
Shareholder agreements

The Board of Directors of IRRAS is not aware of any shareholder agreements or other agreements between the company's shareholders that are intended to achieve joint control over the company. Nor is the Board aware of any agreements or equivalent that could result in a change of control over the company.

Dividends and dividend policy

The Board of Directors of IRRAS has proposed that the Annual General Meeting not pay a dividend for the 2018 fiscal year. The company's financial objective is to have positive cash *flow* by the fourth quarter of 2021 at the latest. The Board does not intend to propose that the Annual General Meeting pay a dividend until positive cash flow can be achieved.

IRRAS SHARE PRICE 2017-11-22–2019-03-31



Source: Six & Web Financial Group

SHAREHOLDERS AS OF DECEMBER 31, 2018 AND KNOWN CHANGES THEREAFTER

	No. of shares	% of shares/votes
Lexington Holding Assets Ltd (BVI)	3,155,727	13.14 %
F.EX Endotherapy Limited	2,934,651	12.22 %
Bacara Holdings Limited	1,430,725	5.96 %
Dr. Kleanthis G. Xanthopoulos	842,878	3.51 %
SystematicGrowth AB	833,725	3.47%
Dr Saeid AB	833,725	3.47%
Nomura PB Nominee LTD	727,338	3.03 %
Fjärde AP-Fonden	595,000	2.48 %
Avanza Pension (nominee share-holders)	553,620	2.31 %
Nyenburgh Holding B.V.	539,515	2.25 %
Nordnet Pensionsförsäkringar	474,721	1.98 %
JP Morgan Bank Luxemburg S.A.	428,742	1.79 %
UBS Switzerland	424,910	1.77 %
Inversis	385,937	1.61 %
Prioritet Capital AB	381,000	1.59%
BNP PariBas	302,337	1.26 %
Other shareholders	9,173,422	38.19%
Total number of shares	**24,017,974**	**100.00 %**

TABLE OF HOLDINGS

Holdings	Number of shareholders
1–500	258
501–5 000	544
5 001–100 000	382
100 001–500 000	26
500 001–	11
Totalt	**1221**

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

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.

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, 2018. 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 publicly traded, commercial-stage medical technology company focused on developing and commercializing innovative solutions for brain surgery. The company's initial product, IRRA*flow*®, addresses the complications associated with the current treatment methods for intracranial bleeding with a dual lumen catheter to administer fluids for irrigating the affected area while draining other fluids. IRRA*flow* received FDA clearance in July 2018.

Regularly during treatment, the catheter is automatically flushed to prevent common catheter occlusions from forming. Because IRRA*flow* is a closed sterile system, it is designed to reduce the documented infection risk of these procedures. In addition, the IRRA*flow* system contains an ICP meter to measure intracranial pressure. The system uses a computer to regulate the desired pressure.

With its unique product portfolio protected by patents and patent applications, IRRAS is well positioned to establish itself as a leader in the medical device market.

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

The company began its commercial launch of IRRA*flow* in US at the end of 2018. Preparations for the launch in several additional countries, including a relaunch in Europe, are under way. The product was initially launched in Europe in 2017, but needed to be recertified since the certification body had ceased operations.

The IRRAS business model is built on selling control units (computers) and then leveraging recurrent revenue streams by selling consumables (primarily catheters and tube sets) for the control units.

Group structure

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

The Swedish Parent Company is responsible for such Group-wide functions as finance, 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.

MULTI-YEAR OVERVIEW, GROUP

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

Significant events during the fiscal year

US launch initiated

At the end of the year, the company began preparations for its launch in the US by recruiting regional sales managers and personnel with backgrounds in marketing. Contact was established with several hospitals, and training of future IRRA*flow* users began. IRRAS also participated in several neurological conferences.

FDA clearance of IRRA*flow*

July 2018, IRRAS received 510(k) clearance from the US Food and Drug Administration (FDA) for US registration of the company's IRRA*flow* system and consumables. The clearance means that the company has the right to market and sell IRRA*flow* in the US.

Expansion of the management team

IRRAS expanded its executive management team during the year. Will Martin joined the company as Chief Commercial Officer and Kellie Fontes came on board as Senior Director, Human Capital. Both report to Dr. Kleanthis G. Xanthopoulos, CEO of IRRAS, and are stationed at the company's US division in San Diego.

Recertification

Intertek, IRRAS' previous certification body, decided not to continue certifying certain products. IRRAS and hundreds of Intertek's other clients therefore needed to obtain updated ISO certification and CE approvals from new certification bodies.

In May, IRRAS received updated ISO 13485:2016 certification and updated CE approvals for both the control unit and the tube set in the IRRA*flow* system. Both products are Class II products. The ISO certification and CE approvals are valid through 2021. For Class III products, such as the IRRAS catheter, more time is normally required for review. The company has not yet received the certification.

Sales and market

IRRAS's first product, IRRA*flow*, is initially intended for treatment of patients with hemorrhagic strokes (bleeding in the brain) and chronic subdural hematoma (bleeding on the surface of the brain). Around one million people in the US and Europe suffer from hemorrhagic strokes and chronic subdural hematoma annually. Approximately 350,000 of these people are treated surgically. IRRAS estimates that the market value of the company's products in Europe and the US is currently just over EUR 1.2 billion per year.

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

IRRAS has launched its product in the US and hopes to see a positive sales trend over the next few years owing to a well thought-out marketing strategy and an excellent product. The product is sold in the US through the company's own sales organisation. The work in the US market will continue through the existing sales organization. As soon as the updated registration clearance in Europe is obtained, a relaunch will take place there as well. In Germany and Austria, the product will be sold through the company's own sales organisation, while sales in the rest of Europe will be through distributors.

In 2019, the company's work with distributors in the rest of the world will be intensified. Agreements have been signed with several distributors globally. In most cases, launching a product in a certain country requires clearance with that country's registration authorities. It is often difficult to judge exactly when such clearances can be obtained.

Earnings and financial position in the Group

Net revenue for the 2018 fiscal year totaled SEK 6.0 million (12.0). Of that revenue, SEK 3.3 million (11.6) is attributable to Germany, and the remainder to the rest of Europe. Owing to the lack of a CE mark (European registration clearance) for the catheter, and launch preparations in the US, no sales were reported after the first quarter of 2018.

The gross loss for the year totaled SEK -14.0 million (6.3).

Operating expenses for 2018 totaled SEK 129.80 million (68.4). The higher operating expenses are due to an increased investment in marketing and sales through the US launch, and to higher development expenses, primarily product maintenance on launched products. The increased operating expenses are also due to higher administrative expenses caused primarily by the costs associated with being listed.

Total research and development expenses for the year amounted to SEK 37.2 million (23.4), of which SEK 14.3 million (10.8) was capitalized and SEK 22.9 million (12.6) was recognized as income.

The net of other operating income and operating expenses for 2018 amounted to SEK 0.5 million (0.6). Other operating income mainly includes exchange rate differences.

Operating loss (EBIT) for 2018 totaled SEK -143.3 million (-61.5). The change for the worse in terms of operating loss is primarily due to increased operating expenses.

Net financial income for 2018 totaled SEK 4.5 million (0.6). The improvement in net financial items is primarily the result of interest income on cash and cash equivalents.

The loss before tax for 2018 totaled SEK -138.8 million (-60.9). The net loss for the year amounted to SEK -138.8 million (-60.9).

Cash flow from operating activities for 2018, after changes in working capital, totaled SEK -97.4 million (-53.7). The negative change in cash flow is primarily attributable to the negative change in earnings, which was partially offset by lower tied-up working capital.

Total net investments, including financial investments, for 2018 totaled SEK -20.3 million (157.0). Of total net investments, investments in intangible assets (primarily capitalized development

expenses) totaled SEK 14.3 million (10.8); investments in and sales of financial assets (investment of part of the share issue proceeds in interest-bearing funds) totaled SEK -35.1 million (145.9); and investments in tangible assets totaled SEK 0.5 million (0.3).

Capital requirements for the year were financed with funds from the share issue carried out in 2017. Cash and cash equivalents amounted to SEK 98.3 million (70.8) at the start of the period and SEK 47.2 million (98.3) at year-end. At the end of the year, there was a total of SEK 110.8 million (145.9) in financial investments.

Production

The US subsidiary, IRRAS USA Inc, is a registered manufacturer of the company's products. All production, however, is carried out by third-party suppliers in the US.

Development

The development of existing and new products is a central, prioritized aspect of IRRAS' operations. IRRAS has several development projects in progress for products in neurosurgery, including the development of a communication system for integration with hospital monitoring systems, a smaller catheter and a laser meter.

Historically, IRRAS has devoted considerable resources to developing products. Development expenses for the next few years are expected to be on a par with those in 2018.

IRRAS' overall production strategy is focused on developing innovative, user-friendly, reliable and high-quality proprietary systems. IRRAS has strengthened internal competence for the development of control units and consumables. However, this in-house expertise is frequently supplemented by external consultants.

Apart from new development, the development division is also responsible for product care. This includes partnerships with third-party suppliers to improve and enhance the efficiency of the components included in the manufacturing process. Product development is carried out by the US subsidiary.

Research and development expenses recognized as income account for 18% (18) 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, risks associated with a dependence 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 customer agreements cannot be signed, or are canceled, this could negatively affect the company's future development, growth and financial position. Negative developments could also arise if competitors offer better and more efficient products at lower prices.

Development risks

There is always a risk that current and future development 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 primarily in their local currencies. Revenue and expenses for the German subsidiary are primarily in EUR, whereas the US subsidiary will have revenue and expenses 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, work is under way to secure possible financing alternatives, either through loans or through new share issues. Given recent developments in the company, however, the Board deems the company's prospects for financing its operations to be favorable. If sufficient financing cannot be obtained, there is a risk that the company may not have the necessary prerequisites for 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 and create 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

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, it will negatively impact its operations.

Dependence on key individuals

IRRAS has a distinctly 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 IRRA*flow*, IRRAS has a unique product that, when launched, met with an excellent reception from users and customers. IRRAS' plan is to sell IRRA*flow* to the greatest extent possible through its own sales organization in countries such as the US and Germany, and via distributors in other countries. Launch preparations, including work on securing registration clearance for the company's products, have begun in several countries. The plan is to launch IRRA*flow* in additional countries as registration clearance is obtained.

In parallel with its work on marketing and selling products, the company is focusing on production expansion, quality assurance of its product and measures to enhance production efficiency, thereby lowering its production costs. This work will continue in 2019, provided that the company arranges financing to ensure its going concern.

The development of new and existing products will always be important for IRRAS. The company has several development projects in progress concerning supplementary products for IRRA*flow*.

Significant events after the end of the fiscal year

First patients in US successfully treated with IRRA*flow*

In early January 2019, the first patients in the US were treated with IRRA*flow*. The treatments were administered by physicians at the University of California, Irvine (UCI) Medical Center in Orange, California. The medical team successfully treated two patients suffering from chronic subdural hematoma, a collection of blood on the surface of the brain.

The IRRAS share and ownership structure

The number of shares increased by 356,111 during the year, totaling 24,017,974 at December 31, 2018. 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, 2018 AND KNOWN CHANGES THEREAFTER

	No. of shares	% of shares/votes
Lexington Holding Assets Ltd (BVI)	3,155,727	13.14 %
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BNP PariBas	302,337	1.26 %
Other shareholders	9,173,422,	38.19%
Total number of shares	24,017,974	100.00 %

Personnel

The average number of employees in the Group for 2018 was 21 (8), of whom 3 (1) in the Parent Company. The breakdown of the average number of employees by country was 3 (1) in Sweden, 13 (2) in the US and 5 (5) in Germany. The average number of women in the Group was 8 (4) and the average number of men was 13 (4).

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 an proactive personnel policy. The company continuously addresses issues related to competency development, work environment and equality. To achieve this, the company hired a Senior Director, Human Capital in early 2018.

Quality assurance

IRRAS is certified under ISO 13485:2016. Work to secure registration clearance is under way in a number of countries.

In 2018, IRRAS received an updated ISO 13485:2016 certificate and new CE approval for its control unit and tube set. Both products are Class II products. The ISO certificate and CE approval are valid through 2021. The CE approval for the catheter is expected in the near future.

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 applicable 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 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.

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 2018 totaled SEK 13.1 million (4.0). The amount relates primarily to invoicing of management fees and other remuneration from subsidiaries. Operating loss (EBIT) amounted to SEK -43.0 million (-45.3). As of December 31, 2018, equity in the Parent Company totaled SEK 307.4 million (338.9). The company's registered share capital at December 31, 2018 totaled SEK 720,539, allocated among 24,017,974 shares. The Parent Company's receivables from Group companies consist of long-term loans and current receivables.

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 60-63. 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, 2018 — SEK 274,919,048 — 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, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Net revenue	5	5,994	11,973
Cost of sales		-19,959	-5,658
Gross profit/loss		**-13,965**	**6,315**
Other operating income	7	1,702	644
Marketing and selling expenses		-62,342	-23,724
Administrative expenses	9	-44,547	-32,061
Research and development expenses		-22,931	-12,613
Other operating expenses	7	-1,245	-26
Operating loss (EBIT)	**6**	**-143,328**	**-61,464**
Financial income		4,819	567
Financial expenses		-333	-4
Net financial items	**8**	**4,486**	**563**
Loss before tax		**-138,842**	**-60,901**
Income tax	12	–	–
Net loss for the year		**-138,842**	**-60,901**
Earnings per share before and after dilution, SEK	26	-5.83	-3.40
Number of shares before dilution, average		23,815,328	17,906,003
Number of shares after dilution, average		23,815,328	17,906,003

Consolidated statement of profit or loss and other comprehensive income

AMOUNTS IN TSEK	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017–Dec 31, 2017
Net loss for the year	**-138,842**	**-60,901**
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	-1,140	-1,200
Other comprehensive income for the year, net of tax	**-1,140**	**-1,200**
Total comprehensive income for the year	**-139,981**	**-62,101**

Consolidated statement of financial position

AMOUNTS IN TSEK	Note	Dec 31, 2018	Dec 31, 2017
ASSETS			
Non-current assets			
Capitalized development expenses	13	38,090	31,515
Patents	13	2,215	2,531
Tangible assets	14	624	207
Financial investments	15	80,757	85,836
Total non-current assets		**121,685**	**120,089**
Current assets			
Inventory	16	3,352	12,204
Advance payments to suppliers		45	306
Current tax receivables		–	929
Other receivables	17	1,933	37,131
Prepaid expenses and accrued income	18	960	226
Current investments	15	30,065	60,082
Cash and cash equivalents		47,244	98,286
Total current assets		**83,599**	**209,163**
TOTAL ASSETS		**205,284**	**329,252**
EQUITY			
Share capital		721	710
Other paid-in capital		440,208	439,611
Reserves		-1,948	-808
Retained earnings, including net loss for the year		-254,826	-123,482
Total equity		**184,154**	**316,030**
LIABILITIES			
Provisions			
Other provisions		370	–
Total provisions		**370**	**–**
Current liabilities			
Accounts payable		8,626	2,288
Other liabilities		2,526	1,348
Accrued expenses and deferred income	20	9,608	9,587
Total current liabilities		**20,760**	**13,223**
TOTAL EQUITY AND LIABILITIES		**205,284**	**329,252**

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, 2017		**86**	**176,211**	**392**	**-81,575**	**95,115**
Comprehensive income						
Net loss for the year					-60,901	**-60,901**
Other comprehensive income						
Translation differences for the year on translation of foreign operations				-1,200		**-1,200**
Total comprehensive income		**–**	**–**	**-1,200**	**-60,901**	**-62,101**
Transactions with shareholders						
Incentive programs	10				19,424	**19,424**
Bonus issue		430			-430	**–**
New share issue		193	292,962			**293,155**
(of which capital subscribed but not paid in)			*30,744*			***30 744***
Issue expenses			-29,563			**-29,563**
Total		624	263,399	–	18,993	**283,016**
Closing equity December 31, 2017	19	**710**	**439,611**	**-808**	**-123,482**	**316,030**

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, 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**
(of which capital subscribed but not paid in)						
Issue expenses*			597			**597**
Redemption of convertible bonds						–
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 cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Cash flow from operating activities			
Operating loss (EBIT)		-143,328	-61,464
Adjustments for non-cash items			
– Reversal of depreciations		8,141	3,706
– Other non-cash items		370	–
– Incentive programs	10	7,442	18,812
Interest received		569	–
Interest paid		-160	-4
Tax paid		929	–
Cash flow from operating activities before changes in working capital		**-126,036**	**-38,951**
Changes in working capital			
Increase/decrease in inventory		9,570	-12,383
Increase/decrease in operating receivables		8,939	-7,439
Increase/decrease in operating payables		10,092	5,043
Total changes in working capital		**28,601**	**-14,778**
Cash flow from operating activities		**-97,435**	**-53,729**
Cash flow from investing activities			
Investments in intangible assets		-14,278	-10,818
Investments in tangible assets		-532	-243
Investments in financial investments		–	-145,917
Sales of financial investments		35,096	–
Cash flow from investing activities		**20,286**	**-156,979**
Cash flow from financing activities			
New share issue		30,744*	263,023
Issue expenses		-5,568*	- 23,995
Cash flow from financing activities		**-25,176**	**239,028**
Cash flow for the period		**-51,972**	**28,321**
Cash and cash equivalents at the beginning of the period		98,286	70,814
Exchange rate differences in cash and cash equivalents		-931	-849
Cash and cash equivalents at the end of the period		**47,244**	**98,286**

* 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	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Net revenue	5	13,081	3,969
Cost of sales		-7,965	-3,336
Gross profit		**5,116**	**633**
Other operating income	7	868	398
Marketing and selling expenses		-4,084	-3,999
Administrative expenses	9	-35,654	-32,559
Research and development expenses		-8,254	-9,759
Other operating expenses	7	-1,010	-23
Operating loss (EBIT)	**6**	**-43,018**	**-45,309**
Other interest income and similar profit/loss items		3,784	143
Interest expenses and similar profit/loss items		-330	-3
Net financial items	**8**	**3,454**	**140**
Loss before tax		-39,565	-45,169
Tax on loss for the year	12	–	–
Net loss for the year		**-39,565**	**-45,169**

Parent Company statement of profit or loss and other comprehensive income

	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Net loss for the year	**-39,565**	**-45,169**
Other comprehensive income for the year, net of tax	–	–
Total comprehensive income for the year	**-39,565**	**-45,169**

Parent Company balance sheet

AMOUNTS IN TSEK	Note	Dec 31, 2018	Dec 31, 2017
ASSETS			
Capital subscribed but not paid in		–	30,744
Non-current assets			
Intangible assets			
Capitalized development expenses	13	38,090	31,515
Patents	13	2,215	2,531
Total intangible assets		**40,305**	**34,046**
Tangible assets			
Equipment, tools, fixtures and fittings	14	416	162
Total tangible assets		**416**	**162**
Financial assets			
Participations in Group companies	24	68,745	24,638
Receivables from Group companies	11	29,595	14,587
Other securities held as non-current assets	15	80,757	85,836
Total financial assets		**179,097**	**125,061**
Total non-current assets		**219,818**	**159,270**
Current assets			
Inventory		–	306
Total inventory		**–**	**306**
Current receivables			
Receivables from Group companies	11	26,330	11,804
Other receivables	17	1,206	1,532
Prepaid expenses and accrued income	18	504	302
Total current receivables		**28,040**	**13,638**
Current investments	15	**30,065**	**60,082**
Cash and bank balances		**37,342**	**85,814**
Total current assets		**95,446**	**159,840**
TOTAL ASSETS		**315,265**	**349,854**

Parent Company balance sheet *cont.*

AMOUNTS IN TSEK	Note	Dec 31, 2018	Dec 31, 2017
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19	721	710
Statutory reserve		–	–
Fund for development expenses		31,779	23,401
Total restricted equity		**32,500**	**24,110**
Non-restricted equity			
Share premium reserve		406,631	406,034
Retained earnings		-92,148	-46,099
Net loss for the year		-39,565	-45,169
Total non-restricted equity		**274,919**	**314,767**
Total equity		**307,419**	**338,877**
Provisions			
Other provisions		370	–
Total provisions	**21**	**370**	**–**
Current liabilities			
Accounts payable		1,705	2,042
Other liabilities		115	174
Accrued expenses and deferred income	20	5,655	8,760
Total current liabilities		**7,476**	**10,976**
TOTAL EQUITY AND LIABILITIES		**315,265**	**349,854**

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, 2017	**86**	**15,017**	**142,635**	**-31,117**	**-25,591**	**101,030**
Comprehensive income						
Appropriation of earnings as decided at AGM				-25,591	25,591	**–**
Net loss for the year					-45,169	**-45,169**
Total comprehensive income	**–**	**–**	**–**	**-25,591**	**-19,578**	**-45,169**
Transactions with shareholders						
Incentive programs				19,424		**19,424**
Bonus issue	430			-430		**-**
New share issue	193		292,962			**293,155**
(of which capital not paid in)			*(30,744)*			***(30,744)***
Issue expenses			-29,563			**-29,563**
Total transactions with shareholders	**624**	**–**	**263,399**	**18,993**	**–**	**283,016**
Provision, fund for development expenses		8,384		-8,384		**–**
Equity December 31, 2017	**710**	**23,401**	**406,034**	**-46,099**	**-45,169**	**338,877**

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, 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**
(of which capital not paid in)						**–**
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 cash flows

AMOUNTS IN TSEK	Note	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Cash flow from operating activities			
Operating loss (EBIT)		-43,018	-45,309
Adjustments for non-cash items			
– Reversal of depreciations		8,108	3,679
– Non-cash provisions		370	–
– Incentive programs	10	4,313	15,367
Interest received		492	–
Interest paid		-330	-3
Cash flow from operating activities before changes in working capital		**-30,065**	**-26,266**
Changes in working capital			
Increase/decrease in other current receivables		-10,804	-12,723
Increase/decrease in operating payables		2,732	2,746
Total changes in working capital		**-8,073**	**-9,978**
Cash flow from operating activities		**-38,137**	**-36,244**
Cash flow from investing activities			
Investments in participations in subsidiaries		-40,979	-10,000
Investments in intangible assets		-14,278	-10,818
Investments in tangible assets		-343	-189
Sales of financial investments		35,096	–
Investments in financial investments		-15,008	-156,423
Cash flow from investing activities		**-35,511**	**-177,430**
Cash flow from financing activities			
New share issue		30,744*	263,023
Issue expenses		-5,568*	-23,995
Cash flow from financing activities		**25,176**	**239,028**
Cash flow for the period		**-48,472**	**25,354**
Cash and cash equivalents at the beginning of the period		85,814	60,460
Exchange rate differences in cash and cash equivalents		–	–
Cash and cash equivalents at the end of the period		**37,342**	**85,814**

* Issue proceeds and issue costs that were not paid as of December 31, 2017 but paid in 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 2018 up until the signing of this report have been applied to the consolidated financial statements.

IFRS 9 Financial Instruments

IFRS 9 addresses the recognition of financial assets and liabilities, and replaces IAS 39 Financial Instruments: Recognition and Measurement. As in IAS 39, financial assets are classified in different categories, some of which are measured at amortized cost and others at fair value. IFRS 9 introduces other categories than those found in IAS 39. Classifications under IFRS 9 are based both on the contractual cash flows of the instrument and on the business model of the company. IFRS 9 also introduces a new model for impairment of financial assets based on expected credit losses instead of actual losses. The purpose of the model is to recognize credit losses earlier than in IAS 39. For liabilities, IFRS 9 largely corresponds with IAS 39.

In accordance with the transition rules in IFRS 9, comparative information has not been restated.

In terms of classification of financial assets and financial liabilities, the transition to IFRS 9 entailed no changes in carrying amount. The table below shows the classification under IAS 39 and the classification under IFRS 9 for the respective items — financial assets and financial liabilities — together with the carrying amount on the transition date.

	Carrying amount, Dec 31, 2017	IAS 39 classification	IFRS 9 classification
Financial investments	85,836	Loans and accounts receivable	Amortized cost
Other receivables	37,131	Loans and accounts receivable	Amortized cost
Accrued income	86	Loans and accounts receivable	Amortized cost
Current investments	60,082	Loans and accounts receivable	Amortized cost
Cash and cash equivalents	98,286	Loans and accounts receivable	Amortized cost
Total	**281,421**		

The application of the impairment rules in IFRS 9 had no material impact provisions recognized for credit losses and no adjustments were therefore made on the transition date.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 *Revenue from Contracts with Customers* establishes how revenue is to be recognized; it replaces IAS 18 Revenue and IAS 11 Construction Contracts as well all related SIC and IFRIC. The principles on which IFRS 15 is based are intended to give users of financial statements more useful information about the company's revenue. The increased transparency obligation means that information about revenue, the time of settlement, uncertainties related to revenue recognition and cash flow attributable to the company's customer contracts must be submitted. 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.

The Group has applied IFRS 15 from January 1, 2018. For revenue recognition, IRRAS AB recognizes primary geographic markets and time. IRRAS AB has concluded that this can also be used to attain the goal of a breakdown in accordance with the disclosure requirements in IFRS 15.

Revenue recognition in 2018 and 2017 occurred at the point in time when the goods were transferred to the customer, which is why no effects arose upon the change of the accounting policy.

Standards, amendments and interpretations of existing standards that will become effective in 2019 or later and are expected to impact the financial statements

IFRS 16 Leases

IFRS 16 *Leases* is effective for periods beginning on or after January 1, 2019 and requires that lessees recognize assets and liabilities attributable to all leases, with exception of leases that are shorter than 12 months and/or relate to small amounts. 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 undertaking to make ongoing payments as a lessee.

The standard is not expected to have a material impact on the consolidated financial statements since the Group's leases are currently few in number and consist mainly of rent for premises. Current leases are shorter than 12 months and/or add up to insignificant amounts. The Group also has short-term leases for vehicles and office equipment.

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's equity instruments are traded in an active 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 the executive management group 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	14 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.

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 flows (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 flows 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 flows 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 flows 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 flows 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 flows and that the terms agreed on for the assets give rise at fixed points in time to cash flows 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.

For the comparison period, IAS 39 was applied for the recognition of financial assets and liabilities. The classification at that time was based on the purpose for which the financial asset or liability was acquired. In the comparison period, all financial assets are classified as loans and receivables 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.

For the 2017 comparison period, the Group assessed whether or not there was objective evidence that a need for impairment existed for a financial asset or group of financial assets at the end of every reporting period. A financial asset or a group of financial assets was impaired only if there was objective evidence of a need for impairment as a result of one or more events that occurred after the initial recognition of the asset and the impact of this event on the estimated future cash flows of the financial asset could be reliably estimated.

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 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 at the lower of cost and net realizable value. The cost of inventory is determined using the first-in, first-out (FIFO) principle and consists of the cost of goods purchased. Borrowing costs are not included in the cost of inventory. Inventory consists of finished products. Net realizable value is the estimated selling price in the ordinary course of business. A required provision for obsolescence 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 gross amount is indicated in Note 10.

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 to be expensed is based on the calculated fair value of the allotted options, and is allocated on a straight-line basis over the vesting period.

Non-market-based conditions for vesting, such as the employee remaining in the company´s service, 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. No re-examination of the calculated value is performed 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 fair 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 receives thus give 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 authorized the CEO to 236,618 shares, which were distributed in early 2018, and the 510(k) clearance authorized the CEO to 475,603 shares which were also distributed during 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 outflow 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 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 has implemented IFRS 15 Revenue from agreements with customers as of January 1, 2018. IFRS 15 replaces IAS 18 Revenue and IAS 11 Entrepreneurial Agreements and related SIC and IFRIC. The extended disclosure obligation means that information on the type of income, the timing of regulation, uncertainties linked to revenue recognition and cash flow attributable to the company's customer contracts shall be provided. According to IFRS 15, revenue must be recognized when the customer receives control of the sold goods or services and is able to use them and receives the benefit from the goods or services. IRRAS AB reports primary geographical markets and the timing of revenue recognition. Reporting of revenues during 2018 and 2017 has taken place at the time when the goods have been transferred to the customer, so no effects have arisen on the change of accounting principle.

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 risks and rewards of ownership of the goods are 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.

Leases

Leases in which a significant portion of the risks and benefits of ownership are retained by the lessor are classified as operating leases. Payments made during the lease term (net of any incentives from the lessor) are recognized in profit or loss on a straight-line basis over the lease term. At present, the Group's leases consist primarily of rent for premises.

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.

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, credit risk and liquidity/financing risks. 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, 2018, 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 company operates primarily in its local markets and its 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 606 (1,197).

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 -5,700 (-7,359) was attributable to the German subsidiary, and net assets totaled TSEK -16,316 (-8,491) 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 570 (736) 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 1,632 (849) upon the translation of the foreign subsidiary.

Of the Group's loss before tax during the fiscal year, approximately TSEK -96,562 (-5,913) was attributable to the US subsidiary, and net assets totaled TSEK -36,292 (14,147) as of the balance sheet date. If the average exchange rate for the USD against the SEK had been 10% higher/lower compared to the average exchange rate during the fiscal year, with all other variables unchanged, the Group's loss before tax for the fiscal year would have been impacted by approximately TSEK 9,656 (591) upon translation of the foreign subsidiary's statement of profit or loss. If the exchange rate for the USD against the SEK had been 10% higher/lower compared to the closing exchange rate at the end of the fiscal year, with all other variables unchanged, the Group's net assets at the end of the fiscal year would have been impacted by approximately TSEK 3,629 (1,415) upon 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 market interest rates. The Group's net interest income is largely dependent on trends in the Swedish market, since the main portion of the Group's cash is held in the Swedish Parent Company and the Group has no 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 768 (599) before tax. The sensitivity analysis is based on an interest rate scenario that 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, 2018, 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, 41% (48) of which have a credit rating of A or higher. 50% (45) 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 (amount in TSEK)	2018-12-31	2017-12-31	2018-12-31	2017-12-31
Bonds, rating				
AA-	–	25,114	–	25,114
A	15,113	15,113	15,113	15,113
A-	30,321	30,321	30,321	30,321
BBB	10,069	10,069	10,069	10,069
N/A	55,317	65,299	55,317	65,299
Total	**110,821**	**145,917**	**110,821**	**145,917**

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	
Liquid assets (amount in TSEK)	2018-12-31	2017-12-31	2018-12-31	2017-12-31
Rating				
AA-	37,342	85,814	37,342	85,814
A+	9,902	12,472	–	–
Total	**47,244**	**98,286**	**37,342**	**85,814**

Maturity analysis
All financial liabilities in the Group 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 because the financial liabilities consist solely of operating payables.

Financial instruments by category

Group	Dec 31, 2018 Amortized cost	Dec 31, 2017 Loans and receivables
Assets in the balance sheet		
Financial investments	80,757	85,836
Current tax receivables	–	929
Other receivables	1,933	37,131
Accrued income	87	86
Current investments	30,065	60,082
Cash and cash equivalents	47,244	98,286
Total	**160,085**	**282,349**

Group	Dec 31, 2018 Other financial liabilities	Dec 31, 2017 Other financial liabilities
Liabilities in the balance sheet		
Accounts payable	8,626	2,288
Other liabilities	2,526	1,348
Accrued expenses	9,608	9,587
Total	**20,760**	**13,223**

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, 2018, the Group had available liquidity of TSEK 47,244 consisting 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, work is under way to secure possible financing alternatives, either through loans or through new share issues. Given recent developments in the company, however, the Board deems the company's prospects for financing its operations to be favorable. If sufficient financing cannot be obtained, there is a risk that the company may not have the necessary prerequisites going concern.

	Group		Parent Company	
Net debt (amounts in TSEK)	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Cash and cash equivalents	47,244	98,286	37,342	85,814
Current investments	30,065	60,082	30,065	60,082
Financial investments	80,757	85,836	80,757	85,836
Total borrowings	–	–	–	–
Net debt	**-158,066**	**-244,203**	**-148,163**	**-231,731**

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 introduce 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. As of the balance sheet date, management's assessment is that future cash flows will be sufficient to cover the investments and that no need for impairment therefore exists.

NOTE 5 NET REVENUE

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

	Group		Parent Company	
	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017–Dec 31, 2017	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017–Dec 31, 2017
Germany	3,298	11,549	4,967	1,286
Europe, excluding Germany	2,696	424	–	–
USA	–	–	8,115	2,683
Other countries	–	–	–	–
Total net revenue by geographic market	**5,994**	**11,973**	**13,081**	**3,969**

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

NOTE 6 BREAKDOWN OF EXPENSES BY TYPE OF COST

Operating profit/loss by type of cost

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Net revenue	5,994	11,973	13,081	3,969
Capitalized work for own account	14,278	10,818	14,278	10,818
Other operating income	1,702	644	868	398
Raw materials and consumables	-6,701	-2,778	–	–
Other external costs	-91,933	-48,179	-42,852	-38,547
Personnel costs	-57,281	-30,211	-19,275	-18,244
Depreciation, amortization and impairment	-8,141	-3,706	-8,108	-3,679
Other operating expenses	-1,245	-26	-1,010	-23
Operating loss (EBIT)	**-143,328**	**-61,464**	**-43,018**	**-45,309**

NOTE 7 OTHER OPERATING INCOME AND OTHER OPERATING EXPENSES

Other operating income

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Exchange differences	1,525	517	868	398
Other	177	128	–	–
Total other operating income	**1,702**	**644**	**868**	**398**

Other operating expenses

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Exchange differences	1,245	23	1,010	23
Other	–	2	–	–
Total other operating expenses	**1,245**	**26**	**1,010**	**23**

NOTE 8 FINANCIAL ITEMS

	Group		Parent Company	
	Jan 1,2018– Dec 31,2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Financial income				
Exchange differences	4,250	565	2,894	–
Interest income	569	2	889	143
Total financial income	**4,819**	**567**	**3,784**	**143**
Financial expenses				
Interest expenses	160	4	156	3
Other financial expenses	173	–	173	–
Total financial expenses	**333**	**4**	**330**	**3**
Profit from financial items, net	**4,486**	**563**	**3,454**	**140**

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.

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
KPMG				
Audit engagement	770	350	770	350
Other audit engagements	–	2,228	–	2,228
Tax advice	–	–	–	–
Other advisory services	2,280	–	2,280	–
Total	**3,050**	**2,578**	**3,050**	**2,578**

* Refers primarily to costs for listing on First North Premier; the majority is thus recognized in equity as issue expenses.

NOTE 10 SALARIES, OTHER REMUNERATION AND SOCIAL SECURITY EXPENSES

Costs for salaries, other remuneration and social security expenses

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Salaries and remuneration	41,505	9,906	12,675	1,960
Social security expenses	3,272	931	1,464	419
Incentive programs	7,442	18,812	4,313	15,367
Pension costs	673	477	673	157
Total	**52,891**	**30,126**	**19,124**	**17,903**

Average number of employees

	Jan 1, 2018– Dec 31, 2018		Jan. 1, 2017 Dec 31, 2017	
	Average number of employees	Of whom men	Average number of employees	Of whom men
Parent Company				
Sweden	3	64%	1	71%
Total in the Parent Company	**3**	**64%**	**1**	**71%**
Subsidiaries				
Germany	5	67%	5	57%
USA	13	57%	2	35%
Total in subsidiaries	**18**	**60%**	**7**	**51%**
Group total	**21**	**60%**	**8**	**53%**

Salaries and other remuneration allocated among senior executives

	Jan 1, 2018– Dec 31, 2018				Jan 1, 2017– Dec 31, 2017			
	Salaries and other remuneration	Pension costs	Incentive programs	Fees invoiced	Salaries and other remuneration	Pension costs	Incentive programs	Fees invoiced
Group								
Board members, CEOs and other senior executives, of whom:	16,583	492	5,315	783	2,722	131	16,741	8,479
President and CEO Kleanthis G. Xanthopoulos	7,117	–	4,313	–	748	–	15,367	6,784
Chairman of the Board Anders P. Wiklund	500	–	–	–	167	–	–	–
Board member Saied Esmaeilzadeh	200	–	–	–	67	–	–	–
Board member Anita Tollstadius	200	–	–	–	67	–	–	–
Board member Marios Fotiadis	200	–	–	–	67	–	–	–
Board member Eva Nilsagård	75	–	–	–	–	–	–	–
Other senior executives	8,291	492	1,002	783	1,608	131	1,375	1,695
Total	**16,583**	**492**	**5,315**	**783**	**2,722**	**131**	**16,741**	**8,479**
Parent Company								
Board members, CEOs and other senior executives, of whom:	10,138	492	4,313	–	1,871	131	15,367	6,784
President and CEO Kleanthis G. Xanthopoulos	7,117	–	4,313	–	748	–	15,367	6,784
Chairman of the Board Anders P. Wiklund	500	–	–	–	167	–	–	–
Board member Saied Esmaeilzadeh	200	–	–	–	67	–	–	–
Board member Anita Tollstadius	200	–	–	–	67	–	–	–
Board member Marios Fotiadis	200	–	–	–	67	–	–	–
Board member Eva Nilsagård	75	–	–	–	–	–	–	–
Other senior executives	1,846	492	–	–	756	131	–	–
Total	**10,138**	**492**	**4,313**	**–**	**1,871**	**131**	**15,367**	**6,784**

* Other senior executives refers to members of the executive management group, except the CEO. In 2018, this included Fredrik Alpsten, Lance Boling, Will Martin (as of March 2018), Kellie Fontes (as of February 2018) and Christos Panatopoulos (through May 2018). In 2017, other senior executives included Fredrik Alpsten (as of October 2017), Lance Boling (as of April 2017) and Christos Panatopoulos (full-year 2017).

Gender distribution among Board members and other senior executives

	Jan 1, 2018–Dec 31, 2018		Jan. 1, 2017 Dec 31, 2017	
	Number on balance sheet date	Of whom men	Number on balance sheet date	Of whom men
Group				
Board members	6	67%	5	80%
CEO and other senior executives	5	80%	4	100%
Group total	**11**	**73%**	**9**	**89%**
Parent Company				
Board members	6	67%	5	80%
CEO and other senior executives	2	100%	2	100%
Parent Company total	**8**	**75%**	**7**	**86%**

Share-based renumerations

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, 2018–Dec 31, 2018	Jan 1, 2017–Dec 31, 2017	Jan 1, 2018–Dec 31, 2018	Jan 1, 2017–Dec 31, 2017
Cost of share-based remuneration				
Incentive program 1	4,340	8,013	2,913	5,378
Incentive program 2	1,061	810	–	–
Incentive program 3	–	–	–	–
Incentive program 4	–	–	–	–
Incentive program 5	641	–	–	–
Share rights program	1,400	9,989	1,400	9,989
Total	**7,442**	**18,812**	**4,313**	**15,367**

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 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, 2018, there were 1,880,000 options outstanding, of which 1,391,429 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, 2018, there were 643,000 options outstanding, of which 410,000 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, 2018, of which 200,000 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 in September 2017 to the Chairman of the Board, 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. 268,750 options were issued in 2018 at no cost to employees in the Group. As of December 31, 2018, none of the options 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 target for 2021 has been set at SEK 275 million and has been announced externally. The sales targets for 2019 and 2020 have been set but have not been announced externally.

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 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.

Share award 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. Half of the shares the CEO receives thus give rise to no dilution. However, 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					Share rights
	Program 1	Program 2	Program 3	Program 4	Program 5	Share award
Number of personnel options/share rights allotted as of Dec 31, 2016	**1,900,000**	**–**	**–**	**–**	**–**	**712,221**
Returned during the period	-40,000	–	–	–	–	–
Allotted during the period	0	350,000	260,000	100,000	–	–
As of Dec 31, 2017	**1,860,000**	**350,000**	**260,000**	**100,000**	**–**	**712,221**
Returned during the period	–	–	–	–	–	–
Assigned 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**

	No. outstanding as of Dec 31, 2018	No. vested as of Dec 31, 2018	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	1,880,000	1,415,180	13.6	25.0	30%	11.5–12.2	0	September 30, 2025
Incentive program 2	643,000	213,056	35.0	30.0–30.8	30%	3.3–4.8	0	October 31, 2021
Incentive program 3	320,000	0	50.0	30.0	30%	1.7	0	October 31, 2020
Incentive program 4	100,000	0	50.0	30.0	30%	1.7	0	October 31, 2020
Incentive program 5	268,750	36,569	25.86	26.0–43.8	30%	3.6–19.3	0	June 15, 2022
Share rights program	0	0	0.0	13.5–28.0	30%	N/A	0	–
Total incentive programs/share rights	**3,211,750**							

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 268 (157).

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Summary of pension benefits				
Pension cost safeguarded through endowment insurance	1,525	–	1,525	–
Total	**1,525**	**–**	**1,525**	**–**

There are 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 gross amount is indicated below.

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Pension obligation				
Opening capital value	–	–	–	–
Cost for the year	1,699	–	1,699	
Change in capital value	-173	–	-173	
Closing capital value	**1,525**	**–**	**1,525**	**–**

	Group		Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Separable asset				
Opening fair value	–	–	–	–
Signed endowment insurances for the year	1,699	–	1,699	
Return for the year	-173	–	-173	
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, 2018**	**Dec 31, 2017**
Receivables from Group Companies, non-current	29,595	14,587
Receivables from Group Companies, current	26,330	11,804

During the fiscal year, Parent Company sales regarding management fees to subsidiaries totaled TSEK 4,967 (3,969) and allocation of earnings to subsidiaries totaled TSEK 8,115 (0), which corresponds to 100% of sales. The entire amount was outstanding on the balance sheet date. No purchases from subsidiaries took place during the fiscal year or during the comparison year.

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, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Consultancy fees invoiced		
Chairman of the Board Anders P. Wiklund	145	233
CEO Dr. Kleanthis G. Xanthopoulos	1,730	–
Board member Christos Panotopoulos	250	–
Total	**2,125**	**233**

The Group leased offices from a party related to President and CEO Kleanthis G. Xanthopoulos in 2018. The cost for the year totaled TSEK 104 (115). The Group also purchased office equipment from a party related to President and CEO Kleanthis G. Xanthopoulos. The cost for the year totaled TSEK 179 (0).

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. The payments refer to remuneration in 2017. For further information, refer to Note 10.

Christos Panotopoulos, the company's second-largest owner and Chief Scientific Officer until May 31, 2018, offers IRRAS consulting services with respect to his medical expertise via his company F.EX.Endotherapy Ltd. This agreement also entitles 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.

The following amounts have been invoiced to IRRAS by related companies:

	Group/Parent Company	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Juno Ekonomi AB (indirectly owned by Serendipity Group)	–	303
Total	**–**	**303**

Transactions with related parties took place on market terms.

NOTE 12 INCOME TAX

	Group		**Parent Company**	
	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Current tax for the year	–	–	**–**	**–**
Total tax on net loss for the year	**–**	**–**	**–**	**–**

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, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Loss before tax	-138,842	-60,901	-39,565	-45,169
Income tax calculated according to the Group's applicable tax rate	30,545	13,398	8,704	9,937
Non-taxable income	–	175	–	0
Non-deductible expenses	-2,191	-4,029	-1,425	-3,340
Unrecognized deductible expenses	-131	5,448	-131	5,448
Loss carryforwards for which no deferred income tax asset was recognized	-35,131	-16,668	-7,148	-12,045
Tax effect of utilized, previously not measured, loss carryforwards	95	–	–	–
Effects of foreign tax rates	6,813	1,676	–	–
Income tax	**0**	**0**	**0**	**0**

The Group's effective tax rate was deemed to be 22%, 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 for 2017 and 2018 is 31%, and the tax rate applied for the US is 29.85% for 2018 and 40% for 2017. 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, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017	Jan 1, 2018– Dec 31, 2018	Jan 1, 2017– Dec 31, 2017
Accumulated loss carryforwards	276,068	145,399	163,533	129,282

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, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Capitalized development expenses				
Opening cost	34,851	24,033	34,851	24,033
Assets capitalized during the year	14,278	10,818	14,278	10,818
Closing accumulated cost	**49,129**	**34,851**	**49,129**	**34,851**
Opening amortization	-3,336	–	-3,336	–
Amortization for the year	-7,703	-3,336	-7,703	-3,336
Closing accumulated amortization	**-11,038**	**-3,336**	**-11,038**	**-3,336**
Closing carrying amount	**38,090**	**31,515**	**38,090**	**31,515**

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Patents				
Opening cost	4,429	4,429	4,429	4,429
Closing accumulated cost	**4,429**	**4,429**	**4,429**	**4,429**
Opening amortization	-1,898	-1,582	-1,898	-1,582
Amortization for the year	-316	-316	-316	-316
Closing accumulated amortization	**-2,215**	**-1,898**	**-2,215**	**-1,898**
Closing carrying amount	**2,215**	**2,531**	**2,215**	**2,531**

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 "Research and development expenses".

NOTE 14 TANGIBLE ASSETS

Equipment, tools, fixtures and fittings

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Opening cost	247	18	189	–
Purchases	534	229	343	189
Exchange differences	2	1	–	–
Closing accumulated cost	**784**	**247**	**532**	**189**
Opening depreciation	-40	-2	-27	–
Depreciation for the year	-120	-39	-89	-27
Exchange differences	-1	0	–	–
Closing accumulated depreciation	**-161**	**-40**	**-116**	**-27**
Closing carrying amount	**624**	**207**	**416**	**162**

NOTE 15 FINANCIAL INVESTMENTS

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
At the beginning of the year	145,917	–	145,917	–
Purchases	–	145,917	–	145,917
Sales	-35,096	–	-35,096	–
Closing carrying amount	**110,821**	**145,917**	**110,821**	**145,917**

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Bonds, long-term	80,757	85,836	80,757	85,836
Bonds, current	30,065	60,082	30,065	60,082
Closing carrying amount	**110,821**	**145,917**	**110,821**	**145,917**

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, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Finished goods and goods for resale	3,352	12,204	–	–
Closing carrying amount	**3,352**	**12,204**	**–**	**–**

NOTE 17 OTHER RECEIVABLES

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Capital subscribed but not paid in	–	30,744	–	–
Tax account	38	–	38	–
Cash deposits	438	235	104	235
VAT receivables	565	5,420	565	565
Other receivables	891	732	498	732
Total other receivables	**1,933**	**37,131**	**1,206**	**1,532**

Capital subscribed but not paid in is recognized on a separate line in the Parent Company balance sheet.

NOTE 18 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Prepaid rent	77	–	41	–
Prepaid insurance costs	622	–	202	–
Accrued interest	87	86	87	242
Other items	174	140	173	61
Total prepaid expenses and accrued income	**960**	**226**	**504**	**302**

NOTE 19 SHARE CAPITAL

Parent Company	No. of shares	Share capital (SEK)
Opening balance at January 1, 2017	**17,217,419**	**86,087**
Bonus issue	–	430,435
New share issue	6,444,444	193,333
Closing balance at December 31, 2017	**23,661,863**	**709,856**
New share issue	356,111	10,683
Closing balance at December 31, 2018	**24,017,974**	**720,539**

The number of shares shown in the above table is the number that is recorded in the Parent Company share register. The changes in equity according to the above table pertain the Parent Company, and more information is presented in the Parent Company statement of changes in equity, which follows the Parent Company 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, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Accrued salaries	3,845	644	2,736	644
Accrued vacation pay	1,828	76	207	76
Accrued social security contributions	548	226	548	226
Other personnel-related items	103	939	103	195
Consultancy fees	2,703	6,590	1,700	6,506
Audit	350	350	350	350
Other	231	761	12	762
Total accrued expenses and deferred income	**9,608**	**9,587**	**5,655**	**8,760**

NOTE 21 PLEDGED ASSETS AND CONTINGENT LIABILITIES

The Parent Company holds endowment insurances that have been pledged as security for its pension commitments; refer to Note 10. The fair value of the endowment insurance, including special employer's contributions, totaled TSEK 1,895 (0) as of December 31, 2018.

NOTE 22 COMMITMENTS

Commitments in respect of operating leases

	Group		Parent Company	
	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017
Within one year	3,120	274	124	124
Within one to five years	259	–	–	–
Later than five years	–	–	–	–
	3,379	**274**	**124**	**124**

The Group's operating leases consist primarily of rent for premises.

NOTE 23 SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE

First patients in US successfully treated with IRRAflow

In early January 2019, the first patients in the US were treated with IRRA*flow*. The treatments were administered by physicians at the University of California, Irvine (UCI) Medical Center in Orange, California. The medical team successfully treated two patients suffering from chronic subdural hematoma, a collection of blood on the surface of the brain.

NOTE 24 PARTICIPATIONS IN GROUP COMPANIES

Parent Company	Dec 31, 2018	Dec 31, 2017
Opening cost	24,638	11,193
Investment	40,979	10,000
Incentive programs	3,129	3,445
Closing carrying amount	**68,745**	**24,638**

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

NOTE 24 PARTICIPATIONS IN GROUP COMPANIES *cont.*

Name	Corp. Reg. No.	Domicile	% of capital and votes	No. of shares	Carrying amount Dec 31, 2018	Carrying amount Dec 31, 2017
IRRAS GmbH	DE308005079	Laichingen	100%	1	3,571	2,737
IRRAS USA Inc	611800152	La Jolla	100%	10,000,000	65,174	21,901
					68,745	**24,638**

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, 2018 – SEK 274,919,048 – 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	**2018**	**2017**	**2018**	**2017**
Earnings per share	-5.83	-3.40	-5.83	-3.40

The amount used in the numerator corresponds with the net loss for the year attributable to the Parent Company's shareholders, TSEK -138,842 (-60,901). The amount used in the denominator is recognized below.

The weighted average number of shares totaled 23,815,328 (17,906,003), 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 24,017,974 (23,661,863).

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, April 17, 2019

The consolidated statement of profit or loss and other comprehensive income, the statement of financial position and the Parent Company statement of profit or loss and balance sheet will be submitted for adoption at the Annual General Meeting on May 14, 2019.

Anders P. Wiklund
Chairman of the Board

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

Saeid Esmaeilzadeh, Ph.D.
Board member

Marios Fotiadis
Board member

Eva Nilsagård
Board member

Anita Tollstadius
Board member

Our Auditor's Report was submitted on 23 April 2019
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 2018. The annual accounts and consolidated accounts of the company are included on pages 24-56 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 2018 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 2018 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 26) and Note 3, (page 47) of the administration report which notes that the company will need additional financing and that the Board is evaluating various alternatives and also that there is a risk for the company to continue operations if adequate financing cannot be obtained. 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 2018 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 April 23 2019
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.

IRRAS AB's corporate governance

Corporate governance is based on Swedish legislation, primarily the Companies Act and the listing agreement with Nasdaq Stockholm. IRRAS AB applies the Swedish Corporate Governance Code ("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 2019 AGM will be held on May 14 at 12:00 p.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 June 1, 2018, 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, director 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 scheduled AGM in 2018.

The composition of the Nomination Committee as of March 2019 is shown in the table below.

Name	Representing	Shareholding, %, March 31, 2019
Christer Hellström	Bacara Holdings Limited	5.96
Marios Fotiadis	Lexington Holding Assets Ltd (BVI)	13.14
Christos Panotopoulos	F.EX Endotherapy Limited	12.22
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 June 1, 2018, Anders P. Wiklund was elected Chairman of the Board, and Saeid Esmaeilzadeh, Marios Fotiadis, Anita Tollstadius and Kleanthis G. Xanthopoulos were elected as Board members. At an extraordinary general meeting on October 1, 2018, Eva Nilsagård was elected as a Board member.

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

MEMBERS OF THE BOARD AFTER THE EXTRAORDINARY GENERAL MEETING ON OCTOBER 1, 2018

Name	Period	Function	Atten-dance	Independent of manage-ment	Independent of owners	Shareholding	Elected	Member Audit Committee	Member Remuneration Committee
Anders P. Wiklund	Jan 1–Dec 31	Chairman	11/11	Yes	Yes	13,182	2016	No	Yes
Saeid Esmaeilzadeh	Jan 1–Dec 31	Member	8/11	Yes	No	833,725	2013	No	Yes
Marios Fotiadis	Oct 1–Dec 31	Member	10/11	Yes	No	4,586,452	2012	No	Yes
Eva Nilsagård	Jan 10–Dec 31	Member	3/3	Yes	Yes	5,000	2018	Yes	No
Anita Tollstadius	Jan 1–Dec 31	Member	10/11	Yes	Yes	2,000	2017	Yes	No
Kleanthis G. Xanthopoulos	Jan 1–Dec 31	Member and President CEO	11/11	No	No	842,878	2015	No	No

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 2018, the Board meetings focused on such subjects as launch plans, product quality, enhancing production efficiency, organizational expansion, risk management and internal control as well as evaluating development projects.

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

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

This decision was based on the size of the company.

Remuneration to Board members

At the AGM in June 2018, it was resolved that a fee of SEK 500,000 would be paid to the Chairman of the Board, and a fee of SEK 200,000 to each of the other non-executive Board members. At the extraordinary general meeting in October 2018, it was resolved that a fee of SEK 200,000 would be paid on an annual basis to the newly elected member Eva Nilsagård, and a fee of SEK 100,000 on an annual basis to the Chairman of the Audit Committee.

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 VP Finance.

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 2018, the Board held 11 meetings. At each 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, reviews of new product opportunities and the 2019 budget. The members of the Board are presented in the table at the top of the page.

Audit Committee

As of the statutory Board meeting in autumn 2017 until October 9, 2018, the Audit Committee consisted of Board members Marios Fotiadis (Chairman), Anders Wiklund and Saeid Esmaeilzadeh. Since October 9, 2018, the Audit Committee has consisted of 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 two meetings were held in 2018.

Remuneration Committee

As of the statutory Board meeting in autumn 2017 until October 9, 2018, the Remuneration Committee consisted of Board members Saeid Esmaeilzadeh (Chairman), Anders Wiklund and Anita Tollstadius. Since October 9, 2018, the Remuneration Committee has consisted of Saeid Esmaeilzadeh (Chairman), Anders Wiklund and Marios Fotiadis.

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 Com-

mittee is to ensure compliance with the established guidelines for remuneration to senior executives. The Committee held one meeting during the year.

Authorization for the Board

At the AGM on June 1, 2018, 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 2,366,000 new shares, corresponding to 10% of the number of shares outstanding at the time.

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 senior executives 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 2018, 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.

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 2018, a great deal of work was put into reinforcing the company's structure and system support for internal control. The various Group companies have been harmonized, a shared business system has been implemented, earnings monitoring has been improved, terms of employment have been harmonized and many processes for improvement are under way. Policy documents have been updated in the form of rules of procedure for the Board as well as instructions for the CEO. 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. This work will be developed further in 2019.

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 company 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 2018 included continued evaluation of the different companies. 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 2019

In 2019, the business and control processes will be further documented and evaluated, primarily through self-assessment.

Board Of Directors

Anders P. Wiklund

Chairman of the Board

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

Education and relevant experience: Pharmacist (M.Sc. Pharm) from Farmaceutiska Institutet. He has also studied Business at Stockholm University. 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 of EfRx Pharmaceuticals SA, Life Medical Sweden AB and Wiklund International AB.

Shareholding in IRRAS: 13,182 shares

Holding of warrants:
100,000 warrants in program 2017/2020.

Anders P. Wiklund is independent in relation to the company and its management and in relation to major shareholders.

Saeid Esmaeilzadeh

Board member

Born in 1974. Board member since 2013. Chairman of the Remuneration Committee.

Education and relevant experience: Saeid Esmaeilzadeh holds a Ph.D. in Chemistry from Stockholm University. Saeid Esmaeilzadeh is the recipient of several awards for research and entrepreneurial accomplishments. He is the founder of several innovative companies within CleanTech, MedTech and Advanced Materials.

Other current assignments in selection: Chairman of the Board of Serendipity Ixora AB, Premune AB and S. Professionals AB. Board member of Diamorph AB, Sdiptech AB, Episurf Medical AB, Serendipity Group AB, Swecure AB, Nextseal AB, Build-r AB, Nextmune MC AB, Nextmune HoldCo AB, Nextmune AB and Xbrane Biopharma AB. Deputy Board member of Serendip Invest AB, VZL Vilande AB, Auremune AB, Leonova CONSULTING AB, Premune IPR AB, Swecure Europe AB, Intelligent Art AB, Swecure IPR AB, Serendipity Innovations AB, DynaSeal LCT AB and Serendipity Ventures AB.

Shareholding in IRRAS: 833,725 shares.

Saeid Esmaeilzadeh is independent in relation to the company and its management, but not in relation to its major shareholders.

Marios Fotiadis

Board member

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

Education and relevant experience: Marios Fotiadis holds an MBA from Columbia University, New York. 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 currently the Chairman and CEO of Cerus Advisors DMCC and a Board member of Klaris SA, Sente Inc., Plastics Unbound Ltd. and Rossart Ltd.

Shareholding in IRRAS: 4,697,334 shares via Lexington Holding Assets Ltd (BVI) and Bacara Holdings Limited.

Marios Fotiadis is independent in relation to the company and its management, but not in relation to its major shareholders.

Eva Nilsagård

Board member

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

Education and relevant experience: Eva Nilsagård holds an M.Sc. in accounting and financial management and an Executive MBA from the School of Business, Economics and Law at the University of Gothenburg. Eva Nilsagård has more than 25 years of experience from senior management positions within finance, strategy and business development from global listed and private companies in the life science and automotive sectors.

Other current assignments: Board member and Chairman of the Audit Committee of AddLife AB (publ), Board member and member of the Audit Committee of Bufab AB (publ), and Board member and member of the Audit Committee of the Swedish Export Credit Company (SEK). She is the founder and CEO of Nilsagård Consulting.

Shareholding in IRRAS: 5,000 shares

Eva Nilsagård is independent in relation to the company and its management and in relation to major shareholders.

Anita Tollstadius

Board member

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

Education and relevant experience: Anita Tollstadius holds an M.Sc. in Pharmacy from Uppsala University and an MBA from the Stockholm School of Economics. Anita Tollstadius has more than 30 years of experience from global strategic marketing and management positions within the life science sector, most recently as CEO of Context Vision for almost nine years.

Other current assignments: Board member of Tollstadius & Co AB.

Shareholding in IRRAS: 2,000 shares

Anita Tollstadius is independent in relation to the company and its management and in relation to major shareholders.

Kleanthis G. Xanthopoulos Ph.D.

President and CEO

Born in 1958. Board member since 2015.

Education and relevant experience: Kleanthis G. Xanthopoulos holds an M.Sc. and a Ph.D. in Molecular Biology from Stockholm University and was an Associate Professor at Karolinska Institutet in Stockholm, Sweden.

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.

He is an Onassis Scholar and has received numerous awards, including E&Y Entrepreneur of the Year in San Diego and CEO of the Year in San Diego.

Other current assignments: Board member of ZosanoPharma Inc. and Sente Inc. Member of management at Cerus Advisors DMCC and Chairman of Helios Inc.

Shareholding in IRRAS: 842,878 shares.

Options in IRRAS: 1,275,000 personnel options under the 2016/2020 program and 43,237 personnel options under the 2018/2022 program.

Kleanthis G. Xanthopoulos is not independent in relation to the company and its management and not in relation to its major shareholders.

Senior management

Kleanthis G. Xanthopoulos Ph.D.

President and CEO

Born in 1958. Joined IRRAS in 2015. Board member since 2015.

Education and relevant experience: Kleanthis G. Xanthopoulos holds an M.Sc. and a Ph.D. in Molecular Biology from Stockholm University and was an Associate Professor at Karolinska Institutet in Stockholm, Sweden.

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.

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Other current assignments: Board member of ZosanoPharma Inc. and Sente Inc. Member of management at Cerus Advisors DMCC and Chairman of Helios Inc.

Shareholding in IRRAS: 842,878 shares.

Options in IRRAS: 1,275,000 personnel options under the 2016/2025 program and 43,237 personnel options under the 2018/2022 program.

Kleanthis G. Xanthopoulos is not independent in relation to the company and its management and not in relation to its major shareholders.

Fredrik Alpsten

Deputy CEO and CFO

Born in 1966. Joined IRRAS in 2017.

Education and relevant experience: Fredrik Alpsten holds an M.Sc. in accounting and financial management from the Stockholm School of Economics. Fredrik Alpsten brings approximately 20 years of operational, financial and strategic business experience as an executive in the medical technology field. Prior to joining IRRAS, he served six years as Senior Vice President and CFO of Boule Diagnostics AB (Boule), which is listed on the Nasdaq Stockholm main market. Prior to his tenure at Boule, he was President and CEO of Doxa AB, a publicly traded medical technology company located in Sweden.

Other current assignments: Chairman of the Board of Personlig Almanacka Nordic AB. Board member and Chairman of the Audit Committee of Binero Group AB (listed on Nasdaq) and Board member of Pharmetheus AB.

Shareholding in IRRAS: Shares: 9,200 shares.

Warrants: 200,000 warrants under the 2017/2020 program and 30,000 personnel options under the 2018/2022 program.

Will Martin

Chief Commercial Officer

Born in 1975. Joined IRRAS in 2018.

Education and relevant experience: Will Martin was a Lieutenant in the US Navy and received a BA from Notre Dame and an MBA from Johns Hopkins University.

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 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: –

Shareholding in IRRAS: 0 shares.

Warrants: 230,000 personnel options under the 2017/2021 program and 32,500 personnel options under the 2016/2025 program.

From March 11, 2019, Dr. Vinny Podichetty is employed as Vice President of Global Clinical Affairs and is a member of the Executive Management Team.

C. Lance Boling

Vice President of Product Development
Born in 1959. Joined IRRAS in 2016.

Education and relevant experience:
C. Lance Boling has a BA in Business Management from the University of Phoenix. C. Lance Boling is an acknowledged expert in the field of medical device development, manufacturing, operations and strategic management. He was formerly Director of Nano Technology Development at Abbott Laboratories and has driven numerous development efforts from inception through commercialization, including holding key leadership positions in disruptive Silicon Valley start-up ventures such as Nanostim, Nevro Corporation, NeuroPace Inc. and Autonomic Technology.

Other current assignments: –

Shareholding in IRRAS: 0 shares.

Warrants: 145,000 personnel options under the 2017/2021 program and 98,341 personnel options under the 2016/2025 program.

Kellie Fontes

Senior Director, Human Capital

Born in 1961. Joined IRRAS in 2018.

Education and relevant experience:
Kellie Fontes holds a B.Sc. in Speech Communication from Montana State University.

Most recently, she served as Employee Relations and Compliance Director at the high-tech systems company General Atomics. Prior to General Atomics, she held several leading HR positions for nearly ten years at GlaxoSmithKline, including US Director.

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: –

Shareholding in IRRAS: 0 shares.

Warrants: 35,000 personnel options under the 2017/2021 program and 2,500 personnel options under the 2018/2022 program.

Adam Sampson

Vice President of Product Excellence

Born in 1968. Joined IRRAS in 2018.

Education and relevant experience:
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.

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.

Shareholding in IRRAS: 0 shares.

Warrants: 47,500 warrants under the 2018/2022 program.

Extended management group

Sabina Berlin

Vice President, Finance

Born in 1983. Joined IRRAS in 2017.

Education and relevant experience: 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. Sabina Berlin has extensive experience in the areas of business control, accounting and business analysis. From 2014 to June 2017, Sabina Berlin served as CEO of Juno Ekonomi, a company providing accounting and payroll services to a number of fast growing companies within life science, tech and professional services.

Other current assignments: Board member and major shareholder of Zymology Consulting AB.

Shareholding in IRRAS: 3,958 shares.

Warrants: 100,000 warrants under the 2017/2020 program and 7,500 personnel options under the 2018/2022 program.

Dessi Lyakov

Director, Regulatory and Quality

Born in 1970. Joined IRRAS in 2017.

Education and relevant experience: Dessi Lyakov holds an M.Sc. in Chemical Engineering the University of Chemical Technology and Metallurgy, Sofia, Bulgaria. She has more than 15 years of experience in the development of quality systems that ensure high quality and promote stable regulatory compliance under various international regulatory agencies in conjunction with development and production.

Her extensive experience of 510(k) submissions, CE certification and direct interaction with global regulatory agencies led to the success of Aalto Scientific and the establishment and growth of AUDIT Microcontrols.

Other current assignments: –

Shareholding in IRRAS: 0 shares.

Warrants: 30,000 personnel options under the 2017/2021 program, 8,571 personnel options under the 2016/2025 program and 3,500 personnel options under the 2018/2022 program.

Dino De Cicco

Senior Director, Product Development

Born in 1973. Joined IRRAS in 2018.

Education and relevant experience: Dino De Cicco has over 20 years of experience in development and commercialization of medical devices in multiple disease segments. Prior to joining IRRAS, he established and managed the Peripheral Vascular (PV) IVUS R&D Department at Philips in San Diego, CA. Prior to joining Philips, Dino De Cicco was the Director of Engineering at NextGen Medical Systems, developing thrombectomy solutions to treat deep vein thrombosis. He has extensive experience of building teams and developing technical expertise with a passion for collaboration, capturing customer voice and applying engineering best practices. His background in clinical science is a key attribute to his success in advancing clinical work*flow*s and solving unmet needs.

Dino De Cicco has a B.Sc. in Biomedical Engineering from University of Southern California. He has authored and contributed to over 20 patents in his career as well as a scientific journal publication.

Other current assignments: –

Shareholding in IRRAS: 0 shares.

Warrants: 25,000 personnel options under the 2018/2022 program.

Annual General Meeting

The 2019 AGM will be held on Tuesday, May 14 at 12:00 p.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, May 8, 2019; and
- register with the company via the form on the company's website, www.irras.com, via e-mail to AGM2019@irras.com or via telephone at +46 10 211 51 79 by Thursday, May 9, 2019 at the latest.
  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 2019 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 May 8, 2019 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

May 7, 2019
Q1 2019 interim report

May 14, 2019
2019 Annual General Meeting

August 29, 2019
Q2 2019 interim report

November 8, 2019
Q3 2019 interim report

IR contact

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