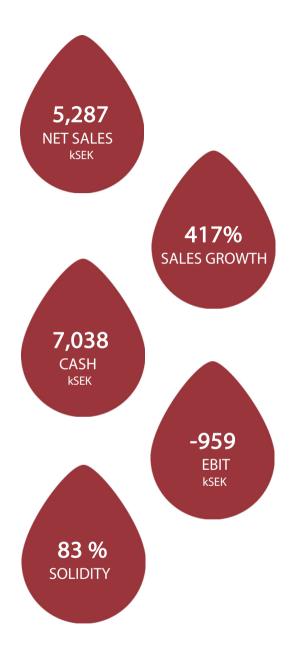


REDSENSE MEDICAL AB (PUBL)
INTERIM REPORT
JANUARY – SEPTEMBER 2023





## JULY - SEPTEMBER 2023

- Net sales amounted to kSEK 5,287 (1,023), an increase of 417%.
- Operating loss, EBIT amounted to kSEK 959 (5,857).
- Result after tax amounted to kSEK -1,008 (-2,372).
- Earnings per share were SEK -0.07 (-0.17).

## SIGNIFICANT EVENTS DURING THE PERIOD

- On July 7, Redsense alarm system was featured in KFF Health News.
- On August 15, Redsense secured a strong autumn with a mSEK 11.2 order.
- On September 27, Redsense Medical arranged Congressional Briefing to address Venous Needle Dislodgement.
- On September 28, Redsense announced that Redsense Medical AB has a new large shareholder.
- On September 29, Redsense Medical AB has been qualified and approved to enter share trading on the OTCQX trading platform in the US under the symbol "RDSNF".

#### SALES GROWTH FOUR OUARTERS IN A ROW

We are pleased to report four quarters in a row with net sales growth. The driver behind the positive development is the US market, and in August we received another large order from one of our US distributors. Part of this mSEK 11.2 order was delivered during the quarter, but most of it is still to be dispatched. Net sales for the third quarter increased by 417 percent to kSEK 5,287 (1,023). The US market remains the foundation and driver of our growth with 98 (98) percent of the net sales. During the quarter the positive development in the UK continued, with an increased interest in our products. The excellent work of our distributor and their promotion of Redsense resulted in orders which were delivered during the quarter.

#### Increasing awareness in our main market

During the quarter, we have been busy in the US with activities to increase awareness and promote the use of blood loss detection alarms. We exhibited at the California Dialysis Council, which was an excellent opportunity to engage with dialysis providers, nurses, dialysis technicians, and other stakeholders.

Home hemodialysis is in focus among dialysis providers, and this modality is gaining popularity thanks to all the benefits that come with home treatment. A driving force is the improved clinical outcome for the patient, but also cost savings both for patients and providers. Home hemodialysis means increased convenience for the patient, and, in the end, improved quality of life. To realize the full potential of home hemodialysis, it is important to address one of the remaining safety issues during hemodialysis; Venous Needle Dislodgement (VND).

It is encouraging that the American Association of Kidney Patients (AAKP) has patient safety high on the agenda, and endorses the use of technologies that can reduce the risk of fatalities and adverse events during home hemodialysis. In September, Redsense participated in the AAKP Annual Patient Meeting, giving a presentation in the section "Issues and Policies Impacting Patient Consumer Choice and Access to Treatments".

As previously communicated, we are pleased that monitoring of VND for home hemodialysis patients is also acknowledged by the US House of Representatives. The Home Hemodialysis Risk Prevention Act (H.R. 3118) is a bipartisan legislation introduced in May 2023, which aims to provide for Medicare coverage of monitoring devices. This is an important initiative, both for patients and dialysis providers, as there is currently no Medicare coverage for blood loss monitoring devices. For Redsense, the enactment of this legislation will be important as the Redsense system is the only blood loss monitoring device cleared by the FDA.

In July, VND was also on the agenda at the AAKP Annual Policy Meeting, attended by a member of Congressman Adrian Smith (NE) office, a sponsor of the legislation from the House of Representatives. Furthermore, Redsense was featured in a KFF Health News report in July, which also was distributed through CBS News. KFF Health News

highlighted the potentially fatal danger of VND, and emphasized the need for a safety system like the Redsense alarm system.

At end of September, Redsense arranged a Congressional briefing to address VND, in order to share knowledge and experience, as to discuss the risks with VND and how to increase patient safety for home hemodialysis patients. The briefing included presentations from AAKP, the Emergency Care Research Institute (ECRI), and our US Clinical Director, Jane Hurst. This event gave the members of the US Congress an understanding of the real risks with VND, and how the enactment of the Home Dialysis Risk Prevention Act can improve patient safety.

To conclude, it is very promising with all the increased awareness of VND among a number of US stakeholders. Moving forward, this support will be instrumental for our continued growth within the US home hemodialysis segment.

#### Good progress with the Clamp

As we have previously communicated, the last step in attaining a CE mark for the Clamp, is a usability study. I am pleased to announce that this study has begun and is underway at the Toronto General Hospital in Canada. There is significant interest for the Clamp, and we are looking forward to launching it in 2024 as it will be an important part of our growth plan.

#### **Looking forward**

Our strategic priorities remain firm: to capitalize on our strong position in the US home hemodialysis segment to further grow our sales, promote the advancement of Home Dialysis Risk Prevention Act, and secure the CE mark of the Clamp to pave the way for market launch.

On another note, I am very pleased that our application for cross-trading at OTCQX Markets was approved at end of September, and with that we have opened for US investors to trade the Redsense share.

We move into the last quarter of the year with a lot of confidence, and I look forward to keeping you updated on our progress. We remain committed to improving safety for dialysis patients - and saving lives!

Pontus Nobréus, CEO Redsense Medical



#### THIS IS REDSENSE MEDICAL

Redsense Medical AB is a medical device innovator established in 2006. Redsense's mission is to improve the safety of and quality of life for dialysis patients worldwide. Redsense has its main market in the US, and in addition distribution partners in Europe and Canada. The corporate headquarter is in Halmstad, Sweden, and for the US sales and marketing operations, Redsense has a US subsidiary. The company has developed the Redsense System, an innovation used for monitoring and alarming in the case of blood leakage during hemodialysis treatment. Redsense Medical solves one of the most serious remaining safety problems within hemodialysis – to quickly detect Venous Needle Dislodgement and catheter leakage to minimize blood leakage.

#### Chronic kidney diseases a growing global challenge

Globally, the number of people with end-stage renal diseases is increasing steadily, and the most common treatment option is chronic dialysis. The number of patients undergoing dialysis several times per week is approaching four million worldwide. The projected growth rate is six percent annually, driven by an ageing population and other factors.

The most common type of dialysis is hemodialysis, and close to 3.5 million people globally are treated weekly with this modality. Today, most of these treatments are performed in clinical settings, but home treatment is gaining popularity thanks to improved clinical outcome, lower cost, increased convenience, and higher quality of life for the patient. This is supported by both political initiatives and promotions from the major dialysis providers.

#### Blood leakage during hemodialysis is a remaining safety problem

Hemodialysis is a well-established treatment method, and it is estimated that more than 500 million treatments are performed annually. However, there are still risks involved and Venous Needle Dislodgement (VND) is a potentially life-threatening complication that can happen to any dialysis patient at any time. VND is estimated to cause three avoidable deaths every day worldwide during hemodialysis.

#### The Redsense solution saves lives

To combat the risk factors involved with hemodialysis, Redsense developed the Redsense System, an innovation used for monitoring hemodialysis treatment and alarming in the event of blood leakage. The system consists of a patented fiber optic sensor which is embedded in a disposable patch designed for either a venous needle or central venous catheter. This sensor is connected to an alarm unit that is triggered when the sensor comes

into contact with blood so the issue can be addressed immediately and the blood flow stopped. Redsense System provides patients, nurses, and caregivers an extra pair of eyes. In essence, Redsense Systems is always alert, focused on one thing only and never looking away.

#### Well established among US dialysis providers

From the very start, development of the company's technology has been based on the demands and safety requirements of healthcare providers in the dialysis sector. The system is the only blood leakage system on the market that is both CE marked and FDA cleared. Redsense is proud to count the five largest dialysis providers and three in the top five best nephrology hospitals in the US among users of the Redsense system. The US department of Veteran Affairs even mandates the use of Redsense System for hemodialysis treatments.

Redsense products are used in both clinics and at home, daily and nocturnally. In recent years, more than million treatments have been carried out with the Redsense System worldwide.

#### Innovation to further improve patient safety

Redsense has developed the Clamp, an accessory to the alarm unit enabling automatic stop of the flow in the blood line in case of an incident, regardless of the type of dialysis machine. The Redsense Clamp is in the final stages of clinical validation to obtain a CE mark before being launched in Canada, Australia, and Europe. With regard the US market, necessary activities are ongoing to prepare for a 510(k) submission.

#### **NET SALES AND RESULTS**

The group's net sales in the third quarter 2023 were kSEK 5,287 (1,023), corresponding to an increase of 417% compared to the third quarter of previous year. The growth was driven by deliveries of the US order stock as well as a new order from one of the US distributors and sales to European distributors. The US was the biggest market with 98 percent (98) of net sales. The gross profit for the group for the third quarter amounted to kSEK 2,944 (493), corresponding to an increase in gross margin to 56 percent (48). This increase of gross margin is an effect of the price adjustment for the alarm unit, at the beginning of 2023.

Other external expenses for the quarter amounted to kSEK 1,914 (2,481). The decrease is mainly due to reduced consulting services for the development of the Redsense Clamp and reduced financial consulting services.

After the board decision not to trade with shares and bonds, the group has lower net financial item kSEK -48 (3,485).

#### **FINANCIAL POSITION**

On September 30, the group's cash and cash equivalents amounted to kSEK 7,038 (3,672) and the deposits, related to short-term investments were kSEK 0 (6,909). A greater stock of raw materials has increased an outflow of cash this third quarter. As of September 30, the company credit facility of SEK 1,000 remains unused.

## **FINANCIAL OVERVIEW**

	Third q	uarter	Nine-mont	th period Jan-Sep
ksek	Q3 2023	Q3 2022	2023	2022
Net sales	5,287	1,023	16,942	6,077
Net sales, change	417%	-71%	179%	181%
Gross profit	2,944	493	8,407	2,425
Gross margin	56%	48%	50%	40%
Operating profit (EBIT)	-959	-5,857	-4,108	-10,506
Earnings per share	-0.07	-0.17	-0.25	-0.44
Cash flow from operating activities	-2,727	-3,900	-3,049	-8,708
Solidity	83%	89%	83%	89%

## **Breakdown of Net Sales Per Quarter**



#### PARENT COMPANY

The Group's parent company, Redsense Medical AB (publ), has one wholly owned subsidiary in the US.

## **RISK AND UNCERTAINTIES**

As an international Group, Redsense is exposed to various risks that affect the possibilities to achieve the established targets. There is operational risk, such as the risk that economic development in the markets and segments where the Group operates could become unstable. There is also financial risk, such as currency risk, interest risk and credit risk.

No major changes in significant risks or uncertainties factors have occurred during the period, regarding geopolitical or other events. Other risks are unchanged compared to the descriptions of Redsense's risks, uncertainties factors and the handling of these in the company's Annual Report for 2022.

#### RELATED-PARTIES TRANSACTIONS

Transaction have taken place during this period between subsidiaries, and remuneration was paid to senior executives in the Group and the Parent Company. One of Patrik Byhmer's associated companies has invoiced kSEK 38 (0) in regarding to consultancy services purchased.

### **HUMAN RECOURSES**

The Group had 5 (5) employees (full time-equivalents) on September 30.

#### **AUDIT REVIEW**

This report has not been reviewed by the company's auditors.

#### **GENERAL INFORMATION**

Information in this report refers to the group, unless otherwise stated. Figures in parentheses indicate the outcome for the corresponding period in the previous year, apart from balance sheet items, where figures in parentheses refers to December 31 of the previous year. Amounts are given in kSEK unless otherwise stated. The amounts may not add up in some cases due to rounding's from SEK to kSEK.

### **C**ALENDAR

Year-end report, Q4 January – December 2023 February 27, 2024 Interim report Q1, January – March 2024 May 8, 2024 Annual General Meeting 2024 May 8, 2024

All financial reports are published at www.redsensemedical.com

#### DECLARATION BY THE BOARD OF DIRECTORS AND CEO

The Board and Directors and the CEO certify that this interim report provides a true and fair overview of the Parent Company's and the Group's operations, financial position and results, and describes significant risk and uncertainties the Parent Company and the Group are exposed to.

Halmstad, November 9, 2023 Redsense Medical AB (publ) The board of Directors and CEO

#### FOR FURTHER INFORMATION

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This information is information that Redsense Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Market Act. The information was submitted for publication, through the agency of the contact person specified above, on November 9, 2023, at 08:30 CET.

## THE SHARE

The Redsense Medical share is listed on Spotlight Stock Market under the ticker REDS and traded on OTCQX Market under the ticker RDSNF. The share was originally listed on Aktietorget (today known as Spotlight Stock Market) on June 5, 2015, relisted on the Nasdaq First North Stockholm on October 2, 2017, before being relisted on Spotlight Stock Market on May 3, 2019. As of September 30, 2023, the company's market capitalization was mSEK 140.

The IPO share price of Redsense Medical in 2015 was SEK 5 per share. On the last day of trading, September 2023, the closing share price was SEK 10. Thus, the total shareholder return since the IPO is 100 percent.

#### SHARE TURNOVER

In total, 1,2 million shares were traded in the third quarter, for a value of mSEK 11.

### SHARE CAPITAL

On September 30, 2023, the share capital of Redsense Medical amounted to SEK 1,404,081, divided into 14,040,810 shares, each with a quota value of SEK 0.10. All shares carry the same voting rights.

#### **OWNERSHIP**

At the turn of the quarter, the ten major owners represented 49 percent of the share capital and voting rights. The largest shareholder at the end of the third quarter was Patrik Byhmer, with a 14 percent ownership via companies and the second largest was the new shareholder ShapeQ.

## THE TEN MAJOR OWNERS AS OF 2023-09-30

B : !  B	4.4.000/
Patrik Byhmer*	14.03%
ShapeQ	6.55%
Avanza Pension	5.36%
Discover Capital Gmbh	5.34%
Nordnet Pensionsförsäkring	4.13%
Swedbank Robur Fonder	3.85%
Futur Pension	3.46%
Aktia Assets Management	2.21%
Martin Olausson	2.16%
Andra AP-fonden	2.14%
Total	49.23%

<sup>\*</sup> Shares held through companies

## **C**ONSOLIDATED INCOME STATEMENT

	2023-07-01	2022-07-01	2023-01-01	2022-01-01	2022-01-01
kSEK	2023-09-30	2022-09-30	2023-09-30	2022-09-30	2022-12-31
Net sales	5,287	1,023	16,942	6,077	14,340
Capitalized development work	11	261	443	1,948	2,413
Other operating income	260	-1,442	371	694	1,036
Total operating income	5,558	-157	17,756	8,719	17,790
Cost of goods sold	-2,343	-530	-8,535	-3,652	-5,489
Other external expenses	-1,914	-2,481	-6,861	-8,578	-12,550
Personnel costs	-2,245	-2,674	-6,422	-6,956	-9,906
Depreciation/Impairment	-16	-14	-46	-39	-53
Total operating costs	-6,518	-5,700	-21,864	-19,225	-27,998
OPERATING RESULT	-959	-5,857	-4,108	-10,506	-10,208
Net financial items	-48	3,485	547	4,302	1,450
Result from financial items	-1,008	-2,372	-3,561	-6,205	-8,758
PROFIT OR LOSS BEFORE TAX	-1,008	-2,372	-3,561	-6,205	-8,758
PROFIT OR LOSS FOR THE PERIOD	-1,008	-2,372	-3,561	-6,205	-8,758

# CONSOLIDATED BALANCE SHEET

kSEK	2023-09-30	2022-09-30	2022-12-31
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development cost	12,796	11,888	12,354
Tangible assets			
Technical equipment and tools	371	379	365
Financial assets			
Total fixed assets	13,167	12,267	12,719
Current assets			
Inventory	2,501	2,096	1,531
Accounts receivable	5,256	1,530	4,934
Other short-term receivables	456	337	326
Prepayment and accrued income	424	1,400	641
Short-term deposits	0	9,802	6,909
Cash and cash equivalents	7,038	4,371	3,672
Total current assets	15,676	19,537	18,013
TOTAL ASSETS	28,843	31,804	30,731

kSEK	2023-09-30	2022-09-30	2022-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,404	1,404	1,404
Restricted reserve	598	598	598
Development fund	12,856	11,948	12,414
Non-restricted equity			
Retained earnings	12,549	20,490	21,491
Profit or loss for the period	-3,561	-6,205	-8,758
Total equity	23,847	28,235	27,149
Liabilities			
Short-term liabilities			
Accounts payable	2,805	2,113	981
Other short-term liabilities	419	399	465
Accruals and deferred income	1,772	1,056	2,136
Total liabilities	4,996	3,568	3,582
TOTAL EQUITY AND LIABILITIES	28,843	31,804	30,731

# CONSOLIDATED CASH FLOW

Cash flow for the period	-2,738	-1,762	3,366	-612	-1,311
Cash flow from financing activities	0	332	0	-2,395	-2,395
Cash flow from investment activities	-11	1,806	6,415	10,491	10,868
Cash flow from operating activities	-2,727	-3,900	-3,049	-8,708	-9,783
ksek	2023-09-30	2022-09-30	2023-09-30	2022-09-30	2022-12-31
	2023-07-01	2022-07-01	2023-01-01	2022-01-01	2022-01-01

# CONSOLIDATED CHANGE IN EQUITY

ksek	Share capital	Contributed capital	Retained earnings	Total equity
Opening balance January 1, 2022	1,404	123,631	-87,543	37,492
Result for the period			-8,758	-8,758
Warrant issuance			252	252
Exchange rate differences and other adjustments			-1,837	-1,837
Closing balance December 31, 2022	1,404	123,631	-97,886	27,149
kSEK	Share capital	Contributed capital	Retained earnings	Total equity
Opening balance January 1, 2022	1,404	123,631	-87,543	37,492
Result for the period	1,707	123,031	-6,205	-6,205
Warrant issuance			176	176
Exchange rate differences and other adjustments			-3,229	-3,229
Closing balance September 30, 2022	1,404	123,631	-96,800	28,235
ksek	Share capital	Contributed capital	Retained earnings	Total equity
Opening balance January 1, 2023	1,404	123,631	-97,886	27,149
Result for the period			-3,561	-3,561
Warrant issuance				0
Exchange rate differences and other adjustments			259	259

# PARENT COMPANY'S INCOME STATEMENT

	2023-07-01	2022-07-01	2023-01-01	2022-01-01	2022-01-01
kSEK	2023-09-30	2022-09-30	2023-09-30	2022-09-30	2022-12-31
Net sales	3,672	717	12,243	4,685	10,516
Capitalized development work	11	261	443	1,948	2,413
Other operating income	260	-1,442	371	694	369
Total operating income	3,943	-463	13,056	7,327	13,298
Cost of goods sold	-2,318	-569	-8,435	-3,895	-5,489
Other external expenses	-1,328	-1,746	-4,897	-6,388	-8,834
Personnel costs	-1,533	-2,097	-4,602	-5,450	-7,591
Depreciation/Impairment	-1,213	-1,211	-3,636	-3,629	-4,840
Total operating costs	-6,392	-5,624	-21,571	-19,361	-26,753
OPERATING RESULT	-2,449	-6,087	-8,515	-12,034	-13,455
Net financial items	-228	3,485	1,426	4,302	1,450
Result from financial items	-2,676	-2,602	-7,089	-7,732	-12,005
PROFIT OR LOSS BEFORE TAX	-2,676	-2,602	-7,089	-7,732	-12,005
PROFIT OR LOSS FOR THE PERIOD	-2,676	-2,602	-7,089	-7,732	-12,005

# PARENT COMPANY'S BALANCE SHEET

kSEK	2023-09-30	2022-09-30	2022-12-31	kSEK	2023-09-30	2022-09-30	2022-12-31
ASSETS				EQUITY AND LIABILITIES			
Fixed assets				Equity			
Intangible assets				Restricted equity			
Capitalized development cost	12,796	11,888	12,354	Share capital	1,404	1,404	1,404
Patent	18,091	22,877	21,680	Restricted reserve	598	598	598
Tangible assets				Development fund	12,856	11,948	12,414
Technical equipment and tools	371	379	365				
Financial assets				Non-restricted equity			
Shares in subsidiaries	7	7	7	Retained earnings	48,921	61,759	61,368
Receivables from group companies	0	14,301	12,346	Profit or loss for the period	-7,089	-7,732	-12,005
Total fixed assets	31,264	49,452	46,751	Total equity	56,691	67,977	63,780
Current assets							
Inventory	724	2,042	689				
Advances to suppliers	1,777	-	789				
Accounts receivable	129	155	150				
Receivables from group companies	21,598	4,980	10,320	Liabilities			
Other short-term receivables	456	337	326	Short-term liabilities			
Prepayment and accrued income	424	1,400	641	Accounts payable	2,792	1,922	688
Short-term deposits	0	9,802	6,909	Other short-term liabilities	427	399	465
Cash and cash equivalents	5,026	3,185	220	Accruals and deferred income	1,489	1,056	1,862
Total current assets	30,135	21,902	20,044	Total liabilities	4,708	3,377	3,015
TOTAL ASSETS	61,399	71,354	66,795	TOTAL EQUITY AND LIABILITIES	61,399	71,354	66,795

## **NOTES**

### NOTE 1 ACCOUNTING PRINCIPLES

These interim financial statements have been prepared in accordance with the Swedish Annual Act and the Swedish Accounting Standards Board BFNAR 2012:1 annual report and consolidated (K3). The accounting policies are the same as the previous year. For further information, please refer to the Annual Report for 2022, page 27.

## NOTE 2 PLEDGED ASSETS AND CONTINGENT LIABILITIES

Pledged assets amounts to mSEK 1.5 as per September 30, 2023. There are no contingent liabilities in the Group.

#### NOTE 3 KEY RATIOS AND FINANCIAL METRICS

Definitions of the key ratios and financial metrics used in the Group's financial reporting.

Graphs of net sales

Redsense has chosen to report a graph of the net sales per quarter and on a rolling 12-month basis as corporate management also follows the development over time on a rolling 12-month basis and believes that this provides supplementary information to the calendar based interim data otherwise given in the report.

- Operation profit/loss, operating margin, EBIT and EBIT margin
  In this report Redsense uses the result measure EBIT, Earnings Before Interest and
  Taxes, as an alternative term for operating profit. EBIT margin is thus an alternative
  term for operating margin, calculated as net sales reduced by cost of goods sold and
  operating cost.
- Gross Profit
  Net sales less cost of goods sold.
- Investments
  Acquisitions of property, plant and equipment, intangible assets and financial assets
- during the period.
- Earnings per share
  Net profit for the period divided by the average number of shares during the period.
- Solidity
  Equity divided by total assets.



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