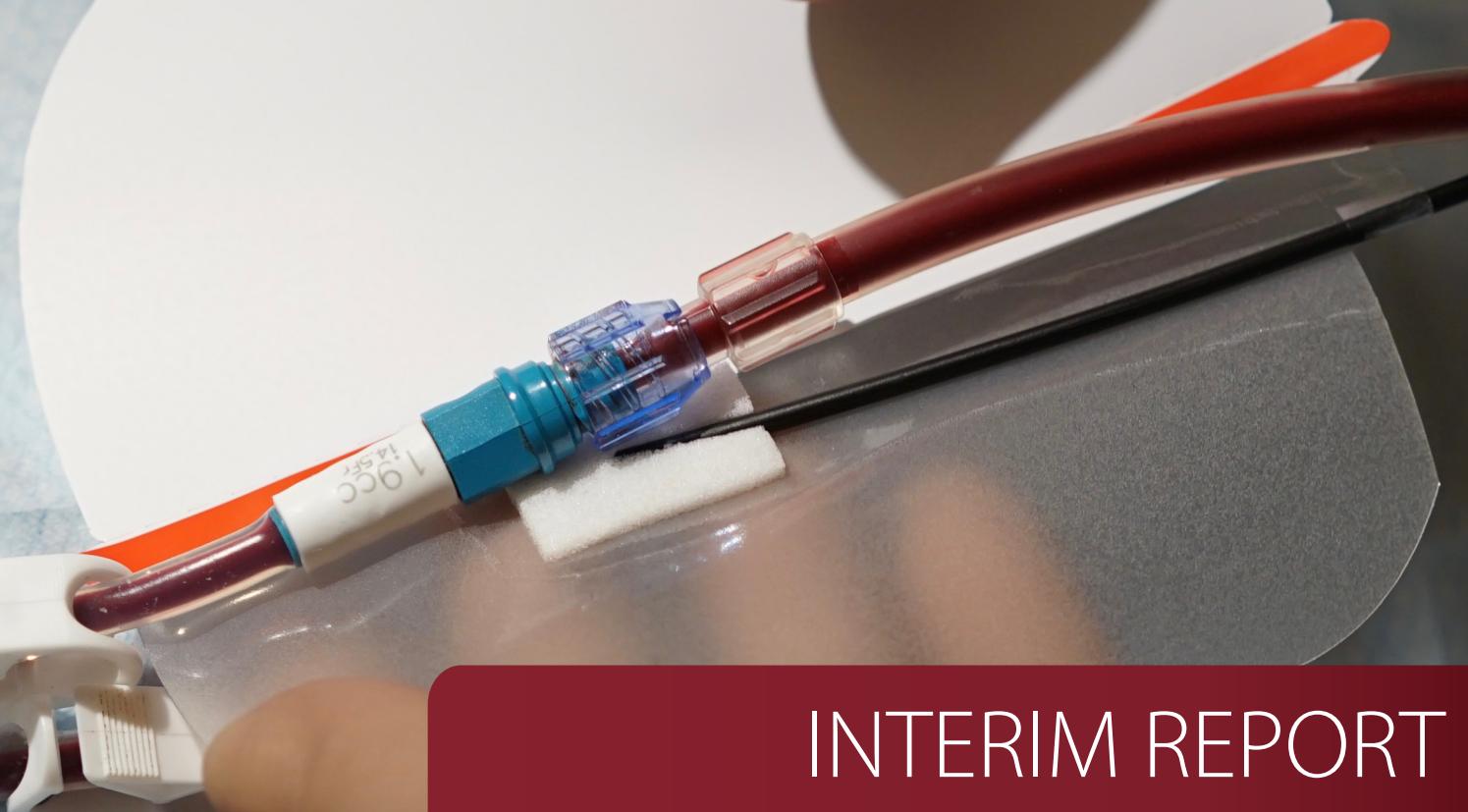




REDSENSE
medical



INTERIM REPORT

Q3

JANUARY – SEPTEMBER 2021

Redsense Medical AB (publ) 556646-4862

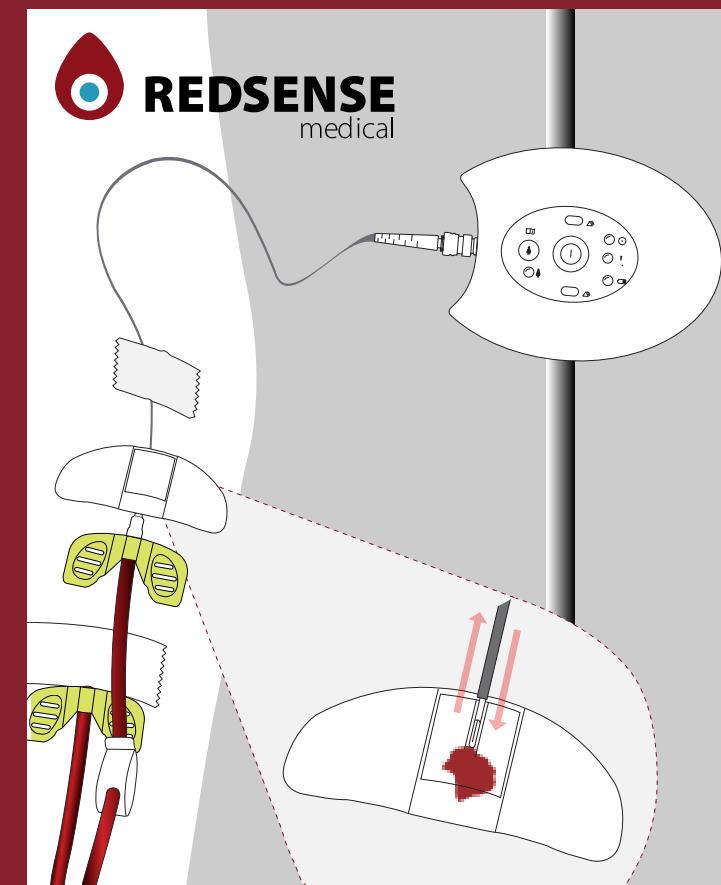
This is Redsense Medical

Saving lives

Redsense Medical AB is born-global medical device innovator established in Sweden in 2006. Redsense's mission is to improve the safety and quality of life for dialysis patients worldwide. The group has its main market in the United States and additional operations in Europe, Oceania and Canada.

Early, reliable warning – without false alarms

Redsense promotes patient safety through highly cost-efficient fiber-optic monitoring of the blood access site during hemodialysis. The Redsense System immediately detects Venous Needle Dislodgement (VND) – a potentially life-threatening complication that causes 21 avoidable deaths per week worldwide. In essence, the Redsense alarm provides nurses, patients and caregivers an extra pair of eyes; always alert, focused on one thing only, never looking away.



Key to at-home safety

Redsense is used in both in clinics and at home, daily and nocturnally. Today, the majority of treatments are performed in clinical settings, but home treatment is gaining popularity thanks to lower cost, increased convenience for the patient, improvements in technology and political initiative. This is where Redsense's solution makes the biggest difference.

A standard element of dialysis care

The number of patients undergoing hemodialysis several times per week due to chronic kidney disease is approaching four million, worldwide. The projected growth rate is six percent annually, driven by ageing population and other factors. Every hemodialysis treatment carries the risk of VND. More than 300,000 treatments are conducted with the Redsense System annually.

- ▶ During **hemodialysis**, blood is pumped from the patient at a rate of about 300-500 ml per minute to be cleaned in a **dialyzer** outside the body.
- ▶ With Redsense, a fiber-optic **sensor layer** integrated in a disposable patch is attached to the access where the blood is returned to the body via the venous needle.
- ▶ **Red light** is carried back and forth to the sensor from an **alarm unit**. If blood is absorbed in the patch, the device observes a reduced level of red light in the return signal.
- ▶ A **visual and audible alarm** is triggered. This alerts the attention of the nursing staff, so that they can **stop the dialysis machine's pump** and prevent further blood loss from the patient.
- ▶ Redsense can be **integrated** with dialysis machines implementing a certain standard. In such cases, the alarm unit can stop the blood flow **without human intervention**.
- ▶ **Redsense Clamp** is a novel accessory product, currently in clinical validation, which equips the Redsense System with the ability to stop any dialysis machine's pump **automatically** by clamping the bloodline as prompted by the alarm unit.

July – September 2021

- Net sales amounted to kSEK 3,566 (2,107), a 69 percent increase compared with the corresponding period in 2020.
- Profit or loss before tax amounted to kSEK -2,547 (-3,213).
- Earnings per share before dilution amounted to SEK -0.18.

January – September 2021

- Net sales amounted to kSEK 6,008 (12,213), a 51 percent decrease compared with the corresponding period in 2020.
- Profit or loss before tax amounted to kSEK -6,937 (-2,958).
- Total equity amounted to kSEK 38,904 at the end of the period.
- Cash and cash equivalents amounted to kSEK 4,277 at the end of the period.
- Earnings per share before dilution amounted to SEK -0.49.

Significant events July – September 2021

- In August, Redsense Medical announced the conclusion of a new distributor agreement with CardioMed Supplies Inc. for Canada and Bermuda.

Significant events after the period

- On 13 October, Redsense Medical announced its first order from Canada.

Net sales triples in Q3 from the last quarter

During the third quarter, we have seen the early signs of normalization that became visible in the second quarter gradually solidify into something that resembles the turning of a corner. In the third quarter, net sales more than tripled, increasing by 236 percent over the previous period, and we expect to see continued strengthening over the course of the fourth quarter.

The COVID-19 situation has not vanished off the map and does remain a burden - but it has, at least in the United States, receded to a point where the general access to clinics and patients has recovered substantially. There is also an unmistakable eagerness in the healthcare system to restore and revive the workings of the pandemic-ridden infrastructure for home hemodialysis. As a result, Redsense's sales are growing, and we are once again making good progress. We are not quite at our pre-pandemic level of growth as of yet, but we continue to press ahead encouraged by the vaccination coverage in the patient population, the reduced load in intensive care units and the greater possibilities to meet in person.

Redsense enters Canada

As of this quarter, our sales activities in North America have expanded to include also Canada and Bermuda in addition to the United States. This is the result of an agreement concluded with the Ontario-based distributor CardioMed Supplies Inc. in mid-August.

While Canada has not eased its restrictions to the same extent as the United States, our new distributor has already set to work, and we received our first order from the new market after the end of the quarter. Moving forward, we hope that more patients will be encouraged to try out home hemodialysis thanks to the added safety provided by our device.

Market introduction of Redsense Clamp comes closer

The venture into Canada follows upon our new activities in the Oceanian market in the first and

second quarters. This should be seen in the context of the Redsense Clamp, our new, soon-to-be-released accessory product and a key enhancement of our offer, which equips the Redsense Alarm with the ability to intervene on its own in any setting where it is used.

We are truly pushing the boundaries with the Redsense Clamp. No other product on the market has the ability to not only detect but also independently stop a blood leakage in progress. As such, the bundling of the Redsense device and the Clamp gives us a more comprehensive solution, a first-mover advantage and decidedly better protection for the patients.

This opens up an opportunity for entry into new markets. We are looking to introduce the Clamp across all of our markets, viz: North America, Europe, and Oceania, pending the clinical validation process. Canada, where we have a long history of cooperation with Toronto University Hospital in relation to the Clamp development, is a natural market to enter in this phase.

By and large, we are en route to launching the Clamp as envisaged; some minor delays emerged in relation to the preparations for clinical validation, as it took longer than anticipated to get clinical access, but on the whole, everything is proceeding according to plan. Of course, that process proceeds in the fourth quarter, in parallel with our handling of the new influx of sales.

In the United States in particular, the political climate is promoting home hemodialysis. The advantage of our position is that we supply a key enabling technology for an ongoing development that will also benefit us: the increasing number of patients dialyzed at home.

Finally, I want to extend my appreciation to the team for all the dedication and hard work. Thank you!



Patrik Byhmer
CEO, Redsense Medical

“We are opening up new markets, in view of the upcoming market launch.”



Financial overview

Sales

During the quarter, the Group's net sales increased by 69 percent compared with the previous year, totaling kSEK 3,566 (2,107). Compared with the previous quarter, Q2 2021, the Group's net sales increased by kSEK 2,501, corresponding to 236 percent. This further entails that Q3 represented 59 percent of the accumulated net sales for the first three quarters of the year, which is attributable to the ongoing restoration of market activity in the US market.

The combined net sales for the period January – September totaled kSEK 6,008 (12,213), a decline of 51 percent compared with the corresponding period of the previous year. This is mainly attributable to the impact of the pandemic, which hampered the ability to conduct new sales during the first half of the year in particular.

The Group's operating result amounted to kSEK -2,852 (-3,056) for the quarter and kSEK -9,218 (-2,898) for January – September.

Operating expenses

The Group's operating costs increased by 46 percent, to kSEK -8,967 (-6,136) during the quarter compared with the corresponding quarter in the previous year. This is mainly attributable to increased consultancy and personnel costs related to the Clamp project, and increased amortizations on patents.

Result and position

The Group's profit or loss for the third quarter of 2021 amounted to kSEK -2,546 (-3,213) before taxes, or SEK -0.18 per share before dilution. The number of shares outstanding was 14,040,810 as of 30 September 2021.

Liquidity and financing

As of 30 September, the Group's cash and cash equivalents amounted to kSEK 4,277 (5,609). In addition, the Group has short-term deposits of kSEK 22,405.

The Group's solidity, calculated as equity as a percentage of the balance sheet total, amounted to 92 (81) percent at the end of the quarter.

Investments

During the quarter, investments were made in tangible fixed assets in the form of machinery for processing plastics relating to the Clamp project. Tangible fixed assets for 2020 were attributable to Redsense's former subsidiary Odinwell, which was spun off as a separate legal entity during the second quarter.

CONSOLIDATED INCOME STATEMENT

SEK	2021-07-01 -2021-09-30	2020-07-01 -2020-09-30	2021-01-01 -2021-09-30	2020-01-01 -2020-09-30
Net sales	3,566,449	2,106,868	6,008,185	12,213,170
Capitalized development work	2,549,084	923,424	4,866,646	923,424
Other operating income	-	49,483	-	49,483
Total operating income	6,115,533	3,079,775	10,874,831	13,186,077
Cost of goods sold	-2,182,773	-2,280,267	-3,837,923	-6,363,047
Other external expenses	-4,822,102	-2,318,776	-10,879,904	-5,370,572
Personnel costs	-1,913,444	-1,488,015	-5,228,601	-4,203,927
Depreciation/Amortization	-48,900	-48,900	-146,700	-146,700
Total operating costs	-8,967,219	-6,135,958	-20,093,128	-16,084,246
OPERATING RESULT	-2,851,686	-3,056,183	-9,218,297	-2,898,169
Securities trading	385,639	-	1,709,863	-
Interest income/ foreign exchange gains	-	-	601,956	19,237
Interest costs/ foreign exchange losses	-80,685	-157,162	-30,489	-79,047
Result from financial items	304,954	-157,162	2,281,330	-59,810
PROFIT OR LOSS BEFORE TAX	-2,546,732	-3,213,345	-6,936,967	-2,957,979
PROFIT OR LOSS FOR THE PERIOD	-2,546,732	-3,213,345	-6,936,967	-2,957,979

CONSOLIDATED BALANCE SHEET

SEK

2021-09-30

2020-12-31

ASSETS

Fixed assets

Intangible fixed assets

Capitalized development costs	7,824,227	5,766,994
Tangible fixed assets	396,846	2,002,264
Financial fixed assets	-	200,010
Shares in associated companies	-	200,010
Total fixed assets	8,221,073	7,969,268

Current assets

Inventories	3,271,170	2,262,159
Advances to suppliers	52,684	75,000
Accounts receivable	3,010,357	2,086,156
Other short-term receivables	462,817	890,334
Receivables from associated companies	625	625
Prepayments and accrued income	247,757	397,214
Short-term deposits	22,405,240	36,016,089
Cash and cash equivalents	4,277,184	29,006,865
Total current assets	33,727,833	70,734,442

TOTAL ASSETS

41,948,907

78,703,710

EQUITY AND LIABILITIES

Equity

Restricted equity

Share capital	1,404,081	1,404,081
Restricted reserves/statutory reserve	18,612,836	16,443,804

Non-restricted equity

Non-restricted reserves/retained earnings	-97,494,734	-58,754,918
Share premium reserve	123,318,577	123,140,573
Profit or loss for the period	-6,936,967	-9,034,880

Total equity

38,903,792

73,198,662

Liabilities

Short-term liabilities

Accounts payable	1,146,924	3,716,115
Other short-term liabilities	1,066,632	531,449
Accruals and deferred income	831,558	1,257,483

Total short-term liabilities

3,045,114

5,505,047

Total liabilities

3,045,114

5,505,047

TOTAL LIABILITIES & EQUITY

41,948,907

78,703,710

CONSOLIDATED CASH FLOW STATEMENT

SEK

2021-07-01 2020-07-01 2021-01-01 2020-01-01
-2021-09-30 -2020-09-30 -2021-09-30 -2020-09-30

Cash flow from operating activities before changes in working capital	-3,328,837	-2,081,659	-13,551,684	-2,075,755
Cash flow from operating activities	13,162,824	1,771,629	16,577,785	1,256,541
Cash flow from investment activities	-25,581,710	-1,349,494	-397,880	-1,375,908
Cash flow from financing activities	-27,357,902	-2,009,249	-27,357,902	-2,468,338
Cash flow for the period	-43,105,625	-3,668,773	-24,729,681	-4,663,460
Liquid assets at the end of the period	4,277,184	5,608,523	4,277,184	5,608,523

PARENT COMPANY'S INCOME STATEMENT

SEK	2021-07-01 -2021-09-30	2020-07-01 -2020-09-30	2021-01-01 -2021-09-30	2020-01-01 -2020-09-30
Net sales	2,199,600	1,595,412	3,834,331	9,336,384
Capitalized development work	2,549,084	923,424	4,866,646	923,424
Other operating income	-	49,483	-	49,483
Total operating income	4,748,684	2,568,319	8,700,977	10,309,291
Cost of goods sold	-2,182,773	-2,280,267	-3,837,923	-6,363,047
Other external expenses	-4,102,805	-2,393,022	-8,941,428	-4,676,103
Personnel costs	-1,468,724	-858,831	-4,070,749	-2,786,647
Depreciation/Amortization	-1,245,471	-48,900	-3,736,414	-146,700
Total operating costs	-8,999,773	-5,581,020	-20,586,514	-13,972,497
OPERATING RESULT	-4,251,089	-3,012,701	-11,885,537	-3,663,206
Securities trading	385,639	-	1,709,863	-
Interest income/ foreign exchange gains	470,374	-	1,132,943	19,237
Interest costs/ foreign exchange losses	-20,072	-157,162	-30,489	-79,047
Result from financial items	835,941	-157,162	2,812,317	-59,810
PROFIT OR LOSS BEFORE TAX	-3,415,148	-3,169,863	-9,073,220	-3,723,016
PROFIT OR LOSS FOR THE PERIOD	-3,415,148	-3,169,863	-9,073,220	-3,723,016

PARENT COMPANY'S BALANCE SHEET

SEK

2021-09-30

2020-12-31

ASSETS

Fixed assets

Intangible fixed assets

Capitalized development costs	35,487,551	34,357,319
Tangible fixed assets	396,846	36,786
Financial fixed assets		
Shares in subsidiaries	30,000,000	60,050,000
Shares in associated companies	-	200,010
Receivables from group companies	15,802,990	14,802,633

Total fixed assets

81,687,387

109,446,748

Current assets

Inventories	2,549,758	1,914,700
Advances to suppliers	52,684	75,000
Accounts receivable	1,295,177	89,915
Other short-term receivables	453,985	572,181
Receivables from associated companies	625	625
Prepayments and accrued income	196,685	338,069
Short-term deposits	22,405,240	36,016,089
Cash and cash equivalents	554,299	24,690,720

Total current assets

27,508,453

63,697,299

TOTAL ASSETS

109,195,840

173,144,047

EQUITY AND LIABILITIES

Equity

Restricted equity

Share capital	1,404,081	1,404,081
Restricted reserves/statutory reserve	18,612,836	13,892,890

Non-restricted equity

Non-restricted reserves/retained earnings	-57,665,892	-14,724,615
Share premium reserve	123,318,577	123,631,079
Profit or loss for the period	-9,073,220	-8,171,331

Total equity

76,596,381

116,032,104

Liabilities

Long-term liabilities

Liabilities to Group companies	29,543,563	-
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Total long-term liabilities

29,543,563

-

Short-term liabilities

Accounts payable	1,144,292	3,716,115
Other short-term liabilities	1,066,632	52,463,354
Accruals and deferred income	844,972	932,474

Total short-term liabilities

3,055,896

57,111,943

Total liabilities

32,599,459

57,111,943

TOTAL LIABILITIES & EQUITY

109,195,840

173,144,047

ADMINISTRATION REPORT

Accounting policies

These interim financial statements have been prepared in accordance with the Swedish Annual Accounts Act as well as 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 2020.

Auditor's review

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

Nomination Committee for the Annual General Meeting 2022

In accordance with the policies adopted by the Annual General Meeting 2021, the Nomination Committee shall consist of the Chairman of the Board and representatives of the three largest shareholders in terms of voting rights as of 30 September each year, according to the shareholder register maintained by Euroclear Sweden AB.

The new Nomination Committee consists of:

- Lars Rodert, appointed by ÖstVäst Capital Management
- Staffan Ringvall, appointed by Handelsbanken Fonder
- Susanne Olauson, appointed by Seventh Sense Adventures Holding AB, Chairman of the Nomination Committee
- Bo Uneus, Chairman of the Board

The Nomination Committee shall prepare, and at the Annual General Meeting present, proposals for the Chairman of the Annual General Meeting; the Board of Directors and the Chairman of the Board; board fees and, where appropriate, remuneration for work in committees; auditors and fees to the auditors; and, where appropriate, amendments to the Nomination Committee's instructions.

Shareholders wishing to submit proposals to the Nomination Committee may do so by email at susanne.olauson@redensemical.com no later than 2 January 2022.

The Nomination Committee's proposal will be presented in the notice of the Annual General Meeting 2022 and on the Company's website: www.redensemical.com

The Annual General Meeting will be held at 5:00 p.m. on 2 May 2022 in Halmstad, Sweden.

Trading Place

Redsense Medical's shares have been listed on the Spotlight Stock Market since 3 May 2019, where they are traded under the ticker REDS.

ADMINISTRATION REPORT

Next publication date

The year-end report 2021 will be published on 22 February 2022.

Contact information

For additional information, please contact the company:

Telephone: +46 35-10 60 30
E-mail: info@redensemical.com

Assurance

The Board of Directors and the CEO ensure, to the best of their ability, that this Q3 interim report provides a true and fair view of Redsense's operations and results.

Redsense Medical is obliged to make the information contained herein public pursuant to the EU market abuse regulation. The information was submitted for publication through the agency of the contact person above at CET 08:30 on 9 November 2021.

Other information

For further information about Redsense Medical AB's operations, please refer to the company website: www.redensemical.com



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