



Focus on US – first sales in US reported early April and acquisition of complementary products in May

First quarter, January - March 2019

- Net revenue totaled SEK 0.0 million (5.9).
- Operating loss (EBIT) amounted to SEK -39.1 million (-21.1).
- Loss after tax totaled SEK -38.7 million (-17.8).
- Earnings per share before and after dilution amounted to SEK -1.61 (-0.75).

Important events during the quarter

First patients in the US successfully treated with IRRAf^{low}®

At the beginning of January, the first patients in the United States were treated with our lead product, IRRAf^{low}. The successful treatments were performed at the University of California–Irvine.

New financial targets

In February the company presented new financial targets. The targets are:

- Revenue exceeding SEK 275 million in 2021
- Gross margin exceeding 72% in 2021
- Cash-flow positive by Q4 2021

Strengthened executive management team

In March, Vinny Podichetty, MD, MS, was hired as VP of Global Clinical Affairs. He is reporting to the President, CEO, and will serve as a member of the executive team.

Evaluates possible listing on Nasdaq Stockholm's main market

The company announced its plans to evaluate a possible listing of its share at the Nasdaq Stockholm's main market in 2019. In addition to Carnegie, IRRAS has also engaged Pareto as a financial advisor.

Important events after the end of the first quarter

Collaboration with AMI-USC

The company entered into an agreement with the Alfred E. Mann

Institute for Biomedical Engineering at the University of Southern California (AMI-USC). Under the terms of the agreement, IRRAS will acquire assets and intellectual property from DermaPort, Inc.

Update on CE-mark recertification

The company received a response from G-MED, its Notified Body, that requests clarifications and additional information regarding the CE Mark recertification of the company's IRRAf^{low} Catheter.

G-MED asked for additional technical clarifications and updates of certain previous older reports performed by the previous Swedish development partner. The requests are part of the routine review cycle and will be addressed by IRRAS in a timely manner.

First sales in US reported

Physician support for IRRAf^{low} has been generated at more than 35 US hospitals. The product approval process is underway at more than 20 hospitals, and almost 10 additional sites are actively evaluating the technology. The feedback thus far has been positive. The first US sales were reported first week of April.

Strengthened position in US by acquiring assets

IRRAS has strengthened its position in the US by acquiring assets of InnerSpace Neuro Solutions. The assets, including four FDA-cleared products, complement IRRAf^{low} and will support IRRAS' positioning as a leading company in the space. The sales of the new products are expected to start in Q3.

Key figures	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2018
Net revenue, SEK million	—	5.9	6.0
Gross margin, %	Neg	38%	Neg
Operating loss (EBIT), SEK million	-39.1	-21.1	-143.3
EBIT margin, %	Neg	Neg	Neg
Loss after tax	-38.7	-17.8	-138.8
EBITDA, SEK million	-36.5	-19.3	-135.2
EBITDA margin, %	Neg	Neg	Neg
Return on equity, %	Neg	Neg	Neg

Comments from the President and CEO

Launch in US

The launch in the US continues according to plan. The first patients were successfully treated in January, and the initial treated patients have been followed with great interest by a number of US hospitals. At the moment, we have support from physicians at more than 35 US hospitals, and our commercial team is taking the needed steps for these facilities to evaluate IRR*A*flow.

In April, AANS (American Association of Neurological Surgeons) held its yearly scientific meeting in San Diego. IRRAS participated and generated significant interest. Our direct sales team is now following up with these leads across the US. In connection with AANS, we had also our first US KOL meeting, which was very well received by the participants.

We believe that the sales process in the US for a new technology takes up to 6 months after initial contact with a new customer before revenue is generated. Our US launch commenced during Q4 2018, and our launch remains on track with the first purchase orders shipped to customers in early April.

Strengthened position in US by acquiring assets, including four FDA-cleared neurocritical care products

We have strengthened our position in US by acquiring the assets of InnerSpace Neuro Solutions. These assets include four FDA-cleared products that complement IRR*A*flow and will support IRRAS' positioning as a leading player in the space. We will initiate sales of the acquired products in Q3. The acquired patents and expertise overlap with planned IRR*A*flow product development and will result in an accelerated timeline and significantly reduced development costs. The acquired products have been used in over 2 000 patients, and their clinical utility is supported by a number of scientific publications.

This acquisition fits perfectly with our strategy to use our innovative fluid exchange technology as a cornerstone to become domain dominant in neurocritical care. We have been following InnerSpace for over a year and are very pleased to complete this transaction. By adding these products to our portfolio, we will use their existing sales channels to introduce IRR*A*flow to new customers, and our team can now offer US hospitals additional cutting edge products to treat neurocritical care patients. This is a unique opportunity for IRRAS to strengthen our position and become a leading supplier in US, the world's most important neurosurgical market.

Update received on CE Mark re-certification of IRR*A*flow

In April, we received the feedback from G-MED after a lengthy period. G-MED has asked for additional technical clarifications and updates of certain previous older reports. The requests are part of the routine review cycle, and we believe that all of their comments are addressable. Having established a productive dialogue with the notified body, we have a clear path forward, and we anticipate responding shortly to the list of questions. We will continue to work closely with the G-MED team to reintroduce this innovative medical device to the EU market, offering patients, neurosurgeons, and hospitals an effective, intelligent solution to treat intracranial bleeding.

First quarter financial overview

The first US sales were reported first week of April. Thus, 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 first quarter of 2019.

EBIT for the first quarter of the year was SEK -39.1 million (-21.1). The increased costs are primarily attributable to the planned organizational expansion within sales and marketing, production, R&D and administration. The average number of employees in the first quarter of 2019 was 32, compared with 17 in the year-earlier period.

Our available liquidity as of March 31, 2019 amounted to SEK 116 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*A*flow will ultimately become the new standard of care in this field, and, during the quarter, we continued to make progress toward accomplishing this mission.

With the 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.



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

Group development January–March 2019

Net revenue

Net revenue for the period January to March 2019 amounted to SEK 0.0 million (5.9).

As a result of the delay of the CE mark and no commercial sales yet in the US, no sales were reported in 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. During the first quarter the department has recognized overhead cost and no reported sales, hence these costs have not been capitalized for the period. The amortization of capitalized development expenses during the period January to March 2019 amounted to SEK 2.5 million (1.7).

The gross income for the first quarter amounted to SEK -6.1 million (2.3).

Operating expenses

Operating expenses for the period January to March totaled SEK 32.9 million (23.8). 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 implementing a new ERP system and increased development expenses.

The market and sales expenses have increased during the quarter mainly due to increased cost for preparation for the US launch. This has mainly been off-set from lower expenses in Germany.

Total research and development expenses in the period amounted to SEK 11.6 million (7.6), of which SEK 2.1 million (2.5) was capitalized and SEK 9.5 million (5.0) was recognized as expense. The expensed R&D expenses include mainly personnel expenses for the employees at these departments and consultant fees. Our team is working to improve already-registered products, and the improvements are not extending the lifetime of the products. Capitalized development expenses include cost for development projects for not yet launched products.

The net of other operating income and operating expenses in the first quarter amounted to SEK -0.1 million (0.4).

Operating loss (EBIT)

Operating loss (EBIT) totaled SEK -39.1 million (-21.1) for the period January to March 2019.

Net financial income

Net financial income totaled SEK 0.4 million (3.1).

Earnings

Loss before tax amounted to SEK -38.7 million (-18.0). Net loss for the period (loss after tax) totaled SEK -38.7 million (-17.8).

Cash flow and liquidity

Cash flow from operating activities from January to March 2019, after the change in working capital, totaled SEK -39.9 million (-21.6).

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

At the end of the period, available liquidity amounted to SEK 116.2 million (234.0), including short and long-term financial investments of SEK 85.8 million (59.6).

Investments

Net investments totaled SEK 2.3 million (2.8), including capitalized development expenses of SEK 2.1 million (2.5).

Assets

As of March 31, 2019, intangible assets totaled SEK 39.8 million (34.8). 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 of capitalized development expenses is recognized under cost of sales.

Equity and liabilities

As of March 31, 2019, the Group's equity amounted to SEK 147.2 million (299.3) and the equity ratio was 90.3% (97.2).

As of March 31, 2019, interest-bearing liabilities totaled SEK 0.0 million (0.0). Current not interest-bearing liabilities totaled SEK 15.2 million (8.5).

Changes in the parent company

The expenses in the parent company have not changed compared with previous year.

Sales per region SEK million	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2018
Germany	—	3.2	3.3
Europe, excluding Germany	—	2.7	2.7
Other regions	—	—	—
Total	—	5.9	6.0

The market

IRRAS's first product, IRRAS^{flow}, is initially intended for treatment of patients with hemorrhagic strokes and chronic subdural hematoma. Around 600,000 people in the US and Europe suffer from hemorrhagic strokes and chronic subdural hematoma annually. Approximately 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 May 7, 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 2018 Annual Report.

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 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.

Number of shares

The number of shares and votes in IRRAS AB at the end of March 2019 totaled 24,017,974. 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 March 31, 2019 (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	2,924,290	12.18%
Bacara Holdings Limited	1,430,725	5.96%
BNP Paribas	1,174,996	4.89%
Dr Kleanthis G. Xanthopoulos	842,878	3.51%
Dr Saeid AB	678,233	2.82%
The Fourth Swedish National Pension Fund	595,000	2.48%
Systematic Growth AB	523,860	2.18%
ABN Amro Global Custody Service	487,876	2.03%
Inversis	458,606	1.91%
UBS Switzerland	444,724	1.85%
Avanza Pension (shares held in trust)	442,575	1.84%
Nordnet Pensionsförsäkringar	431,297	1.80%
JP Morgan Bank Luxembourg S.A.	428,742	1.79%
Prioritet Capital AB	381,000	1.59%
Other shareholders	9,617,445	40.04%
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 March 2019 was 32 (17), of which 4 (3) in the parent company. The breakdown of average number of employees by country was 4 (3) in Sweden, 25 (8) in the US and 3 (6) in Germany. The average number of women in the Group was 11 (9) and the average number of men was 21 (8).

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, May 7, 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	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2018
Net revenue	—	5.9	6.0
Cost of sales	-6.1	-3.6	-20.0
Gross profit/loss	-6.1	2.3	-14.0
<i>Gross margin</i>	<i>Neg</i>	<i>38%</i>	<i>Neg</i>
Other operating income	0.6	0.7	1.7
Marketing and sales expenses	-11.3	-9.2	-62.3
Administrative expenses	-12.1	-9.6	-44.5
Research and development expenses	-9.5	-5.0	-22.9
Other operating expenses	-0.7	-0.3	-1.2
Operating loss (EBIT)	-39.1	-21.1	-143.3
<i>EBIT margin</i>	<i>Neg</i>	<i>Neg</i>	<i>Neg</i>
Net financial income/expenses	0.4	3.1	4.5
Loss before tax	-38.7	-18.0	-138.8
Tax	—	0.1	—
Net loss for the period	-38.7	-17.8	-138.8
Other comprehensive income			
Items that may be subsequently reclassified to profit or loss			
Translation differences for the period on translation of foreign subsidiaries	-0.3	-0.5	-1.1
Total other comprehensive income	-0.3	-0.5	-1.1
Total comprehensive income for the period	-39.0	-18.3	-140.0
Earnings per share before dilution, SEK	-1.61	-0.75	-5.83
Earnings per share after dilution, SEK	-1.61	-0.75	-5.83
Number of shares before dilution, average	24,017,974	23,661,863	23,815,328
Number of shares after dilution, average	24,017,974	23,661,863	23,815,328

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

Consolidated statement of financial position in summary

SEK million	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenses	37.7	32.3	38.1
Licenses/patents	2.1	2.5	2.2
Total intangible assets	39.8	34.8	40.3
Tangible assets			
Property, plant and equipment	0.8	0.5	0.6
Total tangible assets	0.8	0.5	0.6
Financial assets			
Financial investments, bonds	55.8	85.8	80.8
Total financial assets	55.8	85.8	80.8
Deferred tax assets	—	0.1	—
Total non-current assets	96.4	121.1	121.7
Current assets			
Inventory	3.8	15.4	3.4
Financial investments, bonds	30.1	60.1	30.1
Accounts receivable	—	7.2	—
Other receivables	1.4	13.9	1.9
Prepaid expenses and accrued income	1.0	2.0	1.0
Cash and cash equivalents	30.3	88.1	47.2
Total current assets	66.5	186.9	83.6
TOTAL ASSETS	162.9	308.0	205.3

Consolidated statement of financial position in summary (cont.)

SEK million	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
EQUITY			
Share capital	0.7	0.7	0.7
Other paid-in capital	440.2	439.6	440.2
Translation reserve	-2.2	-1.3	-1.9
Retained earnings, including net loss for the period	-291.5	-139.7	-254.8
Total equity	147.2	299.3	184.2
LIABILITIES			
Provisions			
Other provisions	0.5	0.1	0.4
Total provisions	0.5	0.1	0.4
Current liabilities			
Accounts payable	6.4	2.9	8.6
Other liabilities	1.6	0.4	2.5
Accrued expenses and deferred income	7.2	5.2	9.6
Total current liabilities	15.2	8.5	20.8
Total liabilities and provisions	15.7	8.6	21.2
TOTAL EQUITY AND LIABILITIES	162.9	308.0	205.3

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, 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	—	—	—	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
Opening equity January 1, 2019	0.7	440.2	-1.9	-254.8	184.2
<i>Comprehensive income for the period</i>					
Net loss for the period	—	—	—	-38.7	-38.7
Other comprehensive income for the period	—	—	-0.3	—	-0.3
Comprehensive income for the period	—	—	-0.3	-38.7	-39.0
<i>Transactions with shareholders</i>					
Incentive programs	—	—	—	2.0	2.0
Closing equity March 31, 2019	0.7	440.2	-2.2	-291.5	147.2

¹ Reversal of provision for new share issue expenses.

Condensed consolidated statement of cash flows in summary

SEK million	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2017
Operating activities			
Operating loss (EBIT)	-39.1	-21.1	-143.3
Adjustment for non-cash items			
- Depreciation/amortization	2.6	1.8	8.1
- Incentive programs	2.1	1.7	7.4
- Other non-cash items	0.1	0.1	0.4
Interest received	0.1	1.2	0.6
Interest paid	-0.1	-0.1	-0.2
Income tax paid	—	0.9	0.9
Cash flow from operating activities before changes in working capital	-34.3	-15.4	-126.0
Cash flow from changes in working capital			
Increase (-)/decrease (+) in inventory	1.1	-2.2	9.6
Increase (-)/decrease (+) in operating receivables	-0.1	-4.9	8.9
Increase (+)/decrease (-) in operating payables	-2.4	1.3	6.7
Increase (+)/decrease (-) of other current liabilities	-4.3	-0.4	3.4
Cash flow from operating activities	-39.9	-21.6	-97.4
Cash flow from investing activities			
Investment in intangible assets	-2.1	-2.5	-14.3
Investments in tangible assets	-0.2	-0.3	-0.5
Sale of financial assets	25.0	—	35.1
Cash flow from investing activities	22.7	-2.8	20.3
Cash flow from financing activities			
New share issue	—	19.5 ¹	30.7 ¹
New share issue expenses	—	-5.6 ¹	-5.6 ¹
Cash flow from financing activities	—	14.0	25.2
Cash flow for the period	-17.2	-10.4	-52.0
Cash and cash equivalents at the beginning of the period	47.2	98.3	98.3
Exchange rate difference in cash and cash equivalents	0.3	0.2	0.9
Cash and cash equivalents at the end of the period	30.3	88.1	47.2

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	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2018
Net revenue	—	—	—
Cost of sales	-2.5	—	-8.0
Gross profit/loss	-2.5	—	-8.0
Other operating income	0.0	0.6	13.9
Marketing and sales expenses	0.0	-1.4	-4.1
Administrative expenses	-7.9	-8.0	-35.7
Research and development expenses	-0.4	-3.1	-8.3
Other operating expenses	-0.6	-0.3	-1.0
Operating loss (EBIT)	-11.4	-12.1	-43.0
Net financial income	0.0	1.2	3.5
Loss before tax	-11.4	-11.0	-39.6
Tax	—	0.1	—
Net loss for the period	-11.4	-10.8	-39.6

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	Mar 31, 2019	Mar 31, 2018,	Dec 31, 2018
ASSETS			
Capital subscribed but not paid in	—	11.2	—
Non-current assets			
Intangible assets	39.8	34.8	40.3
Tangible assets	0.4	0.4	0.4
Financial assets			
Shares in Group companies	141.2	25.3	68.7
Receivables from Group companies	23.3	24.6	29.6
Financial investments, bonds	55.8	85.8	80.0
Total financial assets	220.2	135.7	179.1
Deferred tax assets	—	0.1	—
Total non-current assets	260.5	171.0	219.8
Current assets			
Inventory	—	0.6	—
Receivables from Group companies	—	15.2	26.3
Financial investments, bonds	30.1	60.1	30.1
Other receivables	1.1	1.9	1.2
Prepaid expenses and accrued income	0.6	0.5	0.5
Cash and bank balances	14.2	76.3	37.3
Total current assets	46.0	154.6	95.4
TOTAL ASSETS	306.5	336.8	315.3
EQUITY AND LIABILITIES			
EQUITY			
Share capital	0.7	0.7	0.7
Fund for capitalized expenditure	29.8	24.2	31.8
Capital surplus	406.6	406.0	406.6
Retained earnings	-127.7	-90.4	-92.1
Loss for the year	-11.4	-10.8	-39.6
Total equity	298.1	329.7	307.4
Provisions	0.5	0.1	0.4
Accounts payable	1.7	2.6	1.7
Liabilities to Group companies	2.0	—	—
Other current liabilities	0.3	0.1	0.1
Accrued expenses and deferred income	4.0	4.3	5.7
Total liabilities and provisions	7.9	7.1	7.9
TOTAL EQUITY AND LIABILITIES	306.5	336.8	315.3

Notes

Note 1 Accounting policies

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

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

Effect of the transition to IFRS 16

IFRS 16 Leases

IFRS 16 Leases requires that lessees recognize assets and liabilities attributable to all leases, with the exception of leases that are shorter than 12 months and/or relate to small amounts. The standard replaces IAS 17 Leases and associated interpretations. In

IFRS 16, the distinction between an operating lease and a finance lease is eliminated and replaced with an approach based on the right of use and undertaking to make ongoing payments as a lessee.

The Group has applied IFRS 16 as of January 1, 2019. The standard has not had any material 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. The Group also has short-term leases for vehicles and office equipment.

Segment reporting

Since IRRAS's equity instruments are traded in an active market, IFRS 8 Operating Segments is applicable. IRRAS's operations are currently focused on development and sales in the *IRRAflow* product area, which is why only one segment has been reported, which is reflected in its entirety in the consolidated financial statements. The 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 2.1 million (1.7) during the first quarter of 2019 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.

During the first quarter 2019, 14,286 options were returned and 15,476 options were distributed. A total of 1,881,191 options were outstanding as of March 31, 2019. The CEO has 1,275,000 options and three members of the executive management group have 32,500, 96,429 and 2,976 options, respectively.

Incentive program No. 2

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

During the first quarter 2019, 50,000 options were returned and 1,912 options were distributed. A total of 594,912 options were outstanding as of March 31, 2019. Three members of the executive management group have 35,000, 146,912 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 first quarter of 2019. A total of 320,000 warrants were outstanding as of March 31, 2019. 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 first quarter of 2019. A total of 100,000 warrants were outstanding as of March 31, 2019. 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 first quarter of 2019, 221,987 options were distributed. A total of 490,737 options were outstanding as of March 31, 2019. The CEO has 43,237 options and two members of the executive management group have 30,000 and 47,500 options, respectively.

Note 3 Related-party transactions

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

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

SEK million	Jan–Mar 2019	Jan–Mar 2018	Explanation
Kleanthis G. Xanthopoulos, President and CEO, Board member	—	1.7	Billed consulting services
Christos Panotopoulos, Owner and former member of company management	—	0.4	Billed consulting 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 March 2019 totaled SEK 27,5 thousand (24). The Group has also purchased office equipment from a person related to President and CEO Kleanthis G. Xanthopoulos. The expense totaled SEK 215 thousand (0).

President and CEO Kleanthis G. Xanthopoulos had a consulting agreement with IRRAS via his company Helios Capital beginning in 2015, in accordance with which he has invoiced for services rendered to the company (such as being its CEO) and for the costs he has incurred (such as travel expenses). The consulting agreement expired on November 22, 2017. Since then, Kleanthis G. Xanthopoulos has been employed by IRRAS AB. Payments in 2018 relate to remuneration regarding 2017.

Note 4 Financial assets and liabilities

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

Use of performance measures not defined by IFRS

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

	Jan–Mar 2019	Jan–Mar 2018	Jan–Dec 2018
Gross margin (Gross profit or loss/Net revenue)			
Gross profit/loss, SEK million	-6.1	2.3	-14.0
Net revenue, SEK million	—	5.9	6.0
Gross margin, %	Neg	38%	Neg
EBIT margin (Operating loss (EBIT)/Net revenue)			
Operating loss (EBIT), SEK million	-39.1	-21.1	-143.3
Net revenue, SEK million	—	5.9	6.0
EBIT margin, %	Neg	Neg	Neg
EBITDA margin (EBITDA/Net revenue)			
Operating loss (EBIT), SEK million	-39.1	-21.1	-143.3
Depreciation/amortization, SEK million	-2.6	-1.8	-8.1
Net revenue, SEK million	—	5.9	6.0
EBITDA margin, %	Neg	Neg	Neg
Return on equity, % (Net profit or loss for the period/Average equity)			
Net loss for the period, SEK million	-38.7	-17.8	-138.8
Average equity, SEK million	165.7	307.7	250.1
Return on equity, %	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. Wildeco is the company's Certified Adviser; +46 8 545 271 00, info@wildeco.se.

Financial information



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Calendar

Q2 2019 Interim Report	August 29, 2019
Q3 2019 Interim Report	November 8, 2019
Annual Shareholders' meeting	May 14, 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 May 7, 2019 at 8:00 a.m. (CET).

IRRAS

WWW.IRRAS.COM

