



Growth despite COVID-19 resurgence

Fourth quarter, October - December 2020

- Net revenue amounted to SEK 2.5 million (3.4).
- Operating loss (EBIT) amounted to SEK -36.8 million (-35.7).
- Loss after tax amounted to SEK -38.1 million (-36.5).
- Earnings per share before and after dilution amounted to SEK -0.57 (-1.27).

Key accomplishments

- Agreement for Hummingbird signed with purchasing network Premier
- Collaboration agreement signed with Karolinska University Hospital
- IRRAf^{low} launched in the Netherlands, Latin America and South Eastern Europe through distributors
- Evaluation agreements signed with hospitals in the US, Denmark and Germany and multiple evaluations in the US completed with positive outlook
- The company's first FDA quality audit performed without remarks
- Transition to inhouse manufacturing of IRRAf^{low} for improved quality and reduced cost
- The Board of Directors proposes no dividend

Period January – December 2020

- Net revenue amounted to SEK 7.4 million (5.3).
- Operating loss (EBIT) amounted to SEK -134.3 million (-151.5).
- Loss after tax amounted to SEK -135.9 million (-151.1).
- Earnings per share before and after dilution amounted to SEK -2.46 (-5.61).

Key accomplishments after the end of the quarter

- Patient treatments started at multiple hospitals in the US, where personnel have been trained during 2020
- Additional evaluation agreements signed in the US

Key figures	Oct-Dec 2020	Oct-Dec 2019	Jan-Dec 2020	Jan-Dec 2019
Net revenue, SEK million	2.5	3.4	7.4	5.3
Gross margin, %	Neg	Neg	Neg	Neg
Operating loss (EBIT), SEK million	-36.8	-35.7	-134.3	-151.5
EBIT margin, %	Neg	Neg	Neg	Neg
Loss after tax	-38.1	-36.5	-135.9	-151.1
EBITDA, SEK million	-32.4	-32.0	-118.0	-138.9
EBITDA margin, %	Neg	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg	Neg

Comments from the CEO

Continued growth despite COVID-19 resurgence

During the course of the 4th quarter, challenges associated with the COVID-19 global pandemic increased and impacted the company's commercial activity. In both the European Union (EU) and the United States (US), another round of lockdowns was instituted, limiting hospital access, reducing the ability to travel, and reducing focus on neurosurgical procedures in hospital intensive care units (ICUs). Despite these challenges, our IRRAS team increased the number of IRRAS^{flow} control units installed globally from 55 to 68 during the quarter and delivered annual revenue growth of 40%.

Increased adoption of IRRAS^{flow} at key accounts

Although hospital access was reduced during Q4, IRRAS was able to complete several ongoing evaluations at key institutions in both the US and Germany.

IRRAS^{flow} evaluations were completed at Buffalo General Medical Center, one of the most influential neurosurgical centers in the world, and with West Virginia University Medicine, another important academic comprehensive stroke center. In both evaluations, 10 patients were treated with positive results. In Germany, BGU Kliniken Halle Bergmannstrost also completed a 90-day evaluation of IRRAS^{flow}. Feedback received during these evaluations indicated that patients experienced improved outcomes and fewer complications with IRRAS^{flow} compared to established treatment methods. IRRAS is currently in discussions to convert all three centers into commercial customers early in 2021.

As the launch of IRRAS^{flow} continues, expanding the network of reference accounts that have adopted the system is an important part of our growth strategy. The reputation and influence of these centers will positively impact the company's ability to attract other stroke centers around the world as customers. Additionally, multiple scientific publications are being prepared for submission to peer-reviewed journals describing the outcomes of the patients treated during these evaluations. When released, such publications will further highlight the advantages of our technology and will help IRRAS accelerate IRRAS^{flow}'s commercialization.

Record number of patients treated in a single quarter

Even with restrictions on our European sales team's movement, the commercial launch of IRRAS^{flow} in Europe began to also gain momentum in Q4. In addition to the completion of the IRRAS^{flow} evaluation with a new customer in Halle, Germany, patient treatments also resumed in Lübeck, a hospital with system experience from the product's initial commercial release in 2017. Furthermore, new revenue was generated from both Sweden and Denmark through IRRAS^{flow} disposable orders to support evaluations at Karolinska Institute and Aarhus University Hospital. Remote training was also completed at influential facilities such as the Queen Square National Hospital for Neurosurgery in London and Erasmus University Medical Center in Rotterdam. As the incidence of COVID-19 declines in each of these areas, IRRAS^{flow} patient treatments will begin.

Based on the impact of the completed evaluations and new European customers, Q4 ended with the most patient treatments completed in IRRAS' history.

Important quality and regulatory milestones achieved

During the quarter, important steps were taken to finalize regulatory approval for the Hummingbird product line in the EU. Documentation that adheres to the more stringent Medical Device Regulation (MDR) standards was submitted for review, and IRRAS projects that this process will be completed during the first half of 2021.

The first phase of the Medical Device Single Audit Program (MDSAP) quality system audit was also completed in Q4. Successful completion of MDSAP confirms that IRRAS' quality system meets required standards to pursue regulatory approval in key markets, including Japan, Australia, Brazil, and Canada. In the US, another significant step towards establishing the company's quality reputation in the marketplace was completed when the Food & Drug Administration (FDA) completed its first company audit with no observations.

Hummingbird poised for commercial breakthrough

CE Mark for Hummingbird is a critical growth objective for IRRAS as the product line will be added to our existing network of distribution partners. In the US, during Q4, a group purchasing agreement for Hummingbird was signed with Premier, a leading buying group made up of over 4,000 US member hospitals. The agreement outlines pricing and contract terms to streamline the hospital product approval process. After the first patient treatment with Hummingbird Solo during Q3, this agreement is expected to accelerate sales of the Hummingbird product line as COVID restrictions are eased and new product approvals increase.

Expansion of distribution network

During the quarter, IRRAS has previously noted that the movement and activity of our European direct sales team again was impacted by COVID restrictions. As a result, our team continued its strategy from earlier in 2020 to focus its attention on activities that could still result in commercial progress.

This evolving focus resulted in the continued expansion of our network of distribution partners in markets where IRRAS does not employ a direct salesforce. In Europe, distribution agreements were signed with KM Innovations BV in The Netherlands and Medical Innovation Solutions that possesses a presence throughout Southeastern Europe, including the key markets of Serbia, Croatia, Romania, North Macedonia, Slovenia and Hungary. Both are leading distributors of world-class neurosurgical medical devices in their markets. Additionally, during Q4, IRRAS shipped its first IRRAS^{flow} systems and generated its initial revenue from Latin America as it established a partnership with the distributor Anade SA. As of today, IRRAS^{flow} has received regulatory clearance in Costa Rica and Argentina, and regulatory clearance is being pursued in five additional markets.

Continued Commercial Investments Underway

Throughout the year, IRRAS has continued to selectively strengthen our sales organization when customer demand and COVID restrictions have allowed. In the US, nurse education specialists have been added to increase our ability to training more new customers. In Europe, after adding sales leaders in Germany and the Nordics, IRRAS added another sales professional in Germany to take advantage of growing demand.

These added training resources are being deployed at customers where launch activities can proceed during the pandemic. Evaluations are underway at the next group of comprehensive stroke centers in the US, and patient treatments began at Baptist Health Jacksonville and Augusta University Medical Center in January 2021. IRRAf^{low} has also been approved for evaluation at other comprehensive stroke centers, including Los Angeles County Hospital and Harbor UCLA, where patient treatments will begin when COVID restrictions are lifted.

As these customer engagement activities continue and as COVID-19 vaccines are deployed globally, we remain optimistic that our growth in the number of IRRAf^{low} evaluations and patient treatments will continue and translate into continued revenue growth. During 2021, IRRAS expects to initiate cooperation with more prestigious stroke centers around the world, which will support our efforts to generate valuable clinical data that confirms the advantages of our technology.

Despite the unforeseen challenges that the COVID-19 pandemic presented in 2020, IRRAS managed to make considerable progress. Our product portfolio continues to be adopted by institutions around the world, and IRRAS has expanded relationships with customers in both direct and distribution markets. IRRAS is better positioned than ever before, and I expect 2021 to be the year when IRRAS shows meaningful growth in revenue and other commercial milestones.

Our ambition is to build the most innovative company in neurocritical care, and we are well on our way to achieving that goal. We look forward to keeping you updated as we bring important treatments to patients in need around the world.

Sincerely,
Kleanthis G. Xanthopoulos, Ph.D.



Group development January – December 2020

Net revenue

Net revenue for the period January to December 2020 amounted to SEK 7.4 million (5.3). Net revenue for the fourth quarter amounted to SEK 2.5 million (3.4).

Gross profit/loss

The gross income for the period January to December 2020 amounted SEK -16.1 million (-33.2). The gross income for the fourth quarter amounted to SEK -5.5 million (-6.8). The main change in gross loss during the period is due to higher sales in 2020 than in previous year and decreased expenses in the manufacturing department 2020.

The amortization of capitalized development expenses during the period January to December 2020 amounted to SEK 10.7 million (9.8) and SEK 2.8 million (2.5) during the fourth quarter.

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.

Operating expenses

Operating expenses for the period January to December 2020 totaled SEK 118.2 million (118.4). Marketing and sales expenses in US increased slightly compared to previous year, due to a strengthened sales organization and regulatory costs, while administrative and development expenses decreased due to reduced dependence to external consultants.

Total research and development expenses in the period amounted to SEK 36.7 million (37.8), of which SEK 7.8 million (8.0) was capitalized and SEK 28.9 million (29.8) was recognized as expense. The expensed R&D costs mainly includes personnel costs for the employees and consultant fees in these departments. Capitalized development expenses include costs for development projects for not yet launched products.

The net of other operating income and operating expenses in the period amounted to SEK 0.7 million (0.0).

Operating loss (EBIT)

Operating loss (EBIT) totaled SEK -134.3 million (-151.5) for the period January to December 2020, and SEK -36.6 million (-35.7) for the fourth quarter.

Net financial income

Net financial income totaled SEK -1.6 million (0.3).

Earnings

Loss before tax amounted to SEK -135.9 million (-151.1). Net loss for the period (loss after tax) amounted to SEK -135.9 million (-151.1).

Sales per region SEK million

	Oct-Dec 2020	Oct-Dec 2019	Jan-Dec 2020	Jan-Dec 2019
Germany	0.1	–	0.1	–
Europe, excluding Germany	1.5	–	3.7	–
USA	0.5	2.9	3.2	4.5
Other regions	0.4	0.4	0.4	0.7
Total	2.5	3.4	7.4	5.3

Cash flow and liquidity

Cash flow from operating activities from January to December 2020, after the change in working capital, totaled SEK -132.2 million (-153.7).

At the end of the period, available liquidity amounted to SEK 135.6 million (85.1), including short and long-term financial investments of SEK 0.0 million (55.6).

During the second quarter, a fully guaranteed rights issue of net SEK 189.5 million was completed.

The company has used government stimulus packages during the second quarter. A Paycheck Protection Program loan was received in the US subsidiary in May, amounting to SEK 6.8 million. The loan serves to maintain employees and can be forgiven during 2021 and recognized as revenue once certain criteria have been confirmed to be fulfilled.

Investments

Net investments totaled SEK 8.7 million (15.4), including capitalized development expenses amounting to SEK 7.8 million (14.8). During 2019, investment in patents purchased from Innerspace amounted to SEK 6.7 million.

Assets

As of December 31, 2020, intangible assets totaled SEK 39.8 million (44.4). These intangible assets comprised capitalized development expenses and capitalized patent expenses.

Capitalized development expenses are amortized on a straight-line basis over assessed useful life estimated to 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.

The increase in inventory is primarily related to the company's planned expansion during the year.

Equity and liabilities

As of December 31, 2020, the Group's equity amounted to SEK 182.4 million (131.5) and the equity ratio was 87.2% (82.7).

As of December 31, 2020, interest-bearing liabilities totaled SEK 3.9 million (6.1). Current non-interest-bearing liabilities totaled SEK 22.7 million (21.5).

Changes in the parent company

The net loss for the period compared to the same period last year has not changed materially.

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

The market

IRRAS's first product, IRRAS*flow*, 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 345,000 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 16 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 a risk that IRRAS*flow* and Hummingbird are not accepted by physicians, hospitals, patients, insurance providers or medical professionals even though the products are approved for marketing and sales or that the expected level or adoption is delayed.

During the fourth quarter, global restrictions due to COVID-19 increased again which affected the company by limiting access to potential customers for sales and training. Several current customers' usage of IRRAS*flow* was also lower than expected, due to limited capacity in intensive care units. This has had a major impact on the company's sales during the quarter in relation to internal expectations, which is in line with how sales in previous quarters have been affected by the pandemic. However, there has been no impact on supply chain or the company's organization, but a latent risk remains. Continued severe restrictions would have a major impact on the company's ability to sell its products, even if revenue generation is still expected despite restrictions. For more details on the company's actions during the pandemic, refer to the comments from the CEO on page 2.

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.

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 and to fluctuating exchange rates.

Financing risk and going concern

The company's liquidity per February 16, 2021 is not sufficient to cover the planned operations in the next 12 months. In light of this, work is underway on possible financial solutions and the Board considers that the prospects are good to finance the company's operations. However, if sufficient financing is not obtained, there is a risk that conditions for going concern are not fulfilled.

For a more detailed description of the company's risks, refer to the 2019 Annual Report, pages 23-24.

The share and shareholders

The IRRAS share was listed at Nasdaq Stockholm in May 2020. Before that, the company was listed at Nasdaq First North Premier Growth Market since 2017. The number of shares and votes in IRRAS AB at the end of September 2020 totaled 66,281,340.

The Board of Directors proposes no dividend.

Shareholders as of December 31, 2020* (and known changes thereafter)	Number of shares	Percent of shares/ votes
Bacara Holdings Limited	16,234,097	24.49%
Fourth National Pension Fund	6,139,362	9.26%
Lexington Holding Assets Ltd	3,155,727	4.76%
Carl-Olof and Jenz Hamrins Foundation	3,000,000	4.53%
Christos Panotopoulos	2,744,000	4.14%
March Asset Management	1,380,449	2.08%
Dr. Kleanthis G. Xanthopoulos	1,101,498	1.66%
Avanza Pension	938,014	1.42%
Lovisa Hamrin	849,024	1.28%
Deka Investments	551,592	0.83%
Total ten largest shareholders	36,093,763	54.46%
Other shareholders	30,187,577	45.54%
Total number of shares	66,281,340	100.00%

*Nominee accounts / shareholders are not included in this compilation

Incentive programs

As of February 16, the company has four incentive programs outstanding for employees and key personnel. These programs can currently increase the number of shares by 4,332,000 (refer to note 2 on page 15).

Analysts following the company

Kristofer Liljeberg	Carnegie
Christian Lee	Pareto Securities
Oscar Bergman	Redeye

Financial calendar

2020 Annual report	March 30, 2021
Annual General Meeting	April 28, 2021
Q1 2020 Interim Report	May 4, 2021
Q2 2020 Interim Report	August 26, 2021
Q3 2020 Interim Report	November 9, 2021

IRRAS' reports are available on the company's webpage.

Auditors review

This report has not 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, February 16, 2021
IRRAS AB (publ)

Marios Fotiadis
Chairman of the Board

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

Anita Tollstadius
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	Oct–Dec 2020	Oct–Dec 2019	Jan–Dec 2020	Jan–Dec 2019
Net revenue	2.5	3.4	7.4	5.3
Cost of sales	-8.0	-10.1	-23.5	-38.4
Gross profit/loss	-5.5	-6.8	-16.1	-33.2
<i>Gross margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Other operating income	0.8	0.3	1.6	1.1
Marketing and sales expenses	-12.7	-11.4	-47.0	-43.1
Administrative expenses	-11.0	-10.8	-43.0	-45.5
Research and development expenses	-8.1	-7.0	-28.9	-29.8
Other operating expenses	-0.3	0.0	-0.9	-1.1
Operating loss (EBIT)	-36.8	-35.7	-134.3	-151.5
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	-1.3	-0.8	-1.6	0.3
Loss before tax	-38.1	-36.5	-135.9	-151.1
Tax	-	-	0.0	0.0
Net loss for the period	-38.1	-36.5	-135.9	-151.1
Other comprehensive income				
Items that may be subsequently reclassified to profit or loss				
Translation differences for the period on translation of foreign subsidiaries	-2.2	-0.6	-3.2	-1.1
Total other comprehensive income	-2.2	-0.6	-3.2	-1.1
Total comprehensive income for the period	-40.2	-37.1	-139.2	-152.2
Earnings per share before dilution, SEK	-0.57	-1.27	-2.46	-5.61
Earnings per share after dilution, SEK	-0.57	-1.27	-2.46	-5.61
Number of shares before dilution, average	66 281 340	28 817 974	55 152 011	26 937 426
Number of shares after dilution, average	66 281 340	28 817 974	55 152 011	26 937 426

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	Dec 31, 2020	Dec 31, 2019
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development expenses	33.3	36.2
Licenses/patents	6.5	8.2
Total intangible assets	39.8	44.4
Right-of-use assets	3.8	6.2
Tangible assets		
Property, plant and equipment	1.3	0.9
Total tangible assets	5.1	7.2
Financial assets		
Financial investments, bonds	-	0.0
Total financial assets	-	0.0
Total non-current assets	44.9	51.6
Current assets		
Inventory	20.9	16.0
Accounts receivable	5.1	2.8
Other receivables	1.3	1.5
Prepaid expenses and accrued income	1.2	2.0
Financial investments, bonds	-	55.6
Cash and cash equivalents	135.6	29.5
Total current assets	164.1	107.4
TOTAL ASSETS	209.0	159.0

Consolidated statement of financial position in summary (cont.)

SEK million	Dec 31, 2020	Dec 31, 2019
EQUITY		
Share capital	2.0	0.9
Other paid-in capital	726.7	537.4
Translation reserve	-6.3	-3.0
Retained earnings, including net loss for the period	-540.0	-403.8
Total equity	182.4	131.5
LIABILITIES		
Provisions		
Other provisions	0.0	0.0
Long term liabilities		
Lease liabilities	0.1	2.0
Total long-term liabilities and provisions	0.1	2.0
Current liabilities		
Lease liabilities	3.9	4.0
Liabilities to credit institutions	6.8	—
Accounts payable	3.4	7.5
Other liabilities	0.5	0.7
Accrued expenses and deferred income	11.9	13.3
Total current liabilities	26.6	25.5
Total liabilities and provisions	26.7	27.5
TOTAL EQUITY AND LIABILITIES	209.0	159.0

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
Opening equity January 1, 2019	0.7	440.2	-1.9	-254.8	184.2
<i>Comprehensive income for the period</i>					
Net loss for the period	-	-	-	-151.1	-151.1
Other comprehensive income for the period	-	-	-1.1	-	-1.1
Comprehensive income for the period	-	-	-1.1	-151.1	-152.2
<i>Transactions with shareholders</i>					
Incentive programs	-	-	-	2.2	2.2
New rights issue	0.1	105.5	-	-	105.6
New rights issue expenses	-	-8.3	-	-	-8.3
Closing equity December 31, 2019	0.9	537.4	-3.0	-403.7	131.5

Opening equity January 1, 2020	0.9	537.4	-3.0	-403.7	131.5
<i>Comprehensive income for the period</i>					
Net loss for the period	-	-	-	-135.9	-135.9
Other comprehensive income for the period	-	-	-3.2	-	-3.6
Comprehensive income for the period	-	-	-3.2	-135.9	-139.2
<i>Transactions with shareholders</i>					
Incentive programs	-	-	-	-0.4	-0.4
New rights issue	1.1	216.2	-	-	217.3
New share issue expenses	-	-26.9	-	-	-26.9
Closing equity December 31, 2020	2.0	726.7	-6.3	-540.0	182.4

Condensed consolidated statement of cash flows in summary

SEK million	Oct–Dec 2020	Oct–Dec 2019	Jan–Dec 2020	Jan–Dec 2019
Operating activities				
Operating loss (EBIT)	-36.8	-35.7	-134.3	-151.5
Adjustment for non-cash items				
- Depreciation/amortization	4.4	3.8	16.3	12.6
- Incentive programs	0.3	-0.5	-0.4	2.2
- Other non-cash items	-	0.0	-	0.0
Interest received	0.0	0.1	0.0	0.5
Interest paid	0.0	-0.1	-0.4	-0.1
Income tax paid	0.0	-	0.0	0.0
Cash flow from operating activities before changes in working capital	-32.1	-32.4	-118.7	-136.3
Cash flow from changes in working capital				
Increase (-)/decrease (+) in inventory	2.7	-4.1	-6.2	-11.1
Increase (-)/decrease (+) in operating receivables	-3.5	-4.0	-4.2	-4.2
Increase (+)/decrease (-) in operating payables	4.3	0.4	-3.6	-2.0
Cash flow from operating activities	-28.7	-40.2	-132.7	-153.7
Cash flow from investing activities				
Investment in intangible assets	-3.2	-1.8	-7.8	-14.8
Investments in tangible assets	-0.1	-0.1	-0.9	-0.6
Sale of financial assets	-	10.1	55.5	55.2
Cash flow from investing activities	-3.3	8.1	46.8	39.8
Cash flow from financing activities				
New share issue	-	-	217.3	105.6
New share issue expenses	-	-	-26.9	-8.3
Liabilities to credit institutions	-0.7	-	6.8	-
Lease liabilities	-0.9	-0.9	-3.8	-1.5
Cash flow from financing activities	-1.5	-0.9	193.4	95.7
Cash flow for the period	-33.6	-32.9	107.5	-18.2
Cash and cash equivalents at the beginning of the period	170.1	63.3	29.5	47.2
Exchange rate difference in cash and cash equivalents	-0.9	-0.9	-1.4	0.4
Cash and cash equivalents at the end of the period	135.6	29.5	135.6	29.5

Parent company statement of profit or loss in summary

SEK million	Oct-Dec 2020	Oct-dec 2019	Jan-Dec 2020	Jan-Dec 2019
Net revenue	1.9	0.5	4.7	1.6
Cost of sales	-2.8	-2.5	-10.7	-9.8
Gross profit/loss	-0.9	-2.0	-6.0	-8.3
Other operating income	0.3	0.2	0.9	0.2
Marketing and sales expenses	-1.5	-0.5	-4.6	-1.1
Administrative expenses	-7.5	-11.1	-29.5	-35.8
Research and development expenses	-0.1	-0.4	-0.5	-1.5
Other operating expenses	-0.1	0.0	-0.5	-0.9
Operating loss (EBIT)	-9.8	-13.9	-40.1	-47.4
Net financial income	-1.1	-0.6	-1.1	0.9
Loss before tax	-10.9	-14.5	-41.2	-46.4
Tax	-	-	-	-
Net loss for the period	-10.9	-14.5	-41.2	-46.4

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	Dec 31, 2020	Dec 31, 2019
ASSETS		
Non-current assets		
Intangible assets	34.9	38.1
Tangible assets	0.2	0.3
Financial assets		
Shares in Group companies	340.9	233.0
Receivables from Group companies	23.1	17.2
Financial investments, bonds	-	0.0
Total financial assets	364.0	250.2
Total non-current assets	399.1	288.6
Current assets		
Other receivables	0.8	0.9
Prepaid expenses and accrued income	0.7	1.9
Financial investments, bonds	-	55.6
Cash and bank balances	116.9	22.7
Total current assets	118.4	81.0
TOTAL ASSETS	517.5	369.6
EQUITY AND LIABILITIES		
EQUITY		
Share capital	2.0	0.9
Fund for capitalized expenditure	30.6	31.7
Capital surplus	693.1	503.8
Retained earnings	-175.1	-129.4
Loss for the year	-41.2	-46.4
Total equity	509.4	360.5
Provisions	-	0.0
Accounts payable	1.5	2.8
Liabilities to Group companies	0.0	0.0
Other current liabilities	0.4	0.3
Accrued expenses and deferred income	6.3	6.0
Total liabilities and provisions	8.1	9.1
TOTAL EQUITY AND LIABILITIES	517.5	369.6

Parent company condensed consolidated statement of cash flows in summary

SEK million	Oct-Dec 2020	Oct-Dec 2019	Jan-Dec 2020	Jan-Dec 2019
Operating activities				
Operating loss (EBIT)	-9.8	-13.9	-40.1	-47.4
Adjustment for non-cash items				
- Depreciation/amortization	2.9	2.6	11.2	10.2
- Incentive programs	0.1	0.5	0.8	1.9
- Other non-cash items	—	-0.4	—	0.0
Interest received	0.0	0.2	0.0	0.8
Interest paid	-0.2	0.0	-0.2	0.0
Cash flow from operating activities before changes in working capital	-7.0	-11.0	-28.4	-34.4
Cash flow from changes in working capital				
Increase (-)/decrease (+) in operating receivables	-0.6	-2.1	3.4	24.9
Increase (+)/decrease (-) in operating payables	5.7	1.3	7.4	1.2
Cash flow from operating activities	-1.9	-11.8	-17.7	-8.3
Cash flow from investing activities				
Investments in participations in subsidiaries	-24.9	-16.4	-118.6	-163.9
Investment in intangible assets	-3.2	-1.8	-7.8	-8.0
Investments in tangible assets	—	—	—	—
Sale of financial assets	—	10.1	55.5	55.2
Amortization from (+) /loans to (-) subsidiaries	—	3.5	-7.6	13.0
Cash flow from investing activities	-28.1	-4.6	-78.5	-103.7
Cash flow from financing activities				
New share issue	—	—	217.3	105.6
New share issue expenses	—	—	-26.9	-8.3
Cash flow from financing activities	—	—	190.4	97.3
Cash flow for the period	-30.0	-16.4	94.2	-14.7
Cash and cash equivalents at the beginning of the period	146.9	39.1	22.7	37.3
Exchange rate difference in cash and cash equivalents	—	—	—	—
Cash and cash equivalents at the end of the period	116.9	22.7	116.9	22.7

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 IRFS 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, 2020. None of the new standards has had any impact on the consolidated or parent company's financial statements as of December 31, 2020.

Segment reporting

Since IRRAS's equity instruments are traded in a market, IFRS 8 Operating Segments is applicable. IRRAS's operations are currently focused on development and sales within a single category of products of the same nature within the neurocritical care 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 four incentive programs outstanding for employees, key personnel and Board members. Two incentive programs has ended during the year. The costs for the incentive programs totaled SEK 0.4 million (-0.1) during the fourth quarter of 2020 and SEK -0.4 million (2.2) for the period from January to December 2020.

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, subject to the requirement that the options are vested (earned). The options are vested at 25% per year.

During the fourth quarter 2020, no options were distributed or forfeited. A total of 1,808,048 options were outstanding as of December 31, 2020. The CEO has 1,275,000 options and three members of the management group have 98,500, 15,000 and 12,976 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, subject to the requirement that the options are vested. The options are vested at 33% per year.

During the fourth quarter 2020, no options were distributed or forfeited. A total of 367,440 options were outstanding as of

December 31, 2020. Two members of the management group have 35,000 and 230,000 options, respectively.

Incentive program No. 3

The options in incentive program 3 expired October 31, 2020.

Incentive program No. 4

The options in incentive program 4 expired October 31, 2020.

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 2019 Annual Report. Each option entitles the holder to subscribe for a new share for SEK 25.86 per share until June 15, 2022, subject to the requirement that the options are vested. The options are vested at 33% per year.

During the fourth quarter of 2020, 7,112 options were forfeited. A total of 517,232 options were outstanding as of December 31, 2020. The CEO has 39,277 options and two members of the management group have 49,990 and 16,274 options, respectively.

Incentive program No. 6

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

During the fourth quarter of 2020, 28,500 options were distributed. A total of 507,024 options were outstanding as of December 31, 2020. The CEO has 125,000 options and four members of the management group have 100,000, 52,000, 15,000 and 12,024 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:

The Group has purchased office equipment from a person related to CEO Kleanthis G. Xanthopoulos. The expense for the period January to December 2020 totaled 7.4 thousand (230.7). The Group has also purchased educational training from a person related to the CEO. The expense for the period totaled 386.6 thousand (0). The Group leased offices from a person related to the CEO until April 2019. The expenses for the period from January to December 2020 totaled SEK 0.0 thousand (37.8).

Note 4 Financial assets and liabilities

Financial assets and liabilities in the balance sheet are reported to the amortized cost 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. The performance measures are calculated on the actual financial statements including IFRS 16.

	Oct-Dec 2020	Oct-Dec 2019	Jan-Dec 2020	Jan-Dec 2019
Gross margin (Gross profit or loss/Net revenue)				
Gross profit/loss, SEK million	-5.5	-6.8	-16.1	-33.2
Net revenue, SEK million	2.5	3.4	7.4	5.3
Gross margin, %	Neg	Neg	Neg	Neg
EBIT margin (Operating loss (EBIT)/Net revenue)				
Operating loss (EBIT), SEK million	-36.8	-35.7	-134.3	-151.5
Net revenue, SEK million	2.5	3.4	7.4	5.3
EBIT margin, %	Neg	Neg	Neg	Neg
EBITDA margin (EBITDA/Net revenue)				
Operating loss (EBIT), SEK million	-36.8	-35.7	-134.3	-151.5
Depreciation/amortization, SEK million	-4.4	-3.8	-16.3	-12.6
Net revenue, SEK million	2.5	3.4	7.4	5.3
EBITDA margin, %	Neg	Neg	Neg	Neg
Return on equity, % (Net profit or loss for the period/Average equity)				
Net loss for the period, SEK million	-38.1	-36.5	-135.9	-151.1
Average equity, SEK million	202.2	150.1	156.9	157.8
Return on equity, %	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 total 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 Stockholm: IRRAS) is a global medical care company focused on delivering innovative medical solutions to improve the lives of critically ill patients. IRRAS designs, develops, and commercializes neurocritical care products that transform patient outcomes and decrease the overall cost of care by addressing complications associated with current treatment methodologies. IRRAS markets and sells its comprehensive, innovative IRRAS*flow* and Hummingbird ICP Monitoring product lines

to hospitals worldwide through its direct sales organization in the United States and select European countries as well as an international network of distribution partners. 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.

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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 February 16, 2020 at 8:00 a.m. (CET).

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