

## Interim report for the first quarter of 2020

January 1 - March 31, 2020

#### The first quarter in figures

- · Net sales amounted to TSEK 7 726 (3,514).
- Loss after taxes amounted to TSEK 18 312 (17 340).
- · Loss per share was SEK 1,0 (1,5).
- Cash flow from current operations was TSEK -21 898 (-22 547).

#### Important events during the first quarter

- The company has signed a new lease for the head office and state of the art manufacturing facility in Uppsala, Sweden.
- Completed transfer of the commercial operations in the United States.
- First sales in France.
- Regulatory approval in Japan for OssDsign Cranial PSI

### Important events after the end of the first quarter

- · Appointment of Vice President of Sales for OssDsign USA Inc.
- OssDsign Cranial PSI granted full nationwide reimbursement in Japan.

#### The COVID-19 pandemic

The initial outbreak of the COVID-19 pandemic has not significantly impacted the first quarter of 2020. However, since the middle of March there has been a widespread postponement of elective surgeries, including those relevant to OssDsign, as healthcare systems manage the pandemic. This has resulted in a reduced level of incoming orders which will have an effect on sales in the second quarter. OssDsign is confident that this will be transient and as hospital priorities are normalized procedure volumes will also return to the levels experienced before the start of the COVID-19 situation, supplemented by additional procedures from currently postponed essential reconstructive surgeries.



## Financial overview

	2020	2019	2019
The group	Jan 1 – March 31	Jan 1 – March 31	Jan 1 - Dec 31
Net sales, TSEK	7 726	3 514	16 876
Operating profit, TSEK	-18 260	-17 126	-83 526
Profit for the period, TSEK	-18 312	-17 340	-84 245
Solidity, %	88%	74%	88%
Earnings per share, SEK	-1,0	-1,5	-5,5
Average number of employees	40,8	29,9	35,5



It is our firm belief that we will return on track and continue the strong sales development when health care priorities in our key markets start to return to normal.

### **CEO Statement**

### Continued consecutive quarterly growth, with Japan firmly in sight

The positive trend from the end of 2019 continues as OssDsign kicks off 2020 with continued consecutive sales growth of 52% in Q1 vs Q4 2019. The implementation of investments made as a result of our IPO in 2019 continue to pay off with the US, our largest single market, increasing Q1 sales 34% vs Q4 2019. In Europe we launched in France, reinforced our efforts in remaining markets, and we are rewarded with sales increasing 67% vs Q4 2019. Strong initial numbers in France indicate that we are able to gain traction in new markets rapidly.

These strong sales figures confirm that executing our post-IPO strategy in 2019 has enabled us to take the company's commercial operations to a new level. We have made substantial investments and structural improvements in the United States and in Europe, in parallel to introducing CranioPlug, and we can now clearly see the results of our efforts. It is especially encouraging that these efforts are starting to show effect also on the bottom-line, as we began to see the anticipated improvement in our operating profit - by 36% in Q1 2020 vs Q4 2019.

Another cornerstone of our post-IPO investments has been the pursuit of a regulatory application in Japan. Just before the end of the quarter we received notification that the Japanese Pharmaceutical and Medical Devices Agency (PMDA) granted approval of OssDsign Cranial PSI for the Japanese market. Earlier than expected, we also just received a positive decision on the level of reimbursement for the product which is expected to come into force during June. We will launch in Japan with a local commercial partner and are currently in final negotiations with potential candidates. Preparations of the regulatory file for CranioPlug in Japan are in progress and filing is expected later this year.

Moving into the second quarter OssDsign was in a strong position to continue delivering both top- and bottom-line growth. However, the ongoing COVID-19 pandemic will have a temporary effect on this development. Healthcare systems all over the world have shifted their focus to the management of the pandemic and as a consequence access to hospitals for sales reps has been stopped and elective surgeries have to a large extent been postponed. The underlying need for our products is still there however. In parallel with managing the COVID-19 situation, life-saving surgeries for stroke and trauma continue to be performed, but the majority of the subsequent essential implant reconstructions are postponed. Many brain tumor surgeries are also postponed due to the current situation but are expected to be rescheduled when hospitals begin to return to normal.

Looking forward, we are confident that the current Impact on sales growth will be transient. We are taking the opportunity to refocus our resources to further improve the efficiency of our CAD and production processes. These are improvements that will further strengthen our profitability in the long-term.

I am very proud to present Q1 results that reflect a successful strategy, good execution and a lot of hard work. It is our firm belief that we will return on track and continue the strong sales development when health care priorities in our key markets start to return to normal. OssDsign will then be in better shape than ever before to support patients and the doctors who serve them, resulting in continued strong sales growth.

Anders Lundqvist, CEO

## **Statement of Operations**

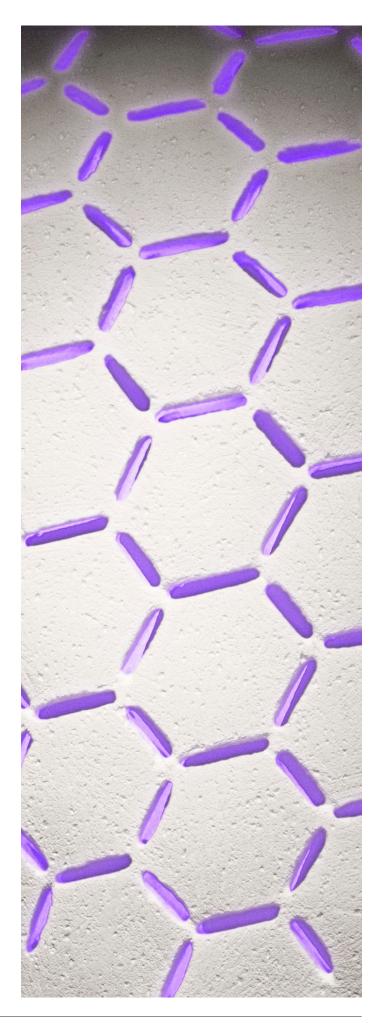
OssDsign AB is a med-tech company that has developed a bioceramic material that, when implanted into a patient's body, is replaced by the patient's own bone during the healing process. Based on this bioceramic material, the company has developed patient-specific cranial and facial implants and an off-the-shelf product for burr hole filling. These products lead to an improved healing process with a low risk of complications, compared with published data for traditional technologies.

#### Status

The products are manufactured at the OssDsign site in Uppsala, Sweden. The company currently has regulatory approval in the EU, US and Japan and has successfully established commercial operations in Europe and the US. In the autumn of 2017, OssDsign initiated commercialization in the US, the world's largest MedTech market. The company sees strong growth potential in the US and intends to carry out significant market initiatives there in the coming years. In addition, OssDsign will invest in continued growth in Europe and establishing a position in the Japanese market.

#### Objectives and Market Potential

Successful market initiatives have generated significant interest in the company's products, resulting in significant sales growth in recent years. OssDsign has determined that there is good potential to establish the company's patient specific and off-the-shelf implants as the standard treatment for cranial and facial defects while continuing to develop new applications based on the current technology platform.



## **Development of profit and** financial position

#### **FIRST QUARTER**

#### Net sales

Net sales for the first quarter of 2020 amounted to TSEK 7 726 (3 514), an increase of 120%, which adjusted for currency effects is an increase of 101%. Continued strong sales growth in the US (+220%) is the biggest factor in this performance. The US is delivering more than 30% growth for the fourth consecutive quarter. European sales were also strong during the first quarter. Germany, England and France were the main drivers of this (+70%). In total, Ossdsign delivered a 51% growth vs Q4-2019 adjusted for currency.

#### Operating profit/loss

Operating profit for the period January - March 2020 amounted to TSEK -18 260 (-17 126). Executed planned investments in the sales and manufacturing organizations increased staff costs by MSEK 4.8. The improved sales of MSEK 4.2 contributed strongly to controlling the increase in the operating loss to TSEK 1134 or 7%. Personnel costs for the first quarter of 2020 are at the same level as in Q4 2019 and the loss has been reduced in comparison with the average result for the second half of 2019 by MSEK 5.9 or 24%.

#### Cash flow, investments and financial position

At the beginning of the period, cash and cash equivalents amounted to TSEK 113 540 and at the end of the period they were TSEK 89 285. Cash flow from financing activities amounted to TSEK -2 486 and was primarily affected by the deposit of an annual rent for new premises, which was paid in January. Moving in will take place in stages from mid-year 2020. The total cash flow for the period was negative by TSEK-24 409 (TSEK 23 325). Net investments in property, plant and equipment amounted to TSEK 25 (TSEK 149) and mainly comprised investments linked to production. Investments in Intangible assets for the period amounted to TSEK 0 (TSEK 94).



### IMPORTANT EVENTS DURING THE **FIRST QUARTER**

#### New lease agreement for the head office in Uppsala, Sweden

The company has signed a new lease for the head office and state of the art manufacturing facilities in Uppsala, Sweden. Exchange of premises will take place in stages starting at miduear 2020.

### Completed transfer of the commercial operations in the United States

In early February OssDsign announced that the transfer of the company's commercial operations in the United States from the former master distributor OssDsign USA Inc., a fully owned subsidiary of OssDsign AB, had been completed. The gradual transition to replace the master distributor with an internal organization has been executed according to OssDsign's strategic plan for the US market. OssDsign will now operate out of its new US office facilities in Columbia, MD. The growing commercial organization will continue to support the existing distributor network in driving sales growth as well as executing clinical and marketing projects in conjunction with key opinion leading neurosurgeons.

#### First sales in France

Since being granted nationwide reimbursement for OssDsign Cranial PSI in France, OssDsign has intensified the commercial preparations on this major European market together with a local sales consultant. The strong demand in France was confirmed during the first quarter with sales secured from several key French hospitals even before the appointment of a commercial partner has been finalized.

#### Regulatory approval in Japan for OssDsign Cranial PSI

On March 30, it was announced that OssDsign received regulatory approval from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for OssDsign Cranial PSI. The company intends to launch OssDsign Cranial PSI in Japan together with a Japanese commercial partner once the decision on the reimbursement level has been received, which is due to be announced during the first half of 2020.

### IMPORTANT EVENTS AFTER THE END OF THE **THIRD QUARTER**

#### Appointment of Vice President of Sales for OssDsign USA Inc.

In May OssDsign announced the appointment of Eric Patermo as Vice President of Sales for OssDsign USA Inc.

Mr. Patermo brings 25 years of experience in the neurosurgical and orthopaedic segments where he most recently served as Vice President of Sales for Burst Biologics (Smart Surgical), a biopharmaceutical manufacturer focusing on technologies to promote bone healing. Previously, Mr. Patermo, amongst other positions, also served as a primary member of the US commercial team for ApaTech Ltd., a British orthobiologics company successfully sold to Baxter for USD 330 million in 2010. With the addition of Mr. Patermo to the OssDsign US team, his sales leadership and strong background in building top performing teams will further accelerate OssDsign's growth as US operations continue to expand.

# OssDsign Cranial PSI granted full nationwide reimbursement

On May 11th, OssDsign received the positive notice that the Ministry of Health, Labour and Welfare (MHLW) in Japan has granted full and nationwide reimbursement for OssDsign Cranial PSI. The decision came earlier than expected and will come into force in early June 2020. Discussions with a Japanese business partner are now close to completion and will be presented along with the details of the market entry strategy in the near future.

#### **THE COVID-19 PANDEMIC**

The initial outbreak of the COVID-19 pandemic has not significantly impacted the first quarter of 2020. However, since the middle of March there has been a widespread postponement of elective surgeries, including those relevant to OssDsign, as healthcare systems manage the pandemic. This has resulted in a reduced level of incoming orders which will have an effect on sales in the second quarter. OssDsign is confident that this will be transient and as hospital priorities are normalized, procedure volumes will also return to the levels experienced before the start of the COVID-19 situation, supplemented by additional procedures from currently postponed essential reconstructive surgeries.

#### OTHER DISCLOSURES

#### Ownership structure

At the end of the first quarter, there were approximately 1 252 shareholders in OssDsign AB, of which the three largest shareholders owned 39.9% of the capital and voting rights. The total number of shares was 17 733 168. The largest shareholders, on March 31, 2020, were SEB Ventures, Karolinska Development AB and Fouriertransform AB

#### Group structure

OssDsign AB is the parent company of the Group, which in addition to OssDsign AB consists of the wholly owned subsidiaries OssDsign Ltd with its registered office in UK and OssDsign USA Inc with its registered office in Maryland, USA.

OssDsign's operations are mainly conducted through the parent company OssDsign AB, based in Uppsala.

#### **Employees**

At the end of the period, there were a total of 40 (30) employees, of whom 46% were women. This includes employees at the office and production plant in Uppsala, as well as sales representatives in Germany, the UK and USA.

#### Financing

The Board regularly reviews the company's existing and forecasted cash flows to ensure that the company has the funds and resources required to conduct the business and the strategic direction decided by the Board. The company's long-term cash requirements are largely determined by how successful current products will be / are on the market.

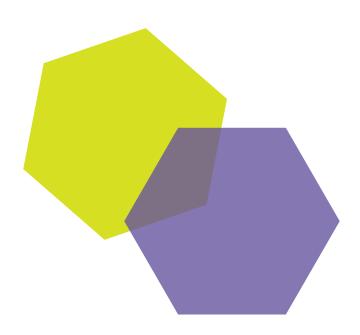
The Board has considered different scenarios regarding the impact on the company's cash flow linked to COVID-19. The Board considers that the financing of the business is deemed to be sufficient to meet requirements for at least 12 months ahead.

#### Transactions with related parties

The subsidiaries OssDsign USA Inc and OssDsign Ltd invoice their costs to the parent company in accordance with transfer pricing agreements. As of the closing date, the Parent Company has a claim on OssDsign USA Inc of TSEK 4 637 and a debt to OssDsign Ltd of TSEK 77.

#### Risks and uncertainties

OssDsign risks and uncertainties include, but are not limited to, financial risks such as future financing, foreign exchange and credit risks. In addition to market risks, there are risks related to OssDsign operations, such as obtaining the necessary government licenses, product development, patents and intellectually property rights, product liability and forward-looking information that may affect the Company. Further information regarding the Company's risk exposure can be found on page 63-65 of OssDsign 2019 Annual report.



# Consolidated summary income statement

	2020	2019	2019
SEK 000'	Jan 1 – March 31	Jan 1 – March 31	Jan 1 – Dec 31
Net sales	7 726	3 514	16 873
Other operating income/Other income	740	459	1723
Work performed by the group/parent company for its own use and capitalized	0	95	95
Raw materials and consumables/Cost of material	-2 502	-1380	-7 205
Other external expenses	-9 300	-9 621	-44 844
Personnel costs	-13 462	-8 639	-44 901
Depreciation, amortization and impairment of tangible and intangible fixed assets/non-financial assets	-1307	-1 452	-4 099
Impairment losses on financial assets	70	34	-176
Other operating expenses/Other expenses	-224	-136	-992
Operating profit	-18 260	-17 126	-83 526
Profit from financial items			
Net interest income	-52	-102	-226
Profit after financial items	-18 312	-17 228	-83 752
Tax expense	-	-112	-493
Profit for the period	-18 312	-17 340	-84 245
Earnings per share			
Basic earnings per share, SEK	-1,0	-1,5	-5,5

# Consolidated summary of comprehensive income

	2020	2019	2019
SEK 000'	Jan 1 – March 31	Jan 1 – March 31	Jan 1 – Dec 31
Profit/loss for the period	-18 312	-17 340	-84 245
Other comprehensive income for the period			
Items that will be reclassified subsequently to profit or loss	169	8	18
Income tax relating to items that will be reclassified	0	0	0
Other comprehensive income for the period	169	8	18
TOTAL COMPREHENSIVE INCOME FOR THE YEAR	-18 143	-17 332	-84 228

# Consolidated summary balance sheet

	2020	2019	2019
SEK 000'	March 31	March 31	Dec 31
ASSETS			
Fixed assets			
Intangible fixed assets	25 611	27 820	26 431
Tangible fixed assets	3 176	7 990	3 608
Total fixed assets	31 101	35 809	30 040
Current assets			
Inventories	1828	1282	1752
Current receivables	7 494	5 853	5 266
Other receivables	1947	1 711	1650
Prepaid expenses and other accrued income	1 0 3 5	787	1020
Cash equivalents	89 285	37 401	113 540
Total current assets	101 589	47 035	123 227
TOTAL ASSETS	132 690	82 844	153 267

	2020	2019	2019
SEK 000'	March 31	March 31	Dec 31
SHAREHOLDER EQUITY AND LIABILITIES			
Equity	117 176	61 150	135 275
Total equity	117 176	61 150	135 275
Long-term liabilities			
Liabilities to credit institutions	2 139	2 652	2 310
Lease liabilities	824	4 058	976
Other liabilities	-	85	-
Total long-term liabilities	2 963	6 795	3 286
Current liabilities			
Liabilities to credit institutions	513	627	513
Accounts payable	2 411	3 095	2 911
Lease liabilities	600	3 022	750
Current tax liability	0	301	356
Other liabilities	1887	1135	1868
Accrued expenses and deferred income	7 141	7 718	8 308
Total current liabilities	12 511	14 899	14 706
Total liabilities	15 514	21694	17 992
TOTAL EQUITY AND LIABILITIES	132 690	82 844	153 267

# Consolidated change in shareholder's equity in summary

SEK 000'	Share Capital	Subscribed Capital Unpaid	Other Capital Contributions	Reserves	Profit (loss) brought forward	Total Equity
Opening balance 2019-01-01	348	330	122 886	17	-76 090	47 492
Profit/loss for the period	-	-	-	-	-17 340	-17 340
Other comprehensive income	-	-	-	32	-	32
Total comprehensive income	-	-	+	32	-17 340	-17 308
Transactions with shareholders						
Interest convertibles	417	-330	32 471	-	-	32 558
Convertibles	-	-	-1591	-	-	-1591
Total transactions with shareholders	417	-330	30 880	-	-	30 966
CLOSING BALANCE 2019-03-31	765	-	153 766	49	-93 429	61 150
Opening balance 2020-01-01	1108	-	294 467	35	-160 335	135 275
Profit/loss for the period	-	-	-	-	-18 312	-18 312
Other comprehensive income	-	-	1+	169	44	213
Total comprehensive income	-	-	+	169	-18 268	-18 099
Transactions with shareholders						
New share issue	-	-	-	-	-	-
Issue expenses	-	-	-	-	-	-
Warrant programmes	-	-	-	-	-	-
Total transactions with shareholders	-	-	-	-	-	-
CLOSING BALANCE 2020-03-31	1108	-	294 467	204	-178 603	117 176

# Consolidated summary statement of cash flows

	2020	2019	2019
SEK 000'	Jan 1 – March 31	Jan 1 – March 31	Jan 1 – Dec 31
Operating activities			
Profit after financial items	-18 312	-17 261	-83 752
Non cash adjustments	962	964	2 752
Income tax paid	-890	23	-685
	-18 240	-16 275	-81685
Change in inventory	-8	71	-411
Change in receivables	-1 568	-495	-20
Change in liabilities	-2 083	-5 848	-4 476
Total change in working capital	-4 126	-6 273	- 4 908
Cash flow from operating activities	-21 898	-22 547	-86 593
Investment activities			
Acquisition of intangible fixed assets	0	-95	-95
Acquisition of tangible fixed assets	-25	-54	-231
Cash flow from investment activities	-25	-149	-326
Financing activities			
New share issue	-	46 177	199 057
New borrowing	-	-	-13 315
Warrants	-	-	1 157
Other change in financial fixed assets	-2314	-	-
Repayment of borrowing	-171	-157	-584
Cash flow from financing activities	-2 486	46 021	186 315
Cash flow for the period	-24 409	23 325	99 396
Cash equivalents at the beginning of the period	113 540	14 077	14 077
Exchange rate differences in cash equivalents	154	-	68
CASH EQUIVALENTS AT THE END OF THE PERIOD	89 285	37 401	113 540

# Summary income statement, parent company

	2020	2019	2019
SEK 000'	Jan 1 – March 31	Jan 1 – March 31	Jan 1 – Dec 31
Net sales	7 471	3 514	17 33
Other operating income/Other income	740	459	1723
Raw materials and consumables/Cost of material	-2 193	-1380	-7 210
			_
Other external expenses	-14 595	-12 294	-62 465
Personnel costs	-8 802	-6 706	-30 613
Depreciation, amortisation and impairment of tangible and intangible fixed assets/non-financial assets	-166	-163	-657
Other operating expenses	-387	-136	-992
Operating profit	-17 932	-16 707	-82 880
Profit from financial items			
Net interest income	-39	-48	-146
Profit after financial items	-17 970	-16 755	-83 026
T			
Tax expense	-	-	-
PROFIT FOR THE PERIOD	-17 970	-16 755	-83 026

<sup>\*</sup> Other comprehensive income in the Parent Company is in line with the profit for the period.

# Summary balance sheet, parent company

	2020	2019	2019
SEK 000'	March 31	March 31	Dec 31
ASSETS			
Subscribed capital unpaid	-	-	15 211
Fixed assets			
Tangible fixed assets	1670	2 305	1 811
Financial assets			
Shares in group companies	-	-	-
Other long-term receivables	2 314	-	-
Total financial fixed assets	2 314	-	-
Total fixed assets	3 984	2 305	1 811
Current assets			
Inventories	1606	1282	1 479
Current receivables	4 961	6 046	3 729
Receivables from group companies	3 402	1079	648
Other receivables	1350	1679	1586
Prepaid expenses and other accrued income	953	842	1062
Cash equivalents	86 113	36 022	112 091
Total current assets	98 918	46 931	120 595
TOTAL ASSETS	102 903	49 235	122 406

	2020	2019	2019
SEK 000'	March 31	March 31	Dec 31
SHAREHOLDER EQUITY AND LIABILITIES			
Equity			
Restricted equity	1108	765	1 108
Non-restricted equity	88 931	32 429	106 857
Total equity	90 39	33 193	107 954
Long-term liabilities			
Liabilities to credit institutions	2 139	2 652	2 310
Other liabilities	-	85	-
Total long-term liabilities	2 139	2 737	2 310
Current liabilities			
Liabilities to credit institutions	513	627	513
Accounts payable	2 392	3 089	2 604
Liabilities to group companies	77	-	-
Current tax liabilities	-	301	356
Other current liabilities	783	740	950
Accrued expenses and deferred income	6 959	8 547	7 263
Total current liabilities	10 724	13 304	12 131
Total liabilities	12 863	16 042	14 441
TOTAL EQUITY AND LIABILITIES	102 903	49 235	122 406

### **Notes**

#### Note 1 | Accounting Principles

This summary interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable regulations in the Swedish Annual Accounts Act. The interim report for the Parent company has been prepared in accordance with the Swedish Annual Accounts Act chapter 9, Interim Financial Reporting. The same accounting and valuation policies have been applied for the Group and the parent Company as in the latest Annual report. Disclosures in accordance with IAS 34.16A occur in the financial reports and the accompanying notes, and also in other parts of the interim report.

#### Note 2 | Estimates and assessments

Estimates and assessments are evaluated on an ongoing basis and are based on historical experience and other factors, including expectations of future events that are considered reasonable under prevailing conditions. There has been no change in the estimates and judgments made in the annual report for 2019.

#### Note 3 | Information regarding operating segments

The Group's operations are divided into operating segments based on the parts of the business the Company's highest executive decision-maker follows up, so called "management approach". The Group's internal reporting is based on the Group management following up the operation as a whole. Based on its internal reporting, the Group has identified that the Group has only one segment.

#### NET SALES BY GEOGRAPHIC MARKET

	January - March		
SEK 000'	2020	2019	
USA	3 328	1039	
Europe	4 155	2 445	
Rest of World	243	30	
TOTAL	7 726	3 514	

Income from external customers has been attributed to individual countries from which the sales has taken place. The Group's fixed assets are located to Sweden and USA.

#### Note 4 | Equity

The share capital of the Parent Company consists only of fully paid ordinary shares with a nominal (quota value) value of SEK 0.0625 / share. The company has 17 733 168 class A shares.

	2020	2019
	Jan 1 – March 31	Jan 1 – March 31
Subscribed and paid shares		
At the beginning of the period	17 733 168	348 007
Registration of new share issue decided 2018	-	330 333
Rights issue	-	86 233
Division of shares 16:1	-	11 468 595
Subscribed and paid shares	17 733 168	12 233 168
Shares for share-based		_
payments		_
SUM AT THE END OF THE PERIOD	1108 323	764 573

During the first quarter of 2019 the Company registered 330 333 shares which were issued and decided upon in 2018. Additionally, the Company issued during the first guarter 2019 a new share issue which increased the number of shares by an additional 86 233. Further, the Company has divided the shares into a ratio of 16:1.

The Company completed a new share issue during the second quarter of 2019, which increased the number of shares by 5 500 000. The total number of shares subsequently amounted to 17 733 168 and with a quota value SEK 0.0625. The Group's issued shares have the same right to distribute and repay invested capital and represent a vote at OssDsign's Annual General Meeting.

Resolved shares that have not yet been issued have been approved solely for use in the Group's options program (for more information see note 7 in the Annual Report 2019). Amounts received for issued shares in addition to the nominal value during the year (premium) are included in the item "Other contributed capital", after deduction for registration and other similar fees and after deduction for attributable tax benefits.

## **Signatures**

The Board of Directors and the CEO provide their assurance that this interim report provides an accurate view of the operations, position and earning of the Group and the Parent Company, and that it also describes the principal risks and uncertainties faced by the Parent Company and the companies included within the Group.

This report has been prepared in both a Swedish and an English version. In the event of any discrepancy between the two, the Swedish version shall apply.

### Scheduled financial reports

Interim Report, second quarter

August 19, 2020

Interim Report, third quarter

November 11, 2020

#### OSSDSIGN AB - UPPSALA MAY 13, 2020

Simon Cartmell Chairman of the Board Viktor Drvota Board member

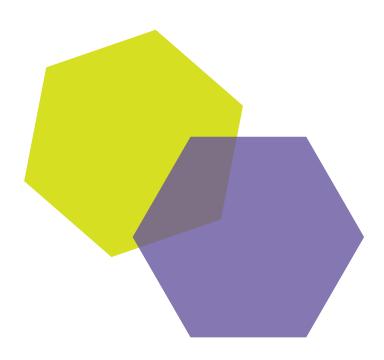
Håkan Engqvist Board member

Newton Aguiar Board member

Anders Qvarnström Board member

Anders Lundqvist

CEO



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