

IRRAflow[®] launch initiated in the US

Fourth quarter, October–December 2018

- Net revenue totaled SEK 0.0 million (0.7).
- Operating loss (EBIT) amounted to SEK -50.1 million (-23.7).
- Loss after tax totaled SEK -50.1 million (-23.2).
- Earnings per share before and after dilution amounted to SEK -2.09 (-1.09).

Important events during the fourth quarter

Launch initiated in the US

During the fourth quarter the company started the launch preparations in the US. Regional sales managers and marketing staff were hired. Contacts were established with hospitals and training of future users of IRRAflow started. IRRAS also participated in a couple of neurosurgery conferences.

New Board member

At an extraordinary general meeting on October 1, Eva Nilsagård was elected as a new Board member. Through Eva, the company is provided with long and broad experience from finance and business development in listed companies.

Important events after the end of the fourth quarter

First Patients in the United States Successfully Treated with IRRAflow[®]

At the beginning of January, the first patients in the United States were treated with IRRAflow. The initial treatments were performed at the University of California – Irvine (UCI) Medical Center, in Orange, California.

The team, led by UCI Health neurosurgeon Dr. Sumeet Vadera, successfully treated two patients suffering from chronic subdural

Period January–December 2018

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

hematomas, a collection of blood on the brain's surface.

Global partnership with Healthlink

IRRAS entered into a partnership with HealthLink Europe & International to serve as IRRAS' global logistics and customer service partner. Through this partnership, the companies will provide IRRAS' worldwide customer base with rapid access to the company's full range of products.

Update on re-certification of catheter CE mark

The delay of the re-certification of the catheter's CE-mark has been frustrating. The company initially submitted an application for re-certification of all three components of the systems in the spring of 2018. The CE Marks for the control unit and the tube set were rapidly received. However, in early summer the notified body informed that the remaining third component of the system, the innovative dual lumen catheter, was deemed to be a Class III product and required more time. In the fall we were informed that the process had been initiated and the timeline for completion would be at the end of the year. IRRAS has now an ongoing and good dialogue with the notified body regarding the recertification. IRRAS has provided them with all requested documents. As previously communicated, the delay is not due to lack of product quality or documentation, but rather caused by high work load at the certification body.

Key figures	Oct–Dec 2018	Oct–Dec 2017	Jan–Dec 2018	Jan–Dec 2017
Net revenue, SEK million	—	0.7	6.0	12.0
Gross margin, %	Neg	Neg	Neg	53%
Operating loss (EBIT), SEK million	-50.1	-23.7	-143.3	-61.5
EBIT margin, %	Neg	Neg	Neg	Neg
Loss after tax	-50.1	-23.2	-138.8	-60.9
EBITDA, SEK million	-47.9	-21.8	-135.2	-57.8
EBITDA margin, %	Neg	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg	Neg

Comments from the President and CEO

At IRRAS, we are building strong foundations for growth. Specifically, during the fourth quarter of 2018, we initiated the launch of our products in the United States, our most important market. Multiple hospitals in the US are being trained, and patients have been treated successfully.

To ensure a successful US launch, we have significantly enhanced our sales and commercial teams in the US with highly qualified individuals who have a demonstrated track record of success in introducing disruptive medical devices to the market. Our sales team is executing on our strategy of “going deep before we go wide”. We try to partner with appropriate physicians and facilities to get clinical results. This methodical approach helps to build the needed foundation for our long-term business by targeting interested physicians and educating health care providers on the advantages of our product compared with competitive alternatives.

We currently have gained shown interests from physicians at more than a dozen hospitals all around US and are now navigating their respective evaluation and approval processes. In the US, it is common that this process can be 3 to 6 months long before revenue is generated. With an enthusiastic initial response from physicians, due to shorter treatment time, we have seen a strong commitment to reduce the required approval time.

While launching in the US, we have also continued our efforts on other global markets during the fourth quarter. The catheter CE mark recertification has not yet been received due to our notified body's backlog. We have a good ongoing dialogue with the notifying body, LNE/G-MED and expect to receive the long-awaited CE-mark in the near future. As we previously communicated, the delay is not due to lack of product quality or documentation, but rather caused by high work load at the certification body. Sales in the EU will resume shortly after the approval.

Fourth quarter financial overview

Due to the delay in the recertification of the CE mark in the EU and pending sales in the US, no sales were reported during the fourth quarter of 2018. We expect revenue in the US will be recorded in the first quarter 2019 and in Europe during the second quarter 2019.

EBIT for the fourth quarter of the year was SEK -50.1 million (-23.7). The increased costs are primarily attributable to the planned ongoing organizational expansion. The average number of employees in the fourth quarter of 2018 was 27, compared with 11 in the year-earlier period. In addition, operating expenses in this period include one-time extra costs of SEK 13 million due to expired inventory, mainly due to the delayed CE mark.

The cash-flow during the quarter was SEK -32 million, and our available liquidity as of December 31, 2018 amounted to SEK 158 million, including short- and long-term financial investments.

Building for future growth at IRRAS

At IRRAS, our mission is clear: to change the lives of millions by creating medical products that transform the current treatment of intracranial bleedings. We believe that IRRASflow will ultimately become the new standard of care in this field, and, during the fourth quarter, we continued to make progress toward accomplishing this mission.

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



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

Group development January–December 2018

Net revenue

Net revenue for 2018 amounted to SEK 6.0 million (12.0). Net revenue for the fourth quarter of 2018 totaled SEK 0.0 million (0.7).

Due to the lack of a CE mark for the catheter and no initiated sales in the US, no sales were reported after the first quarter.

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. The department has recognized over-head costs despite lack of sales, and they have not been capitalized. The amortization on capitalized development expenses amounted to SEK 7.7 million for 2018.

The gross income for 2018 amounted to SEK -14.0 million (6.3). The gross income for the fourth quarter of 2018 totaled SEK -6.9 million (-1.4).

Operating expenses

Operating expenses for 2018 totaled SEK 129.8 million (68.4). The higher operating expenses are primarily attributable to increased marketing and sales expenses, increased administrative expenses resulting from preparation to move to Nasdaq's main list and increased development expenses.

The market and sales expenses have increased during the period mainly due to increased cost for preparation for the US launch.

Operating expenses during the period include also one-time cost of SEK 22 million. SEK 13 million of the one-time cost mainly refers to costs during 2018 for the delayed CE-mark of the catheter, additional cost in the German subsidiary and remaining costs for the two product recalls in 2017. SEK 9 million includes inventory write downs, primarily due to expiration date in some products due to the delayed CE-mark.

Total research and development expenses in the period amounted to SEK 37.2 million (23.4), of which SEK 14.3 million (10.8) was capitalized and SEK 22.9 million (12.6) was recognized as expense. The expensed R&D expenses include mainly personnel expenses for the employees at these departments. They are working with improvements of already registered products and the improvements are not extending the life-time of the products. Research projects are also expensed. Capitalized development expenses include cost for development projects for not yet launched products.

The net of other operating income and operating expenses in 2018 amounted to SEK 0.5 million (0.6).

Operating loss (EBIT)

Operating loss (EBIT) totaled SEK -143.3 million (-61.5) for 2018 and SEK -50.1 million (-23.7) for the fourth quarter.

Net financial income

Net financial income totaled SEK 4.5 million (0.6).

Earnings

Loss before tax amounted to SEK -138.8 million (-60.9). Net loss for the period (loss after tax) totaled SEK -138.8 million (-60.9).

Cash flow and liquidity

Cash flow from operating activities from January to December 2018, after the change in working capital, totaled SEK -97.4 million (-53.7).

The reduced cash flow is primarily attributable to weaker earnings as a result of decreased sales and increased operating expenses.

At the end of the period, available liquidity amounted to SEK 158.1 million (244.2), including short and long-term financial investments of SEK 110.8 million (146.0).

Investments

Net investments totaled SEK 14.8 million (11.0), including capitalized development expenses of SEK 14.3 million (10.8).

Assets

As of December 31, 2018, intangible assets totaled SEK 40.3 million (34.0). 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 14 years. Amortization is recognized under cost of sales.

Equity and liabilities

As of December 31, 2018, the Group's equity amounted to SEK 184.2 million (316.0) and the equity ratio was 89.7% (96.0).

As of December 31, 2018, interest-bearing liabilities totaled SEK 0.0 million (0.0). Current not interest-bearing liabilities totaled SEK 20.8 million (13.2).

Changes in the parent company

The expenses in the parent company increased year-on-year, primarily as a result of the organizational build-up and to adapt the company to Nasdaq's requirements for main list companies. During the year the Group has developed a Transfer Pricing policy and performed a profit/loss split to reallocate expenses in accordance with the new policy. Due to the profit/loss split the parent company shows a profit during the fourth quarter.

Sales per region	Oct–Dec 2018	Oct–Dec 2017	Jan–Dec 2018	Jan–Dec 2017
SEK million				
Germany	—	0.7	3.3	11.7
Europe, excluding Germany	—	—	2.7	0.3
Other regions	—	—	—	—
Total	—	0.7	6.0	12.0

The market

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

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.

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 lose its ability to develop products, that it will not be possible to launch the products on schedule or that market acceptance will be lower 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.

The company's liquidity per February 14, 2019 is not sufficient to cover the planned operations in the next 12 months. In light of this, work is underway on possible financing 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 2017 Annual Report.

Related-party transactions

Refer to note 3 on page 14 for a description of transactions with related parties.

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 from Group companies primarily comprise receivables from the US subsidiary IRRAS USA, Inc. and 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.

Number of shares

The number of shares and votes in IRRAS AB at the end of December 2018 totaled 24,017,974. The number of shares increased by 356,111 during the second and third quarter of 2018. The new issued shares are coming from two of the company's 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 14).

Shareholders as of December 31, 2018 (and known changes thereafter)	Number of shares	Percent of shares/ votes
Lexington Holding Assets Ltd (BVI)	3,155,727	13.14%
F.EX Endotherapy Limited	2,934,651	12.22%
Bacara Holdings Limited	1,430,725	5.96%
Dr Kleanthis G. Xanthopoulos	842,878	3.51%
Nomura PB Nominees Ltd	727,338	3.03%
Systematic Growth AB	678,234	2.82%
Dr Saeid AB	678,233	2.82%
Serendipity Ixora AB	678,077	2.82%
The Fourth Swedish National Pension Fund	595,000	2.48%
Avanza Pension (shares held in trust)	553,620	2.31%
Nyenburgh Holding B.V.	539,515	2.25%
Nordnet Pensionsförsäkringar	474,721	1.98%
JP Morgan Bank Luxembourg S.A.	428,742	1.79%
UBS Switzerland	424,910	1.77%
Inversis	385,937	1.61%
Prioritet Capital AB	381,000	1.59%
BNP Paribas	302,337	1.26%
Other shareholders	8,806,329	35.18%
Total number of shares	24,017,974	100.00%

The IRRAS share is listed at Nasdaq First North Premier. The board of Directors proposes no dividend.

Employees

The average number of employees in the Group from January to December 2018 was 21 (8), of which 3 (1) in the parent company. The breakdown of average number of employees by country was 3 (1) in Sweden, 13 (4) in the US and 5 (3) in Germany. The average number of women in the Group was 8 (3) and the average number of men was 13 (5). At the end of 2018 IRRAS had 29 employees.

The Board of Directors and the CEO certify that this Year-End 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 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

Saeid Esmaeilzadeh, Ph.D.
Board member

Eva Nilsagård
Board member

Auditors' review
This report was not reviewed by the company's auditors.

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

SEK million	Oct–Dec 2018	Oct–Dec 2017	Jan–Dec 2018	Jan–Dec 2017
Net revenue	—	0.7	6.0	12.0
Cost of sales	-6.9	-2.0	-20.0	-5.7
Gross profit/loss	-6.9	-1.4	-14.0	6.3
<i>Gross margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	53%
Other operating income	-0.7	0.2	1.7	0.6
Marketing and sales expenses	-25.6	-13.1	-62.3	-23.7
Administrative expenses	-10.7	-3.1	-44.5	-32.1
Research and development expenses	-6.5	-6.3	-22.9	-12.6
Other operating expenses	-0.2	—	-1.2	—
Operating loss (EBIT)	-50.1	-23.7	-143.3	-61.5
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	0.1	0.5	4.5	0.6
Loss before tax	-50.1	-23.2	-138.8	-60.9
Tax	—	—	—	—
Net loss for the period	-50.1	-23.2	-138.8	-60.9
Other comprehensive income				
Items that may be subsequently reclassified to profit or loss				
Translation differences for the period on translation of foreign subsidiaries	-0.9	-0.5	-1.1	-1.2
Total other comprehensive income	-0.9	-0.5	-1.1	-1.2
Total comprehensive income for the period	-51.0	-23.7	-140.0	-62.1
Earnings per share before dilution, SEK	-2.09	-1,09	-5.83	-3.40
Earnings per share after dilution, SEK	-2.09	-1,09	-5.83	-3.40
Number of shares before dilution, average	24,017,974	21,337,637	23,815,328	17,906,003
Number of shares after dilution, average	24,017,974	21,337,637	23,815,328	17,906,003

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, 2018	Dec 31, 2017
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development expenses	38.1	31.5
Licenses/patents	2.2	2.5
Total intangible assets	40.3	34.0
Tangible assets		
Property, plant and equipment	0.6	0.2
Total tangible assets	0.6	0.2
Financial assets		
Financial investments, bonds	80.8	85.8
Total financial assets	80.8	85.8
Total non-current assets	121.7	120.1
Current assets		
Inventory	3.4	12.5
Financial investments, bonds	30.1	60.1
Accounts receivable	—	—
Current tax receivables	—	0.9
Other receivables	1.9	37.2
Prepaid expenses and accrued income	1.0	0.2
Cash and cash equivalents	47.2	98.3
Total current assets	83.6	209.2
TOTAL ASSETS	205.3	329.3

Consolidated statement of financial position in summary (cont.)

SEK million	Dec 31, 2018	Dec 31, 2017
EQUITY		
Share capital	0.7	0.7
Other paid-in capital	440.2	439.6
Translation reserve	-1.9	-0.8
Retained earnings, including net loss for the period	-254.8	-123.5
Total equity	184.2	316.0
LIABILITIES		
Provisions		
Other provisions	0.4	—
Total provisions	0.4	—
Current liabilities		
Accounts payable	8.6	2.3
Other liabilities	2.5	1.4
Accrued expenses and deferred income	9.6	9.6
Total current liabilities	20.8	13.2
Total liabilities and provisions	21.2	13.2
TOTAL EQUITY AND LIABILITIES	205.3	329.3

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, 2017	0.1	176.2	0.4	-81.6	95.1
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-60.9	-60.9
Other comprehensive income for the period	—	—	-1.2	—	-1.2
Comprehensive income for the period	—	—	-1.2	-60.9	-62.1
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	19.4	19.4
Bonus issue	0.4	—	—	-0.4	—
New share issue <i>(of which subscribed but not paid in)</i>	0.2	293.0 <i>(30.7)</i>	—	—	293.2
New share issue expenses	—	-29.6	—	—	-29.6
Closing equity December 31, 2017	0.7	439.6	-0.8	-123.5	316.0
Opening equity January 1, 2018	0.7	439.6	-0.8	-123.5	316.0
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-138.8	-138.8
Other comprehensive income for the period	—	—	-1.1	—	-1.1
Comprehensive income for the period	—	—	-1.1	-138.8	-139.9
<i>Transactions with shareholders</i>					
Incentive programs	0.0	—	—	7.5	7.5
New share issue expenses	—	0.6 ¹	—	—	0.6
Closing equity December 31, 2018	0.7	440.2	-1.9	-254.8	184.2

¹ Reversal of provision for new share issue expenses.

Condensed consolidated statement of cash flows in summary

SEK million	Jan–Dec 2018	Jan–Dec 2017
Operating activities		
Operating loss (EBIT)	-143.3	-61.5
Adjustment for non-cash items		
- Depreciation/amortization	8.1	3.7
- Incentive programs	7.4	18.8
- Other non-cash items	0.4	—
Interest received	0.6	—
Interest paid	-0.2	—
Income tax paid	0.9	—
Cash flow from operating activities before changes in working capital	-126.0	-39.0
Cash flow from changes in working capital		
Increase (-)/decrease (+) in inventory	9.6	-12.4
Increase (-)/decrease (+) in operating receivables	8.9	-7.4
Increase (+)/decrease (-) in operating payables	6.7	5.0
Increase (+)/decrease (-) of other current liabilities	3.4	—
Cash flow from operating activities	-97.4	-53.7
Cash flow from investing activities		
Investment in intangible assets	-14.3	-10.8
Investments in tangible assets	-0.5	-0.2
Investment in financial assets	—	-145.9
Sale of financial assets	35.1	—
Cash flow from investing activities	20.3	-157.0
Cash flow from financing activities		
New share issue	30.7 ¹	262.4
New share issue expenses	-5.6 ¹	-24.0
Warrants	—	0.6
Cash flow from financing activities	25.2	239.0
Cash flow for the period	-52.0	28.3
Cash and cash equivalents at the beginning of the period	98.3	70.8
Exchange rate difference in cash and cash equivalents	0.9	-0.8
Cash and cash equivalents at the end of the period	47.2	98.3

1 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	Oct–Dec 2018	Oct–Dec 2017	Jan–Dec 2018	Jan–Dec 2017
Net revenue	—	—	—	4.0
Cost of sales	-2.4	—	-8.0	-3.3
Gross profit/loss	-2.4	—	-8.0	0.6
Other operating income	13.1	—	13.9	0.4
Marketing and sales expenses	-0.3	-1.0	-4.1	-4.0
Administrative expenses	-8.5	-9.2	-35.7	-32.6
Research and development expenses	2.5	-4.1	-8.3	-9.8
Other operating expenses	-0.1	—	-1.0	—
Operating loss (EBIT)	4.3	-11.9	-43.0	-45.3
Net financial income	0.2	—	3.5	0.1
Loss after net financial income	4.5	-11.9	-39.6	-45.2
Group contribution	—	—	—	—
Loss before tax	4.5	-11.9	-39.6	-45.2
Tax	—	—	—	—
Net loss for the period	4.5	-11.9	-39.6	-45.2

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	Dec 31, 2018	Dec 31, 2017
ASSETS		
Capital subscribed but not paid in	—	30.7
Non-current assets		
Intangible assets	40.3	34.0
Tangible assets	0.4	0.2
Financial assets		
Shares in Group companies	68.7	24.6
Receivables from Group companies	29.6	14.6
Financial investments, bonds	80.0	85.8
Total financial assets	179.1	125.0
Total non-current assets	219.8	159.2
Current assets		
Inventory	—	0.3
Receivables from Group companies	26.3	11.8
Financial investments, bonds	30.1	60.1
Other receivables	1.2	1.6
Prepaid expenses and accrued income	0.5	0.3
Cash and bank balances	37.3	85.8
Total current assets	95.4	159.8
TOTAL ASSETS	315.3	349.9
EQUITY AND LIABILITIES		
EQUITY		
Share capital	0.7	0.7
Fund for capitalized expenditure	31.8	23.4
Capital surplus	406.6	406.0
Retained earnings	-92.1	-46.1
Loss for the year	-39.6	-45.2
Total equity	307.4	338.9
Provisions	0.4	—
Accounts payable	1.7	2.0
Other current liabilities	0.1	0.2
Accrued expenses and deferred income	5.7	8.8
Total liabilities and provisions	7.9	11.0
TOTAL EQUITY AND LIABILITIES	315.3	349.9

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, 2018. During 2018, the company has begun to apply IFRS 9 Financial Instruments and IFRS 15 Revenue from Contracts with Customers.

Effect of the transition to IFRS 9 and IFRS 15

IFRS 9 Financial Instruments

IFRS 9 Financial Instruments addresses classification, measurement and recognition of financial assets and liabilities.

The Group has applied IFRS 9 since January 1, 2018. The carrying amount of the Group's financial assets following the transition to IFRS 9 has been determined to be unaffected by the new categories in IFRS 9. IFRS 9 also introduces a new model for calculation of a credit loss reserve, which is based on expected credit losses.

Comparative information has not been restated for IFRS 9. Amended policies for amortization of loans and accounts receivable affect the recognized earnings and financial position. The Group applies the simplified method for recognition of expected credit losses with respect to accounts receivable. This means that expected credit losses for outstanding terms are taken into consideration. The general method for expected credit losses is applied for certain financial receivables and cash and cash equivalents. These receivables generally have a short tenor.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 Revenue from Contracts with Customers regulates revenue recognition. The principles on which IFRS 15 is based are intended to give users of financial statements more useful information about the company's revenue. The increased transparency obligation means that information about revenue, the time of settlement,

uncertainties related to revenue recognition and cash flow attributable to the company's customer contracts must be submitted. In accordance with IFRS 15, revenue must be recognized when the customer receives control of the goods or services sold and has the possibility of using and gaining benefits from the goods or services.

The Group has applied IFRS 15 since January 1, 2018. For revenue recognition, IRRAS AB recognized primary geographic markets and time. IRRAS AB has concluded that this can also be used to attain the goal of a breakdown in accordance with the disclosure requirements in IFRS 15. Revenue in 2017 and 2018 have been booked when the product has been transferred to the customer, why no effects has emerged after change of principle.

New and amended standards that have not yet entered force

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 standard is considered to have an immaterial effect on the consolidated financial statements since the Group's leases are currently few in number and consist mainly of rent for premises. Current leases are shorter than 12 months and/or add up to insignificant amounts.

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 IRRASflow product area, which is why only one segment has been reported, which is reflected in its entirety in the consolidated financial statements. The Group's strategic control group and highest executive decision makers, consisting of the Board of directors and the CEO, evaluate the Group's activities from a product and geographical perspective, as of today Germany, the rest of Europe, USA and the rest of the world. See table on page 3.

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 1.7 million (4.1) during the fourth quarter of 2018 and SEK 7.4 million (18.8) for the period from January to December 2018.

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.

No changes to the number of options took place in the fourth quarter of 2018. A total of 1,880,000 options were outstanding as of December 31, 2018. The CEO has 1,275,000 options and two members of the executive management group have 20,000 and 96,429 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.

No changes to the number of options took place in the fourth quarter of 2018. A total of 643,000 options were outstanding as of December 31, 2018. Three members of the executive management group have 35,000, 145,000 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 fourth quarter of 2018. A total of 320,000 warrants were outstanding as of December 31, 2018. One member of the executive management group has 200,000 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 fourth quarter of 2018. A total of 100,000 warrants were outstanding as of December 31, 2018. The Chairman of the Board has 100,000 warrants.

Incentive program No. 5

The total program comprises 732,000 personnel options. 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 fourth quarter of 2018, 202,000 options were distributed. A total of 268,750 options were outstanding as of December 31, 2018. None of the executive management group has options in the program.

Note 3 Related-party transactions

“Related parties” are defined as management, Board members in the parent company and the Group, subsidiaries and major shareholders in the parent company. 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 year.

SEK million	Jan–Dec 2018	Jan–Dec 2017	Explanation
Anders P. Wiklund, Chairman	0.1	0.2	Billed consulting services
Kleanthis G. Xanthopoulos, President and CEO, Board member	1.7	6.8	Billed consulting services
Christos Panotopoulos, Owner and former member of company management	1.0	1.7	Billed consulting services
Juno Ekonomi AB, indirectly owned by Serendipity Group	—	0.3	Accounting services

The Group has leased offices from a person related to President and CEO Kleanthis G. Xanthopoulos during the period. The expenses for the period from January to December 2018 totaled SEK 104 thousand (115). The Group has also purchased office equipment from a person related to President and CEO Kleanthis G. Xanthopoulos. The expense totaled SEK 179 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.

Christos Panotopoulos, the company's second-largest owner and Chief Scientific Officer until May 31, 2018, offers IRRAS consulting services with respect to his medical expertise via his company F.EX.Endotherapy Ltd. The agreement also entitles Christos Panotopoulos to invoice IRRAS for other costs such as travel expenses.

Chairman Anders P. Wiklund had a consulting agreement with IRRAS until August 22, 2017 which entitled him to remuneration for the work he performed for the company. He was also entitled to invoice IRRAS for other costs such as travel expenses. In 2018, he invoiced the company for certain consulting services above and beyond his work on the Board

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.

	Oct–Dec 2018	Oct–Dec 2017	Jan–Dec 2018	Jan–Dec 2017
Gross margin (Gross profit or loss/Net revenue)				
Gross profit/loss, SEK million	-6.9	-1.4	-14.0	6.3
Net revenue, SEK million	-	0.7	6.0	12.0
Gross margin, %	Neg	Neg	Neg	53%
EBIT margin (Operating loss (EBIT)/Net revenue)				
Operating loss (EBIT), SEK million	-50.1	-23.7	-143.3	-61.5
Net revenue, SEK million	-	0.7	6.0	12.0
EBIT margin, %	Neg	Neg	Neg	Neg
EBITDA margin (EBITDA/Net revenue)				
Operating loss (EBIT), SEK million	-50.1	-23.7	-143.3	-61.5
Depreciation/amortization, SEK million	-2.2	-1.8	-8.1	-3.7
Net revenue, SEK million	-	0.7	6.0	12.0
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	-50.1	-23.2	-138.8	-60.9
Average equity, SEK million	208.8	193.7	250.1	205.6
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 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 publicly traded, commercial-stage medical technology company focused on developing and commercializing innovative solutions for brain surgery. The company's initial product, IRRAS*flow*™, addresses the complications associated with the current treatment methods of intracranial bleeding with a dual lumen catheter that combines active irrigation with ongoing fluid drainage. Regularly during treatment, the IRRAS*flow* catheter is automatically flushed to prevent common catheter occlusions from forming. Because IRRAS*flow* is a completely closed system, it is designed to reduce the documented infection risk of these procedures.

With its unique product portfolio protected by patents and patent applications, IRRAS is well positioned to establish itself as a leader in the medical device market. IRRAS maintains its headquarters in Stockholm, Sweden, with corporate offices in Munich, Germany, and San Diego, California, USA. For more information, please visit www.irras.com. The IRRAS share is listed at Nasdaq First North Premier. Wildecos is the company's Certified Adviser.

Financial information



Kleanthis G. Xanthopoulos, Ph.D.,
President and CEO
kleanthis.xantopoulos@irras.com



Fredrik Alpsten
CFO and Deputy CEO
+46 706 67 31 06
fredrik.alpsten@irras.com

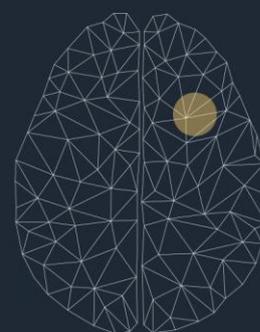
Calendar

Q1 2019 Interim Report	May 7, 2019
Q2 2019 Interim Report	August 29, 2019
Q3 2019 Interim Report	November 8, 2019
Annual Shareholders' meeting	May 14, 2019
Annual report	April 23, 2019

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 14, 2019 at 8:00 a.m. (CET).

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