



## IRRAflow Gaining Traction in US

### Third quarter, July - September 2019

- Net revenue amounted to SEK 0.9 million (0.0).
- Operating loss (EBIT) amounted to SEK -35.9 million (-40.0).
- Loss after tax amounted to SEK -35.7 million (-41.8).
- Earnings per share before and after dilution amounted to SEK -1.24 (-1.75).

### Important events during the quarter

#### Issuance of new patent for core IRRAflow technology

The patent includes both system and method claims for performing and regulating fluid exchange in IRRAflow. The new patent complements the existing patent portfolio and broadens the IP protection for the company's core technology further.

#### Key hires to the company

In September, IRRAS announced the appointments of a Head of Regulatory Affairs and a Director, Project Engineering, to drive IRRAS' continued growth and that Vinny Podichetty VP, Clinical, Regulatory Affairs & Quality, resigned for personal reasons.

### Period January – September 2019

- Net revenue amounted to SEK 1.9 million (6.0).
- Operating loss (EBIT) amounted to SEK -115.7 million (-93.2).
- Loss after tax amounted to SEK -114.6 million (-88.8).
- Earnings per share before and after dilution amounted to SEK -4.36 (-3.74).

#### Other key accomplishment

- During the quarter, the initial clinical experience with IRRAflow in the United States was published in the peer-reviewed World Neurosurgery journal. The peer-reviewed article by Dr. Sumeet Vadera and his team from the University of California, Irvine highlights the use of IRRAflow in chronic subdural hematoma patients and reinforces key messages about the system's safety, treatment impact, and cost effectiveness.

### Important events after the end of the quarter

No important events have taken place after the end of the quarter.

Key figures	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenue, SEK million	0.9	—	1.9	6.0	6.0
Gross margin, %	Neg	Neg	Neg	Neg	Neg
Operating loss (EBIT), SEK million	-35.9	-40.0	-115.7	-93.2	-143.3
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
Loss after tax	-35.7	-41.8	-114.6	-88.8	-138.8
EBITDA, SEK million	-32.5	-37.9	-106.9	-87.3	-135.2
EBITDA margin, %	Neg	Neg	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg	Neg	Neg

# Comments from the President and CEO

During the third quarter of 2019, the IRRAS team continued to make needed progress toward achieving our goal of becoming a global leader in neurocritical care. We remain focused on building a strong foundation across all aspects of our business. As our business matures and our customer base expands, revenue in these early quarters of commercialization may be erratic; however, the company continues to lay a strong foundation with important work that will shape our future. While this quarter does not indicate growth, we are pleased with the progress that we are making in the US and expect meaningful revenue uptake as more hospitals move from the evaluation period to signing contracts.

## Reported additional revenues from US

During the third quarter, we added an additional SEK 0.9 million to our initial IRRAS<sup>flow</sup> revenues in the United States (US). Unfortunately, delays in the hospital approval and purchase order process at several of our early IRRAS<sup>flow</sup> evaluation accounts caused some processes to not be completed prior to the end of the quarter. These circumstances meant that expected revenue was not able to be recognized during the quarter.

Since the US is the world's largest market for neurosurgical procedures, we have focused much of our team's resources toward supporting a successful early market introduction. Response to our IRRAS<sup>flow</sup> technology remains strong, and our sales funnel is full. Patient treatments with IRRAS<sup>flow</sup> continued to increase, and multiple hospital systems moved from evaluating IRRAS<sup>flow</sup> into the approval and purchasing phase.

While interest in IRRAS<sup>flow</sup> remains high, our team of seven sales professionals in the US remains focused on training a prioritized group of 10-15 hospitals at a time to ensure that world-class clinical support is provided, while maintaining a dialog with approximately another 35 hospitals at different stages of the selling process. With our team engaging this small, but growing, number of hospitals as part of our "deep, before wide" strategy, erratic revenue growth is quite normal when one of the hospitals experiences an unexpected delay. As more customers begin to evaluate and purchase IRRAS<sup>flow</sup>, our expectation is that revenue will become more predictable and consistent.

Additionally, initial patient treatments were conducted successfully at three hospitals in Israel during the 3rd quarter, and we look forward to continuing global progress moving forward.

## Hummingbird product line expected to generate sales in US in Q4 2019

We spent a significant amount of effort in the third quarter integrating the Hummingbird products into our growing pipeline. The acquisition of these products in the second quarter from InnerSpace Neuro Solutions, Inc. expanded IRRAS' product portfolio to more completely address a broader range of patients with traumatic brain injury. Each year in the US alone, more than 280,000 people are hospitalized due to a traumatic brain injury.<sup>1</sup> Of the patients that are hospitalized, almost 90% require invasive neuromonitoring to assess the extent of their injuries, and, with IRRAS<sup>flow</sup> and Hummingbird, IRRAS now has the ability to treat all of them.

These acquired products, which include proprietary single and multi-lumen cranial access bolts, parenchymal ICP (Intracranial Pressure) monitoring, and a cranial access kit, are commercially cleared by the US Food and Drug Administration (FDA) and have been used on over 2,000 patients. Additionally, their clinical utility is backed by a number of scientific publications, making these assets a logical, complementary fit for IRRAS and our customers.

During the 4th quarter, our commercial efforts in the US will expand to include our newly acquired Hummingbird products, and we anticipate a positive impact on our revenues in future quarters as we navigate the evaluation and product approval process at new and current clients for these added products.

## Regulatory progress is advancing

During the quarter, IRRAS' regulatory team worked closely with our notified body, LNE/G-MED, to advance our IRRAS<sup>flow</sup> application. This progress moves the company closer to the recertification of our updated CE Mark dossier, which will enable us to relaunch our IRRAS<sup>flow</sup> system in CE Mark countries. In parallel, our team remains focused on securing product regulatory approval in non-CE Mark countries such as Taiwan, Mexico, and Argentina.

## Publication of additional clinical manuscripts highlighting IRRAS<sup>flow</sup> use

During the quarter, two additional clinical publications were released that highlight the use of IRRAS<sup>flow</sup>. Capturing physician experience with IRRAS<sup>flow</sup> and translating these outcomes into impactful evidence of the system's advantages are critical components of the company's strategy. These publications are signs that our focus on generating clinical data is beginning to produce dividends. The initial case experience from Dr. Sumeet Vadera and the University of California, Irvine was published in the peer-reviewed World Neurosurgery journal, and NeuroNews, a leading trade publication, also published a collection of interviews with early adopters of IRRAS<sup>flow</sup> and Hummingbird ICP technologies. In coming quarters, we expect additional impactful clinical data to be released that further substantiates first-line use of our products.

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<sup>1</sup> Taylor CA, Bell JM, Breiding MJ, Xu L. Traumatic Brain Injury-Related Emergency Department Visits, Hospitalizations, and Deaths — United States, 2007 and 2013. MMWR Surveill Summ 2017;66(No. SS-9):1–16.

**Participated in key medical and scientific meetings**

To reflect our progression as a commercial stage company, we showcased the *IRRAflow* and Hummingbird technologies at several key medical and scientific meetings in both the EU and US. These meetings included the European Congress of Neurosurgery (EANS 2019), the Neurocritical Care Society’s annual meeting, and Congress of Neurological Surgeons annual meeting (CNS 2019). Participation in these meetings gives IRRAS the critical opportunity to position the company as a new partner for innovation in neurocritical care and engage current customers, future targets and industry thought leaders. As a result, awareness in our company and brands has never been higher. At EANS, our team engaged European customers and hosted a physician roundtable to begin the process of reintroducing *IRRAflow* to the market. Additionally, during the meetings, more than 100 quality leads were generated that our commercial teams will now pursue, and our marketing team’s engagement on social media generated

multiple pieces of content with more than 10,000 unique impressions.

I am pleased with our progress during the third quarter and our commitment to our customers. While we are disappointed with the quarterly revenue, we believe that the IRRAS technologies are the fundamental basis of many life-saving procedures, and I look forward to keeping you updated on our progress.

Sincerely,

Kleanthis G. Xanthopoulos, Ph.D.



# Group development January – September 2019

## Net revenue

Net revenue for the period January to September 2019 amounted to SEK 1.9 million (6.0). Net revenue for the third quarter amounted to SEK 0.9 million (0.0).

## Gross profit/loss

The gross profit/loss is the difference between net revenue for the period and the cost of sales. Cost of sales include direct manufacturing costs for sold products, depreciation on capitalized development expenses, over-head costs for the manufacturing department and salaries for the employees at the department. Overhead costs derived from the manufacturing department are not capitalized. The amortization of capitalized development expenses during the period January to September 2019 amounted to SEK 7.4 million (5.6) and to SEK 2.5 million (2.0) during the third quarter.

The gross income for the period January to September 2019 amounted to SEK -26.4 million (-7.9). The gross income for the third quarter amounted to SEK -11.9 million (-5.6). The main change in gross income is due to an expanded manufacturing department in support of the US sales launch.

## Operating expenses

Operating expenses for the period January to September totaled SEK 89.2 million (86.3). The operating expenses are primarily attributable to marketing and sales expenses in US, administrative expenses as a result of the company growth, and development expenses in line with previous year.

Total research and development expenses in the period amounted to SEK 29.0 million (23.7), of which SEK 6.2 million (7.2) was capitalized and SEK 22.8 million (16.4) was recognized as expense. The expensed R&D costs include mainly personnel costs for the employees and consultant fees at these departments. Our team is working to improve already-registered products, and the improvements are not extending the lifetime of the products. Capitalized development expenses include cost for development projects for not yet launched products.

The net of other operating income and operating expenses in the period amounted to SEK -0.2 million (1.0).

## Operating loss (EBIT)

Operating loss (EBIT) totaled SEK -115.7 million (-93.2) for the period January to September 2019, and SEK -35.9 million (-40.0) for the third quarter.

## Net financial income

Net financial income totaled SEK 1.1 million (4.4).

Sales per region SEK million	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Germany	—	—	—	3.3	3.3
Europe, excluding Germany	—	—	—	2.7	2.7
USA	0.6	—	1.6	—	—
Other regions	0.3	—	0.3	—	—
<b>Total</b>	<b>0.9</b>	<b>—</b>	<b>1.9</b>	<b>6.0</b>	<b>6.0</b>

## Earnings

Loss before tax amounted to SEK -114.6 million (-88.8). Net loss for the period (loss after tax) amounted to SEK -114.6 million (-88.8).

## Cash flow and liquidity

Cash flow from operating activities from January to September 2019, after the change in working capital, totaled SEK -113.6 million (-72.7).

The increased outflow is primarily attributable to the result for the period as a result of increased operating expenses.

In May 2019, a directed share issue of net SEK 97.3 million was completed. At the end of the period, available liquidity amounted to SEK 129.0 million (189.9), including short and long-term financial investments of SEK 65.7 million (111.0).

## Investments

Net investments totaled SEK 13.5 million (7.5), including capitalized development expenses and investment in patents purchased from Innerspace.

## Assets

As of September 30, 2019, intangible assets totaled SEK 45.7 million (35.4). These intangible assets comprised capitalized development expenses and capitalized patent expenses. The increase in intangible assets beyond capitalized developmental expenses consist primarily of the purchase of assets from Innerspace. Capitalized development expenses are amortized on a straight-line basis over five years and capitalized patent expenses are amortized on a straight-line basis over the patent's lifespan. Amortization of capitalized development expenses is recognized under Cost of sales.

## Equity and liabilities

As of September 30, 2019, the Group's equity amounted to SEK 168.7 million (233.4) and the equity ratio was 84.8% (94.7).

As of September 30, 2019, interest-bearing liabilities totaled SEK 7.3 million (0.0). Current not interest-bearing liabilities totaled SEK 22.2 million (12.8).

## Changes in the parent company

Expenses in the parent company decreased in comparison with the same period last year, primarily due to a transfer of certain sales- and developmental costs from the parent company to the US company.

## Parent company

IRRAS AB (publ), corporate ID number 556872-7134, is a Swedish corporation with its headquarters in Stockholm. The address of the main office is Vasagatan 16, SE-111 20 Stockholm, Sweden.

Receivables and liabilities from Group companies primarily comprise liabilities to the US subsidiary IRRAS USA, Inc. and receivables from the German subsidiary IRRAS GmbH. Shares in group companies have increased due to shareholders' contributions. Risks and uncertainties in the parent company coincide indirectly with those of the Group.

## Employees

The average number of employees in the Group from January to September 2019 was 33 (19), of which 4 (3) in the parent company. The breakdown of average number of employees by country was 4 (3) in Sweden, 27 (10) in the US and 3 (6) in Germany. The average number of women in the Group was 11 (8) and the average number of men was 22 (11).

## Financial objectives

IRRAS has adopted the following financial objectives:

- Income to exceed SEK 275 million 2021
- Gross margin higher than 72% 2021
- Positive cashflow in the fourth quarter 2021

## The market

IRRAS's first product, *IRRAflow*, is initially intended for treatment of patients with hemorrhagic strokes and chronic subdural hematoma. Around 600,000 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. The number of patients is expected to substantially increase in the coming years as a result of population growth, the aging population and an increased share of patients receiving treatment.

## Related-party transactions

Refer to note 3 on page 15 for a description of transactions with related parties.

## Risks and uncertainties

A number of risks and uncertainties are associated with the Group's operations.

There is always a risk that competitors will offer more effective and better products than IRRAS, which could negatively affect sales. Deliveries from the company's suppliers that are incorrect, delayed or never arrive may, in turn, cause delays, deficiency or inaccuracy in the company's deliveries. The company is also always exposed to fluctuating exchange rates.

There is no guarantee that the company's activities will not be subject to restrictions by public authorities, that the company will receive necessary future approval from the authorities or that the company will not lose approvals that have already been received.

There is a risk that the company will fail to develop products, that it will not be possible to launch the products on schedule or that market acceptance will be lower or slower than anticipated. These risks may entail reduced sales and negatively affect the company's earnings. The company is also exposed to customers' inability to pay.

## Financing risk and going concern

The company's liquidity per November 14, 2019 is not sufficient to cover the planned operations in the next 12 months. In light of this, work is underway on possible financial solutions. After considerations of recent development of the company, the Board considers that the prospects are good to finance the company's operations. However, if sufficient financing is not obtained, there is a risk that conditions for going concern are not fulfilled.

For a more detailed description of the company's risks, refer to the 2018 Annual Report, page 26.

## The share and shareholders

The IRRAS share is listed at Nasdaq First North Premier Growth Market since 2017. The number of shares and votes in IRRAS AB at the end of September 2019 totaled 28,817,974.

<b>Shareholders as of September 30, 2019* (and known changes thereafter)</b>	<b>Number of shares</b>	<b>Percent of shares/ votes</b>
Lexington Holding Assets Ltd (BVI)	3,155,727	10.95%
F.EX Endotherapy Limited	2,805,790	9.74%
Bacara Holdings Limited	1,430,725	4.96%
Consensus	1,290,577	4.48%
The Fourth Swedish National Pension Fund	1,245,000	4.32%
Dr Kleanthis G. Xanthopoulos	842,878	2.92%
Dr Saeid AB	833,725	2.89%
Systematic Growth AB	679,352	2.36%
Danica Pension	658,730	2.29%
Coeli	636,784	2.21%
<b>Total ten largest shareholders</b>	<b>14,214,541</b>	<b>47.12%</b>
<b>Other shareholders</b>	<b>14,603,433</b>	<b>52.88%</b>
<b>Total number of shares</b>	<b>28,817,974</b>	<b>100.00%</b>

\*Nominee accounts / shareholders are not included in this compilation

## Incentive programs

At the moment the company has five incentive programs outstanding for employees and key personnel. These programs can currently increase the number of shares by 3,782,000 (refer to note 2 on page 15).

## Analysts following the company

Kristofer Liljeberg	Carnegie
Christian Lee	Pareto

## Financial calendar

2019 Year-End Report	February 14, 2020
Q1 2020 Interim Report	May 14, 2020
Q2 2020 Interim Report	August 27, 2020
Q3 2020 Interim Report	November 10, 2020

## Auditors review

This report has been reviewed by the company's auditors.

The Board of Directors and the CEO certify that this interim report provides a true and fair overview of the Group's and parent company's operations, financial position and earnings, and describes the material risks and uncertainties facing the parent company and the companies included in the Group.

*Stockholm, November 14, 2019  
IRRAS AB (publ)*

Anders P. Wiklund  
Chairman of the Board

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

Anita Tollstadius  
Board member

Marios Fotiadis  
Board member

Catherine Gilmore-Lawless  
Board member

Eva Nilsagård  
Board member

## Consolidated statement of profit or loss and other comprehensive income in summary

SEK million	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenue	0.9	—	1.9	6.0	6.0
Cost of sales	-12.8	-5.6	-28.3	-13.9	-20.0
<b>Gross profit/loss</b>	<b>-11.9</b>	<b>-5.6</b>	<b>-26.4</b>	<b>-7.9</b>	<b>-14.0</b>
<i>Gross margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Other operating income	0.1	1.3	0.8	2.4	1.7
Marketing and sales expenses	-9.5	-15.6	-31.6	-33.0	-62.3
Administrative expenses	-8.5	-11.1	-34.7	-33.9	-44.5
Research and development expenses	-5.9	-8.4	-22.8	-19.4	-22.9
Other operating expenses	-0.2	-0.7	-1.0	-1.4	-1.2
<b>Operating loss (EBIT)</b>	<b>-35.9</b>	<b>-40.0</b>	<b>-115.7</b>	<b>-93.2</b>	<b>-143.3</b>
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	0.2	-1.5	1.1	4.4	4.5
<b>Loss before tax</b>	<b>-35.7</b>	<b>-41.5</b>	<b>-114.6</b>	<b>-88.8</b>	<b>-138.8</b>
Tax	0.0	-0.3	0.0	0.0	—
<b>Net loss for the period</b>	<b>-35.7</b>	<b>-41.8</b>	<b>-114.6</b>	<b>-88.8</b>	<b>-138.8</b>
<b>Other comprehensive income</b>					
Items that may be subsequently reclassified to profit or loss					
Translation differences for the period on translation of foreign subsidiaries	1.0	-0.1	-0.5	-0.2	-1.1
<b>Total other comprehensive income</b>	<b>1.0</b>	<b>-0.1</b>	<b>-0.5</b>	<b>-0.2</b>	<b>-1.1</b>
<b>Total comprehensive income for the period</b>	<b>-34.7</b>	<b>-41.9</b>	<b>-115.1</b>	<b>-89.0</b>	<b>-140.0</b>
Earnings per share before dilution, SEK	-1.24	-1.75	-4.36	-3.74	-5.83
Earnings per share after dilution, SEK	-1.24	-1.75	-4.36	-3.74	-5.83
Number of shares before dilution, average	28,817,974	23,914,608	26,303,688	23,747,037	23,815,328
Number of shares after dilution, average	28,817,974	23,914,608	26,303,688	23,747,037	23,815,328

Since the Group has no minority interest, the earnings are wholly attributable to the owners of the parent company.

## Consolidated statement of financial position in summary

SEK million	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets			
Capitalized development expenses	36.9	33.1	38.1
Licenses/patents	8.8	2.3	2.2
<b>Total intangible assets</b>	<b>45.7</b>	<b>35.4</b>	<b>40.3</b>
Right-of-use assets	7.6	—	—
Tangible assets			
Property, plant and equipment	0.9	0.4	0.6
<b>Total tangible assets</b>	<b>8.5</b>	<b>0.4</b>	<b>0.6</b>
Financial assets			
Financial investments, bonds	45.6	85.9	80.8
<b>Total financial assets</b>	<b>45.6</b>	<b>85.9</b>	<b>80.8</b>
<b>Total non-current assets</b>	<b>99.8</b>	<b>121.7</b>	<b>121.7</b>
<b>Current assets</b>			
Inventory	13.2	12.9	3.4
Financial investments, bonds	20.1	25.0	30.1
Accounts receivable	1.1	—	—
Other receivables	1.1	7.5	1.9
Prepaid expenses and accrued income	0.5	0.5	1.0
Cash and cash equivalents	63.3	78.9	47.2
<b>Total current assets</b>	<b>99.2</b>	<b>124.8</b>	<b>83.6</b>
<b>TOTAL ASSETS</b>	<b>199.0</b>	<b>246.6</b>	<b>205.3</b>



## Consolidated statement of financial position in summary (cont.)

SEK million	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
<b>EQUITY</b>			
Share capital	0.9	0.7	0.7
Other paid-in capital	537.4	440.2	440.2
Translation reserve	-2.4	-1.0	-1.9
Retained earnings, including net loss for the period	-367.1	-206.5	-254.8
<b>Total equity</b>	<b>168.7</b>	<b>233.4</b>	<b>184.2</b>
<b>LIABILITIES</b>			
Provisions			
Other provisions	0.7	0.3	0.4
Long term liabilities			
Lease liabilities	3.1	—	—
<b>Total long-term liabilities and provisions</b>	<b>3.9</b>	<b>0.3</b>	<b>0.4</b>
Current liabilities			
Lease liabilities	4.2	—	—
Accounts payable	8.1	4.6	8.6
Other liabilities	0.2	0.5	2.5
Accrued expenses and deferred income	14.0	7.7	9.6
<b>Total current liabilities</b>	<b>26.4</b>	<b>12.8</b>	<b>20.8</b>
<b>Total liabilities and provisions</b>	<b>30.3</b>	<b>13.2</b>	<b>21.2</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>199.0</b>	<b>246.6</b>	<b>205.3</b>

## Consolidated statement of changes in equity in summary

SEK million	Share capital	Other paid-in capital	Translation reserve	Retained earnings, including net loss for the period	Total equity
<b>Opening equity January 1, 2018</b>	<b>0.7</b>	<b>439.6</b>	<b>-0.8</b>	<b>-123.5</b>	<b>316.0</b>
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-88.8	-88.8
Other comprehensive income for the period	—	—	-0.2	—	-0.2
<b>Comprehensive income for the period</b>	<b>—</b>	<b>—</b>	<b>-0.2</b>	<b>-88.8</b>	<b>-89.0</b>
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	5.8	5.8
New share issue expenses	—	0.6 <sup>1</sup>	—	—	0.6
<b>Closing equity September 30, 2018</b>	<b>0.7</b>	<b>440.2</b>	<b>-1.0</b>	<b>-206.5</b>	<b>233.4</b>
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-50.1	-50.1
Other comprehensive income for the period	—	—	-0.9	—	-0.9
<b>Comprehensive income for the period</b>	<b>—</b>	<b>—</b>	<b>-0.9</b>	<b>-50.1</b>	<b>-51.0</b>
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	1.8	1.8
<b>Closing equity December 31, 2018</b>	<b>0.7</b>	<b>440.2</b>	<b>-1.9</b>	<b>-254.8</b>	<b>184.2</b>
<b>Opening equity January 1, 2019</b>	<b>0.7</b>	<b>440.2</b>	<b>-1.9</b>	<b>-254.8</b>	<b>184.2</b>
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-114.6	-114.6
Other comprehensive income for the period	—	—	-0.5	—	-0.5
<b>Comprehensive income for the period</b>	<b>—</b>	<b>—</b>	<b>-0.5</b>	<b>-114.6</b>	<b>-115.1</b>
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	2.4	2.4
New share issue	0.1	105.5	—	—	105.6
New share issue expenses	—	-8.3	—	—	-8.3
<b>Closing equity September 30, 2019</b>	<b>0.9</b>	<b>537.4</b>	<b>-2.4</b>	<b>-367.1</b>	<b>168.7</b>

<sup>1</sup> Reversal of provision for new share issue expenses.

## Condensed consolidated statement of cash flows in summary

SEK million	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
<b>Operating activities</b>					
Operating loss (EBIT)	-35.9	-40.0	-115.7	-93.2	-143.3
Adjustment for non-cash items					
- Depreciation/amortization	3.5	2.1	8.8	5.9	8.1
- Incentive programs	-1.3	1.2	2.4	5.7	7.4
- Other non-cash items	0.0	0.1	0.4	0.3	0.4
Interest received	0.1	-2.4	0.4	0.4	0.6
Interest paid	-0.1	-0.2	-0.1	-0.2	-0.2
Income tax paid	—	0.0	0.0	0.9	0.9
<b>Cash flow from operating activities before changes in working capital</b>	<b>-33.6</b>	<b>--39.1</b>	<b>-103.9</b>	<b>-80.0</b>	<b>-126.0</b>
Cash flow from changes in working capital					
Increase (-)/decrease (+) in inventory	-5.9	4.0	-7.0	0.1	9.6
Increase (-)/decrease (+) in operating receivables	0.8	8.8	-0.2	4.3	8.9
Increase (+)/decrease (-) in operating payables	1.0	1.8	-2.4	2.9	10.1
<b>Cash flow from operating activities</b>	<b>-37.8</b>	<b>-24.4</b>	<b>-113.6</b>	<b>-72.7</b>	<b>-97.4</b>
Cash flow from investing activities					
Investment in intangible assets	-2.0	-2.3	-13.0	-7.2	-14.3
Investments in tangible assets	0.0	—	-0.5	-0.3	-0.5
Sale of financial assets	0.0	35.0	45.1	35.0	35.1
<b>Cash flow from investing activities</b>	<b>-2.0</b>	<b>32.7</b>	<b>31.7</b>	<b>27.5</b>	<b>20.3</b>
Cash flow from financing activities					
New share issue	—	-0.1	105.6	30.7 <sup>1</sup>	30.7 <sup>1</sup>
New share issue expenses	—	—	-8.3	-5.6 <sup>1</sup>	-5.6 <sup>1</sup>
Lease liabilities	-0.8	—	-0.6	—	—
<b>Cash flow from financing activities</b>	<b>-0.8</b>	<b>-0.1</b>	<b>96.7</b>	<b>25.2</b>	<b>25.2</b>
<b>Cash flow for the period</b>	<b>-40.7</b>	<b>8.1</b>	<b>14.8</b>	<b>-20.1</b>	<b>-52.0</b>
Cash and cash equivalents at the beginning of the period	103.0	71.3	47.2	98.3	98.3
Exchange rate difference in cash and cash equivalents	1.0	-0.5	1.3	0.7	0.9
<b>Cash and cash equivalents at the end of the period</b>	<b>63.3</b>	<b>78.9</b>	<b>63.3</b>	<b>78.9</b>	<b>47.2</b>

<sup>1</sup> Issue proceeds and expenses that were not paid as of December 31, 2017 but were paid during the first half of 2018.

## Parent company statement of profit or loss in summary

SEK million	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenue	0.5	—	1.1	—	13.1
Cost of sales	-2.5	-2.0	-7.4	-5.6	-8.0
<b>Gross profit/loss</b>	<b>-2.0</b>	<b>-2.0</b>	<b>-6.3</b>	<b>-5.6</b>	<b>5.1</b>
Other operating income	0.0	0.1	0.0	0.8	0.9
Marketing and sales expenses	-0.5	-0.6	-0.5	-3.8	-4.1
Administrative expenses	-6.6	-8.5	-24.7	-27.2	-35.7
Research and development expenses	-0.5	-4.3	-1.1	-10.8	-8.3
Other operating expenses	-0.1	-0.1	-0.9	-0.9	-1.0
<b>Operating loss (EBIT)</b>	<b>-9.6</b>	<b>-15.4</b>	<b>-33.5</b>	<b>-47.4</b>	<b>-43.0</b>
Net financial income	0.4	0.2	1.6	3.3	3.5
<b>Loss before tax</b>	<b>-9.3</b>	<b>-15.2</b>	<b>-31.9</b>	<b>-44.1</b>	<b>-39.6</b>
Tax	—	-0.3	—	0.0	—
<b>Net loss for the period</b>	<b>-9.3</b>	<b>-15.5</b>	<b>-31.9</b>	<b>-44.1</b>	<b>-39.6</b>

Since no items are recognized in other comprehensive income, the parent company's loss corresponds with its comprehensive income.

## Parent company statement of financial position in summary

SEK million	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	38.9	35.4	40.3
Tangible assets	0.3	0.3	0.4
Financial assets			
Shares in Group companies	217.2	44.6	68.7
Receivables from Group companies	21.3	29.6	29.6
Financial investments, bonds	45.6	85.9	80.0
<b>Total financial assets</b>	<b>284.1</b>	<b>160.1</b>	<b>179.1</b>
<b>Total non-current assets</b>	<b>323.3</b>	<b>195.9</b>	<b>219.8</b>
<b>Current assets</b>			
Receivables from Group companies	—	15.2	26.3
Financial investments, bonds	20.1	25.0	30.1
Other receivables	0.5	1.7	1.2
Prepaid expenses and accrued income	0.3	0.6	0.5
Cash and bank balances	39.1	71.0	37.3
<b>Total current assets</b>	<b>60.0</b>	<b>113.6</b>	<b>95.4</b>
<b>TOTAL ASSETS</b>	<b>383.3</b>	<b>309.4</b>	<b>315.3</b>
<b>EQUITY AND LIABILITIES</b>			
<b>EQUITY</b>			
Share capital	0.9	0.7	0.7
Fund for capitalized expenditure	31.9	26.4	31.8
Capital surplus	503.8	406.6	406.6
Retained earnings	-129.5	-88.5	-92.1
Loss for the year	-31.9	-44.1	-39.6
<b>Total equity</b>	<b>375.1</b>	<b>301.2</b>	<b>307.4</b>
Provisions	0.7	0.3	0.4
Accounts payable	0.9	3.0	1.7
Liabilities to Group companies	1.7	—	—
Other current liabilities	0.1	0.1	0.1
Accrued expenses and deferred income	4.7	4.9	5.7
<b>Total liabilities and provisions</b>	<b>8.1</b>	<b>8.3</b>	<b>7.9</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>383.3</b>	<b>309.4</b>	<b>315.3</b>

# Notes

## Note 1 Accounting policies

The interim financial report for the IRRAS Group has been prepared in accordance with the International Finance Reporting Standards (IFRS) as adopted by the EU. The Swedish Annual Accounts Act and RFR 1 Complementary accounting rules for groups have also been applied. The Year-End report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting. The parent company applies RFR2 Accounting for legal entities and the Swedish Annual Accounts Act. RFR 2 requires that the parent company apply the same accounting policies as the Group, meaning IFRS should be applied if possible, in the scope permitted by The Swedish Annual Accounts Act, Pension Obligations Vesting Act and of tax reasons.

New or revised IFRS or other IFRIC interpretations have taken effect January 1, 2019. During 2019, the company has begun to apply IFRS 16 Leases.

### Effect of the transition to IFRS 16

#### IFRS 16 Leases

IFRS 16 Leases requires that lessees recognize assets and liabilities attributable to all leases, with the exception of leases that are shorter than 12 months and/or relate to 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 Group has applied IFRS 16 as of January 1, 2019. The standard did not have any material effect on the consolidated financial statements since the Group's leases at the time were few in number and consisted mainly of rent for premises. Leases were shorter than 12 months and/or added up to insignificant amounts. The Group also has short-term leases for vehicles and office equipment.

As of August 1 2019 the Group has an agreement for rented premises in IRRAS USA, Inc, expiring in July 2021, and thus recognizes right of use assets and lease liabilities.

The parent company does not apply IFRS 16.

### Segment reporting

Since IRRAS's equity instruments are traded in an active market, IFRS 8 Operating Segments is applicable. IRRAS's operations are currently focused on development and sales in the *IRRAflow* product area, which is why only one segment has been reported, which is reflected in its entirety in the consolidated financial statements. The Groups strategic control group and highest executive decision makers, consisting of the CEO and a number of other executives which together form the Group management, evaluate the Group's activities from a product and product development perspective. Sales are evaluated from a geographical perspective, as of today Germany, the rest of Europe, USA and the rest of the world. See table on page 4.

## Note 2 Incentive programs

IRRAS has five incentive programs outstanding for employees, key personnel and Board members. The costs for the incentive programs totaled SEK -1.3 million (1.2) during the third quarter of 2019 and SEK 2.4 million (5.8) for the period from January to September 2019.

### Incentive program No. 1

The total program comprises 1,900,000 personnel options. Each option entitles the holder to subscribe for a new share for SEK 13.60 per share until September 30, 2025, but subject to the requirement that the options are vested (earned). The options are vested at 25% per year.

During the third quarter 2019, 4,286 options were returned. A total of 1,712,619 options were outstanding as of September 30, 2019. The CEO has 1,275,000 options and two members of the management group have 32,500, and 2,976 options, respectively.

### Incentive program No. 2

The total program comprises 650,000 personnel options. Each option entitles the holder to subscribe for a new share for SEK 35.00 per share until October 31, 2021, but subject to the requirement that the options are vested. The options are vested at 33% per year.

During the third quarter 2019, 5,000 options were distributed, and 7,500 options were returned. A total of 547,412 options were outstanding as of September 30, 2019. Two members of the management group have 35,000 and 230,000 options, respectively.

### Incentive program No. 3

The total program comprises 400,000 warrants. Each warrant entitles the holder to subscribe for a new share for SEK 50.00 per share until October 31, 2020.

No changes to the number of warrants took place in the third quarter of 2019. A total of 320,000 warrants were outstanding as of September 30, 2019. One member of the management group has 100,000 warrants.

### Incentive program No. 4

The total program comprises 100,000 warrants. Each warrant entitles the holder to subscribe for a new share for SEK 50.00 per share until October 31, 2020.

No changes to the number of warrants took place in the third quarter of 2019. A total of 100,000 warrants were outstanding as of September 30, 2019. The Chairman of the Board has 100,000 warrants.

### Incentive program No. 5

The total program comprises 732,000 personnel 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. For a more detailed description of the vesting terms, refer to the 2018 Annual Report. Each option entitles the holder to subscribe for a new share for SEK 25.86 per share until June 15, 2022, but subject to the requirement that the options are vested. The options are vested at 33% per year.

During the third quarter of 2019, 163,250 options were distributed, and 59,250 options were returned. A total of 612,487 options were outstanding as of September 30, 2019. The CEO has 43,237 options and two members of the management group have 55,500 and 17,500 options, respectively.

## Note 3 Related-party transactions

“Related parties” are defined as members of the company management in the Parent Company, Board of Directors of the Parent Company, and subsidiaries. Shares in the subsidiaries and transactions between Group companies are eliminated in the consolidated financial statements, which is why further information is not provided.

The following related-party transactions have taken place during the period.

SEK million	Jan–Sep 2019	Jan–Sep 2018	Explanation
Anders P. Wiklund, Chairman	—	0.1	Billed consulting services
Kleanthis G. Xanthopoulos, President and CEO, Board member	—	1.7	Billed consulting services
Christos Panotopoulos, Owner and former member of company management	—	0.9	Billed consulting services

The Group has leased offices from a person related to President and CEO Kleanthis G. Xanthopoulos until April 2019. The expenses for the period from January to September 2019 totaled SEK 37.6 thousand (77.2). The Group has also purchased office equipment from a person related to President and CEO Kleanthis G. Xanthopoulos. The expense during the period totaled SEK 220.5 thousand (0).

President and CEO Kleanthis G. Xanthopoulos had a consulting agreement with IRRAS via his company Helios Capital beginning 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. Since then, Kleanthis G. Xanthopoulos has been employed by IRRAS AB. Payments in 2018 relate to remuneration regarding 2017.

## Note 4 Financial assets and liabilities

Financial assets and liabilities in the balance sheet are reported to the purchase price which is assessed to be a good approximation of the real value.

## Use of performance measures not defined by IFRS

The IRRAS Group's financial statements are prepared in accordance with IFRS. Only a few performance measures are defined in IFRS. IRRAS applies the guidelines of the European Securities and Market Authority (ESMA) for alternative performance measures. To support analysis of the Group's development by company management and other stakeholders, IRRAS recognizes certain performance measures not defined in IFRS. It is the opinion of company management that this information facilitates an analysis of the Group's development. The table below shows definitions of performance measures not defined by IFRS and which definitions are not indicated in other parts of the report.

	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
<b>Gross margin (Gross profit or loss/Net revenue)</b>					
Gross profit/loss, SEK million	-11.9	-4.8	-26.4	-7.9	-14.0
Net revenue, SEK million	0.9	—	1.9	6.0	6.0
Gross margin, %	Neg	Neg	Neg	Neg	Neg
<b>EBIT margin (Operating loss (EBIT)/Net revenue)</b>					
Operating loss (EBIT), SEK million	-35.9	-40.0	-115.7	-93.2	-143.3
Net revenue, SEK million	0.9	—	1.9	6.0	6.0
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
<b>EBITDA margin (EBITDA/Net revenue)</b>					
Operating loss (EBIT), SEK million	-35.9	-40.0	-115.7	-93.2	-143.3
Depreciation/amortization, SEK million	-3.5	-2.1	-8.8	-5.9	-8.1
Net revenue, SEK million	0.9	—	1.9	6.0	6.0
EBITDA margin, %	Neg	Neg	Neg	Neg	Neg
<b>Return on equity, % (Net profit or loss for the period/Average equity)</b>					
Net loss for the period, SEK million	-35.7	-41.8	-115.7	-88.8	-138.8
Average equity, SEK million	186.7	253.7	176.4	274.7	250.1
Return on equity, %	Neg	Neg	Neg	Neg	Neg

Definitions:

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

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

*EBITDA (Earnings before interest, tax, depreciation and amortization)*: Earnings before net financial income/expense, tax and depreciation/amortization of tangible and intangible assets

*EBITDA margin*: EBITDA divided by net revenue

*Operating loss (EBIT)*: Gross profit/loss less operating expenses

*EBIT margin*: Operating loss (EBIT) divided by net revenue

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



# This is IRRAS

IRRAS AB (Nasdaq First North Premier Growth Market: IRRAS) is a global healthcare company focused on delivering innovative medical technologies to our customers and their patients. IRRAS designs, develops and commercializes products that improve patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methods in neurocritical care. IRRAS currently markets and sells its IRRASflow and Hummingbird product lines to hospitals worldwide through its direct sales organizations in the U.S. and select

European countries and a network of distribution partners in other markets. IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. For more information, please visit [www.irras.com](http://www.irras.com).

IRRAS AB (publ) is listed on Nasdaq First North Premier Growth Market. Redeye AB is certified adviser of the company with email [certifiedadviser@redeye.se](mailto:certifiedadviser@redeye.se) or phone + 46 8 121 576 90.

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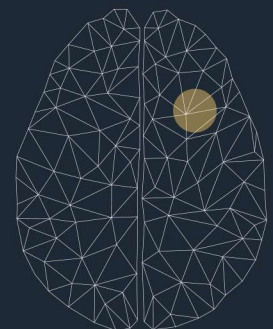
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This document is considered information that IRRAS is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person above, on November 14, 2019 at 8:00 a.m. (CET).

**IRRAS**

[WWW.IRRAS.COM](http://WWW.IRRAS.COM)





## Review report

To the Board of Directors of IRRAS AB (publ)

Corp. id. 556872-7134

### Introduction

We have reviewed the condensed interim financial information (interim report) of IRRAS AB (publ) as of 30 September 2019 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

### Uncertainties regarding going concern assumption

Without affecting our Conclusion above, we draw attention to the company's disclosures of financial position on page 5 which describes that the company is evaluating possible financial solutions to ensure continued operations over the next 12 months. As of the date of our report below, this evaluation is ongoing and financing for the next 12 months is not finalized. This indicates that there are uncertainties that about the company's ability to continue as a going concern.

Stockholm 14 November 2019

KPMG AB

Duane Swanson

Authorized Public Accountant