

Fifth Consecutive Quarter of Revenue Growth

Third quarter, July - September 2021

- Net revenue amounted to SEK 6.1 million (2.1).
- Operating loss (EBIT) amounted to SEK -27.0 million (-31.0).
- Loss after tax amounted to SEK -26.9 million (-31.0).
- EPS before and after dilution amounted to SEK -0.34 (-0.47).

Important events during the quarter

Company Leadership Transition Completed

- On July 1, Will Martin assumed the role of IRRAS President & Chief Executive Officer. Kleanthis G. Xanthopoulos, Ph.D. remains on the company's Board of Directors.

Loan Financing Completed via European Investment Bank

- IRRAS signed a 10M EUR loan agreement that provides non-dilutive financing for IRRAS to fund product development and clinical data generation activities being performed in the EU.

Ventriculitis Case Study Published

- Helsinki University Hospital published a case series that confirmed the ability of IRRAflow to treat patients with pyogenic ventriculitis, an aggressive brain infection.
- Publication documents the ability of IRRAflow to directly deliver antibiotics into the intracranial space for the first time in peer-reviewed literature.

Expanded Quality System Certifications Received after Onsite Inspection

- IRRAS' in-house manufacturing facility for IRRAflow capital equipment was added to its ISO 13485:2016 certification, and the company's MDSAP certificate was extended for 3 years.

Period January – September 2021

- Net revenue amounted to SEK 15.2 million (4.9).
- Operating loss (EBIT) amounted to SEK -93.0 million (-97.5).
- Loss after tax amounted to SEK -92.9 million (-97.8).
- EPS before and after dilution amounted to SEK -1.30 (-1.90).

Important events after the quarter

CE Mark certification received for enhanced IRRAflow Drainage Catheter

- Enhanced catheter with improved kink resistance and increased drainage capabilities now available for patient treatments in Europe.

ACTIVE clinical study initiated by Aarhus University Hospital

- Aarhus University Hospital, a leading hospital in Denmark, began commercial patient treatments with IRRAflow and will capture its results in the ACTIVE investigator-initiated clinical trial to prove the system's superiority versus traditional drainage systems.

First patients enrolled in ARCH clinical study

- Dr. Behnam Rezaei Jahromi from Helsinki University Hospital enrolled the first patient in the ARCH clinical study, which compares use of IRRAflow with clot-busting medication versus traditional drainage systems in patients with intraventricular hemorrhage.

Key figures	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Net revenue, SEK million	6.1	2.1	15.2	4.9	7.4
Gross margin, %	1%	Neg	Neg	Neg	Neg
Operating loss (EBIT), SEK million	-27.0	-31.0	-93.0	-97.5	-134.3
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
Loss after tax	-26.9	-31.0	-92.9	-97.8	-135.9
EBITDA, SEK million	-22.9	-27.0	-80.0	-85.6	-118.0
EBITDA margin, %	Neg	Neg	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg	Neg	Neg

Comments from the CEO

We remain focused on delivering meaningful innovation that positions IRRAS as a leader in neurocritical care. The 3rd quarter of 2021 served the latest important data point that confirms the continued progress in our pursuit of that goal.

The quarterly revenue of MSEK 6.1 during Q3 marked our company's 5th consecutive quarter of growth, even with increased impact during the quarter from the COVID-19 Delta variant. This growth and the strengthening foundation of our business show that IRRAS is well positioned to continue this positive growth trajectory.

Once again, more IRRAS patient treatments occurred during this quarter than any previous one in the company's history. The disposable reorders driven by this usage drove a majority of our quarterly revenue, both in the United States and Europe. Consistent product utilization continues with key customers, such as Buffalo General Medical Center, West Virginia University Hospital, Aarhus University Hospital, and other facilities, and our team is focused on replicating this adoption elsewhere as new customers are added.

We were also encouraged to see our commercial activity in Germany increased during the 3rd quarter. Germany remains an extremely important direct sales market for IRRAS, and, historically, customer reaction from Germany has been positive. During the launch of the first generation IRRAS system in late 2017, a number of German hospitals gained experience with our products. After receiving our updated CE Mark in late 2019, our team's initial relaunch was slowed due to COVID restrictions. During Q3, though, customer access began to increase, and three German customers placed orders to begin IRRAS evaluations. One of these customers had previous experience with IRRAS in 2017, and the other two are newly-added customers.

Finally, in the US, Mount Sinai Health System in New York City, one of the top 20 neurosurgical departments in the world, placed an order to begin using the IRRAS system, which further increased the number of commercial systems in the US from 22 to 26.

Beyond this commercial activity, our IRRAS team also drove other meaningful forward progress during Q3. The relationship with our new notified body, DEKRA, resulted in our existing ISO quality system certificate being extended to cover our new in-house manufacturing facility and our MDSAP quality certification being extended out for 3 years. These accomplishments verify the growing maturity of our company's processes and ensure that we are well positioned to support more markets globally in the future.

Moving forward, our ability to generate impactful clinical data remains the most important factor that will contribute to our long-term growth, and, during Q3, multiple clinical papers were published that strengthen the IRRAS clinical evidence base. Of note, Dr. Behnam Reza Jahromi from Helsinki University Hospital

published a case series in the *Neurosurgery Open* journal that concluded that IRRAS was effective in treating aggressive brain infections without harming the brain tissue by converting a patient's cerebrospinal fluid (CSF) to an antibiotic-consisted fluid, which increased antibiotic effectiveness within the brain. This case series is an important first step in our company's long-term plans to explore IRRAS's ability to deliver drug therapy directly into the intracranial space.

Finally, Q3 2021 allowed us to continue to strengthen the financing of the IRRAS activities. As previously announced, our company finalized a non-dilutive loan with the European Investment Bank that can provide up to EUR 10M in two tranches. Currently, our company has not yet drawn upon these available funds, and in coming quarters, we will outline our projected use of these funds in more detail. The current expectation is that, at an appropriate time in the future, the first available tranche of EUR 5M can be drawn to support planned product development and clinical trial activities in the EU, which will also help extend the company's available financial runway.

We also continued to make progress toward improving our company's margin contribution. We continue to invest our money wisely and drive cost out of the organization with our increased manufacturing capabilities. These efforts resulted in an improved gross profit of SEK 0.1 million for Q3 2021 compared to SEK -3.6 million for the same period last year.

All told, we were pleased with our accomplishments during the third quarter of 2021. Our progress across all aspects of our business – commercial, clinical, quality, and operations – reinforced our forward momentum. In coming quarters, we will launch a next generation version of the IRRAS control unit that will serve as our key product for years to come, and we are excited to see the impact that this new software and operating system will have on our business. Our commercial and clinical progress will continue with more patients being treated in more hospitals around the world with impactful data being collected, and we look forward to sharing these positive results with our shareholders. The future of IRRAS remains bright with many meaningful contributions having occurred during Q3 2021.

Sincerely,

Will Martin,
President and CEO



Group development January – September 2021

Net revenue

Net revenue for the third quarter amounted to SEK 6.1 million (2.1), and net revenue for the period January to September 2021 totaled SEK 15.2 million (4.9).

Positive sales development for both Q3 2021 and the period from January to September 2021 has been driven by increasing contribution from each major component of commercial activity:

- Addition of new accounts within the United States,
- The conversion of US accounts evaluating IRRAS products into commercial customers,
- Growing product adoption at commercial accounts in the United States, leading to disposable reorders,
- A growing number of European direct customers beginning to use IRRAS^{flow}, and
- Increasing contribution from IRRAS growing network of distribution partners, both through initial stocking orders and reorders to support continued growth.

Net revenue from the United States totaled SEK 3.9 million for the period July to September 2021, up from SEK 1.6 million for the same period in 2020. Net revenue from Europe totaled SEK 1.5 million for the period July to September 2021, up from SEK 0.5 million for the same period in 2020. Net revenue from Germany totaled SEK 0.3 million, while net revenue from other regions equaled SEK 0.4 million for the period July to September 2021. Both of these areas contributed no revenue from the same period in 2020.

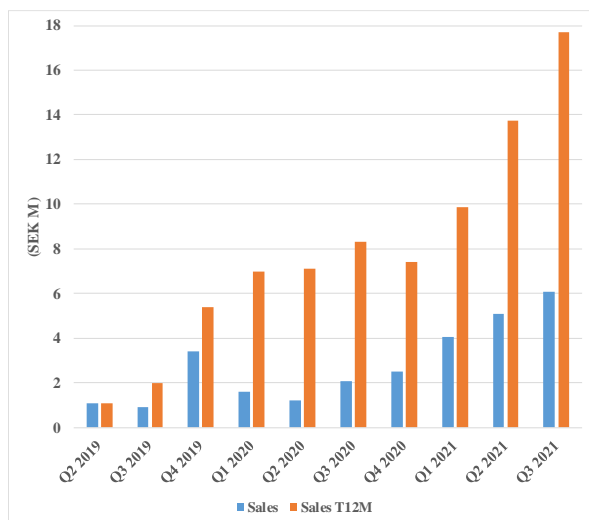


Figure 1 IRRAS Quarterly and Trailing 12-Month Revenue

Gross profit/loss

The gross profit for the period January to September 2021 amounted to SEK -15.6 million (-10.6). The gross profit for the third quarter amounted to SEK 0.1 million (-3.6).

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, overhead costs for the manufacturing department, and salaries for the employees at the manufacturing department.

The amortization of capitalized development expenses during the period January to September 2021 amounted to SEK 8.5 million (7.9) and SEK 2.9 million (2.7) during the third quarter.

Operating expenses

Operating expenses for the period January to September 2021 totaled SEK 85.3 million (87.6). The operating expenses are primarily attributable to marketing and sales expenses in US, administrative expenses as a result of the company growth, research and development expenses, and other operating expenses.

Total research and development expenses in the period amounted to SEK 24.0 million (25.4), of which SEK 4.8 million (4.6) was capitalized and SEK 19.2 million (20.8) was recognized as expense. The expensed R&D costs mainly include 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 7.7 million (0.2). The majority of this total was attributed to the forgiveness of the Paycheck Protection Program loan during Q2 2021 that totaled SEK 6.9 million and was reclassified to other operating revenue

Operating profit/loss (EBIT)

Operating loss (EBIT) totaled SEK -93.0 million (-97.5) for the period January to September 2021, and SEK -27.0 million (-31.0) for the third quarter.

Net financial income

Net financial income totaled SEK 0.1 million (-0.3) for the period January to September 2021.

Earnings

Loss before tax amounted to SEK -92.9 million (-97.8) for the period January to September 2021, and SEK -26.9 million (-31.0) for third quarter. Net loss (loss after tax) amounted to SEK -92.9 million (-97.8) for the period January to September 2021 and SEK -26.9 million (-31.0) for the third quarter.

Cash flow and liquidity

Cash flow from operating activities from January to September 2021, after the change in working capital, totaled SEK -94.6 million (-104.0).

At the end of the period, available liquidity amounted to SEK 95.1 million (170.1).

During the second quarter, a fully guaranteed directed issue of shares of SEK 66.0 million before fees was completed.

Investments

Net investments totaled SEK 4.9 million (5.4) for the period of January to September 2021. This included capitalized development expenses amounting to SEK 4.8 million (4.6) for the period of January to September 2021.

Assets

As of September 30, 2021, intangible assets totaled SEK 35.7 million (40.1). These intangible assets comprised capitalized development expenses and capitalized patent expenses.

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, 2021, the Group's equity amounted to SEK 154.7 million (222.2) and the equity ratio was 91.2 (90.3)%.

As of September 30, 2021, interest-bearing liabilities totaled SEK 1.4 million (3.4). Current non interest-bearing liabilities totaled SEK 13.5 million (20.3).

Changes in the parent company

The reduced net loss for the period compared to the same period last year is primarily due to expenses connected to the listing on Nasdaq Stockholm during 2020.

Sales per region SEK million	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
USA	3.9	1.6	9.0	2.7	3.2
Germany	0.3	—	0.3	—	0.1
Europe, excluding Germany	1.5	0.5	3.9	2.2	3.7
Other regions	0.4	—	2.0	—	0.4
Total	6.1	2.1	15.2	4.9	7.4

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 2021 was 63 (42), of which 7 (6) are employed by the parent company. The breakdown of average number of employees by country was 7 (6) in Sweden, 51 (33) in the US and 4 (3) in Germany. The average number of women in the Group was 31 (15), and the average number of men was 32 (27).

The market

IRRAS' first product, IRRAS*flow*, is initially intended for treatment of patients with hemorrhagic strokes and chronic subdural hematoma. IRRAS also markets the Hummingbird family of products to diagnose intracranial pressure (ICP) and treat traumatic brain injury.

The market opportunity for the Company's products is significant as smoking, reduced cardiovascular health, and an aging population continue to increase the incidence of neurocritical brain pathologies. Each year, in the US and EU alone, approximately 5.4 million people are affected by traumatic brain injury.^{1,2} Of those patients, approximately 235,000 people requiring invasive

monitoring of their ICP where the Hummingbird ICP system can be used.³

On top of that amount, when the brain injury results in active intracranial bleeding, more urgent, invasive treatment is required. Around 600,000 people in the US and Europe suffer from hemorrhagic strokes and chronic subdural hematoma annually, and approximately 345,000 of these people are treated surgically.⁴ In these situations, once the bleeding is under control, the excess blood and the pressure that it creates must be urgently removed to stabilize the patient's condition.

IRRAS estimates that the total addressable market size of the company's products in Europe and the US is currently approximately EUR 1.2 billion.

Related-party transactions

Refer to note 3 on page 14 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 the IRRAS*flow* and Hummingbird products are not accepted by physicians, hospitals, patients, insurance providers or medical professionals, even though the products have received regulatory clearance, or that the expected level of adoption is delayed.

During the third quarter of 2021, IRRAS continued to closely assess the risks associated with COVID-19, especially as new information became available regarding the spread of the Delta variant. Vaccination rates continue to progress in the United States

¹ Centers for Disease Control and Prevention (2019). Surveillance Report of Traumatic Brain Injury-related Emergency Department Visits, Hospitalizations, and Deaths—United States, 2014. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

² Center-TBI EU Traumatic Brain Injury Fact Sheet and Policy Brief

³ Market Study Report, Global Intracranial Pressure (ICP) Monitoring Devices Market Growth, 2019-2024.

⁴ Market data from L3 consulting and internal analysis. Combination of incidence rates combined with market-specific DRG reimbursement data.

and Europe, but, while COVID-related restrictions have eased in some areas, travel restrictions remain. As COVID cases spike, ICU bed space is restricted, and access to customers for sales and training can also be reduced. Several current customers' usage of IRRASflow was also lower than expected due to limited capacity in intensive care units, and other customer evaluations were placed on hold. The pandemic has had a major impact on the company's sales and sales growth during the quarter in relation to internal expectations, which consistent with the sales impact in previous quarters from 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.

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 November 9th, 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 considered these ongoing projects sufficient 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 2020 Annual Report, pages 28-29.

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 2021 totaled 79,481,340.

Shareholders as of September 30, 2021* (and known changes thereafter)	Number of shares	Percent of shares/ votes
Bacara Holdings Limited	19,734,097	24.83%
Fourth National Pension Fund	7,359,362	9.26%
Carl-Olof and Jenz Hamrins Foundation	3,800,000	4.78%
Lexington Holding Assets Ltd	3,155,727	3.97%
Staffan Persson	2,950,005	3.71%
Christos Panotopoulos	2,520,000	3.17%
Avanza Pension	2,135,891	2.69%
Second National Pension Fund	2,000,000	2.52%
March Asset Management	1,713,597	2.16%
Dr. Kleanthis G. Xanthopoulos	1,301,498	1.64%
Total ten largest shareholders	46,670,177	58.72%
Other shareholders	32,811,163	41.28%
Total number of shares	79,481,340	100.00%

*Nominee accounts / shareholders are not included in this compilation

Incentive programs

As of November 9, the company has five incentive programs outstanding for employees and key personnel. These programs can currently increase the number of shares by 5,332,000 (refer to note 2 on page 14).

Analysts following the company

Ulrik Trattner
Oscar Bergman

Carnegie
Redeye

Auditors review

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

Financial calendar

Q4 2021 Year-end Report February 16, 2022

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

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 9, 2021
IRRAS AB (publ)

Marios Fotiadis
Chairman of the Board

Kleanthis G. Xanthopoulos, Ph.D
Board member

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	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Net revenue	6.1	2.1	15.2	4.9	7.4
Cost of sales	-6.0	-5.7	-30.9	-15.5	-23.5
Gross profit/loss	0.1	-3.6	-15.6	-10.6	-16.1
<i>Gross margin</i>	1%	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Other operating income	0.1	0.4	8.0	0.8	1.6
Marketing and sales expenses	-12.4	-11.3	-38.8	-34.3	-47.0
Administrative expenses	-8.8	-8.4	-27.0	-31.9	-43.0
Research and development expenses	-6.0	-7.8	-19.2	-20.8	-28.9
Other operating expenses	—	-0.3	-0.3	-0.6	-0.9
Operating loss (EBIT)	-27.0	-31.0	-93.0	-97.5	-134.3
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	0.1	—	0.1	-0.3	-1.6
Loss before tax	-26.9	-31.0	-92.9	-97.8	-135.9
Tax	—	—	—	—	—
Net loss for the period	-26.9	-31.0	-92.9	-97.8	-135.9
Other comprehensive income					
Items that may be subsequently reclassified to profit or loss					
Translation differences for the period on translation of foreign subsidiaries	1.5	-1.5	2.8	-1.1	-3.2
Total other comprehensive income	1.5	-1.5	2.8	-1.1	-3.2
Total comprehensive income for the period	-25.4	-32.5	-90.1	-98.9	-139.2
Earnings per share before dilution, SEK	-0.34	-0.47	-1.30	-1.90	-2.46
Earnings per share after dilution, SEK	-0.34	-0.47	-1.30	-1.90	-2.46
Number of shares before dilution, average	79,481,340	66,281,340	71,503,318	51,415,155	55,152,011
Number of shares after dilution, average	79,481,340	66,281,340	71,503,318	51,415,155	55,152,011

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, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS			
Non-current assets			
Intangible assets			
Development expenses	29.6	32.9	33.3
Licenses/patents	6.2	7.2	6.5
Total intangible assets	35.7	40.1	39.8
Right-of-use assets	1.2	3.5	3.8
Tangible assets	1.1	1.4	1.3
Machinery and equipment	0.1	—	—
Total tangible assets	2.4	4.9	5.1
Total non-current assets	38.1	45.0	44.9
Current assets			
Inventory	20.4	25.4	20.9
Accounts receivable	13.8	3.4	5.1
Other receivables	1.3	1.3	1.3
Prepaid expenses and accrued income	1.0	0.7	1.2
Cash and cash equivalents	95.1	170.1	135.6
Total current assets	131.6	200.9	164.1
TOTAL ASSETS	169.7	246.0	209.0
EQUITY			
Share capital	2.4	2.0	2.0
Other paid-in capital	787.8	726.7	726.7
Translation reserve	-3.4	-4.1	-6.3
Retained earnings, including net loss for the period	-632.1	-502.3	-540.0
Total equity	154.7	222.2	182.4
LIABILITIES			
Long term liabilities			
Lease liabilities	0.2	0.1	0.1
Total long-term liabilities and provisions	0.2	0.1	0.1
Current liabilities			
Lease liabilities	1.2	3.4	3.9
Liabilities to credit institutions	—	7.5	6.8
Accounts payable	5.3	3.9	3.4
Other liabilities	0.5	0.5	0.5
Accrued expenses and deferred income	7.7	8.4	11.9
Total current liabilities	14.8	23.7	26.6
Total liabilities and provisions	15.0	23.7	26.7
TOTAL EQUITY AND LIABILITIES	169.7	246.0	209.0

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, 2020	0.9	537.4	-3.0	-403.7	131.5
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-97.8	-97.8
Other comprehensive income for the period	—	—	-1.1	—	-1.1
Comprehensive income for the period	—	—	-1.1	-97.8	-98.9
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	-0.7	-0.7
New rights issue	1.1	216.2	—	—	217.3
New share issue expenses	—	-26.9	—	—	-26.9
Closing equity September 30, 2020	2.0	726.7	-4.1	-502.3	222.2
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-38.1	-38.1
Other comprehensive income for the period	—	—	-2.2	—	-2.2
Comprehensive income for the period	—	—	-2.2	-38.1	-40.3
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	0.3	0.3
Closing equity December 31, 2020	2.0	726.7	-6.3	-540.0	182.4
Opening equity January 1, 2021	2.0	726.7	-6.3	-540.0	182.4
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-92.9	-92.9
Other comprehensive income for the period	—	—	2.8	—	2.8
Comprehensive income for the period	—	—	2.8	-92.9	-90.1
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	0.8	0.8
Direct share issue	0.4	65.6	—	—	66.0
New share issue expenses	—	-4.5	—	—	-4.5
Closing equity September 30, 2021	2.4	787.8	-3.4	-632.1	154.7

Condensed consolidated statement of cash flows in summary

SEK million	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Operating activities					
Operating loss (EBIT)	-27.0	-31.0	-93.0	-97.5	-134.3
Adjustment for non-cash items					
- Depreciation/amortization	4.1	4.0	13.0	11.9	16.3
- Incentive programs	0.2	0.4	0.8	-0.7	-0.4
- Other non-cash items	-2.0	—	-3.9	—	—
Interest received	—	—	—	—	—
Interest paid	—	-0.2	—	-0.3	-0.4
Income tax paid	—	—	—	—	—
Cash flow from operating activities before changes in working capital	-24.7	-26.9	-83.1	-86.6	-118.7
Cash flow from changes in working capital					
Increase (-)/decrease (+) in inventory	-3.6	-1.3	-2.1	-8.8	-6.2
Increase (-)/decrease (+) in operating receivables	-2.8	-1.0	-7.1	-0.7	-4.2
Increase (+)/decrease (-) in operating payables	2.6	-0.9	-2.2	-7.8	-3.6
Cash flow from operating activities	-28.6	-30.1	-94.6	-104.0	-132.7
Cash flow from investing activities					
Investment in intangible assets	-1.5	-1.6	-4.8	-4.6	-7.8
Investments in tangible assets	—	-0.7	-0.1	-0.8	-0.9
Sale of financial assets	—	—	—	55.5	55.5
Cash flow from investing activities	-1.5	-2.2	-4.9	50.1	46.8
Cash flow from financing activities					
New share issue	—	—	66.0	217.3	217.3
New share issue expenses	-0.1	-0.2	-4.5	-26.9	-26.9
Liabilities to credit institutions	—	-0.3	—	7.5	6.8
Lease liabilities	-0.9	-1.0	-3.7	-2.9	-3.8
Cash flow from financing activities	-1.0	-1.6	57.9	195.0	193.4
Cash flow for the period	-31.1	-33.9	-41.6	141.1	-107.5
Cash and cash equivalents at the beginning of the period	125.6	204.7	135.6	29.5	29.5
Exchange rate difference in cash and cash equivalents	0.5	-0.7	1.1	-0.5	-1.4
Cash and cash equivalents at the end of the period	95.1	170.1	95.1	170.1	135.6

Parent company statement of profit or loss in summary

SEK million	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Net revenue	0.2	1.2	0.6	2.8	4.7
Cost of sales	-3.1	-2.7	-8.6	-7.9	-10.7
Gross profit/loss	-2.9	-1.5	-8.0	-5.1	-6.0
Other operating income	—	0.4	0.3	0.7	0.9
Marketing and sales expenses	-1.9	-1.5	-4.9	-3.0	-4.6
Administrative expenses	-3.6	-5.3	-15.8	-22.0	-29.5
Research and development expenses	—	-0.1	-0.3	-0.4	-0.5
Other operating expenses	0.1	-0.1	-0.2	-0.4	-0.5
Operating loss (EBIT)	-8.2	-8.2	-28.9	-30.3	-40.1
Net financial income	0.2	0.2	0.4	—	-1.1
Loss before tax	-8.0	-8.0	-28.4	-30.3	-41.2
Tax	—	—	—	—	—
Net loss for the period	-8.0	-8.0	-28.4	-30.3	-41.2

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, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS			
Non-current assets			
Intangible assets	30.9	34.5	34.9
Tangible assets	0.1	0.2	0.2
Financial assets			
Shares in Group companies	418.4	320.1	340.9
Receivables from Group companies	25.9	22.8	23.1
Total financial assets	444.3	342.9	364.0
Total non-current assets	475.4	377.7	399.1
Current assets			
Receivables from Group companies	1.0	—	—
Other receivables	0.6	0.6	0.8
Prepaid expenses and accrued income	0.5	0.6	0.7
Cash and bank balances	70.7	146.9	116.9
Total current assets	72.9	148.0	118.4
TOTAL ASSETS	548.2	525.7	517.5
EQUITY AND LIABILITIES			
EQUITY			
Share capital	2.4	2.0	2.0
Fund for capitalized expenditure	27.2	29.7	30.6
Capital surplus	754.2	693.1	693.1
Retained earnings	-212.0	-174.6	-175.1
Loss for the year	-28.4	-30.3	-41.2
Total equity	543.3	519.9	509.4
Current liabilities			
Accounts payable	1.1	0.7	1.5
Liabilities to Group companies	0.6	0.6	0.0
Other current liabilities	0.4	0.3	0.4
Accrued expenses and deferred income	2.8	4.2	6.3
Total liabilities and provisions	4.9	5.8	8.1
TOTAL EQUITY AND LIABILITIES	548.2	525.7	517.5

Parent company condensed consolidated statement of cash flows in summary

SEK million	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Operating activities					
Operating loss (EBIT)	-8.2	-8.1	-28.9	-30.3	-40.1
Adjustment for non-cash items					
- Depreciation/amortization	3.0	2.8	8.8	8.3	11.2
- Incentive programs	0.1	0.1	0.3	0.7	0.8
- Other non-cash items	—	—	—	—	—
Interest received	—	—	—	—	—
Interest paid	0.1	—	0.2	—	-0.2
Cash flow from operating activities before changes in working capital	-5.0	-5.1	-19.6	-21.4	-28.4
Cash flow from changes in working capital					
Increase (-)/decrease (+) in operating receivables	-2.5	0.5	-0.1	4.0	3.4
Increase (+)/decrease (-) in operating payables	7.0	2.0	3.9	1.6	7.4
Cash flow from operating activities	-0.5	-2.7	-15.8	-15.8	-17.7
Cash flow from investing activities					
Investments in participations in subsidiaries	-24.7	-40.5	-84.1	-93.7	-118.6
Investment in intangible assets	-1.5	-1.6	-4.8	-4.6	-7.8
Sale of financial assets	—	—	—	55.5	55.5
Amortization from (+) /loans to (-) subsidiaries	—	-3.8	-3.0	-7.6	-7.6
Cash flow from investing activities	-26.2	-45.9	-91.9	-50.4	-78.5
Cash flow from financing activities					
New share issue	—	—	66.0	217.3	217.3
New share issue expenses	-0.1	-0.2	-4.5	-26.9	-26.9
Cash flow from financing activities	-0.1	-0.2	61.5	190.4	190.4
Cash flow for the period	-26.8	-48.8	-46.2	124.3	94.2
Cash and cash equivalents at the beginning of the period	97.6	195.7	116.9	22.7	22.7
Cash and cash equivalents at the end of the period	70.7	146.9	70.7	146.9	116.9

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, 2021. None of the new standards has had any impact on the consolidated or parent company's financial statements as of September 30, 2021.

Segment reporting

Since IRRAS' equity instruments are traded in a market, IFRS 8 Operating Segments is applicable. IRRAS' 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 and is reflected in its entirety in the consolidated financial statements. The Group's strategic control 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 for details.

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 0.3 million (0.4) during the third quarter of 2021 and 0.8 million (-0.7) for the period from January to September 2021.

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 third quarter 2021, 16,911 options were terminated. No new options were distributed. A total of 1,691,092 options were outstanding as of September 30, 2021. The CEO has 98,500 options, and two members of the management group have 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 third quarter 2021, 50,000 options were terminated. No new options were distributed.

A total of 278,000 options were outstanding as of September 30, 2021. The CEO has 230,000 options, and one member of the management group have 35,000 options.

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 third quarter of 2021, 41,941 options were terminated. No new options were distributed. A total of 403,622 options were outstanding as of September 30, 2021. One member of the management group has 49,990 options.

Incentive program No. 6

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 eighth 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 third quarter of 2021, 26,491 options were terminated, and no new options were distributed. A total of 827,120 options were outstanding as of September 30, 2021. The CEO has 126,616 options, and two members of the management group have 35,160 and 27,144 options, respectively.

Incentive program No. 7

A new incentive program was approved at the Annual General Meeting on April 28, 2021. The total program comprises 1,000,000 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 eighth 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 third quarter of 2021, 1,000 options were terminated, and 288,500 new options were distributed. A total of 350,000 options were outstanding as of September 30, 2021.

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 educational training from a person related to board member Kleanthis G. Xanthopoulos. The expense for the period January to September 2021 totaled SEK 382.0 thousand (7.5). The Group has also purchased software from a person related to the former CFO Sabina Berlin. The expense for the period totaled SEK 12.0 thousand (0.0).

The Group has purchased consulting services from board member Kleanthis G. Xanthopoulos, to help with the CEO transition. The expense for the period January to September 2021 totaled SEK 118.8 thousand (0.0)

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.



Review report

IRRAS AB

Corp. id. 556872-7134

Introduction

We have reviewed the condensed interim financial information (interim report) of IRRAS AB as of September 30, 2021 and the nine-month period then ended. The Board of Directors and the Chief Executive Officer 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.

Uncertainty related to going concern

Without qualifying our report above, we bring to your attention the information on page 5 of the interim report which states that the cash and cash equivalents as of November 9, 2021 are not sufficient to cover planned operations for the coming 12 months. It is also stated that work is underway on possible financing solutions and also that there is a risk that that if sufficient financing is not obtained, there is a risk that the conditions for going concern are not fulfilled. These conditions indicate the existence of a material uncertainty as to the company's ability to continue as a going concern.

Stockholm, November 9, 2021

KPMG AB

Duane Swanson

Authorized Public Accountant

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.

	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Gross margin (Gross profit or loss/Net revenue)					
Gross profit/loss, SEK million	0.1	-3.6	-15.6	-10.6	-16.1
Net revenue, SEK million	6.1	2.1	15.2	4.9	7.4
Gross margin, %	1%	Neg	Neg	Neg	Neg
EBIT margin (Operating loss (EBIT)/Net revenue)					
Operating loss (EBIT), SEK million	-27.0	-31.0	-93.0	-97.5	-134.3
Net revenue, SEK million	6.1	2.1	15.2	4.9	7.4
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
EBITDA					
Operating loss (EBIT), SEK million	-27.0	-31.0	-93.0	-97.5	-134.3
Add back depreciation/amortization, SEK million	4.1	4.0	13.0	11.9	16.3
EBITDA	-22.9	-27.0	-80.0	-85.6	-118.0
EBITDA margin (EBITDA/Net revenue)					
EBITDA	-22.9	-27.0	-80.0	-85.6	-118.0
Net revenue, SEK million	6.1	2.1	15.2	4.9	7.4
EBITDA margin, %	Neg	Neg	Neg	Neg	Neg
Return on equity, % (Net profit or loss for the period/Average equity)					
Net loss for the period, SEK million	-26.9	-31.0	-92.9	-97.8	-135.9
Average equity, SEK million	167.3	238.4	168.5	176.8	156.9
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 total operating expenses

EBIT margin: Operating profit/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 IRRASflow and Hummingbird ICP Monitoring product

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

Contact



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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 Nov 9, 2021 at 8:00 a.m. (CET).

IRRAS

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