

Preparation for US launch of IRRAflow[®] ongoing, CE mark catheter re-certification now expected at YE 2018

Third quarter, July–September 2018

- Net revenue totaled SEK 0.0 million (11.3).
- Operating loss (EBIT) amounted to SEK -40.0 million (-7.2).
- Loss after tax totaled SEK -41.8 million (-7.3).
- Earnings per share before and after dilution amounted to SEK -1.75 (-0.42).

Important events during the third quarter

FDA clearance of IRRAflow

IRRAS received 510(k) clearance from the US Food and Drug Administration (FDA) for the company's IRRAflow system and consumable products. The FDA decision means that the company now has the right to market and sell IRRAflow in the US. Preparations for US launch are ongoing and include contacts with key neurosurgery centers in the US and numerous marketing activities that are planned through the end of the year.

Preparation launch in the US

IRRAS has started the sales preparations in the US and recruited four regional managers with significant experience bringing medical devices to large markets.

Full year to date January–September 2018

- Net revenue totaled SEK 6.0 million (11.3).
- Operating loss (EBIT) amounted to SEK -93.2 million (-37.8).
- Loss after tax totaled SEK -88.8 million (-37.7).
- Earnings per share before and after dilution amounted to SEK -3.74 (-2.19).

Important events after the end of the third quarter

New Board member

At an extraordinary general meeting on October 1, Eva Nilsagård was elected as a new Board member. Eva Nilsagård has a long and broad experience in finance and business development of listed companies.

Update on re-certification of catheter CE mark

LNE/G-MED, the company's certification body expects that the re-certification process of the IRRAflow catheter to be completed by the end of the year.

Expanded management team

As of October 19, IRRAS's executive management group consists of Kleanthis Xanthopoulos, Fredrik Alpsten, Will Martin, Lance Bolling and Kellie Fontes. The expanded management group also includes Adam Sampson, Dino De Cicco, Dessi Lyakov and Sabina Berlin.

Key figures	Jul–Sep 2018	Jul–Sep 2017	Jan–Sep 2018	Jan–Sep 2017	Jan–Dec 2017
Net revenue, SEK million	—	11.3	6.0	11.3	12.0
Gross margin, %	Neg	68%	Neg	68%	53%
Operating loss (EBIT), SEK million	-40.0	-7.2	-93.2	-37.8	-61.5
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
EBITDA, SEK million	-37.9	-5.4	-87.3	-35.9	-57.8
EBITDA margin, %	Neg	Neg	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg	Neg	Neg

Comments from the President and CEO

During the third quarter of 2018, IRRAS obtained its most significant milestone as a company to date – we were pleased to receive the FDA clearance for our innovative IRR*Aflow* device, which we believe will become the new standard for safe, efficient, and controlled drainage of intracranial fluids. The United States is our most important market and we are hopeful to begin recording sales revenues in the US at year-end 2018.

To ensure we have a successful launch in the US, we have, during the third quarter, significantly enhanced our sales and commercial teams in the US with highly qualified individuals who have advanced numerous medical devices to large markets.

At the beginning of October, we participated, for the first time with an approved product, at the Congress of Neurological Surgeons (CNS) in Houston, Texas. The initial feedback on our product from physicians in the US has been very positive and we look forward to working within these networks to grow recognition and future use of IRR*Aflow*.

While preparing for launch in the US, we also focused substantial efforts on the EU market during the third quarter. The catheter CE mark re-certification has been delayed due to notified body's backlog and we now expect to receive the certificate by the end of the year and anticipate that sales can be resumed in EU in the beginning of 2019.

Third quarter financial overview

Due to the delay in the re-certification of the CE mark in the EU and pending launch in the US, no sales were reported during the third quarter of 2018.

EBIT for the third quarter of the year was SEK -40.0 million (-7.2). The increased costs are primarily attributable to the planned organizational expansion. The average number of employees in the third quarter of 2018 was 21, compared with 8 in the year-earlier period. The preparations for a launch in the US later this year also contributed to the increased costs. In addition, operating expenses in this period include one-time extra costs of SEK 11 million. The one-time costs mainly refer to extra costs in 2018 due to the

delayed CE-mark of the catheter and remaining costs for the two product recalls in 2017.

Our available liquidity as of September 30, 2018 is SEK 190 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 IRR*Aflow* will ultimately become the new standard of care in this field and we continue to make progress toward accomplishing this mission.

With the recent FDA clearance in the US and the anticipated re-certification of the CE mark in the EU, as well as registration of our product in additional countries, we believe the future of IRRAS is bright.



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

Group development, full year to date, January–September 2018

Net revenue

Net revenue for the period from January to September 2018 amounted to SEK 6.0 million (11.3). Net revenue for the third quarter of 2018 totaled SEK 0.0 million (11.3).

Due to the lack of a CE mark for the catheter no sales were reported during the second and third 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 5.6 million for the period January-September 2018.

The gross income for the period from January to September 2018 amounted to SEK -7.1 million (7.7). The gross income for the third quarter of 2018 totaled SEK -4.8 million (7.7).

Operating expenses

Operating expenses for the period from January to September 2018 totaled SEK 87.1 million (49.1). The higher operating expenses are primarily attributable to increased marketing and sales expenses, increased administrative expenses resulting from expanded requirements as a listed company 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. The market and sales expenses during the third quarter 2018 include also one-time cost of SEK 11 million. The one-time cost mainly refers to extra 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.

Total research and development expenses in the period amounted to SEK 23.7 million (16.4), of which SEK 7.2 million (10.1) was capitalized and SEK 16.4 million (6.3) was recognized as expense. The expensed R&D expenses include mainly personnel expenses for the employees at the R&D-department and at the quality and regulatory department. 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 the period amounted to SEK 1.0 million (0.5).

Operating loss (EBIT)

Operating loss (EBIT) totaled SEK -93.2 million (-37.8) for the period from January to September 2018 and SEK -40.0 million (-7.2) for the third quarter.

Net financial income

Net financial income totaled SEK 4.4 million (0.1).

Earnings

Loss before tax amounted to SEK -88.8 million (-37.7). Net loss for the period (loss after tax) totaled SEK -88.8 million (-37.7).

Cash flow and liquidity

Cash flow from operating activities from January to September 2018, after the change in working capital, totaled SEK -72.7 million (-31.3).

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 189.9 million (28.5), including short and long-term financial investments of SEK 110.9 million (0).

Investments

Net investments totaled SEK 7.5 million (10.3), including capitalized development expenses of SEK 7.2 million (10.1).

Assets

As of September 30, 2018, intangible assets totaled SEK 35.4 million (35.1). 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 14 years. Amortization is recognized under cost of sales.

Equity and liabilities

As of September 30, 2018, the Group's equity amounted to SEK 233.4 million (71.4) and the equity ratio was 94.7% (90.6).

As of September 30, 2018, interest-bearing liabilities totaled SEK 0.0 million (0.0). Current not interest-bearing liabilities totaled SEK 12.8 million (7.4).

Changes in the parent company

Losses 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 listed companies.

Sales per region SEK million	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Germany	—	11.0	3.3	11.0	11.7
Europe, excluding Germany	—	0.3	2.7	0.3	0.3
Other regions	—	—	—	—	—
Total	—	11.3	6.0	11.3	12.0

The market

IRRAS's first product, IRRASflow, 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 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 and a risk that the company may not be able to finance its operations. For a more detailed description of the company's risks, refer to the 2017 Annual Report. The risks are considered to be unchanged since the Annual Report was issued.

Related-party transactions

Refer to note 3 on page 13 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 September 2018 totaled 24,017,974. The number of shares increased by 356,111 toward the end of the second quarter and beginning of the 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 13).

Shareholders as of September 30, 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%
Serendipity Group AB	1,356,467	5.65%
Dr Kleanthis G. Xanthopoulos	842,878	3.51%
Serendipity Ixora AB	678,077	2.82%
Nyenburgh Holding B.V.	652,325	2.72%
The Fourth Swedish National Pension Fund	595,000	2.48%
Nomura PB Nominees Ltd.	564,000	2.35%
Avanza Pension (shares held in trust)	550,421	2.29%
ABN Amro Global Custody Services N.V.	538,428	2.24%
Nordnet Pensionsförsäkringar	481,607	2.01%
Other shareholders	10,237,668	42.63%
Total number of shares	24,017,974	100.00%

The IRRAS share is listed at Nasdaq First North Premier.

Employees

The average number of employees in the Group from January to September 2018 was 19 (6), of which 3 (0) in the parent company. The breakdown of average number of employees by country was 3 (0) in Sweden, 10 (1) in the US and 6 (5) in Germany. The average number of women in the Group was 8 (3) and the average number of men was 11 (3).

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 7, 2018
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 reviewed by the company's auditors.

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

SEK million	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Net revenue	—	11.3	6.0	11.3	12.0
Cost of sales	-4.8	-3.6	-13.1	-3.6	-5.7
Gross profit/loss	-4.8	7.7	-7.1	7.7	6.3
<i>Gross margin</i>	<i>Neg</i>	<i>68%</i>	<i>Neg</i>	<i>68%</i>	<i>53%</i>
Other operating income	1.3	0.4	2.4	0.5	0.6
Marketing and sales expenses	-16.8	-4.1	-36.8	-10.7	-23.7
Administrative expenses	-11.1	-11.9	-33.9	-29.0	-32.1
Research and development expenses	-8.0	0.6	-16.4	-6.3	-12.6
Other operating expenses	-0.7	0.1	-1.4	—	—
Operating loss (EBIT)	-40.0	-7.2	-93.2	-37.8	-61.5
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	-1.5	-0.2	4.4	0.1	0.6
Loss before tax	-41.5	-7.3	-88.8	-37.7	-60.9
Tax	-0.3	—	—	—	—
Net loss for the period	-41.8	-7.3	-88.8	-37.7	-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	-0.1	-0.2	-0.2	-0.7	-1.2
Total other comprehensive income	-0.1	-0.2	-0.2	-0.7	-1.2
Total comprehensive income for the period	-41.9	-7.5	-89.0	-38.4	-62.1
Earnings per share before dilution, SEK	-1.75	-0.42	-3.74	-2.19	-3.40
Earnings per share after dilution, SEK	-1.75	-0.42	-3.74	-2.19	-3.40
Number of shares before dilution, average	23,914,608	17,217,419	23,747,037	17,217,419	17,906,003
Number of shares after dilution, average	23,914,608	17,217,419	23,747,037	17,217,419	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	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenses	33.1	32.5	31.5
Licenses/patents	2.3	2.6	2.5
Total intangible assets	35.4	35.1	34.0
Tangible assets			
Property, plant and equipment	0.4	0.2	0.2
Total tangible assets	0.4	0.2	0.2
Financial assets			
Financial investments, bonds	85.9	—	85.8
Total financial assets	85.9	—	85.8
Total non-current assets	121.7	35.3	120.1
Current assets			
Inventory	12.9	5.1	12.5
Financial investments, bonds	25.0	—	60.1
Accounts receivable	0	5.5	—
Current tax receivables	—	—	0.9
Other receivables	7.5	4.2	37.2
Prepaid expenses and accrued income	0.5	0.2	0.2
Cash and cash equivalents	78.9	28.5	98.3
Total current assets	124.8	43.5	209.2
TOTAL ASSETS	246.6	78.8	329.3

Consolidated statement of financial position in summary (cont.)

SEK million	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
EQUITY			
Share capital	0.7	0.1	0.7
Other paid-in capital	440.2	176.2	439.6
Translation reserve	-1.0	-0.3	-0.8
Retained earnings, including net loss for the period	-206.5	-104.5	-123.5
Total equity	233.4	71.4	316.0
LIABILITIES			
Provisions			
Other provisions	0.3	—	—
Total provisions	0.3	—	—
Current liabilities			
Accounts payable	4.6	3.8	2.3
Other liabilities	0.5	0.2	1.4
Accrued expenses and deferred income	7.7	3.3	9.6
Total current liabilities	12.8	7.4	13.2
Total liabilities and provisions	13.2	7.4	13.2
TOTAL EQUITY AND LIABILITIES	246.6	78.8	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
Comprehensive income for the period					
Net loss for the period	—	—	—	-37.7	-37.7
Other comprehensive income for the period	—	—	-0.7	—	-0.7
Comprehensive income for the period	—	—	-0.7	-37.7	-38.4
Transactions with shareholders					
Incentive programs	—	—	—	14.7	14.7
Closing equity September 30, 2017	0.1	176.2	-0.3	-104.6	71.4
Comprehensive income for the period					
Net loss for the period	—	—	—	-23.2	-23.2
Other comprehensive income for the period	—	—	-0.5	—	-0.5
Comprehensive income for the period	—	—	-0.5	-23.2	-23.7
Transactions with shareholders					
Incentive programs	—	—	—	4.7	4.7
Bonus issue	0.4	—	—	-0.4	—
New share issue	0.2	293.0	—	—	293.2
<i>(of which subscribed but not paid in)</i>		<i>(30.7)</i>			
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
Comprehensive income for the period					
Net loss for the period	—	—	—	-88.8	-88.8
Other comprehensive income for the period	—	—	-0.2	—	-0.2
Comprehensive income for the period	—	—	-0.2	-88.8	-89.0
Transactions with shareholders					
Incentive programs	0.0	—	—	5.8	5.8
New share issue expenses	—	0.6 ¹	—	—	0.6
Closing equity September 30, 2018	0.7	440.2	-1.0	-206.5	233.4

¹ Reversal of provision for new share issue expenses.

Condensed consolidated statement of cash flows in summary

SEK million	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Operating activities			
Operating loss (EBIT)	-93.2	-37.8	-61.5
Adjustment for non-cash items			
- Depreciation/amortization	5.9	1.9	3.7
- Incentive programs	5.7	14.7	18.8
- Other non-cash items	0.3	—	—
Interest received	0.4	—	—
Interest paid	-0.1	—	—
Income tax paid	0.9	—	—
Cash flow from operating activities before changes in working capital	-80.0	-21.2	-39.0
Cash flow from changes in working capital			
Increase (-)/decrease (+) in inventory	0.1	-5.1	-12.4
Increase (-)/decrease (+) in operating receivables	4.3	-9.4	-7.4
Increase (+)/decrease (-) in operating payables	2.8	1.3	5.0
Increase (+)/decrease (-) of other current liabilities	0.1	3.0	—
Cash flow from operating activities	-72.7	-31.3	-53.7
Cash flow from investing activities			
Investment in intangible assets	-7.2	-10.1	-10.8
Investments in tangible assets	-0.3	-0.2	-0.2
Investment in financial assets	—	—	-145.9
Sale of financial assets	35.0	—	—
Cash flow from investing activities	27.5	-10.3	-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	-20.1	-41.6	28.3
Cash and cash equivalents at the beginning of the period	98.3	70.8	70.8
Exchange rate difference in cash and cash equivalents	0.7	-0.7	-0.8
Cash and cash equivalents at the end of the period	78.9	28.5	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	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Net revenue	—	—	—	—	4.0
Cost of sales	-2.0	-1.6	-5.6	-1.6	-3.3
Gross profit/loss	-2.0	-1.6	-5.6	-1.6	0.6
Other operating income	0.1	0.3	0.8	0.4	0.4
Marketing and sales expenses	-0.6	-1.0	-3.8	-3.0	-4.0
Administrative expenses	-8.5	-8.8	-27.2	-23.4	-32.6
Research and development expenses	-4.3	0.8	-10.8	-5.7	-9.8
Other operating expenses	-0.1	0.1	-0.9	—	—
Operating loss (EBIT)	-15.4	-10.2	-47.4	-33.4	-45.3
Net financial income	0.2	0.1	3.3	0.1	0.1
Loss after net financial income	-15.2	-10.2	-44.1	-33.3	-45.2
Group contribution	—	—	—	—	—
Loss before tax	-15.2	-10.2	-44.1	-33.3	-45.2
Tax	-0.3	—	—	—	—
Net loss for the period	-15.5	-10.2	-44.1	-33.3	-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	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
ASSETS			
Capital subscribed but not paid in	—	—	30.7
Non-current assets			
Intangible assets	35.4	35.1	34.0
Tangible assets	0.3	0.2	0.2
Financial assets			
Shares in Group companies	44.6	13.9	24.6
Receivables from Group companies	29.6	22.1	14.6
Financial investments, bonds	85.9	—	85.8
Total financial assets	160.1	36.0	125.0
Total non-current assets	195.9	71.3	159.2
Current assets			
Inventory	—	—	0.3
Receivables from Group companies	15.2	0.6	11.8
Financial investments, bonds	25.0	—	60.1
Other receivables	1.7	1.3	1.6
Prepaid expenses and accrued income	0.6	0.1	0.3
Cash and bank balances	71.0	15.3	85.8
Total current assets	113.5	17.3	159.8
TOTAL ASSETS	309.4	88.5	349.9
EQUITY AND LIABILITIES			
EQUITY			
Share capital	0.7	0.1	0.7
Fund for capitalized expenditure	26.4	23.9	23.4
Capital surplus	406.6	142.6	406.0
Retained earnings	-88.5	-50.9	-46.1
Loss for the year	-44.1	-33.3	-45.2
Total equity	301.2	82.5	338.9
Provisions	0.3	—	—
Accounts payable	3.0	3.1	2.0
Other current liabilities	0.1	—	0.2
Accrued expenses and deferred income	4.9	2.9	8.8
Total liabilities and provisions	8.2	6.1	11.0
TOTAL EQUITY AND LIABILITIES	309.4	88.5	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 interim financial 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 in the scope permitted by RFR 2. The same accounting policies have been applied as in the most recently issued Annual Report.

New or revised IFRS or other IFRIC interpretations which have taken effect since January 1, 2018 have not had any particular effect on the Group's financial statements. 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. Since sales are still limited, no effects of the application have emerged. 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.

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 little effect on the consolidated financial statements since the Group's leases are currently limited and consist solely of rent for premises. Current leases are shorter than 12 months and/or add up to insignificant amounts. For this reason, it was not considered necessary to quantify the effects.

The standard will be applicable starting in 2019 and was approved by the EU in 2017.

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. 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 1.2 million (5.7) during the third quarter of 2018 and SEK 5.8 million (14.7) for the period from January to September 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 third quarter of 2018. A total of 1,880,000 options were outstanding as of September 30, 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 third quarter of 2018. A total of 643,000 options were outstanding as of September 30, 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 third quarter of 2018. A total of 320,000 warrants were outstanding as of September 30, 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 third quarter of 2018. A total of 100,000 warrants were outstanding as of September 30, 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 second and third quarters of 2018, 66,750 options were distributed. A total of 665,250 options were outstanding as of September 30, 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–Sep 2018	Jan–Sep 2017	Explanation
Anders P. Wiklund, Chairman	0.1	0.2	Billed consulting services
Kleanthis G. Xanthopoulos, President and CEO, Board member	1.7	4.9	Billed consulting services
Christos Panotopoulos, Owner and former member of company management	0.9	1.2	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 September 2018 totaled SEK 77 thousand (86).

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.

	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Gross margin (Gross profit or loss/Net revenue)					
Gross profit/loss, SEK million	-4.8	7.7	-7.1	7.7	6.3
Net revenue, SEK million	-	11.3	6.0	11.3	12.0
Gross margin, %	Neg	68%	Neg	68%	53%
EBIT margin (Operating loss (EBIT)/Net revenue)					
Operating loss (EBIT), SEK million	-40.0	-7.2	-93.2	-37.8	-61.5
Net revenue, SEK million	-	11.3	6.0	11.3	12.0
EBIT margin, %	Neg	Neg	Neg	Neg	Neg
EBITDA margin (EBITDA/Net revenue)					
Operating loss (EBIT), SEK million	-40.0	-7.2	-93.2	-37.8	-61.5
Depreciation/amortization, SEK million	-2.1	-1.7	-5.9	-1.9	-3.7
Net revenue, SEK million	-	11.3	6.0	11.3	12.0
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	-41.8	-7.3	-88.8	-37.7	-60.9
Average equity, SEK million	253.7	73.3	274.7	83.3	208.8
Return on equity, %	Neg	Neg	Neg	Neg	Neg

Definitions:

Gross profit/loss: Net revenue less cost of sales

Gross margin: Gross profit/loss divided by net revenue

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

EBITDA margin: EBITDA divided by net revenue

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

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

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

This is IRRAS

IRRAS AB (Nasdaq 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.xanthopoulos@irras.com



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

Calendar

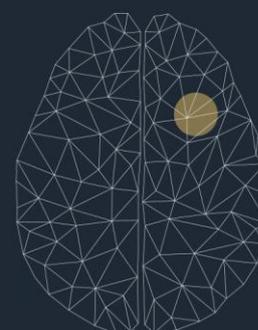
2018 Year-End Report
Q1 2019 Interim Report
Q2 2019 Interim Report
Q3 2019 Interim Report

February 14, 2019
May 15, 2019
August 29, 2019
November 8, 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 November 8, 2018 at 8:00 a.m. (CET).

IRRAS

WWW.IRRAS.COM





Review report

To the Board of Directors of IRRAS AB (publ)

Corp. id. 556872-7134

Introduction

We have reviewed the condensed interim financial information (interim report) of IRRAS AB (publ) as of 30 September 2018 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Stockholm 7 November 2018

KPMG AB

Duane Swanson

Authorized Public Accountant

